TABLE OF CONTENTS
BELMONT HEALTH LAW JOURNAL: VOLUME IV
THE DIGITAL FUTURE OF HEALTHCARE: EMERGING TRENDS IN TELEHEALTH TECHNOLOGY

THE DIGITAL FUTURE OF HEALTHCARE: EMERGING TRENDS IN TELEHEALTH TECHNOLOGY

KEYNOTE SPEAKERS:
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[edited for reading]

OCTOBER 9, 2020

Casey Goggin: Hello. Good morning, afternoon now, and welcome to the Belmont College of Law Health Law Journal 2020 Fall Panel. My name is Casey Goggin, and I am the Editor-In-Chief of the Health Law Journal. On behalf of the journal and the college of law I would like to start by saying thank you for all of you for being here, panelists, audience, everybody, thank you so much. I would like to start by making a few housekeeping announcements. Today's event counts as one free hour of CLE and normally we would hand out the CLE form, but like many things this year we are going to have to do things a little differently. At the end of today's event, we will go ahead and send you a Google link which you will have to fill out. Our managing editor, Joey Kennedy, will go into that in more detail later as to how that process is going to go down. We will also have our symposium director fielding questions in the chat box. So, if you have any questions just direct them that way and she will direct them either to our presenters or to our moderator. So, without further ado, we're going to start with our presentations.

We have two presentations today. The first of which is from Professor Stacey Tovino, from the University of Oklahoma College of Law. Professor Tovino currently serves as a professor of law at the University of Oklahoma. She is a leading expert in Health Law, Bio-Ethics, and Medical Humanities. She has been educated both as an attorney and a medical humanist. Her interdisciplinary research has been in case books, textbooks, encyclopedias, and medical and science journals, in addition to a variety of law review journals including Alabama Law Review, Notre Dame Law Review, Iowa Lar Review, Washington and Lee Law Review, Minnesota Law Review, and Boston College Law Review. Her current research focuses on patient privacy and health information confidentiality, Covid-19 and the law, mental health law, and health technology and the law. She is a frequent speaker on the local, national, and international level. Prior to joining the faculty at the University of Oklahoma, Professor Tovino served as a professor of law and was the founding director of the health law program at the University of Nevada Las Vegas William S. Boyd School of Law where she received the top-tier award. She also has more than two decades of law practice experience, representing a broad range of healthcare providers in civil, regulatory, operational, and financial matters. Professor Tovino graduated magna cum laude from Tulane university and magna cum laude from the University of Houston Law center and earned her PhD with distinction from the University of Texas medical branch. Thank you so much Professor Tovino for being here I'm going to go ahead and kick it off to you.

Professor Tovino: Thank you so much. Let me just share my screen. Am I okay to go now?

Casey Goggin: Yes, Ma'am.

Stacey Tovino: Alright, well thank you very much for allowing me to be here and a thank you to Belmont Health Journal for letting me join this Fall 2020 Panel. Today, I wanted to talk about the rapid and unprecedented deregulation of telehealth and telemedicine during the Covid-19 pandemic. Let me provide some background before I do that. Many of know that on January 31 of this year Secretary of HHS, Alex Azar, formally determined that a public health emergency, or PHE, existed.[1] Although, we most certainly do not need a presidential proclamation of a national, or nationwide emergency, before the secretary of HHS can declare that a public emergency exists, we all know than on March 13 of this year, President Donald Trump proclaimed that there was a nationwide emergency concerning the Covid-19 disease.[2]

What I want to show you today is that in light of this determination and this proclamation, as well as many other similar state determinations and proclamations, as well as federal state agency decisions, we have had a situation that has resulted in the rapid and unprecedented deregulation of telemedicine or telehealth in the United States. Just to show you what my state, the state of Oklahoma defines as telemedicine, in Oklahoma we define telemedicine as a practice of healthcare delivery, diagnosis, consultation, evaluation and treatment by means of a two-way, real time interactive communication system. What I am going to do today in my remaining thirteen-or-so minutes is talk about eight illustrative examples of telehealth of telemedicine deregulation and/or expansion. They include: Telemedicine payment parity, they include an expansion of what we call qualifying or eligible

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[1] U.S. DEPT. OF HEALTH & HUMAN SERVS., *Determination that a Public Health Emergency Exists*, https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx (last updated Jan. 31, 2020).

[2] National Conference of State Legislatures, *President Trump Declares State of Emergency for COVID-19* (Mar. 25, 2020), https://www.ncsl.org/ncsl-in-dc/publications-and-resources/president-trump-declares-state-of-emergency-for-covid-19.aspx.

originating sites, they include an expansion of what we might call qualifying or eligible telecommunication systems.[3] They include an expansion or, what I should say, reduction or removal of in-person medical examination requirements, an expansion of the services that are eligible for provision through telehealth, an expansion of the set of providers or we might say the class of providers who are eligible to deliver services through telehealth, removal of certain in-state licensure requirements, and changes in privacy and security requirements. What I'll do is go through them quickly, one by one, and the first change I want to talk about related to telemedicine payment parity.

Historically, and traditionally, many public healthcare programs and private plans reimburse televisits at a lower rate compared to in-person visits. The first change that I want to show you is, during the Covid-19 pandemic, many of our healthcare programs and private plans have increased the amount that they have reimbursed providers for telehealth as compared to in-person visits in an attempt to further reduce these prior telehealth payment disparities. So, if you look right here you can see the Centers for Medicare and Medicaid Services (CMS) within the federal department of health and human services increasing the rate that they pay providers for seeing Medicare beneficiaries via telehealth.[4] It used to be between fourteen and forty-one dollars per visit and now it is about forty-six to one hundred ten dollars per visit.[5]

Just to give you another illustrative example, here is Governor Phil Murphy in the state of New Jersey, and here he is directing the New Jersey department of banking and insurance to ensure that the rates of payment made to in-network providers for services delivered via telemedicine and telehealth are not lower than the rates established by the care for services delivered via tradition

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[3] Okla. Health Care Auth., *OHCA Policies and Rules: Telehealth* (Sept. 14, 2020), https://oklahoma.gov/ohca/policies-and-rules/xpolicy/medical-providers-fee-for-service/general-provider-policies/general-scope-and-administration/telehealth.html.

[4] CTRS. FOR MEDICARE & MEDICAID SERVS., *Trump Administration Issues Second Round of Sweeping Changes to Support U.S. Healthcare System During COVID-19 Pandemic* (Apr. 30, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid.

[5] *Id.*

or what we call in-person methods.[6] Just to give you one last example, here in United Healthcare, on their website, talking about how they're going to temporarily reimburse providers for telehealth services at their contracted rate for in-person services, so I would say the first big kind of deregulation or telemedicine expansion was made possible by the implementation at the public healthcare program and at the private health plan level of either telemedicine payment mandates or the further implementation of telemedicine payment parity.[7]

Now the second change that I want to talk about relates to qualifying or what we might call originating sites. Historically, many of us know that public healthcare programs, as well as private health plans, frequently require insureds who want to have their telehealth visits reimbursed to be located at certain originating sites. So, for example, if you look at this older regulation, 42 C.F.R. Sec 410.78(b)(3).[8] What this regulation does is require Medicare beneficiaries, if they wish their telehealth services to be reimbursed, to be located at certain originating sites and you can see these at the top of the slide, like the Rural Health Clinic or Critical Access Hospital, but only if they are located, if you look at the bottom of the slide, in something that we call an HPSA which is a health professional shortage area or in a county that is located outside a metropolitan statistical area, or in some other geographically designated area. We call these originating sites. What I want you to know here is that during the Covid-19 pandemic many public healthcare programs and private plans have temporarily waived these originating site requirements.

So, just for example, this is the Coronavirus Preparedness and Response Supplemental Regulations Act of 2020 and President

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[6] STATE OF N. J. DEPT. OF HUMAN SERVS., *Governor Murphy Announces Departmental Actions to Expand Access to Telehealth and Tele-Mental Services in Response to COVID-19* (Mar. 22, 2020), https://www.nj.gov/humanservices/news/press/2020/approved/20200323.html [hereinafter "Governor Murphy Announces"].

[7] United Healthcare, *COVID-19 Telehealth*, https://www.uhcprovider.com/en/resource-library/news/Novel-Coronavirus-COVID-19/covid19-telehealth-services/covid19-telehealth-services-telehealth.html (last updated Jan. 11, 2020) [hereinafter "COVID-19 Telehealth"].

[8] 42 C.F.R. §410.78.

Trump signed this piece of legislation into law on March 6 of this year, and within this law at section 102 we see that the secretary of HHS has the authority now to temporarily waive certain requirements relating to telehealth, including those originating sites or what we'll call site of service requirements, which the secretary of HHS did.[9] Just to give you a state example, this is the state of New Jersey, and I am just using New Jersey as an example because I am originally from New Jersey, but here is New Jersey Medicaid similarly or in a parallel fashion waiving originating site or site of service requirements for telehealth allowing both New Jersey licensed clinicians to provide telehealth from any location and allowing individuals in New Jersey to receive services via telehealth also from any location.[10] Just to give you a private example, here is a screenshot from United Healthcare's website doing the same thing.[11] So, they are saying for all of their individual and fully insured group market health plans they are waiving their originating site requirements during the public health emergency.

Now the third change, that I want to talk about, to telemedicine that has happened during the Covid-19 pandemic is, what I call, the kind of deregulation or the approval or additional qualifying or eligible telecommunication systems. As background, many of you know that both public healthcare programs and private plans traditionally, where they would reimburse a telehealth visit, would require the provider and the patient to use certain interactive telecommunications systems. Defined as two-way, real-time, interactive communications between patients and either the physician or the practitioner.[12] If you look at the bottom of this older regulation, this is pre Covid-19, see how they exclude telephones, fax machines, and mail systems from this definition of approved or eligible interactive telecommunication systems?[13] What I want you to know here is that during the Covid-19 pandemic, many public healthcare programs and private payors have backed off these

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[9] Coronavirus Preparedness & Response Supplemental Appropriations Act, 2020, PL 116-123, March 6, 2020, 134 Stat 145.
[10] Governor Phil Murphy, *Governor Murphy Announces Department Actions to Expand Access to Telehealth and Tele-Mental Health Services in Response to COVID-19* (Mar. 22, 2020), https://www.nj.gov/governor/news/news/562020/20200322b.shtml.
[11] COVID-19 Telehealth, *supra* note 7.
[12] 42 C.F.R. §410.78.
[13] *Id.*

stringent definitions of approved or eligible telecommunication systems. You have state Medicaid agencies, as well as private payors; so, here for example, is the New Jersey governor saying that for New Jersey Medicaid he is going to permit the use of alternative technologies, including technologies available on smartphone devices.[14] And just to give you a Blue Cross and Blue Shield of North Carolina example, here is a screenshot from Blue Cross and Blue Shield's website basically saying that for either providers or members who don't have access to secure video systems, telephones, meaning audio-only visits, can be used instead.[15]

The fourth change or the fourth kind of expansion or deregulation of telemedicine that I wanted to talk about relates to in-person medical examination or medical evaluation requirements. Historically, we all know that many Federal and State laws, as well as public healthcare programs and private health plans, required the first visit between a physician or another practitioner and a patient, meaning the visit that established the physician-patient relationship, and the visit that must occur before certain therapeutics are prescribes. They require that to occur in person and we see that all over federal law, state law, we see it again in our public healthcare programs, we see it in our private health plans. And, what I wanted you to know is, that several federal and state agencies, as well as public health plans and private health plans have backed off the medical in-person medical examination or in-person medical evaluation requirements before the physician-patient relationship can be assumed to exist, and/or before a particular therapeutic can be prescribed. Just as one example, here is the DEA explaining that it's allowing the DEA registered practitioners to prescribe controlled substances without having to interact in-person with their patients because, of course, in person interactions do risk the spread of SARS Cov-2.[16] Just to give you another example, here is the DOJ and DEA also telling practitioners that they have the flexibility during the

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[14] Governor Murphy Announces, *supra* note 6.
[15] BlueCross BlueShield of N.C., *COVID-19: Additional Details About Relief Efforts* (Mar. 3, 2020), https://www.bluecrossnc.com/provider-news/covid-19-additional-details-about-relief-efforts#search=detailed%20COVID-19.
[16] DRUG ENFORCEMENT ADMIN., *How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency*, https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf (last visited Feb. 15, 2021).

public health emergency to prescribe a particular medication assisted treatment for opioid abuse disorder which is viewed as an endorphin to new existing patients with opioid abuse disorder via telephone without requiring those practitioners to first conduct an examination of the patient in person.[17]

Now the fifth change that I wanted to talk about relates to the services that are eligible to be provided through telehealth or telemedicine. Historically, we all know that public healthcare programs, as well a private health plans, have limited the types of services that can be delivered through telehealth or telemedicine and prefer that a certain list of services actually be delivered in person. What I want you to know here is that during the Covid-19 pandemic many health programs and private health plans have increased the number and type of healthcare services that can be delivered through telehealth or telemedicine compared to an in-person visit. Now, this isn't a great illustration, but this is a screenshot of the Center for Medicare and Medicaid Services one page, and if you actually click on the link in the middle of the slide it will take you to a not very pretty, which is why I didn't link to it, excel spreadsheet.[18] On that excel spreadsheet is a vastly expanded list of healthcare services that can be furnished through telehealth and that would be payable onto the Medicare physician fee schedule.[19] Since I am in Oklahoma today, and because I work at the University of Oklahoma, I thought I would give you an Oklahoma Medicaid example, but as you can see here is Oklahoma healthcare authority, which oversees our Oklahoma Medicaid program is explaining that it is allowing the expanded use of telehealth for basically any service that can be provided safely through secure telehealth communication devices for Sooner Care.[20] Sooner Care is just Medicaid for Oklahoma Medicaid members.

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[17] Thomas Prevoznik, *DEA Qualifying Practitioners DEA Qualifying Other Practitioners*, U.S. DEPT. OF JUSTICE: DRUG ENFORCEMENT ADMIN. (Mar. 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.

[18] CTRS. FOR MEDICARE & MEDICAID SERVS., *List of Telehealth Services*, https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes (last updated Jan. 14, 2021).

[19] *Id.*

[20] OKLA. HEALTH CARE AUTH., *Expanded use of telehealth and telephonic services during COVID-19,*

Now the sixth thing I wanted to talk about, and only two, or three from the end, is how during the Covid-19 pandemic, both public health programs and private plans expanded the class of practitioners or providers who are eligible to provide healthcare services through telehealth. Historically, many of us know that our private health programs and private plans would only allow certain healthcare providers, for example, allopathic and osteopathic physicians, maybe physician assistants, and certain registered nurse practitioners to provide services via telehealth, but what I wanted you to know here is that many public healthcare programs, and private health plans, are owing an expanded class of healthcare practitioners to provide services through telehealth. So here you can see, for example, that the Centers for Medicare and Medicaid Services is broadening the class, or range, of practitioners who can provide services through telehealth and that this broadened class includes physical therapists, occupational therapists, and speech language pathologists, just to name a few.[21] To give you another private payor example, here is a screenshot from the BlueCross BlueShield of Illinois website, and if you look in that orange box that's about two-thirds of the way down the side, these are all of the classes or types of healthcare providers who can provide healthcare services through telehealth as opposed to in-person visits and that would be able to get reimbursed from BlueCross BlueShield of Illinois. [22]

Alright, the seventh change I wanted to talk about relates to in-state licensure requirements. Historically or traditionally, all of us know that many public health care programs, private payors, as well as state licensing agencies, would require physicians and other healthcare practitioners, who wanted to provide services through

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https://oklahoma.gov/ohca/providers/telehealth/state-emergency-for-covid-19.html (last updated Dec. 10, 2020).

[21] CTR. FOR MEDICAID & MEDICARE SERVS., *Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19*, https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf (last updated Jan. 28, 2021) [hereinafter "CMS Flexibilities"].

[22] BlueCross BlueShield of Ill., *COVID-19 Preparedness Answers to Frequently Asked Questions (FAQs) from Providers*, https://www.bcbsil.com/pdf/education/covid19_provider_faq.pdf (last updated Jan. 2021).

telehealth, to be actually licensed to practice medicine or their health care profession in the state where the individual who is on the receiving end of the telehealth resided or was located. But during the COVID-19 pandemic, many of our public healthcare programs, our private payors, as well as our state licensing laws have been either waived or amended to allow healthcare practitioners who are currently, and validly, and in good standing licensed in some state to provide telehealth services to residents or individuals who are located in other states, even if that practitioner doesn't happen to be located in what I call that recipient patient state.

So just to give you an example, here's a Centers for Medicare and Medicaid Services explaining that it wants to offer several flexibilities that help fight COVID-19, and you can see that the Centers for Medicare and Medicaid Services is temporarily waiving the Medicare and Medicaid requirement that physicians, as well as non-physician practitioners, be licensed in the state where they're providing services.[23] And just to give you a state example, as opposed to a CMS example, this is just a screenshot of the number of a bill in the state of New Jersey. And if you read this bill, what it would say is that due to the COVID-19 crisis in New Jersey, which of course many of us know is a COVID hotspot, the state of New Jersey is not going to require practitioners who wish to provide telehealth services to New Jersey residents to be licensed to practice medicine or health in the state of New Jersey.[24]

And then the last change that I wanted to talk about relates to privacy and security. Historically, we all know that many federal and state statutes and regulations stringently regulate certain uses and disclosures of certain individually identifiable health information in terms of privacy and security. And, what I did want you to know, is that many federal agencies and state agencies that enforce these privacy and security laws have either issued notices of enforcement discretion, as you can see right here, or have just kind of clarified what their existing laws look like during the COVID-19 pandemic. So, for example this is the Office for Civil Rights within the federal Department of Health and Human Services, and here in

[23] CMS Flexibilities, *supra* note 21, at 8.

[24] New Jersey Assembly Bill 3860, 219th Legislature, https://legiscan.com/NJ/text/A3860/id/2173336.

October they issued a notification of enforcement discretion for certain telehealth remote communications during the nationwide public health emergency.[25] And basically, what they said here is that health care providers who engage in the good faith provision of, not public, but non-public facing telehealth.[26] They are not going to get in trouble under the HIPAA privacy, the HIPAA security, or the HIPAA breach notification rule if an interception or something like that happened to occur.[27]

So, this is actually a formal notice of enforcement discretion, and I just wanted to compare this to what other agencies are doing.[28] This is SAMHSA, which of course, we all know, is a Substance Abuse and Mental Health Services Administration, and here they're not issuing a waiver or a notice of enforcement discretion.[29] But all they're saying is that under 42 CFR Part 2, which is our privacy regulations that govern federally-assisted alcohol and drug abuse treatment providers, that they realize that it would be difficult for these providers to obtain their patients', who have substance use disorders, prior written consent when you're doing telehealth via in person care.[30] And although normally SAMHSA requires a patient to give their prior written consent before their substance use disorder treatment records can be used and disclosed, there is an existing exception in 42 CFR Part 2, which is the exception relating to a bona fide medical emergency that applies or can apply during the COVID-19 pandemic.[31]

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[25] U.S. DEPT. OF HEALTH & HUMAN SERVS., *Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html (last visited Jan. 20, 2021).

[26] *Id.*

[27] *Id.*

[28] SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance*, https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf (last visited Jan 20, 2021).

[29] *Id.*

[30] *Id.*

[31] *Id.*

So, hopefully, I think my time is up but I just wanted to say that I provided you with eight illustrative, but certainly not exhaustive, examples of how telehealth or telemedicine has kind of either been deregulated, or what we might say expanded, during the COVID-19 pandemic. And I hope that one thing we can talk about during the Q&A or maybe that we can hear from our other speakers is the likelihood that these forms of deregulation or expansion will survive the COVID-19 pandemic. And I know we have a health care practitioner on the line and I'm very curious regarding the clinical or the medical appropriateness of maintaining these telehealth and telemedicine forms of deregulation or expansion. But thank you so much!

Paige Goodwin: Thank you, Professor Tovino, for that very informative presentation. We have a couple of minutes left for questions from attendees. So, the first question that we got was, "Do you see the need for telehealth to be reimbursing at in-person rates to ensure access to more patients? If reimbursed at normal telehealth rates, do patients have issues accessing the telehealth that they may need?"

Stacey Tovino: No, that's a very good question. I don't currently work at an insurer, I don't currently, I'm not a clinician. I am just a lawyer and a law professor, and I have a graduate degree in medical humanities so I can't answer that empirically, meaning I don't know how many patients are not getting telehealth services, because maybe their providers don't want to provide telehealth services if there is not payment parity, or are discouraged from providing telehealth services because of payment disparities. That said, there is a robust academic, and I'm very interested to hear from the practitioners later on, but there's a robust academic discussion of whether we should be talking about telemedicine payment parity, which is the same payment for telehealth versus inpatient rates, or maybe, something more like telemedicine or telehealth equality, such that if an in-person visit took 60 minutes, but a telehealth visit took 45 minutes, then the telehealth payment would be up to 75% of the in-person visit. But those are very good questions and I think they're probably better answered by people who treat patients and or patients themselves. But that's a great question.

Paige Goodwin: We have one more question, it says, "I'm interested in how a chiropractor might provide services to a patient via telehealth? I think that must be mostly hands-on."

Stacey Tovino: That's a great question! So that question comes out of the slide or the set of slides where I said historically, public healthcare programs and private health plans would only allow a limited number, or I should say probably class, of health care providers to provide telehealth and telemedicine, like osteopathic and allopathic physicians, nurse practitioners, and physician assistants. As you saw from that one slide, some payors are pretty much allowing any healthcare practitioner under the sun who can efficiently and effectively and safely provide a service during the COVID-19 pandemic to provide it.[32] That is a great question. I don't have a doctoral degree in chiropractic, so I don't know if there are any chiropractic manipulations that can be self-done by a patient, but that's a great question that would probably have to be best answered by a chiropractor. That's a great question though.

But, if we think about the other classes of healthcare practitioners, for example, mental health professionals you can see online, and they can talk to you and they can evaluate your mental state. I've actually seen an ophthalmologist online and they were actually able to look at my eye very closely. My husband has seen a general practitioner and he's been able to cough and have them hear how stuffed up he is, so obviously there are lots of health care providers who can do what they do through telehealth and telemedicine.

Paige Goodwin: Well, that is all the time that we have. Thank you so much again, and I'm going to hand it over to Casey.

Casey you're muted.

Casey Goggin: I started this presentation being so proud of myself for not doing that. Alright, so thank you again Professor Tovino for giving us that very insightful presentation. It was absolutely wonderful. I know I learned a lot.

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[32] CMS Flexibilities, *supra* note 21.

Our next presenter this afternoon is Dr. David Charles, the Medical Director for Vanderbilt Telehealth. He also serves as a professor of neurology and the Vice Chairman for Education, Director of the Movement Disorders Clinic, and is an attending physician at Vanderbilt University. Dr. Charles's current line of telehealth research addresses treatment of people with cervical dystonia, spasticity, and headache. He has offered over 50 publications and is currently leading a study on the continuous quality of improvement of teleneurology services provided in community-based hospitals. Dr. Charles is a member of the American Neurological Association, a Fellow of the American Academy of Neurology, and Chair of the Alliance for Patient Access. He is also a member of the Alpha Omega Honor Medical Society where he received the Candle Award for his positive impact on medical students.

Dr. Charles graduated cum laude from Vanderbilt University School of Engineering with a BS in Computer Science and Mathematics, and in 1990 he went on to earn his medical degree from Vanderbilt University School of Medicine. Prior to joining Vanderbilt, he served as a health policy fellow in the United States Senate on the staff of the Labor Subcommittee for Public Health and Safety and was a nominee for the United States House of Representatives from Tennessee's Sixth Congressional District.

Dr. David Charles: Whoa!

Casey Goggin: Thank you, Dr. Charles, for coming today and I'll let you just begin your presentation.

Dr. David Charles: Thank you so much for that introduction! My goodness, I did not expect all of that. You're very generous. So, I'll begin sharing my screen, and talking with you about telehealth at Vanderbilt. Dr. Tovino, I really enjoyed your presentation. Bear with me one moment. So just want to make sure that everyone can see my screen and hear me okay?

Paige Goodwin: We can see your screen.

Dr. David Charles: Thank you. Very good. Again, I'm David Charles, I serve as Vice Chair of Neurology at Vanderbilt University and Medical Director of Telehealth at Vanderbilt. I want to give you the clinician's perspective on telehealth and maybe just a little bit of a historical perspective as well.

So, most people when they think of telemedicine or telehealth they think of two-way, real time audiovisual connection with the clinician and a patient. This actually began in the 1950s, and I would assert that really the entity that uses telehealth the best and the most is actually the federal government. The Veterans Affairs Administration conducted over 2 million visits for nearly one million veterans last year[33], and the US Army has been using telehealth for years and years. Last year it conducted over 60,000 visits worldwide across 22 different time zones. So, telehealth is not new, but its adoption sort of in mainstream healthcare for non-federal uses has really taken off during the time of COVID.

Before COVID, the barriers to adoption were pretty clear. Commercial insurance companies as well as CMS, so for Medicare and Medicaid, they had very strict limits on the payment of services for telehealth and they were very slow over the past two decades to adopt telehealth because they were basically concerned that there would be this rampant overuse of healthcare services. A second barrier, state medical licensure. So, the idea that states regulate telehealth and clinicians that can provide telehealth across state lines - it really kind of parallels the Thomas Jefferson quote that laws and institutions must keep pace with the progress of the human mind. Here, we have really archaic state medical licensure regulations that have not kept pace with the development of technology and the ability to provide care really anywhere in the world, much less, you know, across state lines.

Lastly, geographic restrictions that Dr. Tovino mentioned. You know, historically, I couldn't see a patient via telehealth in their home or at a private place where they work. Payors would restrict coverage to what they called qualified sites of service, so that might

[33] U.S. DEPT. OF VETERAN AFFAIRS, *VA reports significant increase in Veteran use of telehealth services* (Nov. 22, 2019), https://www.va.gov/opa/pressrel/includes/viewPDF.cfm?id=5365.

be a physician office, a rural health clinic, a hospital outpatient clinic, and so forth. But of the main barriers to adoption in the United States, even though I've listed three here, by far and away commercial insurance companies and the Center for Medicare and Medicaid Services were the overwhelming barrier to Americans having access to telehealth.

So, what about teleneurology at Vanderbilt University Medical Center? So, just to give you by way of background, we provide teleneurology services to eleven community hospitals and what I mean by this is that neurologists at Vanderbilt, using technology, are participating in the care of patients who present to community hospital emergency departments or who are admitted to community hospitals. We do this over FaceTime on iPads. We have an image application that allows us to share, say, an MRI scan of the brain or a CT scan of the brain back and forth. And we started this program in 2014, and the reason we started it is because there is a national shortage of neurologists. There are many communities throughout our nation that have no neurologist on staff at their hospitals.

And so, there's a huge need to project specialty services into community settings, being able to provide urgent care to patients, say for instance, when they present with something like a stroke or a seizure. So, since 2014, we've conducted well over 8000 consultations using iPads and FaceTime. It's fully HIPAA[34] compliant when connected over an encrypted Wi-Fi connection, and here's the take-home message: 88% of the patients are managed at the community hospital. In other words, they can stay closest to their family, closest to their home. Only 12% of the consults, patients seen via consult, require transfer to a higher level of care. So here, this really means that the patient's getting the right care at the right place. Before we had this service, we often saw patients with very minor neurologic conditions being transferred to Vanderbilt and other tertiary centers just because there was no neurologist available in the community setting. So, I would say, that without a doubt, this program, which really launched telehealth at Vanderbilt has been the single largest driver of appropriate health care provided in the appropriate setting, in fact, at the least cost setting. So, while we

[34] HIPAA Privacy Rule, 45 C.F.R. §§160, 164 (2013).

faced all of these barriers from insurance companies, in this case, the hospitals saw the value, so they purchased the service from Vanderbilt. And the insurance companies all through over these last six years have refused to pay for any of these 8,000 consults. It's really been a stark way to illuminate how misguided commercial insurance has been toward telehealth for really the past almost two decades.

So, fast forward to the COVID pandemic, so I will not go through this slide because Dr. Tovino did an outstanding job talking about what the administration has done at the federal level to facilitate the adoption of telehealth during the pandemic. So how did Vanderbilt respond to this? So, within about eight days in early and mid-March we trained over 3,000 physicians and staff in the use of telehealth. Because the federal government, in essence, opened it up, meaning I could see a patient directly in their home over their own device. I could see them at their place of work if they stepped into a private office. I could see the patient wherever the patient wanted to be seen. So, we trained over 3,000 physicians and staff to be ready to provide healthcare via telehealth. We produced educational materials to train those physicians, but also the support staff, to set up these visits and get things ready. And then finally, when our medical students were sent home during COVID, they stepped up, volunteered, organized themselves, and trained over 5,000 patients to get ready for telehealth. Meaning that they tested their equipment and talked them through how to allow their device to use their camera or their microphone and such.

And so that was sort of the beginning of the experience. We immediately launched a quality improvement initiative within the department of neurology, and we ran this from March 18 through May 10.[35] It's IRB approved.[36] And what it included was post-visit surveys of our patients. We evaluated the average travel time and

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[35] Kelly Harper *et al.*, *Vanderbilt University Medical Center Ambulatory Teleneurology COVID-19 Experience*, Online Ahead of Print, TELEMEDICINE & E-HEALTH, https://doi.org/10.1089/tmj.2020.0382 (last visited January 30, 2021).

[36] *See generally* U.S. FOOD & DRUG ADMIN., *Institutional Review Boards (IRBs) and Protection of Human Subjects in Clinical Trials*, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/institutional-review-boards-irbs-and-protection-human-subjects-clinical-trials (last visited January 30, 2021).

distance saved. And then we also surveyed the neurologists that were providing healthcare as well. So, from March 18th to May 10, just in the Department of Neurology, so one single department, not medicine, not pediatrics, not surgery, just in neurology, we conducted nearly 4,000 tele-neurology visits. We surveyed all of those patients and got a 40% response rate.[37] And I don't know if you've done much survey work, but a 40% response rate would be considered excellent. Here's what we found, and I won't read all of these to you, but in short, patients love telehealth.

While you're looking at these responses to the survey, I can share with you a story. So, I conducted a telehealth visit. The gentleman lived east of Knoxville, told us on the call that it was about a four hour drive each way for him to come to Vanderbilt for care. He's in his late 70s. He had a liver transplant many years ago at Vanderbilt and as a consequence of the illness that required him to have a liver transplant, he had a condition called a peripheral neuropathy, meaning that he had very uncomfortable and painful sensations in his feet and to a lesser degree in his hands. And so, our care in the neurology department was helping manage those symptoms, which were a consequence of the illness that led to his liver transplant. It was a one year follow up, we had seen the prior year and it was just to check in with him, make sure that he was tolerating the medicine we had given him okay, and he was still getting some relief from his symptoms.

The visit lasted less than 20 minutes. And in speaking with him at the end of the visit, I asked him, just curious you know, "how do you like, you know, this telehealth visit, and is this your first telehealth visit?" In fact, it was his second telehealth visit. And he said to me, "Dr. Charles, I'm never coming back unless I have to be seen in person for a procedure." He said, "this visit via telehealth just saved an entire day of my life. I would have spent 4 hours driving to Vanderbilt, parking, getting in for the visit, 4 hours returning, and here we completed the visit what? In less than 20 minutes." And so that's just an illustration of one patient's example and how you can imagine he's so highly satisfied. But it goes further than that.

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[37] Harper, *supra* note 35, at 2.

It goes further than that because if you're an employer, let's say that you're Nissan or Bridgestone or the state of Tennessee, the largest employer in our state, or the largest private employer, FedEx, employers now see the benefit of telehealth. Right? A person can be seen at work, someone with a chronic condition, let's say they have MS or diabetes, and they may need to be seen almost monthly for health care visits. Some of those visits can be done via telehealth. If the person can just step into a private place at work, they could in twenty minutes, compete what would have made them miss a half day or even a day of work, depending on where they lived. So now employers get it. So, the game is over for commercial insurance throwing up barriers to telehealth. Hundreds of thousands, if not millions, of Americans now have experienced telehealth. And employers who pay for employer sponsored health insurance get it. Right? They're not going to allow their own health plans, which they for, to prohibit their employees from having access to telehealth because it just drives up their absenteeism at their own company.

So, I think that is the single most important takeaway from what's happened in this telehealth experience. Patients saved in our study about two hours of driving on average across this.[38] We also took the step of what about new versus return visits. So, I had clinicians come up to me telling me they loved telehealth and of course it's not right for all care. Some care has to be done in person. But for those visits where telehealth is appropriate, I was hearing from other physicians that the new patient visit is not as good as the return visit. So, a return visit, the patient and the physician already have an established relationship. They know one another. And it's a check in visit for an ongoing health concern. The new patient, however, has never met the clinician. And the physician-patient relationship really is the cornerstone of health care. And how does a physician and a patient establish that relationship? Well, it actually happens in the first moments that the physician walks in the room. You close the door and you're alone with the patient, in those very first minutes, the patient is already formulating their impressions of the physician. Is the physician someone they think they can trust? Does the physician know what he or she is doing? Well, they keep the things that they hear private.

[38] Harper, *supra* note 35, at 2.

Those are the elements of the patient-physician relationship, and trust, it forms that way. And I have physicians repeatedly tell me that it's difficult over telehealth to form that relationship. And our survey told us the same thing. What you'll see here, and I won't read all of these to you, but returning patients, in other words people being seen via telehealth who had an established healthcare provider, felt that it was probably better.[39] Right, they had greater comfort. They were more satisfied with health care provided via telehealth than the new. Now, don't take away from this that new patients weren't satisfied. I mean the level of satisfaction was remarkably high. It's just that it's a little bit higher in return visits. Alright, next step we surveyed our physicians. 139 faculty, fellows, and residents who had provided tele-neurology care were surveyed on May 10, kind of the conclusion of our most intense slowdown at the medical center. We had a 79% response rate.[40] And if you have any experience surveying physicians, getting a 10% response rate is sometimes considered good. So, this was an absolutely phenomenal response rate here and here is what we found. Again, I won't read them to you, but our clinicians were very pleased with the option to offer telehealth.[41]

So next, the neurologists gave us some comments. I'll just let you read some of these. But, from the patient, you know we had 1,500 patients, individual patients respond to the survey. Their free text comments in the box were just amazing.[42] It was so much fun to read them. I mean, here we are in the middle of a pandemic and we have patients who are just so absolutely thrilled that they were able to continue their health care, they had never thought about telehealth, their insurance company had never even dreamed of letting them use it and just to have such a great experience. And then finally, a few more patient comments listed here. And I'll conclude for questions. Overall, as I already stated earlier in the talk, patient and physician satisfaction is very high. Patients and caregivers, the clinicians have a greater awareness of how telehealth works. And so, as I said earlier, we're never going back. It's just not going to happen. One way or the other, either through legislative process at the federal level or commercial insurance driven by employers,

[39] Harper, *supra* note 35, at 2.
[40] Harper, *supra* note 35, at 4.
[41] *Id.*
[42] *See* Harper, *supra* note 35, at 4.

telehealth is here to stay for sure. I like this quote. One of the students on our team chose it. "Close scrutiny will show that most 'crisis situations' are opportunities to either advance or stay where you are." And I think we've certainly advanced in telehealth. So, with that, I'll take questions.

Casey Goggin: Unfortunately, I think we're a little bit running short on time. So, we will, if we have extra time here at the end, we will pick up and run it back to you. But we're going to shift gears a little bit.

THE DIGITAL FUTURE OF HEALTHCARE: EMERGING TRENDS IN TELEHEALTH TECHNOLOGY

PANELISTS:
TRAVIS LLOYD, *BRADLEY ARANT BOULT CUMMINGS LLP*
NATHAN KOTTKAMP, *WALLER LANSDEN DORTCH & DAVIS LLP*
NESRIN TIFT, *BASS, BERRY & SIMS PLC*

Moderated by Deborah Farringer, Faculty Advisor

[edited for reading]

OCTOBER 9, 2020

Casey Goggin: At this point, we're going to move to the panel portion of today's event. And so, with that, I will introduce our moderator this afternoon, Professor Debbie Farringer. Professor Farringer is the faculty supervisor for the Belmont Health Law Journal and the Director of Health Law Studies at Belmont College of Law. She also serves as the faculty supervisor for the Health Law Journal and the coach of the moot court transactional team. Her scholarship explores operation and impact of health laws and health policy on providers and suppliers. And most recent scholarship concentrates on the unique challenges facing health care industry in the area of cyber security. Her scholarship has been published in the Brooklyn Law Review, Nevada Law Review, Seattle University Law Review, and a bunch of others. Prior to joining faculty at Belmont, Professor Farringer served as Senior Associate General Counsel at the Office of General Counsel for Vanderbilt. And she worked primarily at the Vanderbilt University Medical Center. Prior to that, she worked as an associate at Bass, Berry & Sims in Nashville in the firm's health care regulatory group and she graduated summa cum laude from the University of San Diego. And then after that received her J.D. from Vanderbilt University School of Law, where she was a member of the Order of the Coif. Immediately following law school, she completed a judicial clerkship for Judge H. Emory Widener, Jr. of the United States Court of Appeals in the 4th Circuit. At this time, I'm going to kick it over to Professor Farringer for our panelists.

Professor Farringer: Alright. Thank you so much to everybody. So I'm going to admit, I think I have turned off one of our panelists. Camera is here, so hold on. Nathan, here, let me get you turned on. Let's see here. I think that should do it. Alright so we've got, I want to get them introduced here really quick so we can get to some questions. We've got three attorneys here that all practice at law firms here in Nashville that I'm quite excited to have with us today. We've first got Travis Lloyd. He's a partner at Bradley Arant Boult Cummings and Travis is in the firm's health care practice group. He focuses upon complex regulatory matters, such as fraud and abuse, provider enrollment and reimbursement, and health care information, privacy, and security. Travis graduated cum laude from Davidson College where he was elected to Phi Beta Kappa. He proceeded to earn his law degree from Georgia State College of Law where he graduated magna cum laude. Additionally, he holds a public health degree from Harvard University, where he focused on health law and policy. We've also got Nathan Kottkamp, who is a partner at Waller Lansden Dortch & Davis. Nathan advices on compliance with both federal and state health care regulations, as

well as day to day operational issues. He earned a designation as a certified information privacy professional and assists clients with HIPAA and other data security matters. He earned his bachelor's degree with high honors from William & Mary and his master's degree in bioethics from the University of Pittsburgh. And he earned his law degree with a certificate of advanced study in health law from the University of Pittsburgh School of Law, graduating magna cum laude and Order of the Coif. And lastly, I am excited to welcome Nesrin Tift from the law firm of Bass, Berry and Sims. She advises clients with health care fraud and abuse issues, compliance operations, telemedicine initiatives, and health information, privacy, and security. She's also an active member of the Health Care Compliance Association. She earned her bachelor's degree from Harvard University, graduating magna cum laude and her master's from London School of Economics, and went on to earn her law degree from Vanderbilt. So, we've got a lot of degrees on our panel. I'm excited to talk to all of you about telehealth today. So, I'm going start just with a big broad question about what you're seeing. Given all of the regulatory changes we've just heard about, we've heard the clinician side, we've heard the legal side of sort of the deregulation that's been happening. What are some of the most common legal issues you're seeing in your practices during the pandemic? What are clients calling you about? What are they nervous about? Nesrin, why don't we start with you.

Nesrin Tift: Thanks Debbie. Glad to be here with these wonderful panelists. So, the question, you don't specifically say telehealth. I assume that's what you implied.

Debbie Farringer: Yes.

Nesrin Tift: I think it's fair to broaden it out just a tiny bit because as Nathan and Travis know, sort of the legal challenges and implementing in many cases very rapidly telehealth methodologies, can pose a challenge where that infrastructure is not already in place, and have done so. I think what further compounds that is that you also have for a lot of provider organizations, teleworking. Right, you have telehealth and then you have people working remotely and so you have this sort of unique situation where you have practitioners being able to conduct visit in their homes, patients in some cases in their homes. And I think for a lot of our clients it was an overwhelming scenario to figure out how to get everybody up to speed. I was very heartened to hear Dr. Charles example of the med. students who took it upon themselves to help patients on board in telehealth because that is hugely impactful. And I think when we're talking about privacy and security the patients have to play a role in

that and we have to be able to ask them to do that and to help remind them about observing safeguards on their end and being in a private place. You know, if you do have the ability security features or privacy modes to do that. And the other thing I'll say is I think that there has been an ongoing challenge in access to data during this time. I think there were misconceptions when the pandemic started maybe they're still there with regard to public health reporting. And you know what might be perceived as kind of you know, HIPAA is off the table right now we have all these waivers, you know, basically you can tell anyone you can notify your workforce when a patient has tested positive or when a workforce member has tested positive for COVID and that's not necessarily the case in a lot of ways. Although it was CR's enforcement discretion that has been impactful when it comes to telehealth. HIPPA has permitted disclosures of PHI even for public health purposes are still pretty limited and so I've spent a lot of time helping providers navigate that sort of public health very valid need for information balanced against privacy and really what HIPAA allows which you know it again, looking at again permitted uses and disclosure of PHI, really nothing changed there during the pandemic, it was only on the sort of telehealth side.

Professor Farringer: Thanks, Nathan did you want to go next?

Nathan Kottkamp: Yeah. I think the thing I've seen the most over the last several months is the change in mindset. Some of this is just driven by desperation but a year ago, if I had a client ask me about telehealth, there was a lot of research and measured approach and we don't to get in over skis and all that kind of stuff. And for any number of reasons, once COVID hit I think my clients and others just dove right on in and it's kind of like circumstances and consequences be damned, we'll figure it out on the back end. And so, for some of them we're trying to pry things back or trying to say what kind of documentation are you getting from your patients regarding the limitations to telehealth and that you know it's not perfect and all these sorts of things, but it's really it's the cows out of the barn situation and now it's just evaluating what's out there in the field. I think that's probably the single most significant thing that I've seen them on my clients.

Professor Farringer: Thanks, Travis what about you?

Travis Lloyd: Thanks Debbie and thanks to everyone for inviting me to participate. You know, the past 7 months have been crazy for everyone no matter what you do or where you are. I think as a healthcare lawyer focusing on these issues, my practice has followed sort of us an arc that's probably familiar to my co-panelist which is

in the early days it was sort of the work focus on the possibility of obtaining one off waivers then it shifted to interpreting blanket waivers and now it's more or less imagining life after the waivers, you know, [when] we're no longer in hair on fire mode. But we're seeing a lot of questions about what the world looks like post-pandemic. What's the coverage environment? What payment policy will stick? How do we anticipate the end of this broad government exercise of enforcement discretion whether on the Privacy and security front or the fraud and abuse front? So, ultimately we're often now being asked to help healthcare providers both institutional healthcare providers and technology services providers to really think through their exist strategies from this very unique regulatory environment and to also you know, do a little bit of crystal ball reading.

Professor Farringer: Yeah, it's one thing you pointed out that I thought would be interesting to talk about. I think all of you are well-versed in fraud and abuse issues, there was a recent settlement, actually 350 medical professionals submitting fraudulent claims related to telemedicine,[1] specifically the really high settlement, what are you seeing on that front so as we sort of are your clients nervous are they anticipating a big change in this sort of fraud enforcement that's going to come and kick it on the back end? Travis, you mentioned it slightly, what do you think is coming down the pike is this just one of what's going to be a new log of a fraud issues that are coming up?

Travis Lloyd: Yeah, I guess I'd answer that in a couple ways. I mean first of all I think there is a huge gulf between the world of sham internet pharmacies and DME suppliers the like which are a related subject of that National Health Care fraud takedown[2] that you mentioned and legitimate healthcare providers or telehealth platforms. I don't think it's the end of the use of. I think we see how stretch the term Telehealth becomes. Let me see how the DOJ uses it in his prosecutions it's not exactly the same thing that at least most of us who aren't white collar attorneys are spending our time on. I do think though that anytime you [have] disasters and emergencies, [it] always invite[s] unscrupulous actors and that is certainly the case when you have as in this case huge sums of government spending. So, the idea that there will be scrutiny I think is beyond dispute, I think everyone expects that also this is coming of course at the time

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[1] Dept. of Justice, *National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses* (Dept. 30, 2020), https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants.

[2] *Id.*

when we're in a huge push to modernize the core fraud abuse laws, the Stark Law, [3] and the Anti-Kickback Statute. [4] And in all likelihood those final rules will create more space for renovation more flexibility for value-based care arrangements which will include services delivered through telehealth platforms we don't know how exactly that is going to turn out and it's really essential to keep up with those developments. But I don't think that the sort of headline-grabbing four and a half billion-dollar announcement the other week should be construed as sort of a condemnation of kind of legitimate telehealth platforms that have scaled up quickly and aggressively, like Nathan was saying, during this time of sort of relaxed enforcement. Nevertheless, that's not to say you should proceed without worry, I mean these are core concerns [and] they will remain core concerns. And so, you always [have] outside counsel and a clear understanding of the flow of funds and the movement of patients through the system and make sure you're within the realm of responsible risk-taking

Professor Farringer: Yeah, Nesrin on that front, on sort of the broad everything's waived, what sort of advice are you giving your clients about how to keep the wheels on and make sure that they're sort of approaching things appropriately but also being able to use innovation and take advantage of some of the waivers?

Nesrin Tift: Yeah, sure. So I echo what Travis said and I think we would both be considered lucky that we tend to be advising the clients who are truly trying to do the good faith provision of telehealth and Nathan I'm sure the same way but even then, even with the good faith provision of telehealth, which is you know precisely to what the OCR enforcement discretion applies you have the possibility of practices that have been put in place, as Travis said, in that kind of hair on fire mode you need to reach these patients, we need to figure out a way to keep capacity open in our hospitals or protect people who might be more at risk from having to leave their home and then at some point when you're not in hair on fire mode and you realize you have large amounts of data, of PHI, being transmitted through Facetime, through Zoom, you know and you availed yourselves of the enforcement discretion which is perfectly fine you still have consequences particularly as the public health emergency wanes. And we don't really know what it would look like as far as what as what step OCR will take in ramping back up enforcement, but we also know that things that historically are on OCR's radar like lack of HIPAA security risk assessment blocking access to PHI you know you got telehealth visits which may be part

[3] 42 U.S.C. §1395.
[4] 42 U.S.C. §1320a-7b(b).

of the designated records set and are going to be subject to individuals access requests and we also know OCR, and I know I got one 30 minutes ago and I got a notification that OCR is coming down with another round of penalties in the right to access initiatives so I don't think that OCR is just going to stop you know looking at these issues. So, I think there needs to be some kind of thoughtful, hopefully now that hair on fire mode is hopefully no longer present, documenting risk decisions that are made, and sort of documenting how your organization arrived at a solution or determined that something, even if there were risks that the risks were reasonable and appropriate in light of the public health emergency, and kind of what steps you put in place going forward in your interaction with these vendors and with your workforce.

Nathan Kottkamp: Yeah, and I'll just add I think it's important to recognize that OCR or any agency's enforcement discretion is not equivalent to compliance inception, so you still have to do things like using Zoom for a telehealth visit without any extra additional security. You still need to be considering that and putting it in your risk assessment. Saying, look I don't have any other option my plan is to buy a better platform in three weeks or whatever the case may be. But you don't just get to say well I don't have to do anything at all because the OCR is not enforcing things. So, I just want to be sure that distinction is very, very clear because I think you can get very easily lulled into a state of complacency when everything lifts you are sort of back in that problem I was saying earlier which is all the stuff you got to figure out how do you undo it when you should have been taking incremental steps all along.

Professor Farringer: Yeah, so we got just like a minute or so here left, because I want to release everyone on time. But, to that point Nathan I mean, can you tell us your thoughts on what will stay and go and in terms of some of the privacy, you do a lot with the privacy regulation. It has allowed a lot of access that was previously not allowed. Do you see some changes going forward?

Nathan Kottkamp: Yeah, I think we're going to see what, more than anything, some loosening of the rules about which platforms are allowed to be used. And I think there's always a possibility that FaceTime or Zoom is going to get compromised in some way, but I think we're probably seeing what this much of it is going on around the globe right now. Maybe that's not that big of a concern, we're going to worry about other things about is the care appropriate as opposed to is the platform appropriate. That's my guess. Hard to know for sure though.

Professor Farringer: Nesrin or Travis, any last comments before I take it back to our team to thank everyone for coming.

Travis Kottkamp: Yeah, no, I appreciate the chance to participate. I think that Dr. Charles said it well. You know, that this is clearly here to stay and I think beyond outside counsel perceptive it's just as important as you're working with clients that you build scalable models that haven't been denied for increase coverage. Because I do think that from a reimbursement perspective, we're just going to continue to see expanded coverage modifications in coverage parody and payment parody laws along the lines of what Professor Tovino was saying. It's here to stay and it's just a matter of keeping up with the waves of change.

Professor Farringer: Well, thank you so much, Nesrin did you have any last-minute comments?

Nesrin Tift: I agree.

Professor Farringer: Alright, thank you so much to our panelists. I am going to now kick it back to Paige I think, who is going to tell us a little bit about what's up next for the Journal.

Paige Goodwin: Yeah, thank you everyone for joining us. My name is Paige Goodwin, and I am the Symposium Director and I just wanted to quickly tell you about our upcoming event this Spring. So, in February, we are hosting our health law symposium which will also be exploring immerging trends in health care technology. It will essentially just be an extended version of what we had today. We will have multiple panels, several academic speakers, and people will be able to earn up to three CLE credits. As of right now we are planning on this to be held virtually, but fingers crossed that things get better and we can all be in person. But I will be sending out an email with more about this soon so be on the lookout for that and I hope to see you there. I'm going to hand it over to Joey, our managing editor for closing things out.

Joey Kennedy: Thank you Paige, like Casey mentioned earlier we will be sending a CLE form out via Google forms to the email that you registered with. So, once you receive all those responses we will submit all the attendee information to the CLE commission. We heard there could be a slight delay with that, with them getting innovated with all of these remote and other CLEs. So, we will get those sent in. And I also want to thank our presenters and panelists again for very timely and interesting discussion today. It just seems that telehealth and other remote forms of technology are consuming every day and it is interesting to see what is going on behind the

scenes. I would again like to thank Paige Goodwin, our director for the symposium. She has done so much work on this event and we are very thrilled with the way it has gone today. We appreciate all of you for making time to attend this event today, we are thrilled to have more than double our attendance rate from last year. And we know that the Tennessee Bar is hosting its annual health law forum this week, so we really appreciate you for being with us for this hour. And with all of that be on the lookout for that CLE form in your email and we hope to see you all again this spring for our annual symposium.

Professor Farringer: Thank you so much.

Casey Goggin: Thank you, everyone.

THE NFL AND OPIOID ABUSE:
CHOOSING THE BEST ROUTE TO TACKLE A DIFFICULT PROBLEM

JACOB FREELAND

I. INTRODUCTION

Due to the sheer physical nature of football, the National Football League ("NFL") and its players have a long history of prescribing and using opioids to relieve pain.[1] According to a 2011 survey commissioned by ESPN in which 644 former players were asked about their use of painkillers in their playing days, the following information was discovered: fifty-two percent of former players used prescription opioids during their NFL careers.[2] Among these players, seventy-one percent reported misusing opioids while they were playing in the NFL.[3] Additionally, fifteen percent of retired players who misused prescription opioids while in the NFL reported additional misuse within the past thirty days. Further, fifty-one percent of former NFL players who used opioids while playing in the NFL reported obtaining the painkillers from a combination of doctors and nonmedical sources, such as teammates, trainers, and

[1] Matt Gonzales, *Opioids: A Painful Problem for the NFL*, THE RECOVERY VILLAGE (Jan. 16, 2020), https://www.therecoveryvillage.com/opiate-addiction/related-topics/misuse-nfl/#gref.
[2] *Id.*
[3] *Id.*

even coaches.[4] Lastly, the survey found that former players who misused opioids during their playing careers were over three times more likely to misuse the drugs in the past month than players who used opioids as prescribed.[5]

Many former players have spoken against the regular use of painkillers in the NFL. According to recently retired NFL wide receiver Calvin Johnson, team doctors and physicians were giving out painkillers to players "like candy" during his career.[6] He further stated, "If you were hurting, then you could get them, you know. It was nothing. If you were dependent on them, they were readily available."[7] Former NFL quarterback Brett Favre also admitted that he developed an addiction to prescription painkillers during his career.[8] During his MVP season in 1995, Brett Favre admitted that he took as many as fourteen Vicodin at one time in order to suppress his pain from playing football.[9] Favre stated, "It is really amazing, as I think back, how well I played that year. That was an MVP year for me. But that year, when I woke up in the morning, my first thought was, 'I got to get more pills.'"[10] Further, former player Eugene Monroe, who is an outspoken opponent of painkiller use in the League, stated that opioids were readily dispensed in team locker rooms for several years. He even suggested that NFL teams encourage their players to take and use painkillers.[11]

However, former players are not the only ones complaining about opioid misuse in the NFL. Current NFL superstar Travis Kelce admitted that as a result of his involvement with the NFL, he developed a dependence on opioids.[12] Kelce stated, "During my first surgery, I had no idea that these pain medications were something that I was going to want, that my body was going to want, and that I was going to feel uncomfortable if I didn't have these."[13]

When analyzing the high volume of reports from current and former players, it is clear that there is a long history of painkiller abuse by teams and players in the NFL. To make matters worse, the abuse does not always end when players stop playing.[14] According to former NFL lineman Aaron Gibson, after he retired he was taking as many as 200 pills a day because of the substance dependence he

[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*

developed during his time in the League.[15] Gibson later stated, "If I didn't play in the NFL, I know I wouldn't have been in this situation."[16]

Even the NFL's front office is aware of the issue and has commented openly on the topic. Commissioner Roger Goodell stated, "We obviously put this as a huge priority for us, making sure that we are taking care of our current players as well as our former players." Goodell continued by stating, "Our players are cared for by the world's finest medical professionals. The dedicated medical and training staffs of every NFL club are always and have always been committed to providing their patients with the best possible care."[17]

In short, the history of painkiller abuse by players and distribution of painkillers by team doctors has spurred debate concerning whether or not the NFL should be held liable for the dangerous addictions and resulting injuries to former players' health.[18]

This note will provide a background of the history of opioid use in the National Football League to understand better the context of the issue, the legal discrepancies between the League office and players of determining whether or not the League itself is liable for the negligent distribution of opioids to players and their reliance on the drugs, and what the most feasible solution to this issue is going forward when taking into account the most recent holding in *Dent v. Nat'l Football League*.[19]

Based on current precedent, legal relief is not a viable solution to remedy the NFL's ongoing substance abuse issues. However, the long-term safety of current and future football players, as well as the integrity of the sport, can be saved if instead of resorting to the courts, the players take this battle to state and federal legislatures while simultaneously promoting cultural awareness of the dangers that these prescription practices pose to past, current, and future football players. Part II of this note will examine the relevant legal and procedural history of opioid-related lawsuits that have been filed against the NFL and its franchises. Part III will discuss why legal relief is not a viable form of relief for past, current, and future NFL players under the current precedent on the NFL's role in administering painkillers. Lastly, Part IV of this article will examine why legislative action and cultural awareness is the best

[15] Ken Belson, *For N.F.L Retirees, Opioids Bring More Pain*, N.Y. TIMES (Feb. 3, 2019), https://www.nytimes.com/2019/02/02/sports/nfl-opioids-.html.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] Dent v. Nat'l Football League, 384 F.Supp.3d 1022 (N.D. Cal. April 18, 2019).

possible course of action to achieve meaningful results in an attempt to bring this epidemic to a halt.

II. LEGAL AND PROCEDURAL POSTURE RELATING TO OPIOID ABUSE IN THE NFL

There have been two significant lawsuits filed which involve former players suing the National Football League asserting that the League was liable for negligently distributing opioids to its players. These cases are *Dent v. Nat'l Football League* and *Evans v. Arizona Cardinals*.[20] These two lines of cases both involve state law claims by former players asserting that the NFL has violated various California Statutes relating to the issuance of prescription drugs.[21] A major focal point of both of these cases involves whether these claims by the players are preempted by Section 301 of the Labor Management Relations Act.[22] Before going into a discussion of the relevant cases, it is essential to understand what the Labor Management Relations Act is and precisely why the preemption aspect of this federal legislation comes into play.

A. LABOR MANAGEMENT RELATIONS ACT

Section 301 of the Labor Management Relations Act ("LMRA") on its face provides federal jurisdiction over disputes regarding collective bargaining agreements ("CBA").[23] CBAs are legal contracts between an employer and a union representing the employees.[24] The CBA is the result of negotiations between the employer and union regarding various topics such as wages, hours, and employment conditions.[25] In interpreting the LMRA, the Supreme Court has concluded that when a suit stating a claim under Section 301 is brought, the CBA is interpreted under federal common law and state law claims are preempted.[26] This is to allow parties who are drafting and agreeing on CBAs to have a reliable

[20] Dent v. Nat'l Football League, No. C 14-02324 WHA, 2014 U.S. Dist. LEXIS 174448 (N.D. Cal. Dec. 17, 2014); Evans v. Arizona, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207 (N.D. Cal. July 1, 2016).
[21] *Id.*
[22] *Id.*
[23] Paul J. Zech, *Federal Pre-emption and State Exclusive Remedy Issues in Employment Litigation*, 72 N.D. L. REV. 325, 331 (1996).
[24] Bridget Miller, *What is a Collective Bargaining Agreement?*, HR DAILY ADVISOR (Feb. 17, 2016), https://hrdailyadvisor.blr.com/2016/02/17/what-is-a-collective-bargaining-agreement/.
[25] *Id.*
[26] Zech, *supra* note 23, at 331.

view of the way that the CBA will be interpreted and ruled on by the courts.[27]

However, the Supreme Court has made clear that not every controversy regarding employment or a CBA will be preempted by Section 301.[28] The courts have determined that Section 301 of the LMRA preempts state law as long as the state law claim demands an interpretation of the CBA.[29] If the determination of the state law claim does not require the court to construe or evaluate any terms of the CBA, then the state law claim will not be preempted.[30] Ultimately, LMRA Section 301, which governs actions by an employee against an employer under a CBA, preempts state law claims involving the interpretation of rights and responsibilities under a CBA regardless of whether the plaintiff's claims sound in state tort or contract law.[31] Lastly, federal law exclusively governs suits for breach of collective bargaining agreements as a result of the LMRA.[32]

B. *DENT V. NAT'L FOOTBALL LEAGUE*, 2014

In *Dent*, former NFL player Richard Dent and 1,100 other plaintiffs brought a punitive class action lawsuit against the NFL as an entire organization in 2014 in the United States District Court for the Northern District of California.[33] Dent and his fellow plaintiffs alleged that beginning in 1969, NFL trainers and physicians fraudulently and negligently administered opioids, Toradol, and other medications to players in ways that violated federal laws as well as the American Medical Association's Code of Ethics in what they coined as a "return-to-play scheme."[34] Plaintiffs asserted this scheme was designed to get players to return to the field of play faster, as opposed to letting them heal in ways that were appropriate but resulted in an extended absence from the game.[35] The plaintiffs alleged that due to the League's conduct, they suffered long-standing and continuing mental and physical injuries including,

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[27] *Id.*
[28] *Id.*
[29] *Id.* at 332.
[30] *Id.*
[31] *See generally* Tand v. Solomon Schechter Day School of Nassau Co., 324 F.Supp.2d 379 (E.D. N.Y. 2004).
[32] *See generally* Pitts v. Plumbers & Steamfitters Local Union No. 33, 718 F.Supp.2d 1010 (S.D. Iowa 2010).
[33] Dent v. Nat'l Football League, No. C 14-02324 WHA, 2014 U.S. Dist. LEXIS 174448, at *3 (N.D. Cal. Dec. 17, 2014).
[34] *Id.*
[35] *Id.*

"nerve, knee, and elbow injuries that never healed properly, heart disease, renal failure, and drug addiction."[36]

Dent and the other plaintiffs filed claims including negligence, negligence per se, negligent hiring and retention, negligent misrepresentation, fraudulent concealment, fraud, and loss of consortium.[37] They sought relief in the form of damages, injunctive and declaratory relief, and medical monitoring.[38] In response to these claims, the NFL filed two motions to dismiss.[39] The first motion argued that the players' claims were preempted by Section 301 of the Labor Management Relations Act of 1947.[40] The second motion filed by the NFL argued Dent and his co-plaintiffs failed to state a claim, and that their claims were barred by the statute of limitations.[41]

Responding to these motions, the district court held that Section 301 did preempt the plaintiffs' claims because it would not be possible to address or determine the NFL's negligence without reference to the CBA, and stated that, "it would be essential to take into account the affirmative steps the NFL has taken to protect the health and safety of the players, including the administration of medicine."[42] In their counter argument, Dent and his co-plaintiffs replied that the duties of the NFL could be considered separately from the duties of by the individual clubs and their medical personnel.[43] The district court rejected these arguments and clearly stated that the claim was based on an overarching duty owed by the NFL.[44] To determine the scope of that duty, the court would have to consider the CBA to determine what the NFL required of the individual team doctors.[45]

Additionally, the court emphasized that because the CBA was absent of medical and health responsibility at the League level, it is implied that such medical and health responsibility was only placed upon the individual teams themselves and not on the League as a whole.[46] In short, the plaintiffs in *Dent* were unsuccessful in their attempt to hold the NFL liable for the injuries that the plaintiffs

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[36] *Id.* at *4.
[37] *Id.* at *5.
[38] *Id.*
[39] Dent v. Nat'l Football League, No. C 14-02324 WHA, 2014 U.S. Dist. LEXIS 174448, at *5 (N.D. Cal. Dec. 17, 2014).
[40] *Id.*
[41] *Id.*
[42] *Id.* at *20.
[43] *Id.* at *23.
[44] *Id.* at *24.
[45] Dent v. Nat'l Football League, No. C 14-02324 WHA, 2014 U.S. Dist. LEXIS 174448, at *24 (N.D. Cal. Dec. 17, 2014).
[46] *Id.* at *24-25.

suffered during their time in the NFL because their claims of negligence were preempted under Section 301 of the LMRA, because the court determined that the CBA would have to be interpreted in order to reach a conclusion.[47]

C. EVANS V. ARIZONA CARDINALS

In 2016, *Evans v. Arizona Cardinals* once again raised the issue of the NFL's distribution of painkillers.[48] The same class of plaintiffs in *Dent* once again filed another class action suit in the United States District Court for the Northern District of California.[49] However, in this instance, the plaintiffs brought suit against each of the thirty-two NFL franchises individually.[50] As in *Dent*, the plaintiffs in *Evans* claimed that franchises' trainers and physicians routinely withheld injury-related information from players.[51] They further asserted that the individual NFL franchises illegally provided and administered painkillers without informed consent in violation of California statutory law, in an effort to keep players on the field.[52] In response, the individual franchises moved to dismiss once again under Section 301 and requested that the case be transferred to the Northern District of California where *Dent* was decided.[53] The court granted the defendant's motion for transfer.[54]

In a surprising decision, the court denied the franchisees' motion to dismiss under Section 301, drawing two clear distinctions from *Dent*.[55] First, the court reasoned the claim was directed at the individual clubs themselves instead of the League.[56] For the second distinction, the court reasoned that the claims were directed at intentional conduct in violation of the relevant statutes, instead of negligence.[57] The court stated that these distinctions were significant for two reasons.[58]

First, under *Dent*, the court would be evaluating any possible negligence by the NFL itself, and this would require analyzing what

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[47] *Id.* at *36.
[48] Evans v. Arizona, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207, at *1 (N.D. Cal. July 1, 2016).
[49] *Id.* at *3-4.
[50] *Id.*
[51] *Id.* at *4-5.
[52] *Id.*
[53] Evans v. Arizona, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207, at *6-7 (N.D. Cal. July 1, 2016).
[54] *Id.*
[55] *Id.* at *11-13.
[56] *Id.*
[57] *Id.*
[58] Evans v. Arizona, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207, at *11-13 (N.D. Cal. July 1, 2016).

the NFL had affirmatively done in its CBAs to protect the health of the players through the individual clubs.[59] In contrast, in *Evans* the complaint was directed at the specific clubs themselves, thus the CBA would not need to be evaluated, as in *Dent*, because only the specific clubs' conduct would need to be evaluated.[60]

Second, the claims in *Evans* were grounded in illegal conduct of the clubs themselves and not negligence on behalf of the NFL as in *Dent*.[61] Because of this, the complaint falls under the illegality exception, which states that Section 301 of the LMRA does not grant parties to a CBA the ability to contract for what is illegal.[62] Thus, the CBA would not need to be referenced and the claims are not preempted under Section 301.[63] In short, the Court established in *Evans* that players could bring suit for intentional representation against the individual clubs, but not against the NFL itself.[64]

D. *DENT V. NAT'L FOOTBALL LEAGUE*, 2018

Moving forward, *Dent* experienced a revival in 2018.[65] Stemming from the decision in the 2014 *Dent* case, the players challenged the district court's decision in an appeal before a three-judge panel of the Ninth Circuit Court of Appeals.[66] During the 2018 appeal, the issue before the court of appeals was whether the plaintiffs' state law claims under fraud and negligence required interpretation of or arose from the Collective Bargaining Agreement.[67] The Ninth Circuit emphasized that its role at this current stage of litigation was to take the allegations as true.[68] The court stated that the forum preemption inquiry under Section 301 of the Labor Management Relations Act is "not an inquiry into the merits of a claim; it is an inquiry into the claim's 'legal character' whatever its merits."[69]

To make this determination, the Ninth Circuit settled on and conducted a two-step inquiry in determining whether state law

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[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] Evans v. Arizona, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207, at *11-13 (N.D. Cal. July 1, 2016).
[65] Dent v. Nat'l Football League, 902 F.3d 1109, 1114 (9th Cir. 2018).
[66] *Id.* at 1115.
[67] *Id.*
[68] *Id.* at 1117.
[69] *Id.*

claims were preempted by Section 301.[70] First, the court asked, "whether the cause of action involves 'rights conferred upon an employee by virtue of state law, not by a CBA.'"[71] The court further stated, "If the rights exist 'solely' from the CBA, then the claim is preempted."[72] Second, suppose the rights are independent of the CBA. In that case, the court asks whether an interpretation of the CBA is required to resolve the claim, "such that resolving the entire claim in court threatens the proper role of grievance and arbitration."[73]

Using this two-step framework, the court first applied the framework to Dent's negligence-based claims.[74] In analyzing the first step, the court mentioned that the plaintiffs had shaped their claim as one being negligence *per se*. However, California law does not recognize negligence *per se* as a cause of action, but only as a doctrine. To clarify this, the court stated, "We construe the players' claim as traditional negligence but apply the negligence [*per se*] doctrine."[75]

Specifically, the court found that the statutes CSA, Federal Drug and Cosmetics Act (FDCA), and California Pharmacy Laws would establish a standard of care and stated that, "violation of a statute would give rise to the presumption that it failed to exercise due care."[76]

The players asserted that the NFL violated both federal and state laws that govern the administration of opioids.[77] The Ninth Circuit here reasoned that it did not see the claim as the NFL's mere failure to stop or intervene as viewed by the district court.[78] Instead, the court reasoned that the spirit of the claim was that the NFL itself illegally distributed controlled substances, and therefore its actions directly injured the players.[79] The court placed particular emphasis on its determination that the claim argued that the NFL itself distributed controlled substances. The court read the claim as alleging that the NFL both indirectly and directly supplied players with drugs, and that they managed the illegal distribution of painkillers and anti-inflammatories without informed consent.[80]

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[70] Dent v. Nat'l Football League, 902 F.3d 1109, 1116 (9th Cir. 2018).
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *Id.* at 1117.
[75] Dent v. Nat'l Football League, 902 F.3d 1109, 1117 (9th Cir. 2018).
[76] *Id.* at 1119.
[77] *Id.*
[78] *Id.* at 1118.
[79] *Id.*
[80] Dent v. Nat'l Football League, 902 F.3d 1109, 1118 (9th Cir. 2018).

Continuing with the analysis of the first prong of the two-step inquiry, the court of appeals reasoned that the CBAs did not create a right for the players' to receive medical care from the NFL that did not create an unreasonable risk of harm.[81] In holding this, the court reasoned that the players were not arguing the NFL violated the CBA. Instead, the plaintiffs argued it violated the state and federal laws that govern prescription drugs.[82]

The court then moved to the second prong of the analysis to determine whether the players' claim required interpretation of the CBA.[83] The court stated that analyzing this prong required showing the elements of negligence without referring to the CBA.[84] In doing so, the court stated the elements required for a state claim of negligence in California which are as follows: First, the defendant had a duty or obligation to conform to a certain standard of conduct for the protection of others against unreasonable risk. Second, a breach of duty occurred. Third, causation is present. Fourth, damages are present.[85] The court then analyzed each specific element to determine whether the elements for a *prima facie* case for negligence could be interpreted without going to the CBA.[86]

For the first element, the court of appeals concluded that the NFL's duty to exercise reasonable care in the distribution of controlled substances arose from the "general character of its involvement."[87] Additionally, there is foreseeable harm to individuals hinted by the fact the drugs are labeled a controlled substance in the first place, and carelessness in the handling of these drugs is "both illegal and morally blameworthy given the risk of injury that it entails." Moreover, there is no undue burden upon entities that should be following laws governing prescriptions.[88] Second, the court determined a breach occurred due to the requirements in the federal and state statutes.[89] Third, the court concluded that the question of causation was purely factual.[90] Fourth, the court held that clearly, damages had arisen that did not arise from the CBA.[91] In considering this analysis, the court held

[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] Dent v. Nat'l Football League, 902 F.3d 1109, 1122 (9th Cir. 2018).
[86] *Id.* at 1118-20.
[87] *Id.* at 1118.
[88] *Id.* at 1119.
[89] *Id.*
[90] Dent v. Nat'l Football League, 902 F.3d 1109, 1119 (9th Cir. 2018).
[91] *Id.*

that the plaintiffs' negligence claim alleging the NFL violated state and federal statutes was not preempted by Section 301.[92]

After the appeals court held liability could be found without reference to the CBA, the court analyzed the claims of negligent hiring and retention and negligent misrepresentation. The court stated that because the CBA did not give rise to the duty, nor was it required to determine a breach, there was no preemption for the negligent hiring and retention claim.[93]

In the claim of negligent misrepresentation, the players asserted that the NFL "continuously and systematically" misrepresented the risks associated with the medications at issue, that they reasonably relied on those misrepresentations, and that they were injured as a result.[94] The NFL responded by arguing that the scope of its duty to the players would require interpretation of the CBA provisions related to "medical care, including those that give players the right to access medical facilities, view their medical records, and obtain second opinions."[95] Additionally, the NFL argued it would be impossible to determine if the plaintiffs reasonably relied on the representations without interpreting CBA provisions related to team doctors' disclosure obligations.[96]

The court responded to the NFL's arguments by noting that California law does not require the various parties' disclosures to be weighed, but instead, whether the circumstances were such that it would be reasonable for the plaintiffs to rely on the NFL's statements without independent inquiry or investigation.[97] Although sister courts to the Ninth Circuit found that interpretation of a CBA was necessary, this case differed in that, "no provision of the CBAs even arguably render the players' reliance on the NFL's purported representations unreasonable," and therefore, the claim is not preempted. More importantly, the court stated, "As we have said, none of the CBA provisions address the NFL's responsibilities concerning the distribution of prescription drugs."[98]

Next, the court applied its two-step analysis to *Dent*'s fraud-based claims.[99] The appeals court quickly determined that the players' claims for fraud and fraudulent concealment were not preempted under Section 301.[100] Using case law, the court laid out

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[92] *Id.* at 1121.
[93] *Id.* at 1122-23.
[94] *Id.* at 1123-25.
[95] Dent v. Nat'l Football League, 902 F.3d 1109, 1123-25 (9th Cir. 2018).
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] *Id.* at 1125.
[100] Dent v. Nat'l Football League, 902 F.3d 1109, 1125 (9th Cir. 2018).

the elements required to establish a *prima facie* case for fraud and fraudulent concealment.[101]

The players alleged that the NFL "knew, or should have known, that its provisions and administration of medications created a substantial risk of causing addictions and related physical and mental problems," and the NFL intentionally withheld this information with the intent to deceive the players.[102] The NFL failed to cite any analogous CBA provision that would resolve the players' fraud-based claims. Instead, the NFL again argued that to assess the existence of its duty to make disclosures, as well as whether the players' reliance was reasonable, it was necessary to interpret the CBA provisions that required club physicians to make certain disclosures.[103]

The court disagreed with the NFL's argument and reasoned that because the players' claims were based on the NFL's conduct, interpretating the team-doctor disclosure provisions was not required. Essentially, the court stated that the NFL's duty arose from the character of the act by the NFL and not from the CBA.[104]

Judge Tallman concluded by stating that the NFL's defenses, including CBA provisions on team doctors' disclosure obligations, the qualifications of team medical personnel, and players' rights to obtain second opinions or examine their medical records, were irrelevant to the question of whether the NFL violated federal laws regarding distribution of controlled substances and state law regarding hiring, retention, misrepresentation, and fraud.[105] Thus, the court determined the claims were not preempted under Section 301.[106]

The 2018 *Dent* case concluded that the meaning of CBA terms governing team doctors' disclosure obligations, qualifications of team medical staff, and players' rights to obtain second opinions or review their medical records is not relevant to the question of whether or not the League's conduct itself violated federal laws regarding the distribution of opioids and state law regarding hiring, retention, misrepresentation, and fraud. Thus, no interpretation of the CBA was necessary, and Section 301 did not preempt the plaintiffs' claims. [107]

E. *DENT V. NAT'L FOOTBALL LEAGUE*, 2019

[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] Dent v. Nat'l Football League, 902 F.3d 1109, 1126 (9th Cir. 2018).
[106] *Id.*
[107] *Id.*

Finally, the *Dent* line of lawsuits came to a close in April of 2019.[108] Here, the United States District Court for the Northern District of California reviewed the players' third and final amended complaint, which argued that the NFL was required to, or voluntarily undertook the duty to, comply with federal and state laws regulating the manner in which these opioids were administered and distributed among players. Further, the complaint alleged that the NFL failed to comply with federal and state laws, consistently and repeatedly, from the 1970s through at least 2014, and that failure directly and proximately caused the injuries for which plaintiffs seek damages.[109] In response to the final complaint, the NFL moved to dismiss arguing that the plaintiffs failed to state a claim and that the statute of limitations barred the claim.[110]

By leaning the analysis of the appellate court's findings, the district court determined it was clear that the interpretation of the CBA was not required solely because of the plaintiffs' position that the NFL itself was engaged in the handling, distribution and administration of the painkillers to players.[111] However, the court stressed that in the players' third amendment of their complaint, they now explicitly based their claim of the NFL's direct involvement of the administration of the medication on the "maintenance" and "creation" of the "return-to-play" scheme, as opposed to the direct distribution of the painkillers to the players itself.[112] Thus, the court stated that under this pleading, the plaintiffs are no longer alleging that the NFL violated the relevant California statutes, but that the individual club doctors and trainers are violating the relevant statutes.[113]

Further, the court found problems with the players' pleading because it did not point to any specific allegations that the California statutes in question applied directly to the NFL or that the NFL itself even violated those statutes.[114] The court stated, "despite ninety pages of allegations, nowhere in the third amended complaint do plaintiffs allege, as they previously pitched before our court of appeals, that the NFL undertook to provide direct medical care and treatment to players such that its conduct violated any relevant drug laws."[115] The court of appeals explained that the players' negligence

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[108] Dent v. Nat'l Football League, 384 F.Supp.3d 1022 (N.D. Cal. April 18, 2019).
[109] *Id.* at 1028.
[110] *Id.*
[111] *Id.* at 1029.
[112] *Id.*
[113] Dent v. Nat'l Football League, 384 F.Supp.3d 1022, 1029 (N.D. Cal. April 18, 2019).
[114] *Id.* at 1030.
[115] *Id.*

claim would need to show that the relevant statutes applied to the NFL, the NFL violated those statutes, and the violations resulted in the injuries to the players.[116] The court stated that because the players did not acknowledge in their final amended complaint that the NFL did not itself provide medical care or distribute painkillers to the players, the players failed to plead sufficient facts that would support their claim against the NFL.[117]

The court clarified that the only reason the players were able to escape Section 301 preemption before the court of appeals was only by asserting that the NFL itself was directly involved with the distribution of painkillers.[118] Thus, once they escaped preemption, the players could not "bob and weave" back to other theories of negligence that relied on the NFL's failure to intervene with the individual team's distribution of the medication.[119]

The court concluded that while they were sympathetic to the former players' position and recognized the societal issue that is prominent regarding the opioid epidemic, the players here failed to adequately plead a claim for negligence and granted the NFL's motion to dismiss.[120] Since this was the players' "best and final" pleading, the suit was dismissed with no further chances to be amended.[121]

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[116] *Id.* at 1033.
[117] *Id.*
[118] Dent v. Nat'l Football League, 384 F.Supp.3d 1022, 1032 (N.D. Cal. April 18, 2019).
[119] *Id.*
[120] *Id.* at 1035.
[121] *Id.*

III. LEGAL RELIEF IS NOT A VIABLE FORM OF RELIEF WITH GIVEN FACTS AND PRECEDENT

Seeking relief from the courts is not a viable course of action for former and current NFL players suffering from painkiller addictions because of the precedent and reasoning established in the *Dent* and *Evans* line of cases.[122] These two cases established that Section 301 bars a state law negligence claim against the NFL directly, intentional misrepresentation claims can only be brought against the individual clubs themselves which harms the interests and efficiency of the class as a whole, and that the only viable claims left available for the entire class against the NFL rest with a breach of contract claim regarding the collective bargaining agreement.[123]

First, it is clear from the holding in *Dent* and the factual information brought forward in *Evans* that the players do not have enough evidence to support a claim that the NFL itself was directly involved in the negligent distribution of the painkillers to the players and because of this, the collective bargaining agreement would need to be interpreted, and a negligence claim would be preempted under Section 301 of the LMRA.[124] As a state law negligence claim against the NFL cannot be filed, the former and current players would have to pivot to one of two alternative legal strategies in order to seek some form of legal relief.

One possible legal alternative for the current and former players that is still available is to bring a state law claim for intentional misrepresentation against the individual clubs as opposed to the entire NFL.[125] However, this option presents several challenges and impracticalities regarding the representation of the class as a whole. For one, this route would result in the claims for misrepresentation being aimed directly at each football club involved and the facts would be different as they pertained to each club and player involved.[126] This would add a layer of complexity to seeking legal relief because all members of the class did not play for the same teams, some individuals may gain relief while others may not, and all clubs are individual entities so they all are subject to individualized review when determining whether or not their actions were negligent and would justify the awarding of legal

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[122] *Id.* at 1022.; Evans v. Arizona, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207, at *1 (N.D. Cal. July 1, 2016).
[123] Dent v. Nat'l Football League, 384 F.Supp.3d 1022 (N.D. Cal. April 18, 2019).
[124] *Id.*
[125] *Evans v. Arizona*, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207, at *13 (N.D. Cal. July 1, 2016).
[126] *Id.* at *12.

relief.[127] When understanding the ultimate holding in *Evans*, it is fair to conclude that it is not likely an effective or efficient strategy to continue to seek relief through a class action lawsuit due to the individualized claims of each player that would need to be litigated regarding the specific club's practices that they played for.

Another alternative form of legal relief would be for former and current players to bring a federal breach of contract action against the NFL for violating the terms of the CBA.[128] However, once again, this route presents its own disadvantages and impracticalities. An issue with this legal route is that the remedies that would potentially be acquired from a breach of contract claim regarding the CBA would not likely be as fruitful as a negligence per se claim in violation of California law.[129] In the final holding of *Evans*, Judge Alsup recognized that this legal remedy may not be the most fruitful, stating, "although workers' compensation and collective bargaining remedies are not gold-plated remedies, they are at least remedies recognized under the law."[130] Therefore, under this legal theory, it is not likely that players would be compensated in a manner that would equal the harm that they are currently suffering. Additionally, the CBA between the NFL and its players is subject to change, and has been changed nine times throughout the League's tenure.[131] Thus, former and current players may have claims that arise from different versions of the CBA, which would produce additional complications and reduce efficiency for a class action lawsuit.

In short, legal relief is not a viable solution to resolve the ongoing painkiller issue in professional football. In light of the most recent decision in *Dent*, which firmly stated that under the current facts provided that state law claims for negligence against the NFL itself were preempted under Section 301 of the LMRA, it is not in the best interest of current and former players to seek legal remedies for their substance addictions and abuse. In analyzing the two alternative legal strategies that could still be pursued by current and former players with opioid addictions, the impracticalities and inefficiencies that come with these theories paired with the cost of litigation would weigh against the potential benefit that the players would receive if their attempts were successful.

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[127] *Id.* at *4.
[128] Evans v. Arizona Cardinals Football Club, LLC, 262 F.Supp.3d 935, 942 (N.D. Cal. July 21, 2017).
[129] *Id.*
[130] *Id.*
[131] Associated Press, *Chronology of NFL Labor History Since 1968*, ESPN (Mar. 3, 2011), https://www.espn.com/nfl/news/story?page=nfl_labor_history.

IV. LEGISLATIVE ACTION & CULTURAL AWARENESS AS THE APPROPRIATE ROUTE FOR RELIEF

As courts are unable to provide an adequate remedy to players who have suffered from opioid addictions, and since the NFL cannot be held liable for its negligence in a class action lawsuit, the most appropriate remedy for this ongoing problem would be to take legislative action and spread cultural awareness that can help prevent these dangerous prescription practices from continuing to take place in the future.[132] In determining the appropriate next steps, it is beneficial to analyze the legislative and cultural actions taken in response to the ongoing concussion crisis in the NFL.

A. THE NFL'S CONCUSSION CRISIS

The controversy regarding concussions in the NFL is similar to the debate regarding painkiller use in that it has affected many players, there is an ongoing struggle for legal relief, and there is an abundance of concern and attention from the public.[133] Reports show that many retired NFL players who suffered concussions during their NFL careers have developed long term health defects such as dementia and Chronic Traumatic Encephalopathy ("CTE").[134] Several class action lawsuits were filed to address the long-term health effects former players were suffering as a result of these injuries.[135] Unlike the painkiller lawsuit at hand, former players were actually successful in a class action lawsuit against the NFL and achieved a settlement from the NFL as a result of the litigation.[136] However, while originally this settlement was thought to be a historic breakthrough, many players who suffered from concussions did not receive compensation, and the settlement descended into a battle between plaintiffs' attorneys and the NFL, who is still trying to avoid liability.[137] Thus, even though the lawsuit was held in favor of the players, many players and their families

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[132] Dent v. Nat'l Football League, 384 F.Supp.3d 1022 (N.D. Cal. April 18, 2019); Evans v. Arizona, No. C 26-01030 WHA, 2016 U.S. Dist. LEXIS 86207, at *13 (N.D. Cal. July 1, 2016).
[133] CNN Library, *NFL Concussions Fast Facts*, CNN (Aug. 15, 2019), https://www.cnn.com/2013/08/30/us/nfl-concussions-fast-facts/index.html.
[134] *Id.*
[135] *Id.*
[136] Taylor Simpson-Wood & Robert H. Wood, *When Popular Culture and the NFL Collide: Fan Responsibility in Ending the Concussion Crisis*, 29 MARQ. SPORTS L. REV. 13, 53 (2018).
[137] *Id.*

continue to suffer the effects of serious brain damage from playing football, and the concussion problem continues to persist.[138]

The legal system has not provided adequate relief to former players and did not result in satisfactory solutions to the concussion crisis that the NFL is currently facing. In order to help resolve this epidemic, society turned to legislative action and cultural awareness to make changes to prevent this problem from persisting. In response to the NFL's concussion epidemic, forty-eight states have adopted concussion laws that pertain to their youth sports leagues.[139] These laws are designed to inform and educate young football players and their parents or guardians, and includes a requirement that forces players to sign a concussion information form.[140] Additionally, this legislation requires youth football players who appear to have suffered a concussion to be immediately removed from a game.[141] In addition, this legislation requires that the player be cleared by trained health professionals in the field of concussions before returning.[142]

In response to the concussion epidemic in the NFL, society and popular culture have played a role in bringing awareness to the public about the crisis.[143] For example, a major motion picture starring actor Will Smith entitled "Concussion" was released, which played a role in educating and warning viewers about the long-term health risks and brain damage that one can suffer from playing football.[144] Additionally, with widespread access to media and sports-talk radio available to individuals through television and other media outlets, the rampant dialogue between sportscasters, players and analysts on channels such as ESPN has brought large-scale public awareness to the CTE issue.[145]

This increasing societal awareness has resulted in severe pressure being mounted on the shoulders of the NFL to prevent concussions from taking place on its fields and to increase player safety.[146] This approach, of public awareness and public pressure, has resulted in the NFL refining and increasing the effectiveness of its concussion protocols, which is clearly a positive sign for the

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[138] *Id.*
[139] *Concussion Legislation by State*, NFL (Aug. 9, 2013), http://www.nfl.com/news/story/0ap1000000228347/article/concussion-legislation-by-state.
[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] Wood & Wood, *supra* note 135, at 58.
[144] *Id.*
[145] *Id.*
[146] *Id.* at 54-57.

game moving forward.[147] In the most recent 2019 NFL season, there were 145 reported concussions in the regular season compared to 190 reported concussions just two years prior in the 2017 season.[148] Although the problem has not been eradicated completely, the NFL's changes in protocol and player safety requirements by the NFL seem to be trending in the right direction.[149]

B. THE SOLUTION: APPLYING THESE PRINCIPLES TO PAINKILLER ABUSE IN THE NFL

The most appropriate and realistic remedy for this ongoing problem would be to take legislative action and spread cultural awareness that can help prevent these dangerous prescription practices from taking place in the future. Due to the similarities between the NFL's opioid problem and concussion crisis concerning lack of viable relief for former players, and the potential lifelong harm associated with playing in the NFL, the appropriate solution here should be taken from the playbook that was established in response to the NFL's concussion crisis.

First, like the forty-eight states that implemented and passed legislation that spread awareness pertaining to the dangers of concussions in football and enforced mandatory standards regarding concussion protocols for players at all levels, an appropriate measure to take in response to the opioid problem in the NFL would be for states to take action in the form of legislation to spread awareness of the dangers of opioids and to set clear guidelines for appropriate prescribing practices for sports-related injuries. Although legal claims against the NFL for violations of this proposed legislation may be preempted by Section 301 of the LMRA, these standards would set hard and fast guidelines for non-team physicians for all other levels of sports ranging from youth leagues to college athletics. Additionally, this would help inform the public of the threats that opioids and painkillers pose to young athletes across the country.

Next, similar to the cultural awareness movement that took place relating to the NFL's concussion crisis through the constant discussions on media platforms and major motion picture films, an appropriate solution to combat the NFL's painkiller addiction problem is to raise cultural awareness of the threats that opioid addiction poses on former, current and future NFL players.

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[147] *Id.*

[148] *Incidence of Concussion – 2012-2019*, NFL PLAYER HEALTH & SAFETY (Jan. 23, 2020), https://www.playsmartplaysafe.com/newsroom/reports/injury-data/.

[149] *Id.*

Specifically, as former players who came forward and spoke out about concussion trauma and CTE in the NFL, which resulted in a media frenzy, current players who are experiencing or witnessing these prescription practices first-hand should similarly use their platforms to bring awareness to the issue. This would likely lead to an increase in media coverage of this issue that would shed light on this glaring problem.

Further, like the public pressure from the concussion crisis that forced the NFL to update and improve its concussion protocols and procedures which ultimately led to a decrease in concussions on a per year basis, this increased public awareness would likely lead to an increase in public pressure on the NFL to improve its protocols and procedures regarding proscribing painkillers to players which would likely also lead to a decrease in the number of players who suffer from opioid addiction.

It must be acknowledged that this proposed solution is unable to bring complete relief to the former players who are currently suffering from opioid addiction. However, by taking the issue out of the hands of the courts and giving it to the public and lawmakers, the proposed solution helps combat the continuance of this pestering problem for future generations. This solution would lead to a future for football in which there are clear guidelines for the prescription of opioids to athletes on all levels, and a society that is willing to hold the NFL accountable for improperly engaging in these prescription practices. Ultimately, the passage of legislation mandating specific prescription requirements and the increase of cultural awareness concerning the NFL's unethical practices will increase the amount of public pressure on the NFL and will force the NFL to rectify its prescription protocols, thus benefitting the future of the sport of football as a whole for years to come.

V. CONCLUSION

Although beloved by a vast number of Americans, football is an extremely violent and physical game that unsurprisingly results in a great deal of injuries for its players. As a result, the NFL and its players have a long history of opioid abuse stemming from the administration of painkillers from team doctors to players in order to keep them on the field. This issue led to several class action lawsuits alleging the NFL was negligent in its administration of pain medications to its players. In light of the most recent decision in *Dent*, it is not in the best interest of current and former players to seek legal remedies for their substance addictions and abuse. When analyzing the two alternative legal strategies that could still be

pursued by current and former players with opioid addictions, the impracticalities and inefficiencies that come with these theories, along with the cost of litigation, would weigh against the potential benefit that the players would receive if their attempts were successful.

While there is not an appropriate monetary remedy for former players suffering from painkiller addictions, the long-term safety of current and future football players, as well as the integrity of the sport, can be saved if the players take this battle to state and federal legislatures while simultaneously promoting cultural awareness of the dangers that these prescription practices present to past, current and future football players.

FINDING A CURE TO GUN VIOLENCE:
HOW IMPROVING AMERICA'S MENTAL HEALTH SYSTEM COULD PREVENT FUTURE GUN VIOLENCE

PAIGE GOODWIN

I. INTRODUCTION

On April 22, 2018, Travis Reinking killed four people and injured four others inside a Nashville Waffle House wearing nothing but a green a jacket.[1] Prior to this incident, Reinking had an extensive history of exhibiting significant mental instability.[2] Police reports show that since 2014, his family had been worried about his extreme delusions.[3] In 2016, he was taken into protective custody after he reported that Taylor Swift was stalking him and hacking into his phone.[4] A year later, in 2017, police intervened again after Reinking jumped into a public pool wearing a pink dress and threatened a co-worker with an AR-15 rifle.[5] Then, just one month later, he was arrested when he tried to force his way into the White

[1] Alan Binder et al., *Waffle House Shooting Suspect Once Had His Guns Taken Away. He Got Them Back.*, N.Y. TIMES (Apr. 23, 2018), https://www.nytimes.com/2018/04/23/us/nashville-shooting-suspect-guns.html.
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] Anita Wadhwani, *A history of red flags didn't keep guns out of hands of Waffle House shooting suspect*, THE TENNESSEAN (Apr. 25, 2018), https://www.tennessean.com/story/news/2018/04/25/waffle-house-shooting-suspect-travis-reinking-mental-health-gun-laws/546370002/.

House, claiming he needed to speak with the President.[6] Although the Illinois police revoked his firearms license and ordered his guns be transferred to his father, Reinking got them back, including the gun used in his Waffle House attack. Yet, even after his family, police officers, the Secret Service, and the judicial system all became aware of his mental illness, it largely went untreated.

In a system where it is easier to access a gun than it is to access mental health care,[7] stories like that of Travis Reinking are not uncommon. Between 2017 and 2018, the United States experienced more than fifty mass shootings, or shootings in which three or more people were harmed.[8] In analyzing the circumstances surrounding these attacks, the U.S. Secret Service found a commonality among them: about two-thirds of the attackers had mental health symptoms prior to their attacks.[9] While a majority of mass shooters have a history of showing symptoms of mental illness, only about a quarter had been diagnosed or treated for mental illness prior to their attacks.[10]

Due to the overwhelming rise of mass shootings occurring throughout the country, demands for reforming gun control legislation have caused lawmakers to contemplate the proper policy responses.[11] Since much of the population tends to link mass shootings to mental illness,[12] the focus generally has been on trying to keep firearms out of the hands of the mentally ill. However, as gun control legislation fails to have meaningful effects and mass shootings increasingly become more routine, the discussion has started to change. As a Gallup Poll from August 2019 reveals, a

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[6] *Id.*

[7] *NAMI Statement On Mass Shootings In Texas and Ohio*, NAT'L ALLIANCE ON MENTAL ILLNESS (Aug. 5, 2019), https://www.nami.org/About-NAMI/NAMI-News/2019/NAMI-Statement-on-Mass-Shootings-in-Texas-and-Ohio.

[8] Nsikan Akpan, *Why Mental Illness Can't Predict Mass Shootings*, PUBLIC BROADCASTING SYS. (Aug. 17, 2019), https://www.pbs.org/newshour/science/why-mental-illness-cant-predict-mass-shootings.

[9] U.S. Dep't of Homeland Sec., *Mass Attacks in Public Spaces-2017* (Mar. 2018), https://www.secretservice.gov/forms/USSS_NTAC-Mass_Attacks_in_Public_Spaces-2017.pdf [hereinafter "Mass Attacks 2017"]; U.S. Dep't of Homeland Sec., *Mass Attacks in Public Spaces-2018* (July 2019), https://www.secretservice.gov/data/press/reports/USSS_FY2019_MAPS.pdf [hereinafter "Mass Attacks 2018"].

[10] Akpan, *supra* note 8.

[11] *See* Mark Moore, *Trump calls for mental-health laws, not gun control*, NEW YORK POST (Aug. 5, 2019), https://nypost.com/2019/08/05/trump-calls-for-mental-health-laws-not-gun-control/.

[12] June Gruber & Darby Saxbe, *Five Improvements We Should Make to Mental Health Care*, SLATE (Feb. 27, 2018), https://slate.com/technology/2018/02/how-to-fix-americas-broken-mental-health-care-system.html.

majority of Americans are now blaming the mental health system for mass shootings, instead of easy access to guns.[13]

This trend is not just occurring among the general public.[14] Policymakers are also increasingly blaming mental health for mass shootings.[15] For example, after two back-to-back mass shootings killed 31 people, President Donald Trump addressed the nation, calling for "real bipartisan solutions" to curb mass shootings.[16] Instead of demanding that Congress enact laws restricting gun access from mentally ill people, Trump "urged Congress to reform mental health laws to ensure that psychologically disturbed individuals who may be prone to violence get treatment, and, if necessary, be involuntarily confined."[17]

The shift in focus from gun control to mental health is not only justified but necessary. First, mental health issues typically only dominate the headlines following a mass shooting, and even then, the discussion is usually tied to reforming gun control legislation instead of treatment. What is rarely shown in headlines is that millions of Americans are affected by mental illness each year,[18] but nearly half of those individuals do not have access to adequate mental health care.[19] Second, current federal gun control laws relating to mental health have proven to be unworkable because states are not required to report mental health information to the federal background check system, and there is no standard for what information must be reported.[20] Despite the existence of many

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[13] Lydia Saad, *More Blaming Extremism, Heated Rhetoric for Mass Shootings*, GALLUP (Sept. 11, 2019), https://news.gallup.com/poll/266750/blaming-extremism-heated-rhetoric-mass-shootings.aspx ("The mental health system is faulted by 83% while easy access to guns is faulted by 69%.").

[14] *See* Mike Lillis *Lewis hammers GOP on guns: 'How many more must die?'*, THE HILL (Oct. 4, 2017), https://thehill.com/homenews/house/353860-lewis-hammers-gop-on-guns-how-many-more-must-die (Paul D. Ryan, the speaker of the House, said that "mental health reform is a critical ingredient to making sure that we can try and prevent some of these things from happening in the past.").

[15] *Id.*

[16] *President Trump Address on Mass Shootings*, C-SPAN (Aug. 5, 2019), https://www.c-span.org/video/?463254-1/president-trump-calls-nation-condemn-racism-bigotry-white-supremacy-mass-shootings ("We must reform our mental health laws to better identify mentally disturbed individuals who may commit acts of violence and make sure those people not only get treatment but, when necessary, involuntary confinement.").

[17] Moore, *supra* note 11.

[18] *Mental Health By the Numbers*, NAT'L ALLIANCE ON MENTAL ILLNESS (Sept. 2019), https://www.nami.org/learn-more/mental-health-by-the-numbers.

[19] *The Doctor is Out: Continuing Disparities in Access to Mental and Physical Health Care*, NAT'L ALLIANCE ON MENTAL ILLNESS (Nov. 2017), https://www.nami.org/About-NAMI/Publications-Reports/Public-Policy-Reports/The-Doctor-is-Out/DoctorIsOut.pdf [hereinafter *Doctor is Out*].

[20] *Mental Health Reporting*, GIFFORDS LAW CENTER, (Sept. 13, 2018), https://lawcenter.giffords.org/gun-laws/policy-areas/background-checks/mental-health-reporting.

federal laws prohibiting the mentally ill from accessing firearms, individuals who pose a danger to themselves or others continuously fall through the system and come into possession of firearms.

Thus, the relevant question is not whether there are mechanisms in place to restrict mentally ill individuals from possessing firearms, but rather whether there are additional mechanisms that will better safeguard against gun violence. To be more effective, legislation should focus on intervention and treatment of at-risk individuals who evidence that they pose a heightened risk of danger to themselves or others. Aiming our efforts at preventative mental health measures is a more effective solution than engaging in endless gun control debate. As serious debate surrounding gun violence increases throughout the nation, policy decisions addressing this issue must reflect an accurate understanding of the shortcomings of current federal gun legislation targeting mental illness, as well as the crisis of untreated mental illness in the United States.

This Note will demonstrate how gun control legislation aimed at individuals with mental illnesses has been politically untenable and ineffective at preventing incidents of gun violence. Section II of this Note will introduce the history of both federal and state laws regulating gun control, highlighting those targeting individuals with mental health issues and examining major flaws in the legislation that undermines the federal background check system.

Next, Section III will explain why existing gun legislation is unworkable and ineffective, specifically addressing the discrepancies between various state and federal laws and the barriers to mental health treatment that further hinder gun control. Lastly, Section IV will argue that rather than targeting individuals with mental illness through gun control legislation, legislation should be focused on improving the mental health system to ensure that at-risk individuals receive both the treatment and support necessary. Only then will legislatures develop workable solutions that will deter gun violence.

II. BACKGROUND

Many federal laws are already in place to restrict mentally ill individuals from possessing firearms and guard against firearms being mistakenly sold to dangerous individuals. The principal source of federal regulation prohibiting individuals with mental disorders from possessing firearms was first codified in the Gun

Control Act of 1968 ("Gun Control Act").[21] This prohibition has been further enforced through subsequent legislation, including the Brady Bill,[22] the National Instant Criminal Background Check System ("NICS") Improvement Act,[23] and state laws.[24] While each new law introduces additional language and attempts to improve firearms regulations, this area of law continues to be unclear due to its ambiguous language.[25]

After the assassinations of Martin Luther King Jr. and Senator Robert Kennedy, Congress enacted the Gun Control Act to restrict certain at-risk groups from accessing firearms.[26] The Gun Control Act restricts these groups' access to firearms through two provisions. The first makes it "unlawful for any person to sell or otherwise dispose of any firearm or ammunition to any person knowing or having reasonable cause to believe that such person" falls within one of the Gun Control Act's specified groups.[27] The second provision makes it unlawful for any of these groups to "ship or transport in interstate or foreign commerce, or possess in or affecting commerce, any firearm or ammunition; or receive any firearm or ammunition."[28]

One of the at-risk groups targeted by the Gun Control Act includes anyone who has been "adjudicated as a mental defective" or who has been "committed to any mental institution."[29] Originally, the statute did not define what it meant to be a "mental defective," nor did it define what "committed to a mental institution" required.[30] As such, Congress failed to provide guidance for determining when a person falls within one of these categories of prohibited persons.[31] This lack of clarity in the statutory language resulted in inconsistent

[21] Gun Control Act of 1968, Pub. L. 90-618, 82 Stat. 1213 (codified as amended at 18 U.S.C. § 922 (2012)).
[22] Brady Handgun Violence Prevention Act, Pub. L. No. 103-159, 107 Stat. 1536 (1993) (codified as amended at 18 U.S.C. §§ 921-22 (2012).
[23] NICS Improvement Amendment Act of 2007, Pub. L. No. 110-180, 121 Stat. 2550 (2008).
[24] *See Mental Health Reporting*, *supra* note 20.
[25] Jana R. McCreary, *Falling Between the Atkins and Heller Cracks: Intellectual Disabilities and Firearms*, 15 CHAP. L. REV. 271, 298 (2011).
[26] Franklin E. Zimring, *Firearms and Federal Law: The Gun Control Act of 1968*, 4 J. Legal Stud. 133, 149 (1975).
[27] 18 U.S.C. § 922(d)(4) (2012).
[28] *Id.* at § 922(g)(4).
[29] Gun Control Act of 1968, Pub. L. 90-618, 82 Stat. 1213 (codified as amended at 18 U.S.C. § 922 (2012)).
[30] McCreary, *supra* note 25, at 285.
[31] *Id.*

judicial interpretation and application of the prohibitions on firearm possession among circuit courts.[32]

In an attempt to resolve the discrepancies regarding when the Gun Control Act's mental health-related prohibitions apply, the Bureau of Alcohol, Tobacco, Firearms, and Explosives ("ATF") provided definitions of the language.[33] ATF defines the term "adjudicated as a mental defective" to mean: "a determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease (1) is a danger to himself or other; or (2) lacks the mental capacity to contract or manage his own affairs."[34] The term "committed to a mental institution" means a "formal commitment of a person to a mental institution by a court, board, commission, or other lawful authority," including an involuntary commitment to a mental institution for mental defectiveness, mental illness, or drug use.[35] However, "committed to a mental institution" does not include voluntary admission to a mental institution or a temporary stay for observation.[36]

Another major flaw in the Gun Control Act is that while it prohibited selling firearms to the specific group, it failed to provide a way to determine whether a purchaser was a member of that group.[37] Therefore, Congress created the Brady Handgun Violence Prevention Act ("Brady Bill") in 1993 to correct this gap in the Gun Control Act.[38] The Brady Bill established a waiting period before the purchase of a handgun, during which time local law enforcement officers were to perform background checks and created the National Instant Criminal Background Check System ("NICS"), which provides information about persons not qualified to purchase firearms.[39] The NICS includes four federal databases that:

> contain records, provided by federal and state agencies, on individuals who have been (a) dishonorably discharged from the Armed Forces; (b) are unlawful users of or addicted to a controlled substance; (c) have been adjudicated as a mental

[32] *Id.* at 286-87 (Eighth Circuit found that "mental defective" did not include mental illness but did include intellectual disabilities. In contrast, the Sixth Circuit reasoned that "mental defective" included both mental illness as well as intellectual disabilities.).
[33] 27 C.F.R. § 478.11 (2013).
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] 18 U.S.C. §§ 922 (g)(4), (9) (2012).
[38] Brady Handgun Violence Prevention Act, Pub. L. No. 103-159, 107 Stat. 1536 (1993) (codified as amended at 18 U.S.C. §§ 921-22 (2006)).
[39] *Id.*

> defective or been committed to a mental institution; (d) are illegal or unlawful aliens; or (e) have renounced their U.S. citizenship.[40]

Two of these databases, the Interstate Identification Index and the NICS Index, specifically focus on identifying individuals who are disqualified from possessing firearms due to their mental health history or developmental disability.[41] The Interstate Identification Index, for example, contains "mental health information that states have reported to the FBI as part of their criminal history records, such as findings of not guilty by reason of insanity or incompetence to stand trial."[42]

The Brady Bill, however, was also defective because it failed to account for how it would incentivize states to report any information relating to mental health records to the NICS.[43] While the federal law mandates that states disclose records of individuals disqualified from purchasing firearms to the NICS, the Supreme Court held that Congress could not compel state officials to enact or enforce federal law in *Printz v. United States*.[44] Therefore, the FBI is reliant on states to voluntarily provide records to the NICS, and many states have not been willing to voluntarily disclose pertinent records to the NICS.[45] As of 2007, over a decade after the Brady Bill became law, only twenty-two states provided any mental health information to the NICS.[46]

States frequently blame federal and state privacy laws for their failure to report complete mental health records to the NICS.[47] While the disclosure of such mental health records initially violated the federal Health Insurance and Portability and Accountability Act of 1996 ("HIPAA"), in 2016, the Department of Health and Human Services modified the Privacy Rule to "expressly permit certain covered entities to disclose to the [NICS] the identities of those

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[40] Press Release, Fed. Bureau of Investigation, Response to Inquiries on the FBI's National Instant Background Check System (Apr. 19, 2007), https://archives.fbi.gov/archives/news/pressrel/press-releases/response-to-inquiries-on-the-fbis-national-instant-criminal-background-check-system [hereinafter "Response to Inquiries"].

[41] *Mental Health Reporting*, *supra* note 20.

[42] *Id.*

[43] *Id*.

[44] Printz v. United States, 521 U.S. 898 (1997).

[45] *Mental Health Reporting*, *supra* note 20.

[46] Response to Inquiries, *supra* note 40.

[47] *See Mental Health Reporting*, *supra* note 20; *see also*, Edward C. Liu et al., *Submission of Mental Health Records to NICS and the HIPAA Privacy Rule*, FED'N OF AM. SCIENTIST (Apr. 15, 2013), https://fas.org/sgp/crs/misc/R43040.pdf (stating that approximately half of the states claimed that state and federal health privacy laws caused obstacles to NICS reporting).

individuals who, for mental health reasons, already are prohibited by Federal law from having a firearm."[48] However, this does not create a duty to report, but rather a narrowly tailored exception to the Privacy Rule. The information permitted to be disclosed is very limited in scope and restricted to only those individuals who have been involuntarily committed to a mental institution or have been legally determined to be a "danger to themselves or other or to lack the mental capacity to manage their own affairs." [49] Thus, the exception does not allow reporting of diagnostic or clinical information.[50] Further, the rule's exception does not apply to most providers since it only exempts a "small subset of HIPAA covered entities that either make the mental health determinations that disqualify individuals from having a firearm or are designated by their States to report this information to NICS."[51]

Because of its narrow scope, the changes to HIPAA have had very limited impact, and privacy rules continue to create obstacles to NICS reporting. Even under the modified rule, state laws that prohibit disclosures "would not be preempted under HIPAA and the provider would not be empowered by HIPAA to make such disclosure."[52] Due to "the complexity of the law and the potential for substantial fines," many health care providers are discouraged from disclosing protected health information to NICS. [53] Thus, since the exception only permits, but does not require, the disclosure of mental health information to NICS, many providers choose to play it safe by deciding not to report any information for fear of violating HIPAA.[54]

Due to the lack of state reporting, the federal government has made several attempts to strengthen the NICS and improve its effectiveness through enacting subsequent legislation. In response to the Virginia Tech shooting, Congress passed the NICS Improvement Amendments Act of 2007, [55] which, provided

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[48] Office for Civil Rights, *HIPPA Privacy Rule and the National Instant Criminal Background Check System (NICS)* (June 16, 2017), https://www.hhs.gov/hipaa/for-professionals/special-topics/nics/index.html.
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] Vanessa K. Burrows & Jennifer S. Geetter, *New HIPAA Privacy Rule Permits Disclosures to Background Check System*, NAT'L REVIEW (Jan. 16, 2016), https://www.natlawreview.com/article/new-hipaa-privacy-rule-permits-disclosures-to-background-check-system.
[53] HIPAA Regulatory Alert, *Careful: HIPAA mental health change is limited, and not a free-for-all*, RELIAS MEDIA (Feb. 1, 2016), https://www.reliasmedia.com/articles/137165-careful-hipaa-mental-health-change-is-limited-and-not-a-free-for-all.
[54] *Id.*
[55] NICS Improvement Amendments Act of 2007, Pub. L. No. 110-180, 121 Stat. 2560 (Jan. 8, 2008).

financial incentives to encourage state reporting of mental health information, allowed federal funds to be withheld from states that failed to submit certain information, and offered grants to states for establishing and upgrading their reporting and background check system.[56] However, the NICS Improvement Amendments Act did little to fix the issue since three years after the law took effect, nine states had provided no information and seventeen others had submitted less than twenty-five names of mentally ill people.[57]

More recently, following the 2017 Texas church shooting where the shooter had acquired firearms despite having a dishonorable discharge,[58] Congress created the Fix NICS Act of 2017 in an effort to address these significant problems with reporting relevant information to the NICS.[59] The Fix NICS Act made it mandatory for all federal agencies to report criminal convictions, withhold bonus pay to the political appointees of those agencies that failed to be in "substantial compliance" with their reporting plan, and increased funding for assisting states in reporting to the NICS.[60]

Federal law only provides a minimum level of restrictions on firearm possession by mentally ill individuals. Many states have also created their own gun law restrictions relating to mental health. While most states have adopted gun control laws that largely mirror the language of the federal laws, some states have attempted to enact stricter gun regulations regarding mentally ill individuals. In contrast to the Gun Control Act, which only applies to persons involuntarily committed to a mental institution, several states have broadened the scope of their firearms prohibitions to include individuals who voluntarily commit themselves to mental institutions,[61] and some states even place restrictions on individuals

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[56] *Mental Health Reporting*, *supra* note 20.

[57] Greg Bluestein, *Most states don't follow mental health gun law*, NBC NEWS (Feb. 17, 2011), http://www.nbcnews.com/id/41653442/ns/us_news-crime_and_courts/t/most-states-dont-follow-mental-health-gun-law/#.XaZX7i2ZNmA; *see also*, Craig D. Friedel, *The Mentally Ill Who May Kill Go Unreported Still: Exploration of Potential Nevada NICS Reporting Reform*, 15 NEV. L.J. 1030, 1042 (2015) (stating that the increase of submitted records to NICS was "largely the reflection of a dramatic increase in compliance by only twelve states").

[58] Crimeside Staff, *Texas church shooting: How was Devin Patrick Kelley discharged from the Air Force?*, CBS NEWS (Nov. 6, 2017), https://www.cbsnews.com/news/texas-church-shooting-how-was-devin-patrick-kelley-discharged-from-the-air-force/.

[59] Fix NICS Act of 2017, Pub. L. 115-141 (2017).

[60] Beth Baumann, *What Is the 'Fix NICS' Bill Congress Keeps Talking About?*, TOWNHALL (Mar. 6, 2018), https://townhall.com/notebook/bethbaumann/2018/03/06/what-is-the-fix-nics-bill-congress-keeps-talking-about-n2455875.

[61] *See Mental Health Reporting*, *supra* note 20 (stating that in 2013, Florida enacted a law that required reporting of a voluntarily committed person); Ga. Code Ann. § 16-11-129(b)(1)(J) (applying gun restrictions to those voluntarily committed to a mental

who voluntarily seek inpatient mental health treatment.[62] A number of states also have broader mental health reporting laws that expand the list of mental health information that must be reported to the NICS database. [63]

III. ANALYSIS

A. WHY GUN CONTROL LEGISLATION IS INEFFECTIVE

While many federal and state laws are already in place to restrict access to firearms by mentally ill individuals, the current federal gun control legislation has failed to keep firearms out of the possession of at-risk individuals.[64] Since states are not required to report mental health information to the NICS index, the accuracy of federal background checks is dependent on states voluntarily reporting disqualifying records.[65] However, the FBI's background check is only as good as the records in the NICS databases, and most states have not been willing to disclose many pertinent mental health records of at-risk individuals. [66] As a result, the NICS database is "likely still missing millions of disqualifying histories" due to the data gaps and loopholes that exist under the current system.[67]

Consequently, states' failures to adequately and promptly report relevant records to NICS has enabled several high-profile shooters to pass background checks and obtain firearms. [68] For example, Devin Kelley killed twenty-six people inside a church using a firearm that he legally purchased, despite his "history of disqualifying criminal and mental health records."[69] Kelley was able

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facility); Miss. Code Ann. § 45-9-101 (2013) (prohibiting the possession of firearms to individuals who voluntarily committed themselves to a mental institution).

[62] John Malcolm & Amy Swearer, *Part III: The Current State of Laws Regarding Mental Illness and Guns*, THE HERITAGE FOUNDATION (Feb. 13, 2019), at 3, https://www.heritage.org/civil-society/report/part-iii-the-current-state-laws-regarding-mental-illness-and-guns.

[63] *See Mental Health Reporting*, *supra* note 20 (an Illinois law requires any physician, clinical psychologist, qualified examiner, law enforcement official, or the primary administrator for any school to report any mentally ill individual who presents a "clear and present danger" or demonstrates violent behavior.); *see also* Haw. Rev. Stat. § 134-7(c)(3) (2016) (Hawaii law maintains an even broader definition on persons prohibited to possess firearms by prohibiting any person "diagnosed as having a significant behavioral, emotional, or mental disorder.").

[64] Malcolm & Swearer, *supra* note 62, at 1.

[65] *Id*, at 2-3.

[66] *Id*, at 5.

[67] *Id*, at 3.

[68] *Id.*

[69] *See id.*; Katie Mettler & Alex Horton, *Air Force failed 6 times to keep guns from Texas church shooter before he killed 26, report finds*, WASHINGTON POST (Dec. 7, 2018, 6:38 PM), https://www.washingtonpost.com/national-security/2018/12/08/air-force-failed-six-times-keep-guns-texas-church-shooter-before-he-killed-report-finds/.

to purchase several firearms because the U.S. Air Force failed to report his records to the NICS on six different occasions.[70] Similarly, even though Russel Weston spent fifty-four days in a mental institution for schizophrenia, he was able to pass the federal background check prior to attacking the U.S. Capitol because Montana did not report his mental health records to the NICS.[71]

In addition, some federal background checks fail to identify disqualified individuals because of inconsistencies between two states' differing gun control laws. These inconsistencies allowed the Waffle House shooter, Travis Reinking, to possess assault weapons and, if attempted, to legally purchase a gun in Tennessee.[72] Although Reinking had his firearms license revoked, which stripped him of his right to possess firearms in Illinois, Tennessee does not have a similar law to prevent him from acquiring a gun.[73]

Some states also fail to submit disqualifying mental health histories to the NICS system because of discrepancies between state and federal law. Seung-Hui Cho was able to purchase two semi-automatic handguns, which he used to kill thirty-three people at Virgin Tech, despite his disqualification under federal law. Despite an extensive history of court orders declaring Cho to be mentally ill, an imminent danger to himself, and directing him to receive outpatient treatment, he was able to purchase a gun because those court orders were never submitted to either background check database.[74] Under federal law, Cho was disqualified from purchasing a firearm, but Virginia did not report this information to the NICS because under state law the disclosure was not required.[75] Thus, despite the layers of federal gun regulations already in place, there are still loopholes for otherwise disqualified individuals to pass background checks and legally obtain firearms.

Gun control legislation is also unsuccessful at preventing gun violence long-term because of changes in the political landscape. When the majority political party changes following an election, the new administration tends to rescind or alter the previous administration's policy efforts regarding gun control. For example, shortly after taking office, President Trump repealed an Obama-era

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[70] Mettler & Horton, *supra* note 69.
[71] Malcolm & Swearer, *supra* note 62.
[72] Wadhwani, *supra* note 5.
[72] *Id.*
[73] *Id.*
[74] Michael Lou, *U.S. Rules Made Killer Ineligible to Purchase Gun*, N.Y. TIMES (Apr. 21, 2007), https://www.nytimes.com/2007/04/21/us/21guns.html (Virginia's law on "mental health disqualification addresses only the state criteria," which list two categories for "someone who was 'involuntarily committed' or rule mentally 'incapacitated.'").
[75] *Id.*

regulation [76] that would have required the Social Security Administration to report to the NICS those individuals that receive "Social Security checks for mental illness and people deemed unfit to handle their financial affairs."[77] Therefore, even when the federal government attempts to create meaningful legislation to curb gun violence, it tends to get undermined or overturned by a new administration before it can ever have any impact on gun violence.[78]

Lastly, the issue with the effectiveness of gun control laws could lie in the lack of available treatment for individuals with mental health issues. If mental health treatment is not available, then those at-risk individuals will never be evaluated. In turn, this prevents critical mental health information from being entered into the NICS database. As a result, gun legislation will continue to be ineffective as long as barriers to mental health treatment continue to restrict individuals from receiving necessary treatment. Improving mental health services will benefit the federal background check system by providing more detailed and accurate information about disqualified individuals and this information will actually exist if more people receive the treatment they need.

B. BARRIERS TO MENTAL HEALTH TREATMENT

In a comprehensive study of access to mental health care, the National Council for Behavioral Health determined that "American mental health services are insufficient, and despite high demand, the root of the problem is lack of access – or the ability to find care."[79] While one in five adults in the United States suffer from a mental health condition, a majority of people with a mental illness never receive treatment.[80] The underlying factors causing the current state of the mental health care system in the United States, such as mental health care spending, the number of mental health professionals per capita, and the high costs of treatment, may explain why so many

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[76] *See* Implementation of the NICS Improvement Amendments Act of 2007, 81 FR 91702-01.

[77] Corky Siemaszko, *Trump made it easier for the mentally ill to get guns when he rolled back Obama regulation*, NBC NEWS (Aug. 6, 2019), https://www.nbcnews.com/news/us-news/president-trump-made-it-easier-mentally-ill-get-guns-when-n1039301.

[78] *Id.* ("Had that rule taken effect, the Obama administration predicted it would have added 75,000 names to the national background check database.").

[79] *New Study Reveals Lack of Access as Root Cause for Mental Health Crisis in America*, NAT'L COUNCIL FOR BEHAVIORAL HEALTH (Oct. 10, 2018), https://www.thenationalcouncil.org/press-releases/new-study-reveals-lack-of-access-as-root-cause-for-mental-health-crisis-in-america/ [hereinafter "New Study"].

[80] *The State of Mental Health in America 2018*, MENTAL HEALTH AMERICA, https://www.mhanational.org/issues/state-mental-health-america-2018 (last visited Dec. 7, 2020) (stating 56% of American adults with a mental illness do not receive treatment).

mentally ill individuals go without access to the treatments they medically require.

The inability to pay for the necessary mental health treatment due to the high costs and inadequate insurance coverage for receiving such treatment continues to be one of the largest barriers for accessing treatment.[81] Yet in recent years, there have been steep budget cuts in mental health funding, resulting in limited access to mental health care and higher costs for treatment.[82] President Trump's proposed Fiscal Year 2020 budget reveals critical shortages in mental health support, specifically, major cutbacks in spending for Medicaid and Medicare and major reductions in mental health research.[83] The budget proposal would effectively end the Medicaid expansion under the Affordable Care Act ("ACA"), and instead convert the program's funding into block grants to the states. This change would result in an estimated $777 billion in cuts to Medicaid, which is the largest payer of mental health services in the country.[84] President Trump has also pushed for short-term insurance plans, which do not require coverage for mental health care and typically exclude people with pre-existing conditions, such as mental illness.[85]

While there is some legislation in place that seeks to address the lack of adequate insurance coverage for mental health treatment services, these laws fail to effectively address the issue in its entity and significant inequities remain. Congress passed the Mental Health Parity and Addiction Equity Act ("MHPAEA") in 2008 to require insurers and employers to treat benefits for mental health conditions in the same manner as benefits for physical health treatment.[86] Under the MHPAEA, limitations on treatments or visits

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[81] New Study, *supra* note 79 (42% reported costs and poor insurance coverage as the top barriers for accessing mental health care, and 25% reported having to choose between getting mental health treatment and paying daily necessities.).

[82] James Lake & Mason Spain Turner, *Urgent Need for Improved Mental Health Care and a More Collaborative Model of Care*, THE PERMANENTE JOURNAL 21: 17-0242 (Aug. 11, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5593510/.

[83] *See* Daniel Moritz-Rabson, *Trump Has Tried to Slash Funds for Mental Health Care Despite Post-Shooting Rhetoric*, NEWSWEEK (Aug. 6, 2019), https://www.newsweek.com/trump-has-tried-slash-funds-mental-health-care-despite-post-shooting-rhetoric-1452907; *How the President's Proposed Budget Impacts Critical State Health Programs*, NAT'L ACADEMY FOR STATE HEALTH POLICY (March 18, 2019), https://nashp.org/how-the-presidents-proposed-budget-impacts-critical-state-health-programs/.

[84] *Id.*

[85] *Id.*

[86] *See* Mental Health Parity and Addiction Equity Act of 2008, Pub. L. 110-343, 122 Stat. 3765 [hereinafter "Mental Health Parity"]; Sara R. Collins et al., *Health Insurance Eight Years After the ACA: Fewer Uninsured Americans and Shorter Coverage Gaps, But More Underinsured*, COMMONWEALTH FUND (Feb. 2019), https://doi.org/10.26099/penv-q932.

cannot differ between mental health and medical and surgical benefits.[87] Additionally, financial requirements, like copays and coinsurance for mental health services must be equal to or less than the requirement for most, but not all, medical and surgical benefits.[88] Lastly, if a plan allows patients to go out-of-network for medical and surgical benefits, it must also allow that for mental health benefits.[89]

Despite the extensive scope of the MHPAEA, it provides many generous exemptions and loopholes that allow insurers to escape complying with parity requirements. The MHPAEA does not actually require insurers to cover any mental health benefits; instead, the law only mandates that when mental health benefits are offered, they cannot be more limited when compared to other health benefits they offer. [90] Consequently, since there is no requirement for plans to begin covering mental health services if they currently do not, plans can avoid the law's parity requirements by simply excluding these services altogether.[91] Thus, the MHPAEA fails to achieve true parity since the law did not establish a mandate for insurers to cover certain mental health services.

Additionally, a health plan is allowed to specifically exclude certain diagnoses from its coverage.[92] The MHPAEA also includes a cost exception which exempts certain group health plans from some of the law's requirements if they incur an increased cost of at least one percent from complying with the MHPAEA.[93] As a result of the loopholes in the MHPAEA, access to much-needed treatment is restricted, meaning individuals with mental health needs must "pay out-of-pocket in order to secure treatment." [94] Thus, the MHPAEA does not guarantee that individuals can receive affordable and accessible mental health treatment services.[95]

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[87] Mental Health Parity, *supra* note 86 at 3881-3893.
[88] *Id.*; *see also Does Your Insurance Cover Mental Health Services? What You Need to Know About Mental Health Coverage*, AM. PSYCHOLOGICAL ASS'N (Oct. 10, 2019), https://www.apa.org/helpcenter/parity-guide [hereinafter *Does Your Insurance*] ("For example, its acceptable to pay a $20 copay for a mental health visit and a $10 copay for a primary care visit, as long as your copay is $20 or more for most of the medical/surgical services covered by your plan.").
[89] Mental Health Parity, *supra* note 86 at 3881-3893.
[90] *See* Commonwealth Fund, *supra* note 86; *Does Your Insurance*, *supra* note 88.
[91] *Id.*
[92] *Id.*
[93] *The Mental Health Parity and Addiction Equity Act*, CENTERS FOR MEDICARE & MEDICAID SERVICES, http:// cms.hhs.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/mhpaea_ factsheet.html (last visited Sep. 24, 2014).
[94] *See* Foundation Recovery, *supra* note 86.
[95] *Id.* (A survey conducted by the American Psychological Association in 2014 estimated that nearly 11 million Americans had mental healthcare needs that were not being met.).

In response to the flaws in the MHPAEA, the ACA expanded coverage of mental health benefits and the MHPAEA protections in 2010.[96] Building on the MHPAEA, the ACA requires individual and small group insurers also follow the parity law.[97] Importantly, the ACA also mandates coverage of mental health and substance use disorder services as part of its all essential benefits requirement.[98] However, the ACA also contains crucial flaws and many of its protections have been weakened dramatically by the Trump Administration.[99]

While the MHPAEA and the ACA have made progress in reducing some of the more obvious barriers on mental health, non-quantitative treatment limitations continue to cause significant barriers to accessing mental healthcare.[100] Such limitations include coverage limits on certain types of treatments, restrictions on geographic location and provider specialty, and methods of determining reasonable and customary charges.[101] These non-quantitative limitations have had a significant impact on access to mental healthcare.[102] For example, behavioral healthcare providers were paid over 20% less than primary care services in terms of reimbursements and patients are four times more likely to go out of network to receive mental health treatment.[103]

An additional issue with the current parity legislation is that neither the MHPAEA nor the ACA specifically defined the term

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[96] *See* Commonwealth Fund, *supra* note 86; Kirsten Beronio et al., *Affordable Care Act Expands Mental Health and Substance Use Disorder Benefits and Federal Parity Protections for 62 Million Americans*, U.S. DEP'T OF HEALTH & HUMAN SERVICES (Feb. 20, 2013), https://aspe.hhs.gov/report/affordable-care-act-expands-mental-health-and-substance-use-disorder-benefits-and-federal-parity-protections-62-million-americans.

[97] *Id.*

[98] *Id.*

[99] Timothy S. Jost, *The Affordable Care Act Under the Trump Administration*, COMMONWEALTH FUND (Aug. 30, 2018), https://www.commonwealthfund.org/blog/2018/affordable-care-act-under-trump-administration (Some Trump administration actions have clearly undermined ACA initiatives); *see also* Christine Eibner & Sarah Nowak, *The Effect of Eliminating the Individual Mandate Penalty and the Role of Behavioral Factors*, COMMONWEALTH FUND (July 11, 2018), https://www.commonwealthfund.org/publications/fund-reports/2018/jul/eliminating-individual-mandate-penalty-behavioral-factors (Consumers have faced higher premiums because the Tax Cuts and Jobs Act eliminates the penalty associated with the individual mandate to purchase insurance.).

[100] Steven Ross Johnson, *Mental Health Parity Remains a Challenge 10 Years After Landmark Law*, MODERN HEALTHCARE (Oct. 5, 2018), https://www.modernhealthcare.com/article/20181005/NEWS/181009925/mental-health-parity-remains-a-challenge-10-years-after-landmark-law.

[101] *Id.*

[102] *Id.*

[103] *Id.*

"mental illness."[104] Instead, the statutes provides discretion to health insurance providers with discretion to decide what constitutes a "mental illness." [105] This lack of direction from the federal government resulted in states and individual insurance companies defining mental illness in several different and sometimes inconsistent ways. [106] Because of the wide variance in states definition of mental illness, mentally ill individuals may still receive disparate treatment based on how "mental illness" is defined in that particular state.[107]

The government has also failed to adequately enforce the federal parity laws.[108] The MHPAEA dictates that there must be parity between medical/surgical and mental health benefits, but neglects to provide insurance companies with the applicable standards to abide by.[109] Since neither the MHPAEA nor the ACA provide any guidance on how to evaluate whether a plan achieved parity regarding non-quantitative coverage, there has been "a lack of consistency in the oversight and enforcement on the part of federal and state regulators to get insurers to comply with existing parity laws." [110] Therefore, due to the ambiguity and lack of guidance with non-quantitative coverage limits combined with subtle discriminatory practices, the MHPAEA and ACA have not removed significant barriers to mental health treatment.

Even if an individual has mental health coverage under his or her insurance, mental health providers can choose whether or not to accept insurance.[111] Despite the increasing cost of operating a private practice, many insurance companies have not increased the reimbursement rate for psychologists in over ten years, and other companies have decreased their reimbursement rates.[112] As a result, many mental health professionals refuse to participate in insurance

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[104] Joni Roach, Note, *Discrimination and Mental Illness: Codified in Federal Law and Continued by Agency Interpretation,* 2016 MICH. ST. L. REV. 269, 284-85 (2016).
[105] *Id.*
[106] *Id.* at 285-86 (Arkansas defined "'mental illness' as all mental illnesses and disorders that are listed in the International Classification of Diseases Manual (ICD) and the Diagnostic and Statistical Manual of Mental Disorders (DSM). On the other hand, Iowa law mandates insurance coverage for only 'biologically based mental illness'" but specifically excludes mental disorders that are included under Arkansas law.).
[107] Steven Johnson, *Mental health parity remains a challenge 10 years after landmark law*, MODERN HEALTHCARE (Oct. 5, 2018), https://www.modernhealthcare.com/article/20181005/NEWS/181009925/mental-health-parity-remains-a-challenge-10-years-after-landmark-law.
[108] *Id.*
[109] *Id.*
[110] *Id.* ("…states lack consistent definitions on what constitutes mental health and substance use disorders, how they are covered by insurance, and how much effort should be given toward enforcing compliance.").
[111] *Does Your Insurance*, *supra* note 88.
[112] *Id.*

networks.[113] A study by the Journal of the American Medical Association revealed that only a little over half of psychiatrists nationally take insurance, compared with close to 90% of physicians in other medical specialties.[114] Additionally, psychiatrists participate in Medicare and Medicaid at significantly lower rates than other physicians do.[115] These overly narrow provider networks and high out-of-pocket costs create barriers for patients trying to access mental health services and for physicians trying to refer their patients for psychiatric care.

Another significant barrier to accessing mental healthcare is the severe shortage of mental health professionals throughout the United States.[116] Approximately "91 million Americans live in regions experiencing severe shortages in available mental health professionals."[117] More than 60% of all counties do not have a single psychiatrist,[118] and in states with the lowest mental health workforce, there is up to six times the individuals to only one mental health provider.[119] These shortages may create such a demand for their services that they do not need to seek reimbursement through insurers because they can be selective about the patients they treat.[120] As a result, people with mental health needs experience long wait times to receive care and may even be unable to find care.[121]

The existing models of delivering care and available treatment approaches fail to adequately address the growing crisis of mental health care. Despite the implementation of MHPAEA and ACA, significant barriers still remain, resulting in nearly half of the individuals living with mental health conditions to go without necessary treatment.[122] Under the current healthcare system, people with severe mental illness often do not receive treatment until they have suffered serious consequences. Since access to quality, affordable mental healthcare restores lives and prevents mental health problems from worsening, action must be taken to fill gaps in current federal legislation and promote better access.

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[113] *Doctor is Out*, *supra* note 19.
[114] Tara F. Bishop, et. al., *Acceptance of insurance by psychiatrists and the implications for access to mental health care*, JAMA PSYCHIATRY (Feb. 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3967759/.
[115] *Id.*
[116] Mental Health America, *The State of Mental Health in America 2018*, https://www.mhanational.org/issues/state-mental-health-america-2018 (last visited Dec. 7, 2020) (hereinafter Mental Health America).
[117] Doctor is Out, *supra* note 113.
[118] *Id.*
[119] Mental Health America, *supra* note 116.
[120] *Doctor is Out*, *supra* note 19.
[121] *Id.*
[122] *Id.*

IV. SOLUTION

Current federal gun control laws are unworkable due to their ambiguous statutory language, inconsistent application of what information is reported, their non-binding nature on states, and jurisdictional discrepancies. Additional attempts at correcting these flaws through new federal gun legislation have repeatedly failed to make any significant difference. However, even if the laws were effective at ensuring necessary health information is entered into the NICS database, there is little evidence to support that more adequate reporting of disqualified individuals is associated with a decrease in gun homicide rates. [123]

Meanwhile, mass shootings increasingly continue to occur and people suffering from mental illness continue to receive inadequate treatment and support. While overall the mentally ill population is relatively non-violent, [124] two-thirds of all mass shooters do have a history of suffering from mental illness yet less than a quarter received any mental health treatment prior to their attacks.[125] Thus, these statistics indicate that a significant number of mass shootings could be prevented by treating these at-risk individuals and thereby preventing an act of violence. Therefore, legislation should not be aimed at expanding current gun control legislation. Instead, efforts need to be aimed at preventative mental health measures through legislation focused on improving mental health treatment accessibility in order to ensure at-risk individuals receive the treatment and support they need. In order to accomplish this, legislation should first be focused on making mental health treatment accessible and affordable by reforming the MHPAEA to achieve true parity; and second, states should implement programs in schools and primary care settings to allow for early detection and prevention of mental illnesses.

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[123] Fredrick Vars & Griffin Sims Edwards, *Slipping Through the Cracks? The Impact of Reporting Mental Health Records to the National Firearm Background Check System*, UNIV. OF ALA. LEGAL STUDIES RSCH. PAPER NO. 3127786 (2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3127786.

[124] *See* Heather Stuart, *Violence and Mental Illness: An Overview*, 2 WORLD PSYCHIATRY 121 (2003), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1525086/.

[125] Mass Attacks 2017, *supra* note 9; Mass Attacks 2018, *supra* note 9.

A. REFORMING FEDERAL PARITY LAWS TO IMPROVE ACCESS TO MENTAL HEALTH CARE

Despite their prevalence, mental disorders often go undiagnosed, untreated, or undertreated. According to the National Alliance on Mental Health, every mental health disorder can be improved through proper treatment [126] and the success rate for treating severe mental illness is relatively high: "80 percent for bipolar disorder; 65 percent for major depression; and 60 percent for schizophrenia."[127] Having consistent access to effective treatment options is crucial for individuals with mental disorders because without treatment, individuals may struggle considerably, their conditions may worsen and they may even become a danger to themselves or others. [128] Due to the dramatic consequences that result from mental health illnesses going untreated, such treatment should be "easy to find, affordable and quickly available."[129]

In order for mental health treatment to be accessible, federal parity laws must be reformed and properly enforced to ensure insurance coverage for mental health treatments. The MHPAEA and the ACA theoretically allow for better access to mental health treatment; however, until such regulations are properly enforced, patients will continue to struggle to receive care. While the MHPAEA is federal law, states have the primary authority to enforce and impose penalties for noncompliance of health insurers under their jurisdiction.[130] State insurance commissioners are in a much stronger position to enforce the law by ensuring plan compliance with parity standards *before* plans are sold. Thus, state regulators should require every health insurer to submit a report including the data and analysis that proves it is complying with MHPAEA's requirements before it is permitted to sell insurance plans to consumers. In the absence of oversight from state regulators, the only remedy available for individuals seeking mental health treatment is to engage in a lengthy process of appealing insurance determinations and filing complaints.

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[126] *Individuals with Mental Illness*, NAT'L ALLIANCE ON MENTAL ILLNESS, https://www.nami.org/Find-Support/Living-with-a-Mental-Health-Condition (last visited Dec. 7, 2020).

[127] *Nation's Voice on Mental Illness Unveils Model State Legislation For New National Campaign*, NATIONAL ALLIANCE ON MENTAL ILLNESS, (July 1, 1999), https://www.nami.org/Press-Media/Press-Releases/1999/Nation-s-Voice-On-Mental-Illness-Unveils-Model-Sta.

[128] Joel Young, *Untreated Mental Illness: Understanding the effects*, PSYCHOLOGY TODAY (Dec. 30, 2015), https://www.psychologytoday.com/us/blog/when-your-adult-child-breaks-your-heart/201512/untreated-mental-illness.

[129] *Id.*

[130] 42 U.S.C.A. § 300gg-22.

Given the substantial differences in access to in-network mental health care and out-of-pocket costs compared to other primary and specialty care, state regulators should also routinely conduct market audits of all health insurers and Medicaid managed care organizations for compliance with the MHPAEA. However, the ability to conduct routine and targeted audits is limited by insufficient funding.[131] Currently, state and federal regulators generally only take action to conduct audits after enough consumer complaints have amassed.[132] With proper funding, conducting random audits can become powerful tools for enforcing parity compliance. In order for regulators to adequately ensure compliance with the MHPAEA, sufficient funds must be allocated to enforcement measures.

In addition to enforcement issues, federal legislation would be necessary to fix the significant gaps in the existing law. First, the federal government should create a clear, useable definition of "mental illness" for all insurance plans to follow. Ideally, the federal government should adopt a definition of "mental illness" that includes all psychiatric or psychological conditions classified in the Diagnostic and Statistical Manual of Mental Disorders ("DSM").[133] This would allow for broad protection for individuals with mental illnesses because DSM currently defines mental illness to include all mental disorders that are currently recognized by the American Psychological Association.[134] As a result, the federal government would ensure that individuals with mental illnesses have access to the same insurance coverage regardless of the state where they reside.

Another possible federal reform is to require mandatory insurance coverage of all illnesses and disorders listed in the most current edition of the DSM. This would require that any health insurance provider that provides medical coverage must also make mental health coverage available. This assertive mandate would replace the discretionary language currently in the MHPAEA, which only demands parity when an insurance plan provides mental health coverage. Thus, for mental health parity to truly be achieved, health

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[131] The White House, Fact Sheet, Federal Parity Task Force Takes Steps to Strengthen Insurance Coverage for Mental Health and Substance Use Disorders (Oct. 27, 2016), https://obamawhitehouse.archives.gov/the-press-office/2016/10/27/fact-sheet-mental-health-and-substance-use-disorder-parity-task-force.

[132] *Id.* ("Agencies' capacity to expand enforcement activities, including conducting random audits, is limited by their staffing resources.").

[133] The DSM "is the standard classification of mental disorders used by mental health professionals in the United States." *Diagnostic and Stat. Manual of Mental Disorders (DSM-5)*, AM. PSYCHIATRIC ASS'N, https://perma.cc/V3GJ-2PGP.

[134] *Id.*

insurance providers must be mandated to cover treatments for mental illness, alongside all of the similar physical illnesses.

While laws like MHPAEA and the ACA were meant to make health insurance more generous, these laws are currently underenforced and too weak to fully address the challenges of accessing mental health care. The federal and state governments must undertake greater scrutiny of insurers to force compliance and to penalize and make examples of insurers failing to comply. Additionally, the federal government should make changes to correct the gaps in existing federal parity law by creating a uniform definition of "mental illness" to apply to all insurers and requiring mandatory coverage of mental health benefits under all insurance plans.

B. EARLY DETECTION AND PREVENTION

Implementing programs that promote early detection and treatment of mental disorders is necessary to prevent and minimize the occurrence of mental health problems. According to the National Alliance on Mental Illness, "approximately 50% of lifetime mental health conditions begin by age 14 and 75% begin by age 24. At the same time, the average delay between when symptoms first appear and intervention is approximately 11 years."[135] Thus, mental illness in children often remains undiscovered for far too long. Since this delay in treatment can result in incomplete and prolonged recovery,[136] it is crucial to discover and treat mental illnesses early.

Emerging research suggests that intervening early can disrupt the negative course of some mental illness and may reduce long term disability.[137] Early childhood is a critical period for brain development and related behavior.[138] Neuroscience research reveals that "mental disorders that occur before the age of six can interfere with critical emotional, cognitive, and physical development, and can predict a lifetime of problems in school, at home, and in the community." [139] Without early intervention, child disorders frequently persists into adulthood and "lead to a downward spiral of school failure, poor employment opportunities, and poverty in

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[135] *Mental Health Screening*, NAT'L ALLIANCE ON MENTAL ILLNESS, https://www.nami.org/learn-more/public-policy/mental-health-screening (last visited Dec. 7, 2020).
[136] Joel E. Miller, *The Need for Early Mental Health Screening and Intervention Across the Lifespan*, AM. MENTAL HEALTH COUNSELORS ASS'N EMERGING CLINICAL PRACTICE BRIEF, 2, (2014).
[137] *Id.*
[138] *Id.*
[139] *Id.*

adulthood."[140] Accordingly, "early detection, assessment, and links with treatment and supports is necessary to prevent mental health problems from worsening."[141]

Mental health screenings offer an effective and inexpensive tool for detecting mental disorders, providing early interventions, and determining the appropriate diagnostic follow-up treatment. A screening is a "preliminary procedure used to determine the likelihood that an individual has a particular disease or condition or is at increased risk of developing health or social problems."[142] These screenings assess "risk factors, which can be genetic, behavioral, or environmental," and help "distinguish between those who could benefit from a minimal intervention and others who may require further diagnostic assessment or possible treatment."[143] Since mental health screenings are able to accurately detect onset symptoms of mental illness, they must implement them in multiple settings, routinely provided, and connected to treatment. Specifically, states should implement systematic mental health screenings and preventative treatment measures in primary care settings and public schools.

First, due to the frequent contact and trusted relationship many have with their primary care provider, mental health screening should be routinely administered in a primary care office. Primary care settings are an optimal environment to detect and address behavioral health concerns because approximately 75% of children with mental health problems are seen within primary care settings.[144] Additionally, studies have found that "while people with common mental illnesses have had some contact with primary care services, few received specialty mental health care."[145] Thus, primary care clinicians are often the first point of contact for individuals experiencing mental health issues, and consequently, regular screenings in primary care settings would enable earlier identification of mental disorders, which translates into earlier treatment.

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[140] *Id.* ("For example, research shows that when children with co-existing depression and conduct disorders become adults, they tend to use more health services and have higher health care costs than other adults.").
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] Carol Weitzman and John Leventhal, *Screening for behavioral health problems in primary care*, 2006 CURR. OPINION PEDIATRICS 641, 642 (2006), https://med.emory.edu/departments/pediatrics/_documents/uhi/behavioral-health-screening-in-primary-care.pdf.
[145] Miller, *supra* note 136, at 3 ("59 percent of youth who were referred to specialty mental health care never made it to the specialist.").

While primary care providers are positioned to have a significant role in addressing mental illness, data suggests that primary care providers have consistently underdiagnosed mental health problems in children and that routine, systematic screenings do not occur in most primary care practices.[146] To better address these needs, mental health and primary care services should be integrated to allow for mental disorders to be addressed and treated as primary illnesses.[147] Integrated treatment is a means of coordinating both physical healthcare and mental health interventions in a primary care setting to treat the patient more effectively.[148] Collaborative and integrated care can improve client engagement, allow for better care management, and decrease psychiatric symptoms and disability and the onset of some mental disorders.[149]

Several states have implemented successful approaches to integrate mental health services in primary care settings.[150] For example, Massachusetts Child Psychiatry Access Program ("MCPAP") is a statewide consultation model to help pediatricians and family physicians "promote and manage the behavioral health of their pediatric patients as a fundamental component of overall health and wellness."[151] The project includes six regional consultation teams located at an academic medical center and composed of several child psychiatrists, behavioral health clinicians, resource and referral specialists, and care coordinators.[152] Each team supports local primary care physicians by providing the following services: "immediate clinical consultation over the telephone, expedited face-to-face psychiatric consultation, care coordination for assistance with referrals to community behavioral health services, and continuing professional education specifically designed for primary care providers."[153] Collectively, the teams offer services to

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[146] Weitzman & Leventhal, *supra* note 144 (One of the most commonly stated reason for the lack of mental health screening and treatment in the primary care setting was a lack of training in behavioral health.).
[147] *Id.*
[148] *See Integrated Care*, NAT'L INSTITUTE OF MENTAL HEALTH, https://www.nimh.nih.gov/health/topics/integrated-care/index.html (last visited Dec. 7, 2020).
[149] *Id. at 3.*
[150] *See Successful Examples of Integrated Models from Across the Country*, PRIMARY CARE COLLABORATIVE, https://www.pcpcc.org/content/successful-examples-integrated-models (last visited Dec. 7, 2020).
[151] *Overview, Vision, History*, MASS. CHILD PSYCHIATRY ACCESS PROGRAM, https://www.mcpap.com/About/OverviewVisionHistory.aspx (last visited Dec. 7, 2020).
[152] John Straus and Barry Sarvet, *Behavioral Health Care For Children: The Massachusetts Child Psychiatry Access Project*, (2014), https://www.mcpap.com/pdf/reports/MCPAPHealthAffairsDec2014.pdf.
[153] *Id.*

over 95% of the pediatric providers in Massachusetts and is available to all children and families, regardless of insurance.[154]

For children to have adequate access to mental health care, primary care providers should integrate mental health services into their practices. While primary care providers typically lack extensive behavioral health training, implementing an individual, educational mentoring program, like the MCAP, can fill that gap by guiding primary care physicians in the evaluation, diagnosis, and treatment of mental health conditions. As a result, these programs will enhance primary care physicians' ability to address their patients' mental health needs, and over time, will establish an integrated field of primary care psychiatry "consisting of the prevention of behavioral disorders, through screening and early identification and treatment of emerging psychiatric problems."[155] Therefore, integrating mental health services into a primary care setting offers a promising, viable, and efficient way of ensuring individuals have access to mental health care; and thus, states should adopt programs modeled after the MCAP.

Second, schools also provide an efficient and convenient location for providing preventative interventions among children since almost every child attends school and spends a significant amount of time there.[156] Additionally, schools are the ideal setting for monitoring children's mental health because the first signs of mental disorders often emerge in a school environment. [157] Consequently, school staff frequently observe students' behavioral issues and emotional disorders, and thus should be educated to recognize early warning signs of mental disorders. Because students are much more likely to receive mental health services when they are accessible in schools,[158] schools provide an efficient delivery system for these services.

While many schools have school psychologists and/or counselors, some school districts have implemented a more comprehensive approach in which they have integrated mental

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[154] *Id.* ("the hubs are available to over 95 percent of the 1.5 million children in Massachusetts").
[155] *Id.* at 4.
[156] *Prevention of Mental Disorders: Effective Interventions and Policy Options*, WORLD HEALTH ORG., 30 (2004), https://www.who.int/mental_health/evidence/en/prevention_of_mental_disorders_sr.pdf.
[157] Terry Richardson et al., *School-Based Adolescent Mental Health Programs*, SOCIAL WORK TODAY (2012), https://www.socialworktoday.com/archive/111312p24.shtml.
[158] Research has shown that "students were 21 times more likely to make mental health related visits to school based [facilities] than to community health clinics." *Schools expand mental health care*, AM. PSYCHOL. ASS'N (Jan. 2009), http://www.apa.org/monitor/2009/01/school-clinics.aspx.

health services into existing school programs and initiatives.[159] Most school-based programs allow the mental health needs of students to be identified and addressed on-site through an inter-system collaboration with community health professionals.[160] This approach enables outside specialists to partner with schools to deliver a level of access to mental health services not typically available through standard approaches.[161] Research shows that students who participate in school-based mental health programs have experienced significantly less disciplinary issues, improved academic performance, better mental health, and "increased social competence as well as reductions in internalizing and externalizing problems."[162]

Many states have successfully created sustainable school mental health programs through the use of partnerships and shared resources.[163] For example, the Georgia Apex Program established "partnerships between community-based mental health providers and local schools to provide school-based mental health services;"[164] specifically, providers supply onsite student services, staff training on identifying children with mental health needs, and coordinate follow-up treatments.[165] During the 2017-2018 school year, 29 mental health providers partnered with 396 elementary, middle, and high schools throughout the state.[166] The program delivered more than 60,000 services to students, including: "behavior health and diagnostic assessments; crisis intervention;

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[159] *Id.*
[160] *Id.*
[161] *Id.* ("Community mental health clinicians apply the latest evidence based practices, including dialectical behavioral therapy, trauma-focused cognitive behavioral therapy, and functional family therapy.").
[162] *Id.*
[163] *See Project Aware Ohio*, OHIO DEPT. OF ED., http://education.ohio.gov/Topics/Student-Supports/PBIS-Resources/Project-AWARE-Ohio (Ohio created Project AWARE to support schools by "providing training to detect and respond to mental health challenges and crisis in children and youth and increasing access to behavioral health support for children, youth and families.") (last visited Dec. 7, 2020); *see also Mental Health in Schools,* ILL. DEP'T OF HUM. SERV., http://www.dhs.state.il.us/OneNetLibrary/27897/documents/Mental%20Health/MH2015/YolondaLinares/MentalHealthSchools.pdf ("Illinois Department of Human Services, Division of Mental Health, Child and Adolescent Service System's Mental Health and School Collaboration project seeks to develop systems of support within the educational setting designed to reduce the effects of both internal and external mental health concerns that can cause barriers to learning and engaging in the educational process.") (last visited Dec. 7, 2020).
[164] CEO Staff, *The Georgia APEX Program: School-based Mental Health Services*, GEORGIA HEALTH POLICY CENTER (2019), https://ghpc.gsu.edu/download/the-georgia-apex-program-school-based-mental-health-services-year-3/?wpdmdl=4750039&ind=1565465737963.
[165] *Id.*
[166] *Id.*

psychiatric treatment; community support; and individual, family, and outpatient services."[167] The program improved access to mental health care and early identification by focusing on serving schools located in rural areas where these services are more limited, elementary schools where behavioral conditions can be detected earlier in younger students, and Title I schools where students with less resources have more unmet needs.[168]

Recognizing the growing need, the Center for Medicare and Medicaid services and the Substance Abuse and Mental Health Services Administration recently released a Joint Informational Bulletin to inform states and schools on the ways school districts and states can use Medicaid to support behavioral health services for children in schools.[169] Specifically, states should amend their state Medicaid plan to cover mental health services provided in school-based settings to receive matching federal funds.[170] In Georgia, 83% of the funding for the APEX program comes from Medicaid sources.[171] Accordingly, in order to meet the comprehensive needs of students, states should change their state Medicaid plans to allow billing for school-based mental health services.

The presence of mental illness in children and adolescents, if not properly diagnosed and treated, increases the risk of significant health issues for them as adults and causes an immense psychological, social, and economic burden on society. Given the current limitations in the effectiveness of mental health treatment, the only sustainable method for reducing the burden caused by these disorders is prevention. By implementing programs that provide mental health screenings in accessible locations, such as primary care settings and schools, mental health professionals can ameliorate the negative impact of mental illness. Therefore, states must establish screening procedures to identify mental health problems in

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[167] *Id.*

[168] *The Georgia Apex Program Annual Evaluation Report,* CTR. OF EXCELLENCE FOR CHILDREN'S BEHAVIORAL HEALTH (March 8, 2018), https://gacoeonline.gsu.edu/files/2018/03/Apex-Year-2-Evaluation-Report_Final.pdf (More than three quarters (76%) of the schools served by the Apex Program are located in rural areas, almost half (48.8%) are located in elementary schools, and a majority (92.1%) of Title I schools have Apex programs.).

[169] Elinore McCance-Katz and Calder Lynch, *Guidance to States and School Systems on Addressing Mental Health and Substance Use Issues in Schools*, SUBSTANCE ABUSE AND MENTAL HEALTH SRVS. ADMIN. AND CTR. FOR MEDICARE & MEDICAID SRVS. AND CTR. FOR MEDICAID & CHIP SRVS. (Jul. 1, 2019), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib20190701.pdf.

[170] *Id.*

[171] Laura Harker, *Overview: 2020 Fiscal Year Budget for Dep't of Behavioral Health and Developmental Disabilities*, GEORGIA BUDGET & POLICY INSTITUTE (Feb. 11, 2019), https://gbpi.org/2019/overview-2020-budget-dbhdd/.

schools and primary care settings in order to allow for earlier identification, intervention, and treatment.

V. CONCLUSION

Federal gun control legislation aimed at individuals with mental illnesses has proven unsuccessful at preventing dangerous individuals from accessing a gun before an act of violence occurs, and the mental health system fails to identify and support those in need of treatment. Meanwhile, mass shootings are increasing throughout the country and individuals suffering from severe mental disorders continue to go without receiving necessary treatment. Given the inefficiencies of the current laws and the inability to make change through meaningful gun control legislation, the federal government needs to stop reacting to crisis and, instead, take proactive action to address the issues with the mental health systems in this country. Only then will the federal government achieve workable solutions that will deter gun violence long-term.

Therefore, in order to improve access, the mental health parity laws must first be reformed and properly enforced to prevent insurers from placing greater financial requirements or treatment restrictions on mental health care. Second, states must implement programs in schools and primary care settings to provide a viable and efficient means to uncover, diagnosis, and treat underlying mental disorders early. As these measures are taken, access to adequate mental health treatment may finally be achieved and mental health issues can be minimized and even prevented, thus resulting in a better quality of life for individuals suffering from mental disorders, their families, and their communities.

TO ERR IS HUMAN, UNLESS YOU ARE A HEALTHCARE PROVIDER

JORIE ZAJICEK

I. INTRODUCTION

Charlene Murphy was admitted to the Neurological Intensive Care Unit ("Neuro ICU") at Vanderbilt University Medical Center ("VUMC") on December 24, 2017, with an intraparenchymal hematoma.[1] After showing significant improvement, Ms. Murphy was transferred from the Neuro ICU to the Neurological Step-Down Unit.[2] Less than twenty-four hours later, Ms. Murphy was declared dead.[3]

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[1] U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS"), *Statement of Deficiencies and Plan of Correction,* Vanderbilt University Medical Center (Nov. 8, 2018), at 6-7 [hereinafter "CNS Statement"].
[2] *Id. at* 8.
[3] *Id.* at 52.

Ms. Murphy spent her life in Gallatin, Tennessee, and worked at the local Walmart for twenty-four years.[4] Married for more than fifty-years with two sons, seven grandchildren, and several great-grandchildren, Ms. Murphy's family described her as a "born-again Christian with a friendly smile, a generous spirit and an enthusiastic love of yard sales."[5] Despite experiencing headaches and vision loss, Ms. Murphy was relatively healthy before she went to the hospital on December 24, 2017.[6] Ultimately, Ms. Murphy was diagnosed with a brain bleed, which the doctors suspected was caused by a brain mass.[7] To evaluate the potential mass in Ms. Murphy's brain, Ms. Murphy's physician ordered a Positron Emission Tomography ("PET") scan.[8] On December 26, Ms. Murphy was transported to the Radiology Department, and while there, she complained of claustrophobia and requested anxiety medication, prompting her physician to order her Versed.[9] The Versed administration instructions read, "For PET scan if first milligram is insufficient, can give 1-2 mg additional if needed…."[10] The radiology technician contacted Ms. Murphy's nurse to come and administer the Versed, but the nurse could not leave her other patients.[11] Not wanting Ms. Murphy's scan to be delayed, the nurse asked the help-all nurse, RaDonda Vaught, to go down to the Radiology Department to administer the versed to Ms. Murphy.[12]

Ms. Murphy's physician placed the order for the Versed at 2:47 PM, and the pharmacist verified the Versed at 2:49 PM.[13] While discussing another patient with an orientee, Ms. Vaught searched for Versed under Ms. Murphy's profile in the Automated Dispensing Cabinet ("ADC").[14] Unable to locate the Versed under Ms. Murphy's profile, Ms. Vaught selected the override function, searched "VE," and chose the first medication that appeared on the

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[4] Brett Kelman, *Vanderbilt death: Victim would forgive nurse who mixed up meds, son says*, THE TENNESSEEAN (Feb. 6, 2019, 5:05 PM), https://www.tennessean.com/story/news/health/2019/02/04/vanderbilt-deadly-vecuronium-error-victim-would-forgive-nurse-son-says/2774381002/.

[5] *Id.*; *see also* CHARLENE MARIE MURPHY OBITUARY, CRESTVIEW FUNERAL HOME, MEMORY GARDENS & CREMATION, https://www.crestviewfh.com/obit/charlene-marie-murphey/ (last visited Dec. 1, 2020).

[6] *Id.* at 7.

[7] *Id.*

[8] *Id.* at 45.

[9] *Id.* at 7. Midazolam, marketed under the brand name Versed, is a benzodiazepine that is often used for sedation and in the treatment of anxiety and amnesia. *See* Reed T. Drug Label 55154-2883.

[10] CNS Statement, *supra* note 1, at 7, 20.

[11] *Id.* at 22-23.

[12] *Id.* at 23.

[13] *Id.* at 7.

[14] CNS Statement, *supra* note 1, at 23.

list.[15] At 2:59 PM, Ms. Vaught pulled Vecuronium[16] 10 milligrams from the ADC in the Neuro ICU using the override feature.[17]

Ms. Vaught read the reconstitution instructions on the back of the Vecuronium vial; she then collected a handful of flushes, alcohol swabs, and a blunt tip needle, and placed them in a baggie.[18] Ms. Vaught put one of Ms. Murphy's patient labels on the bag and wrote, "PET scan, Versed 1-2mg" and proceeded to the Radiology Department.[19] Ms. Vaught recognized Ms. Murphy on one of the Neuro ICU beds, so she checked Ms. Murphy's armband and told her she was going "to give her something to help her relax."[20] Ms. Vaught reconstituted the Vecuronium based on the instructions on the back of the vial and administered it to Ms. Murphy before going to the Emergency Department to assess another patient.[21]

Approximately thirty minutes later, at 3:29 PM, the patient's family, nurse, and Ms. Vaught were back on the sixth floor of the critical care tower when they heard an overhead page for a rapid response in radiology.[22] Unsure what patient the rapid response was called for, Ms. Vaught rushed to the Radiology Department and found Ms. Murphy intubated.[23] A transporter had found Ms. Murphy unresponsive and pulseless and began chest compressions, prompting the overhead page.[24]

Once back in the Neuro ICU, Ms. Vaught discovered that she mistakenly administered Vecuronium to Ms. Murphy instead of Versed.[25] Ms. Vaught immediately went to Ms. Murphy's room, where several physicians and a nurse practitioner were discussing Ms. Murphy's condition.[26] Ms. Vaught admitted that she had inadvertently given Ms. Murphy Vecuronium.[27] At that moment, everyone in the room knew what happened.[28] Before leaving the room, the nurse practitioner told Ms. Vaught, "I'm so sorry."[29] Ms.

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[15] *Id.* at 23-24.
[16] Reed T. Drug Label 23360-160 (Vecuronium is a paralytic agent "indicated as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical violation." It has no "known effect on consciousness, the pain threshold or cerebration.").
[17] CNS Statement, *supra* note 1, at 7.
[18] *Id.* at 9.
[19] *Id.*
[20] *Id.*
[21] *Id.* at 10.
[22] *Id.* at 10.
[23] CNS Statement, *supra* note 1, at 10.
[24] *Id.* at 21.
[25] *Id.* at 24.
[26] *Id.*
[27] *Id.*
[28] CNS Statement, *supra* note 1, at 24.
[29] *Id.*

Vaught spoke to management and filled out a Veritas report before leaving the hospital after 8:00 PM.[30]

In the early morning of December 27, 2017, after showing signs of "progression towards but not complete brain death," and a "very low likelihood of neurological recovery," Ms. Murphy's family chose to pursue comfort care measures.[31] Ms. Murphy's resuscitation order was changed from Full Code to Do Not Resuscitate ("DNR"), and she was extubated. At 1:07 AM, Ms. Murphy was declared dead.[32]

Ms. Vaught did not return to VUMC until January 3, 2018, when she was terminated.[33] More than a year later, on February 1, 2019, Ms. Vaught was indicted for reckless homicide and impaired adult abuse.[34] She faces up to twelve years in prison for her mistake.[35]

Almost twenty-years before Ms. Murphy was the victim of a fatal medication error, the Institute of Medicine ("IOM") released a report entitled, *To Err Is Human: Building a Safer Health System*. In this report, the IOM revealed that between 44,000 and 98,000 Americans die each year due to medical error.[36] More recently, in May of 2016, John Hopkins published a study that listed medical errors as the third leading cause of death in the United States, claiming 251,000 lives every year.[37] The 1999 IOM Report laid out a plan to improve quality of care by reducing errors and improving patient safety.[38] The Report explained that for that plan to be met, the culture of blame needed to be broken down because blaming an individual does not change the underlying factors which contribute to an error, so the same error is likely to recur.[39] The Report emphasized that to prevent errors and improve patient safety, there

[30] *Id.* at 25.
[31] *Id.* at 8.
[32] *Id.* at 8.
[33] *Id*. at 11.
[34] Tennessee Bureau of Investigation, *Middle Tennessee Nurse Charged with Patient Abuse, Reckless Homicide*, TBINEWSROOM (Feb. 4, 2019), https://tbinewsroom.com/2019/02/04/middle-tennessee-nurse-charged-with-patient-abuse-reckless-homicide/.
[35] *See* Tenn. Code Ann. § 39-13-215 (Lexis Advance through the 2019 Regular Session); and Tenn. Code Ann. § 40-35-111 (Lexis Advance through the 2019 Regular Session).
[36] Committee on Quality Health Care in America, Institute of Medicine, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1 (Linda T. Kohn et al., eds., 2000) [hereinafter "To Err is Human"].
[37] Makary, M. A., & Daniel, M., *Medical error - the third leading cause of death*, BMJ (2016).
[38] To Err is Human, *supra* note 36, at 5.
[39] To Err is Human, *supra* note 36, at 49.

needs to be a shift in focus to a systems approach to modify the conditions that contribute to errors.[40]

Despite the IOM's 1999 Report, the number of criminal prosecutions of health care providers is on the rise.[41] The first criminal prosecution for a medical act dates back to 1809.[42] Over the next 172 years, appellate courts would hear roughly fifteen similar cases.[43] However, from 1981 to 2001, approximately twenty-four cases of criminally prosecuting health care providers were heard by lower courts alone.[44] This number continues to rise, leading to a heightened concern amongst the medical community, which may lead to dire effects on patient safety.[45]

This note will explore the rise of criminal prosecutions of health care providers for medical errors, absent any intent to harm.[46] This note will demonstrate that in the interest of patient safety and error prevention, there are alternative forms of punishment, other than criminal prosecution, that are better suited to address medical errors when there is no intent to do harm. Part II of this note lays out mechanisms currently in place to address medical errors. Part III attempts to address why some cases are criminally prosecuted by analyzing specific cases. Next, Part IV explores arguments for and against criminal penalties for medical errors. Finally, Part V concludes with the recommendation to improve upon the mechanisms currently in place to address medical errors rather than relying on criminal prosecution.

II. MECHANISMS FOR ADDRESSING MEDICAL ERRORS

Extra-judicial oversight activities carried out by entities such as state licensure and discipline boards, hospital peer review committees, national regulations such as the Health Care Quality Improvement Act of 1986, and civil actions constitute fundamental quality control mechanisms in place to address medical errors.[47] While no one suggests that the current system is perfect, many

[40] *Id.*
[41] Christopher J. Kim, *The Trial of Conrad Murray: Prosecuting Physicians for Criminally Negligent Over-Prescription*, 51 AM. CRIM. L. REV. 517, 519 (2014).
[42] E. Monico et al., *The Criminal Prosecution of Medical Negligence*, 5 THE INTERNET J. OF LAW, HEALTHCARE AND ETHICS 1, 3 (2006); *See* Com. v. Thompson, 6 Mass. 134, 134 (1809).
[43] *Id.*
[44] *Id.*
[45] Alexander McCall Smith, *Criminal or Merely Human?: The Prosecution of Negligent Doctors*, 12 J. CONTEMP. HEALTH L. & POL'Y 131 (1995).
[46] For purposes of this note, an intent to do harm includes impaired healthcare providers.
[47] Robert B Leflar & Futoshi Iwata, *Medical Error as a Reportable Error, as Tort, as Crime: a Transpacific Comparison*, 12 WIDENER L. REV. 189, 191 (2005).

experts recognize that errors result from systems failures.[48] Therefore, to improve patient safety and prevent error, we must unqualifiedly embrace an approach of complete disclosure and transparency.[49] Critics suggest that these mechanisms are inefficient in protecting consumers.[50] These critics point to cases like the notorious Dallas neurosurgeon Christopher Duntsch, who injured almost every patient he treated in the roughly two years that he practiced medicine in Dallas, Texas.[51] Dr. Duntsch operated on thirty-eight patients, thirty-five of which were injured during or after these procedures, "suffering almost unheard-of complications" from nerve damage, to paralysis, and death.[52] Critics use the case of Christopher Duntsch to highlight the inadequacies of the current system, including state licensure, peer review, the National Practitioner Data Bank, and civil actions.

A. **STATE LICENSURE**

Every state has licensing boards tasked with protecting the public health and welfare by enforcing various state practice acts (e.g., nurse practice act, medical practice act, dental practice act, etc.).[53] Historically, a state licensing board was made up of almost all members of that given profession.[54] Today, practically every state requires some lay members "on the theory that they are more likely to hold errant [members] accountable."[55] For example, "[t]he typical medical board today has ten to fifteen members and usually covers osteopathic physicians. . . and no state has a majority of non-physicians."[56] State governors appoint board members to a term of three to eight years depending on the state and are typically funded from licensure fees.[57]

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[48] Joanna C. Schwartz, Note, *Systems Failures in Policing*, 51 SUFFOLK U. L. REV. 535, 544 (2018).
[49] *Id.*
[50] Kara M. McCarthy, Note, *Doing Time for Clinical Crime: The Prosecution of Incompetent Physicians as an Additional Mechanism to Assure Quality Health Care*, 28 SETON HALL L. REV. 569, 614 (1997).
[51] Lauren Beil, *A Surgeon So Bad it was Criminal*, PROPUBLICA (Oct. 2, 2018, 5:00 AM), https://www.propublica.org/article/dr-death-christopher-duntsch-a-surgeon-so-bad-it-was-criminal.
[52] *Id.*
[53] Pablo Aligathe & Randall R. Bovbjerg, *State discipline of physicians: assessing state medical boards through case studies ASPE*, THE URBAN INSTITUTE, HEALTH POLICY CENTER (2006) https://aspe.hhs.gov/basic-report/state-discipline-physicians-assessing-state-medical-boards-thruogh-case-studies [hereinafter "Assessing State Medical Boards"].
[54] *Id.* at 11.
[55] *Id.*
[56] *Id.*
[57] *Id.* at 12, 15.

The two main regulatory functions of state licensing boards are licensure and discipline.[58] Meeting these regulatory functions, state licensing boards license health care professionals, investigate complaints, discipline providers who violate their practice act, and refer providers for evaluation and rehabilitation when appropriate.[59] Licensure requires a demonstration that a member of a given profession has met the minimum education requirements and can demonstrate their knowledge.[60] Licensure boards stipulate "minimum education, training requirements, and certification, among other criteria, for those who seek to acquire or maintain a license to practice a given profession or provide certain services"[61] In summary, licensure ensures the competence of the member of the profession at the time they join the profession.[62]

In contrast, discipline oversees the ongoing practice in a state.[63] Members of a profession can be disciplined for misbehaviors, from business offenses to quality care problems.[64] Disciplinary actions range from non-public warning letters to public reprimand and suspension of license to practice.[65] "The theory is that discipline protects the public directly by removing some problem [members] from practice, restricting their scope of practice, or improving their practice."[66] The threat of discipline also acts to deter members of a profession from practicing beyond their capabilities.[67]

Several factors are impediments or barriers to effective discipline.[68] These factors include low funding and staffing, the capture of boards by medical interests, insufficient legal framework, high costs of investigation and formal legal processes, and fear of litigation by aggrieved members.[69] The disciplinary process typically involves five stages: intake, investigation, pre-hearing process, hearing, and action, with most complaints originating from the public.[70] Three-quarters of investigations end with closure

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[58] *Id.* at 55.
[59] TENNESSEE DEP'T OF HEALTH, HEALTH RELATED BOARDS, https://www.tn.gov/health/health-program-areas/health-professional-boards.html (last visited January 28, 2021).
[60] Assessing State Medical Boards, *supra* note 53, at 8.
[61] *See Joint Hearing on Health Care and Competition Law and Policy Before the FTC and Department of Justice*, 33-34 (Jun. 10, 2003) (statement of Dr. Morris Kleiner).
[62] Assessing State Medical Boards, *supra* note 53, at 8.
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] *Id.* at 8-9.
[67] *Id*. at 9.
[68] *Id.*
[69] *Id.* at 9-10.
[70] *Id.* at 20.

during the investigation because of insufficient evidence to support board action, and only 1.5% of complaints reach a formal hearing.[71] Overall, about 10% of initial complaints result in some level of sanction. A consistent problem all state licensing boards face is backlogging.[72] When a board fails to take prompt action to a report of a member not practicing safely, the board fails to protect the public.[73] This problem was demonstrated in California in the 1990s when a large backlog of uninvestigated complaints resulted in controversial administrative closure of cases without investigations.[74] Similarly, in 2004, an Iowa backlog reached approximately two years' worth of investigations leading to substantial changes in procedures.[75] Massachusetts' large backlog of cases in 1999 led to bad publicity, a crash program of catch-up and review, and a change in leadership.[76] The amount of time it takes to resolve a case depends greatly on how far the case proceeds through the disciplinary process.[77] "Nationally, cases resolved before or during investigation averaged 180 days from intake to closure, 425 days for cases closed after investigation but before hearing, and 675 days to reach a hearing."[78]

Skeptics of state licensing boards believe the boards are ineffective in weeding out incompetent members of a profession, pointing to understaffing, underfunding, and the failure of a self-policing system.[79] While critics often recognize that state licensing boards may offer some protection, they claim that protection is limited by requiring minimum qualifications rather than optimal qualifications. Additionally, these critics believe that once a member of a profession is granted a license, state licensing boards are ineffective at removing members who fail to retain these minimum qualifications.[80] They believe state licensing boards do little to maintain optimal levels of care and protection for patients.[81] However, state licensing boards play an essential role in health care safety and quality assurance because these boards are the only entities with the power to stop members from practicing beyond their scope of practice.[82] If a board can overcome understaffing,

[71] *Id.* at 26.
[72] *Id.* at 29.
[73] *Id.* at 31.
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.* at 32.
[78] *Id.*
[79] McCarthy, *supra* note 50, at 585.
[80] *Id.* at 588.
[81] *Id. at* 588-589.
[82] Assessing State Medical Boards, *supra* note 53, at 63.

underfunding, and outside interests, then it can be successful in protecting the public by moving cases quickly through the disciplinary process to impose appropriate sanctions.[83]

B. **PEER REVIEW**

Attempting to improve the nationwide quality of health care, Congress passed the Health Care Quality Improvement Act of 1986. Congress encouraged good faith peer review by granting immunity to participants in the peer review process.[84] A peer review system is necessary for a hospital's participation in Medicare and accreditation by the Joint Commission.[85] Peer review committees, made up of practicing providers who have specialized knowledge, analyze providers' training, qualifications, and experience upon initial employment, every two years thereafter, and anytime a health care entity has reason to believe quality concerns exist.[86] The peer review committee then recommends whether the provider shall receive or retain medical staff privileges and whether that physician shall have any limitations placed on that privilege.[87] This process is used to evaluate and improve provider quality while preventing providers from practicing substandard medicine.[88]

However, peer review is not without limitations.[89] A peer review system inherently forces providers to pass judgment on their colleagues' professional conduct, but generally, no one wants to speak up.[90] One expert recognized, "[d]octors know who the outliers are. Nurses know. They will know before anyone else knows. You know who you would and would not send your loved one to. But physicians do not want to point fingers. Clearly, anyone can make a mistake, but typically these are not just mistakes, these are violations of standards of care."[91]

Additionally, experts contend that the immunity granted to the peer review process has "the paradoxical effect of undermining

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[83] *Id.* at 64.
[84] Anthony W. Rodgers, Comment, *Procedural Protections During Medical Peer Review: A Reinterpretation of the Health Care Quality Improvement Act of 1986*, 111 PENN ST. L. REV. 1047, 1047 (2007).
[85] Michael Benson et al., *Hospital Quality Improvement: Are peer reviewed immunity, privilege, and confidentiality in the public interest?*, 11 NW. J. L. & SOC. POL'Y. 1, 3 (2016).
[86] Susan O. Scheutzow, *State Medical Peer Review: High Cost but No Benefit-Is It Time for A Change?*, 25 AM. J.L. & MED. 7, 21 (1999).
[87] Rodgers, *supra* note 84, at 1049.
[88] Scheutzow, *supra* note 86, at 14.
[89] McCarthy, *supra* note 50, at 591.
[90] *Id.*
[91] Michael J. Lee, *On Patient Safety: How well do we police ourselves?*, 473 CLINICAL ORTHOPEDICS AND RELATED RESEARCH 1552, 1553 (Jan. 31, 2015).

the quality assurance function of peer review."[92] On the one hand, critics point to bad-faith or a "sham" peer review, and on the other hand, to improper motives for leniency.[93] In some cases, hospitals have used the peer review process to retaliate against doctors. In effect, "the wide perception among doctors that whistleblowers may be punished with sham peer review has an in terrorem effect, discouraging doctors from challenging hospital administrators on issues of healthcare quality."[94] Thus, contributing to a provider's unwillingness to speak up.[95] On the other end of the spectrum, there are often improper motives for leniency at play in the peer review process, including friendships and collaborative relationships.[96] However, because the peer review process is confidential, it would be challenging to discover that a justifiable punishment was withheld due to improper motivations.[97]

While the immunity granted to the peer review process has its setbacks, it also encourages physicians to participate in peer review by protecting them from lawsuits by disciplined physicians.[98] "[D]octors are the most familiar with the relevant standard of care, and hence are best able to judge their fellow physicians, but the fear of litigation discourages them from participating."[99] Further, the peer review process allows hospitals to learn from their mistakes and appropriately address affected parties.[100] Ideally, the protections in place would encourage self-reporting, which would enable peer review committees "to investigate the situation, attempt to settle grievances with the patient, and provide education to other health care providers to reduce the occurrence of such mistakes in the future."[101] Thus, peer review can serve as a pillar of quality assurance in healthcare despite its limitations.[102]

C. NATIONAL PRACTITIONER DATA BANK

In addition to granting immunity to participants in the peer review process, the Health Care Quality Improvement Act of 1986

[92] Benson, *supra* note 85, at 8.
[93] *Id.* at 10.
[94] *Id.* at 9.
[95] *Id.*
[96] *Id.* at 10.
[97] *Id.*
[98] *Id.* at 7.
[99] *Id.*
[100] *Id.* at 8.
[101] *Id.*
[102] McCarthy, *supra* note 50, at 576.

established the National Practitioner Data Bank ("NPDB").[103] To increase support for the peer review immunity provision, the NPDB serves as a quid pro quo provision, compiling certain disciplinary information about health care providers, particularly physicians.[104] The NPDB "is a web-based repository that provides confidential information that employers may query in order to review whether a license is encumbered by a regulatory board action as well as review any reports of malpractice payments or other credentialing results."[105] The NPDB helps prevent providers who have had their privileges revoked by a health care institution from simply switching institutions to gain privileges and continue their practice.[106]

The NPDB includes two basic provisions, reporting and querying. Hospitals are required to report certain disciplinary matters to the NPDB.[107] Generally, matters that affect clinical privileges for over thirty days and are based on competence or professional conduct that could adversely affect the health or welfare of a patient must be reported.[108] While health centers are only required to report clinical privilege actions taken against physicians and dentists, they may report similar actions taken against other licensed health care professionals.[109] In fact, nursing is the most commonly reported profession to the data bank.[110] In addition, medical malpractice payors must also report any payments resulting from a final judgment in, or written settlement of, a medical malpractice claim.[111] The NPDB also serves as a check for hospitals, as hospitals are required to query the NPDB.[112] This query must occur when any licensed health care practitioner seeks

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[103] Yann H.H. Van Geertruyden, *The Fox Guarding the Henhouse: How the Health Care Quality Improvement Act of 1986 and State Peer Review Protection Statutes Have Helped Protect Bad Faith Peer Review in the Medical Community*, 18 J. CONTEMP. HEALTH L. & POL'Y 239, 246 (2001).
[104] Ilene N. Moore, MD, JD et. al., *Rethinking Peer Review: Detecting and Addressing Medical Malpractice Claims Risk*, 59 VAND. L. REV. 1175, 1180 (2006).
[105] Kathleen Russell, *Reporting of Nurse Discipline to the National Practitioner Data Bank*, 9 J. NURSING REG. 21, 21 (2018).
[106] Van Geertruyden, *supra* note 103, at 247.
[107] *See* 42 U.S.C.A. § 11133(a)(1).
[108] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *NPDB Guidebook* (2018), https://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf (last visited Jan. 28, 2021).
[109] *Can health care centers report or query on health care practioners who are not physicians or dentists?*, NPDB, https://www.npdb.hrsa.gov/qa/hc3.jsp (last visited Jan. 28, 2021).
[110] *Id.*
[111] 42 U.S.C.A. § 11133(a).
[112] William O. Quirey Jr. & Jeannie Adams, *National Practitioner Date Bank Revisited - The Lessons of Michael Swango, M.D*. 1, 3, https://www.vsb.org/sections/hl/bank.pdf (last visited Jan. 28, 2021).

admission to the medical staff or applies for clinical privileges and every two years thereafter.[113]

The NPDB can be a useful tool in quality assurance if appropriately used.[114] However, that is not always the case.[115] According to numbers from the Health Resources and Services Administration, "[i]n 2017, 30 state medical boards in the U.S. backgrounded a physician using the database fewer than 100 times. . . [t]hirteen boards didn't even check it once."[116] In addition, one investigation "identified more than 500 physicians who have had problems in one jurisdiction but were allowed to practice with clean licenses in another."[117] Health care providers also raise the concern that the data bank is being misused.[118] The Association of American Physicians and Surgeons recognized the purpose of the data bank is "to prevent so called bad doctors from moving state to state," however, "damaging information is being entered into this data bank with no regard to accuracy" and "good physicians are being reported to the data bank for reasons totally unrelated to patient care."[119] An additional limitation to the NPDB is that the general public cannot obtain access to the information.[120] As a result, consumers are at the mercy of the health care facilities and the state licensing boards to protect them.[121] This limitation is further emphasized by the wide variation in the character of the events being reported and substantial underreporting.[122]

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[113] *Id.*
[114] Matt Wynn & John Fauber, *NPDB Records Often Ignored in Docs' Licensing -Most Medical Boards Rarely Look at Practitioner Data Bak,* MEDPAGE TODAY (Mar. 7, 2018), https://www.medpagetoday.com/special-reports/states-of-disgrace/71600.
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *AAPS Tells Congress: NPDB is Flawed and Should Be Abolished*, AM. ASS'N OF PHARM. SCIENTISTS (Feb. 20, 2018), https://aapsonline.org/aaps-tells-congress-npdb-flawed/.
[119] *Id.*
[120] McCarthy, *supra* note 50, 597-598.
[121] *Id.* at 598.
[122] Haavi Morreim, *Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank,* 27 OHIO ST. J. ON DISP. RESOL. 109, 112 (2012).

D. **CIVIL ACTIONS**

Derived from English common law and developed by rulings in state courts, in the United States medical malpractice lawsuits are a relatively common occurrence.[123] To succeed in a medical malpractice action, an injured patient must show that the provider acted negligently in rendering care and that such negligence resulted in the patient's injury.[124] Medical malpractice actions include four essential elements: a professional duty owed to the patient, a breach of such duty, injury caused by the breach, and resulting damages.[125] These actions require comparing a provider wrongdoer's conduct with the conduct of a reasonable provider with similar skill, training, and knowledge under the same or similar conditions.[126] If the provider's conduct falls below this established standard of care, then the provider is liable.[127] The focus is on an individual provider's medical errors that result in harm, relies on a judge or a jury to evaluate that medical error, and imposes monetary damages if the provider is liable.[128]

While deterring health care professionals from practicing negligently and committing medical errors, the four principal objectives of medical malpractice actions are to achieve justice, compensate those injured, quality improvement via deterrence, and sometimes punishment.[129] As a result, patients might expect medical malpractice actions to act as a deterrent to the improper practice of medicine and to compensate victims.[130] However, only a small number of harmed patients receive compensation.[131]

Ideally, the threat of medical malpractice would force health care professionals to take remedial steps to improve the quality of care they provide.[132] However, experts suggest that in reality, the threat leads to defensive medicine, impairs providers' quality of performance, and inhibits communication.[133] Perceived threats of medical malpractice force physicians to order tests and procedures

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[123] B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPEDICS AND RELATED RES. 339, 339 (2012).
[124] *Id.*
[125] *Id.* at 342.
[126] McCarthy, *supra* note 50, at 577.
[127] *Id.*
[128] *Id.* at 575-576.
[129] Morreim, *supra* note 122, at 113.
[130] Joseph S. Kass & Rachel V. Rose, *Medical Malpractice Reform: Historical Approaches, Alternative Models, and Communication and Resolution Programs*, 18 AMA. J. ETHICS 299, 300 (2016).
[131] *Id.*
[132] Scheutzow, *supra* note 86, at 15.
[133] Morreim, *supra* note 122, at 115-116.

to reduce the perceived risk of litigation. These unnecessary tests can result in billions of dollars annually and can cascade further testing and injury.[134] In addition, "evidence suggests that physicians named in a lawsuit tend to suffer a marked increase in symptoms of depression, including fatigue, insomnia, difficulty concentrating, decreased self-confidence, or a loss of nerve in clinical activities."[135] Medical malpractice actions focus on pinpointing blame resulting in the inhibition of essential communication and system-level quality improvement.[136] Experts recognize that while individuals should be responsible for the quality of their work, a "'bad apple' approach of the tort system focuses on outliers rather than on more pervasive influences."[137] To improve quality, we must understand the problem in detail through ongoing communication and problem-solving.[138] Nonetheless, many experts still view medical malpractice as "a critical component of a comprehensive patient safety solution" and should be viewed as a "productive patient safety tool, one with sharp edges that help increase attention to medical error that cause death or permanent harm to patients."[139]

E. **INADEQUACIES OF THE CURRENT SYSTEM**

Dr. Christopher Duntsch, made infamous in part by the hit podcast "Dr. Death," was a Texas neurosurgeon whose incompetence led to two patient deaths and more than two dozen other patients maimed or paralyzed.[140] In June 2011, Dr. Duntsch began practicing with Minimally Invasive Spine Institute in Dallas and had surgical privileges at Baylor Regional Medical Center in Plano, Texas.[141] In Fall 2011, Dr. Duntsch performed multiple procedures at Baylor that resulted in lawsuits and permanent injuries to three patients.[142] Then, in February 2012, Dr. Duntsch operated on his close friend, leaving him paralyzed from the neck down and

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[134] *Id.* at 115.
[135] *Id.*
[136] *Id.* at 117.
[137] *Id.*
[138] *Id.*
[139] Barry R. Furrow, *The Patient Injury Epidemic: Medical Malpractice Litigation as a Curative Tool*, 4 DREXEL L. REV. 41, 49-50 (2011).
[140] Tanya Eiserer & Mark Smith, *'Dr. Death' highlights loopholes putting patients at risk* (Feb. 10, 2020, 10:23 PM), https://www.wfaa.com/article/news/local/investigates/two-thirds-of-texas-hospitals-have-never-reported-a-bad-doctor-to-national-practitioner-data-bank-records-show/287-13d9f229-43e1-4c0c-8261-4933b09c55e8.
[141] Alan Condon, *Dr. Death to hit TV screens: A timeline of the former neurosurgeon's case*, BECKER'S SPINE REVIEW (Aug. 27, 2019), https://www.beckersspine.com/spine/item/46730-dr-death-to-hit-tv-screens-a-timeline-of-the-former-neurosurgeon-s-case.html.
[142] *Id.*

resulting in his temporary suspension from Baylor.[143] In Spring 2012, after his suspension was lifted, Dr. Duntsch botched another surgery by cutting a patient's major blood vessel, resulting in the patient's death.[144] Dr. Duntsch was ordered to take a drug test following the incident; the first came back diluted with water, but the second came back clean.[145] Dr. Duntsch resigned from Baylor in April 2012.[146] He left with a recommendation letter that said he had "no restrictions or suspensions" on his clinical privileges during his employment.[147] Baylor did not report Dr. Duntsch to the medical board or the National Practitioner Data Bank.[148]

Following his resignation from Baylor, Dr. Duntsch was granted temporary surgical privileges at Dallas Medical Center.[149] His privileges were revoked after two of his three surgeries resulted in a patient's death and another patient permanently disabled.[150] Dr. Robert Henderson, a fellow neurosurgeon, filed a complaint with the Texas Medical Board.[151] However, while the board investigated, Dr. Duntsch was able to keep operating.[152] In May 2013, Dr. Duntsch performed another operation, leaving that patient with permanent brain damage.[153] It was not until June 2013, after numerous complaints, that the Texas Medical Board suspended Dr. Duntsch's license.[154] In February 2017, Dr. Duntsch was charged with five counts of aggravated assault and one count of injury to an elderly person.[155] Ultimately, Dr. Duntsch was convicted and sentenced to life in prison.[156]

The safeguards implemented to protect patients failed when Dr. Duntsch, an incompetent and dangerous physician, was able to continue practicing.[157] As of February 2020, two out of three Texas hospitals had never reported a doctor to the NPDB.[158] Dr. Duntsch was able to move from hospital to hospital without anyone reporting

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[143] *Id.*
[144] *Id.*
[145] Hannah Gilham, *How Dr. Death Managed To Operate In Plain Site for So Long* (May 2, 2019), https://www.ranker.com/list/christopher-duntsch-timeline/hannah-gilham.
[146] Condon, *supra* note 141.
[147] *Id.*
[148] Gilham, *supra* note 145.
[149] *Id.*
[150] Condon, *supra* note 141.
[151] *Id.*
[152] Beil, *supra* note 51.
[153]Condon, *supra* note 141.
[154] *Id.*
[155] *Id.*
[156] *Id.*
[157] Beil, *supra* note 51.
[158] Eiserer & Smith, *supra* note 140.

him.[159] A former Texas Medical Board member recognized, "We failed as a profession to try to acknowledge, recognize and try to stop somebody who was harming the public."[160] It took more than six months and multiple catastrophic surgeries before anyone reported Dr. Duntsch to the state medical board.[161] When someone did report, it took the board another year to investigate, all while Dr. Duntsch was still operating.[162]

The case of Dr. Duntsch demonstrates that the mechanisms in place to address medical errors need to be improved upon, but it does not mean that if implemented correctly, they cannot be successful. Nonetheless, the criminal prosecution of Dr. Duntsch was appropriate because of his active drug and alcohol use in addition to his possible intent to harm his patients.

III. WHY SOME HEALTHCARE PROVIDERS ARE CRIMINALLY PROSECUTED

The perceived inadequacies of the mechanisms currently in place to address medical errors may explain the increase of criminal charges against health care providers. Some experts argue that the current safeguards are insufficient to adequately punish health care professionals who consciously disregard a substantial and unjustifiable risk.[163] However, the effect of criminal charges on improving the quality of care and preventing medical errors is largely debatable and may have dire consequences.[164] Criminal prosecution for medical errors focuses on the health care provider involved, even though most errors result from system failures and several factors that culminate in individual error.[165] Further, it is unclear why one case mandates criminal charges, and another does not.

A sentinel event is "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof… including any process variation for which a recurrence

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[159] Condon, *supra* note 141.
[160] Eiserer & Smith, *supra* note 140.
[161] Beil, *supra* note 51.
[162] *Id.*
[163] McCarthy, *supra* note 50, at 618-619.
[164] *See generally Position Paper on Criminal Prosecution of Health Care Providers for Unintentional Human Error*, TANA.ORG, (Aug. 12, 2011, 5:30 PM), https://taana.org/resource/papers/8859161; Alan Fuchsberg, *When Do Doctor Medical Errors Become Criminal Medical Negligence?*, FUSCHSBERG.COM: BLOG (July 20, 2016), https://www.fuchsberg.com/blog/medical-errors-become-criminal-negligence/.
[165] *See generally* E. Bussey, *Medical Errors Are Result of Systems Failure Medical Errors in U.S. Hospitals Usually Result from Systems Failure*, 9 MEDICO-LEGAL WATCH 96 (2000).

would carry a significant chance of a serious adverse outcome."[166] While sentinel events and medical errors are not synonymous, many sentinel events are the result of preventable medical errors.[167] The Joint Commission reported a total of 824, 804, and 801 sentinel events in 2016, 2017, and 2018 respectively.[168] While the criminal prosecution of medical errors is on the rise, the number of medical errors that result in criminal charges is nominal and disproportional compared to the hundreds of sentinel events and reported 250,000 yearly deaths resulting from medical error. It is unclear at what point a medical error is so egregious to mandate criminal charges, but medical errors that rise to the level of criminal culpability typically tend to involve nurses rather than physicians[169] and involve one or more of the following factors: (1) a highly publicized case, (2) death or serious injury, (3) a failure to self-police, and (4) failure to follow established patient safety measures.

A. **JULIE THAO, RN**

In September 1990, the Wisconsin Board of Nursing licensed Julie Thao as a registered nurse.[170] Starting in 1993, Ms. Thao worked on the labor and delivery unit at St. Mary's Hospital in Madison, Wisconsin.[171] After working two consecutive eight-hour shifts on July 4, 2006, the latter of which ended at midnight, Ms. Thao slept at the hospital before having to report to another eight-hour shift scheduled for 7:00 AM on July 5, 2006.[172] Ms. Thao was assigned two patients; a mother admitted at nineteen-weeks gestation because her membranes had ruptured, and a sixteen-year-

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[166] Jointcommission.org, *Sentinel Events (SE)* (Jan. 2013), https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/camh_2012_update2_24_sepdf.pdf?db=web&hash=FD320B7BAF3E08EC28B44AA51CB21ABE.

[167] *See generally* Paul R. VanOstenberg & Paul Reis, *Understanding and Preventing Sentinel and Adverse Events*, 8 ICU MANAGEMENT & PRACTICE (2013), https://healthmanagement.org/c/icu/issuearticle/understanding-and-preventing-sentinel-and-adverse-events.

[168] Jointcommission.org, *Summary Data of Sentinel Events Reviewed by the Joint Commission* (July 1, 2019), https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/summary-2q-2019.pdf.

[169] Mara Gordon, *When a Nurse is Prosecuted for a Fatal Medical Mistake, Does it Make Medicine Safer?*, NAT'L PUBLIC RADIO (Apr. 10, 2019, 9:44 AM), https://www.npr.org/sections/health-shots/2019/04/10/709971677/when-a-nurse-is-prosecuted-for-a-fatal-medical-mistake-does-it-make-medicine-saf.

[170] State of Wisconsin v. Julie Thao, 200606NUR247 (Nov. 2, 2006) (Final Decision and Order at 1).

[171] *Id.* (Final Decision and Order at 3).

[172] *Id.* (Final Decision and Order at 4).

old mother, Jasmine Gant,[173] admitted for induction of labor because she was past due.[174] Ms. Grant received prenatal care at her local public health clinic and planned to have a natural birth.[175] During her prenatal care, she also tested positive for beta streptococcus, group B, which "resulted in a prophylaxis order of IV penicillin during labor."[176]

Ms. Grant arrived at the hospital on July 5 with her mother, aunt, and brother.[177] The unit secretary prepared Ms. Grant's identification wristband and placed it in her medical chart, and according to hospital policy, Ms. Thao as the primary nurse was responsible for verifying the wrist band and fastening it "to the patient's wrist as soon as possible."[178] However, Ms. Thao would never fasten a wrist band to Ms. Grant's wrist.[179]

Ms. Thao spent an hour educating Ms. Grant on what she could expect during the birthing process and answering questions while also trying to relieve Ms. Grant's anxiety, as this was Ms. Grant's first pregnancy.[180] Ms. Thao examined Ms. Grant's cervix at 10:49 AM, at which time her cervix was "dilated 2 cm and effaced 80%."[181] Ms. Thao then discussed Ms. Grant's birthing plan, "Ms. Grant's mother recalls saying that [her daughter] wanted an epidural only as a last resort."[182] However, Ms. Thao's recollection was that Ms. Grant and her mother wanted an epidural "as early as possible," to which Ms. Thao explained that the epidural could be given when Ms. Grant's cervix was dilated 3-5 centimeters.[183]

Ms. Thao began receiving orders for Ms. Grant at 11:00 AM.[184] First, the order for "Penicillin G, 5 million units IV, may add 1ml Lidocaine 1% PRN.," which Ms. Thao ordered from the pharmacy.[185] Next, "the labor admission orders, which included: starting a one-liter IV bag of lactated ringers to provide water and electrolytes, oxytocin (brand name Pitocin) to be used during labor

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[173] David Wahlberg, *Living, or Wanting to Die, After A Mistake*, MADISON.COM, (June 24, 2007), https://madison.com/news/living-or-wanting-to-die-after-a-mistake/article_446d8639-9b0a-5161-945c-ccaf67d261af.html (Ms. Gant's name was anonyms in Ms. Thao's final decision and order but was publicized in numerous news outlets).
[174] Wisconsin v. Thao, *supra* note 170 (Final Decision and Order at 6).
[175] *Id.* (Final Decision and Order at 6a).
[176] *Id.* (Final Decision and Order at 6b).
[177] *Id.* (Final Decision and Order at 7).
[178] *Id.* (Final Decision and Order at 8).
[179] *Id.*
[180] *Id.* (Final Decision and Order at 10).
[181] *Id.*
[182] *Id.*
[183] *Id.*
[184] *Id.* (Final Decision and Order at 11).
[185] *Id.*

to initiate or improve contractions and oral and IV analgesics for pain as needed."[186] At "around 11:30 AM, the obstetrician ruptured [Ms. Grant's] membranes to begin labor. The obstetrician did not order an epidural."[187] Ms. Thao then went to the medication dispensing cabinet (Pyxis) and entered Ms. Grant's identification before removing several ordered medications and the epidural medications, although it was not ordered.[188] She then took all of the medications and placed them on a counter in the anteroom to Ms. Grant's birthing room.[189] Another nurse received Ms. Grant's penicillin from the pharmacy and added it to the counter in the anteroom before informing Ms. Thao of its location.[190]

The penicillin and the epidural were in 250 cc of liquid in a clear plastic mini-bag of the same size and shape.[191] While the penicillin is given intravenously and the epidural is given into the spine, "the outlets and connections were the same."[192] However, the two bags did have "visible differences between the[ir] appearances."[193] Each of the bags had a print out of their distinctive drug names, the epidural included "a bright pink label approximately three inches square which read 'Epidural Medication.'"[194] Each bag contained a portal, but the epidural portal had an unremovable dark cap, and the penicillin portal had a smaller light-colored removable cap.[195]

Ms. Grant's room had a computer with a monitor, keyboard, and scanner.[196] According to hospital policy, before a nurse can give any medication to a patient, the nurse must scan the patient armband, the nurse ID card to identify who was administering the medication, and then scan it.[197] A little before noon, Ms. Thao hung the IV bag of lactated ringers then added what she thought was the penicillin.[198] However, Ms. Thao hung the epidural, which can only be administered into the spine rather than intravenously.[199] Ms. Thao failed to use the scanning mechanism in place or to read the label.[200] Also, while the penicillin order did not specify the infusion rate, the

[186] *Id.* (Final Decision and Order at 12).
[187] *Id.* (Final Decision and Order at 13).
[188] *Id.* (Final Decision and Order at 14).
[189] *Id.*
[190] *Id.* (Final Decision and Order at 15).
[191] *Id.* (Final Decision and Order at 16).
[192] *Id.*
[193] *Id.*
[194] *Id.*
[195] *Id.* at (Final Decision and Order at 16c).
[196] *Id.* at (Final Decision and Order at 17).
[197] *Id.* at (Final Decision and Order at 17b).
[198] *Id.* at (Final Decision and Order at 18).
[199] *Id.*
[200] *Id.* (Final Decision and Order at 19).

hospital recommends an infusion rate at 180ml/hr, which was printed on the medication bag.[201] However, Ms. Thao infused what she thought was penicillin at 250ml/hr.[202] Almost immediately after beginning the infusion, Ms. Grant experienced a severe adverse reaction and appeared to be seizing.[203] The infusion was stopped, a code blue was called, and advanced cardiopulmonary life support (ACLS) was initiated, but proved unsuccessful.[204] An emergency cesarean section was completed, and the baby was delivered at 12:20 p.m.[205]

After discovering her mistake Ms. Thao "collapsed and was admitted to the hospital as a psychiatric patient" before being fired a few weeks later.[206] Despite the support from the Wisconsin Nurses Association, the Institute for Safe Medication Practices, and the Wisconsin Hospital Association, Ms. Thao was charged with a felony, "criminal neglect of a patient causing great bodily harm."[207] Ms. Thao faced a $25,000 fine and up to six years in prison.[208] In exchange for dropping the felony charge, Ms. Thao entered a "no contest" plea to two misdemeanor counts of "illegally administering prescription drugs."[209] In addition, Ms. Thao's nursing license was suspended for nine months, plus a three year probation period in which she could not work in critical care settings or birthing units.[210] Another condition of the plea agreement, Ms. Thao could not work more than twelve hours in a twenty-four hour period or more than sixty hours per week for two years. Additionally, Ms. Thao had to take classes on preventing medication and health care errors and make three presentations to nurses or nursing students on the topic.[211]

As a result of Ms. Thao's fatal error, there was a formal investigation and report. [212] This report found that systemic

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[201] *Id.* (Final Decision and Order at 21).
[202] *Id.*
[203] *Id.* (Final Decision and Order at 22).
[204] *Id.*
[205] *Id.*
[206] Wahlberg, *supra* note 173.
[207] Diana J. Mason, *Good Nurse-Bad Burse: Is it an Error or a Crime?*, 107 AM. J. NURSING 11 (2007).
[208] Cheryl L. Mee, *Should human error be a crime?*, 37 NURSING2007 6, 6 (February 2007).
[209] *Criminal Case Against Nurse Ends*, 37 NURSING2007 34, 34 (2007).
[210] *Id.*
[211] *Id.*
[212] David Wahlberg, *Report: Systemic problems at St. Mary's set stage for fatal drug error*, WISCONSIN STATE JOURNAL (Mar. 15, 2010), *available at* https://madison.com/wsj/news/local/health_med_fit/report-systemic-problems-at-st-marys-set-stage-for-nurses-fatal-drug-error/article_73b1055e-2fee-11df-9f7a-001cc4c002e0.html.

problems at St. Mary's Hospital contributed to Ms. Thao's fatal mistake.[213] These problems included pressure to prepare epidurals in advance to minimize physician waiting time, ineffective labeling, and sporadic use of patient wristbands and scanners.[214] As a result, St. Mary's Hospital now requires orders for epidurals signed by doctors, warning labels on tubes, not just bags, and has increased the use of wristbands and scanners.[215]

B. **ERIC CROPP, MD**

Eric Cropp was the lead pharmacist at Cleveland's Rainbow Babies and Children's Hospital on February 26, 2006.[216] That day, the computer system was down, resulting in a backlog of orders, the pharmacy was under-staffed, and there was no time for routine work or meal breaks.[217] When a nurse called the pharmacy for a patient's chemotherapy, Dr. Cropp "felt rushed to check the solution so it could be dispensed."[218] That patient, Emily Jerry, was a two-year-old girl battling a tumor on the base of her spine and was undergoing her last round of chemotherapy.[219]

The chemotherapy needed to be prepared by the pharmacy using 0.9% sodium chloride.[220] Working with Dr. Cropp, Ms. Dudash, an experienced pharmacy technician, prepared Emily's chemotherapy with a 23.4% sodium chloride solution, twenty-six times the 0.9% solution required.[221] Dr. Cropp then checked off on the solution, believing it to be the correct 0.9% solution, and the chemotherapy was delivered to the floor where it would be administered to Emily.[222] On March 1, 2006, Emily Jerry died as a result of the error.[223]

After learning about the error, the Ohio Board of Pharmacy investigated the error and permanently revoked Dr. Cropp's

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[213] *Id.*
[214] *Id.*
[215] *Id.*
[216] Kevin McKoy & Erik Brady, Rx for Errors: Drug Error Killed Their Little Girl, USA Today (Feb. 2, 2009), https://usatoday30.usatoday.com/money/industries/health/2008-02-24-emily_N.htm.
[217] Ohio Government Plays Whack-a-Mole with Pharmacist, ISMP.org, (Aug. 27, 2009), https://www.ismp.org/resources/ohio-government-plays-whack-mole-pharmacist.
[218] *Id.*
[219] McKoy & Brady, *supra* note 216.
[220] Bob Watcher, *Jail Time for Medical Error, Redux: The Case of Eric Cropp*, THE HOSPITALLEADER.ORG (Nov. 26, 2009), http://thehospitalleader.org/jail-time-for-a-medical-error-redux-the-case-of-eric-cropp/.
[221] McKoy & Brady, *supra* note 216.
[222] Watcher, *supra* note 220.
[223] McKoy & Brady, *supra* note 216.

license.[224] After Dr. Cropp's license was revoked, a grand jury indicted Dr. Cropp for reckless homicide and involuntary manslaughter, punishable by up to five years in prison.[225] Ms. Dudash did not face any disciplinary action.[226] Emily's mom supported the punishment believing, "Eric Cropp's incompetence goes far beyond conducting one reckless act… he consciously disregarded any and every set standard of protocol regarding patient safety."[227] Emily's father felt sorry for Dr. Cropp, recognizing, "This guy is facing a prison sentence, and I know it was an accident."[228] Dr. Cropp plead guilty to involuntary manslaughter and was sentenced to "six months imprisonment, six months of home confinement, three years of probation, four-hundred hours of community service, and a five thousand dollar fine."[229] As a result of the fatal error, the Ohio legislature passed and implemented Emily's Law. Emily's law requires all pharmacy technicians to be trained, tested, and certified.[230]

C. **KIMBERLY HIATT, RN**

After working at Seattle Children's Hospital for almost twenty-five years, Kimberly Hiatt would make the only medication error of her career.[231] While caring for a critically ill infant in the pediatric intensive care unit, Ms. Hiatt administered 1.4 grams of calcium chloride ("CaCI") instead of the intended 140 milligrams, a ten-fold overdose.[232] On September 14, 2010, Ms. Hiatt self-reported, "I messed up. I've been giving CaCl for years. I was talking to someone while drawing it up. Miscalculated in my head the correct mLs according to the mg/mL. First med error in 25 years working here. I am simply sick about it. Will be more careful in the future."[233]

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[224] *Eric Cropp Weighs in on the Error that Sent Him to Prison*, Inst. for Safe Medicine Practices, (Dec. 3, 2009), https://www.ismp.org/resources/eric-cropp-weighs-error-sent-him-prison [hereinafter "Weighs In"].
[225] Damon Sims, *Eric Cropp, Ex-Pharmacist in Case in Which Emily Jerry Died, Is Ready to Plead No Contest*, CLEVELAND.COM, (Apr. 19, 2009), *https://www.cleveland.com/metro/2009/04/eric_cropp_expharmacist_in_cas.html.*
[226] McKoy & Brady, *supra* note 216.
[227] Watcher, *supra* note 220.
[228] *Id.*
[229] Weighs In, *supra* note 224.
[230] Ohio Bill Analysis, 2008 S.B. 229; *See* Ohio Rev. Code Ann. §4729 (West 2020).
[231] Alexandra Robbins, THE NURSES: A YEAR OF SECRETS, DRAMA, AND MIRACLES WITH THE HEROES OF THE HOSPITAL, 170 (2016).
[232] *Id.*
[233] *Id.*

After reporting her medical error, Ms. Hiatt was escorted from the hospital.[234] Five days later, the critically ill infant would die.[235] However, it is unclear to what extent the medication error contributed to the infant's death.[236] After being placed on administrative leave, Ms. Hiatt was fired several weeks later.[237] As a result of the medical error, the state nursing board put Ms. Hiatt on a four-year probation period during which the board of nursing mandated supervised medication dispensing in addition to a fine.[238] No criminal charges were filed, but on April 3, 2011, Ms. Hiatt committed suicide.[239] In response to the fatal medical error, Seattle Children's Hospital changed its policy to allow only pharmacists and anesthesiologists to access calcium chloride in non-emergency situations.[240]

D. **GERALD EINAUGLER, MD**

On Friday, May 18, 1990, Alida Lamour returned to her nursing home after being treated at Interfaith Hospital for renal disease.[241] While at the nursing home, Dr. Einaugler mistakenly ordered a feeding solution to be administered through Ms. Lamour's dialysis catheter.[242] Two days after the feeding solution had been administered, on Sunday, May 20, 1990, Ms. Lamour was having difficulty breathing, her abdomen was distended, and she vomited.[243] A nurse noticed the error and attempted to drain the remaining feeding solution and notified Dr. Einaugler. Dr. Einaugler then contacted the Chief of Nephrology at Interfaith Hospital, Dr. Irving Dunn.[244] While Dr. Einaugler contends that Dr. Dunn advised him that Ms. Lamour just needed to go to the hospital on Monday for treatment, Dr. Dunn remembers advising Dr. Einaugler to hospitalize Ms. Lamour, although it is unclear if Dr. Dunn advised

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[234] JoNel Allecia, *Nurse's Suicide Highlights Twin Tragedies of Medical Errors*, MSNBC (June 27, 2011), https://www.nbcnews.com/health/health-news/nurses-suicide-highlights-twin-tragedies-medical-errors-flna1C9452213 [hereinafter "Twin Tragedies of Medical Errors"].
[235] *Id.*
[236] *Id.*
[237] *Id.*
[238] Robbins, *supra* note 231, at 170.
[239] Twin Tragedies of Medical Errors, *supra* note 234.
[240] *Medical Error Nurse Suicide*, CHIPSO.ORG, https://www.chpso.org/newsletter/medical-error-nurse-suicide (last visited January 28, 2021).
[241] Einaugler v. Supreme Court, 109 F.3d 836, 838 (2d Cir. 1997).
[242] *Id.*
[243] *Id.*
[244] *Id.*

Dr. Einaugler of the importance of hospitalizing Ms. Lamour immediately.[245]

Later that day, between 11:00 AM and 2:00 PM, Dr. Einaugler reported the mistake to the nursing home supervising physician, Dr. Khaski, and informed him that Ms. Lamour's condition was not thought to be an emergency and could wait until Monday for hospitalization.[246] It is debated whether Dr. Khaski agreed that this was not an emergency.[247] By 4:30 PM, Ms. Lamour was "less responsive, unable to take food by mouth, and looked weak," prompting Dr. Einaugler to transfer Ms. Lamour to the hospital.[248] Ms. Lamour died four days later. Subsequently, Dr. Einaugler was "charged and convicted of reckless endangerment and willful neglect for delaying hospitalization once he knew that to do so would create a serious risk of physical injury."[249] He was sentenced to incarceration for fifty-two weekends. However, Dr. Einaugler was unanimously found innocent of any misconduct by the state licensing board.[250]

E. **DIONNE COOPER, RN**

Ms. Plass was a stay-at-home mother of three and an avid jogger.[251] However, after she ran out of her anti-anxiety drug Klonopin, Ms. Plass had a seizure and was rushed to Broward General Medical Center on April 23, 2006.[252] While there, Ms. Plass was ordered 800 milligrams of the anti-seizure drug Dilantin.[253] A nine-year veteran nurse, Ms. Cooper, worked in the emergency department that day and was Ms. Plass's nurse.[254] After receiving the order for the 800 milligrams of Dilantin, Ms. Cooper obtained thirty-two vials, and because it did not fit in one intravenous bag, Ms. Cooper hooked up two, one in each arm.[255] Ms. Plass's heart stopped, and she died shortly thereafter.[256]

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[245] *Id.* at 839.
[246] Einaugler, 109 F.3d at 839.
[247] *Id.*
[248] *Id.*
[249] *Id.*
[250] Gerald Einaugler, *Innocence is Irrelevant – The Einaugler Case*, 3 *MEDICAL SENTINEL 136, 138 (1998).*
[251] Bob LaMendola, *Overdose kills patient, officials say*, SUN SENTINEL (Jan. 24, 2007), https://www.sun-sentinel.com/news/fl-xpm-2007-01-24-0701230455-story.html.
[252] *Id.*
[253] *Id.*
[254] *Id.*
[255] *Id.*
[256] *Id.*

Ms. Cooper failed to double-check or question the amount of Dilantin she obtained, and instead of administering 800 milligrams, she administered 8000 milligrams or eight grams.[257] The correct dose required 3.2 vials of the drug, not 32 vials.[258] The state Department of Health filed an action to revoke Ms. Cooper's nursing license or discipline her for "gross negligence" due to the error.[259] No criminal charges were filed.[260]

F. **GREGORY HOGLE, DO**

An ear, nose, and throat specialist, Dr. Hogle, failed to review a patient's medical record before deciding, based on his exam, to remove her tracheostomy tube.[261] On April 8, 2005, Dr. Hogle examined Khusni Yusupova for the first and only time and decided to remove her breathing tube.[262] Shortly after. Ms. Yusupova went into cardiac arrest. She died two days later after being removed from life support.[263] Dr. Hogle had access to information relating to Ms. Yusupova's condition, which showed that she had a blockage that likely needed surgery.[264] Dr. Hogle admitted that he made a "serious mistake." The Assistant District Attorney "decided criminal charges were warranted because '… Dr. Hogle had access to information relating to Ms. Yusupova's condition, which he refused to review.'"[265] However, after Dr. Hogle was arrested for manslaughter, the investigation continued, and the decision was finally made not to follow through with criminal charges.[266] Dr. Hogle remains practicing medicine and received no known licensing sanctions as a result of his error.[267]

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[257] *Id.*
[258] *Id.*
[259] *Id.*
[260] *Id.*
[261] Kirk Mitchell, *Doctor is arrested in breathing-tube fatality*, THE DENVER POST (Dec. 3, 2005), https://www.denverpost.com/2005/12/03/doctor-is-arrested-in-breathing-tube-fatality/.
[262] *Charges Declined Against Doctor*, DENVER DA (May 11, 2006), https://www.denverda.org/wp-content/uploads/news-release/2006/Hogle-decision.pdf [hereinafter "Charges Declined"].
[263] *Id.*
[264] Mitchell, *supra* note 261.
[265] *Id.*
[266] Charges Declined, *supra* note 262.
[267] Webite of Gregory A. Hogle, DO, http://www.entcolorado.com (last visited Jan. 29, 2021).

G. **RADONDA VAUGHT, RN**

Though Ms. Murphey's family stated that Ms. Murphy would be upset if she knew Ms. Vaught was going to prison for her mistake, the Nashville District Attorney's office[268] indicted Ms. Vaught for reckless homicide and impaired adult abuse.[269] Ms. Vaught is currently awaiting her trial, which is scheduled for February 2021.[270] While the Tennessee Department of Health previously decided that Ms. Vaught's mistake did not warrant professional discipline as memorialized in an official letter, the department rescinded this decision and filed charges against Ms. Vaught before the Tennessee Board of Nursing.[271] As a result of the fatal mistake, Vanderbilt University Medical Center did a comprehensive review of their medication override list and removed some drugs, updated hospital policies, and procedures regarding patient monitoring, and implemented scanners in the radiology department.[272]

IV. ARGUMENTS FOR AND AGAINST THE CRIMINAL PROSECUTION OF HEALTHCARE PROVIDERS

Adverse medical events are as old as medicine itself.[273] As medicine becomes more complex, the risk of adverse events is even higher.[274] Mark Chassin, president of the Joint Commission, and Jerod Loeb, executive vice president for healthcare quality evaluation at the Joint Commission note, "Hospitals house patients who are increasingly vulnerable to harm due to error, and the

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[268] *See Vanderbilt's Role in The Death of A Patient*, HOSPITAL WATCHDOG, May 22, 2019, https://hospitalwatchdog.org/vanderbilts-role-in-the-death-of-patient-charlene-murphey/ [hereinafter "Vanderbilt's Role"] (Allegations have been made that District Attorney, Glenn Funk, has a conflict of interest due to his multiple professional and personal relationships with Vanderbilt. People now question whether other healthcare providers, including doctors, should fear prosecution.).
[269] *Id.*
[270] Tennessee Bureau of Investigation, *supra* note 35.
[271] Brett Kelman, *RaDonda Vaught: Health officials reverse decision not to punish ex-Vanderbilt nurse for fatal error*, THE TENNESSEAN (Oct. 17, 2019, 11:35 AM), https://www.tennessean.com/story/news/health/2019/10/17/radonda-vaught-vanderbilt-nurse-medication-swap-versed-vecuronium-fatal-error-reckless-homicide/3975427002/.
[272] Vanderbilt's Role, *supra* note 268.
[273] Symposium, *On the Table: An Examination of Medical Malpractice, Litigation, and Methods of Reform: Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation*, 46 NEW ENG. L. REV. 437, 440 (2012).
[274] *Id.* at 439.

complexity of the care hospitals now provide increases the likelihood of those errors."[275]

Traced back to two pioneers in patient safety data collection, Florence Nightingale and Dr. Ernest Codeman, the patient safety movement attempts to define and identify sources of patient injury.[276] In the 1850s, Florence Nightingale, the mother of nursing, determined the role poor living conditions played in soldiers' deaths at army hospitals.[277] The statistical approach she used to show the effects of poor living conditions laid the groundwork for standard statistical approaches for hospitals.[278] In the 1920s, Dr. Codeman, a Boston physician, studied hospital patients' data to learn what worked and what did not and how doctors contributed to bad outcomes.[279] By the 1960s, a seismic shift focused on the problem of patient harm in hospitals.[280] One of the first sophisticated looks at safety in hospital practice, E.M. Schimmel of Yale Medical School, examined adverse outcomes caused by acceptable diagnostic or therapeutic measures.[281] Dr. Schimmel "found that twenty percent of the patients admitted to the medical wards at Yale experienced one or more adverse episodes – some severe – with sixteen out of 240 episodes resulting in death."[282] As a result, Dr. Schimmel called for physicians to better balance benefits and harms in treatment approaches.[283]

Human error is impossible to avoid, and it is more productive to address systems contributors to error than human contributors to error.[284] A profound transformation in the approach to medical errors can be linked to the 1999 IOM Report.[285] The focus shifted from individual human contributions to error to a focus on systemic weaknesses, addressing "system-wide weaknesses in policy, organization, equipment, and technology."[286] The long embraced "'perfectibility' model which assumes that if health-care workers care enough, work hard enough, and are well trained errors will be avoided" was replaced by a culture that "seeks to optimize

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[275] Mark R. Chassin & Jerod M. Loeb, *The Ongoing Quality Improvement Journey: Next Stop, High Reliability*, 30 HEALTH AFFAIRS (April 2011), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0076.
[276] Symposium, *supra* note 273, at 441.
[277] *Id.*
[278] *Id.* at 441-442.
[279] *Id.* at 442.
[280] *Id.*
[281] *Id.*
[282] *Id.*
[283] *Id.*
[284] The Joint Commission, *Human Factor Analysis in Patient Safety Systems*, 13 THE SOURCE 7, 8 (2015).
[285] Schwartz, *supra* note 48, at 542.
[286] *Id.*

the relationship between technology and human, applying information about human behavior, abilities, limitations, and other characteristics to the design of tools, machines, systems, tasks, jobs and environments for effective, productive, safe and comfortable human use."[287] The focus is on "recognizing the potential for error, and developing systems and strategies to learn from mistakes, so as to minimize their occurrence and effects."[288] Under this approach, it is imperative to minimize and learn from errors and near misses, which can only be achieved by reporting adverse events.[289]

The reporting and investigation of medical errors is crucial to prevent the recurrence of error.[290] As humans are not infallible and actions rarely occur in isolation, addressing system error focuses on the "blame" more fairly and is more effective in preventing future errors.[291] The practical implementation of a systemic approach to medical errors can be traced to the prevention of wrong site and wrong patient procedures, the reduction of anoxic brain injury while under anesthesia, the significant decline in central-line associated bloodstream infection ("CLABSI") rates, and the decrease in medication errors.[292] Two decades of patient safety research confirms the characterization of medical error as complex and multifactorial, so any intervention to error must incorporate the wide range of causal factors.[293]

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[287] World Health Organization, *Why applying human factors is important for patient safety* (2012), https://www.who.int/patientsafety/education/curriculum/course2_handout.pdf?ua=1.
[288] *Id.*
[289] *Id.*
[290] *See generally* Bussey, *supra* note 165.
[291] *Id.*
[292] *See* P.F. Stahel *et al*,. *The 5th Anniversary of the "Universal Protocol": pitfalls and pearls revisited*, 3 PATIENT SAF SURG 14, 18 (2009) (The implication of the Universal Protocol which includes a pre-procedure verification process and surgical site marking and a "time out" in the OR are steps mandated to ensure correct patient, procedure, and site); R. Botney, *Improving Patient Safety in Anesthesia: A Success Story?*, 71 INT. J. RADIATION ONCOLOGY BIOL. PHYS., 182, 185 (2007) (After the highlight of medical mishaps that resulted in serious injury or death the Anesthesia Patient Safety Foundation was created. The Foundation is responsible for implementing standard practices, including the use of pulse oximentry and capnography, that prevent anoxic brain injuries.); P.J. Pronovost et al., *Fifteen years after To Err Is Human: a success story to learn from*, 25 BMJ QUAL SAF. 396 (2015) (Through a systems analysis, five distinct elements were used to effectively reduce CLABSI rates by over eighty percent in the fifteen years after the 1999 IOM report); A. Agrawal, *Medication errors: prevention using information technology* systems, 67 BR. J. CLIN. PHARMACOL. 681, 683 (2009) (IT systems including computerized physician order entry, automated dispensing, barcode medication administration, electronic medication reconciliation, and personal health records are key components in the prevention of medical errors.).
[293] David M. Studdert & Michelle M. Mello, *In from the Cold? Law's Evolving Role in Patient Safety*, 68 DEPAUL L. REV. 421, 432 (2019).

Quality improvement is better served by constructing system-level safeguards to reduce the chances of error, as opposed to punitive responses.[294] The lesson to be learned in medical errors "is that quality is not optimally improved by simply demanding that inherently fallible human beings be ever more obsessively attentive. People become fatigued, distracted, or inattentive, and safety systems must plan for this."[295] A response to mistakes, which emphasizes individual culprits, presumes that errors are the product of individual persons' failings, and recommends making those individuals pay a personal price so that they will not make a mistake next time, is out of touch with contemporary realities of quality and safety improvement in complex systems.[296] Addressing mistakes solely through punishment acts to inhibit communication when robust communication is most urgently needed.[297]

Nonetheless, those in support of the criminal prosecution of health care providers look to the current self-governance of health care providers as inadequate and see criminal sanctions as a legitimate quality assurance mechanism.[298] Supporters contend that "current forms of professional discipline cannot serve as an adequate replacement for the prosecutions of criminally negligent medical conduct."[299] These advocates reason that logistical difficulties and accountability issues are insurmountable to self-governing medical institutions that lack the preventative tools to stand alone.[300] As a practical matter, criminal prosecution retains a force of censure that its private and civil equivalents cannot match.[301] Experts point to the inadequacies of state licensing boards, peer review committees, the NPDB, and civil actions and conclude that "the current mechanisms of civil sanctions and disciplinary actions are insufficient to punish adequately health care professionals who intentionally harm patients or consciously disregard a substantial and unjustifiable risk."[302]

On the other hand, Medical associations and physician groups have unanimously taken a position against the criminal prosecution of health care providers absent any intent to harm, as it sets a dangerous precedent.[303] Criminalizing a mistake sends the

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[294] Morreim, *supra* note 122, at 119.
[295] *Id.*
[296] *Id.*
[297] *Id.*
[298] Kim, *supra* note 41, at 538.
[299] *Id.*
[300] *Id.*
[301] *Id.*
[302] McCarthy, *supra* note 50, at 618-619.
[303] *Id.* at 617.

message that mistakes are "something professionally embarrassing, something to be avoided, and if that is not possible, to be denied, muffled and hidden."[304] Evidence shows that the sheer threat of criminal prosecution can halt the reporting of incidents and prevent individuals from coming forward with safety-critical information.[305] "Judicial proceedings, or their possibility, can create a climate of fear about sharing information. It can hamper an organization's ability to learn from its incidents."[306]

Additionally, professional opinion is united behind the idea that criminal prosecution fails to deter medical errors.[307] The American Nurses Association fears that the criminalization of medical errors could "have a chilling effect on reporting and process improvement."[308] While nurses should be held accountable for their practice, errors are best addressed by correction or remediation, and disciplinary action should only be taken if warranted.[309] Harvard physician and professor Lucian Leape observed:

> Physicians and nurses need to accept the notion that error is an inevitable accompaniment of the human condition, even among conscientious professionals with high standards. Errors must be accepted as evidence of systems flaws not character flaws. Until and unless that happens, it is unlikely that substantial progress will be made in reducing medical errors.[310]

Criminal prosecution for a medical mistake conflicts with the principle "that the morally innocent should not be convicted of serious crimes."[311] While providers who make errors should be held accountable and pay for the injuries they cause, those providers do not deserve to lose their liberty and be stigmatized for their mistakes.[312] One expert goes so far to assert:

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[304] Sidney W. A. Dekker, *Criminalization of Medical Errors*, 77 ANZ J. SURG. 831, 835 (2007).
[305] *Id.*
[306] *Id.*
[307] *Id.*
[308] *ANA Responds to Vanderbilt Nurse Incident*, AM. NURSES ASS'N (Feb. 19, 2019), https://www.nursingworld.org/news/news-releases/2019-news-releases/ana-responds-to-vanderbilt-nurse-incident/.
[309] *Id.*
[310] James M. Doyle, *Learning from Error in American Criminal Justice*, 100 J. CRIM. L. & CRIMINOLOGY 109, 147 (2010).
[311] Kim, *supra* note 41, at 536.
[312] McCarthy, *supra* note 50, at 617.

> The long-term consequence for society turning medical mistakes into crimes or culpable malpractice could be less safe health care. If they become the main purveyor of accountability, legal systems could help create a climate in which freely telling accounts of what happened (and what to do about it) becomes difficult. There is risk of a vicious cycle. We may end up turning increasingly to the legal system because the legal system has increasingly created a climate in which telling each other accounts openly is less and less possible. If they take over the dispensing of accountability, legal systems will slowly strangle it.[313]

In addition to siphoning communication, criminal prosecution may make doctors more reluctant to take on difficult cases.[314] The fear of criminal prosecution drives defensive medicine, leading to increased costs and unnecessary tests and treatment.[315] "[D]octors working under a criminal malpractice regime would routinely settle for the most conventional, predictable, and uncontroversial methods in order to shield themselves from the catastrophic professional consequences of a criminal prosecution."[316] In return, stifling the advancement of medicine and causing harm to patients that could benefit from high-risk or experimental treatment.[317] In summary, criminal charges against healthcare providers, absent any intent to harm, are neither required nor beneficial.[318] Ultimately, criminal charges "inhibit error reporting, contribute to a culture of blame, undermine the creation of a culture of safety, accelerate the exodus of practitioners from clinical practice, exacerbate the shortage of healthcare providers, perpetuate the myth that perfect performance is achievable, and impede system improvements."[319]

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[313] Dekker, *supra* note 304, at 836-37.
[314] Kim, *supra* note 41, at 536.
[315] *Id.* at 536-537
[316] *Id.* at 536.
[317] *Id.*
[318] Inst. for Safe Medical Practices, *Criminal Prosecution of Human Error Will Likely have Dangerous Long-Term Consequences* (Mar. 8, 2007), https://www.ismp.org/resources/criminal-prosecution-human-error-will-likely-have-dangerous-long-term-consequences [hereinafter "Inst. for Safe Medical Practices Criminal"].
[319] Inst. for Safe Medical Practices, *Another Round of the Blame Game: A Paralyzing Criminal Indictment that Recklessly Overrides Just Culture,* (Feb. 14, 2019), https://www.ismp.org/resources/another-round-blame-game-paralyzing-criminal-indictment-recklessly-overrides-just-culture [hereinafter "Inst. for Safe Medical Practices Blame"].

V. CONCLUSION

Better processes, not greater individual efforts, produce the greatest enhancements of quality and productivity.[320] The IOM's publication of "To err is human" in 1999 marked "a seismic shift in medicine's approach to error," shifting perspectives about the frequency and causes of medical error and the importance of focusing on systems to make human error less likely.[321] This shift in addressing medical errors has "reduced medical errors not because health care providers got any better at their jobs, but because technologies, checklists, and protocols made it more difficult for them to make mistakes."[322] However, to improve the systems that are essential to making it more difficult for human error to occur, medicine must unqualifiedly embrace an approach of complete disclosure and transparency.[323]

The criminal prosecution of health care providers directly interferes with the ability of providers to openly disclose errors to the detriment of patient safety because absent disclosure, there is no opportunity to benefit from lessons derived from past medical errors and near misses due to a provider's fear of repercussion.[324] When the focus shifts from understanding mistakes to assigning blame, mistakes are driven underground, making them harder to detect and correct.[325] Rather than providing a scapegoat, the true goal of addressing medical error is preventing another error and improved patient safety.[326] Focusing on system error allows for the "free-flowing" of communication and makes it more likely "misses" and "near misses" will be reported, leading to improved safety overall.[327]

While the law clearly allows for the criminal prosecution of healthcare providers who make errors that result in patient harm, despite the lack of intent to cause harm, this course of action is neither required nor beneficial.[328] The mechanisms currently in

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[320] Bill Bornstein, *Medical Mistakes: Human Error or System Failure?*, http://www.whsc.emory.edu/_pubs/momentum/2000fall/onpoint.html (last visited January 28, 2021).
[321] Schwartz, *supra* note 48, at 542.
[322] *Id.* at 544.
[323] *Id.*
[324] Zachary R. Paterick et. al., *The Challenges to Transparency in Reporting Medical Errors*, 5 J. PATIENT SAF. 205, 207 (2009).
[325] U.S. DEP'T OF JUSTICE, *Mending Justice: Sentinel Event Reviews* (Sept. 2014), https://www.ncjrs.gov/pdffiles1/nij/247141.pdf [hereinafter "U.S. DEP'T OF JUSTICE MENDING"].
[326] Bussey, *supra* note 165.
[327] *Id.*
[328] Criminal Prosecution of Human Error, *supra* note 318.

place to address medical errors have some problems, but criminal prosecution is not the answer."[329] The case of Dr. Duntsch clearly demonstrates the inadequacies of the current system, but if implemented correctly and adequately enforced, the existing safeguards can be successful.

Criminal charges for medical errors have an enormous impact on patient safety, sending the wrong message to healthcare providers about the importance of reporting and analyzing errors.[330] If the influx of criminal charges continues, it likely will have a chilling effect on the recruitment and retention of an already depleted workforce.[331] When prosecutors disregard the long-established precedent of relying on licensure, peer review, and civil actions and choose to bring criminal charges against a healthcare provider for an inadvertent error, one must ask whether there will be an influx of charges against other providers or if this is an isolated event prompted by inappropriate motives.[332] Using Glenn Funk's "threshold for reckless homicide," healthcare providers should be uneasy about whether they are next, and society should be apprehensive about how this will affect patient safety.[333] As Dr. Zubin Damania asks:

> For those of us who take care of patients all the time, I ask the question who hasn't made a mistake that's harmed a patient? I'm not raising my hand. I've made those mistakes. If nurses and doctors are afraid of going to jail, what do you think will happen to the reporting of errors from now on.[334]

In the end, the criminal justice system lacks what medicine has found essential to detecting and addressing organizational errors: "a [non-blaming], all-stakeholder, forward-leaning mechanism through which we can learn from error and make systemwide improvements that go beyond disciplining rulebreakers and render similar errors less likely in the future."[335] Therefore, absent any intent, the criminal prosecution of health care providers is inappropriate and will have a dire effect on patient safety.

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[329] Blame Game, *supra* note 319.
[330] *Id.*
[331] *Id.*
[332] Vanderbilt's Role, *supra* note 268.
[333] *Id.*
[334] *Id.*
[335] Sentinel event Review, *supra* note 325.