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WHOLE HEALTH: A COMMUNITY APPROACH TO HEALTHCARE

WHOLE HEALTH: A COMMUNITY APPROACH TO HEALTHCARE

KEYNOTE SPEAKER:

PROFESSOR LAURA HERMER, *MITCHELL HAMLINE SCHOOL OF LAW*

[edited for reading]

FEBRUARY 8, 2019

Speaker 1: If everybody will please go ahead and take their seat, we will move on to the next segment.

Speaker 1: So just a quick reminder we have the updated CLE forms at the registration table, whenever you can fill those just go ahead and drop them off there so we can get sent in for you. Um at this point I will go ahead and introduce our next speaker Professor Laura Hermer from Mitchell Hamline School of Law. Laura Hermer is a professor of law at Mitchell Hamline School of Law in Saint Paul, Minnesota. Her current research focus is on changes in access of health coverage and care under the Affordable Care Act with particular focus on underserved populations.[1] She also recently created and obtained funding for a medical legal partnership and associated coursework between this law school and the United Fellow of Medicine… United Family Medicine, a federally qualified health center in Saint Paul/Minneapolis, Minnesota. In part through the support funded by the Robert Lloyd Johnson Foundation, part of her appointment at Mitchell Hamline Professor Hermer was an Assistant Professor in the Department of Preventative Medicine and Community Health and a member of the Institute of for the Medical Communities at the University of Texas Medical Branch in Galveston, Texas. Please welcome Professor Hermer.

Prof. Laura Hermer:: Thank you everyone, thank you yes. I understand that I am the only thing standing between you and lunch so I am going to try to keep my remarks brief. I often say that and then something quite the opposite happens so let me try to do a better job in that regard. Um what I'd like to talk with you today is um this waiver amendment that Tennessee has under consideration, has just submitted to CMS uh regarding work requirements or instituting work requirements or as they call them community engagement

[1] PATIENT PROTECTION AND AFFORDABLE CARE Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

requirements in the TennCare program.[2] So we've been talking about social determinants of health and we've been having a rather uh broad discussion of that and so this is going to focus it in um much more carefully and on one particular issue. So first I'd like to talk briefly about poverty, personal responsibility, and health um and then give a very very brief uh history of personal responsibility requirements in the Medicaid program, um then I'd like to talk about proposed Amendment 38 to TennCare uh and how many of you are familiar with this going on right now at least somewhat, excellent excellent.[3] Um and then I'd like to talk a bit about defining problems and solutions and just a little bit about what we're really trying to do here and how we might better go about doing that. Okay so um this oh wow this light is super bright, okay um so it is it is uh very unhealthy to be poor and there is plenty of research out there showing that if you're poor you're much more likely to be sick, you are much more likely to live a shorter life than people who are wealthier and there are many studies out there. There's a nice study by Olivia Egen and her colleagues that came out just a little while ago uh I mean 2016 in the American Journal of Public Health that takes all the counties in the United States, so over 3000 counties in the United States, and then ranks them from poorest to wealthiest um and then out of that collection of counties makes new states.[4] Okay and Tennessee actually was one of only five states to contribute a county to both the poorest state and the richest state okay um and as you can see there are rather different population characteristics here.[5] So if we look at the median income the richest state's nearly 90,000 dollars for median income, the poorest state a little under 25,000 dollars.[6] So see the poorest state the 75% of the population is rural, um 37% of the population is African American, nearly half the children are in poverty, and the employment level is more than double that in the richest state.[7] And it also differed, the richest state and the poorest state, they differed based on life

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[2] MEDICAID, AMENDMENT 38, December 28, 2018, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/tn-tenncare-ii-pa6.pdf.
[3] Id.
[4] Olivia Egen, *Health and Social Conditions of the Poorest versus Wealthiest Counties in the United States*, American Journal of Public Health, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5308159/.
[5] Id.
[6] Id.
[7] Id.

expectancy and also on so-called personal behaviors and I could call them choices but there not always quite as contingent on individual choice as one might uh might originally think.[8] So you can see that there is about a six year difference for both men and women in life expectancy between the richest and the poorest states, and when we look at certain health behaviors um you can see maybe there might be some correlations here.[9] So smoking rate is nearly double that in the poorest state than it is in the richest state um the obesity rate is much higher in the poorest state as is the rate of physical inactivity okay um and well these are behaviors they do have a real impact on medical care.[10] So we've been talking today about health versus medical care and really what is the correlation between these um so "Lara" was talking about in the beginning saying that uh medical care counted for only about 10% of a person's total health outcomes um and that uh you have uh population health care characteristics, you have social and economic determinants of health, you have genetic characteristics, those account for about 90% of the rest. These are going to be uh big contributors and so we see for instance with respect to obesity, um 87% of people with Type II Diabetes, Americans with Type II Diabetes, are overweight or obese and um this probably comes as no surprise people who are morbidly obese are more than six times as likely as people who have normal weight to have Type II Diabetes and um diabetes by the way is um is a terribly expensive condition and so on average people with diabetes will cost about, depending on their age, about 6,000 dollars more per year, much more if they're older um than individuals who don't have diabetes so a very expensive condition. This also correlated obesity is correlated with hypertension, certain cancers, myocardial infarction, asthma, and stroke. And just being obese alone costs on average or it adds about 1,900 dollars per year in medical care than people who have a normal BMI. And with respect to smoking the evidence on this is very clear, so smoking is associated strongly with an increased risk of ischemic heart disease, with various cancers, lung cancer, uh aortic aneurisms, respiratory infections, uh impaired fertility, and um a variety of other problems and it adds about 2,500 dollars per year to the health care costs uh to the medical costs um that individuals incur. Um physical inactivity uh is a much lower contributor in terms of health care costs but it certainly factors into

[8] Id.
[9] Id.
[10] Id.

the mix so its associated with a variety of cancers, diabetes, stroke, and also ischemic heart disease. But when you look at low socio-economic status alone okay so if you control for all of those other factors um which are more common in lower income populations, you put those aside, low socio-economic status alone um diminishes a person's lifespan on average by about 2.1 years um so and this is lower or it contributes uh it causes a person uh to have less years of life or is associated with fewer years of life even than alcohol overuse, obesity, and hypertension. So in itself it is unhealthy to be poor. Okay um so what do we do about this? Um in the 1980s Lawrence Mead, a variety of other people um developed this school of thought called the New Paternalism and it holds that people you know many of us have been poor or low income at times in our lives but for individuals who are poor for a much longer period of their life or poor for most of their life, the New Paternalism school hold that these individuals are poorer in large part because they don't know how to live their lives properly. They don't know how to behave. And this is the school of thought that was instrumental in getting the old cash welfare program, aid to Families with Dependent Children or FDC, um repealed and changed into TANF, Temporary Aid to Needy Families, through the personal uh the um Personal Responsibility and Work Opportunity Reconciliation Act of 1996.[11] Um and um and so TANF um cat um or I'm sorry cat um TANF um time limited cash welfare and it also instituted work requirements in the program but it also delinked Medicaid from cash welfare. Why would that be the case? Okay so certain individuals who were pushing the bill wanted Medicaid to still be uh connected with TANF eligibility um but legislators knew that you know poor mothers were going out, they had to work and probably getting very low wage jobs and they're probably not going to have access to private employer sponsored health coverage and when you think about the economics this makes very good sense. And so just looking at you know today's dollar um so if a woman or man for that matter is earning minimum wage is earning about 14,000 dollars per year gross and if they're going to have employer sponsored coverage and employer sponsored coverage costs well north of 6,000 dollars per year on average for employer sponsored coverage for an individual policy, nearly 20,000 dollars for a family policy, so we're talking about tacking on a huge amount of you know

[11] PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996, Pub. L. No. 104-193, 110 Stat. 2105 (1996).

compensation for this individual or diminishing their paycheck um well below what is permitted by law. So that makes sense that you would want them to still have access to Medicaid and if you look in Tennessee, for example, only about 15% of people who are earning poverty level or less and are working um have access to employer sponsored coverage. Um and this is not unusual. Tennessee is not unusual in this regard. So Medicaid was delinked from cash welfare and the eligibility standards are set differently now um but there were some for whom this sat rather badly and they thought that uh individuals on Medicaid should have to do something, show something, they'd have to do something in order to get their Medicaid benefits. And so we started to see these personal responsibility requirements start to creep into the program and they started entering into the program basically um through state impetus. So in Medicaid and in other federal state uh um uh cooperative federalism programs usually welfare programs you can get what's called a section 1115 waiver, section 1115 of Social Security Act allows the Secretary of the relevant department, here Health and Human Services, to waive certain Medicaid requirements if uh he believes in his judgment that they will further the goals of Medicaid.[12] We'll look at what some of those are in just a moment. So states started to seek waivers and were especially encouraged to do so starting under the George W. Bush administration to institute higher co-payments, uh to create uh health savings accounts of various sorts, and to have to make contributions to them, incurring higher penalties for non-emergent use in the emergency department uh, and then also reducing benefits for non-compliant beneficiaries. And these waivers were uh granted with not increasing frequency but with there was an increase in the amount or number or intensity of the personal responsibility requirements that were being requested and granted through the George W. Bush administration. This ratcheted back significantly initially under the Obama administration and then with NFIB v. Sebelius, which made the Medicaid expansion under the Affordable Care Act optional, um HHS started granting these waivers um more regularly or they became more lenient just in an effort to get states to expand their Medicaid population.[13] Okay and now under the Trump administration under Seema Verma who was a major proponent and

[12] 42 U.S.C.A. § 1315 (West 2014).

[13] National Federation of Independent Business et al. v. Sebelius, 567 U.S. 519 (2012).

is a major proponent of these personal responsibility requirements um now she has expressly endorsed this notion of allowing work requirements in the program which the Obama administration, even the George W. Bush administration, had held back from doing. And so in the state Medicaid director letter um just a little over a year ago uh she announced that those were going to be available and a number of states have taken CMS up on this.[14] Okay so already approved and implemented in Arkansas, and just recently in Indiana. Indiana just started up. They are approved but not implemented in a number of other states and then uh in Maine it was approved and then the Governorship changed and that was withdrawn, but they're pending in a variety of other states. Note that most of these states are non-expansion states. Okay so Arkansas and Indiana expanded Medicaid under the Affordable Care Act.[15] Um all of these states have expanded Medicaid or in the case of Wisconsin already have the eligibility up at the Medicaid expansion rate. Um Tennessee of course has not expanded Medicaid, you have somewhat expansive uh eligibility for parents under Medicaid uh but otherwise have not expanded it per se. So let's look at this proposed Amendment 38.[16] The proposal is that all non-disabled, non-elderly, non-pregnant um adults in TennCare will have to work or otherwise fulfill community engagement requirements but basically work. Um and the Department of TennCare did not provide an estimate of the number of individuals who would be impacted with their waiver application um but the financial review board for the General Assembly did some calculations when the bill was going through your legislature um and found that out of the about 300,000 individuals who would be subject to this only about 37,000 of them will not be exempt from reporting for some reason or another. There are tons of exemptions in the waiver application as there are nearly all the other waiver applications. Um so about 37,000 people would be impacted, and they estimated that of those probably about 22,000 will end up losing eligibility because they will fail to report or won't have a job or something of that sort. They will have to work at least 20 hours

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[14] Seema Ferma, *Letter to State Medicaid Director*, Dep't of Health and Human Services, https://www.medicaid.gov/federal-policy-guidance/downloads/smd19002.pdf.

[15] PATIENT PROTECTION AND AFFORDABLE CARE Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

[16] MEDICAID, AMENDMENT 38, December 28, 2018, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/tn-tenncare-ii-pa6.pdf.

per week on average and this is going to be averaged over a six-month period.[17] And so, for at least four out of those six months, they have to meet this twenty-hour a week requirement. And note, that virtually nothing is said in the waiver application about implementation. [18] Compliance will be assessed bi-annually – so, we do know that much – and noncompliant members will be suspended from TennCare until they can show that they have been compliant for at least one month.[19]

Okay. There are a number of problems with this waiver. I'd like to just talk about some of the legal problems, first, before we go into some of the policy issues. Okay. So, I said that we're going to talk about the purpose of Medicaid. And, you can see it here, and it is found in forty-two USC section thirteen, ninety-six dash one.[20] So, Medicaid was enacted for the purpose of enabling each state as far as practicable under those conditions to furnish: one, medical assistance to eligible individuals; or two, rehabilitative and other services to enable people to obtain or retain capacity for independence or self-care.[21]

So, let's talk about those two purposes of the Medicaid program. First, if we're talking about medical assistance that means healthcare. That means healthcare. So, states must furnish healthcare for eligible individuals. As you might imagine, the states that are seeking these community engagement waivers aren't really trying to do so under that first prong. They're going mostly for this second one, rehabilitation of other services. And, saying that, work will help individuals stay independent, and independence is good – you know, people should work for living – they should be able to support themselves. The problem is that when you look at the definition of rehabilitative services and other services in Medicaid, you're talking about services that have been recommended by a physician or other healthcare provider, mostly to help elderly or disabled people stay in the community or to

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[17] MEDICAID, AMENDMENT 38, December 28, 2018, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/tn-tenncare-ii-pa6.pdf.
[18] *Id.*
[19] *Id.*
[20] 42 U.S.C. § 1396-1 (West 2018).
[21] *Id.*

improve their physical functioning. It is not about helping people work – whether that will get them out of poverty or not. [22]

So, Medicaid was enacted in 1965, and it's a really traditional program.[23] Soler was talking earlier about bringing medical care back to 1970. You know, if we're talking about bringing medical care back to 1970, or here in 1965, we are really talking about old-fashioned, really old-school medical care, and we are not talking about the social determinants of health. And, that was not something that was included in the program at all. And so, you might think, well Medicaid is a welfare program, and certainly with cash welfare, we have work requirements, we have all these personal responsibility requirements.

So, let's look at TANF's purpose, okay? The purpose of TANF is to provide assistance to needy families so the children may be cared for in their own homes or homes of relatives too.[24] And, the dependence of needy parents on government benefits by promoting job preparation, work and marriage.[25] Work requirements absolutely fit into the definition of TANF as enacted by Congress – okay? So, Congress repealed AFDC and enacted TANF.[26] This is what we have now. Congress has not done the same thing, yet, to Medicaid. And so, if the Secretary wants to approve these work requirement waivers, and I can get really in the weeds on this – I will spare you all. If the Secretary wants to improve these requirements, that's really outside the scope of the Secretary's legal authority to do so under standard administrative law principles.

If Congress wants to make this change, it can do so. It can do so. And, perhaps it ought to, perhaps it ought not to. That's a matter of policy. Right now, this is outside the scope of the law. There are couple other problems – and by the way, again, that problem is not

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[22] Medicaid.gov, Index Page, *https://www.medicaid.gov/medicaid/index.html* (last visited July 30, 2019).
[23] Medicaid.gov, About Us Page, *https://www.medicaid.gov/about-us/program-history/index.html* (last visited July 30, 2019).
[24] Office of Family Assistance, About TANF Page, *https://www.acf.hhs.gov/ofa/programs/tanf/about* (Last visited July 30, 2019).
[25] *Id.*
[26] CONGRESSIONAL RESEARCH SERVICE, TEMPORARY ASSISTANCE FOR NEEDY FAMILIES (TANF) BLOCK GRANT: A LEGISLATIVE HISTORY, https://crsreports.congress.gov/product/pdf/R/R44668 (Updated April 2, 2019).

specific to Tennessee's waiver. This is problems that all of them have. Tennessee's waiver also fails to provide that estimate of the number of individuals who would be impacted.[27] There is specific federal regulation on this particular topic, and it hasn't met this, and it shouldn't be considered until TennCare provides this estimate. But then it also provides no information about how the proposal's going to be implemented – and this is really problematic.[28]

So, we think again about Arkansas. So, Arkansas is really the only state from which we have any data at this point. Arkansas implemented these work requirements in, I think, June of 2018. So, it's been around for a little bit over six months at this point. So, in the Arkansas works program, over 18,000 beneficiaries have lost their benefits since the program was instituted. And, you can see it goes, you know, the number who have lost benefits goes up here by about 4,000 per month. And then there is less of a jump here between November and December. And, part of the problem here, you know, we don't know whether these people are finding jobs and getting private coverage and getting out of the program – we have no idea because that data is not being collected. That is not how this program is being implemented. Okay. And this is not how any of them are proposed to be implemented to the best of my knowledge.

But another problem with Arkansas' program is that the reporting could only be done online. So, the Arkansas work recipients had to report their hours online every month. And a large number of people in the Arkansas Medicaid program had no access to the Internet. They have no Internet access. And so, they're dropping out. We find that the vast majority of people who are dropping out here, in the yellow for example – and this is from December of last year. A large majority of these people, it's not that they didn't report enough hours, it's that they didn't report at all. But again, we don't know if that's because they thought, oh, nuts, this is just too hard, and it's just not important to me because I don't use much healthcare. Or, if they said, you know, nuts to this, I'm going out and getting a job and I'm going to get private coverage and, you know, goodbye Medicaid.

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[27] MEDICAID, AMENDMENT 38, December 28, 2018, https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/tn-tenncare-ii-pa6.pdf.
[28] *Id.*

Or, if they just didn't have the materials to do the reporting. So, in December, last year, in the middle of December, the state of Arkansas said, okay, we know we've got a problem with this, so we're going to let people report also by telephone. You know, maybe that's what's going on here. But we don't know, and I don't know that they're collecting that data to satisfy that question or to answer that question.

So, you can also see here that the vast number of people are exempt from reporting. So, this is out of about 61,000 beneficiaries who are subject to the work requirements. And that's kind of been the average since this program has started. So, 90% of them are exempt from reporting. Tennessee's numbers from the Financial Review Committee are somewhat similar, by the way, not exempt from reporting about 6,000. So, the number of people from whom they got new information. And then part of the reason why some of these are exempt from reporting this because they're already meeting the work requirements under either TANF or under the food stamp program, under SNAPS. So, the state already knows they're meeting these requirements. They don't have to double report. Okay. So, they will be getting new information from 1,311 people in the month of December. This is a huge amount of "hoo ha" that the state is having to go through in order to get new information from 1,311 people. That's it. Okay. So, if we go back and think about, umm, I'm sorry, let me just, um, okay. Let me just talk about this one little bit.

Now, when you look at the administrative costs to the state, the administrative costs to the state, your Financial Review Board estimated that it would end up costing the state, net. Now, this is after we subtract out all the money that the state's going to be saving from the beneficiaries who get kicked out of the program. You all are still going to be spending nineteen million dollars per year, just on being counted for these administrative costs. So, keeping track of these people and their work requirements and their exemptions and all the rest of that. And, you all are not alone. Okay? So, Minnesota was considering doing this, I'm from Minnesota, and in the last legislative session – well, it was going to be massively expensive to institute these work requirements. And so, we had Republican legislators who were saying, look, I totally, I totally agree with the principle of this, but this is nuts. This is fiscally crazy

to do this. Why would we ever do this? And you know, we ended up not passing that legislation.

So, let's just go back to a moment, to this slide on low SES. So, it's unhealthy to be poor. Why is it, why is poverty, low SES in itself, a risk factor that diminishes a person's lifespan on average? There is research out there – a lot of it done, or at least instituted by a Sir Michael Marmot, through the Whitehall study, looking at the role of stress. And Larry talked at the beginning of the day about stress. So, it is stressful to be impoverished. When the Whitehall study was done, they expected to find that there would be a huge amount of stress in the upper class. Lots of people dropping dead from heart disease because they were stressed out as titans of industry or what have you, you know with their mergers and so forth, and found that actually it's really stressful to be poor.

Why is it stressful to be poor? Well, you know, you're worried about keeping your job. You know that you don't have many skills. You're working in a low wage job, you're easily replaceable, and you could be one sickness away from losing your job. If you lose your job, you might lose the roof over your head. You might not be able to pay your utilities. You've got all these other problems going on. It is super stressful to be poor. If you're poor, you're more likely, you know people of color are more likely to be poor. You have to deal with daily microaggressions from discrimination. It is really stressful.

So, what role would having to report work requirements to prove to the state that you are worthy of your health coverage? You know, if you are a diabetic, you need your health care. You need your insulin, or whatever drugs you're taking to try to keep your diabetes under control so you can work. And, if you then have to report these requirements, particularly if you have to do it through modalities that you might not have access to, what is this – what impact is this going to have on your stress? Is this really going to be doing a lot of good for anyone? And that's the question. What is this really about? What's going on?

So, it increases the state administrative costs – right? It demeans and hassles TennCare members, it treats them like children, and they have to go and report these requirements all the time. Those of you

who work in law firms, you know, you have to do your billable hours, you have to do your billing and you know you all understand that. But you're doing that so that you can get paid – so that you make sure that your clients pay you. You know, this is for health care, and it doesn't improve health. This is not something that is going to improve health. And what's more, these work requirements, you know, the state says, you know, we're going to help connect people up with jobs who don't have employment. That's great! Please, help connect people who are unemployed to work. That's great! Are they doing anything new? Do these programs? No. They are connecting them up with already existing state services that these individuals could take advantage of anyway and probably should be connected with if they're not employed. Okay? So, this really doesn't improve how, and it ultimately applies to this tiny little fraction of members.

So, what really is going on here? That is the question. So, there are better ways of doing this. There are better ways of helping individuals who are low income, get the skills that they need in order to move forward with their lives and their careers. It is great for people to be employed. But you need health care in order to be employed in the first place. If you are not already healthy, you need to get into better health to do this. So, there are ways that we can try to fix this problem. But these solutions are ones that are going to need to come from the community. if you don't have any bootstraps to pull yourself up by, you're going to be in trouble.

So, we all need to work together to help improve these community health efforts, rather the imposing these requirements just on these individuals who are already struggling. Thank you very much. [Applause]

Okay. Any questions? You all desperately want your lunch. Yes?

Audience Member: So, I assume there haven't been any studies on increased morbidity in Arkansas?

Prof. Hermer: It is way too early to get that data. And what's more, to the best of my knowledge, no one knows what has happened to the individuals who have left – who no longer have coverage. So,

we don't know whether the individuals who are remaining are healthier or less healthy. But we also don't know what's happening to the people who are leaving here.

I'd be happy to talk to people afterwards if you all are just desperate to get to lunch. But, thank you all very much. [Applause]

Phillip Fitzgerald: Thank you, Professor Hermer. There is one last thing before lunch, and that is me. I'm Phillip Fitzgerald. I'm the editor-in-chief of the health law journal. It's my pleasure to have had you all here today. The lunch today is sponsored by Waller Lansden Dortch and Davis, and I can't wait to let you go eat it. But I have two points I'd like to make.

The first is, we have a website up: belmonthealthlaw.com, and on that website you can find our previous publications or transcripts from our prior symposiums. We have a blog post on there that does current updates on developments in health law. And, we also accept rolling submissions for articles for publication. So, if you have an article idea – if you have something you'd like to submit for publication, please do so. That's at: belmonthealthlaw.com.

Lastly, I'd like to say that the best thing about the health law journal is that it can act as a conduit for professionals in the education world, the legal world, and the healthcare world. And, it's been great to host this event today. As we all know, Nashville is a hub for publicly traded private healthcare companies not withholding all of the country, and all over the world. And so, the conversations we have here today and the dialogue we have can have an effect beyond these walls and beyond our city. And I want to thank all of you for being here today and being a part of that dialogue. So, thank you very much. And with that, lunch is served!

WHOLE HEALTH: A COMMUNITY APPROACH TO HEALTHCARE

KEYNOTE SPEAKERS:

PROFESSOR LARRY VAN HORN, *VANDERBILT UNIVERSITY OWEN SCHOOL OF MANAGEMENT*

PROFESSOR LEAH R. FOWLER, *HEALTH LAW AND POLICY INSTITUTE*

[edited for reading]

FEBRUARY 8, 2019

Professor Farringer: Hi, I'm Debbie Farringer, I'm a professor here at Belmont, and I'm the director of Health Law Studies, and I wanted to say first thank you so much for coming to our 3rd annual Belmont Health Law Journal Symposium. We are really excited to have everyone here. I wanted to say a quick thank you, first off to the Belmont Health Law Journal staff who have worked tirelessly to put this together today. Our Editor and Chief Bill FitzGerald, our Symposium Director Tanner Yancy our Managing Editor Nikki Caruso and our Symposium Team have worked countless hours to put all of this together, and I am very, very grateful for all of their work. I also want to thank our sponsors today. We have our segment sponsors Gideon, Cooper, & Essary, Bass, Berry & Sims, and Baker Donelson. Our lunch today is going to be hosted by Waller, Lansden, Dortch, & Davis. And then our platinum sponsor here is Sherrard, Roe, Voigt, & Harbison. We are very excited that they have decided to partner with us on the Symposium today. And to that end, I'm going to introduce Mark Ison, who is going to introduce our first speaker. Mark is from Sherrard, Roe.

Mark Ison: Thank you. Thank you also to the Belmont Health Law Journal for all of your work in putting this together. Mr. FitzGerald, you're in charge of this illustrious gathering?

Bill Fitzgerald: I am. [Laughter]

Mark Ison: Thank you very much, and we really look forward to all that we have to learn today. It falls to me to introduce our first speaker, and I apologize for using notes but when you have a speaker as illustrious as Professor Van Horn here you should probably say a few nice things about him.

He is a renowned expert in research on health care management and economics, currently an Associate Professor of Management and the Executive Director of Health Affairs at Vanderbilt University's Owen Graduate School of Management. He is the Founder and Co-Director of the Center for Health Care Market Innovation at Vanderbilt and is also the Co-Director of the Nashville Health Care Council. He holds an MPH and MBA from the University of Rochester and a Ph.D. from The Wharton School at the University of Pennsylvania. He has been honored by the U.S.

Department of Health and Human Services as a Ruth L. Kirschstein National Research Service Award Fellow. Professor Van Horn's research on health care organizations, managerial incentives in nonprofit hospitals and the conduct of managed care firms has appeared in leading publications such as the *Journal of Health Economics*, *Journal of Law and Economics*, *International Journal of Industrial Organizations,* and the *Harvard Business Review*.

Professor Van Horn's current research interests include nonprofit conduct, governance and objectives in healthcare markets, and the measurement of healthcare outcomes and productivity. And so, without further ado, I give you professor Larry Van Horn. [Applause].

Professor Van Horn: So, the key to happiness in life is low expectations, alright. And I'll be, I'll try to be upbeat. I am, I occupy this narrow vision to be a motivational speaker. And I own that space, but I'm an economist, so I see the world through a very particular lens. I do a little work with the law school, I'm currently employed there, and I actually have a paper[1], for those of you that are so inclined, that came out this month in the Stanford Law Review on the impact of apology laws on malpractice liability in the United States. So, if that's your space, I have a great paper that just came out this month. So, I wasn't told what my homework assignment was I guess I can talk about anything and everything that keeps me awake at night or makes me look badass. Getting the topic of the day on the social determinants of health and wellness, I thought it is worthwhile to add a few comments there.

Before I get to that though, everything I say from this point forward in no way shape or form reflects the official views of anybody or organizations of which I'm affiliated, including the dear Vanderbilt University or I sit on a number of public company boards. They aren't responsible for what comes out of my mouth either. This is just Larry unchained, giving you his perspectives on things.

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[1] Benjamin J. McMichael, R. Lawrence Van Horn, W. Kip Viscusi, "Sorry" Is Never Enough: How State Apology Laws Fail to Reduce Medical Malpractice Liability Risk, 71 Stan. L. Rev. 341 (2019).

The topic of social determinants is so massively important. Unfortunately, ninety percent of what determines healthcare has nothing to do with medical care. We spend 3.6 trillion dollars a year, and we are impoverishing America. Ninety percent of it is the environment. The decisions we make day in and day out. Behavior, genetics. It's all those things which are so fundamentally important. And yet we spend all of our time talking about medical care in this country. On top of it, if you look at the United States health care spending and put it in context with other countries. You know we always say, the U.S. health care spending is so anomalous compared to other OECD wealthy countries, and we are overrent. That is one characterization. If you add public health spending and medical care spending, and then you look at how we compare, we are right in the middle of everyone else. What we don't do is we don't invest in public health infrastructure, and public health spending. We have slighted that and shoved all of our money into restorative medical care. And that is probably a very suboptimal resource allocation. Because what we do day in and day out in terms of our social and active environment in our communities has a massive impact.

And so, a homework assignment for all of you, to take away from today, is I want you to go and look at the ted talks on YouTube by Dan Buettner[2] and blue zones. Dan has been here in town and done talks with me in the past. But he traveled the country, the world, supported by National Geographic, trying to find the fountain of youth. The place where people lived a really long time and what did they do. And he identified five regions, and he labeled them blue zones. And there is one in the United States; it's located in California. Where he characterized what was it about the way that people lived their lives that made them live to be over one hundred years old and be in a high functioning capacity and had great mental acuity and what was it about those communities. And it had nothing to do with access to medical care. In fact, most of these communities had very limited access to medical care. They didn't have much access to wealth either. As a byproduct of that, some of the key things that they did was they moved around a lot, they walked. They were a highly mobile group.

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[2] Dan Buettner, *How to live to be 100+*, **TED TALKS** (Sept. 2009), https://www.ted.com/talks/dan_buettner_how_to_live_to_be_100

I don't do any of the things I'm talking about right now. I move too rapidly here, and I start getting moisture on my brow, it's an allergic reaction, which tells me I have to stop. They ate a largely plant-based diet. They drank red wine. In terms of community, the elderly were an essential part of the lifeline of the community, and they maintained a high degree of vitality and community connectedness throughout their lives.

So, Dan profiles this. If you look at his blue zone work they actually went and the problem that research created, this blue zone project, where they've gone around the country trying to rewire the faulty environments of communities to make them more healthy. So, it's short, it's interesting, and you should take a look at that.

You know, notwithstanding the fact that I know all of those things, I make seriously bad life decisions. I have a deep love affair with mayonnaise and Hardees. I love the Frisco Melt. And I have a very difficult time making good life decisions day in and day out. Every morning I take six prescription drugs. I take my ACE Inhibitor, my beta blocker, all those calcium channel blockers to control my hypertension because of all my seething rage. [Laughter].

I take Lipitor to inoculate myself against the consequences of my love affair with Hardees. I take my Synthroid in ways that my endocrinologist would never suggest, as a weight regulating device, speed up my metabolism, and burn it off. That way, I don't have to move too fast. Maybe even a little Celexa, an SSRI to take the edge off. [Laughter].

Here's the point. All of these things that I do day in and day out, don't really solve the underlying problem. I need to change the way I live my life. And that's a much harder proposition. And instead I take a bunch of prescription drugs that aren't going to solve my problem, and in part, it's the only way I can get my money back from my employer who involuntarily, and against my will, converted it to prepaid medical consumption. So, this is about value reclamation if you will.

At the end of the day, the real path is for all of us is to make better life decisions and allow ourselves a path in doing so. And over

the last forty years, we have absolved Americans of that responsibility. That's stress. I mean, all of the stress that we find ourselves under has a massive impact on the loneliness is as costly to your health as having high blood pressure. That stress which is entirely self-imposed by living beyond your means is just as costly as being obese in terms of your life expectancy. And if you look in 43.2% of U.S. counties between 1987 and 2007 the median life expectancy of women has declined. It has nothing to do with medical technology; it has to do with the way our society has devolved if you will.

If you look at the work of Angus Deaton, that he got a Nobel prize for. Men, white men of my demographic, are living shorter. Why? Because they are committing suicide, they have cirrhosis of the liver and a bunch of other diseases which are the result of our bad life decisions. So, this is a huge issue in our society that what we do in U.S. healthcare is we try to point to our providers and say oh population help you have to figure out a way to do something about it. I don't know that there is a business model for it. I don't know that the healthcare delivery system is the right setup to actually address any of these social ills. To me, these issues are about poverty. It's about safety in communities. It's about community attachment and engagement. These are things outside the purview of our medical industry. Yet instead of directing and investing in our community we've thrown the money over here to the healthcare and said you guys fix it. And I personally believe they are ill-equipped to do so.

Which leads us to some key facts I'm going to put out there; this is my public service announcement any time I talk. Do you guys understand how broke we are as a country? I mean it's scary broke. And that's really troublesome because in healthcare, today we have about 50% of medical care is financed by Medicare and Medicaid in the public exchanges. And yet that's predicated on governments, both state and federal, having money and having a balance sheet that can support the service delivery.

You probably are familiar with the fact that we are twenty-two trillion dollars in debt, right? We are running an 800-billion-dollar deficit this year at the federal level. Twenty-two trillion dollars is a big number, but you lose context when you're twenty-

two trillion dollars in because a trillion, a billion, a million, you change the consonant in the front and stuff comes diluted really quick. So, let me help you. A million seconds is just twelve days' worth of seconds. A billion seconds is thirty-two years' worth of seconds. A trillion seconds is thirty-two thousand years' worth of seconds. Everything we are talking about is in trillions here. And we are twenty-two trillion dollars in debt. Now, it's better to create an analogy if I take you back to a household. We are twenty-two trillion dollars in debt, and we bring in about 3.6 trillion dollars in the federal conference per year. So, this is like a household that makes $36,000 a year, has $220,000 on their credit card, seven times. And it's only getting worse.

If you find yourself in the uncomfortable position of being a hospital operator or sitting on the board of one, or if you have hospitals in Illinois, do you know how Illinois Medicaid pays you? IOUs. They don't pay you cash, because they are broke. And you have to wait until they float more bonds and take on more debt for you to actually get paid to pay payroll. So, we have this structural problem where so much of what we are looking towards to support our citizenry is part of the flawed balance sheet that we can't support sustainably**.** That keeps me awake at night. That keeps me angry. That's why I have no hair. [Laughter].

And you know, with the backdrop that healthcare is not the answer to any of these problems to start with. So, the way I like to frame it these days is we've got this conversation going in Washington is, and I don't care which side of the aisle you are on, I think everyone in this room will admit, to a degree, that Washington is a colossal hot mess, a train wreck. In all ways, shape, and form. But you've got the government through health policy pushing all kinds of initiatives, accountable care organization, population health reform. All of these are MIPS, MACRA, APM, trying to engineer changes in health care delivery. In ways that, in really speaking to Medicare and Medicaid and public exchange, which is about 140 million Americans. But all of the things they're doing, I don't think any of us would want to buy it or take it. And everybody in this room, not including the students, probably has employer-sponsored health insurance, which has about 170 million Americans with employer-sponsored health insurance.

So, on one side, we have health policy, Washington, trying to drive the debt over here but the 175 million of us who have employer-sponsored health insurance. What's driving change there? It's the changing cost to your employers. So, in 2006, in the United States, only four percent of Americans were on a high deductible healthcare savings account. There was no price sensitivity. No one was paying for anything out-of-pocket. No one cared what the price of anything was. Today in 2019, thirteen years later, thirty-three percent of Americans face a high deductible. And those deductibles are going to go up year over year as we go forward. It's not uncommon. I have friends that work at Amazon, and they have a $9,000 deductible. I see lots of families with $7,000 deductibles. That's the norm. That's the future. And the path of what is happening on the employer side is for everybody having more and more financial responsibility, having more out of pocket spend and whether you think that's good or not, as an economist, to me it's exactly the path we are on and exactly the path we will continue down. Because at its core, insurance is for high consequence, low probability events. What we got is a bunch of prepaid medical care. And back when I was a kid, my parents had employer-sponsored health insurance called major medical. And forty percent of the Nation's healthcare expenditures in 1970 were paid out of an individual's wallet. Today it's eleven percent. That is not an equilibrium. That being unwound. We are going to go back in the other direction.

Professor Van Horn: That actually, to me, gives me tremendous hope for the future of healthcare because if you ask me what the single biggest problem in U.S. healthcare is today--it's that every single price is wrong. Every price. Whether you're talking drugs, whether you're talking…every single price is completely off the rails. And that has devolved over the last 40 years. If you deliver a baby in the United States, the average cost of delivering a baby is $10,000. The median household income in the United States is $55,000. We're saying that to produce a human being in America cost 20% of the median household's income. Something that we have been doing since the beginning of time. That's criminal and that's an indictment of the U.S. healthcare industry. If I go see my primary care doctor at Vanderbilt, I'm gonna get an EOB explanation of benefits which is going to say they charge $257, and $190 is paid to the provider for what was effectively a seven-minute

visit… in the United States is about a $20,000 a year guy. That means it's 100 bucks an hour. That means I should get 15 minutes of his time for 25 bucks. That simple. That's the way transaction is used to take….

We've created this incredibly complex, byzantine apparatus that surrounds the delivery of medical care that does nothing for value creating for any of us in this room. And that's because up until 2006, the customer of all healthcare providers were third party payers and insurers, it wasn't us. It's only as we've come back into the mix because of the increasing financial responsibility we all have, to having these doctors to having greater cost sharing, that we actually have people who care about price. That is awesome to me because it creates innovation. If I were to show you a chart, when I'm on the road on the Larry going to hell tour, on healthcare, talking about the world of healthcare, and I showed you a chart looking at how healthcare spending is changing in the United States between 1970 and 2010 there's basically no change.

Hospitals roughly the same, doctors roughly the same, pharma roughly the same, DME roughly the same. The industry has had no value added it has basically been captured by $3.6 trillion dollars of interests who want to keep it just the way it is. In over forty years we had tremendous technological innovation, tremendous evolution of what we can do, how we can do it, and to whom. But none of that is reflected and changed in how we spend our dollar in healthcare. Because, we have had control. One of the things that excites me, is that as more and more Americans have high deductible health plans, and that money is sitting in an account, and today, let me give you some context, there's about 400 billion dollars in health savings accounts for most Americans. That's twice the size of the U.S. hotel industry. That's enormous money. And that's creating an incentive for everybody to come to the table and solve the problem of: how do I create value for someone who wants to buy something in healthcare? I don't need to go to see my doc at Vanderbilt Medical Group and wait the 17 to 25 minutes in the waiting room and go through the whole rigamaroll. I can just call Vanderbilt on Call and the nurse will come to my office. [3] If I'm in

[3] See https://www.vanderbilthealth.com/vhoc/.

California, um where they've got heal.com, where you can go online and you can have a board certified physician show up at your home or office within two hours for a flat rate of $99. [4] Average time is 27 minutes.

They employ logistics engineers as they do physicians. And they can do this profitably and sustainably. As you have more and more market entry trying to get a share of that 400 billion-dollar proposition, they're going to be solving our problems in ways that, our, the legacy healthcare delivery system never focused on, because they were focused on third party payers as a customer. And so that creates tremendous dynamism and tremendous opportunities in the market. It also is going to be very challenging for the existing person/board review healthcare. A lot of which is headquartered here in Nashville. Because the way they've operated and done business for the last 40 years is not going to be as impactful going forward. We don't need to be in hospitals. It's just an unfortunate reality. We've got—So much that needs to be done at hospitals can be done at AFCs or at home, or at alternative sites of care. What is the U.S. hospital industry doing in response? They're suing CMS around their site service differential, their intent to change the site service differential. They want to keep it exactly the way it is. So, these special interests want this market to stay exactly the way it is, but with this money flowing out, it creates tremendous opportunities for the money flow to go in a different direction to different providers. And I think that's a very exciting thing, something that gives me a lot of hope. The things that you should be watching that's being pressed right now, in the legal realm, one is the issue of price transparency.

Um, you heard President Trump allude to it in the State of the Union on January 1st, all healthcare providers, hospitals had to put out their prices.[5] They put out charge amounts which were completely useless for anybody buying medical care. But that's a step down the path of making that, that public increase the price dimension in the market. Uh more scrutiny around working with

[4] See https://heal.com/.

[5] See https://www.youtube.com/watch?v=bYj4cDmilxc (President Trump's State of the Union address 2019).

horizontal integration, a lot of which has been expanded and pushed by the ADCA, increasing concerns about that on the anti-trust side as well. So, I think that the future is bright. I think for all of us as Americans, we have great hopes here and great opportunities. It's just that we're gonna need our industry in Nashville to pivot and reorient itself to the new evolving customer, which is us as individuals. Uh, and help us solve problems and help communicate with us in ways that we understand and allow us to buy products and services where we want to buy it at a price what we can afford. And that hasn't been the case in U.S. healthcare for forty years. Uh, so being mindful of time, I want to have-I mean I can go a lot of different directions. Are there questions, kind of things you want to chat about, or uh put on the table that you would like me to respond to uh and tell some pithy stories around? Anybody? Yes.

Question from Audience: I'm concerned about the impact on rural communities, so the loss of hospitals and healthcare facilities, the business model might not be working but yet that community is dramatically affected if they lose the hospital then they can't improve the industry, they can't get jobs. Other than everybody moving to the urban areas, what's a solution to healthcare in the rural areas?

Professor Van Horn: Yeah, so David, that, I mean to that, I worry about it. I'm going to be flying to Tooele, Utah next week to look at a hospital in the middle of nowhere. The problem we have is that no one wants to look at rural America anymore. The population ... two is that we can't get providers to go to rural America. We can't get nurses, and we can't get the volume of clinical service delivery in those communities to support enough quality care. Um, you know Life Point is one provider.[6] I'm hoping that Life Point can reinvent themselves with RCCH and come up with a new model of delivery. But I think unfortunately, many of these rural communities, those hospitals can't be sustained. There's no economic sustainability and quite frankly from a quality perspective, we don't want to be doing stuff there anyways. I think what we got to figure out is what is a minimal footprint that we need to have in a distributive way across rural America such that we can deliver as much care as is clinically

[6] See http://lifepointhealth.net/.

safe and appropriate in that venue and at the same time have those feeders back in. So, Telehealth, Telecoms also can help support some of that. And then we have new delivery models here as well, uh, I don't think any of you are familiar with Contessa Health uh founded by Charlie Martin, Martin Ventures.[7] Um what is it? It's a hospital at home. 40 % of what's done in a hospital, they have clinical care pathways and technology to enable solutions to allow for the delivery of that in your home. Okay now take that to rural America. If you have sufficient home health, resources at play, do you need the bricks and mortar, or could you be doing a lot of these things CHF, COPD, these medical… Technological and psycho-care delivery changes that, all are mitigating against retaining those community hospitals. So what if, they're the hub of the community? So, it's not, to me it's a pretty challenging picture. Yes sir?

Question from Audience: So what's the role of government in helping to pivot profit mode?

Professor Van Horn: Um, so to me uh, and I'll reveal my bias. Yeah, everybody has bias. Everybody has, it's okay, it's part of what makes us human, let's just put it on the table. So I'm a wackjob libertarian, you know? Uh, and to me, what I want is for the government to provide a platform of information to allow markets to operate and then let that innovation come forth in the markets. I think unfortunately, one of the biggest challenges we've had in healthcare is too little innovation. And, because it's been so hard to do it. One of the things that CMS has done under Cimafirm is they've been deregulating, pulling back on regulation, and allowing more flexibility and more innovation both across states and across business lines and I think that's a good thing. So what I would want the government to do is help facilitate transactions where there's gains from trade. Right now, I don't know the prices for anything, period. I would like there, I would like price transparency. Not around charge masters and inputs at the hospital, I want to know how much does it cost to see a doctor? How much to go and have an x-ray? Just getting that information out in the market, and standardizing that, I think would be helpful.

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[7] See https://contessahealth.com/

Um so, listen if you ask me, I would like to pull back on Stark Clause, which I think are really constraining in terms of our ability to affect a ration of healthcare organization and delivery. Um, people talk frequently about, hey, all the money we spent, $500 billion on meaningful use and all the electronic health records and what not and they haven't done anything in terms of actual…in healthcare. Why? Because we, there isn't a business model to create information healthcare transmits with somebody. If all of, take your ATM, you can go anywhere in the world and use your ATM card and you can get money out. Why? Because everybody is getting paid. Your banks getting paid, outer network transaction, the other one is getting paid. In healthcare, data and information can't flow for a lot of regulatory and legal reasons. Um, that's the big friction here. It's not technological one, it's a business model flaw, and a regulatory one. So, I want to see more flexibility, pull back on some of this stuff. Let us move, let us try to figure out new ways of creating value. Uh, that's where I'm at. Okay, we got one or two more minutes. Yes sir?

Question from Audience: So, obviously, consumers having more information and having them buy directly from hospitals, you know with market force and pushing down prices, but isn't there something to be said for healthcare being kind of a unique product that there aren't any alternatives? Like I break my leg, I can't just like go shop around and see who can fix my leg.

Professor Van Horn: Well actually you can.

Question from Audience: Well it would be, the takeaway would be painful and take a lot of time, if it's an emergency.

Professor Van Horn: So, a couple things. One, is that we shouldn't talk about all healthcare being the same. Okay? Right now we talk about all healthcare as being treated through the same financing and delivery of purchase vehicle. Um, routine blocking and tacking medical care is different than chronic care is different than acute care, uh, if you have traumatic incident. All right? So, we should break those down as you get treated very differently. The majority of what we do day in and day out falls into a bucket very minimal to us making trails. Reality is, is that Americans purchase medical care, this block here, in just the way they purchase any other good and

service. And we've got companies, MDSave here in town founded by Paul Ketchel uh that is an online, think about it as Travelocity for medical care.[8] And they've got a bunch of individuals in California who work, who are internet purchase people. And the way people purchase medical care at MDSave is exactly the way it's purchased… The visit-revisit rates, the click-through rates, all the information and time is very similar. Um, so yes, there are certain places where healthcare is special. But there's a lot of other health we do where it is a commodity, it is something that we can increasingly commodify and all of that is a mantle to a new model of purchase, that way we purchase is not new, it's what we used to do in 1970.

Um, a final point, and I want to make sure that I don't take your time. People talk about innovation in healthcare. What I want you to think about is innovation is not gonna solve the entire problem. Innovation starts by solving a targeted problem for a subset and then we learn and diffuse, learn and diffuse. You know, I like to use the example of smartphones. We didn't end up here by having the government say, "How are we going to untether all Americans from corded landline phones with 25-foot chords in their kitchen, so you can go to the bathroom and talk to your girlfriend?" That's not how it started. It was, you saw the problem, uh, corporate executives, who had a high opportunity of cost and time, you gave them a really bad product, the 15 lbs. bag phone that had 45 minutes of life. Okay? It was only during the early targeting. And from that point, over 35 years, we've gotten to the point where everyone in this room lives on this. So, as we think about the future of healthcare and the possibilities, don't think about everything is going to be one size fits all, can be applied to all communities, all groups across all demographics and clinical medical stages and needs. We are going to solve it by solving a particular problem and then having it diffuse as we learn, and that to me is our real hope in healthcare and how we're going to solve the more official problems. So, with that, keeping it back on time, I think we're good. Alright, let's go.

[8] See https://www.mdsave.com/.

Nikki Caruso: Thank you Professor Van Horn. My name is Nikki Caruso and I am a managing editor of the Belmont Health Journal, and I will be introducing you to our first academic speaker of the morning. Professor Leah R. Fowler is a research assistant professor and a research director for the Health Law and Policy Institute focusing on public health law, bioethics, and health legislation and policy. Her current research includes a grant-funded project tracking Texas municipal smoking ordinances and a project exploring barriers to the exchange of patient client information among the professionals participating in medical-legal partnership. In addition to her research, studious Professor Fowler is involved in several Health Law and Policy Institute initiatives including oversight of the Health Law Legislative Fellowship Program and development of a medical legal partnership. She is also a faculty advisor for the Health Law Organization and the Houston Journal of Health Law. Professor Folwer has coauthored papers appearing or forthcoming in Health Matrix, The Journal of Law Medicine, Jamma Internal Medicine, and Theology and Science. She has also written for the Center for Medical Ethics and Health Law Policy's blog, Policy Wise, where she was an editor from 2016 to 2018. She now serves as a faculty editor for the Houston Journal of Health Law and Policy and the Health Law Policy Institute's Health Law Perspective.

Prior to joining the University of Houston, Professor Fowler worked as the Health Policy program manager in the Center of Medical Ethics and Health Policy at Baylor College of Medicine, where she maintains a designation as Health Policy Scholar. Immediately after law school, she practiced law as a personal injury attorney. Professor Fowler earned her Bachelor of Science with Honors in International Health from Georgetown University and her Juris Doctor from the University of Houston Law Center. So please join me in welcoming Professor Fowler.

Professor Fowler: Could I have a PowerPoint? No, I'll totally click it as long as you pull it up. I hate following people who are super funny and dynamic and walk around a lot because that's just not how I would present, because I would trip and fall. Um, but I appreciate you tolerating me after that very dynamic performance. So, all of you I'm sure have used clickers before. This is my first time with this one, so depending on how it goes, we'll see. Um, thank you for the introduction, I'm Leah Fowler and like she said, I

am here from the University of Houston Law Center where I am Research Director and Research Assistant Professor of the Health Law Policy Institute.

It's 2019 so as a quick matter of housekeeping if you are on Twitter, and I imagine most if you if not all of you are, you are welcome to tweet this presentation and you can even tweet @ me or my institution and I promise I won't be distracted by you being on your phones, as long as you don't use flash or something. But that's sort of the extent of the housekeeping issues. I am here today to talk to you about law as healthcare. So why me, why am I in front of you today talking about medical-legal partnerships? First, the University of Houston is experiencing a period of tremendous growth. We are about to open a college of medicine, which is going to be very exciting and it will be focused entirely on educating primary care physicians, and that will be opening its first class in 2020. And in addition to that we will have a federally qualified health center on campus that will be a training ground for these primary care physicians and will also serve as a health resource to the Houston Community that we call home. And as part of that broader educational initiative, we're working on creating a medical-legal partnership to help serve that, so, obviously this takes up a lot of my time during the day. And on top of that I do legal research on medical-legal partnerships, and I also do social science research, which is largely what I'll be speaking about today. And that means I do qualitative empirical work, semi-structured interviews with actual attorneys, clinicians and social workers who work in medical-legal partnerships to explore some of the barriers they encounter in their everyday life. And I think this is a really fun way for academics to do research because so often we're on the inside looking out and this is a way to find out what's happening on the ground, and better understand what's happening for them so when we talk about these challenges we're talking about things that actually impact them.

So I'm going to talk to you a little more about that research today, again if you're hoping to get into the really sticky legal and regulatory issues, that's probably not where I'm going to be going with this presentation and luckily this is a real room of experts so that is, I'm sure there is somebody in here who can answer your questions. Um, I do have one part of my presentation that is sort of participatory, but in a very benign way. Who in here is a practicing

attorney? Yeah, hand raising, great. Does anyone work in a healthcare setting? Keep your hand up. Does anybody work in a medical-legal partnership? I was hoping to get more people to interview. That's okay, but what's awesome about this is this means that some of the ideas that I will present to you will be entirely new and I hope this is a fun and interesting way for you to think about the provision of medical care and also maybe law as healthcare. Oh, good it works.

Alright, so to roadmap my presentation for you, today I'll be talking briefly about the social determinants of health, and you'll be getting a lot more of that later on, health legal needs, which is a different way of looking at the social determinants of health, medical-legal partnerships and the idea of an attorney as a care team member and then we'll move on from that to talk about different challenges integrating legal and medical care together because as you're all probably very familiar with, these are both very siloed services. We develop laws and regulations around this idea that they're separate, so bringing them together can create some unexpected hurtles. And I know in this roadmap I saw I'm going to be talking about challenges last but I'm also gonna present a challenge first, and this one is a little more conceptual than it is practical. This has to do with the way we think about health and the way we think about health law. And I can't take full credit for this idea because it came up in a conversation about multidisciplinary education at a conference I was at last week. And a clinical professor who teaches in a medical-legal partnership and teaches law students how to provide medical-legal partnership services said she likes to begin her classes talking about definitions and we're all lawyers, we love definitions. So, I'll pose this one rhetorically here: What is health? And inevitably when this clinical professor poses this idea of what is health to her students, she's screened with very lofty, ambitious answers, often touching on the WHO's definition of health, which is, "a state of complete physical, mental, and social wellbeing and not merely the absence of disease or infirmity."[9] And I find this definition hilarious.

Because to me, and certainly for attorneys and law students, I am not sure by this definition that any of us have ever actually been

[9] See https://www.who.int/about/who-we-are/constitution.

healthy. But what is really nice about this definition is that it's broad and holistic and it encompasses lots of different factors. But when the same clinical professor I was talking to asks her students 'what is health law?' she gets a very different type of answer. According to her students health law is stark[10] and anti-kickback[11] and fraud and abuse. And the students aren't alone the Texas Board of Legal Specialization says its largely operational, regulatory, and transactional legal issues. And they're not wrong. This is absolutely health law. But I want to propose to you today that where health and law intersect can actually be much more broad than this. And maybe the provision of legal services can actually be a form of health care. Now you don't have to buy this, and you can totally leave here being completely skeptical of this idea. But I want you to keep it in the back of your mind as I'm talking. And maybe, like the CDC says, "Law is a tool for protecting and promoting the health of the public."[12] And this is a great way of thinking of using law to protect public health on a population level. But I can even venture to say that we can even take it a step further and say that in the context of medical-legal partnership, you can use your legal services to in fact improve the health of the individual patient. But to get there, we have to go through the social determinants of health first, so like I promised in my road map, this presentation more appropriately begins here.

So we got a little bit of social determinants health in Larry's not very uplifting talk before. And we will touch on the social determinants of health again, but put very simply, the social determinants of health are where we live, work, and play. And all of these things have different aspects that influence our lives both positively and negatively, and thus can influence health outcomes. And this is all good to say, but it is also nice to spell out on a slide, so here we go. Where we live, like having a stable house can help people follow medical treatment plans, especially when those medications have to be refrigerated or their treatment plan requires electricity. Where we work, having a safe job site is important to promoting health and physical safety. In addition, it can improve our income. And where we play is important because we require safe

[10] 42 U.S.C. § 1395nn.
[11] 42 U.S.C. § 1320a-7b(b).
[12] Center for Disease Control and Prevention, About Us, https://www.cdc.gov/phlp/about/index.html (last visited July 30, 2019).

spaces to promote healthy recreation. We're going to be less inclined to go outside and exercise, even more so than we already are, if our neighborhoods are unsafe, they are poorly lit, or our parks and sidewalks are not maintained. And all of these things are not perfectly siloed, they are completely interrelated. So maybe where you work is unsafe, but also your income is bad so you can't afford to live somewhere good so you live in a food desert so your nutrition is poor so you're stressed, you can't feed your family, you have unhealthy coping mechanisms, and everything is a downward spiral to poor health. And there are lots of ways to visualize the social determinants of health and I think as you are going to pick up during the course of the day is that there is no one right way to talk about social determinants of health. And there is no one right way to visualize them. But I like this one, and you will see very soon why I like this one.

But this is how Healthy People 2020[13] likes to visualize social determinants of health in the context of neighborhood built environment, education, economic stability, access to healthcare, and social and community context. And I like this visual for a number of reasons, but I like it because it relates very closely to the idea of health harming legal needs. And that's why I like it because you didn't even have to remember what it looked like to know that it looks very familiar here. So the National Center for Medical Legal Partnership[14] came up with the mnemonic 'IHELP' to describe health harming legal needs or social determinants that have at their core a legal problem that can be remedied to improve health. And 'I' stands for income, and this relates to legal issues that impact access to resources that can help patients reach basic needs, like appeals of denial of benefits like food stamps or disability. 'H' stands for housing and utilities. And this impacts the physical environment, including housing subsidies, or preventing infection, or utilities shut off, or insuring that a home is actually inhabitable. 'E' stands for education and employment. And these are legal needs that help patients or clients, however you like to talk about them in literature, we often just call them patient-clients which is a whole mouthful, maximize education and job opportunities, such as deal

[13] *See generally* HealthyPeople.gov, https://www.healthypeople.gov (last visited July 30, 2019).
[14] *See generally* National Center for Medical-Legal Partnership, https://medical-legalpartnership.org (last visited July 30, 2019).

with employment discrimination claims or workers' rights or access to specialized education services. 'L' stands for legal status. It is very easy to make assumptions about what that means, and the first thing that probably comes to mind for you is asylum. But this is actually a pretty diverse category, and can include things like resolution of veteran discharge status disputes and also expungement. 'P' stands for personal and family stability. This ensures a safe home and adequate social support. And the types of legal needs that come up a lot with this are restraining orders for victims of domestic violence or issues impacting custody and guardianship. But identifying something as a legal need doesn't necessarily help us understand how its successful resolution helps to improve health outcome. So to that end, I broke it down a little bit like the previous one. This is all adapted from a great chart that you can find I cited in the end, so I certainly take no credit for this, it's also at the bottom.

And to look at it granularly, looking at things that help improve income in the household will help patients make fewer tradeoffs with things like affording medication because if you've perhaps read the news lately then you might remember that medication is very expensive. But this is also easy to explain in the context of an antidote that comes up a lot when talking about medical legal partnerships. The one that comes up often is the idea of the child presented to the emergency room with acute respiratory distress and perhaps the physician can treat maybe what is a recurring asthma attack, but until you can address what might properly be a mold or a pest infestation problem in the home you're going to keep having this child coming back you're not going to be able to fully resolve the medical issue. This is where having an attorney actually can help provide a better medical outcome. And this is important because there are lots of really interesting statistics about low income populations and their unmet legal needs. Some say that 80% of legal needs experienced by low income Americans go unmet, and other statistics still say that every low income American has 2-3 unmet legal needs. And I'm not really sure how one can accurately identify the exact number, but the point I'm making is this is a huge population that has legal needs that by being unmet are adversely impacting their health outcomes.

So if legal services can help improve these outcomes, how do we get them directly to the patient? And this is happening in what are called medical-legal partnerships. And these are healthcare delivery models that integrate legal assistance as a vital component of healthcare and its built on the understanding of three key factors. I've got another animation. One, the social economic and political context in which people live has a fundamental impact on health. This is just like the social determinants of health that we talked about at the beginning of this presentation. Two, these social determinants often manifest in the form of legal needs, i.e. the health harming legal needs we just mentioned. And three, that attorneys have the special tools and skills necessary to address these needs, i.e. all of the attorneys here in this room have the ability to impact the health of their clients on an individual level. And this idea may be new to some people, but it's not entirely new generally. These are actually growing in popularity across the country and are present in 46 different states and I think the last number they identified was about 333 different medical-legal partnerships. They're also not particularly new, and often literature cites the first medical-legal partnership as being in Boston in 1993. Though even before the term medical-legal partnership was formed, attorneys were helping to improve the health outcomes patients in HIV and AID clinics in the 80s. So this is not a totally new idea, but its growing in popularity as we start thinking more about how do we tie physician reinforcement and value to outcomes.

So let's talk a little bit about the ways MLPs can happen and the basic forms that they can take. Yup this is the one that I wanted to be on right now. So there least integrated form, medical-legal partnerships don't look radically different than the way medical and legal services are provided in the real world as it is. And this is technically referred to as like a referral funnel. And in this circumstance, a patient may be seen in the clinic and may be screened for health harming legal needs by a physician or perhaps a social worker. And if they screen positive for a health harming legal need, either the patient will be given referral information to the attorney or the attorney will be contacted with the contact information for the patient. And these are kind of interesting models, and they are serving really important purposes, but from an academic perspective and from a research perspective, these pose fewer challenges than some of the more integrated models. On the

other end of the spectrum of integration, we see the attorney truly as a care team member. In some of these circumstances they are rounding with physicians, they are attending care team meetings, they may be housed physically on the same site as the medical provider, and in some even rarer circumstances, they may have read and write access to the medical record, which obviously raises a ton of red flags for anyone who thinks of things like privacy or confidentiality. And these are super interesting because they challenge our ideas of what law and what health are, and what it means when we bring them together. So between those two poles we have a lot of options about what these can look like and the configuration of the medical legal partnership can vary on a number of factors. On one level its institutional comfort. If the general counselor of risk management of a hospital is uncomfortable with the idea of having an attorney on site, they may be reluctant to be able to house them there. On the other hand, we also have the different type of legal service providers driving what these medical-legal partnerships look like. In some cases they are affiliated with law schools, so they are a part of a larger clinic program where students are introduced to health harming legal needs to address them by direct patient contact and handling the cases themselves. And also with a law school component so they are learning about it in the classroom. Other ones are linked to legal service organizations, so legal aid may partner with a clinic to be able to provide these services. And in other more integrated services, the attorney may be a direct employee of the medical provider. So, they may be housed on site, they may be paid by the medical provider, and in that way they have much more access.

Another thing that will drive the function and the structure of medical-legal partnerships is the type of patient population seen. So that will dictated, largely, the types of legal services provided. For example, if you are in a pediatric clinic, you are more likely to work on issues related to guardianship or individualized education plans. As opposed to a medical-legal partnership that is focused on elders, and then you might have more issues with trusts, wills, and estates. And this is all well and good, but what we are talking about now is a big push towards integrated models for lots of reasons. On one hand we are talking about vulnerable populations, these are people who very easily fall through the cracks. So the more integrated we can have an attorney and the care team, the less likely

we are to loose patients when they leave the clinic. And this can be caused by a number of reasons. Some of them don't have consistent contact with cell phones, some of them don't have consistent addresses, and on top of all of that, you also have people who have a number of pressing things happening in their lives and addressing a legal need may not take priority at that time.

And also, there is more push towards integrated care because limited coordination means more limited solutions. Attorneys and doctors and social workers all approach problems differently. And by having these people working together in the same setting you have more creative solutions that may more completely treat the problem that is impacting the patient. And also, this has come up several times in our interviews though its counter to how I think things often work in a medical setting, patients appreciate that there is broad information sharing between all of these different providers because they like that it alleviates the burden of telling their story over and over again to multiple providers when they think it should just be able to be shared freely. So all of this is well and good, but we are now talking about combining two things in these highly integrated partnerships that are previously very distinct. And as attorneys, and as some care providers, you may be aware that the way we practice these services and the rules, regulations, and laws around our respective practices keep them separate and anticipate them staying separate. But they don't always stay separate now. And because of that, different barriers are encountered.

And that's where we get back to the research I've been conducting at the University of Houston where we talk to attorneys, clinicians, and social workers about the types of barriers that come up. And were going to talk about a few of those now. First, were going to talk about ethical and legal barriers. So obviously the first thing that comes up when we're talking about sharing different types of health information is concerns about HIPAA.[15] And one of the things we found that's really surprising is in speaking to, and we've mostly talked to attorneys at this point, this doesn't seem to be an

[15] *See* Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in sections 18, 26, 29, and 42 U.S.C. (2012)); The HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164(A), (E) (2014).

area of huge concern. And that's not because HIPAA's[16] not important, that's because they felt that they found very good work arounds. On one hand, they usually have patients sign authorization and intake. And on the other hand, they also are looking at exceptions to the privacy rule, and including the idea of legal services in treatment, payment, and healthcare operations. And so largely these things aren't coming up in our discussions. What they have found to be more concerning in these preliminary results is issues about confidentiality. And obviously when we are talking about bringing an attorney into a care team meeting or you are having all these very collaborated discussions about the patient and their legal and their medical case, we have issues about whether or not we are waiving attorney-client privilege or if we are in anyway compromising work product protections. And this is important because there are lots of types of legal cases that can't be handled by medical-legal partnership. And as a former personal injury attorney, one of the ones that logically comes to mind is fee generating cases. And so we have to worry about whether or not the issues that come up in the context of a medical-legal partnership will maybe ultimately be used against that patient client in a subsequent legal proceeding for which they are not using medical-legal partnership services.

We also have the issue of professional obligations. And this one is sort of interesting because we owe different duties to our clients and patients respectively. So this comes up a lot in the context of mandatory reporting requirements. So where a doctor may have to do no harm and seek to promote the best interest of their patient, attorneys must be zealous advocates for their clients rights and interests, and these two things sometime conflict. So if an attorney learns about something where there might be a case of suspected child abuse, they may not be able to bring it up in a care team meeting even though it might promote the best health outcome because it might prompt mandatory reporting requirements on the clinician side, it would go against their client's interest. So in these ways, the flow of information in this truly holistic and integrated care is being stifled. And there aren't clear answers to how we

[16] *See* Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in sections 18, 26, 29, and 42 U.S.C. (2012)); The HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164(A), (E) (2014).

should address this, and that's one of the common things were running into, 'oh you know if you figure out the answer you're going to let us know, right?' 'Ya, definitely will let you know.' But beyond ethical and legal barriers, we also have issues with cultural barriers. And anybody who has had to deal with a physician who might be weary of medical malpractice claims, is already very aware of what these types of barriers can look like. But fear does not just exist on the physician-attorney side, it can also exist on the institution side. So if you have a general counsel or risk management office that is weary of having this third-party attorney wandering around, who might be more attuned to liability, you may not be able to get that same level of integrated care.

But even beyond the attorney, physician, and administrative side, you also have fear on the patient side. We are talking about vulnerable populations, who are already disenfranchised and marginalized and may have had bad experiences with the legal profession already, so they may be less inclined to take up these services. And lastly, I'll talk briefly about logistical barriers. And these can take a lot of different forms, but on its most basic level, hospitals weren't designed to have an entire law firm on site. And so on a very basic level, it's hard to have room for the attorneys to meet and to even have attorney staff on site. And this also extends to the electronic health record. So, the electronic health record would be very expensive to modify, to incorporate any sort of legal information, should that be a direction the medical-legal partnership wants to go. And beyond that, logistical barriers have populated unexpected. So, in one of the interviews, we were talking about limited financial resources, which is a common theme that you will hear in talking about these programs because they are largely grant funded and grant funding is hard to maintain and it's hard to grow with that. And one of the attorneys I was talking to was saying 'an unexpected place I have run into financial constraints is in requesting medical records.' Which is fascinating when you think about attorneys working with a medical provider to represent a patient, but they still have to go the same route of requesting medical records as the rest of us. And she said she had to pay upwards of $2,000 to get medical records in a very specific case. And in some of these circumstances we followed up with these attorneys to figure out if they figured out work arounds to be able to get access to these medical records, and in some small towns and settings they have

been able to develop a sort of back door way to get medical records, but in large cities, they are subject to the same limitations as the rest of us. And anybody who have had to request medical records to support a case knows that its extremely time consuming and extremely expensive. So limited resources are and continue to be a huge hinderance to this sort of integrated care and sharing of information. So what, right?

One of the larger questions that looms in the periphery of all of this type of research is, yes, the literature can identify problems, and yes, we can talk to people about how those problems manifest and we can talk to them about whether they need to address it, but what are the normative implications of this research? And are there certain things we should be trying to do on a policy level to facilitate these types of integrated care? But on the flip side, are there certain things we should be doing to preserve or protect barriers that exists because maybe they exist for legitimate reasons? Unfortunately, none of these have super easy answers, and I certainly can't answer any of them today. But they're ones I want you to think about as you think about whether or not medical-legal partnerships are programs that we absolutely want to promote in the community, and if they are, what types of changes would we need to make. And I also hope that at some point in your life you come back to this idea about what is health and what is health law, and ask yourself if maybe right now, with all the tools you have as an attorney, you have everything it takes to improve the health of not only your community but also your clients. And I would offer that maybe you do, but maybe you don't.

Thank you so much. You can find me at any of these places on the internet. And also, if you are interested in the results of my research, which is still on going, it will be published forthcoming in Northeastern University Law Review. So if you want a copy of that, I look forward to sharing it with you when it is done. And here is a look at some of the sources I cited today. I hope I stayed on time, are we on time? Oh, anyone have questions? I need some water, but does anyone have questions? I am actually going to get that while you all think of all the important questions you have.

Question from Audience: "So have you come across any medical-legal partnerships that have worked outside of hospital settings?"

Professor Van Horn: "Yes."

Question from Audience: "And what kind of settings have those been?"

Professor Van Horn: "So, some of them will work with clinics that stand alone in the community, so they aren't necessarily in a hospital setting. So we've interviewed one or two attorneys that were the legal aid office has partnerships with independent physicians in the community, and those are usually with specialized patient populations."

Question from Audience: "Are those referral models?"

Professor Van Horn: "Those are referral models, yes. Actually, it was partially a referral model, and partially a, one of them was a referral model and one of them was a law clinic base model. They're all referrals that are not imbedded, so they end up getting the patient's information and contact them directly. Which has proven to be like a really hard thing with contacting patients when you have a referral model, and I'm going to go off on a tangent here. This also goes back to the idea of logistical barriers. So even something as simple as having a similar email address or phone number as the medical provider will increase the amount that these patients are willing to even pick up the phone or respond when you are referring to an attorney. So that was an interesting thing that came up in the context of these referral models that have a high level of attrition after someone has been screened positive for health harming legal needs. So there are different creative solutions that you can come up with if you can't physically be on the site. I hope that answered."

Anyone else? Anyone want to know anything else about qualitative research?

Question from Audience: "I'll ask. How much participation do you have and do you see in these legal partnerships? Are attorneys turning up for those as much as other legal aid or volunteer organizations?"

Professor Van Horn: "So, the problem with medical-legal partnerships is the onus of funding often falls on the legal provider. And so you see a lot of legal services providers partnering with it because they have some of the funding necessary and the resources available to do these types of services. Same with law schools, so they may be able to as part of their educational initiative may be able to fund parts of this. So yes, they are getting a lot of attorneys that are interested in this. On the pro bono side, there are certain benefits to getting private attorneys involves, and this also speaks to the funding issues. There's a direct link between promoting pro bono work and becoming future donors, so there's a big push towards getting private attorneys involved in these types of programs too."

WHOLE HEALTH: A COMMUNITY APPROACH TO HEALTHCARE PANEL

PANELISTS:

TERA HAMBRICK, *MATTHEW WALKER HEALTH CENTER*

MARK ISON, *SHERRARD ROE VOIGT & HARBISON, PLC*

DR. JEANNE JAMES, *STATE OF TENNESSEE, DIVISION OF TENNCARE*

CAITLYN PAGE, *WALLER, LANSDEN, DORTCH & DAVIS, LLP*

WILLIAM WRIGHT, *PREMISE HEALTH*

Moderated by Taylor Wilkins, Riggs Davie PLC

FEBRUARY 8, 2019

Larry Ramsey: I would just like to take this time to welcome everybody once again. My name is Larry Ramsey, I am the Symposium Director for the Health Law Journal. So, thank you all for being here. I would also like to make a quick announcement about our C.L.E. form. We are actually going to have the segments listed, and we are actually re-print that an distribute that to you guys so you can check each segment if some of you have to leave early or something like that. And we will distribute that to you as soon as we have it. So, without further ado, I'm going to go ahead and introduce our moderator, Taylor Wilkins for today's panel discussion. He's going to kick it over to the panel. Taylor is a founding member and former managing editor of the Belmont Health Law Journal. He also holds a degree in finance from the University of Tennessee. Prior to joining Riggs Davie PLC, he served as a law clerk for the Honorable Frank G. Clement on the Tennessee Court of Appeals. Taylor's law practice focuses on three main areas: business transactions and counsel, start-up companies, and private investment funds. Taylor assists his business clients with many different legal issues that arise during a business' lifecycle. Taylor helps the business with formation, day-to-day legal issues, and exit strategies. Taylor also represents both buyers and sellers in mergers and acquisitions. In addition to assisting businesses and start-up companies in corporate transactions, fund-raising, and mergers and acquisitions, Taylor also focuses on advising private investment funds. Taylor assists private funds with fund information, structuring, and compliance. At this time, please help me welcome Taylor Wilkins and he will introduce the rest of the panel.

Taylor Wilkins: Thank you very much for that introduction. As you can tell I don't practice in healthcare, but I am very honored to be here today, especially to be able to see how the journal has grown and where we are today. I am also very excited to have such a wonderful panel here to talk us through some exciting issues with these social determinants of health and how our healthcare system is changing. With that, I am not going to read five different bio's. I am going to kick it to our panel here and let them introduce themselves. Maybe we can start on the far end down here with Tera, please.

Tera Hambrick: Hello everyone, I am Tera Hambrick. I currently serve as the Director of Affairs and General Counsel for Matthew Walker Health Comprehensive Health Center. [1] It is a federally qualified health center here in Nashville, our headquarters are here in Nashville. We have three other locations, one in Montgomery County in Clarksville, and one in Rutherford County in Smyrna, and we have school-based facility in Pearl-Cohn Entertainment Magnet High School. So, we have those locations throughout the Middle Tennessee Region. I started with the organization in 2010 and developed the in-house legal services. I am a native of Nashville. I earned my Juris Doctor from Vanderbilt University Law School, I am a classmate with Mark Ison, 2004. I graduated from Fisk University and received my B.A. in political science and psychology. That's the gist of it from me. I guess for fun I like to do indoor skydiving and hang out with my six-year-old great niece.

Caitlyn Page: My name is Caitlyn Page. I am a partner at Waller in the Healthcare Compliance and Operations Group.[2] I represent many of those dinosaur health systems that Larry was talking about earlier, help them work through all of the compliance issues that they might have and trying to keep up with the increasingly complex regulations applicable to hospitals today. An increasing part of my practice is representing providers who want to do direct-to-consumer care. I effectually call it "retail medicine," kind of cutting out the payors. So, that's been an exciting new thing that I've been seeing in my practice. I'm also a Vandy Law grad and I like the idea of saying something fun. I really like to do event planning on the side so: baby showers, parties, weddings; I've done a few weddings.

William Wright: Good morning, I am Will Wright. I am the General Counsel Secretary for Premise Health.[3] Premise is unlike any of the other healthcare providers that anyone has probably seen in Nashville. We are a direct-access model for self-funded employer plans. So that's a mouthful, but what it essentially means is the evolution of the factory nurse has grown into what is now 600 locations. We do occupational health, we have patients that are out

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[1] *See* http://mwchc.org/.
[2] *See* http://www.wallerlaw.com/Services/Healthcare/Healthcare-Compliance-Operations.
[3] *See* https://www.premisehealth.com/.

of our homes, we have pharmacies, representing about 6 million lives. So instead of going through a T.P.A. or a commercial payor, we contract directly with the employer, so a large manufacturing facility or large corporate campus. We will put in a health services clinic, fitness center, pharmacy, wellness, yoga, chiropractor; a lot of different things that address a lot of different avenues for impacting the health of a work force. There's a convenience factor, but there's also productivity, and there's a retention element to it as well. I've been there since 2014, before that I was Chief Legal Officer for the Little Clinic which is a retail community care clinic. Native Nashvillian. I took guitar lessons for a 1926 Grand Ole Opry cast member when I was a wee lad.

Dr. Jeanne James: Good morning everyone. I am Dr. Jeanne James. I am the Chief Medical Officer for Blue Care which is one of the Medicaid-managed care organizations that manages TennCare members in the state of Tennessee. [4] We are responsible for about 600,000 members within our plan. I've been at Blue Care since – for about five years now, but I spent another five years as a Medical Director with the TennCare program, so have had significant time with that area. I am a pediatrician by training, and I went to medical school at the University of Alabama in Birmingham and did residency training at Tulane in New Orleans. If anybody wants to talk disasters, you can see in my bio that I was Chief Medical Officer at Tulane during hurricane Katrina, which is how I ended up here in Nashville after the hurricane, so we can talk that on the side later. I guess I get a bravery medal today for being the doctor in the room of lawyers.

Mark Ison: I'm Mark Ison. I'm a partner at Sherrard Roe Voigt & Harbison and relevant to this, I work in our healthcare operations and regulatory group.[5] I do a lot of mid-market small-market healthcare M&A, lot of venture capital work in this space, with start-ups, a lot of work mostly with non-hospital providers. One of the things I'm proud of is I'm delighted to have the opportunity to teach here at Belmont as an adjunct faculty member in the Health Law program and to see the fruits of the hard work a lot of the current

[4] *See* https://bluecare.bcbst.com.
[5] *See* https://www.srvhlaw.com/.

and former students that I've had the pleasure to work with here. It's very thrilling to see that and I'm very grateful to be here. Wow, we've got to come up with the interests. Classical music and anything in the outdoors.

Taylor Wilkins: Well thank you very much. We've had a lot of talk today on how healthcare is changing and the social determinants of health. Dr. Folwer, Professor Folwer gave us a very good demonstration of that so I'm not going to go into detail on that. But with all of this conversation in the healthcare circles about changing the way we address healthcare, what are you seeing with your practice and your clients that may be examples of how the industry is starting to think differently?

Tera Hambrick: Well I can start. For our organization, because we are a federally-qualified health care center, of course social determinants of health are always a factor in how we structure our care model. We definitely are focused on an integrative approach in a patient center. We are a patient centered, primary care medical home. So, we always integrate some of those considerations about food insecurity, housing stability, and what we've recently done in one of our truly successful projects, we partnered with Second-Harvest Food Bank to have a food pantry on site.[6] So, for those patients who have, are screened for food insecurity, and also have chronic diseases such as cardiovascular disease or diabetes, they will actually have access to the food pantry to go there an select food items that are inclusive. So those efforts are in-house on-site an integrative. We have social service workers who are present and can actually come down and talk with the patients when those clinicians identify those determinants that are present or are higher risk for the patients. They are to connect the patients with those resources. Of course, that requires for us to think creatively about the private and the partnerships and funding. One of the things that Professor Fowler talked about is the funding challenge. Those things are usually grant-funded so we don't have a significant– there is no reimbursement for that social worker's services. So those are things that we have to find extraneous revenue to actually supplement the salary of that social worker. And of course, it's one person. I

[6] *See* https://www.secondharvestmidtn.org/.

mentioned that we have four sites, we have four access points. Those services are strained sometimes because we don't necessarily have the ability to have that integrative model available at all times for every single patient. But where we can, we deploy those resources. So, it makes you think creatively about how to integrate the model and, of course, aligning resources to make it a possibility.

Dr. Jeanne James: I think for us as we've done as a health plan, case management services for members with chronic disease, we've realized, certainly for a long time now, that it's very hard to get a patient to or a member to think about making a change in their diet or their medication regimen if what they're worried about is whether or not they're going to be able to pay their rent or whether or not they have food access. So, we very often we have to solve or address those kinds of issues before we can even engage a member in anything that's medical. I think for us, we think about as a health plan as having list of resource of providers, but our inventory now of community agencies and partners like that for us to partner and work with and refer members to is probably just as big as our list of providers now because we've got to address those things before we can even get someone's attention about something that's a health need.

William Wright: I would say for our clients which are the employers, we see them increasingly focused on not just a medical model, but that integrated touchpoints. We have some that are very invested in lifestyle medicine, which is forks over knives, and we have gone so far, we hired registered dieticians, chefs to help people to learn how to cook within rural communities where they don't have access to a lot of things, not quite food desserts but pretty close. I think they're starting to see the value in bringing that into an integrative model and we do some of the condition management with the pharmacy.[7] Having access, and our model is a essentially on-site work clinics, so its where the people are showing up to work, and being able to reach out and have a constant line of communication with that work force and to reinforce those messages of health and wellbeing, I think we are able to see some

[7] *See* https://www.forksoverknives.com/.

outcomes that are sort of outliers. We really focus on that constant contact point and communication and reinforcing those good habits.

Mark Ison: And I would say from the other direction, seeing a lot of entrepreneurs really starting to push against the current payment models. They're thinking maybe even more aggressively than government and payors in terms of outcomes-based care, and bundled payments and coming up with ways to manage certain disease states or certain conditions that are multi-disciplinary that just wouldn't work in a fee-for-service model at all and they're being aggressive and actually going out and negotiating with payors. To say "here's what we can offer your members who have this condition or who are dealing with this type of factors" and actually pushing from that direction and saying "we have a better mouse trap, you know, if you'll come up with a way to pay us for it, you know, let's talk about how that could work. We think this will be a mutually beneficial arrangement." We are seeing more and more of that and that's really exciting as well to see the innovation coming from that direction.

Caitlyn Page: I would say, on the hospital side, my clients are, especially with this, movement away from fee-for-service to paying for quality, my clients are starting to recognize the importance of addressing factors outside of just the episode of care. Especially when you as a provider are going to be responsible for paying for any complications that arise out of a procedure, that's really helped my clients to start to pay attention to what causes these complications, what is causing these patients to have issues that make them come back. Currently the legal landscape is very challenging for hospitals to do a whole lot about that, but we are seeing some movement from the government in the form of new safe harbors and exceptions. I have seen several clients getting out there and trying to do things like transportation programs to help those who don't have a car get to their appointments, discount programs for certain patient populations to help them get access to healthy food, so we are definitely seeing a shift in our world as well.

Taylor Wilkins: Recently, H.H. Secretary Alex Azar stated that Medicaid may soon Medicaid may soon allow hospitals to health systems to directly pay for housing or healthy food or these other

solutions we've discussed today for "the whole person."[8] I know we've kind of addressed it throughout the day, but what's the theory behind that statement maybe why now is the time that we've really made a push for that? Dr. James I'm going to single you out on this one.

Dr. Jeanne James: Okay. Well I think, and we've done some work recently in our health plan around members who frequently utilize the emergency room. Folks are going to the emergency room every two or three or four weeks and we look at a very long list of chronic conditions that they may have. But when you actually meet with those members and talk to them about why they're going to the emergency room, it's because they've run out of food. It's because they're lonely and isolated. It's because their caregiver is exhausted and needs rest bed and so they just come to the E.R. So it's really just been eye-opening for us to see and while you look at all these diagnoses on these E.R. claims, the real reason that they're coming there links much more back to these sort of social determinate-type issues, and we've got to solve those problems. You know, maybe it's somebody whose housing is unstable and maybe they can stay on somebody's sofa for a couple of weeks but when they get tired of them, then they end up in the E.R. again. Until we solve the housing issue, we are never going to solve that recurrent use of the E.R. I think that's true of lots of Medicaid programs and I think that's part of why C.M.S. that has started to recognize this. One of the things that I'm interested though, in then, if those then become things that we include in our services, what's the end point? How do we categorize those things and what do we include and not include? We've seen in Medicaid for a while now, we already do cover some housing services, we've covered transportation for a very long time, but we cover some things now that we call "supported housing" that are for people with chronic mental health conditions that have some supervision of medication administration and that sort of thing. I think we're starting to see that. Some of you may have seen a news article not too long ago that Kaiser bought an apartment building a

[8] Paul Barr and Virgil Dickson, *CMS may allow hospitals to pay for housing through Medicaid*, Modern Healthcare (Nov. 14, 2018), https://www.modernhealthcare.com/article/20181114/NEWS/181119981/cms-may-allow-hospitals-to-pay-for-housing-through-medicaid.

few weeks ago in the California area.[9] I think we are starting to see even big health plans thinking about housing in particular is an issue that the default very often becomes the E.R. if that's your challenge.

Taylor Wilkins: I guess we have talked about it a little bit but, is C.M.S. the best agency to be dealing with this? We have other agencies to deal with housing and deal with nutrition, should healthcare be the one that's stepping in and saying, "yeah we'll find you adequate housing."?

Dr. Jeanne James: Yeah, I don't know that I know the answer to that. I do know that we as a health plan have recognized the need that, I spend as much time in meeting with the United Way and the food banks and those kinds of folks as I do with providers today. Because, particularly for our population, those are the kinds of resources that we really need. So, I think we sort of recognize that we have to have that broader view. Professor Van Horn mentioned earlier about those studies and it really is true, the medical intervention is about 10% and genetics is about 20% and the rest is all environmental and social factors, so we've really had to add that to our spectrum. But whether it's for C.M.S. to reimburse for those things or for us to find more ways to not be siloed and have us work more closely with those who do housing and those who do food and those sorts of things, I'm not sure where we'll end up but I am excited that that's the focus now because I think that that's where we need to be. We as a health plan have recognized the need that, you know, I spend as much time in meetings with the United Way and the food banks and those kinds of folks as I do with providers today. Because, particularly for our population those are the kinds of resources that we really need. So, I think that we sort of recognize that we have that broader view. Professor Vanhorn mentioned earlier about those studies, and it really is true that you know the medical intervention is about ten percent, and the other ninety percent is genetics about twenty percent, and the rest of it is all environmental and social factors and so we have just really had to

[9] Kimberly Veklerov, *Kaiser funding helps keep Oakland apartments affordable for 50 residents*, San Fransisco Chronicle (Jan. 15, 2019), https://www.sfchronicle.com/bayarea/article/Kaiser-funding-helps-keep-Oakland-apartment-13536854.php.

add that to our spectrum. But, whether it's for CMS to reimburse some of those things or for us to find more ways to not be siloed and have us work more closely with those who do housing, and those who do food and those sorts of things. You know, I'm not sure where we'll end up. But I am excited that that's the focus now because I think that that is where we need to be.

Taylor Wilkins: Well I won't continue to single you out Dr. James, but not being in the area of healthcare, I remember somewhat from law school that I had Professor Ison, a very good professor. So, in recalling these, what are some of the federal laws that inhibit some of these things? Trent just mentioned transportation, we have mentioned housing, what are some of the federal laws that prohibit providers from actually providing them services currently?

Mark Ison: I can start off. In addition to the fact that the way the statutes are currently written I don't think there's federal funding, FFP, housing is not eligible for FFP under Medicaid for instance. But, from more provider specific categories, I mean certainly we have laws in place that would affect CMP (Civil Monetary Penalties Act) that would prevent a provider from saying, you know, in some cases, "Hey, let me help you out with that." You know that can be an inducement to a beneficiary.[10] Now whether that's helping somebody out with a social determinant of health, a social need impacting or medical care should be looked at that way. That's certainly something for further discussion, but the way that it's currently written, other than some narrow categories for things that you can give to pregnant women for instance to encourage them to take advantage of prenatal care. Limited transportation, carve outs missing in the Anti-kickback statute (Inaudible). You know there are some very specific things, but, usually government is really lagging behind. The Anti-kickback Statute, the Stark Law, a lot of these regulations are sort of, years ago, Professor Glenstine at Vanderbilt would call it the "Soviet Style of Regulation."[11] Everything is illegal. Except for what we say is legal. So his point there is that under those laws it is all forbidden, you can't do any of these things. There is no flexibility, except for the twenty-eight safe

[10] 42 U.S.C. §1320a-7a.
[11] 42 U.S.C. §1320a-7b(b); 42 U.S.C. §1395.

harbors and the twenty-nine Stark exceptions and some guidance from the OIG on this or that.[12] So that structure is definitely slowing things down in terms of the ability to find ways to provide these additional non-medical benefits to patients.[13]

Caitlyn Page: You know, compounding the problem is that even when there are exceptions set forth the OIG declines to define any part of the exception. So CMP does have some safe harbors for financial need but they refuse to tell you how you can determine financial need. But, if you do it wrong, then you can be subject to some severe penalties, possibly exclusion. So, it's very terrifying for clients, especially those who have targets on their back already just by virtue of their size and the nature of their business to, you know, get out there and just try something new and just hope the OIG thinks it's okay.

William Wright: I was going to say, even where there are exceptions and preventative incentives or something for preventative care, you know, what one agency may give the other takes away. DOL will look at some biometric incentives or something for meeting certain health standards with a suspicious eye that you're collecting some information that can be used in an ADA or Gina ill manner, so it's not just one hurdle you kind of have to look at them all together. So, sometimes people just throw their hands up and say we don't want to even get close to it.

Taylor Wilkins: Would there need to be maybe specific waivers that the government could come out with guidance, or would it just need to be complete reform on those?

William Wright: Inter-agency communication I think is what we have not seen.

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[12] 42 CFR §1001.952 (Safe Harbor provision of The Anti-Kickback Statute); 42 CFR §411.357 (Exceptions to Stark Law).

[13] Office of Inspector General, Dept. of Health and Human Services, https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp (last visited Oct. 6, 2019).

Mark Ison: That is true. You know, something as simple as employee wellness programs. They have shown to be effective. Get people out there providing employees with better food and options at lunch and exercise opportunities and helping them, encouraging them to do things like a health assessment and understand what morbidities they may have and how to manage high blood pressure. You know, things like that. Something as simple as that runs into all sorts of issues with the ADA and with HIPAA. There is guidance from CMS, there is guidance from the OCR, there is guidance from the department of labor and none of it dovetails. You are constantly wondering, "Well when they said it this way and they said it this way, do those two things mean the same thing or do they mean something a little different?" So what is the least common denominator for what I can do for my program? So to your point, interagency communication would be key.

Caitlyn Page: Stark and Kick-back (inaudible) in particular they are so very similar, but so different once you get down into the details, and I think I read that right now CMS and OIG both requested comments on potential proposals to deal mostly with coordination of care but presumably as part of that dealing with some social determinants of health, so I'm hoping that the timing seems such that they are considering trying to keep things in line with each other which would be extremely helpful if they could do that.

Tera Hambrick: I too am hoping that there be some specific guidance that addresses these unique situations that are coming about to talk about the pilot program that CMS is doing in some states where the programs actually allow for direct payment of housing costs. You know, that is in itself is unique and it's not just providing food. That's a healthy option to the patient that's directly tied to their diabetes case or improving their health outcomes that you can measure pretty quickly. So that's something that's so unique that I think that we really need and are hopeful for some specific guidance on those types of things that we will be including on our platform as we provide our model of care.

Taylor Wilkins: For our panelists who represent either insurers, providers who are not really tethered by the Medicare or Medicaid,

what are you seeing in the industry that is shifting to this kind of thought, this outcome based, social determinants of health thing? Will you kind of touched on what Premise health is doing, what exactly is how the industry responding?

William Wright: Well, I think the number one thing is the fundamental economic model; sort of what Larry was touching on, we don't do fee for service, we build a capacity model. So, we work with a client to develop what sort of their outcomes are. Start with a goal and start with a target. But, we don't bill fee for service. So, again our average patient visit is 27 minutes, 30 minutes, probably 40 minutes on the first visit and the following visit is an average of about 27, 30 minutes. So that the physicians don't have to meet the grind of clicking people through and the staging between a nurse or nurse practitioner, a PA. The physician and the escalation model is totally different and we just see better results with the more time we can spend and then some of the inter-coordination we have with pharmacies and the ability to use pharmacists to help with condition management stuff, they are a fantastic resource. So the more communication and the collaboration we have with them and our pharmacies are also on site. So there is just a care model there that isn't based on fee for service, it is not based on volume. Then we have performance for guarantee so if we don't reach the outcomes or show a savings then we haven't a financial incentive to meet that, but it's quality driven it's not volume driven so it's a model that is working for us, it's working for our clients and employers. How it could be expanded in the community or in a different scenario is yet to be seen. It's very interesting to not be tethered to the fee for service model.

Tera Hambrick: In the community health center context it is a little bit different because you do have those quality outcomes and those are driven by the progress of the patient. At the same time, you do have service that you have to deliver to a certain number of patients to continue that federal funding that we receive in order to provide the subsidized care. So, volume is at the same time tied to these quality outcomes. But, what it really drives is how our teams are structured so we are looking at and considering the medication therapy management with the pharmacists, so we have clinical pharmacists that we're recruiting so the actual structuring of your

clinician and your care team, that model of recruitment is different so you are going to have more social workers on your staff, you are going to have those clinical pharmacists, and those case managers who are important in terms of coordinating the care. So the care team for the patient is driven by the level of staff that are actually following the patient after the visit. So they are following up to say , "hey did you get your prescription, are you doing those things," so the care is starting with the clinicians inside, but those that are following up after they leave the clinic, so a lot of the work happens after they leave that point of care.

Taylor Wilkins: To the extent that we are starting to get more changes to the reimbursement structures and specifically ones that include reimbursements for these social determinants of health programs, what potential abuses do you guys see these health care programs? I know that a lot of the anti-kickback or fraud abuse statutes try to prevent these things, but I don't know how that is going to adjust to reimbursement for these social determinant programs.

Mark Ison: Well as long as you are going to reimburse for service you are going to have those same problems, you are just going to shift them into other areas, right? Now you are going to have housing fraud, and unnecessary food. I don't know, make it up. There's no end to the creativity of the criminal mind, right? Lex Luthor, the criminal genius has to be a bigger genius than the regular genius. And, people will come up with ways to abuse the system. I think fundamentally for a lot of this stuff to work, you've got to move away from fee for service and toward an outcomes-based reimbursement and wow… that's intrusive (inaudible). How do you do that? If I knew, I'd be on a beach somewhere. The fact is that if the government healthcare system is going to move into more and more and more and more of the rest of our lives, you can't just keep paying people for input, you've got to pay them for the output. I think you can back into the rest of it from there, but I think that is the only way, personally, that it's going to work.

Caitlyn Page: You have your standard issue of people who are trying to get a particular patient population, so they are going to offer benefits to those people but not these other people who are

financially less desirable patients, and that's always been an issue. I think that is in part what CMP laws were designed to protect so the more you open that up there is obviously a potential for further abuses, but that's true with any innovation and I feel like we should start by solving these problems and then we will deal with those when we get there. So, see what kind of abuses are coming up, you know that's how the home health space became so much more challenging, is we opened it up and realized like oh it's really easy to take advantage of this system, let's ring that back in.

Tera Hambrick: The other concern that I think ties into what I think Dr. James talked about, how do you know when those supportive services should reach an end point? So, in terms of what's a reasonable amount, is it six months of housing support or subsidies? Is it a year? How do you determine what the cutoff is to provide those additional points to address in social determinants of health? So, there you are going to get to the point where you have this ballooning cost because you have to define where there is a bright line as to where you do it and it is going to be different for every patient. So, I think that factors into how some of these services can bleed over into abuses and how does the government regulate that in a way to make it fair to the patient to actually support true quality outcomes in the patient's care. That's the biggest question I think is going to come out of that too.

Taylor Wilkins: And on the opposite side of that, what are some of your clients fears with reliance on these outcome-based reimbursement models. I mean it sounds great, but when you start putting it in practice, what are some of the issues the clients face or just their concerns moving forward?

Mark Ison: I think it's a lot like when teachers get upset about compensation models based on educational outcomes. I mean the human is a complicated animal, and health is a complicated thing. When you decide you want a pay based on outcomes, you have to decide who is responsible for the outcome. You have to decide where to put the incentive, or the punishment. Like the carrier or the stick, and where does it operate? Who gets punished financially if things don't turn out the way they could have, or should have, or might have? Is that person the one who had the ability to control

that? So, one example, just a small micro example. I've worked with a relatively small OBGYN practice in a rural part of Tennessee. Pretty much the only game in town, in terms of OBGYN. They see a lot of TennCare patients and TennCare implemented their episodes of care program where childbirth (OB) is paid based on… your payment to that can be, I think increased or decreased, based on cost of caring for the mother and the child from the period of time, I think it is a couple of months even prior to pregnancy through a couple of months afterward.[14] The doctor who does the delivery is the one who receives the incentive or the punishment. Well, this OBGYN practice, and we actually were on phone calls with folks at TennCare about this, were upset because they were not seeing the patient in many cases until midway through pregnancy. There were months that went by before the patient had even sought prenatal care. In some cases, these were mothers, well, I mean it is the same social determinants of health we are talking about, in many cases they were on TennCare. Many times they were lower income, they had housing issues, they have domestic issues, they have other financial issues, they have opioid addiction, you know all of these things that tend to… you know, Charles Marie would say in his latest book a clustering in these certain parts of our country. They said, "What are supposed to do about that? You say that you are incentivizing us to practice more effectively, and to deliver better outcomes, but we can't impact some of these outcomes. We can't impact whether someone has gone to the emergency room for routine care five times before they ever come to see us. We can't guarantee you that they are going to show up for all of their prenatal appointments." So, that I think if you are going to start moving into that model you have to think critically about who is responsible for various aspects of the outcome and how you parse that in terms of the financial or other incentives.

Caitlyn Page: And I would say that the way that CMS is implementing pay for performance now is … you know I think some people would question whether the right way to do it is to just piece by piece by piece. We're going to do joint replacement; we're going to do this cardiac episode. The individual programs they are coming up with are extremely complicated, very difficult to stay in

[14] TennCare Episodes of Care, https://www.tn.gov/tenncare/health-care-innovation/episodes-of-care.html (last visited Oct. 6, 2019).

compliance with. They do come with some waivers from the fraud and abuse laws, but even those, I was looking at the one for BPCI advance, it's 25 pages just explaining the waiver itself.[15] So, I think a lot of my clients are very concerned about trying to stay in compliance with the existing healthcare laws and all of these additional layers that CMS has put on top of them. Not to mention the coordination of care issues. We've got HIPAA and all these other laws that really make it difficult to work together and we have to invest a significant amount of money in infrastructure for EHR and data management. Which, those EHR companies have been getting hit a lot as well. It is a little bit of a scary world out there, and I think some of it is by verge of the fact that CNS is doing one thing at a time and not really looking at it globally.

Mark Ison: It creates a lot of jobs for lawyers.

Dr. Jeanne James: I think too that it's systematic of the fact that we are trying to accomplish some pretty significant transformations, but the current processes still have to go on. So we are living with one foot in each world right. So you know, ultimately, and even if you get back to the example about episodes what we are hoping to transform care to be is that you know a provider has a panel of patients that are their panel that they have you know responsibility for and then benefit from the successes in their improved outcomes. But we still live in a world today where things don't start until the patient shows up. You know, so um, so things like a practice move to do this sort of outreach that my health plan does today to try to get people into a visit. You know, we're still living in that, in that, transition world of you know, how we look at, um you know, do providers just see one patient at a time when they come in the door, or are we going to move to something where it's a panel or a population of folks that they, manage and then we can measure and build these programs of the . . . . It's really hard to be in the middle of both, you know.

Taylor Wilkins: So in these systems, where do the social determinants help play into these reimbursement models? You know if you got your situation where someone comes in and they haven't

[15] Bundled Payments for Care Improvement Advanced (BPCI Advanced)

been going to prenatal care, they haven't been doing that does it need to, does the reimbursement need to be adjusted for that? Is the? Does the, do the social determinants of health need to be ahead of that time where they are making sure that patient is in the hospital earlier? Or is it something where you've got maybe a bundled payment system and part of that payment is for things such as prenatal care and I mean where do the social determinants play into the outcome space?

Dr. Jeanne James: I think we are just starting to develop the tools to keep track of those things, you know, in all of the value based in outcome and payment models. You got do some risk and adjustment right? You can't just say that all patients are the same, you got to account for the fact that one provider that takes care of a lot of really sick people, then I want that counted into my risk adjustment so that the outcomes and the successes are measured fairly. And I think that many of these social determinants are in fact other risk factors, right? But we haven't had a way until recently to have codes and ways to keep track of those things for us to take those things into account. So I think that is one of the things that, that I hope will be into, to increase soon so that we can, you know, we can take that into account and give a provider credit for that. The fact that you manage this difficult homeless population, or you managed this difficult population that also, you know, has, some other concerns so that we can factor it into, into those models.

Mark Ison: And there is already some of that right? I mean, you know hospitals get paid more for taking patients that come in with this list of preexisting conditions and this media health care issue that they do for somebody without those things. And you know, physical therapist, when a patient comes in they have to evaluate that patient, and say "where are they now?" And based one where they are now, based on that indicates where they have to go. And that indicates, you know, the way the reimbursement is going to be. So, maybe we will have ICD 11, you know it includes all sorts of other social determinates in health, in addition to being attacked by an alligator.[16] Which I think it is one that we tend, yeah.

[16] International Classification of Diseases, 11th Revision, https://icd.who.int/en (last visited Oct. 6, 2019).

Taylor Wilkins: You know we've talked about it a little bit today and how technology really plays a role in tracking and telemedicine how is this really changing the world of health care? Um, what are you seeing in your practice in ways clients are responding to new technology as we move to telemedicine and, uh, other aspects? So, so what are your clients seeing or what are you seeing from clients?

William Wright: Well for us, we just made a big investment in epic bariatric care shop primarily. But any secondary, tertiary any health systems we want to interface with more or less epic has won that battle. And so for us to be able to communicate, and the meaningful use did a lot of good but it also scrambled the field a lot so there are a lot of dispirited systems that do not talk to each other, um inapproachability really has kind of come out of that as a project, uh as goal result. So, it allows us to do a lot of good things with the local health system so we can see if there has been any ER visits a scan that we don't have to reorder, there is a lot of savings there. And then the virtual health, telemedicine angle of it. You can distribute your capacity, among the geography. There is restrictions on, you know, state licensure and the federation model that's allowing more and easier access for uh physicians to practice across state lines. That's still an issue, but we're making progress. I think it's, you know, five years ago it was the next thing and then it stalled for a little while and I think it's back. I think the expectations are lowered to quote Larry. But I think it's, it's not going away. And so technology is going to be used in every interaction you know we see in the physician care provider interaction encounter.

Mark Ison: Even outside of reimbursement, you know, technology can be used in ways that you don't really pay for. I mean obviously, uh, it helps to get paid for them, but in a lot of cases you know. . . . And you called me professor earlier and I do not claim that on a rarity, you know, the title. One of the reasons is that I don't put the work in that professors put in right? I did teach a class, but I don't do the research so I don't have research on this. But my thought is that, you know, touching an encounter with a patient in terms of compliance with the health care plan, in terms of checking in with them to see if there are things that can be helped. Can you, in today's environment, can you refer them to, um, a medical legal partnership,

can you refer them to a housing agency? You know, some of these things you would have to do now. And technology can help with some of that in ways where the patient doesn't have to come into the doctor's office every day. Maybe there is a, maybe there is a transportation issue you know? But everything doesn't have to happen in the doctor's office, and so if what you've done is, and this is what I mentioned at the beginning, when I'm seeing this with some startups that are coming up with different ways to deliver, um, care and certain limited circumstances, and going to payers and saying "here is what we can do, and let's come up with a way for you to pay us for it because I think you're going to save money in the long run." And what these innovators are doing is saying, "Look, you know, we can communicate with that patient and using social workers and lawyers and you know, chaplains and whatever else you need. We can do that through video conferencing, and we can use wearable tech to keep track of people, and as long as there is some way for that to be financially viable, it doesn't have to be even in the current, you know, difficult state of telemedicine reimbursement. It doesn't have to be the doctor actually doing a diagnosis over Skype or over a telemedicine platform. So that's another way that I am seeing it used.

Caitlyn Page: And I think that, you know, in addition to making access to care easier, uh, technology has really helped in the data management side of things. You have to think about physicians' offices with paper records and nobody was ever sharing anything, you don't really learn a lot from that but now we are having you know, EHR systems in place to share information. You know, the law is still trying to catch up with that but uh there are opportunities now to start learning from what we are seeing and sharing that information with each other in way that we haven't been able to do before. And I think that's one of the big drivers of you know social determinates of health becoming so prominent is through starting to realize that this is a, this is a, big issue. That this is what is causing a lot of our unnecessary expenditures a lot of visits to the ER which you know, as a hospital you have to, you have to treat them no matter what their situation is financially, and so it's you know, ringing in ER visits is in everybody's best interest and learning how to help in other ways helps with that problem. And technology is really creating some opportunities to do that.

Tera Hambrick: One thing for technology and opportunity, and I know we keep saying that it's a lot, but there is so many parts of the equation to have to catch up to what we are already doing. When you talk about the social determinates of health and all these different partners of stake holders that come to the table the EHRs and the technology that is out there isn't built towards their focus and their work. So it's catching up it's a lot of times in our practice and lots of practices around the country the record keeping is disjoint. So, tracking some of those outcomes takes a lot more work, so it's labor intensive and that can be one of those factors that's a little discouraging. Because you have the social workers' report center here and they're not in a coding field, where you can mine that data very easily and so it takes a little bit of manual labor. So trying to take that component out of it is what the commissions and the other providers are asking or the stake holders are asking to see and hopeful that it's coming pretty soon where these EHRs will become some open type of network where all of these inputs can come in meaningfully spit out outcome results that you can quickly adapt and change your strategy with the basic population.

Caitlyn Page: And I think the OCR is actually currently requesting for proposals to help them deal with the coordination of care issues in relation to patient privacy so that's kind of been exciting to see that they're going to pay attention to that. I think that they are started to recognize that even if you can with health care operations sort of cobble your way towards a compliance situation that a lot of people are afraid to do that especially with the stakes these days and penalty that are closing so. It sounds like they're actually going to start thinking about creating some specific, you know, exceptions or permitted exposures in connection to coordination to care would be really nice.

Dr. Jeanne James: That's a particular issue in Tennessee around the opioid epidemic right? Because there are even some additional things, and um, rules about not disclosing because of employment impact and all of those kinds of things. So on the one hand I want to help coordinate care after a patient has had an overdose in the ER but what things can I tell some other provider without needing additional expressed permission of that member? And so, I think it's

another one of those that across agencies you know it is important, and I understand why there is employment protection so that your employer doesn't find out about this opioid addiction issue, but it gets in the way of us being able to get people quickly to care. So there are a lot of those kind of siloed examples.

Taylor Wilkins: Um, and, you know, with that, the technology what are some obstacles that you or maybe your clients specifically facing in trying to develop these laws that obviously move a lot slower than technology does. I mean I know telemedicine there's specific issues maybe with state law that address certain things, so what are some obstacles that your clients are facing with trying to develop these new technologies in the health care field?

Dr. Jeanne James: I think for us at the practice level, and I think that's even with working with practices with their electronic health records is depending on the size of your practice you know hospitals have and IT department to update their medical record and that sort of thing. Um, but um, a medium-sized office practice, you know, then it maybe one of the doctor's is sort of an IT guy on the side, but you know, they don't have that same level of support. So we've actually had to do some of those as a health plan. To sort of help them, you know, learn how to run reports on those EHRs or update it to something that's more useful so there's that whole sort of IT, uh, support need that I think a lot of small multimedia providers feel the pain of.

Caitlyn Page: You know, telemedicine, is a great, a great thing and it really helps you get, um, helps people to get care who otherwise can't make it to a doctor's office for any number of reasons. But the state laws are just now starting to consider making that an option so up until now it's been extremely difficult to engage in telemedicine. Some states have requirements that you have to physically examine a patient as a doctor in order to authorize anybody to treat them, that obviously makes telemedicine kind of useless. So, some states are starting to roll that back or institute new exceptions for telemedicine and others are not. And so, if you want to do something on a national scale it becomes very tricky because you have to go state by state and assess can "I operate here" And if so, "What do I need to change

about my business model to do that?" and often times it is your entire business model has to change so. Which is obviously not ideal.

Taylor Wilkins: We've talked about a lot of the issues with data and being able to move these electronic health records and recently there has been a lot with, uh, these disrupters in the field such as Amazon or Apple with their resources and what they're doing with super data now. What issues do you all perceive arising out of you know them coming into the health care field with the use of data and information? . . . . No issues?

Will Wright: Yeah, and this is aside from the JP Berkshire mega health solve solutions that they are going to come up with. Um, you know, I think they are mining the data, it's there, they're finding out there are startups in play one called X, E, A, L, T, H . . . .Xealth, xealther, cross-out ealther. But they are partnering with physicians, this is exactly, uh, to offer ancillary products, uh nobody represents them, to their patients after you see your physician they will push a panel of not prescription things not DME, but some of those ancillary products.[17] They will show up in an email and they can select what they think is best for you, so it, that is where we start to get into the creepy sort of "why is my physician recommending, you know, this sort of arm brace for me opposed to just letting me kind of pick it out?" There could be some benefits to it, but there could be a lot of inadvertent information that could derive from that. The example of, obviously arm sleeve but, here is the blood pressure monitor you should use for your home use, well amazon might not have the ICD-10 that your hyper tensive or pre-hyper tensive, but they know that you just bought a, that it was pushed through a blood pressure cuff and you know with two or three little cookie crumbs they can piece together pretty quickly what your health status is. So I mean, I'd say we be very careful.

Mark Ison: A couple of things on that. One is people wring their hands an awful lot about privacy and yet we got an entire generation growing up now that has no sense of privacy, right? I mean everything is on, you know, social media and you know you're just sort of out there. Um, we also have, you know, we carry around these

[17] *See* https://xealth.io/.

iPhones, right? And it's very convenient to have Google Maps and Fandango and you know and to have and let them tell you what the movie is showing at the theater near you. You don't have to search for it, why? Because they are tracking your location, you know? It's very nice to have amazon recommend things to you, because they have your entire purchase history. I have always maintained that my amazon history is much more incriminating than my health record. I mean, because they could write a complete profile on me probably. What I read, what I eat, what I do in my spare time, what -- you know. So, I wonder, just wonder I mean I've always felt personally, and this is pretty controversial statement that HIPAA is the biggest solution in search of a problem in US history, right? I mean, don't we have laws that you cannot discriminate on someone based on their health care, you know their health status, right? We have laws that prohibit identity theft and fraud from somebody's social security number and all this stuff. So, I wonder if, you know at the end of the day we've got a society that is kind of moving on a little bit from this notion of everything has to be super-secret. And frankly there is nothing in my health record, and I know that is not true for all people, right? I know that there are some things that carry stigmas and you know, and some people have personal concerns, but I'd say most of us, there is nothing in our health record that would, so what? You know? It's like, so on the one hand, you know, I wonder if this is overblown. I think if our society may eventually realize we are going to have to give up a modicum of privacy in order to have these conveniences and these efficiencies. On the other side of that though is, in our country there is only a couple countries in the world that allow advertising of pharmaceuticals on television. It's us and then I think it might be New Zealand or something, and we use pharmaceuticals at a rate that is you know many many times, ten times more than other countries that do not allow that.[18] Expand that to health care in general and put that in the hands of amazon.com. You know? All of a sudden, we are being recommended a lot more than just, you know, Lipitor. We are being recommended whole suits of health care solutions, shopping carts of health care services or items that you know we need, that they think, we didn't know we needed now we have to have. I wonder if that's not the more

[18] John Marshall, *Why You See Such Weird Drug Commercials on TV All the Time*, Thrillest (Mar. 23, 2016) https://www.thrillist.com/health/nation/why-are-prescription-drug-advertisements-legal-in-america.

dangerous question. It's not that I went to the doctor last year and my cholesterol was a little higher than maybe it should've been. It's that, you know, is that going to damage the economics of our healthcare system moving further? So.

Caitlyn Page: I will say that the data analytics and logistics are you know are a huge part of advancing healthcare and I don't know anybody better than amazon for those services. So if there's a possible opportunity here for Amazon to come in and help address some of the issues that we've talked about with data, managing data, and getting everybody on the same platform or getting the platforms to act together and just the algorithms necessary to take the data and actually do something with it and produce reports and make decisions so it could be a very exciting thing for them to start taking an interest in healthcare as well.

Dr. Jeanne James: I mean even something as simple as scheduling appointments in a doctor's office is really archaic when you think about how other industries handle scheduling. Right? You know? You think its 8-5 it's you know I've got to you know call a week ahead, those kinds of things. So I really think in some ways I've always thought that healthcare was a little too isolated from some other industries in terms of innovation that we don't borrow from other industries for things like that you know were schedule flexibility is much better at my veterinarian's office than it is at my primary care provider's office.

Taylor Wilkins: Well, with that I think we've still got some time, I think we're on schedule. If anyone has any questions, feel free please.

Question: Yes. Its seems that the issues that you're addressing may be two fold. We're talking about what might be going on now, as Dr. James said we've have our foot at one side and then we're trying to look at another side. But when we kind of look at the big picture of why we are even here. You look at children not being able to get fed at school for different reasons. Professor Fowler talked about the MLPs, are there other types of partnerships that we could consider that we could give voice to even help us not in this state? I mean at some point how would we slow down so that we're not in this

constant state? How do we help people not stay in this state of constant need? You know can we give voice to that? I mean it's bigger than us, I get it. But should we be talking school systems are there things that we can give voice to that can help that?

Tera Hambrick: I definitely think it takes a strategic alliance with many different organizations. So yes, we should go to the schools. We should be looking at programs that help deal with early educations and give the support and services that can address those things that keep the student from finishing school. So that's part of what it is. But the number of stakeholders that need to come to the table is broad. You know? It's not just the school. It's also the employer who's work hours don't permit the parents, they're working two jobs and they can't come home and help the student with homework. Or, the child is up late because they're caring for siblings. Its pulling in childcare resources and all that. So it's such a large platform that I think we're just taking one bite at a time. But I do think that organizations have to align, and healthcare entities play a role in identifying what those things are so when you have those patients that come in and screen positive for some social determinates of health risk factors. . .(inaudible) The more integrated the services are the better the outcomes. So one of the things that we do is, we integrate behavioral health at the point of the primary care visits so that when the patient comes in for their physical, they have access to a mental health professional that same day. Because if they are identifying this issue or these stressors at that visit, but you're waiting to get them into care, like someone else mentioned, on the panel, they do make it to that appointment. But if you create the integration right there, there is a realistic arc of actually seeing some benefits as they continue in the process. And it's a slow-moving evolution but it's something that requires so many different stake holders in the community coming to the table: non-profits, the for profit sector, governmental agencies, and all the social services agencies that actually bear on that because it's actually more than one factor that prevents that child from graduating or finishing their education. That's my take on it.

Dr. Jeanne James: I wonder too if the professional education system can help with this some too. You know all of us as doctors, or lawyers, or other professionals are educated in a pretty solid

system as well and if there's an opportunity like the partnership that you talked about with the medical school and the law school and your partnerships. If there were ways to cross people over early in their training, then we train physicians to be used to interacting with all those other types of professionals from the beginning instead of just our lane of this is the thing that doctors do. I hope that at the education level we can see that happen.

Tera Hambrick: That model is developing at the Area Hills Education Consortium so communities throughout the country and Tennessee area "consortium" actually has those students that are in the clinical fields: dentists, physicians, and social workers who all are actually learning those things in the school system and professional education. And then when they leave they are placed in settings such as community health centers and clinics and actually developing that practice perspective before they even start their professional practice.

Question: Many public schools in the state don't have school nurses anymore, I mean that's a frontline position to help families and students in this holistic health experience that we are trying to achieve. So are there any programs to help get medical professionals back in the public school setting?

Tera Hambrick: Yes. I will try not to monopolize. So again there are safety net providers like community health centers and the governmental departments that have some resources to make physicians available, there are options to do that. But when that community health center establishes a school based clinic, the model is geared toward the students. But you have to think outside the box: is this model profitable? Does this work in terms of us allowing that amount of resources for the number of students that actually access the care there? So in terms of the business model, thinking about how that works. How do we expand that beyond just the student? We want the teachers and the professionals that are in the school to actually access the services too. Can we open that to the community and make it a model of something that fizzes out. Because that's what happens a lot. We actually have an access point that is available but then the model is not sustainable. So in order to make that sustainable, how do we reach a diverse patient population outside

the four walls of the school? But yes, being there integrated to the school makes a difference and it gives you an access point for identifying some of those social determinates of health that impact the entire family because of that one contact with the student. That model is a revenue intensive model in terms of the outputs you have to make for that because you may have a provider, a clinical support person (a medical assistant or a nurse), and some administrative personnel on site. And they may at that point see two patients, so that's a significant investment. It's worth it, but at the same time how do you make that sustainable? I think that has been the challenge for organizations like ours and other entities that want to make a difference and have been greatly impacting the school system.

Question: It seems that we've talked about sort of two buckets in terms of trying to address social determinates. One is like government coordination so to the extent that all the different departments that handle all of these different things that are arguably supposed to be under the Social Security Administration, right. So we could go with government and have government better coordinate so that we have housing and food and some of the safety nets that are one side alone are health safety nets. Versus, I mean I think the other bucket that we've been talking about is do we need to think totally outside the box and think about this just outside the government: innovation, doing healthcare differently, going through new models of care, new ways of thinking about it. What do you think is going to come first or needs to come first or those two things exist together? What are your thoughts on those two pathways in thinking about this issue?

Will Wright: They live together now. Like Larry said, basically we do half of them through a government funded and half through the ESI, the employer sponsored insurance. And so they live together and I think the innovations are different and they have different motives. But this doesn't mean that they can't grow up at the same time. So what I see on the employer sponsored side is but you have to have that employer, that employer's got to be sort of sophisticated and really caring about their workforce. I mean what I see when an employer is really invested in their workforce its usually in the manufacturing facilities. There are smaller rural in Mississippi,

Alabama, Indiana, Midwest and they don't really have that option and so its access to healthcare it's not even getting them to the minutia. They don't have nurses, they don't have primary care, but for the employer stepping up and saying, "I care about this workforce so I'm going to invest and ensure that they have that access." I think it helps from the administrative side. We can cut a lot of the expense by the way our model, which is low administrative overhead, as opposed to the government where you have to sort of coordinate, and make sure you have to jump through this hoop and that grant is funded or you don't run afoul of that part. There probably blessing and talons on both sides of it. But I think they can coexist and work together. Hopefully we can work some of this from each side.

Mark Ison: And that's fantastic. That's really impressive. Like on the employer's side particularly. On the provider's side, the government is the largest purchaser of healthcare and not only that but the government regulates so many other aspects of healthcare. Right? I mean, HIPAA applies whether it's a Medicare claim or a BlueCross claim, you know? So a physician practice, a primary care practice, that may be a lot of what we're talking about here, right, is primary care that would be dealing with the social determinates of health is already making such an invest to comply with this model of reimbursement, this regime of regulations, do they have resources? Money? Time? Expertise? To really boldly experiment when they're outside that. I wonder because in so many cases its difficult on the innovation side. I mean something as basic as the corporal practice of medicine rules. Those apply regardless of whether you're doing government healthcare or private healthcare. And you know that's a big impediment to healthcare entrepreneurship and some of that I know is based on concerns of public health but some of its just based good old competitive conduct by physicians who control physician licensing boards, etc. So I mean, there has to be a balance. Government has to be willing to come to the table because of its primary role. I mean most practices and most hospitals can't survive without government reimbursement without participating in these government programs. That has driven the standard for so long. Everything from reimburse is always tied to "What percentage of Medicare is it?" So many other things that have to have come to be understood as common practice

in the healthcare areas are all driven by what the government does. It can come from all angles but without massive reform at the government level, I just don't see how the physician caught in the middle is going to be able to both be able to spend all this time on working with patients through social determinants of health and yet on the other side stamp widgets and get patients through every fifteen minutes so he can get his Medicare reimbursement.

Caitlyn Page: I think the best thing the government could do would be focus to removing barrier to the innovation that the providers are coming up with because I think the providers know more than anybody on how to help their patients. At least better than someone very far removed from the situation. You know I have some clients who just said "well we're not going to take Medicare and Medicaid and we're just going to do this directly with the consumer." And they're using telemedicine and they're using some really great sophisticated software on the patient intake level and they've created some really great efficiencies, and through all those technologies such that they can offer these services directly to the patient. You come in this urgent care center and it's a hundred bucks a visit and then if you have, we can treat you for these things, and they have a price sheet and it kind of that dream where you treat healthcare like you do other services. You go in and there's prices and you know them in advance and you can get what you need and have some predictability there. So they're able to do that but only because they said we're just not going to take Medicare and Medicaid. And that creates. And as you said that's a big payer so that's a big turn off.

Question: Since you're talking about the social determinates of health, Chattanooga and Hamilton County and BlueCross BlueShield are involved in on a project to identify fifty people who are chronically homeless and severely and persistently mentally ill who are cycling through the criminal justice system as well as the healthcare system over and over.[19] That is supportive housing is probably cheaper. But HIPAA is creating some of the difficulties there because it's easy for the jail to say we see these people all the

[19] Megan Gienapp, *An Ambitious Approach to Homelessness*, Metro Ideas Project (Mar. 13, 2018) https://metroideas.org/blog/an-ambitious-approach-to-homelessness/.

time but you and that industry can't communicate back. And as we do social determinates of health, that's in that over and over again as you're working with housing homeless agencies and other non-medical institutions. You see work arounds because that is definitely something that needs to change at the federal level.

Dr. Jeanne James: I think we're continuing in trying to work on it. Sometimes the short term work around is we identify a member and as long as they give permission we can move forward. But sometimes it's hard to get to folks to get that individual consent. I know we're continuing to work on that because it's such an important issue. We've done some work recently across the state with some wanting to share information and referrals with some other community agencies and we are still working through the barriers of how do we do that between a primary care practice and the United Way or some other agency like that. And in the short term, we as the health plan sort of have to be intermediary because at least for now we are the ones who can pass those referrals back and forth. I hope eventually we will solve some of those things. I guess I would defer to my legal colleagues about what has to change in terms of regulations for that to work. But you're right, there's so much important use case of it right in front of us that I think it's something we've got to continue to pursue.

Taylor Wilkins: Any other questions? Bueller? Bueller? With that, go ahead and join me in thanking our panelist.

HELP US, HELP YOU:
BIG TECH AND THE FUTURE OF PERSONAL HEALTH RECORDS

CLAY BREWER

I. INTRODUCTION

Ed Dentel went to his local primary care physician due to chest pains.[1] The physician ran a few tests, but the results were all normal.[2] Perhaps he should change his diet? Get some exercise? But over the next few months, the chest pains continued.[3] Aware of the new health features in his new Apple Watch Series 4, such as the ECG app (electrocardiogram application), Ed decided to try it out.[4] The ECG is used to detect atrial fibrillation or A-fib for

[1] Michael Potuck, *New Development in case of Apple Watch customer who discovered heart condition with ECG app, featured on Good Morning America*, 9TO5MAC (Dec. 11, 2018), https://9to5mac.com/2018/12/11/apple-watch-ecg-saves-life-a-fib/.
[2] *Id.*
[3] *Id.*
[4] *Id.*

short.[5] In other words, the test analyzes the heart and detects whether there are any irregular heartbeats.[6] To his surprise, the watch detected A-fib, so Ed tried again.[7] The next morning, he tried again, and again, and again. Still A-fib. Switched wrists, no change. Then thinking that with a new device and knowing that Apple has said false positives are possible with all technology, Ed asked his wife to try it out.[8] No A-fib, no discrepancies with her readings.[9] Ed immediately drove to his local clinic, but, due to the wait, Ed almost decided to leave.[10] He cannot skip important meetings for work because of a dumb watch, can he? But he decided to wait it out. Ed explains that "he felt like a hypochondriac explaining that his watch told him something was wrong. But he was quickly given an ECG[11] by a technician, who called for a doctor." The watch was correct, the doctor read the results and responded, "Yup, you're in AFib.[12] This thing may have just saved your life."[13] Ed still believes if it were not for the

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[5] *Id.*
[6] *See Medicine Plus: Atrial Fibrillation*, United States National Library of Medicine, https://medlineplus.gov/atrialfibrillation.html.
[7] Potuck, *supra* note 1.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] The same technology used by the Apple Watch Series 4 is also used by physicians within the doctor's office. EKG and ECG are synonymous. The difference in acronym is based on whether the test name is translated from German elektro-kardiographie or from English electrocardiogram (ECG). *ECG vs. EKG: What's the Difference?*, NEUROSKY, (May 25, 2015), http://neurosky.com/2015/05/ecg-vs-ekg-whats-the-difference/.
[12] Potuck, *supra* note 1.
[13] *Id.*

Apple Watch, he could be dead having never returned to the physician.[14]

The intersection of technology and healthcare can bring individuals like Ed amazing benefits. But what about the risks of so much personal medical data being available to these same companies that claim to advance our well-being? Tim Cook, the CEO of Apple, believes that privacy is a fundamental human right and that Apple seeks to enrich the lives of individuals and provide great products, not make the individual the product. Mr. Cook stated in a recent interview with CNBC's Jim Cramer, "[w]e are taking what has been with the institution and empowering the individual to manage their health."[15] But what if Mr. Cook and Apple did not have these views? What if they suddenly believed that the customer was, in fact, now the product? Could they change this policy without any legal repercussions? The answer, in short, is yes.

For example, the sudden rise in 23andme, a company that tests your DNA to trace your genetics,[16] can perhaps be more illustrative of the risks presented to an individual's privacy. The

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[14] *Id*.
[15] Lauren Fiener, *Apple CEO Tim Cook speaks with CNBC's Jim Cramer: Full transcript*, CNBC, (Updated Jan. 9, 2019), https://www.cnbc.com/2019/01/08/apple-ceo-tim-cook-interview-cnbc-jim-cramer-transcript.html.
[16] 23andme Media Center, (2019), https://mediacenter.23andme.com.

delivery man drops a small package off at your home.[17] A vial kit is contained inside.[18] You open the box, take out the vial, and spit into the vial.[19] You then follow the instructions and register the vial's barcode on 23andme's website, the kit is placed back in the mail with a sample of your saliva in the vial, and sent back to the laboratory for testing.[20] Your results will be returned in three to five weeks.[21] And "[i]n each drop of spit lies a whole story of ancestry, health, and connectedness that is about to unfold."[22] This all appears to be quite harmless and reveals many curiosities about ourselves and our family history. But in the words of iconic college football Coach Lee Corso[23], "not so fast, my friend."[24]

Once the results are received, where did the saliva sample go? Where are the DNA records filed? Unbeknownst to many, 23andme and others can sell your anonymized information they retrieve to third parties, and pharmaceutical company

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[17] 23andme: How it Works, (2019), https://www.23andme.com/howitworks/.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] 23andme, *supra* note 16.
[23] Legendary college football coach and co-host of ESPN's College GameDay television show. https://espnmediazone.com/us/bios/corso_lee/.
[24] Ava Wallace, *Not so fast, my friend: A Stroke couldn't rob ESPN's Lee Corso of 'College Gameday'*
WASHINGTON POST (Oct. 14, 2017),
https://www.washingtonpost.com/news/sports/wp/2017/10/14/not-so-fast-my-friend-a-stroke-couldnt-rob-espns-lee-corso-of-college-gameday/?utm_term=.5e0baae9a7a6.

GlaxoSmithKline[25] has a $300 million stake in 23andme.[26] Does it make sense that the ordinary individual is required to explicitly opt-out in order to prevent their data from being shared with such pharmaceutical companies? When was the last time any of us actually read the terms and conditions of a product anyways? Or, if we did, if we actually understood it? So much for "informed consent."

The use of such technology undoubtedly brings remarkable results.[27] But there is more to it than the ordinary individual may know. What if large corporations could discover this medical information or, better yet, we freely gave it to them? What if such companies could then sell this information to large databases or simply the highest bidder? Initially, most would shrug this off. I have nothing to hide. So what if someone knows I went to the doctor last week for a cold or to have a plantar wart removed? But

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[25] "[GlaxoSmithKline] ha[s] 3 global businesses that research, develop, and manufacture innovative pharmaceutical medicines, vaccines and consumer healthcare products." GlaxoSmithKline, (2019), https://www.gsk.com/en-gb/about-us/.

[26] Erin Brodwin, *DNA-testing company 23andMe has signed a $300 million deal with a drug giant. Here's how to delete your data if that freaks you out*, (July 25, 2018), https://www.businessinsider.com/dna-testing-delete-your-data-23andme-ancestry-2018-7; *GSK and 23andme sign agreement to leverage genetic insights for the development of novel medicines*, (July 25, 2018), https://www.gsk.com/en-gb/media/press-releases/gsk-and-23andme-sign-agreement-to-leverage-genetic-insights-for-the-development-of-novel-medicines/.

[27] *5 Ways Technology is Improving Health*, UNIVERSITY OF ILLINOIS AT CHICAGO: HEALTH INFORMATICS BLOG, (last visited January 27, 2019), https://healthinformatics.uic.edu/blog/5-ways-technology-is-improving-health/.

if this information is accessible, then what other information might be? Who has access? What inferences could arise?

The rise of cybercrime targeting healthcare further highlights the high demand for private health information.[28] For example, in July 2018, Singapore's Ministry of Health reported that hackers accessed and exported the personal health records of 1.5 million patients, including the health records of Prime Minister Lee Hsien Loong.[29] Through this breach, the hackers were able to extract specific "data on outpatient-dispensed medications" of 160,000 patients including the prime minister.[30] According to CNBC, medical records continue to be a hot commodity on the dark-web receiving sometimes three times or more as much per record as compared to Social Security numbers.[31] If these are the prices on the dark-web, imagine the heightened prices for legally

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[28] Kate O'Flaherty, *Why Cyber-Criminals Are Attacking Healthcare - - And How to Stop Them*, FORBES, (Oct. 5, 2018), https://www.forbes.com/sites/kateoflahertyuk/2018/10/05/why-cyber-criminals-are-attacking-healthcare-and-how-to-stop-them/#d2da6c7f69eb.

[29] Jessica Davis, *Hackers breach 1.5 million Singapore patient records, including the prime minister's*, HEALTHCARE IT NEWS, (July 20, 2018), https://www.healthcareitnews.com/news/hackers-breach-15-million-singapore-patient-records-including-prime-ministers.

[30] *Id.*

[31] Jill Cornfield, *The dark web is a fraudster's bargain-hunting paradise*, CNBC, (July 2, 2018), https://www.cnbc.com/2018/06/29/the-dark-web-is-a-fraudsters-bargain-hunting-paradise.html; *See Medical Data: One Of The Hottest Commodities On The Dark Web*, SOURING EAGLES CONSULTING DATABASE BLOG, (May 30, 2018), https://soaringeagle.biz/medical-data-hot-commodity-on-dark-web/; Brian Stack, *Here's How Much Your Personal Information Is Selling for on the Dark Web*, EXPERIAN, (Updated April 9, 2018), https://www.experian.com/blogs/ask-experian/heres-how-much-your-personal-information-is-selling-for-on-the-dark-web/

obtained medical information that we consent, often unwittingly, to give up.

However, the future appears to hold more technology involved within healthcare, not less.[32] And the explicit desires of tech powerhouses such as Apple, Amazon, and Alphabet's Google to address the problems of the American healthcare system appear to bring forth significant benefits.[33] The growth of technology over the last decade has developed a society more connected than ever before.[34] From monitoring your heart on an Apple Watch to receiving your prescriptions via Amazon Prime, and flagging potentially future medical issues with Google's artificial intelligence, the benefits seem infinite if they can become a

[32] Erica Bettencourt, *Technology Trends Are The Future For Healthcare*, DIVERSITYNURSINGBLOG, (March 15, 2018), http://blog.diversitynursing.com/blog/these-technology-trends-are-the-future-for-healthcare.
[33] Natasha Singer, *How Big Tech Is Going After Your Health Care*, NY TIMES, (Dec. 26, 2017), https://www.nytimes.com/2017/12/26/technology/big-tech-health-care.html.
[34] Sean Illing, *Technology isn't just changing society–it's changing what it means to be human: A conversation with historian of science Michael Bess*, VOX, (Feb. 23, 2018), https://www.vox.com/technology/2018/2/23/16992816/facebook-twitter-tech-artificial-intelligence-crispr; *The connected future: Internet of Things forecast*, ERICSSON MOBILITY REPORT, (last visited January 27, 2019), https://www.ericsson.com/en/mobility-report/internet-of-things-forecast.

reality.[35] Yet as the old proverb goes, "the road to hell is paved with good intentions."[36]

The more reliant society becomes on technology and the ever-growing Internet of Things ("IOT")[37], the more vulnerable society becomes to not only the traditional fears of cyberattacks ,but more so to the power that is freely granted to those corporations that possess such information with virtually no regulatory restraint.[38] Technology will only continue to grow within our daily lives.[39] And the convergence of technology and healthcare demonstrates the ever-expanding tentacles of big tech.[40]

This note will address the issues that will inevitably arise as this convergence of tech and healthcare continue. Part I will discuss a few of the current laws and regulations that seek to

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[35] Dylan Scott, *Why Apple, Amazon, and Google are making big health care moves: Silicon Valley wants to disrupt your health care*, VOX, (March 6, 2018), https://www.healthleadersmedia.com/finance/why-apple-amazon-and-google-are-making-big-health-care-moves.

[36] Soren Kierkegaard, *Works of Love*, (Charles E. Moore ed., *Provocations: Spiritual Writings of Kierkegaard*, 14, Plough Publishing House 2007) (1847) available at: http://www-astro.physics.ox.ac.uk/~ddarg/pdf/Provocations.

[37] "The Internet of Things is a network of physical objects–vehicles, machines, home appliances, and more–that use sensors and [application programming interfaces] to connect and exchange data over the Internet." *What is the Internet of Things (IoT)?*, SAP SE, (Feb. 19, 2019), https://www.sap.com/trends/internet-of-things.html.

[38] Barry R. Furrow, et al., *Health Law: Cases, Materials And Problems*, 174 (8th ed. 2018).

[39] According to a 2018 Nielsen Total Audience Report, "American adults spend over 11 hours per day listening to, watching, reading or generally interacting with media." *Time Flies: U.S. Adults Now Spend Nearly Half A Day Interacting With Media*, NIELSEN, (July 31, 2018), https://www.nielsen.com/us/en/insights/news/2018/time-flies-us-adults-now-spend-nearly-half-a-day-interacting-with-media.print.html.

[40] Nancy Huynh, *How the "Big 4" Tech Companies Are Leading Healthcare Innovation*, (Aug. 27, 2018), https://healthcareweekly.com/how-the-big-4-tech-companies-are-leading-healthcare-innovation/.

protect personal health records in the United States' and Europe, specifically in comparing the United States Health Insurance Accountability and Portability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH") with the European Union's much broader response to data privacy concerns via the General Data Protection Regulation ("GDPR").

To follow, Part II will introduce three of the tech giants– Apple, Amazon, and Google–to give a glimpse into their individual visions to tackle healthcare's most vexing problems while presenting how these companies will test the current legal framework of medical data privacy. Lastly, Part III will provide initial thoughts to restructure the current legal framework for private health information in the United States similarly to that of the European Union in order to protect an individual while also seeking to not stifle big tech's health innovation, but to enable it.

Part I: The Law As We Know It

HIPAA & HITECH

In 1996, Congress passed and President Bill Clinton signed into law the Health Insurance Portability and Accountability Act ("HIPAA"), which would "ensure the portability of health benefits when workers change or lose their jobs and will protect workers against discrimination by health plans based on their health

status."[41] However, the turn of the millennium welcomed "the rise of electronic record keeping and the Internet" increasing the need to better streamline the transmission of health records, and for greater privacy and security of an individual's medical data.[42]

To meet the guidelines established in HIPAA, the Department of Health and Human Services ("HHS") promulgated the Privacy[43] and Security Rules.[44] In the initial preamble to the Privacy Rule in 2000, HHS identified three major purposes for the newly promulgated regulation:

> "(1) To protect and enhance the rights of consumers by providing them access to their health information and controlling inappropriate use of that information; (2) to improve the quality of health care in the U.S. by restoring trust in the health care system among consumers, health care professionals, and the multitude of organizations and individuals committed to the delivery of care; and (3) to improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, and individual organizations and individuals."[45]

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[41] *Statement on Signing the Health Insurance Portability and Accountability Act of 1996*, University of California at Santa Barbara: The American Presidency Project, https://www.presidency.ucsb.edu/documents/statement-signing-the-health-insurance-portability-and-accountability-act-1996.
[42] Furrow, *supra* note 39, at 172.
[43] HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164 (2013).
[44] HIPAA Security Rule, 45 C.F.R. § 164(c) (2013). The Security Rule will not be discussed further in this note, but "sets forth standards for keeping health data secure, including encryption and other technological and organizations requirements." Furrow, *supra* note 39, at 172.
[45] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000).

These rules were an effort to promote the industry as a whole to adopt electronic health record ("EHR") systems.[46] However, from reluctance to change to the costs associated with adopting EHR, the optimism that existed did not catch on as originally hoped.[47] This led to the enactment of the Health Information Technology for Economic and Clinical Health Act ("HITECH") in 2009, which sought to catalyze EHR adoption across the country as well as establish a structure for notifying the public and HHS about data breaches and the protection of an individual's private health information ("PHI"). [48] HITECH provided the Office of the National Coordinator for Health Information Technology ("ONC") the power to begin offering financial incentives in 2011 to providers that adopted EHR and demonstrated meaningful use of such technology,[49] but would impose penalties on those providers that had yet to adopt EHR by 2015.[50] The HITECH amendments of 2009 were implemented through the Omnibus HIPAA rulemaking of 2013[51] that led to the Privacy Rule's current form while also linking the Privacy Rule with the Security Rule, the Enforcement Rule,[52] and the Breach Notification Rule.[53]

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[46] Furrow, *supra* note 39, at 172-73.
[47] *Id.* at 193.
[48] *Id.* at 190.
[49] 42 U.S.C. §§ 300jj to jj-51 (2016).
[50] 42 U.S.C. § 1320d-5 (2009).
[51] 45 C.F.R. Part 160, Subpart D (2013).
[52] 42 U.S.C. §§ 300jj to jj-51.
[53] 42 C.F.R. §§ 164.400 to 164.414 (2009).

The Privacy Rule will be the primary focus of this note's HIPAA discussion. In order to adequately understand how the big technology companies can impact the current legal framework, one must first understand what is currently covered under the Privacy Rule.

The most significant definitions of the Privacy Rule include: (1) protected health information; (2) covered entities; and (3) business associates.[54] Protected health information, also known as individually identifiable health information, has an expansive definition but can be understood to include an individual's health information "created or received by a health care provider, health plan, employer, or health care clearinghouse" that identifies or reasonably could be used to identify a particular individual.[55] In contrast to the broad definition of protected health information, the entities that are subject to HIPAA are significantly limited in regards to the ever-growing landscape of technology companies that have continued to enter the health sphere since the Privacy Rule's beginning in 2002 and its latest iteration in 2013.[56] Covered entities are defined under HIPAA as a health plan;[57] a health care

[54] Farrow, *supra* note 39.
[55] *Id.* at § 160.103-Definitions.
[56] *Guidance on HIPAA & Cloud Computing*, Dept. of Health and Human Servs., https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html.
[57] Examples include: health insurance companies, health management organizations. (HMOs), company health plans, and government programs that

clearinghouse;[58] or a health care provider that transmits any health information in electronic form in connection with a transaction.[59] Business associates are entities that "on behalf of a covered entity . . . creates, receives, maintains, or transmits protected health information for a function or activity regulated by [HIPAA]."[60] The "on behalf of" language is a key part of the business associate definition analysis because if the entity is operating exclusively with consumers, (i.e., Apple, Amazon, or Google) then HIPAA would not apply unless the current definition of covered entity were to change.[61]

HIPAA and its related rules and regulations "set[ ] a floor of ground rules for health care providers, health plans, and health care clearinghouses to follow, in order to protect patients and encourage them to seek needed care."[62] In other words, this means that entities that fall under HIPAA are obligated to comply but also may fall subject to more stringent state laws.[63] As a result of this

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pay for health care, such as Medicare and Medicaid. https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html.

[58] Examples include: "entities that process nonstandard health information they receive from another entity into a standard (i.e., standard electronic format or data content), or vice versa. https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html.

[59] Examples include: doctors, clinics, psychologists, and dentists "but only if they transmit any information in an electronic form in connection with a transaction for which HHS has adopted a standard." https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html.

[60] HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164.

[61] Dept. of Health & Human Servs., s*upra* note 56.

[62] Furrow, *supra* note 39, at 174.

[63] Stephanie Baum, *Lawyer: It's time to pre-empt state medical privacy laws that differ from HIPAA*, MEDCITY NEWS ,(April 29, 2017),

potentiality, there could be fifty additional laws for entities to comply with while also complying with HIPAA. At the time the preamble to the Privacy Rule was written, "[r]ules requiring the protection of health privacy in the United States ha[d] been enacted primarily by the states . . . . [but the Privacy Rule] establish[ed] for the first time a set of basic national privacy standards . . . that provide[d] all Americans with a basic level of protection."[64] However revolutionary the Privacy Rule may have been at the time of the preamble's presentation, technology has changed significantly causing this national standard an annoyance as opposed to a protective data privacy regulation because the big tech companies now entering the arena are not necessarily being covered. Additionally, the possibility of a multitude of state laws causes difficulty for companies to continue to innovate and abide by separate regulations depending on the location or citizenry of the business operation.[65] As a result, many tech CEOs expressed their support for a national standard before Congress with the condition that state laws such as that of California[66] would be

https://medcitynews.com/2017/04/lawyer-time-pre-empt-state-medical-data-privacy-laws-differ-hipaa/?rf=1

[64] 65 Fed. Reg. 82642.

[65] David Shepardson, *Tech companies back U.S. privacy law if it preempts California's*, REUTERS, (Sept. 26, 2018), https://www.reuters.com/article/us-usa-tech-congress/tech-companies-back-u-s-privacy-law-if-it-preempts-californias-idUSKCN1M62TE.

[66] *Id.* "California Governor Jerry Brown signed [a] data privacy [law] aimed at giving consumers more control over how companies collect and manage their personal information."

preempted. [67] The California law, known as the California Consumer Privacy Act of 2018, will go into effect in 2020 and for purposes of this note can be similarly linked to that of the GDPR in Europe.[68]

Lastly, even assuming HIPAA covers much of the information and entities that would raise concerns for the individual in regards to their personal medical data, "there is no private right of action for individuals whose information has been used or disclosed in violation of the law."[69] The Office of Civil rights under HHS is given the regulatory authority to investigate such violation and state attorneys general are also permitted to do so by filing in federal district court due to HIPAA being a federal law. [70] Preventing a private right of action may prevent the common cliche of "flooding the courts" but does little to empower the individual in owning their personal information. The enforcement powers being placed solely in the hands of elected officials or regulatory career officers places the rights of the individual to the subjective decisions of others. Moreover, a part of the 2013 Omnibus HIPAA Rule, there are possible criminal penalties for "[a] person who knowingly obtains or discloses

[67] *Id.*
[68] Kristen J. Matthews and Courtney M. Bowman, *The California Consumer Privacy Act of 2018*, PRIVACY LAW BLOG, (July 13, 2018), https://privacylaw.proskauer.com/2018/07/articles/data-privacy-laws/the-california-consumer-privacy-act-of-2018/.
[69] Furrow, *supra* note 39, at 189.
[70] 42 U.S.C. § 1320d-5 (2013).

individually identifiable health information in violation of HIPAA,"[71] and civil penalties that an "annual maximum of $1.5 million for a violation."[72] For a large corporation making billions every quarter, this is hardly a disincentive.

GDPR

Events like Yahoo's data breach that exposed private information of millions of Yahoo email users[73], and the disclosure that Facebook user data was directly shared with third parties like Cambridge Analytica[74], revealed how exposed technology can make an individual, bringing the world of 1984[75] from fiction to reality.

The European Union put into effect the General Data Protection Regulation ("GDPR")[76] on May 25, 2018.[77] The twenty-eight member countries[78] of the European Union implemented this

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[71] 45 C.F.R. § 160.408 (2013).
[72] 45 C.F.R. § 160.404 (2016).
[73] Oath: A Verizon Company, *Yahoo provides notice to additional users affected by previously disclosed 2013 data theft*, (Oct. 3, 2017), https://www.oath.com/press/yahoo-provides-notice-to-additional-users-affected-by-previously/.
[74] Andrea Valdez, *Everything You Need to Know About Facebook and Cambridge Analytica*, WIRED (March 23, 2018), https://www.wired.com/story/wired-facebook-cambridge-analytica-coverage/; Vindu Goel, *The Week in Tech: A Breach That Ripples Far Beyond Facebook*, NY TIMES (Oct. 5, 2018), https://www.nytimes.com/2018/10/05/technology/facebook-breach.html.
[75] George Orwell, 1984, (1949).
[76]Council Regulation 2016/679, of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, 2016 O.J. (L 269).
[77] *EU GDPR*, https://eugdpr.org (last visited June 26, 2019).
[78] Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia,

revamped regulation to protect the personal data of citizens of the European Union ("EU"), to prevent invasions of privacy, and to empower the individual in owning their own data.[79] To put the GDPR in comparison to HIPAA, Reg Harnish, the CEO of GreyCastle Security,[80] writes that GDPR can go much further than HIPAA in both punitive fines and its scope of coverage because "[u]nlike HIPPA, which has a maximum fine penalty of $1.5 million per year[81] for violations of an identical provision, GDPR fines can cost up to $24 million or four percent of the violator's annual global revenue, whichever is greater."[82] In essence, these large punishments are focused on Europe's desire to "alter[ ] how businesses and public sector organizations [ ] handle the information of their customers. [while] also boost[ing] the rights of

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Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden. European Union, https://europa.eu/european-union/about-eu/countries_en (last visited June 26, 2019). The United Kingdom is the twenty-eighth member of the EU but is in the process of leaving after the decision to leave prevailed in the June 23, 2016, referendum. (Author's note).

[79] The GDPR builds upon and replaces the 1995 data protection directive in order to modernize legislation with societal and technological advancements. In the words of the United Kingdom's information commissioner, Elizabeth Denham, "The GDPR is a step change for data protection . . . It's still an evolution, not a revolution."
Matt Burgess, *What is GDPR? The summary guide to GDPR compliance in the UK*, WIRED (January 21, 2019), https://www.wired.co.uk/article/what-is-gdpr-uk-eu-legislation-compliance-summary-fines-2018.

[80] Cybersecurity service company. *See* GreyCastle Security, https://www.greycastlesecurity.com/company/ (last visited June 26, 2019).

[81] 45 C.F.R. § 160.404.

[82] Reg Harnish, *7 Things Healthcare Organizations Need to Know About GDPR*, HIT CONSULTANT (March 21, 2018), https://hitconsultant.net/2018/03/21/healthcare-organizations-gdpr/; Commission Regulation (EU) 2016/679, Article 83, available at: https://gdpr-info.eu/art-83-gdpr/.

individuals and giv[ing the individual] more control over their information."[83] Stated more simply, the GDPR "is designed to (1) harmonize data privacy laws across Europe; (2) protect and empower all EU citizens data privacy; and (3) reshape the way organizations across the region approach data privacy." [84] For example, French authorities under the auspices of the GDPR implemented a $57 million fine against Google on January 21, 2019, the largest fine under the new law.[85] The European Union is currently made of twenty-eight members, which all individually may enforce the GDPR.[86] Under GDPR, "a big part of the new rule is a requirement that companies explain to users how their data is being collected and used, and in many cases seek consent from users to collect it."[87] As a result of this new regulatory power, France's National Data Protection Commission revealed that "Google violated rules requiring information about data collection to be transparent, and users to be sufficiently informed . . . in some cases requiring up to five or six clicks" for information to become discoverable" making the individual unlikely to pursue further and

[83] *See supra* note 79.
[84] *See* https://eugdpr.org. The actual link to the European Commission can be found at: https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en.
[85] Sam Schechner, *Google Fined $57 Million in Biggest Penalty Yet Under New European Law*, THE WALL STREET JOURNAL (Jan. 21, 2019), https://www.wsj.com/articles/google-fined-57-million-by-french-regulator-11548085558?mod=djemalertNEWS.
[86] Article 77, available at: https://gdpr-info.eu/art-77-gdpr/.
[87] *See supra* note 85.

resulting in Google not "obtain[ing] appropriate consent for personalized ads on Google's platforms."[88] From this example of Google, the central idea of the GDPR can be further understood to recognize that "not only will organisations [sic] have to ensure that personal data is gathered legally and under strict conditions, but those who collect and manage it will be obliged to protect it from misuse and exploitation, as well as respect the rights of data owners."[89]

Now with this central idea in mind, three key terms must be defined: (1) controllers; (2) processors; and (3) personal data. These can be loosely compared to HIPAA's current covered entity and business associate methodology.[90] Under Article 4 of the GDPR, controllers are defined as a "person, public authority, agency, or other body which, alone or jointly with others, determines the purposes and means of processing of personal data;" while processors are defined as a "person, public authority, agency, or other body which processes personal data on behalf of the controller" with controllers also being held responsible to ensure that contracts with processors are GDPR compliant.[91]

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[88] *See supra* note 85.
[89] Danny Palmer, *What is GDPR? Everything you need to know about the new general data protection regulations*, ZDNET (May 23, 2018), https://www.zdnet.com/article/gdpr-an-executive-guide-to-what-you-need-to-know/.
[90] Article 4, available at: https://gdpr-info.eu/art-4-gdpr/.
[91] *See supra* note 89.

Personal data as "any information that relates to an identified or identifiable living individual."[92]

Arguably the more important aspect of GDPR that distinguishes it from HIPAA and other like-situated American counterparts is determining what is covered and who must comply. Even though GDPR is a law implemented by the European Union, "the legislation extends further than the borders of Europe itself, as international organisations [sic] based outside the region but with activity on 'European soil' will still need to comply." [93] Interestingly enough, "[t]he European Commission claims that by having a single supervisor authority for the entire EU, it will make it simpler and cheaper for businesses to operate within the region."[94] The GDPR is similar to HIPAA in that it does not directly provide a private right of action for the individual, but it does establish two significant provisions that place great power within the individual's hands. The first is under Article 17 designated the right to erasure or, more colloquially, the 'right to be forgotten.'[95] Upon request by the individual, the company must erase the data they possess on the individual if one of six

[92] Examples include: a name and surname, a home address, an IP address, data held by a hospital or doctor, which could be a symbol that uniquely identifies a person. *See* https://ec.europa.eu/info/law/law-topic/data-protection/reform/what-personal-data_en.
[93] *See supra* note 85.
[94] *Id*.
[95] Article 17, available at: https://gdpr-info.eu/issues/right-to-be-forgotten/.

conditions are met.[96] However, this idea does present challenges for medical data when all information can be considered impactful for further treatment. Secondly, Article 20 is designated the 'right of portability' granting the individual the right to gain access to the data companies have on them[97] with Article 21 providing the 'right to object' requiring companies to make it clear and precise for an individual to be able to opt-in or opt-out of sharing certain information[98]

Part II: The Big Three

The connection between of technology and healthcare has been a common topic since President Clinton signed HIPAA into law in 1996 with such a connection being premised upon the goals that healthcare policy revolves around: (1) cost, (2) quality, (3) access, and (4) choice.[99] However, technology has changed rapidly since 1996 and even since the 2013 HIPAA Omnibus.[100]

The difficulty in balancing these four goals has led to optimism with the entrance of large technology corporations–such as Apple, Amazon, and Google–bringing their connected user-base, extended consumer-data information, and hundreds of

[96] *Id*.
[97] Article 20, available at https://gdpr-info.eu/art-20-gdpr/.
[98] Article 21, available at https://gdpr-info.eu/art-21-gdpr/.
[99] *See supra* note 39, at 1.
[100] At the time of HIPAA in 1996, such items as the iPhone (2007), Fitbit (2007), iPad (2010), Samsung Galaxy S (2010), Apple Watch (2015) were likely linked closer to an episode of The Jetsons than reality. (Author's note).

billions of dollars to join the juggling act.[101] Apple, Amazon, and Google, three of the world's largest companies by market capitalization and name recognition,[102] come into contact with millions of individuals on a daily basis. From using the iPhone or Apple Watch and its various applications, to the commonly used Google search engine, from Amazon Prime[103] or walking into a Whole Foods[104], to Amazon's Web Services[105], individuals from all walks of life interact with these tech giants for nearly everything everyday. These companies are attempting to bring their successes within these various fields to the healthcare sector in order to remedy the difficult balancing act that is the American healthcare system.[106] However, success in one field does not guarantee success in another. Dan D'Orazio, CEO of healthcare

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[101] Art Kleiner, *A Doctor's Prescription: Data May Finally Be Good for Your Health*, STRATEGY+BUSINESS (Oct. 8, 2018), https://www.strategy-business.com/article/A-Doctors-Prescription-Data-May-Finally-Be-Good-for-Your-Health?gko=e3c4e.

[102] Gil Press, *How Apple, Amazon, Facebook, Google And Microsoft Made 2018 The Year That IT Mattered A Lot*, FORBES (Dec. 30, 2018), https://www.forbes.com/sites/gilpress/2018/12/30/how-apple-amazon-facebook-google-and-microsoft-made-2018-the-year-that-it-mattered-a-lot/#3592eedb1cee.

[103] Amazon Prime is a paid for service subscription model that allows customers to receive free shipping from Amazon along with a variety of other benefits. *See generally* https://www.amazon.com/amazonprime?_encoding=UTF8&%2AVersion%2A=1&%2Aentries%2A=0.

[104] Amazon began its purchase of the national supermarket chain in 2017. Nick Wingfield and Michael J. de la Merced, *Amazon to Buy Whole Foods for $. 13.4 Billion*, NY TIMES (June 16, 2017), https://www.nytimes.com/2017/06/16/business/dealbook/amazon-whole-foods.html.

[105] Amazon Web Services (AWS) is Amazon's cloud computing platform that assists in analyzing large amounts of data, data storage, among other tasks. *See* generally https://aws.amazon.com.

[106] See s*upra* note 39.

research firm Sage Growth Partners[107], reiterates the belief of many currently within the healthcare industry: "We try to tell people that come in from outside that things don't necessarily translate well from other industries."[108] Professor Scott Galloway of New York University Stern School of Business takes a much more hostile approach designating three of these companies as a part of the four horsemen[109] and questioning their ability to free reign across society:

> "[w]e know these companies aren't benevolent beings, yet we invite them into the most intimate areas of our lives. We willingly divulge personal updates, knowing they'll be used for profit. Our media elevate the executives . . . Our governments grant them special treatment . . . So, are these entities the Four Horsemen of god, love, sex, and consumption?[110] Or are they the Four Horsemen of the apocalypse? The answer is yes to both questions."[111]

Because of the benefits technology has brought to our lives and can bring to healthcare, this note does not go as far as Professor Galloway to all but indict big tech power. But this note

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[107] Marketing and growth consulting firm for healthcare organizations. *See* http://sage-growth.com/index.php/about/.
[108] Klint Finley, *Embattled Tech Companies Charge Deeper Into Health Care*, WIRED (March 1, 2018), https://www.wired.com/story/embattled-tech-companies-charge-deeper-into-health-care/.
[109] Scott Galloway, The Four: The Hidden DNA Amazon, Apple, Facebook, and Google, (1st ed. 2017). Professor Galloway's fourth horseman is Facebook, but Facebook will not be addressed within this note. (Author's note).
[110] *Id.* at 3-5. In his book, Galloway argues that Google's Search capabilities make it like a god of information, Apple's luxury status appeals to sex, Facebook's social media presence of sharing appeals to our desire for love, and Amazon's vast array of options appeal to our desire to consume. (Author's note).
[111] *Id.* at 2.

does urge for restructuring the current regulatory framework for heath; fully understanding that not every CEO will have similar privacy beliefs as Apple's Tim Cook[112]. Many issues can arise with different companies entering healthcare such as increases in the difficulty of not only the interoperability[113] of the information across different platforms[114], but also the potentiality of these companies profiting off a patient's medical data.[115]

APPLE

In addressing privacy at the International Conference of Data Protection and Privacy Commissioners in Brussels, Belgium, Apple CEO Tim Cook urged for the adoption of stronger data

[112] Tim Cook has expressed multiple times that he believes, and that Apple as a company believes, that privacy is a fundamental human right. Jim Vincent, *Tim Cook warns of 'data-industrial complex' in call for comprehensive US privacy laws*, THE VERGE (Oct. 24, 2018), https://www.theverge.com/2018/10/24/18017842/tim-cook-data-privacy-laws-us-speech-brussels.

[113] The extent to which devices and networks can talk to one another. One way of thinking about this would be to think of the difficulties one may commonly have converting documents created on Apple's Pages interface versus Microsoft's Word. Competing companies make different software and have different operations. Many do not freely create universally compatible products to specifically not promote the use of a competitor. *See generally* https://www.himss.org/library/interoperability-standards/what-is-interoperability.

[114] Although beyond the scope of this note, it is important to know that information blocking can be a serious issue with rivals not permitting incompatible software to relate use its databases preventing health care providers from accessing all of an individual's records. Congress has attempted to remedy the situation in the 21st Century Cures Act with the Office of Management and Budget reviewing a proposed rule from the Office of the National Coordinator. *See generally* Mandy Roth, *Countdown To Information Blocking Rule In Progress*, HEALTH LEADERS MEDIA (Sept. 28, 2018), https://www.healthleadersmedia.com/innovation/countdown-information-blocking-rule-progress.

[115] *See supra* note 26.

protection within the United States.[116] First, Cook discussed the wonders of good that technology has brought to individuals but followed with a warning for the future:

> "[W]e see vividly–painfully–how technology can harm rather than help. Platforms and algorithms that promised to improve our lives can actually magnify our worst human tendencies. Rogue actors and even governments have taken advantage of user trust to deepen division, incite violence, and even undermine our shared sense of what is true and what is false.
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> . . . .
>
> And those of us who believe in technology's potential for good must not shrink from this moment. Now more than ever . . . we must ask ourselves a fundamental question: What kind of world do we want to live in?"[117]

This small excerpt alone can cause one to pause and truly think about the type of control that technology has over an individual's daily life. As of February 1, 2018, Apple announced that there are 1.3 billion actively used Apple products in the world.[118] According to the United States Census Bureau, there are roughly 7.53 billion people in the world.[119] As a result, Apple has roughly 17% as many devices in use as there are individuals in the world.

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[116] Apple Holic, *Complete Transcript, video of Apple CEO Tim Cook's EU privacy speech*, COMPUTERWORLD https://www.computerworld.com/article/3315623/security/complete-transcript-video-of-apple-ceo-tim-cooks-eu-privacy-speech.html.
[117] *See supra* note 103.
[118] Juli Clover, *Apple Now Has 1.3 Billion Active Devices Worldwide*, MACRUMORS (Feb. 1, 2018), https://www.macrumors.com/2018/02/01/apple-now-has-1-3-billion-active-devices-worldwide/. Apple press release available at: https://www.apple.com/newsroom/2018/02/apple-reports-first-quarter-results/.
[119] United States Census Bureau, https://www.census.gov/popclock/, (last visited January 27, 2019).

In previous years and continuing into 2019, Apple has hired dozens of doctors to assist in the company's entrance into healthcare.[120] With the growing features from the Health App on the iPhone to the health focus abilities of the Apple Watch Series 4, Apple is demonstrating its commitment to growing its focus from purely wellness and fitness to essentially a health company.[121] There is no question that Mr. Cook is pushing Apple in a direction that he proclaims will have individuals look back on these times and truly believe that Apple's greatest contribution to mankind was health.[122] So where does this contribution begin?

First, Apple has continued to gain more and more recognition for its innovative fifth iteration of the Apple Watch with the introduction of the Apple Watch Series 4 in the fall of 2018.[123] Apple displays the new Apple Watch as "inspir[ing] you to live a healthier life by helping you manage everything from everyday stress to calories burned" while also introducing the new

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[120] Christina Farr, *Apple now has dozens of doctors on staff, showing it's serious about health tech*, CNBC (Dec. 12, 2018), https://www.cnbc.com/2018/12/12/apple-has-dozens-of-doctors-on-staff.html.
[121] *Id.*
[122] Chance Miller, *Tim Cook teases 'new services' coming in 2019, says Apple's 'greatest contribution to mankind' will be health-related*, 9TO5MAC (Jan. 8, 2019), https://9to5mac.com/2019/01/08/tim-cook-services-health-care/.
[123] Kathleen Felton, *The Apple Watch Series 4: Everything You Need to Know About the Game-Changing New Health Features*, HEALTH (Sept. 13, 2018), https://www.health.com/condition/heart-disease/apple-watch-series-4; Chance Miller, *Apple officially announces Apple Watch Series 4 with larger display, thinner body, more*, 9TO5MAC (Sept. 12, 2018), https://9to5mac.com/2018/09/12/apple-watch-series-4-announced-release-price/; Sara Salinas, *Apple adds heart monitoring to Apple Watch*, CNBC (Sept, 12, 2018), https://www.cnbc.com/2018/09/12/apple-watch-series-4.html.

ECG[124] app that "is capable of generating an ECG similar to a single-lead electrocardiogram."[125] Apple is focused on enriching the lives of individuals across the world by enabling individuals to take a proactive approach towards their health. Within 30 seconds, the ECG app can indicate whether your heart rhythm shows signs of atrial fibrillation–a serious form of irregular heart rhythm" while keeping all such data from the Apple Watch encrypted on the device for the individual's personal use and ability to share with whom the individual so chooses.[126] In other words, Apple freely chooses to keep an individual's personal data on the device, there is no law or regulation making this mandatory.

Apple also recently introduced the fall detection feature on the Apple Watch that uses the accelerometer and gyroscope to create "a hard fall alert" to "easily initiate a call to emergency services[,] dismiss the alert[,or i]f you're unresponsive after 60 seconds, the emergency call will be placed automatically and a message with your location will be sent to your emergency contacts."[127] There is no doubt that such capabilities have already produced significant results with the ECG feature–described in the

[124] *See supra* note 11.
[125] *See generally* https://www.apple.com/apple-watch-series-4/health/.
[126] *Id.*
[127] *Id.*

introduction of this note–causing an individual to go to the doctor and discover his atrial fibrillation and potentially saving his life.[128]

Second, Apple highlights its Health App that links Activity[129], Sleep[130], Mindfulness[131], and Nutrition[132] as an easily accessible platform stored on an individual's iPhone that "consolidate[ ] health data from iPhone, Apple Watch, and third-party apps you already use . . . . And it recommends other helpful apps . . . making it simpler than ever to move your health forward."[133] The Health App "makes it easy to keep tabs on a wide array of data . . . from measurements of your blood pressure and blood glucose to records for your weight and reproductive health."[134] These capabilities will also permit the patient to keep one's health records–such as lab results and immunizations–within one place from multiple institutions.[135] As with the majority of Apple's services, an individual's personal information such as Touch ID[136], FaceID[137], and personal health information is stored

[128] *See supra* note 1.
[129] *See* https://www.apple.com/ios/health/.
[130] *Id.*
[131] *Id.*
[132] *Id.*
[133] *Id.*
[134] *Id.*
[135] Participating health institutions can be found at https://support.apple.com/en-us/HT208647. Essentially empowering the individual to own their data and present it to the doctor as opposed to it being stored elsewhere. (Author's note).
[136] TouchID is the ability of the individual to use their fingerprint to unlock their Apple devices and approve certain actions such as payments. *See* https://support.apple.com/en-us/HT201371.

on the individual's device and encrypted on the device itself and while in transit between devices.[138] This commitment to encryption and customer privacy is created to prohibit even Apple from accessing such data without the individual's explicit permission.[139] But remember, this is an Apple policy decision and not mandated by any law or regulation. However, Apple warns the user that "[a]pps that access HealthKit are required to have a privacy policy, so be sure to review these policies before providing apps with access to your health and fitness data."[140] An inference that one may use to identify that Apple is aware that HIPAA does not apply to these types of records unless a HIPAA covered party is present.

Moreover, Apple permits individuals to explicitly opt-into "a software framework for apps [designated ResearchKit] that let medical researchers gather robust and meaningful data" from the individual to better improve diagnoses and cures going forward and CareKit that is "a software framework for apps that let you better understand and manage your medical conditions" further enabling individuals to take advantage of their freedom to choose.[141] Such research capabilities through this platform has permitted app creators to further understand the effects and

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[137] FaceID is a continuation of the TouchID technology idea that uses sensor technology to do the same things. As TouchID but with an individual's face when looking at the device. See https://support.apple.com/en-us/HT208108.
[138] *See* https://www.apple.com/privacy/approach-to-privacy/.
[139] *See* s*upra* note 116.
[140] *Id.*
[141] *See* https://www.apple.com/researchkit/.

possible remedies to Parkinson's disease using the iPhone's "gyroscope and other iPhone features to measure dexterity, balance, gait, and memory" and also using "front-facing HD camera in iPhone, along with innovative facial recognition algorithms" to assist in diagnosing and treating autism earlier without the need for always going to a specialist.[142]

The notion presented by Tim Cook that society will look back on Apple and believe that their greatest contribution was health, from these few examples above, appears to be not too far from reality. The self-regulation that Apple's policy implements to protect a user's privacy is more of an exception to the rule as opposed to the rule itself. The two remaining companies will flirt more with the line due to their business models in health focusing more on data collection and artificial intelligence as opposed to providing software with their own personal hardware products. But in continuing, it is crucial to remember that a policy is not a mandated law.[143]

AMAZON

Amazon has a much different approach than Apple and is focused on what it can do in the future in regards to utilizing

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[142] *Id.*

[143] Carolyn Beeler, *Who gets access to the data my Apple Watch collects?*, WHYY (April 30, 2015), https://whyy.org/segments/who-gets-access-to-the-data-my-apple-watch-collects/.

software and the expansion of its cloud[144] platform, Amazon Web Services ("AWS"), while also seeking to grow its e-commerce scope to provide individuals with more affordable drugs and timely deliveries.[145] In April 2018, Amazon CEO Jeff Bezos announced that Amazon Prime membership exceeded 100 million subscribers globally.[146] These subscribers provide countless amounts of data that Amazon could use to further enhance its healthcare ambitions.[147] The thought of an Amazon health continues to raise concerns with privacy experts who "say the company's increasingly dominant role in our lives raises concerns about how personal data is collected and used," imagine the Alexa in the corner, the shopping lists and wish lists we have created?[148]

These privacy concerns became a reality in healthcare on January 30, 2018, when Amazon announced its joint-venture[149] with global banking institution JP Morgan Chase & Co.[150] and

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[144] Eric Griffith, *What is Cloud Computing?*, PCMAG (May 3, 2016), https://www.pcmag.com/article2/0,2817,2372163,00.asp.
[145] Farrow, s*upra* note 38.
[146] Dennis Green, *Jeff Bezos finally reveals how many people pay for Amazon Prime*, BUSINESS INSIDER (April 18, 2018), https://www.businessinsider.com/amazon-prime-member-numbers-revealed-2018-4.
[147] *Id.*
[148] *Id.*
[149] Angelica LaVito and Jeff Cox, *Amazon, Berkshire Hathaway, and JP Morgan Chase to partner on US employee health care*, CNBC, (Jan. 30, 2018), https://www.cnbc.com/2018/01/30/amazon-berkshire-hathaway-and-jpmorgan-chase-to-partner-on-us-employee-health-care.html.
[150] "J.P. Morgan is a global leader in financial services." See About Us, J.P. Morgan, https://www.jpmorgan.com/country/US/EN/about (last visited June 25, 2019).

holding company Berkshire Hathaway[151] seeking to transform the healthcare industry by cutting costs and improving quality of care illustrated with Berkshire Hathaway CEO Warren Buffet claiming that "the ballooning costs of healthcare act as a hungry tapeworm on the American economy."[152] The response appears to be mostly positive about the implications Amazon can have on healthcare with industry professionals such as Idris Adjerid–a management information technology professor at the University of Notre Dame–believing that "Amazon in particular can play a strong role if it promotes a greater presence for technological advances including artificial intelligence, and information sharing platforms into health care."[153] But the privacy concerns are monumental for different reasons exhibited by Harvard Law Professor I. Glenn Cohen stating, "Amazon already has huge amounts of our data–we give it to them in exchange for two-day shipping . . . . But what happens when you add in actual health-care data? Many people are already concerned about who has access to that information, and this exacerbates those concerns." [154] Amazon CEO Jeff Bezos

[151] Berkshire Hathaway is a global conglomerate holding company controlling entities such as Geico, Clayton Homes, Duracell, and Dairy Queen. *See Berkshire Hathaway*, http://www.berkshirehathaway.com (last visited June 25, 2019).
[152] LaVito, *supra* note 149.
[153] *Id.*
[154] Abha Bhattarai, *Privacy experts alarmed as Amazon moves into health care industry*, WASHINGTON POST (Jan. 30, 2018), https://www.washingtonpost.com/news/business/wp/2018/01/30/amazon-

acknowledged that "[t]he healthcare system is complex, and we enter into this challenge open-eyed about the degree of difficulty," while JPMorgan Chase CEO Jamie Dimon expressed his belief that "[o]ur people want transparency, knowledge, and control when it comes to managing their healthcare."[155]

The hiring of renowned surgeon Dr. Atul Gawande further illustrates Amazon's desire to enter the healthcare market and make an impact, beginning with improving the care of the workforce of the three companies and expanding from there.[156] The combination of the three companies roughly 1.2 million person workforce[157] plus the global reach of Amazon Prime and other Amazon users, the amounts of customer data that Amazon will have access to raises more concerns than the initial thought may recognize. By organizing their operations together, Amazon will have a global operation with information on individuals ranging from an individual's credit card information, address, family members, prescriptions, weekly deliveries of goods of all types and more. The future of Amazon health is still to be determined, but the use of data is certainly within that future. On

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already-has-huge-amounts-of-our-data-what-happens-when-you-add-healthcare-to-the-mix/?noredirect=on&utm_term=.fba456b06d67.

[155] LaVito, *supra* note 149.

[156] Angelica LaVito, *Dr. Atul Gawande to start as CEO of Buffett, Bezos and Dimon's health-care venture*, CNBC (July. 9, 2018), https://www.cnbc.com/2018/07/06/dr-atul-gawande-to-start-as-ceo-buffett-bezos-dimon-health-venture.html.

[157] *Id*.

one hand, predictive technology can be used to help improve our personal health and get the individual what is needed, but, on the other, our next side ad could be a medicine that could reveal our most intimate details.

Amazon's cloud service network, AWS, will only further this mission of implementing artificial intelligence and data crunching. Idris Adjerid, while mentioning above[158] his optimism for Amazon's health future, stated, "Amazon is a data-centric company that's good at artificial intelligence and machine learning, so it doesn't take much to see that that's what they'll bring to the health-care industry."[159]

Amazon's entire business model is built upon a foundation of personal data.[160] Professor Galloway, who labeled Amazon as one of his Four Horsemen, writes that "Amazon now offers everything you need, before you need it, delivered in an hour to the 500 million wealthiest households on the planet."[161] This global power and access to data will permit Amazon to expand upon its healthcare ambitions but will it be at the expense of the individual's "private" medical records? Peter Swire, law professor at Georgia Tech University and former White House coordinator

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[158] LaVito, *supra* note 149.
[159] Bhattarai, *supra* note 154.
[160] Dave Gershgorn, et al., *What is Amazon, really*, QUARTZ (Aug. 20, 2017), https://qz.com/1051814/what-is-amazon-really/.
[161] Galloway, *supra* note 109, at 56.

for HIPAA discussed that "[HIPAA] covers traditional health insurance and provider health care, but it doesn't cover many of the other sources of health-related data that today's technology generates . . . . It doesn't cover, for example, the books you buy about health care or the many fitness and health-care apps you may have on your phone."[162]

ALPHABET'S GOOGLE[163]

Similarly to Amazon's machine learning and cloud based networks, Google is also betting on data configuration and artificial intelligence to make its mark on the healthcare sector.[164] According to a research report by CBInsights,[165] Alphabet is focusing the most attention towards its artificial intelligence capabilities in organizing and interpreting data to provide quicker diagnoses, detect specific trends, and develop disease and lifestyle

[162] Bhattarai, *supra* note 154.

[163] Google was originally founded as its search engine but after Google began to spread into other sectors it created Alphabet in 2015 as its parent company that brought under its wing many former Google subsidiaries and Google itself. To promote note clarity, no distinction will be made between the two and mentioning Google will refer the reader to all of its capacities. *See generally* Jillian D'Onfro, *Google is now Alphabet*, BUSINESS INSIDER (Oct. 2, 2015), https://www.businessinsider.com/google-officially-becomes-alphabet-today-2015-10.

[164] Research Report, *How Google Plans To Use AI To Reinvent The $3 Trillion US Healthcare Industry*, CBINSIGHTS, https://www.cbinsights.com/research/report/google-strategy-healthcare/ (last visited January 27, 2019).

[165] CB Insights' machine intelligence platform, intelligence analysts, and global network of executives and startups empower people to articulate compelling answers to difficult questions — about growth, about the competition, and about technology. See generally https://www.cbinsights.com/about. (Author's note).

management.[166] Recent acquisitions have brought Verily and DeepMind, among others, under the Alphabet umbrella of data accumulation.[167] Major focuses for the company following these recent acquisitions include detection and management of eye disease, diabetes, and heart disease.[168] Verily states that they "are running longitudinal studies to better understand ways to predict and prevent disease onset and progression,"[169] while DeepMind focuses broadly on issues ranging "[f]rom climate change to the need for radically improved healthcare, too many problems suffer from painfully slow progress, their complexity overwhelming our ability to find solutions."[170]

For entities that fall within HIPAA's sphere of influence and seek to use Google's cloud network, they "must review and accept Google's Business Associate Agreement," but "[n]ot all Google Cloud products are designed to comply with HIPAA and only specified products are covered under [Google's] Business Associate Agreement."[171] However, one must keep in mind that this is a limited agreement for entities that would like to have their

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[166] *How Google Plans To Use AI To Reinvent The $3 Trillion Healthcare Industry*, *supra* note 164.
[167] *Id.*
[168] *Id.*
[169] *See Projects*, Verily, https://verily.com/projects/ (last visited June 23, 2019).
[170] *See About Us*, DeepMind, https://deepmind.com/about/ (last visited June 23, 2019).
[171] *See generally Standards, Regulations & Certifications*, Google Cloud, https://cloud.google.com/security/compliance/hipaa-compliance/ (last visited 7/1/2019).

operations maintain compliance with Google products. This does not apply to information that the individual possesses on their own and Google, by simple virtue of it being their product, has access to.

Part III: Enriching Lives While Ensuring Privacy

While Tim Cook states that, privacy is a fundamental human right, and positions Apple as taking what has been traditionally with the institutions and using it to empower the individual, the laws and regulations of the United States and the fifty individual states do not directly support such a notion.[172] The many laws of the United States are vast and overwhelming yet "employ[ ] a 'sectoral' approach to data privacy rather than the 'comprehensive' approach used by jurisdictions such as the European Union."[173] For this reason and due to the potentiality of an individual's medical data being used for improper purposes– such as selling, marketing, profiteering and the like– restructuring must be made in order to credence to the original framework that HIPPA and HITECH established–to ensure the privacy of every individual is guaranteed in the laws and regulations of this country as opposed to the whims of the individual company's executives. As James Madison wrote, "If men were angels, no government

[172] Baum, *supra* note 63.
[173] Nicholas Camillo and Devika Kornbacher, *Example of FIPPS in Current Data Privacy Laws*, 2018 TXCLE Intell. Prop. L. 3-IV, 2018 WL 6186992.

would be necessary." [174] Unfortunately, recent events, from Yahoo[175] and Facebook[176] to the latest fine against Google under the GDPR [177], have vividly demonstrated that an individual's personal data, especially health records, cannot and should not be left to such angelic conditionals.

The protections provided individuals within HIPAA and HITECH will likely cover many operations that the aforementioned companies of Apple, Amazon, and Google will conduct with covered entities, but likelihoods and probabilities are not adequate in a health context when one's health relies upon the accuracy and reliability of such records. However, personal health information that the individual freely provides through platforms such as Apple's Health App and Apple Watch would not fall under HIPAA or HITECH protections unless these companies grow into the definitions provided by the rules or contract with those entities that are. As a result, the United States should adopt a national GDPR Plus[178] framework for healthcare and all such entities that operate within healthcare in order to properly regulate entities such

[174] THE FEDERALIST NO. 51, at 322 (James Madison) (Clinton Rossiter ed., 1961).
[175] *Yahoo provides notice to additional users affected by previously disclosed 2013 data theft, supra* note 73.
[176] Valdez, *supra* note 74.
[177] Schechner, *supra* note *85.*
[178] This is not recognized terminology but simply a name the author has developed for purposes of this note to analogize to the EU's GDPR law while adding the Plus terminology to designate the link solely to health information and establish the difference between that which is proposed and that of the EU.

as the tech giants while also giving full control to the individual over his or her medical data. As put by Tim Cook in his recent op-ed piece in *Time Magazine*:

> "Meaningful, comprehensive federal privacy legislation should not only aim to put consumers in control of their data, it should also shine a light on actors trafficking in your data behind the scenes
>
> . . . .
>
> We cannot lose sight of the most important constituency: individuals trying to win back their right to privacy. Technology has the potential to keep changing the world for the better, but it will never achieve that potential without the full faith and confidence of the people who use it."[179]

GDPR PLUS FOR HEALTHCARE?

At the outset, this proposition is not meant to be exhaustive, comprehensive, or a full analysis of a potential GDPR Plus option, but rather meant to promote further discussion of this topic and to express the need for proper individual protections. This section will briefly address some overlying concepts to promote future analysis and debate.

In order to fully establish the proposals to follow under GDPR Plus, there will be needed cooperation from the tech giants for further innovation to provide that the individual personally owns his or her medical data as opposed to relying upon the

[179] Tim Cook, *You Deserve Privacy Online: Here's How You Could Actually Get It Done*, (Jan. 16, 2019), TIME MAGAZINE, http://time.com/collection/davos-2019/5502591/tim-cook-data-privacy/.

transfer of records from the healthcare provider.[180] If an individual's medical data could all be stored on one's personal device as well as in a personal cloud provider under a system similar to Apple's iCloud Apple ID[181] service or the organ donor heart logo on an individual's driver's license,[182] providers can be certain that the information provided by the individual patient is accurate but more importantly only accessible to those with expressed consent. The implications of the individual possessing his or her own medical data would then require all companies such as the three mentioned above and third party app developers to request an opt-in capability as opposed to an adhesive contractual feel of agree or disagree, all or nothing.

A common argument against such regulation would be that it stifles innovation due to costs being used in order to comply with the regulations instead. Although valid, this contention is misguided because the current framework provides for the ability of fifty states to be creating their own data privacy laws while also

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[180] Jennifer Shoaf Richardson, *CEOs Lead Charge for National Consumer Privacy Law*, WORKPLACE PRIVACY, DATA MANAGEMENT & SECURITY REPORT (Jan. 17, 2019), https://www.workplaceprivacyreport.com/2019/01/articles/data-security/ceos-lead-charge-for-national-consumer-privacy-law/.

[181] When an individual uses iCloud, the individual uses an email as the username and. Also has a password. Whenever the individual signs into that account on any Apple device, the individual can choose to bring all information present on another device and previously saved. Additionally, the individual may sync all device simultaneously so that information added to one will immediately sync to the other. *See generally* iCloud: What is I ICloud?, Apple (June 20, 2019), https://support.apple.com/kb/PH2608?locale=en_US.

[182] This is essentially an opt-in for your information, tissues and organs to be used to benefit others.

having HIPAA to consider. If a more innovative friendly HIPAA alternative were to be created that would seek to foresee the needed innovation of big tech while also permitting the individual to know the data that is collected and who possessed access to it, the innovation could actually grow exponentially because companies would know their specific parameters and individuals would be safer by knowing what information is out there and who has it.

A main issue with HIPPA and GDPR would be that both prohibit a private right of action, which removes the individual's ability to challenge unless a party were to act on their behalf. Additionally, HIPAA is reactionary not covering new technologies unless they were to partner with the old covered entities and GDPR is too broad covering nearly everything granting too much power to the individual that virtually removes all data that could be used to increase innovation. As a result, a balance should be found between the individual's right and the companies ability to grow and continue to benefit society.

Conclusion

As the big technological powers of Apple, Amazon, and Google continue to innovate and enter the healthcare sector, it would be wise for lawmakers to implement a legal framework to

ensure the protection of an individual's medical data while also embracing further innovation that can benefit the lives of billions across the globe. HIPAA and HITECH were arguably sufficient and perhaps innovative at the turn of the millennium, but the technological advances that have occurred since their inception cry out for an updated framework that connects society's growing concern for privacy in a world of connectedness to society's growing desire to improve our lives and personal health. An opt-in approach would be a good beginning to empower the individual while also preventing the inhibition of innovation that is often the common critique of initial regulatory implementation. The current structure with HIPAA provides for all information to be covered and not transmitted unless specifically designated. This designated approach mirrors a command economy methodology that is resemblant of reactionary additions as opposed to assessing where innovation is going and regulating proactively. Consequently, innovation is often stifled, innocent and or harmless conduct constitute violations, and new developments such as those presented within this note are not covered or present another problem that continues the reactionary cycle approach.

As a result, a uniform system that connects the fifty states under the guidance of a GDPR Plus link would be wise to tackle the inevitably unforeseen consequences that technological

innovation in healthcare can present while also avoiding the multitude of regulatory overlap with the current HIPAA as a floor approach. Although this note does not present by any means an exhaustive analysis or a satisfactory proposal, these questions should be addressed to ensure that society can adjust appropriately to changing circumstances in the future as opposed to reacting radically due to unpreparedness. Technology and healthcare will only become more connected in the future, not less. The future will be what we make it. We best begin making it now.

BLOCKCHAIN FOR DSCSA COMPLIANCE

RYLAND CLOSE

I. INTRODUCTION

As the pharmaceutical supply chain continues to expand globally, issues with substandard drugs pose a growing problem for the US pharmaceutical industry. Counterfeit drugs and diverted drugs are two significant problems in the pharmaceutical supply chain that stem in part from inadequate tracking and tracing of the drug. Traditional methods such as holograms, unique watermarks, tamper-proof packaging, and color changing inks are currently being used to help secure the supply chain against counterfeit

drugs and drug diversion.[1] While these methods provide improved security, making it more difficult to counterfeit a drug, they fail to adequately address the major underlying problem of tracking a drug's pedigree from manufacturer to consumer and everywhere in between.

The World Health Organization has estimated that 10% of drugs in the global market are counterfeit.[2] Since 2000, every single state in the US has experienced an incident with counterfeit drugs.[3] There are a variety of dangers that patients face as a result of counterfeit drugs. For example, the counterfeit drug may contain no active ingredient, it may contain no active ingredient combined with harmful ingredients, it may contain an entirely wrong active ingredient, or the drug may contain the wrong concentration or an incorrect dose of the correct active ingredient.[4] In any of these scenarios, patients face serious health risks, whether it be receiving no actual medicine, taking the wrong medicine, or receiving a potentially dangerous incorrect dosage. The dangers counterfeit drugs present are exemplified when over five-hundred children

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[1] Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, Cambridge Innovation Institute, http://www.bio-itworld.com/newsitems/2006/january/11-18-06-news-supply-chain/.
[2] Bill Berkot, *Fake Avastin shows little protection of drug supply*, Reuters (Mar. 12, 2012), https://www.reuters.com/article/us-avastin-drug-fake/fake-avastin-shows-little-protection-of-drug-supply-idUSBRE82B0YY20120312.
[3] The Partnership for Safe Medicines, *Counterfeit Drugs in America: Crimes, Victims & Solutions*, Fact Pack, 2nd Edition (Mar. 2017), http://www.safemedicines.org/wp-content/uploads/Fact-Pack-2017-web-copy.pdf.
[4] Erwin A. Blackstone, Joseph P. Fuhr Jr. & Steve Pociask, *The Health and Economic Effects of Counterfeit Drugs*, Am. Health & Drug Benefits (June 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4105729/#R11.

across the globe died of counterfeit cough medicine that was tainted with antifreeze.[5] In recent years, deaths from counterfeit drugs containing the potent ingredient fentanyl have frequently appeared in news headlines stemming from America's opioid crisis. Fentanyl has been found in counterfeit versions of popular opiates such as oxycodone and hydrocodone, as well as counterfeit Xanax. These counterfeits have been found in 44 states and have caused deaths in 26 of those states. [6]

Drug diversion, like counterfeit drugs, is a serious problem in the pharmaceutical supply chain. A diverted drug is one which has "been removed from the regulated distribution channels but then reintroduced into the wholesale marketplace through various means."[7] Drugs are often reintroduced into the legitimate market through the creation of a false drug pedigree. This false pedigree is a falsified history of the drug's path through the pharmaceutical supply chain that conceals the fact that the drug ever left the market, thus making the drug appear as if it came from a legitimate source.[8] Drug diverters repurchase pharmaceuticals that have been dispensed to patients at a discounted price, repackage the drugs,

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[5] Liang BA, *Fade to black: importation and counterfeit drugs*, Am. J. Law Med. 2006; 32: 279–323.
[6] *Fatal Doses of Fentanyl Increasingly Found in Counterfeit Medications*, Partnership for Drug-Free Kids (Oct. 11, 2018), https://drugfree.org/learn/drug-and-alcohol-news/fatal-doses-of-fentanyl-increasingly-found-in-counterfeit-medications/.
[7] U.S. v. Charles Jeffrey Edwards (Counts 1 - 28), Brenda Elise Edwards (Counts 1-27), Jerrod Nichols Smith (Counts 1-16; Count 28)., 2013 WL 12210003 (M.D. Tenn.).
[8] *See* Id.

and then resell the product into the wholesale pharmaceutical market.[9] Drug diversion poses similar risks as counterfeit drugs, as diverted drugs may be expired, stored in improper conditions, or adulterated in some way that causes the drug to lose its potency or become dangerous.[10]

Part I of this Note will illustrate the problems posed by drug counterfeiting and drug diversion, describe current solutions being used to address these problems, and conclude with a discussion of federal legislation that seeks to fix these weaknesses in the pharmaceutical supply chain, focusing on the tracking and tracing requirements that the DSCSA imposes on supply chain participants. In Part II, this Note will examine the development of blockchain technology as well as examine its defining characteristics. Part III will explore current industry efforts to apply blockchain technology to supply chain uses and contends that blockchain is uniquely fit to meet the DSCSA tracking and tracing requirements and fix the weak points in the global pharmaceutical supply chain that allow counterfeit or diverted drugs to enter into the legitimate wholesale market. This Note concludes with a recommendation that the Federal Drug Administration (FDA) continue to monitor industry progress and make accommodations necessary with regard to enforcement of

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[9] *See* Id.
[10] *See* Id.

DSCSA requirements, including potentially extending its deadline for compliance, so as to ensure that members of the pharmaceutical industry have appropriate time to properly develop and implement the best possible supply chain solution, solutions that will likely rely on blockchain technology at some point in the future.

II. BACKGROUND

The US has one of the safest drug supply chains in the world; however, our system is not impenetrable.[11] While this Note is primarily concerned with issues involving counterfeit and diverted drugs, these are just two examples of a broader problem of contaminated, expired, adulterated, or otherwise substandard drugs that are entering the US market as a result of flaws in the supply chain. Drug counterfeiting and drug diversion are both ultimately a result of a failure to track and trace a drug from manufacturer, to repackager, to wholesale distributor, to dispenser. Medications are currently tracked and traced through the supply chain through the use of drug pedigrees that the seller provides to the buyer of a medication.[12] A drug pedigree is, "a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all

[11] FOOD AND DRUG ADMIN., DRUG SUPPLY CHAIN INTEGRITY, (Oct. 22, 2018), https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm.

[12] FOOD AND DRUG ADMIN., CPG SEC. 160.900 PRESCRIPTION DRUG MARKETING ACT -- PEDIGREE REQUIREMENTS UNDER 21 CFR PART 203. SECTION 503(E)(1)(A) OF PDMA, (Mar. 6, 2015), https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm073857.htm.

parties to them."[13] Maintaining secure and accurate drug pedigrees is essential to protecting the US as well as the global supply chain against counterfeit and diverted drugs. Currently drug pedigrees are typically kept as paper or electronic documents, which are susceptible fraud or forgery as evidenced by the multitude of counterfeit and diverted drug incidents. These forged or fraudulent drug pedigrees, known as false drug pedigrees, are created by parties to obscure the actual origins of the drug they are selling. The cases explored in this section highlight how the creation of false drug pedigrees allows for the introduction of counterfeit medication and diverted drugs into the legitimate market.

A. COUNTERFEIT MEDICINE

In 2018 a group of Canadian pharmaceutical companies were convicted of selling counterfeit and misbranded medication throughout the United States.[14] The group of companies including Canada Drugs and its subsidiaries, Rockley Ventures and River East Supplies, was ordered to surrender $29 million in proceeds and to pay a $5 million fine.[15] The FDA found that Canada Drugs was selling unapproved drugs that were labelled with foreign

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[13] *Id.*
[14] U.S. ATTORNEY'S OFFICE DISTRICT OF MONTANA, CANADIAN DRUG FIRM ADMITS SELLING COUNTERFEIT AND MISBRANDED PRESCRIPTION DRUGS THROUGHOUT THE UNITED STATES, (Apr. 13, 2018), https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs.
[15] *Id.*

languages and had inadequate instructions for use.[16] In order to sell these unapproved and misbranded drugs to US buyers, Canada Drugs purchased other pharmaceutical companies, using the companies' established brand names, drug inventories, and list of customers essentially as shell companies to distribute their product.[17] The U.S. Attorney's Office for the District of Montana stated, "[i]n order to avoid detection, Canada Drugs and its affiliated companies falsified customs forms concerning the value of the drugs shipped into the United States."[18] Canada drugs utilized one such subsidiary company, River East Supplies, to sell counterfeit cancer drugs, Avastin and its Turkish counterpart-drug Altuzan, in the United States.[19] Laboratory testing revealed that these counterfeit cancer drugs had no active ingredient.[20] This is particularly dangerous as the cancer patients taking the counterfeit medication were receiving no benefit from the medication. This creates the risk that upon observing that the counterfeit cancer medicine is not working as expected, unknowing doctors may prescribe a different course of treatment, ultimately depriving the patient of the benefits that the legitimate drug may have provided.

Canada Drugs' counterfeit drug operation highlights weakness in the current regulation of the pharmaceutical supply

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[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*

chain. By using subsidiary companies with established business relationships in the United States and by creating false drug pedigrees, Canada Drugs was able to circumvent the protections provided by the regulatory system and introduce counterfeit drugs into the legitimate market. With a secure, accurate drug pedigree that traces each drug from the distributor back to its manufacturer, Canada Drugs' illegal operation would most likely not have been possible. Part C of this Note explores legislative initiatives designed to create a better system for protecting against false drug pedigrees such as the ones utilized by Canada Drugs.

B. DRUG DIVERSION

A recent drug diversion operation centered around a warehouse in Nashville, Tennessee illuminates the flaws in the supply chain that allow for drug diversion and drug counterfeiting. In 2013, three individuals who ran and operated Cumberland Distribution, Inc. ("Cumberland") were indicted and charged with diverting over $50 million of HIV/AIDS, anti-psychotic, anti-depressant, blood pressure, diabetes, and other medications.[21] The United States District Court for the Middle District of Tennessee found that Cumberland was engaged in a street diversion scheme, in which the company purchased various drugs off of the black market, created false drug pedigrees, and resold the medication

[21] U.S. v. Charles Jeffrey Edwards (Counts 1 - 28), Brenda Elise Edwards (Counts 1-27), Jerrod Nichols Smith (Counts 1-16; Count 28)., 2013 WL 12210003 (M.D. Tenn.).

into the legitimate market.[22] From 2006 to 2009, Cumberland purchased millions of dollars worth of medication from unlicensed street suppliers based in New York City and Miami who had previously purchased the drugs from patients in the surrounding areas.[23] After purchasing the drugs from the street suppliers, many of the drugs were shipped to a warehouse in Nashville where they were repackaged to look as if they were newly manufactured drugs.[24] The repackaged drugs were then shipped from the Nashville warehouse directly to pharmacies around the country.[25]

Cumberland also shipped many of the drugs it purchased on the black market to shell companies that it operated in Arkansas and Louisiana.[26] These companies, which were licensed to sell medications, created false drug pedigrees showing that the shell companies had purchased the drugs from legitimate, licensed, drug wholesalers, thus hiding the fact that the drugs were actually sourced from the street suppliers.[27] The drugs were then shipped to the Nashville warehouse where they were repackaged and shipped, along with their seemingly legitimate false drug pedigrees, to pharmacies across the country.[28]

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[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*

The Cumberland case illustrates the dangers of drug diversion, as unknowing pharmacies that purchased the drugs from Cumberland reported various problems with the drugs. These problems included bottles that contained the wrong medicine, wrong dosage information, and shockingly, even some bottles that contained breath mints instead of medicine. If it were not for the false drug pedigrees that Cumberland provided to the dispensing pharmacies, the pharmacies could have entirely avoided doing business with Cumberland.

C. LEGISLATION

Concern over the introduction of counterfeit or substandard drugs into the market is nothing new. Over a century ago, Congress first addressed the issue by enacting the original Food and Drugs Act in 1906, which prohibited the trade of "misbranded and adulterated foods, drinks and drugs."[29] Today, the Prescription Drug Marketing Act of 1987 and the Drug Supply Chain Security Act are integral parts of the current federal initiative to secure and protect the pharmaceutical supply chain from substandard drugs entering the market through illegitimate means like counterfeiting and diversion.

[29] FOOD AND DRUG ADMIN., MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY, (Feb. 1, 2018), https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history.

i. PRESCRIPTION DRUG MARKETING ACT OF 1987

The Prescription Drug Marketing Act of 1987 (PDMA) established drug pedigree requirements for certain wholesale distributors.[30] The PDMA was designed to "(1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs."[31] The PDMA requires unauthorized distributors to "provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug."[32] However, as illustrated by drug diversion schemes like Cumberland Distribution, Inc., merely requiring a distributor to provide a buyer with a pedigree containing the transaction history of a drug does not eliminate the risk of counterfeit or diverted drugs entering the market, as pedigree documents are susceptible to forgery and fraud.

Another potential gap in the protection provided by the PDMA is that only unauthorized distributors are required to provide drug pedigrees.[33] The act defines an unauthorized distributor as "a distributor who does not have an ongoing

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[30] 21 C.F.R. § 203.50 (2006).
[31] FOOD AND DRUG ADMIN., PRESCRIPTION DRUG MARKETING ACT OF 1987, (Mar. 29, 2018), https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/prescriptiondrugmarketingactof1987/default.htm.
[32] 21 C.F.R. § 203.50 (2006).
[33] *See* 21 C.F.R. § 203.3 (2008).

relationship with a manufacturer to sell or distribute its products"[34] While many counterfeit or diverted drugs enter the market through such unauthorized distributors, authorized distributors have also introduced counterfeit or diverted drugs into to legitimate as evidenced by Canada Drugs' counterfeiting scheme in which they used authorized shell companies with ongoing relationships with US purchasers.[35] Once in the hands of unknowing, authorized distributors, the diverted or counterfeit drugs could be sold to buyers without the security of providing a drug pedigree to the buyer. While the PDMA surely increased the security of the pharmaceutical supply chain, it left work to be done to further reduce the risk of substandard drugs entering the legitimate market.

ii. DRUG SUPPLY CHAIN SECURITY ACT

In 2013, Congress enacted the Drug Supply Chain Security Act (DSCSA) to address these regulatory gaps in the supply chain left by the PDMA and further protect consumers from counterfeit and diverted drugs, among other things.[36] According to the FDA, the DSCSA "outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are

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[34] 21 C.F.R. § 203.3 (2008).
[35] U.S. ATTORNEY'S OFFICE DISTRICT OF MONTANA, CANADIAN DRUG FIRM ADMITS SELLING COUNTERFEIT AND MISBRANDED PRESCRIPTION DRUGS THROUGHOUT THE UNITED STATES, (Apr. 13, 2018), https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs.
[36] FDA, DRUG SUPPLY CHAIN SECURITY ACT (DSCSA), (May 22, 2019), https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

distributed in the United States."[37] On January 1, 2015, the PDMA's pedigree requirement was replaced by the tracking and tracing standards required by the DSCSA.[38] Additionally, the DSCSA prohibits manufacturers from trading with any unauthorized trading partners, thus at least partially patching the gap left by the PDMA pedigree requirements that only required purchasers to get drug pedigrees from unauthorized distributors before doing business with them.[39]

As for the information that must be supplied under the DSCSA, the act requires the "exchange of transaction information, transaction history, and transaction statements" for each transaction of a drug throughout the supply chain.[40] Transaction information under the DSCSA includes information concerning the name or names of the product, the dosage, the National Drug Code number of the product, the date of the transaction, the lot number, and the names of the businesses involved in the transaction among other things.[41] The DSCSA defines transaction history as, "a statement in paper or electronic form, including the transaction information for each prior transaction going back to the

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[37] *Id.*
[38] FDA, DRUG SUPPLY CHAIN SECURITY ACT PRODUCT TRACING REQUIREMENTS FREQUENTLY ASKED QUESTIONS, (June 29, 2017), https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-product-tracing-requirements-frequently-asked-questions.
[39] 21 U.S.C.A. § 360eee-1(b)(3) (West, Westlaw through Pub. L. No. 116-21).
[40] *Id.* § 360eee-1(a)(2)(A).
[41] *Id.* § 360eee(26).

manufacturer of the product."[42] The transaction statement must state that:

> the entity transferring ownership in a transaction -- (A) is authorized as required under the Drug Supply Chain Security Act; (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 360eee-1 of this title; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 360eee-1 of this title; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.[43]

It is essential to understand with whom information must be shared under the DSCSA. The DSCSA requires that participants in the drug supply chain provide transaction information, transaction history, and transaction statements to the subsequent entity that is taking ownership of the drug.[44] For example, a manufacturer is required to provide a subsequent wholesale distributor with the required information.[45] Likewise, the wholesale distributor is prohibited from accepting product from a manufacturer that does not provide the required information along with the product.[46] In addition to providing the required information to the subsequent owner, entities must also have

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[42] *Id*. § 360eee(25).
[43] *Id*. § 360eee(27).
[44] *Id.* § 360eee-1(a)(2)(A)(i).
[45] *Id.* § 360eee-1(b)(1)(A).
[46] *Id.* § 360eee-1(c)(1)(A)(i).

"systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required."[47] Additionally each entity must have:

> The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required-- (i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).[48]

Thus, upon receiving a request for the information, each entity must be prepared to provide a complete transaction history and transaction information to the Secretary or any other participant who handled the product in the supply chain, regardless of whether they directly engaged with one another or whether there were other market participants,

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[47] *Id.* § 360eee-1(g)(1)(D).
[48] *Id.* § 360eee-1(g)(1)(E).

further removed, that exchanged the product in between them.[49]

The DSCSA gave companies a ten-year deadline to implement the act's tracking system requirements, mandating that all companies involved in the pharmaceutical supply chain implement a system allowing for the traceability of drugs at individually by November 27, 2023.[50] The DSCSA's provided path to compliance can be broken down into three distinct stages of implementation: product verification, serialization, and traceability.[51] To achieve the first step of product verification, companies must be able to promptly provide the FDA with the product's chain of custody at any time so that the FDA can verify it.[52] To achieve the second stage of serialization, companies must create a system by which they can identify each product at a unit level which can be utilized for identification on lots, cases, and packages.[53] To achieve the final step requiring traceability on the product level, companies must have in place the interoperable system which can store information from each transaction; such a

[49] *Id.* § 360eee-1(g)(1)(E).
[50] *Id.* § 360eee-1(g).
[51] Edwin Lopez, *The Drug Supply Chain Security Act: A Progress Report*, Supply Chain Dive (Apr. 23, 2018), https://www.supplychaindive.com/news/Drug-Supply-Chain-Security-Act-progress-serialization-spotlight/521862/.
[52] *Id*.
[53] *Id*.

system must be in place for every member of the product's supply chain from manufacturers to the final dispensers.[54]

These requirements apply to each member of the supply chain including manufacturers, re-packagers, wholesale distributors, third party logistics providers, and dispensers like pharmacies or hospitals.[55] The Center for Supply Chain Studies has raised concerns with the DSCSA requirement that any given entity in the supply chain must trace transaction information and history through each entity back to the manufacturer, noting that providing this information "could require tens of thousands of electronic connections between previously 'unconnected' participants. Essentially, each supply chain participant might need to form an electronic connection with each potential company participating in their supply chain. *Currently, no such electronic system exists.*"[56] Blockchain appears to be an ideal solution to this problem, given that information stored on a blockchain can be immediately accessed and audited by any member of the network. Transaction information, history, and statements stored on a blockchain platform that is shared between all participants in the product's

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[54] *Id*.
[55] *Id*.
[56] CENTER FOR SUPPLY CHAIN STUDIES, THE DRUG SUPPLY CHAIN SECURITY ACT AND BLOCKCHAIN – A WHITE PAPER FOR STAKEHOLDERS IN THE PHARMACEUTICAL SUPPLY CHAIN, CENTER FOR SUPPLY CHAIN STUDIES (Jun. 21, 2018), https://static1.squarespace.com/static/563240cae4b056714fc21c26/t/5b3a552c2b6a28f30c0c5d31/1530549553630/C4SCS+White+Paper_+DSCSA+and+Blockchain+Study_FINAL4.pdf (emphasis in original).

supply chain could be immediately accessed and audited by any entity in the blockchain's network.[57]

D. CURRENT TRACKING SOLUTIONS

Meeting the DSCSA implementation stages for a complex interoperable tracking system between all members involved in a product's chain of custody in time for the ten-year timeline has proved challenging for companies responsible to implementing the changes.[58] The FDA has been accommodating with regards to these ongoing challenges by pushing back enforcement deadlines.[59] For example, originally the deadline for all manufacturers to serialize their products was November 27, 2017.[60] However in September 2018, following the passage of the original deadline and after receiving requests from smaller contract manufacturing organizations for a grace period[61], the FDA published guidance stating that it would delay enforcement of its product identifier requirements from November 27, 2017, to November 27, 2018.[62] It is not just a few small companies that are

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[57] *See* Maryanne Murray, *Blockchain Explained*, Reuters (Jun 15, 2018), http://graphics.reuters.com/TECHNOLOGY-BLOCKCHAIN/010070P11GN/index.html.

[58] Lopez, *supra* note 51, at 12.
[59] U.S. DEPT. OF HEALTH AND HUMAN SERVS., FOOD AND DRUG ADMIN., et al., *PRODUCT IDENTIFIER REQUIREMENTS UNDER THE DRUG SUPPLY CHAIN SECURITY ACT – COMPLIANCE POLICY*, (Sep. 2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.
[60] *Id*.
[61] Brajinder Singh, *DSCSA Enforcement Delay – What it Means for You*, (Jul. 3, 2017), https://clarkstonconsulting.com/insights/dscsa-enforcement-delay/.
[62] FDA, *supra* note 59, at 13.

lagging behind the DSCSA's ideal implementation deadlines.[63] A survey of over 660 companies in the pharmaceutical supply chain revealed that only 25% of companies were actually ready to meet the deadline of November 2017.[64] As the November 2018 deadline has come and gone, it appears that more FDA accommodation may be necessary going forward as companies continue to struggle to keep their implantation on track for the final 2023 traceability goal.[65]

Companies are currently incorporating an array of different technologies to build a system for collecting, tracking, and tracing data and for establishing databases for storing and sharing that data. Companies have used radio-frequency identification (RFID), barcodes, and web-based tracking systems based on tracking codes such as the type utilized by FedEx and UPS tracking to track and collect data concerning the pedigree of drugs through the supply chain.[66] The FDA's published guidance for the industry on complying with the DSCSA allows for the use of "paper or electronic versions of invoices; paper versions of packing slips; Electronic Data Interchange (EDI) standards ... EPCIS (Electronic Product Code Information Services), which defines a data-sharing

[63] Lopez, *supra* note 51 at 12.
[64] *Id*.
[65] Health Distribution Alliance, *Three Takeaways from the FDA Public Meetings on DSCSA*, Mar. 26, 2018, https://www.hda.org/news/hda-blog/2018/07/25/08/29/three-takeaways-from-the-fda-public-meetings-on-dscsa.
[66] Susannah Patton, *Cracks in the Pharmaceutical Supply Chain*, Cambridge Innovation Institute, (Jan. 11, 2006), http://www.bio-itworld.com/newsitems/2006/january/11-18-06-news-supply-chain/.

interface that enables supply-chain partners to capture and communicate data about the movement and status of objects in the supply chain."[67] The FDA's guidance notes that email-based or web-based portals for exchanging information are acceptable.[68]

A relational database is one option that companies are utilizing for tracking a drug's pedigree. Data in a relational database is stored in multiple tables that are interrelated–think Master excel spreadsheet combined with its multiple slave spreadsheets. When using a relational database for DSCSA compliance, each manufacturer manages its own database for tracking a product's information. Relational databases allow for easy manipulation of data which is stored in multiple tables in the database, as "[e]ach table of data can be updated without disrupting the others."[69] Additionally any mistakes in the data must be manually checked against the other tables.[70] While the increase manageability of data may be a benefit in some contexts, this is exactly the kind of flexibility that could allow for fraudulent altering of data to create false drug pedigree information in a database. As there is no system for relational databases that automatically detects such changes in data, such breaches could go

[67] FOOD AND DRUG ADMIN., DSCSA STANDARDS FOR THE INTEROPERABLE EXCHANGE OF INFORMATION FOR TRACING OF CERTAIN HUMAN, FINISHED, PRESCRIPTION DRUGS: HOW TO EXCHANGE PRODUCT TRACING INFORMATION - GUIDANCE FOR INDUSTRY, (2014).
[68] *Id*.
[69] *What is a Relational Database Management System?*, Sisense (2019), https://www.sisense.com/glossary/relational-database/.
[70] *Id*.

unnoticed for some time. Thus, a relational database does not appear to be a good option for DSCSA compliance because "each database owner is responsible for the accuracy, reliability and security of its own database."[71] In other words, it requires trust between parties, something that should be minimized in order to create the most secure system. Blockchain on the other hand, operates without trust between parties.

Another option is the one-up and one-down method in which transaction information is only shared between entities who directly trade with one another. Like a relational database, this system has the weakness of being dependent on each individual entity for the accuracy and security of the information. Additionally, given the DSCSA requirement that parties must be able to make transaction history, transactions information, and transaction statements available to any other party in the drug's supply chain, the one-up and one-down method is a poor option for sharing such information throughout members of the supply chain that are further removed from the party that must share the information.

A database stored on blockchain would provide protection for the gaps left by current methods of tracking data because once

[71] Nicholas Basta, *Blockchain: the technology to make DSCSA work after 2023?*, Pharmaceutical Commerce (Jul. 24, 2017), http://pharmaceuticalcommerce.com/information-technology/blockchain-technology-make-dscsa-work-2023/.

entered, data stored on a blockchain is nearly impossible to change and the data is instantly available to any party on the network. Thus, unlike current systems of tracking information, a blockchain database offers heightened security, increased auditability, and can operate in an environment devoid of trust.

III. BLOCKCHAIN & SMART CONTRACTS

A. BLOCKCHAIN

When most people hear the term blockchain they likely think of cryptocurrencies like Bitcoin, the first and probably most well-known use of blockchain. Bitcoin was developed in 2008 when a white paper was published under the name Satoshi Nakamoto describing Bitcoin as a peer to peer network designed to fix the problem of double spending of electronic cash, that is fraudulently using the same electronic cash to pay two different people.[72] Blockchain is the underlying technology that supports platforms such as Bitcoin or the smart-contract enabled Ethereum.[73] Blockchain's potential disruptive effect has been compared to that of the internet,[74] and indeed, just like the internet, blockchain technology has the potential to be applied to a wide-

[72] SATOSHI NAKAMOTO, BITCOIN.ORG, BITCOIN: A PEER-TO-PEER ELECTRONIC CASH SYSTEM 4 (2008), https://bitcoin.org/bitcoin.pdf.
[73] *What is Ethereum?*, http://ethdocs.org/en/latest/introduction/what-is-ethereum.html.
[74] *Blockchain Regulatory Landscape: Key Reference Materials as of April 25, 2018*, 20180510P NYCBAR .5.

array of uses across many different fields.[75] A survey conducted by Deloitte of over 1,000 executives representing companies from seven countries and a wide array of industries including healthcare, technology, pharmaceutical, automotive, oil and gas, and financial services revealed that supply chain is at the top of the list of use cases that companies are currently working on for blockchain technology: (1) supply chain, (2) the internet of things, (3) digital identity, (4) digital records, (5) digital currency, (6) payments, and (7) voting.[76]

At its core, blockchain is a database for recording transactions; it is list of transactions distributed among many different computers on a network.[77] Blockchain is a time-stamped digital ledger that is shared across a decentralized network of computers, known as nodes.[78] Blockchain securely records a chronological log of transactions, events, or any information the user wishes to store.[79] Blockchain uses cryptography to create an immutable record of transactions so that they are extremely hard to change.[80] Additionally, a copy of the entire record is available at

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[75] *See* DELOITTE, *BREAKING BLOCKCHAIN OPEN – DELOITTE'S 2018 GLOBAL BLOCKCHAIN SURVEY (PDF)*(2018) https://www2.deloitte.com/global/en/pages/energy-and-resources/articles/gx-innovation-blockchain-survey.html.
[76] *Id.*
[77] *See* Murray, *supra* note 57, at 13.
[78] *Id.*
[79] *Id.*
[80] *Id.*

all times to all users of a peer-to-peer blockchain network.[81] As a result of this heightened security, blockchain databases may operate as a trustless network, thus eliminating the need for validation of data by third-party intermediaries or central authorities.[82]

There are several different types of blockchain, two of the most significant being private and public blockchains.[83] Understanding the distinctions between private and public chains is important for analyzing which for type of blockchain database would be best suited for the needs of companies within the pharmaceutical supply chain. The main difference between a public and private blockchain is who has access to participate in the network.[84] For a public blockchain, the network is completely open to the public.[85] Participants wishing to join a private blockchain on the other hand must receive an invitation to join the network, and their joining of the network "must be validated by either the network starter or by a set of rules put in place by the network starter."[86] Because the openness of a public blockchain provides less privacy and security for transactions,[87] businesses

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[81] *Id.*
[82] Id.
[83] Praveen Jayachandran, *The difference between public and private blockchain*, IBM (May 31, 2017), https://www.ibm.com/blogs/blockchain/2017/05/the-difference-between-public-and-private-blockchain/.
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*

seeking to implement blockchain networks for purposes of tracking and tracing drugs through the supply chain in compliance with DSCSA would probably be best served by a private blockchain which would allow the parties to limit participants in the network to those parties who are involved in the product's supply chain.

The process in which data is recorded on a blockchain illuminates the meaning behind the term blockchain: a blockchain database is essentially individual blocks of data connected together to form a chain.[88] The process of storing data first begins when a transaction is recorded.[89] Next, the various computers in the network, called nodes, check the details of the transaction to make sure it is valid.[90] The records that the network accepts as valid are then added to a block.[91] Each block contains its own unique code called a hash, as well as the hash of the previous block, and a copy of the data being stored on the block.[92] That block is then added to the blockchain. The hash codes link all of the blocks together in a specific, chronological order, thus forming a chain.[93]

The fact that each block is connected to the next block ad infinitum forming a chain of data is what provides the database with the immutability that is one of blockchain's defining

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[88] *See* Murray, *supra* note 57, at 13.
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] *Id.*

characteristics.[94] Because each block is linked together through its hash, if someone attempts to alter one single block of data the next block in the chain would no longer recognize the changed block because its hash would not match that of the previous hash.[95] Thus, to successfully change data, the individual would have to recalculate the next block to match up the hashes that link the two.[96] They would then have to repeat that step for every block, recalculating the hash of every single block on the chain, which would take an enormous amount of time and a huge amount of computing power.[97] So, although it is not technically 100% impossible to change the data stored on the chain, the data stored on a blockchain is very, very difficult to alter.[98]

The immutability of data and the permanence that blockchain allows for can be either a benefit or a hindrance depending on the application of the technology. For example, the immutability of data is exactly what makes blockchain technology perfect for a cryptocurrency application like Bitcoin, because once a transaction is recorded on the chain it cannot be changed or deleted, making double spending of electronic currency nearly impossible.[99] On the other hand, the permanent nature of

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[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] SATOSHI NAKAMOTO, BITCOIN.ORG, BITCOIN: A PEER-TO-PEER ELECTRONIC CASH SYSTEM 4 (2008), https://bitcoin.org/bitcoin.pdf.

blockchain has been cause for concern for some people.[100] There are certainly situations in other fields where immutability would be a problem rather than a solution, situations where it would be desirable to be able to alter or delete data.[101] Blockchain may not be the best solution in these particular instances.[102]

IV. ANALYSIS

A. BLOCKCHAIN

In order to best comply with the DSCSA requirement for an "electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States,"[103] companies need a database that allows them to securely and quickly collect, store, and share data concerning a drug's transaction history. Blockchain appears to be the technology best-suited to meet these requirements due to its immutability and decentralization.

Blockchain's characteristic immutability is ideal for purposes of ensuring that transaction information on drug pedigrees are secure, accurate, and compliant with DSCSA standards. Illegal drug diversion and counterfeit drug schemes like the ones Cumberland and Canada Drugs operated rely heavily on

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[100] Jason Bloomberg, *Eight Reasons To Be Skeptical About Blockchain*, Forbes (May 31, 2017), https://www.forbes.com/sites/jasonbloomberg/2017/05/31/eight-reasons-to-be-skeptical-about-blockchain/#10a56a785eb1.
[101] *Id.*
[102] *Id.*
[103] *Id.*

the creation of false drug pedigrees that the offenders fabricate. With no easy way to verify these false drug pedigrees, pharmacies accept the product and end up unknowingly dispensing substandard drugs to customers.[104] The creation of false drug pedigrees would be extremely difficult if the transaction history of a drug were stored on a blockchain database that was shared between all parties on the drug's supply chain. Upon changing hands from the manufacturer to the distributor, this transaction would be permanently recorded on the drug's pedigree which would be stored on a blockchain database. Each transaction down the line would be similarly recorded. The key here with a blockchain is that each party on the network must verify the entry of data, so those wishing to make a false drug pedigree would be unable to go back and alter a drug's pedigree or create a false drug pedigree from scratch, because the entries would not be validated by other members of the chain.

An additional feature of blockchain which makes it a good solution for DSCSA compliance is the fact that it is a decentralized database. Because blockchain is decentralized and data is constantly validated by each member of the network, a process

[104] *See* U.S. v. Charles Jeffrey Edwards (Counts 1 - 28), Brenda Elise Edwards (Counts 1-27), Jerrod Nichols Smith (Counts 1-16; Count 28)., 2013 WL 12210003 (M.D. Tenn.).

known as consensus,[105] a blockchain database would allow for increased visibility, auditability, transparency, and sharing of transaction information with government officials or non-adjacent trading partners.

Multiple businesses and organizations have launched pilot programs that are currently exploring blockchain's potential to improve the pharmaceutical supply chain and achieve DSCSA compliance. Business and supply chain industry leaders such as IBM[106] and GS1[107] are exploring blockchain technology's potential to revolutionize supply chain management. The Center for Supply Chain Studies[108] and the Healthcare Distribution Alliance (HDA)[109] have taken a more specific approach, focusing on blockchain's potential as a pharmaceutical supply chain solution for DSCSA compliance.

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[105] Praveen Jayachandran, *The difference between public and private blockchain*, IBM (May 31, 2017), https://www.ibm.com/blogs/blockchain/2017/05/the-difference-between-public-and-private-blockchain/.

[106] IBM INSTITUTE FOR BUSINESS VALUE, TRUST IN TRADE – TOWARD STRONGER SUPPLY CHAINS, IBM (2016), https://public.dhe.ibm.com/common/ssi/ecm/gb/en/gbe03771usen/gbe03771usen-00_GBE03771USEN.pdf.

[107] GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.

[108] CENTER FOR SUPPLY CHAIN STUDIES, THE DRUG SUPPLY CHAIN SECURITY ACT AND BLOCKCHAIN – A WHITE PAPER FOR STAKEHOLDERS IN THE PHARMACEUTICAL SUPPLY CHAIN, CENTER FOR SUPPLY CHAIN STUDIES (Jun. 21, 2018), https://static1.squarespace.com/static/563240cae4b056714fc21c26/t/5b3a552c2b6a28f30c0c5d31/1530549553630/C4SCS+White+Paper_+DSCSA+and+Blockchain+Study_FINAL4.pdf.

[109] Justine Freisleben, *VRS Update: Past, Present, Future*, HDA (Dec. 12, 2018), https://www.hda.org/news/hda-blog/2018/12/07/14/44/2018-12-12-vrs-update-past-present-future?rtb=1.

GS1, the organization that revolutionized the business and supply chain world when it introduced the barcode in 1974[110], is currently examining blockchain as a supply chain application.[111] GS1 is an organization that helps businesses across the globe improve business communication through implementing supply chain standards like the scannable barcodes you see on essentially everything you purchase from a store.[112] With over a million major businesses such as Coca-Cola, Wal-Mart, and Google, as members of the organization GS1 is in an extremely influential position, and perhaps the best position, to implement blockchain as the new standard for supply chain.[113] Recently GS1 has taken the position that blockchain "will shape the future and rewrite the rules for personal and corporate finance, medicine, supply chain transparency, identity verification, construction and more."[114]

While maintaining that blockchain technology will play a crucial role in setting new standards for global supply chain, a recent paper published by GS1 addresses several "implementation challenges" that businesses should keep in mind while preparing to

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[110] *About GS1*, https://www.gs1.org/about.
[111] *See* GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.
[112] *What we do*, GS1, https://www.gs1.org/about/what-we-do.
[113] *About GS1*, https://www.gs1.org/about.
[114] *GS1 releases new position paper on the future of blockchain technology*, (Oct. 17, 2018), https://www.gs1.org/articles/2463/gs1-releases-new-position-paper-future-blockchain-technology.

implement blockchain.[115] The paper makes it clear that blockchain will not be an overnight solution to current supply chain issues, and that in order to realize the full benefits of a successful blockchain implementation, businesses will have to a invest a great deal of time, effort, and money.[116] Specifically, GS1 identifies four areas as potential implementation challenges: "(1) Business processes around data, (2) Standards and best practices for data, (3) Interoperability and discovery of data between ecosystems, and (4) Governance, including permissions and participation."[117]

GS1 begins by pointing out that most businesses don't currently have systems in place to capture and share the type of data that will be shared throughout the blockchain network.[118] For example, companies' Warehouse Management Systems that "are not designed to collect and share traceability data" will need to implement processes through which they can collect data and share it with not only direct trading partners but also more removed partners throughout the supply chain network.[119] The second challenge businesses will have to overcome in order to successfully implement blockchain is deciding on a set of best

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[115] GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] *Id.*

practices for data sharing.[120] GS1 notes that one practice gaining favor among industry experts is the practice of "storing a small amount of reference data on enterprise ledgers, while ensuring that richer data can be stored and accessed through applications that reside "off-chain" in traditional data stores."[121] The third challenge companies will face is achieving complete interoperability between various different blockchain networks.[122] The paper notes that there is an increasing number of different types of blockchain networks and that as the number of blockchain networks continues to grow companies must make sure that these different networks are able to communicate with one another if necessary.[123] The fourth and final hurdle companies will face is the issue of governance; that is, companies must decide on "clear set of rules is needed to define the engagement between participants" in the blockchain platform.[124] These rules should address questions like who can participate in the network, what each participant has the power to do in each network, how privacy concerns will be managed, and what data will be stored.[125]

While this GS1 paper broadly focuses on the global supply chain as a whole, each of these four areas of concern are issues that

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[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] *Id.*
[125] *Id.*

pharmaceutical companies will have to grapple with in order to implement blockchain in the pharmaceutical supply chain. While programs such as GS1's point to the conclusion that blockchain is bound to become an integral part of our supply chain at some point in the future, pharmaceutical companies currently face the question of whether they will be able to overcome these obstacles to implementation and have a blockchain system for tracking and tracing drugs in place in time for the various DSCSA deadlines, particularly the final 2023 deadline.

The HDA, a national organization representing primary pharmaceutical distributors, is working on several pilot programs involving blockchain technology to meet the DSCSA tracking and tracing requirements.[126] HDA's Verification Router Service (VRS) which HDA defines as an "interoperable network of companies and technologies that enables verification requests and responses through a look-up directory that is either on a blockchain or where a copy is managed by each solution provider."[127] Testing of the system within both a blockchain and a peer-to-peer network is currently underway, and "testing within the blockchain environment is being managed separately by a blockchain solution

[126] Justine Freisleben, *VRS Update: Past, Present, Future*, HDA (Dec. 12, 2018), https://www.hda.org/news/hda-blog/2018/12/07/14/44/2018-12-12-vrs-update-past-present-future?rtb=1.
[127] *Id.*

provider."[128] The HDA has forwarded their VRS standards to GS1 and predicts that the program will be completed by January 2019.[129] While the HDA's VRS blockchain is just one example of an application in the pharmaceutical supply chain, its apparent success bodes well for the future of blockchain in the pharmaceutical supply chain.

B. FOOD INDUSTRY AS MODEL FOR IMPLEMENTATION OF BLOCKCHAIN FOR SUPPLY CHAIN

Recent implementations of blockchain to secure the supply chain in the food industry may serve as a useful model for the pharmaceutical industry. In 2017, Walmart, Unilever, Nestle, and other major food companies partnered with IBM to implement a blockchain platform designed to, "maintain secure digital records and improve the traceability of their foodstuffs, like chicken, chocolate, and bananas."[130] For the food industry, tracking food through the use of blockchain technology can be used to improve safety and reduce food borne illness.[131] Currently, investigations into the origin of food borne illnesses take weeks, however

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[128] *Id.*

[129] Justine Freisleben, *Verification Router Service Progress Update*, HDA (Jun. 6, 2018), https://www.hda.org/news/hda-blog/2018/07/25/08/42/verification-router-service-progress-update

[130] Robert Hackett, *Walmart and 9 Food Giants Team Up on IBM Blockchain Plans*, Fortune (Aug. 22, 2017), http://fortune.com/2017/08/22/walmart-blockchain-ibm-food-nestle-unilever-tyson-dole/.

[131] *See* Id.

blockchain could shorten that investigation time to seconds.[132] So far Walmart has experimented with using blockchain to track the import of Chinese pork and Mexican mangoes, and these experiments have been so promising that other companies in the food industry are following Walmart's lead.[133] The Vice President of Food Safety at Walmart stated that, "we believe the one-step-up and one-step-back model of food traceability is outdated for the 21st century.... Leveraging blockchain as the enabling technology and GS1 standards as the universal language, we believe we can create a more digital and transparent food system that will benefit people and the planet."[134]

Howard Popoola, Kroger's VP of corporate food technology and regulatory compliance, has credited Walmart's foray into blockchain with bringing "legitimacy" to blockchain's use in the food industry, noting that, "[t]he food industry is ripe for a solution like that."[135] Poor fruit puns aside, with five years until the DSCSA's 2023 deadline for full compliance, it looks like the pharmaceutical industry is ripe for its own blockchain solution. Just as food companies are beginning to use blockchain to track

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[132] *Id.*
[133] *Id.*
[134] GS1, BRIDGING BLOCKCHAINS – INTEROPERABILITY IS ESSENTIAL TO THE FUTURE OF DATA SHARING, GS1 (2018), https://www.gs1.org/sites/default/files/bridging_blockchains_-_interoperability_is_essential_to_the_future_of_da.pdf.
[135] Robert Hackett, *Walmart and 9 Food Giants Team Up on IBM Blockchain Plans*, Fortune (Aug. 22, 2017), http://fortune.com/2017/08/22/walmart-blockchain-ibm-food-nestle-unilever-tyson-dole/.

food products "across a complex network that includes farmers, brokers, distributors, processors, retailers, regulators, and consumers,"[136] pharmaceutical companies should follow suit by using blockchain to track pharmaceuticals across the complex network of manufacturers, wholesale distributors, and dispensers. The pharmaceutical industry and the food industry face similar issues concerning protecting their supply chains against contaminated products. In both industries, tracking and tracing of products is essential to protecting the end consumer from dangers like contaminated drugs or food.

V. CONCLUSION

As blockchain continues to gain momentum and gain legitimacy as a technology with various business applications it seems likely that it could eventually be a major disruptor in supply chain on a global scale. With industry leaders such as IBM and GS1 putting substantial efforts into helping businesses implement blockchain for supply chain management this goal may be realized sooner rather than later. The characteristics of blockchain, particularly its immutability and decentralized structure, make it appear as if the technology was designed as a solution for tracking requirements of the DSCSA. With a blockchain database in place companies could easily share data across a large network of trading partners and could instantly provide necessary transaction

[136] *Id.*

information to governmental agencies that request it. Additionally, due to the difficulty of altering or deleting data once it is stored on the blockchain, fraudulently created false drug pedigrees that allow counterfeit and diverted drugs to enter the legitimate market may become a thing of the past. While blockchain seems a perfect fit for DSCSA compliance, it remains to be seen whether businesses will be able to implement the technology in time for the 2023 deadline prescribed by the DSCSA.

With the great potential blockchain is showing, it may be beneficial for the FDA to continue to monitor industry progress and make accommodations necessary with regard to enforcement of DSCSA requirements, including potentially extending its deadline for compliance. Extending the end deadline for compliance would allow the FDA to ensure that businesses in pharmaceutical industry have appropriate time to properly develop and implement the best possible supply chain solution. Implementing blockchain will take time, but it appears to be the best solution to the supply chain problems addressed by the DSCSA. While meeting the 2023 deadline would be ideal, this quickly approaching deadline could lead businesses to hurriedly work on existing systems to make them DSCSA compliant rather than dedicating their time and money to develop blockchain which could provide the best possible solution in the long term.

FINDING THE POSITIVE IN A POSITIVE DRUG TEST:

HOW NARROWING THE DEFINITION OF AN INDIVIDUALIZED PRE-EMPLOYMENT ASSESSMENT UNDER THE ADA CAN ENCOURAGE RECOVERY FROM OPIOID DEPENDENCE

SARAH FERRARO

I. INTRODUCTION

A "national emergency" that is "destroying families and shattering communities all across the country."[1] That is how the last two Presidents of the United States refer to the nation's prescription drug addiction problem.[2] Despite their political differences, Presidents Trump and Obama have found a common enemy in opioid abuse.

The issue has united members of both presidents' parties in a scramble to legislate away what the Department of Health and Human Services declared a "public health emergency" in 2017.[3] As midterm elections approached in the fall of 2018, members of Congress agreed on a 653-page bill to address prescription drug dependency.[4] Just two days after the bill passed committee, the House of Representatives approved the mix of criminal and health reform measures.[5] While many legislators were pleased with the expansion of inpatient treatment programs, some advisors from the medical field worry not enough of the federal budget was allocated

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[1] Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, N.Y. TIMES, Oct. 26, 2017, https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html; Kathleen Hennessey, *Obama says U.S. will tackle prescription drug and heroin abuse*, PBS NEWS HOUR, Oct. 21, 2015, https://www.pbs.org/newshour/politics/obama-announce-plans-fight-heroin-use.
[2] *Id.*
[3] U.S. DEP'T OF HEALTH AND HUM. SERV., DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2017).
[4] Jessica Hill, *In Rare Bipartisan Accord, House and Senate Reach Compromise on Opioid Bill*, N.Y. TIMES, Sept. 26, 2018, https://www.nytimes.com/2018/09/26/health/opioid-bill-congress.html.
[5] *Id.*

to help the uninsured or Medicare beneficiaries access medical care.[6] The movement to address addiction extends to state legislatures as well: from 2016 to 2017, more than 30 states considered at least 130 bills related to the prescription of opioids.[7]

Because legislation that is focused on limiting the prescription of opioids invites more push back from the pharmaceutical industry, many federal and state measures focus on access to treatment options.[8] While Medication Assisted Treatment (MAT) is not the most widely-accessible treatment option, studies have shown it decreases opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission.[9] In MAT, health professionals prescribe one of several FDA-approved medications that have essentially the same effect as opioids but are less addictive.[10] The medications do not result in a high, but rather reduce cravings and withdrawal, creating a more realistic path to recovery.[11]

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[6] *Id.*
[7] Prescribing Policies: States Confront Opioid Overdose Epidemic, Nat'l Conf. of State Legs. (Apr. 5, 2018), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx.
[8] Allison Petersen, Sharon C. Peters, Mary Holloway Richard & Anna Whites, *State Legislative Responses to the Opioid Crisis: Leading Examples*, 11 J. Health & Life Sci. L. 30, 38 (2018).
[9] *Effective Treatments for Opioid Addiction*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction (last updated Nov. 2016).
[10] *Id.*
[11] *Id.*

However, the similarities between these FDA-approved medications and highly addictive opioids that make MAT effective are also creating challenges for patients. When patients apply for a job, some employers require a pre-employment drug screening.[12] Often, the drug screening shows a positive result[13]. Even though the positive result comes from medications legally prescribed to the applicant through their recovery program, some employers have revoked employment offers or terminated existing employment pursuant to company drug policies.[14] Recovering from drug addiction is a disability protected by the Americans with Disabilities Act (ADA).[15] Thus, according to the EEOC, employers who terminate employment or an offer of employment on the grounds of a drug test affected by MAT are engaging in disability discrimination.[16] There is, however, a defense for employers concerned about hiring prescription drug users to work in safety-sensitive positions.[17] An individual is not qualified for ADA protection when, if hired, he or she would pose a direct threat to

[12] Letter from Joon H. Kim, United States Attorney for the Southern District of New York, to the New York State Office of the Attorney General (Oct. 3, 2017), https://lac.org/wp-content/uploads/2018/02/DOJ-SDNY-ltr-to-OCA-10.3.17.pdf.
[13] *Id.*
[14] *Id.*
[15]U.S. Commission on Civil Rights, Sharing the Dream: Is the ADA Accommodating All? (2000).
[16] Press Release, EEOC, *EEOC Sues Randstad for Disability Discrimination* (Nov. 3, 2015), https://www.eeoc.gov/eeoc/newsroom/release/11-3-15a.cfm.
[17] 42 U.S.C.A. § 12101(b)(2) (West, Westlaw through Pub. L. No. 115-231).

health or safety in the workplace that could not be remedied through a reasonable accommodation.[18]

This note will address the disparities in the way courts have analyzed the direct threat exception to ADA protection, and why a uniform application of the exception is crucial to both employers and those in recovery. Part I examines how opioids have devolved from an effective pain management tool to a national enemy. This section will answer common questions about why opioids are so addictive and why doctors prescribe them in the first place. It also addresses the scope of the ADA and the direct threat exception used to justify a decision not to hire a prescription drug user, as well as the effort of ADA enforcement agencies to call attention to illegal hiring practices involving MAT.

Part II includes an analysis of several ADA employment discrimination cases implicating MAT. The cases demonstrate the widely varied standards courts have to define the "individualized assessment" required as proof for employers raising a defense to a discrimination claim.

Part III proposes a uniform standard by which to judge the individualized assessment. It explains why establishing a more specific standard, requiring an examination by a medical professional as part of the direct threat analysis, serves public

[18] 29 C.F.R. § 1630.2(r) (2012).

policy interests. Further, it predicts how the outcome of a pending EEOC case could give employers further guidance with regard to the timing of the individualized assessment. This section concludes by encouraging employers to reform their drug screening policies, with specific practice pointers. These methods will achieve the goal of balancing employers' right to enforce drug-free workplace policies with the protections granted by the ADA.

II. BACKGROUND

A. The history of clinical opioid use

Although the use of opioid medications in America has skyrocketed over the past 15 years, opioids are by no means a novel way to relieve pain.[19] In fact, the 21st Century rise in addiction and overdose rates is not the first epidemic the United States has experienced.[20] The 1840s saw a rise in the prescription of opium and morphine to treat a wide range of conditions causing chronic pain.[21] The medications were used to treat everything from hangovers to soldiers' war injuries.[22] By the 1890s, the nationwide opioid supply was capable of supporting five addicted individuals for every 1,000 citizens.[23]

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[19] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559-74 (Mar. 2015).
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] The most common profile of an opioid-addicted patient at this time was a white woman with a chronic condition (but often the doctors themselves also had an addiction to the opioids they prescribed). *Id.*

At this time, the rapid spread of addiction was attributed to the minimal understanding of chronic pain and the lack of alternative treatments. Despite medical advancements over the past century, the addiction problem persists.[24] The medical field now understands a major contributing factor to the addictive power of opioids is not how often doctors prescribe them but the chemical makeup of the drug.[25]

The term "opioid" is used to describe a class of drugs used primarily to reduce pain.[26] The term encompasses illegal drugs like heroin, approved but rarely prescribed substances like fentanyl, and commonly prescribed medications like oxycodone.[27] When any of these opioids travel through the bloodstream, the chemicals attach to receptors on brain cells.[28] This reaction triggers the same biochemical feeling of pleasure that promotes engaging in basic life functions such as eating and sex.[29] Chronic use results in structural and functional changes in parts of the brain that control impulse, reward, and motivation.[30] Further, other areas of the brain create memories around the release of dopamine during opioid use,

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[24] *Id.*
[25] *Id.*
[26] *Opioid Basics*, Ctrs. For Disease Control and Prevention, https://www.cdc.gov/drugoverdose/opioids/index.html (last updated Aug. 24, 2017).
[27] *Id.*
[28] Thomas R. Kosten, M.D. and Tony P. George, M.D., The Neurobiology of Opioid Dependence: Implications for Treatment, Sci. Prac. Persp. 13-20 (July 2002).
[29] *Id.*
[30] Kolodny, *supra* note 19.

resulting in a craving for the drug when a person encounters people or situations that bring up those memories.[31]

What makes opioids so addictive is not only the biochemical positive reinforcement but the negative reinforcement that happens when the pleasure reaction in the neurons wears off.[32] The alterations to dopamine reception created by escalating opioid use mean the brain may function more normally when opioids are in the system than when they are not.[33] Clinical researchers say that makes the difficulty of withdrawal one of the most significant factors driving opioid dependence.[34]

B. The spread of addiction to epidemic status

The addictive chemical nature of opioids was exacerbated by several external factors at the end of the 20th Century, leading to the "epidemic" as it exists in 2018. In the 1990s, pharmaceutical companies made an effort to assure doctors that their patients would not become addicted to prescribed opioid pain relievers.[35] Specifically, researchers point to the introduction of OxyContin, an extended-release form of oxycodone, as a major contributor to the acceleration of opioid prescriptions after 1995.[36] By the time the

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[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *What is the U.S. Opioid Epidemic?*, U.S. Dep't of Health and Human Servs., https://www.hhs.gov/opioids/about-the-epidemic/index.html (last updated Sept. 19, 2018).
[36] Kolodny, *supra* note 19.

medical community recognized the highly addictive capacity of these medications, both prescription and non-prescription opioids were already widely misused.[37]

Between prescriptions and illegal uses, opioid-related overdoses killed more than 130 people in the U.S. every day from 2016 to 2017.[38] The death rate is rising among both men and women, all races, and adults of nearly all ages.[39] Opioid abuse has also contributed to a rise in related diseases.[40]

The epidemic has not only affected public health but also has left its mark on the nation's economic health. The Centers for Disease Control and Prevention estimates that prescription opioid misuse alone costs the United States $78.5 billion a year.[41] Those expenditures are attributed to the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[42]

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[37] In fact, about a quarter of patients who are prescribed opioids for chronic pain misuse them. That behavior often leads to abuse of illegal drugs- about 80 percent of people who use heroin first misused prescription opioids. *Opioid Overdose Crisis*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one (last updated Mar. 2018).
[38] *What is the U.S. Opioid Epidemic?*, *supra* note 35.
[39] *Opioid Overdose: Data Overview*, Ctrs. For Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/index.html (last updated July 18, 2017).
[40] *See, e.g., Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (last updated Sept. 2015); *Opioid Overdose Crisis*, *supra* note 37.
[41] *Opioid Overdose Crisis*, *supra* note 37.
[42] *Id.*

C. Legislative response to the opioid epidemic

The rising cost of treating and prosecuting addictive behaviors as well as increasing overdose death rates have prompted action from municipal, state, and federal legislators. While Congress has made several attempts to combat the opioid crisis, President Trump signed the most far-reaching legislation into law in 2018.[43] The SUPPORT for Patients and Communities Act combines 58 bills aimed at addiction prevention and treatment.[44] It makes changes to state and federal Medicaid programs, including requiring coverage for services provided by certified opioid treatment programs.[45] The Act also increases the maximum number of patients that providers may initially treat with MAT.[46] The funding for the sweeping package is supported by a $4 billion appropriation to opioid crisis relief efforts in the 2018 omnibus spending bill.[47] In a rare showing of overwhelming bipartisan support, both chambers passed the Act in a 396-14 vote.[48]

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[43] Marianna Sotomayor, *Trump signs sweeping opioid bill with vow to end 'scourge' of drug addiction*, NBC NEWS, Oct. 24, 2018, https://www.nbcnews.com/politics/congress/trump-signs-sweeping-opioid-bill-vow-end-scourge-drug-addiction-n923976.
[44] Ashley Killough & Phil Mattingly, *House approves massive opioids legislation*, CNN, June 22, 2018, https://www.cnn.com/2018/06/22/politics/house-opioids-bill/index.html.
[45] SUPPORT for Patients and Communities Act, H.R. 6, 115th Cong. (2018).
[46] *Id.*
[47] Killough & Mattingly, *supra* note 44.
[48] *Id.* While some legislators continued to express concerns that Republican promises to cut Medicare and Medicaid would increase opioid death rates, President Trump was confident the SUPPORT Act would "at least make an

Individual states have also made efforts to address the opioid epidemic, with much of the legislation focused on prescribing practices of pain medication.[49] The first limitations were proposed in 2016, and by the end of that year, seven states had enacted requirements for physicians prescribing opioids.[50] According to the National Conference of State Legislatures, that number rose to 28 states by early 2018.[51] These prescribing policies typically limit first-time opioid prescriptions, most commonly to a supply lasting only seven days.[52] Many of these laws are based on guidelines promulgated by the Center for Disease Control and Prevention (CDC) in 2016.[53] Beyond initial prescription, states have also addressed prescription drug monitoring programs, pain clinic regulation, and access to naloxone (medication used to reverse an overdose) in opioid legislation.[54]

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extremely big dent in this terrible, terrible problem." Marianna Sotomayor, *supra* note 43.

[49] *Prescribing Policies: States Confront Opioid Overdose Epidemic*, Nat'l Conf. of State Legs. (Apr. 5, 2018), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx.

[50] *Id.*

[51] *Id.*

[52] *Id.*

[53] In general, the guidelines recommend lowering dosage recommendations and providing specific recommendations regarding monitoring and discontinuation. Allison Petersen, Sharon C. Peters, Mary Holloway Richard & Anna Whites, *State Legislative Responses to the Opioid Crisis: Leading Examples*, 11 J. Health & Life Sci. L. 30, 38 (2018).

[54] *Prescribing Policies: States Confront Opioid Overdose Epidemic*, *supra* note 49.

Tennessee has taken a comprehensive approach to address the opioid epidemic through its "TN Together" initiative. The Tennessee Department of Health recorded 1,776 overdose deaths statewide in 2017.[55] The Department attributes over two-thirds of those deaths to opioids.[56] State lawmakers have worked to exercise more control over prescribing practices through the Prescription Safety Act of 2016.[57] The Act enhanced the Controlled Substance Monitoring Database Program, which providers are required to consult before issuing opioid prescriptions.[58] Tennessee amended these guidelines in 2018, requiring database checks every six months throughout treatment.[59] However, some states have gone further than Tennessee in controlling prescription practices, authorizing departments of health, or even regulatory boards to set their own opioid prescription limits.[60] Overall, more than 30 states considered at least 130 bills related to opioid prescribing in 2016 and 2017.[61]

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[55] TN TOGETHER: ENDING THE OPIOID CRISIS, https://www.tn.gov/opioids (last visited Oct. 6, 2018).
[56] *Id.*
[57] Brad Sayles & Kelly L. Frey, *Addressing the Opioid Epidemic in Our School Systems*, Nashville Bar Journal, August/September 2018, at 7.
[58] *Id.*
[59] H.B. 1831, 110th Gen. Assemb., Reg. Sess. (Tenn. 2018).
[60] *Prescribing Policies: States Confront Opioid Overdose Epidemic*, *supra* note 49.
[61] *Id.*

D. Protections granted by the Americans with Disabilities Act

In 1990, Congress implemented the Americans with Disabilities Act (ADA) to provide "clear, strong, consistent, enforceable standards addressing discrimination against individuals with disabilities."[62] Critically, the ADA creates a cause of action for protected individuals when employers discriminate against them on the basis of their disability.[63] The Act defines disability as "(A) a physical or mental impairment that substantially limits one or more major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment."[64] In addition to the ADA's definition, enforcing agencies such as the Department of Justice and the Department of Transportation have issued their own regulations as to who is entitled to protection under the Act.[65] The term disability is interpreted broadly, as are the "major life activities" affected by an impairment.[66]

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[62] 42 U.S.C.A. § 12101(b)(2) (West, Westlaw through Pub. L. No. 115-231).
[63] U.S. Dept. of Justice, Civil Rights Division, Opioid Use Disorders and the Americans with Disabilities Act: Eliminating Discriminatory Barriers to Treatment and Recovery (April 15, 2018), https://6ae8bbf0cbc766a02526-db9b3cfd1a1d7334c57f016ab97d9d02.ssl.cf2.rackcdn.com/asam_cb218186bdb13ed3a2427fd90e1e7316.pdf.
[64] 42 U.S.C.A. § 12102(1) (West, Westlaw through Pub. L. No. 115-231).
[65] NTS Am. Jur. 2d *Americans with Disabilities Act* § 2 (2018).
[66] U.S. Dept. of Justice, Civil Rights Division, Opioid Use Disorders and the Americans with Disabilities Act: Eliminating Discriminatory Barriers to Treatment and Recovery (April 15, 2018), https://6ae8bbf0cbc766a02526-db9b3cfd1a1d7334c57f016ab97d9d02.ssl.cf2.rackcdn.com/asam_cb218186bdb13ed3a2427fd90e1e7316.pdf.

Although protection is liberally granted by the ADA due to the broad interpretation of the disability classification, it does have limits. The Act's protections do *not* apply to individuals who are currently engaging in the use of illegal drugs.[67] A drug is illegal when its possession or distribution is prohibited by the Controlled Substances Act.[68] Protection is also excluded from those using legally prescribed drugs in an illegal manner.[69] In the context of employment, "currently engaging" does not require that illegal drug use has occurred in a matter of days or weeks preceding the employment action in question.[70] Instead, it is sufficient the illegal drug use occurred recently enough to give the employer reason to believe the individual is actively engaged in such conduct.[71]

While drug abuse is not a protected disability as defined by the ADA, there is a distinction between ongoing use and addiction.[72] Addiction is a protected disability under the Act, as long as an individual is not currently using the drugs illegally.[73] More specifically, these protections only apply to those who are or were *addicted* to illegal substances, as opposed to those who were casual users.[74] Thus, the ADA applies to those who have

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[67] NTS Am. Jur. 2d *Americans with Disabilities Act* § 5 (2018).
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] U.S. COMMISSION ON CIVIL RIGHTS, SHARING THE DREAM: IS THE ADA ACCOMMODATING ALL? (2000), https://www.usccr.gov/pubs/ada/ch4.htm.

successfully completed a supervised drug rehabilitation program, are participating in such a program, or are mistakenly regarded as using drugs illegally.[75]

The ADA requirements apply to employers in both the public and private sectors.[76] Public sector employers are limited by the Fourth Amendment, which generally restricts drug testing to those suspected of current drug use or individuals whose position is "safety-sensitive."[77] Still, the decisions employers make based on those tests are largely unregulated by common law or statute.[78] The Supreme Court bolstered that freedom in *Skinner v. Railway Labor Executives' Association*, the seminal case on employer drug testing.[79] There, the Court held mandatory drug and alcohol tests were reasonable under the Fourth Amendment in industries subject to government regulation, like the railroad in *Skinner*.[80] The Court reasoned that even without a warrant or reasonable suspicion of employee impairment, drug testing served a compelling

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[75] U.S. DEPT. OF JUSTICE CIVIL RIGHTS DIVISION, OPIOID USE DISORDERS AND THE AMERICANS WITH DISABILITIES ACT: ELIMINATING DISCRIMINATORY BARRIERS TO TREATMENT AND RECOVERY (2018), https://6ae8bbf0cbc766a02526-db9b3cfd1a1d7334c57f016ab97d9d02.ssl.cf2.rackcdn.com/asam_cb218186bdb13ed3a2427fd90e1e7316.pdf.
[76] *Id.*
[77] Stacy Hickox, *It's Time to Rein in Employer Drug Testing*, 11 Harv. L. & Pol'y Rev. 419, 420 (2017).
[78] *Id.*
[79] See *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602 (1989).
[80] *Id.* at 628.

government interest that outweighed employees' privacy concerns.[81]

In the private sector, only employers with 15 or more employees are subject to ADA requirements.[82] Courts have consistently protected private sector employers' right to investigate, by inquiry or drug test, the drug use of employees.[83] In the hiring context, employers may inquire about past or present drug use.[84] However, employers may not use that information to exclude the individual, unless they have a reason to do so unrelated to the disability and that legitimate job criterion cannot be met with reasonable accommodation.[85] The ADA does not place any restrictions on employers' right to require drug tests for prospective or current employees. However, "[i]f a person is excluded from a job because the employer erroneously "regarded" him or her to be a drug abuser, currently using drugs illegally, and a drug test revealed the presence of a lawfully prescribed drug, the employer would be liable under the ADA."[86]

If an applicant or employee believes he or she is entitled to ADA protection and an employer has not complied with the requirements of the Act, the individual may file a complaint with

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[81] *Id*.
[82] U.S. DEPT. OF JUSTICE CIVIL RIGHTS DIVISION, *supra* note 75.
[83] Stacy Hickox, *supra* note 77, at 420.
[84] U.S. COMMISSION ON CIVIL RIGHTS, *supra* note 74.
[85] *Id*.
[86] *Id*.

the Department of Justice or another enforcing agency such as the Equal Employment Opportunity Commission (EEOC).[87] Individuals can resolve these complaints through either the ADA mediation program, an investigation by a United States Attorney's Office, or litigation.[88]

Several affirmative defenses are available to employers facing discrimination claims under the ADA.[89] This paper will primarily address the "direct threat" defense, which precludes an individual from qualifying for ADA protection if he or she would "pose a direct threat to the health or safety of other individuals in the workplace."[90] The defense only applies if the threat cannot be eliminated or reduced by reasonable accommodation.[91] Whether or not an individual poses a direct threat is a fact-specific analysis that requires "an individualized assessment of the individual's present ability to safely perform the essential functions of the job."[92]

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[87] U.S. DEPT. OF JUSTICE CIVIL RIGHTS DIVISION, *supra* note 75.
[88] U.S. Dept. of Justice Civil Rights Division, *How to File an ADA Complaint with the U.S. Department of Justice*, https://www.ada.gov/filing_complaint.htm#5 (last visited Oct. 7, 2018).
[89] Samuel Brown Petsonk & Anne Marie Lofaso, *Working for Recovery: How the Americans with Disabilities Act & State Human Rights Laws Can Facilitate Successful Rehab. for Alcoholics & Drug Addicts*, 120 W. Va. L. Rev. 891, 914 (2018).
[90] 42 U.S.C.A. § 12113(b) (West, Westlaw through Pub. L. No. 115-281).
[91] 29 C.F.R. § 1630.2(r) (2012).
[92] *See* argument *infra* Section III.A.

E. The Department of Justice intervention and concerns about MAT

One United States Attorney's Office has addressed concerns about employers' discrimination against applicants who are enrolled in an MAT program.[93] A 2017 letter to the New York State Attorney General urged state courts to become more familiar with the protections guaranteed to individuals in recovery by the ADA.[94] In the letter, the United States Attorney Joon Kim asserts the ADA prohibits state courts from "(l) denying the MAT participant the benefits of their services, programs, or activities; (2) excluding the MAT participant from their services, programs, or activities; or (3) otherwise subjecting the MAT participant to discrimination, by reason of her disability."[95]

While Kim's letter points out that the number of contexts in which these protections apply is far-reaching, he offers the example of family court proceedings.[96] If a court provides certain services to parents seeking custody of a child, Kim advises, the court may not deny those services to otherwise eligible parents who are receiving MAT.[97] The ADA does not require public entities to provide its services to individuals who pose a "direct

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[93] Letter from Joon H. Kim, United States Attorney for the Southern District of New York, to the New York State Office of the Attorney General (Oct. 3, 2017), https://lac.org/wp-content/uploads/2018/02/DOJ-SDNY-ltr-to-OCA-10.3.17.pdf.
[94] *Id*.
[95] *Id*.
[96] *Id*.
[97] *Id*.

threat to the health or safety of others."[98] However, Kim cautions that courts may not presume that individuals receiving MAT are a "direct threat" based on assumptions that MAT participants are likely to relapse to using illegal drugs or are likely to be associated with crime.[99] State courts' enforcement of ADA protections has important implications, Kim says, because judicial decisions may reinforce a stigma that MAT "replaces one addiction with another" and therefore deter addicted individuals from seeking a treatment that has proven effective.[100]

However, there are some circumstances in which an applicant may not be fit for employment during prescribed MAT. As employers may point out, despite being less addictive and lower risk than traditional opioids, MAT can present some side effects.[101] Incorrect dosages can result in fatigue, confusion, attention issues, vision problems, or loss of coordination.[102] These possible effects have raised concerns about the ability of MAT patients to safely perform certain jobs, including those that involve operating heavy machinery or frequent driving.[103]

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[98] *Id*.
[99] *Id*.
[100] *Id*.
[101] Addiction Treatment Forum, *Methadone & Mental Functioning* (2002), http://www.atforum.com/documents/english/Methadone_and_Mental_Functioning.pdf.
[102] *Id*.
[103] *See, e.g.*, State v. Schories, 827 N.W.2d 659, 669 (Iowa 2013), as corrected (Feb. 25, 2013) (opining prescription drug use could be a defense to a DUI prosecution, although it likely would be unsuccessful in that particular case

Due to these possible MAT effects, an employer may be able to legally terminate employment or decline to offer employment based on a finding that the applicant or employee exhibits those symptoms and they would prevent him or her from performing the job or would pose a direct threat to safety.[104]

III. Analysis

A. MAT discrimination suits filed by the EEOC

In recent years, multiple ADA enforcement agencies have taken steps to address discrimination against opioid-addicted individuals seeking treatment through MAT.[105] While the EEOC has fully litigated some of these cases, many have settled after the filing of the initial complaint.[106]

i. *EEOC v. Randstad*

In November 2015, the EEOC filed suit against a Maryland temporary labor agency, which the EEOC claimed had discriminated against a prospective employee based on her

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because the driver there was not complying with his doctor's prescribed use of methadone).

[104] Joanne Bush et al., *Confronting The Opioid Emergency In The Workplace*, https://www.jonesday.com/files/Publication/8c5e74cd-4e9d-4b6a-8692-53a1e77b93f7/Presentation/PublicationAttachment/5b2d29a5-b659-4c88-a8f7-54c50435e19c/Confronting%20The%20Opioid%20Emergency%20In%20The%20Workplace%20-%20Law360.pdf.

[105] Joon H. Kim, *supra* note 93.

[106] *See, e.g.*, Press Release, EEOC, *Foothills Child Development Center Agrees to Settle EEOC Disability Discrimination Lawsuit* (May 15, 2018), https://www.eeoc.gov/eeoc/newsroom/release/5-15-18.cfm; Press Release, EEOC, *Volvo Group North America To Pay $70,000 To Settle EEOC Disability Discrimination Suit* (Jan. 19, 2018), https://www.eeoc.gov/eeoc/newsroom/release/1-19-18a.cfm.

participation in a MAT program.[107] The prospective employee, April Cox, was recovering from a 19-year heroin addiction.[108] She sought treatment at a rehabilitation center, where she was prescribed methadone as well as monthly counseling.[109] As part of the program, she also underwent regular urine testing.[110] During her treatment, Ms. Cox worked as a package handler on various assignments through a temporary labor agency.[111]

In 2015, four years after Ms. Cox had used any illegal drugs, she applied for a job through Randstad, a different temporary labor agency.[112] Randstad's site manager interviewed Ms. Cox, told her she had sufficient experience to continue the hiring process, and requested a drug screening in the form of a urine sample.[113] When Ms. Cox immediately disclosed her prescribed methadone use, the manager took the urine sample cup back, saying "I'm sure we don't hire people on methadone, but I will contact my supervisor."[114] According to the complaint, Randstad did not respond to several attempts by Ms. Cox to follow up, until the next month, when the manager told Ms. Cox she

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[107] Press Release, EEOC, *EEOC Sues Randstad for Disability Discrimination* (Nov. 3, 2015), https://www.eeoc.gov/eeoc/newsroom/release/11-3-15a.cfm [hereinafter *Randstad Suit*].
[108] Compl. at ¶ 13, EEOC v. Randstad, No. 15CV03354, 2015 WL 13666335 (D.Md. Nov. 3, 2015).
[109] *Id*.
[110] *Id*.
[111] *Id*.
[112] *Id*.
[113] *Id*.
[114] *Id*.

would not be hired due to her methadone use.[115] The EEOC alleged that Randstad violated federal law when it denied Ms. Cox employment "based on unwarranted or speculative fears or biases about her disability or her medically supervised drug rehabilitation."[116]

After first attempting to reach a settlement through its pre-litigation conciliation process, the EEOC filed suit on behalf of Ms. Cox.[117] Just over three months later, the parties settled.[118] Randstad agreed to pay $50,000 to Ms. Cox and signed a consent decree promising to comply with the ADA going forward.[119] The consent decree requires Randstad to ensure employees in hiring roles do not reject applicants due to MAT status, provide ADA training to employees, and regularly report to the EEOC on its compliance with the settlement terms.[120]

ii. *EEOC v. Hussey Cooper*

An earlier Pennsylvania case also involved an applicant enrolled in an MAT program, but seemed to present a more tenable defense for the employer.[121] In *EEOC v. Hussey Cooper Ltd.*, the

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[115] *Id*.
[116] *Randstad Suit*, supra note 106.
[117] Press Release, EEOC, *Randstad Will Pay $50,000 to Settle EEOC Disability Discrimination Lawsuit* (Feb. 8, 2016), https://www.eeoc.gov/eeoc/newsroom/release/2-8-16a.cfm.
[118] *Id*.
[119] *Id*.
[120] *Id*.
[121] See *EEOC v. Hussey Copper Ltd.*, 696 F. Supp. 2d 505 (W.D. Pa. 2010).

defendant operated a mill for the fabrication of copper products.[122] Donald Teaford applied to work as a laborer in the mill, a position that would involve working around "moving molten metal, cranes, rolling mills, acid and lead baths, forklift trucks, coils of copper traveling above and knives used to cut copper."[123] Laborers must rotate through various production jobs in the mill before bidding on a permanent position, and Hussey Cooper considered all of the production jobs "safety-sensitive."[124] The company made an offer of employment to Mr. Teaford, conditional upon his successful completion of a background check, physical exam, and drug test.[125] The physical exam included a drug screening in the form of a urine sample, which in Mr. Teaford's case, tested positive for methadone.[126]

Hussey Cooper contracted with an occupational medicine facility to conduct and review the results of these tests.[127] Mr. Teaford explained his history of opiate dependency and enrollment in a supervised treatment program to the facility's medical director.[128] The medical director did not examine Mr. Teaford himself but did reach out to Mr. Teaford's physicians and the

[122] *Id.* at 507.
[123] *Id*.
[124] *Id*.
[125] *Id*.
[126] *Id*. at 508.
[127] *Id*.
[128] *Id*.

methadone clinic to confirm his treatment plan.[129] The medical director ultimately advised Hussey Cooper that Mr. Teaford should be denied any safety-sensitive position due to his medication.[130] Hussey Cooper's safety supervisor determined that the company could make no reasonable accommodation for Mr. Teaford and rescinded his conditional offer of employment.[131]

In June 2008, the EEOC filed a discrimination action against Hussey Cooper on behalf of Mr. Teaford.[132] In a September 2009 motion for summary judgment, Hussey Cooper claimed its actions were not discriminatory as a matter of law because even if Mr. Teaford qualified for ADA protection, he "would present a direct threat to the health or safety of others if he were allowed to work in the mill."[133] The EEOC's expert, a certified member of the American Society of Addiction Medicine, testified that the "direct threat" exception did not apply to Mr. Teaford.[134] The expert cited fact sheets published by the federal government, which stated that "controlled methadone usage 'does not impair cognitive functions' and 'has no adverse side effects on mental capability, intelligence, or employability . . .'"[135]

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[129] *Id*. at 509.
[130] *Id*. at 510.
[131] *Id*. at 512.
[132] *Id*. at 514.
[133] *Id*. at 519.
[134] *Id*. at 513.
[135] *Id*.

The United States District Court for the Western District of Pennsylvania denied Hussey Cooper's motion for summary judgment.[136] The court reasoned the medical director's "individualized assessment" of Mr. Teaford was not sufficient to determine that he would pose a direct threat by working in the mill as a matter of law.[137] The parties then tried the case in front of a jury but reached a settlement agreement after the third day of trial.[138] Hussey Cooper agreed to pay $85,000 in monetary relief to Mr. Teaford and hire him as a mason utility laborer.[139] The five-year consent decree also enjoined Hussey Copper from engaging in any employment practice that discriminates based on disability.[140]

iii. *EEOC v. Steel Painters, LLC.*

Based on courts' broad interpretation of the ADA pre-offer protections in the foregoing cases, it seems the EEOC should be successful in more recent suits on behalf of similarly-situated plaintiffs. However, less clear is the scope of ADA protections for individuals recovering from addiction who, instead of being denied work based on *pre-employment* screening, are hired and then later *fired* based on drug test results.

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[136] *Id*. at 521.
[137] *Id.*
[138] Press Release, EEOC, *Hussey Copper To Pay $85,000 To Settle EEOC Disability Discrimination Lawsuit* (February 11, 2011), https://www.eeoc.gov/eeoc/newsroom/release/2-11-11.cfm.
[139] *Id*.
[140] *Id*.

In 2018, the EEOC filed a complaint against a Texas-based painting company that fired an employee who was participating in an opioid treatment program.[141] Matthew Kimball became dependent on opioid pain medication following a shoulder injury in 2012.[142] He sought treatment through a supervised methadone program and had been undergoing monthly counseling and drug testing for three years when he was hired to work as a painter for the defendant, Steel Painters.[143] He took a drug test a few days before he began working, and then worked a full week for Steel Painters.[144] At the start of his second week of work, Mr. Kimball was removed from his job site when his drug screening results came back positive.[145] Despite Mr. Kimball producing his methadone prescription information and offering to take a physical examination so that the defendant's doctor could clear him to work, Steel Painters issued a termination notice, noting they would not recommend Mr. Kimball for rehire.[146]

The EEOC has asked the Eastern District of Texas to grant a permanent injunction prohibiting Steel Painters from engaging in any future disability discrimination, back pay, and damages on

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[141] Complaint at ¶ 26, EEOC v. Steel Painters, LLC, No. 1:18-cv-00303, 2018 WL 3301664 (E.D.Tex. June 28, 2018).
[142] *Id*. at ¶ 15.
[143] *Id*. at ¶ 16-17.
[144] *Id*.
[145] *Id*. at ¶ 18.
[146] *Id*. at ¶ 20-23.

behalf of Mr. Kimball, and reinstatement to a "suitable position" at Steel Painters.[147] To avoid liability, Steel Painters must prove it lawfully terminated Mr. Kimball because he cannot perform the essential functions of the job, which would preclude him from protection as a "qualified individual" under the ADA.[148] If the court finds the ADA does apply to Mr. Kimball, the EEOC will likely be granted its requested injunctive, compensatory, and punitive relief. A "direct threat" defense asserted by Steel Painters would likely fail, since the *Hussey* court was hesitant to find that the defense applied in a copper mill setting, and a reasonable person would find painting is objectively less dangerous.[149]

B. Discrimination cases involving medications comparable to MAT

Physicians' capacity for prescribing MAT has increased steadily over the past decade, but the case law interpreting its effect on employability is still sparse.[150] However, employment discrimination cases involving prescription pain medication are instructive, as ADA protections apply uniformly to all legally prescribed medications, provided the substantially limiting

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[147] Press Release, EEOC, *Steel Painters Sued by EEOC For Disability Discrimination* (June 29, 2018), https://www.eeoc.gov/eeoc/newsroom/release/6-29-18a.cfm.
[148] 29 C.F.R. § 1630.2(r) (2012).
[149] See *EEOC v. Hussey Copper Ltd.*, 696 F. Supp. 2d 505 (W.D. Pa. 2010).
[150] Christopher M. Jones et al., *National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment*, 105 Am. J. Pub. Health e55 (2015).

disability still exists when the mitigating factors of the prescription are considered.[151] As such, the following cases examine the way courts have treated prescription medication in the employment discrimination context for the sake of comparison.

i. Gaus v. Norfolk Southern

The biochemical similarities between opiates and MAT drugs like methadone[152] also translate to legal similarities: whether illicit or legally prescribed, both types of drugs are subject to the same ADA analysis, provided a disability is implicated.[153] In *Gaus v. Norfolk Southern Railway Co.*, the plaintiff had worked as an electrician for the defendant for about five years before losing his job due to his use of prescription pain medication.[154]

Mr. Gaus suffered from chronic pain in his joints, hip, back, and abdomen.[155] Norfolk Southern Railway ("NSR") granted Mr. Gaus medical leave, and for the next nine months, Mr. Gaus underwent treatment for his various conditions.[156] When he attempted to return to work, his physician and the physician hired by NSR examined him.[157] Although both opined Mr. Gaus could

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[151] 45A Am. Jur. 2d Job Discrimination § 192 (2018).
[152] *Effective Treatments for Opioid Addiction*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction (last updated Nov. 2016).
[153] 45A Am. Jur. 2d Job Discrimination § 192 (2018).
[154] *Gaus v. Norfolk S. Ry. Co.*, No. 09–1698, 2011 WL 4527359, at *7 (W.D. Pa. Sept. 28, 2011).
[155] *Id*. at *3.
[156] *Id*. at *2.
[157] *Id*. at *3.

return to work, the NSR medical department "felt that the medical evidence was insufficient and that it required more information."[158] After reviewing the information provided by Mr. Gaus' physicians, the NSR medical department decided he was not cleared to return to work as an electrician, calling it a "safety-sensitive position," but cleared him to work in a sedentary position doing primarily clerical work.[159] The department based this finding on NSR's medical guidelines.[160]

Although NSR later cleared Mr. Gaus to return work as an electrician after further medical treatment,[161] Mr. Gaus filed suit, claiming NSR discriminated against him by refusing to allow him to return to work due to his chronic pain medications.[162] The United States District Court for the Western District of Pennsylvania denied NSR's motion for summary judgment,[163] holding the company's assessment of Mr. Gaus did not meet the requirements set forth by federal law.

> The Equal Employment Opportunity Commission's interpretative guidance makes clear that 29 C.F.R. § 1630.2(r) (2011) does not

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[158] *Id*.
[159] *Id*. at *4 ("Dr. Lina had two concerns at that time, based on the available medical evidence: (1) Gaus had not established a suitable record of control and stability of his chronic pain condition; and (2) Gaus' frequent narcotics use.") (internal quotations omitted).
[160] *Id*.
[161] *Id.* at *9.
[162] *Id.* at *12.
[163] The motion for summary judgment was denied only in part, as it related to the prescription pain medication and corresponding denial of clearance to return to work; it was granted as to Gaus' earlier claims of discrimination, which are beyond the scope of this paper. *Id*. at *32.

> require that the employer's physician personally examine the employee. What is required, however, is that the employer base its determination of a direct safety threat on objective evidence from physicians or other medical professionals who have observed or examined the employee, and/or direct input obtained from the employee.

Gaus v. Norfolk S. Ry. Co., No. 09–1698, 2011 WL 4527359, at *12 (W.D. Pa. Sept. 28, 2011).

The court reasoned that NSR's individualized assessment was insufficient because its physician relied on the fact that Mr. Gaus' medications fell outside NSR's company guidelines.[164] Specifically, the court pointed to NSR's failure to consider the lack of side effects Mr. Gaus experienced from his medications and disregard of the reports from his treating physicians.[165]

ii. Carter v. McCreary Modern, Inc.

In contrast, another district court addressing the "direct threat" defense for safety-sensitive positions involving prescription pain medication held in favor of the defendant.[166] In *Carter v. McCreary Modern, Inc.*, the defendant furniture manufacturer ("McCreary") retracted a conditional offer of employment, citing safety concerns associated with medication the plaintiff took for back pain.[167] Ms. Carter applied for a job as a hard-mark cutter,

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[164] *Id.* at *27.
[165] *Id.*
[166] See *Carter v. McCreary Modern, Inc.*, No. 5:10–CV–014–RLV, 2011 WL 3444090 (W.D.N.C. Aug. 8, 2011), *aff'd*, 468 F. App'x 219 (4th Cir. 2012).
[167] *Carter v. McCreary Modern, Inc.*, No. 5:10–CV–014–RLV, 2011 WL 3444090, at *1 (W.D.N.C. Aug. 8, 2011).

which involves the use of a motorized knife.[168] She told McCreary's occupational nurse that she (Ms. Carter) "had no medical restrictions and could perform the essential functions of the cloth cutter position," but also disclosed her use of several pain medications for back pain.[169] Although Ms. Carter passed four exercises, a spine exam, and a grip test, her preliminary drug screening was positive, and McCreary retracted the employment offer.[170]

On cross-motions for summary judgment, the Western District of North Carolina held McCreary's individualized assessment of Ms. Carter fulfilled the requirements of the ADA, and that its determination of her ability to safely perform the job of the hand-mark cutter was objectively reasonable.[171] In granting McCreary's motion for summary judgment, the court reasoned that "[Ms. Carter's] use of opiates is of legitimate concern to an employer whose employees use a motorized knife."[172] The court relied on Ms. Carter's medical records, in which she stated to her physician one year prior that "muscle relaxers make her sleepy,"

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[168] *Id.* at *1, *5.
[169] *Id.* at *1 ("Plaintiff also disclosed that she took medications for her back pain, including hydrocodone, cyclobenzaprine, and acetaminophen, but only as needed and never when she was working.").
[170] *Id.*
[171] *Id.* at *5
[172] *Id.*

holding McCreary was objectively reasonable in determining this made Ms. Carter unfit for that particular job.[173]

IV. Argument

A. Raising the bar for the individualized assessment required by the ADA

Federal law establishes a clear exception to the protections of individual applicants under the ADA.[174] That the "direct threat" exception requires an individualized assessment of each applicant is well settled[175], but what that assessment looks like is incredibly fact-specific and varies based on each case.[176] This ambiguity creates uncertainty for both applicants and employers, especially in the area of blanket policies regarding legal prescription drug use.[177]

The EEOC's administrative guidance only requires that the analysis include a weighing of (1) the duration of the risk; (2) the nature and severity of the potential harm; (3) the likelihood that the potential harm will occur; and (4) the imminence of the potential harm.[178] In weighing these factors (called the *Arline* factors after the Supreme Court case which the EEOC largely based its

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[173] *Carter v. McCreary Modern, Inc.*, No. 5:10–CV–014–RLV, 2011 WL 3444090, at *1, *5 (W.D.N.C. Aug. 8, 2011).
[174] 29 C.F.R. § 1630.2(r) (2012).
[175] 42 Am. Jur. Proof of Facts 3d 1 (1997).
[176] Ann Hubbard, *Understanding and Implementing the ADA's Direct Threat Defense*, 95 Nw. U. L. Rev. 1279, 1307 (2001).
[177] Elisa Y. Lee, *An American Way of Life: Prescription Drug Use in the Modern ADA Workplace*, 45 Colum. J. L. Soc. Probs. 303, 336-37 (2011).
[178] 29 C.F.R. § 1630.2(r) (2011).

regulations on),[179] the employer must rely on "reasonable medical judgment that relies on the most current medical knowledge and/or on the best available objective evidence."[180] However, lower courts have discussed whether an employer's direct threat determination should include an examination by the employer's physician or occupational medicine professional.

The *Gaus* court specifically addressed this issue when the employer, in that case, raised as a defense the fact that its physician had examined the applicant.[181] The court interpreted the EEOC's guidance as *not* requiring a personal examination but held the employer's actions still did not meet the individualized assessment requirements.[182]

The *Gaus* court distinguished *Hussey*, an opinion that gave great weight to the need for an employer's physician (or other health professional) to examine the applicant.[183] In that case, the fact that the medical director "did not meet with or personally examine [the applicant], but based his opinion on the nurse practitioner's evaluation and his knowledge gained from various literary sources about methadone" was of consequence.[184]

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[179] *Sch. Bd. of Nassau Cty., Fla. v. Arline*, 480 U.S. 273, 288 (1987).
[180] 29 C.F.R. § 1630.2(r) (2011).
[181] *Gaus v. Norfolk S. Ry. Co.*, No. 09–1698, 2011 WL 4527359, at *28 (W.D. Pa. Sept. 28, 2011).
[182] *Id.*
[183] *Id.* at *27.
[184] *Id.* (citing *EEOC v. Hussey Copper Ltd.*, 696 F. Supp. 2d 505, 518 (W.D. Pa. 2010)).

Similarly, the *Carter* court, which granted the employer's motion for summary judgment, relied on the testimony of the employer's occupational nurse, who examined the applicant herself.[185] Several circuit courts of appeals have also relied heavily on the existence of an examination at or near the time of the application for employment in upholding an employer's direct threat defense.[186] This evidence is important because it recognizes the fundamental purpose of the individualized assessment, which Justice Brennan opined was "protecting handicapped individuals from deprivations based on prejudice, stereotypes, or unfounded fear, while giving appropriate weight to such legitimate concerns of grantees as avoiding exposing others to significant health and safety risks."[187]

If an employer's physician or nurse is to determine whether an applicant would pose a direct threat to workplace safety based on reviewing medical records, without personally examining the applicant, there is more room for prejudice, stereotypes, or unfounded fear to taint that medical opinion. This was exactly the

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[185] *Carter v. McCreary Modern, Inc.*, No. 5:10–CV–014–RLV, 2011 WL 3444090, at *1 (W.D.N.C. Aug. 8, 2011).

[186] *E.g.*, *Darnell v. Thermafiber, Inc*., 417 F.3d 657, 660 (7th Cir. 2005) (holding an employer reasonably relied on the opinion of a physician who, despite not being familiar with the applicant's medical history, interviewed the applicant about his failure to regulate his glucose levels); *McGeshick v. Principi*, 357 F.3d 1146, 1151 (10th Cir. 2004) (holding an employer's decision not to hire a job applicant with Meniere's disease was proper because it was based on the advice of physicians who reviewed the applicant's medical records and treated him for his symptoms). The *McGeshick* plaintiff claimed discrimination under the Federal Rehabilitation Act, but the elements are identical to that of an ADA claim. *Henrietta D. v. Bloomberg*,331 F.3d 261, 272 (2d Cir.2003).

[187] *Sch. Bd. of Nassau Cty., Fla. v. Arline*, 480 U.S. 273, 287 (1987).

concern of the EEOC in filing the *Randstad* complaint, which claimed the employer based its decision not to hire solely on the positive result returned by the pre-employment drug screening.[188] By failing to conduct any further inquiry into the cause of the positive result, the plaintiff reasoned, the employer did not fulfill the individualized assessment required by federal law.[189]

This type of knee-jerk decision and its destructive impact on MAT patients trying to find work can be remedied. Medical judgment is more likely to be "reasonable," as is required by the EEOC's administrative guidance,[190] if it includes a current physical examination *by the decision-maker*, not a remote contractor. These high standards for the requisite individualized assessment are particularly important when they implicate a disability with such stigma, as is the case with opioid dependence.[191]

B. Why timing may matter for employers using a safety exception to the ADA

Raising the standard for what qualifies under the direct threat exception may create concern that any defense employers have under the Act is effectively revoked. However, the outcome

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[188] Complaint at ¶ 13, EEOC v. Randstad, No. 15CV03354, 2015 WL 13666335 (D.Md. Nov. 3, 2015).
[189] *Id.*
[190] 29 C.F.R. § 1630.2(r) (2011).
[191] Karen McElrath & Herman Joseph, *Medication-Assisted Treatment (MAT) for Opioid Addiction: Introduction to the Special Issue*, 53 Substance Use & Misuse (SPECIAL ISSUE) 177 (2018).

of the *Steel Painters* case may provide a framework by which to strike a balance between applicant protection and an employer's right to ensure a safe workplace. The distinction, in that case, is that the worker had been hired, and was actually on the job for a week before the company received his positive drug test and terminated him.[192] In contrast, many other ADA discrimination cases involving a drug screening are *pre-employment*.

Because the direct threat defense requires employers to show the existence of "a significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation,"[193] it follows that allowing an individual to begin work would provide clear evidence of whether or not the individual has met the test. In other words, termination based on an individualized assessment *during* employment, as opposed to *pre-employment*, allows a court to base an ADA ruling on more than mere speculation.

The *Steel Painters* employer did not raise such a defense in its answer to the worker's discrimination claim.[194] Nonetheless, a decision in favor of the company could set a precedent, giving

[192] Complaint at ¶ 17, EEOC v. Steel Painters, LLC, No. 1:18-cv-00303, 2018 WL 3301664 (E.D.Tex. June 28, 2018).
[193] 29 C.F.R. § 1630.2(r) (2012).
[194] Second Amended Answer By Steel Painters, LLC, f/k/a Steel Painters, Inc. at 6-8, EEOC v. Steel Painters, LLC, No. 1:18-cv-00303 (E.D.Tex. Nov. 2, 2018).

employers greater deference in decision-making after hiring a protected individual.

C. A call for specificity in panels used for pre-employment drug screenings

Notwithstanding concerns about employers abusing drug screenings to discriminate against disabled applicants, the ability to conduct screenings before and during employment is an important part of the American workforce. Empirical data has shown that the implementation of regular testing programs significantly reduces drug abuse in worker populations subject to such testing.[195]

However, the *type* of test utilized by an employer can mean the difference between legally protecting safety through a drug-free workplace policy, and illegally discriminating against a job applicant. Federal agencies conducting drug testing are subject to standardized procedures established by the Substance Abuse and Mental Health Services Administration (SAMHSA, a division of the Department of Health and Human Services).[196] The procedures

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[195] Quest Diagnostics' Drug Testing Index summarizes more than seven million urine drug test results from both the general U.S. workforce and federally mandated safety-sensitive workforce (which includes pilots, bus drivers, and nuclear power plant operators). Since the Drug Testing Index was first published in 1989, the U.S. workforce has sustained a constant decline in positive urine drug test results. Press Release, Quest Diagnostics, *Cocaine Use Among U.S. Workers Declines Sharply in 2008, According to Quest Diagnostics Drug Testing Index*™ (May 6, 2009), http://newsroom.questdiagnostics.com/press-releases?item=94599&mobile=No.

[196] *Workplace Drug Testing*, Drug & Alcohol Testing Industry Association, http://www.datia.org/datia-resources/27-credentialing/cpc-and-cpct/931-workplace-drug-testing.html (last visited Oct. 27, 2018).

require the test, most commonly a urine sample, to identify five illicit drugs: amphetamines, THC, cocaine, opiates, and phencyclidine.[197]

This typical five-panel opiate immunoassay (antibodies designed to bind with a specific drug) only detects morphine, codeine, and heroin.[198] Thus, federal agencies and federally-regulated employers in the private sector applying this five-panel immunoassay will typically not be impacted in their employment decisions by MAT using methadone or buprenorphine.[199] However, the legal issue arises for private employers, most of which are not restricted to this five-panel test and may choose to administer an eight or ten-panel test that can identify additional substances.[200] The typical ten-panel test can identify synthetic opiates such as fentanyl and methadone.[201] Thus, while more panels present the opportunity for more specific results, they may also open the door to confusion absent a proper analysis. In fact, one study of clinicians analyzing standard urine drug tests revealed: "the majority were not aware of morphine as a common metabolite of codeine, which may lead to false accusations of illicit

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[197] *Id.*
[198] *Appropriate Use of Drug Testing in Clinical Addiction Medicine*, Am. Soc'y of Addiction Med. 1, 21 (2017), https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2.
[199] *Workplace Drug Testing*, *supra* note 195.
[200] *Id.*
[201] *Id.*

opiate use."[202] Blood testing presents similar challenges; however, research shows certain methods separate structural isomers in the blood, effectively differentiating between illicit and legal opioids.[203]

While biochemistry is implicated in the important distinctions between drug tests, employers do not need to have scientific training to avoid ADA liability in hiring practices. Compliance while maintaining testing programs is simply a matter of communication with the drug testing lab. Although private employers are not required to follow the SAHMSA regulations required of federal agencies, it is advisable for them to do so. However, if employers opt for a test with ten or more panels, they should inquire as to whether the test indicate if a reaction with methodone or another synthetic opiate immunoassay causes any positive results.

Even if the laboratory is unable to distinguish the immunoassay that triggered the positive result, the positive result itself gives the employer cause to conduct an inquiry into (1) whether the drug is legally prescribed, and (2) whether any interference with the essential functions of the job can be mitigated

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[202] Christopher J. Keary et al., *Toxicologic Testing for Opiates: Understanding False-Positive and False-Negative Test Results*, 14 Primary Care Companion for CNS Disorders 4 (2012).
[203] Marianne Skov-Skov Bergh et al., *Addressing the Fentanyl Epidemic by Multiplex UHPLC-MS/MS Analysis of Whole Blood* (2018).

through reasonable accommodations.[204] If the answer to either inquiry is "yes," the ADA prohibits the employer from terminating or declining to hire the employee or applicant, respectively.[205]

Further, the timing of a drug test can impact its legality.[206] During the hiring process, drug testing is only designed for employers to determine whether an applicant is using drugs and whether such use is legal.[207] At that stage, an employer may ask the applicant if they have a legal prescription for methadone or buprenorphine, but may not ask the reason for the prescription, as such information "could reveal disability-related information the employer is not permitted to ask about before a job offer."[208] Conversely, after an offer of employment has been made or during employment, the employer may ask why the need for a methadone or buprenorphine prescription if there is a "business necessity" for such information.[209] Should the need arise to solicit more information about an employee or applicant's drug use, it is

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[204] Joanne Bush et al., *Confronting The Opioid Emergency In The Workplace*, https://www.jonesday.com/files/Publication/8c5e74cd-4e9d-4b6a-8692-53a1e77b93f7/Presentation/PublicationAttachment/5b2d29a5-b659-4c88-a8f7-54c50435e19c/Confronting%20The%20Opioid%20Emergency%20In%20The%20Workplace%20-%20Law360.pdf.
[205] 29 C.F.R. § 1630.9 (2011).
[206] *Questions and Answers from Webinar: Medication Assisted Treatment: Special Anti-Discrimination Issues* (2009), https://www.samhsa.gov/sites/default/files/partnersforrecovery/docs/QA_Medication-Assisted_Treatment_Anti-Discrimination.pdf.
[207] *Id.*
[208] *Id.*
[209] *Id.*

advisable to delegate any inquiries resulting from a drug screening to a designated medical review officer.[210]

V. Conclusion

Drug testing reform can only go so far to ensure individuals recovering from opioid dependency are granted equal access to employment. A large part of the challenge faced by those in recovery is attributed to the stigma associated with their illness: though MAT patients may not feel "disabled," they must often identify as such to fall under the umbrella of protections granted by the ADA.[211] The hiring policies instituted by employers are an important part of alleviating that stigma while preserving equal access.

Still, employers face uncertainty in navigating whether an individual enrolled in an MAT program may be qualified to safely perform a job. The aforementioned case law shows a variety of practices that have been deemed acceptable individualized assessments by courts. To remedy this lack of uniformity, the EEOC should promulgate more specific administrative guidance in this area of the ADA. In particular, regulations requiring an

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[210] Baker Donelson, *On Drugs and at Work: Keeping Your Work Force Safe and ADA-Compliant in the Opioid Epidemic* (Aug. 14, 2017), http://www.jdsupra.com/legalnews/on-drugs-and-at-work-keeping-your-work-52848/.

[211] Alison Knopf, *Methadone Patients Don't Feel "Disabled," But They Do Have a Protected "Disability" Under the ADA*, Addiction Treatment Forum (June 18, 2018), http://atforum.com/2018/06/methadone-patients-dont-feel-disabled-but-they-do-have-a-protected-disability-under-the-ada/.

individualized assessment to include an examination by the employer's physician or nurse will best serve the interests of public health. Courts can play a role in encouraging the passage of such regulations by holding assessments, based only on a remote review of medical records, or speculation based on an individual's history of opioid dependence, are insufficient for defending a discrimination claim.

Additionally, research on the effectiveness of MAT programs should contribute to abating the stigma associated with those in recovery. According to the National Institute of Drug Abuse, individuals who participate in methadone maintenance treatment face the likelihood of becoming and remaining employed.[212] This positive empirical data may reassure hiring managers that employability is not affected by enrollment in MAT programs.

Ensuring individuals in recovery have equal access to employment is crucial to addressing the crisis that is opioid addiction in the United States. Although employment policies are only a piece of the proverbial puzzle, they are an important piece. As one scholar put it, "[p]rivate employers represent an indispensable source of payors for patient services to support recovery and drug treatment, and the provision of reasonable

[212] National Institute of Drug Abuse, *Methadone Research Web Guide*, Part B-24 (2011), https://www.drugabuse.gov/sites/default/files/pdf/partb.pdf.

accommodations provides a mechanism for accessing those payors."[213] Working in conjunction with jurists, legislators, and healthcare providers, employers can maximize that indispensable role to expand access to MAT and in so, doing slow the spiral of opioid dependence nationwide.

[213] Samuel Brown Petsonk & Anne Marie Lofaso, *Working for Recovery: How the Americans with Disabilities Act & State Human Rights Laws Can Facilitate Successful Rehab. for Alcoholics & Drug Addicts*, 120 W. Va. L. Rev. 891, 914 (2018).