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ALL HEALTH CARE IS LOCAL: EXPLORING THE ROLES OF CITIES AND STATES IN HEALTH CARE DELIVERY AND REFORM

KEYNOTE SPEAKER: REPRESENTATIVE JEREMY FAISON
[edited for reading]

FEBRUARY 9, 2018

Rep. Jeremy Faison: Good morning. It's good to be with you guys. I'm Jeremy Faison and I do get to represent the most beautiful part of the whole state of Tennessee. I often tell people if God actually lived in Tennessee, He would live where I live. All of you have heard of the Gatlinburg area. I live just deeper in the mountains than Gatlinburg. I represent Cobb County, Green County, Jefferson County, and it's an amazing place. If you've never been there, come on over. Spend your money in my district. You'll have fun when you come there.

So, this morning I'm going to talk to you about the legal justification for Tennessee to expand cannabis for certain sick Tennesseans. You're looking at a guy who was elected as a conservative. I came down the wave of President Obama's midterm election and I was able to defeat a Democrat and I'm a pro-gun guy, pro-life guy—'Merica, freedom, that's kind of who I am. I lead worship at my church—active with that. But I support this plant called cannabis and it's an enigma to a lot of my colleagues.

My colleague right here. I think he was shocked at 4 years ago when I came out and said, "hey, we need to do something with this plant as it relates to Tennessee." It kind of shocked because no Republican has ever been that stupid. All of a sudden, this redneck from East Tennessee said, "hey, there's something in pot." And a lot of people were like, "Yeah, Jeremy, Fox County has been growing it for years. It's been the number one cash crop for years in Tennessee, so we get it."

But you know, what I found out is there's actually some huge benefits and so this healthcare law symposium, we can talk [about]

a lot of different things, and I'm on the healthcare committee, the sub and the full, and we could talk about a lot of different laws. I just thought maybe you would like to hear a perspective of how I got where I got and what brought me to the position that I'm willing to go out there in the Bible Belt as a Christian and say, "hey, this is the right thing to do, it's the right thing for Tennessee, and this is the right thing for sick people."

Martin Luther King, rightly said one time from jail, "a just law is a man-made code that squares with the moral law of God. An unjust law is a code that is out of harmony with the moral law."[1] There are times that we as legislators in Nashville, or in DC, get it wrong. The truth is, we probably get it wrong more than we get it right. There are times that we have passed unjust laws and I believe there is a right time to disobey an unjust law. I believe I can prove to you if I had enough time that a prohibition on the cannabis plant was an unjust law from the beginning.

You say, "well, Jeremy, how can you say that?" Well, when we study the cannabis law or canvas and get deep into it and I've traced the use of the hemp plant and the marijuana plant back to around 3000 BC. Historians tell us—and I'm a little bit nervous speaking to attorneys because they are all phenomenally more intelligent than I am. I killed bugs for a living and I'm probably not a very bright guy compared to y'all, so it takes a lot more studying for me to speak to y'all than it probably would for y'all to speak to me, so I'm a little bit nervous about that, but... So I've done an immense amount of research and if you go back to the Assyrian nation, the Assyrians are some of the first organized people group that we could find that had an organized government and we can find them somewhere in the neighborhood of 2500 to 3000 BC.[2] So we're looking at 5,000 years of history. Okay. So when you go back to them and trace it forward from the Assyrians, around 3000 BC, trace the court come all the way up to the 20th century, 1930s. Every government, every organized people group in the world in the history of the world used the cannabis plant for industrial purposes and for medicinal purposes.[3] That Asian side of our planet did phenomenal things with it. You follow that all the way up for 5,000 years, come to the 20th century and all of a sudden we had this thing

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[1] Martin Luther King Jr., Letter From Birmingham Jail 6 (American Friends Services Committee eds., 1963).

[2] *See generally Assyria, Ancient Kingdom, Mesopotamia*, ENCYCLOPEDIA BRITANNICA (Dec. 2017), https://www.britannica.com/place/Assyria.

[3] *See* Antonio Waldo Zuardi*, History of Cannabis as a Medicine: A Review*, REVISTA BRASILEIRA DE PSIQUIATRIA VOL. 28 NO. 2 (June 2006), http://www.scielo.br/pdf/rbp/v28n2/29785.pdf.

called the industrial revolution, and we have this massive thing called corporate greed. I know none of you good liberals have ever heard of that term. You don't know what I'm talking about, do you?

They weren't going by legislation. They were able to buy competition out. One of the things that our government was founded on is to stop the ruling class. Do you know what I mean when I say the ruling class? That's the view of the top, being able to dominate the legislative process and buy what they want. And when the ruling class buys what they want, they're able to sequester the ones who are actually doing the work. So Henry Ford, first car, the shell of his car—and you can find a YouTube video of them hitting it with an axe—made from hemp fibers.[4]

There was huge problems with that because the cotton industry didn't like it. Our first flag that was sewn by Betsy Ross was sewn with hemp fibers.[5] All of the drafts of our Declaration of Independence were written on cannabis paper—hemp paper.[6]

So in the industrial revolution you find out there's all this competition going on and there's people, corporate guys realized, "hey, we need to put a stop to this because you can grow an acre of hemp with no pesticides." So the DuPont was ticked. They won't be able to sell their pesticides and herbicides. Right? You can grow an acre of that—the guys who were making paper, realized, "hey man, if we can grow trees and we can make paper with no competition from people who can make paper out of hemp..." So we were able to get it defeated. And there's a guy named Anslinger who was extremely racist, a so and so horrible human being, and he would tell Congress—he, his position was created because he failed with prohibition when they realized it was a disaster. So immediately when Anslinger failed with prohibition, he turned to this thing called marijuana--and he would tell Congress because we were extremely racist society at that time, he would tell Congress, listen, the black men are giving the white women this plant and making them smoke

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[4] Nejat Akay, *Henry Ford's 'plastic hemp car' from 1941*, YOUTUBE (Dec. 7, 2012), https://www.youtube.com/watch?v=srgE6Tzi3Lg.

[5] According to hemp advocate Michael Bowman, Betsy Ross's flag was made of hemp. Emily Heil, *Hemp flag to fly high over the capitol building*, WASH. POST (July. 2013), https://www.washingtonpost.com/blogs/in-the-loop/post/hemp-flag-to-fly-high-over-capitol-building/2013/07/02/ac69c120-e264-11e2-aef3-339619eab080_blog.html?utm_term=.27a391130a1c.

[6] *Declaration of Independence Paper*, Thomas Jefferson Encyclopedia, https://www.monticello.org/site/jefferson/declaration-independence-paper (last visited July 27, 2018).

it so they can have them and take the white women from them.[7] He told them that in Congress.

So we bought this lie, hook, line, and sinker. We said, "this plant's the devil, regardless of whether God put it on there or not. And regardless of what we used it for 5,000 years, this must be the devil." And we have believed these silly lies for eighty-two years now. And you've heard of reefer madness,[8] all of y'all that are a child of the sixties? You know what I'm talking about? Definitely you—if you've got gray hair, you know what I'm talking about.

So we bought this lie hook, line, and sinker. And what I'm telling you today, as Martin Luther King said, a just law squares with the moral law. There was nothing immoral about the use of this plant from the beginning. So we had to bring all type of lies and motions to get Congress to buy this idea and put this plant as a schedule one drug. Now the whole notion—do y'all know what I mean when I say schedule one, what that means? There is absolutely zero benefit to society.[9] This is going to blow your mind. Some of you won't believe me and you're going to go home and look it up and say man, that hillbilly was right. Cocaine is a schedule two.[10] Is there an anesthesiologist in here? I don't see any. Anesthesiologists use cocaine today in the hospitals.[11] There's cocaine being legally used today. We bought this stupid lie so good that we were able to get congress to put marijuana as a schedule one and we still use cocaine as a schedule two. That's how stupid we got. I mean this is like double down, special kind of stupid what we're doing right?

So first of all the justification of what I'm doing, the justification starts with one thing. First of all, it was prevalent and commonplace in society for 5,000 years that we can trace humankind and nothing was bad. Once you have a track record—are all of y'all out of school, are there any students in here? So we find out, you'll find out that case law is as good as legislative law

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[7] *See* Laura Smith, *How a racist hate-monger masterminded America's War on Drugs*, TIMELINE (Feb. 2018), https://timeline.com/harry-anslinger-racist-war-on-drugs-prison-industrial-complex-fb5cbc281189.

[8] Reefer Madness (Motion Picture Ventures 1972).

[9] Schedule 1 drugs have no accepted medical use in the United States. 21 U.S.C. § 812(b)(1)(B); Marijuana is a schedule 1 drug. § 812(c)(Schedule 1)(c)(10). *See also Drug Scheduling*, Drug Enforcement Agency, https://www.dea.gov/druginfo/ds.shtml (last visited July, 27. 2018).

[10] 21 U.S.C. § 812(c)(Schedule II)(4).

[11] Cocaine acts as a local anesthetic by blocking conduction of nerve impulses. Jay W. Marks, MD and Omudhome Ogbru, PharmD, *Cocaine Hydrochlorid*e, MEDICINE NET, https://www.medicinenet.com/cocaine_hydrochloride-topical/article.htm (last visited July 9, 2018).

that I pass. You understand what I'm saying? Case law—a judge will look back on case law and then will decide what happened in a case, and that case is as powerful or is as pertinent as the law that I passed in Nashville. So when we have 5,000 years of a record of what we're doing and our first four presidents are using this plant and said, hey, this is the right thing to do... maybe we shouldn't have done that in the first place.

The next justification of what I'm doing is: America is there. Have you heard of Quinnipiac University? Quinnipiac is one of the most sought-after polls,[12] if you're into politics at all. People pay attention when Quinnipiac releases a poll, they're like, "okay, who's ahead, who's behind what do they need to do, what are the people thinking? In January 11th of this year, Quinnipiac released a poll. It's a beautiful poll, you should read all kinds of neat stuff in it. Interesting thing that was in it: January 11th of this year, 91 percent of the general public voters in America say the cannabis plant ought to be available to sick people.[13] When you see that poll, and I want to remind our colleagues that are against it in office, who's the boss? See, the way our government is set up is that we're not the boss. We are not the ruling class. Y'all are the boss. The people who are paying the bill, and when you find out that Quinnipiac University has released a poll, ninety-one percent, it says, people often have access to this plant and we're still wondering why we should do this. That poll also says, only six percent of the population of the US shouldn't, and then two percent haven't made their mind up. That two percent will never make up their mind, but the truth is we should listen to that 91...if 91 percent of Americans agree on something... My God, that might be a good idea to think what they're doing. You can't get 91 percent on anything in this world. We couldn't probably get 91 percent agreement. Well, y'all are pretty...attorneys, so maybe ninety one percent of agreement. It's rare to find 91 percent. Right? So that's the second thing.

Now I'm going to switch gears for a minute. Have you ever heard of the intent of the law? When the senator and myself pass law and we're in committee, often the chair of the committee or somebody who's intelligent on the committee would say, what is your intent? Because law is funny sometimes and when you get into litigation, some of y'all might, I guess the vast majority of attorneys don't ever actually litigate, but some of you will end up litigating

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[12] Quinnipiac University Poll, https://poll.qu.edu/ (last visited July 9, 2018).
[13] Dreamers Should Stay, American Voters Say 8-1, Quinnipiac University National Poll Finds; Do Not Enforce Federal Pot Laws, U.S. Voters Say 3-1, Quinnipiac University Poll, (Jan. 11, 2018) https://poll.qu.edu/images/polling/us/us01112018_ubn985.pdf/.

and one day you're going to be in this law suit. You're going to be defending somebody and the written law can at times look gray and difficult and you want to present your case to the judge and so you are going to go back and listen and look for the intent of the law that the legislator said on record. Now we have a thing called the journal. Everything that's said in committee and everything that's said on the House floor or the Senate floor is recorded and you, as attorneys, some of y'all have probably done this. Y'all have gone and found the journal, found that video, and you listened very intently for the intent of the law. Even if the law might be a little bit gray and you struggled trying to understand what it is. You want to know exactly the guy who wrote the law, what his intent was. So in 2014, we've got this Senator, Roy Roth, and another senator, Blumenauer. In 2014, remember I'm giving you justifications, legally, of why I'm doing what I'm doing. It's called the Rohrabacher-Blumenauer amendment and the federal appropriations act that they amended it in 2014 to benefit me and a lot of other states.[14] I had just passed my original cannabis oil bill, old bill for a little girl named Josie Mathis[15] in Greene County, Tennessee, and I didn't want the federal government coming after us.

And so several other states had been doing stuff. We petitioned. I called Senator Lamar Alexander and said, please make sure this amendment goes on to the federal appropriations act. Here's what the amendment says. None of the funds made available in this act to the Department of Justice may be used with respect to the states of Alabama, Alaska, Arizona, it goes on to include Tennessee, to prevent such states from implementing their own state laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

Very few people in America realize that that has been in our federal appropriations act since 2014. Now I'm going to (probably shouldn't do this) but I'm going to tell you anyway. Our wonderful people in the US Senate and the US House. They take great pains and pay lots of money and do a lot. They fight hard to never actually take a stand on something. Have you noticed? In the last 20 years, they really do big fat bagel.

I mean, it's an amazing thing to see them actually vote on something of substance. Why? So what I've been told, it's like

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[14] *Federal marijuana protections safe for now with stopgap spending bill*, THE CANNABIST (Dec. 7, 2017), https://www.thecannabist.co/2017/12/07/federal-budget-medical-marijuana-rohrabacher-blumenauer/94177/.
[15] 2014 Tenn. Pub. Acts 936.

winning the lottery. Once you get into Congress or once you get to the US Senate and I would love to tell you that's just the Democrats that do that, but unfortunately, I can't tell you that it's the Republicans, it's the Democrats, it's the whole lot of them. They're all consumed with keeping their seat there. It's like they will almost sell their mom or their first born just to be able to retain that position because you're kind of like a god. There is only 435 in the house and there's 330,000,000 here. I mean, it's an elite club. And if you make it to the US Senate, oh my God. You get asked to sit on these boards and they fly you all over the world, have elaborate thanks for you because you're a board member. Have you ever noticed that a guy can go in Congress making a governor's salary $180,000 and after a few years he's worth $20 million? I mean, something is an issue here and by the way, this happens, Democrat and Republican alike, so often people say, Jeremy, why hasn't Congress taken this from Schedule One to Schedule Two or just given it to the states? Well, they don't want to answer to their voters. The reason that you never see anything of substance come from DC or whatever you do see that comes from DC is so watered down that it tries to please everybody. And the truth is, you know, you cannot please everybody. You have to stand on what you believe is right and you go for that. And unfortunately, they try to milquetoast it down so much that when they finally do have to answer to their voters that it's really not much that they have to answer about. So these guys in Congress have never wanted to go back to their voters and say, we did this when it comes to cannabis.

So they sneak in this little amendment, but that little amendment has power for me and what I'm trying to do in Tennessee. I listen to the video of Senator [audio interference] of what his intent was. He says, Mr. Chairman, my intent in this is to protect these states who are pursuing medical marijuana for all these different purposes. That's the intent of what he's doing. Now, law enforcement—do we have law enforcement here today? They are freaked out about it because Congress has not actually passed a law to say we can do this. But in my opinion, and I think that time will tell, we don't have any case law yet because nobody's sued the state that's done this. You would think seriously the federal government would sue a state and stop a state, we have 30 states now doing this.[16] They haven't done that. They haven't done that because the Department of Justice's hands have been tied with the money that they've been given. In the federal appropriations act, Congress gives

[16] Lopez, German, *Marijuana is legal for medical purposes in 30 states*, Vox (June 26, 2018), https://www.vox.com/cards/marijuana-legalization/what-is-medical-marijuana.

them money and tells them to act and bring justice to society. But oh, Department of Justice. While you're bringing justice to society, we're tying your hands when it comes to cannabis, so those are the reasons that I'm doing what I'm doing.

Do you want to hear some specifics of the bill and what I'm trying to do, because you might be litigating it one day. I want to introduce something called the Medical Cannabis Act Only and what I'm doing is I'm trying to bring oil-based products to the state of Tennessee.[17] There's one thing that I wanted more than anything but it, a lobbyist had been hired and this is my message from day one. I want the state of Tennessee to be able to grow cultivate, manufacturer, and produce cannabis products. I don't want our citizens to have to go to Colorado or Arizona or anyplace else to buy cannabis and the cool thing, if we get this, our product is regulated.

It's tested, it's proven and it's predictable. We know that's a good word for attorneys. It's predictable, right? We want that. So the sick Tennesseans that I know, I want them to be able to have something when they walk into a dispensary that is very predictable and they know they buy and they buy it in Memphis or if they buy it in mountain city, is predictable, it's tested and they know exactly what they're getting. We have thousands of Tennesseans that I've met all across the state who are using street weed right now to help their problems, which I would say it's probably safer than a lot of stuff the FDA has approved--and I could talk about the FDA for an hour.

They're the devil. Just think about how many pills they have approved that's killed people. Think about that for a minute. Talk about the ruling class.... These peckerwoods, they've approved pills we've taken off dozens of times in my forty-one years on this planet and they were paid to approve stuff and then we found that it kills a bunch of people. Just look at opium, my gosh... By the way, opiates have toxins in them.[18] So we're creating a cannabis advisory Commission of eleven members that are attorneys, doctors, patient advocates, they will oversee everything that this comes to.[19] You will be able to get a license to grow, get a license to manufacture, you can get a license to dispense. I have 14 qualifying conditions if

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[17] *TN State Rep. Jeremy Faison Outlines New Medicinal Marijuana Legislation*, Jeremy Faison Conservative, (Jan. 18, 2018), https://www.jeremyfaison4tn.com/tn-state-rep-jeremy-faison-outlines-new-medical-marijuana-legislation/.

[18] Knott, Laurence, MD, *Opiate Poisoning*, PATIENT, (Aug. 12, 2014), https://patient.info/doctor/Opiate-Poisoning.

[19] Jeremy Faison Conservative, *supra* note 17.

you're interested: HIV, hepatitis, ALS, PTSD, Alzheimer's disease, severe arthritis, inflammatory bowel disease, multiple sclerosis, Parkinson's, schizophrenia, a chronic, debilitating disease or medical condition with a confirmation diagnosis or treatment of such disease on the condition of approval that produces one or more of the following: cachexia, peripheral neuropathy, severe chronic pain, severe seizures and epilepsy, persistent muscle spasms…

And then we've also given the cannabis commission the ability to move forward. So my whole goal was, if I can pass this bill, is that cannabis never has to come back up in the Tennessee legislature because it's such a political situation. So I'm putting that this cannabis advisory commission has the ability to promulgate rules and that basically have immense amount of authority and they can do anything with this plan basically without ever having to come back to us. They wanted me to take a few questions before I stopped. Yes ma'am.

Audience Member: Regardless of the legal, ethical, medical whatever…what is the economic impact?

Rep. Faison: Good question. Met with fiscal review this week and we have a, a group of people that are paid to establish the value of every bill we file and historically they have killed bills or passed bills based on what the fiscal impact on the state of Tennessee.[20] Right now, the fiscal analysts have--and we went back and forth qualifying how many Tennesseans we found, 1.2 million Tennesseans who would qualify to buy a cannabis if my bill passed. What I'm being told right now is that we're looking somewhere in the tune of $20 million. That might not sound like a lot, but at the end of the year, he and I are in a debate and we're fighting over a million dollars. Now, as the cannabis is established in Tennessee and the market is established, you're going to see that grows. And in Tennessee once people see they don't have to go anywhere else and can stay here, you're going to see that that's going to grow your, by my estimation, it's going to be $500 million by the third year.

We've appropriated some money to law enforcement to actually go after drugs that are really dangerous but they're not interested in that. The truth is on law enforcement, guys, is that they make a dang fortune on civil asset forfeiture, if we're just being honest with each other, they don't fight this because they've got some

[20] Fiscal Review Joint Committee, Tennessee General Assembly, http://www.capitol.tn.gov/joint/committees/fiscal-review/ (last visited July 9, 2018).

moral high ground that they think cannabis is the devil. They know that this is a cash cow for them. They want to be able to stick people in prison; there's an enormous amount of money here. So they're always gonna fight it. We're just going to have to tell them that this is how it is. Yes sir?

Audience Member: [The question is unclear, but essentially asks whether this would just shift lobbyist focus and create a whole new group of problems].

Rep. Faison: So lobbyists don't really work on the commissions the way you would think. Lobbyists work on us. I chaired for about four years and one of these boards or commissions, and there's hundreds of them in Tennessee—lobbyists don't, they don't use their agenda that way. Lobbyists always come back to us as legislators, to put the torque on them. That, hasn't happened and I'm not saying it couldn't happen, but ultimately my goal would be to realize that this plant is relatively benign, as far as being dangerous, and that we ought to allow the people who need it to have access to it. So we're just taking baby steps and that's what happens in a lot of these states. They realize what they've done and they're freaking out at first. Then they realize, oh my gosh, it says sky's not falling and you'll find more freedom. We should just allow people to find their own destination--that's a novel idea. Yes, sir?

Audience Member: You told a lot of truth here today. Are you sure you're a conservative?

Rep. Faison: True conservatism is believing in personal accountability and freedom. It can get twisted and turned any way you want, but a true conservative believes that government has a very limited role in your life. We are not your daddy. And so I would take opposition to that—there's some in my party that have hijacked the term "conservative" and they turned it to...some would say we want to legislate from the Bible instead of legislate from the Constitution. That's not conservative if you legislate from the Bible. But I would also say on the liberal side that they have become consumed with government control of everything. A couple of months ago I went to JFK's new museum, Profiles in Courage, if he was alive today, he would be considered conservative. Everybody's got their own view, but a true conservative believes that the constitution stands alone and doesn't need to be monkeyed with, number one and number two that you deserve personal accountability and have the freedom to be. I thoroughly enjoyed it, God bless y'all.

ALL HEALTH CARE IS LOCAL: EXPLORING THE ROLES OF CITIES AND STATES IN HEALTH CARE DELIVERY AND REFORM

KEYNOTE SPEAKER: SENATOR JEFF YARBRO
[edited for reading]

FEBRUARY 9, 2018

Sen. Jeff Yarbro: Thank you. So, we in the Tennessee State Senate do our best not to socialize with those who are members of the House of Representatives, but I had the opportunity just this past summer to serve on a committee with, it was—I kid you not—the joint ad hoc committee on medical cannabis, and it was co-chaired by representative Faison and as everyone can see here today, he is actually a passionate guy and one of the more entertaining human beings amongst the 132 of us. He also mentioned the book Profiles in Courage by John Kennedy. If you serve long in this business, you recognize there's a reason that that's a relatively short book, but I do think that Representative Faison is someone who is, who has been willing to buck people around and the powers that be on this particular issue. And I appreciate that from anybody in our legislature.

So, I'm going to talk a little bit about just the big changes in the way that we make healthcare policy at the state and local level. So one of my favorite writers is David Foster Wallace who, before his death, gave a speech at Kenyon college and he started with a story. There are these two young fish swimming one day and an older fish passed them, nodded, and said, "morning boys, how's the water?" They continue swimming on a little while and then eventually one looks over the other. It says, "what the hell is water?" I start there because the daily barrage of political information, the shutdown scandals, the tweets and tantrums on Cable News, make it difficult to see what I think have been some pretty big shifts in the water that makes up the way that we actually make healthcare policy and maybe lots of other policy.

And my point of departure there is--we're in a law school, right, at a CLE, I'm going to talk about cases. In *NFIB v. Sebelius*, which everybody talked about for a time, [it was] the Supreme Court'sdecision on whether the Affordable Care Act was unconstitutional.[1] So at the time, you know, liberals were overjoyed that Justice Roberts had written this opinion saying that it was constitutional. Conservatives felt betrayed, they had another David Souter on their hands that was making this decision affirming President Obama's signature accomplishment. But I think less noticed at the time, that's something that we felt a lot more since it's the part of that decision that says the federal government could not use its taxing and spending authority to coerce states to be part of the Medicaid expansion, which was in the Affordable Care Act.[2]

I think Justice Roberts—I just did a little googling on my phone here—but Justice Roberts referred to that as that saying, the threatened loss of 10 percent of state budgets was an economic dragooning that gave states, no real choice.[3] And so building on the line of cases that began with *South Dakota v. Dole* that says the federal government can condition highway funds on whether states adopted a higher drinking age, but built on the implicit limits on the federal government's ability to compel states, Justice Roberts said that the ACA went too far.[4] Justice Ginsburg disagreed, saying it makes no sense that we would have to repeal the whole act and redo it because if Congress had repealed the entire act and reenacted the existing parts of Medicaid and the new parts of Medicaid, there certainly wouldn't have been any problem.[5] But since, as soon as it happened in the way that it did and it was the threat of existing funds, I mean, she sort of felt that line didn't work.

I don't want to get into that. The formal federalism aspects of that to me are less interesting. I think that the sort of more pragmatic federalist effects are bigger and more significant because it's altered the dynamics in which we make policy around the country. So since that time, we're at a pretty, you know, entrenched space where thirty-three states expanded it and eighteen haven't. And I think it was probably done in the context that, you know, the states are laboratories of democracy, that we think about, what we're going to see what works in various places. And then other states are going to follow suit one way or the other. That sort of comes from Justice Brandeis's decision where he sort of says if the states choose,

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[1] Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012).
[2] *Id.* at 648.
[3] *Id.* at 582.
[4] *Id.* (*citing* S.D. v. Dole, 438 U.S. 203, 205 (1987)).
[5] *Sebelius*, 567 U.S. at 636.

they can pick novel ways to attack social and economic problems without risking the whole country on it.[6]

And as we see what works, more states will adopt what works and as we see what doesn't work, more states will kind of go against that. And that's really not what we've seen here. And I'm going to say some facts and stuff that might be contentious, but I think last fall there's sort of—somebody collected the 150 plus studies of the Medicaid expansion and looked at all of the data from all these reports and there's no question that we've seen in those states, higher degrees of coverage, lower numbers of uninsured populations, higher rates of access to care, higher degrees of utilization, greater affordability, actually declining Medicaid cost per patient.[7] Largely economic growth, very little strain on state budgets, neutral effects on state labor markets, and you know, that's better reviews than most laws get, frankly.

Especially that part. I mean, there's lots of criticisms of the larger parts of some of the individual market parts of [the] ACA. Those fears have been much more borne out by reality than the Medicaid piece. But because of the way we've structured this thing, the Medicaid one is the one that we're fighting about. I'm sure that there are people here that think that I've just cited some 153 crazy liberal studies, but you know, I'm looking for lots of the information out there. And that's a pretty broad range of ideological stuff that's been gathered to look at, but we got to this place where, in the United States, if a bunch of scientists get together and say there's going to be an eclipse on a certain day between these two minutes and it's going to be visible in this precise spot on the planet, people go out and buy plane tickets, you know.[8] And take the day off work and go there, but we don't actually listen to the sort of facts that affect our political life in the same way.

But regardless of all that we haven't seen, as data comes out, that people are making different decisions. If anything, people are doubling down on that. And so, this strategy of sort of not adopting has fundamentally worked. If you looked at the numbers, people that

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[6] New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932).

[7] Larisa Antonisse et al., *The Effects of Medicaid Expansion Under the ACA: Updated Findings from a Literature Review*, KAISER FAM. FOUND. (Mar. 28, 2018), https://www.kff.org/medicaid/issue-brief/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review-march-2018/.

[8] Dennis Green, *Prices for flights to eclipse-viewing hot spots have spiraled out of control,* BUSINESS INSIDER (Aug. 16, 2017) https://www.businessinsider.com/solar-eclipse-flight-nashville-how-much-2017-8.

work in the states that have expanded are less supportive of the law, which kind of makes sense. They didn't accrue the benefits of the law. And I think, largely because that's complicated, obscured and partially excused by the way that we think about politics and…it's the federal government's problem....that's sort of been built in so that when you have a change of government at the national level, the states that didn't expand are more likely to have members of Congress that are willing to repeal that part of the law and to attach new requirements or whatever, what have you.

What I think has been fascinating about the last couple of years is you haven't seen the will at the federal level, or the ability at the federal level, to actually make a change in this policy. When repeal and replace was sort of ultimately unsuccessful, Mitch McConnell who's spent a fair bit of time on this issue, kind of came out and said, this is the law of the land.[9] But you still see a different level of engagement by the states on this point. And frankly, it's about to be used in a different way. So now sort of using the same principle that states can go one way or another in their Medicaid policies, the Trump administration is now operating like a whole different set of options to the states. I'm not in the prediction business, especially after the 2016 election, but I think that there will be some difficulty in imposing nationwide work requirements on Medicaid.

I just don't think that's going to happen. What they probably will be able to do is to allow the Trump administration to grant waivers to states, which they can do right now, right? So that the states themselves can impose work requirements. One of the governors that's applying for a waiver right now did sort of say, "I think this will actually cut our rolls by over a hundred thousand people."[10] And so, you know, as we sort of see-saw back and forth at the national level, it means that our red and blue states take advantage of the expansion or cut backs when their favorite party's in charge. And the two states's healthcare systems are going to continue to split or very well could continue to split and that, you know, so instead of having the advantages of federalism sort of undermined by this nationalized hyper partisanship, instead of

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[9] Kristina Peterson & Stephanie Armour, *GOP Senate Leader Mitch McConnell Abandons Health-Care Bill*, WALL ST. J. (July 18, 2017), https://www.wsj.com/articles/gop-senate-leader-mcconnell-abandons-health-care-bill-1500348064.

[10] Deborah Yetter, *Kentucky may cut Medicaid for 500K if it loses court battle*, THE COURIER J. (June 20, 2018), https://www.courier-journal.com/story/news/politics/2018/06/20/ruling-against-matt-bevin-medicaid-plan-could-disrupt-care-thousands-kentucky/715557002/.

seeing the fostering of local experimentation, you're really seeing more partisan elaboration, which really has a big chance of changing the way this works.

I mean, who else heard the Tip O'Neill statement? You know, "all politics is local."[11] In some ways that's right, but really right now it's absolutely not. All politics is national in today's world. If you look at the math on it. So, 1984, Ronald Reagan wins basically the entire country—49 states—one state and district of Columbia are the only people that go the other way.[12] That same year, Democrats probably lost three or you know, a handful, I think it's less than 10 seats in the House of Representatives and they actually picked up seats in the United States Senate, including right here in Tennessee. It was the year Al Gore won. That is unthinkable in today's world that you would see a national election go one way and underlying elections go the other.

So this past election, 2016, for the first time in the history of the republic, every United States Senate race went the same way as the presidential race. It's literally never happened before, but you have all sorts of candidates who do different things, trying to adjust to Donald Trump. Some were embracing him, some were hiding from him, and some were criticizing him openly. And none of that turned out to matter. It only mattered whether he won their state. And so what that means is that we have this nationalized dialogue and while we technically fight every one of our elections out to the 50 yard line, the 50 yard line is not set on a district by district level or a state by state level anymore. It's set by these, you know, [from Representative Faison] "peckerwoods" and we're all electing our local officials, our state officials based on their politics instead of our problems. We're sort of reverting to this different kind of politics, which is, it starts making a real difference in all sorts of things.

But like Representative Faison was talking about with medical marijuana, I think that the expansion/non-expansion states have some significant level of overlap with the states that adopted medical marijuana. You can even look at the numbers on this. A study came out very recently saying states that have medical

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[11] *See* Thomas P. O'Neill & Gary Hymel, *All Politics is Local and Other Rules of the Game* (1994).

[12] Toni Monkivic, *50 Years of Electoral College Maps: How the U.S. Turned Red Blue*, N.Y. TIMES (Aug. 22, 2016), https://www.nytimes.com/2016/08/23/upshot/50-years-of-electoral-college-maps-how-the-us-turned-red-and-blue.html.

marijuana see about 20 percent fewer deaths by opiates.[13] In a state where we are having, we have more deaths by opiates than we do by either car accidents or firearms,[14] that's something that you would expect us to take seriously. And that's why I value so much, that this has become a bipartisan movement to really address this issue because that gives me some hope.

But if you look at the opiate epidemic, which is really hard to put in context just how big this is. So, how many people are here? I mean if this room were the state of Tennessee, basically the first two rows would be at some level of opiate misuse, abuse or treatment. It's one in six people in the state are at some level of misuse, abuse, or treatment. We have 300,000 people that have a disorder that needs to be treated at that level.[15] We had over 20,000 people that OD'd had to go to a hospital or died last year.[16] It is a stunning problem and at the end of the day we're going to spend less on a treatment under current proposals than the Ensworth School spent on its new tennis court.[17] And that's true. It's just numbers. And this is an expensive thing. If you look at the states where people are really trying to—every state is dealing with this. Blue states, actually, in the northeast had a bigger opiate problem that caused more deaths than a state like ours.[18]

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[13] Kate Sheridan, *Where Marijuana is Legal, Opioid Prescriptions Fall,* SCIENTIFIC AMERICAN (Apr. 2, 2018) https://www.scientificamerican.com/article/where-marijuana-is-legal-opioid-prescriptions-fall/.

[14] *Data Dashboard*, Department of Health, https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html (last visited July 27, 2018) (used to show the overdose numbers for 2016); *Tennessee Traffic Fatality Rate 1950-2016*, Department of Health, *available at* https://www.tn.gov/content/dam/tn/safety/documents/FatalityRate1950-2016.pdf (last visited July 27, 2018) (used to show the traffic fatality death numbers for 2016); *Stats of the State of Tennessee*, Centers for Disease Control and Prevention (Apr. 9, 2018), https://www.cdc.gov/nchs/pressroom/states/tennessee/tennessee.htm (used to show the firearm death numbers for 2016).

[15] *Opioid Frequently Asked Questions*, TN Together, https://www.tn.gov/opioids/education-and-prevention/educational-information/opioid-frequently-asked-questions.html (last visited July 27, 2018).

[16] *Data Dashboard*, Department of Health, https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html (last visited July 27, 2018).

[17] *Ensworth Tennis Complex*, Johnson Johnson Crabtree Architects P.C., http://jjca.com/Portfolios/Ensworth-Tennis-Complex (last visited July 27, 2018); *Ending the Opioid Crisis*, TN Together, *available at* https://www.tn.gov/content/dam/tn/governorsoffice-documents/governorsoffice-documents/TNtogetherFAQs.pdf (last visited July 27, 2018).

[18] Drug Overdose Mortality by State, Ctrs. for Disease Control and Prevention (Jan. 10, 2018), https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm (last visited July 27 2018).

But you can see some of the models that are being adopted. And so, I think it's Vermont, I don't know, but I think it's in Vermont they adopted something call the hub and spoke model where they aligned lots of local and state agencies with nonprofits and they are doing everything they can to get people into treatment and to keep them there at a level of truly activating lots of parts of the community.[19] And they're running a program that costs probably $16,000 a year per participant. It starts about 8,000 participants a year. That's about $132 million dollars. Vermont's a state that is 10 times smaller than us. They have 650,000 people to our 6.6 million. And despite being an order of magnitudes smaller, they're spending five times more than what we're proposing. But that's something that--it's not because they care more it's because they've made a different decision and it's not actually their money.

They've done the, they're using the funds that come out of Medicaid expansion to attack the problem in a different way. And when we come at that problem as Tennesseans, we don't even have the same tools in the tool box to look at. I've talked to providers, for-profit companies that have offices here in Tennessee to work on the opiate epidemic, but they don't actually do the work here in Tennessee because there's not the funding base to support it. You can ask anybody that would probably have the people that work in provider communities or hospitals. The business model is just shifting in lots of different places and some of that's demographic and natural--that's going to happen everywhere. But the change in the way that economic modeling works for hospitals in states that have this and states that don't is just different.

And if we're going to continue on this pathway, where not only do we have an expansion/non-expansion divergence, then we have a work requirement/non-work requirement divergence. You can really see the states continuing to split here to where just the way we approach policy, which then affects the way that businesses come in and work in that system, and then ultimately affects the way that we as the insured, as patients, interact with it. It's going to change dramatically. And that is... we don't really know what that looks like. I mean, we're starting to see bigger divergences in the health world. During the post-World War Two era, it was unheard of for a place to have a lower life expectancy the next year in the United States. Life expectancies are supposed to go up, right? As you look across the history of Western civilization, life expectancies

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[19] *Hub and Spoke*, vermont.gov, http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke (last visited July 27, 2018).

go up unless there's like a Spanish flu, but what you're seeing right now in the country... so I have little factoids. Tennessee's got one of the counties in the country that has had the fastest, one of the, one of the 50 counties with the biggest decline in life expectancy. And so the life expectancy in Grundy County in 1980, it was an average of 73 and is now at 72.[20] I mean, what's a year? But that's not the way this works. That means a lot more people dying at 40. A lot of people dying at 50. It means a lot of lower quality of life for human beings. You compare that to Breckenridge, Colorado. So in 1980, the life expectancy was higher than Grundy County's. It was 79, so people were expected to live six years longer.[21] And I think, in 2014/2015, the life expectancy in that same county in Colorado jumped up.[22] So we went from having a six year difference in life expectancy to a 15 year difference in life expectancy.

And that is a remarkably dramatic thing that at some level we have a moral obligation to do something about. And if not, even if you have an active dislike of humankind, the economics of this aren't sustainable. Our state is a net recipient of federal funds and continuing to worsen those problems and expecting that to continue without changes is probably an unwise thing.

And I mean, I think that we're at a really important moment right now where we've got to figure out whether these kinds of partisan fissures in the world have become so cemented that they are just part of the landscape like the Appalachian Mountains or the Tennessee River, or whether they are going to give way and we're going to return to a place where we're actually making policy decisions based on merits and outcomes. And, and you know, always tempered by politics. You know, we like this, and I don't think anybody thinks that politics has got to go away or the ideology is going to go away. But the place that we're in is a strange one where we venture becoming two republics sharing a common border with a remarkably different health, economic, and life prospects for people that live in one of them and people that live in another one of them. And that is a sort of alarming to me, and I think that you end up having two choices if you start dealing with that reality. One is that we sort of turn back the clock on that a little bit and try to find ourselves back to a space where, you know, the federal government allows you to recognize their state differences, generally speaking, kind of continue moving in that direction.

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[20] *US Health Map*, The Institute for Health Metrics and Evaluation, https://vizhub.healthdata.org/subnational/usa (last visited July 27, 2018).
[21] *Id.*
[22] *Id.*

And as changes get made by one party, we sort of adopt and improve upon those as changes get made by another party. We sort of adopt and improve on those. To use a Medicare policy in the sixties to some Reagan economic policy in the eighties are, at this point, largely accepted by both sides as kind of who we are. But here we're in a place where a fight that happened is a fight that's still happening. And if we don't figure out a way to get past that, then it requires something different of us to start recognizing that if we continue on that pathway, what are the implications for a state like Tennessee? Are there places where you just have to acknowledge that we are in a different context of policy making and figuring out how to be a laboratory with a different set of tools and maybe we'll find ways to solve problems that wouldn't have been available to people that are operating in a different set.

Maybe we won't, but I think on some level we have to start being honest about this very real change and figuring out which model is going to actually make sense for us. And while this is not the most optimistic speech I've ever given, I think the stakes are very high here. I really do. And I think that most casual observers of American politics kind of have like a status quo optimism, pendulum shift. Like it swings back and forth. Things sort of right themselves out over time and for a good deal of the 20th century that was entirely true, but what we're seeing right now is operating differently than that. That doesn't mean that it's, it's stuck in that pathway, but without a change, if the status quo that we've seen for the last now 10, 15 years carries on, I think we find ourselves in a really, really different place. All that being said, anybody that was looking at politics during the Clinton, the Bush years would've been, would've predicted much more easily that a Clinton under a Bush would follow them in office as opposed to a Barack Obama and a Donald Trump. We as a society are really capable of being remarkably dynamic politically. We as people, regardless of side of the aisle, tend to value citizenship, tend to value each other. And I really do think that we have the capacity to, regardless of how these structural things kind of worked out, find our way somewhat back to a place of good decision making. But I do think that we only do that if we are serious about it. Take the challenge that we face head on and actually find the people of goodwill who disagree with us on all sorts of things and find ways forward though. With that, I'll say, that's all.

Rep. Jeremy Faison: Can you quantify the numbers for me about Colorado and I'll tell you, I've been out to Colorado three times. They exercise out there.

Sen. Yarbro: Yeah, I mean I looked at it this morning and I was kind of blown away by it and Breckenridge is a part of Colorado where they're fine with pot being legal, but they don't use it that much because it would interfere with their snowboarding. And we've got lots of those kinds of issues that are a big deal. And while it's easy to judge economic success by GDP, if you look at the history of the world, places that have increased, the life expectancy... that really ends up being something that matters in a big way.

Audience Member: Is there a move on the part of your peers to focus on Tennessee and the needs of Tennessee rather than being partisan, [audio interference] so we can get Tennessee solutions for Tennesseans?

Senator Yarbro: No.

[laughter]

I don't want to be unkind because I do think there are ways in which we can. So last year, when we passed the Legal Exchange Bill,[23] which would be unthinkable ideologically, because I think people feel the opioid epidemic happening very personally in their communities and know people that are dying. When we as law makers, most people who do this are well intentioned and want to help people, and as long as the issue doesn't get lost in what I like to call the MSNBC/Fox News vortex we're actually capable of doing good things. But we live in a world where the MSNBC/ Fox News vortex grows every day, where now whether I say "Merry Christmas" and whether I stand in my living room to watch the National Anthem during the Super Bowl has become super-charged politics. So it's harder to separate out those issues that feel like they're state and local issues from that partisan overlay. But I think that's the challenge, not just for people like Jeremy and me, but for everyone in the room and everybody in the state.

[23] S.B. 2359, 110th Gen. Assemb., Reg. Sess. (Tenn. 2018)(amending Tenn. Code Ann. § 68 to authorize county or district health departments to operate a needle and hypodermic syringe exchange program on petition of the county legislative body and approval by the department of health).

ALL HEALTH CARE IS LOCAL: EXPLORING THE ROLES OF CITIES AND STATES IN HEALTH CARE DELIVERY AND REFORM

INDUSTRY PANEL

PANELISTS:
JAY HARDCASTLE, *BRADLEY ARANT BOULT CUMMINGS LLP*
ANDREW MCDONALD, *LBMC FAMILY OF COMPANIES*
JULIE WATSON LAMPLEY, *BUTLER SNOW, LLP*
KIM LOONEY, *WALLER LANSDEN DORTCH & DAVIS, LLP*

Moderated by Craig Stewart, Bass, Berry & Sims, PLC

FEBRUARY 9, 2018

Mr. Stewart: Thanks, Julianne, for the introduction. Thanks to the students who are working on the Belmont Health Law Journal for organizing this event and for allowing me to participate. Thanks to all the audience members for returning to the second session of the day, welcome back. We are lucky to have four, wonderful, accomplished, insightful, intelligent and experienced panelists, who I am happy to introduce.

To my immediate right, is Kim Looney. Kim is a partner at *Waller* here in town. She advises healthcare providers on day-to-day operational issues such as recruitment and employment and regulatory issues such as ongoing compliance with STARK and federal and state anti-kickback regulations. She earned her law degree from Vanderbilt University and her B.S. in Business Administration from the University of Tennessee. Kim currently serves on the board of directors of the American Health Lawyers Association (AHLA) and she previously served as the vice-chair of the AHLA's physician organization's practice group. She frequently speaks at state and national teleconferences and seminars on a wide range of healthcare topics and she's recognized by Chambers USA

for her healthcare regulatory experience, and by Best Lawyers in the category of healthcare law.

To Kim's immediate right, is Jay Hardcastle, who is a partner at *Bradley*. He advises hospitals, surgery centers, physicians with a particular emphasis in radiology, long-term care providers, imaging centers, cancer centers, and other participants in the healthcare industry in connections with joint venture formation, general regulatory issues, corporate matters, and the purchase and sale of healthcare facilities. Jay also focuses on drafting contracts for providers and physicians, advising clients on Medicare and Medicaid issues, providing assistance in the defense of whistleblower claims, and advising tax-exempt entities in healthcare areas. He's a member of the AHLA; the National Bar Association—he's the former chair of the health law committee; the Tennessee Bar Association—former chair of the health law section; and the American Bar Association—a member of the health law section. Jay has served on many boards of directors of local non-profits, interestingly, including the boards of the Nashville Symphony, Friends of Radnor Lake, the conservancy for Centennial Park and the Parthenon, as well as Nashville Table, now part of the Second Harvest Food bank.

To Jay's immediate right, is Julie Watson-Lampley from *Butler Snow*. She's the practice group leader of the healthcare regulatory and transactions group. She focuses on healthcare law, commercial contracting, mergers and acquisitions and anti-trust law. Her experience includes the broad representation of pharmaceutical and medical device companies, including both publicly held and privately owned pharmaceutical manufacturers, medical device companies, and research organizations. Julie has provided advice and services regarding Stark, anti-kickback, anti-trust issues, privacy policies and programs, compliance programs, manage care contracting, physician recruitment and employment, hospital-based physician contracting, entity formation and operation, and issues related to tax-exempt healthcare providers.

To my far right is our final panelist, Andrew McDonald. As shareholder in charge of healthcare consulting at LBMC, PC, and owner and operator of LBMC Physician Business Solutions, LLC, Andrew works with a team of experienced healthcare professionals that possess diverse backgrounds in accounting, coding, compliance, financial analysis, hospital and physician integration, IT consulting, revenue cycle, transaction advisory services, and other healthcare management services. Andrew is a graduate of the University of Alabama with a bachelor's degree in commerce and

business administration and a master of science degree in hospital and health administration from the University of Alabama at Birmingham. The American College of Healthcare Executives recognized Andrew as a fellow of the college in 1994, highlighting his commitment to the highest standards of executive performance, community leadership, and continuing education for the betterment of patient care through outstanding leadership in healthcare entities.

So between the four of them, we've covered just about every conceivable healthcare industry item. It's my great joy to introduce them; we've got a great group of panelists. Let's briefly thank them for their time.

[applause]

Let's jump right in. I'm going to try to reserve 10 minutes for questions at the end, but we'll see how the discussion goes.

As is the theme of today--all healthcare is local—the federal government appears to be putting more emphasis on states regulating healthcare. For example, as the previous panel mentioned, the Trump administration recently announced a policy to have work requirements for able-bodied Medicaid beneficiaries.[1] From an industry perspective, how do you see this shift impacting our healthcare industry here in Tennessee as well as clients in other states? For this one, Kim, can you get us kicked off?

Ms. Looney: I think this is definitely a trend that a lot of states have already jumped on board with.[2] I think I saw that Tennessee is looking to do this as well.[3] I don't think it's necessarily a bad thing to give more control to the states. I'm just not sure how well having this work requirement, in addition to the many other requirements we have on Medicaid, would work.

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[1] *See* Exec. Order No. 13,828, 83 Fed. Reg. 15941 (Apr. 10, 2018), *available at* http://www.federalregister.gov/documents/2018/04/13/2018-07874/reducing-poverty-in-america-by-promoting-opportunity-and-economic-mobility/.

[2] Currently, Arkansas, Indiana, and New Hampshire have an approved Section 1115 waiver from CMS that implement some form of work requirements in their Medicaid programs. Another seven states, Arizona, Kansas, Maine, Mississippi, Ohio, Utah, and Wisconsin have pending Section 1115 waivers from CMS that would implement similar work requirements. *See generally Medicaid Waiver Tracker: Which States Have Approved and Pending Section 1115 Medicaid Waivers?* KAISER FAM. FOUND., https://www.kff.org/medicaid/issue-brief/which-states-have-approved-and-pending-section-1115-medicaid-waivers/ (last modified Jul. 26, 2018).

[3] *See* 2018 Tenn. Pub. Acts 869 (H.B. 1551).

I think that partly, it will be difficult to administer. I think it would be difficult for the state and I think that, from the standpoint of the client—any of the providers—it could actually adversely impact the people that they currently provide services to who may be on Medicaid.

Something else one of the other states is doing is changing from offering Medicaid to people up to 138% of the poverty level and bumping it back down to the poverty level.[4] That is going to make a difference as well. The thinking is that in some ways this shifts the burden of providing care to the federal government. At the end of the day, this is still something that is going to be difficult to administer and it's going to be hard for the clients because if it's going to impact the people that are covered, it's going to be hard for them to get reimbursement.

One of the things I also thought was interesting is that there are a number of advocacy groups that have challenged that requirement. It's been approved by the federal government that you can have a work requirement and that's been challenged in Kentucky. There's a class action suit and the Southern Law Poverty Center, the National Health Law Program and the Kentucky Equal Justice Center are all challenging that,[5] so I think it will be interesting to see how that works out.

Mr. Stewart: Did anyone else want to chime in? I think this is an interesting topic. Kim had suggested there might be an adverse impact and difficulty in administration. I thought that was an interesting point.

Mr. Hardcastle: What this means to me, as someone who's really been with providers for most of my career, is less money. That's what I hear when I hear this. And I don't mean that as a bad thing—it may be that less money is okay, but that is what I hear when I hear

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[4] Arkansas and Massachusetts have sought to reduce the income eligibility level for Medicaid beneficiaries to be set at 100% of the Federal Poverty Level. However, both of these requests have been denied by CMS "at this time." *See generally* Centers for Medicare & Medicaid Services (for Massachusetts, *available at* https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-ca.pdf/, (Jun. 27, 2018); for Arkansas, *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ar/ar-works-ca.pdf/, (Mar. 5, 2018)).

[5] *See* Stewart v. Azar, No. CV 18-152 (JEB), 2018 WL 3203384 (D.D.C. Jun. 29, 2018).

"block grants"[6], when I hear "per capita caps."[7] I don't hear anyone saying "we're going to give you more money than we used to give you for doing the same thing. In fact, it's just like a lot of industries under pressure, including professional industries, where clients are asking for the same thing for less money. And they may be asking for different things for less money.

I think if we're going to go that route, and I think we are—since healthcare as a portion of the GDP is so high now,[8] we're all going to be working just to pay our health insurance premiums and it's this giant thing where we may all be working for health insurance companies and providers to pay our health insurance premiums—we're going to have to stop thinking along the lines we've always thought and maybe take some sacred cows off the table and not focus on legal absolutes.

So, for example, it's been a long-time thesis in the private bar and compliance departments and enforcement mechanisms at the state and federal level that the purity of the referral decision cannot be corrupted by money.[9] It's been a big thing among the

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[6] A "block grant" is a grant from the government to be used for a specific service offered by the State. In the context of Medicaid, states would get a fixed amount of federal grants that would be based on the state and federal Medicaid spending in that state. *See* Shefali Luthra, *Everything You Need To Know About Block Grants – The Heart Of GOP's Medicaid Plans*, KAISER HEALTH NEWS (Jan. 24, 2017), http://khn.org/news/block-grants-medicaid-faq/.

[7] A "per capita cap" is a grant from the federal government based on the number of people in a particular program. Thus, in the Medicaid context, federal funding per enrollee would be capped at a fixed amount, and then multiplied by the number of enrollees. *See* Robin Rudowitz, *5 Key Questions: Medicaid Block Grants & Per Capita Caps*, KAISER FAM. FOUND. (Jan. 31, 2017), http://www.kff.org/medicaid/issue-brief/5-key-questions-medicaid-block-grants-per-capita-caps/.

[8] As of 2016, healthcare spending grew to $3.3 trillion, or $10,348 per person, equaling 17.9% of the GDP. Healthcare spending is projected to grow at an average rate of 5.5 percent per year for the 2017-2026 period, reaching an estimated total of $5.7 trillion in healthcare spending by 2026. *See* Centers for Medicare & Medicaid Services: NHE Fact Sheet (last modified Apr. 17, 2018, 8:29 AM), *available at* https://cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html/).

[9] Many professions, such as the practice of medicine and law, are often forbidden from referring patients or clients that will result in a financial gain to the referring person (*see* 42 U.S.C. § 1395nn, also known as the "Stark" law, which generally prohibits physicians from making a referral to another entity in which that physician has a financial relationship; *see also* Model Rules of Prof'l Conduct r. 5.4 (Am. Bar Ass'n, 8th Ed. 2015), which, in relevant part, prohibits lawyers from permitting a person who refers, employs, or pays the lawyer to

commercial consultants and the anti-trust bar and the FTC and the DOJ that scale is bad and that corroboration can deepen vertical sorts of scales, and can create heavy market power in one area that can be very disruptive for society as a whole. In the tax exemption area, there are plenty of folks that have grown up in an environment where venturing outside of your core charitable mission is bad,[10] and creates some exemption risks and in, of course, Stark areas—very, very technical, it's sort of like the kickback areas—feeling amongst the private bar, enforcement mechanisms, and compliance departments if you step outside the guidelines, you could get in really big trouble and that is the current state of affairs. I think if we're going to go this route and start thinking that you need to toss everything into a giant public policy blender and think what the best outcome is and not skew so closely to those former sacred cows.

And there's some thinking in Congress and CMS that it might be okay, and even in the DOJ and FTC and states' Attorney Generals as they look at anti-trust enforcement. The anti-trust folks have healthcare principles that have been out for a long time that relax enforcement amongst certain cooperative activities that create anti-trust concerns.[11]

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render legal services for another, from regulating or influencing "the lawyer's professional judgment in rendering such legal services.").

[10] The joint venture structure between non-profit and for-profit hospitals has, in many cases, jeopardized the tax-exempt status of nonprofit hospitals. By working with a for-profit hospital, a nonprofit hospital risks venturing outside of its charitable purpose (providing care to the poor and the community at large), as a for-profit hospital largely operates to benefit private, not public, interests. This, in turn, can result in the revocation of a nonprofit hospital's tax-exempt status. *See generally* Andrea I. Castro, *Overview of the Tax Treatment of Nonprofit Hospitals and Their For-Profit Subsidiaries: A Short-Sighted View Could Be Very Bad Medicine*, 15 PACE L. REV. 501 (1995); *see also Utah County v. Intermountain Health Care, Inc.*, 709 P.2d 265, 271-72 (Utah 1985) (there is "increasing irrelevance of the distinction between nonprofit and for-profit hospitals for purposes of discovering the element of charity in their operations…Nonprofit corporations can own for-profit corporations without losing their federal nonprofit tax status as long as the profits of the for-profit corporations are used to further the nonprofit purposes of the parent organization…The emergence of hospital organizations with both for-profit and nonprofit components [, however,] has increasingly destroyed the charitable pretentions of nonprofit organizations[.]").

[11] In 2011, the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") (collectively, "the agencies"), in consultation with the Centers for Medicare & Medicaid Services ("CMS"), released their final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011) (hereinafter "Statement"). The Statement is intended to foster the formation of Accountable Care Organizations ("ACOs") by loosening the enforcement of antitrust laws, when applicable. First, the Statement applies to

ACOs require various incentives to work, and those incentives may run afoul of tax-exemption laws, sometimes even anti-trust laws, but mostly anti-kickback and Stark laws.[12] There are waivers associated with some of that material built into the ACO and just recently there is a lot of pressure from this administration and the prior administration to get healthcare to be more efficient. One way to do that is through pending MACRA payment system, which involves sending payments to doctors.[13] It's hard for the private healthcare bar and the private compliance community to understand exactly how all those payments are going to be effective with Stark.

One of my colleagues has been briefing me on HR-4206 and its companion bill in the Senate that would actually relax Stark to allow for more creative payment mechanisms that would essentially allow for payments to physicians that would otherwise curdle your

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"collaborations [(ACOs)] among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Shared Savings Program." *Id.* at 67,027. The agencies will then apply a "rule of reason" analysis to ACOs that meet certain conditions, evaluating "whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration's potential procompetitive efficiencies are likely to outweigh those effects." *Id.* The Statement further establishes a "safety zone," *see id.* at 67,028, in which the agencies will not enforce, absent extraordinary circumstances, the antitrust laws for ACOs that meet the CMS eligibility criteria for and intend to participate in the Shared Savings Program, and are highly unlikely to raise significant competitive concerns.

[12] 42 C.F.R. § 425.20 (Oct. 25, 2014) (An [accountable care organization] participant means an entity identified by a Medicare-enrolled billing [Taxpayer Identification Number] through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118."); Notice 2014-67, 2014-46 I.R.B. 822 (addressing initial guidance for an entity to avoid breaching the private business prohibition for tax-exempt bond financing under § 501(c)(3) of the Internal Revenue Code); *see also A Roadmap for New Physicians: Fraud & Abuse Laws*, Office of Inspector General United States Dep't of Health & Human Services (2018), https://oig.hhs.gov/compliance/physician-education/01laws.asp (analyzing the basics of the "five most important Federal fraud and abuse laws that apply to physicians).

[13] Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C.A. §§ 1395w-6, 1395kk-2; *MACRA In a* Minute, American Academy of Family Physicians, (2018), https://www.aafp.org/practice-management/payment/medicare-payment/macra60.html; *Quality Payment Program*, Ctrs. for Medicare and Medicaid Servs. (Dec. 19, 2016) *available at* https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf.

blood as to the potential associated regulatory implications.[14] Now, that's just on the drawing board. MACRA is a reality, so the regulatory stuff is behind it.

So that's my theme here is that we need to toss this absolutism over some of these things and think about broader public policy because some of the thinking behind tax exemption, anti-trust laws, some of those public policies and some of the bad things they're designed to prevent may in fact occur, but you may pick up efficiencies in quality improvements that might make it okay.

Ms. Looney: I think, actually, I have heard at one time that Pete Stark said that if he had known how it would turn out he would not have started down that road.[15] So, it is kind of interesting. I've heard Jim Cooper say during a discussion, "would [we] like to see some of these laws relaxed?" and it's like, yeah, clients would love to see them relaxed a little bit. I think that I agree with Jay—I know there's a lot going on with this requirement to work—and that may be one answer, but maybe we need to take a broader picture and see what else is out there and really revamp it.

Tennessee is one of those states that's been operating under a Medicaid waiver for a long time now.[16] I mean, some of the people in this room, if they're still in law school at Belmont probably weren't born when Tenncare came into being. It was in January of 1994.

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[14] H. Res. 4206, 115th Cong. § 2 (2017), S. Res. 2051 § 2, 115th Cong. (2017) (proposed legislation in both chambers of Congress to relax payment prohibitions within the Stark Law to enable alternative payment methods and promote consumer protections); But see Roy Edroso, *Foot-dragging on Stark reform leaves APMs at risk*, Decision Health: Part B News (March 29, 2018), https://www.greensfelder.com/media/news/312_Butler_Part%20B%20News_Foot-dragging%20on%20Stark%20reform%20leaves%20APMs%20at%20risk_Apr2018.pdf.

[15] Janet Adamy, *Pete Stark: Law Regulating Doctors Mostly Helped Lawyers,* WALL ST. J. (Oct. 22, 2014), https://blogs.wsj.com/washwire/2014/10/22/pete-stark-law-regulating-doctors-mostly-helped-lawyers/ (addressing how Senator Stark would likely not vote for his namesake bill today and "the law got to be as thick as a phonebook for all the exemptions").

[16] Tenn. Div. of TennCare, Extension of TennCare Demonstration (2018) https://www.tn.gov/tenncare/policy-guidelines/extension-of-tenncare-demonstration.html (explaining that "TennCare is a Medicaid demonstration program that has operated under waivers of certain provisions of federal law since 1994).

Mr. Hardcastle: And 1994 was about where the first anti-trust guidelines came out and we still see massive anti-trust enforcement in healthcare.[17] One of the interesting things about this bill is that it changes the statutory language that authorizes the publication of exceptions to Stark. It says in lieu of allowing exceptions that are okay as long as they do not present a risk of program or patient abuse, they've added the word "significant risk."[18] That may seem subtle, but it's shifting away from an absolute way of thinking to a relative, kind of holistic, public policy way of thinking. To me, that is the most important thing in an otherwise inscrutably technical bill talking about EPMs and MIPs.

Ms. Looney: Well, there's room for argument.

Mr. Hardcastle: Mhmm, right.

Mr. McDonald: I think, thinking about Tennessee, we basically did not elect to expand Medicaid throughout the state, so what happened? We had 8 hospitals that closed.[19] Right, wrong, or indifferent. Maybe some of them needed to close, but we've got a really unique situation in northeast Tennessee where Mountain States and Wellmont have basically stiff-armed the FTC and created, in essence, a monopoly in both their market and in

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[17] U.S. Dept't of Justice & FTC, *Statements of Antitrust Enforcement Policy in Health Care* (Aug. 1996) *available at* https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf;
Bill Baer, *The Role of Antitrust Enforcement in Health Care Markets* (Nov. 13, 2015), *available at* https://www.justice.gov/opa/file/794051/download; Lisl Dunlop, *Top Five Healthcare Antitrust Trends to Watch in 2017* (January 23, 2017), https://www.manatt.com/Insights/Newsletters/Health-Update/Top-Five-Healthcare-Antitrust-Trends-to-Watch-in-2; Emily Rappleye, *Healthcare antitrust enforcement remains a top priority for DOJ* (May 30, 2018), https://www.beckershospitalreview.com/hospital-transactions-and-valuation/healthcare-antitrust-enforcement-remains-a-top-priority-for-doj.html.

[18] S. 2051, 115th Cong. § 2 (Nov. 1, 2017) *available at* 4, 7 https://www.congress.gov/115/bills/s2051/BILLS-115s2051is.pdf.

[19] Carole R. Myers & Madison Kahl, *Stop cascade of rural hospital closures in Tennessee,* THE TENNESSEAN (June 23, 2017), https://www.tennessean.com/story/opinion/2017/06/23/stop-cascade-rural-hospital-closures-tennessee/425504001/; Jordan Buie, *Medicaid expansion may be unlikely in Tennessee*, THE TENNESSEAN (Jan 21, 2018) https://www.tennessean.com/story/news/politics/2018/01/21/medicaid-expansion-may-unlikely-tennessee-even-backers-seek-compromise/1046118001/; *Where the states stand on Medicaid expansion*, Advisory Board (June 8, 2018), https://www.advisory.com/daily-briefing/resources/primers/medicaidmap.

Virginia.[20] So you have two states that basically, and I think on Jauary 31st, the merger finally went through, so it's going to create a really unique situation to watch there.

My glass is usually half-full. I, with the expertise in everything that we have being healthcare in my company . . . The level of expertise and what we will do with a block grant may end up being, actually, more money for the state of Tennessee as opposed to less than what we're getting now and compared to other states, too. I think it's going to be really neat to watch and interesting to see how it all plays out.

Mr. Stewart: Drilling down a little further on this point: Of course, if we knew all the answers, we wouldn't have a panel anyway and we wouldn't have clients asking us questions, but what issues do your clients worry most about in this area arising if Congress continues to put more responsibilities on states with block grant funding, and increased flexibility of waiver programs? Are there certain things your clients are more concerned than others?

Ms. Lampley: You know, the money is going to be a big thing.

Ms. Looney: But I also see something… if it goes back to the states, that might be good in some ways, but in other ways it's a bigger challenge for your large national healthcare companies because instead of worrying about a lot of the reimbursement and payment on a federal level, now they're going to have to worry about it more on a state level than they already do. So that also adds potentially some infrastructure to those companies. So, I think that that might not be a good thing.

Ms. Lampley: I agree. What we hear a lot about is the financial liability as funds get tighter and tighter. More facilities are closed and we see a lot of others who are struggling so we really have to watch that balance between cutting funding and putting providers at risk—especially in rural areas—of going out of business in the process.

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[20] Phil Galewitz, *In Appalachia, Two Hospital Giants Seek State-Sanctioned Monopoly* KAISER HEALTH NEWS (July 24, 2017), https://khn.org/news/in-appalachia-two-hospital-giants-seek-state-sanctioned-monopoly/ (addressing that antitrust concerns are being subverted by appealing to the public interest and establishing a legal agreement, known as a Certificate of Public Agreement (COPA), to come under state overwatch); See also Alex Kacik, *Mountain States, Wellmont skirt federal regulations and score state merger approval*, MODERN HEALTHCARE (Nov. 3, 2017), http://www.modernhealthcare.com/article/20171103/NEWS/171109954.

Mr. Stewart: Closing the loop on this topic, do you see certain long-term consequences of work requirements for entitlement programs, generally, that you may not have already touched on?

Mr. Hardcastle: I've got a view on that. It's an uninformed view as a citizen as opposed to a policy-maker . . . I know we had the policy folks up here before us and they're welcome to change things. My own feeling is that a long-term consequence of that would be some administrative cost and burdens on folks enforcing that as opposed to a big societal shift.

Because I spend a big hunk of my life in another role working with a nonprofit that's currently out its executive director and so I have to step in and do a lot of stuff that an executive director would normally do and it works with the working poor and supplying emergency rental assistance and I should send you the link and you should all go there [laughter] and from that I have a somewhat biased view of the working poor which is that they're working already, so I'm just not sure there's this large population of employable—I know there are certain people who are disabled and have addiction issues and things like that—people who are now in the expansion program who are not working. That's just, I don't have any data to support that. Mark's over there shaking his head thinking "now I know who you voted for" [laughter] Anyway, I don't see that as having a long-term effect on anything because I don't think it's a huge problem to begin with other than now people are going to have to administer these enforcement programs.

Mr. Stewart: Great. I'll shift gears a little bit. Under the current health plan there has been an increase in mergers and acquisitions in our healthcare sphere. How has that impacted the industry as a whole from your perspective? I'll kick this one to Andrew to get us started.

Mr. McDonald: It's exciting stuff.

Ms. Looney: I will say, it's really cool and really exciting.

Mr. McDonald: The deal flow in 2017 was off from a transaction standpoint by a couple of points compared to a record setting year in 2016 but the actual deal value average was up to 145% total deal value for 2017.[21] Nine hundred and sixty-seven (967) deals resulted

[21] Jacqueline LaPointe, *Healthcare Merger, Acquisition Deal Value Increases 145% in 2017* REVCYCLE INTELLIGENCE (Jan. 29, 2018),

in a total deal value of 175 million dollars.[22] We rocked along during the year with some pretty interesting stuff.

I'm like all these folks up here, I tend to follow the physician piece. In my mind, I've been doing this for a week or two and physicians—nothing really happens in our 2.7 trillion-dollar healthcare system without a physician picking up a pen or an iPad and ordering something—these are the folks I tend to take note of and try to take care of. But for a long time, they've been divided and conquered and it's really nice to see a 22% rise in most deals.

And we're seeing at LBMC a lot of single specialty roll ups on a national platform, primarily in dermatology and anesthesia [and] urgent care, certainly, even had success with orthopedic and ophthalmology. So, it's been neat to see that but when the mergers hit, we hit 5 mega deals that absolutely changed the landscape.

The star in all this activity was a real head-scratcher initially for me when I heard it coming out in October and November. CVS, the country's largest drugstore is buying Aetna.[23] I said, "what in the wide world of sports are we doing here?" And in essence when you really drill down, you've got 10,000 stores that are basically going to be converted into more clinic-type retail space with 23 million enrollees through Aetna. I'm sure they're going to be strongly encouraged to go through those 10,000 doors instead of going to Walgreens. So, it creates a really interesting scenario and puts the insurance company closer to the patient than I've seen in a long, long time.

Other deals of note, on a vertical and a horizontal basis, the Catholics were very, very active on the topic of systems. The 5 big systems, you had CHI out of Denver and Dignity Health out of San Francisco announce they're putting a merger together--27 states--it's going to be a pretty big deal.[24] Ascension out of St. Louis and

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https://revcycleintelligence.com/news/healthcare-merger-acquisition-deal-value-increased-145-in-2017.

[22] *US Health Services Deals 3 Insights Year-end 2017*, PricewaterhouseCoopers, 1 (2018).

[23] Michael J. de la Merced & Reed Abelson, *CVS to Buy Aetna for $69 Billion in a Deal That May Reshape the Health Industry*, N.Y. TIMES, Dec. 3, 2017, https://www.nytimes.com/2017/12/03/business/dealbook/cvs-is-said-to-agree-to-buy-aetna-reshaping-health-care-industry.html.

[24] Press Release, Dignity Health, Dignity Health and Catholic Health Initiatives to Combine to Form New Catholic Health System Focused on Creating Healthier Communities (Dec. 7, 2017) https://www.dignityhealth.org/about-us/press-center/press-releases/dignity-health-and-catholic-health-initiatives-announcement.

you have Providence St. Joe out of Washington who are putting together a 28-state deal that will be about $45 billion in overall revenue and will fly right on past our own HCA, which is the largest hospital operator.[25] Those two deals were not even included in the $175 million so it's been interesting.

The other, on the physician front, you have DaVita selling their physician service line to United Healthcare and United healthcare now owns 30,000 physicians and clinicians.[26] So, you're seeing a lot of different types of activity and it's exciting to see the payers…. you look up, you have Anthem and Cigna. They basically were trying to merge and the FTC shut that down.[27] You have Aetna and Humana, and they ended up, Aetna ended up with a billion-dollar breakup fee along with about $800 million in transaction fees,[28] so the payer market was interesting and then they turned around and were purchased by CVS. So it was a very interesting year. Thoughts?

Mr. Hardcastle: I've got a lot of regrets, regrets of my career and among them is I did not get one cent of $800,000,000. Yeah, I think this is a response to some of the things Julie and Kim were saying that there's a perception, whether it's a state and local driven thing or federal driven thing, there'll be less money. And so what are we going to do about it? Well we're going to do something. I mean, you know, a lot of, uh, you know, type A executives out there for all their fresh out of business school type A hard running folks, and they're going to do something. Um, and then I took a look at somebody who probably had the same source materials as we were preparing, but there was United SCA. Okay. That's kind of a vertical thing. United

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[25] Keshia Hannam, *Ascension and Providence St. Joseph in Talks to Form U.S. 's Largest Hospital Operator*, FORTUNE (Dec. 11, 2017), http://fortune.com/2017/12/11/ascension-providence-merger/.

[26] Reuters Staff, *UnitedHealth to buy DaVita primary care unit for $4.9 billion*, Reuters (Dec. 6, 2017), https://www.reuters.com/article/us-davita-m-a-unitedhealth/unitedhealth-to-buy-davita-primary-care-unit-for-4-9-billion-idUSKBN1E01HJ.

[27] United States v. Anthem, Inc., 236 F.Supp.3d 171, 259 (D.D.C. 2017) (enjoining the merger because Anthem's acquisition of Cigna may substantially lessen the competition in the market for the sale of medical health insurance to national accounts in the fourteen Anthem states and the sale of medical insurance to large group employers in the Richmond, Virginia market).

[28] Bertha Coombs, *The Mega Merger Is Off: Aetna and Humana End $34 Billion Deal, Aetna to Pay $1B Fee*, NBC NEWS (Feb. 14, 2017), https://www.nbcnews.com/business/business-news/mega-merger-aetna-humana-end-34-billion-deal-aetna-pay-n720591.

insurance company buying SCA.[29] The country's largest outpatient surgery center provider.

So now we have a provider and you had the insurance company, United, buying big hunks of DaVita's medical practices. So now United owns all these medical practices--they did beforehand--now they own more. CVS and Aetna, I mean that is a very interesting combination. Ascension, Providence, CHI, Dignity, DaVita, Humana, Aetna, Cigna, (both those blew up) Carolinas and UNC, two big nonprofits, high market, Penn State, Advocate and Aurora Steward and Iasis and Ascension and Providence. Not all those closed and some, I bet you, wouldn't. Carolina's, it's getting so big. That's what I call the other CHS, Carolinas Health System based in Charlotte. It's changing its name, or just changed it last week to Atrium because it's buying a system in Georgia and doesn't want to be known as Carolinas anymore.[30] Of those I count, let's see, nine that are what I would call mergers of scale. So, they're just reacting to the phenomena that Kim was describing by getting bigger.

And some of those, if you're looking, are not in overlapping markets or they are in overlapping markets, but that can't be the primary thesis behind the move. When you kind of get concentration on market, you can, frankly, raise prices and dominate. That's not really what's happening here. What's happening is people just want to get bigger because they think of safety and it'll be too big to fail and they can reduce overhead costs and fire. You know, you've taken Aetna Humana and you have probably $300 or $400 million for the management costs savings you can throw out of the system on day one. The United SCA, […], CVS, Aetna...clearly, you know, interesting plays trying to break out of the mold. Another reason not to think in absolute terms. It might be okay for an insurance company to own a medical practice. It may be okay for a, you know, a drugstore, to own an insurance company. And now I saw in the cover of Modern Healthcare, until we want to figure out what they were talking about, the Inner Mountain, Ascension, SSM and Trinity--four gigantic nonprofit systems--now want to make their own generic drugs because they feel like they've been held up by

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[29] Press Release, UnitedHealth Group, Surgical Care Affiliates (SCA), OptumCare to Combine (Jan. 9, 2017), https://www.unitedhealthgroup.com/newsroom/2017/0109scaoptumcare.html.

[30] Press Release, Carolinas HealthCare System, Atrium Health Announced as Newest Chapter in Storied History of Carolinas HealthCare System (Feb. 7, 2018), https://www.carolinashealthcare.org/about-us/newsroom/News/2018/02/Atrium-Health-Announced-as-Newest-Chapter-in-Storied-History-of-Carolinas-HealthCare-System.

some generic drug manufacturers on some pricing issues.[31] So they want to get into the actual manufacturing business. I think that's all a response to stuff.

Ms. Looney: Well you've got big companies that want to get into their own healthcare business, they're going to start with their employees and then probably make a market and the point is to keep the overhead down so you know if you're not going to get--you can either cut expenses or you can get more money-- and if you're not going to get more money then you got to cut expenses in response. I mean, you know, it's just sort of the way the world works and the way the market, but I will say when you do look at some of these, and Jay said maybe it's okay, I think that's kind of a point also is you're going to have to be careful. I mean for CVS to own Aetna, you've got to make sure there's not some inappropriate control there. For United owning all the physician practices, you've got to make sure they're not dictating and doing something that's contrary to the physicians' independent medical judgment and there's a lot they can do and it may or may not be good, but it is interesting.

Mr. Hardcastle: You have to watch some of these incentives go the other direction. The general feeling now and, in truth, fee for service where the physician is not with the insurance company, I mean I've seen someone do this--do you know what I'm going to say?--this is the most expensive piece of medical equipment in the world, right here. But now it's going to be the other way and there may be some abuses on the other side. [cross talk] And it depends. Your vocabulary is different depending on the situation you're in. If you were a British doctor you would not say that it is medically necessary for an 82 year old person to have a hip replacement and it would not be in your vocabulary in a system largely driven by budget as opposed to a system that where it's more or less fee for service and there is no real budget.

Mr. McDonald: When I started my healthcare career in 1983, I think our GDP percentage was around eight percent, so today it is 18 percent and I think everybody, everybody is up in arms about that and that type of spending can't be supported.[32] We can't support that anymore so we're going to see some real interesting things. I think this year, I think the CVS, while it was an interesting move, the more

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[31] Press Release, Intermountain Healthcare, Leading U.S. Health Systems Announce Plans to Develop a Not-for-profit Generic Drug Company (Jan. 18, 2018), https://intermountainhealthcare.org/news/2018/01/leading-us-health-systems-announce-plans-to-develop-a-not-for-profit-generic-drug-company/.

[32] *See* U.S. Ctrs. for Medicare & Medicaid Servs., NHE Fact Sheet (2018).

you drill down on it, you have disruptors like an Amazon with what they're talking about,[33] JP Morgan and Berkshire Hathaway, top of their list is the drug management program,[34] and I think it really scares CVS. I think it scares Walgreens, so you have a disruptor that's coming in. We've had other people take a run at healthcare, like Google health and they kind of came in and they googled right on out.[35] It's an interesting career and you'll find it's harder than it looks.

Ms. Lampley: The discussion on the generic drugs brings my world into the discussion too, as far as mergers and acquisitions and things going on in the life sciences industry. Pharma, medical device research organizations...we're seeing a lot of unusual activity in those areas as well where they are normally competitors. Big pharma companies are actually coming together and collaborating on projects. One that we were lucky enough to work on a few years ago was between Eli Lilly and Boehringer Ingelheim when they did really an unprecedented--at that point--collaboration to co-market their suite of diabetes drugs.[36] So that was a very unusual-- but it's all about pharma companies being under price reduction pressure, increased costs to research and bringing products to market, increased difficulty in insurance formulary approvals and things like that. They're looking for creative ways to do that. Another thing we're seeing a lot of is that the big pharmas are looking more, not at in-house development of their products, but going out and licensing or buying small and mid-cap companies.

I spend a lot of time in the bay area and San Francisco with smaller pharma companies and it's just astounding, the movement in that industry. It really is just a constant movement of buying and

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[33] Amazon enters the online pharmacy market. *See* Robert Langreth & Zachary Tracer, *Amazon Makes $1 Billion Splash in Health Care, Buying PillPack*, Bloomberg (June 28, 2018), https://www.bloomberg.com/news/articles/2018-06-28/amazon-makes-big-foray-into-health-care-with-pillpack-purchase.

[34] Zachary Tracer, *Amazon-Berkshire-JPMorgan Health Venture Takes Aim at Middlemen*, BLOOMBERG (June 24, 2018), https://www.bloomberg.com/news/articles/2018-06-24/amazon-berkshire-jpmorgan-health-venture-takes-aim-at-middlemen.

[35] Brian Dolan, *Official: Google Health shuts down because it couldn't scale adoption*, MOBIHEALTHNEWS (June 24, 2011), https://www.mobihealthnews.com/11453/official-google-health-shuts-down-because-it-couldnt-scale.

[36] Eli Lilly and Co., *Lilly and Boehringer Ingelheim Announce Strategic Alliance to Bring New Diabetes Treatments to Patients Worldwide*, PR NEWSWIRE (Jan. 11, 2011), https://www.prnewswire.com/news-releases/lilly-and-boehringer-ingelheim-announce-strategic-alliance-to-bring-new-diabetes-treatments-to-patients-worldwide-113263519.html.

selling and collaborating and coming together in a lot of unusual ways at a speed much faster than we've seen before. Not to mention academic medical centers and other research organizations who are combining their own networks so that the research clinical sites are coming together and forming a larger and larger network to conduct the research. It's all about the economies of scale and trying to do it efficiently.

Mr. Stewart: I'm going to interrupt and cut us off talking about M & A. You can tell the five of us are curious and fiery about mergers and acquisitions, but write down your questions and ask us at the end or ask us at lunch because I'm going to move on a little bit. Julie, you actually provided us with a bit of a segue. I wanted to ask about certain sectors of the healthcare industry, for example, hospitals, physician practices, and home health. You mentioned the pharmaceutical industry will react differently to this system that relies more heavily on control by the states, are there any certain industries that you work with particularly that will react curiously? Not necessarily just Julie. Anybody?

Ms. Lampley: In my world, life sciences, it's not so much state specific because it is federally driven. Now in my work with dialysis providers, hospitals, and other institutions there are a lot of state specific issues that come up.

Mr. Hardcastle: On the budget side, there will be benefit management initiatives that focus on pharmaceuticals. I believe one of our prior panelists mentioned that a drug was substituted, but I think that was as a result of opioid abuse issues. But there are private companies that specialize, pharmacy benefit managers or PBMs, that work with insurance companies and Medicaid programs and other people who were influential in buying lots and lots of drugs, and they would come to the state and they would help you develop this so-called formulary of drugs. So, we'll drive volume to a particular manufacturer and maybe distributors are somehow in there also, in return for price concessions. But also, it's mostly, you know, we're just frankly looking for the cheapest, most effective drug and we're going to cut out all the marketing noise and the influence that the marketing apparatus has on the medical professions and say you can prescribe whatever you want.

This is why if you're a patient, we're going to have various mechanisms to call the pharmacy to fill this drug for this condition. And that is a very local state response I think. But it usually relies on national companies to help them figure that out. You can go to school for, I think Belmont is a great example here, for a PharmD

program, which is essentially the equivalent of a PhD and that sort of thing.[37] And you need these pharmacies to help you figure out how to handle that if you're in Medicaid.

Ms. Lampley: I was just going to say that one of the things when TennCare came into being and they started their formulary was they had a limit on the drugs.[38] There are a lot of major companies whose drugs were not included on the formulary because they were more expensive.

Mr. Hardcastle: There are other ways to manage that, by the way, besides the state looking to a formulary and the formulary people looking to an expensive for-profit company. I mean the state could get into the business of buying drugs, which would of course curdle the blood of many of us in here and has all kinds of political implications. But, with the state probably in that business already in subtle ways by buying drugs for various state operated clinics or metro, you know, the city operated clinics.

The national healthcare council has this trip every other year. They go to another country, you study a healthcare system in the other country. And I've always thought it was a giant waste of money and who are these money-wasting, time-wasting people who go on these trips? And then they said it was going to be in Paris and I said I was going to go. And I did. And they set up these lunches and one of the lunches was a "meet a French pharmaceutical executive" lunch. And so every table got a french pharmaceutical executive and so I sat with the Pfizer person who was head of Pfizer, France, and he was telling me interesting things like, for example, it is completely out of the question, it never will happen, culturally unthinkable to have an ad for a drug in France will--we will never tolerate that. So I don't know what you do with all the paired bathtubs in France, but they're not in sales.

But the other thing they do is they buy their health system. They have sort of like four Medicares over there, depending on who joined your Medicare system, depending on whether you're in a certain kind of industry, they're industry specific sorts of things.[39]

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[37] *See* Belmont University, PharmD Curriculum, http://www.belmont.edu/pharmacy/academics/curriculum.html

[38] Cyril F. Chang & Stephanie C. Steinberg, *TennCare Timeline: Major Events and Milestones from 1992 to 2016*, Methodist Le Bonheur Center for Healthcare Economics, the University of Memphis, 2 (September 2016), http://www.memphis.edu/mlche/index.php.

[39] Isabelle Durand-Zaleski, *The French Health Care System*, International Health Care System Profiles,

And they buy the drugs and they would have one negotiation per year with Pfizer and they go to the mat and then they're done for another year. And that's the price of that drug. And it's all budgeted in the budget. And guess what, it's a lot cheaper over here. Now I'm not advocating we do that. The states could have a different response and that's what we're going to buy it. And guess what, we're not going pay very much.

Mr. Stewart: Does anybody else have a comment on what you think we should do, federal or state, changing our regulations in this area? Okay.

Speaking of, when pharmaceutical companies get a patent on a new molecule, they have 20 years to recoup the cost of developing a drug out of it. So these companies look for loopholes in the law to have the ability to extend their patent and they'll often develop a new chemical entity to prevent the drug from going generic.[40] There's a big debate about whether we should allow this. Are there any changes that you guys would recommend to balance the interest of protecting the patients who are in need but also encouraging drug companies to continue to conduct extensive research on the new drugs?

Ms. Lampley: I'll take the first stab at that one. Then I'll sort of combine it with some of the conversation that we've been having. And that is about FDA regulatory changes that have been discussed a lot, not really at state level, but more at federal level. The Trump administration has made some pretty bold statements about its desire to reduce the time required for the whole development and approval process.[41]

Quite frankly, I think we probably have it about right because the FDA's primary purpose really is to protect the patient, right? That's what they need to be looking at. So what may save

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https://international.commonwealthfund.org/countries/france/ (last visited Aug. 2, 2018).

[40] Cynthia Koons & Robert Langreth, *The Loopholes Drug Companies Use to Keep Prices High*, BLOOMBERG (Dec. 20, 2017), https://www.bloomberg.com/news/features/2017-12-20/the-loopholes-drug-companies-use-to-keep-prices-high.

[41] Jen Christensen, *Trump Vows to 'Slash Restraints' on Drug Development for FDA*, CNN, https://www.cnn.com/2017/03/01/health/trump-fda-slash-restraints/index.html (last visited July 20, 2018) (Speaking to a group of pharmaceutical company executives, Trump vowed to "streamlin[e] the process so that from [the pharmaceutical companies'] standpoint . . . [they] can actually get [the drugs] approved – if it works – instead of waiting for many, many years.").

some time and some money on the private side might also put patients more at risk on the healthcare side. So I think probably we have that balance about right. And I thought it was also interesting that in big Pharma's reaction to the Trump administration's statements and they generally took that approach as well.

Which was: yeah, it cost us a lot of money and it takes us a long time, but that's probably necessary. One of the reasons for that is the insurance formularies. Even if you get past the FDA, you don't get a dime if someone's not going to reimburse for the product. Not only do you have to prove that it's safe and effective to get on the formulary, you have to prove that it's better than what they're currently doing and usually at a more cost-effective level.[42] So it is very difficult. So that's to say that all of that analysis that they gathered during the FDA approval process, they're going to need anyway when they get to the formulary and the insurance company level.

One thing that, based on the conversation here, I think a lot of us would probably agree is at a state level, you need to start looking at your insurance rates and maybe look at how exclusive you should or should not be, and what other alternatives that should be available to the patients rather than pushing money to a specific big manufacturer or developer of drugs.

But to get to the patent issue specifically, there are animal trials first, then there are phase one through four human trials. There are serious adverse event trials, there are data gathering trials, there are all these trials that have to be conducted in order to bring a product to approval.[43] For every success where they do finally achieve approval, you can take my word for it, there are many failures. That same kind of effort was put in up to a certain level and then they met a road block and a stop.

And of course, the patent process, the reason that's there, the reason patent process protection even exists is to allow, in my case, the drug manufacturer or drug developer to recoup that cost.[44] So

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[42] Gordon D. Schiff et al., *A Prescription for Improving Drug Formulary Decision Making*, PLOS MEDICINE, http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001220 (last visited July 27, 2018)(The efficacy and safety requirements entail questioning the "quality and strength of the evidence" and the formulary studies, as well as searching for safe "administration and preparation" of the drug and the "adequacy of the experience with the drug.").

[43] 21 U.S.C. § 355(b) (2012).

[44] 35 U.S.C. § 154 (2012).

the government has looked at that and said that they think 20 years is probably a reasonable time to be able to recoup that cost.[45] It's not really 20 years, it's 20 years from the time you filed the application.[46] And most of the time you want to protect your product pretty early on during that trial phase. So, you've lost several years in the process of actually bringing it to approval, which shortens your time.

Ms. Looney: The only thing is I think that when it comes time to price the drug, it's not necessarily priced on recouping the money over that time period. I mean a lot of times the drugs, especially the ones that are new and very effective and are going to be prescribed, are priced based on what the market will bear. I'm not saying that's necessarily a bad thing, but I think that you have to account for recouping the money on all those other products that didn't make it.

But I remember reading about Revlimid, which is now on the market, but it was experimental for a while.[47] [...] The price of it--because what it was replacing was blood transfusions--so if the blood transfusions cost, and they were expensive, I will say they were 50, 60, 70 grand a year depending on how often you had to have them, the drug company priced Revlimid at about 20 percent less than that.[48] So it was comparable. You're still talking about 50 grand at year for a drug, you know, but a very effective drug. It's working so I would say okay, 20 years may be the right amount of time, and I don't think it's anything that you can look... you can't do a cost benefit analysis for each particular drug for that 20 years. I think that you have to take into consideration all the ones that don't work.

Ms. Lampley: That's right. And the unknowns, right? The future risk of something going wrong once it gets on the market. When there's a big class action advertisement on one of the big news channels saying during every break, "call us if something's happened," it really is a potential cost that at the time that you price the product and the time of your patent expires, you don't even know that it's out there. It can happen anytime, but that's all to say: there is that legitimate reason for having the patent there and not shortening it, but with respect to extensions, of course any game can be played and any program can be abused.

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[45] *Id.*
[46] *Id.*
[47] DRUGS.COM, *Revlimid Approval History*, https://www.drugs.com/history/revlimid.html (last visited July 20, 2018).
[48] DRUGS.COM, *Revlimid Prices, Coupons, and Patient Assistance Programs*, https://www.drugs.com/price-guide/revlimid (last visited July 20, 2018).

One of the changes that I would suggest, and I think it would be a very good one, is to really look more carefully when a company wants to file an extension on a patent that's about to expire. In some cases there really is a change. It's a significant change and it's protectable, but in some cases it may be just a way to extend the patent further.[49] Of course, the generic drugs are the ones that are most angry when that happens because it delays their ability to introduce some competitor in the market. But another change that I think would be helpful in addition to looking at extensions more carefully than we might already be doing, is to allow generics to really come on quick. I do think that's a place where the FDA process could be shortened as much as possible because the safety and the effectiveness has already been proven. It's just a small change in the generic world.

We also have biosimilars and I won't get into that, but that's a whole other world that we have to consider too as competing products that may necessarily have to wait until the patent expires.[50]

With advertisements—that's incredibly expensive for pharmaceutical companies and it's a trend of "well, they're doing that so we have to do it, too" and it's all about being an informed patient. A patient now wants to go in and know what they're asking for and sometimes demand a certain product. It costs Pharma companies a lot of money to have that visibility. So I think that's another way we could look, at the state level, at cost of advertisement and the actual effect on the price of the drug in having that advertisement. One more thing, I think what we really need to do is to provide more leniency under anti-kickback and other restrictions to drug companies because the ones that I represent are very passionate about helping patients, waiver of copays, waiver of deductibles, charitable care, giving the drug away to the population that needs it.

But because our federal restrictions are sometimes so prohibitive, we're unable to do really everything that we would like

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[49] *See Ortho-McNeil Pharm., Inc. v. Lupin Pharms., Inc.,* 603 F.3d 1377 (Fed. Cir. 2010) (after a drug manufacturer made slight changes to a successful drug formula, the court gave a patent extension to Ortho-McNeil); *see also* Himanshu Gupta et al., *Patent Protection Strategies*, J. OF PHARMACY AND BIOALLIED SCIENCES, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/?report =reader (last visited July 20, 2018).

[50] Joe Nocera, *Why the Biosimilar Drug Revolution Hasn't Arrived*, BLOOMBERG, https://www.bloomberg.com/view/articles/2017-09-07/why-the-biosimilar-drug-revolution-hasn-t-arrived (last visited July 20, 2018).

to do as a pharma company.[51] So I think that's another area that we really need to step back and let people take care of patients as they would like to do.

Mr. Stewart: I think this is an interesting topic. I'm going to freeze the conversation and get to the audience in our last couple of minutes. Does anybody have any questions that they wanted us to address before we have to disappear?

Audience Member: I have to say that the pharmacy ads irritate me to death, you know, we're, we're past the time that we're not going to do it. But when we say things like, "tell your physician if you had a kidney transplant," well give me a break. Why should the physician prescribe something just because a patient walks in and demands it? But the question is: it must be an effective tool, or Pharma wouldn't do it, but on the back side, you know, the consumer or the physicians, do you get any backlash? And I'm all for information, you know, for patients that have certain conditions when you do that lengthy side effects thing, which I think is really good, but some of these drugs just seem inappropriate for a patient to go in and say, I saw this on TV and I want this drug.

Mr. Hardcastle: That was exactly the argument that the Pfizer Guy in France was saying. You're stirring up demand where none exists, but you know, the counterpart to that is that, about 10 years ago, we started to hear the phrase "consumer driven healthcare" and that's, you know, information-driven and the ads do provide some information. Sideline: my wife rescues dogs--copious amounts of dogs-- and they come to us with either no names or just really stupid names. I mean, I don't how many Jack Russell terriers you can name Jack Daniels, but anyway, I found that the drug, we have Otesla now, currently the drugs provide nice names for the rescue dogs and some other things. Yasmin, Otesla daschhunds.

Ms. Lampley: I agree about the informed patient. I think it puts probably undue pressure on a lot of physicians and I think another result is it puts perhaps warranted pressure on insurance drug formularies, and those who are putting them together, because of

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[51] Andria Jacobs, *Waiving Copay and Deductibles Waves a Red Flag,* AM. J. OF MANAGED CARE, https://www.ajmc.com/contributor/andria-jacobs-rn-ms-cen-cphq/2015/07/waiving-copays-and-deductibles-waves-a-red-flag (last visited July 20, 2018); *see* 42 U.S.C. § 1320a-7b (2012) (The Anti-Kickback Statute restricts healthcare providers from accepting bribes to gain referrals for items the government reimburses.); *see also* 31 U.S.C. § 3729 (2012) (The False Claims Act restricts companies from defrauding governmental healthcare programs by holding them responsible for their fraudulent actions.).

patient demand. There are a lot of different aspects to it, but to me, it could easily interfere with physician judgment and patient satisfaction with their physician for really very unwarranted reasons.

Audience Member: Julie. But the same is true of all that unwanted advertising that people see on tv and they think, oh, because some plaintiffs' ad that's been made into an infomercial says if you take this drug, you may be entitled to compensation also has and is building up the cost of drugs.

Mr. McDonald: Just two things that were brought to mind when you talked about granted in a class action suit, the oversight is not as great by the courts, but you still have the litigation standpoint with a single person writing a script and then prescribing the drug. That ultimately resulted in either the acceptance of the claim or denial of the claim.

On the second part, I mean there is, there is obviously a place for consumer information and consumer guidance that has been kind of called a war for advertising for quite some time, but fundamentally wasn't that the job of the physician? Doesn't the advertising actually spur kind of a hypochondriac mentality on the part of the consumers rather than giving an honest and detailed account of, of their particular symptoms? They're focused on whatever symptoms correspond to the publicly available information. So that, you know, I see that I have a, you know, kind of a burning sensation in my hand so it must be this particular ailment. So that everything that I was going to talk about is going to be focused on that particular ailment and that creates kind of an information chasm between the physician and the consumer rather than a bridge.

Ms. Looney: It's not giving the physician the opportunity to diagnose you, basically, because you come in saying, I know this is what I have and this is a drug I want. And I think Julie touched on a really important point because it is going to pay, you know, pay for value, kind of point, physician satisfaction. And what your patients think about the physicians is a really important metric that is being measured.[52]

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[52] Erin E. Sullivan & Andy Ellner, *Strong Patient-Provider Relationships Drive Healthier Outcomes*, Harv. Bus. Rev., https://hbr.org/2015/10/strong-patient-provider-relationships-drive-healthier-outcomes (last visited July 20, 2018); *see also* CMS, *Consumer Assessment of Healthcare Providers & Systems*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/ (last visited July 28, 2018).

And so if your doctor doesn't give you the drug you want or ticks you off, then you're not going to evaluate them very well. And that could be an excellent doctor who says you're just fine on the drugs you're on, which are generics that have been around forever. They're controlling your symptoms. You don't need this nice new Humira or whatever. You see all these things that--I have rheumatoid arthritis, so I see those all the time and I'm not, I'm on Methotrexate, Prednisone, all of which have been around forever that are really cheap. But you know, it's interesting because it's something that's important and you know, I get you do want information. I do think it's good.

I think part of it--because your drug reps are allowed to take information, but your doctors don't really sit around getting information and you can't take them to breakfast and lunch and all those things they used to do anymore when you might get 15 minutes of the doctor's time. So you know, we've kind of ratcheted it back one way and so then, now you have all those direct to consumer ads and they are very annoying ads. Because if you can't get the drug reps to be able to get the doctor, she's got to get to the patient and the doctors are watching these ads too, so you've got to get to them.

Audience Member 2: I've got a couple of questions about tort reform and its effect on say, I guess, cost of care and whether or not it's having the intended effect. And also on the legal profession; how are you seeing it in your professional practices day in, day out?

Ms. Looney: I think that for us probably in particular, it's not so much affecting what we do, but I think tort reform can be good. If you can cut back on the cost that the drug companies are having to pay for the lawsuits and frivolous lawsuits then it means, you know, they don't have to charge $50,000 for the drug.

Ms. Lampley: That's right. The reserves they have to set aside for the potential liability moving forward. That all goes into the pricing and then if some states have tort reform and others don't, obviously then you have the forum shopping that goes on. I think it's a need. Things have to be controlled.

Mr. Hardcastle: Yeah. I will offer a slightly different viewpoint. Slightly different. I think that tort reform in Tennessee as it applies to medical malpractice claims against physicians has, with various caps, reduced the likelihood of people bringing a suit. So I think it has had the intended effect. It's just not worth it to a lot of plaintiffs' lawyers to take suits without essentially catastrophic damages and

ways around the caps. I don't know that it's had any effect on, and Mark may know from his prior life, had any effect on malpractice premiums, practice patterns... I mean, there's some possibility that all it's done is left some people out in the cold.

Ms. Looney: I think that's the point. There are some lawsuits that need to be brought. There are some plaintiffs who have truly been injured and truly suffered and it's just kind of balancing all that with throwing it all out and figuring out what's best.

Mr. Hardcastle: Yeah. And having been in this business for a long time, of course, probably most people in here have a sort of a negative bias against plaintiff lawsuits, but they have a reason and I remember traveling once and crossing, like, an ancient Roman aqueduct covered with tourists with about a 400 foot drop and no guard rails and all I could think of was "this country needs more plaintiffs' lawyers."

Audience Member 3: What the savvy plaintiff lawyer has done is shift those claims to the manufacturer of the drug. So what we often see will be a case where it is medical malpractice and, of course, the companies we represent, we don't place blame on the doctors. So what it's done is it's decreased [audio interference] but it's increased it in the type of clients. And some of the judgments are astronomical, astronomical. We have a client at a $720,000,000 verdict in California or something that I think is one of the most ridiculous things I've ever seen.

Mr. Hardcastle: So preparing for this, I started thinking about this idea of all these absolutes out there and how they have constrained development and it reminded me of something I read as an undergraduate and I threw away a bunch of books and somehow I saved this.

So this is a commentary from a famous legal scholar named Alexander Bickel who died in 1974, young, but he was counting on Edmund Burke, who was an Irish political philosopher whose whole theory was you should not have these absolutes, you should take all these things and put them in a blender and this is what Bickel said about Burke:

"There are no absolutes that a complex society can live with in its law. There is only the computing principle that Burke spoke of--adding, subtracting, multiplying, dividing. It is the most enduring instinct of our legal order, which is more Burkean than some care to acknowledge, to resist the assertion of absolute claims

and, therefore, a waste of breath to make them. Even absolute rights that the legal orders seems, absentmindedly, to create (anti-trust or anti-kickback, whatever), if very rarely, do not endure. Circumstances erode them. Better to recognize from the first that the computing principle is all there is, ought to be, or can be."[53]

[53] Alexander M. Bickel, The Morality of Consent 88, (Yale U. Press) (1977).

ALL HEALTH CARE IS LOCAL: EXPLORING THE ROLES OF CITIES AND STATES IN HEALTH CARE DELIVERY AND REFORM

GOVERNMENT PANEL SUMMARY

PANELISTS:
TONY HULLENDER, *OFFICE OF THE ATTORNEY GENERAL OF TENNESSEE*
GABE ROBERTS, *STATE OF TENNESSEE, DIVISION OF TENNCARE*
CHRISTOPHER SABIS, *OFFICE OF THE UNITED STATES ATTORNEY, MIDDLE DISTRICT OF TENNESSEE*
JANE YOUNG, *TENNESSEE DEPARTMENT OF HEALTH*

Moderated by Marc Overlock, Metropolitan Nashville Hospital Authority

FEBRUARY 9, 2018

On Friday February 9th, 2018, the Belmont Health Law Journal hosted a symposium entitled *All Health Care is Local: Exploring the Roles of Cities and States in Health Care Delivery and Reform*. A panel of government lawyers representing various state and federal agencies and organizations took part in the symposium. Among them were Tony Hullender from the Office of the Attorney General of Tennessee, Gabe Roberts from the Division of TennCare, Christopher Sabis from the Office of the United States Attorney, Middle District of Tennessee, and Jane Young, General Counsel for the Tennessee Department of Health. The panel was moderated by Marc Overlock, General Counsel for the Metropolitan Nashville Hospital Authority. The symposium was held in the Randall and Sadie Baskin Center, located on the campus of Belmont University in Nashville, Tennessee.

The following is a summary of the discussion that took place. The panel opened with a discussion of what the impact to TennCare would be if the federal government put more pressure on the states to regulate healthcare.[1] The panelists discussed the Indiana Medicaid waiver that had been recently approved, as well as amendments to TennCare waivers.[2] The conversation then pivoted to whether Tennessee would implement work requirements for TennCare beneficiaries and, if so, what those requirements might look like. The consensus was that work requirements could be a possibility, but that such requirements actually would not have a significant impact, as it is doubtful that a substantial number of Tennesseans would be affected by their implementation.

The panel then discussed initiatives undertaken by the State of Tennessee to combat the opioid crisis. Ms. Young explained the components of the Tennessee Together initiative, which had been recently announced by the Governor.[3] The initiative contains three major components: 1) prevention; 2) treatment; and 3) law enforcement.[4] It consists of proposed legislation and Governor Haslam's proposed FY 19 budget, as well as other executive actions. The proposed legislation portion would prescribe limits for opioids and increasing the frequency with which providers must check the Controlled Substance Monitoring Database, a prescription-monitoring program.[5] In addition, some of the proposed legislation involves adding fentanyl analogues to Schedule 1 drugs, which are drugs that have no accepted medical use and high potential for abuse.[6]

With regard to the executive portions of the initiative, the Governor has, by Executive Order, appointed a group of medical education experts to develop curricula for use in medical, dental, nursing, and similar schools regarding pain management and opioid use treatment.[7] Further, the proposed FY 19 budget would provide

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[1] Mandy Pellegrin, *How U.S. House Medicaid Reforms Could Impact Tenncare*, THE SYCAMORE INSTITUTE (2017), https://www.sycamoreinstitutetn.org/2017/03/10/ahca-impact-tenncare/ (last visited Nov. 11, 2018).

[2] Medicaid Waivers, THE ARC OF INDIANA, https://www.arcind.org/supports-services/medicaid-waivers/ (last visited Nov 11, 2018).

[3] Ending the Opioid Crisis, TENNESSEE STATE GOVERNMENT, https://www.tn.gov/governor/2018-legislative-priorities/tn-together.html (last visited Nov 11, 2018).

[4] 2017 Legis. Bill Hist. TN H.B. 1831

[5] *Id*.

[6] 2017 Legis. Bill Hist. TN H.B. 1832

[7] *Haslam Establishes Commission on Pain and Addiction Medicine Education*, State of Tenn. Off. of the Att'y Gen.,

$25 million for treatment of those with a substance use disorder, and contains a sentence credit provision for criminal offenders who are under the jurisdiction of the Department of Corrections.[8]

In addition to the Tennessee Together Initiative, Mr. Hullender explained that Tennessee, through the Attorney General, was leading the investigation into malfeasance on the part of drug manufacturers. [9]

Concerning the federal government's aid in remedying the opioid crisis, Mr. Overlock stated it had begun to put additional focus on hiring experienced Assistant United States Attorneys who were dedicated to combatting opioid fraud. Mr. Overlock also mentioned that one such position had been created in the Eastern District of Tennessee.[10] Ms. Young revealed that the Tennessee Department of Health had received a grant from the Centers for Disease Control and Prevention, which had been used to hire new staff members such as epidemiologists.[11] On a negative note, Mr. Roberts stated Substance Abuse and Mental Health Services Administration (SAMHSA) regulations made intervention difficult, as Managed Care Organizations are reluctant to contact enrollees when they see the enrollee doctor shopping.

As far as the state government's involvement in combatting the opioid epidemic, the Tennessee Department of Health's primary enforcement tool is the Controlled Substance Monitoring Database ("CSMD)".[12] CSMD has been a vital tool in discovering abuses in the dispensing and prescribing of controlled substances to patients.

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https://www.tn.gov/governor/news/2018/1/24/haslam-establishes-commission-on-pain-and-addiction-medicine-education.html (last visited Nov 12, 2018).

[8] Anita Wadhwani, *Gov. Bill Haslam unveils $30 million plan to combat opioid crisis in Tennessee*, THE TENNESSEAN (2018), https://www.tennessean.com/story/news/politics/2018/01/22/gov-bill-haslams-plan-combat-opioid-crisis-include-boosts-prevention-treatment-and-law-enforcement/1054217001/ (last visited Nov 12, 2018).

[9] *Tennessee Attorney General Sues Purdue Pharma*, State of Tenn. Off. of the Att'y Gen., https://www.tn.gov/attorneygeneral/news/2018/5/15/pr18-10.html (last visited Nov. 10, 2018).

[10] Press Release, *Eastern District of Tennessee Selected to Participate in Department of Justice Opioid Fraud and Abuse Detection Unit,* Dep't of Justice, https://www.justice.gov/usao-edtn/pr/eastern-district-tennessee-selected-participate-department-justice-opioid-fraud-and (last visited Nov. 10, 2018).

[11] *CDC Awards $28.6 Million to Help States Fight Opioid Overdose Epidemic,* CENTERS FOR DISEASE CONTROL AND PREVENTION https://www.cdc.gov/media/releases/2017/p0905-opioid-funding.html (last visited Nov. 10, 2018).

[12] Health Professional Boards Controlled Substance Monitoring Database Program, Tenn. Dep't of Health, https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board.html (last visited Nov. 10, 2018).

Data analysts review hospital discharge data and nonfatal overdoses in order to drive the state's response to the opioid epidemic.

TennCare is also working to develop ways to legally share data[13] and to align its reimbursement policies regarding opioids.[14] Developing relationships with law enforcement will also play an important part in the Tennessee Department of Health's response.[15]

The panelists were asked their personal opinions on what changes the federal government could make to improve health care in America. Answers ranged from focusing on prevention and population health to increasing resources dedicated to combatting fraud.

The panel finished with a discussion of fraud issues associated with electronic health records ("EHR").[16] Mr. Hullender explained how EHR systems that routinely populate similar data may make a provider look suspicious.[17] Mr. Sabis reinforced this, mentioning that EHR systems have created new opportunities for fraud, and that automatic and pre-populating of medical charts has become a huge drain on resources.[18]

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[13] *eHealth Information Exchange*. Tenn. Div. of TennCare. https://www.tn.gov/tenncare/providers/ehealth-information-exchange-overview/ehealth-information-exchange-web-page-faqs.html.
[14] *TennCare's Opioid Strategy*. Tenn. Div. of TennCare. https://www.tn.gov/tenncare/tenncare-s-opioid-strategy.html.
[15] Mandy Pellegrin and Courtnee Melton, *The Opioid Epidemic in Tennessee: 2018 Update on New Policy Actions*, THE SYCAMORE INSTITUTE (August 9, 2018), https://www.sycamoreinstitutetn.org/2018/08/09/opioid-epidemic-tn-policy-actions/.
[16] *HER-enabled fraud remains a concern*, MEDICAL ECONOMICS (August 1, 2016), http://www.medicaleconomics.com/editors-choice-me/ehr-enabled-fraud-remains-concern.
[17] *Medicare Fraud & Abuse: Prevention, Detection, and Reporting*, Centers for Medicare & Medicaid Services (September 2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/fraud_and_abuse.pdf.
[18] Holly Louie, *False and Nonsensical Medical Records Reportedly Not Unusual*, ICD10 MONITOR (October 31, 2017), https://www.icd10monitor.com/false-and-nonsensical-medical-records-reportedly-not-unusual.

IMPLEMENTING 501(R): HAS 501(R) LIVED UP TO ITS INTENDED PURPOSE? AND WHAT THE IRS' 2017 REVOCATION ACTION MEANS FOR THE TAX-EXEMPT HOSPITAL COMMUNITY

BRANDON HUBER

A hospital refuses to provide chemotherapy treatment to a woman suffering from leukemia until she pays over $100,000 up-front.[1] A university medical center redirects poor and uninsured patients from its emergency room to other local clinics.[2] Another hospital refers its low-income patients to its for-profit debt collection agency before offering any assistance or charity care options.[3] At first glance, the scenarios above seem like they would

[1] Barbara Martinez, *Cash Before Chemo: Hospitals Get Tough,* United States Senate Committee on Finance (Apr. 28, 2008), https://www.finance.senate.gov/imo/media/doc/061008lktest.pdf.

[2] Bruce Japsen, *ER Doctors Condemn University of Chicago Plan to Divert Patients,* CHICAGO TRIBUNE (Feb. 20, 2009), http://articles.chicagotribune.com/2009-02-20/news/0902190858_1_emergency-patients-emergency-room-community-hospitals.

[3] Paul Kiel, *From the E.R. to the Courtroom: How Nonprofit Hospitals Are Seizing Patients' Wages,* PROPUBLICA (Dec. 19, 2014), https://www.propublica.org/article/how-nonprofit-hospitals-are-seizing-patients-wages/.

be relegated to a thing of the past; or worse, the type of behavior that only for-profit healthcare organizations engage in to maximize their profits.

Unfortunately, each one of these stories share a troublesome commonality: All involve actions taken by nonprofit hospitals. Beyond that, all three hospitals maintain federal tax-exempt status; meaning, that in addition to all of the benefits they receive from their respective status as nonprofit entities, all three hospitals are exempt from paying federal income tax.[4] Historically, tax-exempt status was granted by the federal government on a *quid pro quo* basis to hospitals that demonstrated an ability to meet a societal need through the use of "charity care[5]," thereby reducing the burden on the government of providing these health services directly.[6] As illustrated by the examples above, however, the reality of the situation is that this arrangement has not lived up to its intended purpose.

How much charity care should a tax-exempt hospital provide to its community in exchange for its tax-exempt status?[7] Does the amount of charity care provided by tax-exempt hospitals, as a whole, justify the loss in tax revenue the government would have otherwise generated? Over the years, questions similar to those posed above have been the subject of fierce debate amongst experts and health consumers alike.[8] Although this Note does not attempt to address

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[4] 26 U.S.C. § 501(c)(3) (2012).

[5] The concept of charity care has varied over the years, and there has been some confusion as to how it should be defined. As a result, it is not uncommon for charity care to be confused with "bad debt," which involves unreimbursed care provided by a hospital for which payment was expected but never received. For purposes of this Note, charity care, in contrast to bad debt, consists of services for which a hospital did not receive, nor expected to receive, payment because the patient's inability to pay had previously been determined prior to treatment. *American Hospital Association Uncompensated Hospital Care Cost Fact Sheet*, A.H.A. (Dec. 2010), https://www.aha.org/system/files/content/00-10/10uncompensatedcare.pdf.

[6] IHC Health Plans, Inc. v. Comm'r, 325 F.3d 1188, 1195 (10th Cir. 2003) ("The public-benefit requirement highlights the *quid pro quo* nature of tax exemptions: the public is willing to relieve an organization from the burden of taxation in exchange for the public benefit it provides.").

[7] "Nonprofit status is a state law concept. Nonprofit status may make an organization eligible for certain benefits, such as state sales, property and income tax exemptions. Although most federal tax-exempt organizations are nonprofit organizations, organizing as a nonprofit organization at the state level does not automatically grant the organization exemption from federal income tax." IRS, *Frequently Asked Questions About Applying for Tax Exemption, Internal Revenue Service* (Jun. 14, 2018), https://www.irs.gov/charities-non-profits/frequently-asked-questions-about-applying-for-tax-exemption.

[8] According to Paula Song, professor of health services organization at Ohio State University, the goal of affording tax-exemption status is to get close to the value of tax exemption in community benefit. Song further states, however, that "most [tax-exempt] hospitals aren't providing that." Elisabeth Rosenthal,

every issue of concern surrounding this expansive topic, it will examine Congress' relatively recent attempt—through the incorporation of Section 501(r) into the Internal Revenue Code—to resolve some of the flaws inherent in the current hospital-specific regulations. This Note also analyzes whether the IRS' 2017 revocation action changes anything for tax-exempt hospitals, and whether the implementation—and IRS enforcement—of Section 501(r) has achieved its goal.

This Note proceeds in four parts. Part I steps back and takes a brief look at the history and background of federal tax law; specifically, as it relates to the hospital-specific requirements the IRS has placed on hospitals seeking to qualify or maintain tax-exempt status over the years. Additionally, Part I discusses the incorporation and implementation of Section 501(r) into the Internal Revenue Code ("IRC"). Part II then explores the IRS' enforcement of Section 501(r), including the IRS' 2017 decision to revoke a "dual status" hospital's tax-exempt status for non-compliance. Then, Part II will conclude by explaining how tax-exempt hospitals can ensure they are in compliance with Section 501(r) and do not experience this same fate. Part III discusses the ripple effects of the IRS' revocation action; the potential effects of such an action on similarly situated hospitals; and whether the IRS' revocation action signals a change in the way Congress views—and the IRS enforces—hospital tax-exemption. Finally, Part IV of this Note considers whether Section 501(r) goes far enough to address the problems with the current system. Part IV will then conclude by presenting a brief argument for why Section 501(r) is a step in the right direction, and, with the implementation of a few small changes, can do even better.

I. BACKGROUND AND HISTORY OF FEDERAL TAX-EXEMPTION

Since the inception of federal tax laws, organizations "organized and operated" for certain specified purposes have been deemed to qualify for tax-exemption status.[9] Tax-exempt hospitals,

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Benefits Questioned in Tax Breaks for Nonprofit Hospitals, N.Y. TIMES (Dec. 16, 2013), http://www.nytimes.com/2013/12/17/us/benefits-questioned-in-tax-breaks-for-nonprofit-hospitals.html.

[9] *See* 26 U.S.C. § 501(c)(3) (2012) ("Corporations, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation (except as otherwise provided in subsection (h)), and which does not participate in, or intervene in (including the publishing or distributing

as well as other nonprofit healthcare entities, have historically qualified for tax-exempt status under the "charitable organization" provision of the code, or what is more familiarly known as "501(c)(3) organizations."[10]

Historically, in order to qualify as a charitable organization and in turn qualify for tax-exempt status, an organization must meet two main requirements.[11] First, the organization must be "organized and operated" *exclusively* for a charitable purpose.[12] Second, the organization must satisfy both the requirements of, what has been termed, the "organizational" and "operational" tests.[13] To meet the requirements of the organizational test, an organization must establish, on the basis of its corporate charter, "that [the organization] was organized exclusively for one or more exempt purposes without reference to its operations."[14] To satisfy the organizational test, the IRS need look no further than an organization's charter and by-laws to ascertain its stated purpose(s).

Correspondingly, an organization satisfies the operational test only if the organization primarily engages in activities that accomplish or further its exempt purpose(s).[15] The operational test, unlike its counterpart, is less straightforward and has proven to be a more exacting standard—the full scope of which falls outside the purview of this Note.[16] To determine whether an organization is primarily engaged in activities that further its tax-exempt purpose, the IRS will analyze the conduct of the organization to ensure the organization does not engage in, *inter alia*, any private inurement or

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of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.").

[10] *See Community Benefit 501(r)edx: An Analysis of the Patient Protection and Affordable Care Act's Limitations under Community Benefit Reform*, 7 ST. LOUIS U. J. HEALTH L. & POL'Y 449, 454. ("Charitable hospitals are considered tax-exempt under § 501(c)(3) of the Code, although the section of the United States Code [] does not specifically mention hospitals as tax-exempt.").

[11] *See Id.* (citing Barry A. Furrow et al., HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 977 (Thomson West, 6th ed. 2008).

[12] *Id.*

[13] *Id.*

[14] 26 U.S.C. § 501(c)(3) (2012); *see also* Thomas K. Hyatt & Bruce R. Hopkins, *The Law of Tax-Exempt Healthcare Organizations* 6 (John Wiley & Sons eds., 3d ed. 2008).

[15] *See Operational Test Internal Revenue Code Section 501(c)(3)*, Internal Revenue Service (Last updated Jul. 3, 2018) https://www.irs.gov/charities-nonprofits/charitable-organizations/operational-test-internal-revenue-code-section-501c3 ("An organization will be regarded as *operated exclusively* for one or more exempt purposes only if it engages primarily in activities that accomplish exempt purposes specified in section 501(c)(3). An organization will not be so regarded if more than an insubstantial part of its activities does not further an exempt purpose.").

[16] For a more detailed discussion on the operational test *see* Jessica Pena & Alexander L.T. Reid, *A Call For Reform of the Operational Test For Unrelated Commercial Activity*, N.Y.U. L. REV. 76, 6 (2001).

private benefit; significant business activity unrelated to its exempt purpose; and politics or substantial lobbying efforts.[17]

A. Hospital Tax-Exemption and the Charity Care Standard

In addition to the general requirements imposed on 501(c)(3) organizations, over the years, the IRS began implementing healthcare-specific requirements.[18] Technically, nonprofit hospitals have never expressly been classified as tax-exempt organizations. In fact, the promotion of health is not listed, at least by the terms of IRC Section 501(c)(3), as a charitable purpose. In reality, it was not until 1956 that the IRS started to recognize nonprofit hospital work as a charitable, tax-exempt purpose. Over the second half of the twentieth century, the IRS issued several key revenue rulings that offered further clarification and guidance to hospitals seeking tax-exempt status.[19]

The first such guidance came in 1956 when the IRS issued Revenue Ruling 56-185, which is more commonly known as the "financial ability" standard.[20] Most notably, Revenue Ruling 56-185 required that tax-exempt hospitals, "to the extent of [their] financial ability," provide health services to individuals unable to pay.[21] The implementation of the "financial ability" standard was a huge step forward in addressing indigent healthcare needs. With that said, however, the "financial ability" standard failed to specify a minimum level of free care a tax-exempt hospital would be required to provide in order to maintain tax-exempt status. Simply put, although tax-exempt hospitals could continue to charge for services they provided, no longer would they be allowed to selectively treat only those patients with the ability to pay for healthcare services.

Due to the passage of Medicare and Medicaid programs in 1965,[22] there seemed to be some confusion as to whether hospitals

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[17] *See* Treas. Reg. § 1.501(c)(3)-1(c).
[18] *See* Rev. Rul. 56-185, 1956-1 C.B. 202.
[19] *See id.; see also* Rev. Rul. 69-545, 1969-2 C.B. 117.
[20] *See id.*
[21] *Id.*
[22] *See* 42 U.S.C. § 1395 (2012) (Medicare amendment); *see id.* § 1396 (2012) (Medicaid amendment). Signed into law by President Lyndon B. Johnson as amendments to the Social Security Act in 1965, both Medicare and Medicaid provide supplemental insurance coverage to large subsects of the American population. Run primarily by the federal government, the Medicare insurance program provides financial assistance to certain elderly and disabled individuals seeking medical care. Medicaid, on the other hand, although still technically a federal program, is run primarily by the states. Unlike Medicare, Medicaid is a social welfare program implemented for the purpose of providing financial assistance to certain families and individuals with low incomes. Because each state contributes a certain level of funding to the Medicaid program, qualifying for Medicaid assistance varies on a state-by-state basis. *See generally* Digital

would still be required to provide free or below-cost care to individuals who were not covered by Medicare or Medicaid. In fact, some people even believed that within a few years after the passage of the Medicare and Medicaid programs there would no longer be a need to provide free medical care.[23] As a result, the IRS again modified the standard in 1969 when it released Revenue Ruling 69-545, which is now more commonly known as the "community benefit" standard.[24] Under the revised "community benefit" standard, hospitals that "promoted health" to the benefit of the community would now be deemed eligible for tax-exempt status.[25] Under this standard, regardless of the level of free care offered by a hospital, as long as a hospital operated an emergency room and benefited a broad enough class of persons to classify as serving the community as a whole, the hospital was deemed to have met the requirements of the "community benefit" standard.

Consequently, the ruling effectively did away with Revenue Ruling 56-185's requirement that hospitals provide free or below cost service to those unable to pay in order to maintain tax-exempt status.[26] As such, according to Revenue Ruling 69-545, so long as a hospital was operating a full-time emergency room and did not deny treatment to those in need of emergency care, a hospital was considered to have met the community benefit standard and was thus eligible for tax-exempt status.[27]

The IRS again modified this standard in 1989 when it released Revenue Ruling 83-157.[28] In doing so, the IRS relaxed the standard even further, determining that hospitals were no longer required to operate an emergency room that was open to the general public in order to meet the community benefit test.[29] The IRS clarified, however, that a hospital wanting to qualify for tax-exempt status without providing open and accessible emergency room

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Communications Division (DCD), *What is the difference between Medicare and Medicaid?* HHS.gov (Last visited Jan. 6, 2018), https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html; *see also Johnson Signs Medicare into Law*, History.com (Last updated Jul. 30, 2018), http://www.history.com/this-day-in-history/johnson-signs-medicare-into-law.

[23] *See* Anne Somers, *Hospital Regulation: The Dilemma of Public Policy* (Princeton, N.J.: Princeton University Press, 1969), p. 41 ("Thanks to Medicare, Medicaid, and numerous other public and private mechanisms for financing care for the indigent and medically indigent, in a few years free medical care will approach the vanishing point.").

[24] Rev. Rul. 69-545, 1969-2 C.B. 117.

[25] *Id.*

[26] Ceilia M. McGregor, *The Community Benefit Standard for Nonprofit Hospitals: Which Community, and for Whose Benefit?* 23 J. CONTEMP. HEALTH L. & POL'Y 302, 330 (2007).

[27] Rev. Rul. 69-545, 1969-2 C.B. 117.

[28] Rev. Rul. 83-157, 1983-2 C.B. 94.

[29] *Id.*

services to all would still be required to meet certain additional factors indicating the hospital still operated for the benefit of the public at large.[30]

These factors included, but were not limited to: (1) whether the hospital's board was made up of members of the community; (2) the hospital had implemented an open medical staff policy; (3) the hospital treated patients on public aid programs such as Medicare and Medicaid; as well as (4) whether the hospital had invested any of its surplus in revenue to "improve[e] [the hospital's] facilities, equipment, patient care, medical training, education, and research."[31] Thus, it seems clear that the IRS purposely defined the community benefit standard as broadly as possible to recognize the diverse needs of every community, and to afford tax-exempt hospitals the opportunity to meet those needs however they best saw fit.

Since the implementation of the community benefit standard, however, critics have argued that the standard does not do enough to differentiate between tax-exempt hospitals and their for-profit counterparts.[32] For example, health law professor, Mary Crossley, points out:

> [T]he vagueness of the existing federal community benefit standard and its historically lax enforcement mean that we do not really know what or how much beneficial conduct flows from tax exemption and its forgone revenue, or whether that conduct is closely related to improving access and health outcomes for the uninsured or other groups.[33]

Related to this failure of the community benefit standard to distinguish tax-exempt hospitals from their for-profit counterparts, other critics have pointed out the difficulty in determining which tax-exempt hospitals are actually providing substantial assistance and which ones are not.[34] In a study conducted in 2013, and subsequently published in *The New England Journal of Medicine*, hospital expenditures on charity care and other community benefits varied anywhere from twenty percent of some hospital operating

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[30] *Id.*
[31] *Id.*
[32] *Id.*
[32] Susannah C. Tahk, *Tax-Exempt Hospitals And Their Communities*, 6 COLUM. J. TAX L. 33, 41 (2014).
[33] *Id.* (citing Mary A. Crossley, *Nonprofit Hospitals, Tax Exemption and Access for the Uninsured*, 2 PITT J. ENVTL. PUB. HEALTH. L. 32-36 (2008).
[34] *Id.* at 42.

costs all the way down to less than one percent of others.[35]

Additionally, in its own study conducted in 2009, the IRS found that only a "small subgroup of tax-exempt hospitals [] seemed to be supplying most of the free or discounted care and other types of community benefits…."[36] The IRS' findings went on to state that "[u]ncompensated care and aggregate community benefit expenditures were unevenly distributed among hospitals and concentrated in a relatively small group."[37] As a result of all this, a series of lawsuits were filed against several tax-exempt hospitals in which the plaintiffs argued, albeit unsuccessfully, that tax-exempt hospitals, "while complying with the language of Revenue Ruling 69-545, actually violated the more general requirement that tax-exempt organizations serve the public interest."[38]

In one such case, a class action suit was brought challenging the authority of the IRS to enact and implement the community benefit standard on the grounds that the standard was "inconsistent with the term 'charitable' in IRC Section 501(c)(3) because it did not require treatment of the poor."[39] The issue before the Court hinged on whether the plaintiffs had suffered an injury due to the IRS' alleged misconduct. The case was ultimately dismissed on the grounds that the plaintiffs lacked standing to bring the suit.[40] The Supreme Court held that the plaintiffs failed to demonstrate that they had suffered an injury in fact, and therefore lacked standing.[41] The Court reasoned that "it was 'purely speculative' as to whether the hospitals had denied treatment because of the new ruling and not for other reasons and whether the plaintiffs' success would result in care being provided since hospitals could choose to give up their tax-exempt status if the cost was too high."[42]

The inadequacies of the community benefit standard became even more apparent when considered in light of the current climate of the healthcare industry as a whole. There is little disagreement over the profitability of the healthcare industry in America, but just

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[35] Gary J. Young et al., *Provision of Community Benefits by Tax-Exempt U.S. Hospitals*, 368 NEW ENG. J. MED. 1519 (2013).
[36] Tahk, *supra* note 32, at 42.
[37] *Id.* (citing IRS, *IRS Exempt Organizations (TE/GE) Hospital Compliance Projects Final Report* (2009), *available at* http://www.irs.gov/pub/irs-tege/frepthospproj.pdf).
[38] *Id.* (citing Leah S. Batchis, *Can Lawsuits Help the Uninsured Access Affordable Hospital Care? Potential Theories for Uninsured Patient Plaintiffs*, 78 TEMP. L. REV. 493, n.104 (2005)).
[39] Erika Lunder & Edward Liu, Cong. Research Serv., RL34605, *501(c)(3) Hospitals and the Community Benefit Standard* (2009) (referring to United States Supreme Court case *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26 (1976)).
[40] *Id.*
[41] *Id.*
[42] *Id.*

how profitable is it? According to the Centers for Medicare & Medicaid Services ("CMS"), the national health expenditures in 2016 reached a staggering $3.3 trillion, or $10,348 per person.[43]

Although much of the revenue generated within the industry can be attributed to, *inter alia*, the growth and expansion of biotech and pharmacy companies, spending on hospital care alone continues to increase, rising 4.7 percent in 2016 from the previous year, or $1.1 trillion.[44] Also, with a recent Forbes report projecting the healthcare industry to be one of the most profitable industries in the coming years, the strong growth rate the industry has enjoyed over the last few years does not appear to be on the decline anytime within the foreseeable future.[45]

Despite the healthcare industry's current growth, however, not every hospital has been able to share in these record-setting profits.[46] In fact, since the Affordable Care Act's ("ACA") coverage expansions have kicked in, much of the revenue has gone to the top hospital systems in the country.[47] To illustrate, the top seven hospitals in the country, as ranked by *U.S. News & World Report*, saw their revenues increase over fifteen percent within the span of two years.[48] Moreover, according to a 2016 study co-authored by health care economist, Gerard Anderson, seven of the ten most profitable hospitals in the country are nonprofit, tax-exempt entities.[49] Meanwhile, during the same two-year period, the charity care provided by these hospitals dropped by over thirty-five percent, despite the fact that the combined total of charity care provided by

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[43] *National Health Expenditures 2016 Highlights*, Ctrs. for Medicare and Medicaid, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-andReports/NationalHealthExpendData/downloads/highlight.pdf (last visited Jan. 4, 2018).

[44] *Id.*

[45] *See* Liyan Chen, *The Most Profitable Industries In 2016,* FORBES (Dec. 21, 2015), https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#14ebdb9d5716 (projecting health technology to be the most profitable sector in 2016 with a 21.6% net profit margin).

[46] *See* Becker's Healthcare, *60 things to know about the hospital industry*, BECKER'S HOSP. REV. (Jan. 14, 2016), https://www.beckershospitalreview.com/lists/50-things-to-know-about-the-hospital-industry-2016.html (57 rural hospitals have closed since 2010, and another 283 hospitals are at risk of closure).

[47] Dan Diamond, *How Hospitals Got Richer off Obamacare,* POLITICO (Jul. 17, 2017), https://www.politico.com/interactives/2017/obamacare-nonprofit-hospital-taxes/.

[48] *Id.*

[49] Ge Bai & Gerard F. Anderson, *A More Detailed Understanding of Factors Associated With Hospital Profitability*, HEALTH AFF. (May 1, 2016), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2015.1193.

these hospitals was already less than two percent of their total revenue.[50]

Nevertheless, in spite of these record-setting profits, millions of Americans remain uninsured,[51] and millions more, as a result of their medical bills, struggle to pay for even the most basic necessities, such as rent, food, and heat.[52] For example, notwithstanding the ACA's attempts to make affordable health coverage available to more individuals, medically related expenditures accounted for nearly sixty percent of all U.S. bankruptcies filed in 2013.[53] And, although medically related bankruptcies are largely a problem of the uninsured, a study conducted by both the *New York Times* and *Kaiser Family Foundation* found that "… roughly 20 percent of people under 65 with health insurance nonetheless reported having problems paying their medical bills over the last year."[54]

Consequently, for many of the reasons mentioned above, tax-exempt hospitals have been the subject of a fair amount of criticism over the past few years for not doing enough to help alleviate these issues.[55] As indicated by a recent *Politico* analysis, there is a significant amount of controversy surrounding the current requirements in place for tax-exempt hospitals and the role they should be playing in their communities.[56]

While experts continue to debate what the root cause of these issues might be, critics of the current system tend to agree on at least one thing: Tax-exempt hospitals, on the whole, are not providing enough value to their communities to justify the tax breaks they receive. Nevertheless, despite this criticism, as well as the community benefit standard's complete lack of efficacy, until the relatively recent developments of the ACA, the standard continued

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[50] *Id.*

[51] *Key Facts about the Uninsured Population,* HENRY J. KAISER FAM. FOUND. (Sept. 19, 2017), https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/.

[52] *See* Christina LaMontagne, *NerdWallet Health Finds Medical Bankruptcy Accounts for Majority of Personal Bankruptcies,* NERDWALLET (Mar. 26, 2014), https://www.nerdwallet.com/blog/health/medical-bankruptcy/. ("Nearly 10M American adults (ages 19-64) will be unable to pay for basic necessities like rent, food, and heat due to their medical bills.")

[53] *Id.*

[54] Margot Sanger-Katz, *Even Insured Can Face Crushing Medical Debt*, *Study Finds,* N.Y. TIMES (Jan. 5, 2016), https://www.nytimes.com/2016/01/06/upshot/lost-jobs-houses-savings-even-insured-often-face-crushing-medical-debt.html.

[55] *See generally* Michael Fricke, *The Case Against Income Tax Exemption for Nonprofits,* 89 ST. JOHN'S L. REV. 1129, 1129-83 (2016).

[56] *See* Politico, *supra* note 47.

to operate as the key determining factor for whether a hospital qualified for federal tax-exempt status.[57]

B. Incorporation of Section 501(r)

Due to the underwhelming results produced by tax-exempt hospitals under the community benefit standard, Congress looked to pass legislation that would help ensure that tax-exempt hospitals provided value to their communities that more closely corresponded to the value they received as tax-exempt organizations. Over the years, various ideas to reform the community benefit standard were proposed, including a legislative proposal that would have required tax-exempt hospitals spend a minimum of five percent of their annual net revenue on providing free care to indigent members of their communities.[58] Critics of proposed legislative changes to the community benefit standard argued that implementing such quotas and ridged benchmark standards would prevent hospitals from being able to be responsive to their own individual communities.[59]

Although most of these proposed reforms would never make it out of the draft stage of the legislative process, many of the ideas would later serve as the foundation for the new hospital-specific regulations that would be rolled out under the ACA.[60] Accordingly, due in large part to the efforts of Senator Charles Grassley[61], Congress promulgated the latest requirements for charitable 501(c)(3) hospitals in 2010 by enacting Section 501(r) of the ACA.[62] In addition to the community benefit standard, the new law required that hospitals adhere to a more exacting standard in return for tax-exempt 501(c)(3) status, including implementation of new rules concerning hospitals' financial policies, and the methods for assessing as well as acting on their community needs.[63] According to the latest regulations, hospital organizations seeking to maintain tax-exempt status must now comply with four additional requirements contained in Section 501(r) of the IRC.[64]

First, Section 501(r) requires that tax-exempt hospitals establish written financial assistance and emergency medical care

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[57] Tahk, *supra* note 32, at 40.
[58] *See* Senate Committee on Finance—Minority, *Tax Exempt Hospitals: Discussion Draft* at 7 (Jul. 18, 2007), https://www.finance.senate.gov/imo/media/doc/prg071907a.pdf.
[59] Joe Carlson, *Unlocking the community chest*, MOD. HEALTHCARE (Oct. 20, 2008), http://www.modernhealthcare.com/article/20081020/NEWS/810179939.
[60] Tahk, *supra* note 32, at 44.
[61] Chuck Grassley is the senior Senator from Iowa, serving since 1981. Senator Grassley is currently the ranking Republican on the Judiciary Committee.
[62] 26 U.S.C. § 501(r) (2012).
[63] *Id.*
[64] § 501(r)

policies ("FAPs").[65] Although Section 501(r) does not specifically lay out the eligibility criteria that a hospital's FAP must meet in order to comply with the statute, as long as a hospital's FAP includes the type of financial assistance the hospital has made available, and clearly states the eligibility criteria that an individual must meet to receive financial assistance, the hospital's FAP will be deemed to comply with Section 501(r)'s FAP requirements.[66]

Second, Section 501(r) requires that tax-exempt hospitals limit the amounts charged for emergency or other medically necessary care to individuals eligible for assistance under the hospital's FAP.[67] Now, tax-exempt hospitals are no longer allowed to charge uninsured patients—seeking emergency or other medically necessary care—any more than hospitals would otherwise charge individuals covered by insurance. The statute does, however, offer hospitals some flexibility as to the method used for calculating the amount "generally billed" for a particular medical service.[68] For example, the IRS has provided hospitals with two different methods of calculating the amount that is generally billed for a particular service—*i.e.*, the "look-back" and "prospective" methods.[69] Under the "look-back" method, the appropriate amount is determined by using a hospital's actual past claims paid out by both Medicare and private health insurers.[70] Alternatively, the "prospective" method provides hospitals with the ability to "estimate the amount that Medicare would reimburse the hospital for the care in question if the eligible patient were actually a Medicare fee-for-service beneficiary."[71]

Third, Section 501(r) also requires that tax-exempt hospitals make reasonable efforts to determine whether an individual is eligible for assistance under the hospital's FAP before engaging in "extraordinary collection actions" against the individual.[72] A hospital engages in extraordinary collection actions when the hospital either: (1) utilizes legal or judicial processes to procure payment of a charge that is otherwise covered under the hospital's

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[65] § 501(r)(4)(A)-(B).
[66] *Id.*
[66] Rachel Weisblatt, *Uncharitable Hospitals: Why the IRS Needs Intermediate Sanctions to Regulate Tax-Exempt Hospitals*, 55 B.C. L. REV. 687, 695 (2014).
[67] § 501(r)(5)(A)-(B).
[68] *See generally Additional Requirements for Charitable Hospitals,* 77 Fed. Reg. 38148-01, 38165 (proposed Jun. 26, 2012)(to be codified at 26 C.F.R. pt. 1).
[69] Weisblatt, *supra* note 66, at 696.
[70] *Id.*
[71] *Id.*
[72] *See* § 501(r)(6) ("Billing and collection requirements. An organization meets the requirement of this paragraph only if the organization does not engage in extraordinary collection actions before the organization has made reasonable efforts to determine whether the individual is eligible for assistance under the financial assistance policy ….").

FAP; (2) sells off any debt incurred by an individual to a debt collection agency; or (3) reports an individual's lack of payment to a consumer credit reporting agency.[73] Actions that require a legal or judicial process include, but are not limited to, obtaining a lien on an individual's property; forcing foreclosing on real property or seizing an individual's personal property; initiating a civil suit; or garnishing an individual's wages.[74]

Fourth, Section 501(r) mandates that tax-exempt hospitals conduct a community health needs assessment ("CHNA") at least once every three years.[75] In conducting the CHNA, the hospital should seek the input and advice of various representatives and health experts within the community in which the hospital resides.[76] Moreover, once a hospital has finalized its CHNA, the hospital must adopt an implementation strategy that allows the hospital to address the health needs of the community identified within its CHNA.[77]

Lastly, in order to fully comply with Section 501(r)'s CHNA requirements, the hospital organization must make its CHNA widely available to the public.[78] This is accomplished by uploading the CHNA to the hospital's website or some other easily accessible public forum.[79] Most importantly, any tax-exempt hospital that fails to conduct and implement a valid CHNA may be subject to a $50,000 excise tax fine for each year the hospital is not in compliance.[80] Except for the CHNA requirement, which went into effect for tax years beginning in 2012, each of the other Section 501(r) requirements went into immediate effect.[81]

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[73] *See* Weisblatt, *supra* note 66, at 696-97 (citing Prop. Treas. Reg. § 1.501(r)-6, 77 Fed. Reg. 38148, 38166 (Jun. 26, 2012) ("Actions that require a legal or judicial process include: (1) obtaining a lien on an individual's property; (2) foreclosing on an individual's real property; (3) attaching or seizing an individual's personal property; (4) commencing a civil suit against an individual; (5) causing an individual's arrest; (6) subjecting an individual to a writ of body attachment; and (7) garnishing an individual's wages.").

[74] *Id.* at 696.

[75] § 501(r)(3)(A)-(B).

[76] § 501(r)(3)(B)(i) ("[CHNA must] take[] into account input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health.").

[77] *Id.*

[78] § 501(r)(3)(B)(ii).

[79] 26 C.F.R. § 1.501(r)-3(b)(7)(i)(A)

[80] *See* Treas. Reg. § 53.4959-1 (2015) (allowing the imposition of a $ 50,000 excise tax on hospitals that fail to meet CHNA requirements).

[81] 1 Taxation of Hospitals & Health Care Organizations § 4.03 (2018) ("The effective dates for Section 501(r) were set forth in the statute itself. The financial assistance policy requirement, the restrictions-on-charges requirement, and the billing and collection requirement apply to taxable years beginning after the date of enactment of the Affordable Care Act, March 23, 2010. The CHNA and implementation plan requirement applies to taxable years beginning after March 23, 2012.").

II. THE IRS' ENFORCEMENT OF SECTION 501(R)

In early August of this past year, the IRS released a letter dated February 14, 2017, which stated that the IRS had revoked a "dual status" hospital's tax-exempt status for failing to comply with Section 501(r)'s requirements.[82] While the IRS did not identify the name of the hospital, the letter points out that the reason for the revocation action specifically related to the hospital's failure to follow through and implement Section 501(r)'s CHNA requirements.[83] More specifically, the hospital failed to conduct a community health needs assessment, adopt an implementation strategy, and promulgate the strategy to the public.[84]

The revocation of the hospital's tax-exempt status comes on the heels of heightened IRS enforcement measures to ensure hospital compliance. In the Tax Exempt and Government Entities FY 2017 Work Plan, released in September of 2016, the IRS stated that it conducted a review of 968 hospitals' websites and Schedule H filings, and had made a determination to refer 363, or nearly forty percent, of those hospitals for field examinations.[85] The Work Plan further indicated that the IRS intended to continue to conduct these reviews to ensure that hospitals were complying with Section 501(r)'s requirements.[86]

Despite the hospital industry having been placed on notice of these examinations, however, the IRS' revocation announcement came as a surprise to many within the industry.[87] Due to the unique circumstances surrounding the situation as the first revocation action taken by the IRS for noncompliance with Section 501(r), the announcement not only shocked many within the healthcare industry, but, more specifically, caused a significant amount of angst within the tax-exempt community regarding the extent to which the IRS was willing to go in order to enforce these new regulations.[88]

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[82] *See* Final Adverse Determination Letter (F.A.D.L), 3618 (Rev. 6-2012) (Feb. 14, 2017), https://www.irs.gov/pub/irs-wd/201731014.pdf.
[83] *Id.*
[84] *Id.*
[85] *Tax Exempt and Government Entities FY 2017 Work Plan*, IRS (amended Mar. 8, 2017), https://www.irs.gov/pub/irs-tege/tege_fy2017_work_plan.pdf.
[86] *Id.*
[87] Meg Bryant, *Reading The Tea Leaves in a Hospital's Loss of Tax-Exempt Status*, Healthcare Dive (Sept. 12, 2017), https://www.healthcaredive.com/news/reading-the-tea-leaves-in-a-hospitals-loss-of-tax-exempt-status/504363/.
[88] Rich Daly, *IRS Makes First Revocation of Hospital Not-for-Profit Status Under 501(r),* Healthcare Fin. Mgmt. Ass'n (Aug. 15, 2017), https://www.hfma.org/Content.aspx?id=55271.

III. THE EFFECT OF THE IRS' REVOCATION ACTION, AND WHETHER IT SIGNALS A CHANGE IN THE IRS' HESITANCY TO USE REVOCATION AS AN ENFORCEMENT MECHANISM

Over the years, the tax-exempt community had become accustomed to the IRS' lax enforcement of the community benefit standard; which, explains the community's response to the IRS' revocation action.[89] Historically, complete revocation of tax-exempt status was the only mechanism available to the IRS to enforce hospital compliance with the community benefit standard.[90] Due in large part to the far-reaching effects of revocation, however, the IRS has exhibited a hesitancy to use revocation to enforce the standard in years past.[91]

For most hospitals, revocation of tax-exempt status means more than not having to pay federal income taxes.[92] In fact, loss of tax-exempt status could force hospitals to cut back on offering valuable health services to the community, or worse, close down altogether. To illustrate, a hospital that has its tax-exempt status revoked, in addition to now having to pay income taxes, is also likely to lose its federal unemployment tax exemption, as well as its communications services excise tax exemption.[93]

Additionally, because many states confer nonprofit status on organizations that already qualify for federal tax-exemption, when a hospital's tax-exempt status is revoked, many states will often follow suit and revoke the hospital's nonprofit status, too.[94] Meaning, that once a hospital loses its federal tax-exempt status, there is a good chance the hospital will likely also lose any state tax benefits that come along with being classified as a nonprofit organization within the state.[95] Although nonprofit tax benefits vary state-to-state, the benefits usually include, but are not limited to, exemption from state property taxes, as well as exemption from state income tax, if applicable.[96]

Furthermore, the potential fall-out resulting from revocation does not stop there. In addition to the new tax liabilities mentioned above, revocation of tax-exempt status has the potential to affect a

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[89] Weisblatt, *supra* note 63, at 700.
[90] *Id.* at 697.
[91] *Id.*
[92] *Id.* (citing Jessica Berg, *Putting the Community Benefit Back into the "Community Benefit" Standard*, 44 GA. L. REV. 375, 380 (2010).
[93] *See Id*. at 698 (citing I.R.C. § 3301 (2012); § 4251 (2012)).
[94] *Id.*
[95] *Id.*
[96] *Frequently Asked Questions About Applying for Tax Exemption Internal Revenue Service*, IRS, https://www.irs.gov/charities-nonprofits/frequently-asked-questions-about-applying-for-tax-exemption (last updated June 14, 2018).

hospital's ability to raise capital.[97] For example, no longer would charitable donations to the hospital be eligible for personal tax benefits.[98] As a result, the revenue a hospital could expect to receive through personal charitable donations would undoubtedly decrease. Additionally, revocation of tax-exempt status prohibits a hospital from being able to issue tax-exempt "qualified bonds," thus cutting off one of the more effective means nonprofit hospitals have of raising capital.[99] In sum, there can be little question as to why the IRS was so hesitant to use revocation as a means of enforcing the community benefit standard in years past, and also explains the industry's shock at the news that the IRS had actually used revocation as a means of enforcing Section 501(r).

Further details surrounding the IRS' revocation action, however, strongly suggest that the situation was more akin to that of an outlier rather than the new norm. Instead, what is more likely, the IRS used the uniqueness of the situation as an opportunity to send a strong message to the rest of the tax-exempt community that the new regulations should not be taken lightly. The uniqueness of this particular revocation action is demonstrated by the fact that the hospital seemed to have freely relinquished its tax-exempt status; making it clear the hospital thought it had more to gain through noncompliance than to adhere to the new CHNA requirements.[100]

First, in its revocation letter, the IRS specifically stated that a Revenue Agent had met with the executive team of the hospital– including the CEO, CFO, and COO–and on several occasions during the interview, the hospital's administration team made clear that the hospital "really did not need, actually have any use for, or want their tax-exempt status..."[101] Additionally, although the hospital's administrators indicated that the "[hospital] had neither the will, financial resources, nor the staff to follow through with the CHNA process,"[102] the letter included some additional statements made by the hospital's administration team indicating that a lack of resources was not the only—nor was it the main—reason for choosing not to comply with Section 501(r)'s CHNA requirements. For example, the letter states that the hospital's administrators freely admitted to only maintaining tax-exempt status "in case any liabilities arose relating to the prior management company who had originally obtained this status from the [IRS]."[103]

Moreover, the letter went on to state that the hospital's administrators also claimed that the hospital's tax-exempt status

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[97] Weisblatt, *supra* note 63, at 699.
[98] *Id.*
[99] *Id.*
[100] *See* F.A.D.L., *supra* note 82, at 2.
[101] *Id.*
[102] *Id.* at 6.
[103] *Id.* at 2.

"actually prevented the [hospital] from becoming involved in some of the various Medicaid reimbursement or payment arrangements."[104] Thus, as demonstrated by the words and actions of the hospital's administration team, not only did the hospital not value its 501(c)(3) status, but it was clear the hospital thought it was better off without it.

Second, the requirements of Section 501(r) are set up in such a way that if the hospital was serious about complying with the regulations, it would likely have been able to do so. As previously indicated, unlike the enforcement measures available to the IRS under the community benefit standard, which limited the IRS' enforcement options to either complete revocation or turning a blind eye to noncompliance altogether, under the new Section 501(r) regulations, the IRS has at least some flexibility to work with noncompliant hospitals before pursuing revocation.[105]

For example, the regulations specifically allow for the IRS to excuse or dismiss minor or inadvertent violations.[106] However, according to the tax director of BDO Consulting's healthcare and nonprofit and education practices, Laura Kalick, it is important to remember that minor really does mean minor.[107] According to the regulations, an example of a minor violation would include a situation where documents may have been temporarily unavailable due to a hospital's website being down.[108]

With that said, the IRS is free to dismiss other types of infractions or violations, provided they do not rise to the level willful or egregious noncompliance with the regulations, and are promptly disclosed and corrected by the offending hospital.[109] And, while it is true that the IRS still retains the ultimate authority to revoke a hospital's tax-exempt status in instances of willful or egregious violations of Section 501(r),[110] the regulations specifically require

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[104] *Id*.

[105] Crossley, *Health and Taxes: Hospitals, Community Health and the IRS*, 16 YALE J. HEALTH POL'Y L. & ETHICS 51, 97 n. 201 (2016) ("The possible consequences range from the revocation of §501(c)(3) status for an organization, to the imposition of a $50,000 excise tax, to the IRS's ignoring minor omissions and errors that are either inadvertent or due to reasonable cause. If a hospital organization operates multiple hospitals and one of them fails to comply, the income from the noncompliant hospital facility will be subject to taxation.").

[106] 26 C.F.R. § 1.501(r)-2(b)(1)(ii) (2015); Erica A. Clausen and Abbey L. Hendricks, *Cultivating the Benefit of § 501(r)(3) Requirements for Nonprofit Hospitals*, 20 LEWIS & CLARK L. REV. 1025, 1038 (2016) ("An omission or error related to the CHNA that is minor or inadvertent is not considered to be a "failure" to meet § 501(r) obligations, therefore penalties under § 4959 are not appropriate."); *See* T.D. 9708, 2015-5 I.R.B. 344-45.

[107] *See* Bryant, *supra* note 87.

[108] Rev. Proc. 2015-21, 2015-13 I.R.B. 817, § 5.03 (Mar. 10, 2015).

[109] *Id.* § 5.04.

[110] 26 C.F.R. § 1.501(r)-(2)(c).

that in the event such a case arises, the IRS should apply a facts and circumstances test in order to determine whether revocation is warranted.[111]

Moreover, although the new regulations provide the IRS with the authority to levy excise fines of $50,000 per year against hospitals that fail to conduct a valid CHNA, typical of most types of healthcare legislation, the IRS has not specifically defined how a valid CHNA must be conducted and implemented to be in compliance with Section 501(r).[112] Meaning, so long as the basic requirements of the CHNA are met, the framework of Section 501(r) provides flexibility by which hospitals can creatively address the healthcare needs and disparities within their own communities without fear of being penalized for non-adherence to a ridged and formalized standard. It would seem, then, due to the flexibility available to the IRS in situations not arising to the level of willful noncompliance, the IRS may be willing to forgive instances of noncompliance, so long as a good faith effort to comply with the regulations can readily be determined.

Furthermore, although more details would need to be known in order to assess the exact feasibility of this particular hospital's ability to conduct and implement a valid CHNA, in order to demonstrate compliance with Stark[113] and the Federal Anti-

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[111] *Id.* § 1.501(r)-(2)(a) (Factors the Commissioner will take into consideration include: "(1) Whether the organization has previously failed to meet the requirements of section 501(r), and, if so, whether the same type of failure previously occurred. (2) The size, scope, nature, and significance of the organization's failure(s). (3) In the case of an organization that operates more than one hospital facility, the number, size, and significance of the facilities that have failed to meet the section 501(r) requirements relative to those that have complied with these requirements. (4) The reason for the failure(s). (5) Whether the organization had, prior to the failure(s), established practices or procedures (formal or informal) reasonably designed to promote and facilitate overall compliance with the section 501(r) requirements. (6) Whether the practices or procedures had been routinely followed and the failure(s) occurred through an oversight or mistake in applying them. (7) Whether the organization has implemented safeguards that are reasonably calculated to prevent similar failures from occurring in the future. (8) Whether the organization corrected the failure(s) as promptly after discovery as is reasonable given the nature of the failure(s). (9) Whether the organization took the measures described in paragraphs (a)(7) and (a)(8) of this section before the Commissioner discovered the failure(s).").

[112] Allison Simpson & David Williams, *The How's and Why's of A Community Health Needs Assessment: A Project Guide for Health Care Attorneys,* Health Lawyers (2012), https://www.healthlawyers.org/Events/Programs/Materials/Documents/Tax12/f_simpson_williams.pdf.

[113] *See* 42 USC § 1395nn (2018) (For Stark law enacted for the purpose of curbing physician self-referral which lead to increasing healthcare prices).

Kickback Statute,[114] hospitals have conducted similar types of assessments for years and are likely already familiar with assessing the healthcare needs of their communities.[115] In fact, in order to develop compliance plans, most—if not all—hospitals have already analyzed the demographics, as well as accessibility to healthcare facilities and physician services within their community.[116]

The feasibility of conducting and implementing a valid CHNA is further demonstrated by the release of the IRS' final rule clarifying the implementation and requirements of Section 501(r).[117] According to the final rule, published by the Federal Register on Dec. 31, 2014, hospitals are allowed to collaborate with each other to produce a single, joint CHNA report and implementation strategy.[118] Meaning, hospitals are free to collaborate and consolidate resources, so long as the hospitals have defined their communities to be the same, and the leadership teams from each hospital agree to adopt and implement the CHNA strategy.[119] As a result, in addition to a host of useful information available to the hospital online (*i.e.*, CHNA templates, assessment and implementation plans posted online by other hospitals, *etc.*), the hospital may have been able to seek the assistance of another hospital to produce a valid CHNA.

Finally, further signaling the uniqueness of the situation at hand—and why this particular revocation action is unlikely to signal a change in regards to the IRS' willingness to rely on revocation as a realistic option—is the fact that the hospital operated as a "dual status" hospital.[120] "Dual status" hospitals are government-run hospitals that do not require 501(c)(3) status to qualify for exemptions as charitable organizations.[121] As a "dual status"

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[114] *See id.* § 1320a-7b(b) (For the Anti-Kickback Statute, making it a criminal offense—unless a safe harbor applies—to knowingly and willfully exchange any remuneration, or anything of value, in order to induce or receive a reward for referring items of service payable by federal health care programs).

[115] For an example of a typical hospital compliance plan *see Iredell Health System (IHS) Compliance Plan,* (2015), https://www.iredellhealth.org/documents/2015-Iredell-Compliance-Plan.pdf.

[116] *See id.*

[117] *See generally* I.R.C. § 501(r).

[118] *See* Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return, 79 Fed. Reg. 78, 954-01, 2015-5 I.R.B. 337 (Dec. 31, 2014).

[119] *Id.*

[120] F.A.D.L., *supra* note 82, at 2.

[121] Marc Berger, *IRS Revokes Hospital's Tax-Exempt Status, Shedding Light on Section 501(r) Compliance Concerns*, BDO (Aug. 17, 2017), https://www.bdo.com/blogs/healthcare/august-2017/irs-revokes-hospital%E2%80%99s-tax-exempt-status ("A dual status hospital is a government hospital that would be exempt from tax because of its relation to the government. Forty or so years ago, many government hospitals applied for

hospital, the loss of tax-exempt status is unlikely to affect the hospital's bottom line in any meaningful way.

This begs the question: *would the IRS have revoked the hospital's tax-exemption status had the hospital not qualified as a "dual status" hospital?* On the one hand, the answer to this question is: *maybe*. Considering the hospital's complete lack of action, as well as the statements made by the hospital's administrators to the Revenue Agent, it is clear that the hospital was operating in willful violation of Section 501(r)—undoubtedly. On the other hand, however, due to the hospital's "dual status," the facts tend to indicate there is a strong possibility the IRS would not have acted in the same way had the hospital had more to lose, or, at the very least, demonstrated a willingness and good faith effort to comply.

With that said, depending on how much value a particular hospital places on its tax-exempt status, there is also a good chance that had the situation involved a non "dual status" hospital, the hospital would have done more to work with the IRS in order to keep its tax-exempt status intact. As a result, outside of the unique circumstances this particular situation presents, it is hard to imagine a situation in which a hospital would willingly give up its tax-exempt status without at least contesting the revocation action in some way or another.

Nevertheless, Despite the unique circumstances surrounding the revocation action, tax-exempt hospitals would be well served to acknowledge the potential implications of such a decision. Recognizing there are challenges associated with implementing the new Section 501(r) regulations,[122] there are ways in which tax-exempt hospitals can ensure revocation of their tax-exempt status never occurs.

First, tax-exempt hospitals' policies must be up-to-date.[123] That is, to comply with the final rule, tax-exempt hospitals must ensure their financial assistance, billing, and collection policies are all up-to-date.[124] According to health law attorney, Andrew Kloeckner, if a hospital has not updated these policies since

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section 501(c)(3) status so they could take advantage of offering certain pension plans to their employees that were only available to the employees of section 501(c)(3) organizations, and to make it easier to solicit charitable contributions with the familiar 501(c)(3) status.").

[122] *See* Michael Wyland, *Hospital Loses IRS Tax Exemption for Noncompliance with ACA*, NONPROFIT QUARTERLY (Aug. 18, 2017), https://nonprofitquarterly.org/2017/08/18/hospital-loses-irs-tax-exemption/ (Initial cost estimates for conducting and implementing a valid CHNA can range anywhere from $60,000 to $150,000 depending on the size of the hospital, as well as the complexity of the community it serves).

[123] 26 C.F.R. § 1.501(r)(4)(b)(1)(i).

[124] Andrew Kloeckner, *IRS Actively Auditing Hospitals For 501(r) Compliance*, Baird Holm, LLP (Jun. 14, 2017), https://www.bairdholm.com/in-the-news/entry/irs-actively-auditing-hospitals-for-501-r-compliance.html.

December 29, 2014, the hospital is unlikely to be compliant with the new regulations.[125] Additionally, it is important to note, these policies can only be approved by the Board of Directors for the hospital, or, in some cases, a subcommittee of the Board.[126]

Second, it is not enough that a CHNA was conducted. In fact, there is evidence that the "dual status" hospital discussed above had in fact completed a CHNA before losing its tax-exemption status.[127] According to the IRS' revocation letter, the hospital claimed to have conducted a CHNA.[128] The letter goes on to state, however, that "[t]he CHNA report was never made widely available for the public via a website."[129] Consequently, in addition to conducting a CHNA, to ensure compliance, tax-exempt hospitals must upload their CHNA reports to their websites.[130] It is not enough that these reports merely exist and are available upon request.[131]

Third, tax-exempt hospitals must act on the information produced in these CHNAs.[132] In addition to conducting CHNAs and making them widely available to the public, tax-exempt hospitals' leadership teams must develop, implement, and put into action plans that address the community needs identified in each hospital CHNA.[133] Lastly, using Form 990,[134] tax-exempt hospitals are required to report a description of how they are addressing these needs, and "provide a description of any needs their CHNAs are not addressing, and the reasons for why those needs are not being addressed."[135]

IV. EVALUATING 501(R): DOES IT GO FAR ENOUGH?

As previously mentioned, Congress—by enacting Section 501(r) into the ACA—altered the legal framework surrounding hospital tax-exemption.[136] This change, although not perfect, is a step in the right direction. Now, for the first time, due mainly to Section 501(r)'s "Schedule H" requirement, hospitals must justify

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[125] *Id.*
[126] § 1.501(r)(4)(d)(1).
[127] F.A.D.L., *supra* note 82, at 2.
[128] *Id.*
[129] *Id*.
[130] § 501(r)-3(b)(7)(i)(A).
[131] F.A.D.L., *supra* note 82, at 2.
[132] § 1.501(r)-3(a)(2).
[133] *Id.*
[134] *About Form 990, Return of Organization Exempt from Income Tax*, IRS https://www.irs.gov/forms-pubs/about-form-990 ("Tax-exempt organizations, nonexempt charitable trusts, and section 527 political organizations file this form to provide the IRS with the information required by section 6033.").
[135] Kloeckner, *supra* note 125.
[136] Tahk, *supra* note 32, at 35.

their tax-exempt status by demonstrating that they are benefiting their communities.[137] And, using the answers provided through these Schedule H filings, we now have hard, concrete data by which we can quantify the "benefits" being provided by tax-exempt hospitals.[138] In turn, this information can be used to hold the tax-exempt hospital community more accountable.

The results of these Schedule H filings may come as a surprise. Taken together, the data suggests that, although the manner and mode by which hospitals have chosen to benefit their communities varies, tax-exempt hospitals *are*, on the whole, responding to the needs of their communities.[139] In fact, the data from the Schedule H filings revealed that the median amount of charity care provided by tax-exempt hospitals is 5.04% of total operating budget, with a mean of 6.01%.[140] And, after adding in other community benefit variables such as "bad debt," the mean rises to 8.58% of total expenses, or a median of 7.45%—a higher percentage than the mandatory charity care minimum of 5% advocated for by Senator Grassley, and others.[141]

Keeping this in mind, of concern, however, is the large gap between hospitals that far exceed 7.5% in community benefit expenditure and those that fall far below—with hospital expenditures on community benefits ranging anywhere from some hospitals spending as little as 1% to some hospitals spending as much as 20% of their entire budgets on providing these services.[142] Again, requiring that hospitals spend a mandatory minimum of 5% on charity care is not the answer. Imposing a mandatory minimum, however well-intentioned, although likely to help ameliorate the disparity between hospital charity care spending on some level, would result in an even more undesirable outcome: A decline in overall charity care spending across the board.[143] A mandatory minimum would only incentivize hospitals at the high end of the charity care decile to reduce their charity care spending—as was demonstrated to be the case in Texas after the passage of its own mandatory minimum law[144]— in order to more closely conform to the minimum statutory requirement.

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[137] *Id.*
[138] *Id.*
[139] *Id.* at 36.
[140] *Id.* at 61.
[141] *Id.*
[142] Young, *supra* note 35, at 1522.
[143] Tahk, *supra* note 32, at 53.
[144] *See* Tahk, *supra* note 32, at 53 (1993 Texas law requiring that the State's nonprofit hospitals spend a fixed percentage of net revenue (generally 4%) on charity care actually resulted in an overall decrease in charity care spending across the board).

Unfortunately, there are no easy policy answers to address, what appears to be, the proclivity of some hospitals to provide substantially far less charity care than their peers.[145] However, all is not lost. As Susannah Tahk, Assistant Professor of Law at the University of Wisconsin Law School points out, there are a few viable options that could easily be implemented that would immediately help to even the playing field and more closely align hospital charity care spending, without causing a reduction in overall charity care spending.[146]

First, Congress should define, for purposes of the CHNA requirement, the communities in which each hospital operates by taking geographic location into account. Ironically, this was the original approach taken by the IRS before altering its position in response to public comments that recommended that geographical boundaries not be included in the definition of community.[147] As a result, under the current regulations, hospitals are free to define their communities as they see fit, applying a "facts-and-circumstances approach."[148] Consequently, although a hospital may not define its community in a way that excludes "medically underserved, low-income, or minority populations who are part of its patient populations,"[149] there is very little oversight into how hospitals define their individual communities. This lack of oversight, as well as a clear definition of community, incentivizes hospitals to define their communities in ways that are most advantageous to themselves. Adopting a clear definition of community, based on geographical boundaries, as part of the CHNA requirement would ensure that tax-exempt hospitals actually service their communities.

Second, Section 501(r)'s FAP requirement should be more clearly defined. At present, under Section 501(r)'s FAP requirements, tax-exempt hospitals are free to determine the substance of their own individual FAPs, so long as the FAPs are responsive to hospitals' self-performed CHNAs.[150] Under the current regulations, because tax-exempt hospitals are free to establish their own FAPs, a hospital could hypothetically speaking, implement a FAP that essentially states that the hospital does not offer any free or discounted care. As a result, the hospital would still be able to charge indigent patients chargemaster—*i.e.*, highly inflated—rates.[151] If, in response, the indigent patient could not afford to pay these rates a hospital could, after first making a

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[145] *Id.* at 81.
[146] *Id.*
[147] *See* Community Health Needs Assessments for Charitable Hospitals, 78 Fed. Reg. 20523 (proposed Apr. 5, 2013).
[148] *Id.* at 20529.
[149] *Id.*
[150] *See* Tahk, *supra* note 32, at 46.
[151] *Id.*

determination that the patient is not eligible for any free or discounted care under the hospital's FAP, foreclose, without recourse, on the indigent patient's home for nonpayment.[152] Due to the flexibility Congress has afforded tax-exempt hospitals to determine the substantive details of their own FAPs, the disparity in charity care being provided amongst tax-exempt hospitals should not come as a surprise.

To help resolve this issue, and ultimately close the disparity gap in charity care spending, Congress should require that all hospital FAPs include certain baseline specifications: For example, all FAPs should calculate aid eligibility using patients' income as the determining factor. At present, over 25% of hospitals do not currently use income as a means for determining aid eligibility, relying instead on some other metric (*i.e.*, insurance status, medical indigence, Medicare/Medicaid recipient, *etc.*).[153] Incorporating a requirement that hospitals look at patient income to determine aid eligibility will result in uniformity across hospital FAPs—making it easier to calculate each hospital's charity care output.

Not only should income be the universal determinant for whether a patient qualifies for aid eligibility, but the income eligibility line should be unambiguous and consistent across the board. Although this Note does not presume to know where this line should be drawn, looking at a patient's income as a percentage of the federal poverty line (FPL) seems to be the most logical and clear-cut solution. Hypothetically speaking—and for purposes of illustration—the line for free care could be drawn at 200-300% of the Federal Poverty Line (FPL). This number would increase, on the other hand, for determining whether a patient is eligible for discounted care—*e.g.*, 300-400% of FPL. No matter where the line is ultimately drawn, a clear-cut rule would not only make it easier for hospitals to implement but would help to ensure that the most indigent patients are the first to receive these free or discounted health services.

Incorporating these changes, while still understanding they are not the be-all-end-all to every issue of concern, will—taken in conjunction with the other requirements of Section 501(r)—help to improve the disparity gap in charity care spending between tax-exempt hospitals; thus, help to ensure that hospitals receiving the benefits of tax-exemption are also contributing their fair share back into their communities.

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[152] *Id.*
[153] *Id.* at 71.

V. CONCLUSION

In conclusion, the historically amorphous nature of the regulations surrounding hospital tax-exemption, taken in conjunction with IRS' lax enforcement, have caused many to question the efficacy of tax-exempt hospitals. Section 501(r), however, is a step in the right direction. Section 501(r), for the first time, places unambiguous and quantifiable requirements on hospitals seeking tax-exempt status. Because of Section 501(r), specifically the Schedule H filing requirement, we now have the ability to take a closer look at hospital expenditures on charity care. Nevertheless, the reality of the situation remains, despite the introduction of Section 501(r) and the IRS' recent revocation action, there has been little substantive change. As a result, the new regulations (as written and presently enforced) do not pose a serious threat that loss of tax-exempt status will occur to hospitals that demonstrate an interest—even to the slightest degree—in maintaining tax-exempt status.

Based on the findings of the Schedule H filings, however, there are certain measurable steps Congress can take to improve upon Section 501(r), and thus ensure every hospital receiving the benefits of tax-exemption are contributing their fair share of charity care services to their communities. These steps include, but are not limited to: (1) Adopting a clear definition of community that is based on geographical boundaries; and (2) Expanding Section 501(r)'s existing FAP requirement to also include a requirement that hospitals determine financial assistance eligibility by looking at patients' income, as a percentage of the FPL. Implementing these relatively simple changes into the Code will help to ensure that Section 501(r) accomplishes its intended purpose.

AMERICA: LAND OF THE SHACKLED

LAUREN MARTIN

I. INTRODUCTION

When Elizabeth Warren, United States Senator for Massachusetts, ran into Gavin Newsom, the Lieutenant Governor of California, on her way to discuss the Dignity for Incarcerated Women Act,[1] his response was representative of the majority of reactions she gets when she mentions the bill: "What? They do that?"[2] The Dignity Act, a bill that was introduced in Congress on July 11, 2017, "would make a series of common-sense reforms to

[1] S. 1524, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/1524/text.

[2] C.J. Ciaramella, *Bill Introduced in Congress to Ban Shackling and Solitary Confinement of Pregnant Women*, REASON.COM: HIT & RUN (July 11, 2017, 5:30 PM), http://reason.com/blog/2017/07/11/bill-introduced-in-congress-to-ban-shack.

how the federal system treats incarcerated women."[3] One such reform includes a ban on the use of restraints on pregnant inmates.[4] Although at first blush it may seem like an archaic practice, the shackling of pregnant inmates, even during labor, continues to be a problem in the United States.

Despite adverse rulings by several courts, the practice of shackling pregnant inmates persists, forcing women who were pregnant and subjected to the use of restraints to litigate the issue in hopes of restoring their dignity and attaining compensation for lingering injuries caused by shackling.[5] As established by the courts, shackling pregnant inmates constitutes a condition of confinement in violation of the Eighth Amendment prohibition against cruel and unusual punishment.[6] Several states have been proactive in enacting anti-shackling legislation,[7] and a bill has recently been introduced in Congress which would ban the practice in federal prisons.[8] However, despite adverse court rulings and a few state statutes, the practice persists in those places that do not have legislation in place to protect these women's rights.[9] For this reason, it is necessary that both the federal government and state governments enact legislation banning the practice, so that this human rights violation might be eradicated, and so that the United States might be worthy of its reputation as the land of the free.

This Note will demonstrate the detrimental effects of shackling a pregnant woman and will examine some of the efforts currently being made to prohibit the practice, as well as provide some suggestions for prohibitory legislation. Part II of this Note will discuss the background of this pervasive issue, both how it has been viewed by the courts and the ways in which it has been dealt with

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[3] *Senators Booker, Warren, Durbin, Harris Introduce Landmark Bill to Reform the Way Women Are Treated Behind Bars*, ELIZABETH WARREN: U.S. SENATOR FOR MASS. (July 11, 2017), https://www.warren.senate.gov/?p=press_release&id=1727.

[4] *Id.*

[5] *See* Villegas v. Metro. Gov't of Nashville, 709 F.3d 563 (6th Cir. 2013); Nelson v. Corr. Med. Sers, 583 F.3d 522 (8th Cir. 2009); Brawley v. Washington, 712 F. Supp. 2d 1208 (W.D. Wash. 2010); Women Prisoners of the D.C. Dep't of Corr. v. District of Columbia, *et al.*, 877 F. Supp. 634 (D.D.C. 1994).

[6] *See* cases cited *supra* note 5.

[7] AZ, CA, CO, DE, D.C., FL, HI, ID, IL, LA, ME, MD, MA, MN, NV, NM, NY, PA, RI, TX, VT, WA, WV. *2017 ACOG State Legislation Tally*, Am. Cong. of Obstetrics and Gynecology, https://www.acog.org/-/media/Departments/State-Legislative-Activities/2017ShacklingTally.pdf?dmc=1&ts=20171029T2052480513.

[8] S. 1524, 115th Cong. (2017), https://www.congress.gov/bill/115th-congress/senate-bill/1524/text.

[9] Martin v. County of Milwaukee, *et al.*, No. 2:14-cv-00200 (E.D. Wis. 2014) (occurring in a state which, even in 2017, has not enacted anti-shackling legislation).

by state legislatures that have enacted anti-shackling laws. Part III of this Note will analyze the positions of those who support a ban on the use of restraints on pregnant inmates and detainees. Part III will also address *Martin v. County of Milwaukee*, a case tried in July of 2017 which concerns issues central to this Note. Part IV will demonstrate the necessity of anti-shackling legislation and present suggestions for legislators to consider when enacting a statute of this kind.

II. BACKGROUND

A. Case Law

There are four major cases addressing shackling of pregnant women: *Women Prisoners of the D.C. Department of Corrections v. District of Columbia, et al.*[10]; *Nelson v. Correctional Medical Services*[11]; *Brawley v. Washington*[12]; and *Villegas v. Metropolitan Government of Nashville*.[13] These cases are important in understanding how this issue has progressed through the courts and in establishing a base knowledge of existing precedent, which holds that shackling is a violation of the Eighth Amendment to the Constitution of the United States, and is thus a violation of basic human rights.

In order to establish an Eighth Amendment claim, plaintiffs are required to meet a relatively high bar. The courts have held that in order to prevail on an Eighth Amendment claim of cruel and unusual punishment, an inmate must satisfy a two-part test involving both an objective prong and a subjective prong.[14] The first prong, the objective analysis, asks "whether shackling pregnant detainees in the manner and under the circumstances in which Plaintiff was shackled creates a substantial risk of serious harm that society chooses not to tolerate."[15] In other words, "the shackling of pregnant detainees while in labor [must] offend[] contemporary standards of human decency such that the practice violates the Eighth Amendment's prohibition against 'cruel and wanton infliction of pain'…"[16] The courts recognize that prison is not intended to be "comfortable," so "only those deprivations denying the minimal civilized measure of life's necessities are sufficiently grave to form

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[10] *See* Women Prisoners of the D.C. Dep't of Corr. v. District of Columbia, *et al.*, 877 F. Supp. 634 (D.D.C. 1994).
[11] Nelson v. Corr.l Med. Servs, 583 F.3d 522 (8th Cir. 2009).
[12] Brawley v. Washington, 712 F. Supp. 2d 1208 (W.D. Wash. 2010).
[13] Villegas v. Metro. Gov't of Nashville, 709 F.3d 563 (6th Cir. 2013).
[14] *Id.* at 571.
[15] *Id.*
[16] *Id.* at 574.

the basis" of a Plaintiff's claim.[17] As to what exactly constitutes a contemporary standard of decency, the courts will look to expert opinion, "but such information does not define the 'constitutional minima' and 'cannot weigh as heavily in determining contemporary standards of decency as the public attitude toward a given sanction.'"[18]

The second prong, or the subjective portion of the analysis, asks "whether the officers had knowledge of the substantial risk, recognized the serious harm that such a risk could cause, and, nonetheless, disregarded it."[19] Thus, the plaintiff asserting an Eighth Amendment claim for shackling during pregnancy must establish "that prison officials acted with 'deliberate indifference' to inmate health or safety."[20] There are several ways an inmate might prove deliberate indifference on the part of prison officials. For example, a plaintiff may introduce "circumstantial evidence" which could allow a jury to find that "a prison official knew of a substantial risk from the very fact that the risk was obvious."[21] In addition, a plaintiff may demonstrate that "the risk was 'longstanding, pervasive, well-documented, or expressly noted by prison officials in the past, and the circumstances suggest that the defendant-official being sued had been exposed to information concerning the risk and thus "must have known" about it."[22] Although it is possible for a prison official to claim ignorance, he or she "may not refuse to investigate facts or inferences that he strongly suspects indicate the existence of a condition which violates the Eighth Amendment."[23]

i. Women Prisoners

Women Prisoners of the D.C. Dep't of Corr. v. District of Columbia, which was certified as a class action in December of 1993, was brought by and representative of "all women prisoners who are incarcerated in the District of Columbia correctional system as of October 1, 1993, and all women prisoners who will hereafter be incarcerated in the D.C. correctional system."[24] The class alleged many different forms of abuse against the D.C. correctional system, including shackling pregnant inmates during pregnancy, labor, and postpartum recovery.[25] One such inmate, identified as Jane Doe L, was forced to give birth in her jail cell after jail officials refused to

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[17] *Women Prisoners of the D.C. Dep't of Corr.*, 877 F.Supp. at 663.
[18] *Id.* at 664.
[19] *Villegas*, 709 F.3d at 575.
[20] *Women Prisoners of the D.C. Dep't of Corr.*, 877 F.Supp. at 664.
[21] *Id.* at 664.
[22] *Id.*
[23] *Id.*
[24] *See Women Prisoners of the D.C. Dep't of Corr.*, 877 F.Supp. at 638-39.
[25] *Id.* at 646-47.

transport her to the hospital, despite the fact that her contractions were a mere five minutes apart.[26] Almost immediately after she delivered her baby, "guards placed her in handcuffs and leg shackles and sent her by ambulance" to the hospital.[27]

In examining the case, the court found additional evidence of the use of restraints on pregnant inmates.[28] For example, "[a] physician's assistant stated that even when a woman is in labor 'their ankles and their hands are cuffed.'"[29] It was also common practice to restrain pregnant inmates by means of "leg shackles, handcuffs and a belly chain with a box that connects the handcuffs and the belly chain" while transporting them to medical appointments.[30]

Presented with these facts, the court found that shackling pregnant inmates while in labor and during postpartum recovery was inhumane, and thus a violation of 42 U.S.C. § 1983 and the Eighth Amendment.[31] In particular, the court held that these practices "violate[d] contemporary standards of decency."[32] However, the court did limit its finding by stating that instances in which a woman had a history of escape or assault may qualify as acceptable reasons for shackling.[33] In addition, the court only took issue with shackling during labor and immediately following.[34] It found no problem in utilizing leg shackles during the third trimester of pregnancy, but did state that "the physical limitations of pregnancy and the pain involved in delivery make complete shackling redundant and unacceptable in light of the risk of injury to a woman and baby."[35]

ii. *Nelson*

Shawanna Nelson had, to say the least, a harrowing experience as a woman who was pregnant when arrested and delivered her child while incarcerated.[36] When the time came to deliver her child, Nelson was shackled during transport to the hospital, her legs were shackled to the wheelchair upon arrival, and both of her ankles were shackled to her hospital bed.[37] By the time she was given a hospital bed, Nelson's cervix was dilated to 7 centimeters, meaning she was in the final stages of labor when her

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[26] *Id.* at 646.
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Id.* at 668-69.
[32] *Id.* at 668.
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] Nelson v. Corr. Med. Servs., 583 F.3d 522, 524 (8th Cir. 2009).
[37] *Id.* at 525.

ankles were shackled to both sides of her hospital bed.[38] Each time a nurse came to measure her cervix, her shackles were removed and then replaced as soon as the nurse had finished.[39] Nelson was forced to endure all of this despite the fact that she "did not present a flight risk or any other security concern."[40] In fact, "[the Officer's] own testimony indicate[d] that she was aware that shackling a woman in labor was hazardous and contrary to medical needs."[41] Nelson's shackles were finally removed just before she was taken to the delivery room, but only at the doctor's request.[42] Nelson alleged that being shackled before, during, and after labor caused severe repercussions, including: extreme mental anguish and pain, permanent hip injury, torn stomach muscles, an umbilical hernia requiring surgical repair, damage to her sciatic nerve, injured and deformed hips, inability to sleep or bear weight on her left side or sit or stand for extended periods, and inability to have more children.[43]

Interestingly, the Arkansas Department of Corrections had policies in place which should have suggested to the officers that shackling Nelson was inappropriate.[44] For instance, "Administrative Regulation 403 … stated the ADC policy that shackles were to be used 'only when circumstances require the protection of inmates, staff, or other individuals from potential harm or to deter the possibility of escape.'"[45] In addition, "any officer responsible for transporting an inmate to a hospital [was required] to 'use good judgment in balancing security concerns with the wishes of treatment staff and the medical needs of the inmate' before shackling an inmate during a hospital stay."[46] Yet, despite these policies, the officers shackled Nelson, and, as a consequence, she sustained serious permanent injuries.[47]

In reviewing Nelson's case, the court first examined whether the officer who shackled Nelson had acted with deliberate indifference.[48] The court found that the Officer should have been aware of the risk of harm to Nelson and her unborn child.[49] This, coupled with the Officer's own testimony that she would not shackle a pregnant woman due to the possibility of adverse health

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[38] *Id.*
[39] *Id.* at 526.
[40] *Id.* at 534
[41] *Id.*
[42] *Id.* at 526.
[43] *Id.*
[44] *Id.* at 527.
[45] *Id*.
[46] *Id.*
[47] *Id*. at 526.
[48] *Id.* at 528.
[49] *Id.* at 529-531.

consequences, was central to the court's determination that the Officer had acted with deliberate indifference.[50]

Next, the court considered whether the constitutional right which Nelson asserted was established at the time the event at issue took place.[51] Not only did the court find that Nelson's right to be free from restraints during pregnancy, labor, and delivery had been clearly established by lower courts, it also found that it had been acknowledged by the Supreme Court of the United States.[52] In making this determination, the court considered several cases, including *Women Prisoners*.[53] The court reasoned that because the federal district court's decision regarding the use of restraints on pregnant inmates in *Women Prisoners* had not been appealed by the government, a constitutional violation in such a case had been clearly established.[54] Accordingly, with both the deliberate indifference element and the clearly established right element of the offense satisfied, the court held that Nelson's Eighth Amendment right to be free from cruel and unusual punishment had been breached.[55]

iii. *Brawley*

In 2006, Casandra Brawley was incarcerated in the Washington State Corrections Center for Women.[56] At the time, she was five months pregnant.[57] Each and every time Brawley was taken to a prenatal medical appointment, "she was placed in full restraints," which included "a metal chain around her waist [with] her hands […] handcuffed together, and the handcuffs were attached to the waist chain."[58] Although the Officer who transported Brawley to the hospital when she went into labor admitted she did not consider her a security risk, Brawley was placed in handcuffs and a waist chain, with the two restraints attached.[59] When Brawley was given a hospital room, the chain and handcuffs were taken off, but the officers chained one of her ankles to her hospital bed.[60] When she was moved to a delivery room, Brawley's ankles were chained to her wheelchair.[61] She was unchained and then re-chained after her

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[50] *Id.*
[51] *Id.* at 531.
[52] *Id.* at 533.
[53] *Id.* at 532-533.
[54] *Id.* at 533.
[55] *Id.* at 534.
[56] Brawley v. Washington, 712 F. Supp. 2d 1208, 1211 (W.D. Wash. 2010).
[57] *Id.*
[58] *Id.*
[59] *Id.* at 1212.
[60] *Id.* at 1213.
[61] *Id.*

epidural, and her restraints were finally removed just prior to her emergency cesarean operation.[62] After her surgery, her ankle was again chained to the bed.[63] Even when Brawley was taken to the NICU to see her newborn child, she was chained to her wheelchair.[64]

Perhaps one of the most troubling portions of Brawley's experience occurred when her newborn son was in a bed in her hospital room and began to make choking or vomiting noises.[65] Had she been free, Brawley could have quickly gotten up from her bed and administered the help the infant clearly needed. [66] But since Brawley was chained to her bed, her only option was to call for help and trust a nurse would arrive in time.[67]

The court found that Brawley had indeed been forced to "endure[] unnecessary pain, was exposed to a sufficiently serious risk of harm, and had a serious medical need when she was shackled to the hospital bed…."[68] Further, the court held that "Common sense, and the DOC's own policy, tell us that it is not good practice to shackle women to a hospital bed while they are in labor."[69] In other words, it should have been *common sense* not to shackle a pregnant woman in labor. Thus, the first element of the court's analysis, that Brawley had a serious medical need, had been clearly satisfied.[70]

In examining whether Brawley's right to be free from restraints during labor was an established constitutional right, the court found that "by April of 2007 shackling inmates while they are in labor was clearly established as a violation of the Eighth Amendment's prohibition against cruel and unusual punishment."[71] That is, by the time Brawley experienced this treatment, her right to be free from such degrading practices had been clearly established and was protected by the Constitution.[72] Despite this, Brawley, like others both before and after her, was forced to endure this violation of her basic human rights.

iv. *Villegas*

Juana Villegas was nine months pregnant when she was arrested for driving without a driver's license and then detained

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[62] *Id.* at 1213-1214.
[63] *Id.* at 1214.
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.* at 1219.
[69] *Id.*
[70] *Id.* at 1220.
[71] *Id.* at 1221.
[72] *Id.* (citing *Nelson v. Corr. Med. Servs*., 583 F.3d 522, 533 (8th Cir. 2009)).

when it was found that she did not have adequate immigration documentation.[73] Just two days after being booked into the jail, Villegas went into labor.[74] She was transported to the hospital in handcuffs and leg restraints.[75] Upon arrival at the hospital, her handcuffs were taken off, but one of Villegas' legs was shackled to her hospital bed.[76] One of the nurses told the officer that Villegas should not be restrained, but the officer ignored her.[77] Villegas was un-shackled and re-shackled at multiple points throughout both labor and postpartum recovery.[78]

The court, like others, evaluated Villegas' case using a combination of conditions of confinement and serious medical needs analyses.[79] The court found both that shackling posed a risk of harm to Villegas and that "the shackling of pregnant detainees while in labor offends contemporary standards of human decency such that the practice violates the Eighth Amendment's prohibition against the 'unnecessary and wanton infliction of pain'…"[80] Thus, Villegas' right to be free from cruel and unusual punishment had been violated. However, the court held that "…the right to be free from shackling during labor is not unqualified."[81] In so finding, the court listed two exceptions: (1) restraints may be used if the inmate posed a flight risk; and (2) restraints may be used if the inmate poses a substantial risk of harm to herself or others. [82]

B. State Legislation

Thus far, only 22 states and the District of Columbia have adopted legislation banning the practice of shackling pregnant inmates.[83] The American College of Obstetrics and Gynecology has listed six areas which it suggests states address in enacting this type of legislation.[84] These are:

1. Broadly restrict restraints during labor, delivery, postpartum and transport to a medical facility;

2. Allow medical personnel to have restraints

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[73] Villegas v. Metro. Gov't of Nashville, 709 F.3d 563, 566 (6th Cir. 2013).
[74] *Id.*
[75] *Id.*
[76] *Id.* at 567.
[77] *Id.*
[78] *Id.*
[79] *Id.* at 571.
[80] *Id.* at 574.
[81] *Id.*
[82] *Id.*
[83] *See supra* note 7.
[84] *Id.*

removed immediately;

3. Require written documentation by corrections personnel of the use of restraints;

4. Apply to juveniles;

5. Require corrections personnel to remain outside delivery room for privacy concerns; and

6. Address additional health concerns of pregnant inmates (including adequate prenatal care, appropriate maternal nutrition and nutrition counseling, HIV and substance screening and treatment).[85]

Each state with legislation limiting the use of restraints has addressed the first category in its coverage.[86] However, fewer states cover fewer categories as the list continues.[87]

In 2010, The Rebecca Project for Human Rights and the National Women's Law Center partnered to create a state-by-state report card reviewing several aspects of reproductive care provided to incarcerated women.[88] One of the areas reviewed was the use of restraints during pregnancy. At the time of the report, only ten states had adopted laws addressing shackling.[89] The report found that thirty-six states had failed to "comprehensively limit, or limit at all, the use of restraints on pregnant women during transportation, labor and delivery and postpartum recuperation."[90] Of the states lacking any statute dealing with the practice of shackling, "[t]wenty-two states either have no policy at all addressing when restraints can be used on pregnant women or have a policy which allows for the use of dangerous leg irons or waist chains."[91] Equally as shocking, "eleven states either allow any officer to make the determination [to use restraints for security reasons] or do not have a policy on who determines whether the woman is a security risk."[92] Perhaps most unsettling of all, "[t]hirty-four states do not require each incident of

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[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *Mothers Behind Bars: A state-by-state report card and analysis of federal policies on conditions of confinement for pregnant and parenting women and the effect on their children*, Nat'l Women's L. Center (Oct. 2010), https://www.nwlc.org/sites/default/files/pdfs/mothersbehindbars2010.pdf.
[89] *Id.* at 6.
[90] *Id.*
[91] *Id.*
[92] *Id.* at 7.

the use of restraints to be reported or reviewed by an independent body."[93]

One aspect of policies against restraining pregnant women that seems to be shared by the courts, by advocates of anti-shackling legislation, and by the states, is the inclusion of exceptions to a prohibition of the practice.[94] In general, these exceptions are: (1) restraints may be used if the woman poses a significant risk of harm to herself or others; and (2) restraints may be used if the woman poses a flight risk. For example, New Mexico's statute regarding shackling pregnant inmates states:

> "A. An adult or juvenile correctional facility, detention center or local jail shall use the least restrictive restraints necessary when the facility has actual or constructive knowledge that an inmate is in the second or third trimester of pregnancy. No restraints of any kind shall be used on an inmate who is in labor, delivering her baby or recuperating from the delivery unless there are compelling grounds to believe that the inmate presents:
>
> (1) an immediate and serious threat of harm to herself, staff or others; or
> (2) a substantial flight risk and cannot be reasonably contained by other means.
>
> B. If an inmate who is in labor or who is delivering her baby is restrained, only the least restrictive restraints necessary to ensure safety and security shall be used."[95]

Thus, states consider exceptions to a blanket prohibition on the use

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[93] *Id.*

[94] *See Nelson*, 583 F.3d at 533; *Villegas*, 709 F.3d at 574; G.A. Res. 70/175, annex, at 48(2), Nelson Mandela Rules, (Dec. 17, 2015); *Health Care for Pregnant and Postpartum Incarcerated Women and Adolescent Females*, Comm. Op. No. 511, at 4, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (2011), https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Pregnant-and-Postpartum-Incarcerated-Women-and-Adolescent-Females; *An "Act to prohibit the shackling of pregnant prisoners" model state legislation*, AM. MEDICAL ASSOC. (2015), https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/arc/shackling-pregnant-prisoners-issue-brief.pdf; N.M. Stat. Ann. § 33-1-4.2 (West); Tex. Gov't Code Ann. § 501.066 (West); Tex. Loc. Gov't Code Ann. § 361.082 (West); Vt. Stat. Ann. tit. 28, § 801a (West); N.Y. Correct. Law § 611 (McKinney); Colo. Rev. Stat. Ann. § 17-1-113.7 (West 2006); Wash. Rev. Code Ann. § 72.09.651 (West).

[95] N.M. Stat. Ann. § 33-1-14.2 (West, Westlaw current through the end of the Second Regular Session of the 53rd Legislature).

of restraints to be imperative to the success of implementation of this type of legislation.

C. FEDERAL LEGISLATION

i. Federal Bureau of Prisons

In 2008, the Federal Bureau of Prisons ("FBOP") instituted policy against shackling pregnant inmates.[96] However, the FBOP only exclusively banned the use of belly chains.[97] With regard to such other restraints as handcuffs and leg shackles, the FBOP left the decision to the discretion of prison officials.[98] This discretion is not unqualified, however, and restraints are generally not considered necessary unless the inmate poses a significant risk of harm or a risk of escape.[99] These exceptions are analogous to those in state legislation discussed above.

ii. Congress

On July 11, 2017, the Dignity for Incarcerated Women Act (the "Dignity Act") was introduced in the Senate and referred to the Committee on the Judiciary.[100] Sponsored by Senator Cory Booker, along with Senators Elizabeth Warren, Richard Durbin, and Kamala Harris, the bill would mandate significant changes in multiple areas concerning health care and basic rights for incarcerated women.[101] In particular, it calls for a complete ban on the use of restraints on pregnant women:

> "A Federal penal or correctional institution may not use instruments of restraint, including handcuffs, chains, iron, straitjackets, or similar items, on a prisoner who is pregnant."[102]

Thus, the bill includes none of the exceptions that most state statutes, court opinions, and model bills do, nor does it provide for detainees. Although admirable in its attempt to institute a complete ban on the use of restraints on pregnant federal inmates, the bill is unlikely to pass without at least some exceptions to the blanket rule. The perception that inmates may be dangerous and may attempt

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[96] FED. BUREAU OF PRISONS, PROGRAM STATEMENT: ESCORTED TRIPS, NO. 5538.05, at 11(a) (Oct. 6, 2008), http://www.bop.gov/policy/progstat/5538_07.pdf.
[97] *Id.*
[98] *Id.* at § 570.44.
[99] *Id.*
[100] *See supra* note 1.
[101] *Id.*
[102] *Id.* at § 4050(d)(2).

escape if left unrestrained is too pervasive for a complete ban to pass a bipartisan Congress.

III. ANALYSIS

A. Leading health and civil rights organizations, as well as the United Nations, oppose shackling pregnant inmates.

The American Congress of Obstetricians and Gynecologists ("ACOG"), one of the leading voices against the use of restraints on pregnant incarcerated women, has listed multiple ways in which the imposition of restraints might harm both the mother and her child.[103] The complete ACOG table listing some of the various potential consequences associated with shackling is reproduced on the last page of this Note and includes such medical risks as: heightened risk of falling and lessened ability to break a fall; hindered ability of medical professionals to examine the woman in labor; increased risk of injury if the mother suffers from seizures brought on by preeclampsia; decreased ability to move around in order to alleviate pain; and hindered ability of medical professionals to prepare the woman for emergency situations such as a cesarean delivery.[104]

The ACOG has acknowledged that the FBOP, US Marshals Service, and other organizations have established policies against shackling, but "[t]hese standards serve as guidelines and are voluntary, not mandatory. State and local prisons are not required to abide by either the Federal Bureau of Prisons policy or the National Commission on Correctional Health Care standards…"[105] Without mandatory requirements for jails and their staff, the basic rights of American women will continue to be infringed upon.

The American Medical Association ("AMA") has also lent its voice to those speaking against the use of restraints during pregnancy. The AMA's Advocacy Resource Center formulated a report on the use of shackles on pregnant inmates in 2015, finding no justified reason to continue the custom.[106] Not only did the AMA point out that "[t]he vast majority of female prisoners or detainees are … non-violent offenders," it also found that "[w]hile states

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[103] *Health Care for Pregnant and Postpartum Incarcerated Women and Adolescent Females*, Comm. Op. No. 511, at 3-4, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (2011), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co511.pdf?dmc=1&ts=20180628T1710410017

[104] *Id.* at 3.

[105] *Id.*

[106] *An "Act to prohibit the shackling of pregnant prisoners" model state legislation*, at 1, AM. MEDICAL ASSOC. (2015), https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/arc/shackling-pregnant-prisoners-issue-brief.pdf.

justify using restraints to prevent escapes, no women in labor have ever attempted escape."[107] At its 2010 Annual Meeting, the AMA "adopted policy condemning the practice of shackling pregnant prisoners" and recommended the AMA formulate a model bill.[108] In so doing, the AMA expressed approval of New Mexico's anti-shackling statute (reproduced above).[109] In its model legislation, the AMA provided for the very same exceptions that most states and courts have encouraged – significant risk of harm and risk of escape – and considers these to be rare occasions.[110] However, "[t]he AMA model state legislation extends the shackling prohibition to the second and third trimester due to safety risks shackling poses to pregnant women…"[111] Thus, the AMA model legislation is slightly more comprehensive than those employed by most states.

The American Civil Liberties Union ("ACLU") has also worked to end the practice of restraining pregnant inmates and detainees. According to the ACLU, the risk of adverse consequences of shackling a pregnant mother are unacceptable both to the pregnant woman and to her child.[112] In its own words, "Shackling pregnant women is dangerous and inhumane. Although widely regarded as an assault on human dignity as well as an unsafe medical practice, women prisoners are still routinely shackled during pregnancy and childbirth."[113] The ACLU does not take this issue lightly, as evidenced by their representation of Shawanna Nelson in her fight for justice.[114] Like the AMA, the ACLU reported that not one state with a policy or statute against the use of shackles had "reported any escapes or threats to medical or correctional staff from pregnant prisoners since prohibiting shackling."[115] Further, the ACLU categorizes the practice as "degrading, unnecessary, and a violation of human rights."[116]

Perhaps most persuasive, the United Nations itself has adopted anti-shackling rules in its Standard Minimum Rules for the Treatment of Prisoners, which were renamed as the Nelson Mandela Rules in December 2015.[117] The rule states: "Instruments of restraint

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[107] *Id.* at 3.
[108] *Id.* at 1.
[109] *Id.*
[110] *Id.* at 4.
[111] *Id.* at 2.
[112] *ACLU Briefing Paper: The Shackling of Pregnant Women & Girls in U.S. Prisons, Jails & Youth Detention Centers*, at 1, AM. CIVIL LIBERTIES UNION (OCT. 10, 2012), https://www.aclu.org/files/assets/anti-shackling_briefing_paper_stand_alone.pdf.
[113] *Id.*
[114] *Id.* at 3.
[115] *Id.* at 5.
[116] *Id.* at 1.
[117] *See* G.A. Res. 70/175, annex, Nelson Mandela Rules, (Dec. 17, 2015); U.N. Office on Drugs and Crime, *The Nelson Mandela Rules, an updated Guide for*

shall never be used on women during labour, during childbirth and immediately after childbirth."[118] The United States of America is a member of the United Nations, and as a member, is charged with an obligation to "promote solutions of international economic, social, *health*, and related problems" (emphasis added).[119] These standard rules formulated by the UN were considered by that body to be necessary in order to advise Member States on "good principles and practice in the treatment of prisoners and prison management."[120] However, the United States clearly has not taken this crucial portion of the Nelson Mandela Rules seriously. America cannot truly be considered a protector of human rights unless and until it implements such standard minimum rules outlined by the Nelson Mandela Rules for the treatment of pregnant female inmates and detainees.

B. *Martin v. County of Milwaukee, et al.*

In 2013, Shonda Martin was pregnant and became incarcerated in the Milwaukee County Jail.[121] Martin was subjected to horrific sexual assault during this time by Officer Thicklen, one of the employees at the jail.[122] Not only did he assault her while she was pregnant, he immediately resumed his attacks after she delivered her baby.[123]

As if not enough for Martin to be subjected to abuse by Officer Thicklen, Martin was also shackled by one wrist and one leg restraint throughout labor.[124] Only the leg restraint was removed while Martin delivered her child.[125] Martin's case was tried by a jury in July of 2017. As to her Fourteenth Amendment Due Process claims for the sexual assault committed against her by Officer Thicklen, the jury awarded her $6.7 million.[126] However, as to her shackling claim, the jury awarded her nothing.[127]

Martin's failure to exact justice on her shackling claim stems from the tactics employed by her counsel. In her original complaint,

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Prison Management in line with Human Rights, https://www.unodc.org/documents/justice-and-prison-reform/GA-RESOLUTION/E_ebook.pdf (last visited Jan. 6, 2018).

[118] G.A. Res. 70/175, annex, at 48(2), Nelson Mandela Rules, (Dec. 17, 2015).

[119] U.N. Charter art. 55, ¶ 1(b).

[120] *See* G.A. Res. 70/175, *supra* note 106, Preliminary observation 1.

[121] First Amended Complaint at 3, Martin v. County of Milwaukee, *et al.*, No. 2:14-cv-00200 (E.D. Wis. 2014).

[122] *Id.* at 3-8.

[123] *Id.* at 6-7.

[124] *Id.* at 10.

[125] *Id.*

[126] Amended Judgment at 1, Martin v. County of Milwaukee, *et al.*, No. 2:14-cv-00200 (E.D. Wis. 2014).

[127] *Id.* at 2.

Martin categorized the use of restraints during her pregnancy as an Eighth Amendment violation.[128] However, in her amended complaint, Martin categorized her claim as a Fourteenth Amendment Due Process violation.[129] The flaw lies here. Because she relied on the Fourteenth Amendment for this claim, the test employed by the court was different. Whereas an Eighth Amendment claim requires a complainant to demonstrate that an official was deliberately indifferent to a serious medical need, Martin's Fourteenth Amendment claim required her to demonstrate that the jail had a policy that was not reasonably calculated to achieve a legitimate goal, and as a result of this policy, Martin suffered harm.[130] Although the jury did find that the use of shackles was not reasonably calculated to achieve a legitimate purpose, it also determined that Martin had not suffered any harm.[131] This is arguable in itself, as Martin most likely did suffer some extent of mental and emotional harm as a result of being shackled throughout labor, delivery, and postpartum recovery. However, considering the practically identical facts between Martin and the cases discussed previously – *Women Prisoners*, *Nelson*, *Brawley*, and *Villegas* – Martin almost assuredly would have prevailed if she had brought the proper Eighth Amendment claim. The error here lies with the choices made by her counsel.

It is important to note that shackling is an Eighth Amendment violation, and that a jury specifically found it did not breach Martin's Fourteenth Amendment Due Process rights.[132] Had pregnant inmates' right to be free from shackling been established as a principle protected by Due Process, it would have automatically been recognized across the country.[133] No state would be able to infringe upon this basic right of female prisoners.[134] However, because it was not a Fourteenth Amendment right under substantive due process, it is necessary for the federal government to enact legislation to keep shackling from being used against pregnant female prisoners and detainees in federal prisons. Additionally, it is necessary for states to enact prohibitory legislation in order to protect state and local inmates.

Despite Martin's loss with regard to the unconstitutional use

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[128] Complaint at 10, Martin v. County of Milwaukee, *et al.*, No. 2:14-cv-00200 (E.D. Wis. 2014).
[129] First Amended Complaint at 10-11, Martin v. County of Milwaukee, *et al.*, No. 2:14-cv-00200 (E.D. Wis. 2014).
[130] Jury Instructions at 17, Martin v. County of Milwaukee, *et al.*, No. 2:14-cv-00200 (E.D. Wis. 2014).
[131] Amended Judgment at 2, Martin v. County of Milwaukee, *et al.*, No. 2:14-cv-00200 (E.D. Wis. 2014).
[132] *Id*.
[133] *See* Obergefell v. Hodges, 135 S. Ct. 2584, 2607-08 (2015).
[134] *See id.*

of shackling during her pregnancy, this case is important to demonstrate that this problem is tangible and continually existent in the United States. Martin's case is analogous to those which came before, proving that the policy and practice is widespread. Without legislation to prevent this practice from occurring, the basic human rights of these already underprivileged women will continue to be infringed. As a result, not only will the health of the mother be endangered, but the health and life of her unborn child.

IV. ARGUMENT

An examination of the cases involving shackling claims of pregnant inmates and detainees might suggest that it is agreed and established that shackling is wrong.[135] From that conclusion, one could naturally assume that because it is an established constitutional violation, the federal and state governments would take steps to prevent similar instances from occurring. However, only 22 states have implemented legislation protecting female prisoners from this practice.[136] Senator Cory Booker, one of the proponents of the Dignity for Incarcerated Women Act, blames this absence of action on a lack of discourse surrounding the practice.[137] This lack of dialogue must be remedied, because in reality, the facts are these:

- 60% of women in state prisons were previously victims of abuse.[138]
- The overwhelming majority of women arrested are taken into custody for non-violent offenses. In fact, violent offense arrests constituted only 17% of women arrested in 1998.[139]
- Overall, women account for only about 14% of violent offenders. Men count for almost 6 times this number.[140]
- Of female violent offenders, 75% committed mere simple

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[135] *See* cases cited *supra* note 5.
[136] *See supra* note 7.
[137] *Senators Booker, Warren, Durbin, Harris Introduce Landmark Bill to Reform the Way Women Are Treated Behind Bars*, ELIZABETH WARREN: U.S. SENATOR FOR MASS. (July 11, 2017), https://www.warren.senate.gov /?p=press_release&id=1727.
[138] Lawrence A. Greenfield & Tracy L. Snell, Bureau of Justice Statistics, U.S. Dep't of Justice, Women Offenders at 1 (1999), *available at* https://www.bjs.gov/content/pub/pdf/wo.pdf.
[139] *Id.* at 5.
[140] *Id.* at 1.

assault.[141]

- Approximately 950,000 women were involved with the criminal justice system in 1998. In other words, 1 out of every 109 adult American women.[142]

- An estimated 6% of women committed to local jails were pregnant at the time, and an estimated 5% of women committed to state prisons were pregnant when admitted. [143]

- Approximately 3% of women in local jails received prenatal care once admitted, compared to about 4% of women in state prisons.[144]

The number of women in the criminal justice system continues to increase.[145] The vast majority of these women are non-violent offenders.[146] In addition, a majority have been past victims of physical or sexual abuse.[147] Our criminal justice system receives these women, commits them to confinement, and then shackles them to their wheelchairs and hospital beds while they give birth to their children, as if they were no better than animals. This method of punishment – cruel and unusual punishment to be precise – shows them that not only were they worthless in the minds of those who abused them, but they are also worthless in the eyes of the criminal justice system, those employed by the criminal justice system, and the greater American people.

Although it might at first seem like common sense to allow a woman to be free from restraint during such a critical time as labor, delivery, and postpartum recovery, the preceding cases demonstrate that this is not the truth. In order to protect the rights of these women, who themselves may not be able to adequately defend their cause, we must ensure that this practice is banned, and that those who breach this ban will be liable for the human rights violation they have committed. The incarcerated women who suffer these instances of punishment are themselves serving time in order to establish justice for their wrongs. It is only fitting and in conformity with American principles of justice that those who commit offenses against these women are also held liable for their actions.

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[141] *Id.*
[142] *Id.*
[143] *Id.* at 8.
[144] *Id.*
[145] Aleks Kajstura & Russ Immarigeon, *States of Women's Incarceration: The Global Context*, PRISON POLICY INITIATIVE, https://www.prisonpolicy.org/global/women/ (last visited Jan. 6, 2018).
[146] Greenfield & Snell, *supra* note 138 at 5.
[147] *Id*. at 1.

Further, as explained by the ACOG, the policies implemented by the FBOP, US Marshals Service, and similar institutions are insufficient to guard women in either federal prisons or in state prisons.[148] This is because they are not mandatory standards, but merely suggest appropriate conduct.[149] In order to protect female inmates and detainees from the use of shackles throughout the course of pregnancy, mandatory provisions, i.e., state and federal legislation, must be put in place to more effectively regulate the conduct of those overseeing these women.[150]

However, as the courts and others have found, the right to be free from restraint is not and should not be unqualified. This Note recognizes that there are certain *rare* but necessary circumstances in which restraints might be used, and recommends that all states and the federal government enact legislation banning the practice of shackling pregnant inmates similar to that employed by New Mexico.[151] Yet, a few necessary changes should be made to this statute.

First, the "compelling grounds" on which an inmate might be subjected to the use of restraints should be defined. Such definition should include a non-exhaustive but exemplary list of the unusual circumstances that might justify the use of restraints. In addition, if one of those compelling grounds is found by a prison official, the official should seek the agreement of at least two other prison officials as to whether or not restraints should be utilized. Further, any use of restraints as a result of one of the compelling grounds should be documented in a report submitted by the official, and signed by the two officials who agreed restraints should be utilized.

Second, section (B), which allows for the least restrictive restraints necessary if a pregnant inmate or detainee is shackled, should be amended to prohibit all use of restraint during delivery of the child. The potential health risks and the woman's interest in being free from restraints during the intense stress of childbirth are such that restraints should never be used during this time.

Third, the statute should expressly provide for the liability of those who breach a woman's constitutional right to be free from restraint during pregnancy. An inmate's right to be free from the use

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[148] *Health Care for Pregnant and Postpartum Incarcerated Women and Adolescent Females*, Comm. Op. No. 511, at 4, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (2011), *available at* https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Pregnant-and-Postpartum-Incarcerated-Women-and-Adolescent-Females.

[149] *Id*.

[150] *See id*.

[151] N.M. Stat. Ann. § 33-1-4.2 (West, Westlaw current through the end of the Second Regular Session of the 53rd Legislature).

of restraints and therefore from cruel and unusual punishment should not be taken lightly. It is necessary to notify those that might engage in restraining a pregnant inmate that they could potentially face liability for their actions in order to ensure the end of this practice.

In formulating anti-shackling legislation, it is recommended that legislators examine the American Medical Association's model bill titled "An Act to Prohibit the Shackling of Pregnant Prisoners."[152] The model bill provides:

> "**Section 4. Requirements.** Restraint of Prisoners and Detainees
>
> (a) An adult or juvenile correctional institution shall use the least restrictive restraints necessary when the correctional institution has actual or constructive knowledge that a prisoner or detainee is in the second or third trimester of pregnancy. No restraints of any kind shall be used on a prisoner or detainee during labor, transport to a medical facility, delivery, and postpartum recovery unless there are compelling grounds to believe that the prisoner or detainee presents:
>
> (1) an immediate and serious threat of harm to herself, staff or others; or
>
> (2) a substantial flight risk and cannot be reasonably contained by other means.
>
> (b) Under no circumstances shall leg or waist restraints be used on any prisoner or detainee who is in labor or delivery.
>
> (c) If restraints are used on a prisoner or detainee pursuant to subsection (a), the corrections official shall make written findings within ten (10) days as to the extraordinary circumstance that dictated the use of the restraints to ensure the safety and security of the prisoner or detainee, the staff of the correctional institution or medical facility, other prisoners or detainees, or the public. These findings shall be kept on file for at least five (5) years

[152] *An Act to Prohibit the Shackling of Pregnant Prisoners*, AM. MED. ASSOC.: ADVOCACY RESOURCE CENTER (Oct. 2010), https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/arc/shackling-pregnant-prisoners-model-bill.pdf.

> and be made available for public inspection, except that no information identifying any prisoner or detainees shall be made public in violation of [insert relevant section] without the prisoner or detainee's prior written consent.
>
> **Section 5. Enforcement.** Notice to Prisoners and Detainees
>
> (a) Within 30 days of the effectiveness of this Act, all correctional institutions in [State] shall develop rules pursuant to this Act.
> (b) Correctional institutions shall inform prisoners and detainees of the rules developed pursuant to subsection (a) upon admission to the correctional institution and … post policies or practices pursuant to this Act in locations in the correctional institution where such notices are commonly posted, including common housing areas and medical care facilities.
> (c) Within 60 days of the effectiveness of this Act, correctional institutions shall inform prisoners and detainees within the custody of the correctional institution of the rules developed pursuant to subsection (a)."[153]

The AMA's model bill provides for many of the suggestions made by this Note. However, the language of the model bill should be altered to provide for those recommendations not included by the AMA. For example, "compelling grounds" should be defined in the definitions section of the statute. The definition should include a non-exhaustive but exemplary list of the rare circumstances which might allow for the use of restraints. Also, section (b) of the bill should be amended so that leg or waist restraints may not be used at any time during a woman's pregnancy. Nonetheless, taken as a whole, the AMA's model bill is a good example of model legislation for states and the federal government to consider when enacting anti-shackling statutes.

V. CONCLUSION

Although it presents itself as the "land of the free," America's reputation does suffer from more than one example of human rights abuse. One such abuse is the use of restraints on

[153] *Id.*

pregnant inmates and detainees. This practice has been denounced by the United Nations, by the Federal Bureau of Prisons, by multiple United States courts, and by multiple states.[154] However, as evidenced by *Martin v. County of Milwaukee*, the practice still persists. In order to end this violation of the Eighth Amendment to the Constitution of the United States and protect the rights of these already underprivileged women, it is necessary for both the federal government and individual state governments to enact legislation banning the practice. Not only must the practice be banned, anti-shackling legislation must provide for the liability of those who breach a woman's right to be free from restraint during pregnancy, labor, delivery, and postpartum recovery. America cannot attempt to establish principles of freedom and justice throughout the rest of the world if those same principles are not recognized and protected at home.

[154] *See* G.A. Res. 70/175, annex, at 48(2), Nelson Mandela Rules, (Dec. 17, 2015); FED. BUREAU OF PRISONS, PROGRAM STATEMENT: ESCORTED TRIPS, NO. 5538.05, at 11(a) (Oct. 6, 2008), *available at* http://www.bop.gov/policy/progstat/5538_07.pdf; Villegas v. Metro. Gov't of Nashville, 709 F.3d 563 (6th Cir. 2013); Nelson v. Corr. Med. Servs, 583 F.3d 522 (8th Cir. 2009); Brawley v. Washington, 712 F. Supp. 2d 1208 (W.D. Wash. 2010); Women Prisoners of the D.C. Dep't of Corr. v. District of Columbia, *et al.*, 877 F. Supp. 634 (D.D.C. 1994); *2017 ACOG State Legislation Tally*, Am. Cong. of Obstetrics and Gynecology (Mar. 2018), https://www.acog.org/-/media/Departments/State-Legislative-Activities/2017ShacklingTally.pdf?dmc=1&ts=20171029T2052480513.

Box 2. Examples of the Health Effects of Restraints

Nausea and vomiting are common symptoms of early pregnancy. Adding the discomfort of shackles to a woman already suffering is cruel and inhumane.

It is important for women to have the ability to break their falls. Shackling increases the risk of falls and decreases the woman's ability to protect herself and the fetus if she does fall.

If a woman has abdominal pain during pregnancy, a number of tests to evaluate for conditions such as appendicitis, preterm labor, or kidney infection may not be performed while a woman is shackled.

Prompt and uninhibited assessment for vaginal bleeding during pregnancy is important. Shackling can delay diagnosis, which may pose a threat to the health of the woman or the fetus.

Hypertensive disease occurs in approximately 12-22% of pregnancies, and is directly responsible for 17.6% of maternal deaths in the United States. Preeclampsia can result in seizures, which may not be safely treated in a shackled patient.

Women are at increased risk of venous thrombosis during pregnancy and the postpartum period. Limited mobility caused by shackling may increase this risk and may compromise the health of the woman and the fetus.

Shackling interferes with normal labor and delivery:

- The ability to ambulate during labor increases the likelihood for adequate pain management, successful cervical dilation, and a successful vaginal delivery.
- Women need to be able to move or be moved in preparation for emergencies for labor and delivery, including should dystocia, hemorrhage, or abnormalities of the fetal heart rate requiring intervention, including urgent cesarean delivery.

After delivery, a healthy baby should remain with the mother to facilitate mother-child bonding. Shackles may prevent or inhibit this bonding and interfere with the mother's safe handling of her infant.

As the infant grows, mothers should be part of the child's care (ie, take the baby to child wellness visits and immunizations) to enhance their bond. Shackling while attending to the child's health care needs may interfere with her ability to be involved in these activities.

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[155] *See supra* note 148.

STATE REGULATION OF GENERIC DRUG PRICE GOUGING

PHILIP FITZGERALD

INTRODUCTION

"I know he's the most hated man in America," said one of the prospective jurors in the securities fraud trial of Martin Skhreli – the notorious "Pharma Bro" who raised the price of a generic, life-saving drug from $13.50 to $750 per pill.[1] According to Zoe Thomas and Tim Swift at BBC News, "He's been called a 'morally bankrupt sociopath', a 'scumbag' a 'garbage monster' and everything that is wrong with capitalism.'"[2] To the public, Skhreli was the personification of rampant greed gone wrong; however, he was not alone in raising prices to unconscionable levels for life-saving drugs and other necessary medications. Around the same time that Skhreli's company, Turing Pharmaceuticals LLC ("Turing"), was increasing prices, other companies, such as Valeant Pharmaceuticals International, Inc. ("Valeant"), Retrophin Inc. ("Retrophin"), and Rodelis Therapeutics ("Rodelis") also increased prices on generic

[1] Renae Merle, *Pharma Bro Trial Hits Speed Bump, Finding Jurors Who Don't Already Dislike Him*, WASH. POST (June 28, 2017), https://www.washingtonpost.com/news/business/wp/2017/06/27/pharma-bro-martin-skhreli-goes-on-trial-where-he-finds-another-kind-of-limelight/?utm_term=.ab4ad3364076.

[2] Zoe Thomas & Tim Swift, *Who is Martin Shkreli- "The Most Hated Man in America,"* BBC NEWS (Aug. 4, 2017), http://www.bbc.com/news/world-us-canada-34331761.

drugs to exorbitant levels.[3] While Skhreli drew the bulk of media attention through his ostentatious behavior,[4] the Government Accountability Office conducted a study that found that out of a basket of 1,441 established generic drugs, more than 300 had at least one extraordinary price increase of 100 percent or more from the beginning of 2010 to the beginning of 2015.[5]

These recent forays of pharmaceutical companies into charging whatever-the-market-will-bear for previously inexpensive treatments have made "price gouging" a key term in discussions on rising health care costs. Pursuant to such discussions, state legislators are working to pass laws that prevent pharmaceutical companies from charging excessive prices for their drugs.[6] In addition to the state of Maryland passing a generic drug price-gouging law in 2017, the states of Massachusetts, New York, Rhode Island, and Tennessee are also considering price gouging legislation to reign in pharmaceutical costs.[7] These laws attempt to remedy the situation by putting a cap on drug price increases and/or requiring greater pricing transparency in the pharmaceutical market.

This note acknowledges that the high cost of drugs, both generic and patented, is an important issue for patients and policy makers alike. This note focuses solely on generic drugs, as the rights of drug patent holders are protected by the Copyright Clause of the United States Constitution,[8] which this note does not seek to address. Additionally, although the cost of drugs can be heavily impacted by Congress and federal regulatory agencies such as the Department of Health and Human Services and the Food and Drug Administration, this note will only look at the measures being taken by legislatures at the state level.

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[3] Andrew Pollack, *Drug Goes from $13.50 a tablet to $750, Overnight,* N.Y. TIMES (Sept. 20, 2015), https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?mcubz=0.

[4] Emily Jane Fox, *Pharma Bro Martin Shkreli Is Even More Terrible Than You Thought*, VANITY FAIR (Feb. 19, 2016), https://www.vanityfair.com/news/2016/02/pharma-bro-martin-shkreli-threat.

[5] U.S. Gov't Accountability Off., GAO-16-706, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases (Aug. 2016), https://www.gao.gov/assets/680/679022.pdf [hereinafter GAO Report].

[6] *To Dent Soaring Drug Costs, States Turn to 'Price-Gouging' Laws*, MANAGED CARE MAG. (Sept. 6, 2017), https://www.managedcaremag.com/archives/2017/9/dent-soaring-drug-costs-states-turn-price-gouging-laws.

[7] *Id.*

[8] U.S. Const. art. I, § 8, cl. 8.

Part I of this note will explain how generic drugs are brought to market, how manufacturers were able to charge so much for these generic or off-patent drugs without challenges from competitors, as well as what the consequences of price spikes are for patients, hospitals and insurers. Part I will also delve into the history of price gouging laws and examine the results from past economic regulations. Part II of this note will analyze the benefits and drawbacks of the relevant state laws and legislation regulating generic drug price increases. Part III of this note argues that state laws that cap prices on generic drugs should not be enacted, as they may result in shortages of necessary drugs; however, laws requiring greater transparency for drug price increases should be enacted to allow patients and providers the opportunity to find alternatives and to signal competitors that there may be an opportunity to enter the market.

I. BACKGROUND ON GENERIC DRUGS AND THE HISTORY OF PRICE GOUGING LAWS

A. Price Spikes in the Generic Market

Analyzing new laws regarding the generic drug market requires an understanding of the Hatch-Waxman Act ("Act"), which created the modern generic drug industry.[9] The Act was intended "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[10] Prior to the Act, when a manufacturer wished to produce a drug for which patent protection had expired, the manufacturer was required to conduct expensive and lengthy premarket clinical trials of the drug to prove its safety and efficacy.[11] This costly process reduced the incentive for manufacturers to enter the generic drug market, which resulted in less competition and higher prices for prescription drugs.[12]

To ensure a competitive market that would lower prices, the Act established an expedited system for generic drug approval.[13]

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[9] *See* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need A Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293 (2015).
[10] Abbot Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990)(Edwards, J., dissenting).
[11] Kesselheim, *supra* note 9, at 297.
[12] *Id.*
[13] *Id.* at 301.

Rather than conduct clinical trials, the generic drug manufacturer only had to show that the active ingredients in the new generic drug were the same as the original listed drug, that the "route of administration, the dosage form, and the strength of the new drug [were] the same as those of the listed drug, and that the generic drug [was] absorbed by the body at the same rate as the listed drug (bioequivalent)."[14] Because it was easier for manufacturers to enter the market, robust competition in the generic pharmaceutical industry ensued. The new process under the Act resulted in decades of relief from rising prescription drug costs.[15] On average, generic drugs cost 80 percent less than brand-name drugs.[16] How then was Skhreli and his ilk able to raise their prices on generic and off-patent[17] drugs as if they had a monopoly?

Following a spate of high profile drug price spikes, the bipartisan Senate Special Committee on Aging began an investigation into abrupt and dramatic price increases in prescription drugs whose patents had expired.[18] Turing, Valeant, Retrophin, and Rodelis were the focus of the investigation and the committee uncovered a business model used by these companies to exploit market failures. The business model consists of five key elements: (1) acquire a sole-source drug, with only one manufacturer and no immediate competition; (2) ensure the drug was the gold standard—the best drug for the condition it treats; (3) select a drug serving a

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[14] *Id.* at 301-02 (*quoting* 21 U.S.C. § 355 (j)(2)(A)(ii)-(iii)).

[15] *Understanding Recent Trends in Generic Drug Prices*, U.S. Dep't of Health and Human Servs., (Jan. 27, 2016), *available at* https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices.

[16] Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Healthcare System* (2016) [hereinafter "Sudden Price Spikes"], *available at* https://www.congress.gov/114/crpt/srpt429/CRPT-114srpt429.pdf.

[17] For purposes of this note "off-patent" refers to a drug that is not under patent protection and "generic" refers to one that is the biological equivalent of another drug. *See generally* Generic Drug Development, FDA, https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandageneric s/ucm142112.htm (last updated July 19, 2018).

[18] *See, e.g.*, Press Release, *Collins, McCaskill Open Senate Investigation into Rx Drug Pricing, Announce Intention to Hold Hearings,* Senate Special Committee on Aging, (Nov. 4, 2015), https://www.aging.senate.gov/press-releases/collins-mccaskill-open-senate-investigation-into-rx-drug-pricing-announce-intention-to-hold-hearings.

small market which would be unattractive to competitors and which was too small to mount an organized opposition; (4) control access to the drug through a closed distribution system where a drug could not be obtained through normal channels, thus depriving competitors access to samples of the drug for bioequivalency tests; and (5) price gouge by charging as much as possible.[19]

The drug that Turing acquired, Daraprim, is used to treat a rare tropical parasite, toxoplasmosis, that typically is only dangerous in HIV/AIDS and cancer patients due to their weakened immune system.[20] Daraprim is an off-patent drug for which patent protection had expired decades ago; however, at the time, there were no other manufacturers producing it.[21] This made Daraprim a sole-source drug.

Turing believed that Daraprim was considered by physicians to be the gold standard of drugs for treating toxoplasmosis, and that doctors would go out of their way to make sure patients had access to the drug because it was the best available treatment.[22] There was a substandard alternative to Daraprim used by a small subset of physicians, but it did not diminish Daraprims's value as the gold standard.[23]

Daraprim was also a small market drug; it only sold 9,708 units (bottles) in 2014 with net sales under $5 million.[24] Turing had analyzed the market and found that just 10.8 percent of off-patent drugs with under $10 million in annual sales faced generic competition within three years.[25] Turing found that a significant amount of effort and resources was required to serve small patient populations, and that manufacturers were not likely to compete in those markets.[26] Additionally, Turing also believed that the number of Daraprim patients was "too small to stimulate a significant lobbying effort were the cost of therapy to become an issue."[27] If the price were to rise drastically, Turing counted on the relatively insignificant population to be ignored.

Turing not only purchased a sole-source drug, but also attempted to protect its *de facto* monopoly status by restricting its

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[19] Sudden Price Spikes, *supra* note 16, at 4.
[20] Naren P. Tallapragada, *Off-Patent Drugs at Brand-Name Prices: A Puzzle for Policymakers*, J. LAW BIOSCI. 3 (1): 238-47 (2016).
[21] *Id.*
[22] Sudden Price Spikes, *supra* note 16, at 34.
[23] *Id.*
[24] *Id.* at 36.
[25] *Id.*
[26] *Id.*
[27] *Id.* (Turing's internal documents).

distribution.[28] Under "closed distribution," the drug cannot be obtained through normal pharmacy channels, but instead had to be obtained from "specialty" pharmacies.[29] This means that Turing could control the distribution of its product to prevent other generic drug manufacturers from getting their hands on Daraprim.[30] For a drug manufacturer to get a generic alternative approved by the FDA, the manufacturer must perform bioequivalency tests, and the manufacturer is required to have a supply of the original drug.[31] By closing distribution, Turing was able to keep Daraprim out of the hands of any generic manufacturers who would try to manufacture a lower priced alternative. Lastly, the goal of this business plan is to charge monopoly prices, and Turing completed the final phase of its business plan by raising the price of Daraprim 5,000 percent overnight.[32]

Drug price spikes have a terrible effect on patients gaining access to the treatment they need. These price increases also interfere with physicians and hospitals providing care to their communities. Furthermore, price increases also elevate the costs of private insurance and government programs, which have a broader impact on all consumers.

Sudden price hikes can create a financial crisis that compounds a patient's health issues. The Senate Committee on Aging found that following price spikes, some patients were forced to go without vital medicine, skip doses, or hoard pills out of fear that their next refill would not be affordable.[33] Patients who were able to maintain coverage for their medication through insurance worried that they could lose access without warning if the drugs were dropped from their insurance plan's formulary, and patients getting their medication through Patient Assistance Programs[34] worried that their application for assistance could be denied at any point.[35]

Following Turing's price increase of Daraprim, from $1,350 to $75,000 for a bottle of 100 pills, patients experienced treatment interruptions or went without treatment entirely, and some insurance

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[28] *Id*.
[29] *Id.*
[30] *Id.* at 37.
[31] *Id.* at 31
[32] Pollack, *supra* note 3.
[33] Sudden Price Spikes *supra* note 16 at 98.
[34] Patient Assistance Programs help patients who cannot afford the drugs they need. *See, e.g.*, *Merck's Patient Assistance Program*, Merck Helps (last visited on May 23, 2018), https://www.merckhelps.com.
[35] Sudden Price Spikes, *supra* note 16, at 98.

companies made it more difficult for their beneficiaries to get Daraprim.[36]

When Valeant raised prices on two of its drugs used to treat Wilson disease,[37] patients who had been successfully managing their disease with those drugs for most of their lives were suddenly at risk of losing treatment.[38] While some patients managed to get assistance in order to obtain the medication they needed, many had to go without medication for some time, thus increasing the risk to their health, while others switched to medications that posed additional risks, side effects and lifestyle restrictions.[39]

Price spikes can also affect patients by placing undue burdens on physicians, hospitals and insurers. Valeant had increased the prices of two drugs that were primarily used by hospitals for emergency care: one by 720 percent and the other by 310 percent.[40] The Committee found that the extra costs put a strain on hospital budgets, and in attempting to lower costs, physicians lost time with patients, which contributed to hospital inefficiency because they had to expend effort searching for substitute drugs and developing new treatment protocols.[41] Additionally, hospitals began rationing these drugs and did not stock them on every crash cart in the hospital, which increased the time it took for a patient to receive the drugs in an emergency.[42] The Committee also heard testimony that the increased drug prices would cause hospitals to cut back on services to the broader community.[43]

Rising drug prices also affect private insurance companies by increasing costs, which are then passed on to the consumer in the

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[36] *Id.* at 102.

[37] Wilson's disease can be fatal if left untreated, serious complications include scarring of the liver, liver failure, persistent neurological problems, kidney problems, psychological problems, and blood problems. *Wilson's Disease*, Mayo Clinic (March 7, 2018), https://www.mayoclinic.org/diseases-conditions/wilsons-disease/symptoms-causes/syc-20353251.

[38] Sudden Price Spikes *supra* note 16 at 99.

[39] *Id.* citing Qato, Dima M, et al., *Changes in Prescription and Over-the-Counter Medication and Dietary Supplement Use Among Older Adults in the United States*, *2005 vs 2011*, 176 J. AM. MED. ASSOC. 473, 473 (Apr. 2016).

[40] Sudden Price Spikes *supra* note 16 at 64.

[41] *Id.* at 105.

[42] *Id.*

[43] Sudden Price Spikes *supra* note 16 at 105 (explaining that initiatives to connect low-income and vulnerable communities with health care services, food, transportation and housing, as well as initiatives to stem the opioid crises would be at risk of being cut because of price hikes).

form of higher premiums and/or a lower percentage of coverage.[44] A patient with insurance coverage may not notice the immediate effect of a price spike (unless they have a high deductible to meet and are billed for the prescription); however, the patient will still feel the effect in the form of across-the-board increases in premium costs, deductibles and consumer cost share.[45]

Federal government programs such as Medicare, Medicaid, Veterans Affairs and the Children's Health Insurance Program spend around $126 billion on prescription drugs.[46] Drug price spikes contribute to higher government expenditures, which are ultimately borne by American taxpayers.

In 2016, Medicare asked the Government Accountability Office ("GAO") to study trends in generic drug pricing.[47] The GAO interviewed manufacturers, pharmacy associations, plan sponsors and their Pharmacy Benefit Managers ("PBM") – almost all of which indicated that competition, influenced by various factors, impacts the price of generic drugs.[48] The manufacturers explained that the generic drug market operates like a commodities market – the manufacturers submit their offer to their customers (pharmacies or wholesalers), and if another manufacturer offers a lower price to a customer, then the competing offeror is asked to match the price or risk losing market to the other manufacturer.[49] When a manufacturer brings a generic drug into an established market, it typically offers a lower price than that of the current market in order to build its customer base.[50] The price falls as each new

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[44] Skinner, Ginger, *Why Drug Costs Keep Rising—and What You Can Do About It*. CONSUMER REPORTS (May 16, 2017), *available at* https://www.consumerreports.org/drug-prices/why-drug-costs-keep-rising-what-you-can-do-about-it/ (explaining that insurance companies may also reduce coverage for certain drugs during the year or drop them entirely from their formulary).

[45] *Is There a Cure for High Drug Prices?*, CONSUMER REPORTS, https://www.consumerreports.org/drugs/cure-for-high-drug-prices/(last updated July 29, 2016),

[46] Sudden Price Spikes *supra* note 16 (citing CMS, *Prescription Drug Expenditures*, National Health Expenditures by Type of Service and Source of Funds, CY 1960-2015, at lines 287,289,292,294,295,299,302, and 308, which totals to $126.246 billion, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html).

[47] GAO Report *supra* note 5.

[48] *Id.* at 23.

[49] *Id.*

[50] *Id.*

manufacturer enters the market, with one manufacturer noting that each entrant typically results in a twenty-percent decline in price.[51] The price stays low until manufacturers begin exiting the market.[52] As such, it follows that prices should fall if manufacturers decide later on to re-enter the market.

While generic drugs contribute to lower overall drug prices, the GAO found that the rate at which generic drugs contribute to lower prices is declining.[53] The GAO also found that the decline in generic drug prices has been significantly slowed by price hikes.[54] Out of a basket of 1,441 generic drugs, the GAO found that 315 drugs experienced an extraordinary price increase (categorized as one-hundred percent or more) from 2010 to 2015.[55] These drugs increased the average price of the GAO's established drug basket by twenty-five percentage points. Specifically, the average price of the 1,441 drugs fell by fourteen percent – when calculated without those 315 drugs, the average price fell by thirty-nine percent.[56] Furthermore, the GAO also found that the price increases lasted for longer than a year and most did not go down in price after the increase.[57] Price spikes are an emerging trend in the generic drug market and have considerably slowed the downward movement in generic drug prices. While Martin Skhreli managed to exploit a sole-sourced drug for monopoly level price hikes, extraordinary price increases have been occurring with greater frequency throughout the generic drug market. These price hikes place patients' overall health and well-being at risk while simultaneously increasing insurance costs and costs of government programs.

B. Price Gouging Laws

Governments have a long history of using price controls to assuage popular enmity against rising prices.[58] Price controls have been an issue dating as far back as the Second Century A.D., when the Roman Empire was challenged by rapid price increases in

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[51] *Id.*
[52] *Id.*
[53] *See Id.* at 16.
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.* at 17.
[58] *See generally* Hugh Rockoff, *Drastic Measures: A History of Wage and Price Controls in the United States*, (Cambridge University Press 1984); *see also Income Policies In the United States: Historical Review and Some Issues*, Congressional Budget Office (1977), *available at* https://www.cbo.gov/publication/20636?index=10150.

commodities.[59] At the time, emperor Diocletian had recently split the empire into four ruling parts, which had the effect of raising taxes across the land. Additionally, emperor Diocletian had also debased the currency, which resulted in a rapid upwards movement in pricing.[60] Diocletian blamed the price increases on greed, and he intended to rectify the problem through government intervention, stating:

> But since it is the sole desire of untamed fury to feel no love for the ties of our common humanity . . . it suits us, who are the watchful parents of the whole human race, that justice step in as an arbiter in the case, in order that the long-hoped-for result, which humanity could not achieve by itself, may, by the remedies which our fore-thought suggests, be contributed toward the general alleviation of all.[61]

To combat high prices, Diocletian issued his Edict fixing maximum prices for thousands of consumer items.[62] Stiff penalties were imposed on any merchant selling wares for more than the mandated maximum price.[63] This resulted in a drastic shortage of goods as merchants hoarded their wares, awaiting a better time to sell.[64] Prices went even higher, and any trading that happened occurred on the black market.[65] Despite the good intentions behind the Edict, Diocletian's price fixing solution had resulted in even higher prices, and four years after the Edict, Diocletian abdicated his power and the law was rescinded.[66]

A more recent example of a price control legislation is Hawaii's gas cap law. In 2002, Hawaii became the first state to pass

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[59] *Id.* at 35.
[60] *Id.* at 37-38; *see also* Hans Kirchberger, *An Ancient Experience With Price Control*, J. OF FARM ECON., Vol. 24, No. 3 621-636 (Aug. 1942) (explaining that farmers let land go untilled because high taxes made it unprofitable to work the land, and subsequently because food was in shorter supply, prices went up. As a means of getting more money into circulation to help with the price increases, rather than cutting taxes on farmers, Diocletian replaced silver coins for copper, essentially debasing the currency, which resulted in rapid price hikes which were met with price controls.)
[61] Roland G. Kent, *The Edict of Diocletian Fixing Maximum Prices*, 69 U. PA. L. REV. 35, 41-42 (1921)
[62] *Id.* at 39.
[63] *Id.* at 40.
[64] *Id.*
[65] *Id.*
[66] *Id.*

legislation with the main objective of establishing a maximum wholesale gasoline price cap.[67] At the time, Hawaii's gasoline market had not only posted the highest prices in the country for the past five years, but also maintained an "upwardly sticky" trend which did not fluctuate downward with the rest of the country.[68] The legislature perceived that there was a lack of competition at the wholesale level, and responded by enacting a law to cap prices for gasoline sold from the refinery.[69] The price was capped at the average regular unleaded gasoline price of three interstate markets.[70] After the wholesale cap went into effect, prices at the pump promptly went up, with some experts opining that prices would have gone higher without the price cap, and detractors saying that it increased prices because it allowed gas companies to charge up to the maximum allowed.[71] The law was suspended by the state's governor eight months after it went into effect.[72]

A few years after the suspension, studies indicated that the price for fuel was trading at more than what the capped price would have pegged it at.[73] An argument in favor of the price caps was that oil costs were on an upward trajectory when the caps were implemented, so even though it did not appear that the caps were working to the Hawaiians, prices were still held in check relative to where they would have risen.[74]

Many price gouging laws were enacted by state legislatures because of complaints from the public about price hikes for essential goods following a disaster.[75] Following the terrorist attacks of

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[67] *See* Brandon H. Ito, *Price Controls in Paradise: Foreshadowing the Legal and Economic Consequences of Hawai'i's Gasoline Price Cap Law*, 27 U. HAW. L. REV. 549 (2005).

[68] *Id.* at 550 (explaining that prices would go up when the mainland price goes up, but prices would not go down when the mainland price went down, taking into account transportation costs of the oil to Hawaii and its surrounding islands).

[69] *Id.* at 551.

[70] *Id.*

[71] Mark Niesse, *Hawaii Gas Cap Running on Fumes*, WASH. POST (May 6, 2006), http://www.washingtonpost.com/wp-dyn/content/article/2006/05/05/AR2006050501294.html.

[72] *Id.*

[73] Greg Wiles, *Hawaii Gas Above 'Cap' Level of Suspended Law*, HONOLULU ADVERTISER, Jan. 27 2010, http://the.honoluluadvertiser.com/article/2010/Jan/27/ln/hawaii1270349.html.

[74] *Id.*

[75] Geoffrey C. Rapp, *Gouging: Terrorist Attacks, Hurricanes, and the Legal and Economic Aspects of Post-Disaster Price Regulation*, 94 KY. L.J. 535, 542 (2006).

September 11, 2001, some businesses in Tennessee engaged in price gouging, which spurred the legislature to enact a law to protect consumers when a "declared state of emergency results in abnormal disruptions of the market."[76] Tennessee's law also states that "protecting the public from price gouging is a vital function of state government in providing for the health, safety, and welfare of consumers."[77] California also has a price gouging statute, which was enacted to protect consumers following a natural or man-made disaster.[78] More than half of all states in the U.S. have some form of price gouging law on the books.[79] These laws typically follow one of three models in instituting price caps:

1) Percentage Price Caps that bar price hikes from exceeding a percentage increase from the pre-emergency level.
2) Unconscionability laws that focus on gross disparities between the offered price and the price prior to the emergency.
3) No Increase laws that bar any price increases beyond costs associated with the disaster.[80]

Although prohibitions on excessive price increases following a disaster are supported by most people, economists claim that they "discourage extraordinary supply efforts that would help bring goods in high demand into the affected area."[81] A prevailing argument against price controls is that price caps reduce the supply of the product being regulated.[82] In a market, prices are set by two

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[76] Tenn. Code. Ann. § 47-18-5101 (2002).
[77] *Id.*
[78] Ca. Penal Code § 396.
[79] Emily Bae, *Are Anti-Price Gouging Legislations Effective Against Sellers During Disasters*, 4 ENTREPRENEURIAL BUS. L.J. 79, 83 (2009).
[80] *Id.*
[81] Andrew Sorkin, *Hurricane Price Gouging is Despicable, Right? Not to Some Economists*, N.Y. TIMES (Sept. 11, 2017) (quoting Michael Giberson, instructor with the Ctr. for Energy Commerce in the Rawls College of Bus. at Texas Tech Univ.), https://www.nytimes.com/2017/09/11/business/hurricane-price-gouging.html.
[82] *See* John Maynard Keynes, *The Economic Consequences of the Peace* (1920) ("The presumption of a spurious value for the currency, by the force of law expressed in the regulation of prices, contains in itself, however, the seeds of final economic decay, and soon dries up the sources of ultimate supply"), *available at* https://www.gutenberg.org/files/15776/15776-h/15776-h.htm.; *see also* Bruce Bartlett, *The Futility of Price Controls*, FORBES (Jan. 15, 2010),

factors: (1) the buyer's demand and (2) the seller's supply. The more the buyer demands the product, the more the seller can charge.[83] Economists argue that in a free market, high prices are inevitable until demand subsides or supply expands.[84] High prices are an important element in getting necessary resources where they are most needed, but an artificial cap on prices will result in a shortage of supply, thus leaving people without the commodities they need.[85] Price hikes following a disaster signal scarcity, which puts consumers on notice to be more judicious in their use of resources, and those prices signal to potential producers that there is room to enter the market.[86] If prices are kept artificially low then consumers will not conserve scarce resources and producers will not increase supplies, which would result in shortages of necessary goods.[87] Although public sentiment may demand a political solution to the problem of price hikes, oftentimes price controls result in shortages.

II. STATE LAWS REGULATING DRUG PRICES

In the last year, many states have introduced legislation with the purpose of countering prescription drug price hikes.[88] Such legislation typically attempts to regulate prices by either placing a cap on drug price increases, or by requiring detailed reporting and advance notice of large price increases to relevant state agencies.[89]

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https://forbes.com/2010/01/14/venezuela-inflation-price-controls-opinions-columnists-bruce-bartlett.html#e0472c658272.

[83] Emily Bae, *Are Anti-Price Gouging Legislations Effective Against Sellers During Disasters*, 4 ENTREPRENEURIAL BUS. L.J. 79, 81 (2009) (citing Eugene Silberberg, *Principles of Microeconomics* (Pearson Custom Publishing 5th 2007)).

[84] *See* Gregory N. Mankiw, *I Paid $2,500 for a 'Hamilton' Ticket. I'm Happy About It*, N.Y. TIMES (Oct. 21, 2016), https://www.nytimes.com/2016/10/23/upshot/i-paid-2500-for-a-hamilton-ticket-im-happy-about-it.html?smprod=nytcore-iphone&smid=nytcore-iphone-share&mtrref=t.co.

[85] Donald J. Boudreaux, *Price Gouging' after a Disaster is Good for the Public*, WALL ST. J. (Oct. 3 2017), https://www.wsj.com/articles/price-gouging-after-a-disaster-is-good-for-the-public-1507071457.

[86] Sorkin, *supra* note 81.

[87] Matt Zwolinski, *The Ethics of Price Gouging*, BUS. ETHICS Q., 18(3), 347, 362-63 (2008), http://facpub.stjohns.edu/~flanagap/3305/readings/Zwolinski_Price_Gouging.pdf

[88] Boudreaux, *supra* note 85.

[89] Kimberly Leonard, *California to Pass Drug Price Transparency Bill*, WASH. EXAMINER (Dec. 8, 2017),

On October 1, 2017, Maryland became the first state in the country to enact a generic drug price gouging law.[90] The first-of-its-kind law has both a price gouging prohibition and a notice requirement. First, it prohibits manufacturers of essential off-patent or generic drugs from engaging in price gouging.[91] Second, it allows the Maryland Medical Assistance Program ("MMAP")[92] to notify the Attorney General of any increase in the price of any essential off-patent or generic drug.[93]

Under the first provision, an off-patent or generic drug means any prescription drug for which exclusive marketing rights have expired.[94] A drug that is "essential" is defined as one that has either appeared on the Model List of Essential Medicines adopted by the World Health Organization,[95] or that has been designated as essential by the Secretary because of its effectiveness in treating life-threatening or debilitating chronic health conditions.[96] Maryland's law defines price gouging as "an unconscionable increase in the price of a prescription drug."[97] An "unconscionable increase" is an "excessive" increase which is not justified by the cost of producing or marketing the drug, and the consumer has no meaningful choice about purchasing the drug, either because they need it for their health or because there is not enough competition in the market.[98]

Under the notice provision, MMAP may notify the Attorney General if the price increases 50% or more in the wholesale acquisition or in the price paid by MMAP for the drug within the preceding one year period.[99] The Attorney General may request from the drug manufacturer a statement that itemizes the components of the cost of producing the drug and identifies the circumstances and timing of any expenditures made by the

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http://www.washingtonexaminer.com/california-to-pass-drug-price-transparency-bill/article/2636919.

[90] Md. Code Ann., Health–Gen. § 2-802 (2017)

[91] *Id.*

[92] Maryland's name for its Medicaid program. *See* Public Assistance, Maryland.gov, dhr.maryland.gov/weathering-tough-ties/medical-assistance/#medi (last visited Sept. 4, 2018).

[93] § 2-803.

[94] § 2-801(b)(1)(i).

[95] *Model List of Essential Medicines*, World Health Organization (2017), *available at* http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017_FINAL_amendedAug2017.pdf?ua=1.

[96] § 2-801(b)(2)(ii).

[97] § 2-801(c).

[98] § 2-801(f).

[99] § 2-803(a)(1).

manufacturer to market the drug.[100] A manufacturer may be required to produce any relevant records or other documents.[101]

After Maryland's generic drug price gouging bill was passed into law, the Association for Accessible Medicine ("AAM") brought an action challenging the constitutionality of the new law.[102] AAM is a non-profit, voluntary association representing a number of manufacturers and distributors of generic and biosimilar medicines.[103] AAM alleged that Maryland's law violates the dormant Commerce Clause because it "regulates conduct occurring wholly outside the state, because its members are manufacturers and wholesalers of generic drugs who almost all reside outside of Maryland, operate under national contracts, and do not sell directly to actors in Maryland."[104] AAM also alleged that Maryland's law is impermissibly vague under the Due Process Clause of the 14th amendment because "the definition of 'unconscionable' increase' is keyed on 'expansive adjectives,' including 'excessive,' 'justified,' 'appropriate,' and 'meaningful.'"[105] On the Defendants' Motion to Dismiss, the district court dismissed the first cause of action under the dormant Commerce Clause,[106] but did not dismiss AAM's claim under the Fourteenth Amendment Due Process Clause.[107] AAM then appealed, and the Fourth Circuit held that Maryland's statute was unconstitutional because it violated the dormant commerce clause.[108] The Court emphasized that it was not prohibiting Maryland from regulating price gouging, only that Maryland could not do so "in the manner utilized by the Act."[109] Maryland may

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[100] § 2-803(b).
[101] § 2-803(c).
[102] Ass'n for Accessible Meds. v. Frosh, No. MJG-17-1860, 2017 U.S. Dist. LEXIS 161168 (D. Md. Sep. 29, 2017).
[103] *Id.* at *2.
[104] *Id.* at *14.
[105] *Id.* at *2,*26.
[106] *Id.* at *15,*21-22 (finding that Maryland's law would only be applicable to prices charged on drugs to be sold within Maryland, and that the State's legitimate interest in protecting its citizens was not shown by AAM to be outweighed by the burden on interstate commerce).
[107] *Id.* at *26-28 (finding that the term "unconscionable" has been defined by judges only in the contracts context, and even though the term is defined within the statute with broader language, the comparative term "excessive" requires a benchmark to measure from, which is not clearly stated in the law).
[108] Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 674 (4th Cir. 2018) (sympathizing with affected consumers but constrained to apply the dormant commerce clause).
[109] *Id.* (finding that the Act regulated transactions that took place outside of Maryland).

petition the Supreme Court for a writ of certiorari, or it may simply redraft the law to only regulate in-state transactions, as the Court seems to be suggesting.[110] Regardless of how Maryland goes forward, one of the main criticisms is that price gouging laws will have the unintended consequence of affecting the availability of essential generic drugs in Maryland.[111] If Maryland enacts a law which becomes too burdensome on pharmaceutical companies, they may simply exit the market, which would force residents to acquire their drugs from outside the state.

On October 9, 2017, California passed a law requiring drug companies to provide advance notice of drug price increases.[112] The law requires manufacturers to notify purchasers in writing and at least sixty days prior to an increase of over sixteen percent of a prescription drug's price.[113] Manufacturers must also report information about drug price increases quarterly to the Office of Statewide Health Planning and Development.[114] The report requires virtually all financial information related to the cost of the drug, the history of the drug's acquisition, and whether any changes have been made to the drug.[115] This information will be published within sixty days of receipt from a manufacturer on a per drug basis to ensure identification.[116] This law creates much greater transparency for drug price increases and puts all interested parties, including competitors, on notice that prices are rising.

Shortly after being enacted, California's law was challenged by the Pharmaceutical Research and Manufacturers of America ("PhRMA") as being unconstitutional as a violation of: (1) the Commerce Clause, because it directly restricts the drug list price used nationwide; (2) the First Amendment, because the mandatory reporting requirement constitutes compelled speech; and (3) the Fourteenth Amendment's Due Process Clause, because the language of the statute does not address notice requirements for price

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[110] *Id.* (explaining that "Maryland must address this concern via a statute that complies with the dormant commerce clause of the U.S. Constitution").
[111] Thomas Hemphill, *Maryland's Drug Pricing Law: The Potential Consequences*, REALCLEAR HEALTH (June 9, 2017), http://www.realclearhealth.com/articles/2017/06/09/marylands_drug_price_gouging_law_the_potential_consequences_110628.html.
[112] S.B. 17, Cal. 2017-2018, reg. sess. (Cal. 2017)(enacted).
[113] *Id*. at 127677.
[114] *Id.* at 127679.
[115] *Id.*
[116] *Id.*

increases that occur within sixty days of the enactment of the law.[117] In addition to the constitutional arguments, criticisms of California's law are that the advance notice requirement diminishes competition by creating informal price arrangements between manufacturers,[118] and that the law would create shortages by encouraging wholesalers and distributors to stockpile drugs in the sixty days prior to the increase so that they may benefit from buying the drug at the lower price and selling it when it goes up.[119] However, since informal price fixing schemes can easily occur over dinner meetings and phone calls,[120] the risk that a reporting requirement intended to protect consumers will facilitate price fixing is significantly outweighed by its benefits. Additionally, stockpiling is not a real issue since most manufacturers already negotiate distribution service agreements with wholesalers that recapture the value of price appreciation, which prevents the wholesaler from benefiting on inventory bought at a lower price.[121] California's transparency law may work to discourage price hikes because its advance notice requirement would signal to consumers to seek alternatives, and it would also signal to competitors that there may be room to enter the market.

Tennessee has also recently proposed legislation in response to drug price increases. Tennessee's proposed legislation is known as the "Prescription Drug Fair Pricing Act" ("PDFPA").[122] Under the proposed legislation, the commissioner of health in consultation with TennCare[123] will examine changes in prices for essential generic drugs in prescription drug programs operated by the state

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[117] Complaint for Declaratory and Injunctive Relief ¶¶ 1-12, Pharmaceutical Research and Manufacturers of America v. Brown, No. 2:17-cv-02573 (E.D. Cal. Dec. 8, 2017).
[118] *Id.* at ¶ 6.
[119] Ian Spatz, *California Takes on Drug Pricing: Real Progress or Illusion?*, HEALTH AFFAIRS (Oct. 2, 2017), https://www.healthaffairs.org/do/10.1377/hblog20171002.062240/full/.
[120] *See* Jeremy Olson, *Minnesota Expands Generic Medicine Price-Fixing Lawsuit*, STAR TRIBUNE (Oct. 31, 2017) (reporting that a Minnesota sales person arranged meetings where company reps could agree to inflate prices), http://www.startribune.com/price-fixing-lawsuit-targeting-minnesota-reps-is-expanded/454325993/.
[121] *How Wholesalers Profit from Brand Name Price Inflation*, DRUG CHANNELS (Oct. 5, 2015), http://www.drugchannels.net/2015/10/how-wholesalers-profit-from-brand-name.html.
[122] H.B. 1328, 110th Gen. Assemb., first reg. sess. (Tenn. 2017).
[123] TennCare is the state of Tennesee's Medicaid program. *See* TennCare, tn.gov https://www.tn.gov/tenncare/members-applicants/eligibility/tenncare-medicaid.html (last visited on Jan. 5, 2018).

over the past five years.[124] The commissioner shall report the finding of the study and any recommendations for appropriate action to prevent price gouging for essential generic drugs. Additionally, the PDFPA would require the Commissioner of Commerce and Insurance to examine issues relating to price transparency for prescription drug pricing, and to make any recommendations for appropriate action to implement price transparency.[125] This bill takes a "wait and see" approach to fair drug pricing. Its key provisions being that drug price changes and price transparency issues will be looked at.

While the California and Maryland laws have been passed, several states have pending legislation addressing the same issue. New York has a million-dollar solution to price gouging in the drug market.[126] If a drug manufacturer or wholesaler sells pharmaceuticals at an unconscionably extreme price, then it is subject to a one-million-dollar fine and payment of restitution to aggrieved consumers.[127] Under New York's proposed legislation, a determination of price gouging is based on a combination of the unconscionably extreme price and the unfair leverage or unconscionable means to get that price.[128] Evidence must be shown that there is a gross disparity between the price of the drug when it led to legal action and the price of the drug over the six months prior, or that the amount charged grossly exceeded the price at which the pharmaceuticals were available by other consumers.[129] The defendant may rebut a prima facie case of price gouging by providing evidence that costs outside the defendant's control are responsible for the price increase.[130] Unlike the Maryland law, New York's law sets a less ambiguous benchmark with which to measure what an "unconscionable" price is. The law also makes a provision for price increases that are related to production costs. However, New York's proposed legislation makes no distinction between brand name or generic drugs, which may cause it to run afoul of the Copyright Clause.[131] Additionally, the penalty is so large that it may discourage producers from entering the market place or,

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[124] Tenn. H.B. 1328.
[125] *Id.*
[126] S.B. 2402, 2017-2018 Leg., Reg. Sess. (N.Y. 2017).
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] U.S. Const. art. I, § 8, cl. 8 ("to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries").

alternatively, encourage producers to leave, which would reduce competition and potentially create shortages.

Rhode Island takes price gouging prohibitions to a new level. Rhode Island's proposed legislation makes it a felony to charge unreasonably excessive prices for vital drugs or pharmaceuticals in times of market emergency or market shortages.[132] Under Rhode Island's bill, "unreasonably excessive drug pricing" means there is a gross disparity between the amount charged and the average price at which the drug was available for sale within the local area in the course of the thirty days preceding the declaration of a market emergency.[133] In calculating the disparity, the bill accounts for costs attributable to retailers, suppliers, and replacement costs imposed by the vendor's source, while also excluding discounted prices offered as a bona fide manufacturer's or supplier's limited discounts or rebates.[134] The bill's provisions would only be applicable during a market emergency, which is any declaration of a state of emergency by the state governor or the President, or a market shortage where the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level.[135] Because of its criminal penalties, this bill may go even further than the New York bill in reducing the number of market participants, thus creating an even greater risk of a shortage. Producers whose costs go up during a market emergency would be open to criminal liability should they pass those costs on to consumers. While the bill does take their costs into account, criminal penalties may dissuade producers from participating in the market.

Massachusetts has proposed a price transparency bill that would require drug companies that increase prices to provide to the Attorney General a justification for the increase in the wholesale acquisition cost of the drug.[136] The bill limits the reporting requirement to the fifteen prescription drugs that the State spends significant health care dollars on and for which the acquisition cost has increased by fifty percent or more over the past five years or by fifteen percent in the past twelve months.[137] Manufacturers that fail to provide the required information are subject to a $10,000 fine per violation.[138] This bill is similar to California's transparency law, but the reporting requirement is limited to only the drugs that cost the state the most money. While this may help to protect state expenditures, medically necessary drugs used by a small population

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[132] H.B. 5032, 2017 Leg., Reg. Sess. (R.I. 2017).
[133] *Id.*
[134] *Id.*
[135] *Id.*
[136] S.B. 627, 190th Gen. Ct., reg. sess. (Mass. 2017).
[137] *Id.*
[138] *Id.*

would not be required to report if their total costs were below the fifteen most expensive drugs overall. This bill would not address the most recent spate of drug price hikes because the most egregious price spikes occurred in small market drugs.

The states mentioned above are not the only ones pursuing legislation, many other states have introduced legislation in an attempt to regulate price spikes either through price caps, reporting requirements, or a combination of the two.[139]

III. WHAT LAWS SHOULD STATES ENACT TO PROTECT THEIR CITIZENS?

This note argues that to combat price gouging in the generic drug market, states should not enact price controls, but should instead pursue legislation that increases drug price transparency. Although the drug market does not work like other markets, price controls will most likely result in shortages of needed drugs. However, transparency laws with advance notice requirements for price increases will act as signals to consumers to begin searching for alternative sources of medication, and competitors will be put on notice that there is an opportunity to enter the market.

There is a strong argument for controlling prices in the drug market, in particular, because consumers do not have a choice to switch to another drug, and there is no time to wait for the market to correct itself through competition, as discontinuing a necessary drug can result in serious injury or death. Unlike markets for fuel or other commodities, the healthcare market has variables that cause it to act unlike other markets, a primary distinction being that when it comes to essential healthcare, there are no viable alternate markets.[140] If gas goes up in price, consumers can reduce their consumption by carpooling, walking, bicycling or taking public transportation.[141] For most goods on the market, a consumer can switch to an alternative, or exit the market altogether. Essential medicines are

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[139] *Curbing Unfair Drug Prices: A Primer for States*, Global Health Justice Partnership (Aug. 2017), https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf.

[140] *See* Kenneth Joseph Arrow, *Uncertainty and the Welfare Economics of Medical Care (American Economic Review, 1963)*, J. OF HEALTH POL., POL'Y AND L., Vol. 26, Number 5, 141-143 (Oct. 2001), *reprinted at* http://www.who.int/bulletin/volumes/82/2/PHCBP.pdf.

[141] *As Fuel Prices Surge, Bike Business Rolls Along*, NBC NEWS (May 11, 2008), http://www.nbcnews.com/id/24566705/ns/business-us_business/t/fuel-prices-surge-bike-business-rolls-along/#.WnznOWaZNsM.

different because in many cases the alternative to treatment is suffering and death. When prices go up, patients risk serious damage to their health if they cut down on their treatment or decide forego treatment altogether. There is no real choice for the consumer. Additionally, medical conditions are not going to wait for competitors to enter the market after a price spike. In the time it takes for a generic manufacturer to see the price signal and decide to compete in that market, as well as get approval from the FDA to manufacture a generic equivalent and bring it to market, patients who are cutting down on medication or foregoing treatment entirely will most likely suffer adverse effects. A popular quote among economists is that "the market can stay irrational longer than you can stay solvent."[142] In the case of a newborn infant with toxoplasmosis, the market can stay irrational longer than the baby can stay asymptomatic.[143]

While the specter of a sick infant creates a sense of urgency to remedy the issue through sheer political will, it does not benefit the patient if law-makers forget that price controls have a tendency to limit the number of market participants by removing incentives to bring more supply to meet the demand. Merchants in ancient Rome removed their wares from the marketplace when confronted with Diocletian's Edict,[144] and shortages of goods following a hurricane are exacerbated when price gouging laws disincentivize people from bringing supplies to the affected area.[145] While the drug market may act differently than other markets, fewer incentives to participate in the market will result in less supply. Should shortages occur, a patient would have no alternative other than to forego medication. In a realm where prices simply went up, a patient who could not afford medication would be able to seek financial relief through several avenues.[146] In a world where medication is in short supply, a patient would be left with no cure. On balance, the patient is better off seeking financial assistance to secure expensive medication than being without medication because it is not being produced or sold. A state whose price-control laws discourage drug providers to the point that they no longer participate in the market ultimately drives its citizens to seek relief outside of its borders. It is a distinct possibility that the citizens of Maryland would be forced

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[142] Paul Krugman, *How Did Economists Get It So Wrong*, N.Y. TIMES MAG. (Sept. 2, 2009), http://www.nytimes.com/2009/09/06/magazine/06Economic-t.html.

[143] *See* Sudden Price Spikes *supra* note 16 at 103.

[144] Kent *supra* note 61 at 39-40.

[145] Zwolinski *supra* note 87, at 362-63.

[146] *See* Partnership for Prescription Assistance, https://www.pparx.org/prescription_assistance_programs/list_of_participating_programs (last visited Jan. 7, 2018).

to seek their medications elsewhere because drug producers did not wish to be subjected to the fees, penalties and other regulatory burdens imposed by the recent legislation.

Capping generic drug price increases may also increase the average price of drugs. Just as the gas price cap in Hawaii may have caused the price to go up to the maximum allowed, by enacting a set percentage increase, drug producers would then be able to raise prices to the maximum allowed without incurring a penalty. The incentive for doing so, besides increasing profits, would be to offset losses from not being able to increase prices as needed in the future without incurring regulatory scrutiny. While the GAO found that the average cost of generic drugs was declining despite the price spikes, a set price increase cap may cause the prices of those drugs to rise. While small market patients would have some price protections, an overall increase in prices would have a detrimental effect on insurers and government programs.

Laws that increase drug price transparency and require advance notice of price hikes are a good way to keep generic drug prices down. Unlike most markets where the price of a commodity is readily available to buyers and sellers, the true cost of pharmaceuticals is obscured by a web of rebates and discounts between pharmacy benefit managers, manufacturers, and insurance companies.[147] Because of a lack of information, buyers do not always know how much they are truly paying, and other producers do not know when prices are appropriate to manufacture a competing generic drug. By requiring drug companies to give the state sufficient prior notice of a price hike, as well as the detailed reasons therefor, the state can publish that information to signal competitors. This could lower prices by either accelerating the entrance of market participants, or by discouraging drug manufacturers from raising prices exorbitantly to avoid drawing in more competition. Advance notice of a price hike could also signal to patients, physicians, and hospitals that the drug is entering a period of scarcity, and that they should conserve its use, find alternative treatments, or find alternative sources for the drug (i.e. compounding pharmacies).[148]

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[147] Grace-Marie Turner, *Price Transparency is Critical to Drug Price Solutions*, FORBES (July 11, 2017), https://www.forbes.com/sites/gracemarieturner/2017/07/11/price-transparency-is-critical-to-drug-pricing-solutions/#5055cc56204a.

[148] "Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient." *Compounding and the FDA: Questions and Answers*, FDA,

California's drug price transparency law sets out detailed reporting requirements,[149] as does Massachusetts's transparency bill.[150] A new law regulating drug price transparency should have an advance notice requirement for price hikes in excess of a specific benchmark measure. Although California's law is being challenged because its benchmark is ambiguous, Massachusetts sets its benchmark as the "average manufacturer price,"[151] which is "[t]he average price paid to the manufacturer for the drug in the United States by—(i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer."[152] Having a specific benchmark price would help to alleviate challenges that the law is unconstitutionally vague. Additionally, a transparency law should take into account production and marketing costs so that a manufacturer is not unduly penalized for increasing prices because of increased costs. Unlike the Massachusetts law, which limits the reporting to the fifteen prescription drugs that the state spends the most money on,[153] a state reporting law should apply to each drug that has experienced a large price increase. One of the key elements of the Turing business plan was to target drugs with a small patient population,[154] and under the Massachusetts law, Turing might not have had to report its increases because its total costs may have been less than the fifteen costliest drugs, by total state expenditure. A transparency law should also require an explanation for the price increase, as well as an itemized listing of the cost of the drug's ingredients, much like California's law.[155] Lastly, the state should publish the relevant cost information in a timely fashion in order to alert consumers, third-party payers, and competitors that a price hike is on the way.

CONCLUSION

"Pharma Bro" Martin Shkreli infuriated the public, and that anger has manifested as price gouging laws that seek to implement price controls on pharmaceuticals. State legislatures are bound by the will of their constituents to do something about these egregious offenders. But while price controls are an emotionally satisfying

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https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last updated June 22, 2018).

[149] Cal. S.B. 17.

[150] Mass. S.B. 627.

[151] *Id.*

[152] Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(k)(1)(A).

[153] Mass. S.B. 627.

[154] Sudden Price Spikes *supra* note 16.

[155] Cal. S.B. 17.

way to solve the problem of high prices, they typically result in shortages of the items at issue. The unintended consequences of price controls have a long history. A better approach is to implement transparency laws that require advance notice of a price hike so that consumers can make adjustments and competitors can lay plans to participate in the market. While patients in financial need may have to seek assistance while awaiting a correction in price, in the long run they would be better served if states focus on ways to increase competition in the drug market.