New York State Continuing Legal Education Board

25 Beaver Street, Room 888, New York, NY 10004
Phone: (212) 428-2105 • E-mail: CLE@nycourts.gov
Website: www.nycourts.gov/attorneys/cle

APPLICATION FOR ACCREDITATION OF AN INDIVIDUAL COURSE ACTIVITY (FOR USE BY SPONSORING ORGANIZATION)

To apply, please: (a) email your completed application, along with all required attachments, to CLE@nycourts.gov, AND (b) mail a printed copy of your application, with all required attachments, to NYS CLE Board, 25 Beaver Street, Room 888, New York, NY 10004. We can accept emails up to 15 MB with attachments. Please use PDF format only. (If the written materials – item 4 of the required attachments – are not available in advance, you may submit this application immediately following the course.)

SPONSOR INFORMATION	
Name of Sponsoring Organization	The Association for Healthcare Risk Management of New York, Inc. (DBA: AHRMNY)
Address	Street: PO Box 4200, Grand Central Station City: New York State: NY Zip: 10163
E-mail	ahrmny@gmail.com
Phone	973-641-5311
COURSE INFORMATION	
Title	AHRMNY Annual Educational Conference The intersection of Criminal Law and Clinical Practice
Date(s)	June 10, 2022
Location	Hyatt Centric Wall Street,75 Wall Street City: New York State: NY
LEVEL OF DIFFICULTY The content of the course is appropriate for:	[ ] newly admitted attorneys *only* (attorneys admitted two years or less) [ ] experienced attorneys *only* (attorneys admitted more than two years) [✔] *both* newly admitted and experienced attorneys
REGISTRATION FEE How much will you charge attorneys to attend this course?	[ ] Free of charge [ ] Fee of $ $100, $150 or $175 If a fee is charged, please see item 8 of this application.
Has this course been approved for CLE credit, or submitted for approval, in other states?	[✔] No [ ] Application Pending — If so, which state(s)?_____ [ ] Yes — If yes, which state(s)?_____ If this course has been submitted for approval in another jurisdiction, you may not need to submit this individual course application to the New York State CLE Board. Please refer to New York's Approved Jurisdiction policy available on the CLE website at www.nycourts.gov/attorneys/cle/approvedjurisdictions.shtml.

CERTIFICATION

(A) Sponsor acknowledges and agrees to comply with all CLE Program Rules and CLE Board Regulations and Guidelines. Sponsor understands that the CLE Program Rules and the CLE Board Regulations and Guidelines are available on the CLE website and that printed copies are available by contacting the CLE Board.
(B) Sponsor certifies that the faculty of this program includes no disbarred attorneys.
(C) Sponsor certifies that this application is complete and includes all required attachments.
(D) Sponsor understands that once reviewed, this application will not be re-reviewed to consider additional materials supplied at a later time that should have been included with this application.
(E) Sponsor certifies that the above information, and all information contained in the following pages and attachments, is true.

Kisha Wright — SPONSOR REPRESENTATIVE *(print name)*

Administrative Manager — TITLE

SIGNATURE: Kisha Wright DATE: 6/7/2022

SPONSORING ORGANIZATION: AHRMNY

TITLE OF COURSE: The intersection of Criminal Law and Clinical Practice

REQUIRED ATTACHMENTS			
In support of your application, please include:			*Office Use Only*
1.	**Timed agenda**	Attach a ***final version*** of the timed agenda for the course (not a draft). The timed agenda should set forth: • the topics presented • the time allotted to each topic • breaks (if any), and • the presenter(s) for each topic/session (if co-presented or presented as a panel presentation, so indicate)	
2.	**Brochure/Course Announcement**	Attach a brochure, advertisement or announcement for the course (if not available, attach a course description).	
3.	**Faculty Biographies**	Attach a biography for every faculty member that includes: • educational background and degrees earned, and • for attorney faculty members, the jurisdiction(s) in which admitted to practice law (attach a separate sheet if necessary) *Note*: The faculty must include at least one attorney in good standing who actively participates in the program. For multi-session programs, each session should include attorney faculty participation.	
4.	**Written Materials**	Attach a printed copy of the complete set of written materials distributed to attendees. *Note*: Written materials must be distributed to attendees at or before the start of the program, not afterwards. If distributed electronically in advance of the program, there should be extra printed copies available at the program for participants who request them. Please keep in mind that the written materials for a CLE course must: • specifically address each topic presented in the course • reflect that they are timely • be thorough, high quality, readable and carefully prepared • cover those matters that one would expect for a comprehensive and professional treatment of the subject matter of the course **Brief outlines, even if in the form of presentation slides, do not meet the standards for accreditation.**	
5.	**Attendance Verification Forms**	Attach any forms associated with your attendance verification procedure. Please see item 10 for more information.	
Office Use Only			

TITLE OF COURSE: The intersection of Criminal Law and Clinical Practice

6. TIME/CATEGORIES

(a) Indicate the total minutes of instruction for which you seek CLE credit (not including breaks, meals, introductions or topics without corresponding written materials) in each of the applicable categories below. A definition for each category is available on the CLE website at: http://www.nycourts.gov/attorneys/cle/CategoriesofCredit.pdf.

Areas of Professional Practice	Law Practice Management	Skills	Ethics and Professionalism	Diversity, Inclusion and Elimination of Bias
60 minutes	minutes	minutes	minutes	minutes

(b) Ethics Credit - List all session(s) for which you seek CLE credit in the category of *Ethics and Professionalism* (or clearly indicate those sessions directly on the agenda).

(c) Diversity, Inclusion and Elimination of Bias Credit - List all session(s) for which you seek CLE credit in the category of *Diversity, Inclusion and Elimination of Bias* (or clearly indicate those sessions directly on the agenda).

7. AUDIENCE

(a) Describe the audience to which the course is directed and advertised.

Attorneys (employment and medical malpractice), Claims Professionals, Risk Management Professionals, Patient Safety Professionals, Insurance Professionals, Compliance Professionals, Physicians, and Nurses.

(b) If open to nonattorneys, estimate the percentage of **attorneys** in the audience **(** 50 **%)** and explain how each session of the course (for which you seek CLE credit) will help attorneys, as attorneys, improve their legal skills. Attach additional sheets if necessary.

Attorneys attending this presentation will learn:

1. When does Clinical contact cross over into Criminal exposure?
2. Hospital/Institutional exposure for criminal conduct of employees.
3. Frequent scenarios where exposure may occur and remediation measures

8. FINANCIAL AID POLICY

If you charge attorneys a registration fee, your application is **ineligible for review without a financial aid policy**. Therefore, if you charge a fee, please state your financial aid policy including the specific procedures attorneys must follow to request financial aid and the specific criteria for award of aid. Please see the Financial Aid Policy Guidelines for CLE Providers on the CLE website at: http://www.nycourts.gov/attorneys/cle/financialaidpolicyforCLEproviders.pdf .

(a) Specific **procedures** attorneys must follow to request financial aid:

Attorneys may apply for financial aid scholarships by emailing AHRMNY Education Committee as outlined in financial aid policy (attached)

(b) Specific **criteria** for award of aid (for example, unemployed attorneys attend free of charge and attorneys who earn less than $50,000/year receive a 50% discount):

Unemployed = Full scholarship
Income up to $35,000 = 75% discount
Income $35,000-$50,000 50% discount
Income above $50,000 = no discount

TITLE OF COURSE: The intersection of Criminal Law and Clinical Practice

9. FORMAT/METHOD OF PARTICIPATION	
Please select the format(s) in which the course will be presented. For some formats, you must indicate the method(s) by which attendees participate (that is, seated together in a group setting or individual dial in/log in/self-study). As you make your selection, please note that experienced attorneys (attorneys admitted more than two years) may take courses for CLE credit in any format listed below. However, there are special requirements for newly admitted attorneys (attorneys admitted two years or less). To learn more about those requirements, please visit the CLE website: http://www.nycourts.gov/attorneys/cle/index.shtml.	
(A) LIVE - Check all that apply:	
☑ **Traditional live classroom setting** • *all* of the faculty in room with participants • participants are seated together in a group setting	**Webconference** (interaction with remote audience via telephone line, e-mail, etc. during program; questions allowed during program) ☐ participants are seated together in a group setting ☐ individual dial in/log in
☐ **Videoconference - fully interactive** • every participant in every location can see and hear not only the presenter(s) but any participant in any location who asks a question • participants are seated together in a group setting	**Teleconference** (interaction with remote audience via telephone line, e-mail, etc. during program; questions allowed during program) ☐ participants are seated together in a group setting ☐ individual dial in/log in
☐ **Videoconference (not *fully* interactive)** • participants are seated together in a group setting	**Live Broadcast/Webcast/Telecast** (no interaction with remote audience during program) ☐ participants are seated together in a group setting ☐ individual dial in/log in

For every selection above, please answer the following questions, (i) - (iii). If you made more than one selection above, please attach a separate sheet and answer the below questions for every selection you made.

(i) How will you verify attendance? (Please see item 10 for more information.)

All attendees will be required to sign in/out on the attendance verification sheet (attached)

(ii) How will you distribute written materials? *Note*: Written materials must be distributed at or before the start of the program, not afterwards. For group settings, if written materials are distributed electronically in advance of the program, there should be extra printed copies available at the program for participants who request them.

Speaker handouts will be distributed to all registered attendees via email 3 days prior to the program. Hard copies will be available at the registration desk for walk-in, unregistered attendees.

(iii) How will you distribute evaluation surveys? *Note*: The evaluation survey should address the **content, instruction and written materials of the course, and, where applicable, the physical setting and/or any technology used during the program** (such as presentation slides). You will be asked to tally the results of the evaluation surveys.

The conference evaluation will be distributed immediately to all attendees at conclusion of the presentation via email. Reminder emails will be sent periodically for those that have not submitted evaluation.

TITLE OF COURSE: The intersection of Criminal Law and Clinical Practice

(B) PRERECORDED - Check all that apply:	
Audio CD ☐ participants are seated together in a group setting ☐ self-study	**DVD/Video CD** ☐ participants are seated together in a group setting ☐ self-study
Audio file (MP3, podcast, etc.) ☐ participants are seated together in a group setting ☐ self-study	**Video file (vodcast, etc.)** ☐ participants are seated together in a group setting ☐ self-study
Online audio (including archived recorded programs) ☐ participants are seated together in a group setting ☐ self-study	**Online video (including archived recorded programs)** ☐ participants are seated together in a group setting ☐ self-study

For every selection you made above, please answer the following questions, (i) - (iv). If you made more than one selection above, please attach a separate sheet and answer the below questions for every selection you made.

(i) How will you verify attendance? (Please see item 10 for more information.)

N/A

(ii) How will you distribute written materials? *Note*: Written materials must be distributed at or before the start of the program, not afterwards. For group settings, if written materials are distributed electronically in advance of the program, there should be extra printed copies available at the program for participants who request them.

N/A

(iii) How will you distribute evaluation surveys? *Note*: The evaluation survey should address the **content, instruction and written materials of the course, any technology used during the program, and, where applicable, the physical setting**. You will be asked to tally the results of the evaluation surveys.

N/A

(iv) Submit a **sample** of each prerecorded format selected above (a copy of the DVD, CD, etc.). For online programs, provide instructions and a password for online access. If codes are used for verification of attendance, provide the codes for the sample you are submitting and the location of the codes (for example, code 36tk73 located at 42:14).

N/A

TITLE OF COURSE: The intersection of Criminal Law and Clinical Practice

10. ATTENDANCE VERIFICATION	
Group Setting	When participants are seated together in a group setting, attendance is often verified by using a sign in/sign out sheet. A sample is available on the CLE website. If you create your own sign in/sign out sheet, please note that it should include: **the name of the program, the date, the location (city/state) and the start/end times**. If you have a *sign in* sheet, without a *sign out*, please be sure to explain how you will be able to verify there were no early departures. (For multi-day and/or multi-session programs, a separate sign in/sign out sheet may be needed for each session to verify attendance.)
Individual Dial In/Log In/ Self-Study	When there is individual participation (such as when an attorney individually dials in or logs in to a teleconference or webconference from a remote location such as from home or a private office, or individually views/listens to a prerecorded program), attendance is often verified by way of course codes. (A separate code should appear and/or be announced at least every 50 minutes during a program.) Please note that an attendance verification procedure that relies on the *log in/log out times* of attorneys who dial in or log in to a teleconference, webconference, webcast, etc., does not meet New York's accreditation standards.
Sample forms (including a sample sign in/sign out sheet and a sample affirmation with course codes) are available on the CLE website at: www.nycourts.gov/attorneys/cle/attendance_verification.shtml.	

Please check here to confirm that you understand that, as the sponsor of the program, you are required to verify attendance:	Please check: [✔]

11. ORGANIZATION OF WRITTEN MATERIALS	
To facilitate the CLE Board's review of your application, please check here to confirm that you have organized the written materials (by using, for example, tabs or labels or cover sheets) to clearly identify the written materials that correspond to each topic listed on the agenda. A printed copy of the complete set of written materials distributed to attendees must be included with your application. Please keep in mind that the written materials must specifically address each topic presented.	Please check: [✔]

12. PRESENTATION SLIDES	
A complete set of written materials *distributed to attendees* must be included with your application. If you include presentation slides with your application, please check here to confirm that at or before the start of the program, the slides are distributed to participants as part of the written materials for the program.	Please check: [✔]

Thank you for your application.

To avoid delays in processing time, please be sure to fully respond to all questions and include all required attachments.

New York State Continuing Legal Education Board

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SPONSOR INFORMATION	
Name of Sponsoring Organization	The Association for Healthcare Risk Management of New York, Inc. (DBA: AHRMNY)
Address	Street: PO Box 4200, Grand Central Station City: New York State: NY Zip: 10163
E-mail	ahrmny@gmail.com
Phone	973-641-5311
COURSE INFORMATION	
Title	AHRMNY Annual Educational Conference Two Sides of the Same Coin: Shielding QA Materials and Defining the Value of Your Case
Date(s)	June 10, 2022
Location	Hyatt Centric Wall Street,75 Wall Street City: New York State: NY
LEVEL OF DIFFICULTY The content of the course is appropriate for:	[ ] newly admitted attorneys *only* (attorneys admitted two years or less) [ ] experienced attorneys *only* (attorneys admitted more than two years) [✔] *both* newly admitted and experienced attorneys
REGISTRATION FEE How much will you charge attorneys to attend this course?	[ ] Free of charge [ ] Fee of $ $100, $150 or $175 If a fee is charged, please see item 8 of this application.
Has this course been approved for CLE credit, or submitted for approval, in other states?	[✔] No [ ] Application Pending — If so, which state(s)?_____ [ ] Yes — If yes, which state(s)?_____ If this course has been submitted for approval in another jurisdiction, you may not need to submit this individual course application to the New York State CLE Board. Please refer to New York's Approved Jurisdiction policy available on the CLE website at www.nycourts.gov/attorneys/cle/approvedjurisdictions.shtml.

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(E) Sponsor certifies that the above information, and all information contained in the following pages and attachments, is true.

Kisha Wright — SPONSOR REPRESENTATIVE *(print name)*

Administrative Manager — TITLE

SIGNATURE: Kisha Wright DATE: 6/7/2022

SPONSORING ORGANIZATION: AHRMNY

TITLE OF COURSE: Shielding QA Materials and Defining the Value of Your Case

REQUIRED ATTACHMENTS			
In support of your application, please include:			*Office Use Only*
1.	**Timed agenda**	Attach a ***final version*** of the timed agenda for the course (not a draft). The timed agenda should set forth: • the topics presented • the time allotted to each topic • breaks (if any), and • the presenter(s) for each topic/session (if co-presented or presented as a panel presentation, so indicate)	
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3.	**Faculty Biographies**	Attach a biography for every faculty member that includes: • educational background and degrees earned, and • for attorney faculty members, the jurisdiction(s) in which admitted to practice law (attach a separate sheet if necessary) *Note*: The faculty must include at least one attorney in good standing who actively participates in the program. For multi-session programs, each session should include attorney faculty participation.	
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5.	**Attendance Verification Forms**	Attach any forms associated with your attendance verification procedure. Please see item 10 for more information.	
Office Use Only			

TITLE OF COURSE: Shielding QA Materials and Defining the Value of Your Case

6. TIME/CATEGORIES

(a) Indicate the total minutes of instruction for which you seek CLE credit (not including breaks, meals, introductions or topics without corresponding written materials) in each of the applicable categories below. A definition for each category is available on the CLE website at: http://www.nycourts.gov/attorneys/cle/CategoriesofCredit.pdf.

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60 minutes	minutes	minutes	minutes	minutes

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(c) Diversity, Inclusion and Elimination of Bias Credit - List all session(s) for which you seek CLE credit in the category of *Diversity, Inclusion and Elimination of Bias* (or clearly indicate those sessions directly on the agenda).

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(a) Describe the audience to which the course is directed and advertised.

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Attorneys attending this presentation will learn:
1. Navigating recent developments in the law of the quality assurance privilege.
2. How to set the value of the case on defendant's terms and without consideration of insurance disclosure

8. FINANCIAL AID POLICY

If you charge attorneys a registration fee, your application is **ineligible for review without a financial aid policy**. Therefore, if you charge a fee, please state your financial aid policy including the specific procedures attorneys must follow to request financial aid and the specific criteria for award of aid. Please see the Financial Aid Policy Guidelines for CLE Providers on the CLE website at: http://www.nycourts.gov/attorneys/cle/financialaidpolicyforCLEproviders.pdf .

(a) Specific **procedures** attorneys must follow to request financial aid:

Attorneys may apply for financial aid scholarships by emailing AHRMNY Education Committee as outlined in financial aid policy (attached)

(b) Specific **criteria** for award of aid (for example, unemployed attorneys attend free of charge and attorneys who earn less than $50,000/year receive a 50% discount):

Unemployed = Full scholarship
Income up to $35,000 = 75% discount
Income $35,000-$50,000 50% discount
Income above $50,000 = no discount

TITLE OF COURSE: Shielding QA Materials and Defining The Value Of Your Case

9. FORMAT/METHOD OF PARTICIPATION	
Please select the format(s) in which the course will be presented. For some formats, you must indicate the method(s) by which attendees participate (that is, seated together in a group setting or individual dial in/log in/self-study). As you make your selection, please note that experienced attorneys (attorneys admitted more than two years) may take courses for CLE credit in any format listed below. However, there are special requirements for newly admitted attorneys (attorneys admitted two years or less). To learn more about those requirements, please visit the CLE website: http://www.nycourts.gov/attorneys/cle/index.shtml.	
(A) LIVE - Check all that apply:	
☑ **Traditional live classroom setting** • *all* of the faculty in room with participants • participants are seated together in a group setting	**Webconference** (interaction with remote audience via telephone line, e-mail, etc. during program; questions allowed during program) ☐ participants are seated together in a group setting ☐ individual dial in/log in
☐ **Videoconference - fully interactive** • every participant in every location can see and hear not only the presenter(s) but any participant in any location who asks a question • participants are seated together in a group setting	**Teleconference** (interaction with remote audience via telephone line, e-mail, etc. during program; questions allowed during program) ☐ participants are seated together in a group setting ☐ individual dial in/log in
☐ **Videoconference (not *fully* interactive)** • participants are seated together in a group setting	**Live Broadcast/Webcast/Telecast** (no interaction with remote audience during program) ☐ participants are seated together in a group setting ☐ individual dial in/log in

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(i) How will you verify attendance? (Please see item 10 for more information.)

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(ii) How will you distribute written materials? *Note*: Written materials must be distributed at or before the start of the program, not afterwards. For group settings, if written materials are distributed electronically in advance of the program, there should be extra printed copies available at the program for participants who request them.

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TITLE OF COURSE: Shielding QA Materials and Defining The Value Of Your Case

(B) PRERECORDED - Check all that apply:	
Audio CD ☐ participants are seated together in a group setting ☐ self-study	**DVD/Video CD** ☐ participants are seated together in a group setting ☐ self-study
Audio file (MP3, podcast, etc.) ☐ participants are seated together in a group setting ☐ self-study	**Video file (vodcast, etc.)** ☐ participants are seated together in a group setting ☐ self-study
Online audio (including archived recorded programs) ☐ participants are seated together in a group setting ☐ self-study	**Online video (including archived recorded programs)** ☐ participants are seated together in a group setting ☐ self-study

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(i) How will you verify attendance? (Please see item 10 for more information.)

N/A

(ii) How will you distribute written materials? *Note*: Written materials must be distributed at or before the start of the program, not afterwards. For group settings, if written materials are distributed electronically in advance of the program, there should be extra printed copies available at the program for participants who request them.

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N/A

(iv) Submit a **sample** of each prerecorded format selected above (a copy of the DVD, CD, etc.). For online programs, provide instructions and a password for online access. If codes are used for verification of attendance, provide the codes for the sample you are submitting and the location of the codes (for example, code 36tk73 located at 42:14).

N/A

TITLE OF COURSE: Shielding QA Materials and Defining The Value Of Your Case

10. ATTENDANCE VERIFICATION	
Group Setting	When participants are seated together in a group setting, attendance is often verified by using a sign in/sign out sheet. A sample is available on the CLE website. If you create your own sign in/sign out sheet, please note that it should include: **the name of the program, the date, the location (city/state) and the start/end times**. If you have a *sign in* sheet, without a *sign out*, please be sure to explain how you will be able to verify there were no early departures. (For multi-day and/or multi-session programs, a separate sign in/sign out sheet may be needed for each session to verify attendance.)
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Sample forms (including a sample sign in/sign out sheet and a sample affirmation with course codes) are available on the CLE website at: www.nycourts.gov/attorneys/cle/attendance_verification.shtml.	

Please check here to confirm that you understand that, as the sponsor of the program, you are required to verify attendance:	Please check: [✔]

11. ORGANIZATION OF WRITTEN MATERIALS	
To facilitate the CLE Board's review of your application, please check here to confirm that you have organized the written materials (by using, for example, tabs or labels or cover sheets) to clearly identify the written materials that correspond to each topic listed on the agenda. A printed copy of the complete set of written materials distributed to attendees must be included with your application. Please keep in mind that the written materials must specifically address each topic presented.	Please check: [✔]

12. PRESENTATION SLIDES	
A complete set of written materials *distributed to attendees* must be included with your application. If you include presentation slides with your application, please check here to confirm that at or before the start of the program, the slides are distributed to participants as part of the written materials for the program.	Please check: [✔]

Thank you for your application.

To avoid delays in processing time, please be sure to fully respond to all questions and include all required attachments.

AHRMNY Annual Conference

The intersection of Criminal Law and Clinical Practice

11:00 am – 12:00 pm EST
Live Traditional Classroom Setting

11:00-11:15	James Kachadoorian will present on the topic "when does clinical contact cross over into criminal exposure.
11:15-11:30	Margaret Garrett will discuss hospital/institutional exposure for criminal conduct of employees.
11:30-11:35	James Kachadoorian will speak on application of law related to employee criminal conduct.
11:35-11:50	Andrea Restifo will present frequent scenarios where exposure may occur and remediation measures.
11:50-11:55	James Kachadoorian will speak on application of the law related to remediation.
11:55 – 12:00	Q&A from audience as time allows.

Two Sides of The Same Coin:
Shielding QA Materials and Defining The Value Of Your Case

2:45 pm – 3:45 pm EST
Live Traditional Classroom Setting

2:45-3:15	Caryn Lilling will discuss how to navigate recent developments in the law of the quality assurance privilege
3:15-3:40	Seth Weinberg will discuss how to set the value of the case on the defendant's terms and without consideration of insurance disclosure
3:40-3:45	Q&A from audience as time allows.

CELEBRATING 40 YEARS OF SERVICE

AHRMNY

The Association for Healthcare Risk Management of New York, Inc.

2022 FULL-DAY ANNUAL EDUCATIONAL CONFERENCE



About The Event

AHRMNY is pleased to bring back our in-person full-day annual educational conference*. This event will feature Keynote speakers and break-out sessions followed by a rooftop cocktail reception.

Date : Friday, June 10th, 2022
Time : 8:30 am - 6:00 pm
Location: Hyatt Centric Wall Street Hotel
75 Wall Street, NYC

Limited space available.
Reserve your place early.

CLICK HERE TO REGISTER

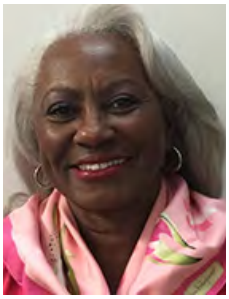
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***The educational presentations will be recorded and available to order 1-2 weeks after the conference.**

Guest Speakers

SPEAKER BIOS - CLICK HERE



Bonnie Boone
Insurance Broker
Risk Transfer Specialist



Jeremy Brigham, FCAS, MAAA
Managing Director
Willis Towers Watson



Ann D. Gaffey
RN, MSN, CPHRM, DFASHRM
President
Healthcare Risk and Safety Strategies, LLC



Margaret Garrett
BSN, MED, JD, CPHRM, DFASHRM
President
Risk Management Consulting



Stuart R. Levine
Chairman of the Board and CEO
Stuart Levine & Associates



James W. Kachadoorian
Partner
Wilson Elser Moskowitz Edelman & Dicker, LLP



Caryn L. Lilling
Partner
Mauro Lilling Naparty LLP



Rob Marshall
CPCU, RPLU, AIC, RIMS-CRMP, MBA
Client Advocate, Corporate Risk & Broking
Healthcare/Life Science Practice
Willis Towers Watson



Barbara McCarthy
RN, MPH, CIC, CPHQ, CPHRM, FASHRM
Enterprise Risk Officer
Beverly Hospital



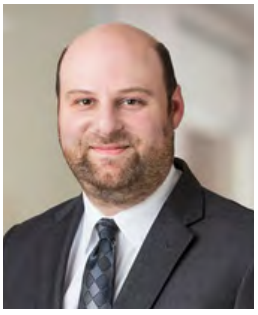
Mike Midgley
RN, JD, MPH, CPHRM, DFASHRM
Head of Loss Control
Munich Re Specialty Insurance



Andrea Restifo
RN, MPA, MHCDS
Northwell Health
North Shore University Hospital



John Telenko, RPLU
VP & Underwriting Leader, Hospitals
MedPro Group



Seth M. Weinberg
Partner
Mauro Lilling Napary LLP

Program Agenda

8:30-9:30 Registration & Breakfast

9:30-9:45 Welcome & Announcements
- *Robert Marshall, AHRMNY President*

9:45-10:45 **Morning Keynote Address**
Healthy Fundamentals Ensure Risk Mitigation in Healthcare
- *Stuart R. Levine*

10:45-11:00 BREAK

11:00-12:00 Morning Plenary Session
The intersection of Criminal Law and Clinical Practice
- *James Kachadoorian*
- *Margaret Garrett*
- *Andrea Restifo*

12:00-1:00 LUNCH

1:00-1:30 Annual Business Meeting

1:30-2:30 **Afternoon Keynote Address**
Connecting ASHRM Leaders and Planning for the Future
- *Barbara McCarthy*
- *Margaret Garrett*
- *Mike Midgley*
- *Ann Gaffey*

2:30-2:45 BREAK

2:45-3:45 Afternoon Breakout Sessions
(A) Two Sides of the Same Coin:
Shielding QA Materials and Defining the Value of Your Case
- *Caryn Lilling*
- *Seth Weinberg*

(B) Update in Risk Financing
- *Jeremy Brigham*
- *John Telenko*
- *Rob Marshall*
- *Bonnie Boone*

3:45-4:00 End of Conference - Wrap Up and Announcements

4:00-6:00 Rooftop Cocktail Reception

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Click here for AHRMNY's financial aid policy

CONTINUING EDUCATION CREDITS:
Continuing education credits for this program is pending review by the American Society for Healthcare Risk Management for CEUs toward the designations of CPHRM, DFASHRM, and FASHRM and the New York State Continuing Legal Education Board for CLE credits.

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U.S. District Court, Northern District of New York

Memberships & Affiliations

New York State Bar Association
Bronx County Bar Association

Awards & Distinctions

McLaughlin Oral Advocacy Outstanding Litigation Award, Suffolk University Law School, 1983
Outstanding Arson/Homicide Investigation, Mock Trial Bureau of Bronx County Fire Investigation, 1991
Exemplary Long Term Investigation, New York City Department of Investigations, 1991

Education

Suffolk University Law School, J.D., 1986

Jim Kachadoorian focuses his trial practice on the defense of hospitals and health care professionals in state and federal medical malpractice litigation. Drawing on his background as a former assistant district attorney, Jim also represents hospital clients and their satellite facilities in the investigation of assaults and other alleged criminal conduct by their employees.

With 20 years of experience in the medical malpractice field, Jim has tried to verdict dozens of personal injury and wrongful death cases on behalf of major New York metropolitan hospitals and their physicians and insurance carriers. A number of these cases have involved claims by athletes against orthopedic surgeons and other medical professionals alleging career-ending injuries. Jim also provides value-added services to help clients avoid litigation, including presenting periodic in-services to medical and nursing staff, conducting mock trials as part of residency training programs, and advising risk management committees on litigation and coverage issues.

After law school, Jim served for five years as an assistant district attorney in the Bronx County, NY, District Attorney's Office, of which he spent 18 months in the arson/homicide unit and a year as liaison to the New York City Department of Corrections responsible for all homicides, escapes, assaults and related medical clinic cases at Riker's Island.

Trinity College, B.A., 1982

Certifications/Licenses





Ms. Meg Garrett, a Villanova University, College of Nursing graduate, was a Navy Nurse doing the Vietnam War. Recently retired, she had a thirty plus year career in the Risk Management/ Legal Department at the Johns Hopkins Health System. In her role as Vice President of Risk Management and Chief Legal Counsel, she was responsible for designing, implementing and overseeing all aspects of the Risk Management Program. She was responsible for integrating the Risk Management and Patient Safety at six major US hospitals and numerous international facilities. She continues to advise Senior Leaders in matters regarding Patient Safety, Ethics, Risk Management, Legal and Regulatory matters. She has a proven track record for preparing and coordinating Joint Commission and other regulatory surveys. Meg has been active with ASHRM since early 2000. She has been a member of numerous committees, the Board and currently serves as the 2021 President of American Society of Healthcare Risk Management (ASHRM) She has also been active in the Maryland -DC Society of Healthcare Risk Management and has served as President and Board member for many years. Meg currently is President of her own Risk Management Consulting Corporation. She is also adjunct faculty at Villanova University and Johns Hopkins University College of Nursing. She is a guest lecturer at University of Maryland Carey School of Law and has mentored over 200 law students in her career. She is a founding member of the American Association of Nurse Attorneys. Meg is active on many Boards including Health Care for the Homeless and Elizabeth House which both sponsor programs for the underserved. She is a national and internationally recognized speaker on Patient Safety, Risk Management, Medical Staff and Nursing, and Health Care Law.

North Shore University Hospital
Northwell Health



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arestifo@northwell.edu

Andrea Restifo, MPA, MHCDS, is associate executive director for North Shore University Hospital (NSUH), a tertiary care facility with 756 beds. She oversees quality management, safety services, infection prevention, pathology, blood bank, social work and case management. Andrea is responsible for communicating information related to regulatory preparation, quality management methodology, best practices, lessons learned from occurrences to prevent harm, and the establishment of quality/safety initiatives throughout the hospital.

Under Andrea's leadership, NSUH has made tremendous strides in becoming highly reliable organizations. She has collaborated on instructional materials for performance improvement that have been presented at numerous national and international healthcare conferences. She is co-author of the book, "The Quality Handbook for Health Care Organizations: A Manager's Guide to Tools and Programs," (Jossey-Bass) which was published in 2004. In addition, she co-authored chapters in two books relating to transplant quality assurance and performance improvement.

Over the years she has the honor to formally mentor dozens of interns, administrative fellows, students, nurses and physicians about quality management's vital function and methodologies. In 2011, she was awarded the hospital's Medical Staff Distinguished Service Award. Andrea is a member of the American College of Healthcare Executives, National Association for Healthcare Quality, International Society for Quality in Health Care, American Society for Healthcare Risk Management NY chapter, American College of Medical Quality and Villanova University Nursing Alumni Society. She serves on the New York Organ Donor Network of the Board of Directors Medical Advisory Committee. In 2019, she received the United Hospital Fund the Excellence in Health Care Award for Quality Improvement Champion.

She completed her Bachelor of Science in nursing at Villanova University. She has a Master of Public Administration degree from Long Island University and a Master of Health Care Delivery Science from Dartmouth College. She currently teaches at Hofstra University as an Adjunct Assistant Professor.

MAURO | LILLING | NAPARTY LLP

Appellate Advocacy & Litigation Strategy



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Caryn L. Lilling is a founding partner of the firm, having joined Mauro Lilling Naparty LLP almost 30 years ago. Caryn has prepared and argued hundreds of significant pre- and post-trial motions, in addition to appeals in state and federal courts across a wide range of practice areas. She has published extensively on various topics in her field and is a frequent lecturer for insurance companies, corporations, hospitals, and bar associations.

Caryn frequently appears as monitoring appellate counsel where, unlike typical monitoring counsel, MLN's experienced appellate attorneys partner with and assist trial counsel in developing the overall case strategy, preserving the record, identifying the need for and preparing trial motions, and providing an objective appellate perspective throughout the trial. The firm routinely appears in this capacity in high exposure matters across the country, all in an effort to leverage better outcomes, including more favorable settlements.

In addition to the more traditional roles of appellate counsel, Caryn's firm is also called upon to aggressively define and defend damages. In 2013, along with her partner, Caryn spearheaded the firm's national growth as coordinating counsel on damages and, in particular, how to mitigate damages for future medical expenses in tort cases. In that role Caryn has become a leading voice on the topic. Numerous companies, carriers and hospitals now turn to Caryn and her team to develop pre-trial, trial and mediation strategies to mitigate damages in catastrophic injury cases.

Caryn has earned Martindale Hubbell's highest peer review rating of AV®, having been designated as Preeminent™ in appellate practice. This distinction is awarded to less than five percent of all United States lawyers. Caryn was also selected for recognition on the 2019 list of the Best Lawyers in America in the area of appellate practice and was named as one of the top women attorneys in the New York Metro Area specializing in appellate practice, as spotlighted in the New York Times Magazine. The firm has also been recognized by the New York Law Journal as the seventh largest women-owned firm in New York State.

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Appellate Advocacy & Litigation Strategy



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Seth M. Weinberg is a partner of Mauro Lilling Naparty LLP, the largest firm in the Northeast that handles appeals and litigation strategy. Seth has handled numerous appeals and complex motion practice in state and federal courts. His practice spans multiple areas of law including medical and other professional malpractice; construction law; employment law; general negligence; products liability; asbestos; trust and estates; real property disputes; insurance coverage and commercial litigation.

As a co-director of the firm's coverage unit, Seth routinely assists the firm's clients in analyzing their coverage positions and representing them in declaratory judgment actions across the country. Seth is also a co-director of the firm's efforts as COVID-19 litigation coordinating counsel for a large hospital system in the New York Metro Area.

From 2014 through 2020 Super Lawyers named Seth as a Rising Star in its Metro Edition as one of the top attorneys in New York under the age of 40. No more than 2.5 percent of the lawyers in the state were selected to the list. He has also served as the co-chairman of the Suffolk County Bar Association's Appellate Practice Committee and given numerous lectures on a wide variety of legal issues. Seth is also a former member of the New York State Bar Association's Committee on Civil Practice Law and Rules.

Seth graduated from the State University of New York, *magna cum laude*, with a B.A. in political science. He attended Touro College's Jacob D. Fuchsberg Law Center and graduated *cum laude*. Before joining MLN, Seth was the director of appellate litigation at one of Long Island's largest insurance defense firms.

Financial Aid Policy

The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) is the New York Chapter of the American Society for Healthcare Risk Management (ASHRM). Founded in 1982, AHRMNY is a non-profit, 501(c)(3) organization and has has been the leading educational organization committed to healthcare risk management and patient safety in New York. Our members include risk managers, patient safety officers, administrators, healthcare/medical malpractice defense attorneys, insurance professionals, quality assurance professionals, patient experience professionals, long term care administrators, physicians and nurses.

AHRMNY's purpose is to enhance the quality of the delivery of health services and the professional practice of health care and health care related risk management through our educational programs. Our educational programs promote professional development, provide a medium for interchange of ideas among members and colleagues, and assist in the development of professional relationships among other healthcare, risk management and legal professionals in order to facilitate free exchange of information and solution of mutual problems.

AHRMNY holds 3-5 educational programs each year and offers a limited number of scholarships that are available to risk management/patient safety students, law students, and recent graduates not yet employed or current attorneys and risk management/patient safety professionals that might be experiencing financial hardship.

Income guidelines for scholarships are as follows:

Umemployed	Full scholarship
Income up to $35,000	75% discount
Income $35,000-$50,000	50% discount
Income above $50,000	No discount

All requests must be made in writing to the Education Committee at ahrmny@gmail.com and should describe the applicant's interest in the topic and justification for a waiver or reduction of fees. If approved, the scholarship will be applied to the specific educational program requested.

James W. Kachadoorian
June 10, 2022

Clinical v. Criminal Conduct

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Topics for Discussion

- Overview of the issues
- Identifying misconduct
- Examples of civil vs. criminal distinction

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Overview

- On occasion, clinical interactions have resulted in criminal exposure
- A physician or staff member's professional license and person record are both on the line
- Requires use of both professional liability and criminal defense team to achieve favorable outcome

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Identifying Misconduct

- Child abuse
- Sexual abuse
- Interactions with mentally ill patients

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Examples

- Pediatrician accused of child abuse during visit with autistic child
- Nursing care
- Dental setting
- Pharmacy errors

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Remediation Measures

- Additional chaperone in room
- Video surveillance in public areas
- Ensuring chart is well-documented
- Hospital safeguards

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Summary

- Identify the risks
- Implement safeguards
- Reconcile and remediate

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The Intersection of Criminal Law and Clinical Practice –

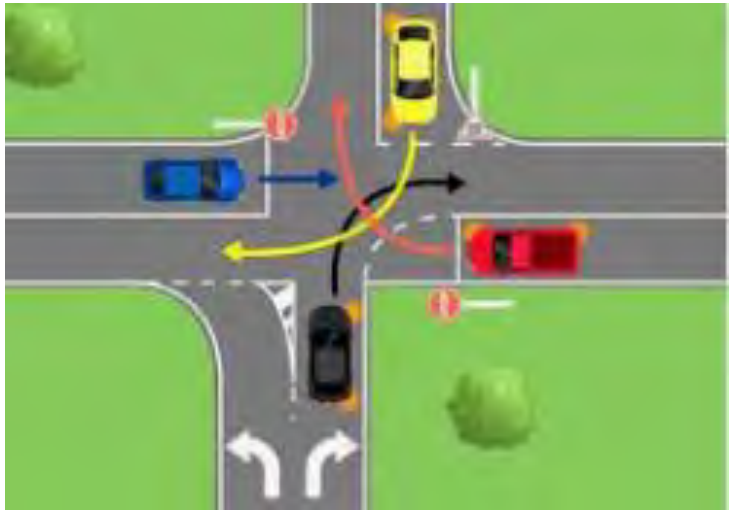
Quality Management Leader View

Andrea Restifo, RN, MPA, MHCDS

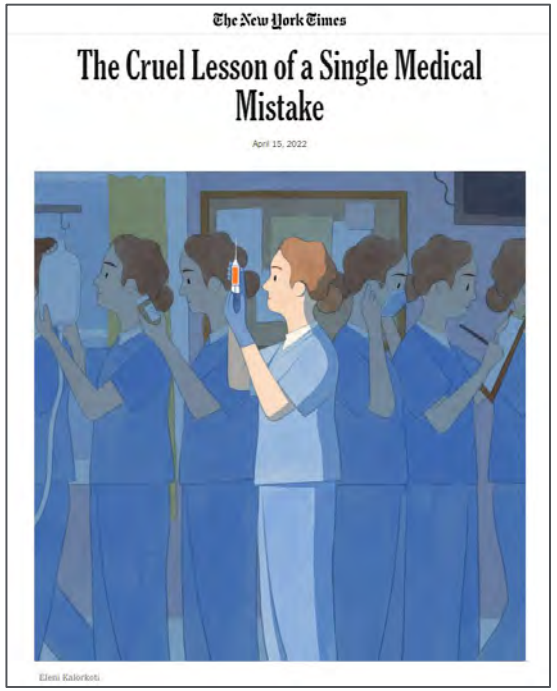
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Northwell Health®

Working harder for the *next* patient to prevent medical errors…

Are we prepared to report errors and near misses if human error and transparency can lead to loss of their job and even prison?



Impulse vs Intention

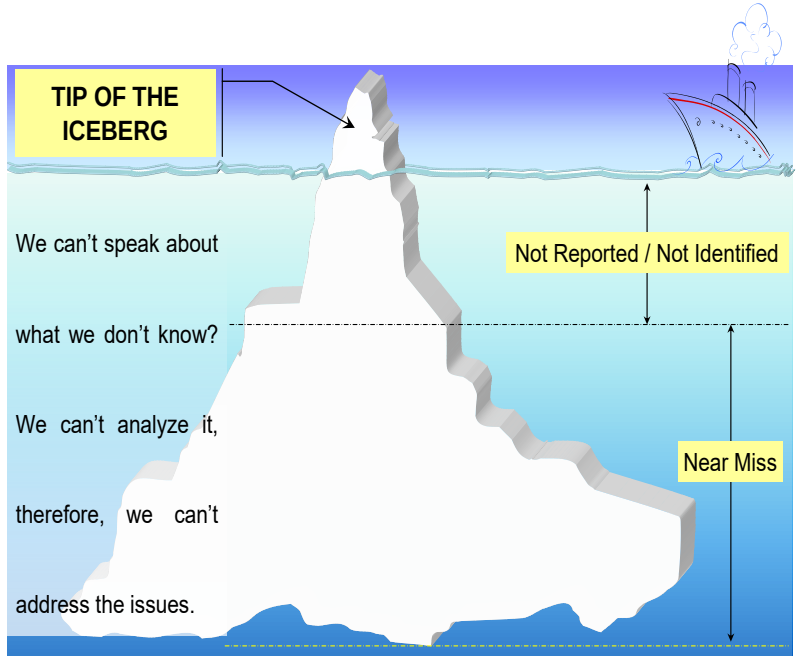


Our patients and communities depend on us to be accessible, engaging, and to be intentional listeners and excellent communicators and provide safe care.

But we have challenges…

- Individual vs System
- Staffing shortages and pandemic burnout have led to increased stress and demoralization, increases the likelihood of medical error
  - Pressures that contribute to human errors: long hours, high caseloads, confusing electronic health record (EHR) documentation, imperfect processes, and on-the-job complacency
- Healthcare workers have been encouraged towards transparency to report
- True Just Culture
- Medication dispensing system overrides were a part of the everyday administration of medications
- Easier to offer help - harder to ask for help



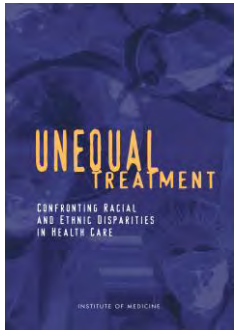


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Guiding Principles





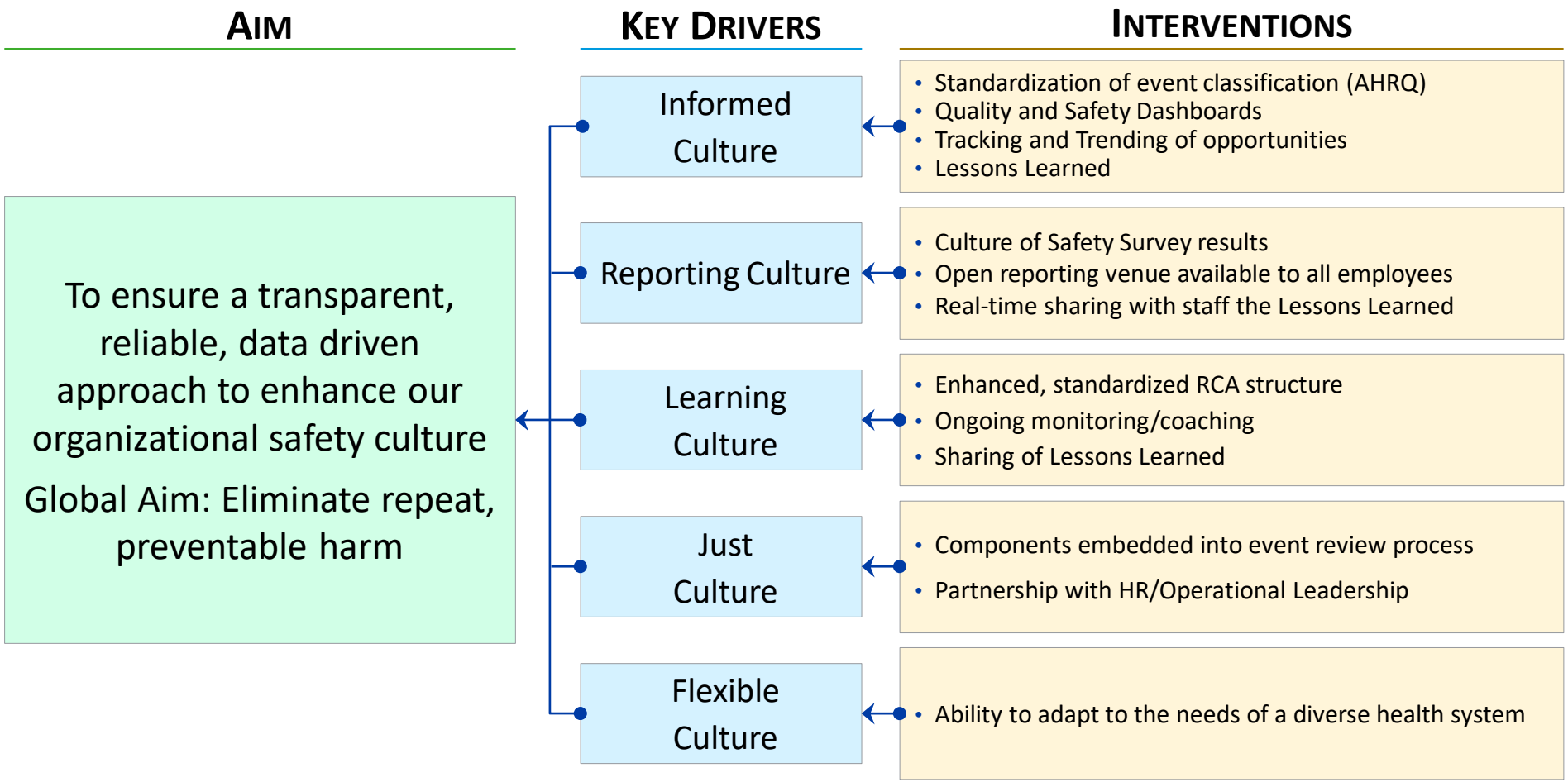
- Patients first, safety always
- The Six Aims of the National Academy of Sciences (formerly the Institute of Medicine). Healthcare must be:

1)	Safe	4)	Timely
2)	Effective	5)	Efficient
3)	Patient Centered	6)	Equitable

- Teamwork and open, two-way communication promote a culture of patient safety
- High reliability and resilience are essential for optimal patient outcomes
- Individuals make mistakes – expect them and prepare for them



Safety Culture



Source: Northwell System Clinical Excellence & Quality Performance Improvement and Safety Plan

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Organizational Response - Serious Adverse Events

- **Notification -** Immediate
  - Leadership (Site, Institute for Clinical Excellence and Quality/Patient Safety and Risk Management
- **Debriefing -** As close to the event as possible
- **External reporting -** Reported within 24 hours of awareness and as appropriate agencies (DOH, OMH, TJC and Justice Center)
- **RCA** - Facility process in place
- **Disclosure** - Facility Process in place
- **Code Lavender**

HIERARCHY OF RISK REDUCTION ACTIONS

STRONGER ACTIONS

- Architectural/physical plant changes
- New device with usability testing before purchasing
- Engineering control or interlock (forcing functions)
- Simplify the process and remove unnecessary steps
- Standardize on equipment or process
- Tangible involvement and action by leadership in support of patient safety
- High Reliability Training (perpetual, including simulation, competency evaluation, staff off patient care, leadership sanctioned)

INTERMEDIATE ACTIONS

- Software enhancements/modifications
- Eliminate/reduce distractions (sterile medical environment)
- Checklist/cognitive aid
- Eliminate look and sound alikes
- Read back
- Enhanced documentation/communication
- Redundancy
- Training using simulation

WEAKER ACTIONS

- Double checks
- Warnings and labels
- New procedure/memorandum/policy
- Training
- Additional study/analysis

Root Cause: *Medication Error – December 24, 2017*

PEOPLE

- Experienced RN, role model, conduct aligns with mission and vision,
- Designated as a HELP-All Nurse, worked in NICU, preceptor of new graduate
- Radiology RN too busy to administer
- Primary RN could not go to radiology and sought out Help all nurse to prevent the case from being cancelled
- Retrieved wrong drug, failed to detect and correct mistake, multi-tasking
- Radiology tech present did not speak up
- No self-checks

INFORMATION

- Patient needed medication to manage anxiety
- Communication of the anxiolytic was verbally communicated as Versed, not midazolam
- Label on the front of the vial not read
- "Types" in VE and Vecuronium appears at the top of list

POLICY

- Radiology/hospital sedation policy
- Monitor policy
- Override policy
- Vecuronium was not constrained nor differentiated form other vials in the ADC nor programed screen warnings



COMPETENCY / TRAINING

- No job description for Help RN,
- Both RNs did not routinely administer Versed
- Patient monitoring off the unit was discussed by primary RN; radiology Tech concluding monitoring was not indicated- ICU LEVEL
- Knowledge deficit Midazolam is the generic name of Versed

ENVIRONMENT / EQUIPMENT

- Worked in NICU
- Anxiolytic need was not anticipated in radiology
- Monitoring,
- No bar code scanning in radiology
- Real time EHR documentation access in not available in radiology
- Too much easy access in the ADC system
- Recommendation to store separately
- Radiology holding area no monitoring
- Plan to waste remainder of drug in ICU

LEADERSHIP

- The timeliness of pharmacy review of provider orders was variable
- Patient had about 20 drugs via override, monitoring how much the Override function is used
- Lack of staff knowledge of protocols
- Staff competency /training
- Disallowing a family member to accompany the patient to radiology
- Distraction free zones to avoid multitasking

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Safety, Experience & Engagement Rounds 2022

S.E.E Rounds Launched April 29th Patient Experience Week

Structure

Who?

- Two Rounding Team Members (Clinical and Non-Clinical) are assigned to a unit/department to facilitate SEE Rounds
- Unit Leads and Providers to participate in team huddle
- Executive to rotate through areas every month

What?

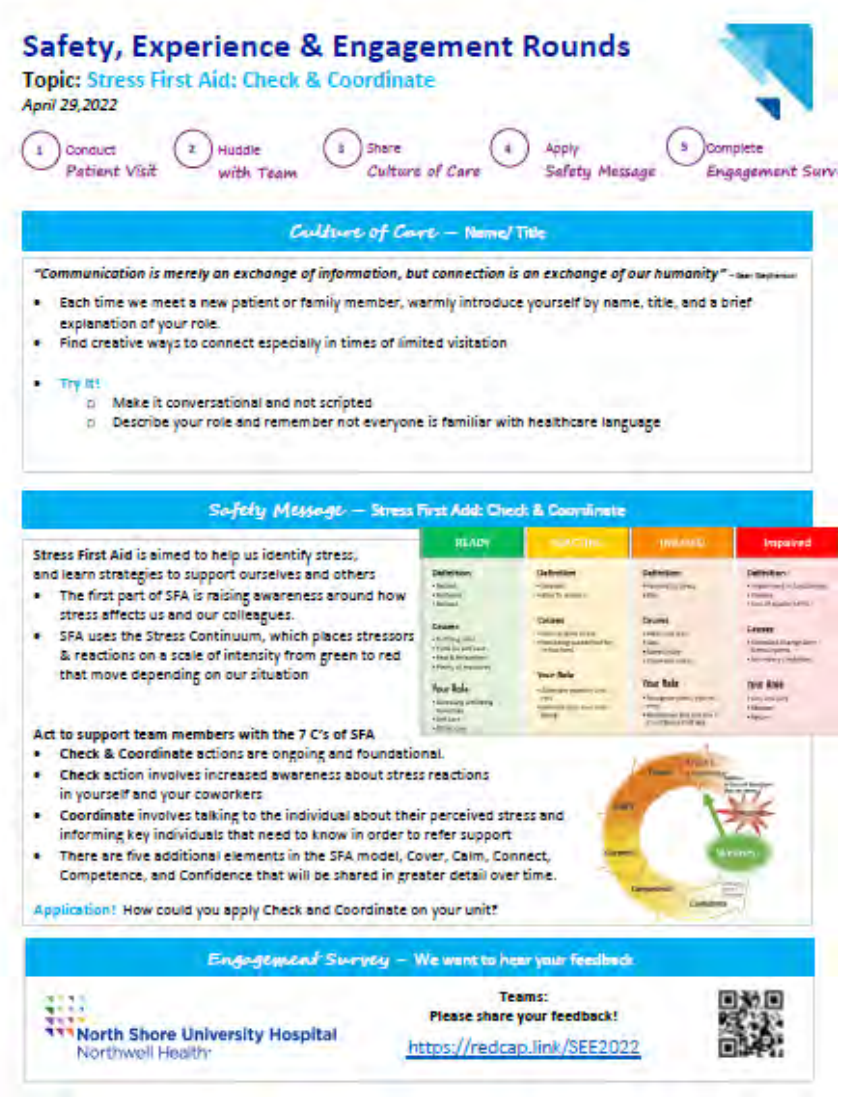
- New Topics Every 2 Weeks (include PX, Safety, Engagement, Quality, Regulatory etc.)
- Redcap survey to capture data on patient experience, safety concerns, team successes
  - Redcap alerts for escalating safety concerns
- Report Out biweekly at Situational Awareness (Monday)

When?

- Cadence: Bi-weekly, every other Friday. Time to be coordinated per unit.
- S.E.E Rounds topic to be included in off shift visibility rounds

Process of Rounds

1 Conduct Patient Visit	2 Huddle with Team	3 Share Culture of Care	4 Apply Safety Message	5 Complete Engagement Survey
(5 minutes)	(5-15 minutes)			(1-3 minutes)



Example of Topic Sheet

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Leadership

- Accountability
- Just culture
- Communication
- Transparency and close the loop
- Resources and Competency
- Visibility
- Culture of Patient Safety Survey



Northwell Health

Our Culture of Safety

Dear colleague,

As caregivers, we embrace our responsibility to deliver safe patient care, and our culture of safety is designed to protect those in our care, as well as you and your fellow providers.

The tragic case of a former Tennessee nurse who was recently found guilty in the accidental injection death of an elderly patient presents an opportunity to reflect on the critical importance of our vibrant culture of safety that is centered on continuous improvement.

We are proud of everything we have achieved together and recognize the importance of always striving to do better. Our focus on enhancing our foundation of safe care will enable us to make the most of the systems we currently have in place and strengthen them where needed. Ultimately, our culture of safety is powered by several commitments we make together.

- We will continue actively looking for opportunities to further strengthen our safety protocols and practices, where needed, to help minimize the possibility of adverse outcomes. We welcome your ongoing feedback regarding how any of the devices, equipment or protocols that facilitate safe care can be improved in some way. Please share any input with your leadership so we can evaluate and take action as appropriate.

- We will continue driving awareness and adherence to the comprehensive systems, protocols and safety mechanisms we already have in place – particularly in our medication dispensing systems, infusion pumps, and bar code medication management scanning system. This is the best way to protect our patients and each other.

- Finally, we remain committed to a Just Culture at Northwell, one element of which is transparently reporting near misses, errors and incidents through our legally-protected improveNorth patient safety event reporting application. This sharing, which is done in a non-punitive fashion, enables us all to learn and further improve the systems and processes that enable safe care of our patients.

In the coming weeks and months, we look forward to talking more about this critical topic during rounding and working with you to advance opportunities to strengthen the systems already in place.

Thank you for your continued compassion, dedication and expertise in all that you do to deliver high quality and safe care to the patients and communities we serve.

Thank you



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arestifo@northwell.edu

Learning Objectives/Summary:

When a healthcare provider's actions are considered egregious, there is more on the line than medical license revocation or monetary recovery. It is becoming increasingly common that criminal prosecution of healthcare providers is sought out to resolve unfortunate errors in the field of medicine. Heightened media coverage on these issues causes the public to seek more severe punishments after an alleged medical error has occurred.

Additional sources:

Law Review Articles (PDFs attached)

- Boston University School of Law – Medicine, Death and the Criminal Law
- Saint Louis University Law Journal – Physicians Who Break the Law
- **AbuDagga, Azza et al. "Time to End Physician Sexual Abuse of Patients: Calling the U.S. Medical Community to Action." Journal of general internal medicine vol. 34,7 (2019): 1330-1333. doi:10.1007/s11606-019-05014-6**
- **Pimienta AL, Giblon RE. The case for medical chaperones. Fam Pract Manag. 2018;25(5):6-8**
- **Muellenberg, Erin L. "Lessons Learned from Medical Criminals." National Law Review, Volume XI, Number 303.**
- **Obasogie, Osagie K. et al. "Medical Professionals, Excessive Force, and the Fourth Amendment." California Law Review, Volume 109:1.**
- **Bal BS, Brenner LH. The Law and Social Values: Medical Necessity and Criminal Prosecution. *Clin Orthop Relat Res*. 2016;474(4):887-891. doi:10.1007/s11999-016-4725-3**

Examples in Media

- https://www.vox.com/science-and-health/23046679/radonda-vaught-nurse-medication-medical-error-patient-safety-lawsuit-vanderbilt
- https://www.nytimes.com/2011/11/08/us/doctor-found-guilty-in-michael-jacksons-death.html
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LEGAL ISSUES IN MEDICINE

MEDICINE, DEATH, AND THE CRIMINAL LAW

GEORGE J. ANNAS, J.D., M.P.H.

ERRORS in medicine are common and are at least partly responsible for the deaths of 180,000 patients a year.[1,2] There is increasing concern about medical errors and the steps that should be taken to prevent them.[1] Until recently, hospitals have addressed errors after the fact, through mortality and morbidity conferences, incident reports, and the like, rather than before the fact, through attention to systems defects and prevention. Likewise, medical-malpractice litigation can be filed only after an injury has occurred. Malpractice litigation is intended to create incentives to improve the quality of medical care by making physicians and hospitals accountable for their actions, but works by providing compensation for injury. A third mechanism, sanction by state medical licensing boards, can have a more direct effect, since action can be taken on the basis of a physician's danger to patients — even if consistently negligent acts have not resulted in injuries. Nonetheless, licensing boards have not sought out marginally competent physicians and usually do not take action until there has been grievous harm to a patient or until a physician has been convicted of a crime.[1]

Criminal charges related to the practice of medicine have primarily involved insurance fraud (including Medicare and Medicaid fraud), sexual abuse of patients, or illegal use or prescription of controlled substances. Criminal prosecution is generally thought to serve three goals: deterrence, retribution, and rehabilitation. In medicine, rehabilitation is often considered the only goal of sanctions by licensing boards. The ineffectiveness of such sanctions and malpractice litigation in deterring error-prone behavior might make the criminal law seem a necessary mechanism for prevention (deterrence), and the criminal law is, of course, the only legitimate social mechanism we have for punishment (retribution) in cases involving intentional or deliberate disregard for patients' safety.

Criminal prosecution of physicians for the deaths of patients remains extraordinarily rare.[3] Three recent cases, however, provide an opportunity to examine the use of the criminal law as a response to egregious medical acts that result in death. The three cases, from New York, Colorado, and Wisconsin, represent a range of criminal prosecutions. As the *Washington Post* stated in an editorial, "These three cases have particularly shocking facts and terrible consequences for which civil and professional penalties may not be enough."[4]

THE NEW YORK CASE

Dr. Gerald Einaugler's patient was a 78-year-old woman with end-stage renal disease, diabetes, cardiovascular disease, and senility. She was transferred from Brooklyn's Interfaith Medical Center to a nursing home across the street in May 1990.[5] At the nursing home, Dr. Einaugler mistook the patient's peritoneal-dialysis catheter for a gastrostomy tube and directed the staff to feed the patient through it. She received several feedings through the dialysis catheter before the mistake was discovered by a nurse. After he had been notified of the mistake, Dr. Einaugler telephoned the chief nephrologist at the medical center, who advised him to "get the patient into the hospital."[6] After talking to the nephrologist, Dr. Einaugler went to the nursing home to examine the patient but decided to delay her transfer. A New York appeals court stated, "Although the defendant knew that peritonitis could be fatal if untreated, he did not direct the patient's transfer to the hospital for more than 10 hours after his conversation with the nephrologist."[6] On admission, peritonitis was diagnosed, and the patient died within days. Testimony by experts for both the prosecution and defense

> established that proper medical care required treating the patient as soon as peritonitis was suspected, and following the advice of the nephrologist. Thus the evidence established that the defendant was aware of, and consciously disregarded, a substantial risk of serious physical injury to the patient by delaying her transfer to the hospital, and that his conduct constituted a gross deviation from the standard of conduct a reasonable person would observe in the situation.[6]

Because of the delay, in July 1993 Dr. Einaugler was convicted of reckless endangerment of his patient and willful violation of New York's health laws. In October 1994, the appeals court unanimously upheld the verdict, ruling that the jury could have found the above account factual beyond a reasonable doubt.[6] In addition to supporting the conviction for reckless endangerment in the second degree, the appeals court found that the physician's action violated New York's public health laws, which prohibit a physician from "willfully" committing "an act of neglect."[6] Willful neglect is defined as "knowingly" failing to "provide timely, consistent, safe, adequate, and appropriate services, treatment, and/or care to a patient or resident of a residential health care facility."[6]

Medical organizations, including the American Medical Association, have called the prosecution of Dr. Einaugler an inappropriate response to an error in medical judgment. As one leading legal commentator noted, "You know it's an unusual case when the American Medical Association's defense of a physician is that what he did was medical negligence."[7] In this case, however, the physician was accused of a conscious (i.e., intentional) disregard for the patient's safety in failing to transfer her to a hospital for treatment, not an error in medical judgment or a mistake in properly identifying a feeding tube. As the appeals court said simply and unanimously, this case "does not support the proposition that medical professionals need fear the prospect of unwarranted criminal prosecutions for honest errors of medical judgment."[6] The prosecutor's theory, that Dr. Einaugler delayed his patient's transfer in an

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attempt to cover up his original negligence, was consistent with a conscious disregard for the patient's safety,[6] and the appeals court decided that the jury had ample evidence to reach this verdict. Dr. Einaugler was sentenced to spend 52 weekends in jail.[5] The sentence was later stayed, in March 1995, pending a further hearing in U.S. District Court.

The law defines reckless endangerment as the conscious disregard of a known and substantial likelihood of injury to the patient. If the patient dies as a result, a charge of manslaughter is appropriate. Such a charge was not made in this case, perhaps because the district attorney did not believe he could prove beyond a reasonable doubt that had the patient been transferred sooner, she would have survived. An even more recent case in New York provides an example of a case in which a manslaughter charge seems appropriate. In July and August 1995, Dr. David Benjamin was tried for manslaughter on the basis of allegations that he knowingly and intentionally performed a procedure (a late abortion) that he did not have the skills to perform and that his deliberate indifference to the health and safety of his patient led directly to her death from excessive bleeding.[8] The physician's license to practice medicine had already been revoked for "gross incompetence and negligence" in connection with five previous cases involving life-threatening uterine perforations. This death occurred during the three weeks he was allowed to continue practicing medicine, before the revocation became final.[8]

The Colorado Case

On July 8, 1993, Dr. Joseph J. Verbrugge, Jr., an anesthesiologist, fell asleep during a mastoidectomy at St. Joseph Hospital in Denver. The patient, eight-year-old Richard Leonard, died. Judith F. Schulman, an administrative-law judge, conducted a hearing for the Colorado Board of Medical Examiners. She found that Dr. Verbrugge had been "grossly negligent" in performing a series of specific acts "covering virtually every aspect" of the patient's care.[9] In her words, the "respondent . . . failed to calibrate the anesthesia machine's oxygen analyzer . . . failed to monitor properly during surgery . . . failed to adequately respond to evidence of a developing crisis during surgery . . . failed to remain awake and otherwise alert and vigilant at certain times during the surgery. . . . Charting . . . in certain cases was also falsified."[8,9]

The boy's temperature had risen to 107°F (41.6°C), and his breathing tube was half blocked with mucus. It is unclear exactly how long Dr. Verbrugge was asleep or why the nurses did not wake him up. Contending that the child died of malignant hyperthermia, Dr. Verbrugge argued that he should not be held responsible. The judge, however, found that it was his lack of vigilance that "in all likelihood directly resulted" in the patient's death, that even if the child had had malignant hyperthermia, he should have had a 90 percent chance of survival, and that "if the main problem was an obstructed airway, early recognition would have resolved the problem completely."[9] Dr. Verbrugge's medical license, which had been summarily suspended in July 1993, was revoked on the basis of these findings. On April 4, 1995, Dr. Verbrugge was charged with manslaughter in connection with the boy's death.[10] It was also alleged that he had fallen asleep during at least six other operations from September 1990 through March 1993, although no criminal charges were filed regarding those allegations.[10] The trial has not yet been held.

The Wisconsin Case

The Wisconsin case involved two women, 29-year-old Karin Smith, who died in 1995, and 39-year-old Dolores Geary, who died in 1993; both died of treatable cervical cancer after the misreading of several Pap smears. Smith had reported problems at 15 office visits over a three-year period during which practitioners at her health maintenance organization (HMO) had performed three biopsies and obtained three Pap smears, all but one of which (the last) were misread. Geary, a member of the same HMO, also had two Pap smears reported as normal before a 1991 hysterectomy, during which advanced cervical cancer was discovered. The HMO contracted with Chem-Bio Corporation to read the smears in both cases. A six-member inquest jury heard evidence that the laboratory's director, a physician, paid a technician on a piecework basis to read Pap smears. The technician had read 31,000 smears for Chem-Bio and 16,000 for other laboratories in 1989, an annual rate four times higher than that recommended by the American Society of Cytology.[11]

On April 7, 1995, the inquest jury recommended that criminal charges be brought against the director, the technician, and the laboratory. The district attorney, however, charged only the laboratory — with reckless homicide. The trial date has been set for December 4. Of course, if the corporation is found guilty, it cannot be put in prison; the punishment will most likely be a fine. The physician agreed that for the next six years, he will not serve as a laboratory director, will not supervise any cytotechnologists, and will not do any work in which he is responsible for quality control.[12] The technician agreed not to read Pap smears on a piecework basis, not to work more than 42 hours a week, and to obey all regulations that govern the number of Pap smears a technician can read in a day. Malpractice suits against the laboratory director, the cytotechnologists, and several other physicians were settled in the amounts of $6.3 million for Mrs. Smith's family and $3.5 million for Mrs. Geary's family.[11]

Criminal Standards in Medicine

These three cases illustrate different applications of the criminal law. In terms of the more traditional remedies, only one has resulted in a decision by a licensing board to limit a physician's ability to practice medicine (the Colorado case), and only one (the Wisconsin case) has resulted in a completed malpractice action. In fact, no civil suit was possible in the New York case, because the deceased had no family and apparently had no estate. Only one of these cases may have involved financial motives to provide grossly substand-

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ard care (the Wisconsin case). Nonetheless, in all the cases, criminal charges were brought in instances in which patients died.

Although criminal prosecutions of physicians are extremely rare, when they do occur, they almost always involve charges of reckless or intentional gross deviation from the accepted standard of care.[3,13] This standard is much higher than that used in medical-malpractice lawsuits, which, to be successful, require only proof of a breach of duty resulting in harm to the patient. Breach of duty is the failure to provide the level of care or treatment that would have met the standard of care — that is, the level that would have been considered acceptable in the medical community. Deviation from the standard of care, including a mistake of fact or judgment, is usually denoted simply as negligence or medical malpractice. Unlike a criminal charge, which must be proved beyond a reasonable doubt, a charge of malpractice need be proved only by a preponderance of the evidence.

The Massachusetts Supreme Judicial Court has put physicians' concern about criminal liability in proper perspective: "Little need be said about criminal liability: there is precious little precedent, and what there is suggests that a doctor will be protected if he acts on a good faith judgment that is not grievously unreasonable by medical standards."[14] Thus, a physician will not be held criminally liable for the death of a patient if that death is the result of a good-faith error of judgment or an inadvertent mistake.[3,15] In the rare cases of criminal prosecution, charges have usually been brought because a pattern of deaths and reckless disregard for patients' safety has emerged and, for some reason, the physician's license has not been revoked.

In a recent California case, for example, a physician was convicted of second-degree murder for intentional conduct resulting in the deaths of nine patients over an 11-year period. The court found that the doctor was "subjectively aware his methods of home and office deliveries were life-endangering, but consciously and deliberately disregarded these risks."[16] The court explained the difference between second-degree murder and manslaughter as follows:

> Second degree murder based on malice is committed when the defendant does not intend to kill, but engages in conduct which endangers the life of another, and acts deliberately with conscious disregard for life. An essential distinction between [second degree murder and] manslaughter based on criminal negligence, is that in the former the defendant subjectively realized the risk to human life created by his conduct, whereas in the latter the defendant's conduct objectively endangered life, but he did not subjectively realize the risk.[16]

Even a large number of deaths will not be sufficient for a criminal conviction unless the prosecution can demonstrate the requisite intent or recklessness, which will usually also involve identifying a specific standard of care that the physician grossly violated and that caused the deaths. For example, an appeals court in New Jersey reversed the conviction of a physician on the charge of involuntary manslaughter for the deaths of 12 of his patients from hepatitis contracted through intravenous injections.[17] The primary reason for the reversal was that the state was unable to prove the precise manner in which hepatitis was transmitted to the patients (the state suggested four possible theories of causation, including the multiple use of saline bottles and tubing). Thus, the state could not demonstrate that the defendant had recklessly and grossly deviated from the accepted standard in the care of his patients, because it could not show (beyond a reasonable doubt) that all the ways in which the virus would have been transmitted involved criminal negligence.[17]

A physician can be prosecuted for a single death that was caused by intentional or reckless disregard of life, but such prosecutions usually involve cases in which there has been repeated and intentional disregard for a patient's welfare over a period of time. In a Pennsylvania case, for example, a physician was found guilty of involuntary manslaughter after issuing dozens of prescriptions for controlled substances, including barbiturates, which led to the death of his patient. The appeals court found that the physician "consciously disregarded a substantial and unjustified risk, which disregard involved a gross deviation from the standard of conduct a reasonable person would have observed."[18] The case of Dr. Verbrugge is typical of the few cases involving charges of involuntary manslaughter that have been brought against physicians, in that it involved a series of acts showing conscious disregard for a patient's safety. Prosecutors seem unwilling to bring charges of criminal negligence on the basis of only one act, probably because they think it will be difficult to convince a jury that an isolated act demonstrates intentional indifference to a patient's welfare.

In this respect, the case of Dr. Einaugler is somewhat unusual. He was charged not with the death of his patient but with the failure to transfer her to the hospital for proper treatment in a timely manner. His misidentification of the dialysis tube was thus viewed as an inadvertent error, whereas his failure to act to protect the patient after he discovered the error was considered a conscious decision to risk her life for no medical reason. It is disturbing that the New York licensing board found that Dr. Einaugler's care of this patient was not substandard and that there was no need to discourage such treatment. Prosecutors may feel an additional obligation to the public to take action when professional self-regulation does not function to protect the public.

Of the three cases, the Wisconsin case is the most unusual, yet also the one that may exemplify the types of criminal cases that will become more frequent in our current system of market-driven medical care. The prosecutor did not bring criminal charges against the laboratory director, apparently because he believed that the public could be adequately protected by the director's agreement not to run a laboratory for six years and because at least some punishment had been meted out through malpractice litigation. The prosecutor did bring criminal charges against the laboratory.

We will continue to see criminal cases, and they are likely to differ from the current cases involving fraud, sexual abuse, and illegal drug prescription in frequency rather than in kind.[19] Some new cases, however, may in-

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volve patients' deaths from acts or omissions motivated by the desire to cut costs. Making more money is not a matter of medical judgment. If a healthy bottom line becomes more important than the health of the patient, it will seem perfectly reasonable for prosecutors to use the criminal law to protect patients and punish offenders. Prosecutors must, however, demonstrate that the physicians involved knew their cost-cutting measures would put patients' lives at risk and consciously or recklessly disregarded that risk. It may not be possible to provide such proof in most cases. However, individual officers or directors of medical organizations could be charged with manslaughter if they pursued policies they knew would result in death or if they were aware of the substantial risk of death and consciously disregarded it in setting organizational rules. Obviously, corporations and managers who are not physicians cannot use the defense of good-faith medical judgment, since nonphysicians cannot make medical judgments.

Conclusions

When a physician's egregious medical acts result in the death of a patient, the public expects that some action will be taken against the physician. Therefore, prosecutors may be more likely to turn to criminal prosecutions if proposals are enacted to limit civil liability by making it much harder for injured patients to sue negligent physicians. Also, if medical licensing boards continue to be ineffective in imposing sanctions against grossly negligent and incompetent behavior by physicians, prosecutors may conclude that criminal charges are the only way to protect the public.

The medical profession's reputation for acting in the best interests of patients is undermined not only by the publicity that criminal prosecutions generate but also by cost cutting in a competitive medical market. Physicians can respond positively by strengthening licensing boards, articulating and following reasonable standards of care, and developing more effective injury-prevention programs. Responsible physicians have nothing to fear from the criminal law. When physicians intentionally or recklessly disregard their patients' safety, however, they properly face criminal prosecution.

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BOOK REVIEWS

Community Child Health: An action plan for today

By Judith S. Palfrey. 302 pp. Westport, Conn., Praeger, 1994. $55. ISBN 0-275-94696-7.

Judith Palfrey has written a well-organized, readable book about children's health as it is affected by forces in the community. Physicians, social workers, and community health workers, as well as politicians and others who shape public policy, would benefit from reading it.

Palfrey leads the reader to conclude that we have entered a new era in child health. She divides the 20th century into the initial classic period, when physiologic investigation and technological innovation led to remarkable improvements in nutrition, the treatment of infectious diseases, and approaches to prematurity, and the second period, characterized by the "new morbidity," with attention to psychosocial and educational concepts. Palfrey introduces us to a third period, in which children suffer from epidemics of violence, acquired immunodeficiency syndrome, homelessness, and social disorder. She also includes the increasing numbers of survivors of chronic disease, children who initially benefited from high-technology care but who are now left with the chronic aftermath. She portrays the present status of childhood health with brief, practical clinical vignettes and suggests how child health workers could involve the community in attacking these problems. She advocates an inclusive approach that would extend far beyond individual practitioners and even beyond the established teams of hospital-based physicians, nurses, social workers, and dietitians in large cities. She invites teachers, community members, and others to help solve the problems children face in their homes, neighborhoods, and schools.

Drawing on 20 years of experience in the community-health arena in Boston, Palfrey gives detailed plans of action. Concrete examples include averting teenage pregnancy, controlling infection in a group home, and caring for preschoolers with chronic illness. The last chapters encourage community political action to improve the lot of children. They explore the political realities that hamper even well-meaning attempts to assist children living in poverty or in disrupted families, children in violent environments and foster and group care, and children with chronic diseases. The author's message is one of optimism, in spite of widespread problems facing such children. Her prescription is for a focused approach, often starting with small, achievable goals and established granting agencies. A team may then build on their successes and pursue more ambitious needs. The book clearly identifies many resources, each chapter has a large supply of endnotes, and a 29-page bibliography ensures that this is a practical tool.

Palfrey is a leader in applying the resources of Children's Hospital of Boston, well known for highly technical tertiary care activities, to the preventive and continuing-care issues of

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Criminal prosecution for medical manslaughter

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Introduction

Doctors like everybody else do make the occasional error. Sometimes these mistakes have disastrous consequences and somebody might even die. But when is an unintentional error so serious that a criminal offence has been committed?

Gross negligence is currently the legal threshold for medical manslaughter in English criminal law. Interpretation of 'gross negligence' is contentious and this does give rise to some uneasiness within the medical profession. However, it is not only the definition of 'gross negligence' which is problematic, the underlying intuitions about moral luck and personal control are controversial as well.

Judges and juries often face a difficult, if not impossible, task in medical manslaughter cases when deciding whether a criminal offence has been committed. One way to solve these problems would be to use a clearly-defined objective norm for personal failure as threshold, but this will imply a higher threshold for criminal prosecution.

Prosecutions for medical manslaughter

A review by Ferner and McDowell[1] showed that in England the number of doctors charged with manslaughter had increased dramatically since the 1990s. Quick[2] looked at medical manslaughter in general, not only manslaughter committed by doctors, and he also found an increase. In his study there was also some evidence for a regional variation (with more prosecutions in the north-west of England) and for racial differences (with more non-white people being prosecuted). Both Ferner and McDowell[1] and Quick[2] obtained their data via searching newspaper articles. It could be that there has been only an increase in reporting and not in prosecutions as such, but this seems unlikely.

The Crown Prosecution Service (CPS) might be somewhat more likely to prosecute than in the past. There is some evidence for this as an acquittal in medical manslaughter cases occurs more frequently than in 'normal' manslaughter trials. Given the recent increase there is the possibility that the legal concepts are not always interpreted in the same way.

Gross negligence

In England the legal criterion for manslaughter in the context of medical treatment is gross negligence as formulated in *R v Adomako*.[3] There has to be a breach in the duty of care which is so serious that it constitutes a crime. This will depend on both the seriousness of the breach of duty (i.e. departure from the proper standard of care) and on all circumstances in which the defendant was placed when it occurred. The defendant's conduct must have fallen far below the standard of a reasonable practitioner. But how to judge this?

With many offences the circumstances are important in determining the sentence, but not in deciding whether somebody is guilty. With medical manslaughter it is different: the circumstances also determine whether somebody has committed the offence. In all likelihood prosecutors, juries and judges find it difficult to get a clear grasp of all the circumstances because they have no personal experience of working in hospitals, operating theatres, et cetera.

Quick[2] stated on the basis of interviews with members of staff at the CPS that in practice the CPS only tends to start a prosecution if there are two expert witnesses willing to state in court that it was gross negligence. Quick does not discuss how the CPS finds their expert witnesses, but they might well be selected from a very limited group of doctors who are known

to the CPS. Quick mentions how experts sometimes change their views. Apparently, the concept of medical manslaughter is also difficult for experts, even though they know the circumstances.

Different types of error

Not all errors are the same and in some cases gross negligence is plausible. Ferner and McDowell[1] made a distinction between different types of errors: mistakes (i.e. errors in planning an action); slips (failures in execution an action often because of a momentary loss of concentration); technical errors; and violations (deliberate deviations from safe practices). There tends to be less controversy about the interpretation of gross negligence in case of violations. In a few of Ferner and McDowell's examples the person convicted had been intoxicated while making the error.

However, people have also been found guilty or pleaded guilty in cases of slips or mistakes. One of the examples is a doctor pleading guilty after a junior doctor he was supervising administered vincristine intrathecally and the patient died. An external inquiry into this event had identified many other contributory factors, but only this particular doctor was prosecuted.[4]

Competent and experienced doctors can make the occasional error and in practice errors happen quite frequently.[5] Why and when should the CPS start prosecution? This is not just a question of how to interpret gross negligence. There are difficulties with underlying intuitions regarding punishment for errors which need clarification.

Moral luck

Medical negligence is not the only area of the law where there are difficulties with unintentional consequences of actions. The concept of moral luck[6] is somewhat counterintuitive, but in cases of clear rule violations is generally accepted. An example will make this clear.

Suppose somebody is driving home after a party and his blood alcohol level is above the legal limit. It might well be that nothing happens, there is no accident and the person is not caught by the police. But suppose that this person has an accident. If he hits a tree and there is damage to his car, he is unlikely to get a prison sentence and will probably only get a fine and/or a driving ban. If he hits a child and the child dies, he will go to jail. Furthermore, thorough investigations to show whether the road was slippery and whether even a driver who had not been drinking alcohol could have had the same accident will not be done in general.

In all instances, the person was doing the same thing, driving under the influence of alcohol, and in all instances there was no intention to harm. The consequences of the driving under the influence of alcohol differed but were beyond the control of the person involved, and the person was either lucky or unlucky. Still, there is no debate about the rationale behind drink driving laws. Apparently it is generally accepted that one can do something wrong and that luck determines whether one gets (severely) punished or not at all.

The situation is more difficult if there is no alcohol use or other clear rule violation. Every driver has moments of lack of attention. Suppose somebody hits a tree while driving because he was not paying enough attention. It is unlikely that there will be a prosecution at all. Now suppose somebody kills a child who runs across the street and the driver does not manage to stop the car quickly enough; he was probably inattentive, but perhaps it was not possible to stop in time anyway. This is a situation where convictions are problematic. How can you prove that somebody could have stopped and that it was an error of criminal severity that he did not?

Generally, it is difficult to make a decision whether somebody made an error so serious that one should accept the consequences, including criminal conviction. This seems to be possible only, when there has been a clear objective rule violation (such as drinking alcohol before driving). Therefore, using the concept of 'moral luck' there are arguments for prosecuting only violations and no other errors.

Overestimation of personal control in case of a bad outcome

Prima facie it seems that humans decide on the basis of the facts whether somebody had control over a certain situation or not. However, experimental research shows that this is not always the case.

Knobe[7] presented test participants with one of the following vignettes:

- Scenario 1: The vice president of a company went to the chairman of the board and said, 'We are thinking of starting a new program. It will help us increase profits, but it will also harm the environment.' The chairman of the board answered, 'I don't care at all about harming the environment. I just want to make as much profit as I can. Let's start the new program.' They started the new program. Sure enough, the environment was harmed.

or

- Scenario 2: The vice president of a company went to the chairman of the board and said, 'We are thinking of starting a new program. It will help us increase profits, and it will also help the environment.' The chairman of the board answered, 'I don't care at all about helping the environment. I just want to make as much profit as I can. Let's start the new program.' They started the new program. Sure enough, the environment was helped.

When presented with scenario 1, 85% of the subjects said that the vice president intentionally harmed the environment, and when presented with scenario 2, only 23% of the subjects said that the vice president intentionally helped the environment. Apparently, if the outcome is bad, subjects are more likely to say that the person had control over the situation. Although the scenarios used by Knobe[7] are different from making an error, his study gives some evidence that people might well overestimate the influence somebody has had in preventing a bad outcome.

Experts, the CPS, judges and juries face an impossible task if they have to judge gross negligence in case of slips, technical errors and mistakes. It is not just knowing the circumstances, it is also estimating the amount of influence somebody had over the situation and this is quite difficult to do. There is an intuitive pull that, because somebody died, somebody must have committed a criminal offence, but this is not always justified.

Conclusion and possible alternative

The current concept of gross negligence is difficult to interpret and this is problematic, especially because there has been an increase in the number of prosecutions; there is also some evidence for regional variations and racial differences. However, the problems are not only with the definition of gross negligence but also with the underlying intuitions when prosecution is justified.

Regarding prosecuting medical errors, there are no major problems with prosecuting clinical negligence in cases of clear rule violations: behaviour which would be a criminal offence anyway or conscious departure from established guidelines. An example would be that somebody was drunk while making the error. Regional variations and racial differences can be acceptable in cases of clear rule violations because of the objective evidence.

However, in cases of mistakes, slips and technical errors the situation is different. Subjective recklessness has been proposed as criterion by Quick[2] and it is already recognized as a factor in determining gross negligence. However, subjective recklessness can be vague as well and can be influenced by psychological factors, such as described by Knobe's[7] research. This makes regional variations and racial differences difficult to explain; it could well be based on a prejudice.

Prosecution in cases of unintentional errors when there has been no violation of the law or a conscious deviation of clinical guidelines should probably stop because it is impossible to judge whether somebody has done something so severely wrong that criminal conviction is justified. A person should also not be prosecuted if the rule violations have been forced upon him or her. If there is no criminal prosecution this does not mean that nothing is happening as health professionals can still have their fitness to practise assessed by their regulatory bodies, such as the GMC.

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The New York Times https://www.nytimes.com/2011/11/08/us/doctor-found-guilty-in-michael-jacksons-death.html

Doctor Is Guilty in Michael Jackson's Death

By Jennifer Medina

Nov. 7, 2011

LOS ANGELES — Michael Jackson, among the most famous performers in pop music history, spent his final days in a sleep-deprived haze of medication and misery until finally succumbing to a fatal dose of potent drugs provided by the private physician he had hired to act as his personal pharmaceutical dispensary, a jury decided on Monday.

The physician, Dr. Conrad Murray, was found guilty of involuntary manslaughter nearly two and a half years after Jackson's shocking death at age 50. The verdict came after nearly 50 witnesses, 22 days of testimony and less than two days of deliberation by a jury of seven men and five women. The trial had focused primarily on whether Dr. Murray was guilty of abdicating his duty or of acting with reckless criminal negligence, directly causing his patient's death.

Dr. Murray, 58, faces up to four years in prison and the loss of his medical license. He sat stoically as the verdict was read and did not react as he was led out of the courtroom in handcuffs. Judge Michael Pastor ruled that he should be held without bail until his sentencing, set for Nov. 29.

Jackson, who had become a star as a child in Gary, Ind., singing with his siblings in the Jackson 5, grew into one of the best-known performers in the world. Though increasingly eccentric in his later years, often living on a secluded California estate he called Neverland, Jackson always had a fervent core of fans and, despite scandals, his lavish lifestyle and persistent money woes, always seemed just a comeback away from a return to the top.

Hundreds of fans showed their devotion by gathering outside the downtown courthouse throughout the trial — many of them sporting Jackson's signature single white glove. On Monday, they chanted "Justice, justice" and spent hours after the verdict dancing to his hits, from "Beat It" to "I Want You Back." Huge crowds had also gathered outside the California court where Jackson was tried, and acquitted, on child molesting charges in 2005.



Dr. Conrad Murray during the final stage of his trial on Thursday. Pool photo by Kevork Djansezian

The singer's parents, Joe and Katherine Jackson, and siblings La Toya, Jermaine and Randy were in the courtroom for the verdict. The family left the courthouse without speaking to the hordes of reporters gathered outside, simply saying they were "very happy" with the verdict and flashing a thumb.

Dr. Murray, a Houston cardiologist, was paid $150,000 a month to work as Jackson's personal physician as he rehearsed in Los Angeles for "This Is It," a series of 50 sold-out concerts in London that he needed to pay off hundreds of millions of dollars in mounting debts.

Testimony showed that Dr. Murray had stayed with Jackson at least six nights a week and was regularly asked — and sometimes begged — by the insomniac singer to give him drugs powerful enough to put him to sleep. Jackson, Dr. Murray told the authorities, was especially eager to be administered propofol, a surgical anesthetic that put him to sleep when other powerful sedatives could not. Testimony indicated that propofol, in conjunction with other drugs in the singer's system, had played the key role in his death on June 25, 2009.

Prosecutors tried to paint Dr. Murray as a money-hungry physician who would do things no reputable doctor would do — including improperly and recklessly administering an anesthetic normally given only in a hospital. The full retinue of drugs given to Jackson while he was under Dr. Murray's care was so beyond normal practice, prosecutors said, that it amounted to a "pharmaceutical experiment."

For its part, the defense tried to portray Jackson as a man so desperate to make his comeback concerts a success that he was willing to take wild chances and grew terrified that he would not be able to perform to his own exacting standards without more rest and less stress.

The morning Jackson died, Dr. Murray told investigators during a recording played in State Superior Court here, the singer told him, "Just make me sleep; it doesn't matter what happens."



Joe and Katherine Jackson, Michael Jackson's parents, arrived at the courthouse in Los Angeles on Monday. Bret Hartman/Associated Press

When Jackson died, he was more than $400 million in debt, but since his death, his estate has prospered, generating more than $310 million and paying off most of his debts.

The estate has struck several lucrative deals, including a movie, video games, a new recording contract and two productions by Cirque du Soleil.

Shortly after Jackson's death, Dr. Murray told investigators that the pop star would routinely plead with him to administer more propofol, calling it his "milk." The defense argued that Jackson gave himself the fatal dose of the drug. The Los Angeles County coroner ruled that Jackson's death was caused by "acute propofol intoxication," in combination with two other drugs in his system.

Two days after Jackson's death, Dr. Murray told investigators that he had been using propofol almost nightly for two months to help the singer sleep.

In their closing arguments, prosecutors repeatedly invoked Jackson's three children to a jury that included nine parents, saying that the singer wanted to perform, in part, so that they could see their father on stage. David Walgren, the deputy district attorney in charge of the case, described the frantic moments after Dr. Murray realized that Jackson was not responsive and as the pop star's children watched him lie lifeless on his bed.

Prosecutors sought to show that Dr. Murray veered significantly from acceptable medical practice at nearly every turn: by administering the propofol, not having proper monitoring equipment and failing to call 911 right away, among other things. They said Dr. Murray had not kept any records of administering propofol but had taken time to record Jackson's voice on his iPhone.

He did not tell the paramedics who arrived at Jackson's home about the propofol, which prosecutors said showed that he knew he was responsible for the singer's death. Just one day before the trial ended, Dr. Murray decided he would not testify.

Steve Cooley, the Los Angeles County district attorney, said that he hoped the trial would send a message to other "unscrupulous, corrupt" doctors who help fuel patients' reliance on powerful drugs.

"In Los Angeles we see many examples of high-profile people losing their lives because of their addiction to prescribed medication," Mr. Cooley said. "To the extent that someone dies as a result of their playing the role of Dr. Feelgood, they will be held accountable."

Mr. Cooley said that he doubted that Dr. Murray would serve a full four-year sentence because of the state's chronically overcrowded prisons.

In one of the most dramatic moments in the trial, prosecutors played the iPhone recording Dr. Murray made of Jackson toward the end of his life and the court heard the singer rambling about his dream of building the world's largest children's hospital.

"I'm going to do that for them," Jackson is heard saying in slurred speech. "That will be remembered more than my performances. My performances will be up there helping my children and always be my dream. I love them. I love them because I didn't have a childhood. I had no childhood. I feel their pain."

When his voice trailed off, Dr. Murray waited several seconds before asking, "You O.K.?"

After several more seconds, Jackson answered, "I am asleep."

Doctors charged with manslaughter in the course of medical practice, 1795–2005: a literature review

R E Ferner Sarah E McDowell

J R Soc Med 2006;**99**:309–314

SUMMARY

Objectives: To quantify the number of doctors charged with manslaughter in the course of legitimate medical practice and to classify cases, as mistakes, slips (or lapses), and violations, using a recognized classification of human error system.

Design: We searched newspaper databases, Medline, Embase, and the Wellcome library catalogue to identify relevant cases from 1795 to December 2005.

Setting: Medical practice in the United Kingdom.

Main outcome measure: Number of doctors charged with manslaughter in the course of medical practice.

Results: We identified 85 doctors charged with manslaughter since 1795. The number of doctors charged was relatively high in the mid-19th century and the inter-war years, and has dramatically increased since 1990. Sixty of the doctors were acquitted, 22 were convicted, and three pleaded guilty. Most doctors were charged as a consequence of mistakes (37) or slips (17), and a minority because of alleged violations (16).

Conclusions: The number of doctors prosecuted for manslaughter has risen steeply since 1990, but the proportion of doctors convicted remains low. Prosecution for deliberately violating rules is understandable, but accounts for only a minority of these cases. Unconscious errors—mistakes and slips (or lapses)—are an inescapable consequence of human actions and prosecution of individuals is unlikely to improve patient safety. That requires improvement to the complex systems of health care.

INTRODUCTION

Medical errors have serious consequences.[1] Between 44 000 and 98 000 patients may die every year in US hospitals from preventable errors in their care.[2] When a death occurs as a result of such an error, the desire to attribute blame can lead to criminal proceedings; the 1990s saw a marked increase in the number of doctors charged with manslaughter.[3,4] We have examined British data on doctors charged with manslaughter in the course of medical practice from the early 19th century to the present day.

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SEARCH STRATEGY

We searched *The Times Digital Archive* (1795–1985), *The Scotsman Digital Archive* (1817–1950), and the *Lexis Nexis* (1985–December 2005) databases using the text words *doctor, anaesthetist, or surgeon* and *manslaughter*, to identify relevant newspaper articles and case law reports. We also searched Medline (1955–December 2005) and Embase (1974–December 2005) using the text word *manslaughter*. In addition, we searched the titles and abstracts of the *Lancet* (1823–December 2005) electronically using the text words *manslaughter, assizes, criminal court*, or *verdict*. Finally, we carried out a search of the Wellcome library catalogue using the search term *manslaughter*. Where information on potentially relevant cases was incomplete, we also hand searched the indexes of the *Lancet* and the *BMJ* for the year during which a case was tried. A previous article[5] was limited to errors in administering anaesthetics or prescribing or giving medicines in the years 1970–1999. Here we extend the search to include all medical practitioners charged with manslaughter from 1795–2005. We divided the cases we identified, according to a recognized classification of human error,[6,7] as mistakes, slips or lapses, and violations.

RESULTS

We initially identified 177 health professionals charged with manslaughter. Forty-seven individuals were not medically qualified. Three medical students, who were practicing as fully qualified doctors, even though they had not obtained the legal qualifications were also excluded from the analysis. Thirty-one practitioners were accused of manslaughter associated with criminal abortion rather than errors during legitimate practice, and we also excluded them. The outcomes of the cases of three doctors could not be found, and are not reported here. Therefore 75 cases, involving 85 doctors, were identified in the period 1795–2005 (Figure 1).

The number of doctors charged with manslaughter since 1795 was relatively high in the mid-19th century and the inter-war years, and has dramatically increased since 1990

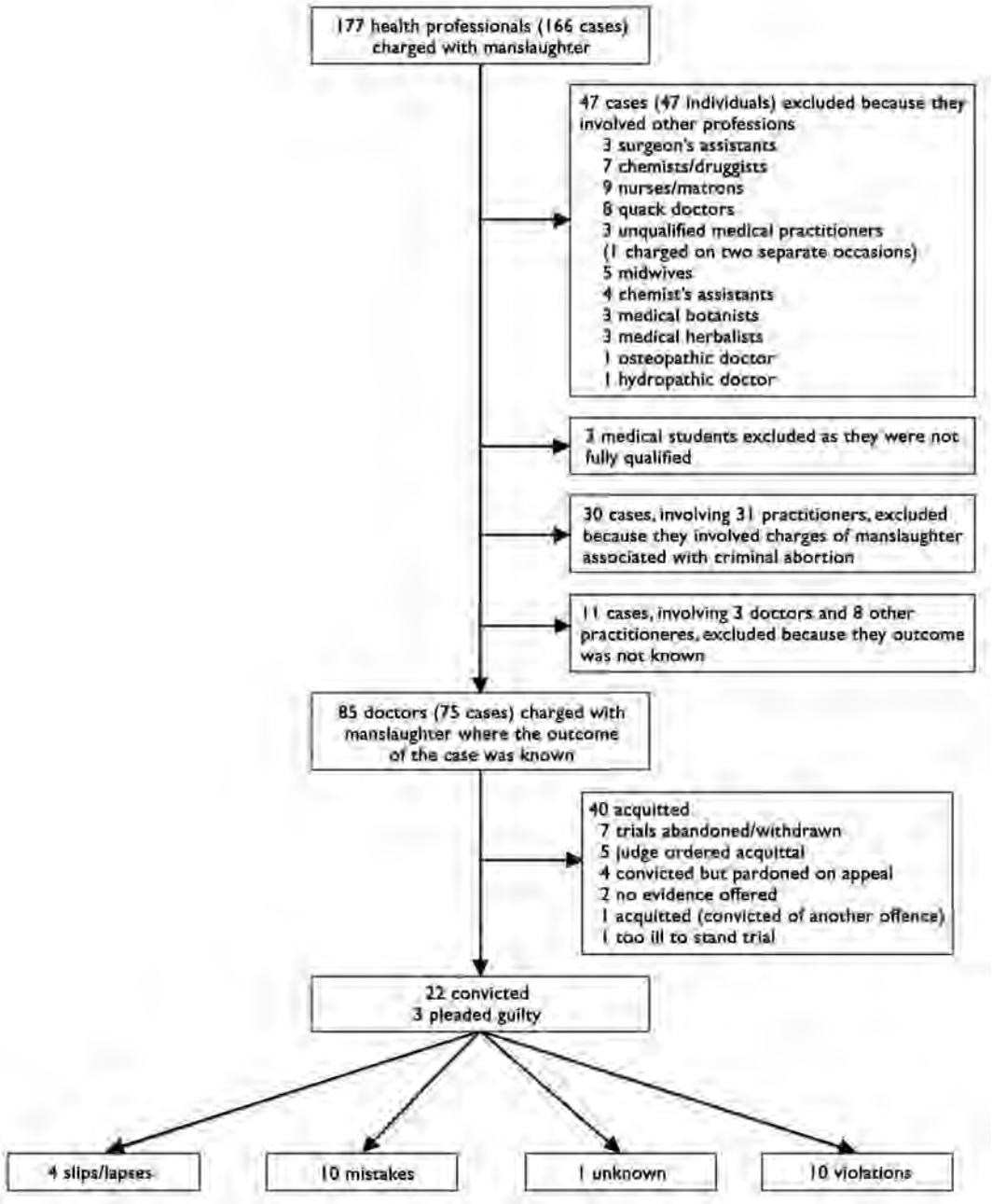


Figure 1 **Flow chart of search strategy**

(Figure 2). The majority of the cases from the 19th century related to obstetrics (19 of 32 cases), while most cases in the 20th century involved errors in the administration or prescribing of medicines (Table 1).

Sixty (71%) doctors charged with manslaughter were acquitted, with 22 doctors being convicted and three pleading guilty to the charge. Since 1975, 44 doctors have been charged, of whom 30 (68%) were acquitted and 14 pleaded guilty to or were convicted of manslaughter (Table 2).

The earliest case was of a Dr Raeburn, who in 1831 was charged with manslaughter following the death of a woman after childbirth.[8]

Doctors were most commonly charged with manslaughter as a result of mistakes (37/85 doctors), which are errors in the planning of an action. Ten of these doctors (27%) were convicted. The cases of 17 doctors were classified as slips, which are errors in the execution of an action that often occur as a result of distraction or momentary failure of concentration. Four of these doctors (24%) were convicted. There were also three cases that involved technical errors, which occur when there is a failure to carry out an action successfully even if the plan of action and technique are appropriate. Sixteen were classified as violations, in which there is a deliberate deviation from safe practices. Ten of

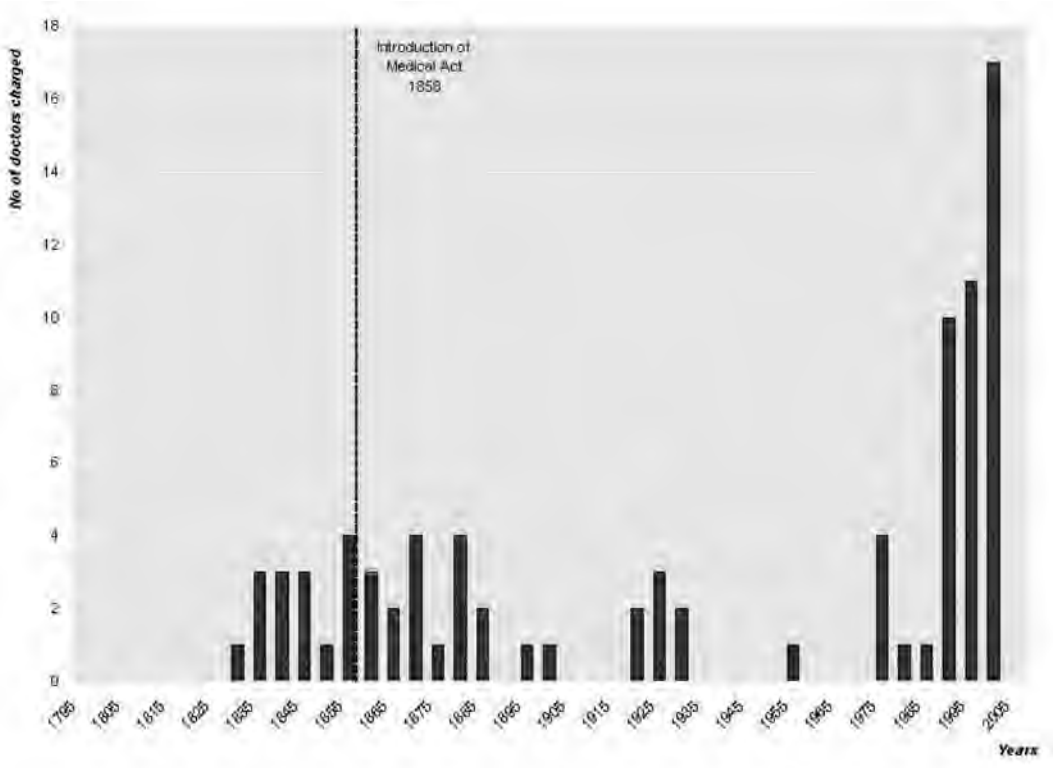


Figure 2 **Number of doctors charged with manslaughter as a result of the death of a patient, 1795 to 2005 (excluding abortion cases)**

these doctors (63%) were convicted. In 11 cases, involving 12 doctors, there was insufficient information to classify the case. Examples of cases that were classified are presented below.

Mistakes

Case 1 (1844)

A 6-week-old girl was prescribed a mixture containing two drops of laudanum [a tincture of opium] and died. The mixture contained four times the standard dose. The prescribing surgeon was charged with manslaughter but acquitted.[9]

Case 2 (1874)

A woman died from an overdose of morphia administered by her husband, a surgeon, to help her to sleep. He allegedly administered 17 grains (778 mg) of morphia over a 3-hour period. He was charged with manslaughter but acquitted.[10]

Case 3 (1999)

A general practitioner administered 30 mg of diamorphine to a 55-year-old man suffering from lower back pain. The patient died from respiratory failure. The maximum recommended initial dose of diamorphine is 10 mg. The GP was charged with manslaughter and convicted.[11]

Case 4 (2001)

A 20-year-old emaciated man with muscular dystrophy died after circumcision. The surgeon guessed the patient's weight and inadvertently gave three times the recommended dose of lidocaine. He was charged with manslaughter but acquitted.[12]

Slips and lapses

Case 5 (1867)

A woman was prescribed three tablespoons of medicine obtained from a doctor, which was supposed to contain bismuth, henbane, and quassia. In error, the medicine was made up with strychnine, not bismuth, and the woman died. The doctor was charged with manslaughter but acquitted.[13]

Case 6 (1978)

A 4-year-old boy who had had a brain tumour removed was given 650 mg of methotrexate into the cerebral ventricles, developed convulsions, and died. The dose of methotrexate was 20 times too great. The junior doctor who had given the injection had taken the dosage from the case notes, '. . . not knowing that it related only to intravenous drips'. She was charged with manslaughter but acquitted.[14]

Table 1 **Number of doctors charged with manslaughter, by type of case**

Type of case	*Total charged*	*From 1795–1899*	*From 1900–2005*
Obstetric care	22	19	3
Inappropriate treatment/ Failure to diagnosis	18	8	10
Surgery	9	0	9
Medicines	36	5	31
Total	85	32	53

Table 2 **Number of doctors charged with and convicted of manslaughter**

Years	*Total charged*	*Total convicted/ pleaded guilty*	*Convicted*
1795–1824	0	0	0%
1825–1854	11	4	36%
1855–1884	18	4	22%
1885–1914	4	1	25%
1915–1944	7	1	14%
1945–1974	1	1	100%
1975–2005	44	14	32%
1795–1899	32	9	28%
1900–2005	53	16	30%

Case 7 (2003)

An 18-year-old man with leukaemia was due to receive cytosine, to be injected intrathecally that day; and vincristine, to be injected intravenously the next day. The senior house officer correctly administered the cytosine, but the registrar then handed his junior the vincristine and told him to inject it into the patient's spine. Although the SHO checked twice to be certain of the registrar's instructions, he was told to go ahead with the injection. The registrar was charged with manslaughter and pleaded guilty.[15]

Case 8 (2004)

A 6-week-old boy died after cardiac arrest during surgery for pyloric stenosis. The anaesthetist injected air into the bloodstream instead of the nasogastric tube. The anaesthetist was charged with manslaughter but acquitted.[16]

Technical errors

Case 9 (1875)

A woman died during childbirth and the surgeon was charged with manslaughter due to alleged unskilful treatment. Following inquiries, it was found that the doctor followed a course of treatment that would have been followed by any skilful surgeon and the case was withdrawn.[17]

Case 10 (2001)

A 16-year-old girl being treated for leukaemia died after an attempt to insert a Hickman line (central venous catheter) caused cardiac rupture. The surgeon was charged with manslaughter but acquitted.[18]

Violations

Case 11 (1839)

A woman died following childbirth. The post mortem examination revealed injuries to the woman that had been caused by the unskilful and violent use of some instrument. The surgeon may have been intoxicated during the delivery and was charged with manslaughter, but acquitted.[19]

Case 12 (1859)

A woman died several days after an instrumental delivery, as the result of a large vaginal wound. It was alleged that the doctor had been 'fresh' (drunk) and had been deficient of ordinary skill and caution, or had, by intoxication, rendered himself unfit. He was charged with manslaughter and found guilty.[20]

Case 13 (1959)

A 2-year-old boy died from hypoxia that occurred during a hernia operation. The anaesthetist had deliberately inhaled anaesthetic before and during the operation. He was charged with manslaughter and found guilty.[21]

Case 14 (2004)

A 71-year-old woman died after suffering catastrophic blood loss during surgery to remove a cancerous tumour from her liver. The surgeon admitted that he should not have continued the operation after finding that the tumour was twice the size he had expected, and was near important blood vessels. He was also alleged to have had his picture taken with her dissected liver during the operation. He was charged with manslaughter and other offences. He pleaded guilty to manslaughter.[22]

HISTORICAL PERSPECTIVE: THE CHARGE OF INVOLUNTARY MANSLAUGHTER OVER THE PAST TWO CENTURIES

We set out to identify qualified doctors, but the formal distinction between legally qualified and unqualified practitioners was not made until the Medical Act 1858. Before this, many patients used the services of unlicensed practitioners, of whom several were charged with manslaughter.

In the early 19th century, the law recognized that medical practitioners were not immune to human error; juries were directed to convict a practitioner only if the prosecution had proved that the individual owed the patient a duty of care, and had acted with gross want of skill and care. For example, in 1862 Frederick Robinson, a surgeon, was charged with the death of a woman following childbirth.[23] Instead of removing the placenta, he had dragged out a portion of the intestines. The judge stated:

'Every medical man was of course liable to make a mistake, and he would not be criminally responsible for the consequences if it should appear that he had exercised reasonable skill and caution, and it was only in the case where a medical man, as he had before stated, was guilty of gross negligence, or evinced a gross want of knowledge of his profession, that he could be held criminally responsible.'

Robinson was convicted and imprisoned.

Unlicensed practitioners were held accountable by the law in a similar manner to licensed practitioners in the period before the Medical Act 1858. For example, in 1834, a chemist named Joseph Webb was charged following the death of patient to whom he had administered medicine for the treatment of smallpox.[24] The judge in this case stated that:

'. . . in these cases there is no difference between a licensed physician or surgeon, and a person acting as a physician or surgeon without a licence. In either case, if a party having competent degree of skill and knowledge, makes an accidental mistake in his treatment of a patient, through which mistake death ensues, he is not thereby guilty of manslaughter: but if where proper medical assistance can be had, a person totally ignorant of the science of medicine takes upon himself to administer a violent and dangerous remedy to one labouring under a disease, and death ensues in consequence of this dangerous remedy having been so administered, then he is guilty of manslaughter.'

Webb was acquitted.

Judicial attitudes seem to have changed after the Medical Act 1858. In 1859, William Crick, a medical botanist was charged with causing the death of a child by giving a dose of *Lobelia inflata* (an emetic herb).[25] The judge stated:

'If the prisoner had been a medical man I should have recommended you to take the most favourable view of his conduct, for it would be most fatal to the efficiency of the medical profession if no one could administer medicine without a halter round his neck.'

Crick was acquitted.

The law relating to involuntary manslaughter has been clarified by two medical cases. Dr Percy Bateman was convicted in 1925 of gross negligence manslaughter after a woman died following childbirth. During manual removal of the placenta, he had mistakenly removed a portion of the uterus. The Court of Criminal Appeal quashed his conviction, stating that to be convicted, the defendant's negligence must be '. . . so gross that it showed such a disregard for the life and safety of others as to amount to a crime against the state and conduct deserving punishment'.[26]

In 1995 the House of Lords considered the case of John Adomako, an anaesthetist, convicted of gross negligence manslaughter after the death of a patient following a cardiac arrest during surgery for a retinal detachment.[27] The anaesthetist noticed hypoxia only when a blood pressure alarm sounded some 4½ min after the endotracheal tube became disconnected from the oxygen supply. The House of Lords held that gross negligence defined in the Bateman case was the appropriate test in manslaughter cases involving breach of duty.

DISCUSSION

We identified 85 doctors over the past two centuries who were charged with manslaughter due to medical errors. Leahy Taylor stated the earliest known case[13] was tried in 1867.[28] However, we identified several cases of licensed doctors, as well as unqualified practitioners, who were charged with manslaughter before this.

There were many cases in the middle of the 19th century, the majority related to obstetrics. This may be explained by the increasing medicalization of childbirth during that time. The 1800s saw increased, and often injudicious, use of forceps and a high rate of maternal mortality, which did not alter dramatically until the early 1940s.[29] The introduction of powerful, sometimes dangerous, medicines in the 20th century, may also explain why the majority of cases from this period involved medicines.

Several cases involved drunkenness or brutal lack of skill, but many were classified as mistakes (errors in planning) or slips (errors in executing an action). Slips are inherent to human cognition and are more likely to occur when an individual is tired, distracted, or interrupted. They can only be prevented or minimized when the systems and processes in which doctors work are made safer. This is most likely to happen when practitioners are candid about their errors.[30]

The dramatic increase in the number of doctors charged with manslaughter over the past two decades is evident. However, the conviction rate remains at around 30%. In the UK, the

'. . . Crown Prosecutors must be satisfied that there is enough evidence to provide a ''realistic prospect of conviction'' . . . [that is] that a jury or a bench of magistrates, properly directed in accordance with the law, will be more likely than not to convict the defendant of the charge alleged.'[31]

The Crown Prosecution Service charges too many doctors, even by its own standards.

Limitations of our study

We may have failed to identify some relevant cases and we explicitly excluded non-qualified practitioners from the search strategy and analysis, which may have led to a biased representation of the early 19th century. The results are presented without consideration to the actual number of practising doctors or the number of interactions between doctor and patient. They therefore do not provide insight into the actual proportion of doctors charged with manslaughter or the proportion of patients whose death led to charges of manslaughter.

CONCLUSIONS

The criminal prosecution of a doctor is appropriate when there is clear evidence of violation of safety rules. However, human error is unavoidable in the course of care. Charging doctors with manslaughter following a medical error may be an emotionally satisfying way to exact retribution, but if individual doctors are singled out for punishment it will become much harder to foster an open culture. Faults in the system will remain hidden, and more patients will die.

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Competing interests RE Ferner has received fees for writing medicolegal reports. Sarah E McDowell has no competing interests.

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Medicolegal Sidebar

The Law and Social Values: Medical Necessity and Criminal Prosecution

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Introduction

Where criminal law and medicine intersect, complexity arises. An ever-shifting foundation of case law makes this territory dangerous but also interesting to explore. Perhaps no subject is on more physicians' minds than the risk of prosecution for Medicare fraud, particularly with respect to the performance of unnecessary procedures. At the heart of this question exist two controversial issues in medicine and law: (1) How does one differentiate between a necessary and unnecessary medical procedure given the uncertainty in the practice of medicine; and (2) what constitutes a healthcare crime?

Medical Necessity and Crime

The medical necessity dilemma has spawned many books [1, 5, 10–12] by authors who raise concerns about whether or not medical and surgical practice patterns reflect custom and culture, rather than well-established scientific evidence. Accordingly, author Shannon Brownlee in *Overtreated* [1] proposes that one-third of the medicine that patients receive is unnecessary. She states, "Doctors lack the evidence they need to know which treatments are most effective and which drugs and devices really work" [1]. The late Kerr White MD, the founding chair of The Department of Health Policy and Management at Johns Hopkins University and the Deputy Director for Health Care Services for the Rockefeller Foundation stated it another way in *Medicine & Culture* [11], "About 15% of all contemporary clinical interventions are supported by objective scientific evidence that they do more good than harm." In orthopaedic surgery specifically, questions have been recently raised about the effectiveness of common operations such as knee arthroscopy [7], knee replacement [13], and spinal surgery [9].

The second question appears simple, but is highly complex—what constitutes a healthcare crime? The question of healthcare criminal conduct can be easy to resolve within a certain context.

Note from the Editor-in-Chief: We are pleased to publish the next installment of "Medicolegal Sidebar" in Clinical Orthopaedics and Related Research®. *The goal of this quarterly column is to encourage thoughtful debate about how the law and medicine interact, and how this interaction affects the practice of orthopaedic surgery. We welcome reader feedback on all of our columns and articles; please send your comments to eic@clinorthop.org.*

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For example, if a physician or surgeon bills for procedures that are not performed, then that physician or surgeon has committed a crime. This is no different from stealing directly from Medicare or other third-party insurers. But the question of whether a physician or surgeon has committed a crime because his or her procedures are deemed to be medically unnecessary is much more complicated and fraught with the potential for prosecutorial abuse. Prosecutions based on lack of medical necessity are not premised on improper billings, but rather the often-obscure criteria regarding whether the procedures would benefit the patient.

Criminal prosecutions of surgeons based on allegations of medical necessity are rare enough to be sensationalized in newspaper headlines, if and when they do occur. The legal standard for proving crime is far more stringent than that needed to prove a civil wrong-doing, such as medical negligence. Indeed, when it comes to medical practice, our legal system has maintained a traditional, and some would say, an extreme deference toward physician judgment. Thus, criminal prosecutions for unnecessary surgery, as in the case below, are triggered only when some element of the practice pattern defies accepted norms in a particularly egregious way, or when the harm is perceived to be systemic and recurrent. These considerations do not apply to the overwhelming majority of physicians in practice.

United States v McLean

A recent legal case, *United States v McLean* [14], demonstrated the problems inherent in prosecuting a physician or surgeon for unnecessary procedures. Following a review from a hospital peer-review committee, the federal government charged Dr. McLean, an interventional cardiologist from Maryland, with performing medically unnecessary coronary stent procedures. He was indicted under 18 U.S.C. § 1347, a federal statute that states that if a person commits healthcare fraud, he or she shall be fined and/or imprisoned up to 10 years. If the violation results in bodily injury or death, he or she can be imprisoned up to 20 years or for life, respectively [8].

At trial, the federal government introduced testimony from two expert cardiologists who testified that it was generally accepted that coronary stents were not medically necessary in the absence of 70% stenosis, and symptoms such as chest pain or a positive stress test. Dr. McLean's former patients who had received stents testified that they never experienced chest pain even though Dr. McLean recorded chest discomfort in his medical records [14].

It was Dr. McLean's contention that the government's medical standard for coronary stents was incorrect. He also argued that evaluating degrees of stenosis by angiograms is highly subjective, and that his stent placements were appropriate and necessary. He called an expert witness who testified that during the relevant period of time, elective stents are considered medically appropriate if a patient had at least 50% stenosis and evidence of ischemia or angina. This expert's review of five cases that were named in the indictment was that four had met the standard of care. Many grateful patients of Dr. McLean also testified on his behalf.

Following 10 days of trial, a jury convicted Dr. McLean of healthcare fraud, sentencing him to more than 8 years in prison, with monetary restitution of USD 579,070.

On appeal, the Fourth Circuit Court of Appeals affirmed Dr. McLean's conviction [14].

Analysis of the Appellate Decision

In his appeal, Dr. McLean had argued that his conviction was unconstitutional because of the doctrine of "constitutional vagueness." Under American constitutional law, a legal statute can be void for vagueness. There are a variety of reasons why this protective constitutional doctrine exists. One reason is that

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no one should be punished as a criminal under laws that do not explicitly and definitively identify a proscribed conduct. As the US Supreme Court clarified in the 1926 legal case, *Connally v General Construction Co*, "[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law" [2].

The *McLean* decision raises difficult questions that are relevant to all physicians. Was Dr. McLean sufficiently on notice that his implantations of coronary stents were so inappropriate that his conduct constituted a federal crime? Most physicians will agree that there is seldom a bright line in medicine that clearly differentiates medically unnecessary versus medically necessary procedures. While it is true that in any community or large hospital, there is a range of surgical indications practiced by aggressive, high-volume surgeons versus those who favor a conservative, nonoperative approach, it is worth remembering that the *McLean* litigation represents conduct that was clearly an outlier. While the appeal was made on the argument that the precise amount of coronary stenosis, or lack thereof, which would make stent placement a criminal act is not sufficiently settled among professionals, the facts of the case showed that Dr. McLean had systematically engaged in other misconduct, such as altering entries in the medical records to justify billing for stent procedures, and falsifying billing for surgery and followup care. Thus, as the appellate court correctly concluded, Dr. McLean's argument that no one really knows how aggressive a stent-placing cardiologist has to be in order to end up with a criminal conviction based on medical necessity was simply disingenuous.

Even so, *McLean* represents a tension between two competing principles of law. On the one hand, if medical necessity is interpreted broadly, many, if not most, physicians or surgeons can be prosecuted on the whim of the justice department, at least in theory. On the other hand, if medical necessity is construed narrowly, then physicians and surgeons can engage in highly questionable procedures for profit without fear of prosecution or accountability. There has been an interesting epilogue to the *McLean* case. In 2015, *The New York Times* published an article that begins by stating, "At a time of increasing scrutiny of procedures to open blocked heart arteries, cardiologists are turning to—and reaping huge payments from—controversial techniques that relieve blockages in the arms and legs" [3]. The article went on to state, "Medical experts are questioning the necessity of some of these treatments, and many believe the condition is more safely treated with drugs and exercise" [3].

A maxim of good trial law is that for every good argument, there is an equally good counter-argument. For the sake of argument therefore, is it possible that the experts who testified against Dr. McLean were engaged in negligent activity themselves? In other words, were these testifying experts so conservative in their approach that patients in their care were dying from unnecessary withholding of coronary stenting? If so, and absent clearly-defined gold-standard criteria for the implantation of coronary stents, is it fair to say that Dr. McLean's professional conduct should not have been prosecuted? Perhaps so, but in the *McLean* litigation, it was not simply the medical practice that raised questions, rather, it was the efforts to cover up misconduct that triggered further inquiry and led to criminal proceedings. The fact is that if the prosecutor had nothing more to offer than expert arguments and counter-arguments about how much coronary stenosis is needed to make a stenting procedure a criminal act, there is no question that Dr. McLean would not even have been indicted. This reflects the threshold needed to bring about a criminal indictment in our legal system. Instead, the facts in *McLean* showed a clear pattern of alteration of records, including factual data that were falsified to create justifications for stent surgery, and fraudulent billing that was inconsistent with the operations

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performed, and the followup care provided.

Discussion

Most of the physician concern about liability in medicine surrounds medical malpractice litigation. Physician leaders have argued that medical malpractice lawsuits contribute to increasing healthcare costs [6], and subsequent reforms, such as those targeted at limiting damage awards in medical malpractice litigation have been enacted in many states. In contrast, the potential consequences of healthcare fraud for alleged medically unnecessary procedures have attracted little attention so far, aside from the occasional, sensational newspaper article.

Medical negligence lawsuits may affect the majority of physicians in some specialties, such as orthopaedic surgery. Assuming the plaintiff is successful, the resolution of medical malpractice lawsuits is always measured in monetary damages that are indemnified through insurance. In contrast, criminal prosecutions of physicians, such as for allegations of medically unnecessary procedures or fraudulent billing, are vanishingly rare and require a high standard of proof for successful prosecution. The penalties associated with such litigation are serious however, and can include a prison sentence, in addition to monetary damages.

While rare, healthcare fraud is a crime, and should be a concern to those familiar with the American criminal justice system [4].

In light of the *McLean* litigation, if an orthopaedic surgeon, for example, were to perform total knee or hip procedures and a group of his peers alleged that 25% of the procedures he performed were unnecessary, should the orthopaedic surgeon be indicted for healthcare fraud? The facts of the *McLean* case offer some guidance to this question, and reassurance. An outlier physician with an egregious volume of surgery, questionable indications, or unusually high incidence of patient injury would be reported to the hospital system, or to the local medical board. Indeed, this was the case with Dr. McLean, and an internal inquiry by his peers did identify serious and systemic concerns with his patient selection criteria. Further inquiry then revealed fraudulent billing patterns, patient record alteration, and other conduct that crossed the threshold for criminal behavior, on a repetitive basis.

While there is no quick answer to the question of when our justice system should indict physicians and surgeons for medically unnecessary procedures, the first line of inquiry toward maintaining quality and patient safety is peer-driven, such as from a peer-review committee, or similar body. Depending upon the circumstances, peer review may identify correctable practice patterns that are amenable to proctoring, further training, or mentorship. Credible, independent peer review is a powerful tool available to the medical community to identify physicians who might stray outside the bounds of proper indications for a procedure, and take corrective action in a timely manner. The medical community should strive to ensure that the peer-review process is truly independent, fair, and not driven by competitive or political motives. Data concerning physician operative volumes, outcomes, and complications should be available to peer-review bodies so that outliers can be identified, and patient harm avoided.

While the *McLean* case reflects the successful prosecution of a physician for improper surgery and billing, and the appellate component of the litigation addressed the provocative subject of medical necessity, for the overwhelming majority of physicians, the threat of criminal prosecution from medically unnecessary procedures is entirely avoidable.

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Medical Professionals, Excessive Force, and the Fourth Amendment

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Police use of force is a persistent problem in American cities, and the number of people killed at the hands of law enforcement has not decreased even as social movements raise greater awareness. This context has led to reform conversations on use of force that seek less violent ways for police to engage the public. One example of how this might occur is through partnerships between police and medical professionals to use chemical restraints—drugs traditionally used in hospital settings to calm agitated or aggressive patients—to sedate people who refuse or are unable to comply with law enforcement. The injury and, at times, death that can result gives rise to a key yet unexplored constitutional issue: does the Fourth Amendment allow medical professionals to collaborate with police and use chemical restraints during routine arrests? When, if at all, does the use of powerful sedatives by paramedics to facilitate an arrest become an unreasonable use of force? Federal courts have been inconsistent on these issues and overly deferential to medical professionals and law enforcement. In this Article, we provide the first scholarly analysis of how Fourth Amendment rules concerning use of force apply to medical practitioners who partner with law enforcement to chemically subdue arrestees—not for their medical benefit, but to assist police. After analyzing the legal, medical, and ethical contours of this novel constitutional issue, we argue that Fourth Amendment limits on chemical restraints in policing should mirror existing federal regulations on using such drugs in healthcare settings found in Title 42 of the Code of Federal Regulations. In this way, medical necessity, individual autonomy, and the person's wellbeing would be prioritized over convenience to law enforcement. This approach might also clarify medical practitioners' role during police stops and arrests and provide guidance on how they may participate in a way that conforms with both Fourth Amendment norms and their professional commitment to promoting patient health and safety.

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INTRODUCTION

John Powell had just finished visiting his cousin at North Memorial Hospital near Minneapolis, Minnesota.[1] As he entered the hospital parking

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1. John Croman, *Man Files Lawsuit Over Ketamine Injection*, KARE11 (July 14, 2018, 1:35 PM), https://www.kare11.com/article/news/man-files-lawsuit-over-ketamine-injection/89-573408858 [https://perma.cc/N4XV-C3H2].

garage, he saw a group of police officers near his car.[2] Earlier that day, the police responded to a 9-1-1 call placed by a hospital employee about a "very light skinned or Hispanic male" in the parking lot with a gun who appeared to be suicidal.[3] Powell—a Black man with a dark complexion—did not match this description.[4] Nevertheless, the officers drew their weapons when they saw Powell, ordered him to the ground, and handcuffed him.[5] Later, the police claimed that Powell approached them with what they thought was a firearm,[6] but was then determined to be his car keys.[7] The police held him on the ground in the rain for about an hour.[8]

The employee who made the 9-1-1 call confirmed that Powell was not the person she saw earlier.[9] Yet, the officers still refused to release Powell and kept him detained in a squad car.[10] Frustrated, Powell began kicking and screaming.[11] From the back of the car, Powell could see a North Memorial Hospital ambulance arrive.[12] Paramedics stepped out and huddled with officers.[13] A paramedic then approached Powell, still handcuffed in the back of the car, and stuck the needle of a syringe that contained a drug called ketamine in his arm.[14] All Powell remembers after that is falling over.[15] Powell's breathing stopped due to an adverse reaction to the drug, which required immediate medical attention to save his life.[16] Powell was intubated and hospitalized.[17]

* * *

Excessive use of force by law enforcement has been a critical issue for many years,[18] but public discussion has substantially increased as a result of social movements protesting police shootings of unarmed people.[19] Some have

2. Andy Mannix, *Lawsuit Says Police Detained Innocent Man at North Memorial, Urged Paramedics to Use Ketamine to Sedate Him*, STAR TRIB. (July 12, 2018, 11:14 AM), https://www.startribune.com/lawsuit-says-police-detained-innocent-man-at-north-memorial-urged-paramedics-to-use-ketamine-to-sedate-him/487951331 [https://perma.cc/3LVJ-AB45].

3. Amended Complaint at 3–4, Powell v. Staycoff, No. 17-cv-3018 PAM/SER, 2019 WL 2524771 (D. Minn. June 19, 2019).

4. *Id.* at 4–5.

5. *Id.* at 5.

6. *Id.* at 6–7.

7. *Id.* at 7–8.

8. Croman, *supra* note 1.

9. *Id.*

10. *Id.*

11. Mannix, *supra* note 2.

12. Croman, *supra* note 1.

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. Complaint and Jury Demand, *supra* note 3, at 7.

18. *See, e.g.*, FRANKLIN E. ZIMRING, WHEN POLICE KILL (2017); PAUL BUTLER, CHOKEHOLD: POLICING BLACK MEN (2017).

19. *See* Osagie K. Obasogie & Zachary Newman, *Black Lives Matter and Respectability Politics in Local News Accounts of Officer-Involved Civilian Deaths: An Early Empirical Assessment*, 2016 WIS. L. REV. 541, 542.

responded to this concern by calling on law enforcement to deploy tactics that de-escalate tense situations and use non-lethal approaches more frequently for detaining individuals.[20] In light of these efforts to shift police practices away from deadly use of force, partnerships between law enforcement and paramedics[21] that rely on chemical restraints—drugs commonly used by medical professionals to sedate agitated patients—could become an attractive option for subduing police detainees. This might limit death, injury, and other adverse health outcomes connected to police use of force.

These developments raise new and unanswered questions about use-of-force tactics that involve medical providers collaborating with law enforcement. In *Graham v. Connor*, the U.S. Supreme Court held that the Fourth Amendment provides the sole constitutional guidance for when and how police and other state actors can use force against members of the public.[22] These limits prohibit police and other state officials from deploying unreasonable levels of force.[23] Yet, how should courts think about the Fourth Amendment reasonableness standard in relation to medical providers working with police and using drugs like ketamine

20. In a 2000 report on the use of chemical restraint in law enforcement, the authors note, "There is a need for non-lethal techniques with a high degree of specificity, selectivity, safety, and reversibility to avoid producing a lasting impairment to the subject(s) or individual(s) activating the technique. Consideration of the use of calmatives as non-lethal techniques is both timely and warranted." JOAN M. LAKOSKI, W. BOSSEAU MURRAY & JOHN M. KENNY, THE ADVANTAGES AND LIMITATIONS OF CALMATIVES FOR USE AS A NON-LETHAL TECHNIQUE 6 (2000), https://erowid.org/psychoactives/war/war_article1.pdf [https://perma.cc/K9PN-ASU6].

21. There are technical differences between paramedics, emergency medical technicians (EMTs), and other first responders who may render medical assistance in pre-hospital settings. *See generally What's the Difference Between an EMT and a Paramedic?*, UCLA CTR. FOR PREHOSPITAL CARE, https://www.cpc.mednet.ucla.edu/node/27 [https://perma.cc/AW8R-BGHE]. For the sake of brevity, we will use the term "paramedic" throughout this Article to capture the range of professionals who may act in this capacity.

22. The *Graham* court noted:

> Today we make explicit what was implicit in *Garner*'s analysis, and hold that *all* claims that law enforcement officers have used excessive force—deadly or not—in the course of an arrest, investigatory stop, or other "seizure" of a free citizen should be analyzed under the Fourth Amendment and its 'reasonableness' standard, rather than under a "substantive due process" approach. Because the Fourth Amendment provides an explicit textual source of constitutional protection against this sort of physically intrusive governmental conduct, that Amendment, not the more generalized notion of "substantive due process," must be the guide for analyzing these claims.

Graham v. Connor, 490 U.S. 386, 395 (1989) (referencing Tennessee v. Garner, 471 U.S. 1 (1985)).

23. In the majority opinion for *Graham*, Justice Rehnquist did not provide an exact definition of what "reasonable" means in the excessive force context. Rehnquist noted:

> Because "[t]he test of reasonableness under the Fourth Amendment is not capable of precise definition or mechanical application," Bell v. Wolfish, 441 U.S. 520, 559 (1979), however, its proper application requires careful attention to the facts and circumstances of each particular case, including the severity of the crime at issue, whether the suspect poses an immediate threat to the safety of the officers or others, and whether he is actively resisting arrest or attempting to evade arrest by flight.

Id. at 396 (alteration in original).

to chemically restrain people—not for medical purposes, but to assist in their arrest or detention?

At least two novel Fourth Amendment concerns emerge. The first issue deals with *who* is using force. How do constitutional rules governing use of force apply to medical providers, as opposed to police, when these providers collaborate with law enforcement to detain citizens in public or pre-hospital settings? Although police often work with paramedics to respond to calls for service, legal scholars have not closely examined the constitutional limits that apply when professionals other than the police use force to detain citizens.[24] The second issue deals with the *type of force* used. If a paramedic uses drugs to sedate and detain a citizen in a manner that causes harm, does this chemical restraint count as "force" for constitutional purposes? The Supreme Court has not yet considered this issue, though several lower courts have, albeit inconsistently.[25] As law enforcement seeks to respond to public demands for police to use less lethal tactics during arrests and investigations, these questions situate the legal framework for evolving forms of force that may be used.

This Article explores how the Fourth Amendment might limit medical providers' use of chemical restraints in detaining members of the public. Unlike scholarship concerning the ways that law restricts medical providers in their interactions with people in *clinical environments*, this Article focuses on paramedics interacting with people in public or *pre-clinical* settings, where their professional expertise is used for law enforcement rather than medical purposes. While collaboration between paramedics and police is a common aspect of first-

24. Scholars have explored the growing apparatus of private policing (security guards, institutional police forces, etc.) and how the law should treat private police forces; however, most of that work centers on issues other than excessive force. *See, e.g.*, Heidi Boghosian, *Applying Restraints to Private Police*, 70 MO. L. REV. 177, 177 (2005); David A. Sklansky, *The Private Police*, 46 UCLA L. REV. 1165, 1169–70 (1999); Leigh J. Jahnig, *Under School Colors: Private University Police As State Actors Under § 1983*, 110 NW. U. L. REV. 249, 251 (2015). In addition, scholars have focused on the state-action doctrine—the principle that certain constitutional protections, including the Fourth and Fourteenth Amendments, apply only to state and local governments and not to private parties—and discussed the implications of expanding Section 1983 claims for excessive force to private actors. John L. Watts, *Tyranny by Proxy: State Action and the Private Use of Deadly Force*, 89 NOTRE DAME L. REV. 1237, 1238–39 (2014).

25. *Compare* Est. of Barnwell v. Grigsby, 801 F. App'x 354, 370–71 (6th Cir. 2020) (granting judgment as a matter of law to paramedic facing excessive-force claim because the paramedic did not act in a law-enforcement capacity), Thompson v. Cope, 900 F.3d 414, 422–23 (7th Cir. 2018) (granting qualified immunity to paramedic and dismissing excessive-force claim because paramedic would not have known that Fourth Amendment rules apply to paramedics), *and* Peete v. Metro. Gov't of Nashville, 486 F.3d 217, 221 (6th Cir. 2007) (holding that qualified immunity shields paramedics from Fourth Amendment claims when they act to render aid rather than to enforce the law), *with* Green v. City of New York, 465 F.3d 65, 83 (2d Cir. 2006) (allowing excessive-force claim against paramedic to proceed past summary judgement because the law clearly established at the time of the incident that "a competent adult could not be seized and transported for treatment unless she presented a danger to herself or others"), *and* Haas v. County of El Dorado, No. 2:12-cv-00265-MCE-KJN, 2012 WL 1414115, at *9–10 (E.D. Cal. Apr. 23, 2012) (denying paramedic's motion to dismiss excessive-force claim on the grounds that paramedic acted in a law-enforcement capacity when he injected the plaintiff with a tranquilizer).

responders' work, Fourth Amendment use-of-force literature has often overlooked the implications of these partnerships. This Article makes an important contribution by identifying and discussing whether unnecessary and often dangerous chemical restraints used by paramedics for the purpose of an arrest or detainment might constitute excessive use of force under the Fourth Amendment. It also engages the ethics of chemical restraints to provide three proposals aimed at preventing situations akin to what happened to John Powell in Minneapolis. These proposals attempt to guard against the possibility of a troublesome future where police and paramedics jointly engage in life-threatening uses of chemical restraints for convenience rather than for arrestees' health.

Part I introduces the constitutional limits to the use of force as it typically occurs in the context of an encounter between the police and private citizens. We provide a brief history of the Fourth Amendment to highlight the purpose of constitutional restrictions on police force, outline the current legal standards courts use in evaluating excessive-force claims, and discuss how the Fourth Amendment framework developed by courts has limitations in addressing police violence. This Section also briefly reviews the existing scholarly literature on the use of force and the Fourth Amendment. In doing so, we draw attention to the fact that despite this voluminous literature, scholars have not examined how existing constitutional limits on the use of force during an arrest or investigatory stop might apply to medical professionals. Part II discusses the law surrounding medical professionals' use of chemical restraints in both clinical and pre-clinical settings. To add context to this discussion, we analyze two medical research studies on ketamine that were conducted by a Minneapolis-area hospital system and often led to partnerships between paramedics and police officers in public, pre-hospital settings. This study and the resulting informal collaborations between police and paramedics to administer ketamine, exposed by the *Minneapolis Star Tribune* in the summer of 2018,[26] demonstrates that John Powell's life-threatening encounter with chemical restraints was not an isolated incident. While there are not many official figures on the number of police departments that partner with local paramedics to administer ketamine, nor on how often chemical restraints are used during police activity across the country,[27]

26. Andy Mannix, *At Urging of Minneapolis Police, Hennepin EMS Workers Subdued Dozens with a Powerful Sedative*, STAR TRIB. (June 15, 2018), https://www.startribune.com/at-urging-of-police-hennepin-emts-subdued-dozens-with-powerful-sedative/485607381 [https://perma.cc/3RKF-E98A].

27. An investigation by KUNC found that paramedics and emergency medical technicians in Colorado used ketamine 902 times over thirty months to treat individuals thought to be experiencing excited delirium. *See* Michael de Yoanna & Rae Solomon, *Medics in Colorado Dosed 902 People with Ketamine for 'Excited Delirium' in 2.5 Years*, KUNC (July 21, 2020), https://www.kunc.org/post/medics-colorado-dosed-902-people-ketamine-excited-delirium-25-years#stream/0 [https://perma.cc/BH55-AGGX]. This is an important context for understanding the police/EMT collaboration that led to the ketamine injection and subsequent death of Elijah McClain in Aurora, CO in 2019. This incident is discussed in more detail in the conclusion.

it is clear that Minneapolis is not alone.[28] Accordingly, our review of practices in Minneapolis serves as a reasonable description of how this might occur elsewhere.

Part III draws upon current legal frameworks, as well as observations from the ketamine episodes in Minneapolis, to offer three recommendations that can prevent medical providers from using excessive force and keep police from supplanting medical providers' professional and ethical duties. We argue that first, medical providers should develop use-of-force guidelines that provide clear rules regarding when and what type of force is appropriate for healthcare professionals to use. Second, first-responder policies are needed at the state and local level to create a firewall between police and medical professionals so that the former do not unduly influence the decision-making of the latter. Third, when plaintiffs bring Section 1983 excessive-force claims against paramedics who use chemical restraints, courts should use existing federal regulations governing medical professionals' use of these drugs in hospital settings (e.g., 42 C.F.R. § 482.13) to inform their considerations of whether particular uses of chemical restraints in public or pre-hospital settings meet Fourth Amendment standards concerning reasonableness.

We then conclude with a discussion of the theoretical contributions this Article makes in expanding our understanding of what Osagie Obasogie and Zachary Newman have called in previous work an "[e]ndogenous Fourth Amendment."[29] This notion of legal endogeneity[30] characterizes federal courts' tendency to defer to police departments' internal policy preferences in defining the constitutional reasonableness of force incidents rather than developing

28. *See, e.g.*, Elise Schmelzer, *Death of Unarmed 23-Year-Old in Police Custody Prompts Questions About Increasingly Common Use of Ketamine As Sedative For Agitated Patients*, DENVER POST (Oct. 14, 2019, 6:00 AM), https://www.denverpost.com/2019/10/14/ketamine-sedative-law-enforcement-elijah-mcclain [https://perma.cc/525B-VHTJ]; Nick Blizzard, *Suspect Sedated with Drugs After Fighting 4 Police Officers, Tasers*, DAYTON DAILY NEWS (Jan. 23, 2020), https://www.daytondailynews.com/news/local/new-details-suspect-sedated-with-drugs-after-fighting-police-officers-tasers/FcwwN0L4As6cJRjAFBYQUL [https://perma.cc/J623-2XZA].

29. Osagie K. Obasogie & Zachary Newman, *The Endogenous Fourth Amendment: An Empirical Assessment of How Police Understandings of Excessive Force Become Constitutional Law*, 104 CORNELL L. REV. 1281, 1281 (2019).

30. Legal endogeneity theory was first developed by Lauren Edelman in the context of organizational studies and employment law to offer an empirical explanation for why race and gender discrimination persists in workplaces after major statutory developments in anti-discrimination law. *See* LAUREN B. EDELMAN, WORKING LAW: COURTS, CORPORATIONS, AND SYMBOLIC CIVIL RIGHTS (2016). Edelman finds, in short, that in response to these statutory changes, work organizations created anti-discrimination policies that are largely symbolic and do not address the structural nature of discrimination. *Id.* at 38. When litigation arises, federal courts tend to reference, refer, or defer to these workplace administrative policies as an appropriate interpretation and implementation of antidiscrimination statutes like Title VII. *Id.* at 173. This allows these laws to be defined by the managerial preferences of employers rather than by independent judicial assessments that could be more favorable to employees. *Id.* at 228. Therefore, the legal meaning of these anti-discrimination reforms is created by endogenous or internal dynamics within the workplace that reflect managerial preferences and not by external determinants or sources of law. *Id.*

independent standards. Courts often use the administrative rules regarding use of force created by police in response to *Graham v. Connor* as the standard for what the Fourth Amendment requires. This dynamic allows police perspectives to *become* constitutional law, often to the detriment of victims pursuing legal remedies. The authors argue that federal courts' deferential posture can be disrupted in favor of more impartial ways to understand which types of force should be seen as "reasonable" and lawful under the Fourth Amendment. By using democratic sources of constitutional interpretation that include broader community sensibilities, diverse constituents' perspectives, and other expert opinions, federal courts can apply standards regarding the appropriate use of force that balance the needs and expectations of community members with those of law enforcement. This can be understood as *anti-endogeneity*, or resisting determinations of Fourth Amendment reasonableness that are tied to the organizational preferences of the group meant to be regulated and seeking more equitable standpoints for constitutional interpretation. In the context of medical professionals and chemical restraints, existing federal regulations on the appropriate use of these drugs in hospital settings should inform federal courts' understanding of paramedics' obligations and detainees' rights in *pre-hospital* environments. This provides an important theoretical framework that prioritizes patient health and safety over convenience to law enforcement and medical professionals. Moreover, as a method of interpreting Fourth Amendment reasonableness, first discussed by Obasogie and Newman[31] and further developed in this Article, *anti-endogeneity* could offer new ways to think about broader efforts encouraging use-of-force reform that can serve the public good.

I.
EXCESSIVE FORCE AND THE FOURTH AMENDMENT: DOCTRINAL AND SCHOLARLY PERSPECTIVES

The Fourth Amendment provides constitutional protection against unreasonable uses of force by the government.[32] Most excessive force claims are in response to violence perpetuated by law enforcement. As such, it is important to understand how the Fourth Amendment operates in these cases before examining how it might work in situations involving medical providers. This Section provides that context. It starts with a brief history of the Fourth Amendment and its intended purpose of shielding individuals from state power. It then discusses the expansion of the Fourth Amendment through two key Supreme Court decisions—*Tennessee v. Garner* (1985) and *Graham v. Connor* (1989)—and outlines the doctrinal standards that govern Fourth Amendment excessive-force cases. After explaining the current state of Fourth Amendment

31. *See generally* Osagie K. Obasogie & Zachary Newman, *Constitutional Interpretation Without Judges: Police Violence, Excessive Force, and Remaking the Fourth Amendment*, 105 VA. L. REV. 425 (2019).

32. *See* U.S. CONST. amend. IV.

use-of-force doctrine, this Section briefly explores scholars' perspectives on Fourth Amendment use-of-force jurisprudence to highlight common themes and to draw attention to the absence of research regarding constitutional limitations on medical practitioners' use of chemical restraints for law enforcement purposes.

A. Fourth Amendment Limitations on Use of Force

The Fourth Amendment is part of the Bill of Rights, which reflects a constitutional commitment to the idea that individuals are entitled to protection from abuses of state power.[33] The framers of the Constitution crafted the Bill of Rights based on British attempts to "prescribe the individual rights of the citizenry,"[34] reflecting a concern with the proper relationship between individuals and the federal government. While the Bill of Rights deals specifically with the boundaries of federal power, the Fourteenth Amendment's Due Process Clause incorporated most of these amendments so that they also apply to state governments.[35] The rights contained in these amendments are primarily a set of negative freedoms intended to give all citizens the right to be free from specific types of state conduct. Consistent with this framing, the language of the Fourth Amendment provides:

> The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.[36]

Thus, the Fourth Amendment, in theory, protects individual liberty and privacy by guaranteeing protection from unreasonable searches and seizures. The U.S. Supreme Court has come to understand police use of force as a "seizure" within the meaning of the Fourth Amendment.

Modern criminal procedure originated between 1920 and 1940 through Supreme Court cases involving Black defendants who suffered lynching or egregious injustices in criminal trials in southern states under "Jim Crow justice."[37] The development of case law invalidating convictions under the

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33. *See* 1 JAMES BRYCE, THE AMERICAN COMMONWEALTH 483–84 (1888) ("[The] ten amendments made immediately after the adoption of the Constitution . . . constitute what the Americans, following the English precedent, call a Bill of Rights, securing the individual citizen and the states against the encroachments of federal power.").

34. Joyce A. McCray Pearson, *The Federal and State Bills of Rights: A Historical Look at the Relationship Between America's Documents of Individual Freedom*, 36 HOW. L.J. 43, 45 (1993).

35. *See* Donald A. Dripps, *The Fourteenth Amendment, the Bill of Rights, and the (First) Criminal Procedure Revolution*, 18 J. CONTEMP. LEGAL ISSUES 469, 470 (2009) ("The theory that the Fourteenth Amendment incorporates the Bill of Rights established the foundation for the Warren Court's 'criminal procedure revolution.'").

36. U.S. CONST. amend. IV.

37. Michael J. Klarman, *The Racial Origins of Modern Criminal Procedure*, 99 MICH. L. REV. 48, 49 (2000).

Fourteenth Amendment on the basis of the right to counsel, biased judges, knowingly-perjured testimony, and coerced confessions "required a departure from a century and a half of tradition and legal precedent, both grounded in federalism concerns"[38] that customarily left these issues to state and local governments. These departures, however, were not necessarily instances of judicial protection of minorities from majoritarian misbehavior but a reflection of a growing national consensus that Jim Crow laws were no longer defensible.[39] This paved the way for criminal procedure decisions in later cases involving the limits of state power in the context of police use-of-force doctrine.

The Court continued to expand constitutional rights in the criminal procedure realm during the mid-century Warren Court era. During this time, the Court began to "use the Constitution as the primary means of regulating the police."[40] This new constitutional discourse on police activity focused on expanding rights and remedies in the context of searches and seizures. These developments limited the power of the state, via the police, to infringe upon citizens' personal property or restrict bodily autonomy.

The current constitutional standard for "what counts" as excessive force is a relatively recent development. Much of this conversation centers around 42 U.S.C. § 1983, which creates a private cause of action against state officials who deprive individuals of constitutional rights. This federal statute codifies the Civil Rights Act of 1871, which was created during Reconstruction in response to racist violence against persons who were formerly enslaved. It largely laid dormant until the Supreme Court's 1961 decision in *Monroe v. Pape*, which rejuvenated such federal civil rights claims.[41] From this period until the late 1980s, federal courts used a variety of legal doctrines to assess claims that a police use-of-force incident violated an individual's constitutional rights.[42] Following a 1973 Second Circuit decision in *Johnson v. Glick*, substantive due

38. *Id.* at 48.

39. *See id.* at 93. Klarman notes that these

> early cases almost certainly were consonant with dominant national opinion at the time. Even within the South, significant support existed for the results in these cases. As noted earlier, these rulings only bound the southern states to abstract norms of behavior that they generally had embraced on their own. In the North, meanwhile, although blacks suffered oppressive discrimination in housing, employment, and public accommodations, the criminal justice system approached somewhat nearer to the ideal of colorblindness. Thus, it is erroneous to conceive of these landmark criminal procedure cases as instances of judicial protection of minority rights from majoritarian oppression. Rather, they better exemplify the paradigm of judicial imposition of a national consensus on resistant state outliers (with the qualification that even the southern states generally accepted these norms in the abstract).

Id.

40. Rachel A. Harmon, *The Problem of Policing*, 110 MICH. L. REV. 761, 765 (2012).

41. 365 U.S. 167 (1961) (holding that 42 U.S.C. § 1983 provided a cause of action for Mr. Monroe to sue Chicago police officers for an unreasonable search and seizure), *overruled in part by* Monell v. Dep't of Soc. Servs., 436 U.S. 658 (1978).

42. Osagie K. Obasogie & Zachary Newman, *The Futile Fourth Amendment: Understanding Police Excessive Force Doctrine Through an Empirical Assessment of* Graham v. Connor, 112 NW. U. L. REV. 1465 (2018).

process under the Fourteenth Amendment emerged as a dominant (though not exclusive) framework from which federal courts examined whether certain applications of police force violated the constitution. *Johnson v. Glick* focused heavily on the subjective intent of police officers, noting that courts should examine whether police used force in "good faith" or "maliciously and sadistically for the very purpose of causing harm."[43]

Two Supreme Court decisions during the 1980s changed use-of-force jurisprudence. The first case was *Tennessee v. Garner* (1985), which involved the death of Edward Garner, a Black fifteen-year-old.[44] Garner was unarmed and fleeing the scene of a suspected burglary.[45] While Garner climbed over a fence attempting to escape arrest, a Memphis police officer shot him in the back of the head and killed him.[46] Garner's father sued both the officer who shot his son and the Memphis police department.[47] The Court noted that apprehension by use of deadly force constitutes a seizure under the Fourth Amendment.[48] As to when deadly force is reasonable to use, the Court held:

> [I]f the suspect threatens the officer with a weapon or there is probable cause to believe that he has committed a crime involving the infliction or threatened infliction of serious physical harm, deadly force may be used if necessary to prevent escape, and if, where feasible, some warning has been given.[49]

The Court held that using deadly force on a fleeing person who did not pose any of these threats is unconstitutional, leading to a determination that the Tennessee state statute (as well as similar laws in several other states) that permitted such force could no longer stand.[50] *Garner* has been celebrated for creating a bright-line rule that prohibits deadly force in these circumstances.

This decision largely spoke to the unlawfulness of state statutes that allowed deadly force against unarmed persons fleeing from the police. Although influential, *Garner* did not directly address which constitutional standard federal courts should use to determine when police use of force becomes excessive. In *Graham v. Connor* (1989), the Court made a definitive statement that put all

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43. Johnson v. Glick, 481 F.2d 1028, 1033 (2d Cir. 1973), *abrogated by* Graham v. Connor, 490 U.S. 386 (1989).

44. 471 U.S. 1 (1985).

45. *Id.* at 3–4.

46. *Id.*

47. *Id.* at 5.

48. *Id.* at 7.

49. *Id.* at 11–12.

50. *Id.* at 11 ("The use of deadly force to prevent the escape of all felony suspects, whatever the circumstances, is constitutionally unreasonable. It is not better that all felony suspects die than that they escape. Where the suspect poses no immediate threat to the officer and no threat to others, the harm resulting from failing to apprehend him does not justify the use of deadly force to do so. It is no doubt unfortunate when a suspect who is in sight escapes, but the fact that the police arrive a little late or are a little slower afoot does not always justify killing the suspect. A police officer may not seize an unarmed, nondangerous suspect by shooting him dead. The Tennessee statute is unconstitutional insofar as it authorizes the use of deadly force against such fleeing suspects.").

excessive-force claims into the terrain of the Fourth Amendment.[51] The case involved a situation where DeThorne Graham, a diabetic, experienced an insulin reaction that was misinterpreted by the police as him being an unruly and uncooperative "drunk."[52] The police treated Graham harshly as they pinned him down on the sidewalk, handcuffed him, and threw him into a patrol car.[53] As a result of this encounter, Graham sustained a broken foot, several lacerations, and a persistent ringing in his ear.[54] Graham brought a Section 1983 suit in federal district court, claiming that the excessive use of force by the officers violated his Fourteenth Amendment substantive due process rights.[55] The trial and appellate courts sided with the police officers.[56] Yet, when the case reached the Supreme Court, the justices rejected the argument that excessive-force claims fall under the Fourteenth Amendment.[57] Instead, they held that excessive force claims "are properly analyzed under the Fourth Amendment's 'objective reasonableness' standard, rather than under a substantive due process standard."[58]

The *Graham* court explained this shift by noting that "[d]etermining whether the force used to effect a particular seizure is reasonable under the Fourth Amendment requires a careful balancing of the nature and quality of the intrusion on the individual's Fourth Amendment interests against the

51. 490 U.S. 386, 388 (1989) ("This case requires us to decide what constitutional standard governs a free citizen's claim that law enforcement officials used excessive force in the course of making an arrest, investigatory stop, or other 'seizure' of his person. We hold that such claims are properly analyzed under the Fourth Amendment's 'objective reasonableness' standard, rather than under a substantive due process standard.").

52. *Id.* at 389.

53. *Id.*

54. *Id.* at 390.

55. *Id.*

56. *Id.* at 391.

57. *Id.* at 393–94.

58. *Id.* at 388. While the Court framed excessive-force claims as violations of the Fourth Amendment, this does not preclude individuals from bringing claims involving excessive force under the Fourteenth Amendment. The standard that a plaintiff must meet to establish a due-process violation under the Fourteenth Amendment is higher than the standard for an unlawful seizure or excessive force claim under the Fourth Amendment. Whereas an alleged Fourth Amendment violation is evaluated under a reasonableness standard, *Ohio v. Robinette*, 519 U.S. 33, 34 (1996), "the Due Process Clause is violated by executive action only when it 'can properly be characterized as arbitrary, or conscience shocking, in a constitutional sense.'" Cnty. of Sacramento v. Lewis, 523 U.S. 833, 847 (1998) (quoting Collins v. City of Harker Heights, 503 U.S. 115, 128 (1992)); *accord* Porter v. Osborn, 546 F.3d 1131, 1137 (9th Cir. 2008) ("[O]nly official conduct that 'shocks the conscience' is cognizable as a due process violation.") (citing *Lewis*, 523 U.S. at 846).

> Where actual deliberation is practical, then an officer's 'deliberate indifference' may suffice to shock the conscience. On the other hand, where a law enforcement officer makes a snap judgment because of an escalating situation, his conduct may be found to shock the conscience only if he acts with a purpose to harm unrelated to legitimate law enforcement objectives.

Hayes v. Cnty of San Diego, 736 F.3d 1223, 1230 (9th Cir. 2013) (citing Wilkinson v. Torres, 610 F.3d 546, 554 (9th Cir. 2010)).

countervailing governmental interests at stake."[59] To do so, a court must evaluate the facts and circumstances of each particular case. Three factors courts must consider are "[(1)] the severity of the crime at issue, [(2)] whether the suspect poses an immediate threat to the safety of the officers or others, and [(3)] whether he is actively resisting arrest or attempting to evade arrest by flight."[60] Some federal courts have found, however, that these factors are not exhaustive.[61] Since "there are no per se rules in the Fourth Amendment excessive force context,"[62] courts must "examine the totality of the circumstances and consider 'whatever specific factors may be appropriate in a particular case, whether or not listed in *Graham*.'"[63]

In addition, the Court has explained that "[t]he 'reasonableness' of a particular use of force must be judged from the perspective of a reasonable officer on the scene, rather than with the 20/20 vision of hindsight."[64] This is because "[t]he calculus of reasonableness must embody allowance for the fact that police officers are often forced to make split-second judgments—in circumstances that are tense, uncertain, and rapidly evolving—about the amount of force that is necessary in a particular situation."[65]

Since *Graham*, federal courts have largely used Fourth Amendment standards to determine the lawfulness of police use of force. The Supreme Court reaffirmed this approach to excessive-force claims in 2007 in *Scott v. Harris*.[66] In this case, a police officer used the bumper of his patrol car to stop a fleeing suspect in a vehicle, leading the car to roll down an embankment and overturn.[67] The suspect in the car was severely injured and brought a Section 1983 excessive-force claim against the officer.[68] Citing *Graham*, the Court noted, "[i]t is . . . conceded, by both sides, that a claim of excessive force in the course of making [a] . . . seizure of [the] person . . . [is] properly analyzed under the Fourth Amendment's objective reasonableness standard. The question we need to answer is whether Scott's actions were objectively reasonable."[69]

In light of these doctrinal developments, the next Section describes scholars' interpretations of the Fourth Amendment's limits on police use of force.

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59. *Graham*, 490 U.S. at 396 (quoting Tennessee v. Garner, 471 U.S. 1, 8 (1985) (internal quotation marks omitted).

60. *Id.*

61. *See, e.g.*, George v. Morris, 736 F.3d 829, 837–38 (9th Cir. 2013).

62. Mattos v. Agarano, 661 F.3d 433, 441 (9th Cir. 2011) (en banc).

63. Bryan v. MacPherson, 630 F.3d 805, 826 (9th Cir. 2010).

64. *Graham*, 490 U.S. at 396 (citing Terry v. Ohio, 392 U.S. 1, 20–22 (1968)); *see id.* ("'Not every push or shove, even if it may later seem unnecessary in the peace of a judge's chambers,' violates the Fourth Amendment." (citation omitted)).

65. *Id.* at 396–97.

66. 550 U.S. 372 (2007).

67. *Id.* at 375.

68. *Id.* at 375–76.

69. *Id.* at 381 (quoting *Graham*, 490 U.S. at 386) (citation and internal quotation marks omitted).

B. Scholarly Perspectives on the Fourth Amendment and Police Use of Force

Legal scholarship discussing police use of force and constitutional law provides important evaluations of how courts have interpreted the Fourth Amendment. Scholars have emphasized the limitations and flaws of the Fourth Amendment as a mechanism for addressing police use of force. For example, Rachel Harmon has written that Fourth Amendment use-of-force jurisprudence is "indeterminate and undertheorized, particularly as applied to nondeadly force."[70] Harmon argues that this indeterminacy on when and how police can use force is in stark contrast with basic criminal law, which has justification defenses that serve as a "well-established conceptual structure for deciding when, how, and why one person may justifiably use force against another."[71] This effort at bringing the rules regarding police use of force in line with existing criminal law is important and insightful as it draws attention to the wide latitude and deference given to police through a Fourth Amendment reasonableness standard that leaves most excessive-force claims without remedy. Harmon's call for importing a justification standard into Fourth Amendment excessive-force inquiries highlights the extent to which this area of law is largely underdeveloped, which can allow questionable practices—such as the use of chemical restraints—to emerge without broader consideration of their constitutionality.

Brandon Garrett and Seth Stoughton also explore the lack of clarity provided by the Fourth Amendment and federal courts' interpretations of it in their article *A Tactical Fourth Amendment*.[72] Garrett and Stoughton observe that most police departments do not have specific policies that describe when officers can use force on community members and instead reference a force continuum that embraces relativism rather than clear standards.[73] They argue that this lack

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70. Rachel A. Harmon, *When is Police Violence Justified?*, 102 NW. U. L. REV. 1119, 1119 (2008).

71. *Id.* at 1120. Harmon notes that:

> Specifically, the law of justification defenses permits individuals to use force to serve particular well-defined interests, such as to protect themselves or others, under specific, carefully delineated conditions, i.e., when that force is necessary to protect against an imminent threat to one of those interests and is proportional to that threat. Analogously, I contend that the Fourth Amendment permits police uses of force only to serve directly the state's distinct interests in (1) facilitating its institutions of criminal law, most commonly by enabling a lawful arrest; (2) protecting public order; and (3) protecting the officer from physical harm. Moreover, even if one of these interests is at stake, a use of force should be considered unreasonable—and therefore unconstitutional under the Fourth Amendment—unless it is a response to an imminent threat to one of these interests, the force reasonably appears necessary in both degree and kind to protect the interest, and the harm the force threatens is not substantially disproportionate to the interest it protects. In this way, the substructure of justification defenses can be used to analyze whether a police use of force is constitutional.

Id. (footnote omitted).

72. Brandon Garrett & Seth Stoughton, *A Tactical Fourth Amendment*, 103 VA. L. REV. 211 (2017).

73. *Id.* at 213, 278–80.

of tactical guidance produces unlawful uses of force, leading the authors to harken back to earlier periods in the 1970s and 1980s that emphasized tactical training to minimize force.[74] While this approach initially found some support by the Supreme Court in *Tennessee v. Garner* (where the court created a bright-line tactical rule against shooting fleeing unarmed persons), this emphasis on court-imposed tactical limits dissipated after *Graham v. Connor*.[75] Garrett and Stoughton argue that this post-*Graham* case law has hindered sound police tactics and training and "confound[ed] efforts to draft clear use-of-force policies."[76]

Other scholars, like Nancy Marcus, have also tried to reclaim *Tennessee v. Garner* as an important constitutional limitation on police use of force that is still relevant after *Graham v. Connor* and that should be central to police training.[77] Marcus argues that *Tennessee v. Garner* should be revived in the Fourth Amendment context to further move use-of-force case law toward defining firm rules that establish when police are precluded from using specific levels of force.[78]

Scholars have also placed issues of race and racism at the heart of the Fourth Amendment's failure to protect victims of police violence who are largely

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74. *Id.* at 216–17.

75. *Id.* at 217 ("The impediments [to tactical policing] are the result of the flexible, 'totality of the circumstances' analysis that the Supreme Court adopted to govern use of force under the Fourth Amendment. That flexible standard grows out of a mantra first articulated by the Court in the 1989 decision in *Graham*: that officers make 'split-second' decisions in use-of-force situations. That description, originating in Justice Sandra Day O'Conner's dissent in *Garner*, has animated the Court's excessive-force case law ever since.").

76. *Id.*

77. Marcus states that:

> What the police who killed Eric Harris, Walter Scott, and Samuel DuBose failed to grasp, with terrible repercussions, is that the Supreme Court in *Garner*, while acknowledging the need of law enforcement to restrain fleeing felons, emphatically held that lethal force is *not* a constitutional means of accomplishing that end, declaring: "It is not better that all felony suspects die than that they escape." *Garner*'s holding necessarily extends to prohibit lethal force against fleeing unarmed suspects of mere misdemeanors, not just felons, and to individuals who are not suspected of any particular crime at all (such as Eric Garner, Eric Harris, and Walter Scott).
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> Although *Tennessee v. Garner*'s limitations were clearly not at the forefront of the officers' minds in those cases, to this day, *Garner* remains the seminal Supreme Court case limiting the use of deadly force by law enforcement officers. This is true even if *Garner* is not sufficiently emphasized in use-of-force trainings or universally understood by both law enforcement and civilian populations. To fully appreciate the necessary role that *Garner* must play in use-of-force training and analyses of cases involving police killings, it is important to recognize that *Garner* is as much good law today as the day it was decided. This is the case even after the subsequent *Graham v. Connor* decision that articulated a broader objective reasonableness standard for analyses of use-of-force generally (i.e., not just in those cases specifically involving lethal force against fleeing suspects).

Nancy C. Marcus, *From Edward to Eric Garner and Beyond: The Importance of Constitutional Limitations on Lethal Use of Force in Police Reform*, 12 DUKE J. CONST. L. & PUB. POL'Y 53, 80 (2016) (footnotes omitted).

78. *Id.* at 82.

Black and Brown. A foundational article from this perspective is Michael Klarman's *The Racial Origins of Modern Criminal Procedure*, which argues that "the linkage between the birth of modern criminal procedure and southern black defendants is no fortuity."[79] While not specifically about excessive force, Klarman's article draws attention to the role of race and racism in shaping the development of criminal procedure in the mid to late twentieth century. Klarman points to the egregiousness of southern injustice that led appellate courts to articulate basic rules for how people are to be treated when accused or suspected of a crime.[80] Other scholars, such as Tracey Maclin[81] and Devon Carbado,[82] have also explored the impact of race in Fourth Amendment cases. While the cases Maclin and Carbado study concern stops and pretextual seizures and do not pertain directly to use of force, their scholarship nonetheless offers insight and doctrinal context that can inform our understanding of how race factors into excessive force claims. These authors demonstrate that by framing Fourth

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79. Klarman, *supra* note 37, at 48.

80. Klarman makes three points about southern injustice giving rise to modern criminal procedure:

> First, the southern state appellate courts and the United States Supreme Court were operating on the basis of different paradigms when they evaluated the fairness of these criminal trials. For the southern courts, the simple fact that these defendants enjoyed the formalities of a criminal trial, rather than being lynched, represented a significant advance over what likely would have transpired in the pre-World War I era. For the United States Supreme Court, on the other hand, criminal trials were supposed to be about adjudicating guilt or innocence, not simply avoiding a lynching. Second, because these southern criminal trials were so egregiously unfair, public opinion in the nation generally supported the Supreme Court's interventions. Thus, these early criminal procedure cases hardly represent the sort of countermajoritarian judicial decision-making one often associates with landmark criminal procedure decisions such as *Mapp* or *Miranda*. Third and finally, it is possible that the southern state courts themselves would have intervened to rectify the obvious injustices involved in these cases had the circumstances been a little different. Southern courts in the post-World War I period were becoming more committed to norms of procedural fairness, even in cases involving black defendants charged with serious interracial crimes. Yet, in cases that aroused outside criticism of the South or that posed broader challenges to the system of white supremacy, the southern state courts regressed. Cases that might never have reached the United States Supreme Court a decade or two earlier slipped through the state system uncorrected, thus providing the occasion for landmark criminal procedure rulings.

Id. at 49 (footnote omitted).

81. *See, e.g.*, Tracey Maclin, *Race and the Fourth Amendment*, 51 VAND. L. REV. 333 (1998) (criticizing the Supreme Court's decision in *Whren v. United States*, 517 U.S. 806 (1996), which held that an officer's subjective motivation for effecting an otherwise-authorized traffic stop does not bear on the Fourth Amendment's "reasonableness" inquiry, as enabling pretextual, racially-motivated traffic stops, which disproportionately burden Black motorists).

82. Carbado notes:

> [V]irtually none of this literature links the Supreme Court's racial insensitivity in the Fourth Amendment context to racial ideology—that is, commitments about and conceptions of race. Put another way, the race and Fourth Amendment scholarship fails to examine the nexus between the development of Fourth Amendment doctrine on the one hand, and ideological notions about what race is and should be on the other.

Devon W. Carbado, *(E)racing the Fourth Amendment*, 100 MICH. L. REV. 946, 965 (2002) (footnote omitted).

Amendment matters in abstract doctrinal terms that are inattentive to the racial backdrop that shapes many police interactions, the Court and many Fourth Amendment scholars have failed to develop a doctrine that might actually limit police excessive force.

Scholars have also voiced concern about the individualism embedded in Fourth Amendment case law that "frame[s] excessive force as a problem that derives from rogue police officers who harbor racial animus against African Americans" and ignores the structural dimensions of police violence.[83] Obasogie and Newman argue that the history, text, and jurisprudence of the Fourth Amendment suggest that it was developed to address individual grievances, which raises questions regarding whether it is capable of speaking to group phenomena such as racialized police violence.[84] Other scholars have similarly argued that the Fourth Amendment precipitates disproportionate police contact with racial minorities, in that it codifies rather than limits the ability of police to harass and inappropriately use force on people of color.[85]

These arguments regarding the role of race in Fourth Amendment jurisprudence give rise to more particular claims concerning the nature of excessive-force jurisprudence. For example, Paul Butler does not mince words in his book *Chokehold: Policing Black Men* when he states, "The problem is the criminal process itself. Cops routinely hurt and humiliate black people because that is what they are paid to do. Virtually every objective investigation of a U.S. law enforcement agency finds that the police, *as policy*, treat African Americans with contempt."[86] Butler argues that excessive use of force is police department policy that reflects explicit racism in policing and is essentially sanctioned by federal courts.[87] Similarly, Alice Ristroph resists claims that the rules pertaining to police use of force suffer from constitutional ambiguity and argues that the seizure authority given to police under the Fourth Amendment predictably leads to excessive and deadly uses of force.[88] This constitutive approach—that is, that law constitutes or produces these outcomes[89]—aligns with concerns of explicit

83. Devon W. Carbado & Patrick Rock, *What Exposes African Americans to Police Violence?*, 51 HARV. C.R.-C.L. L. REV. 159, 161 (2016).

84. Obasogie & Newman, *supra* note 42, at 1470–75.

85. *See, e.g.*, Maclin, *supra* note 81, at 337–40; Jordan Blair Woods, *Decriminalization, Police Authority, and Routine Traffic Stops*, 62 UCLA L. REV. 672, 683–84 (2015).

86. BUTLER, *supra* note 18, at 2.

87. *Id.* at 187–89.

88. Alice Ristroph, *The Constitution of Police Violence*, 64 UCLA L. REV. 1182 (2017).

89. Ristroph notes that:

> [T]he usual critiques of police shootings operate on the underlying assumption that the officer who chose to shoot made a bad choice against a backdrop of reasonable, if somewhat indeterminate, legal guidelines. Responsibility for the killings is placed with the officers (or, in the view of the officers' defenders, with the noncompliant suspects) and not with the constitutional doctrine that structures police authority, nor with the people who have crafted that doctrine, nor with The People on whose behalf the doctrine is said to be crafted.
>
> This focus on the officer overlooks what it [*sic*] is sometimes called the constitutive function of constitutional law.

racism articulated by Butler and others in that it suggests that excessive use of force by the police is a feature of modern policing, not an aberration.

Butler, Ristroph, and others make these claims about the persistent role of explicit racial bias in policing against what has become an increasingly popular explanation for the racially disproportionate nature of police excessive force: implicit bias. Social psychologists have developed experimental exercises suggesting that much of the decision-making concerning policing, including use of force, is driven by unconscious bias rather than a singular conscious disdain for minority groups.[90] For example, L. Song Richardson writes that "unconscious racial biases and implicit white favoritism can result in racial disparities in police violence."[91] This research has led to the emergence and growth of implicit bias training for police officers that attempts to reduce force incidents and their disproportionate impact on communities of color.[92] From this standpoint, reducing police use of force is not simply a matter of changing tactics or refining judicial interpretations of which behaviors are reasonable under the Fourth Amendment. It also involves broader institutional and structural shifts that can change the cognitive biases of officers.

It is clear that the legacy of explicit racial bias in criminal procedure continues to shape interpretations and applications of the Fourth Amendment,[93] while implicit bias has been shown to impact the decision-making of many professionals, including those working in law and medicine.[94] Yet this Article takes a more constitutive[95] approach to understanding the relationship between

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Id. at 1187 (footnote omitted).

90. *See, e.g.*, Jennifer L. Eberhardt, Phillip Atiba Goff, Valerie J. Purdie & Paul G. Davies, *Seeing Black: Race, Crime, and Visual Processing*, 87 J. PERSONALITY & SOC. PSYCH. 876 (2004); LORIE A. FRIDELL, PRODUCING BIAS-FREE POLICING 7–29 (2017).

91. L. Song Richardson, *Police Racial Violence: Lessons from Social Psychology*, 83 FORDHAM L. REV. 2961, 2962 (2015).

92. *See, e.g.*, Al Baker, *Confronting Implicit Bias in the New York Police Department*, N.Y. TIMES (July 15, 2018), https://www.nytimes.com/2018/07/15/nyregion/bias-training-police.html [https://perma.cc/2B92-WHLT]; Tom James, *Can Cops Unlearn Their Unconscious Biases?*, ATLANTIC (Dec. 23, 2017), https://www.theatlantic.com/politics/archive/2017/12/implicit-bias-training-salt-lake/548996 [https://perma.cc/CWV8-QFST].

93. *See, e.g.*, Carbado, *supra* note 82; BUTLER, *supra* note 18.

94. *See, e.g.*, IMPLICIT RACIAL BIAS ACROSS THE LAW (Justin D. Levinson & Robert J. Smith eds., 2012); DAYNA BOWEN MATTHEW, JUST MEDICINE: A CURE FOR RACIAL INEQUALITY IN AMERICAN HEALTH CARE (2015).

95. Constitutive approaches to understanding race and racism focus on the social and legal practices that make certain ideas about human difference thinkable and coherent. Our understanding of human groups does not stem from isolated observations that impress social meaning upon us. Rather, an entire network of social practices creates the conditions for us to see the world and interpret differences in specific ways. Understanding this conditioning process that constitutes people's worldview on race and other matters can help us understand how race (and practices that we create around the idea of human difference) are created, maintained, and justified. For an extended conversation, see OSAGIE K. OBASOGIE, BLINDED BY SIGHT: SEEING RACE THROUGH THE EYES OF THE BLIND (2014). This constitutive approach to race aligns strongly with the constitutive approaches to law as described by Ristroph, *supra* note 88. Race and law are mutually constitutive, meaning that the existing configuration of one is not possible without the other. Both inform the legitimation of

the Fourth Amendment, chemical restraints, and minority communities. This approach is attentive to the set of social and legal conditions that make it possible for law enforcement and medical professionals to think that injecting arrestees with powerful drugs comports with their professional, legal, and ethical obligations.

In light of the broad literature on the Fourth Amendment and use of force, it is curious that there is little research that explores the constitutional implications of use of force by medical professionals who partner with law enforcement. Excessive force is largely conceptualized in legal scholarship in one way: bad cops who violently attack community members. Given the shifting social and political climate where people are demanding that police officers use less violent tools when engaging the community, it is important to take a close look at medical professionals' use of chemical restraints in public settings as a way to understand how force and its implications may be changing. The ketamine incidents in Minneapolis provide a helpful case study for examining these issues. The next Section discusses the situation in Minneapolis to explore the Fourth Amendment implications that may arise when medical providers use chemical restraints to induce compliance with law enforcement and whether this practice might constitute a form of excessive force.

II.
MEDICAL PROFESSIONALS AND CHEMICAL RESTRAINTS

John Powell's detainment by Minneapolis police and nearly fatal chemical restraint by paramedics[96] demonstrates how alternative forms of force thought to be less lethal may raise many of the same concerns as traditional uses of force. In this Section, we begin by investigating the use of chemical restraints in healthcare settings to understand and compare their use in pre-clinical settings for law enforcement purposes. Through our analysis of a Minneapolis-area study designed to test ketamine's efficacy when used by paramedics in the field, we examine how ketamine as a chemical restraint shifted from a medical to a criminal justice tool in Minneapolis and how blurred lines between healthcare and law enforcement can lead to Fourth Amendment issues that have gone largely unexplored.

A. Chemical Restraints in Healthcare Settings

Chemical restraints are used in healthcare settings to control people who exhibit agitation or other behavioral problems that might lead them to harm themselves or others. Medical professionals often prefer sedating patients instead of using physical restraints that can make it more difficult to treat patients in

practices and roles that shape police use of force. *See generally* Laura E. Gómez, *Understanding Law and Race as Mutually Constitutive: An Invitation to Explore an Emerging Field*, 6 ANN. REV. L. & SOC. SCI. 487 (2010).

96. Mannix, *supra* note 2.

need.[97] Much of the conversation surrounding the use of chemical restraints has occurred in nursing homes, although they are not uncommon in other areas such as psychiatric care facilities and emergency medicine.[98] These drugs can be taken orally or through injection (intramuscular and intravenous), depending on the cooperation of the patient.[99]

There are three different types of drugs that medical providers typically use to chemically restrain agitated patients. The first set of drugs are known as *benzodiazepines*, which are primarily used to treat anxiety by impacting brain neurotransmitters.[100] Lorazepam is a favorite of this class of medication among providers when used as a chemical restraint "because of its rapid onset, lack of active metabolites, effectiveness in patients intoxicated with a sympathomimetic agent such as cocaine, and availability in oral, IM, and IV formulations."[101] Midazolam is another *benzodiazepine* used to subdue agitated or confused patients. The second type of drug used for chemical restraint are *typical antipsychotics*. They are helpful when treating agitated patients suffering from a preexisting psychiatric problem. While these drugs can be used in conjunction with *benzodiazepines*, some typical antipsychotics like Haloperidol are known to cause significant side effects, including severe muscle spasms and contractions known as extrapyramidal syndrome that, in limited instances, have emerged in patients days after a single dose.[102] Lastly, a new generation of *atypical antipsychotics* are also used for chemical restraint. This includes drugs such as Olanzapine, Risperidone, and Ziprasidone. Atypical antipsychotic drugs are generally seen as an improvement over the previous generation, in that they "provide more tranquilization and less sedation . . . [while also having a] lower incidence of [extrapyramidal syndrome] from the serotonergic activity."[103]

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97. Coburn and Mycyk note that:

> Physical restraints can be counterproductive because struggling against restraints may prevent obtaining a history or completing a thorough physical examination. Chemical restraints can help gain better control of the agitated patient and allow evaluation and treatment. Complications associated with struggling against physical restraints, such as hyperthermia, dehydration, rhabdomyolysis, or lactic acidosis, can all be minimized with the early use of chemical sedation.

Victoria A. Coburn & Mark B. Mycyk, *Physical and Chemical Restraints*, 27 EMERGENCY MED. CLINICS N. AM. 655, 660 (2009) (footnote omitted).

98. *See generally Chemical Restraint in the ED*, ACEP NOW (Dec. 1, 2012), https://www.acepnow.com/article/chemical-restraint-ed/?singlepage=1 [https://perma.cc/PVL6-TWYZ].

99. "[I]f no immediate threat is displayed and the patient is cooperative, oral medications should be considered as first-line therapy, followed by either IM or IV administration, depending on the medication choice and ease of access." Benjamin B. Mattingly & Andrew D. Small, *Chemical Restraint*, MEDSCAPE (Nov. 21, 2016), https://emedicine.medscape.com/article/109717-overview#a2 [https://perma.cc/CZK7-YS8T].

100. Richard I. Shader & David J. Greenblatt, *Use of Benzodiazepines in Anxiety Disorders*, 328 NEW ENGLAND J. MED. 1398 (1993).

101. Coburn & Mycyk, *supra* note 97, at 662.

102. *Id.* at 660.

103. *Id.* at 661.

It is important to note that the Food and Drug Administration has not approved any of the drugs used as chemical restraints in healthcare settings. These drugs are developed and approved for patients suffering from specific psychiatric and behavioral disorders, yet are used off-label as chemical restraints on patients largely without regard to whether they have been diagnosed with these indicated health concerns.[104] Indeed, using these drugs for their calmative effect rather than indicated purpose is a key aspect of chemical restraint, in that they are not necessarily *prescribed* to a patient, but used singularly, intermittently, or as needed to change patients' mood or behavior. In a 2007 hearing before a House subcommittee on Oversight and Investigations, Associate Director Dr. David Graham of the FDA Office of Surveillance and Epidemiology warned of the dangers of this approach:

> I would pay careful attention to antipsychotic medications. . . . The trend is the atypicals because they reputedly have a better safety profile, a lower side effect profile. . . . The problem with these drugs are [*sic*] that we know that they are being used extensively off label in nursing homes to sedate elderly patients with dementia and other types of plot [*sic*] disorders. It is known that the drugs don't work in those settings. And it is off label, they just do what they want. But the fact is, is that it increases mortality perhaps by 100 percents [*sic*]. It doubles mortality. So I did a back-of-the-envelope calculation on this and you have probably got 15,000 elderly people in nursing homes dying each year from the off-label use of antipsychotic medications for an indication that FDA knows the drug doesn't work. This problem has been known to FDA for years and years and years . . . .[105]

As Dr. Graham noted, even in controlled environments such as hospitals and nursing homes, the use of powerful drugs to sedate rather than treat a diagnosed illness can lead to patient harm and premature death.

B. Federal Regulations on Chemical Restraints in Healthcare

Developments in nursing home standards played an important role in establishing the current legal and regulatory framework governing the use of chemical restraints in healthcare settings. When Medicare and Medicaid were established in 1965, nursing home standards "were weak and all but a few nursing facilities were able to meet the standards, despite reports of poor quality care."[106] Subsequent federal legislation in 1967 and 1972 also missed the mark,

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104. Krista Maier, *Chemical Restraints and Off-Label Drug Use in Nursing Homes*, 16 MICH. ST. U. J. MED. & L. 243, 255–56 (2012).

105. *The Adequacy of FDA to Assure the Safety of the Nation's Drug Supply: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Com.*, 110th Cong. 66 (2007) (statement of David J. Graham, Associate Director, Science and Medicine, FDA Office of Surveillance and Epidemiology).

106. JOSHUA M. WIENER, MARC P. FREIMAN & DAVID BROWN, NURSING HOME CARE QUALITY 3 (2007),

as it "focused on nursing homes' ability to provide care rather than the quality of care received by residents—in other words, structure rather than process and outcome."[107] The Reagan Administration's attempt to loosen government oversight of nursing homes was strongly opposed by consumer advocates who worked closely with Congress, which twice passed legislation to thwart the Administration's efforts.[108] This impasse was resolved by requesting an independent assessment from the Institute of Medicine (IOM) in 1986 to study the condition of nursing homes in the United States so as "to recommend changes in regulatory policies and procedures to enhance the ability of the regulatory system to assure that nursing home residents receive satisfactory care."[109] The report produced by the IOM committee, titled *Improving the Quality of Care in Nursing Homes*, "proposed sweeping reforms, most of which became law in 1987 with the passage of the Nursing Home Reform Act, part of the Omnibus Budget Reconciliation Act of 1987."[110]

Title 42 of the Code of Federal Regulations contains implementing regulations for this Act. For example, 42 C.F.R. § 483 clearly states that residents at nursing facilities have "[t]he right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms."[111] After the Nursing Home Reform Act was passed, nursing home oversight was split between the federal government and states, with the Centers for Medicare and Medicaid Services (CMS) enacting regulations that states had to implement to ensure compliance by individual nursing homes.[112] The CMS manual defines chemical restraints as "any drug that

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https://pdfs.semanticscholar.org/41fc/9bfef13d1a3591cf84ba37ebd48b729c4e7e.pdf?_ga=2.143089269.1592105359.1579408484-1604635965.1578888055 [https://perma.cc/2UEN-EGFQ].

107. *Id.*

108. *Id.* at 5.

109. COMM. ON NURSING HOME REGUL., INST. OF MED., IMPROVING THE QUALITY OF CARE IN NURSING HOMES 1 (1986).

110. Martin Klauber & Bernadette Wright, *The 1987 Nursing Home Reform Act*, AARP, https://www.aarp.org/home-garden/livable-communities/info-2001/the_1987_nursing_home_reform_act.html [https://perma.cc/48RT-V9BW].

111. 42 C.F.R. § 483.10(e)(1) (2019); *see also* 42 U.S.C. § 1396r(c)(1)(A)(ii) (2018) ("[Patients have t]he right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms. Restraints may only be imposed (I) to ensure the physical safety of the resident or other residents, and (II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).").

112.

> The federal Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring that all healthcare providers that participate in the Medicare and/or Medicaid programs are in compliance with federal health and safety standards. To ensure that nursing homes that participate in one or both of these programs (the vast majority of U.S. nursing homes) meet these standards, CMS delegates responsibility to state governments, which oversee quality assurance in the nursing homes within their states. This delegation is carried out through a written contract with each state, usually a state's department of health (DOH), to conduct surveys (inspections) of individual nursing homes as well as to provide other

is used for discipline or convenience and not required to treat medical symptoms"[113] and prioritizes patient autonomy as stated in Section 483.[114] Similarly, 42 C.F.R § 482.13, promulgated in 1986, conditions hospital participation in Medicare and Medicaid on whether "[a]ll patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff."[115] To be sure, chemical restraints are still used in hospitals and nursing home settings.[116] But legal and professional trends since these regulations were enacted in the 1980s have moved away from using chemical restraints to ease the work of staff members and to only using them to ensure patient and staff safety.[117] Many states have

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> quality assurance functions, such as responding to consumer complaints about a facility's care. Because these contractual activities are the principle means by which providers are held accountable for meeting federal standards, they are critical to ensuring both quality of care for nursing home residents across the country as well as appropriate use of the government funding that pays for a substantial portion of nursing home care. Thus, the efficacy of CMS's oversight of each state agency's performance in its surveying and oversight activities, as dictated by these contracts, is crucial.

CYNTHIA RUDDER, RICHARD J. MOLLOT, MAGGIE BAUMER & IAN DRISCOLL, GOVERNMENT MONITORING & OVERSIGHT OF NURSING HOME CARE: THE RELATIONSHIP BETWEEN FEDERAL AND STATE AGENCIES 9 (2010) (footnotes omitted), https://theconsumervoice.org/uploads/files/issues/LTCCC-Report.pdf [https://perma.cc/PQ2X-QZDT].

113. CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUM. SERVS., CMS MANUAL SYSTEM: PUB. 100-07 STATE OPERATIONS PROVIDER CERTIFICATION 3 (2016), https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R157SOMA.pdf [https://perma.cc/TRA9-99ZX].

114. CMS regulations also state:

> Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident's unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative's request or approval.

Id. at 4.

115. 42 C.F.R. § 482.13(e) (2019).

116. *See* Maier, *supra* note 104, at 257. Maier notes that:

> Despite the regulations, nursing homes still use medications as a way to control residents. In 2001 over 27% of Medicare beneficiaries in nursing homes received an antipsychotic prescription—the highest level in over a decade. Yet, according to a 1999 study, only 8% of nursing home residents had been diagnosed with "other mental disorders." Further, a study of 2004 nursing home data revealed that over 86.3% of nursing home patients receiving an antipsychotic drug received it for an off-label use. Most of those patients had been diagnosed with dementia, and 63% of them were residents in a for-profit facility. Finally, over 75% of those beneficiaries were enrollees in either Medicare or Medicaid. While over time the percentage of residents receiving antipsychotic medications for off-label uses has decreased, in 2008, CMS reported that almost 20% of nursing home residents receiving antipsychotic medications did not have a psychotic or related diagnosis.

Id. at 256–57 (footnotes omitted).

117. Michael Silverman notes in *Emergency Physicians Monthly* that:

> More and more hospitals are changing their restraint policies or trying to go restraint free.

reaffirmed these values in their laws and regulations governing healthcare settings.[118]

While the Nursing Home Reform Act demonstrates a commitment to curtailing the use of chemical restraints in nursing facilities, it remains unclear whether the Act provided residents with an affirmative right to sue nursing homes that violate the rules regarding chemical restraints. Indeed, circuit courts have been inconsistent on whether the Nursing Home Reform Act authorizes a private cause of action for residents against nursing homes or if it creates rights that can be enforced by 42 U.S.C § 1983. The Ninth Circuit most recently addressed this issue in 2019, holding that the Act is sufficiently rights-creating such that it could be enforced via Section 1983.[119] In reaching that conclusion, it joined the Third Circuit, which has allowed Section 1983 claims as a vehicle to enforce rights under the Act since 2009.[120] Meanwhile, the Second Circuit, as well as several district courts, have held that the Act provides no cause of action for private plaintiffs or enforceable rights under Section 1983.[121] Perhaps because of this, as well as many nursing home residents' limited resources, there are few cases that interpret the regulations governing chemical restraints in nursing homes.[122] In the next Section, we move from discussing chemical

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> The patient population in the ED often times has patients who will continue to require some sort of restraint to protect the patient and/or the staff. The goals of the provider are to diagnose and treat the patient's underlying medical problem which may require effectively using medications to help control the patient's symptoms so that they can be more participatory in their plan of care. Accurate and thorough documentation on these patients is critical.

Michael Silverman, *Restraints: All Holds Barred?*, EMERGENCY PHYSICIANS MONTHLY (Oct. 10, 2016), https://epmonthly.com/article/all-holds-barred [https://perma.cc/23HM-FQVM].

118. For example, the California Code of Regulations states that patients in healthcare facilities have the right:

> To be free from psychotherapeutic drugs and physical restraints used for the purpose of patient discipline or staff convenience and to be free from psychotherapeutic drugs used as a chemical restraint . . . except in an emergency which threatens to bring immediate injury to the patient or others. If a chemical restraint is administered during an emergency, such medication shall be only that which is required to treat the emergency condition and shall be provided in ways that are least restrictive of the personal liberty of the patient and used only for a specified and limited period of time.

CAL. CODE REGS. tit. 22, § 72527(a)(24) (2020). Similarly, state law in New York states that health care facilities must ensure that "the resident is free . . . from any psychotropic drug administered for purposes of discipline or convenience, and not required to treat the resident's medical conditions or symptoms . . . ." N.Y. COMP. CODES R. & REGS. tit. 10, § 415.4(a)(1) (2020).

119. Anderson v. Ghaly, 930 F.3d 1066, 1070 (9th Cir. 2019).

120. Grammer v. John J. Kane Reg'l Ctrs.-Glen Hazel, 570 F.3d 520 (3d Cir. 2009).

121. *See* Prince v. Dicker, 29 F. App'x 52, at *54 (2d Cir. 2002); Duncan v. Johnson–Mathers Health Care, Inc., No. 5:09-CV-00417-KKC, 2010 WL 3000718, at *10 (E.D. Ky. July 28, 2010); Baum v. N. Dutchess Hosp., 764 F. Supp. 2d 410, 425 (N.D.N.Y. 2011).

122. A search conducted in January 2020 of all cases citing the parts of the regulations that deal with chemical and physical restraints resulted in only 186 total cases, and of that set, only 5 cases mentioned "chemical" or "chemical restraint." None described clearly relevant fact patterns. In some cases, it is unclear from the fact pattern whether the issue pertained to physical or chemical restraint. *See, e.g.*, Lakeridge Villa Health Care Ctr. v. Leavitt, 202 F. App'x 903 (6th Cir. 2006). There is also evidence that concerns regarding chemical restraints in nursing homes are often brought under state law.

restraints in clinical settings to cases involving chemical restraints and their use in pre-hospital or public settings. As an example of how chemical restraints operate in public settings, we examine a Minneapolis clinical trial involving the use of ketamine as a chemical restraint and describe how chemical restraints can shift from a healthcare tool to a law enforcement tactic.

C. Chemical Restraints as Law Enforcement Tactic: Minneapolis Case Study

As Brandon Garrett and Seth Stoughton note in their article "A Tactical Fourth Amendment," there is growing concern that police officers do not have enough tactical guidance on how to properly diffuse tense situations without resorting to deadly force or other avoidable forms of violence.[123] While Garrett and Stoughton advocate reconstructing the existing constitutional test regarding "what counts" as excessive force,[124] others address tactical ambiguity in use-of-force law and policy by arguing for expanding the tools that are available to law enforcement. This has led to a growing number of researchers and law enforcement practitioners who are interested in exploring the use of chemical restraints as part of policing practice.[125] John Powell's detainment and chemical restraint in Minneapolis exemplifies how evolving norms regarding the use of force are creating Fourth Amendment challenges that have gone largely unaddressed. There are no official statistics on how often police officers partner with medical professionals to administer chemical restraints in pre-hospital settings. Thus, the Powell incident in Minnesota, where ketamine was used as a chemical restraint, provides unusual insight into how this practice may develop in different parts of the country.[126]

See, e.g., Fiala v. Bickford Senior Living Grp., LLC, 43 N.E.3d 1234 (Ill. App. Ct. 2015) (bringing a claim under the Illinois Nursing Home Care Act, 210 ILL. COMP. STAT. 45/1-101 et seq. (West 2014)); Robicheaux v. Adly, 827 So. 2d 429 (La. Ct. App. 2002) (bringing a claim that, in part, concerns chemical restraints under Louisiana's Patient's Bill of Rights, LA. STAT. ANN. § 40:2010.8(A)(9) (2020)).

123. Garrett and Stoughton note:

> As ongoing public controversy over high-profile police killings drives home, the rules governing police use of force remain deeply contested. Members of the public may assume that police rules and procedures provide detailed direction about when officers can use deadly force. However, many agencies train officers to respond to threats according to a force "continuum" that does not provide hard-edged rules for when police can use deadly force. Nor, as recent cases have illustrated, does a criminal prosecution under state law readily lend itself to defining when police uses of force are appropriate.

Garrett & Stoughton, *supra* note 72, at 213.

124. *Id.* at 275 n.282.

125. *See, e.g.*, Danielle M. Weiss, *Calming Down: Could Sedative Drugs Be a Less-Lethal Option?*, NAT'L INST. JUST. (October 2008), https://nij.ojp.gov/topics/articles/calming-down-could-sedative-drugs-be-less-lethal-option [https://perma.cc/YJ6L-8C8S]; LAKOSKI ET AL., *supra* note 20.

126. For other examples of ketamine being used as a chemical restraint by law enforcement, see Schmelzer, *supra* note 28; Blizzard, *supra* note 28.

1. Ketamine's Accepted Medical Uses

Law enforcement researchers and policymakers currently favor a wider range of drugs for use as chemical restraints than what is typically used in healthcare settings.[127] While it is common for healthcare professionals to use benzodiazepines, typical antipsychotics, and atypical antipsychotics, researchers examining the use of chemical restraints in law enforcement have looked beyond these three drug classes to identify over a hundred different compounds that could be administered.[128] Ketamine has become a popular choice.

Developed in 1962 and approved for human use in 1970, ketamine quickly became a widely used battlefield anesthetic during the Vietnam War.[129] Its properties made it possible for physicians to perform painful surgeries in remote locations. As a dissociative anesthetic, ketamine distorts perception of sight and sounds, produces feelings of detachment from the environment and one's self, and induces insensitivity to pain.[130] The drug "exerts its effect by 'disconnecting' the thalamocortical and limbic systems [of the brain], effectively dissociating the central nervous system from outside stimuli (eg [*sic*], pain, sight, sound)."[131] Its effects put one in a "trancelike cataleptic state of 'sensory isolation' . . . characterized by potent analgesia, sedation, and amnesia while maintaining cardiovascular stability and preserving spontaneous respirations and protective airway reflexes."[132]

Today, ketamine continues to be used to facilitate sedation during surgery.[133] It is the most popular drug for painful surgical procedures in children.[134] It is sold under the brand name Ketalar and in generic versions as an injection.[135] According to its FDA-approved product labeling, the drug can be used for the following purposes: (1) "as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation;" (2) "for the induction of anesthesia prior to the administration of other general anesthetic agents;" and (3) "to supplement low-potency agents, such as nitrous oxide."[136] When used for these approved purposes, ketamine has several potential side-

127. *See generally* LAKOSKI ET AL., *supra* note 20; Weiss, *supra* note 125.

128. *See* LAKOSKI ET AL., *supra* note 20, at 15–16.

129. *Ketamine*, CTR. FOR SUBSTANCE ABUSE RSCH. (Oct. 29, 2013), http://www.cesar.umd.edu/cesar/drugs/ketamine.asp [https://perma.cc/D84Y-GFY5].

130. *Id.*

131. Steven M. Green, Mark G. Roback, Robert M. Kennedy & Baruch Krauss, *Clinical Practice Guideline for Emergency Department Ketamine Dissociative Sedation: 2011 Update*, 57 ANNALS EMERGENCY MED. 449, 449 (2011).

132. *Id.* (footnote omitted).

133. *Ketamine*, JOHNS HOPKINS ALL CHILDREN'S HOSP., https://www.hopkinsallchildrens.org/patients-families/health-library/healthdocnew/ketamine [https://perma.cc/B8BY-2PG3]; Green et al., *supra* note 131, at 449.

134. Green et al., *supra* note 131, at 449.

135. PAR PHARM., KETALAR (KETAMINE HYDROCHLORIDE) INJECTION 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/016812s043lbl.pdf [https://perma.cc/6Z43-LXWM].

136. *Id.* at 3.

effects, including "severe depression of respiration or apnea," "airway obstruction," and psychological "emergence reactions" involving "dream-like states, vivid imagery, hallucinations, and emergence delirium."[137]

In addition to its legitimate medical purposes, ketamine is illegally used for recreational purposes.[138] People use it to experience hallucinations and to feel separated from their bodies.[139] Ketamine can, however, cause "a terrifying sense of almost complete detachment that may feel like a near-death experience" and is similar to having a "bad trip on LSD."[140] Ketamine is also one of the three most commonly used drugs for sexual assault.[141] It is favored by perpetrators because it comes in a clear liquid form that cannot easily be detected when added to drinks and very quickly renders a victim unconscious.[142]

Ketamine has been tested experimentally in public settings as a drug to relax and calm people experiencing different levels of agitation. Paramedics responding to emergency 9-1-1 calls conducted these experiments. In these studies, if the paramedic determined that a person is sufficiently agitated to qualify for inclusion in the research, the paramedic gave the subject an experimental dose of ketamine before transporting them to the hospital. Researchers in one such study found that in nearly half of all cases, the patient experienced dangerous complications, including depressed breathing for a period long enough to require intubation.[143] We will now turn to a discussion of how a hospital organization in Minneapolis carried out these experiments, often in collaboration with the police.

2. Minneapolis Case Study: Experiments Using Ketamine in Emergency Medicine

Physicians at the Minneapolis-based hospital organization Hennepin Healthcare conducted two clinical trials that involved paramedics using ketamine on community members. The purpose of the experiments was to test ketamine's efficacy in sedating people experiencing "acute undifferentiated agitation."[144] In the experiments, paramedics responded to 9-1-1 calls-for-service about medical emergencies and then administered ketamine to agitated

137. *Id.* at 1, 4, 7 (capitalization altered).

138. JOHNS HOPKINS ALL CHILDREN'S HOSP., *supra* note 133.

139. *Id.*

140. *Id.*

141. *Date Rape Drugs*, OFF. ON WOMEN'S HEALTH (Apr. 26, 2019), https://www.womenshealth.gov/a-z-topics/date-rape-drugs [https://perma.cc/9PZ5-6ATP].

142. *Id.*

143. Jon B. Cole, Johanna C. Moore, Paul C. Nystrom, Benjamin S. Orozco, Samuel J. Stellpflug, Rebecca L. Kornas, Brandon J. Fryza, Lila W. Steinberg, Alex O'Brien-Lambert, Peter Bache-Wiig, Kristin M. Engebretsen & Jeffrey D. Ho, *A Prospective Study of Ketamine Versus Haloperidol for Severe Prehospital Agitation*, 54 CLINICAL TOXICOLOGY 556, 556 (2016) (finding, in a clinical trial of ketamine versus haloperidol in prehospital settings, that complications occurred in 49 percent of patients that received ketamine and that 39 percent of subjects had to be intubated).

144. *Id.*

patients before transporting them to the hospital.[145] Many, though not all, of these incidents involved law enforcement encouraging or directing paramedics to inject agitated individuals with ketamine after they were arrested or detained. Nevertheless, this set of experiments provides a context for understanding how law enforcement often became active participants in the decision to administer ketamine. As we discuss in more detail below, Hennepin Healthcare did not require paramedics to obtain patients' informed consent before enrolling them in the experiments and giving them trial doses of ketamine.[146] Researchers designed the studies to compare ketamine with the two most commonly used drugs for treating "agitation"—haloperidol and midazolam.

When used in medical terminology, "agitation" refers to "a temporary disruption of typical physician–patient collaboration . . . [which] interfere[s] with assessment and treatment during a period when immediate treatment is necessitated."[147] An agitated individual might exhibit "motor restlessness, heightened responsivity to internal and external stimuli, irritability, [or] inappropriate or purposeless verbal or motor activity . . . ."[148] More severe forms of agitation might involve "explosive and/or unpredictable anger; intimidating behavior; restlessness, pacing, or excessive movement; physical and/or verbal self-abusiveness; demeaning or hostile verbal behavior; uncooperative or demanding behavior or resistance to care; and impulsive or impatient behavior or low tolerance for pain or frustration."[149]

The first Minneapolis-based study on the use of ketamine to treat agitation began in October 2014. The study was designed to compare the effects of ketamine to haloperidol.[150] Throughout the one-year study, paramedics responding to emergency calls-for-service determined if patients qualified and, if so, enrolled the patients as subjects. For the first three months of the study, paramedics treated enrolled subjects with haloperidol. For the next six months, haloperidol was removed from all ambulances, and paramedics treated subjects with ketamine. Then for the final three months, paramedics went back to treating subjects with haloperidol.[151] To measure the efficacy of ketamine and haloperidol, paramedics used stopwatches to record how long it took patients to

145. *Id.*

146. *Id.*

147. Michael H. Allen, *Managing the Agitated Psychotic Patient: A Reappraisal of the Evidence*, 61 J. CLINICAL PSYCHIATRY (SUPP. 14) 11, 12 (2000).

148. Bruno Pacciardi, Mauro Mauri, Claudio Cargioli, Simone Belli, Biagio Cotugno, Luca Di Paolo & Stefano Pini, *Issues in the Management of Acute Agitation: How Much Current Guidelines Consider Safety?*, 4 FRONTIERS PSYCHIATRY, May 2013, at 1, 1.

149. Michael H. Allen, Glenn W. Currier, Daniel Carpenter, Ruth W. Ross & John P. Docherty, *Introduction: Methods, Commentary, and Summary*, 11 J. PSYCHIATRIC PRAC. (SUPP. 1) 5, 9 (2005).

150. Cole et al., *supra* note 143, at 557.

151. *Id.*

reach sedation after administering either drug.[152] Paramedics also recorded complications and whether individuals had to be intubated.[153]

Patient consent was not required before enrolling in the study because Hennepin Healthcare's institutional review board (IRB)—the organization tasked with reviewing human subjects research—decided that the study was eligible for a waiver.[154] 45 C.F.R. § 46.116 allows such a waiver when: (1) the research "involves no more than minimal risk to the subjects"; (2) "[t]he research could not practicably be carried out without the requested waiver or alteration"; (3) the waiver "will not adversely affect the rights and welfare of the subjects"; and (4) subjects are provided, when available, with additional information and details after they participate in the trial.[155] Hennepin Healthcare did perform a "community consultation" with "caregivers affected by [the] study as well as a select group of patients at a local homeless shelter's inpatient chemical dependency program," "given the particularly vulnerable nature of this patient population."[156]

To determine who qualified for the study, paramedics used the Altered Mental Status Scale (AMSS). The AMSS assesses levels of alertness or sedation, agitation, or intoxication.[157] The scale allows medical providers to assign scores

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152. *Id.*

153. *Id.*

154. *Id.*

155. *See* 45 C.F.R. § 46.116(f)(3)(i)–(v) (2020). "[M]inimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations. 45 CFR §§ 46.102(i); 46.116(f)(3)(i)–(v) (2020). There is an additional regulation allowing informed consent requirements to be waived in emergency-medicine research. 21 C.F.R. § 50.24 (2020). This regulation does not require an IRB to find that the research involves no more than minimum risks. *See id.*; U.S. DEP'T OF HEALTH & HUM. SERVS. ET AL., GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS, CLINICAL INVESTIGATORS, AND SPONSORS: EXCEPTION FROM INFORMED CONSENT REQUIREMENTS FOR EMERGENCY RESEARCH (2013). Instead, the regulation allows a waiver where:

> 1) the research involves human subjects who cannot give consent because of life-threatening medical conditions; 2) the condition requires immediate intervention; 3) available treatments are unproven or unsatisfactory and further research is needed to determine which therapy is best; 4) the research might provide benefit to the study subject; 5) clinical equipoise exists between the study and standard treatment; 6) the research cannot occur without the exception; 7) intervention must start before consent from a legally authorized representative is feasible and there is no way to identify likely subjects prospectively; 8) the primary investigator attempts to contact, within the therapeutic widow [sic], the legally authorized representative or a family member who might object; and 9) the primary investigator has provided an informed consent document to use if and when feasible.

Terri A. Schmidt et al., *Confronting the Ethical Challenges to Informed Consent in Emergency Medicine Research*, 11 ACAD. EMERGENCY MED. 1082, 1087 (2004). It is important to also note that the researchers in the Minneapolis trial relied upon the pre-2018 version of 45 C.F.R § 46.116. After the revision to the Common Rule in 2018, this part of the statute was amended to include an additional grounds for waiver regarding the use of "identifiable private information or identifiable biospecimens," provided that "the research could not practicably be carried out without using such information or biospecimens in an identifiable format." 45 C.F.R § 46.116(f)(3)(iii) (2020).

156. Cole et al., *supra* note 143, at 557.

157. *Id.*

to an individual based off the medical providers' observations of the individual's responsiveness, speech, facial expressions, and eyes.[158] Qualified patients presented with "severe acute undifferentiated agitation,"[159] which the study defined as an AMSS score of 2 or 3. A score of 2 corresponds to "[a]nxious, agitated" responsiveness, "[l]oud outbursts" in speech, and "[n]ormal" facial expressions and eyes, while a score of 3 corresponds to "[v]ery anxious, agitated" responsiveness with a "mild physical element of violence," "[l]oud outbursts" in speech, "[a]gitated" facial expressions, and "[n]ormal" eyes.[160] The trial excluded patients with profound agitation, which was defined as an AMSS score of 4 ("[c]ombative, very violent, or out of control").[161] These patients were excluded because the researchers' institution "deemed it unethical and unwise to withhold ketamine from the most profoundly agitated patients at any time for both patient and caregiver safety."[162]

The results of the study showed that ketamine worked faster than the previous treatment but also caused significant problems. The median time to sedation using ketamine was only five minutes, whereas the median time using haloperidol was seventeen minutes.[163] However, 49 percent of patients receiving ketamine experienced complications, compared to just 5 percent of those receiving haloperidol.[164] Subjects receiving ketamine were almost ten times more likely to have breathing problems that required intubation.[165] In total, 39 percent of patients receiving ketamine had to be intubated due to some form of airway obstruction, whereas only 4 percent of patients receiving haloperidol required intubation.[166]

It is likely that these results were not surprising, as many of the researchers knew prior to the study that ketamine posed great risks. Indeed, approximately two years before this trial, many of the same investigators published a paper in *Prehospital Emergency Care* that presented two case reports on the use of prehospital ketamine for the management of what is thought to be the most profound type of agitation, known as excited delirium syndrome.[167] In that paper, they explicitly warned that ketamine should only be considered as a treatment

158. *Id.*
159. *Id.*
160. *Id.*
161. *Id.*
162. *Id.*
163. *Id.* at 560.
164. *Id.* at 560–61.
165. *Id.* at 556.
166. *Id.* at 560.
167. Jeffrey D. Ho, Stephen W. Smith, Paul C. Nystrom, Donald M. Dawes, Benjamin S. Orozco, Jon B. Cole & William G. Heegaard, *Successful Management of Excited Delirium Syndrome with Prehospital Ketamine: Two Case Examples*, 17 PREHOSPITAL EMERGENCY CARE 274, 274 (2013). For a critical discussion of excited delirium syndrome, see Michael Barajas, *Excited. Delirious. Dead.*, TEX. OBSERVER (Oct. 16, 2017), https://www.texasobserver.org/excited-delirious-dead/ [https://perma.cc/P7WZ-2TBN].

for extreme instances of agitation and that it should not be used in patients with lesser degrees of agitation (including severe agitation and acute agitation) because of the drug's known toxicities. They warned:

> We would caution against using ketamine sedation in situations that do not warrant the immediate need for interruption of the severe, life-threatening, metabolic acidosis/catecholamine surge crisis seen in late-stage [excited delirium syndrome]. . . . We would advocate that ketamine not be the chemical solution for every unruly or belligerent subjects [*sic*], as this would lead to overuse with unnecessary risk.[168]

Despite these recommendations, the researchers decided to proceed with the 2014 study. And then, after finding that ketamine posed a significantly higher rate of complications, many of the same researchers decided to conduct yet another study in August 2017.

This second trial was also done under the auspices of Hennepin Healthcare and compared the efficacy of ketamine to midazolam.[169] This study largely mirrored the first in terms of research design. Qualifying participants were given ketamine for the first six months of the study and midazolam in the second six months.[170] Paramedics recorded the time it took each drug to sedate individuals and whether individuals suffered from complications and needed intubation.[171] This time, however, the study had more prospective participants because it included both severely agitated and profoundly agitated patients.[172] Hennepin Healthcare again waived informed consent requirements based on its assessment that the study involved no more than minimum risks.[173] The trial was suspended on June 25, 2018, after details about the study were exposed by the *Minneapolis Star Tribune*.[174]

The public was eventually made fully aware of Hennepin Healthcare's experimental use of ketamine after the Minneapolis Office of Police Conduct Review (OPCR), a neutral agency that investigates police misbehavior, issued a report revealing the use of the drug in situations involving paramedics and police officers.[175] The OPCR investigation started after a Fall 2017 audit of police body camera footage of use-of-force incidents revealed multiple episodes where paramedics injected detained or arrested individuals with an unknown substance that made them fall unconscious.[176] Several police reports identified the drug

168. *Id.* at 277.

169. HENNEPIN HEALTHCARE RSCH. INST., *Ketamine Versus Midazolam for Prehospital Agitation*, CLINICALTRIALS.GOV (Apr. 5, 2019), https://clinicaltrials.gov/ct2/show/NCT03554915 [https://perma.cc/UA9D-JJZ2].

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.*

174. MINNEAPOLIS, MPD INVOLVEMENT IN PRE-HOSPITAL SEDATION 4 (2018) [hereinafter OPCR REPORT].

175. *See generally id.*

176. *Id.* at 3.

administered as ketamine.[177] The OPCR reported its findings to the Minneapolis director of civil rights, who instructed the OPCR to begin a thorough investigation of the use of ketamine in calls-for-service involving the Minneapolis Police Department (MPD).[178] In the course of that investigation, an anonymous source released a draft version of the report to the media.[179]

The final report was released in July 2018 and concluded that the number of police reports mentioning ketamine increased from two in 2010 to sixty-two in 2017.[180] In one case, ketamine had been administered four separate times to the same person.[181] The report includes demographic information about the people involved in the incidents from 2016 to 2017. Black community members were disproportionately represented,[182] comprising 40 percent of the people injected with ketamine yet only constituting 19.4 percent of the Minneapolis population.[183] These figures should be understood in the context of other racial disparities regarding policing in Minneapolis, which includes using force against Black people seven times more often than against white people.[184] Moreover, Minneapolis's racial inequalities in policing are compounded by racial disparities in other areas, including income, unemployment, poverty, homeownership, incarceration, and education.[185] These concurrent and overlapping inequalities create a social context where the overall devaluation of the Black community can lead to the increased, and often unnecessary, use of dangerous chemical restraints by paramedics.

OPCR analysts found and reviewed body-camera footage of eight instances that took place between 2016 and 2018. In these incidents, the footage showed Minneapolis Police Department officers participating in the decision to administer ketamine.[186] This participation ranged from officers telling medics to

177. *Id.*

178. *Id.*

179. *Id.* at 6.

180. *Id.* at 10.

181. *Id.*

182. *Id.* app. 5. Race was reported by the officers. The racial demographics of the citizens involved in the incidents were as follows: 40 percent Black, 39 percent White, 10 percent American Indian/Alaskan Native, 9 percent Other/Mixed Race, 2 percent Unknown/Unreported. *Id.*

183. *QuickFacts: Minneapolis City, Minnesota*, U.S. CENSUS BUREAU, https://www.census.gov/quickfacts/minneapoliscityminnesota [https://perma.cc/LA6P-KA72].

184. Richard A. Oppel Jr. & Lazaro Gamio, *Minneapolis Police Use Force Against Black People at 7 Times the Rate of Whites*, N.Y. TIMES (June 3, 2020), https://www.nytimes.com/interactive/2020/06/03/us/minneapolis-police-use-of-force.html [https://perma.cc/5WB6-PZ3B].

185. Greg Rosalsky, *Minneapolis Ranks Near the Bottom for Racial Equality*, NPR (June 2, 2020, 6:30 AM), https://www.npr.org/sections/money/2020/06/02/867195676/minneapolis-ranks-near-the-bottom-for-racial-equality [https://perma.cc/A2MR-2WVE]; *see also* Christopher Ingraham, *Racial Inequality in Minneapolis is Among the Worst in the Nation*, WASH. POST (May 30, 2020), https://www.washingtonpost.com/business/2020/05/30/minneapolis-racial-inequality [https://web.archive.org/web/20200603053057/https://www.washingtonpost.com/business/2020/05/30/minneapolis-racial-inequality/].

186. OPCR REPORT, *supra* note 174, at 10.

bring ketamine ("When EMS gets here, just tell them to bring the ketamine in") to instances where medics asked the officers whether the individual should be sedated ("You guys want us to give him something?").[187] Though officers did not inject anyone, they often assisted by holding down or restraining individuals while paramedics administered the drug.[188] Individuals who were given ketamine as a chemical restraint were also physically restrained with handcuffs in 88 percent of cases, restrained by EMS devices (typically stretchers with straps) in 43 percent of cases, had spit hoods[189] placed on them in 33 percent of cases, and were secured with hobbles or leg restraints in 15 percent of cases.[190] At the time of the audit, MPD did not have a policy addressing interactions between paramedics and police or the use of chemical restraints such as ketamine.

The OPCR report contained alarming details regarding multiple—and seemingly routine—incidents where police officers pressured paramedics to use ketamine as a chemical restraint.[191] The body-camera footage of several incidents reviewed by OPCR revealed that in some cases, the police requested ketamine even though an individual had already been subdued.[192] In one case, an officer spoke with paramedics about giving an individual a shot of ketamine.[193] When the individual saw the needle, he said he did not want the shot, adding, "[W]hoa, whoa, that's not cool!" He pleaded, "I don't need that!"[194] He was then injected with the drug twice and secured to a chair.[195] Shortly after, he became nonverbal and his vocalizations unintelligible, prompting one officer to remark, "he just hit the K-hole," a slang term for the intense delirium brought on by ketamine.[196]

In another incident, police responded to a call involving an "emotionally disturbed" person contemplating suicide.[197] The police found the person in his residence sleeping face down on a couch, and they double-handcuffed him without resistance.[198] When the paramedics arrived, one of the officers made an

187. *Id.*
188. *Id.* at 11.
189. Spit masks–or spit hoods–have been used by law enforcement officers for years, often in jails and prisons. Most are made from nylon mesh that loosely cover a person's head with an elastic band to keep it affixed around their neck. Some have plastic that covers the mouth and nose portion. Scott Morris, *Justified by Myth, Spit Hoods Can Kill*, OAKLAND REP. (Aug. 12, 2019), https://www.oaklandreporter.org/2019/08/justified-by-myth-spit-hoods-can-kill.html [https://perma.cc/9HJ3-LS2W].
190. OPCR REPORT, *supra* note 174, at 11.
191. *Id.* at 12–15.
192. *Id.*
193. *Id.* at 15.
194. *Id.*
195. *Id.*
196. *Id.*
197. *Id.* at 12.
198. *Id.*

"injection" motion toward the individual and laughed.[199] The officer then radioed, "[T]ell [the paramedics] they're going to have to bring a shot in."[200] Shortly before being taken to the ambulance, the individual yelled, "[L]et me go!"[201] The officer replied, "[I]n about two seconds when they shove a needle in your ass. They'll give you a little ketamine."[202] At the hospital, once the individual was taken to a room, an officer stated, "[He] needs a locker [*sic*] room unless you're going to give [him] a shot, because [he] needs a shot . . . ."[203]

The report also suggests that paramedics may have administered ketamine to people because it would benefit Hennepin Healthcare's research experiment and not because it was medically necessary. Body-camera footage from one case showed a woman, after being maced by police, asking for an asthma pump. Instead, a paramedic gave her an injection of ketamine. "If [she] was having an asthma attack, giving ketamine actually helps patients and we're doing a study for agitation anyway so I had to give [her] ketamine,"[204] the unnamed paramedic told a police officer. After receiving ketamine, the woman's breathing stopped, and medical staff resuscitated her, according to the report.[205] The authors of the OPCR report said that it was "troubling that the dictate of the 'study' mentioned by the paramedics appears to have played a significant role in the decision to administer ketamine."[206]

There is also evidence that police instructed the paramedics about how much ketamine to administer. During one incident, an individual—who had been given ketamine on at least four separate occasions in one year—was confronted by the police after an alleged jaywalking incident and began taunting the officers.[207] The officers told the individual to stop using profanity, and when the individual continued to use inappropriate language, the officers attempted to detain him. The individual actively resisted arrest and scratched an officer. Then the officers handcuffed and hobbled him, fitted him with a spit hood, and strapped him to a stretcher. Once inside an ambulance, the individual loudly objected to arrest and the officers' force. A paramedic said, "[A]re you gonna draw it [ketamine] up[?]"[208] The person was given the ketamine injection despite his objection as the officer restraining him referred to the drug as "the good

199. *Id.*
200. *Id.*
201. *Id.*
202. *Id.*
203. *Id.*
204. *Id.* at 13.
205. *Id.*
206. Andy Mannix, *Ketamine study at Hennepin Healthcare Suspended After Criticism from Politicians*, STAR TRIB. (June 26, 2018, 11:38 AM), https://www.startribune.com/ketamine-study-at-hennepin-healthcare-suspended-after-criticism-from-politicians-minneapolis-police-sedate/486507021 [https://perma.cc/Y7DV-RRZV].
207. OPCR REPORT, *supra* note 174, at 14.
208. *Id.*

stuff."[209] The injection did not cause the individual to fall unconscious, and the group discussed giving him more ketamine, to which he replied, "[D]on't give me anything."[210] The officer then suggested to the paramedic that "[l]ast time" it took "two doses."[211] The officer told the paramedic that he had seen the person a few nights earlier.[212]

Another key concern raised was whether the studies actually involved only minimal risks—a concept used in clinical trials to, in part, determine whether waivers of consent requirements are appropriate.[213] Public Citizen's Health Research Group—a consumer-protection organization—and dozens of doctors, lawyers, and bioethicists submitted a letter to the U.S. Department of Health and Human Services requesting a formal compliance oversight investigation. With respect to the waiver of consent, the letter stated:

> A prospective clinical trial in which human subjects were assigned by a research protocol to receive the general anesthetic ketamine or a different powerful sedative drug for agitation, rather than according to the clinical judgment of the health care professionals caring for the subjects, clearly exceeded minimal risk and therefore was **not** eligible for waiver of informed consent under HHS regulations at 45 C.F.R. § 46.116(d).[214]

The conclusion of the OPCR report included policy recommendations for the Minneapolis Police Department, such as creating a policy governing appropriate interactions between MPD officers and emergency medical responders; providing MPD officers with training about interactions with emergency medical responders; exploring the addition of rules regarding "emotionally disturbed persons" to the MPD policies and procedures; establishing a protocol for medical research involving police detainees; and exploring options for notifications of medical research involving detainees.[215] The report also called for training paramedics about interactions with police officers who may try to participate in decision-making about giving pharmaceuticals to patients.

But such policy recommendations, which regulate partnerships between police and paramedics using ketamine in pre-hospital settings, raise significant legal issues that have yet to be resolved. The collaboration between police and medical professionals to use chemical restraints for subduing detained individuals raises at least two novel constitutional questions. First, do Fourth

209. *Id.*
210. *Id.*
211. *Id.*
212. *Id.*
213. Letter from Michael A. Carome, Dir., Pub. Citizen Health Rsch. Grp. et al., to Scott Gottlieb, Comm'r, Food and Drug Admin. & Jerry Menikoff, Dir., HHS Off. for Hum. Rsch. Prots., at 2 (July 25, 2018) (on file with author).
214. *Id.* at 7.
215. OPCR REPORT, *supra* note 174, at 16.

Amendment restraints on police use of force also apply to medical providers who are jointly responding to emergency calls-for-service with the police? Second, are chemical restraints administered by medical professionals in pre-hospital settings a form of "force" regulated by the Fourth Amendment? We address these questions in the next Section, which examines how Fourth Amendment rules governing use of force might apply to medical providers who use chemical restraints in public settings.

III.
LAW, MEDICAL PROFESSIONALS, AND USE OF FORCE

Legal scholars have published a considerable amount of literature on the Fourth Amendment and use of force, but there is little material on how the Fourth Amendment might address use of force by people other than police officers. As the ketamine incidents in Minneapolis demonstrate, paramedics and other medical providers work closely with police when responding to emergency calls-for-service, and sometimes these incidents involve forcibly subduing people. This close relationship between police and paramedics, in conjunction with new demands for police officers to use less violence,[216] might lead medical providers and police to explore using chemical restraints in routine law enforcement matters as a seemingly less lethal form of force. Given this potential, it is critical to understand how existing constitutional rules might apply to medical providers when they use chemical restraints for this purpose. This Section explores these issues.[217]

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216. *See, e.g.*, Emily Bazelon, Alicia Garza, Phillip Atiba Goff, Vanita Gupta, Sam Sinyangwe & J. Scott Thomson, *A Discussion About How to Reform Policing*, N.Y. TIMES MAG. (June 13, 2020), https://www.nytimes.com/interactive/2020/06/13/magazine/police-reform.html [https://perma.cc/2WCD-G7MZ]; #8CANTWAIT, https://8cantwait.org [https://perma.cc/6ETT-EEQU?type=image]; #8TOABOLITION, https://www.8toabolition.com [https://perma.cc/KJU7-PYEC].

217. A separate constitutional issue worth flagging is the Fourteenth Amendment right to refuse medical treatment and the corollary liberty interest in being free from unwanted medical interventions. The Supreme Court has held that under the Due Process Clause of the Fourteenth Amendment, individuals have "a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs." Washington v. Harper, 494 U.S. 210, 221–22 (1990). There have been several cases involving Fourteenth Amendment claims against paramedics and other health-care workers for the forcible administration of chemical restraints. Courts generally find due process violations in chemical restraints beyond the extent necessary to ensure patient health or safety. *See* Olafson v. Schulz, No. 3:14-cv-90, 2017 WL 4172154, at *7 (D.N.D. Aug. 22, 2017) (concluding that a chemical restraint does not violate a patient's due process rights if the patient is a danger to himself or others), *report and recommendation adopted*, 2017 WL 4170349 (D.N.D. Sept. 19, 2017); Morgan v. Rabun, 128 F.3d 694, 696–97 (8th Cir. 1997) (recognizing the liberty interest in being free from forcible administration of psychotropic drugs and requiring a showing of dangerousness in order for involuntary chemical restraint to be permissible); Thomas S. *ex rel* Brooks v. Flaherty, 699 F. Supp. 1178, 1188 (W.D.N.C. 1988) (concluding that chemical restraints were used beyond the extent necessary to secure safety and therefore violated substantive due process rights), *aff'd*, 902 F.2d 250 (4th Cir. 1990); Rennie v. Klein, 720 F.2d 266, 269 (3d Cir. 1983) (holding that chemical restraints that substantively depart from accepted medical judgment, practice, or standards violate the constitutional right to refuse medical treatment).

While there are not any Supreme Court decisions that directly deal with medical providers using force, a few federal district and circuit courts have examined this topic. In this Section, we examine these lower court cases to reveal several insights about how the Fourth Amendment operates in the context of medical providers using chemical restraints in public settings. We first examine the broad issue of state action as it relates to medical providers and explain when public and privately employed professionals fall under the purview of the Fourth Amendment. Next, we discuss cases that specifically engage the question of whether chemical restraints constitute excessive force. These cases suggest that chemical restraints are a constitutionally recognized form of force and may amount to excessive force when used for a non-medical purpose that causes harm. An excessive force claim against a medical provider in this context likely hinges on what the court believes the medical provider's purpose to be in using a chemical restraint. Courts finding that providers used chemical restraints as part of ongoing medical treatment generally dismissed excessive-force claims, whereas courts finding that providers used chemical restraints to aid law enforcement allowed them to proceed.

At the end of this Section, we tie the existing precedent on medical providers' use of force back to the critical issues raised by the ketamine incidents in Minneapolis. This allows us to better understand the relationship between chemical restraints, law, and medicine in Fourth Amendment contexts.

A. Constitutional Torts and Medical Providers as State Actors

Most excessive-force cases involve police officers, while harms that implicate medical professionals typically fall under tort law.[218] This might lead some to assume that Fourth Amendment rules on use of force do not apply to medical providers. Fourth Amendment standards, however, do not apply to police officers alone.[219] Indeed, courts have held that a variety of individuals—including firefighters, social workers, and healthcare providers—have used unreasonable or excessive force in violation of Fourth Amendment standards.[220] The rules determining which categories of people may be regulated by the Fourth Amendment do not emerge clearly from the Constitution itself. These categories

218. *See* Gwen Seabourne, *The Role of the Tort of Battery in Medical Law*, 24 ANGLO-AM. L. REV. 265 (1995).

219. *See* 42 U.S.C. § 1983 (2018) (imposing liability on every person who, under the color of a state statute, ordinance, or regulation, causes the deprivation of another's federally protected right); *supra* Part I.A.

220. *See, e.g.*, Michigan v. Tyler, 436 U.S. 499, 506 (1978) (holding that the Fourth Amendment applied to firefighters investigating the cause of a fire); Doe v. Heck, 327 F.3d 492, 510 (7th Cir. 2003) (applying the Fourth Amendment to a child welfare caseworker who, accompanied by a police officer, removed a child from class to question him about circumstances in his home); Cole v. City of Chicago, No. 06 C 4704, 2008 WL 68687, at *6 (N.D. Ill. Jan. 4, 2008) (allowing excessive-force claim against paramedic to proceed).

materialize instead from the statutory mechanism for enforcing constitutional rights: 42 U.S.C. § 1983.

Section 1983 allows people deprived of their federal constitutional rights to sue in federal court and receive monetary damages or an injunction to prevent further constitutional violations.[221] However, Section 1983 only applies when the person who committed the constitutional violation acted "under color of state law."[222] To meet this requirement, generally, the constitutional violator must be a state or local actor[223] rather than a private individual. These actors include government entities as well as individual public officials, officers, and employees.[224] In addition, the government actor must have committed the violation while either performing or purporting to perform her official government duties.[225]

The "under color of state law" requirement is key to understanding how Fourth Amendment standards might apply to healthcare providers. In the healthcare context, some providers, such as public hospital employees, are public officials. In cases involving public employees, therefore, there is no dispute that the Fourth Amendment standards concerning use of force apply. But many healthcare providers work for privately-owned health care companies. Does the Fourth Amendment apply in this context?

Courts apply Section 1983 to private actors under a few circumstances, two of which are most relevant to healthcare.[226] The first circumstance, known as the *traditional public function test*, occurs when a private actor is contracted to perform activities that are typically handled by the government.[227] Examples include firefighting, police activity, and prison services, including the provision of healthcare to incarcerated persons.[228] In *West v. Atkins*, the Supreme Court found that a doctor under a contract with the state to provide medical care to incarcerated persons acted under the color of law for the purposes of Section 1983.[229] Other cases have also indicated that providing medical services can

221. 42 U.S.C. § 1983 (2018).

222. *See* West v. Atkins, 487 U.S. 42, 48 (1988).

223. The U.S. Supreme Court held that federal actors who violate constitutional rights are held to a similar standard. *See* Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics, 403 U.S. 388 (1971).

224. *West*, 487 U.S. at 48; Filarsky v. Delia, 566 U.S. 377 (2012).

225. *West*, 487 U.S. at 48.

226. For a description of the various state action tests used by federal courts, see Julie K. Brown, Note, *Less is More: Decluttering the State Action Doctrine*, 73 MO. L. REV. 561 (2008). For example, another approach to understanding state action involves private actors performing exclusively public functions. *See* Jack M. Beermann, *Why do Plaintiffs Sue Private Parties Under Section 1983?*, 26 CARDOZO L. REV. 1, 26 (2004). This only arises in the context of elections and private property, and thus has no application to health-care providers. *Id.*

227. *See* Richard Frankel, *Regulating Privatized Government though § 1983*, 76 U. CHI. L. REV. 1449, 1453 (2009).

228. Flagg Bros. v. Brooks, 436 U.S. 149, 163–64 (1978).

229. 487 U.S. at 52–54; *see also* Hicks v. Frey, 992 F.2d 1450, 1458 (6th Cir. 1993) ("It is clear that a private entity which contracts with the state to perform a traditional state function such as

constitute a public function. For example, the Tenth Circuit noted that performing "necessary municipal functions," including running nursing facilities, constitutes state action.[230] A district court in Arizona concluded that a private entity that contracted with the state to provide state-mandated health services through a government program was a state actor.[231] As such, many privately-employed medical providers will fall under the purview of Section 1983, either because they contract with government entities to provide services or because the services they offer constitute public functions.

The second circumstance that may give rise to Section 1983 liability for a private medical provider, known as *joint action* or *joint participation theory*, applies when a private actor works alongside and in conjunction with government actors. This theory is the most relevant to incidents that involve paramedics using chemical restraints to aid law enforcement, such as the ketamine incidents in Minneapolis. Under the joint action theory, a private party can be said to have acted "under color of state law" for the purposes of Section 1983 when the private party is a "willful participant in joint activity with the State or its agents."[232] There is no firm rule for determining what constitutes being a "willful participant" in "joint activity" with the state,[233] but courts generally look to the actual interactions between state and private actors in a given situation, as opposed to the general relationship between the two. [234]

The key Supreme Court case on the right to bring claims under Section 1983 against private actors via joint action theory is *Adickes v. SH Kress & Co.*[235] In *Adickes*, private department-store employees allegedly worked jointly with the police to maintain racial segregation at the store's lunch counter.[236] The Court said that the petitioner could bring a claim against the restaurant workers if she could prove that the store employee and the police "reached an understanding to deny [the petitioner] service in [the store], or to cause her subsequent arrest because she was a white person in the company of Negroes."[237] The Court explained:

> [A] private party involved in such a conspiracy, even though not an official of the State, can be liable under § 1983. "Private persons, jointly engaged with state officials in the prohibited action, are acting 'under color' of law for purposes of the statute. To act 'under color' of law does

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providing medical services to prison inmates may be sued under § 1983 as one acting 'under color of state law.'" (citing *West*, 487 U.S. at 54)), *abrogated in part by* Farmer v. Brennan, 511 U.S. 825 (1994).

230. Tool Box v. Ogden City Corp., 316 F.3d 1167, 1176 (10th Cir. 2003), *vacated on reh'g en banc*, 355 F.3d 1236 (10th Cir. 2004) (en banc).

231. J.K. *ex rel.* R.K. v. Dillenberg, 836 F. Supp. 694, 699 (D. Ariz. 1993).

232. Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass'n, 531 U.S. 288, 294, 296 (2001).

233. *See* Frankel, *supra* note 227, at 1453 n.26.

234. *See, e.g.*, Adickes v. S. H. Kress & Co., 398 U.S. 144 (1970); Youngblood v. Hy-Vee Food Stores, Inc., 266 F.3d 851, 855 (8th Cir. 2001).

235. 398 U.S. at 144.

236. *Id.* at 153–57.

237. *Id.* at 152.

> not require that the accused be an officer of the State. It is enough that he is a willful participant in joint activity with the State or its agents."[238]

The department-store employees argued that there was no evidence that they conspired with the police and that they therefore could not be sued under Section 1983. The Court, however, concluded that the petitioner only needed to show that police were present in the store when the managers enforced the racial segregation policy in order for a jury to reasonably conclude that the store owners and police worked together to deny the petitioner service.[239] The Court's analysis in *Adickes* leads to a broad conception of joint action that includes not only explicit agreements to act together, but also any mutual "meeting of the minds."[240]

In the context of medical providers using chemical restraints, these two legal doctrines—the traditional public function test and joint action theory—demonstrate that there are many ways in which privately-employed medical providers might be treated as state actors acting under color of state law. Under the traditional public function test, if private paramedics work under a contract to provide state-mandated health services, the paramedics would likely qualify as state actors. But more to the point, the joint action theory provides a clear path to liability for medical providers who use chemical restraints in public settings to induce legal compliance. If a medical provider uses chemical restraints to make someone comply to an officer's commands, she is working in a law enforcement capacity. The joint action theory applies because paramedics in this context are acting with police as arms of the state. Regardless of whether the paramedics are employed by public or private entities, medical providers working with police in such situations are acting "under color of law" for the purposes of Section 1983.

The main takeaway from these doctrines is that medical providers are likely subject to Fourth Amendment rules governing use of force if they use chemical restraints to assist police in making a detention or arrest. With this in mind, we now turn to a discussion of the cases examining whether paramedics' use of chemical restraints in pre-hospital contexts raise Fourth Amendment concerns.

B. Federal Court Decisions on Medical Providers and Chemical Restraints

There are a few notable federal cases where individuals sued paramedics for using chemical restraints in public settings. These cases, like the ketamine incidents in Minneapolis, involve paramedics responding to 9-1-1 calls and then injecting individuals with chemical restraints before transporting them to the hospital. An analysis of these cases fills an existing gap in the use-of-force

238. *Id.* (quoting United States v. Price, 383 U.S. 787, 794 (1966)).
239. *Id.* at 158.
240. *Id.* at 158.

literature and can improve our understanding of the use of chemical restraints in non-clinical settings.

The cases involving medical providers and chemical restraints bring clarity to the following two critical Fourth Amendment issues: The first relates to chemical restraints as a form of force used in interactions with the public. When used to induce legal compliance, a review of existing federal court decisions suggests that giving an individual a drug such as ketamine is deemed a type of "force" for Fourth Amendment constitutional purposes. The second relates to how courts analyze the substantive question of what type of medical force qualifies as "excessive." Courts are prone to dismiss excessive-force claims against paramedics if they were pursuing a medical purpose rather than a law enforcement purpose when administering the chemical restraint.[241] As we discuss in more detail through the cases below, the issue of a paramedic's purpose emerges in excessive-force cases during the court's analysis of whether paramedics are entitled to qualified immunity. To demonstrate how this analysis operates, we examine a series of cases from federal courts that have had an opportunity to review this issue, which includes the Sixth Circuit, Seventh Circuit, Second Circuit, and Eastern District of California.

1. The Sixth Circuit: Medical Treatment vs. Law Enforcement

In *Peete v. Nashville*, a young man's grandmother called 9-1-1 because he was having a seizure.[242] The five defendants—paramedics, emergency medical technicians, and firefighters employed by the city—arrived and pinned the man down, applied pressure to his head and neck, and failed to make sure that he had clear airways, which led to the man's death.[243] His estate brought a Section 1983 excessive force claim against the paramedics.[244] The issue in the case centered on whether the paramedics were entitled to qualified immunity.[245]

Paramedics like the one in *Peete* often raise qualified immunity defenses in excessive-force cases because it potentially shields them from liability. Qualified immunity extends to public officials performing their official duties in circumstances where the law governing the constitutional right at issue is not deemed to be "clearly established" at the time of the events in question.[246] The

241. *See* Est. of Barnwell v. Grigsby, 801 F. App'x 354, 370–71 (6th Cir. 2020); Thompson v. Cope, 900 F.3d 414, 417 (7th Cir. 2018); McKenna v. Edgell, 617 F.3d 432, 435 (6th Cir. 2010); Peete v. Nashville, 486 F.3d 217, 222 (6th Cir. 2007); Frank v. Cascade Healthcare Cmty., Inc., No. 6:11-cv-06402-AA, 2014 WL 793073, at *6 (D. Or. Feb. 23, 2014), *aff'd*, 688 F. App'x 461 (9th Cir. 2017) (mem.).

242. 486 F.3d at 219–20.

243. *Id.*

244. *Id.* at 219.

245. *Id.* at 219–21.

246. The Supreme Court has said that it "'do[es] not require a case directly on point' for a right to be clearly established," but that "existing precedent must have placed the statutory or constitutional question beyond debate." White v. Pauly, 137 S. Ct. 548, 551 (2017) (per curiam) (quoting Mullenix v. Luna, 577 U.S. 7, 12 (2015)). It has also emphasized that "clearly established law must be

issue of whether there is "clearly established" law governing medical providers' use of force in the Fourth Amendment context is often the key dispute in excessive-force cases involving medical professionals. For many courts, the answer to this question depends upon the purpose pursued by the medic, or what role they were playing when they made the decision to use a chemical restraint.

The district court in *Peete* initially denied qualified immunity to the defendants, who then appealed to the Sixth Circuit.[247] In its decision, the Sixth Circuit held that qualified immunity is more readily available to medical professionals when they are providing aid as opposed to enforcing the law.[248] Addressing the "clearly established law" prong of the qualified immunity test, the court stated that there were "no cases applying the Fourth Amendment to paramedics coming to the aid of an unconscious individual as a result of a 911 call by a family member."[249] The court further concluded that "where the purpose is to render solicited aid in an emergency rather than to enforce the law . . . there is no federal case authority creating a constitutional liability for the [conduct] alleged in the instant case."[250] Therefore, even though the paramedics "badly botched the job,"[251] they were entitled to qualified immunity.

The Sixth Circuit reaffirmed the importance of distinguishing between actions intended for medical purposes and actions in support of law-enforcement aims in *McKenna v. Edgell*.[252] *McKenna*, like *Peete*, did not involve chemical restraints, but the case is nevertheless a useful illustration of the way the Sixth Circuit conceptualizes actions intended to serve a law enforcement purpose. In *McKenna*, a daughter called 9-1-1 when her father was having a seizure.[253] The parties disputed the specifics about what happened after the officers arrived, but they agreed that the officers handcuffed the father.[254] They also searched his dresser drawer and medicine cabinet, allegedly looking for drugs, and ran his license plates.[255] The father brought a Section 1983 excessive-force claim based on the officers' decision to handcuff and restrain him immediately following his seizure.[256] The key question in the case was whether the officers acted with a medical purpose or a law enforcement purpose in their interactions with the

'particularized' to the facts of the case" and "not be defined 'at a high level of generality.'" *Id.* at 552 (quoting Anderson v. Creighton, 483 U.S. 635, 6340 (1987)); Ashcroft v. al-Kidd, 563 U.S. 731, 742 (2011).

247. 486 F.3d at 219.
248. *Id.* at 221.
249. *Id.* at 220.
250. *Id.* at 221.
251. *Id.* at 222.
252. 617 F.3d 432 (6th Cir. 2010).
253. *Id.* at 435.
254. *Id.*
255. *Id.* at 436.
256. *Id.*

father.[257] At the district court, the judge rejected the officers' argument that they were acting with a medical purpose and therefore were entitled to qualified immunity, and the case went to trial.[258] The jury found that the officers were not entitled to qualified immunity and awarded damages to the father.[259] On appeal, the Sixth Circuit affirmed the jury's finding that the officers acted in a law-enforcement rather than a medical-provider capacity because the officers conducted a search of the father's home and ran a background check on license plates during the incident.[260] The question of the officers' role in the incident was not based simply on their official positions as law enforcement officers.[261] Rather, their role was determined through an analysis of the specific actions they took in the case.[262] The case thus demonstrates that for a Fourth Amendment and qualified immunity analysis, police and medical providers alike can potentially act in either a law-enforcement or an emergency-medical-response capacity. Specific factual questions about the defendant's role in the incident, such as whether the defendant assisted in a search or performed other law-enforcement tasks, is what ultimately determines whether the defendant can face Section 1983 liability for excessive force.

The Sixth Circuit recently revisited this issue in an unpublished opinion, *Estate of Barnwell v. Grigsby*.[263] This case concerned a Tennessee resident named Dustin Barnwell who died after a paramedic injected him with a chemical restraint.[264] Barnwell's fiancée had called 9-1-1 because she believed he was overdosing on prescription drugs.[265] Officers arrived at Barnwell's home and woke him up.[266] Barnwell became combative, and the officers handcuffed him.[267] Several paramedics then arrived and administered a drug called succinylcholine—a muscle relaxant that causes paralysis—which inhibited his ability to breathe on his own.[268] Barnwell began to suffer from cardiac issues and had to be intubated.[269] He died shortly afterwards at the hospital.[270] Barnwell's estate sued the officers and paramedics for damages under 42 U.S.C. § 1983.

257. *Id.* at 439–40 ("We conclude that whether the officers were entitled to qualified immunity depends on whether they acted in a law-enforcement capacity or in an emergency-medical-response capacity when engaging in the conduct that McKenna claimed violated the Fourth Amendment.").
258. *Id.* at 436–37.
259. *Id.* at 437.
260. *Id.* at 443.
261. *Id.* at 440–41.
262. *Id.*
263. Est. of Barnwell v. Grigsby, 801 F. App'x 354, 370–71 (6th Cir. 2020).
264. *Id.* at 359
265. *Id.* at 358.
266. *Id.*
267. *Id.*
268. *Id.* at 359.
269. *Id.*
270. *Id.*

The district court in *Barnwell* rejected the paramedics' argument for summary judgment based on qualified immunity.[271] The court reasoned that summary judgement was improper because genuine issues of material fact remained regarding both the medical necessity of using the drug and the paramedics' intent in administering it.[272] The district court emphasized that the plaintiff's expert opined there was no medical reason to paralyze decedent's lungs.[273] On appeal, the Sixth Circuit affirmed the district court ruling and concluded that there was a genuine factual dispute about whether or not it was medically necessary to administer the paralytic drug.[274] The case eventually went to trial, but on the third day of trial, the court granted the defendants' motion for judgement as a matter of law and disposed of the excessive force claims against the paramedics.[275] The court reasoned that the plaintiffs did not provide sufficient proof that the paramedics who administered the paralytic drug acted in a law enforcement capacity.[276]

Based on this precedent, future cases in the Sixth Circuit regarding medical professionals' use of chemical restraints in public settings will likely depend upon whether the medical professionals intended to render medical care or to induce compliance with law enforcement. As we discuss in more detail in the conclusion of this section, the only medical purpose for using a chemical restraint is to protect a patient's health and safety. Accordingly, when chemical restraints are used for any other purpose, courts should conclude that the person administering them is not acting with a medical purpose. Under Sixth Circuit law, such a provider would not be entitled to qualified immunity.

2. The Seventh Circuit: Deference to Medical Professionals

The Sixth Circuit's distinction between interventions intended as medical aid and actions done with a law enforcement purpose in *Peete* and *McKenna* had the potential to set a standard for other circuits to follow in use-of-force cases against medical providers. However, when the Seventh Circuit cited to these cases, it produced inconsistent rules and outcomes. One Seventh Circuit case, *Thompson v. City of Indianapolis*, serves as an example.

In *Thompson v. City of Indianapolis*, the family of Dusty Heishman sued an Indianapolis-area hospital system and a paramedic after Heishman died

271. Est. of Barnwell v. Roane Cnty., No.: 3:13-CV-124-PLR-HBG, 2016 WL 5937821, at *7 (E.D. Tenn. June 16, 2016) *aff'd* Est. of Barnwell v. Grigsby, 801 F. App'x 354 (6th Cir. 2020). The court also denied the police officer defendants' motion for summary judgment on qualified immunity grounds. *Id.*

272. *Id.* at *7.

273. *Id.*

274. Est. of Barnwell by S.C.B. v. Grigsby, 681 F. App'x 435, 442 (6th Cir. 2017).

275. Est. of Barnwell v. Grigsby, 801 F. App'x 354, 370–71 (6th Cir. 2020).

276. *Id.*

following an arrest.[277] Police officers initially responded to a 9-1-1 call reporting that Heishman was acting erratically.[278] When the officers arrived, they found Heishman naked and alone in the middle of a road.[279] They put him in leg shackles and handcuffs and held him on the ground face down "with approximately four officers staying in physical contact with him."[280] Paramedics were not called to the scene. They only happened to be in the area because they were responding to an unrelated call about a dog bite and the officers asked the paramedic crew to take a look at Heishman.[281] When the paramedics approached Heishman, he "was lying prone in the middle of the street, was handcuffed behind his back with leg shackles on, and had been tased."[282] It appeared to the paramedics that Heishman was under the influence of drugs.[283] Despite the fact that he was already restrained, one of the paramedics gave Heishman an injection of a sedative drug known as Versed.[284] No one monitored his vital signs after the chemical restraint was administered.[285] As they transported him to an ambulance, the paramedics and officers realized that Heishman had stopped breathing.[286] Heishman had gone into cardiac and respiratory arrest.[287] Though he was temporarily revived, he had lost all brain functioning and died several days later.[288]

Heishman's family brought a Section 1983 excessive force claim against the paramedic who administered the chemical restraint. The paramedic—relying on the *Peete* decision from the Sixth Circuit—argued that he believed it was necessary to administer the chemical restraint in the course of providing medical treatment.[289] According to the defendant, he did not violate Fourth Amendment standards, or at the very least was entitled to qualified immunity, because he had intended to provide medical care.[290] The plaintiffs argued that because the police had already handcuffed and shackled Heishman, and left him lying in a prone position on the ground and not actively resisting, there was no medical need to use a chemical restraint for his own or others' safety.[291] The plaintiffs also

277. No. 1:15-cv-01712-TWP-DML, 2017 WL 4248006, at *1 (S.D. Ind. Sept. 25, 2017), *rev'd and remanded sub nom.* Thompson v. Cope, 900 F.3d 414 (7th Cir. 2018).
278. *Id.* at *2.
279. *Id.*
280. *Id.*
281. *Id.*
282. *Id.*
283. *Id.*
284. *Id.* at *3.
285. *Id.*
286. *Id.*
287. *Id.*
288. *Id.*
289. *Id.* at *5 (citing Peete v. Nashville, 486 F.3d 217, 221 (6th Cir. 2007)).
290. *Id.*
291. *Id.*

emphasized the fact that the paramedic administered the chemical restraint after discussing the situation with law enforcement officers.[292]

The district court concluded that the paramedic administered a chemical restraint to Heishman to assist law enforcement officers in effectuating an arrest.[293] The court said that although Heishman was under the influence of drugs and in what the paramedic described as a state of "excited delirium," the chemical restraint used by the paramedic to assist in the arrest was an unreasonable use of force because Heishman was already restrained on the ground, handcuffed, and leg-shackled when the chemical restraint was administered.[294] The court further held that because there was a clearly established right to be free from excessive force in the course of an arrest, and because the paramedic had used unreasonable force, the paramedic was not entitled to qualified immunity.[295]

On appeal, the Seventh Circuit reversed the district court decision.[296] The court reframed the factual situation as one involving the "administ[ration of] a therapeutic drug in response to a medical emergency."[297] The court's view was that:

> [T]he question for qualified immunity is whether it was clearly established in 2014 that a paramedic "seizes" an arrestee and is subject to Fourth Amendment limits on excessive force by sedating the arrestee—who appears to the paramedic to be suffering from a medical emergency—before taking the arrestee by ambulance to the hospital.[298]

The court stated that a paramedic or lawyer reasonably familiar with Fourth Amendment law would not have known that Fourth Amendment rules apply to "treatment in the field during a medical emergency."[299] The court also said that the plaintiffs identified no cases where a court found a medical provider violated Fourth Amendment standards for "using a therapeutic drug to sedate an arrestee to be taken safely to the hospital."[300] The court did cite two cases holding that paramedics can be liable for transgressions of Fourth Amendment standards related to chemical restraints: a California district court case, *Haas v. County of El Dorado* (which we discuss in more detail below), and the district court decision in *Estate of Barnwell* (from our discussion of the Sixth Circuit's approach to this issue).[301] The court distinguished these cases in just one line, stating: "we doubt that the reasoning of those cases applies."[302] The court

292. *Id.* at *6.
293. *Id.*
294. *Id.* at *5.
295. *Id.* at *6.
296. Thompson v. Cope, 900 F.3d 414 (7th Cir. 2018).
297. *Id.* at 423.
298. *Id.* at 422.
299. *Id.* at 422–23.
300. *Id.*
301. *Id.* at 420.
302. *Id.* at 421.

deferred the issue of whether the paramedic violated Heishman's constitutional rights because it found the qualified immunity issue dispositive.[303]

The Seventh Circuit's decision to reframe the issue as one about medical providers rendering therapeutic treatment is puzzling because the court did not overturn the district court's finding that the paramedic acted in a law-enforcement capacity. Indeed, the defendants argued that the evidence at the district court was insufficient to support the conclusion that the paramedic acted in a law-enforcement capacity and the Seventh Circuit declined the invitation to revisit those factual issues.[304] Nonetheless, the court—citing the Sixth Circuit decision in *Peete*—went on to describe the paramedic as acting in a medical capacity through its entire qualified immunity analysis.[305]

Although the Seventh Circuit did not refer to the medical-treatment-versus-law-enforcement capacity test explicitly, the reasoning in its qualified immunity analysis essentially follows the same rule. The Seventh Circuit's decision provides that any individual who is acting in the course of rendering medical aid is shielded from the requirements of the Fourth Amendment because there is no clearly established Fourth Amendment caselaw stating that badly-botched medical treatment can constitute excessive force.[306] This leaves enormous room for courts to determine whether a chemical restraint used in a given context was administered for law-enforcement purposes or for medical purposes. Indeed, that is exactly what happened in this case: the district court relied on the fact that Heishman was already incapacitated to determine that the alleged medical justification for the chemical restraint was unpersuasive, whereas the circuit court interpreted the same facts as an instance of paramedics rendering a "therapeutic drug" in a medical emergency.[307] As we discuss in Part IV, guidelines from in-patient healthcare contexts can help better inform courts' decisions about whether chemical restraints are used for medical purposes or law-enforcement purposes in a given circumstance.

3. Different Paths Taken By The Second Circuit and Eastern District of California

The medical-versus-law-enforcement rule adopted by the Sixth and Seventh circuits is not indicative of how all courts decide cases involving paramedics and the Fourth Amendment. At least two courts—the Second Circuit and a district court in California—have departed from the Sixth and Seventh Circuits' determination that acting with a medical purpose entitles one to

303. *Id.* at 420–21.
304. *Id.* at 420.
305. *Id.* (citing Peete v. Nashville, 486 F.3d 217, 221 (6th Cir. 2007)).
306. *Id.* at 423.
307. *Id.*; Thompson v. City of Indianapolis, No. 1:15-cv-01712-TWP-DML, 2017 WL 4248006, at *6–7 (S.D. Ind. Sept. 25, 2017), *rev'd and remanded sub nom.* Thompson v. Cope, 900 F.3d at 414.

qualified immunity from use-of-force claims.[308] In the Second Circuit case *Green v. City of New York*, a plaintiff with the neuro-muscular disease ALS sued emergency medical responders and police officers after they seized him from his home and forced his transfer to a hospital despite his and his family's insistence that he did not require medical assistance.[309] The plaintiff's daughter initially called 9-1-1 because the plaintiff was having trouble breathing.[310] Before the emergency responders arrived, the plaintiff's family was able to help him regain his ability to breathe.[311] The plaintiff communicated to the emergency medical responders that he did not wish to be transported to the hospital.[312] Several police officers arrived, announced that they were in command, and demanded that the medical providers take him to the hospital.[313] The officers knocked the plaintiff's wife to the floor while they began to move the plaintiff,[314] and threatened to handcuff her.[315] The plaintiff brought a Section 1983 suit, alleging that the paramedics and police unreasonably seized him in violation of the Fourth Amendment.[316] The Second Circuit allowed the claim to survive summary judgment and denied the defendants' qualified immunity defense.[317] The court concluded that "it was clearly established at the time of the incident under review that a competent adult could not be seized and transported for treatment unless she presented a danger to herself or others."[318] The fact that the medical providers may have intended to provide treatment did not shield them from liability for rendering medical aid using unreasonable force under the circumstances.[319]

Although the Second Circuit's decision conflicts with the Sixth Circuit's view, a California district court in 2012 decided a case about chemical restraints by combining the two circuits' standards. This case, *Haas v. County of El Dorado*,[320] highlights how paramedics who use chemical restraints to help police officers are necessarily acting in a law-enforcement, rather than a medical-provider, capacity.

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308. *See* Green v. City of New York, 465 F.3d 65, 84 (2d Cir. 2006); Haas v. County of El Dorado, No. 2:12-cv-00265-MCE-KJN, 2012 WL 1414115, at *4–10 (E.D. Cal. Apr. 23, 2012). Some courts have, however, adopted the distinction between a medical purpose and a law-enforcement purpose when adjudicating claims against police officers that claimed to have rendered medical assistance. *See* Frank v. Cascade Healthcare Cmty., Inc., No. 6:11-cv-06402-AA, 2014 WL 793073, at *5–6 (D. Or. Feb. 23, 2014) (relying on the distinction between officers acting in a law enforcement capacity and in an emergency responder capacity to conclude that restraints to render medical assistance are not Fourth Amendment violations), *aff'd*, 688 F. App'x 461 (9th Cir. 2017) (mem.).

309. 465 F.3d at 72–73.

310. *Id.* at 70.

311. *Id.*

312. *Id.*

313. *Id.* at 71.

314. *Id.* at 72.

315. *Id.* at 73.

316. *Id.*

317. *Id.* at 83.

318. *Id.*

319. *Id.* at 83–84.

320. No. 2:12-cv-00265-MCE-KJN, 2012 WL 1414115, at *4–10 (E.D. Cal. Apr. 23, 2012).

In *Haas*, a preschool teacher began to feel lightheaded and fainted as he walked out of his classroom.[321] His coworkers thought he may have had a seizure and called 9-1-1.[322] Haas quickly recovered, was able to stand on his own, and said that he was feeling better.[323] When the paramedics arrived, they insisted on taking the teacher to the hospital, but Haas said he did not want or need to go to the hospital.[324] The paramedics called the police for assistance and continued to insist that the teacher go to the hospital when the officers arrived.[325] When Haas refused, the officers tackled him and the paramedics injected him with midazolam—a drug that, like ketamine, is often used to facilitate sedation before surgery.[326]

Haas sued the paramedics and police officers under Section 1983 for use of excessive force.[327] The court first discussed the Second Circuit's standard as stated in *Green* that it is unreasonable to seize a person for medical treatment unless the person is a danger to herself or others.[328] The court then looked to the Sixth Circuit cases holding that the issue of whether a medical provider or police officer is entitled to qualified immunity depends on whether they acted in a law-enforcement or in an emergency-medical-response capacity.[329] The court then synthesized the law on medical providers using force as follows:

> [D]efendants . . . who "seize" an individual while responding to a 911 call requesting medical assistance are entitled to qualified immunity when: 1) the plaintiff was unconscious, incompetent to refuse medical treatment, or dangerous; 2) defendants acted as medical emergency responders, as opposed to law enforcement officer [*sic*]; *and* 3) the plaintiff was in actual or apparent need of medical assistance.[330]

The most interesting part is the court's brief analysis of the second element: whether the paramedics acted in a law-enforcement or an emergency-medical responder capacity when using a chemical restraint. On that issue, the court found that the paramedics were acting as law enforcement officers rather than emergency medical responders because they "injected a tranquilizer into [Haas] not for the purpose of rendering medical aid but for the purpose of assisting law enforcement officers in restraining [him]."[331] This, along with the fact that Haas competently refused medical treatment and did not need medical assistance, led the court to reject the defendants' argument that the paramedics

321. *Id.* at *1.
322. *Id.*
323. *Id.*
324. *Id.*
325. *Id.* at *1–2.
326. *Id.* at *2.
327. *Id.* at *4.
328. *Id.* at *7 (citing Green v. City of New York, 465 F.3d 65, 83 (2d Cir. 2006)).
329. *Id.* at *8 (citing McKenna v. Edgell, 617 F.3d 432, 439–40 (6th Cir. 2010)).
330. *Id.* at *9.
331. *Id.*

were entitled to qualified immunity, thus allowing the Section 1983 claim to proceed.[332]

* * *

These cases demonstrate several important points about how Fourth Amendment use-of-force standards apply to medical providers who use chemical restraints on individuals outside of clinical settings. First, in each case, the court recognized that when a medical provider uses a chemical restraint to seize an individual and move them to a hospital or jail, the provider has engaged in behavior that qualifies as force. Chemical restraints might not be the type of force that comes to mind when we think about state and police violence, but the cases above and the ketamine incidents in Minneapolis demonstrate how the definition of "force" and its implications may be changing. As the courts have correctly recognized, incapacitating an individual against their will via chemical restraint is a form of force.

Second, some courts conclude that medical providers or other officials who use an unreasonable amount of force in encounters with the public can be held responsible for violating Fourth Amendment standards in Section 1983 litigation.[333] However, other courts use the doctrine of qualified immunity to shield medical providers from liability.[334] Courts that apply qualified immunity to claims against medical providers focus on the distinction between acting with a medical-responder purpose and a law-enforcement purpose. Courts have not clearly delineated the contours of this distinction, but what is clear—as the California district court in *Haas* recognized—is that a medical provider who uses a chemical restraint is only acting with a medical purpose if the restraint is necessary to protect a patient's health or safety.[335] Any other uses of chemical restraints, including using the restraint to help officers secure legal compliance, suggests that the provider is acting with a law-enforcement purpose and should be subject to Fourth Amendment standards. This idea has important implications for situations like those that occurred during the Hennepin trials in Minneapolis, where paramedics used ketamine at the direction of police to help facilitate arrests and without concern for the health of the person being arrested.[336] In cases where medical providers submit to the police officer's request for a chemical restraint despite the lack of a medical reason to do so, it should be clear to courts that the medical providers are acting in a law-enforcement capacity.

But what are we to make of the medical-purpose versus law-enforcement-purpose more generally? On the one hand, the test may be problematic insofar as it is always difficult to determine a person's intent. Courts may struggle to

332. *Id.* at *1, *10.

333. *See id.* at *4–10.

334. *See* Thompson v. Cope, 900 F.3d 414, 420–21 (7th Cir. 2018); Peete v. Nashville, 486 F.3d 217, 219–20 (6th Cir. 2007).

335. *Haas*, 2012 WL 1414115, at *9.

336. *See* OPCR REPORT, *supra* note 174, at 12–15.

find a consistent and proper way to determine the purpose of a medical provider's actions. Yet on the other hand, there are some clear lines that courts could draw. If a medical provider intervenes, using chemical restraints or otherwise, to help the police, but the intervention is unnecessary from a medical perspective, courts could treat the medic as a law-enforcement agent. One benefit of the test is that it reinforces that paramedics ought to *always* act exclusively as medical care providers. While paramedics often work alongside police, it is critical that they exercise independent judgment and preserve their roles as medical providers with duties to patients. In the Section that follows, we provide three recommendations that can ensure paramedics maintain this distinct role when responding to emergencies alongside police officers.

IV.
RECOMMENDATIONS: TOWARD THE ETHICAL USE OF MEDICINE IN POLICING

The ketamine incidents in Minneapolis highlight the risk that police officers might participate in or co-opt the medical decision-making process when they work with paramedics to respond to emergency calls for service. We may see more incidents in the future where police task paramedics with using chemical restraints to help police officers secure legal compliance. This Section provides recommendations to establish proper boundaries between medical providers and police and to clarify the relationship between the Fourth Amendment's restrictions on unreasonable force and the use of chemical restraints on community members. These recommendations focus on (1) developing state and local laws that create a firewall between medical professionals and law enforcement in pre-hospital settings that allows medical providers to focus on serving patients while maintaining independence from police; (2) creating use-of-force policies for medical providers that inform them of the constitutional limits of medical force; and (3) encouraging courts to use existing federal regulations governing chemical restraints in medical settings to determine the constitutional reasonableness of using chemical restraints in public or pre-hospital settings.

First, state and local laws should establish the autonomy of healthcare providers and healthcare institutions. Medical professionals and the police may work together in responding to emergencies. Yet, the police are oriented to public criminal justice goals while medical professionals are oriented to individual patients' well-being. Medical providers on the scene with police should not be treated as an arm of law enforcement. The relationship must be carefully managed to maintain medical providers' independence.

The public's trust in both medical providers and law enforcement officers depends on each institutions' sovereignty and ability to exercise independent judgment within their respective spheres of expertise. At a minimum, state and local laws should affirm that police may not directly or indirectly pressure medical providers to take any actions during emergency encounters. Police

should not participate in healthcare providers' discussion of a person's condition or possible treatments. To mitigate against subtle forms of police coercion or communication through body language or gestures, police and medical professionals should maintain physical distance in pre-hospital settings and document all conversations between units. Any use of chemical restraints or other pharmaceuticals should be at the sole discretion of medical professionals and police should not participate in medical providers' decisions about whether they should administer a particular drug.

Second, just as police have local use-of-force guidelines that develop in the context of the Fourth Amendment,[337] medical professionals should also have guidelines that speak to the appropriate uses of force in pre-hospital settings. The federal rules governing the use of chemical restraints in nursing homes prohibit the use of such restraints except where used to protect patient safety. Even when the law permits chemical restraints in the medical context, it protects the patient's right of refusal unless they are in imminent harm.[338] The guidance for medical professionals and statement of patients' rights found in these federal regulations should extend beyond the nursing home setting to include paramedics' interactions with the community.

Use-of-force policies for medical practitioners should further provide detailed outlines and examples of situations in which force can be used and what level of chemical or physical force is appropriate. Moreover, these guidelines should prioritize community members' health and autonomy and explain that law enforcement should have no influence on decisions regarding patient health and safety.

Given that emergency medical responders are often involved when police subdue a person, medical providers also need to be trained on how to interact with the police. Medical providers should know how to tactfully refuse to assist police in seizing an individual if the seizure does not promote the individual's health or safety; to only use chemical restraint when it is medically necessary; and to not let an officer's recommendations supplant their own medical judgment. Policies should also make medical providers aware of their right—indeed, obligation—to refuse police officers' attempts to intervene in medical decision-making. Policies should clearly state that it is lawful for medical

337. *See generally* Obasogie & Newman, *supra* note 29. One finding from this research is that all of the local use-of-force policies surveyed included a reference to *Graham v. Connor*, which shows that local municipalities create their policies with Fourth Amendment standards in mind. *Id.* at 1303.

338. *See* 42 C.F.R. § 483.12(a)(2) (2020) (noting that nursing facilities must "[e]nsure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints."); *see also* 42 C.F.R. § 483.10(e)(1) (2020) (stating that patients have "[t]he right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with § 483.12(a)(2).").

professionals to rebuff police officer's request for medically unnecessary interventions. Training on how to respond if a police officer inserts themselves into the medical decision-making process is also critical. Giving medical providers clear language they could use in response to improper requests would empower them to respond appropriately. This training could reduce the chances that medical professionals misuse or weaponize chemical restraints in pursuit of the interests of the criminal justice system.

At the same time, existing use-of-force trainings and policies for law enforcement should emphasize the need for separation between police and medical professionals. These trainings should instruct police officers that it is inappropriate to suggest how to provide care or to ask medical providers for assistance in seizing suspects. In addition, law enforcement policies should clearly state that chemical restraints can be unlawful force when used inappropriately. Police departments are responsible for establishing guidelines that outline officers' work with medical providers using chemical force. An injection of ketamine or other chemical restraints may seem innocuous, but it can lead to grave harms, if not death—not unlike other uses of force.

Lastly, it is important for federal courts to recognize that existing laws and regulations on chemical restraints in healthcare settings can inform what courts might consider a constitutionally reasonable use of chemical restraints in pre-clinical or public settings. Fourth Amendment standards for reasonableness apply in the context of Section 1983 use-of-force litigation and therefore shape how federal courts view the behavior of medical professionals who use chemical restraints. Federal statutes and regulations pertaining to nursing home care state that (1) medical professionals should never use chemical restraints merely for the sake of convenience; (2) chemical restraints should only be used when it is necessary to protect a patient's safety; and (3) that a patient has a right to refuse unless the restraint is required to prevent imminent harm to the patient or others. These standards are what federal law considers to be the reasonable use of chemical restraints in hospital settings, and it should inform their reasonable use in pre-hospital settings when paramedics collaborate with law enforcement. Chemical restraints used for the sake of convenience or to help officers secure compliance would not meet these federal guidelines and therefore should not be a reasonable use of force under *Graham*. Yet, chemical restraints used to prevent a police detainee from imminently harming herself or others would comply with existing federal regulations and would meet Fourth Amendment reasonableness standards. We see aspects of this approach in some jurisdictions. Yet in other jurisdictions, a more explicit connection between the federal standards on chemical restraints in hospital and pre-hospital settings could help fill an absent analysis on the intersection of the Fourth Amendment, medical providers, and chemical restraints and provide a framework for consistent application in federal courts. This improved understanding may help prevent future instances like those

in Minneapolis, where the unnecessary use of chemical restraints became dangerous law enforcement tools.

Paramedics who work with police to detain individuals are part of the broader social problem of racialized police violence. Institutions that regularly collaborate with law enforcement to surveil the lives and activities of vulnerable communities—social welfare agencies,[339] low-income healthcare facilities,[340] child protective services,[341] and others—often absorb carceral logics[342] when interacting with communities they are supposed to serve and support. Paramedics can also adopt these carceral frameworks when working with communities of color. This adoption can lead them to unwittingly substitute law enforcement perspectives that often see Black and Brown people as threats instead of using their own patient-centered training that instructs them to treat all people in distress with compassion. This is how institutional and structural racism operates: dominant logics link together across institutional spaces to create a network of collaborative bias that normalizes racial oppression. Adoption of carceral logics also explains how, as seen in Minneapolis, paramedics can quickly—and, at times, enthusiastically—submit to the racialized requests of law enforcement to use dangerous chemical restraints disproportionately on people of color.

Acknowledging the Fourth Amendment implications of medical professionals using chemical restraints in pre-hospital settings can have real, material consequences for everyday interactions between police, paramedics, and community members. Developing constitutional boundaries on these interactions is important because these rules establish the framework for policies, customs, and cultures that shape police use of force.

Using existing federal health regulations to inform reasonableness under the Fourth Amendment is just the beginning. More encompassing social, legal, and political engagement with the use of chemical restraints and other emerging police tactics will require interventions in many other areas. However, given that the current constitutional framing views issues of force exclusively through the Fourth Amendment, it is important to situate medical professionals' use of chemical restraints within these constitutional guarantees of individual rights and restrictions on police use of force.

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339. Sheila P. Vakharia, *"Social Workers Belong in Police Departments" Is an Offensive Statement*, FILTER (June 10, 2020), https://filtermag.org/social-workers-police-departments [https://perma.cc/4GEJ-RJXJ].

340. *See* KHIARA M. BRIDGES, THE POVERTY OF PRIVACY RIGHTS (2017).

341. *See* DOROTHY ROBERTS, SHATTERED BONDS: THE COLOR OF CHILD WELFARE (2002).

342. This term "refers to the variety of ways our bodies, minds, and actions have been shaped by the idea and practices of imprisonment—even for people who do not see themselves connected explicitly to prisons." *About Us: Frequently Asked Questions*, ROCHESTER DECARCERATION RSCH. INITIATIVE, http://www.sas.rochester.edu/rdri/about/faq.html [https://perma.cc/WV5S-MF32].

CONCLUSION

Elijah McClain had just left a local convenience store in Aurora, Colorado.[343] The twenty-three-year-old had a slight frame and regularly wore ski masks, even during the summer, as he had anemia and often became cold.[344] A passerby called 9-1-1 after seeing McClain, a masked Black man, walking down the street, saying that he looked suspicious.[345] As McClain carried his groceries, three Aurora police officers responded to the call and stopped him.[346] Police body-cam footage captured the increasingly hostile interaction, where officers initiated a struggle with McClain after he repeatedly asked to be left alone.[347] He was brought to the ground by the officers, put into a chokehold, and handcuffed face-down with his hands behind his back. While handcuffed and immobilized, Aurora Fire Rescue arrived at the scene and injected McClain with five hundred milligrams of ketamine.[348] McClain went into cardiac arrest in the ambulance on the way to the hospital. He was pronounced brain dead several days later and taken off of life support.[349]

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343. Lucy Tompkins, *Here's What You Need to Know About Elijah McClain's Death*, N.Y. TIMES (Aug. 16, 2020), https://www.nytimes.com/article/who-was-elijah-mcclain.html [https://perma.cc/M549-F2FV].

344. Kieran Nicholson, *No Criminal Charges Against Aurora Officers in Death of Elijah McClain*, DENVER POST (Nov. 23, 2019, 9:59 AM), https://www.denverpost.com/2019/11/23/elijah-mcclain-dead-no-charges-aurora-officers [https://perma.cc/4QEX-KALK].

345. Michael Roberts, *Attorney Rips "Undetermined" Autopsy in Elijah McClain Aurora Police Death*, WESTWORD (Nov. 13, 2019, 5:15 AM), https://www.westword.com/news/elijah-mcclain-aurora-police-death-autopsy-report-ripped-by-attorney-11546039 [https://perma.cc/P5DR-NYZS].

346. Tompkins, *supra* note 343.

347. An officer got close to McClain and touched him. "Stop tensing up, dude. Stop tensing up," the officer said. McClain said:

> "I am going home. . . . Leave me alone," and "Let me go. No, let me go. I am an introvert. Please respect my boundaries that I am speaking."
>
> A struggle escalated, and three officers wrangled McClain toward a lawn, eventually taking him down.

Nicholson, *supra* note 344.

348. Reports suggest that there was some communication between police and medics regarding the use of ketamine on McClain before Aurora Fire Rescue arrived. NBC News reported, "A medic told officers that 'when the ambulance gets here, we're going to go ahead and give him some ketamine.' The officers responded, 'Sounds good,' and they told the medic that McClain appeared to be 'on' something and that he had 'incredible strength.'" Erik Ortiz, *Elijah McClain Was Injected with Ketamine While Handcuffed. Some Medical Experts Worry About its Use During Police Calls*, NBC NEWS (July 3, 2020, 5:20PM), https://www.nbcnews.com/news/us-news/elijah-mcclain-was-injected-ketamine-while-handcuffed-some-medical-experts-n1232697 [https://perma.cc/6TUW-3HTN]; *see also* Schmelzer, *supra* note 28.

349. Elise Schmelzer, *Aurora Man to Be Taken Off Life Support After Confrontation with Police Left Him Dead*, DENVER POST (June 9, 2020, 11:58 AM), https://www.denverpost.com/2019/08/30/elijah-mcclain-aurora-police-death [https://web.archive.org/web/20201003092728/https://www.denverpost.com/2019/08/30/elijah-mcclain-aurora-police-death/].

McClain's autopsy lists his cause of death as "[u]ndetermined."[350] However, the evidence suggests that ketamine may have played a significant role. Aurora Fire Rescue claimed that they injected McClain because he exhibited "excited delirium"—a condition of profound agitation that law enforcement and medical examiners often use to justify use of force.[351] Excited delirium "is not a currently recognized medical or psychiatric diagnosis according to either the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IVTR) of the American Psychiatric Association or the International Classification of Diseases (ICD-9) of the World Health Organization."[352] As the attorney representing the McClain family notes, the police body-cam video refutes the medics' claim in that "[t]he video shows the opposite of anybody showing any signs of excited delirium. . . . There's no legal or factual reason why a chemical restraint was used because [McClain] was already totally still and totally compliant."[353] The *Denver Post* reported that first responders' use of ketamine had become "increasingly common," with "[n]inety fire departments and emergency medical service agencies across Colorado – including those in Aurora, Denver and Colorado Springs – hav[ing] waivers from the Colorado Department of Public Health and Environment to use ketamine to treat excited delirium . . . ."[354] Paramedics in Colorado have administered ketamine to over nine hundred people over a two and a half year period—180 times in the first half of 2020 alone.[355] Elijah McClain's death draws attention to the dire risks of casually and indiscriminately using chemical restraints to police marginalized communities. The most vulnerable populations who disproportionately contact

350. MONICA BRONCUCIA-JORDAN, OFF. OF THE CORONER, ADAMS & BROOMFIELD CNTYS., AUTOPSY REPORT OF ELIJAH MCCLAIN (2019), https://www.scribd.com/document/434633869/Elijah-McClain-Autopsy-Report#download [https://perma.cc/D4UN-7JFG].

351.

> [N]early all reported cases of excited delirium involve people who are fighting with police. . . . [ACLU attorney Eric] Balaban charges that police officials are using the diagnosis "as a means of white-washing what may be excessive use of force and inappropriate use of control techniques by officers during an arrest."

Laura Sullivan, *Death by Excited Delirium: Diagnosis or Coverup?*, NPR (Feb. 26, 2007, 4:00PM), https://www.npr.org/templates/story/story.php?storyId=7608386 [https://perma.cc/BFR6-NWJ5].

352. Asia Takeuchi, Terence L. Ahern & Sean O. Henderson., *Excited Delirium*, 12 W.J. EMERGENCY MED. 77, 77 (2011).

353. Schmelzer, *supra* note 28.

354. *Id.* In the state of Colorado, a local fire, paramedic, or other "agency's medical director must apply for a waiver from the state health department for paramedics to use [ketamine] on patients who experience excited delirium. . . . In 2018, according to state records, the drug was administered 265 times with a total of 14 cases that involved one or more complication." Lori Jane Gliha, *Problem Solvers Investigation: Colorado Paramedics Injecting Sedative Ketamine into Agitated Patients*, FOX 31 DENVER (Nov. 21, 2019), https://kdvr.com/2019/11/21/problem-solvers-investigation-colorado-paramedics-injecting-sedative-ketamine-into-agitated-patients [https://perma.cc/WSK4-PVBW]. For an example of local guidelines in Colorado on the use of ketamine, see COLO. SPRINGS FIRE DEP'T & AM. MED. RESPONSE, PREHOSPITAL PRACTICE GUIDELINES (2019), https://coloradosprings.gov/sites/default/files/inline-images/prehospital_practice_guidelines_2.11.19.pdf [https://perma.cc/ZRZ9-522X].

355. de Yoanna & Solomon, *supra* note 27.

law enforcement—people who are unhoused, racial minorities, and those with preexisting mental health or other medical issues—are most likely to bear the consequences of chemical restraints when law enforcement uses them as a policing strategy, which exacerbates social inequalities.

There are important counterarguments that might support the use of chemical restraints during some police engagements. Some may argue that chemical restraints offer a kinder and gentler way for police to subdue individuals who may be a danger to themselves or others, which can lead to fewer instances of deadly force and therefore save lives. The idea is that the use of drugs under the supervision of a paramedic is safer than physical forms of police force, or that using different drugs might address any particular danger presented by ketamine. Another perspective is that close collaboration between first responders—particularly police and paramedics—is important to promote open communication and decision-making. Bringing in outside legal or regulatory frameworks that restrict the nature of these conversations in pre-clinical settings might ultimately lead to inefficient exchanges between professionals and patient harm. These are certainly important considerations. But these perspectives obscure a key point: patient need as determined by medical professionals should singularly determine the use of chemical restraints without influence from law enforcement or concern for any police investigation.

Law enforcement has the ability to use physical restraints while paramedics have the ability to use chemical restraints. This separation must be maintained. Police could discuss a detainee's physical condition with a paramedic, and a paramedic could use this information to independently conclude that a chemical restraint might benefit the health of a patient. For example, if a paramedic receives information that a detained person has been extremely agitated to the point that they might harm themselves, the paramedic might examine the person and conclude that a chemical restraint could be beneficial. In this hypothetical, communication between police and paramedics is needed for the paramedic to understand the detained person's health status so that she can make a decision that would protect the patient's interest. This situation is fundamentally different from the examples from Minneapolis discussed above, where police ask paramedics to administer chemical restraints not to protect detainees' health, but to simply make their jobs easier. This practice not only violates professional and ethical guidelines, but can also lead to significant patient harm.

This Article has drawn attention to the growing use of chemical restraints by medical practitioners for law enforcement purposes and argues that this practice constitutes an unreasonable use of force when done for the convenience of police rather than the health of those they detain. By putting existing practices and federal regulations concerning chemical restraints in conversation with Fourth Amendment use-of-force standards and existing case law, this Article demonstrates the significant constitutional issues that courts need to address to protect individual rights. Put simply, if using chemical restraints on an already

compliant or physically restrained person in a hospital setting conflicts with federal regulations on clinical care, then similar acts towards John Powell, Elijah McClain, or any other detained person in public or pre-clinical settings should also be an unreasonable use of force that violates the Fourth Amendment.

The doctrinal contributions of this Article are connected to the expansion of Osagie Obasogie and Zachary Newman's important theoretical argument concerning federal courts' understanding of Fourth Amendment reasonableness in relation to excessive force. In *The Endogenous Fourth Amendment*, Obasogie and Newman extend legal endogeneity theory, first developed by Lauren Edelman as a way to understand federal statutory law,[356] to the realm of constitutional law.[357]

Edelman developed legal endogeneity theory to understand the organizational dynamics that allow federal statutes like Title VII, initially designed to protect women and minorities from workplace discrimination, to become a means for organizations to reassert and rearticulate their often biased preferences, practices, and perspectives as the legal rule.[358] Characteristics of legal endogeneity are (1) ambiguous legal text intended to stimulate reform that (2) organizations respond to with symbolic gestures rather than substantive change that (3) federal courts defer to as actual compliance (instead of creating independent standards). Legal endogeneity theory shows how federal statutes meant to curb discrimination become mechanisms of oppression.[359] Applying this theory to the Fourth Amendment, Obasogie and Newman question the largely-held assumption that the Fourth Amendment has an exogenous effect on defining the lawfulness of police force. In other words, they question the assumption that Fourth Amendment text shapes what counts as reasonable or unreasonable police use of force against community members.[360] The authors engage in an empirical and doctrinal analysis of use-of-force policies from the seventy-five largest cities and find that this traditional understanding of the Fourth Amendment is often incorrect.[361] Their analysis shows that federal courts' understanding of constitutional reasonableness routinely defers to police conceptions of reasonable force as stated in their administrative use-of-force policies.[362] Federal courts often hold that a police officer does not offend the Fourth Amendment if their particular use of force is consistent with police department policy.[363] Therefore, courts often do not create the meaning of reasonableness exogenously or from judicial or textual mechanisms, but

356. EDELMAN, *supra* note 30.
357. Obasogie & Newman, *supra* note 29.
358. EDELMAN, *supra* note 30, at 3–20.
359. *Id.* at 12.
360. *See* Obasogie & Newman, *supra* note 29.
361. *Id.* at 1286.
362. *Id.* at 1288.
363. *Id.*; *see also* Christopher Logel, Comment, *Cracking* Graham*: Police Department Policy and Excessive Force*, 20 BERKELEY J. AFR.-AM. L. & POL'Y 27 (2018).

endogenously by police organizations whose internally-developed rules on when and how to use force *become* the constitutional standard.[364]

Legal endogeneity in the Fourth Amendment context usually absolves police use of force—even when such force might otherwise might be seen as excessive.[365] Judicial deference to police preferences limits accountability when force becomes unreasonable. Yet, understanding how legal endogeneity shapes the application of Fourth Amendment rules creates important opportunities for disruption and reform. Obasogie and Newman note in a separate Article titled *Constitutional Interpretation Without Judges*, "If courts are going to defer to police in defining the constitutional meaning of excessive force, then grassroots efforts to change police behavior can not only positively impact individual communities, but perhaps 'filter up' to have a more synergistic effect in reshaping the constitutional rule."[366]

This Article's discussion of chemical restraints used in pre-clinical settings exemplifies this potential. As a doctrinal matter, chemical restraints should be understood as a form of force, and Fourth Amendment restrictions ought to apply to medical professionals who administer these drugs for law enforcement purposes. However, Obasogie and Newman's commitment to *anti-endogeneity* in Fourth Amendment jurisprudence informs our argument that federal courts ought to seek guidance from other health law regulations to understand what "reasonable" means in the context of paramedics use of chemical restraints. As a normative claim, anti-endogeneity discourages uncritical judicial deference to police norms, practices, and preferences[367] in defining constitutional standards. Instead, anti-endogeneity moves toward democratic sources to interpret ambiguous constitutional text about use of force on community members. Obasogie and Newman sketch the possibilities of this approach:

> If police largely control the administrative site where use of force policies are developed and ultimately impact how federal courts think about the constitutional boundaries of excessive force, then citizens, stakeholders, and the public can work with police to intervene at this point. Disrupting the very mechanism that police use to limit accountability can create the conditions for reimagining the Fourth

364. Obasogie & Newman, *supra* note 29, at 1287–88.

365. For example, in a 2008 case from a federal district court in Texas, the court found that an officer's knee strike to the plaintiff that caused significant damage was not unreasonable because "[u]nder the Fort Worth Police Department's guidelines, a knee strike is considered an intermediate use of force" and thus, by definition, "not the deadly use of force or a technique that could cause serious injury." Peterson v. City of Fort Worth, No. 4:06-CV-332-Y, 2008 WL 440301, at *10 (N.D. Tex. Feb. 19, 2008), *aff'd*, 588 F.3d 838 (5th Cir. 2009). From the court's perspective, the plaintiff's ruptured femoral artery did not matter. What became dispositive was how the police use of force policy characterized the particular action.

366. Obasogie & Newman, *supra* note 31, at 427–28.

367. Judicial deference to police preferences and perspectives occurs in many aspects of criminal procedure. *See* Anna Lvovsky, *The Judicial Presumption of Police Expertise*, 130 HARV. L. REV. 1995, 1997–98 (2017); Aziz Z. Huq, *Fourth Amendment Gloss*, 113 NW. U. L. REV. 701, 703 (2019).

> Amendment from the "bottom up." This can play an important role in both preventing police use of force before it happens while also providing rules to point to in demonstrating liability when officers deviate from force policies and violate rights. If these policies are reframed with improved values and strategies for avoiding force, and courts continue to deem them relevant in signaling compliance, then legal endogeneity could be inverted from a process police use to protect themselves to one where the public could intervene for reform.[368]

These "bottom up" sources for interpreting the Fourth Amendment could include federal statutes and regulations created by a representative arm of government that describe when chemical restraints can be used in hospital settings. This would exemplify a broader community and professional sensibility regarding what is reasonable and appropriate.

The democratic processes tied to developing federal statutes or administrative regulations often reflect a series of conversations among stakeholders on what works best for various constituencies and how government should engage a particular issue. As discussed in Part III.B of this Article, the Nursing Home Reform Act that was codified in Title 42 of the Code of Federal Regulations articulates a strong aversion to non-medical uses of chemical restraints. This standpoint is the result of extended discussions between medical providers, advocates for nursing home residents, and legislators. It is further informed by an independent report from policy experts at the Institute of Medicine (now called the National Academy of Medicine). The deliberative process tied to developing federal statutes or administrative laws and policies creates a wealth of knowledge on stakeholders' experiences, concerns, and needs. Where there is textual ambiguity in the Fourth Amendment on the meaning of "reasonableness," *anti-endogeneity* suggests that federal courts should define terms in ways that support the interest of the broadest constituency, not the narrow policy preferences of the police or paramedics—the very government actors that the Fourth Amendment is designed to regulate. By drawing upon parallel interpretations found in other democratic and deliberative spaces, federal courts can enforce otherwise ambiguous constitutional text in ways that best serve the community.

Developing mechanisms to disrupt legal endogeneity in Fourth Amendment jurisprudence is an important opportunity for reforming how police and paramedics use force in communities. Although professional expertise is important, deferring to the interests of law enforcement entities to define what counts as appropriate use of force leaves community members vulnerable and excluded from the process of determining how the law should treat them.[369]

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368. Obasogie & Newman, *supra* note 31, at 444–45.

369. Aspects of this argument align with an important literature in administrative law on selecting which agencies make particular decisions and considering the tradeoffs in choosing between agencies to achieve regulatory goals. For a discussion, see, for example, Eric Biber, *Too Many Things to Do: How to Deal with the Dysfunctions of Multiple-Goal Agencies*, 33 HARV. ENV'T L. REV. 1 (2009); Eric

Applying standards on chemical restraints developed in other branches of government to interpret Fourth Amendment "reasonableness" is a key mechanism to ensure that community standards inform government officials' treatment of people. This mechanism is an important sensibility in Fourth Amendment jurisprudence that courts have undervalued, and its enforcement in the context of chemical restraints might be a critical first step to rethinking many aspects of use-of-force inquiries.

Biber, *Which Science? Whose Science? How Scientific Disciplines Can Shape Environmental Law*, 79 U. CHI. L. REV. 471 (2012).

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Medicolegal Sidebar

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Medicolegal Sidebar: Unnecessary Medical Care and Physician Liability

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Introduction

Whether commonly prescribed medical interventions are truly beneficial and medically necessary has long been recognized as a medicolegal concern [1, 2, 7, 16]. In 1953, the Executive Director of the American College of Surgeons, Paul Hawley MD, commented that the public would be outraged if it knew the amount of unnecessary surgery that was performed [16]. In 1976, the American Medical Association called for congressional hearings to address a report that cited 11,900 patient deaths from unnecessary surgery done during 1974 [7].

Today, well-designed clinical trials can identify procedures that do not offer any benefit. But data alone may not change long-held clinical practices. Studies have shown no long-term benefit of surgery for low-back pain when compared to nonsurgical treatment [15], yet spinal decompression and fusion operations for chronic low back pain continue to be performed at high rates in the United States [3]. Similarly, studies have also shown that knee arthroscopic surgery for degenerative meniscal tears has no advantage over sham surgery [14], but arthroscopic meniscectomy is commonly performed across the United States [11].

In a previous column [2], we discussed how medically unnecessary procedures, when performed deliberately for monetary gain, may be construed as criminal activity. In this column, we address the reasons that drive unnecessary treatments, potential sources of civil liability from such treatments, and what physicians can do to reduce medically unnecessary procedures.

Doing Nothing Is Hard To Do

In an interview with *USA Today*, Lucian Leape MD, Adjunct Professor of Health Policy at the Harvard School of Public Health, noted that medical overtreatment is driven primarily by financial incentives [5]. Fee-for-service payments, for example, incentivize hospitals and doctors to do more, which may include unnecessary medical interventions. And patients are more than willing to undergo additional testing if it adds to their peace of mind. The culture of surgical training itself, and the personality types of surgeons, may also nudge young surgeons toward choosing surgical care over nonsurgical interventions [10].

But doesn't the physician have an obligation to step in when he or she believes a requested procedure yields little or no value for the patient? Atul Gawande MD, MPH, Professor of Health Policy and Management at the Harvard School of Public Health admitted that "it is difficult to do nothing" [8]. In older patients with prostate carcinoma for example, surgery carries risks that probably outweigh any benefits, since most patients will die with the disease rather than from it. Even so, with better screening to identify prostate carcinoma earlier, some patients may pressure surgeons to intervene.

A note from the Editor-in-Chief: We are pleased to publish the next installment of "Medicolegal Sidebar" in Clinical Orthopaedics and Related Research®. *The goal of this quarterly column is to encourage thoughtful debate about how the law and medicine interact, and how this interaction affects the practice of orthopaedic surgery. We welcome reader feedback on all of our columns and articles; please send your comments to eic@clinorthop.org.*

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The practice of defensive medicine contributes to excessive testing, which physicians believe may discourage medical malpractice lawsuits. A 2012 study showed that more than 96% of orthopaedic surgeons reported performing medical interventions out of a concern for medical liability, leading to an estimated USD 2 billion in annual costs [13]. In 2007, economist David M. Cutler said that "most estimates suggest that about 20% to 30% of medical spending could be eliminated with no adverse effects on patient outcomes" [6]. In 2010, the Institute of Medicine reported that 30% of all U.S. healthcare spending, or about USD 765 billion a year, was not necessary [9]. Excessive healthcare spending is likely to continue as long as physician worries about medical liability lead to the ordering of additional tests to avoid a missed diagnosis or lead to interventions in hopes of avoiding poor outcomes.

Liability Risk From Overtreatment

In medical malpractice lawsuits, the plaintiffs must show that the physician violated the standard of care. Since medical practices vary across physicians and geographic regions, the lack of medical necessity is an attractive, alternative theory for plaintiffs who cannot otherwise show a standard of care violation. This area of jurisprudence is undeveloped, with courts generally relying on competing expert witness testimony to identify the lack of medical necessity. Unnecessary surgery was the main allegation, for example, in *Lee v Brain and Spine Specialists, P.A.*, where a Maryland plaintiff underwent a four-level cervical fusion after a motor vehicle accident. Radiographs and MRI were negative except for a small herniated disc. When esophageal injury and vocal cord paralysis occurred from improper retractor placement, which are known complications of cervical surgery, the plaintiff alleged that the operation should never have been done in the first place [12].

In 2012, Louisiana cardiologist Dr. Mehmood Patel was criminally charged and convicted of performing unnecessary coronary stent placement and balloon angioplasty procedures [18]. From 1999 to 2003, Dr. Patel had been the highest-billing interventional cardiologist in Louisiana. Similarly, in *United States v McLean* [17], a busy cardiologist was convicted of fraud; he had placed coronary stents in vessels with only 50% blockages. Government experts convinced the jury that without at least a 70% coronary blockage, coronary stenting was medically unnecessary. In 2015, an Indiana family filed a lawsuit against a now-deceased orthopaedic surgeon, alleging unnecessary performance of a distal clavicle resection on their 16-year old wrestler son; a medical review panel consisting of three orthopaedic surgeons agreed that the operation was not necessary, and the jury returned a verdict in favor of the injured patient [19].

The above convictions leave unanswered questions for physicians who are concerned about unnecessary treatments. In patients with stable angina, medication alone may be equally effective to coronary stents, even with 70% coronary blockage. Since expert testimony did not address stable versus unstable angina, it is possible that the government's own experts were also sometimes placing unnecessary stents. If the *McLean* threshold for 70% coronary blockage constitutes medical necessity, is stent placement in a 69% blocked coronary vessel always unnecessary? Can technology reliably distinguish between 69% versus 70% coronary occlusion? In the above example of the distal clavicle resection, would most reasonable orthopaedic surgeons not advise a patient to either live with pain, or have an elective operation that could return a patient to sports, as the defendant orthopaedic surgeons claims to have done? As these examples show, in some conditions, few, if any, bright lines exist to guide clinicians between necessary versus unnecessary treatments.

Analysis

In economic transactions, if the seller has superior information, the buyer is usually disadvantaged. In physician-patient interactions, the physician has vastly superior medical knowledge; this information asymmetry may itself contribute to excessive treatment. In other words, since physicians are financially incentivized to perform more surgery and tests, they may be motivated to overstate the benefits of certain tests and procedures, while understating their risks when communicating with their patients. Patients in turn may accept this information as authoritative and proceed with a test or intervention as advised by their physicians, when the driving motive may be financial gain, rather than meaningful patient benefit.

Instead of acting as a defensive shield, data suggest that medical overtreatments may increase professional risk. A 2013 study of the National Practitioner Data Bank showed that more than 1000 physicians had made monetary settlements in malpractice claims involving unnecessary or inappropriate surgical procedures since 2005 [5]. We believe that case law will eventually evolve to recognize and compensate patients for damages related to overtreatment. Also, in time, informed-consent law likely will come to require a more-thorough discussion of the relative benefits and

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Medicolegal Sidebar

attendant risks of procedures, in order to balance the inherent information asymmetry in the physician-patient relationship.

Discussion

Shared decision-making, a patient-centered practice model in which clinicians and patients share available clinical evidence and the patient is encouraged to consider all options toward independent decision-making, may be effective in reducing the incidence of unnecessary medical care. While supported by the medical community, the application of shared decision-making may be limited by the time pressures of medical practice [16]. For example, in a study of patient-physician encounters related to lung cancer, investigators found that a discussion of the risks and harms of screening procedures for lung cancer, while highly relevant, was virtually nonexistent [4]. Shared-decision making could work to reduce unnecessary medical treatments if physicians are forthright about treatments that may be available as an option, but in fact have limited to no value for the patient, regardless of whether the physician has other incentives to prescribe the treatment. If time is limited, educational resources could help patients distinguish between treatments that add value, versus those that add only costs and risks.

Medical overtreatments are an unresolved concern in our society and contribute to patient injury and increased costs. The law evolves in response to changing societal values and concerns. As society increases its focus on medical procedures and tests that add no value, the legal landscape related to medical necessity will change accordingly. Excess medical testing and treatments may be driven by a legitimate concern on the part of physicians to shield themselves against the risk of litigation. There are few, if any restraints against routine overtesting and overtreating arising from such liability concerns. As the examples from case law show, physician liability from medically unnecessary treatments usually arises when financial incentives and greed overwhelm concerns for patient welfare and ethical standards. In reality, most physicians focus on doing what is best for their patients. An honest disclosure of the true value, or lack thereof pertaining to a test or procedure will help patients make rational treatment decisions. Tools such as shared decision-making and the informed consent process can drive evidence-based patient choices that are economically and medically appropriate.

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Preventing Egregious Ethical Violations in Medical Practice: Evidence-Informed Recommendations from a Multidisciplinary Working Group

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Abstract

This article reports the consensus recommendations of a working group that was convened at the end of a 4-year research project funded by the National Institutes of Health that examined 280 cases of egregious ethical violations in medical practice. The group reviewed data from the parent project, as well as other research on sexual abuse of patients, criminal prescribing of controlled substances, and unnecessary invasive procedures that were prosecuted as fraud. The working group embraced the goals of making such violations significantly less frequent and, when they do occur, identifying them sooner and taking necessary steps to ensure they are not repeated. Following review of data and previously published recommendations, the working group developed 10 recommendations that provide a starting point to meet these goals. Recommendations address leadership, oversight, tracking, disciplinary actions, education of patients, partnerships with law enforcement, further research and related matters. The working group recognized the need for further refinement of the recommendations to ensure feasibility and appropriate balance between protection of patients and fairness to physicians. While full implementation of appropriate measures will require time and study, we believe it is urgent to take visible actions to acknowledge and address the problem at hand.

Introduction

This article reports on the recommendations developed by a multidisciplinary working group that was convened to address the problem of egregious ethical violations in medicine. By egregious violations, we mean clear violations of codes of medical ethics and law that directly harm patients. The working group meeting followed four years of research on cases of violations led by a team at Washington University School of Medicine (WUSM) with funding from the National Institute of Aging (NIA). Detailed methods and findings from the background studies are reported elsewhere.[1-3]

Background

Codes of medical ethics and professionalism commit physicians to acting in accord with core values of medicine, including care for patients, altruism, competence, compassion, and respect for patient autonomy.[4,5] Such values support the relationships needed to meet the goals of medicine — healing, prevention of disease, and palliation of pain and suffering.[6]

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While it is challenging to live up to these ethical ideals in all patient encounters,[7] egregious ethical violations appear to be relatively rare. Such violations are naturally hidden events. When they become apparent, disciplinary actions provide some of the most trustworthy prevalence data: approximately 5 in 1,000 physicians are disciplined by a state medical board per year, and only 1.1 in 1,000 receives severe disciplinary action involving license revocation, suspension, or surrender.[8-10]

While rare, the rate of severe disciplinary actions against physicians is nevertheless similar to the rate of new diagnoses of breast cancer each year (1.3 in 1,000) and much more common than new diagnoses of HIV (0.14 in 1,000) — both of which are widely recognized urgent challenges for medicine and public health.[11] Moreover, most egregious violations are never reported to state medical boards,[2,3,12,13] and when they are reported, some boards infrequently take action against a physician's license.[9,14] Thus, such violations — while uncommon — are undoubtedly far more prevalent than current databases such as the National Practitioners Database (NPDB) indicate.

As noted, the working group was particularly concerned with a subset of the causes of disciplinary action by boards: egregious violations of medical ethics such as sexual abuse of patients, criminal or negligent prescribing of opioids, or performing unnecessary surgeries for profit.[15] The WUSM team focused on these three behaviors because they not only contradict the core values of medicine, but also directly harm patients. Additionally, prior research by the team indicated that these forms of wrongdoing were sufficiently frequent to accrue at least 75 cases in each area of wrongdoing, which was necessary for purposes of statistical modeling.[16]

The recent case of Larry Nassar, a physician who practiced sports medicine, illustrates many of the dynamics commonly found by the WUSM research team in such cases. Across more than 20 years, Nassar sexually molested more than 265 girls (as young as 6 years of age) and young adult women.[17-19] In a lawsuit filed in April 2017, a woman claimed that Nassar had sexually assaulted her while he was still in medical school in 1992.[17] Additionally, he was convicted of receiving and possessing child pornography[20] and charged with practicing without a license in Texas[21] and obstruction-of-justice for destroying and concealing evidence.[20] While Nassar completed a residency and fellowship, we found no evidence that he was board certified.[18] It has been reported that he was almost dismissed from medical school after two semesters because he failed biochemistry twice.[22] In at least eight instances, his victims reported his behavior to someone in leadership, who failed to report the behavior to the state medical board.[18] When law enforcement was first notified, Nassar managed to distort his actions and present them as within the standard of care. No witnesses were involved to dispute his claims.[18] In repeated instances, Nassar sexually assaulted his victims when their parents were in the room, demonstrating not only his boldness but also the trust that patients and others have that a physician will only perform medically-appropriate actions according to the standard of care.[20]

The recent extended investigative report "Doctors and Sex Abuse" by the *Atlanta Journal-Constitution* illustrates the damage that such violations pose to the reputation of medicine, particularly when ongoing abuse is permitted to continue through oversight failures.[13,23-25]

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Within the current social climate in the United States, characterized by a growing awareness and intolerance of sexual harassment, it is particularly appropriate for the field of medicine to take actions to identify, appropriately respond to, and prevent such egregious violations of medical ethics. However, we believe it is most appropriate to view the problem of sexual abuse of patients as one species within a larger genus: egregious ethical violations that directly harm patients. Prescribing opioids for profit to those with known substance user disorders[26-28] or performing unnecessary invasive procedures for profit, such as spinal fusion surgeries or cardiac catheterizations,[29-31] cause patients psychological, physical, and financial harm, and in some cases death.[32]

Many features of the Nassar case are common across different kinds of egregious ethical violations: The violations were committed by a male, repeated, and selfishly motivated; oversight was lax or absent; and individuals who learned about the violations failed to take decisive action.[1-3,33] Accordingly, many of the actions that need to be taken to identify cases sooner and respond decisively are the same across different kinds of violations.

To address this matter, the authors convened as a working group on October 2 and 3, 2017. The working group consisted of four PhD-level investigators from the research team with backgrounds in social science research and bioethics, and nine external experts. Experts included a patient advocate, a health lawyer, legal counsel for a state medical board, and physicians from the Association of American Medical Colleges (AAMC), Accreditation Council for Graduate Medical Education, American Medical Association Council on Ethical and Judicial Affairs, the Federation of State Medical Board's (FSMB) *Journal of Medical Regulation*, the Academy for Professionalism in Health Care, and the Physicians Assessment and Clinical Education Program. All members agreed that they did not speak on behalf of any institutions or programs. However, members were selected in light of their expertise, which often derived from relevant experience in such settings.

Prior to convening the working group meeting, WUSM research team members conducted a systematic review of the literature on legal and disciplinary actions in medicine. Structured search terms were developed with research librarians from the Washington University Schools of Law and Medicine. Searches were conducted using Lexis-Nexis and PubMed from 2007 onwards. The team examined 2,386 records from Lexis-Nexis and 5,176 records from PubMed. Relevant papers were summarized for working group members in three categories: empirical studies, recommendations from legal scholars, and general background information.

The working group meeting opened with four sessions: a general overview of disciplinary actions, and three sessions on specific forms of violations — namely, sexual abuse of patients, negligent or criminal prescribing of opioids, and the performance of unnecessary (fraudulent) invasive procedures. Two subgroups were formed: one focused on education and remediation, and one focused on policy and oversight. Each session adopted a similar format:

- Presentation of data from the literature review and the WUSM study team's project

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- Subgroup evaluation of recommendations offered in the published literature and generation of new recommendations
- Plenary discussion of all recommendations

Recommendations were then revised based on plenary group discussions and post-meeting review of a draft document.

The group set the goals of offering recommendations that would prevent the majority of instances of egregious ethical violations and, when such violations did occur, help oversight programs to identify them sooner and take the steps necessary to ensure they are not repeated. The consensus of the group was that each of the recommendations offered is worth pursuing. By "pursuing" we mean there is reason to believe a recommendation will be effective in fostering the goals of the project, while recognizing that any recommendation will require closer examination and adaptation by policymakers and stakeholders to ensure that they are feasible and balance obligations. To use an analogy from architecture, we offer a schematic design rather than a blueprint with technical specifications.

Recommendations

We recommend pursuing the following actions to prevent and appropriately respond to egregious ethical violations in medicine.

1. Recruit Trainees, Physicians and Staff Who Embrace the Positive, Core Values of Medicine

Medical schools and medical centers must seek trainees at all levels (medical students, residents, fellows), attending physicians, and staff who demonstrate a commitment to core values in medicine such as caring for persons, altruism, competence, compassion, and respect for patient autonomy. It is controversial and of questionable efficacy to prospectively screen medical students, residents, fellows and staff using personality testing aimed at identifying deficits. Focusing on commitment to positive values may be more fruitful in advancing the mission of medicine.[34-37] A growing body of literature has defined the positive values and traits associated with medical professionalism.[7,38-40] While assessment lags behind, there is a consensus that assessing professionalism requires a multi-model approach, [41] which might include the use of standardized patients,[42] validated tests using realistic vignettes,[43] multi-source or 360° surveys,[44] or direct observation of behaviors.[45]

2. Educate Leaders to Create a Culture of Professional Integrity

Many of the problems observed in medicine are reflected within the broader cultures in which physicians work. Changing national and institutional cultures in ways that demonstrate respect for all persons will support professional behavior.[41] Leaders need to be particularly sensitive to their role in enforcing policies and supporting interventions to end serious wrongdoing by physicians. Far too often, cases of egregious ethical violations are ignored, covered up, or even enabled by leaders. To combat problems of cynicism and inaction, medical students, residents, nurses and others who are often in the best position to observe and report wrongdoing must be empowered to do so. Further, as they may feel

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particularly vulnerable to retaliation, they must be protected. A culture of professional integrity can protect patients and whistleblowers more than current laws.[46,47] To accomplish this goal, leaders must investigate credible complaints in a timely manner that balances concerns for privacy with the need for transparency. Leaders must not tolerate behavior that threatens patient safety or creates a hostile workplace.[48] Leaders in medicine must be selected for their character, experience, and abilities, and be provided with formal training to ensure that they have the skills needed to lead effectively with integrity.[49,50] We recommend that leadership programs for physicians incorporate sessions focused on rationales and strategies for responding effectively to allegations of egregious wrongdoing. These sessions might be led by individuals with expertise in organizational psychology and human resources.

3. Provide Feedback to Physicians

Studies indicate that physicians often make positive changes to behavior when provided with objective data comparing them to peers[51-55] or with 360º (multisource) feedback from diverse colleagues.[56] The following three examples illustrate ways of providing feedback from diverse stakeholders. First, institutions can conduct physician evaluations using multisource feedback from a large number of individuals, including patients, caregivers, family members, supervisors, physician peers, allied health co-workers, and trainees. Such feedback can support positive behavior change while protecting evaluator identities. Second, prescription drug monitoring plans (PDMPs) can be used not only to track patterns of “drug-seeking patients” but also to provide feedback to physicians on their prescribing patterns vis-à-vis peers within their specialty. Third, medical consultants can be encouraged to provide feedback to referring physicians and vice versa. This would increase the perception of peer oversight, which may also be protective against egregious ethical violations.[2]

4. Increase Oversight by Physician Peers and Colleagues

Oversight may include feedback, but implies a more systematic approach to observation, including establishing a sense of being observed. Some data indicate that peer oversight and group practices may be protective against serious practice violations.[57-60] We offer three examples of the kind of oversight that could be provided more consistently by building on existing systems. First, medical societies can require peer review of cases involving invasive or risky procedures. We recommend that all persons who conduct risky invasive procedures participate in registries sponsored by medical societies. Second, many settings, such as solo medical practices, make ongoing peer-review by highly qualified physicians difficult. However, utilizing electronic medical records, it is possible to provide peer review at a distance. Peer reviewers might be incentivized by offering CME credits for participating in auditing processes. Third, chaperones should be provided by default when an intimate examination is medically indicated. Chaperones should be absent only at a patient’s request. These requirements must be enforced.[1,61] In some cases, following harmful deviations from standards of care, we recommend that physicians lose the right to practice in the absence of peers.

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5. Track Wrongdoing and Consequences

Tracking wrongdoing is essential to protecting patients by providing data to inform decisions of disciplinary committees, patients who seek information on their physicians, and researchers who seek to understand professional violations. Tracking consequences enables transparent evaluation by state medical boards and other disciplinary bodies. Several steps can be taken to improve the quality of tracking. We recommend that the NPDB guidelines require that state medical boards and reporting institutions provide descriptions of the facts of a case, thus enabling trained NPDB staff to code appropriately. Appropriate coding will avoid the use of uninformative categories such as “other” and “not applicable” — the most common codes used at present, when codes are assigned.[9,62] To permit identification of links between specific forms of wrongdoing and the disciplinary actions taken, we recommend connecting NPDB data to state medical board data.[63]

We recommend the creation of a national tracking system to track serious disciplinary actions against individuals through medical school, graduate medical education, and medical practice to facilitate rapid response to wrongdoing. Such a database — because it might track more minor violations and even accusations — might be highly confidential and accessible only to those who are investigating or adjudicating cases. Negligent reporting, credentialing, privileging, and failure to report physicians under disciplinary scrutiny by institutions should be recognized as causes of action when patients are unnecessarily harmed by a physician with a history of professional violations.[64] Institutions should be protected from legal liability when sharing information in good faith with other institutions regarding a physician’s past performance. We encourage establishing a system whereby private insurers could share with the Centers for Medicare and Medicaid Services information about physician billing patterns to enable earlier detection of fraudulent or illegal behaviors by expanding the pool of available data.[65,66] Either a national PDMP should be established or states must be able to query neighboring states’ PDMPs without increasing the administrative burden (e.g., by using a single log-in portal).

6. Foster the Establishment of More Uniform and Transparent Actions by State Medical Boards

Currently, tremendous variation exists in how state medical boards respond to instances of serious wrongdoing.[9,14] In some states, physicians commonly return to practice following severe disciplinary action for egregious professional violations.[9,15,24,67-70] We encourage the FSMB to provide leadership by sharing best practices across state medical boards and publishing examples of sensible and effective model statutes. We recommend that boards publish their disciplinary actions on publicly available websites. While some boards do this already, many do not, or the data they publish are vague and incomplete.[71]

7. Across All Career Stages, Permanently Remove Individuals from Medicine Following Egregious Violations or a Persistent Failure to Serve the Goals of Medicine

Individuals who demonstrate disregard for the well-being of others, a lack of remorse for harming others, and illegal behaviors do not act in accordance with the core values of medicine and pose a significant threat to patients. From the first day of medical school through medical practice, patterns of behavior that run contrary to the goals of medicine

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should be monitored and treated in the same manner as gross incompetence. The response should be both rapid and fair for the protection of patients and physicians. Medical boards should have and exercise the authority to permanently revoke or suspend medical licenses for first-time egregious offenses that run counter to the core values of medicine (e.g., rape or risky unnecessary invasive procedures done for profit) or for repeated lesser offenses following remediation efforts. Medical schools and institutions sponsoring residencies and fellowships should exercise their authority to dismiss medical students, residents, and fellows on the same grounds.

8. Partner with Law Enforcement in Appropriate Ways

Given different standards of evidence and procedures, administrative review of cases (e.g., of sexual abuse) by state medical boards may provide less stressful approaches to investigation and adjudication for patients who have been victimized, compared to criminal investigations. Boards typically also have the authority to remove a physician from medical practice more swiftly than criminal systems. Nevertheless, the protection offered to the public by administrative review and action may fall short of that provided by criminal prosecution. Boards should routinely ask patient victims (e.g., victims of sexual abuse) whether they want to work with law enforcement to pursue criminal charges. Patients' wishes not to pursue such charges should be respected. Boards should be mindful of their obligation to work with law enforcement in cases involving mandatory reporting. We encourage law enforcement to provide boards with highly trained liaisons to support investigations involving all relevant criminal activities, including unnecessary invasive procedures and sexual abuse, in ways similar to the support provided for investigating inappropriate opioid prescriptions and false claims.

9. Provide Patients with Educational Materials to Inform Expectations and Choices

Patients must not shoulder the burden of ensuring competent and professional service from physicians. However, it is appropriate to empower patients by providing information to inform reasonable expectations. For example, it would be appropriate to provide patients with written information on the use of chaperones for intimate examinations and how a well woman exam or a sports physical is appropriately conducted. Patients should be provided with information, such as American Board of Internal Medicine's *Choosing Wisely* brochures, that describe when invasive procedures are indicated,[72] as well as the right to request a second opinion, particularly if patients have any reservations about the medical necessity of procedures. Vulnerable patients should have access to patient advocates and consent monitors when considering invasive or risky procedures.

10. Conduct Basic Research to Understand the Factors that Lead to Egregious Ethical Violations

Very little data exist that help to explain how and why egregious ethical violations occur in medical practice. Effective prevention and remediation efforts will require access to detailed data on cases and novel analytic approaches to identify causal factors. We recommend that state medical bards and the NPDB partner with researchers to identify data points to collect when investigating and reporting cases and eliminate the use of vague descriptions of the reasons for disciplinary action such as "not applicable" and "other."

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Some studies have found rates of board certification among wrongdoers to be significantly lower than those of the general U.S. physician population.[1,2,73,74] However, no data identify the specific factors associated with board certification that might be protective of integrity in medicine. Accordingly, at this time, we recommended further research to understand the specific elements of post-graduate training that may enhance competence and professionalism in medicine.

While the vast majority of male physicians are never sanctioned by a state medical board,[8] the overwhelming majority of physicians who commit egregious ethical violations are male.[1,2,57,60] The impact of increased gender diversity on overall professionalism in medicine is worthy of study, including gender diversity in positions of leadership within medical centers and healthcare institutions.[75,76]

It is important to conduct research aimed at identifying barriers and facilitators to implementing reforms, and to track and evaluate progress in implementing reforms.

It is appropriate for agencies and institutions that support research on health care — including the National Institutes of Health and the Agency for Healthcare Research and Quality — and institutions that are directly responsible for oversight of medical practice — including the FSMB, the Joint Commission, and all health care systems — to support research on these topics.

While these ten recommendations focus on the field of medicine, we acknowledge that protecting patients requires that all health care professionals abide by high standards. We encourage medical societies and health care institutions to work with state medical boards and allied health-credentialing boards to consider the steps necessary to prevent and appropriately respond to egregious ethical violations by all health care professionals.

Conclusions

The responsibility for reducing egregious ethical violations belongs to the field of medicine and health care leadership. Patients, medical students, and nurses may observe egregious ethical violations. However, patients may not want to relive trauma when they have been victimized, and medical students, nurses, and junior colleagues may fear retaliation and career harm if they act as whistleblowers. This is particularly true in institutional cultures that are tolerant of wrongdoing or unprofessional behavior. None of the recommendations we offer depend upon increased action from vulnerable groups, though some of them support such action, for example, when patients who were victimized wish to cooperate with law enforcement.

While the vast majority of physicians are committed to the well-being of their patients and behave with professional integrity, a small minority repeatedly commit egregious ethical violations. We embrace the goals of making such violations significantly less frequent and, when they do occur, identifying them sooner and taking the steps necessary to ensure they are not repeated. The ten recommendations offered by our working group provide a schematic design to meet these goals. Implementation of these recommendations will require the commitment of specific groups following debate and refinement of the

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recommendations. Above we recommended specific actions for the FSMB, namely, that it "provide leadership by sharing best practices across state medical boards," publish "examples of sensible and effective model statutes" (e.g., rules for mandatory reporting, whistle-blower protection, mandatory revocation, and public reporting), and support collaborative research aimed at understanding predictors of egregious violations and barriers and facilitators to implementing reforms.

While full implementation of appropriate measures will take time and study, we believe it is urgent to take visible actions to acknowledge and address the problem at hand.

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Vox

A nurse made a fatal error. Why was she charged with a crime?

How the RaDonda Vaught case threatens patient safety.

By Keren Landman | @landmanspeaking | May 2, 2022, 9:20am EDT



RaDonda Vaught and her attorney Peter Strianse listen as verdicts are read at the end of her trial in Nashville, Tennessee, on March 25. The jury found Vaught, a former nurse, guilty of criminally negligent homicide in the death of a patient who was accidentally given the wrong medication. | Nicole Hester/The Tennessean via AP

Diana Campion, a nurse practitioner who lives in Florida, recently contemplated going back to bedside nursing part-time. Doing so would require refreshing a skill set she hadn't used for a few years — titrating intravenous drips and performing other complex nursing tasks involved in managing sick, complicated patients. Given the soaring demand for nurses, it initially seemed worthwhile.

But after hearing about the highly publicized verdict handed down in the **case of RaDonda Vaught**, a Nashville nurse whose medication error led to the death of a 75-year-old woman, as well as verdicts in several other recent **criminal cases** against nurses who made medical errors, Campion decided against it.

To her, the verdicts communicated that when nurses make mistakes, their careers can be destroyed. "If there is a fatal error, it's the nurse that will stand alone," Campion said. "It's not worth it."

American health care systems are encouraged to strive for a "**culture of safety**," which frames accountability as something to be **shared by individuals and institutions**. But in reality, both health care facilities and the law sometimes treat medication errors as individual failures rather than systemic ones. When that happens, it's nurses who often take the blame for institutional problems.

"Nurses especially are the low-hanging fruit," said Edie Brous, a nurse and attorney in East Stroudsburg, Pennsylvania, who has experience representing healthcare professionals before regulatory agencies and licensing boards and has **written** about criminalizing medical errors. Many people are involved in medical treatment —including doctors and pharmacists — but nurses often take the fall because they ultimately administered the drug, she said.

Vaught's verdict is unusual in that it happened at all. Nurses typically aren't charged with crimes for medical errors. More typically, medical errors are addressed through licensure boards and occasionally in civil lawsuits.

Additionally, the verdict comes when America's nurses are in a **particularly tough spot**. The pandemic has led to staffing shortages that have left many in the profession frightened and **burned out**. "Nurses are fried," said Brous.

At a time of enormous strain for the profession, Vaught's case threatens to undermine patient safety by blaming nurses for problems that are hospitals' to fix. The alienation that results not only reduces the likelihood nurses will help improve the systems in which they work, but also risks driving essential workers away from the profession.

Already, nurses like Campion have determined that the benefits of working at the bedside are not worth the risk. If more follow in her steps, hospitals could get less safe for providers and patients.

Vaught's lethal error, explained

On the day after Christmas in 2017, RaDonda Vaught was **working a shift** as a "help all" nurse in the neurologic intensive care unit at Vanderbilt University Medical Center. "Help all" is what it sounds like: The job involved multitasking, helping with nursing needs across the unit as they arose in real time. But that wasn't all — Vaught was also orienting a new employee during her shift.

At the time, Vaught had been a nurse for a little over two years. She had no violations on her record.

She was **asked to administer Versed, a sedative**, to a patient named Charlene Murphey. When Vaught couldn't find the medication in one of the hospital's electronic prescribing cabinets, she manually overrode the machine's system to get it, a fairly **common practice in that hospital at that time** due to a persistent software problem. However, instead of taking Versed out of the cabinet, Vaught accidentally obtained and administered vecuronium, a powerful paralytic.

Murphey died the following day as a result of the error. Vanderbilt fired Vaught but did not report the medical error to state or federal regulators as it was required to do. Eventually, the hospital settled a civil lawsuit out of court with Murphey's family.

In late 2018, an anonymous tip alerted the Centers for Medicare and Medicaid Services and the Tennessee Department of Health to Vaught's unreported medical error. The Tennessee Bureau of Investigation found **multiple instances of wrongdoing** and coverups on the hospital's part. According to later testimony of a Tennessee Bureau of Investigation (TBI) agent, Vanderbilt bore a **"heavy burden of responsibility"** in Murphey's death. However, the health department did not punish the hospital; it only punished Vaught, ultimately revoking her nursing license.

But the most surprising part of Vaught's story is what happened next. After an investigation, the Nashville District Attorney's office indicted her in 2019 on two criminal charges: reckless homicide and impaired adult abuse.

Criminal charges for medical errors are rare

It was an unusual move to charge Vaught, said Robert Gatter, a health law expert at Saint Louis University. Generally, he explained, if someone in the US wants to pursue legal action for a medical error, they sue for compensation through the civil court system.

In contrast, the goal of criminal cases is not to compensate, but to punish.

"The criminal law is generally only used in health care when a provider is using their position to intentionally harm others," said Gatter. Courts have tried so-called "**mercy killings**" — medically assisted deaths for terminally ill people — as criminal cases. Other well-known criminal cases against providers include that of **Christopher Duntsch**, an incompetent neurosurgeon who continued operating despite a string of catastrophic outcomes for his patients. Duntsch only stopped performing surgeries after being convicted in criminal court of causing serious bodily injury to an elderly person. He was sentenced to life in prison.

It's not clear why the Nashville district attorney decided to prosecute Vaught's case — after all, she had already had her nursing license revoked. District attorneys rarely prosecute cases of medical error in criminal courts, especially ones in which the wrongdoing does not appear to be intentional.

But when they do decide to prosecute, these decisions are often politically driven, said Brous. "They want to look like they're tough on crime," she said. "They want to be high-profile during an election year or when they're running for reelection. And this gets in the newspaper."

The office of Nashville's district attorney, Glenn Funk, **responded to scrutiny** of his decision to prosecute Vaught's case with a statement. "This was not a case about a simple mistake," the statement read. "This was a case about gross neglect," of which the statement listed 18 instances.

In a **radio interview**, Funk, who is also an **adjunct professor** at Vanderbilt Law School, said, "Our job is public safety, and we wanted to make sure that the public was safe."

In late March, a jury **found Vaught guilty** of criminally negligent homicide and abuse of an impaired adult, charges that could carry **up to 8 years of prison time**. Her sentencing is scheduled to take place on May 13.



Nurses walk to a courtroom to show support for RaDonda Vaught during a hearing in Nashville, Tennessee, in February 2019. | Mark Humphrey/AP

Punishing individuals for medical errors leads to less safety for patients

RaDonda Vaught's case — where a medical error is treated as an individual, criminal failure rather than a systemic one — is rare, but not **unprecedented**. In another recent, less well-publicized case, a Philadelphia nurse was **charged** with felony neglect and involuntary manslaughter when her nursing home patient died after a fall; she had neglected to conduct neurological checks after the fall, reportedly because she was providing care to **38 other patients** in the facility.

The argument here is not about whether nurses should be held accountable for their errors; everyone I spoke with about Vaught's case agrees she bears responsibility for her actions and should face consequences. The real issue is that criminalizing a nurse's error lets hospitals off the hook for the systemic changes that would improve patient safety.

"Almost no mistakes happen in a hospital by just one person," said Gatter. Systems exist to prevent medical errors, he said. If those systems don't work or exist only on paper, errors will happen.

In this case, the system failures were clear: During an unannounced visit to Vanderbilt University Medical Center in late 2018, federal investigators found multiple deficiencies, some of which placed patients at "serious and immediate threat," according to the **105-page memo documenting the details**. For example, hospital policies didn't require that a second nurse sign off on the use of a highly dangerous medication like vecuronium, nor did it require that patients receiving sedatives be hooked up to a heart and lung monitor. Focusing the blame on one nurse's error shifts the attention away from those deficiencies.

"I'm quite concerned that this nurse is getting thrown under the bus, and in the hubbub of giving her a jail sentence, that the system itself will escape close examination," said Gatter.

Even if a nurse were solely responsible for a medical error resulting in patient harm, the way to prevent that nurse from causing further harm is to revoke their license, said Gatter. It's much harder to explain how punishing a nurse with jail time further prevents them from endangering others.

However, it's easy to see how that type of punishment can itself **create and compound safety risks**, he said.

That's because severely punishing individuals for systemic problems has a **chilling** effect on others' willingness to report mistakes.

"By instilling the fear of severe penalties … cover-ups are sure to follow," wrote the Institute for Safe Medication Practices (ISMP) in a **scathing analysis of the case**. If a practitioner makes a medication error that doesn't cause patient harm and knows people who make errors can be charged with crimes, the ISMP asked, what's their incentive to report the error?

Less transparency in error reporting also means hospitals have fewer opportunities to correct big problems. That means faulty systems stay in place, which translates into more vulnerability and stress for health care providers and less safety for patients.

"I would never get on an airplane today if I thought that if a pilot made a mistake, he was going to the big house," said Brous. "Because they're not going to report mistakes that way, and that doesn't keep the next pilot from making a mistake."

Mark Rothstein is a health law expert at the University of Louisville who is on an external advisory board to a group studying genetic privacy at Vanderbilt University Medical Center.

I asked him if there could be any benefit to sending a nurse to prison for a medical error. In response, he raised questions about what the public expects of workers operating in high-risk professions.

"What do you get from prosecuting police officers?" he said by way of comparison. "Police officers make mistakes all the time. Sometimes they're minor, sometimes they're major — but if the recklessness, the culpability, the indifference to the public rises to a certain level, then the public is demanding a criminal prosecution as a form of deterrent."

The consequences for professional malpractice should ideally deter wrongdoing without discouraging people from entering the profession altogether — but finding that balance is challenging. Of Vaught's case, Rothstein said, "Whether this would have any deterrent effect on nursing practice, I haven't the faintest idea."

This verdict is landing at a time of dangerously low morale among nurses

American nursing was **under enormous strain** well before the pandemic. But with the US population aging, surging retirements among bedside nurses and nurse educators, and nurse staffing levels reduced ever lower to contain costs, the pandemic has tipped parts of the country into a full-on **nursing shortage**.

The last thing the profession needs is another reason for nurses to leave jobs providing direct patient care, but that's exactly the effect the Vaught ruling is having, said Janice Maloof Tomaso, a nurse in Marshfield, Massachusetts.

When nurses see other nurses thrown under the bus by their employers, they are disincentivized from taking on the high-complexity work of caring for sick patients because of the increased threat of liability, she said — even if they are nowhere near Tennessee. While the exodus is mostly anecdotal for now, the **anecdotes are numerous**.

"We are all her — every single nurse," Maloof Tomaso said of Vaught.

The fact that Vaught's case was a product of a local prosecutor's decision is irrelevant to many nurses' decisions, as is the coming result of the sentencing hearing. "The damage is already done," said Maloof Tomaso. "People are horrified that she even went through this." All nurses have made mistakes and many are thinking, "'that could have been me, and I'm not sticking around for it,'" she said.

There's a better way for state legislators and hospitals to handle medical errors

There are currently few legal barriers to prevent district attorneys from bringing criminal charges in other cases of medical errors leading to patient harm. However, if state legislators changed laws to prevent prosecutors from charging health care providers with criminal homicide or manslaughter charges on the basis of medical errors, it would make it harder to criminalize unintentional mistakes.

It's really our nation's hospitals that could and should lead the charge on dealing with medical errors in a way that sustainably improves patient safety, said Brous. There are models for this, she said: In 2006, after three babies died as a result of a medication error in an Indianapolis hospital, it was the hospital that took responsibility.

"Whenever something like this happens, it is not an individual responsibility, it's an institutional responsibility," Sam Odle, the hospital's president and CEO, **told reporters** at the time. As Brous remembers it, the institution's representatives acknowledged it lacked procedural safeguards necessary to prevent the error and spoke of the nurses who had administered the medication as secondary victims traumatized by their system's failure. "That's what hospitals need to do," she said.

The voices of nurses themselves play perhaps the most important role in forging a better way ahead. "We're silenced a lot," said Brous. "Nurses need to have a voice that's being heard."

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The Case for Medical Chaperones

ALLEN L. PIMIENTA, MD, AND RACHEL E. GIBLON, MSC

It's time for more discussion about how best to incorporate chaperones in primary care.

"Do you have a few minutes to chaperone a Pap smear?" I [Dr. Pimienta] have been in medical practice for only a few years, but I have already lost count of how many times I've asked that question of my nursing staff. In family medicine, we are taught to be sensitive to patient modesty when providing a thorough physical exam, but best practices for chaperoned exams are unclear at best.

References to medical chaperones began to appear in the literature in the 1970s and 1980s, with varying connotations and differing role descriptions.[1,2] Currently, the American Medical Association (AMA) says any authorized member of the health care team can serve as a medical chaperone as long as there are clear expectations to uphold professional standards of privacy and confidentiality.[3] The addition of medical chaperones to the patient encounter coincided with increasing rates of medical litigation in the United States,[4] although it is unclear that this was the catalyst. In any event, it appears the intended use was to protect the interests of both patients and physicians.

> Although a number of associations and government bodies have attempted to centralize recommendations on this topic, these guidelines are often ambiguous and conflicting.

Family physicians are routinely entrusted by their patients to perform the most sensitive physical exams. Unfortunately, every year there are news stories and litigation alleging cases of physician misconduct during patient encounters. The "Me Too" movement has recently empowered more individuals to speak up about improper sexual behavior within and beyond medicine. In this environment, patients may be increasingly wary of their own health care providers. Physicians, too, understand that they can become targets to unethical or unwell patients who may allege misconduct that never happened but is difficult to disprove without witnesses.[5]

ARE CHAPERONES THE SOLUTION?

How often do inappropriate examinations occur, and does the use of chaperones reduce cases of inappropriate conduct? Unfortunately, current statistics available through the National Practitioner Data Bank (NPDB) do not provide details on these types of cases.[6] One estimate indicated that almost 11 percent of provider misconduct reports were sexual in nature.[7] The most rigorous published studies conclude that we lack sufficient information on malpractice to accurately establish the rates and types of physician misconduct.[6]

There also have been no studies examining whether the presence of medical chaperones decreases the risk of physician misconduct. Some studies have investigated whether medical chaperones affect patient satisfaction, and the results generally indicated that patients

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found it respectful to be offered a chaperone and, depending on the country, often expected one.[8,9]

Finally, it is important to note that many victims do not report sexual violations by their physician, with one study estimating that fewer than 1 in 10 victims choose to report it.[10]

The lack of hard evidence notwithstanding, if we agree that chaperoned exams have value, difficult implementation questions arise, including these: Must chaperone expectations apply to physicians of both genders? How does the sexual orientation of the patient and physician factor into the chaperone selection? What happens if the patient declines the offer of a chaperone, but the physician feels he or she must bring one in anyway? How does the presence of a third person in the exam room affect the physician-patient relationship? Will we come to a point when physicians can no longer examine any patient alone? Where do the resources come from? Where is the line to be drawn?

Although a number of associations and government bodies have attempted to centralize recommendations on this topic, these guidelines are often ambiguous and conflicting. The AMA Code of Ethics recommends, in part, notifying patients about chaperone guidelines and always honoring a patient's request to have a chaperone.[3] The American College of Obstetricians and Gynecologists recommends, in part, accommodating patient requests for a chaperone, regardless of the physician's gender.[11] The American Academy of Pediatrics (AAP) explicitly recommends having a chaperone attend genital, rectal, and breast exams of adolescent patients but also recommends using shared decision making if the patient is old enough.[12] The exam of an infant, toddler, or child should always be performed in the presence of a parent or guardian, according to the AAP policy. The American College of Physicians Ethics Manual says, in part, that "in general, the more intimate the examination, the more the physician is encouraged to offer the presence of a chaperone."[13] The American Academy of Family Physicians has not published recommendations on the use of chaperones.

Several states have implemented legal mandates that range from requiring that physicians offer a chaperone for intimate examinations (Ohio)[14] to defining an examination of the genitals or breasts by a physician of the opposite gender without a chaperone as professional misconduct (Georgia).[15] In Canada, associations in the individual provinces have made their own recommendations.[16] In the United Kingdom, the General Medical Council requires that a physician offer a chaperone for an intimate examination whenever possible.[17]

STARTING THE DISCUSSION

Ideally, each practice, department, or institution would implement a medical chaperone policy for all providers to follow. However, standard approaches may not be pragmatic or sustainable. Explicitly requiring a chaperone for every visit would place a greater burden on staff and increase already ballooning health care costs. In addition, there will be physicians who feel uneasy with or outright reject the idea that they need to be chaperoned. There will be patients who do not want an extra person present for sensitive examinations. Insurance companies may have their own requirements that would override departmental or local policy. Ultimately, as is the case with much of medicine, decisions about chaperoning will continue to be made on a case-by-case basis.

Ideally, each practice, department, or institution would implement a medical chaperone policy for all providers to follow.

Nevertheless, it is imperative that we start talking about chaperones in our practices. Speak with your patients about their preferences regarding medical chaperones, and have frank conversations with your colleagues about current policies and procedures. Having a local or enterprise-wide consensus on the use of chaperones will improve the quality of care from the perspectives of both the physician and the patient.

To encourage such discussion, and understanding the limitations of staffing and costs, here are several ideas to consider for

how to handle medical chaperones in your practice:

1. Offer a medical chaperone to any patient undergoing genital, rectal, breast, or full-body skin exams.

2. Provide information explaining chaperones and chaperoned exams when a patient first seeks care at your practice.

3. Document in every patient's chart his or her preference regarding chaperones; front-desk staff could ask about this during check-in to make the process more standardized.

4. If your practice consensus is to require a chaperone for certain types of examination, apply this requirement to both male and female physicians.

5. Develop chaperone selection criteria that consider issues such as gender and training.

6. Develop practice guidelines that support both the physician and the patient in cases where a patient declines a chaperone but the physician still feels uncomfortable. These guidelines could allow you to defer the exam to another day or to another physician or chaperone, and should reassure the patient that this is standard practice.

7. Do not allow the process of ensuring that an exam is chaperoned to interfere with appropriate and timely patient care and clinical judgment.

8. Document all encounters involving chaperones in the electronic health record, including names, time, and date.

Personally, I [Dr. Pimienta] find the notion of a chaperoned exam troubling because I feel it implies that the physician has ulterior and possibly harmful motives that require third-party supervision. However, in light of the recent string of high-profile physician misconduct cases, I recognize the importance of chaperones. I hope that one day in my career, we physicians will be able to win back the trust of the public and remedy the malpractice of the small minority of our profession. FPM

> Having a local or enterprise-wide consensus on the use of chaperones will improve the quality of care from the perspectives of both the physician and the patient.

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Send comments to **fpmedit@aafp.org,** or add your comments to the article online.

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Medicolegal Sidebar

The Law and Social Values: Medical Necessity and Criminal Prosecution

B. Sonny Bal MD, JD, MBA, Lawrence H. Brenner JD

Introduction

Where criminal law and medicine intersect, complexity arises. An ever-shifting foundation of case law makes this territory dangerous but also interesting to explore. Perhaps no subject is on more physicians' minds than the risk of prosecution for Medicare fraud, particularly with respect to the performance of unnecessary procedures. At the heart of this question exist two controversial issues in medicine and law: (1) How does one differentiate between a necessary and unnecessary medical procedure given the uncertainty in the practice of medicine; and (2) what constitutes a healthcare crime?

Medical Necessity and Crime

The medical necessity dilemma has spawned many books [1, 5, 10–12] by authors who raise concerns about whether or not medical and surgical practice patterns reflect custom and culture, rather than well-established scientific evidence. Accordingly, author Shannon Brownlee in *Overtreated* [1] proposes that one-third of the medicine that patients receive is unnecessary. She states, "Doctors lack the evidence they need to know which treatments are most effective and which drugs and devices really work" [1]. The late Kerr White MD, the founding chair of The Department of Health Policy and Management at Johns Hopkins University and the Deputy Director for Health Care Services for the Rockefeller Foundation stated it another way in *Medicine & Culture* [11], "About 15% of all contemporary clinical interventions are supported by objective scientific evidence that they do more good than harm." In orthopaedic surgery specifically, questions have been recently raised about the effectiveness of common operations such as knee arthroscopy [7], knee replacement [13], and spinal surgery [9].

The second question appears simple, but is highly complex—what constitutes a healthcare crime? The question of healthcare criminal conduct can be easy to resolve within a certain context.

Note from the Editor-in-Chief: We are pleased to publish the next installment of "Medicolegal Sidebar" in Clinical Orthopaedics and Related Research®. *The goal of this quarterly column is to encourage thoughtful debate about how the law and medicine interact, and how this interaction affects the practice of orthopaedic surgery. We welcome reader feedback on all of our columns and articles; please send your comments to eic@clinorthop.org.*

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For example, if a physician or surgeon bills for procedures that are not performed, then that physician or surgeon has committed a crime. This is no different from stealing directly from Medicare or other third-party insurers. But the question of whether a physician or surgeon has committed a crime because his or her procedures are deemed to be medically unnecessary is much more complicated and fraught with the potential for prosecutorial abuse. Prosecutions based on lack of medical necessity are not premised on improper billings, but rather the often-obscure criteria regarding whether the procedures would benefit the patient.

Criminal prosecutions of surgeons based on allegations of medical necessity are rare enough to be sensationalized in newspaper headlines, if and when they do occur. The legal standard for proving crime is far more stringent than that needed to prove a civil wrong-doing, such as medical negligence. Indeed, when it comes to medical practice, our legal system has maintained a traditional, and some would say, an extreme deference toward physician judgment. Thus, criminal prosecutions for unnecessary surgery, as in the case below, are triggered only when some element of the practice pattern defies accepted norms in a particularly egregious way, or when the harm is perceived to be systemic and recurrent. These considerations do not apply to the overwhelming majority of physicians in practice.

United States v McLean

A recent legal case, *United States v McLean* [14], demonstrated the problems inherent in prosecuting a physician or surgeon for unnecessary procedures. Following a review from a hospital peer-review committee, the federal government charged Dr. McLean, an interventional cardiologist from Maryland, with performing medically unnecessary coronary stent procedures. He was indicted under 18 U.S.C. § 1347, a federal statute that states that if a person commits healthcare fraud, he or she shall be fined and/or imprisoned up to 10 years. If the violation results in bodily injury or death, he or she can be imprisoned up to 20 years or for life, respectively [8].

At trial, the federal government introduced testimony from two expert cardiologists who testified that it was generally accepted that coronary stents were not medically necessary in the absence of 70% stenosis, and symptoms such as chest pain or a positive stress test. Dr. McLean's former patients who had received stents testified that they never experienced chest pain even though Dr. McLean recorded chest discomfort in his medical records [14].

It was Dr. McLean's contention that the government's medical standard for coronary stents was incorrect. He also argued that evaluating degrees of stenosis by angiograms is highly subjective, and that his stent placements were appropriate and necessary. He called an expert witness who testified that during the relevant period of time, elective stents are considered medically appropriate if a patient had at least 50% stenosis and evidence of ischemia or angina. This expert's review of five cases that were named in the indictment was that four had met the standard of care. Many grateful patients of Dr. McLean also testified on his behalf.

Following 10 days of trial, a jury convicted Dr. McLean of healthcare fraud, sentencing him to more than 8 years in prison, with monetary restitution of USD 579,070.

On appeal, the Fourth Circuit Court of Appeals affirmed Dr. McLean's conviction [14].

Analysis of the Appellate Decision

In his appeal, Dr. McLean had argued that his conviction was unconstitutional because of the doctrine of "constitutional vagueness." Under American constitutional law, a legal statute can be void for vagueness. There are a variety of reasons why this protective constitutional doctrine exists. One reason is that

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no one should be punished as a criminal under laws that do not explicitly and definitively identify a proscribed conduct. As the US Supreme Court clarified in the 1926 legal case, *Connally v General Construction Co*, "[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law" [2].

The *McLean* decision raises difficult questions that are relevant to all physicians. Was Dr. McLean sufficiently on notice that his implantations of coronary stents were so inappropriate that his conduct constituted a federal crime? Most physicians will agree that there is seldom a bright line in medicine that clearly differentiates medically unnecessary versus medically necessary procedures. While it is true that in any community or large hospital, there is a range of surgical indications practiced by aggressive, high-volume surgeons versus those who favor a conservative, nonoperative approach, it is worth remembering that the *McLean* litigation represents conduct that was clearly an outlier. While the appeal was made on the argument that the precise amount of coronary stenosis, or lack thereof, which would make stent placement a criminal act is not sufficiently settled among professionals, the facts of the case showed that Dr. McLean had systematically engaged in other misconduct, such as altering entries in the medical records to justify billing for stent procedures, and falsifying billing for surgery and followup care. Thus, as the appellate court correctly concluded, Dr. McLean's argument that no one really knows how aggressive a stent-placing cardiologist has to be in order to end up with a criminal conviction based on medical necessity was simply disingenuous.

Even so, *McLean* represents a tension between two competing principles of law. On the one hand, if medical necessity is interpreted broadly, many, if not most, physicians or surgeons can be prosecuted on the whim of the justice department, at least in theory. On the other hand, if medical necessity is construed narrowly, then physicians and surgeons can engage in highly questionable procedures for profit without fear of prosecution or accountability. There has been an interesting epilogue to the *McLean* case. In 2015, *The New York Times* published an article that begins by stating, "At a time of increasing scrutiny of procedures to open blocked heart arteries, cardiologists are turning to—and reaping huge payments from—controversial techniques that relieve blockages in the arms and legs" [3]. The article went on to state, "Medical experts are questioning the necessity of some of these treatments, and many believe the condition is more safely treated with drugs and exercise" [3].

A maxim of good trial law is that for every good argument, there is an equally good counter-argument. For the sake of argument therefore, is it possible that the experts who testified against Dr. McLean were engaged in negligent activity themselves? In other words, were these testifying experts so conservative in their approach that patients in their care were dying from unnecessary withholding of coronary stenting? If so, and absent clearly-defined gold-standard criteria for the implantation of coronary stents, is it fair to say that Dr. McLean's professional conduct should not have been prosecuted? Perhaps so, but in the *McLean* litigation, it was not simply the medical practice that raised questions, rather, it was the efforts to cover up misconduct that triggered further inquiry and led to criminal proceedings. The fact is that if the prosecutor had nothing more to offer than expert arguments and counter-arguments about how much coronary stenosis is needed to make a stenting procedure a criminal act, there is no question that Dr. McLean would not even have been indicted. This reflects the threshold needed to bring about a criminal indictment in our legal system. Instead, the facts in *McLean* showed a clear pattern of alteration of records, including factual data that were falsified to create justifications for stent surgery, and fraudulent billing that was inconsistent with the operations

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performed, and the followup care provided.

Discussion

Most of the physician concern about liability in medicine surrounds medical malpractice litigation. Physician leaders have argued that medical malpractice lawsuits contribute to increasing healthcare costs [6], and subsequent reforms, such as those targeted at limiting damage awards in medical malpractice litigation have been enacted in many states. In contrast, the potential consequences of healthcare fraud for alleged medically unnecessary procedures have attracted little attention so far, aside from the occasional, sensational newspaper article.

Medical negligence lawsuits may affect the majority of physicians in some specialties, such as orthopaedic surgery. Assuming the plaintiff is successful, the resolution of medical malpractice lawsuits is always measured in monetary damages that are indemnified through insurance. In contrast, criminal prosecutions of physicians, such as for allegations of medically unnecessary procedures or fraudulent billing, are vanishingly rare and require a high standard of proof for successful prosecution. The penalties associated with such litigation are serious however, and can include a prison sentence, in addition to monetary damages.

While rare, healthcare fraud is a crime, and should be a concern to those familiar with the American criminal justice system [4].

In light of the *McLean* litigation, if an orthopaedic surgeon, for example, were to perform total knee or hip procedures and a group of his peers alleged that 25% of the procedures he performed were unnecessary, should the orthopaedic surgeon be indicted for healthcare fraud? The facts of the *McLean* case offer some guidance to this question, and reassurance. An outlier physician with an egregious volume of surgery, questionable indications, or unusually high incidence of patient injury would be reported to the hospital system, or to the local medical board. Indeed, this was the case with Dr. McLean, and an internal inquiry by his peers did identify serious and systemic concerns with his patient selection criteria. Further inquiry then revealed fraudulent billing patterns, patient record alteration, and other conduct that crossed the threshold for criminal behavior, on a repetitive basis.

While there is no quick answer to the question of when our justice system should indict physicians and surgeons for medically unnecessary procedures, the first line of inquiry toward maintaining quality and patient safety is peer-driven, such as from a peer-review committee, or similar body. Depending upon the circumstances, peer review may identify correctable practice patterns that are amenable to proctoring, further training, or mentorship. Credible, independent peer review is a powerful tool available to the medical community to identify physicians who might stray outside the bounds of proper indications for a procedure, and take corrective action in a timely manner. The medical community should strive to ensure that the peer-review process is truly independent, fair, and not driven by competitive or political motives. Data concerning physician operative volumes, outcomes, and complications should be available to peer-review bodies so that outliers can be identified, and patient harm avoided.

While the *McLean* case reflects the successful prosecution of a physician for improper surgery and billing, and the appellate component of the litigation addressed the provocative subject of medical necessity, for the overwhelming majority of physicians, the threat of criminal prosecution from medically unnecessary procedures is entirely avoidable.

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THE
NATIONAL LAW REVIEW

Lessons Learned from Medical Criminals



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Alerts

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Saturday, October 30, 2021

We present two case studies of medical criminals, a doctor and a nurses aid, to highlight the lessons learned and opportunities for effective peer review, credentialing, and early intervention to protect patient safety.

"***Doctors are Good***!" This statement reflects a foundational assumption of most people when accessing medical care for themselves or their family. Although rare, some doctors do bad things; in fact, some doctors and other health care providers are criminals. By studying the doctors and other health care providers who are caught and prosecuted for criminal wrongdoing relating to patient care, we have a distinct opportunity to learn where systems may be improved to identify and prevent the "bad doctors and other healthcare providers" from treating our patients, friends, family, and the unwary.

Robert Morris Levy, M.D.

"How did [the former Dr.] Levy[1] misdiagnose, or non-diagnose, 3,000 cases without having been discovered by audits or second opinions?" This public comment published with The Washington Post's article on former pathologist Robert Morris Levy strikes to the heart of what every medical staff professional seeks to protect against: a bad provider who is not identified through initial credentialing, recredentialing, or ongoing peer review. After being arrested and charged with 15 counts of manslaughter, in January 2021, Levy pleaded guilty to three counts of manslaughter and was sentenced to 20 years in prison.

How did this happen? The Department of Veterans Affairs Office of Inspector General ("OIG") undertook a comprehensive analysis of Levy's decade-long tenure as the Chief of Pathology at Veterans Health Care System of the Ozarks in Fayetteville, Arkansas, resulting in a lengthy report published on June 2, 2021.[2] The findings were stunning and pointed out multiple missed opportunities to identify and intervene during Levy's initial application, periodic recredentialing, and multiple staff reports of impairment when on duty.

OIG Investigation

After Levy was fired in 2018, the VA sent in a team of pathologists to conduct a "look-back[3]" and who reviewed 33,902 cases from 2005 to 2017. The team confirmed 3,619 misdiagnoses, 589 of which were determined to have the potential for negative impact on the veterans' patient care/treatment. Unfortunately, there was not merely the "potential" for negative impact but actual harm, with 15 fatalities directly attributable to Levy's erroneous diagnoses. Levy's misdiagnoses and falsification of records, through which he falsely claimed his peer concurred with his diagnoses, led to at least 15 deaths where veterans were either treated incorrectly or not treated at all. His mistakes delayed medical care for an unknown number of veterans and led to unnecessary treatment for others.

The retrospective review identified intervention opportunities that may have averted this tragedy, starting with Levy's initial application in 2005. He disclosed a previous conviction in 1996 related to driving while intoxicated. His background revealed he was only employed at his prior hospital for a period of eight months. Three of his peer references were from his most recent employment, with only one reference going back more than two years. Levy was initially hired as a *locum tenens* provider and almost immediately elevated to a service chief position. During his first two years of practice, his probationary period, he had a high error rate that was only identified during the look-back. As only one of two pathologists[4] there was no process in place to review Levy's pathology practice and establish his clinical competency during the probationary period. During reappointments, Levy's "peer" references were all from physicians who were not pathologists and who could not be expected to reasonably attest to his clinical competency.

Additionally, Levy was the chair of the pathology quality management committee and responsible for reporting the number of major diagnostic discrepancies (those that would affect the patient's clinical care) to the medical staff Tissue Committee and

Quality Management Committee. The Tissue Committee meeting minutes from November 2009 through September 2017 reflected *zero* major discrepancies, without any discussion challenging the data. This same information was reported to the hospital leaders. The hospital's quality management staff had the ability to generate reports of major diagnostic discrepancy cases from the computer system but failed to do so during Levy's tenure. This occurred despite hospital leadership's knowledge that a patient received incorrect treatment in 2014, resulting from an amended pathology report that reflected a major diagnostic discrepancy. Surprisingly, there was no increased scrutiny of Levy's pathology cases following discovery.

Throughout his tenure Levy was subject to peer review as part of the medical staff's ongoing provider practice evaluation ("OPPE"). But that peer review was limited to a random selection of 10 percent of his cases which were overread by another external pathologist. However, this random selection OPPE process would not and did not detect the error rate identified during the retrospective review. The College of American Pathologists ("CAP") provides the following guidance for peer review: "there is evidence that targeted review (review of a specific type of case) is more efficient at finding important diagnostic discrepancies or errors than randomly selecting cases for review."[5] Unfortunately, the VA did not follow the CAP guidance which would have provided an opportunity for earlier detection.

Impairment

The failure to follow-up on the items in Levy's initial application related to his prior DUI, lack of "peer" references of the same specialty, and failure to follow the CAP guidance on peer review, were signs that might have led to an earlier intervention and potential discovery of the problem. Perhaps the most concerning misstep was the failure of medical staff leadership to effectively intervene in light of multiple reports of Levy's possible impairment. The chief of staff received periodic informal reports that Levy smelled like alcohol. On one occasion in 2014, the chief of staff investigated, and Levy said he had been drinking a lot of juice, which caused the odor. Levy was not required to take a blood or urine test and no further investigation occurred at that time. In 2015, there were two additional reports to the chief of staff that Levy had the odor of alcohol, red glassy eyes, and hand tremors. Levy voluntarily agreed to testing, but due to misinformation received from human resources, the testing was not performed. In 2016, Levy was again reported for signs of impairment and agreed to testing. The testing showed Levy to have a high blood alcohol level. Levy was immediately removed from clinical care and sent for rehabilitation. After completing a three-month inpatient alcohol treatment program, Levy was allowed to return to work and later received a bonus for stellar performance. However, the medical staff leadership did not conduct ongoing monitoring after Levy returned to clinical practice. By this time, Levy was ordering a substance on the internet known as 2-methyl-2-butanol (2M2B), which would mask the alcohol level in his blood in the event a blood test was required.

Part of the justification for allowing Levy to return to work was the lack of evidence of adverse clinical outcomes. However, the medical staff had not conducted a comprehensive review of his cases. Additionally, leadership did not investigate previously reported concerns that Levy had subverted the pathology and laboratory

quality management program, repeatedly misrepresented second reviews of cases, and was deficient in communication with providers when there were significant changes in diagnoses. Although medical staff policy required a second read by a different pathologist when there was a new diagnosis of cancer, Levy was entering concurrence statements into some patients records when a second pathologist had not reviewed the pathology slides or agreed with the interpretation or diagnosis. This pattern was not discovered until the retrospective review.

Termination (finally…)

Levy was removed from clinical practice and terminated in 2018 when he was arrested for driving under the influence. Only then did the medical staff engage in the retrospective review, with its findings followed by Levy's arrest and charges for manslaughter and mail fraud.[6]

Reta Mays: Medical Serial Killer

"Medical Serial Killers" are a rare but known phenomenon.[7] Reta Mays was a nursing assistant at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia. On July 14, 2020, she pleaded guilty to seven counts of second-degree murder and one count of assault with the intent to commit murder of patients at the VA Medical Center. Ms. Mays pleaded guilty to deliberately administering insulin to these patients in 2017 and 2018, resulting in hypoglycemia and death. Ms. Mays admitted that she intentionally administered the insulin because she believed the patients were suffering and she wanted them to pass "gently."

After the Office of Inspector General ("OIG") became involved, a lengthy investigation ensued which encompassed review of 200 patient deaths, thousands of documents, and 75 interviews. "The OIG found that the facility had serious, pervasive, and deep-rooted clinical and administrative failures that contributed to Ms. Mays's criminal actions not being identified and stopped earlier."[8] The OIG blamed weaknesses in many of the facility's systems and culture of safety for the devasting consequences.

Background

Prior to joining the VA, Ms. Mays had been with the Department of Corrections where she had been the subject of multiple allegations of excessive force. However, before hiring Ms. Mays in June 2015, no one at the VA contacted her prior employer to determine her employment status, skills, and performance. Ms. Mays's background information was not reviewed even though it had been flagged. Potentially, had this simple step been followed, Ms. Mays might not have been hired.

Additionally, while Ms. Mays was given excellent performance ratings, according to her supervisors, she was verbally counseled for improperly accessing a blood sample from a blood tube, leaving a patient in soiled bedding at the end of her shift, repeated incidents of disconnecting IV lines, and turning off or clearing IV pump data.

According to facility policies, Ms. Mays was not allowed access to the medication room nor medication carts. However, the investigators learned that, in practice, Ms. Mays and other nursing assistants had full access to the medication room. The pharmacy failed to identify the high use of both insulin and the medications used to reverse hypoglycemia at the facility, both of which were evident on retrospective review, but were never identified and brought to leadership's attention.

Peer Review Deficiencies

The medical workup of the patients with hypoglycemia failed to adequately evaluate the cause of hypoglycemia in patients. Hypoglycemia is rare in patients who are not receiving medication for diabetes. External causes should have been considered when the initial evaluation failed to identify a clinical cause for the patient's hypoglycemia. In one case, the hospitalist considered surreptitious insulin administration and discussed his concerns with the nurse manager. However, the hospital and medical staff conducted no further follow-up. The hospitalists also failed to order an endocrinology consultation, which may have led to further scrutiny and detection of external insulin administration.

Medical record documentation was found to be scarce and sometimes lacking altogether, which further led to the failure to detect Ms. Mays's activities. Lack of adequate and comprehensive documentation, combined with a lack of communication regarding patients and their unexplained episodes of hypoglycemia during hand-off to the next hospitalist, was a significant contributing factor to the failure to detect Ms. Mays's acts. The fact that the hospitalists were working varying shifts and the absence of meaningful communication contributed to the hospitalists failing to identify the pattern of hypoglycemic episodes and deaths at the hospital.

Other contributing factors to Ms. Mays's ability to continue to harm patients was the failure to follow policies on reporting of adverse events. The unexplained hypoglycemic episodes and deaths would have qualified for adverse event reporting but were not reported. The quality program did not contain critical quality information. The mortality review conducted by the risk manager was superficial even though the hospital had a cluster of deaths attributed to hypoglycemia.

Discovering a Medical Serial Killer

In 2018, the VA Facility Director identified the pattern of unexplained deaths from hypoglycemia and called for an investigation that ultimately identified Ms. Mays and her involvement. Ms. Mays was removed from her employment once the investigation was completed. Ms. Mays was later criminally charged and received seven life sentences for her acts.

Lessons Learned (again)

Not unlike the Texas criminal prosecution of Christopher Duntsch, aka Dr. Death, for two patient deaths and multiple adverse outcomes, Levy and Ms. Mays presented several opportunities for the hospital, its medical staff, and leadership to detect and prevent Levy and Ms. Mays from engaging in further clinical practice. And, like Duntsch, it was the criminal justice system that brought final resolution for the

patients and their families when the credentialing, peer review and quality systems failed.

Conclusion

The cases of the former Dr. Levy and Ms. Mays emphasize the need for careful credentialing, peer review, and identification of red flags. Background checks must be appropriately scrutinized. Peer references must be from peers who can attest to an individual's clinical competence and those references should cover at least the past five years. Hospitals and healthcare organizations must have an effective peer review system that includes a meaningful review of cases using peer review indicators or processes that are published, supported by objective evidence, and proven to be effective. If the hospital has a small number of providers in the specialty under review, make arrangements with other institutions or external review organizations to conduct periodic reviews targeted to identify problems. When long periods of internal review of a service never identify a problem or opportunity for improvement, scrutinize, and revamp the review process. Assume that perfect clinical outcomes for prolonged periods are not the norm and find new ways to look at the data. Conduct prompt and thorough mortality reviews. If the death is unexplained, look further and always look for patterns. Most importantly, take complaints about providers related to competence, quality, or impairment seriously and follow up. Know that a blood or urine test may not reveal drug or alcohol use – the clinical signs of impairment must be taken just as seriously as objective diagnostic tests.

No peer review system is perfect. Continued vigilance and avoiding complacency are the best defenses to rare criminal medical providers.

FOOTNOTES

[1] When Levy lost his license, he was no longer allowed to use the title of "Doctor"

[2] www.va.gov/oig/publications/report-summary.asp?id=4945

[3] "Look-back" was the term used in the OIG report to describe the retrospective review of cases.

[4] The other pathologist was Levy's subordinate and not in a position to perform peer evaluation.

[5] College of American Pathologists, "About Us," The College of American Pathologists is an organization of board-certified pathologists. Association of Directors of Anatomic and Surgical Pathology, "Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology,"

[6] Mail fraud was the result of purchasing 2M2B on the internet.

[7] Medical Serial Killers: The So-Called Angels of Mercy, Crimetraveller.org, May 31, 2021

[8] Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia, Veterans Health Administration, Office of Healthcare Inspections, Report #20-03593-140, May 11, 2021.

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PERSPECTIVE

Time to End Physician Sexual Abuse of Patients: Calling the U.S. Medical Community to Action

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Despite the strict prohibition against all forms of sexual relations between physicians and their patients, some physicians cross this bright line and abuse their patients sexually. The true extent of sexual abuse of patients by physicians in the U.S. health care system is unknown. An analysis of National Practitioner Data Bank reports of adverse disciplinary actions taken by state medical boards, peer-review sanctions by institutions, and malpractice payments shows that a very small number of physicians have faced "reportable" consequences for this unethical behavior. However, physician self-reported data suggest that the problem occurs at a higher rate. We discuss the factors that can explain why such sexual abuse of patients is a persistent problem in the U.S. health care system. We implore the medical community to begin a candid discussion of this problem and call for an explicit zero-tolerance standard against sexual abuse of patients by physicians. This standard must be coupled with regulatory, institutional, and cultural changes to realize its promise. We propose initial recommendations toward that end.

KEY WORDS: medical board; sexual abuse; sexual misconduct; National Practitioner Data Bank; zero tolerance.

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The prohibition against physician sexual relations with their patients, which can cause lasting damage to patients, is one of the most universally agreed upon ethical principles in medicine. For example, in 1991, the American Medical Association (AMA) declared unequivocally that these relations are unethical, noting that this prohibition was incorporated into the Hippocratic oath.[1] Other professional medical organizations and state medical boards have echoed this stance.

Yet numerous reports of physicians who have violated this prohibition (such as the disgraced gymnastics physician, Lawrence Nassar) indicate that more definitive action is needed to prevent physician sexual abuse of patients in the U.S.A.

In this Perspective, we discuss the available evidence on the extent of physician sexual abuse of patients in the U.S.A. and factors that contribute to this problem, and we propose recommendations to safeguard against it.

Sexual contact between a physician and a patient or any behavior or remarks of a sexual nature by physicians toward patients have been legally considered sexual abuse since 1994 in Ontario, Canada, under the province's Regulated Health Professions Act, which defines sexual abuse as[2]: "(a) sexual intercourse or other forms of physical sexual relations between the [physician] and the patient, (b) touching, of a sexual nature, of the patient by the [physician], or (c) behavior or remarks of a sexual nature by the [physician] towards the patient." One explicit purpose of the Ontario law is "to eradicate the sexual abuse of patients by [physicians]." The term sexual abuse does not exist in U.S. state regulations of physicians. In lieu of "sexual abuse," the U.S. medical community, including the Federation of State Medical Boards (FSMB), uses the term "sexual misconduct" to characterize this unethical behavior. Although U.S. definitions of sexual misconduct tend to overlap with Ontario's definition of sexual abuse, the former term encompasses misconduct that does not involve patients and fails to connote the profound unethical nature of sexual relations between physicians and their patients.

DATA ON PHYSICIAN SEXUAL ABUSE AND SEXUAL MISCONDUCT

A 2017 exploratory analysis of 101 cases of physician sexual abuse of patients found that the primary forms of abuse in these cases were inappropriate touching (33%), sodomy (31%), rape (16%), child molestation (14%), and purportedly consensual sex (7%).[3] It also revealed that certain patient characteristics (such as female gender and young age) and certain physician characteristics (including male gender, age greater than 39, and consistently examining patients alone in nonacademic settings) were associated with physician sexual abuse.[3] However, the authors concluded that "there were no necessary conditions for [sexual abuse] cases to occur except for the sexual urges of the physicians."

A 1998 study identified 567 U.S. physicians who were disciplined by state medical boards from 1981 through 1996 for sex-related offenses (including sexual intercourse, rape,

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sexual molestation, and sexual favors for drugs), 75% of which involved patients. These violations would have been considered physician sexual abuse of patients as defined by the aforementioned Ontario law.[4]

Our 2016 analysis of data from the U.S. National Practitioner Data Bank (NPDB) showed that from January 2003 through September 2013, 862 physicians had state licensing disciplinary actions because of sexual misconduct, totaling 974 such actions.[5] These numbers represent fewer than 0.1% of all licensed U.S. physicians.[5] The U.S. rate of such disciplinary actions was approximately 9.5 per 10,000 physicians per 10 years. Importantly, the NPDB Public Use Data do not report any details about the nature of the sexual misconduct.

In comparison, data from a 2011 study of disciplinary actions by medical licensing authorities in Canada from 2000 to 2009[6] showed an approximate rate of disciplinary actions for sexual misconduct of 25.1 per 10,000 physicians per 10 years. Thus, the Canadian rate of discipline for sexual misconduct was 2.6 times higher than the U.S. rate. Like the U.S. study, the Canadian study did not characterize the nature of the sexual misconduct. Also, neither study reported the proportions of sexual misconduct that involved patients.

Despite the limitations of both studies, the difference in the rates of disciplinary actions for sexual misconduct by U.S. and Canadian medical licensing authorities likely reflects more frequent detection and disciplining of physicians who commit sexual misconduct in Canada rather than more frequent sexual misconduct by Canadian physicians; there is no evidence that Canadian physicians are more prone to sexual misconduct than U.S. physicians.

Studies analyzing reports of disciplinary actions for physician sexual misconduct likely underestimate the scope of the problem. For example, a 1996 anonymous random national survey of U.S. physician members of the AMA (response rate = 52%) showed that 3.4% of the respondents reported a history of personal sexual contact (genital–genital, oral–genital, or anal–genital) with one or more patients.[7]

FACTORS THAT ALLOW THIS PROBLEM TO PERSIST

Several factors may explain why physician sexual abuse of patients continues to be a persistent problem in the U.S.A. First, many cases of physician sexual abuse of patients go unreported. This is because patients may be shocked and consumed by feelings of disbelief, guilt, or shame; may be fearful that they will not be believed due to the significant power imbalance between physicians and their patients; or may be unwilling to publicly disclose the abuse. Additionally, victims may not know how to navigate the regulatory system to seek redress for the harms of physician sexual abuse, such as filing a complaint with the state medical boards that licensed the physicians. Even when they file complaints, victims can be further traumatized by the investigation and legal procedures, which may lead them to withdraw their complaints. Importantly, physicians often are unwilling to report their impaired or incompetent colleagues to relevant authorities,[8] likely due to the absence of enforceable legal mandates for such reporting.

Second, according to the FSMB, many hospitals and health care organizations regularly ignore or circumvent reporting requirements for medical boards regarding impaired physicians.[9]

Third, medical boards may not always act on complaints of physician sexual abuse of patients, especially when there is no material evidence or witnesses.[10, 11] A 2006 report found that two-thirds of all complaints received by medical boards were closed either due to inadequate evidence to support the charges or because these cases were resolved informally, through a notice of concern or a similar communication with the involved physician.[12] The report noted that only 1.5% of the overall complaints to medical boards reached the formal hearing stage.

There is evidence that even when medical boards discipline physicians for sexual abuse, those physicians often are permitted to resume medical practice. For example, a 2016 nationwide investigation of thousands of medical board orders for physicians who were disciplined for sexually abusing patients or other sex-related offenses since 1999 found that more than one-half of these physicians were still licensed to practice.[13] Little information exists on the effectiveness of possible safeguards, such as counseling of sexually abusive physicians, to prevent recidivism and possible harm to future patients. Additionally, the aforementioned 2016 NPDB analysis showed that medical boards did not discipline 70% of the physicians who had peer-review sanctions or malpractice payments made on their behalf due to sexual misconduct.[5]

PROPOSED RECOMMENDATIONS TO ADDRESS PHYSICIAN SEXUAL ABUSE OF PATIENTS

Physician sexual abuse of patients must be classified as "never events": No patient should ever experience any form of sexual abuse, or fear of being subjected to such behavior, by a physician. We offer the following recommendations as initial steps to reach this goal:

(1) Replace the term "sexual misconduct" currently used in the U.S. medical community with the term "sexual abuse" when referring to any physician conduct that meets the Ontario Regulated Health Professions Act's definition of the latter term. Furthermore, the U.S. medical community and all state medical practice acts, as the Government of Ontario and the Medical Council of New Zealand[14] did, should adopt an explicit "zero-tolerance" standard against all forms of physician sexual abuse of patients. This standard should be incorporated into all applicable policies and regulations governing U.S. physicians.

(2) Educate physicians at every stage of their training and careers about the enormity of sexual abuse of patients, how to avoid it, and how to seek help if they are struggling with challenges to their professional boundaries with patients.
(3) Educate the public about how to prevent, recognize, and report physician sexual abuse. This should be a shared responsibility between state medical boards and health care institutions.
(4) Encourage and facilitate patient and patient surrogate reporting of all forms of physician sexual abuse. This recommendation can be accomplished by having health care institutions and medical boards establish standardized processes, which should be made known to patients and their surrogates, for filing complaints regarding any physician sexual abuse they may have experienced or witnessed and hiring patient-advocate professionals with whom patients and their surrogates can be encouraged to discuss such allegations.
(5) The medical community should mandate reporting by physicians and other health care professionals of any witnessed or suspected physician sexual abuse of a patient and should institute necessary measures to prevent reprisal against individuals who make such reports. Penalties for failing to report physician sexual abuse of patients should be set and enforced. Educational bystander intervention training should be encouraged to equip physicians and other health care professionals with the skills necessary to take appropriate action if they witness or suspect physician sexual abuse of patients.
(6) Medical boards and health care institutions should investigate each complaint of alleged physician sexual abuse of patients and conduct hearings if there are grounds for proceeding (while providing due process for the accused physician and for patient witnesses). The 2006 FSMB guidelines for state medical boards for dealing with physician sexual misconduct are a good resource.[15] However, these guidelines need to be vetted further by other stakeholders to determine the best practices for handling these cases. Similar guidelines are needed for health care institutions. We acknowledge that innocent physicians may be falsely accused of sexual abuse. Therefore, all complaints of alleged physician sexual abuse of patients should be pursued fairly and through due process.
(7) Health care institutions and medical boards should discipline physicians who are found to have engaged in any form of sexual abuse of patients. Health care institutions should be required to report physicians found to have engaged in such behavior to the appropriate medical board. Clear penalties (including suspension and revocation of medical license and clinical privileges) should be established and enforced by the medical community. The severity and length of these penalties should be based on the severity of the type of sexual abuse. In no case should public safety be compromised for any financial consideration, such as the revenue generated by the offending physician.
(8) Health care institutions and medical boards also should report physicians who were found to have engaged in sexual intercourse or other forms of physical sexual relations or touching of a sexual nature of a patient to law enforcement authorities in all cases, not just when the victim is a child.
(9) Medical boards should disclose on their websites complete information concerning all disciplinary actions against physicians who have been found to have sexually abused their patients.
(10) Health care institutions and medical boards should establish and fund programs to provide subsidized psychological counseling for all patients who were found to have been abused by their physicians. These institutions can seek reimbursement for such costs from the sexually abusive physicians.
(11) Health care institutions should provide trained chaperones to act as "practice monitors" during breast, full-body skin, genital, and rectal exams, having previously discussed this issue when patients first seek care.[16] The offer should be made regardless of the physician's gender.[17]

CONCLUSION

It is time for the U.S. medical community to begin a candid discussion of what needs to be done to end physician sexual abuse of patients. Each medical board, professional organization, and health care institution should evaluate its current systems and procedures regarding this problem and should take comprehensive and stronger actions, including seeking legislation, to protect patients from all physicians who evade medical ethics, betray the trust of their patients, and exploit the patient–physician relationship for their own sexual gratification.

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Compliance with Ethical Standards:

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News

Urologist who was jailed for manslaughter is allowed back to work

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Clare Dyer

Author affiliations

A consultant urologist who was jailed for manslaughter after he failed to treat a life threatening infection in a young mother quickly enough has been allowed to return to work under conditions set by a fitness to practise panel.

Sudhanshu Garg, 46, served one year of a two year jail sentence after he pleaded guilty to manslaughter through gross negligence in 2012.**1** He also admitted having altered patient notes in an attempt to cover his mistake.

In August 2008 he had been on call over the bank holiday weekend at Bradford Royal Infirmary, in his first consultant post, when Lisa Quinn, 37, was admitted with a kidney infection. Garg saw her 24 hours after admission, but he did not order an ultrasound scan or take the opportunity to transfer her to Leeds for emergency treatment, despite what the court heard was a “rapidly developing and life threatening infection.”

Quinn finally underwent a nephrostomy three days after her admission but died three hours after the operation. Garg later falsified her notes in what the judge called “a blatant attempt to disguise and conceal evidence of your failures.” If Garg had performed his duties correctly, the judge said, “the overwhelming probability is that she could have survived.”

Garg served one year in prison and one on licence. Soon after his release, in July 2013, he appeared before a panel of the Medical Practitioners Tribunal Service and was suspended for 12 months. This week’s hearing sought to establish his fitness to return to practice.

In an unusual display of unanimity, Garg’s counsel and the barrister for the General Medical Council both agreed that his fitness to practise was still impaired because he had not kept his medical knowledge fully up to date. They both suggested that he be allowed to return to work with conditions. The panel chairman, Jack Crane, told Garg that the panel “considered that you had paid your debt to society and that you should be given an opportunity to demonstrate full remediation of your failings.”

Quinn’s death had been “a single isolated incident and not a pattern of misconduct or deficient professional performance,” said Crane. He added, “This serious incident occurred in a difficult and intimidating working environment where communication was poor. Further, at the time of the event in question, you had been on call for

eight or nine days and nights and were acutely distressed and confused when you altered the patient's medical records following her death.

"It is clear that you recognise your own limits and that your approach to returning to clinical practice is a cautious one, having regard to the importance of patient safety."

The panel imposed conditions on Garg's registration for 18 months, requiring that he work in the NHS only, that he not undertake any short term locum work, that he appoint a workplace reporter and educational supervisor, and that he notify regulators of any post that he takes up.

Garg told the panel that he planned initially to return to India, to work in his father's clinic and at a nearby hospital there, but that he hoped to return to the United Kingdom later. Although the conditions imposed by the panel for 18 months can begin to apply only when he returns to the UK, Garg told the panel he intended to follow them informally during his time in India.

Notes

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When Do Opioid Prescribers Become Criminals?

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Abstract

In February 2016, Dr. Hsiu-Ying Tseng was sentenced to 30-years to life in prison after a jury found her guilty of second-degree murder for three patient drug overdose deaths in California. For the first time in American history, a physician was held criminally liable for the murder of a patient by means of extreme recklessness in opioid prescribing. Although Dr. Tseng's unique conviction reflects her outlier prescribing practices, the conviction and sentencing has sent ripples through the medical community, causing concerns for many physicians who now worry they will be held criminally liable when their patients abuse and misuse opioid prescriptions. However, physicians—particularly the majority that prescribe opioids in an earnest attempt to alleviate legitimate patient pain—may take comfort that the legal risks can be managed. Prescribers can take a number of steps to minimize criminal liability concerns, including following available guidelines, such as those recently issued on opioid prescribing for chronic pain by the Centers for Disease Control and Prevention. While outlier physicians like Dr. Tseng may meet the standards for criminal liability, criminal prosecution may do little to curb prescription opioid abuse—an epidemic that calls for more upstream prevention measures.

In February 2016, a California judge sentenced Dr. Hsiu-Ying Tseng ("Dr. Tseng") to 30-years to life in prison after a jury found her guilty of second-degree murder for three patient drug overdose deaths.[1] This marked the first time in American history that a physician was held criminally liable for the *murder* of a patient by means of extreme recklessness in opioid prescribing. Although Dr. Tseng's unique conviction reflects her outlier prescribing practices, the recently spotlighted potential for criminal penalty may have a chilling effect on physicians treating patients for pain.

A general practitioner in southern California since 2007, Dr. Tseng played a role in at least twelve patient overdose deaths, all by prescribing opioids in dangerous ways—namely, in high quantities or dosages, with polypharmacy potential, and with limited knowledge of patient symptoms or history.[1] Despite receiving repeated warnings from coroners and law

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enforcement officials that her patients fatally overdosed on their medication, Dr. Tseng failed to alter her practices.[1] While Dr. Tseng's explicit awareness and conscious disregard of the risks resulted in a murder conviction, the case is unlikely to increase the prospect of criminal charges for the majority of opioid prescribers legitimately treating patients with pain. Moreover, while the small number of physicians who truly act as drug dealers or grossly deviate from recommended clinical practices warrant criminal prosecution, this approach may do little to curb prescription opioid abuse—an epidemic that calls for prevention and treatment measures of broader scope.

Criminal Liability for Prescribers

The recent move to hold physicians like Dr. Tseng criminally responsible for patient overdose is a logical extension of the prescription opioid epidemic's iatrogenic roots. A heightened focus on adequate pain management in the 1990s and early 2000s liberalized opioid prescribing.[2] Prescribers even faced threats of tort liability and medical licensing board sanction for inadequate opioid prescribing for chronic pain.[2] This climate change that legitimized opioid prescribing resulted in sharp increases in the supply and prescribing of opioids and laid the foundation for abuse.[3]

As fatal overdoses involving prescription opioids increase, a small but growing number of physicians face criminal charges for opioid prescribing under state homicide or controlled substance laws or the federal Controlled Substances Act (CSA).[4,5] Physicians traditionally confront civil medical malpractice suits, restrictions on hospital privileges, and medical board discipline related to patient injuries attributed to their care, including negligent prescribing.[5] But more recently, extreme cases like Dr. Tseng's raise the question: when do physician opioid prescribing behaviors become criminal?

Although there is no clearly defined threshold for a prescriber to be criminally (as opposed to civilly) charged, he or she must exhibit a blameworthy, or culpable, state of mind.[6] Murder charges under state homicide laws can follow when a physician engages in risky opioid prescribing that is likely to result in an adverse consequence, such as death, *purposefully* or with a *subjective understanding* of the risks (Table). Lesser involuntary manslaughter (sometimes termed "criminal negligence") charges require *reckless* prescribing, where the prescriber should have been aware of the risks but evidence suggests they subjectively did not appreciate them (Table). Under the CSA and many comparable state controlled substance laws, it is a crime to prescribe controlled substances, such as opioids, for reasons other than a legitimate medical purpose and in the usual course of professional practice.[4]

While a medical malpractice suit might settle for $500,000, leaving a blemish on a physician's record but inflicting little punishment other than the monetary fees (traditionally covered by physician malpractice insurance), stiffer penalties are imposed on criminals. Those convicted of murder, like Dr. Tseng, can face significant prison time or even the death penalty (Table). Involuntary manslaughter charges typically carry shorter prison times or substantial fines or both (Table). Furthermore, if a physician is convicted of murder or manslaughter, his or her license can be permanently revoked by the state medical board,

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making such charges an enticing option for prosecutors aiming to deter improper prescribing in egregious cases.[5] Penalties for violations of the CSA or state controlled substance laws can also be harsh (Table) and are often accompanied by medical board temporary suspensions of physicians' licenses.[5]

Regrettably, no clear guideposts mark what makes an opioid prescriber a criminal, given varied prescribing contexts and legal standards across states.[5] Juries often have a hard time assessing a prescriber's culpable state of mind and therefore look to objective practices to infer what the prescriber was thinking.[6,7] Objective evidence presented in Dr. Tseng's case and others that resulted in criminal charges include: explicit notice of patient overdoses but failure to change prescribing; failure to conduct thorough patient exams and take histories (including asking about drug use); prescribing in extremely high volumes (e.g., thousands of prescriptions per year) and dosages; and being linked to a pattern of patient overdose deaths (Table). Although such elements increase the perception of criminal wrongdoing, actual convictions can be highly unpredictable and circumstantial.

Beyond the Criminal Justice System

New possibilities for murder conviction carry important implications for how physicians approach opioid prescribing going forward. As the medical community is often risk-averse, the threat of consequences like Dr. Tseng's, coupled with an inability to fully control the environment in which patients receive and self-administer prescription drugs, may render physicians more reluctant to prescribe opioids, even when benefits of their use may outweigh harms. The inadvertent aftermath may be undertreated patients with chronic pain. In some cases, such as in rural America, finding alternative treatment may not be a possibility for patients.

However, physicians—particularly the majority who prescribe opioids in an earnest attempt to alleviate legitimate patient pain—may take comfort that the legal risks can be managed. Prescribers can take a number of steps to minimize perceived commission of a crime. In broad strokes, physicians should vigorously validate that opioid treatment is a clinically appropriate option for their patients, assiduously assure that the patients remain appropriate candidates post-prescribing, and readily revise the course of treatment if patients manifest any indications of abuse.[5] Specific actions physicians can take to minimize their criminal liability exposure include: taking thorough patient histories and performing clinical tests to assess symptoms and abuse potential; educating themselves on appropriate pain prescribing and patients as to opioid risks; checking their state prescription drug monitoring programs (PDMPs) for abuse flags or polypharmacy concerns; following available guidelines, such as those recently issued on opioid prescribing for chronic pain by the Centers for Disease Control and Prevention;[3] referring patients to pain specialists when appropriate; and carefully documenting the above actions in a patient's medical file.

While some see criminal convictions as a positive step that may deter future dangerous prescribing, more likely they will have little impact on the larger epidemic to which physicians and prescribing norms contribute heavily. Rather than a small subset of physicians accounting for a disproportionately large percentage of opioid prescribing, the

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phenomenon is distributed across many prescribers.[8] Although certain rogue providers, like Dr. Tseng or "pill mill" clinics that dole out large quantities of opioids, exhibit criminal culpability, blameworthiness for widespread opioid over-prescribing in the broader medical community is less clearly attributed.[3] Many drug seekers—like the two college students who drove over 300 miles in pursuit of quick prescription fixes before returning home and overdosing in the murder case against Dr. Tseng[1]—are already addicted before resorting to drug-dealing physicians. Dr. Tseng's behavior and that of "pill mills" engaged in irresponsible, outlier opioid prescribing, warrant criminal charges and medical board discipline, to send a clear message to those tempted by the pecuniary gain. But, combating opioid abuse in America will require going beyond the criminal justice system and instead focus on more judicious, informed opioid prescribing across all contexts. Specific prevention measures—such as the prescriber steps recommended above that serve the dual benefit of reducing physician liability exposure, developing better tools to help prescribers identify at-risk patients,[9] making the opioid overdose reversal drug naloxone more readily available, increasing addiction treatment availability, and better understanding individual propensities toward addiction— will go much further towards addressing prescription opioid abuse.

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Table:

High Profile Criminal Cases against Opioid Prescribers for Patient Overdoses.

Case	Description of Criminal Charges	Level of Criminal Intent	Potential Penalties	Outcome of Case
***State of Florida v. Gerald Klein*, Florida Palm Beach County Circuit Court, Palm Beach County (2015)**	Dr. Klein was charged with **first-degree murder** for the 2009 overdose death of 24-year old Joseph Bartolucci. Dr. Klein was accused of causing Bartolucci's death by overprescribing opioid pain medications and his clinic was accused of pumping thousands of hydromorphone and oxycodone pills into the community on a daily basis in complete disregard of the safety of the community.	Florida state laws specify first degree murder for a homicide caused by unlawful distribution of controlled substances *knowingly*. No *premeditation* requirement, but the drug must be proven to be the proximate cause of the death of the user. (Fla. Stat. §782.04(1)(a)3).	Death penalty or life imprisonment without the possibility of parole (Fla. Stat. §775.082(1)).	The jury acquitted Dr. Klein on the first-degree murder charge, as the patient was found responsible for his own death, but Dr. Klein was convicted on one minor drug charge.
***State of California vs. Hsiu-Ying Tseng*, Superior Court of California, County of Los Angeles (2016)**	Dr. Tseng, was arrested in 2012 on **second degree murder** charges for the overdose deaths of Joey Rovero, Vu Nguyen, and Steven Ogle as a result of prescriptions she wrote. Despite being notified over a dozen times that her patients had overdosed, Tseng continued irresponsible prescribing practices. According to evidence presented, these included: providing prescriptions in as little as three minutes and absent a physical exam to patients with evidence of addiction; and writing more than 27,000 prescriptions over a three-year period starting in January 2007 (an average of 25 per day).	Unlawful killing of a human being with *malice aforethought* (i.e., with an appreciation of the risk). (Cal. Pen. Code § 187–189).	Imprisonment for 15 years to life (Cal. Pen. Code § 190(a)).	The jury found Dr. Tseng guilty of second degree murder. The judge sentenced Dr. Tseng to 30-years to life in prison.
***State of Iowa v. Daniel J. Baldi*, Iowa District Court, Polk County(2014)**	Pain specialist Dr. Baldi was charged with seven counts of **involuntary manslaughter** for the overdose deaths of his patients, including Paul Gray, the bassist of the band Slipknot. Baldi was accused of unintentionally causing Gray's death by writing high-dose prescription opioids, to a known addict from December 2005-May 2010.	Unintentionally causing the death of a human being, including by the commission of an act in a manner likely to cause death or serious injury (Iowa. Code § 707.5).	Imprisonment for up to 2 years and fines of at least $625 but not to exceed $6,250 (Iowa. Code § 903.1(2)).	The jury acquitted Dr. Baldi on all involuntary manslaughter charges, as there was no clear evidence showing the patients in question died from overdoses of drugs the Dr. Baldi prescribed.
***United States v. William E. Hurwitz*, United States District Court for the Eastern District of Virginia (2007)**	In a retrial, Dr. Hurwitz was charged with over 50 counts of **drug trafficking**, including several counts of drug-trafficking resulting in serious bodily injury and drug-trafficking resulting in death in 2004. He was accused of distributing pain medicine in violation of the Controlled Substances Act.	*Knowingly* and *intentionally* distributing drugs outside the bounds of medical practice (21 U.S.C. § 841(a)).	Imprisonment for up to 20 years and fine of $1 million (21 U.S.C. § 841(b)).	In the retrial, the jury found Dr. Hurwitz guilty of 33 counts of drug trafficking. The judge sentenced Dr. Hurwitz to four years and nine months in prison.

PHYSICIANS WHO BREAK THE LAW

DIANE E. HOFFMANN*

The medical profession has, of course, many dedicated people who give of themselves and literally sacrifice their own interests for the sake of their patients. The point is that medicine has its share of both angels and scoundrels.[1]

INTRODUCTION

In her article, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, Sandra Johnson focuses on doctors who comply with the law despite their belief that the law is "bad," i.e., causes them to behave in ways that are harmful to their patients.[2] Physicians who obey laws they claim are bad may hurt patients by failing to treat them or treating them inappropriately. They may under-medicate their patients or subject them to unnecessary procedures or tests. These laws may also have a "chilling effect" on physician behavior, causing them not only to inadequately treat their own patients but also to refuse to see certain types of patients, e.g., those who are "the sickest or highest-risk,"[3] or to provide patients with certain kinds of

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1. DAVID MECHANIC, MEDICAL SOCIOLOGY 116 (2d ed. 1978), *quoted in* Paul D. Jesilow et al., *Medical Criminals: Physicians and White-Collar Offenses*, 2 JUST. Q. 149, 163 (1985).

2. Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973 (2009). Johnson provides the following examples of bad law claims:

> [M]alpractice litigation that makes doctors practice "defensive medicine"; . . . patients' rights that make doctors provide futile care; . . . controlled substances laws that require [doctors] to neglect their patients in pain or to deny their patients the sterile injection tools that would prevent the spread of disease; . . . antitrust laws that prevent doctors from organizing themselves in ways that would produce more cost-effective and accessible care; and . . . regulations that impede important medical research.

Id. at 974–75 (footnotes omitted).

3. John Liederbach et al., *The Criminalization of Physician Violence: Social Control in Transformation?*, 18 JUST. Q. 141, 165 (2001).

treatment or services.[4] Such physicians may be described as overly cautious or as "over-complying" with the law. They stay far away from the line demarcating what is legal and illegal.[5]

There are a number of reasons why physicians might over-comply with the law, e.g., the law's complexity and uncertainty, the fact that they misunderstand the law, or the possibility that they have unique personal characteristics that make them more sensitive (i.e., risk averse) to entanglements with the law.[6] Research on the deterrence value of law has shown that "[p]eople who have conventional values or strong social ties are . . . easier to deter, possibly because arrest—or other legal action—brings the offence to the attention of other (conventional) people who matter to them and thereby jeopardise valued social relationships."[7] In the case of physicians, such action would also significantly affect their reputation, and thus may lead to hypersensitivity to possible arrest for violation of the law.

4. *See, e.g.*, Lawrence O. Gostin, Commentary, *Abortion Politics: Clinical Freedom, Trust in the Judiciary, and the Autonomy of Women*, 298 JAMA 1562, 1563 (2007) (arguing that the Partial-Birth Abortion Ban Act, upheld by the Supreme Court in *Gonzales v. Carhart*, 550 U.S. 124 (2007), will have a chilling effect on physician willingness to perform procedures used to end medically dangerous pregnancies); Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231, 309 (2008) (describing the chilling effect of the Controlled Substances Act and its enforcement on physician willingness to treat chronic pain patients or to prescribe opioids for pain management); Blaine Harden, *Court Rules on Aided Suicide*, WASH. POST, May 27, 2004, at A2 (stating that the 2001 "Ashcroft Order," regarding the illegality of prescribing controlled substances for assisted suicide, had a chilling effect on Oregon physicians carrying out requests under Oregon's assisted suicide law).

5. These physicians practice in a way that is in the 40%–60% range, rather than the 30%–70% range, of the safe harbor that Professor Johnson describes. *See* Johnson, *supra* note 2, at 1018–22. Johnson uses an illustration to show how doctors often operate well inside the "safe harbor" range. She asks the reader to

> assume a range of interventions from 1 to 100, and that the range of appropriate treatment lies between 10 to 90. To retain a margin for prosecutorial or regulatory discretion in individual cases, the clinical safe harbor is set to cover behavior in the range of 30 to 70. This means that while doctors practicing in the range between 10 and 30 and between 70 and 90 are engaged in legitimate medical practice, they simply are not guaranteed protection from government scrutiny.

Id. at 1021. She asserts, "[t]he risk-averse doctor who fears investigation and potential prosecution by enforcement agencies and the rational doctor who calculates the risks and benefits of choosing to treat one type of patient over another both stay well within the identified safe harbors." *Id.*

6. *See id.* at 978 (stating that there has been some research on the training of physicians indicating that they have a "heightened sensitivity to shame associated with errors, a refined notion of the centrality of character, and the attachment of serious moral content to breaches of particular, but not all, standards of behavior").

7. Jonathan P. Shepherd, *Criminal Deterrence as a Public Health Strategy*, 358 LANCET 1717, 1719 (2001) (footnote omitted).

Physicians who over-comply with the law may also overestimate the probability of being identified or captured in a law enforcement net. Stories in the media about physicians who are arrested and prosecuted, that focus on arbitrary or prejudicial enforcement, also undoubtedly fuel physician fears of the law.[8]

While the large majority of physicians operate within the law, there are some who do not. These physicians may not share the same personal traits as other physicians that lead to hypersensitivity of being caught for lawbreaking. In this essay, I explore why physicians break the law, how law enforcement responds when they do, and what, if anything, we can learn from cases about physicians who break the law, about the laws they break and their enforcement. In this exploration, I focus on two areas of physician lawbreaking: (1) violations of business-related laws (non-clinical), and (2) violations of laws relating directly to patient care. The first area deals primarily with physician failure to comply with laws addressing insurance fraud; the second, with situations where physicians violate the law in order to provide what they believe is clinically appropriate care to their patients.

I. PHYSICIANS WHO BREAK FRAUD LAWS

Some of the most common violations of the law by physicians involve insurance fraud, overstepping sexual boundaries, and drug abuse or diversion of controlled substances.[9] The question of why physicians engage in violations of the law in these areas has been underexplored in the literature.[10] The reasons, no doubt, differ with the type of crime. Although none of these crimes by physicians have been studied extensively, insurance fraud appears to be the most common type of lawbreaking by physicians and the crime for which there is the most abundant information. Insurance fraud involves crimes

8. *See, e.g.*, Hoffmann, *supra* note 4, at 239–40 (describing the case of Dr. Frank Fisher, who spent five months in jail prior to a hearing at which the charges against him for murder were dismissed or reduced and later dropped due to insufficient evidence); *see also* Chad D. Kollas et al., *Criminal Prosecutions of Physicians Providing Palliative or End-of-Life Care*, 11 J. PALLIATIVE MED. 233, 235 (2008) (describing the case of Dr. Robert Weitzel, in which the prosecutor failed to disclose exculpatory evidence).

9. *See* George J. Annas, *Medicine, Death, and the Criminal Law*, 333 NEW ENG. J. MED. 527, 527 (1995) ("Criminal charges related to the practice of medicine have primarily involved insurance fraud (including Medicare and Medicaid fraud), sexual abuse of patients, or illegal use or prescription of controlled substances.").

10. *See* Jesilow et al., *supra* note 1, at 149, 151–52 ("Few textbooks on deviance or criminology attend to offenses by physicians, probably because of the respect, power, and trust that the profession engenders. In addition, there is little systematic investigative or social science work on the range of illegal medical acts. In part, this results because access to information is difficult to obtain, as the strength of the profession has served to protect it from close scrutiny." (citation omitted)).

in which physicians knowingly defraud commercial or government insurers, in particular, Medicare and Medicaid, by making a false statement or representation in connection with payment for services rendered or participation in an insurance program.[11] The laws governing these behaviors, at their most basic level, apply a generally accepted moral value (i.e., do not steal) to our current government and commercial health insurance programs.

Insurance fraud is considered a type of white-collar crime,[12] and while much of white-collar crime focuses on corporate offenses, these crimes also include lawbreaking by professionals. Perhaps the first person to write about physicians as white-collar criminals was Edwin H. Sutherland. In his 1949 book, *White Collar Crime*,[13] Sutherland included crimes by doctors, as he believed studying their violations of the law could provide "particularly important information in assessing why persons who seemingly have no 'real' or 'true' need to enrich themselves nevertheless do so by illegal means."[14] In the book, Sutherland listed the types of crimes committed by doctors at the time. They included "illegal sales of alcohol and narcotics, abortion, illegal services to underworld criminals, fraudulent reports and testimony in accident cases, fraud in income tax returns, extreme instances of unnecessary treatment and surgical operations, fake specialists, restriction of competition, and fee-splitting."[15]

Today, doctors commit white-collar crimes when they take kickbacks on referrals or prescriptions, order questionable procedures or inaccurately report procedures, overbill patients and insurers, bill for services they have not provided, or bill for patients and clinical entities that do not exist. Empirical research on why physicians commit white-collar crime reveals that, for the most part, it is for the same reasons that other professionals do: the belief, which is in large part true, that the probability of getting caught is low,[16] the opportunity is readily available, and the reward is potentially great. White-collar crimes, such as fraud, are also relatively easy to hide and hard to

11. Such false billing involving federal health care plans constitutes a federal crime and, in most cases, a felony. *See* BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 1009 (5th ed. 2004).

12. 1 ENCYCLOPEDIA OF WHITE-COLLAR & CORPORATE CRIME 317 (Lawrence M. Salinger ed., 2005).

13. EDWIN H. SUTHERLAND, WHITE COLLAR CRIME (1949).

14. Jesilow et al., *supra* note 1, at 152 (discussing Sutherland's view on doctors' violations of the law). The authors further state that "Sutherland was also interested in decimating contemporary theories which insisted that Freudian complexes, immigrant status, and poverty 'caused' crime: doctors and other white-collar criminals, he noted, rarely fell into such categories." *Id.*

15. SUTHERLAND, *supra* note 13, at 12.

16. Relative to their incidence, arrests are very rarely made. White-collar crime is rarely prosecuted, and individuals who are prosecuted are rarely convicted. ERICH GOODE, DEVIANT BEHAVIOR 218–19 (8th ed. 2008).

detect.[17] The acts tend to "be made up of complex, sophisticated, and relatively technical actions" and "intermingled with legitimate behavior."[18]

In a 1991 *JAMA* article, *Fraud by Physicians Against Medicaid*,[19] the authors report on their interviews of over forty physicians who ran afoul of the Medicaid fraud and abuse laws. They consistently found that the physicians viewed the violation as easy—there was no known victim, only an impersonal billing process—and they simply had to check a procedure on a form that was more expensive than the procedure actually performed, or inflate the amount of time they spent with a patient.[20]

Physicians, like other professionals, also engage in white-collar crimes for personal reasons such as striving to achieve a certain lifestyle or because of an economic or family crisis. The literature indicates that white-collar criminals are motivated by two factors: economic difficulty and greed.[21] Often the behavior that enables a physician to engage in fraud is partially learned from others in the profession as "professional values may effectively neutralize [the doctor's] conflicts of conscience."[22] In justifying Medicaid fraud, for example, some physicians said they did it to make back what was owed them, alluding to the low Medicaid reimbursement rates.[23] Moreover, "occupational norms may support an attitude on the part of some professionals that they are 'above the law.'"[24]

Interviews with physicians prosecuted for Medicaid fraud revealed a group of people reluctant to say that greed was the reason for their behavior; they were more likely to attribute it to carelessness and to see themselves as "sacrificial lambs hung out to dry" by disgruntled employees, "stupid laws," or "bureaucratic nonsense."[25] They also felt that the Medicaid rules, which can be "mercilessly nitpicking," stood "in the way of important and humane service demands."[26] They resented the outside control of these regulations on

17. *Id.*

18. *Id.*

19. Paul Jesilow et al., *Fraud by Physicians Against Medicaid*, 266 JAMA 3318 (1991).

20. *Id.* The authors provide examples of physicians who billed 4800 hours in a year, who billed for services to persons who were dead, or billed for services when they were on vacation. *Id.* at 3319. One physician performed abortions on women who were not pregnant and in one case on a woman who had had a hysterectomy. *Id.*

21. *See* ALEX THIO, DEVIANT BEHAVIOR 343–44 (6th ed. 2001) (discussing the causes of white-collar crime).

22. Jesilow et al., *supra* note 19, at 3321.

23. *Id.* at 3320.

24. *See* PAUL JESILOW ET AL., PRESCRIPTION FOR PROFIT: HOW DOCTORS DEFRAUD MEDICAID (1993), *as reprinted in* ABOUT CRIMINALS 156 (Mark Pogrebin ed., 2004) ("A subculture of medical delinquency . . . arises, thrives, and grows in large part because of the tension between bureaucratic regulation and professional norms of autonomy.").

25. Jesilow et al., *supra* note 19, at 3320.

26. JESILOW ET AL., *supra* note 24, at 150.

their independence and autonomy.[27] An example given by one physician prosecuted for Medicaid fraud was his treatment "of a fourteen-year-old girl who was having her third abortion in less than six months. He had given the girl birth control pills, but she obviously hadn't taken them. When she came back for the third abortion, he coaxed her into allowing him to insert an IUD," telling her he could insert it right after he performed the abortion.[28] Medicaid would not pay for the IUD insertion because the IUD was "done at the same time as the abortion."[29] The physician "subsequently got into difficulty in part by falsifying the dates that he did the two procedures."[30]

Clearly, this physician viewed the law that prevented him from billing for the procedure under these circumstances as "bad law." The rule was established in light of the fact that when the two covered procedures are performed together the cost to the physician of the insertion of the IUD is nominal—"the small cost of the IUD and the minimal extra time to insert it."[31] Before the advent of Medicaid, the physician might have performed such a service for free, yet, in this case, he was not willing to forgo the additional small expense of the IUD insertion. Instead, he felt cheated because he was unable to charge for the full cost of the procedure (which included a new office visit).[32] He chose to frame the issue as one in which his patient would be harmed if he required her to come back for a second visit as she would be unlikely to return and might become pregnant again.[33]

The view that the Medicaid rules and their enforcement are unfair and irrational was a common perspective among those interviewed. One respondent "insisted that Medicaid not only invited but demanded cheating."[34] He appeared to resent the fact that the enforcers were not "medical people" and described them as knowing "nothing about the services being provided."[35] He defended his actions by saying:

> They've built in systems that either ask for somebody to cheat . . . or to cheat the patient on the type of care that's provided. You put somebody in the position where lying is the most reasonable course, and they will lie. The

27. *See id.* at 156.

28. *Id.* at 153.

29. *Id.*

30. Jesilow, *supra* note 19, at 3320.

31. JESILOW ET AL., *supra* note 24, at 154.

32. *Id.*

33. *Id.* at 153. The case description does not indicate whether the alleged wrongdoing occurred before or after the 1976 Hyde Amendment, which prohibited Medicaid payment for abortion except under narrow circumstances. *See* Hyde Amendment of 1976, Pub. L. No. 94-439, § 209, 90 Stat. 1418, 1434 (codified as amended at 42 U.S.C. § 1397ee(c)(1), (7) (2000)). Most likely, however, it occurred prior to 1976 when many states covered abortions under Medicaid.

34. JESILOW ET AL., *supra* note 24, at 154.

35. *Id.*

> patients will lie; the doctor may even lie on what they say about what happened.[36]

Physicians may obtain their views about compliance with the Medicare and Medicaid programs as early as medical school. In a study of medical student attitudes toward physicians who committed Medicare or Medicaid fraud, Keenan et al. gave students a series of hypotheticals, based on real cases, in which physicians violated the fraud and abuse laws and asked them what sort of sanctions the physicians should receive for their violations of the law.[37] Thirty-five percent (35%) of the respondents blamed the government programs, rather than the physicians, for violation of the program rules.[38] The students cited several programmatic features as contributors to physicians' fraudulent behavior. These included the low level of reimbursement, the paperwork and bureaucracy, and the programs' inefficiency.[39] By blaming the programs, the students shifted the responsibility for the wrongful acts away from the physicians and toward the flaws of the programs themselves.[40] The authors concluded that "[s]tudents believed that the regulations and policies governing these programs actually promoted fraud and abuse among physicians, despite the voluntary nature of physician participation."[41]

Physicians may also engage in private insurance fraud, which can be the basis of criminal arrest and prosecution under various state laws[42] as well as under the federal Health Insurance Portability and Accountability Act (HIPAA).[43] In the 1990s, due to the use of utilization review in managed care plans, many physicians reported pressure to alter a patient's medical records to support insurance coverage for the patient's treatment. In a survey of over 700 physicians, Wynia et al. sought to determine "whether financial pressures, practice characteristics, and/or . . . personal characteristics influence physicians' use of deception with third party payers."[44] The survey was

36. *Id.* at 155.

37. Constance E. Keenan et al., *Medical Students' Attitudes on Physician Fraud and Abuse in the Medicare and Medicaid Programs*, 60 J. MED. EDUC. 167 (1985).

38. *Id.* at 172.

39. *Id.*

40. *Id.*

41. *Id.*

42. *See, e.g.*, Illinois Insurance Claims Fraud Prevention Act, 740 ILL. COMP. STAT. ANN. 92/1 to 92/45 (2002); New Jersey Insurance Fraud Prevention Act, N.J. STAT. ANN. §§ 17:33A-1 to -30 (West 1994 & Supp. 2008).

43. Health Insurance Portability & Accountability Act of 1996, Pub. L. No. 104-191, §§ 241–50, 110 Stat. 1936, 2016 (codified in scattered sections of 18 U.S.C. (2006)).

44. M. Wynia et al., *Physician Responses to Utilization Review Pressures: Results of a National Physician Survey*, *in* SELECTED PAPERS FROM THE ASS'N HEALTH SERVICES RESEARCH ANNUAL MEETING JUNE 21–23 1998, at 244 (1999) [hereinafter Wynia, *Physician Responses to Utilization Review Pressures*], *available at* http://gateway.nlm.nih.gov/Meeting Abstracts/ma?f=102193686.html. The study results were published in further detail in *JAMA*.

conducted in 1998 and the results were reported at a 1999 meeting of the Association of Health Services Researchers. Of the 61% who responded,

> 28% had exaggerated the severity of patients' conditions to help them avoid early discharge from the hospital; 23% had changed official (billing) diagnoses to help patients secure coverage for needed treatments or services; and 9% had reported symptoms that patients did not actually have to help them secure coverage for needed treatments.[45]

Those physicians who engaged in these deceptive practices were more likely than their colleagues to be "less satisfied with medical practice, less financially secure, . . . less likely to report having enough time during patient visits, more likely to find insurance company intrusions annoying, and more likely to believe that 'gaming the system' for patients was necessary to provide high quality care."[46] Moreover, these physicians were not swayed by the threat of prosecution as they believed their actions were necessary for the health of their patients. Interestingly, while a large majority of respondents (87%) believed that all physicians had a responsibility to try to contain health care costs, 55% said "they would be more aggressive in cost control efforts if they knew that money saved would go towards serving more needy patients."[47]

While fraud laws are an effort to protect the public purse and insurance monies that are part of a communal fund, and they may also protect patients (e.g., from unnecessary procedures), physicians claim complying with them may hurt patients. This claim often reflects a misconception, however, when it is not compliance with the fraud laws that hurts patients but compliance with some other law, regulation, or policy. For example, physicians may violate commercial insurance fraud regulations because they disagree with the insurance policies or the interpretation of the policies by the insurance company. Most often this occurs when it is the physician's medical opinion that the proposed treatment or continued treatment is medically necessary. In the context of Medicare and Medicaid fraud, it is the billing rules that some physicians argue encourage care that harms patients, e.g., rules that encourage physicians to have patients come back for a second visit in order to charge for a procedure that could be done during the first visit.[48]

Matthew K. Wynia et al., *Physician Manipulation of Reimbursement Rules for Patients: Between a Rock and a Hard Place*, 283 JAMA 1858, 1861 (2000) [hereinafter Wynia, *Physician Manipulation of Reimbursement Rules for Patients*].

45. Wynia, *Physician Responses to Utilization Review Pressures*, *supra* note 44, at 244.

46. *Id.*

47. *Id.*

48. *See* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006, 70 Fed. Reg. 70116, 70261 (Nov. 21, 2005) (stating that the Centers for Medicare and Medicaid Services (CMS) reimburses a same-visit, second procedure at 50% of the fee schedule rate, and that "the multiple procedure payment reduction for surgery . . . has been a longstanding policy").

II. HOW THE CRIMINAL JUSTICE SYSTEM TREATS PHYSICIANS WHO VIOLATE FRAUD LAWS

When physicians intentionally violate the fraud laws, most of us would agree that they should be punished, perhaps more harshly than nonprofessionals who commit more routine street-crimes, given their privileged position in society. Yet white-collar criminals, more broadly, are perceived to be treated less harshly than nonprofessionals. There is little data, however, to determine whether that perception is valid.[49] Whether or not physicians who commit fraud are treated more or less harshly by the criminal justice system requires information about several components of the system: at the front end, whether physicians are arrested and prosecuted more frequently than non-physicians engaging in similar crimes; and at the back end, whether physicians are convicted more or less frequently and whether they are sanctioned more or less harshly than non-physicians committing similar crimes.

As regards law enforcement efforts to identify and arrest physicians who engage in fraud, considerable resources are being used to detect and combat medical fraud. At the federal level, such efforts by the Department of Health and Human Services (DHHS) and the Department of Justice (DOJ) were "consolidated and strengthened" by the passage of HIPAA.[50] In enacting HIPAA, Congress directed the Secretary of DHHS and the Attorney General to establish a "joint Health Care Fraud and Abuse Control Program and created a dedicated funding stream for health care fraud and abuse control activities."[51] Resources devoted to Medicaid fraud control at the state level have also increased.[52] The additional resources for detection of physicians engaging in

49. In fact, there is some evidence to show the opposite. Based on a vignette study, Rosoff found that "for serious offenses (homicides not related to medical practice), respondents allocate harsher verdicts to physicians with higher-status specialties." Liederbach et al., *supra* note 3, at 163 (citing Stephen M. Rosoff, *Physicians as Criminal Defendants: Specialty, Sanctions, and Status Liability*, 13 LAW & HUM. BEHAV. 231 (1989)). Also, Shaw and Skolnick found that an offender's status may "increase harshness [of the sanction] when the [offense] is related to professional practice (an altercation in the office with a patient)." *Id.* (citing Jerry I. Shaw & Paul Skolnick, *When Is Defendant Status a Shield or a Liability?: Clarification and Extension*, 20 LAW & HUM. BEHAV. 431 (1996)).

50. *See* U.S. DEP'T OF HEALTH & HUMAN SERVICES & U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 1998 (1999), http://www.usdoj.gov/dag/pubdoc/98hipaa_ar.htm [hereinafter DHHS & DOJ, ANNUAL REPORT].

51. *Budgeting to Fight Waste, Fraud and Abuse: Hearing Before the H. Comm. on the Budget*, 110th Cong. 8 (July 17, 2007) (statement of Mike O. Leavitt, Secretary, U.S. Department of Health & Human Services).

52. Jeffrey Blumengold & Christopher Panczner, *ForThoughts—Edition 5: The Shifting Landscape of Health Care Fraud and Regulatory Compliance*, DELOITTE, http://www.deloitte.com/dtt/article/0,1002,cid%253D218791,00.html (last visited May 12, 2009).

fraud and abuse have significantly increased the number of physician arrests and prosecutions.[53]

While insurance fraud continues to be difficult to detect, law enforcement agents are assisted in their efforts by False Claims Act relators or "whistle-blowers."[54] In some cases, the relator may be a prior employee, in others he or she may be a patient. Relators are entitled to a percentage of the government's recovery and therefore have an incentive to come forth with information.[55] More recently, law enforcement agencies have created programs to "ferret out fraud through data matching, data mining, and . . . the hiring of contractors to go out as third parties to look for fraud, waste, abuse, or errors."[56]

In order to determine whether physicians are treated differently than nonprofessionals once they are arrested, we would need to know whether they are more or less likely to be prosecuted and convicted. Writing twenty-five years ago, Jesilow, Pontell, and Geis asserted that "[t]he status of doctors preclude[d] the rough and insensitive treatment often accorded to street offenders,"[57] and quoted a federal agent in support of their observation who said:

> U.S. attorneys are extraordinarily kind to doctors, because even if they are crooks, theoretically they're still providing some useful services for the community. . . . There's a double standard for doctors because there aren't many other categories of white-collar criminals that are looked upon as a community of people who save lives.[58]

Today, that does not appear to be the case, at least with respect to health care fraud. According to a joint annual report by DHHS and DOJ, "[f]ederal prosecutors filed 322 criminal health care fraud cases in 1998—a 14 percent increase over the previous year."[59] During that same year, "326 defendants

53. *See* RONALD T. LIBBY, THE CRIMINALIZATION OF MEDICINE: AMERICA'S WAR ON DOCTORS 40 (2008) ("The number of fraud investigators in the OIG of HHS increased by 40 percent from 1998 to 2005. In 1998, there were 260 auditors and 136 criminal investigators. In 2006, there were 1,500 investigators and attorneys."). In addition, "FBI health fraud investigations increased by more than 400 percent from 591 in 1992 to 2,547 cases in 2005." *Id.*

54. *See* Joan H. Krause, *A Patient-Centered Approach to Health Care Fraud Recovery*, 96 J. CRIM. L. & CRIMINOLOGY 579, 585 (2006) (discussing the False Claims Act's status as the "centerpiece of the government's anti-fraud efforts").

55. *See id.* (noting that relators can "retain fifteen to thirty percent of the proceeds"). *See also* U.S. DEP'T OF HEALTH & HUMAN SERVICES & U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FY 2007 5 (2008), *available at* http://www.usdoj.gov/dag/pubdoc/hcfacreport2007.pdf (reporting that $122 million in recovered funds were awarded to relators in fiscal year 2007).

56. Blumengold & Panczner, *supra* note 52.

57. Jesilow et al., *supra* note 1, at 161.

58. *Id.* (alteration in original).

59. *See* DHHS & DOJ, ANNUAL REPORT, *supra* note 50.

were convicted of health care fraud-related crimes."[60] A decade later, "[i]n fiscal year 2007, the federal government alone initiated 878 criminal . . . investigations . . . and was successful in obtaining 560 criminal convictions."[61]

While in many cases the physicians enter into a plea bargain with the prosecutor, if the case goes to trial, often the outcome is based on the sympathies of the jury and the judge. As regards whether white-collar criminals (not physicians specifically) are incarcerated more or less frequently than others, in 2002 Paul Rosenzweig, a Senior Research Fellow in the Center for Legal and Judicial Studies at the Heritage Foundation, testified on the question before the Senate Subcommittee on Crime and Drugs.[62] Based on an empirical study of past crimes, he found that when one controls for non-discretionary sentencing (i.e., takes out crimes that were subject to federal sentencing guidelines and just looks at those where judges had discretion as between incarceration and a non-jail alternative) the results are equivocal—professionals have not been treated less harshly or more harshly than others.[63] Lengths of prison sentences, however, have been largely determined by the Federal Sentencing Guidelines, which were put in place to address sentencing disparities. In establishing the Guidelines, the Federal Sentencing Commission looked at past practices and collected data on more than 40,000 cases.[64] While the Commission was guided by historical data, it chose to depart from past practices in crimes of an economic or regulatory nature, as those crimes had been punished "less severely than other apparently equivalent behavior."[65] Consequently, the Guidelines made "an effort to upgrade the penalties for regulatory and economic, white-collar offenses."[66] In addition, Rosenzweig found that "courts d[id] not appear to depart from the [federal sentencing] guidelines with any greater frequency in white-collar cases than in street-crime cases."[67]

60. *Id.*

61. Blumengold & Panczner, *supra* note 52.

62. *Penalties for White Collar Crime: Hearing Before the Subcomm. on Crime and Drugs of the S. Comm. on the Judiciary*, 107th Cong. 144 (2002) [hereinafter Rosenzweig Testimony] (testimony of Paul Rosenzweig, Senior Legal Research Fellow, Center for Legal and Judicial Studies, The Heritage Foundation).

63. *Id.* at 148.

64. *Id.* at 151.

65. *Id.* (internal quotation marks omitted).

66. *Id.*; *see also* Liederbach et al., *supra* note 3, at 147 (stating that historical inequities in the treatment of white-collar and street-crimes have led to a "commitment to equal treatment under the law").

67. Rosenzweig Testimony, *supra* note 62, at 150. Rosenzweig's analysis was based on decisions made before 2005, when the Supreme Court in *United States v. Booker*, 543 U.S. 220 (2005), found that the Federal Sentencing Guidelines as originally constituted violated the Sixth Amendment right to trial by jury and struck down provisions of the law making them mandatory. The Federal Sentencing Guidelines are now advisory—judges are not required to follow them but

There is no specific data as to whether physicians are incarcerated with any more frequency than non-physicians or whether they are subject to shorter or longer prison terms. However, physicians who violate fraud laws today are subject to more significant penalties than was the case ten to twelve years ago—"[s]ince 1996, the fines and prison sentences for medical doctors have dramatically increased. The amount of the fraud is now tripled plus $10,000 is added for each instance of overbilling."[68] This increase in fines has significant implications. Prosecutors often "use the federal . . . sentencing guidelines to intimidate doctors into pleading guilty to felonies and paying huge fines in exchange for a reduced prison sentence."[69] Based on this data, it appears that physicians who break fraud laws are treated at least comparably to, and arguably more harshly than, those who commit common law fraud.[70]

Moreover, it appears that some physicians are prosecuted for unintentional violations of the law. Physicians, for example, who bill Medicare for lab tests that are not recognized by Medicare, or who bill for a procedure or service using the wrong HCPCS/CPT code,[71] may be deemed to have engaged in a criminal offense.[72] The absence of intent is not determinative. While the

must use them as a reference. *Booker*, 543 U.S. at 264 ("The district courts, while not bound to apply the Guidelines, must consult those Guidelines and take them into account when sentencing."). Prior to *Booker*, judges were able to depart from the Guidelines only under specified circumstances, most notably when a defendant provided substantial assistance to the prosecution. *See* LISA M. SEGHETTI & ALISON M. SMITH, CONGRESSIONAL RESEARCH SERVICE, FEDERAL SENTENCING GUIDELINES: BACKGROUND, LEGAL ANALYSIS, AND POLICY OPTIONS, at CRS-15 (2007), *available at* http://www.fas.org/sgp/crs/misc/RL32766.pdf.

68. LIBBY, *supra* note 53, at 25. Violations of the False Claims Act may include criminal prosecution as well as civil and administrative actions and penalties. *See* 18 U.S.C. §§ 286–287 (2006) (providing for fines and prison sentences of up to five years for fraud against the government and up to ten years for conspiracy to defraud). Often both criminal and civil charges are brought. The statutory fines are designated under the civil provisions of the False Claims Act. *See* 31 U.S.C. § 3729(a) (2006). The penalties of $5,000 to $10,000 per offense have been adjusted upward to account for inflation. *See* Civil Monetary Policies Inflation Adjustment, 28 C.F.R. § 85.3(9) (2008).

69. LIBBY, *supra* note 53, at 25.

70. Other white-collar fraud committed in the business setting is also subject to harsh penalties. Revisions to the Sentencing Guidelines, including significant increases in prison sentences and fines, for individuals and corporations convicted of white-collar and financial crimes were made in response to a congressional directive in the Sarbanes-Oxley Act. *See* Stephanos Bibas, *White-Collar Plea Bargaining and Sentencing After* Booker, 47 WM. & MARY L. REV. 721, 726–27 (2005).

71. HCPCS/CPT codes are codes assigned by Medicare and other insurers to each medical service performed by a physician for purposes of uniformity of reimbursement.

72. *See, e.g.*, United States v. Janati, No. 05-4255, 2007 WL 2197065, at **1 (4th Cir. Aug. 1, 2007) (physician convicted of criminal fraud for using wrong code for office visits). Correctly coding claims is apparently quite difficult. *See* Mitchell S. King et al., *Accuracy of CPT Evaluation and Management Coding by Family Physician*s, 14 J. AM. BOARD FAM. MED. 184, 188 (2001) (noting the "substantial" coding error rate in a survey of 600 physicians).

mental state required to find criminal liability under the False Claims Act is a "knowing" violation, i.e., the physician knowingly submitted a false claim,[73] the knowledge standard may be satisfied by a showing of "conscious avoidance" of knowledge of the truth or "reckless disregard" for the truth.[74] In addition, under the False Claims Act, civil penalties may be imposed when a physician "acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required."[75]

Prosecutors, in a number of cases, have stretched the boundaries of "reckless disregard of the truth or falsity of the information" and courts have differed in the interpretation of the phrase, with some equating it with "aggravated gross negligence"[76] and others requiring something closer to intentional harm. Because it is often difficult to determine whether a physician intentionally submitted a false claim or committed an error, physicians have been criminally charged when they mistakenly submit the wrong billing code for a patient. In a recent case, a federal judge found that the government's criminal fraud case against a physician was frivolous because the government failed to provide evidence of the defendant's requisite mental state.[77] The defendant was awarded nearly $300,000 in legal fees.[78] A criminal law professor who worked with the defendant on the case commented that often in these cases "[the government] is just looking at CPT code usage and anybody out on the tail of the distribution is targeted for criminal prosecution" even if there is no evidence of intentional wrongdoing.[79] Doctors in these cases often

73. *See* 18 U.S.C. § 287 (providing criminal liability for any claim, or claims, presented to the U.S. Government that is "knowing[ly] . . . false, fictitious, or fraudulent"). *Cf.* 31 U.S.C. § 3729 (providing civil liability for false claims "knowingly" presented to the government for payment or approval); 18 U.S.C. § 1347 (providing criminal liability for false claims "knowingly" submitted to a health care benefit program).

74. *See* United States v. Nazon, 940 F.2d 255, 258 (7th Cir. 1991) (upholding jury instructions interpreting 18 U.S.C. § 287, which permitted the jurors to "infer knowledge from a combination of suspicion and indifference to the truth" (emphasis omitted)); United States v. Gold, 743 F.2d 800, 822 (11th Cir. 1984) (approving the use of a "conscious avoidance" jury instruction in medical fraud case against optician).

75. 31 U.S.C. § 3729(b).

76. *See, e.g.*, United States v. Krizek, 111 F.3d 934, 941–42 (D.C. Cir. 1997).

77. *See* Amy Lynn Sorrel, *Judge Rules Criminal Fraud Case Against Idaho Doctor Is Frivolous*, AM. MED. NEWS, Aug. 20, 2007, http://www.ama-assn.org/amednews/2007/08/20/gvsb0820.htm.

78. *Id.*

79. *Id.* (alteration in original) (quoting Jeffrey S. Parker, Professor of Law, George Mason University) (internal quotation marks omitted).

settle "even when they did nothing wrong, because the financial stakes are so high," and sometimes they face significant jail time.[80]

III. PHYSICIANS WHO BREAK LAWS INVOLVING PATIENT CARE

A second category of laws that physicians break govern clinical practice and patient treatment rather than business-related activities. Examples range from prescribing opioids for chronic pain patients or medical marijuana for cancer patients to helping a terminally ill patient end his or her life.

In the case of physicians who break the law regarding prescribing of opioids, reasons may vary from greed to a desire to appropriately treat their patients' pain. Under the Controlled Substances Act[81] (CSA), to find a physician guilty of criminal violation of the law for prescribing controlled substances, the prosecution must prove that the physician knowingly or intentionally prescribed outside "the usual course of . . . professional practice" or not for a "legitimate medical purpose."[82] In some cases, physicians intentionally violate the law by knowingly prescribing without a medical purpose. Generally, the purpose of such prescribing is monetary gain or sexual favors; physicians demand such benefits in exchange for the prescription. The "patient" may need the drug to feed an addiction or may sell it on the street. In these circumstances, law enforcement is ideally swift and harsh.[83]

On the other hand, physicians may violate the CSA in order to treat their patients. In these cases, they may believe they are complying with the law as they are prescribing for a legitimate medical purpose and within, what they believe, is the usual course of professional practice. Dozens of physicians have been arrested for what they argue is appropriate treatment of chronic pain patients.[84] An example is Dr. William Hurwitz. Hurwitz, who practiced in northern Virginia, was arrested for prescribing large dosages of opioids that prosecutors alleged were related to several deaths.[85] Yet, many of his patients asserted that he had greatly improved the quality of their lives, and a number of

80. *Id.* (citing Robert S. Salcido, attorney in Washington, D.C. and former Justice Department civil fraud lawyer); *see also* Roccy DeFrancesco, *Surplus Medicare Fraud Insurance*, PHYSICIAN'S NEWS DIGEST, July 2005, http://www.physiciansnews.com/finance/705.html.

81. 21 U.S.C. §§ 801–971 (2006).

82. *See* 21 U.S.C. § 830(b)(3)(A)(ii) (2006); 21 C.F.R. § 1306.04(a) (2008).

83. *See* Hoffmann, *supra* note 4, at 236–38 (providing statistics and description of a number of cases in which physicians have been investigated, arrested, and prosecuted for prescribing controlled substances).

84. *See id.* at 239–56 (describing the cases of Drs. Frank Fisher, Cecil Knox, William Hurwitz, Jeri Hassman, and Ronald McIver).

85. *Id*. at 246.

pain experts described him as a caring physician.[86] Hurwitz was initially sentenced to twenty-five years in prison, despite the prosecution's argument that he should receive a life sentence.[87] The sentence was subsequently reduced to fifty-seven months after he successfully appealed the initial conviction on the grounds that the court wrongly "instructed the jury that it could not consider Hurwitz's 'good faith' in his prescribing."[88]

Physicians have also been arrested and prosecuted in California for growing and dispensing marijuana for cancer and HIV patients. California passed the country's first law permitting physicians to "prescribe" marijuana for medical purposes in 1996.[89] The law, also known as Proposition 215, requires patients who wish to grow or buy marijuana to treat their symptoms to obtain written or oral authorization from their physician.[90] Such patients and their designated primary care givers are protected from criminal prosecution under California law for obtaining, possessing, or cultivating marijuana for patients' personal medical use. Physicians who comply with the state law, however, can be prosecuted for violation of the federal CSA, which categorizes marijuana as a Schedule I drug that cannot lawfully be prescribed for any reason.[91] According to medical marijuana advocates, an estimated 1500 physicians in California, "mostly oncologists and AIDS specialists," have authorized medical marijuana for a patient.[92] However, most of the authorizations have been from a small group of about a dozen physicians.[93] In 2005, Dr. Mollie Fry was arrested by federal drug agents for growing marijuana and issuing written authorizations to many patients.[94] Fry, "a cancer survivor who learned about the benefits of medical marijuana while enduring chemotherapy and a double mastectomy,"[95] set up a practice in a small town in

86. One physician said he was "doing heroic things for his patients." *Id.* at 247 (quoting Dr. James Campbell, Professor of Neurosurgery and Director of the Blaustein Pain Treatment Center at Johns Hopkins University).

87. *Id.* at 249.

88. Hoffmann, *supra* note 4, at 249.

89. California Compassionate Use Act of 1996, CAL. HEALTH & SAFETY CODE § 11362.5 (West Supp. 2009).

90. *Id.* § 11362.5(d).

91. *See* Gonzales v. Raich, 545 U.S. 1 (2005).

92. Lisa Leff, *Calif. 'Pot Docs' Put Selves at Risk*, WASHINGTONPOST.COM, Nov. 5, 2006, http://washingtonpost.com/wp-dyn/content/article/2006/11/04/AR2006110400516_pf.html.

93. *Id.*

94. Dean E. Murphy, *Arrests Follow Searches in Medical Marijuana Raids*, N.Y. TIMES, June 23, 2005, at A12 (noting that Fry wrote a recommendation for marijuana to an undercover federal agent, which Fry's husband, Dale Schafer, filled).

95. *New Book Exposes the First Federal Trial of a Medical Marijuana Doctor*, MED. MARIJUANA AM., Dec. 4, 2008, http://www.medicalmarijuanaofamerica.com/content/view/246/110/ (reviewing VANESSA NELSON, COOL MADNESS: THE TRIAL OF DR. MOLLIE FRY AND DALE SCHAFER (2008)).

northern California "and began recommending medical marijuana to her patients in accordance with state law."[96] Under federal law, Fry was able to recommend marijuana use to her patients[97] but was not able to grow it for her patients or for herself.[98] Fry believed that she was doing the right thing for her patients and was willing to go to jail for it.[99] She was sentenced to a five year prison sentence, the minimum sentence based on the volume of marijuana that she had cultivated.[100] Judge Damrell, in sentencing the defendant, stated that he took "no pleasure in imposing [the] sentence,"[101] implying that the recommended five-year sentence under the Federal Sentencing Guidelines did not seem appropriate in the case.

In these and other cases involving patient care, physicians may intentionally or knowingly break the law because they believe it is in their patient's best interest to do so or because such action is consistent with their professional norms. They perceive complying with the law as breaching their duty to their patients as well as violating their autonomy and contravening their judgment as to what is the right thing to do.[102] Their behavior is consistent with

> [n]ormative theories of compliance with law [which] hold that people obey the law because they believe it is right to do so. This sense of rightness may arise because the behavior required by the law is consistent with the individual's own sense of right and wrong, or from a sense that the law is the product of a "legitimate" or fair authority that is entitled to obedience.[103]

96. *Id.*

97. Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) (holding that physicians who recommend the use of cannabis to patients as specified under California law are protected by the First Amendment).

98. United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 486 (2001) (holding that there is no medical necessity exception to the CSA's prohibition against manufacturing and distributing cannabis).

99. *See* Leff, *supra* note 92 (quoting Fry as saying, "What did I take an oath to do? To do no harm and to alleviate pain and suffering . . . I'm going to be true to my oath, and I'm even willing to go to prison for it." (internal quotation marks omitted)).

100. *Medical Marijuana: California Dr. Molly [sic] Fry Sentenced to Five Years*, DRUG WAR CHRON., Mar. 28, 2008, http://stopthedrugwar.org/chronicle/529/molly_fry_sentenced_five_years_medical_marijuana.

101. News Release, U.S. Drug Enforcement Admin., California Doctor-Lawyer Couple Get Five Years for Growing and Selling Marijuana (Mar. 20, 2008), http://www.usdoj.gov/dea/pubs/states/newsrel/sanfran032008.html (internal quotation marks omitted) (noting the prosecution argued that Fry and her husband sold the marijuana as a money making scheme rather than to treat patients).

102. *See* Kent Greenawalt, Commentary, *Legal Enforcement of Morality*, 85 J. CRIM. L. & CRIMINOLOGY 710, 718 (1995) ("The most serious breach of someone's autonomy involves coercion that contravenes that person's own rational, reflective judgment.").

103. Zita Lazzarini et al., *Evaluating the Impact of Criminal Laws on HIV Risk Behavior*, 30 J.L. MED. & ETHICS 239, 249 (2002) (citing T. TYLER, WHY PEOPLE OBEY THE LAW (1990);

In these cases, physicians are not complying with the law because they disagree normatively with its requirements. Furthermore, they may distrust the government's judgments as to what is in their own interest as well as in their patients' best interest.[104]

Physician advocates might label these actions by physicians as "civil disobedience." The American Medical Association (AMA) Code of Medical Ethics actually condones civil disobedience in some circumstances, stating:

> Ethical values and legal principles are usually closely related, but ethical obligations typically exceed legal duties. In some cases, the law mandates unethical conduct. In general, when physicians believe a law is unjust, they should work to change the law. In exceptional circumstances of unjust laws, ethical responsibilities should supersede legal obligations.[105]

While some physicians who break the law may engage in "true" civil disobedience, technically, most physicians who break the law do so because they perceive it as bad for their patients, and thus are not engaging in what is more traditionally defined as civil disobedience. In an effort to distinguish civil disobedience from other forms of lawbreaking, Childress constructed a framework for moral analysis of illegal action.[106] He contrasts features of lawbreaking that are more or less morally justifiable.[107] Acts, for example, that are open and public, nonviolent, and justified by higher law or conscience, are generally less morally culpable than those that are clandestine, evasive of law enforcement, and violent.[108] True civil disobedience, according to Childress, is a nonviolent act publicly performed for the purpose of protesting a law or

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Tom R. Tyler, *Public Trust and Confidence in Legal Authorities: What Do Majority and Minority Group Members Want from the Law and Legal Institutions?*, 19 BEHAV. SCI. & L. 215 (2001)).

104. *See* Greenawalt, *supra* note 102, at 719 ("Exactly how much paternalism people will countenance depends on how strongly they rate the value of autonomy and to what degree they trust the judgments of the government as to what is in their self-interests.").

105. AM. MED. ASS'N, CODE OF MEDICAL ETHICS: THE RELATION OF LAW AND ETHICS Op. 1.02; *see also* Chalmers C. Clark, Letter to the Editor, *Civil Disobedience: The Devil Is in the Details*, HASTINGS CENTER REP., July–Aug. 2005, at 4 (responding to Robert Macauley, *The Hippocratic Underground: Civil Disobedience and Health Care Reform*, HASTINGS CENTER REP., Jan.–Feb. 2005, at 38) ("As a public trust, the medical profession has a lofty responsibility to respect law, but respect for law does not imply slavishness. The higher duty of the profession, according to its social contract, is to the priority of patient benefit. The medical profession is a socially endowed moral autonomy . . . . [A]s public trust diminishes, professional autonomy likewise declines. In service of the ongoing need for public persuasion, laws or policies that cut against patient benefit must be strenuously resisted—through proper channels—yet indeed, as last resort, the laws must be broken.").

106. James F. Childress, *Civil Disobedience, Conscientious Objection, and Evasive Noncompliance: A Framework for the Analysis and Assessment of Illegal Actions in Health Care*, 10 J. MED. & PHIL. 63, 65 (1985).

107. *Id.*

108. *Id.*

government policy, where the wrongdoer is willing to undergo arrest and prosecution.[109]

Childress distinguished civil disobedience from "conscientious objection" and "evasive noncompliance."[110] Conscientious objection is a refusal to obey based on personal moral beliefs rather than on a belief that the law should be changed—a "moral-political" justification.[111] Unlike civil disobedience, evasive noncompliance is not done overtly or submissively; it is covert and evasive.[112] Physician lawbreaking may fall into any of these three categories depending on its specific elements.

When physicians break law they view as harmful to their patients, the acts are nonviolent but are generally not done openly as doing so would breach patient confidentiality and privacy. In these cases, doctors are violating the law primarily so that they can assist their patients or practice what they think is good medicine. This may be both a matter of conscience and pragmatic. Physicians no doubt disagree with the law they are violating and may think it should be changed, but they may not be engaged in formal actions to change the law. In some cases, physicians do not want to change the law but believe that in a specific case, e.g., euthanasia, the law should not apply. In these cases, Childress would categorize the physician's actions as conscientious objection.[113] Most physicians, although not all, are not submissive to arrest and punishment; nor are they typically evasive, i.e., they do not run from the law and the illegal acts they perform may be done in the presence of other health care providers. Some physicians may also underestimate the legal risk associated with their actions. Under Childress's typology of dissent, physicians who break what they believe to be bad law but do not do so openly or submissively, would be committing evasive noncompliance.[114]

True civil disobedience in health care does occur, although it is relatively rare. For example, the actions of Dr. Jack Kevorkian would appear to meet the traditional definition of civil disobedience. Kevorkian engaged in a nonviolent act (assisting his patients terminate their lives),[115] openly and, in at least one

109. *See id.* at 66; *see also* Matthew R. Hall, *Guilty but Civilly Disobedient: Reconciling Civil Disobedience and the Rule of Law*, 28 CARDOZO L. REV. 2083 (2007) (proposing a doctrinal definition of civil disobedience).

110. Childress, *supra* note106, at 67–69.

111. *Id.* at 68.

112. *Id.* at 68–69.

113. *See id.* at 68 (defining "conscientious objection" as "public, nonviolent, and submissive violations of law based on personal-moral . . . convictions and intended primarily to witness to those principles or values").

114. *See id.* at 68–69 (defining "evasive noncompliance" as "illegal action [that] is both covert and evasive").

115. *See* Childress, *supra* note106, at 75 (defining "violence as intentional and unauthorized harm or injury to a person against his/her will," and noting that "mercy killing," although an

case, publicly, for the purpose of changing the law regarding physician-assisted suicide.[116] Dr. Timothy Quill also, arguably, committed civil disobedience when he published an article in the *New England Journal of Medicine* admitting that he had assisted a patient end her life.[117] In the area of reproductive rights, Dr. C. Lee Buxton, a professor at Yale School of Medicine, and Estelle Griswold, then executive director of the Planned Parenthood League of Connecticut, engaged in civil disobedience when they opened a birth control clinic in New Haven, Connecticut, intending to challenge the validity of a Connecticut statute that banned prescribing of oral contraceptives.[118]

In addition to violation of the laws regarding prescribing controlled substances, i.e., opioids and marijuana, there are a number of cases where physicians have broken or continue to break the law because they view it as harmful to their patients. For example, prior to *Roe v. Wade*,[119] there was widespread violation of the laws prohibiting abortion.[120] In 1955, Planned Parenthood organized a conference on abortion in the United States where conferees speculated that there could be between 200,000 and 1.2 million abortions performed annually.[121] Clearly, it was not an area where many doctors were being prosecuted or feared prosecution.

In these cases, physicians felt compelled to perform "abortions for pregnant women who might otherwise resort to dangerous, back-alley procedures," and also because they wanted to honor their patient's self-

intentional act, does not qualify as a violent act unless "it intentionally inflicts a harm or injury on a person against that person's will").

116. In a 1998 broadcast of *60 Minutes*, Kevorkian permitted the airing of a videotape showing him assisting Thomas Youk, a fifty-two year old male in the final stages of ALS, end his life. *60 Minutes: Death by Doctor* (CBS television broadcast Nov. 22, 1998), *available at* http://www.cbsnews.com/video/watch/?id=4462047n%3fsource=search_video.

117. Timothy E. Quill, *Death and Dignity: A Case of Individualized Decision-Making*, 324 NEW ENG. J. MED. 691 (1991); *see also* Lawrence K. Altman, *Doctor Says He Gave Patient Drug to Help Her Commit Suicide*, N.Y. TIMES, Mar. 7, 1991, at A1 (discussing how Dr. Quill "agonized" over the decision to help his patient when she asked him to assist her in ending her life).

118. Ellen Chesler, *Public Triumphs, Private Rights*, MS. MAG., Summer 2005, *available at* http://www.msmagazine.com/summer2005/birthcontrol.asp. Buxton and Griswold were arrested for dispensing contraceptives to a married couple and convicted and fined $100 each. *Id.* They appealed the conviction. Their case went to the Supreme Court, which determined that the Connecticut law was unconstitutional. *See* Griswold v. Connecticut, 381 U.S. 479 (1965).

119. 410 U.S. 113 (1973).

120. *See* Childress, *supra* note 106, at 64 ("Birth control and abortion have perhaps been the subjects of most illegal actions by both professionals and lay people over the last century or so [in the area of health care].").

121. JAMES RISEN & JUDY L. THOMAS, WRATH OF ANGELS: THE AMERICAN ABORTION WAR 10–11 (1998).

determination regarding her desire not to have a child.[122] Arguably, it was the "ideological and humanitarian impulses of [these] physicians pushing them into law-breaking."[123] The law's reaction to this lawbreaking was, for the most part, not to prosecute physicians unless the practice came to public attention.[124] Yet, many physicians were uncomfortable with the criminalization of the procedure, and physicians as a group became involved in the effort to change the law.[125]

An additional example where physicians may break the law because they believe it is harmful to their patients is when laws and regulations mandate aggressive treatment of severely disabled infants with life threatening conditions even when the parents have requested termination or withholding of such treatment. These laws include the Child Abuse Prevention and Treatment Act[126] (CAPTA) and its accompanying regulations (also known as the "Baby

122. *See* Michael L. Gross, *Physician-Assisted Draft Evasion: Civil Disobedience, Medicine, and War*, 14 CAMBRIDGE Q. HEALTHCARE ETHICS 444, 448 (2005). Abortions were often performed by non-physicians, primarily "midwives and herbalists." Jesilow et al., *supra* note 1, at 156.

123. Jesilow et al., *supra* note 1, at 157. While many physicians had altruistic goals in helping women who requested an abortion, it is also true that physicians were behind the early efforts to criminalize it, in large part to prevent abortions by competitors, i.e., lay abortionists. *Id.* at 156.

124. *See* Samuel W. Buell, Note, *Criminal Abortion Revisited*, 66 N.Y.U. L. REV. 1774, 1789–90 (1991) (citing J. BATES & E. ZAWADZKI, CRIMINAL ABORTION 35–75 (1964)) (stating that there were few abortion convictions because the effort required of law enforcement was not justified in light of the ambivalent attitude toward the laws). The literature indicates that the few prosecutions that were performed "targeted notorious or unusually large abortion "rings" or "mills"; legitimate doctors were rarely prosecuted. *Id.* at 1790; *see also* Daniel G. Wyllie, Comment, *Abortion Reform in Michigan—An Analysis of the Proposed Code's Provisions*, 14 WAYNE L. REV. 1006 (1968).

125. Dr. Alan Guttmacher, an outspoken obstetrician for the legalization of abortion, sat in on meetings of the American Law Institute (ALI), pushing them to write model legislation that would decriminalize abortion. RISEN & THOMAS, *supra* note 121, at 11. Subsequently the AMA endorsed the ALI plan (although it only allowed abortion to preserve the life or health of the mother or in cases of rape, incest, or severe fetal abnormalities). *Id.*

126. Child Abuse Prevention and Treatment Act, Pub. L. No. 93-247, 88 Stat. 4 (1974) (codified as amended at 42 U.S.C. §§ 5101–5116i (2000 & Supp. IV 2007)). CAPTA provides that as a condition of receipt of funds for child abuse prevention and treatment programs, states must incorporate within their definition of medical neglect the failure to provide life sustaining treatment to severely disabled newborns except in very limited circumstances. 42 U.S.C. § 5106a(b)(2)(B); *see* 45 C.F.R. § 1340.15 app. (2007) (giving "interpretive guidelines" regarding allowable exceptions to "medically indicated treatment" of disabled infants). Failure to incorporate the definition means that states are denied federal funds for these programs. 42 U.S.C. § 5106a(b)(2)(B). Where states have incorporated the federal definition of medical neglect into their own definition, physicians could be prosecuted for failure to report the case to child protective services, or for manslaughter or criminal negligence for failure to treat when they

Doe Rules"), and the Born-Alive Infants Protection Act of 2002[127] (BAIPA). In cases involving treatment of severely disabled newborns, physicians may break the rules because (1) they believe it is not in the infant's best interest to continue treatment, but rather that it perpetuates the infant's suffering, and (2) because it deprives the child's parents of the right to make treatment decisions for the child. While physicians may violate the law by failing to treat these infants, this is also an area where law enforcement agents do not seem to prosecute physicians.[128] Despite such lack of enforcement, there was speculation a few years ago that physicians who failed to adequately treat newborns might be new targets of prosecutors. In April 2005, DHHS announced it would be investigating all circumstances where an individual or entity was reported to be withholding medical care from an infant born alive in potential violation of federal statutes (specifically, BAIPA).[129] DHHS also instructed state child protective service agencies that are responsible for implementing regulations to enforce the 1984 Baby Doe Rules and to insist on local execution of legal remedies to prevent non-treatment decisions deemed impermissible by the Baby Doe Rules.[130] Some argued that this directive signaled an end to a period of benign regulatory neglect in this area,[131] yet cases of physicians arrested for violation of these laws have not surfaced.

In addition to physician-assisted suicide, distribution of contraceptives, abortion, treatment of seriously disabled newborns, reporting of child abuse

know that such failure would lead to serious harm or to the death of the child. *See id.* § 5106a(b)(2)(B)(ii)–(iii).

127. Born-Alive Infants Protection Act of 2002, Pub. L. No. 107-207, 116 Stat. 926 (codified as amended at 1 U.S.C. § 8 (2006)). BAIPA provides that a viable infant that is born alive must be treated as a person under the law. *Id.*

128. Irene Hurst, Letters to the Editor, *First Rule: Choose Your Battles Wisely*, 116 PEDIATRICS 288 (2005) (stating that "no state has prosecuted a single doctor, nurse, medical institution, or family under these regulations").

129. ADMIN. FOR CHILDREN & FAMILIES, U.S. DEP'T OF HEALTH & HUMAN SERVS., LOG. NO. ACYF-CB-PI-05-01, PROGRAM INSTRUCTIONS (2005); *see* Ceci Connolly, *Doctors Are Warned on Fetus Care: Guidelines Are Issued on Born-Alive Infants Protection Act*, WASH. POST, Apr. 23, 2005, at A7.

130. *See* Laura Hermer, *The "Born-Alive Infants Protection Act" and Its Potential Impact on Medical Care and Practice*, HEALTH L. PERSP., Sept. 27, 2006, *available at* http://www.law.uh.edu/healthlaw/perspectives/2006/(LH)BAIPA.pdf ("Because of the clear connection the CAPTA memorandum makes between the failure to provide medical treatment and state child abuse and neglect laws, it appears that physicians and hospitals may be subject to a criminal charge of abuse and neglect should they withhold medical care from premature and/or disabled infants.").

131. *See* Sadath A. Sayeed, *Baby Doe Redux? The Department of Health and Human Services and the Born-Alive Infants Protection Act of 2002: A Cautionary Note on Normative Neonatal Practice*, 116 PEDIATRICS e576, e577 (2005) ("[T]he current administration's resurrection of recently quiescent oversight of the treatment of imperiled newborns agitates the legal fault line that physicians walk along when caring for these infants.").

and neglect, and dispensing of marijuana, physicians may also exercise "civil disobedience" in order to protect patients or to act consistently with their ethical norms by performing involuntary euthanasia, terminating treatment when they deem it futile, or handing out clean needles to addicts to prevent the spread of HIV. These issues raise profound questions about how the law should react to violations of what the violators call "bad law" and how we should assess such laws.

IV. RESPONSE OF LAW ENFORCEMENT TO PHYSICIANS WHO VIOLATE LAWS RELATING TO PATIENT CARE

The response of law enforcement to physicians who violate the law because they claim it harms their patients ranges from seemingly conscious disregard for the impact of their actions on patient care and the relevant medical evidence, to wise inaction. In several cases involving patient care, prosecutors, arguably, do not appropriately exercise their discretion and target physicians who are providing a needed service to a population that finds it difficult to obtain care. This appeared to be the case in the arrest and prosecution of Dr. Frank Fisher.[132] Fisher, who graduated from Harvard Medical School, operated a clinic in northern California where he served a large Medi-Cal[133] population.[134] He had a history of working with indigent clients and in underserved communities, including on Native American reservations.[135] In California, approximately 5%–10% of his 3,000 patients "suffered from severe, chronic intractable pain."[136] He was charged with five counts of first degree murder stemming from his prescribing of opioids.[137] At least three of the murder charges appeared entirely bogus. "For example, one of the patients for whom he prescribed opioids died as a passenger in an automobile accident. Another death occurred when a non-patient stole and overdosed on medications that Fisher had prescribed to a patient."[138] A third patient actually died while Fisher was in jail and she was unable to obtain her medications.[139] The murder and drug diversion charges against Fisher were all subsequently dismissed or dropped, but not until after he served five months in

132. Hoffmann, *supra* note 4, at 239–42 (discussing Fisher's arrest, prosecution, and the consequent effects on his practice of medicine).

133. In California, the Medicaid program is referred to as Medi-Cal. *See* Medi-Cal: Provider Homepage, http://www.medi-cal.ca.gov/ (last visited May 19, 2009).

134. Hoffmann, supra note 4, at 239.

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.* at 240 (footnote omitted).

139. Hoffmann, *supra* note 4, at 240.

prison awaiting a preliminary hearing.[140] The arrests and prosecutions of other pain physicians have also left their patients without adequate pain treatment.

Once law enforcement agents decide to arrest a physician, their tactics may also be unnecessarily dramatic and fear-inducing. Often physicians are arrested in front of their patients. This has been the case for numerous physicians arrested for prescribing opioids to their patients. In the case of Fisher, for example, "over twenty armed law enforcement agents stormed into Fisher's clinic and arrested him."[141] Similarly, "more than a dozen federal agents burst into [Dr. Cecil] Knox's office with guns drawn while he was seeing patients and arrested him. He was taken away in handcuffs and leg irons."[142] Federal officials also "marched into Dr. Jeri Hassman's office while she was treating a patient, 'took off her jewelry, put her in handcuffs and led her to jail.'"[143]

In the case of physicians prescribing opioids for pain patients, law enforcement agents may also pose as patients, attempting to trick the doctor into inappropriately prescribing. Prosecutors have also engaged in questionable trial tactics. During the trial of Dr. William Hurwitz, six past presidents of the American Pain Society sent a letter to Hurwitz's lawyer citing "'misrepresentations' by one of the Justice Department's expert witnesses."[144] In the case of Dr. Robert Weitzel, a physician arrested for murder of four severely ill elderly nursing home patients who allegedly died under his care because he gave them opioid analgesics to manage their pain and dyspnea, the prosecution withheld exculpatory evidence—testimony by a palliative care expert that Weitzel did not engage in any criminal wrongdoing.[145] The judge referred to the prosecution's behavior as "contraven[ing] manifest constitutional, legal, and ethical duties."[146]

Sentencing in these cases can also seem harsh. In fact, in some cases, the judge appears constrained by the Federal Sentencing Guidelines and would have preferred a more compassionate response. In the prosecution of Dr. Mollie Fry, for authorizing marijuana and growing marijuana for use by her patients, herself, and her husband, the judge described the five-year minimum sentence as a "'tragedy' that should 'never have happened.'"[147] Perhaps

140. *Id.*

141. *Id.* at 239.

142. *Id.* at 242 (footnote omitted).

143. *Id.* at 250 (quoting Marc Kaufman, *Worried Pain Doctors Decry Prosecutions*, WASH. POST, Dec. 29, 2003, at A1).

144. Hoffmann, *supra* note 4, at 248–49, 248 n.123.

145. *See* Kollas et al., *supra* note 8, at 235.

146. *Id.* (internal quotation marks omitted).

147. *Fry and Shafer Released on Bail Pending Appeal*, INDYBAY, Mar. 31, 2007, http://www.indybay.org/newsitems/2008/03/31/18489777.php (quoting U.S. District Court Judge

because of the judge's sympathy for Fry, he subsequently granted her release on bail, stating that Fry (and her husband) had "substantial" grounds for appeal that justified their release on bail, including "entrapment, the defendants' state of mind, and the conflict between state and federal laws."[148]

In contrast to these cases, where the law enforcement response seems to have ignored claims of patient well-being and been overly harsh, the legal system has responded much more discriminately, even compassionately in a number of cases where physicians appear to be acting to help their patients. This seems to have been the response in the early abortion and contraceptive cases, where law enforcement rarely prosecuted physicians or, if they did so, only for the most blatant of violations. Similarly, it seems to characterize the system's current lack of aggressive enforcement of the Baby Doe Rules despite the passage of the BAIPA and recent pronouncements of DHHS.

The latter, more tepid, response may be especially true when the law is in flux or when there is considerable societal ambivalence about a law. This may explain the legal system's response to the cases of Dr. Jack Kevorkian and Dr. Timothy Quill. Kevorkian assisted over 100 individuals end their lives.[149] Between 1990 and 1999 he was arrested and prosecuted numerous times, all unsuccessfully, until the case of Thomas Youk in 1999.[150] In 1990 and 1992 Kevorkian was indicted for murder in the death of three individuals; however, the cases were dismissed because Michigan had no law against assisting suicide and he had "merely" helped the individuals end their own lives with his "suicide machine."[151] After these unsuccessful prosecutions, the Michigan legislature hurried to pass a fifteen-month ban on assisted suicide.[152]

Frank Damrell); *see also New Book Exposes the First Federal Trial of a Medical Marijuana Doctor*, *supra* note 95 (discussing the circumstances leading to Fry's arrest).

148. *Fry and Shafer Released on Bail Pending Appeal*, *supra* note 147.

149. Monica Davey, *Kevorkian Freed After Years in Prison for Aiding Suicide*, N.Y. TIMES, June 2, 2007, at A8.

150. People v. Kevorkian, 639 N.W.2d 291 (Mich. Ct. App. 2001) (affirming Kevorkian's conviction for second degree murder and delivery of controlled substances); *see* Frontline: The Kevorkian Verdict: Chronology, http://www.pbs.org/wgbh/pages/frontline/kevorkian/chronology.html (last visited May 20, 2009).

151. *See* People v. Kevorkian, Nos. CR-92-111590-FC, 92-DA-5303-AR, 1992 WL 12597834 (Mich. Cir. Ct. July 21, 1992) (finding that "physician assisted suicide was not a crime in Michigan," thus dismissing the charges of open murder brought against Kevorkian in 1992 for assisting in the suicides of Marjorie Wantz and Sherry Miller); William E. Schmidt, *Prosecutors Drop Criminal Case Against Doctor Involved in Suicide*, N.Y. TIMES, Dec. 15, 1990, at 10 (noting that the Michigan district court dismissed murder charges brought against Kevorkian for assisting Jane Adkins commit suicide in 1990 and "[d]eclar[ed] that the debate over euthanasia and suicide must be sorted out by the state lawmakers rather than" the courts); *see also* Frontline: The Kevorkian Verdict: Chronology, *supra* note 150.

152. MICH. COMP. LAWS SERV. §§ 752.1021–.1027 (LEXISNEXIS 2001); *see also* Frontline: The Kevorkian Verdict: Chronology, *supra* note 150 (noting passage of assisted suicide ban).

Kevorkian violated the ban several times, but there was some uncertainty about the ban's constitutionality,[153] and a jury found him not guilty of violating the ban although he admitted to assisting a suicide during the fifteen-month period. Subsequently, the state's court of appeals found the ban unconstitutional for "technical" reasons, but shortly thereafter the Michigan Supreme Court reversed the court of appeals decision.[154] The supreme court also declared that a statutory ban was not necessary to prosecute an individual for assisted suicide; under the common law, assisted suicide could be prosecuted as a felony with a five-year prison term.[155] Despite this declaration, Michigan juries on three occasions acquitted Kevorkian in subsequent prosecutions for assisted suicide.[156] During this period, many viewed Kevorkian as a hero, helping the cause of physician-assisted dying.[157] It was not until 1999 when Kevorkian was tried for the first degree murder of Thomas Youk that he was found guilty.[158] The Youk case, however, was different from the prior cases in that Youk, who had Lou Gehrig's disease, was unable to trigger his own death, and Kevorkian directly injected him with a lethal drug.[159] The act was also televised on *60 Minutes*.[160] The jury ultimately found Kevorkian guilty of

153. A judge in Wayne County determined the law to be unconstitutional, but an Oakland County prosecutor said the ruling was not binding in his jurisdiction. *Suicide Law Struck Down, but Kevorkian Stays Jailed*, N.Y. TIMES, Dec. 14, 1993, at A18; *see generally* Hobbins v. Att'y Gen., 518 N.W.2d 487 (Mich. Ct. App. 1994) (discussing procedural histories of appeals that it consolidated from the Wayne and Oakland circuit courts regarding the constitutionality of the assisted suicide ban), *rev'd* People v. Kevorkian, 527 N.W.2d 714 (Mich. 1994).

154. *Hobbins*, 518 N.W.2d at 491 (holding the legislation criminalizing assisted suicide constitutionally infirm because it contained "two distinct objects"), *rev'd*, *Kevorkian*, 527 N.W.2d 714.

155. *Kevorkian*, 527 N.W.2d at 739 ("[E]ven absent a statute that specifically proscribes assisted suicide, prosecution and punishment for assisting in a suicide would not be precluded. Rather, such conduct may be prosecuted as a separate common-law offense . . . .").

156. *See* Frontline: The Kevorkian Verdict: Chronology, *supra* note 150 (noting the three instances in which Michigan juries acquitted Kevorkian on charges brought against him under the state's assisted suicide ban, including May 2, 1994 for the death of Thomas Hyde; March 8, 1996 for two separate deaths; and April 1, 1996 for the deaths of Marjorie Wantz and Sherry Miller); *Newshour: CBS' Assisted Suicide Decision* (PBS television broadcast Nov. 24, 1998), *transcript available at* http://www.pbs.org/newshour/bb/media/july-dec98/suicide_11-24.html (referencing interview between CBS's Mike Wallace and Jack Kevorkian); *see e.g.*, David Margolick, *Jury Acquits Dr. Kevorkian of Illegally Aiding a Suicide*, N.Y. TIMES, May 3, 1994, at A20 (discussing Michigan's assisted suicide ban in light of Kevorkian's acquittal of charges brought against him for assisting Thomas Hyde commit suicide).

157. *See* Michael Betzold, *The Selling of Doctor Death: How Jack Kevorkian Became a National Hero*, NEW REPUBLIC, May 26, 1997, at 22.

158. *See* People v. Kevorkian, 639 N.W.2d 291, 296 (Mich. Ct. App. 2001).

159. *See id.*

160. *See 60 Minutes: Death by Doctor*, *supra* note 116; *see also* Kevorkian, 639 N.W.2d at 296 (noting that the videotapes of Kevorkian administering lethal drugs to Youk, which were aired on *60 Minutes*, were shown to the jury during trial).

second degree murder and the judge sentenced him to ten to twenty-five years in prison.[161] In her sentencing statement, Judge Jessica Cooper was undoubtedly influenced by Kevorkian's blatant disregard for the law stating: "[Y]ou had the audacity to go on national television, show the world what you did and dare the legal system to stop you. Well, sir, consider yourself stopped."[162]

The response of the criminal justice system to the public disclosure by Dr. Timothy Quill that he had assisted one of his patients who suffered from leukemia end her life, was clearly one of compassion.[163] In an article in the *New England Journal of Medicine*,[164] Quill stated that he prescribed the patient, a forty-five-year old woman, "with enough barbiturates . . . to commit suicide when and if the time came . . . . [He] made sure that she knew how to use the barbiturates for sleep, and also that she knew the amount needed to commit suicide."[165] The prosecutor brought the case before a grand jury, seeking a criminal indictment. The grand jury, clearly sympathetic to the plight of the patient, declined to indict Quill on criminal charges.[166]

As demonstrated by these cases and others, there are a number of ways in which the criminal justice system may respond to physician lawbreaking when society is strongly divided about the correctness of the law. Prosecutors may give low priority to enforcement, or, as in the case of Quill, a grand jury may decline to issue an indictment.[167] If the case goes to court, juries are often sympathetic to physicians when they are performing what is perceived as a merciful act. In many cases, such as those of Kevorkian, where a physician has been prosecuted for physician-assisted suicide or euthanasia, he or she has been acquitted.[168] In some cases, this may be a result of jury nullification. When a physician is found guilty, judges may have some discretion in how they sentence physicians accused of these kinds of crimes and may be more

161. Kevorkian, 639 N.W.2d at 296.

162. *Statement from Judge to Kevorkian*, N.Y. TIMES, Apr. 14, 1999, at A23.

163. *See supra* text accompanying note 117.

164. Quill, *supra* note 117.

165. *Id.* at 693; *see also* Lawrence K. Altman, *Jury Declines to Indict a Doctor Who Said He Aided in a Suicide*, N.Y. TIMES, July 27, 1991, at A1 (discussing Quill's indictment by a grand jury for charges brought against him related to his role in his patient's suicide).

166. *See* Altman, *supra* note 165.

167. *See also* Kollas et al., *supra* note 8, at 235–36 (discussing *Louisiana v. Pou*, in which the Louisiana Attorney General was unable to obtain a grand jury indictment against Dr. Anna Pou, who allegedly euthanized four patients who could not be evacuated from a health care facility after Hurricane Katrina struck New Orleans).

168. *See, e.g.*, David J. Garrow, *Letting the Public Decide About Assisted Suicide*, N.Y. TIMES, June 29, 1997, at E4 (describing the acquittal of Dr. Ernesto Pinzon-Reyes on charges of "hastening the death of a terminally ill cancer patient"); Ronald J. Hansen, *Kevorkian Released from Prison After 8 Years*, DETROIT NEWS, June 2, 2007, at 1 (noting that Kevorkian had been acquitted in several cases of assisted suicide, until he represented himself in court).

lenient when societal views about the issue are strongly divided. The various points in the process offer a set of safety valves to put the brakes on a system that might otherwise be too quick to lump all accused in the same category.

Prosecutor reluctance to enforce or charge and jury reluctance to convict may stem from two problems with the relevant laws: the lack of a consensus as to their moral validity and to their medical justification. Often, these laws have a moral basis and there is not agreement among the profession or across society as to whether the prohibited actions are wrong as a normative matter. While some legal enforcement of morality may be uncontroversial—when the law requires some to refrain from acts that "others" think are immoral, but the target of the law does not—compliance may be limited.[169] This may be especially true when the moral judgments are religiously based.[170]

Additionally, these laws are medically questionable. There is often disagreement within the profession as to what is medically appropriate in some of these cases, e.g., physicians may not agree on what is the appropriate dosage of opioids to prescribe to a chronic pain patient; what treatment is in the best interest of a severely impaired and premature newborn; when medical care is truly futile; or whether physician-assisted suicide is justified. Different views within the profession prevent establishment of a unified standard of care and make arguments to harshly treat these physicians more difficult.[171]

V. OBSERVATIONS, SUGGESTIONS, AND CONCLUSION

The ways in which physicians respond to the law affirm David Mechanic's observation that medicine has its share of angels *and* scoundrels; yet it is not always clear in which group they belong. For those physicians who break the law, the reasons for their actions will no doubt affect our assessment. When greed is the motivation, we want to condemn physicians for their actions and punish them harshly. In the case of violation of the fraud laws, these doctors appear to view themselves as "above the law" and, as Professor Johnson suggests, to push the boundaries of safe harbors.[172] These physicians may also lack the sensitivity to either the legal or extra-legal sanctions that accompany lawbreaking and do not see breaking these laws as being in conflict with their professional identity. They often view the laws as unfair and feel their actions are justified in order to receive "appropriate" compensation for their work.

169. *See* Greenawalt, *supra* note 102, at 710 ("[M]uch legal enforcement of morality is uncontroversial and rarely discussed.").

170. *Id.*

171. *See* Kollas et al., *supra* note 8, at 233 (finding that "divergent views of the standard of care" were a feature of the five cases they reviewed in which physicians were criminally prosecuted in conjunction with palliative or end of life care).

172. Johnson, *supra* note 2, at 1019 ("There is some sense that doctors are willing to push the envelope on the financial side . . . and are less willing to do that . . . in their clinical decisions.").

Yet, there are other physicians for whom greed is not the basis of their violation of the fraud laws. In some cases, they believe the insurance rules are harmful to their patients, in others, their violation of the law is not intentional; it is due to negligence and ignorance of the law. Similarly, when physicians violate the CSA because they are prescribing opioids for chronic pain patients, in some cases the motivation may be greed, but often it is because they are trying to treat their patients' pain. In the latter case, they may not know they are breaking the law or they may disagree with the law, believing that their prescribing is appropriate. In many of these cases, as well as some fraud cases, the government response appears overly zealous and lacks judicious discretion. However, in cases where the motivation for the physician's action is clearly not greed but is patient care, the legal response varies from wise inaction to disregard of relevant medical evidence.

In this section, based on the reasons that physicians appear to violate both the fraud laws and laws regarding patient care, as well as observations about how our law enforcement system reacts to this physician behavior, I make a series of suggestions. These suggestions are geared toward improving physician compliance with the law and improving the quality of patient care.

A. Need for Law Enforcement to Consider Impact on Patients

In exercising its discretion to pursue physicians for alleged wrongdoing, law enforcement appears to ignore the impact of its actions on patient care. Failure to take this factor into account is misguided. The impact assessment should begin with some consideration of the trauma caused to patients by law enforcement personnel who barge into physicians' offices to arrest them while they are seeing patients, with guns drawn, and in SWAT team attire.[173] Such dramatic and strong-arm tactics seem wholly unnecessary and are likely harmful to the innocent patients who are forced to witness them.

Moreover, law enforcement should consider how arrest and prosecution of physicians may affect patient access to health care. Doctors who are arrested and prosecuted for fraud or inappropriate prescribing not only face possible jail time and fines but are also likely to lose their licenses, staff privileges, or both. Effectively, they are lost from the numbers of physicians available to treat patients. The little data that is available seems to indicate that often the physicians who are targeted for arrest by prosecutors for fraud are working in

173. *See, e.g.*, Hoffmann, *supra* note 4, at 242 (discussing the arrest of Dr. Cecil Knox based on various charges related to his prescribing of narcotics) (citing Maia Szalavitz, *Dr. Feelscared: Drug Warriors Put the Fear of Prosecution in Physicians Who Dare to Treat Pain*, REASON, Aug. 2004, at 32); *see also supra* text accompanying notes 142–43.

underserved areas or with underserved populations.[174] Taking these physicians out of circulation may mean that their patients lack access to a licensed physician, except in a medical emergency.

These arrests and prosecutions may also have a chilling effect on the behavior of other physicians.[175] A national survey of 331 doctors conducted by the Association of American Physicians and Surgeons (AAPS) in July 1999, regarding the impact of Medicare regulations and the increased government crackdown on fraudulent billing, revealed that "[i]ncreased fear of prosecution or government retaliation has had a negative impact on patients' access to doctors and their ability to receive certain services such as surgery."[176] Over 80% reported "increased fear of prosecution or investigation in the prior three years"; 71% "reported making changes in their practice to avoid the threat of prosecution, including greatly restricting services."[177] More than one-third (34%) of all physician respondents had restricted services, such as surgery, to Medicare patients.[178] Almost one-fourth (23%) said they were not accepting new Medicare patients, and reported that the desire to avoid unpleasant or even threatening encounters with Medicare was a reason for this change in practice pattern.[179] Respondents also complained that compliance with Medicare regulations took a significant amount of their time away from patient care.[180]

In addition, the arrest and prosecution of physicians for prescribing opioids has had far-reaching impacts on the treatment of chronic pain patients. Due to the limited number of physicians willing to treat this patient population, these prosecutions have made it more difficult, in some cases impossible, for chronic pain patients to find physicians who will treat them.[181]

B. Complexity/Legitimacy of Laws

The fact that such a large number of physicians are being arrested and prosecuted for fraud and prescription drug violations raises the possibility of

174. *See* Dayna Bowen Matthew, *An Economic Model to Analyze the Impact of False Claims Act Cases on Access to Healthcare for the Elderly, Disabled, Rural and Inner-City Poor*, 27 AM. J.L. &. MED. 439, 462–66 (2001).

175. *See generally id.* (discussing the "chilling effect" in terms of physician behavior that results from the uncertainty or inability to predict which behavior will lead to false certification prosecutions).

176. *See* Press Release, Ass'n of Am. Physicians & Surgeons, Doctors' Study: Medicare "Fraud" Crackdown Hurts Patients (Feb. 4, 2000), *available at* http://aapsonline.org/press/medspr.htm.

177. *Id.*

178. *Id.*

179. *Id.*

180. *See id.*

181. *See* Hoffmann, *supra* note 4, at 235.

overreaching on the part of prosecutors, and should raise red-flags for those of us concerned about the legitimacy of the rules *and* their enforcement, as well as their impact on patient care and the health care system.

Physicians who violate the fraud laws, in some cases, may have been motivated by their moral evaluation of the act, i.e., they may not have viewed their behavior as wrong or they may have viewed the law as unfair. The literature lends support to this interpretation of the behavior of physicians who intentionally break the fraud laws.[182] Both physicians and medical students were more likely to blame the Medicare and Medicaid billing rules for physician arrests and prosecutions than the actions of the physicians.[183]

The literature on white-collar crime acknowledges that one's moral beliefs, independent of considerations of costs and benefits, can constrain illegal behavior.[184] But, perhaps equally likely, moral beliefs may lead to illegal behavior if the law is deemed to be unfair or unjust. In those circumstances, the response of the criminal justice system is typically to increase sanctions in order to ensure compliance. Over the last decade in fact, the sanctions for violation of the fraud laws have been significantly increased.[185] Another route, however, could be to either persuade physicians that the Medicare and Medicaid billing procedures are fair or to change them so that they are fairer.

Physician reaction to the fraud laws stems largely from the complexity of the billing rules for Medicare and Medicaid. Thus, this may be a starting point for reform. In Japan, the perceived unfairness of the medical insurance reimbursement system led to widespread fraud but the government, understanding the flaws of the system, elected not to aggressively prosecute physicians who violated the rules.[186] In the United States, we have a reimbursement system that is perceived as unfair yet it is aggressively enforced. The two in combination seem especially misguided and suggest the need to simplify or rework the Medicare and Medicaid rules for billing and fraud control and, or at least until that occurs, adopt a less aggressive enforcement policy.

Physician complaints about laws stem from concerns not only about the fairness of the laws but also about the fairness of their enforcement. In the

182. *See* Raymond Paternoster & Sally Simpson, *Sanction Threats and Appeals to Morality: Testing a Rational Choice Model of Corporate Crime*, 30 LAW & SOC'Y REV. 549, 579 (1996) (finding that white-collar criminals use a utilitarian calculation when deciding to break the law but include in that calculation their moral assessment of the law).

183. *See* Keenan et al., *supra* note 37, at 170–71.

184. Paternoster & Simpson, *supra* note 182, at 554.

185. *See supra* text accompanying notes 50–56.

186. *See* Ames Gross & Gayatri B. Koolwal, *Patient Disclosure Rights in Japan's Healthcare System*, PAC. BRIDGE MED., Mar. 1998, http://www.pacificbridgemedical.com/publications/japan/1998_patient_disclosure_rights_in_japans.htm (noting that the "Japanese are loathe to use [legal] means" to improve the quality of patient care).

fraud area, there are numerous anecdotes about physicians who have been criminally prosecuted for relatively minor infractions, i.e., less than a few hundred dollars of overbilling.[187] In some cases, the sanctions also seem largely incommensurate with the violation. Moreover, at least early in the program's history, numerous financial incentives existed for law enforcement agents to arrest and prosecute physicians for fraud violations.[188] These allegations and facts contribute to a perception that the entire fraud enforcement system is unfair and threatens the overall legitimacy of the fraud control effort. Professor William Sage has observed that the focus of the fraud laws on protecting the financial integrity of the Medicare and Medicaid systems rather than patient welfare "tends to breed cynicism among physicians and brings fraud enforcement into conflict with sound health policy."[189] Others have warned that more aggressive law enforcement initiatives "could threaten the long-term political support that is essential to sustaining [fraud control] efforts and might upset the balance between effective fraud control and the burden of compliance."[190]

C. Turning Negligence into Crime

An additional observation that surfaces after reviewing the cases in which physicians "break the law" is the broad reach of the law to include unintentional violations. There is general agreement that someone who intentionally or knowingly breaks a good law should be prosecuted and punished. However, when the violation of the law is unknowing or unintentional,[191] criminal sanctions may not be appropriate as applied to

187. *See* LIBBY, *supra* note 53, at 32. For example, Libby notes that "[d]uring Richard Kusserow's tenure as [Inspector General of DHHS] from 1981 to 1992, he inaugurated a veritable reign of terror against physicians and other providers. [He] encouraged trivial and malicious prosecutions of doctors for alleged fraud of less than a hundred dollars." *Id.* Libby also provides examples of similarly aggressive prosecutions by state Medicaid Fraud Control Units (FCU). He cites the Hawaii FCU, under the direction of George Yamamoto, which "prosecuted an optician who was convicted of a criminal felony for overbilling Medicaid by $7.75." *Id.* at 34.

188. Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 246 (2004) (describing funding and incentives in fraud control).

189. William M. Sage, *Fraud and Abuse Law*, 282 JAMA 1179, 1180 (1999). Sage refers to "burdensome coding requirements for evaluation and management [that] continue the unfortunate transformation of the medical record from a clinical management tool into a defensive document." *Id.*

190. ROBERT BERENSON ET AL., AARP PUB. POLICY INST., COST CONTAINMENT IN MEDICARE: A REVIEW OF WHAT WORKS AND WHAT DOESN'T 61 (2008), *available at* http://assets.aarp.org/rgcenter/health/2008_18_medicare.pdf.

191. The Model Penal Code includes intentional, knowing, reckless, and negligent as mental states that may be sufficient to establish criminal intent. MODEL PENAL CODE § 2.02(2)(a)–(d) (1962).

physicians, despite the fact that the law may allow for it. In these cases, the law may be overly broad, permitting criminal prosecution for negligence.

As regards the fraud laws, it is difficult to know whether physicians intentionally or knowingly violate the law, but it appears that in some cases physicians are being arrested, prosecuted, and threatened with criminal sanctions for technical, or regulatory, violations. Given the multitude and complexity of rules governing Medicare and Medicaid billing, it is possible that in some cases physicians are not intentionally violating the law but are making mistakes in their billing practices. Again, prosecutions for such actions raise concerns about fairness and legitimacy. Rosenzweig argues that as we expand what constitutes criminal wrongs "to include trivial matters more suitably treated as civil wrongs, those who act in good faith yet get caught by the arbitrary exercise of governmental authority perceive themselves as victims of an over-zealous regulatory state that trivializes crime . . . and erodes its moral footing."[192] Certainly, an argument can be made that such violations should not be subject to criminal prosecution at all, but if they are, sanctions for those who unintentionally commit these technical violations should be less severe than for those where intentionality is clear.[193]

In addition to the arrests and prosecutions of physicians for fraud, scores of physicians are being arrested and prosecuted for drug abuse and diversion based on a standard that is "uncomfortably close" to a civil malpractice standard.[194] The standard has led to the conviction of numerous physicians who were prescribing large volumes of scheduled drugs, e.g., opioids, and treating a large number of chronic pain patients. In many of these cases, there was no evidence that the physicians benefited financially from their prescribing (other than for the office visit). Moreover, "experts disputed the 'reasonableness' of the physician's prescribing practices; and . . . the physician's patients often included drug addicts who lied to the physician to obtain their drugs."[195]

In addition, under the CSA, while the statutory language for criminal liability requires that a physician knowingly violate the law,[196] the courts have eroded that requirement in a way that is arguably harmful to patients. As in the cases of fraud, "[b]ecause determining what the physician actually knew or intended is difficult, 'courts have held that a deliberate course of conduct whereby the defendant avoids the requisite guilty knowledge may be held

192. Rosenzweig Testimony, *supra* note 62, at 145.

193. *See id.* at 152–53.

194. Under the CSA, a physician is guilty of criminal conduct if he or she prescribes without a "legitimate medical purpose" and outside "the usual course of his professional practice." 21 C.F.R. § 1306.04(a) (2008); *see supra* text accompanying notes 76–82.

195. Hoffmann, *supra* note 4, at 239.

196. *See supra* text accompanying notes 76–82.

tantamount to guilty knowledge per se.'"[197] In these cases, the trial court often issues to the jury a "'conscious avoidance' charge, also known as a 'willful blindness' instruction"[198] or an "ostrich instruction, because the defendant is considered by the court to have, figuratively, stuck his head in the sand to avoid learning truths that would otherwise have been patently obvious to the average reasonable person."[199]

For the more common cases of illegal drug distribution, the instructions have been used where the defendant is accused of transporting drugs in a suitcase or handbag and claims not to have been aware that the bag contained the drugs. The instructions, however, have been borrowed from that setting and applied in cases against physicians who prescribed drugs to patients who subsequently diverted them. In these cases, the prosecution argues that the physician "deliberately ignored facts that would have led [a reasonable physician] to believe the patient was diverting the drugs."[200]

A willful blindness instruction is inappropriate in this context as it undermines the doctor-patient relationship. I have argued elsewhere that:

> [d]octors . . . must develop a trusting relationship with their patients, which requires them to listen to their patients and believe their accounts of their symptoms . . . . [T]his is especially true in the field of pain management where there is no objective test for pain. Neither is there a wholly accurate test to determine whether the patient is telling the truth or fabricating his symptoms. Physicians who ignore their patient's pain accounts would be arguably negligent. Prosecutors and the DEA argue that "doctors violate the law when they prescribe pain pills to patients who they know—or reasonably should know—are selling or abusing the drugs." But, this puts physicians in the position of being watch dogs for law enforcement or, at least, suspicious of their patients' claims of pain.[201]

Deborah Hellman, in an article that focuses on the use of the willful blindness instruction in these cases and whether the physician's professional

197. Hoffmann, *supra* note 4, at 276 (quoting Deborah Sprenger, Annotation, *Propriety of Instruction of Jury on "Conscious Avoidance" of Knowledge of Nature of Substance or Transaction in Prosecution for Possession or Distribution of Drugs*, 109 A.L.R. FED. 710, 713, § 2[a] (1992)).

198. *Id.*

199. *Id.* at 276 n.340 (quoting Sprenger, *supra* note 197, at 710, 713, § 2[a]) (internal quotation marks omitted).

200. *Id.* at 276–77.

201. *Id.* at 303 (footnotes omitted). Dr. William Hurwitz, a pain doctor who was criminally prosecuted under this standard, has written that the standard "forces doctors who try to treat pain to act like police, reinforcing a perverse medical paternalism that subverts the ethical imperatives designed to protect patient autonomy and dignity. This distortion of the patient-physician relationship stigmatizes patients and erodes their trust." *Id.* at 304 (quoting William E. Hurwitz, *Pain Control in the Police State of Medicine (Part II)*, 8 J. AM. PHYS. & SURGEONS 13, 14 (2003)) (internal quotation marks omitted).

obligations should provide a defense to the charges at issue, argues both that "[p]rosecuting doctors for being willfully blind to a patient's wrongful reselling of drugs criminalizes physicians' trust in their patients" and that "doctors treating patients in pain act rightly in trusting their patients, and thus the law erroneously imposes criminal sanctions on actions that are morally justified."[202]

The expansion of the white-collar criminal law and drug control laws to include unintentional violations may also have led to recent criminal prosecutions of physicians for medical negligence. There are no comprehensive data on the number of cases in which physicians have been prosecuted for criminal negligence, but, while the numbers are quite small,[203] they appear to be growing.

In 1990, the AMA commented that the "prosecution of physicians for clinical mistakes was 'almost unknown.'"[204] However, a series of criminal prosecutions of physicians in the late 1980s and early 1990s prompted the AMA to adopt a resolution "to insure that medical decision-making exercised in good faith, does not become a violation of criminal law."[205] In 1995, the AMA adopted a more formal statement on the subject condemning the "current trend" of the criminalization of medical malpractice.[206] At the time of that statement, "the AMA estimated [that] only about [ten] physicians nationwide had been prosecuted for medical negligence" but feared increased prosecutions in this area.[207] Two articles published in 2001 and one article published in 2007 describe cases where physicians were prosecuted for medical negligence in the recent past. Filkins identified nine cases between 1981 and 1995;[208] Liederbach et al. identified fifteen cases between 1986 and 1999,[209] and Kollas et al. reviewed five criminal prosecutions against physicians occurring between 1992 and 2005 involving palliative or end of life care.[210]

202. Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701, 702 (2009).

203. *See* James A. Filkins, "*With No Evil Intent": The Criminal Prosecution of Physicians for Medical Negligence*, 22 J. LEGAL MED. 467, 471–72 (2001) (noting that there are only fifteen reported appellate decisions of such prosecutions between 1809 and 1981).

204. *Id.* at 469–70 (quoting *Pennsylvania Prosecutor Finds No Grounds for Charges Against Surgeon*, AM. MED. NEWS, June 1, 1990, at 5).

205. *Id.* at 470 (quoting Morton M. Kurtz, *Criminalization of Medical Judgment, Resolution 223*, PROC. AM. MED. ASS'N INTERIM MEETING (1993)).

206. *Id.* (quoting *Criminalization of Health Care Decision-Making, Resolution 202*, PROC. AM. MED. ASS'N, INTERIM MEETING (1995)) (internal quotation marks omitted); *see also* Liederbach et al., *supra* note 3, at 164 (citing AMA Policy H-160.946).

207. Filkins, *supra* note 203, at 470.

208. *Id.* at 471–90. The cases actually include prosecutions of eight physicians and one corporation for medical negligence. *Id.* at 471.

209. Liederbach et al., *supra* note 3, at 150–56.

210. Kollas et al., *supra* note 8, at 234–36.

Research on these cases indicates that a common element is disagreement about the relevant standard of care. Filkins observed that these cases are often inappropriately addressed in the criminal justice system as prosecutors fail to establish that the physician breached a standard of care or that the physician's actions caused the patient's harm.[211] Rather, the physician's state of mind acts as a substitute for careful scrutiny of the physician's actions and their impact on the patient's injury.[212] He argues that "[a] defendant physician's state of mind should be weighed only after the issues of causation and standard of care have been resolved and all the facts considered. To do otherwise exposes physicians 'to potential criminal liability for their actions related purely to their exercise of professional clinical judgment.'"[213] Kollas et al. similarly concluded that establishing a violation of the standard of care was a weak link in the prosecution of a number of physicians who were charged with homicide for the death of patients who were terminally ill.[214]

The justification for use of the criminal laws has traditionally included deterrence, rehabilitation, and retribution. When physicians are prosecuted for negligent acts, it is unlikely that such actions will have a deterrent effect. Deterrence is grounded in rational choice theory, which assumes actors weigh the costs and benefits of their acts. When their acts are not intentional, such a model has less explanatory value.[215] Alternatively, efforts to prosecute physicians for negligent acts may have an "anti-deterrent" effect. Liederbach et al. speculate that "when prosecutions occur, they will trigger an 'oppositional culture' among doctors, in which physicians band together to define such intervention as illegitimate and characterize the doctors to which they are applied as scapegoats of politically ambitious prosecutors."[216] If this is so, they conclude that "such resistance to control might create 'defiance' and produce effects that undermine deterrence."[217]

The goal of rehabilitation is also unlikely to be met through criminal sanctions for negligent behavior. Arguably, these physicians could benefit from mentoring or retraining, but they will not be subject to these forms of

211. Filkins, *supra* note 203, at 498.

212. *Id.* at 498.

213. *Id.* at 498–99 (quoting State v. Naramore, 965 P.2d 211, 224 (Kan. Ct. App. 1998) (Brazil, C.J., dissenting)).

214. Kollas et al., *supra* note 8, at 237–38.

215. *See* Liederbach, *supra* note 3, at 166 ("[T]he extent to which white-collar offenders are deterrable by legal sanctions remains uncertain. This issue is likely to be complicated still further in the case of doctors, where the behavior targeted for deterrence is perhaps not intended nor due to rational calculation . . . ." (citation omitted)).

216. *Id.*

217. *Id.* But Liederbach et al. also hypothesize that such prosecutions could have a deterrent effect by creating stronger incentives for doctors to police their peers and adopt practices that reduce medical errors and improve patient safety. *Id.* at 167.

rehabilitation through the criminal justice system.[218] These educational approaches, however, could be imposed by state medical boards, if they were to become more active in disciplining these types of cases.

This leaves retribution as the primary objective for prosecution of physicians for gross medical malpractice. This justification for criminalization is least applicable when intent is absent.

D. Need for Law Enforcement Self-Assessment Regarding Impact

It also becomes clear, from reviewing physician lawbreaking and the law enforcement response, that there is a failure on the part of law enforcement to adequately evaluate its own effectiveness. For example, regarding the fraud laws and their enforcement, while there appear to be some indications that the increased expenditure on fraud control has had a deterrent effect, the impact of that effect is unknown.[219] Moreover, there appear to be few efforts to determine whether the costs associated with the system are commensurate with the benefit. Efforts to evaluate the cost-effectiveness of the laws and their enforcement seem to focus most often on return on investment, i.e., the number of government dollars spent on enforcement and the dollars recovered from fines and sanctions, rather than an effort to look at the full costs and benefits of the program to society.[220] The latter, for example, would include the cost to physicians of compliance with the complex billing rules,[221] the costs of false positives (i.e., those physicians who are inappropriately captured, prosecuted, and sanctioned), the costs to patients who are unable to find a physician to treat them or who are denied care, as well as any benefits that may result from reductions in unnecessary treatment.[222] In addition, there does not appear to be

218. *See generally* Russell E. Farbiarz, *Victim-Offender Mediation: A New Way of Disciplining America's Doctors*, 12 MICH. ST. U. J. MED. & L. 359, 362 (2008) (noting that rehabilitation was "abandoned as the primary goal [of the criminal justice system] in the 1970's and 1980's" but that it could be reintroduced to physicians through victim-offender mediation).

219. *See* BERENSON ET AL., *supra* note 190, at 60.

220. *See, e.g.*, *id.* at 61.

221. Sage has observed that "fraud compliance has become a full-time job for providers as well as enforcers, raising the risk of symbiotic bureaucracies that waste rather than preserve resources." Sage, *supra* note 189, at 1180.

222. An academic study by Becker et al., for example,

> analyzed the impact of increased support for fraud enforcement activities on the costs and quality of care provided to Medicare patients . . . . The authors concluded that increased fraud enforcement resources result in greater declines in expenditures . . . without evidence of an increase in adverse health outcomes. There were, however, significant differences in the effects of increased enforcement across different types of patients (e.g., age, gender, and race) and hospitals (e.g., ownership type, size, and location).

BERENSON ET AL., *supra* note 190, at 60 (citing David Becker et al., *Detecting Medicare Abuse*, 24 J. HEALTH ECON. 189, 189–210 (2005)).

consideration of the potential benefit of alternatives to aggressive enforcement of the fraud laws.

There is some acknowledgement in the literature that the fraud laws were initially quite effective at reducing large scale fraud and blatant violations of the law such as "Medicaid mills" where physicians billed for services not rendered.[223] Today, the law enforcement efforts related to these laws seem more targeted at uncovering fraud in mainstream medical practice where the wrongdoing is often based on technical violations of the law and is very costly to discover and prosecute.[224] While enforcement efforts are assisted by whistleblowers, they still require painstaking record review and attention to minute billing details.[225] These more recent efforts may have diminishing returns, especially when the violations are associated with technical oversights. Moreover, a recent report by AARP, based on interviews with several former government officials, found that "efforts to enlist beneficiaries[] [as whistleblowers to] help in identifying fraud have not been successful" due to the complexity of the Medicare billing rules and the "difficulty of distinguishing innocent billing errors from intentional fraud."[226]

Finally, policy makers should consider the effectiveness of the fraud control laws and their enforcement in comparison to alternative approaches to combating fraud. Hyman argues, for example, "that Medicare has underinvested in prepayment claims review and has compensated for this by imposing very severe sanctions on fraudulent claims through the [False Claims Act] and other legal tools."[227] Similarly, in the area of prosecution of physicians for prescribing of opioids, the U.S. Drug Enforcement Administration (DEA) does not appear to have evaluated whether its efforts have reduced drug diversion and abuse and/or how those efforts have affected patient access to care.

Failure to assess their practices appears to be quite common among law enforcement entities. In his testimony before the Senate Subcommittee on Crime and Drugs in 2002, Rosenzweig pointed out that

> there is virtually no data on whether or not criminal enforcement programs actually have a deterrent effect, much less assessments of the quantum of that effect. Instead, agencies prosecuting white-collar crime routinely report only

223. *See* Paul E. Kalb, *Health Care Fraud and Abuse*, 282 JAMA 1163, 1163 (1999).

224. *See id.*

225. *See* LIBBY, *supra* note 53, at 24 ("The government has broadened its definition of health fraud at a time that most 'big time' fraud in health care has been eliminated. Prosecutors are now increasingly forced to concentrate upon nit-picking technical interpretations of regulations to convict solo practitioners.").

226. BERENSON ET AL., *supra* note 190, at 60.

227. *Id.* at 60–61 (citing David A. Hyman, *HIPAA and Health Care Fraud: An Empirical Perspective*, 22 CATO J. 151 (2002)).

> the number of cases they have brought, without any attempt to determine the effectiveness of their activity.[228]

Nor do they appear to assess the costs of their activities beyond government expenditures.

These comments highlight a major difference between medical practice and law enforcement practice. While quality improvement has become an integral part of health care systems, the concept seems to be foreign to law enforcement. Law enforcement agencies do not appear to make efforts to assess the impact of their practices or whether they are achieving their ultimate goals and at what cost.

E. Need for System of Expert Advice to Law Enforcement

Many of the cases where law enforcement has "overreached" might have been avoided by prosecutors and law enforcement agents if they had consulted or collaborated with medical experts to determine whether the physician who was the target of their investigation was a threat to the public by virtue of their medical practice. This is especially true in the context of physicians arrested for the prescribing of opioids or for gross negligence. Such medical expertise could come from state medical boards. Arguably, there needs to be better collaboration between state medical boards and prosecutors. In a study of cases where physicians were prosecuted for drug diversion, Reidenberg and Willis found that in the large majority, state medical boards had not been consulted at all prior to the physician's criminal indictment.[229]

In a number of other countries, e.g., Japan, New Zealand, Saudi Arabia, and India, physicians are prosecuted for medical acts largely because of the "lack of alternative forms of redress," such as disciplinary actions by medical boards.[230] Given the existence of these entities in the United States, however, it seems inappropriate to jump to the criminal justice system to address cases related to standards of patient care. State medical boards are certainly better equipped to evaluate acceptable medical practice and the threat of a physician's practices to public welfare than are federal and state prosecutors.[231] Admittedly, state medical boards are often underfunded and understaffed and

228. Rosenzweig Testimony, *supra* note 62, at 155.

229. M.M. Reidenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients*, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 905 (2007).

230. Edward Monico et al., *The Criminal Prosecution of Medical Negligence*, 5 INTERNET J.L., HEALTHCARE & ETHICS 1 (2007), http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijlhe/vol5n1/criminal.xml.

231. *See* Hoffmann, *supra* note 4, at 307 (arguing in the context of prosecution for drug diversion that medical boards are "better equipped to determine whether the volume and dosages of opioids prescribed for a patient are consistent with acceptable medical practice than are federal and state prosecutors").

cannot devote the resources necessary to adequately police all cases of physician wrongdoing. But, there is no reason why federal law enforcement agents should not consult with state medical boards regarding the need for disciplinary action in a given case, especially before criminal prosecution. In addition, greater resources could be devoted to state medical boards, perhaps by reallocating resources currently being devoted to federal and state criminal enforcement of medical wrongdoing. Such a shift may both reduce the need for criminal action and improve the quality of medical care.

F. Physician Disobedience as Call for Further Scrutiny and Possible Legal Change

A final observation when looking across the ways in which law enforcement responds to physician violation of the law, is that when physicians intentionally violate the law to care for patients or engage in actions that might be categorized as civil disobedience, more often than not, they appear to be dealt with fairly by the individualized safety valves incorporated in the criminal justice system. Perhaps, as a result, initiatives to change these laws are often ineffective. Failure on the part of legislators to respond to bad law claims where physicians are being criminally prosecuted, however, may be based on an effort to signal moral wrongdoing rather than on evidence that the laws are providing greater benefit than harm. In many of these cases, legislators considered the *potential* negative patient impact of the laws and struck a balance between the competing policy and moral arguments that shape where the line is drawn between legal and illegal activity. While in some cases, the policy arguments might weigh in favor of repealing the law, legislators have decided that there are important values or moral reasons to keep the law in effect.

In many cases, however, the moral values that have tipped the balance in the legislative equation are not uniformly shared by society. Oftentimes these moral values may blind legislators to new policy arguments or empirical evidence. But, legislators should be open to new information and data about the impact and effectiveness of the laws that they passed, willing to consider a recalibration of the balance.

When physician lawbreaking in the patient's interest is fairly isolated, the criminal justice system may respond appropriately and compassionately. But when physician lawbreaking based on asserted fiduciary duties to patients becomes more widespread, policy makers should seek to collect and compile data on the impact of the law on patients. Initial assumptions underlying the passage of the law may have been misguided or not empirically supported. For example, discussions regarding the criminalization of physician-assisted dying came to the fore during the time that Dr. Jack Kevorkian was assisting

individuals end their lives.[232] The policy arguments put forth by those who opposed the legalization of physician-assisted suicide included concerns that vulnerable individuals, including the elderly, women, the uninsured, the poor, and people with limited education, would be overrepresented in the group of individuals who would take advantage of the service, as they would be "considered marginal and expendable and come under pressure to end their lives prematurely."[233] Ten years of experience and empirical data from Oregon, where physician-assisted suicide is legal, have shown that these concerns have not been borne out.[234] Instead, the results indicate an improvement of end of life care in Oregon and, in particular, knowledge of palliative care and use of hospice.[235]

Initiatives based on empirical data of the impact of various laws on patient care may help to persuade policy makers of the need to change existing laws. On the other hand, policy arguments cannot necessarily counter moral concerns. Yet, by providing better data to inform policy arguments and challenge unfounded views, the debate can be narrowed down to the core issues at stake, whether they are morally, policy, or politically driven.

In conclusion, I agree with Professor Johnson that when we encounter a situation where physicians complain about bad law because it prevents them from appropriately treating patients, we should take such claims seriously and legislators should treat them as sentinel events. This is especially true when physicians break the law, not out of some selfish motive, but in order to provide better care to their patients. And, even when doctors who break the law have motives that are difficult to disentangle but may include dual motivations, i.e., patient care and economic gain, we should not ignore them but rather urge greater efforts at evaluating the impact of these laws on patient care.

232. *See supra* text accompanying notes 149–62.

233. KATHRYN L. TUCKER, AM. CONSTITUTION SOC'Y FOR LAW & POLICY, CHOICE AT THE END OF LIFE: LESSONS FROM OREGON 8 (June 2008), http://www.acslaw.org/files/Kathryn%20L.%20Tucker%20Issue%20Brief.pdf (citing Brief for Not Dead Yet et al., as Amici Curiae in Support of Defendants-Appellants, Glucksberg v. Washington, 521 U.S. 702 (1997)).

234. *See* Margaret P. Battin et al., *Legal Physician-Assisted Dying in Oregon and the Netherlands: Evidence Concerning the Impact on Patients in "Vulnerable" Groups*, 33 J. MED. ETHICS 591, 597 (2007) ("[W]e found no evidence to justify the grave and important concern often expressed about the potential for abuse—namely, the fear that legalised physician-assisted dying will target the vulnerable or pose the greatest risk to people in vulnerable groups.").

235. *See* TUCKER, *supra* note 233, at 9. Based on this data, recently the American Public Health Association and the American College of Legal Medicine joined the American Medical Women's Association and the American Medical Students' Association in adopting policies supporting the practice of aid in dying. *Id.* at 12.

Two Sides of the Same Coin: Shielding QA Materials and Defining the Value of Your Case

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I. The Siegel Case

- The rule set down by the Second Department can be boiled down to this:
  - Courts will presume a statement made in a Quality Assurance document came from a party defendant unless the defendant can establish otherwise.

How did we get here?

- The QA report in Siegel was turned over to the court for an *in camera* review.
    - The report showed three things:
        1. That two of the named defendants were in attendance at the QA meeting;
        2. Statements in the report were attributed to "the committee"; and
        3. One statement was attributed to the "Trauma Medical Director," which was a title held by a named defendant

How did we get here?

- The trial court held that the defendants could not establish that all of the statements recorded in the QA report were made by non-parties and ordered the disclosure of the entire report.

- On appeal the Second Department held that the burden was on the defendant to establish that the statements at issue were made by non-parties. Moreover, the court held that burden cannot be met by simply stating it is impossible to tell who made the statement that is recorded in the minutes.

The First Department Joins In

- In Newman v Mount Sinai Med. Ctr., Inc. (2022 NY Slip Op 03327 [1st Dept 2022]), the First Department cited to Siegel in holding that the defendant failed to establish that the quality assurance privilege applied in that case.

II. What Siegel did not change

- While Siegel did raise the burden of proof on a defendant, it did not change the scope of the statutory privileges at issue.

- What is the statutory privilege and its exception?

  - The Public Health Law and the Education Law contain privileges for Quality Assurance Materials. There is, however, an exception to this privilege. There is no privilege for the statements of "any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting."

II. What Siegel did not change

- Corrective Action
  - Siegel itself found that any documents concerning corrective actions remain privileged.
  - The court noted that the statutory exception to the privilege only applied to statements of parties made about the treatment and care of the patient.
  - Since the subsequent QA meetings and reports in Siegel dealt with corrective actions to be undertaken in the future, they were not subject to disclosure. This holding also applied to the portions of the QA meeting minutes where statements about patient care were made.

What Do Courts Look To When Examining The Privilege?

1. Who Said it?

2. Where/how was it said?

Who said it?

- The statute eliminates the privilege for a party to the lawsuit.
- Does that mean every provider that the plaintiff names regardless of whether they really have a connection to the treatment?
  - *Maybe*. Hasbrouck v Caedo (296 AD2d 749 [3d Dept 2002]).

Who said it?

- The plaintiff in Hasbrouck v Caedo (296 AD2d 740 [3d Dept 2002]) sued, among others, the chief of surgery who was also a member of the peer review committee. The allegation was that the chief of surgery directed the surgeon not to perform the surgery that was ultimately performed.
- The plaintiff sought to compel the chief of surgery to answer questions about what transpired at the peer review committee meeting.
- The Appellate Division examined the veracity of the allegations against the chief of surgery. It concluded that the only evidence that the chief of surgery gave a directive was inadmissible hearsay. Thus, the court was unwilling to find that the chief could be compelled to testify merely because the plaintiff named him as a defendant in the action.

Who said it?

What to do?

- At the QA stage, assume everyone who touched the patient will be a party to the suit and what they say at a QA meeting will not be privileged.
- At the risk management/lawsuit stage, identify which physicians are seemingly incorrectly named and determine if they made any statements to the QA committee.
    - If they did, begin to examine the providers real relationship to the case.

Where was it said?

- The exception to the privilege applies to statements made by: "any person *in attendance* at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting."
- Does that mean statements given to QA personnel outside of a meeting are privileged?
    - *Maybe.*

Where was it said?

- The downstate rule:
  - In Santero v Kotwal (4 AD3d 464 [2d Dept 2004]), the plaintiff sought an incident report regarding the surgical procedure at issue. The report was not the minutes of a Quality Assurance meeting. The Second Department held that any statements of parties contained in the report were subject to disclosure.

Where was it said?

- The upstate rule:
  - The defendant physician in Swartzenberg v Trivedi (189 AD2d 151 [4th Dept 1993]) was asked by the QA Committee to draft a memorandum concerning the care which was reviewed by the QA committee. The Fourth Department concluded that the memorandum submitted by the defendant physician was subject to disclosure.
    - The court noted that providing protection for statements made outside the confines of a QA meeting will promote an environment where physicians give statements in writing to protect statements that would have been subject to disclosure if they were made at a meeting.

Where was it said?

- The upstate rule :
  - The Fourth Department revisited Swartzenberg in Nowelle B. v Hamilton Med., Inc. (174 AD3d 1345 [4th Dept 2019]).
  - The plaintiff in Nowelle B. sought any statement made by a defendant during the QA process. The statements were not made during a QA meeting and were not made at the behest of the QA committee.
  - The Fourth Department focused on the statute's use of the phrase "in attendance at the meeting," to hold that the statements were not subject to disclosure because they were not made as part of a QA meeting.

Where was it said?

- The majority of the Nowelle B. court explicitly said it would be splitting from the Second Department's decision in Santero.
- As to Swartzenberg, the Nowelle B. majority held that the privilege is waived when the QA committee requests the statements be made outside the confines of a QA meeting.
- The concurring Justice in Nowelle B. would have effectively overruled Swartzenberg and found that any statements made by a party defendant outside the confines of a QA meeting are privileged

Where was it said?

What to do?

- From the QA perspective, try to minimize the comments from treating providers as much as possible. Whether it is written statements, or someone at a QA meeting or in a QA document repeating what a provider said, the statements could be subject to disclosure.
- From the Risk Management perspective, any case where someone gives a statement outside the confines of a QA meeting should be flagged for special consideration.
    - There is a split in authority between two departments of the Appellate Division. That is a basis for the Court of Appeals hearing a case. However, the arguments need to be preserved throughout the course of the litigation.

III. Back to Siegel

Siegel did not change the scope of the privilege; it changed the burden of proof of establishing the existence of the privilege.

What to do in light of Siegel's Changes



- Keep attendance lists of meetings.
  - If someone who treated the patient is at the meeting, keep detailed records of who said what at the meeting.
- If information is included in QA files from outside the meeting, keep detailed information as to:
  - 1. Where the information came from; and
  - 2. Who made any statements contained in the materials.
- After reviewing the materials, have a discussion with defense counsel on whether it is advisable to move for a protective order to prevent disclosure of all or part of the materials.

Changes to Insurance Disclosures

- Copies of all policies must be provided to plaintiff within 90 days of serving the answer. A plaintiff can stipulate to accept the declarations page, but that stipulation can be unilaterally withdrawn.

- Contact information of a claims representative must be provided.

- The total available limits available to the insured must be disclosed.

Damages As Part Of Anchoring Strategy

It's Time To Change The Game

- For too long plaintiffs have been allowed to control the playing field when it comes to damages
- Defendants need to be more assertive from the beginning of the case

Benefits To A Different, More Aggressive Damages Approach

- Better postures the case if it needs to be tried
- Provides an opportunity for new legal challenges
  - To limit or reduce damages figures presented to the jury
    - Motion to preclude for lack of expertise
    - Motion to preclude for lack of foundation
    - Frye or Daubert motion
  - To challenge limits on evidence (such as collateral source rules) and create additional appellate issues
- Provides an additional tool for negotiating cases
  - Challenges plaintiffs' use of the life care plan or lien to anchor settlement demands and provides a credible counter-anchor

Anchoring

- What is it?
  - Based in psychology
  - People are unduly influenced by the initial number they encounter
  - People start with the recommended number and adjust up or down from that number
  - Anchoring effect can happen with completely arbitrary anchors
    - In Tversky and Kahneman's classic study, they asked participants to estimate the percentage of African countries that make up the United Nations after being shown an arbitrary percentage selected by a roulette wheel. When the wheel landed on 65 percent, the average estimate by participants was 45 percent, but when the wheel hit 10 percent, the average estimate was 25 percent
      - Tversky, A. & Kahneman D., Judgment under Uncertainty: Heuristics and Biases, 185 Science 1124 (1974)

Taking Back Control

- Don’t wait: Defendant can anchor the value
- Early case assessment and expanding discovery
- Rethinking experts
- Targeting items of damages
- Bringing reality back to the courtroom

New Approaches To Damages

- Early case assessment
  - Use experience to anticipate plaintiff's experts and likely damages claims
  - Identify areas of damages that are most susceptible to challenge and that comprise anticipated largest components of plaintiff's damages claims
  - Prepare damages models

New Approaches To Damages

- Expanded discovery
  - Early damages discovery
    - Itemized liens
    - Complete health insurance files
    - School, therapy or home health records, if applicable
    - Liens or litigation funding
  - Motion practice
  - Strategic use and timing of depositions and IME
    - Plaintiff
    - Family
    - Treating physician
    - Fiduciary: guardian, conservator, trustee

Setting The Table Through Discovery

- Sample family deposition

Q. Okay. And those were agencies you said?
A. Mm-hmm, yes.
Q. Are you -- is the family currently using any other help or agencies?
A. No, Sue is the only one that comes now.
Q. And what was the reason for not using the agencies?
A. They just didn't work out for one reason or another and it's very expensive.
Q. Okay. But my understanding is later the family paid out of pocket for her caregivers?
A. Yes.
Q. Okay. And those caregivers did not work out and were extremely expensive?
A. Correct.
Q. Okay. What was the reason for these caregivers not working out?
A. Well, they would come in and we would specifically ask or request to have a certain person that was qualified to not have long fingernails, wear a lot of jewelry. These are just examples, okay?
Q. That's all I'm looking for.
A. You know, that I can kind of remember, so one would show up, and the fingernails would be this long. You cannot have that when you're taking care of Chantel for many, many reasons, I mean you could scratch Chantel, you could get your fingernail clipped on her PEG tube. You can't have dangling jewelry, and these were the kind of people that were sent to us. We would try them and ask them not to do that and then it eventually was like, look, we have to find somebody else, things like that. Maybe they wouldn't show up when we would have their schedule, then they wouldn't should up. One her foot got hurt or something. It was too far. They didn't realize this is what they were up against. They weren't told I had to do that, and then they would challenge us on we were here to give her just a shower. That's not what they told me, things like that, so it's like different reasons depending on who came, what it was. They didn't want -- they didn't know how to use the Hoyer lift. We would ask for someone that has medical training background are familiar with certain things. We would train them on other things, you know, so it was just different kinds of reasons.

Setting The Table Through Discovery

- Sample treating physician deposition

Q. Do you believe that she needs a CAT scan or an X-ray of her hand or an X-ray of her forearm now or in the future?

A. No.

Q. How about a -- any home modifications that you think is reasonable and necessary for [redacted] due to her condition today?

MS. [redacted]: Same objection. Lack of foundation.

A. I mean, she may benefit from some, you know, hand therapy, assistive devices if she has trouble opening bottles or cans or different things like that.

BY MR. BRZEZINSKI:

Q. Do you -- do you have an opinion whether or not she needs a split adjustable king-size bed because of her hand?

A. No.

Q. She doesn't need that?

A. No.

Q. Do you believe that she needs a comprehensive driving evaluation?

A. No.

Q. How about vocational rehabilitation assistance, do you think she needs that?

A. No.

MS. [redacted]: Can I just have a running objection to all these questions --

MR. BRZEZINSKI: Sure.

MS. [redacted]: -- please?

BY MR. BRZEZINSKI:

Q. Do you believe that she needs an assistive technology evaluation or assistive technology equipment?

A. I think I need a life plan evaluation. No.

Q. Yeah.

A. No. She...

Q. Neither of those are reasonable or necessary?

A. No.

Q. And to get those types of things, a doctor should order those types of things before they're available anyway, right?

Anchoring Techniques

- When to anchor
  - Discovery
  - Mediation
  - Jury voir dire
  - Examination of witness
  - Experts
  - Closing

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Date of Program: **6/10/2022** **Start Time:** **11:00 am** **End Time:** **12:00 pm**

Location of Program (city, state): **New York, NY**

Print Name	Sign in	Time in	Sign out	Time out

Program Title: **Shielding QA Materials and Defining The Value Of Your Case**

Date of Program: **6/10/2022** **Start Time:** **2:45 pm** **End Time:** **3:45 pm**

Location of Program (city, state): **New York, NY**

Print Name	Sign in	Time in	Sign out	Time out