INDUSTRIES PERSPECTIVES ON HEALTHCARE: DELIVERY IN AN UNCERTAIN POLICY FUTURE

PANELISTS:
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Moderated by Professor Debbie Farringer, Belmont University College of Law

JANUARY 27, 2017

Professor Farringer: Thanks to everyone for coming. Thanks to Aubrey Beckham and Taylor Wilkins and Grace Ann for putting all of this together and for all their hard work. And for the whole team that came together pretty quickly. Actually, you know we just formed the journal and had all the student involvement at the very beginning of this first semester of the year. So to throw all this together and pull it all out has been amazing, so thanks so much to the students.

I am really excited to be able to introduce our panelists here for Industry Perspectives. And, its been really funny in trying to craft questions to think through what to ask these folks. It seems like it changes day to day with everything that is happening because it is such a moving target right now, in terms of where things are going and what we can expect. So a lot of what we are going to talk about today probably is just "what are some of the various things that have been thrown out there that might be changing the landscape of healthcare and what can practitioners think about?" "What do we need to consider?" And hopefully can just have some good conversation about various policy proposals and pieces and parts of health care reform.

So I am going to introduce our panelists. First, to my right here, is Michael Regier. He is general counsel and secretary for Vanderbilt University Medical Center in Nashville, Tennessee. He received his bachelor's degree in business administration with highest distinction from the University of Kansas and his Juris Doctorate from the University of Virginia School of Law, where he

was a Dillard Fellow. He became General Counsel and Secretary of VMC on April 30th, 2016. He is responsible for all legal and regulatory matters as well as risk management and insurance, as well as the compliance program, which I am sure is a huge, huge job, so he has been busy. Before joining VUMC he had served since August 2012 as Vice President and Chief Legal Officer of Atlantic Health Systems in Morristown, New Jersey. Which I believe is a four-hospital – five hospital health system in New Jersey. And before there he served since June of 2007 as Senior Vice President of Legal Affairs and General Counsel and Secretary of VHA, now Visiant, in Irving, Texas. While at VHA he had responsibilities in legal, risk management, office services, public relations, and corporate communications teams, as well as the company's office of public policy in Washington, DC. Prior to VHA, Mr. Regier served since September 1995 as Senior Vice President, General Counsel, Secretary, and Corporate Responsibility Officer for the Seton Healthcare Network, now Seton Healthcare Family in Austin, Texas, where he was responsible for legal and corporate governance matters as well as the compliance program. He also has been in practice in Chicago, Illinois, prior to that since 1985.

To his right is Mr. Dick Cowart. Mr. Cowart is a recognized authority in advising senior management regarding policy, regulatory, and business issues relating to healthcare. He serves as strategic counsel to healthcare companies, both for-profit and non-profit, and counsels providers on business, policy, and governance issues, with an emphasis on business transactions. You might have seen him – he is nationally known speaker and writer on healthcare issues and is the national columnist for Medical News Inc. for 18 years and is our own local health business columnist for the Tennessean for more than 10 years. Mr. Cowart graduated Magna Cum Laude from the University of Southern Mississippi with his BSBA and with Honors from the University of Mississippi School of Law.

And our final panelist, to the far right, is Mr. Darin Gordon. He is the former Director of Tennessee's Medicaid program, TennCare, with 20 years of experience in public health finance, policy, and operations. He has served both Democratic and Republican governors and had been in healthcare policy and innovation nationally, through consultations with over 35 states. Mr. Gordon is a fellow of the Medical Leadership Institute, and a member of the Inaugural class of the Nashville Healthcare Council fellows program, and board member of Leadership Healthcare. Mr. Gordon is a member of the Cressey & Company Distinguished Executives Council and a Director of Addus Homecare, Unified

Care Group, and Siloam Health. He also serves as Chairman of 180 Health Partners and is an advisor for myNexus. He is President and CEO of Gordon and Associates, LLC.

So, thank you for coming.

As we get started, one of the things that I wanted to talk about first is, it seems relatively certain that at least some parts, or potentially all (it's not totally clear at this point), but some parts of the ACA[1] will be repealed. And there are various proposals for different replacement plans that have been discussed. And one of those proposals is the idea of changing Medicaid from its current structure into a "block grant" program. So can you describe—Mr. Gordon, I don't know if you are the best one to take this one given your history—but tell the audience a bit about what "block grant" programs are, what that would mean for the TennCare program and other Medicaid programs, and just some general information about "block grant" programs and how Tennessee would potentially prioritize needy populations under that.

Mr. Gordon: Sure. First, thanks for having me, I really appreciate it. Obviously, everywhere I go, the topic comes up pretty regularly. But, before I describe block grants, it might be helpful to orient people to kind of the current state of financing in Medicaid. Think about it in two parts: there are two investors in Medicaid—the state and the federal government. The primary investor is the federal government; they really put more into the equation. In essence, it is an open-entitlement program from the federal perspective. If a person is eligible for the program, or they need services that are covered under Medicaid, the federal government will put forth the funds needed to reimburse the state for their share of the cost of those services. However, on the state side, while they still have bought into this open entitlement concept, they are limited by the amount of state appropriation that they can contribute to this equation. So, it's not as if money can keep going to Medicaid no matter what as I think some of the articles out there imply today. It comes that way from the federal government, free flowing and no cap, but it still requires states to come up with their share of the funding. I remember talking to different finance commissioners over the years, and when they come in and try to figure out Medicaid and seeing that's the largest budget item, they would ask me "so how much total money can we get?" And I would respond, "as much state dollars as we can come up with to match it." But they would always respond, "there has got to be a limit," but there is no limit. And they

[1] 42. U.S.C. § 18001 *et seq*. (West 2017).

are baffled by this. I mean, literally, they would have to ask me this question over and over to get past it. But accepting federal dollars is always a challenge for states; and it creates a bit of friction because the states are constantly needing to make changes to these very large programs due to state dollar limitations, but the federal government limits states' flexibility to change these programs to live within the available state funds.

Okay, so, think about the block grant concept now. If there is a "one size fits all" on block grants is being contemplated, this will cause folks to be scared and worried—I tell people "I'm not scared of the concept of a block grant." I am, however, concerned over the details of a block grant. The idea being that, instead of the feds saying "regardless of how many people you have, or how many services are needed, I'm going to send you a set amount of money, the concept would be that "I'm going to send you some fixed amount of money from which to work with." Now, is that less than what you got the year before? Is it what you go the year before but trended at a slower trend rate? All those things matter. States can work within this, if designed well. I can tell you, I can design a block grant scenario that is something that I would be quite comfortable with. But, we don't know if that's ultimately going to be the case. Depending on how this comes through Congress, it could be more of a "function with 90% less money than you had the year before" approach. Then, that begs the question, "what types of changes am I allowed to make in order to live within that?" So, funding and flexibility are hand in hand in this equation. You can't answer only half of the equation. Like "we are going to give you this flexibility" – "Well that's great, so tell me what the financing is going to look like." And vice-versa. They are inextricably linked. The debate is on what it's going to look like. We will see. Is it a dramatic change? Yes. That is probably why you're hearing about this as regularly as you are. Because it's fundamental to the program and how it has been run for the last 50 years. It is worth pointing out that, block grants are not new. The concept of block grants in Medicaid actually was voted on in the Senate and the House under Clinton and ultimately passed in both houses under Clinton but ultimately was not signed into law by the President. So it is not a new concept. But, I think that people feel, more than any other time in our history, that we are likely to see some significant change in the financing of Medicaid. In order to, one, constrain the growth, and two, give more flexibility to the states to manage available funds.

Mr. Cowart: If I might add just two quick points. First, the CMS administrator, Seema Verma, is not yet confirmed, and she is a good friend of Darin Gordon and Vice President Pence. In Indiana, they

had operated under a very broad waiver, so the idea that there would be a lot more flexibility is safe to say. Secondly, you may recall that the *Sebelius*[2] decision was really the first United States Supreme Court decision on the Affordable Care Act[3]. They stated that the federal government couldn't cram down the Medicaid expansion on the states. So I think that while there will be more flexibility, I think there will not be a cram down—I think the states will be given options. And depending on if your trend rate is up or your trend rate is down, and what your benefit package is, states will be able to design their flexibility.

Professor Farringer: That leads me to one question – or actually, go ahead.

Mr. Regier: Well, I was only going to say the only other caveat, is that's probably the first thing that the Republican majority will go after. And we can say to keep your eye on at a very high level, two things: the flexibility afforded to Executive Director and Chief Medical Officer of the State Medicaid plans; and then "where is the baseline set?" I think states, like Tennessee, that have been very, very efficient in managing their Medicaid plans (some might say stingy) and have had a 1.5% annual growth could be disadvantaged versus states like the state of New York, who have been experiencing 12 to 14% of year over year of growth, and also how that's will impact states with an 1115 waiver. That of course includes Tennessee, which was the first state in the nation to go to a fully managed care plan approach starting in 1994.

Professor Farringer: That leads nicely into my segue – do you think that states will be provided funding under block grants based on existing population or based on the amount of money they have been given in the past; so, are states that did not expand going to be negatively affected by the lack expansion?

Mr. Gordon: I would tell you, amongst the states, and some folks at the federal level, there are people who are trying to sort through this. The questions that they raise are "Are we at a disadvantage for not having expanded?" Similar to what was just said, the concept's specifics are not "out there." It's not a concept that makes me run and hide. But all those details have to be thought through. And there seems to be a push to hurry up and get something out there. I would say, since everyone has agreed that there is going to be a replacement at the same time a repeal is imposed—we aren't going to have an immediate crisis here. I would just encourage everyone

[2] Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012).
[3] *See generally* 42. U.S.C. § 18001 *et seq*.

working on this to be thoughtful, if there is ever a time to take something slow, 18% of GDP is something that we should REALLY take our time on to get it right. Make sure that you go through all these different levels of questions and make sure that you don't set up a system with perverse incentives.

Professor Farringer: Okay, so, that leads me to another question, sort of about the idea of repeal and replace. Most of what we talk about—most of what we hear about—is the pieces that need to be repealed. We don't hear a lot about the quality improvement and the quality-centered programs and a lot of the pilot programs that were enacted in connection with the ACA.[4] So, what do you think is going to happen to some of those sorts of programs[5] and pilot programs and reimbursement explorations that have been going on as part of the ACA, that really have nothing to do with insurance, nothing to do with the individual mandate, and not, I would say, the kind of hot-button issues that are causing the repeal discussion?

Mr. Regier: You are talking about, I think, the perfect storm scenario for hospitals. One thing that I would point out is the quality-based programs that are built into the ACA[6] really didn't start–these didn't originate with President Obama. President Bush and former Health & Human Services Secretary Leavitt, had actually started the pay-for-performance quality-based system well before President Obama was elected into office. So these were Republican ideas that were wrapped into the ACA to appeal to those on the "R" side of the aisle, to try gain some political support for that statute. You know, as part of the "three-legged stool" of insurance reforms: increasing access to coverage, and improving quality while lowering costs—the three broad components of the ACA. I don't expect the quality initiatives to go away—they generally are saving money for the federal government. Which is—when the policy perspective is "we aren't getting what we are paying for in healthcare" –which IS the policy perspective on the federal level, I don't expect this will go away. A risk for providers, though, is that as pay-for-performance is forcing down Medicare reimbursement (which for a typical hospital provider is 40% to 45%, even so much as 50%), some institutions, at the same time, will lose the Medicaid expansion, which means we

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[4] 42 U.S.C. § 1395b-1 (West 2017); *see e.g.*, Ctrs. for Medicare & Medicaid Servs., *Linking Quality to Payment*, *available at*https://www.medicare.gov/hospitalcompare/linking-quality-to-payment.html (last visited Nov. 1, 2017).

[5] *See e.g.*, Melinda K. Abrams et al., *The Affordable Care Act's Payment and Delivery System Reforms: A Progress Report at Five Years*, THE COMMONWEALTH FUND (May 7, 2015) http://www.commonwealthfund.org/publications/issue-briefs/2015/may/aca-payment-and-delivery-system-reforms-at-5-years.

[6] 42 U.S.C. § 1395b-1; 42 U.S.C. §§ 299b –31, 300kk, & 3299b.

will not have people getting Medicaid coverage; we will lose the mandate, and we are definitely going to lose the tax credits and tax subsidies provided under the ACA[7], which will affect individuals' ability to buy insurance coverage. So I think there may be something to replace that, but it is likely that there will be fewer people with insurance—so more uncompensated care. And, we still have the reductions in disproportionate share funding because that was part of the bargain about expanding coverage. We will reduce the—there is a payment stream called the disproportionate share hospital funding which is made available by the federal government to those providers that provide a very high degree of care to the Medicaid population—which is, I think, admittedly outside the beltway to be reimbursed. That, I don't think, will come back, because the fiscal pressure is too great, and so you are going to have continued pressure on providers by way of lower reimbursement, higher quality expectations, fewer people with insurance, and fewer dollars coming from the federal government to help offset that cost. It's a dream world.

Mr. Cowart: First off, Repeal and Replace—I think we will talk about that separately. On quality, I think the two big pieces of bipartisan legislation were MACRA[8] and Healthy Cures[9], both of which passed the House and Senate with supermajorities. So, I think those are pretty solid. However, we have an HHS Secretary who is a general orthopedic surgeon.[10] If you were to ask him if we should design quality regulations in Washington, he would tell you that's nice but physicians decide quality not Washington bureaucrats. Regarding competition, if we are ever going to have true price competition we've got to have common prices, and we've got to have some degree of transparency. What people are buying and what does it cost. The process works best when the government can set some parameters. Frame the marketplace, and then withdraw and allow the marketplace to do its thing. I think there is a lot of interest in creating a marketplace, creating transparency, getting pricing and quality data into the marketplace but not trying to regulate it from Washington. And I think you are going to see some interesting things that we have in Tennessee. Now, I think, one of the more interesting things is what the state put in its state employee health plan request for proposal. It included a section on bundled payments to cover all the state employee healthcare insurance. Whoever won

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[7] 42 U.S.C. § 18082. Ctrs. for Medicare and Medicaid Servs., *Premium Tax Credit*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/premium-tax-credit/ (last visited Nov. 1, 2017).

[8] Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114–10, 129 Stat. 87 (2015).

[9] 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

[10] Secretary of Health and Human Services at the time of publication was Tom Price.

that contract had to create pricing for 75 of these highest use procedures—essentially creating a pricing framework that could be used as marketplace price and transparency. The State was attempting to use its purchasing power to create a marketplace but not necessarily regulate that marketplace.

Mr. Gordon: Dr. Price, the future secretary of HHS, said a lot of things early on[11] that caused me to be concerned for the future of the Center of Medicare and Medicaid Innovation[12] but also about value based purchasing in general. Even before being considered for the Secretary of HHS, while he was with the Georgia Medical Association, he made comments regarding concerns over the move to value based purchasing.[13] However, at his confirmation hearing a few days ago, he actually said he could see how the Center could be repurposed and used to promote innovations at the state level and how the move to value is the new direction things are moving towards. He said "I could see some value with continuing CMMI with a different focus" but he didn't really go into a lot of detail. To some degree it made me feel "will the priorities be the same?" Probably not. May there be some different things they invest in? Probably. Dick is right, the degree of control of those programs might be lessened and allow things to flow more naturally from the states. But the idea of value first is one of the biggest components of all that. With Tennessee being a leader of the country on the move from volume to value, this is important. If you look at Arkansas or Ohio, you see other states stepping out as well and doing similar things to Tennessee and trying to move things forward. Medicare has been sampling a lot of value based models, but the states have been sampling a lot of value based models as well. So the move to value isn't just being driven from within the beltway. So, even if they change some direction at the federal level on this topic, states will continue to push forward. In fact, I said whenever we applied for a grant to help implement value based purchasing that, I wish we hadn't applied for the grant because we could have moved faster without it than with the grant. So the interest to move from volume has always been driven by the states because, like has been stated, it

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[11] Linda Qiu, *Schumer: Trump and his HHS Pick Tom Price at Odds on Medicare*, POLITIFACT (Jan. 10, 2017, 1:58 PM) http://www.politifact.com/truth-o-meter/statements/2017/jan/10/charles-schumer/schumer-trump-and-his-hhs-pick-tom-price-odds-medi/.

[12] 42 U.S.C. § 1315a.

[13] *See* Bruce Japsen, *As Trump's HHS Secretary, Tom Price Could Slow Shift to Value-Based Care*, FORBES (Nov. 29, 2016, 7:02 AM) https://www.forbes.com/sites/brucejapsen/2016/11/29/as-trumps-hhs-secretary-tom-price-could-slow-shift-to-value-based-care/#5f8ec250636f; *see also* Shannon Muchmore, *As HHS Secretary, Price Would Likely Focus on State Healthcare Reform*, MODERN HEALTHCARE (Nov. 22, 2016), http://www.modernhealthcare.com/article/20161122/NEWS/161129971.

is a building block to a more functioning market. In and of itself, it isn't going to make a functioning market, although it is a critical tool. Once you get to a point of understanding what all is encompassed in a particular procedure—from start to finish—then you are better able to help people understand what all they would be purchasing and how to compare, apples to apples, both quality and cost. So, I don't see that movement stopping. Dr. Price's more recent comments are encouraging to a lot of folks. It gives comfort that, in some form or fashion, there will continue to be a focus and funding to support greater innovation.

To your point, I think we do see a lot of uncertainty, not just with providers but also the investment community. There are a lot of folks holding back to wait and see where things are headed. If anyone is out there right now trying to get providers to sign a new agreement with them related to some grant they received, I would probably think they are going to have a hard time convincing the provider to change processes and change their systems to accommodate that right now. So I think the broader system is pausing, or at least has slowed down, for the moment until we see more details on what is likely to come. And when those details are available, things will gear back up and we will begin to see changes accelerate once again.

Professor Farringer: Do you think that is true for accountable care organizations (ACOs)?

Mr. Gordon: I do think that is true for some ACOs. It depends on where or how they originated. Some ACOs came directly out of grant funding from Medicare. Others originated more organically–driven by local market dynamics. Some ACOs were born out of a change in the healthcare world more generally. But if, let's say, Medicare suddenly does back out, of participating in ACOs, then the ACOs are going to be hard-pressed to make it work. Could they continue? Yes. The big question would be what would be everyone's purchasing situation? If I as a payer go to Vanderbilt and I say I am going to do an ACO arrangement this way and another person says they will do it a different way, and another says they will do it yet another way, you are setting Vanderbilt, and the model, up for failure. So, if any one of those large payers back out, then an ACO is going to struggle to bet a viable option. And I don't think we know enough at this point.

Mr. Cowart: I think it is important to understand that in the 50+ years we have had Medicare, it was principally a fee for service programs; Part A for hospitals and Part B for doctors and

outpatients. In the early 90s, Part C, Medicare Advantage is created, and then Medicare Part D under President Bush for pharmacy benefits. You had essentially two models at both ends of the spectrum - fee for service and capitation. What is in the middle is a shared savings program. Medicare's version of that is called an Accountable Care Organization. And there is a lot in the private sector also private payers. So, I think there is going to be a lot of activity in the shared savings space—that is not limited only to Medicare ACOs.

Professor Farringer: It will just be how we all coalesce.

Mr. Regier: Well, I mean the clear impetus is to say to the provider community, (from the payer's side), "we expect you to be prepared to accept financial and operating risks for a population of our enrollees for a period of time, and for all the services they need from the beginning of life to the end of life." So, there is flexibility in how you do that. Like, how you structure that kind of a model. We have taken the approach today to try to assemble an affiliated network, on the theory that you cannot afford to own everything. An affiliated network, to one day be in the position to be able to accept that degree of risk for a population, is difficult. So that is one way that you can try to position yourself to be like an ACO at that level.

Mr. Gordon: One last point on that…any of those payment or quality initiatives that we have talked about in this conversation, require some degree of alignment. States are out there and they are trying out new things and so are the private payers, they are out front. And everyone is concerned what Medicare is going to do. All the efforts over the last 5 years since the states were investing in this could all be for nothing if Medicare goes in a completely different direction. If they go in another direction it can shift the entire system. So that is something that everyone is going to want to watch. Not so much "will an ACO develop?" I think the elements and the principles behind those are fine. I think that the principles will still be there. I think the question will be "will Medicare come out with a direction or will they let it be something that everyone else drives?"

Professor Farringer: Okay! So, one other thing that has been talked about, I think it was talked about in the debates leading up to the Presidential election and significantly since the election, is the idea that we would include in any replacement plan the ability of people to purchase insurance across state lines. So, maybe talk about that a little bit to the audience and tell us some of the pros and cons of the approach and why its proponents say it would ultimately reduce

healthcare spending. And then any legal concerns that might come up with that – especially I think on the insurance side from the state's perspective. States all have their own insurance laws that are driven towards protecting their residents, related to making sure that their residents and insurers of the state are not doing things that are hurtful to their own residents. So, what are some of the legal implications for states as we think through this?

Mr. Cowart: Sure. We might need a primer on Repeal and Replace before we do a primer on insurance. Repeal and Replace is a campaign term. We are not going to replace the Affordable Care Act without 60 Republican senators. And you may recall six years ago when Scott Brown won the election in Massachusetts, there were only 59 Democrat Senators. Because they attempted to cram through the Affordable Care Act, there are many technical errors. And they ultimately had to pass it through using budget reconciliation. For those law students who are here, the House represents the passion of the People. They pass things pretty much on party lines. The Senate is supposed to be the waiting pot for deliberation, so it takes 60 votes to suspend debate, or cloture. It is not 60 votes to pass. So that's why that magic number is 60; otherwise you have filibusters. Now one of the things that is exempt from cloture is the federal budget. The nation needs to have an annual budget. So it only requires a majority. And by the way, since we are watching it on TV every morning, the Democrats decided that every confirmation, except the United States Supreme Court, is exempt from cloture. The nominees are all going to be confirmed unless there is some crime in their background. On Repeal and Replace, it is largely going to be budget-driven because of reconciliation—it's got to be. It's going to take away the individual mandate,[14] take away the employer mandates,[15] and the Cadillac tax,[16] and take away the medical device tax,[17] all of which produces the money to fund everything. Without new taxes you can't do much because you don't have any money. So the reformers have got to say "what can we do that doesn't require new taxes?" Because also we want to pass tax reform. All that is kind of a stage. You have to understand that you have to fill the vacuum

[14] 26 U.S.C. § 5000A (West 2017); *see also*78 FED. REG. 78256-01 (Dec. 26, 2013) (to be codified at 26 C.F.R. at pts. 1 and 602); *See e.g.*, Ctrs. for Medicare and Medicare Servs., *The Fee for Not Having Health Insurance*, HEALTHCARE.GOV, https://www.healthcare.gov/fees/fee-for-not-being-covered/ (last visited Nov. 1, 2017).
[15] 26 U.S.C. § 4980H; *see also* Internal Rev. Serv., *Questions and Answers on Employer Shared Responsibility Provisions Under the Affordable Care Act*, U.S. Dep't of Treasury, https://www.irs.gov/affordable-care-act/employers/questions-and-answers-on-employer-shared-responsibility-provisions-under-the-affordable-care-act (last visited Nov. 1, 2017).
[16] 26 U.S.C. § 4980I.
[17] Internal Rev. Serv., *Medical Devise Excise Tax*, U.S. Dep't of Treasury, https://www.irs.gov/newsroom/medical-device-excise-tax-frequently-asked-questions (last visited Nov. 1, 2017).

with something. If you want to know the founding of Repeal and Replace principles, there was a Blair House summit[18] with five leading Democrats and five leading Republicans, go to the CSPAN in the archives, find the Republican plan of the summit, and those are the building blocks.[19] One of those building blocks is insurance across state lines. Insurance across state lines is really likely. When we look at auto insurance, costs are down. It is a lot less expensive than it used to be because it is a highly competitive model. For auto insurance, there are all kinds of coverage packages. The Affordable Care Act[20] has a standard national benefit package. We mustn't change that. We must also end up with more catastrophic coverage. The process thus far is whoever can provide the cheapest price gets the business. People buy on price, not on benefits. Unless they are really sick, and then, if you are an insurer, you don't want them to buy anything. The other thing is, we never federalized any insurance regulation. Property, casualty, and life insurance, since the early 1900s, has been regulated by the states. The whole concern of the state insurance commissioners has been to try and regulate this in some way. It has them scared—I mean really scared. And particularly in states like Tennessee where the insurance commissioner doesn't have a lot of statutory authority.

Professor Farringer: Read between the lines! I was going to ask you about that. Do you think it is too difficult?

Mr. Gordon: I think it is going to happen. I think it will pass. I think you will see that. I think where it will fall is less clear. I think all our crystal balls are out of order. I think it will pass, the question will be, is it realistic? And also, how will it play out? Each state's commissioner of insurance has developed a set of regulatory guidelines and regulatory frameworks. For them to say that their own standards are not good standards would be unusual. To have someone come into your state and not abide by those standards, is probably going to be problematic. An Insurance commissioner would likely be a little concerned about that. But I also think about it from a market perspective because in some cases it is not because of the regulatory framework that a plan isn't going into a market. Even if you change the regulatory criteria, they will still have to

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[18] *White House Health Care Summit, Part 1*, C-SPAN (Feb. 25, 2010) https://www.c-span.org/video/?292260-1/white-house-health-care-summit-part-1; *see also* Kristi Keck, John Helton and David DeSola, *Highlights from Obama's Health Care Summit*, CNN POLITICS (Feb. 25, 2010 9:12 PM) http://www.cnn.com/2010/POLITICS/02/25/health.care.summit.updates/index.html.

[19] Noam N. Levey and Kyle Kim, *A Side-by-Side Comparison of Obamacare and the GOP's replacement plans*, L. A. TIMES (July 13, 2017).

[20] 42 U.S.C. § 18022.

make a business decision on how likely they could be successful in penetrating that market. If it is just not something that they think they can do successfully, regardless of the regulatory environment, then they just won't do it. If you think about what is involved when you take my insurance product and move from Tennessee to Alabama, then that insurance company has to maintain a presence there and establish provider networks there to support mer. We will just have to see how that plays out. There will be a long run-away before we see it play out and get a better sense of the practical implications of that.

Mr. Gordon: I like the theory of it, I am just stumbling over the details of how you are actually going to make this work. Are you going to have a federally mandated set of minimum benefits that must be offered as a condition of federal law? And then, how transparent is that going to be to a consumer? If the approach is that there would be some set of standard disclosure requirements, and consumers could at least look at some standard format to say "this is clearly what is covered, this is what I'm getting," that kind of conversation might be helpful to a consumer trying to compare their options. How you have that for 50 states, which already have an established framework, is going to require a long time to create and implement. It will take a long, long time. And I suspect that there will be many theories on how that will and ought to be done. There are some folks that are very aggressive and there are other states that are not as aggressive from a regulatory perspective, and so how does that all play out?

Professor Farringer: Okay, let's jump a little bit into…Dick, you alluded to one of the biggest things that has been mentioned—the removal of the individual mandate, which is the removal of the requirement that all purchase insurance, either under an exchange or through their employer. So, there has not been a lot of talk of the other two pegs of that equation, which are subsidies and credits provided to individuals that cannot afford insurance, and then also the fact that right now insurers cannot deny insurance to those individuals with preexisting conditions. So, talk to me about the individual mandate. And if the administration says that we are not going to enforce it or if that is the only piece that changes, what is the implication? What do insurers think about that? What do providers think about that? What are the implications?

Mr. Cowart: At least politically, Congress has to keep the no preexisting condition provision[21] and they have to keep the children,

[21] 45 C.F.R. § 147.108 (2017)

up to age 26,[22] on the parent's policy provision—those are key. But again, what Congress does next is dependent on how much money is available and whether they reconcile tax cuts while removing (the "repeal" part is removing that tax part) the tax credits. At the end of the day you have "x" amount of dollars. It is not nearly the same amount of money that Congress had under the Affordable Care Act. I think that these will be tax credits. There is some discussion about making it catastrophic coverage credit, so making it kind of a chronic disease super fund that is administrated at the state levels. To say that these are available in a catastrophe, the government's role in funding this and the citizen's role in funding primary care. So I believe that there will not be an individual mandate. There is probably going to be an employer mandate. That is just an anathema to this administration.

Mr. Regier: I am going to say this, part of the deal from the hospital industry's perspective, part of the deal was "we are going to get an coverage expansion and so we hospitals are going to suck it up and take reductions in Medicare payments and in disproportionate share funding." So that deal, now appears to be going away. I am very concerned just as a public health matter at the number of people who will no longer have insurance. I have heard too many people still saying "repeal and restore." A number of folks are saying "we are getting rid of this horrible bill and we are going to restore choice"—well, choice was no insurance for 47 million people in this country. That was not a choice and that is not acceptable. So that, I think, is going to be a very big priority for the provider side. And I am encouraged because the President has said that it is going to be huge, it is going to be great, and it is going to be wonderful. And, at Vanderbilt, I would say that we are ready to sit down and talk with anybody at any time and at any place to collaborate on a plan to increase access to coverage for people in Tennessee and the surrounding states.

Professor Farringer: What about insurers?

Mr. Gordon: Providers and insurers actually are in agreement on the idea of broadly based coverage, for a variety of reasons. Really, on the insurance side, the whole idea behind the mandate was to balance out the risk pools. States that have expanded to 138% of the poverty level, took on some of the risk for those that were 100-138% of poverty that would have otherwise been incurred in the individual market in those states and that may have moderated the risk in those

[22] 29 C.F.R. § 2590.715-2714 (2017); Ctrs. for Medicare and Medicaid Servs., *Premium Tax Credit*, HEALTHCARE.GOV, https://www.healthcare.gov/young-adults/children-under-26 (last visited Nov. 1, 2017).

markets, but even so, there were still problems. Risk adjustments, risk corridors and reinsurance would have helped stabilize the market as well but these common actuarial tools ended up getting caught in the political world and were not fully leveraged. If you use these actuarial levers that are common to stabilize a volatile market, you help to balance out some of the issues. We would not have seen the degree of issues that seem to have played out across the country if those tools could have been more fully used. I say all that but the individual mandate was also supposed to be a way to try to balance out all that, but it didn't work. There is a lot of interconnectedness. Does that mean you cannot do things? No. It just means you have to understand how all these things fit together. I, personally, was not convinced that the way that the individual mandate was structured, that it, had enough of an effect that people were looking for and hoped for. So, that one component, and I haven't seen information out there that says "those that got insured, that the mandate was the biggest driver or if it was the subsidies?" So the question is what works most effectively? A lot would argue, it goes back to Dick's point, people are very price sensitive. When you look at the penalties, I mean, I had people reach out to me saying "I did the math, I want a non-ACA plan, it is significantly less costly than an ACA compliant plan." [23] But I would say, in looking at the entire system, you have to recognize that price matters.

Mr. Cowart: Michael mentioned one phrase I want to—one of the big wild cards—"Repeal and Restore." The "Restore" piece depends on provider unity. If you are in the South, you needed to expand Medicaid to get whole. There are many moving parts. If we are going to end up with an auto insurance model, providers may close ranks and say "Restore my Medicare cuts." Restore my Medicare payments and I'll deal with that. And it would not be a bad judgment call for a provider. If you restore these healthcare cuts and you eliminate the taxes, there is no money to fund anything. That is why you end up with these local options—because there is no money except for a few tax credits.

[23] *What Does ACA-Compliant Mean?*, HEALTHCHOICEONE, https://healthchoiceone.com/what-does-aca-compliant-mean/ (last visited Nov. 1, 2017).

FRAUD AND ABUSE PANEL

FEATURING: ELLEN BOWDEN MCINTYRE, ASSISTANT UNITED STATES ATTORNEY MIDDLE DISTRICT OF TENNESSEE,[*]

PATSY POWERS, *WALLER, LANSDEN, DORTCH & DAVIS,*

AND

BRIAN ROARK, *BASS, BERRY & SIMS*

Moderated by Daniel Patten, Waller Lansden, Dortch & Davis

January 27, 2017

Zach Gureasko: All right. If you can all take your seats, please, we're going to go ahead and get started again. I am going to introduce our moderator, Daniel Patten. Before I do so, Aubrey briefly alluded to our online Health Law Journal. I just wanted to make you guys aware of a particular date. We accept practitioner's submissions and we accept them on a rolling basis, but we basically have a deadline in the spring and a deadline in the fall. We don't have the fall set up yet, but the deadline in the spring is March 3rd. Some time within the coming days, the person in charge of our website will open a portal where you can drop your submissions, and this can be anything from a full article to a short essay. Ideally something longer than maybe you would see on like a blog post, but just, you know, anything you have that you want to submit to us, we are happy to take. Again, that deadline is March 3rd and that will be through a portal on our website. Then we'll have selected those submissions that we will publish by March 31st. Again, we'll be accepting them at any time, but we just have two firm deadlines

[*] The views of Ms. McIntyre expressed here are her own personal views and do not necessarily reflect the views of the U.S. Attorney's Office or the Department of Justice.

just to enable us to kind of review the things that have been submitted, discuss, and decide which ones are going to be published. The second part that I wanted to talk about is the blog that we have on that website, again, healthlaw.belmont.edu. The blog is student led and we're going to keep it updated regularly with the happenings in the health care community. As we all know, these change every hour in the health care community so we're going to keep that updated very frequently with submissions from our students. So I just wanted to get that deadline out there as well as generate some interest in the blog, and have you start looking at that for some guidance in some of these issues that we've been talking about and will continue to talk about.

Now, we're going to have a panel discussion on some concerns that we have about value based reimbursement structures, and our moderator is going to be Daniel Patten. Daniel graduated with his Bachelors from Wake Forest University, and then he received his J.D. here at Belmont University College of Law with high honors. While he was here, he received the Health Law Certificate and the ABA BNA award for excellence in the study of health law. He was also the executive editor of the Belmont Law Review and he is now in his third year working for *Waller* in the health group focusing on transactional and operational issues. He's going to go ahead and introduce the rest of the panelists, but if you'll join me in welcoming Daniel Patten.

Daniel Patten: Thanks, Zach. I'm excited to be here, back at Belmont. Just before we begin I want to say that the quality of the health law program Belmont has established is a testament to Debbie Farringer's hard work. All of these questions originated from student questions and ideas, which made my job a lot easier. I want to thank the students for putting that together. The panel today consists of two private practice attorneys and one government attorney. We have litigators and regulatory attorneys, so a good mix of attorneys across the spectrum.

Starting on the far end is Brian Roark, who is the head of the *Bass, Berry & Sims* healthcare fraud task force. He's also an adjunct professor at Vanderbilt University, teaching Fraud and Abuse and is the chair of the health law section of the TBA.

To his left is Ellen Bowden McIntyre, who is an assistant U.S. Attorney in Nashville. She has been there since 2003 and handles various cases primarily on the False Claims Act[1] and other health

[1] 31 U.S.C. §§ 3729-3733 (2009).

care fraud, on both the civil and criminal side. She attended Penn and received her J.D. from Columbia Law. Before she was an AUSA, she served as a senior trial attorney at the Justice Department's Civil Rights Division, and worked as a staff attorney at the Southern Poverty Law Center.

Finally, to Ellen's left, is Patsy Powers. Patsy is a partner at *Waller* and her office is two doors down from me, most importantly, right? She earned her B.S. at Vanderbilt and her J.D. at Tennessee College of Law. Patsy serves on the board of the Sloam Family Health Center.

So, to kick things off for the Fraud and Abuse panel, I would like to start with the private practice attorneys. What are some current challenges for clients, and where do you see the biggest challenges for your clients today in connection with the appliance of fraud and abuse? Additionally, what are some potential effects or potential concerns moving forward with the repeal of ACA[2]?

Patsy Powers: Anybody who's in the healthcare industry is familiar with and used to change. They're used to changing laws, changing regulations, and to a certain extent, changing enforcement. But, I think, what we're seeing now, is a wave of change that is far greater than what most people have ever expected. It's not only related to the Affordable Care Act but also the changing enforcement climate. My favorite example is employment of physicians. For years, employing physicians was the safest way for a hospital to engage with their practitioners because there is an applicable safe harbor,[3] an exemption under the anti-kickback statute, and a Stark Law exception.[4] It was very easy for hospitals to employ physicians if the parties were not in a corporate practice state. And so, assuming that you are not in a corporate practice state, it was a nice way to go. Recently however, although the law hasn't changed, and the regulations haven't changed. The *qui tam* relators became very active, with the result being that the enforcement climate has changed. The result is that the definition of "commercial reasonableness," an element in the Stark Law employment exception, [5] is closely scrutinized by whistleblowers. The most obvious scenario is a physician whose professional collections are less than his salary. Absent countervailing circumstances like high indigent population, poor payer mix, or difficulty retaining a specialty, the relationship may be prosecuted as an arrangement that

[2] 42 U.S.C. §300gg (2010).
[3] 42 C.F.R. § 411.357 (2017).
[4] *Id*.
[5] *Id.*

is not commercially reasonable. The enforcement climate has upended our view of what's safe, what's comfortable, and what are safe financial relationships for our clients to have with physicians.

Brian Roark: Yeah, I would agree with Patsy. The biggest challenge is the overwhelming complexity of the laws and regulations that are out there. But as Patsy said, that's already baked into the DNA of a lot of health care companies. I would say that one of the biggest challenges today, in particular sometimes for smaller health care companies, is dealing with so much regulation or so many different outside entities that are looking into what they are doing that forces them into a position of having to be a lot more reactive than proactive. One of my clients used a term this week that I like a lot, which is they sometimes feel like there is "regulatory harassment." That many times, obviously excluding Ellen, sometimes in the government there can be a tendency to paint with a broad brush. A lot of companies out there feel like they are really trying to do things the right way, but that doesn't mean that they are always perfect, and many times they may violate a particular regulation. Sometimes the government doesn't see that and appreciate that the cost of dealing with an investigation or defending a matter—just the cost of that—even if they're ultimately able to show that they didn't do anything inappropriate, can be overwhelming. And I would say, one of the big things that we're watching in my sector on the litigation side, is not necessarily just changes in the ACA and what may come from that, but what's going to happen with government enforcement under the Trump administration. Health care fraud enforcement is not a partisan issue. Just because the Republicans are now in charge doesn't mean that fraud enforcement is going to decline. One of the biggest proponents of the False Claims Act[6] is a Republican senator from Iowa, Senator Grassley. That being said, we are waiting to see how the Trump administration may change focus. Is there going to be more focus on areas like immigration, and is that going to mean less enforcement on things like health care fraud? And then I just want to mention, locally, there is a great article that came out yesterday in the *Nashville Scene* about what may happen with changes with U.S. attorneys and with judges in Nashville.[7] The article features a lot of interesting quotes from Dean Gonzales here at Belmont, reflecting on his experiences as Attorney General. Plus, we're waiting to see if there is a new U.S. Attorney in Nashville and how will that change the focus. And then, news from just yesterday, or two days ago, the

[6] 31 U.S.C. §§3729-3733 (2009).
[7] Stephen Elliot, *Order in the Court: Nashville's Federal Judiciary Enters Trump's America*, NASHVILLE SCENE (2017), *available at* http://www.nashvillescene.com/news/features/article/20850167/order-in-the-court.

Middle District of Tennessee has four judges, lifetime appointments. The Chief Judge in Nashville, Kevin Sharp, announced that he is resigning and stepping down from the bench and is going into private practice. Interestingly, he is going to open the Nashville office of a qui tam whistle blower law firm, *Sanford Heisler*. So read into that what you will. But you know, it's extremely interesting in Nashville that you have someone leaving lifetime appointment who's going to go over and do plaintiff's side health care fraud cases.

Daniel Patten: Talking about the False Claims Act, which I think we all agree is a well-used arrow in the quiver of the government, last year the Supreme Court decided a case of Universal Healthcare in *U.S. ex rel. Escobar v. Universal Health Services, Inc.*,[8] which analyzed the theory on implied false certification that many courts have been using for purposes of determining liability under the False Claims Act. Ellen, if you could tell the group who might be unfamiliar with this issue, a little about the background of the case, the circuit split, and discuss this new definition of materiality. How, under *Escobar*, pleadings may have changed or just generally how it may have changed the litigation of these cases.

Ellen McIntyre: Sure, and just a tad bit of background on the case in case folks here haven't read it. Basically, it came out of a Massachusetts District Court False Claims Act case, in which a Medicaid recipient had gotten services from Universal Health Services, which gave counseling services, prescribed medicine, and that sort of thing. It turned out that 23 of the providers there actually weren't properly licensed to be doing what they were doing -- like they had nurses who were not supervised who were prescribing medications. All this was in violation of Medicaid requirements in the State of Massachusetts. But these requirements were not expressly designated as a condition of payment. And so, therefore, a whistleblower filed a False Claims Act lawsuit, and the District Court granted the motion to dismiss because this violation—although clearly not legal—was not expressly designated as a condition of payment, which has been an issue brewing in the circuit courts. The case winds up at the Supreme Court, and the Supreme Court had two big rulings. Number one, an implied certification, in other words, submitting a claim in which you're not complying but you're not saying, "I am complying," can be an actionable False Claims Act violation. So the Court endorsed that theory, which was mostly endorsed out there but there were still some arguments about it. So that can be a basis for liability, and it can constitute a

[8] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016).

misleading half-truth, the term that the Supreme Court used.[9] The Court also said that you don't have to have an express condition of payment. It is relevant and you can look at that, but the absence of an express designation of a condition of payment is not dispositive. You can look at other things. The key question is materiality, and that's the other big ruling. *Escobar* gives a big explanation of what the Supreme Court expects the materiality standard to be, and the Court tweaked that language a little bit. So what the Court said about materiality is that you can look at it from two perspectives: one is the perspective of a reasonable person and would they think that something is a material condition of payment. Or, you can also look at it from the perspective of the likely or actual behavior of the recipient, even if a reasonable person doesn't value it.[10] So you sort of have two doors that you can fit through whether you're a regulator, or the U.S. government, or a state government. And so, that's obviously a significant ruling, as a June 2016 Supreme Court case.

The other part of the question was how pleadings change. From the government's perspective, I don't think it really changes so much about what we thought was required, but clearly the language is a little bit different now. Like for one, I don't think we were focusing on reasonable person or, putting conduct in specific, linguistic boxes. So I think it's definitely true that if the government files a complaint in intervention in a qui tam or if we file our own original case without a qui tam, the government is going to try to track that *Escobar* language and fit within that language. I think we were already basically doing that. But having said that, the government is going to be more careful, and probably good lawyers are going to be more careful in the way they plead things. Obviously these arguments are going to come up from the defense, and I would let Brian segue into that, but this is the new standard. It is not really that different from the old standard.

Brian Roark: Yeah, the government has been taking the position that *Escobar* did not really change anything. The defendants, on the other hand, say it's a radically different and much higher standard in terms of what a plaintiff has to show to be able to establish liability under the False Claims Act. The example that I like to use to talk about *Escobar* is alcohol-based hand rub dispensers because nobody ever expects to talk about that. There are, please look it up afterwards, there are significant federal regulations specifying for hospitals, for ambulatory surgery centers, not only that they have to have alcohol-based hand rub dispensers but how they're supposed

[9] *Id*. at 2001.
[10] *Id*. at 2003.

to be installed, and where they can be and where they can't be. That is a federal regulation. If you think about that being on one end of the continuum, that if a hospital violates that regulation in some way, really nobody thinks you can bring an FCA case on that basis. On the other end of the spectrum, let's say you have the Anti-kickback statute or the Stark law. If you violate the Anti-kickback statute, everyone understands you can be sued under the FCA for that.[11] So if those are the two ends of the spectrum, you have all this area in between of the thousands of regulations that are out there. If you violate this particular one, does that subject you to FCA liability? Does that mean you potentially, by being in violation of that, in billing Medicare that you might be required to make a repayment? And *Escobar* attempted to weigh in on that question, but the parameters it has put around that question in some ways has made it harder for providers these days. Previously, the rule was more around if something is labeled as a condition of payment, then you could be liable under the FCA. But if it's labeled a condition of participation, if it just goes to a survey issue, you couldn't. The Supreme Court said we're not going to apply the test that just looks at that label because that would make it too easy for the government to put that label on every single regulation. Instead, we're going to get into "do you really think that this is essential to the services that are being provided?" But I mean, Patsy, in your practice has this made it harder?

Brian Roark: And I would agree with Ellen, that *Escobar* is not changing very much the kinds of cases that the government is going to be bringing under the FCA, but you still have to deal with a lot of these crazy whistleblowers and relators out there, who might really might bring an FCA lawsuit about hand dispensers or something else. The government may decline that lawsuit but more and more often defendants are still having to go and litigate with relators over some of these issues.

Ellen McIntyre: It is true that getting rid of the condition of payment—sort of bright line test—makes it easier for the government to bring certain cases where there wasn't an express designation, because that limitation has now gone away. Now there is still a test obviously. But yes, I agree, it is a subjective test.

Daniel Patten: So moving from the relator or the government coming after providers aspect of the False Claims Act, I would like to focus on the self-policing aspects of self-disclosure. CMS[12] and

[11] 31 U.S.C. § 3730 (2010).
[12] *Self-Referral Disclosure Protocol*, Ctrs. for Medicaid & Medicare Servs. (2017),

OIG,[13] the protocols they released have been out for some time. I know on the CMS side, the increase in volume and the response has been quite delayed. Patsy, could you speak on where you see the system right now? Has the government been effective in communicating or clarifying that process? Do you think that process is developing in a positive way?

Patsy Powers: The process is a mystery. The positive aspect of the CMS Self-Referral Disclosure Protocol is that the final settlement amount is much less than the penalties due and owing in an initial disclosure. The CMS disclosure protocol for Stark violations generally is that you disclose to CMS each way that you violated Stark and the amount of money that you owe back to the government for each of those violations. Then you get an email from CMS confirming they received the disclosure. It's often years before you hear anything else. Sometimes it is difficult to even identify the person reviewing the disclosure. You have to really work with CMS and find the right person, and even then, CMS won't tell you anything. Similarly, on its website, CMS identifies past settlements and the amounts of the settlements, but not the amount that was originally submitted with the disclosure.[14] But by word of mouth and experience, we've learned that the settlements generally range between six to ten percent of the disclosed amount received by the provider from claims tainted by a Stark violation. So if it's a $70 million disclosure, then the settlement may be $7 million. So that's helpful because that takes some of the difficulty away from the process when you can advise a client that even though they disclosed $10 million in tainted claims, they will probably have to pay less than a million dollars. But there is no certainty to that six to ten percent range. That's just been the typical experience so far, which is better than it could be, CMS could be trying to collect 100%. There is also a lot of conversation in Washington about changing Stark and maybe keeping the prohibition related to physician investment in entities that provide designated health service. CMS certainly has reduced the burden of Stark in certain respects with the changes that came about last year. For example, CMS clarified that the written agreement requirement for certain compensation arrangements can be satisfied by a collection of either emails or letters or documents or board minutes that can be pieced together to establish a written arrangement.[15] CMS also lessened the rules for

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https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html [hereinafter "Stark Self-Disclosure Protocol"].

[13] *Provider Self-Disclosure Protocol*, Office of Inspector Gen., U.S. Dep't of Health and Hum. Servs., https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp.

[14] *See* Stark Self-Disclosure Protocol, *supra* note 12.

[15] 42 C.F.R. 411.357 (2017); 80 Fed. Reg. 70886, 71315-17 (Nov. 16, 2015).

holdover leases so that the time period for a holdover, rather than just being six months, can continue for a longer period of time so long as the rent paid during the holdover remains fair market value.[16] So, while CMS has lessened the burden a little on providers, the disclosure process is really a black box. And, at the end of the day if CMS comes back and says, "You owe us a million dollars," there isn't a discussion about it. It's just, "here's where you are," which is a little disturbing because providers don't really have any opportunity to discuss it, negotiate or anything.

Brian Roark: Yeah. I would agree. CMS has really pushed and encouraged providers to use the self-disclosure protocol. At the same time, CMS discloses very little information about matters that have been successfully resolved. So if you're a provider, there's very—absent being able to talk to another company about what result they had, absent being able to talk to an attorney who might be able to share information about a past experience--there's very little insight. At the end of the day, if we have a client that finds a very obvious issue, you've been paying a physician and there's no written agreement and there's nothing to argue that there's a written arrangement, they will use the Stark Self-Disclosure Protocol. But for other issues, we really look creatively for ways to not.

Daniel Patten: So, we talked about False Claims liability often being connected to liability under the Anti-Kickback Statute[17] and the Stark Law.[18] Anti-kickback being the foundation for a lot of these claims, which came about in contemplation of a fee-for-service system. Today, however, reimbursement is switching to more of a value-based system. CMS has announced that its goal is to have 50 percent of all reimbursements for medical services under value-based reimbursement methodology.[19] How will we see this shift? How will that impact the fraud and abuse laws? Are we going to see more waivers? Are they going to lose their teeth? Could this have downstream impacts on FCA, litigation and potential lawsuits in the future?

Patsy Powers: That remains to be seen. The whole premise of the Anti-Kickback Statute and Stark Law, in respect to payments to physicians, is that the payments are fair market value. Under value-

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[16] 42 C.F.R. 411.357(a)(7) (2017); 80 Fed. Reg. 70886, 71319-20 (Nov. 16, 2015).
[17] 42 U.S.C. §1320a-7b (2015).
[18] 42 U.S.C. § 411.1395nn (2010).
[19] *What Is Value-Based Care, What It Means for Providers?,* REVCYCLEINTELLIGENCE (2016), http://revcycleintelligence.com/features/what-is-value-based-care-what-it-means-for-providers.

based payment models, payments to physicians should still be fair market value. Of course, with some value-based payment models there may be a bucket of shared savings to be divided among physicians, a hospital, a home health agency, etc. If for example, you go to a hospital for a hip replacement and each of the various providers sufficiently participate in the patient's care, then each of the providers should enjoy the benefit of the shared savings money. If, however, any of the money paid to a physician is above fair market value, then is that a problem? It shouldn't be, which is partially why the ACOs have waivers to the anti-kickback statute and Stark Law that are broad, you just have a waiver. For other arrangements, there need to be similar waivers to protect reasonable payments to physicians. The prior panel talked about how the commercial payers, Medicaid, and Medicare all have to have, to some extent, a common payment methodology so that providers do not have to abide by different programs and arrangements. And so, if say a commercial payer and Medicare each have similar requirements for bundled payments, then that works very well in terms of care delivery and the documentation required. But, the money from each payer might not be the same. Dr. Farringer might receive $10,000 in bonuses for patients treated efficiently while participating in a bundle for Blue Cross and a substantially similar bundle for Medicare. The question then becomes whether that $10,000 payment is for the right mix of patients or not. In other words, is the right amount being attributed to Medicare versus Blue Cross? Should providers really have to track that? Should they have to track whether or not that's a fair market value allocation of the bonus for the commercial insurance, Medicare and Medicaid? That would be very difficult and that sort of compliance effort arguably shouldn't be necessary. If you're doing the job well, you're providing quality service and you're engaging in these alternative payment models, should you really have to worry about fair market values? And so more waivers, I think, are appropriate. But in the meantime, we're sort of living in both worlds. And that is what Michael was saying—it's a challenge, operating a hospital right now in all of these different worlds is a huge challenge. So yes, more waivers are necessary.

Brian Roark: As Daniel phrased the question; the Anti-Kickback Statute and Stark Law rose out of a fee-for-service reimbursement system, with the thought being that those laws were the proper ways to govern excesses in that type system. As we move away from fee-for-service reimbursement, we move towards encouraging more integration between the hospital and rehab, or the hospital and a home health company. Arrangements that are viewed suspect under Stark Law or Anti-Kickback are exactly what the government or

payers are trying to encourage these days and the law no longer fits that. I wish that I were smart enough to say, "Here are the ways to change the law." It's either waiver, or it's either when we're dealing with fee-for-service kind of payment structures, potentially doing away with it all together.

Daniel Patten: For the litigators here, do you see any issues that are starting to arise in district courts and courts of appeals in connection with fraud and abuse laws that have an impact on current approaches to compliance?

Ellen McIntyre: Well in general, of course, there's just more *qui tams*. This means both that the government ends up intervening in more *qui tams*, but also that the government still declines a chunk of *qui tams*. One change is that a lot of those relators are going forward without the government, which didn't used to happen. Now obviously this has spillover effects in terms of what providers do, and it probably is sort of a policing tool, even if it hasn't hit a particular provider with a suit being filed against them.

There is also of course a huge increase in recoveries annually by the federal government. I think that the government got an additional billion dollars over last year. These are gigantic numbers. I think also that it's not so much based on a change in the law, but just kind of a change in the climate, with all of these factors.

There is also an expansion of things that the government is looking at, and not just in terms of what comes in the door and what a whistleblower might file. Such as, in our district, in the Middle District of Tennessee, we are one of ten districts in the U.S. that launched its own Elder Justice Task Force in 2016.[20] The Justice Department has also created an Elder Justice website, which is a new initiative. There are various ways in which most people might not think of Elder Justice, for instance, as something that could be the subject of a False Claims Act action. But elder issues are increasing around the country. Look at skilled nursing facilities, look at the quality of care concerns. Quality of care is probably increasingly going to be something that the government looks at when they're thinking about False Claims Act concerns and how it impacts patient care. Are patients getting what they should be getting? As opposed to the Purell example. I don't think we were ever focusing on Purell. I've never seen a case about Purell.

[20] Elder Justice Task Forces, The U.S. Dep't of Justice, https://www.justice.gov/elderjustice/task-forces (last visited Dec. 28, 2017).

Brian Roark: Not yet.

Ellen McIntyre: I'm not going to say too much about that. The government is concerned about serious violations that impact patients or the government fisc in significant ways. Sometimes people just think about only hospitals being affected, and I don't mean that the hospitals don't have to comply, but it's sort of a big picture. The big picture is just services that Medicare and Medicaid fund, and whether there are substantial false claims in conjunction with those services across the board. That's my general insight.

Brian Roark: I would add a couple of trends that I have seen: One, the government's increasing use of data, which is not a new trend for you all here, but more of just—I think in the past, for a lot of AUSAs like Ellen, if they wanted to analyze some data, that would require making a request and getting some specialists to come and help them. These days, what I have seen is that it is just much easier for AUSAs, while they're on the phone with you, to be able to pull up on their computers and see for this particular doctor, is this doctor fiftieth percentile for whatever particular procedure, is this doctor ninetieth percentile, is this doctor off the charts. Also, where the government may start an investigation looking at issue A: Someone files a *qui tam*, a *qui tam* makes allegations about this doctor's lease arrangement. The government looks into that and finds that there's not really support of that. But, oh by the way, as long as they're looking into that doctor's lease arrangement, what they do notice is this doctor appears to be an outlier with respect to how many stents he or she is doing in the state of Tennessee versus other doctors. I've been amazed at how much of this data you can even pull up on the *Wall Street Journal* or the Open Payments website[21] just to see for a particular physician, you know, if the number one doctor in the state—or number two doctor in the state for stents that $3 million in Medicare reimbursements last year. It sort of stands out if number two is $3 million and number one is at $9 million. It stands out, and the government, in my view, is paying closer attention to that. The other item that I would mention that is really significant right now is what's going to happen in terms of statistical sampling. If the government is investigating conduct that went on at ten different facilities, if they say we think these ten facilities are providing too much therapy or therapy at too high a level, and we think that that touches on 40,000 claims over this time period, the government wants to move forward on a medical necessity issue. Can the government simply put on proof on what happened with respect to 40 patients and say that that then extrapolates across the 40,000? Or

[21] Open Payments, Ctrs. for Medicaid & Medicare Servs., https://www.cms.gov/openpayments/ (last modified Dec. 01, 2017).

is the government obligated to go and prove fraud with respect to, brick by brick, each individual case? It's the difference in, is the trial going to last one week? Is the trial going to last one year? The scary part about a trial lasting one-week is it makes it very easy for the government to be able to bring some really massive fraud cases and have a big swing in the balance just based on how the proof may come in on a handful of patients.

Daniel Patten: Do you see an increase in relying on contractors, such as ZPIC's? It is a good way to provide oversight at a low cost to the government.

Brian Roark: I see it continuing. I think under a Republican administration, that you will see more outsourcing and the continued pushing of audit and compliance function to outside third parties and giving them some incentive to go and find the fraud. I think there's some scary stuff going on in some jurisdictions right now. In the state of Florida right now, long term care and home health, just sort of some out of control payment suspensions that the ZPIC in Florida has been instituting right now. In a system where you're dealing with a ZPIC, if they're out of control, what do you do about that? You know, if the ZPIC doesn't work for Ellen, and I'm not really sure that they work for CMS. They can put providers into difficult circumstances with few ways to make that stop.

Ellen McIntyre: Although, I think that's usually discussed with CMS. But yes, I think there are more payment suspensions. I think that's correct.

Patsy Powers: The data issue is a big one. The government has access to all kinds of data, and that's only increasing as our delivery systems and payment models become more sophisticated and providers collect and report more and more data on quality, outcome, utilization and more. For example, data about how many times I tell my doctor I might take my medications each month, very personal health data is being collected. There are all kinds of data that a provider is required to report under new payment systems, and we don't know yet all the different ways that a provider might accurately report or inaccurately report. But we do know that there are, and likely will be, ways for a provider to increase their reimbursement depending on the data reported under these new payment systems after 2019. So, the use of the data, the accurate reporting of the data, and the accurate review of the data is going to transform things significantly. It's not clear yet how this transformation will play out. But it could be very, very significant, depending on how these third party contractors who are empowered

to review the data, slice and dice it in different ways. A provider might not even know who's looking at their data.

Daniel Patten: For the last few minutes, I want to open it up for questions.

"WHAT'S NEXT?"

KEY NOTE SPEAKER: CONGRESSMAN JIM COOPER[1]
[edited for reading]

JANUARY 27, 2017

Jim Cooper: Thank-you Grace Ann. I am honored to be back at Belmont. It's a great place.

I'm going to try to be of maximum use to you so I hope that you will be coming up with questions. I will do my best to try to answer them. As the Chinese curse goes, "May you live in interesting times." We are certainly doing that.

Let me start off with a few slides, and hopefully that will provoke some questions. This is the way I see the progression of recent American history. Unfortunately, the South was always a bastion of fee-for-service care; it still largely is. Managed care has largely failed us because it was largely managing costs, not care, in the '80s and '90s. Providers talk about value-based care, and "better" **is** better, but "better" is very hard to define. This field is very trendy right now. I'm a big advocate for pay-for-performance, but you have to be able to measure performance.

So, what's next? The bottom line is that "better" is still way too expensive. Health costs are a crushing burden on both families and our nation. You can cite the usual statistic that half of bankruptcies are caused by healthcare expenses. You will discover that the median bankrupting health care expense is about $3,000, so healthcare has become something that we view as a quasi-free good. No one wants to pay the full price, or even a fair price.

With our employer-sponsored benefit system, we are used to seeing only one quarter of the health care price tags on our pay stubs. We ignore the employer portion, which is largely taken out of our foregone cash wage increases, and we wonder why wages have been

[1] Congressman Jim Cooper was born and raised in Tennessee. He and Martha, his wife of thirty years, live in Nashville and have three children. A New York Times columnist called him "the House's conscience, a lonely voice for civility in this ugly era" and a "tart-tongued moderate" who "seeks bipartisanship on fiscal matters and other issues in a polarized political climate." USA Today named him one of the "Brave 38" of a "tiny band of heroes" in Congress for his work on a bipartisan budget plan. In Congress, he's known for his work on the federal budget, health care and government reform. He's also a businessman, attorney and part-time Vanderbilt professor when Congress is not in session.

sagging in America for forty years. The healthcare sector is taking our cash wage increases from us, and that is an astonishing insight. It could be the greatest robbery of all time. Because to take everybody's forgone cash pay raise in America for forty years, and put it in the health sector, and get away with it, that's amazing.

I teach this at Vanderbilt's business school. In fact, I was just there this morning for several hours. So, if I'm glossing over some of these things quickly, especially economics for lawyers, stop me, and I'll try to be clearer. We are in a massive health care bubble right now, and this bubble is particularly threatening for Nashville, because, as I have explained in many other talks, we don't even use real accounting in Washington for Medicare and Medicaid. We are only seeing a tiny fraction of their cost in congressional budgeting.

The Trump administration gives every sign of making this problem worse because he has promised not to touch Medicare. He has also presented a budget that adds $10 trillion in extra debt over the next ten years. Sadly, the Democrats are copying that, almost completely. They wanted to make Obamacare the issue, not debt reduction. Paul Krugman wrote in this morning's *New York Times*, "Where are the deficit scolds when we need them?"[2] Well, I am a deficit scold, and I'm still scolding. Deficits are a problem that we, as individuals and as a nation, don't want to acknowledge.

Political parties play the game of obstructionism. Democrats hated Republican obstructionism when they could obstruct. Now Republicans are hating our obstructionism when we can obstruct. I believe in fair play, and we shouldn't be hypocritical about things. Now, it's very tempting to be hypocritical. Many of our senators, in particular, have had to reverse all of their previous speeches. They are, somehow, overcoming their embarrassment. Wouldn't it be nice if we didn't have to have these wide pendulum swings.

The Flashpoints: the things in health care debates that really get people upset. If you're a Democrat, you talk about the number of uninsured, and that's terrible. And the repeal of Obamacare is about to throw at least 20 million people out in the cold without insurance. And that is a genuinely bad problem. The uninsured are largely powerless. We should be embarrassed here in Tennessee because, a few years ago [during early TennCare reforms], we almost had the lowest percentage of uninsured in America. We were second only to Hawaii, and we didn't care enough about that accomplishment to keep it. That was a landmark, signal accomplishment that put us ahead of the rest of the nation. This was largely in the Gov. McWherter era, but then, for fiscal and other reasons, we largely gave our accomplishment up. A low number of uninsured is a strong indicator of health system equity.

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[2] Paul Krugman, *Making the Rust Belt Rustier*, N.Y. TIMES (Jan. 27, 2017).

Right now, we're hearing a lot about health **insurance premium increases**, as if we hadn't experienced forty years of premium hikes. We should all know that healthcare expenses have gone up 2.5% higher than the rate of inflation for forty years. Now, the last five years were a period of relative moderation, but the forty-year trend is staggering. And we're shocked that premiums are still going up? So many people in America have no sense of history. I'm not justifying the latest premium increases, but that's been a Republican flashpoint. It's like gas prices at the pump. People don't get angry about the prices of snacks at convenience stores, which is actually how most retail gas establishments make their money. But when it comes to the price at the pump, one or two pennies shifts markets.

Deductible increases. The phrase now is that we have such high deductibles that healthcare is too expensive to use. That's when your deductibles are $5,000 to $10,000. That's really self-pay until you've met your deductible. You have no insurance until you get a catastrophic problem, and then the converse problem happens, and healthcare's problem is it's too cheap, because you're not really paying the bill anymore. It's 90% to 100% free.

Gaps in coverage. That's what's currently in vogue. Obamacare is too expensive. Let's return your freedom of choice so you can get that policy you used to have or the policy that was affordable. Beware: many of those policies had lifetime limits, exclusions, all sorts of things that nobody in their right mind would want to have. The good old days were not as great as some people remember.

What I've only talked about so far are financing issues, and that's great for business school, but what really matters to people is delivery of care. And these are often unspoken issues, at least in the political realm. Medical care itself is the third leading cause of death in America![3] That's from the *British Medical Journal*; some American medical journals say it's the fifth or sixth leading cause of death. Whoa! This is what we are doing to ourselves, folks. This is astonishing. The Institute of Medicine Report "To Err Is Human"[4] came out sixteen years ago claiming one hundred thousand unnecessary deaths in America every year due to preventable medical error. That's like jumbo jets falling out of the sky every week, and we aren't upset about that? In medicine, of course, these are individual, not group, tragedies. (Now, you tend to hear about

[3] Martin A. Makary and Michael Daniel, *Medical Error – The Third Leading Cause of Death in the US*, THE BMJ (May 3, 3016), http://www.bmj.com/content/353/bmj.i2139.
[4] *To Err Is Human: Building A Safer Health System*, INSTITUTE OF MEDICINE (Nov. 2000), https://www.nap.edu/resource/9728/To-Err-is-Human-1999--report-brief.pdf.

VA medical malpractice, because the VA is a public entity. In contrast, private hospitals settle their bad cases.)

Drug price increases. There has been publicity about these, particularly with companies like EpiPen after they raised the price from $100 to $600 of potentially life-saving anaphylactic shock treatment, and moved their corporate headquarters from America to Holland (where by law they cannot sell their product for over $100). And the president of the company is the daughter of a US Senator, Joe Manchin of West Virginia. This is very embarrassing for price-gouging drug companies.

Life expectancy in many rural parts of the country is decreasing for women. Now, part of that decrease is due to behavioral issues, but this isn't progress; this is regress. You have a problem here, too, with the opioid epidemic that is largely the result of prescription drugs. For evidence of this, one of the popular commercials on TV now is for "opioid-induced constipation," because so many of us get constipated due to overdosing on opioids. This is a problem caused by a problem. An additional problem is that antibiotics are failing us due to over-prescription and patient abuse. Finally, doctors don't have time to listen to patients anymore. To me, these health care delivery issues should be much more engaging than finance issues, but you rarely hear about these as much.

Financing really influences delivery. You know that value is defined as price times efficacy. Somehow access to care has become more important in the public mind than the care itself. But the quality of care is super, super important. That's where the value comes from.

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[5] is probably the biggest new federal law having to do with value. The Reg just came out this year, and it contains a forest of acronyms.[6]

First, understand why MACRA passed. Congress finally, after ten or fifteen years of fruitless debate, decided to bargain to solve the "doc fix" problem, which is the sustainable growth rate (SGR) problem.[7] The deal was, we had to pass the "doc fix" to keep the docs happy. The price of that was asking the docs to behave. The trouble is that Congress doesn't know how to get doctors to behave.

The Reg is massive, dense. The Reg tries to give doctors 2 to 4 percent more money if they improve their results, if they behave

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[5] Medicare Access and Chip Reauthorization Act of 2015, PL 114-10, 129 Stat 87 (2015).
[6] 81 FED. REG. 77008-01 (Nov. 4, 2016) (codified at 42 C.F.R. § 414 and 42 C.F.R. §495).
[7] Conor Ryan, *Explaining The Medicare Sustainable Growth Rate,* AM. ACTION FORUM (Mar. 26, 2015), https://www.americanactionforum.org/insight/explaining-the-medicare-sustainable-growth-rate/.

in better ways. Now providers want that little bit of extra money, but what people miss in MACRA (and the reason I voted against it), was because this will cost us hundreds of billions, even trillions of dollars. One price tag on this is $4 trillion dollars. All this new federal money goes to one profession, physicians. Why are we doing this? Because Congress years ago established a price/unit equation that, when the volume of procedures increased unreasonably, we would lower the unit price so that doctors' income could remain stable. The intent was not to punish physicians but to not be reward them for huge volume increases. Now, we are rewarding them for the volume increases, and we are paying them extra.

This is not how MACRA was portrayed to the public. It was portrayed that every year we are going to cut doctors reimbursement for Medicare by 24%, or by 23%, or by 28%, and nobody wanted that to happen. Nobody was looking at volume part of the equation, only the unit price. Then, last year when it artificially looked cheaper to do the "doc fix," we fixed the doctors.[8]

This is another massive transfer of wealth in this country that most people are not aware of. In return for as much as $4 trillion we get physicians to practice better, to have better outcomes, to have more teamwork in medicine. We can only enforce that improvement through this MACRA Reg, this bureaucratic rule, which is a lawyer's field day but a nightmare for practitioners.

Financing really owns delivery of care. It's almost taboo to say this because, in Washington, Congress is afraid of doctors. We are afraid of hospitals. We are afraid of anybody who is actually involved in the nitty gritty of care. We will pay them some more money if they promise to behave better, but that's about the extent of our involvement. So what will doctors really have to do to earn their bail out?

My perspective of this is shockingly bipartisan for somebody in Washington because I'm a Blue Dog Democrat, which means I only vote with my party about 80% of the time. That makes me a dangerous radical because almost everybody else in Washington votes for their party about 99% of the time, certainly anybody who is on TV a lot or anybody who advances in party rank. If you aren't loyal, if you aren't reliable, they don't want you around. I try to look at what I'm voting on to decide whether it's good for Tennessee or not, good for America. That approach is considered hopelessly old fashioned.

Essentially, we have lost our Congress today. What we have is parliament. In parliament, people vote for their party. In Congress, you're supposed to vote your conscience and your district. A parliament without a prime minister is a recipe for chaos. Even if we

[8] Louise Radnofsky, *What is the 'Doc Fix'?*, WALL ST. J. BLOG (Mar. 26, 2015) https://blogs.wsj.com/washwire/2015/03/26/what-is-the-doc-fix/.

without the current president, we would have gridlock due to the partisanship in our parliament.

I've offered rival bills to Clintoncare and Obamacare before those presidential proposals were voted on by Congress. I relied on the Jackson Hole Group for these market-based bipartisan approaches. The first one, in the early 1990s, was called Cooper-Breaux.[9] The next one, I was smart enough not to have my name on while I was its marketing director in the House of Representatives. It was called Wyden-Bennett, [10] and it was also completely bipartisan.

You start off with an equal number of Democrats and Republicans on the bill, which is the way every major bill should be in Congress because health care, in particular, shouldn't be a partisan slugfest. The last thing you want to think about when you are sick or injured is politics.

But, during the Obamacare debates, my colleagues on the Democratic side tried belatedly to be bipartisan. They offered some very tempting bait for Republicans. They offered to give them credit for an entire malpractice package. We could have had relief for physicians and other providers if there had been one Republican who was willing to say, "put my name on the bill."

See, the parliamentary aspect, the party-loyalty aspect of Congress, is so severe that Republicans didn't want to give a Democratic president credit for any major victory. One of my favorite phrases is, "Any jackass can kick a barn down. It takes a carpenter to build one." Nobody in Congress wants to be in the carpentry business anymore.

Proof of this was the bipartisan, conservative alternative to Obamacare called Wyden-Bennett. Few business groups in America supported it because it was too difficult for Realtors, the Retail Federation, the National Restaurant Association, etc. to marshal their members behind that plan, or any plan. It was much easier to criticize, and that's another reason why we end up with partisan bills.

Right now, during the "Obamacare repeal and replace" crisis we trying to move to value in health care. Obamacare will be repealed at least in name, but there will be no replacement. Senator Lamar Alexander (R-TN) has said it would take three years to come up with a replacement. Diane Black has said, more optimistically, it

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[9]Also known as the "Managed Competition Plan." *See* Cox News Service, *Rival to Clinton Health Plan Faulted for Insuring Too Fee*, CHICAGO TRIBUNE (May 5, 1994), http://articles.chicagotribune.com/1994-05-05/news/9405050150_1_rep-jim-cooper-health-insurance-clinton-s-plan.

[10] Also known as the "Healthy Americans Act." *See* Edwin Park, *An Examination of the Wyden-Bennett Health Reform Plan*, CTR. ON BUDGET AND POLICY PRIORITIES (Sep. 24, 2008), https://www.cbpp.org/research/an-examination-of-the-wyden-bennett-health-reform-plan.

would take two years. And that is just to come up with plans that Republicans could support, not bipartisan plans.

The shocking thing is, Republicans are already seven years late. Because, if folks like me could produce an alternative for Obamacare, where were they? All the conservative think tanks agree on this. Check out the American Enterprise Institute, a very notable conservative think tank. They published a journal article last year saying it's long overdue for Republicans to have a replacement plan, so where is one?[11]

The Republican Obamacare replacement plan is a list of Band-Aids because that's the only thing they could come up with. Some of these Band-Aids could help. A well-placed Band-Aid could be good: stop bleeding, stop infection.

But Band-Aids are not a comprehensive plan. If you repeal Obamacare, by April of this year insurance companies have to come up with their rates for next year, and they will have no idea what they are going to do without a replacement already passed by Congress. This is amazing. Why is America, the greatest country in the world, in this time crunch? Because when Republicans try to beat something with nothing, which is what they are trying to do by taking down Obamacare with no replacement except a few Band-Aids, that's the dilemma we face.

What are the Band-Aids?

Interstate Insurance. Sounds great, but you know that it's a little more complicated than you think. First off, it's already allowed by Obamacare, but there are few takers. Georgia tried it a little bit. Why are there no takers? Because how would Blue Cross of Tennessee suddenly start selling insurance in Alabama? First of all, Blue Cross of Alabama already owns that market. It's as close to a monopoly as you can find in this country, and you have to develop local networks of providers, doctors and hospitals, who are willing to sign up with Blue Cross of Tennessee. How many of them are going to do that in Alabama and risk the anger of Blue Cross of Alabama? It's like zero.

Interstate sale of insurance might work with car insurance or something like that, and don't forget regulatory capture. I've been in the room a time or two when the insurance industry in Tennessee picked the insurance commissioner. Do you think they picked a real watch-dog with sharp teeth? That's not the way it works. So this is a very poor Band-Aid.

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[11] James C. Capretta, *The GOP Should Provide Health Insurance for All Americans*, AM. ENTER. INST. (Dec. 23, 2016), http://www.aei.org/publication/the-gop-should-provide-health-insurance-for-all-americans/.

State High-Risk Pools. A traditional, conservative solution. That's the way it used to be in most states. Let's go back to the good old days. I hope you read the *Wall Street Journal* on state high-risk pools.[12] They have a graph of what states were doing when state high-risk pools were in full strength before Obamacare had eroded some of them. This slide shows Tennessee, our wonderful state. We had 3,265 enrollees statewide, and we weren't paying for all of that program. Is that a solution? That's like one of the smallest Band-Aids you can find. That basically allows politicians to take some of the worst complainers and say, "Hey get a high-risk policy. By the way, we will subsidize it a little bit."

This last week or two, I have talked to hospital companies, and they've said we could go back to high-risk pools but, to make this program work, we would need thirty-seven billion dollars. No one in Congress is thinking of spending more than a billion or two. That's a big gap between one to two billion and thirty-seven billion dollars. How do you bridge that gap?

Friday, a week ago, we passed the budget for the United States of America for 2017,[13] and that money was not in there. How much money is thirty-seven billion dollars? That is three Mexican walls. Three. So where are we going to find the money? Our own Diane Black is the Chairman of the House Budget Committee. Grover Norquist is not keen on people raising taxes, and other groups don't want to be cut by thirty-seven billion dollars. So, the chances of hospital groups getting a fully funded Band-Aid for high-risk pools approaches zero because the votes have already been cast for the budget for 2017. Now this May, we will vote on the budget for 2018. Maybe there is greater hope for that budget.

Block-Granting Medicaid. Another common trope. It's going to be the answer to all our problems. States love the idea of more state discretion. They can run the program, but remember where most of the money comes from for Medicaid: from the Feds. We have an automatic problem any time the administrator of a program is not paying for it. This is almost a complete disconnect, and it got worse in the later stages of Obamacare when Medicaid expansion was 90% paid-for by the federal government.

Republicans tend to hate Medicaid because it's not benefitting their supporters. It's welfare. Doctors hate it because of low reimbursement, although reimbursement is higher here in Tennessee. There are many instances in which TennCare pays our providers well, way better than in some other states.

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[12] Drew Altman, *High-Risk Pools as Fallback for High-Cost Patients Require New Rules*, WALL ST. J. (Jan 23, 2017).
[13] Office of Mgmt. and Budget, *2017 United States Budget Estimate*, INSIDE GOV (2017), http://federal-budget.insidegov.com/l/120/2017-Estimate.

What will block granting do? Republican governors are getting smarter, like Governor Scott of Florida, like John Kasich of Ohio, like Governor Hutchinson from Arkansas, realizing that, in return for short-term discretion, they are going to have real fiscal problems going forward because Congress is not going to adjust Medicaid spending with healthcare inflation, which is inflation plus 2.5%. They're going to be squeezed. More and more governors are saying, "Hey, that's not a good deal for us."

What we need to do is fundamentally restructure Medicaid so there's not this gamesmanship with the FMAP. States are pretending to pay for programing but really coming up with state dollars, only recycling federal dollars. During the questioning of Tom Price for his confirmation hearing, a new U.S. senator named Kennedy from Louisiana raised a related question. The senator stated that it's not in the interest of states to prosecute Medicaid fraud because they wouldn't be saving their own money. They would mainly be helping the federal government save its money, so why do it? That was an amazing question. Even fraud prosecution is hurt when you have state-level gamesmanship.

Gaps in Insurance Coverage. That's what a lot of people are talking about now. Let's go ahead and let people buy defective insurance policies. Is that a good idea? Well, it's true that Obamacare benefits are expensive. Why are they expensive? Because, in most states, they tried to rely on the private sector to determine policy benefit levels. Now, you could reduce the number of state-level mandates because many providers groups have gotten legislatures to require acupuncture or free wigs or whatever, and it probably shouldn't have been done. There are thousands of such mandates spread out across states. So we could curb those, but I don't think anybody wants to return to lifetime limits on policies or get rid of preexisting conditions or coverage of adult children.

This **community rating** issue is a little trickier. Obamacare allows 64 year-olds to be charged as much as three times more than 21 year-old, a three-to-one ratio.[14] Many Republicans want to move that ratio to increase to five-to-one. Will that really help? I really hope we have more intergenerational equity in this country so that we realize that Grandma is still part of our family, and the young people are not immortal (as sometimes they believe). Having fairer pricing on health insurance is very important.

We probably need to keep the **individual mandate** to make any of this work, and that sounds like preserving a Democratic idea, but where did Obamacare get the idea? It is a conservative idea from Romneycare, and from the Heritage Foundation and the American Enterprise Institute. It's all about individual responsibility. How are

[14] Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010).

Republicans able to do a 180-U-turn on this topic, to abandon their own principles? A headline in the *New York Times* today is "Republicans abandoning their prior philosophy to accommodate the new administration."[15] You want to be flexible in life but you don't want to be unprincipled.

I hear folks champion **health savings accounts**, and they are great, especially for high-income people, but that is a tax break; that is not insurance. That is really self-pay, and we probably need more of that because someone has to ration care, and it's not popular to mention the "R" word. The only question is whether you are self-rationing or somebody else does it. We hate other people doing it, so we prefer that we do it ourselves. What happens with health savings accounts and high deductibles? People skimp on necessary care and then they overconsume, once the deductible has been met. Can't we be smarter than that? There's got to be a better way. The deductible is not only poorly understood by regular people, it's such a primitive rationing device.

This is something I came up with years ago. It explains our conundrum of cost, quality, access. You can have two but not three, and it's a perpetual problem. Well, why is this a trilemma? Because the main players in this debate refuse to understand each other. The main players are the physicians, patients, and businesses.

Physicians are motivated by the Hippocratic Oath, and the bottom line for them is, they will try anything that is not harming the patient. Treatments cannot be too extravagant if the patient benefits, because they aren't worried about who's paying the bill. Most doctors have no idea. My wife was prescribed a very simple cholesterol control medicine the other day. One little bottle of pills was $700. The doctor never told us that. The generic was $10. That's a big difference.

Patients, we have a natural survival instinct, but we really only pay attention to that copay or deductible because that's the only part that we see when we are paying the bills.

Only the business tries to do the economic or rational thing, which is optimize marginal cost and marginal benefit, because they look at the whole premium. But we don't listen to business in many health care debates. Therefore, it's like three ships passing in the night. How can we help our physician friends and our patient friends and our business friends to all get on the same page here because we are all talking about the same thing? It's like the blind men and an elephant. One touches a wall, one a snake, one a tree. They are all touching an elephant. We've got to realize we are all touching the elephant here.

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[15] Jennifer Steinhauer, *Republicans Now Marching With Trump on Ideas They Had Opposed*, NEW YORK TIMES (Jan. 26, 2017).

To me, this is the way things are working. The fee-for-service world still largely dominates the South. I was talking to a Vanderbilt Founder's Medalist, a brain surgeon, brilliant person, who chose to practice in a small Georgia town. I asked him why. He said well, he wanted to be the last place in America affected by managed care. Congratulations. You can't hide from economics. You can't hide from the future. And you shouldn't bury your talents in a town where they can't be fully utilized. When we move from the fee-for-service world, we have two basic choices: more personal responsibility or more provider responsibility.

Personal responsibility means either consumer-driven health plans with high deductibles. Provider responsibility involves getting providers to bear more risk? It's one thing they are so reluctant to do. Providers are the natural bearers of risk. They are the ones trying to sell a service, and if you're selling something that's too expensive, usually you offer vendor financing. But our providers haven't been organized enough to offer vendor financing, so insurance companies came in and became middle-men.

Authors like David Goldhill—a reformer from the right, not from the left—wants to put health insurance companies out of business. Instead of helping the market, he thinks they perpetuate healthcare inflation. They are not shoppers in patients' best interests. Now, it's considered unpatriotic to criticize something from the private sector, but how are these even private-sector firms when they benefit from the third largest health program in America at a cost to you of $250 billion a year in tax breaks? These are heavily subsidized private health insurance companies, if they are even still private. Blue Cross, in addition, gets its own explicit subsidy in the tax code, and yet they are private? Give me a break. They are more like public utilities than private entities.

The goal is to get somehow through consumer-driven health plans to some other risk bearing entity to wellness, because that's what we all want. I think what we really want is not just value-based care because, see, that is not completely consumer-oriented. What we want is patient satisfaction. What you want in any industry is a happy customer. With Wal-Mart, it is "everyday low prices" on stuff that you want to buy, not what Wal-Mart wants you to buy. It's not complicated. Where are the "everyday low prices" in medicine?

So often, we conflate higher prices with higher value because we don't have an easy metric. This is sometimes called perfume pricing. How do you sell more perfume? You raise the price. It might not smell good, but at least it smells expensive. You don't want cheap stuff. This is sometimes how silly people are when it comes to making individual choices.

These are just a few thoughts. Hopefully, it provoked some of your thinking. I will be happy to try to answer any questions you have. Thank-you for letting me be here today.

NOT GUILTY, AGAIN

CHASE DOSCHER[1]

INTRODUCTION

Historically, there has been little incentive for healthcare and pharmaceutical corporations to adhere strictly to federal administrative regulations. The monetary penalties, while in the billions of dollars, have paled in comparison to the profits reaped by the unlawful marketing, off-label usages, and fraudulent billing to federal healthcare programs. In 2015, former Attorney General, Sally Yates, issued the now famous Yates Memorandum to take the first step in curbing this trend of corporate misconduct. Through this memorandum, the Department of Justice reaffirmed its commitment to prosecuting not only corporations, but to hold their executives personally liable for regulatory violations committed under their watch. On paper, this is an attainable goal. In reality, federal prosecutors have been faced with seemingly insurmountable difficulties of proving executive intent and knowledge, overcoming attorney-client corporate privilege, and ultimately, convincing juries that are reluctant to convict corporate individuals for the crimes of their company. This note will examine the history of criminal prosecution of corporate executives which gave rise to the need for the Yates Memorandum, it will analyze the Yates Memorandum and explore the expanding impact of the document, and, finally, discuss

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[1] Chase Doscher is currently a third year student at Belmont University College of Law. He submitted this note during the second semester of his second year. Mr. Doscher is currently serving as the Editor in Chief of the Belmont Health Law journal. He would like to thank Professor Deborah Farringer for all of the constant support and leadership of the initial issue of this Journal. Additionally, He would like to thank the entire Journal staff for their dedicated work in the past two years.

potential solutions to the numerous challenges faced by federal prosecutors in accomplishing the goals of the Yates Memorandum. This Note will argue that despite the mounting challenges of implementation and prosecution of corporate officers, there are viable solutions to give teeth to the original purpose of the Yates Memorandum and curb corporate misconduct.

I. FOUNDATION OF THE RESPONSIBLE CORPORATE OFFICER DOCTRINE

The "Responsible Corporate Officer" doctrine (RCO doctrine), also described as the "crime of doing nothing,"[2] is a procedural process that regulators and Federal prosecutors are now applying against corporate executives in administrative, civil, and even criminal actions.[3] The RCO doctrine is aptly categorized as a crime of doing nothing because, at its core, the doctrine focuses on the "person's position in an entity as the basis for imposing liability and not whether he or she had a culpable intent, was aware of any wrongdoing, or had any direct involvement whatsoever."[4] More recently, courts are applying the theory of liability in the public health and welfare context.[5] It has been expanded in scope to encapsulate a wider range of regulatory violations and crimes. Along with a wider scope comes a wider range of applications that can result in harsher, criminal exposure for individuals.

Today, the Responsible Corporate Officer doctrine effects not only the top brass of the corporate suite, but reaches out to a wide range of corporate management. The RCO doctrine can impose felony criminal charges on officers and exposure for the acts of their subordinates within the corporation. This reality remains true even though the officer did not intend for the bad acts to occur or was consciously aware of the regulations that were being violated.[6]

Justice Jackson of the United States Supreme Court stated in *Morissette v. United States*, "[c]rime, as a compound concept, generally constituted only from concurrence of an evil-meaning mind with an evil-doing hand, was congenial to an intense

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[2] Brent J. Gurney, et al., Commentary, *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA*, 22 Andrews Litigation Reporter 1 (West 2007), *available at* https://www.wilmerhale.com/uploadedFiles/WilmerHale_Shared_Content/Files/Editorial/Publication/The%20Crime%20of%20Doing%20Nothing.pdf.

[3] M.E. Clark, *The Responsible Corporate Officer Doctrine*, Duane Morris LLP (Jan. & Feb. 2012), http://www.duanemorris.com/articles/static/clark_healthcarecompliance_0112.pdf..

[4] *Id.* at 5.

[5] D.E. Frulla, et al., *Responsible Corporate Officer Doctrine: Strict Criminal Liability for Regulatory Violations*, Kelley Drye (Oct. 24, 2013), http://www.kelleydrye.com/publications/articles/1771/_pdf/style=pdf/articles_1771.pdf.

[6] *Id.*

individualism and took deep and early root in American Soil."[7] It is important to note the deviation from the historical notion of criminal prosecution in American jurisprudence. The vast majority of criminal offenses require the unity of the bad act, *actus reus*, and bad intent, *mens rea*. Here, however, the legislature has created a discrete subset of offenses based on violation of administrative regulation relating to public health and welfare. These offenses, notably, lack the *mens rea* elements, but instead operate as strict liability offenses.[8] The RCO doctrine is not a newcomer to American jurisprudence, but instead has been a slow build from its incipience in *United States v. Dotterweich.*

In 1943, the United States Supreme Court, in *United States v. Dotterweich,* 320 U.S. 277 (1943), granted certiorari to address whether a corporate executive had to have personal knowledge of regulatory violations to be held criminally responsible.[9] The defendant was the president of a corporation which purchased drugs from manufacturers, repackaged them, and then shipped them out to physicians under their corporate label.[10] On at least two occasions, the labels for the drugs were incorrect and thus the corporation was prosecuted for criminal violation of the Federal Food, Drug, and Cosmetic Act (FDCA) §§ 301-392. At the end of the proceedings, the jury reached their verdict in which they acquitted the corporation, but found Dotterweich guilty. He was sentenced to probation for 60-days and a fine.

The United States Supreme Court upheld his conviction and stated, "legislation dispenses with the conventional requirement for criminal conduct – an awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent, but standing in responsible relation to a public danger."[11] The Supreme Court's impact went far beyond the holding in this singular case. Their reasoning stated that "Congress could place a great burden on corporate officers to comply with regulation that directly affect public health and welfare.[12] Criminal liability, for the violation of an administrative regulation, stretches to all those having "such a responsible share in the furtherance of the transaction which the statute outlaws."[13] The next stage in the development of the RCO doctrine came into being when the Supreme Court decided *Morissette v. United States.*

Justice Jackson, in *Morissette*, stated technological and society advances following the Industrial Revolution have yielded,

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[7] Morissette v. United States, 342 U.S. 246, 251-52 (1952).
[8] *Id.*
[9] United States v. Dotterweich, 320 U.S. 277, 284 (1943).
[10] *Id.* at 281.
[11] *Id.*
[12] *Id.* at 284-85.
[13] *See* Gurney, *supra* note 2, at 3 (citing *Dotterweich*, 320 U.S. at 284).

"dangers [that] have engendered increasingly numerous and detailed regulations which heighten the duties of those in control of particular industries, trades, properties or activities that affect public health, safety or welfare." 342 U.S. at 253-54. "Justice Jackson further explained, '[m]any of those are not in the nature of positive aggression or invasions, with which the common law so often dealt, but are in the nature of neglect where a duty requires care, or inaction where it imposes a duty.'"[14] However, the *Morissette* Court was prudent to limit this new category of offenses to misdemeanors, with little to no risk of incarceration, rather than more serious felony offenses.[15]

Finally, the Supreme Court decided the seminal case of *United States v. Park* in 1975. In *Park* the Court, as in *Dotterweich*, faced a violation of FDCA. Park was the CEO of a national food chain. Over the course of three years, FDA inspectors found repeated contamination in several of the company's food storage warehouses. Both the company and Park were charged with five misdemeanor counts under § 301(k) for causing the adulteration of food products being stored for later sale. The company plead guilty, but Park decided to go to trial. The trial court instructed the jury that in order to find Park guilty, the jury must find that he had "a responsible relationship" to the sanitary conditions in the company's warehouses[16]. Further, the trial court stated that the primary question before the jury was whether Park, "by virtue of his position in the company, had a position of authority and responsibility in the situation out of which the charges arose."[17] The jury convicted Park of all counts. Following a reversal by the Fourth Circuit Court of Appeals, the Supreme Court granted certiorari.

The Supreme Court affirmed the trial court's jury instructions noting that the "FDCA imposes not only a positive duty to seek out and remedy violations when they occur but also and primarily, a duty to implement measures that will insure that violations will not occur."[18] The Court concluded that "the government established a prima facie case… when it introduced evidence sufficient to warrant a finding by the trier of facts that the defendant had, by reason of his position in the corporation, responsibility and authority to prevent in the first instance, or promptly correct, the violation complained of, and that he failed to do so."[19] In accordance with *Park*, and the RCO doctrine, a court could impute knowledge of administrative regulation, for strict liability offenses, and impose the corporate subordinate acts upon

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[14] *Dotterweich,* 320 U.S. at 256.
[15] *Id.* at 273.
[16] *United States v. Park,* 421 U.S. 658, 665 (1975).
[17] *Id.*
[18] *Id.* at 672.
[19] *Id.* at 673-74.

the responsible officer. Despite the growth in scope of the RCO doctrine, the Supreme Court has held firm to *Morissette* in that when an offense is punishable by a felony, the court should not presume knowledge on the defendant. "[T]hat because a felony carries a much harsher stigma, a court should be careful not to dispose of a felony *mens rea* requirement on the same basis as when applying the RCO doctrine.[20]" Currently, the federal government utilizes the RCO doctrine in an effort to change corporate culture and steer corporate conduct away from habitual regulation violations[21]. In addition to levied charges, there has been a marked increase in the scale and in the amount of financial settlements, civil penalties, and criminal charges levied against both healthcare and pharmaceutical corporations and individual executives.

II. HISTORY OF CRIMINAL AND CIVIL PENALTIES

The inability of paltry financial penalties to serve as a deterrent to further wrongdoing heightens the importance of other enforcement avenues.[22] However, despite the plethora of settlements reached with the pharmaceutical industry under the False Claims Act (FCA), Department of Justice (DOJ) has, with a few exceptions, not held company heads accountable for overseeing the fraudulent activities at issue in the settlements.[23]

Public Citizen reported that in the period of 1991 through 2015 there were 329 reported civil settlements, 35 civil-criminal settlements, and nine reported criminal settlements with $28 billion in civil penalties and $7.8 billion in criminal penalties.[24] All of the reported criminal penalties, from 1991 through 2015, were federal and decreased exponentially over the last two years.[25] When considered in totality between federal and state settlements, there was a total of 373 between 1991 through 2015. These settlements reached a total amount of roughly $35.7 billion. In 2012-13, combined criminal penalties totaled $7.2 billion but by 2014-15, the total had decreased 98% to just $44 million. There were two "civil-criminal settlements" in 2014-15, down from nine in the previous year, and there have been no reported criminal settlements since 2012.[26]

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[20] Staples v. United States, 511 U.S. 600, 618 (1994).
[21] *See* Frulla, *supra* note 5.
[22] Sammy Almashat, M.D., M.P.H., *et al*., *Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015*, PUBLICCITIZEN, *at 25* (Mar. 31, 2016), *available at* https://www.citizen.org/sites/default/files/publiccitizen-pharmasettlements1991-2015-chartbook.pdf.
[23] *Id*. at 25.
[24] *Id.* at 10.
[25] *Id*.
[26] *Id*.

In the time period studied, Public Citizen totaled the amount of federal settlements at $31.9 billion, with just $2.4 billion in federal penalties recovered in 2014 and 2015. This amount, while substantial, is significantly reduced from the amount recovered in 2012-2013, $8.7 billion. Likewise, the number of settlements decreased in the same time period from 22 in 2012-2013 to 19 settlements in 2014-2015, with each averaging out to $395 million per settlement.[27] It is important to note that half of the recovered settlements in 2014-2015, roughly $1.2 billion was due to one case in which the Federal Trade Commission (FTC) settled with Teva over alleged monopolistic practices[28]. Among the reported federal settlements, the False Claims Act was the most commonly invoked law in civil settlements, while the FDCA was the most commonly invoked law in criminal prosecution. Out of all the federal prosecutions, qui tam (whistleblower) revelations amounted for 81 of 140 (58%) of all federal settlements and $22.8 of $31.9 billion (71%) of recovered penalties.

Through the end of 2014, the following cases resulted in guilty pleas by, or convictions of, executives of pharmaceutical companies. In 2007, three executives from Purdue Pharma pled guilty to "deceiving doctors and patients about the risks of lucrative painkiller Oxycontin" and paid a fine of $34.5 million[29]. In 2009, Former InterMune CEO, Scott Harkonen, was convicted for approving a press release which advertised Actimmune, one of the company's drugs, for off-label uses. Harkonen was sentenced to six-months home confinement and forced to pay $20,000 in fines[30]. In the same year, Thomas Farina and Mary Holloway, both operated as sales representatives for Pfizer, were convicted for promoting the painkiller Bextra for off-label uses. Farina was sentenced to six months of home confinement and Holloway to two-years probation and a $75,000 fine[31]. Finally, in 2011, former KV Pharmaceuticals CEO, Marc Hermelin, pled guilty to two misdemeanor charges under the FDCA and was ordered to pay the amount of $1.9 million in fines and forfeitures and sentenced to 30-days in prison, of which

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[27] *Id*. at 8.
[28] *Id*.
[29] Barry Meier. *In Guilty Plea, OxyContin Maker to Pay $600 Million,* N.Y. TIMES (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.
[30] Greg Stohr. *Ex-InterMune CEO Harkonen's Conviction Let Stand by Court,* BLOOMBERG BUS. (Dec. 16, 2013), https://www.bloomberg.com/amp/news/articles/2013-12-16/ex-intermune-ceo-harkonen-s-conviction-let-stand-by-court.
[31] Jim Edwards, *Pfizer Exec Gets 6 Months' Home Confinement for Off-Label Bextra Sales,* CBS. NEWS (last updated July 20, 2009.), http://www.cbsnews.com/news/pfizer-exec-gets-6-months-home-confinement-for-off-label-bextra-sales.

he served 15, for "failing to report that some of his company's tablets were oversized and possibly dangerous."[32]

These reported data sets can only be considered to be the Olympics of corporate wrongdoing and settlements in the studied time period of 1991 through 2015. In that period, GlaxoSmithKline and Pfizer took gold and silver medals with $7.9 and $3.9 billion in settlements respectively. Johnson & Johnson, Merck, Abbott, Eli Lilly, Teva, Shering-Plough, Novartis, and AstraZeneca took home bronze and received honorable mentions with each paying penalties of at least $1 billion in the same time period. To the average person, settlements of this magnitude would appear to be enough to curb any future corporate wrongdoing, but this is not the case. In the time period covered in this study, the total financial penalties totaled roughly $35.7 billion. Consider that amount in comparison to the realized net profits of only the 11 largest pharmaceutical companies, $711 billion[33]. The amounts faced by corporations simply is not enough to deter the alleged regulatory violations. Consider the largest reported single settlement in the study.

GlaxoSmithKline paid $3 billion for violations involving multiple of drugs. "On just the three drugs involved in the criminal plea agreement – Paxil, Wellbutrin SR, and Avandia – GlaxoSmithKline made $28 billion in sales, or nine times the total fines for all implicated products in the settlement."[34] The amount of penalties, even considering the largest monetary penalty faced, are doing little to curb regulatory violations or incentivize complete compliance with administrative regulation. Criminal prosecution of corporate executive and other employees resulting in prison sentences for the most egregious violations may be necessary and thus set the stage for Deputy Attorney General Sally Yates to issue her September 9, 2015 memorandum.

III. THE YATES MEMORANDUM

In response to the growing concerns that pure financial penalties and settlements were doing little to effectively curb wrongdoing by healthcare and pharmaceutical corporations, Deputy Attorney General Sally Quillian Yates, on September 9, 2015, issued a memorandum on Individual Accountability for Corporate

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[32] Press Release, U.S. Dep't of Justice, *Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case* (last updated Sept. 15, 2014), https://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case.

[33] *See* Almashat, *supra* note 22, at 23.

[34] *Id*. at 23-24.

Wrongdoing.[35] The purpose of this memorandum was simple. Yates stated "Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens…One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing." [36] Accountability of corporate executives, those who perpetrate, or should have known to prevent such wrongdoing, is important for several reasons. First, as Yates stated, accountability deters future illegal activity. It incentivizes changes in corporate behavior. It ensures that proper parties are held responsible for their actions. Finally, and most importantly, accountability promotes the public's confidence in our justice system.

The challenge in realizing the goals set forth in this memorandum lie in that, in large corporations, responsibility can be diffuse and decisions are made throughout the corporations and at all levels of managerial authority. In such situations, it can be, and is, difficult to determine if an individual possessed the knowledge and requisite criminal intent to establish them personally "guilty beyond a reasonable doubt."[37] This challenge is particularly true in regards to high level executives, who are often well insulated from the day-to-day operations of the corporation in which many of the violations occur.

The Yates Memorandum set out the framework from which federal prosecutors may face these challenges head on. Six key steps have been formulated to "strengthen [the] pursuit of individual corporate wrongdoing." First, in order to qualify for any cooperation credit, "typically consists of reduced fines in civil or administrative cases or potential shorter sentences in criminal cases"[38], corporations must provide to the Department all relevant facts relating to the individual responsible for the misconduct as criminal and civil investigations should focus on individuals from their inception. Criminal and civil attorneys handling corporate investigations should be in routine communications with one another. Absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation. Department attorneys should not resolve matters

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[35] Sally Quillian Yates, U.S. Dep't of Justice, Office of the Deputy Attorney General, *Individual Accountability for Corporate Wrongdoing* (Sept. 9, 2015), http://src.bna.com/hg.
[36] *Id*.
[37] *Id*.
[38] Jonathan C. Schwartz & David G. Buffa, *Cooperation Credit in Enforcement Proceedings: The Importance of Independence*, A.B.A. (Aug. 8, 2016), http://apps.americanbar.org/litigation/committees/commercial/articles/summer2016-0816-cooperation-credit-enforcement-proceedings-importance-of-independence.html.

with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases. Finally, civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on consideration beyond that individual's ability to pay.[39]

The government's twin aims of this memorandum, of returning government money to the public and to hold the wrongdoers accountable and deter future violative actions, are equally important. However, the twin aims can come into apparent tension when a federal prosecutor is determining whether to levy civil charges against an individual who may not have sufficient personal resources to pay any financial penalty imposed. The goal of individual accountability supersedes the individual's ability to pay. Yates clearly stated that, "[p]ursuit of civil actions against culpable individuals should not be governed solely by those individuals' ability to pay.

In other words, the fact that an individual may not have sufficient resources to satisfy a significant judgment should not control the decision on whether to bring suit. Rather, Department attorneys should consider the following factors. First, was the individual's misconduct serious? Second, if so, is the misconduct actionable? Third, will the evidence admissible against the individual "probably be sufficient to obtain and sustain a judgment."[40] Finally, ask whether pursuing the charge reflects an important federal interest.[41] Only by seeking to hold all individuals accountable, in view of the above mentioned factors, can the Department of Justice ensure that it is "doing everything in its power to minimize corporate fraud, and, over the course of time, minimize losses to the public fisc through fraud.[42]

Under this new approach by the Department of Justice and Office of the Attorney General, corporations face increased pressure to comply with administrative regulations. Instead of the corporation and executives facing solely monetary penalties, and potential exclusion from participation in the Medicare and Medicaid, now corporate executives face potential criminal charges resulting in prison sentences. All of these measures are designed to deter future wrongdoing, incentivize long overdue changes to corporate behavior, and ensure that the proper parties are held responsible for violations. Just as Former Deputy General Yates stated, "Americans should never believe, even incorrectly, that

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[39] Yates, *supra* note 35, at 2-3.
[40] *Id*. at 7.
[41] *Id*.
[42] *Id*.

one's criminal activity will go unpunished simply because it was committed on behalf of a corporation."[43] The impact of the memorandum was almost immediate with the first prosecution coming a short seven weeks after the publication of the memorandum.

IV. THE IMPACT OF THE YATES MEMORANDUM

The Yates memorandum serves an important purpose in helping shape the future of corporate conduct, and specifically the future compliance with administrative regulation. As Eric Holder, Former Attorney General of the United States, stated, "few things discourage criminal activity at a firm – or incentivize changes in corporate behavior – like the prospect of individual decision makers being held accountable."[44] While corporations can plead guilty and have their stock prices return to profitable levels in a matter of time, executives that plead guilty can face years of incarceration. The Yates Memorandum marks a notable shift in policy. Executives can no longer protect themselves behind the veil of corporate limited liability, but instead face the full force of punishment both their personal and their corporation's wrongdoing.[45] The impact of the Yates memo, and challenges faced by federal prosecutors, will be examined in four notable cases.

Historically, the Department of Justice punished healthcare and pharmaceutical companies with mammoth financial settlements, without actually holding the individuals charged with responsibility of such companies accountable. This was true until October, 29, 2015. The U.S. Attorney's Office for the District of Massachusetts announced that they had formally arrested the former president of Warner Chilcott, W. Carl Reichel on an indictment of conspiring to violate the Anti-Kickback Statute.[46] The indictment charged Reichel with an allegedly integral role in Warner Chilcott's

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[43] Sally Quillian Yates, *Deputy Attorney General Sally Quillian Yates Delivers Remarks at New York University School of Law Announcing New Policy on Individual Liberty in Matters of Corporate Wrongdoing,* U.S. Dep't of Justice (Sept. 10, 2015), https://www.justice.gov/opa/speech/deputy-attorney-general-sally-quillian-yates-delivers-remarks-new-york-university-school.

[44] Eric Holder, *Attorney General Holder Remarks on Financial Fraud Prosecutions at NYU School of Law,* U.S. Dep't of Justice (Sept. 17, 2014), https://www.justice.gov/opa/speech/attorney-general-holder-remarks-financial-fraud-prosecutions-nyu-school-law.

[45] Dustin Aponte, *et al.*, *The Yates Memo and Big Pharma: Individual Prosecutions for Corporate Misconduct*, ABA (Sept. 12, 2016), http://apps.americanbar.org/litigation/committees/health/articles/summer2016-0916-yates-memo-big-pharma-individual-prosecutions-corporate-misconduct.html.

[46] Gary Giampetruzzi, *Not Guilty, Again: Individual Corporate Liability in the Wake of the Reichel Acquittal*, PAUL HASTINGS LLP (June 22, 2016), https://www.paulhastings.com/publications-items/details/?id=6cc9e969-2334-6428-811c-ff00004cbded.

scheme to pay kickbacks, in the form of speaker fees, dinners, and other remunerations, for high volume of prescription of the company's drugs.[47] However, on the same day that the U.S. Attorney's Office announced the arrest of Reichel, the office also announced that Warner Chilcott would pay a reported $125 million to settle both the civil claims and criminal charges levied against them.[48]

The impact of the Yates memorandum is clear. In this instance, the corporation has formally settled the charges against it for a monetary penalty, but the U.S. Attorney's Office continues to pursue independent criminal charges against the executive for his personal role in the wrongdoings. In announcing such an independent indictment, U.S. Attorney Carmen Ortiz stated the indictment "demonstrate[s] that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud."[49]

At trial, the government asserted that there were two Warner Chilcott corporation, "one on paper that followed the law, and one which Reichel directed, that broke the law."[50] The government offered the testimony of ten former Warner Chilcott employees, several had pled guilty to federal charges and entered into plea agreements to cooperate with the government in exchange for the government's recommendation that they receive lighter sentences.[51] Several of the witnesses testified to providing kickbacks to prescribing physicians and that it was Reichel who truly directed the operation.[52] Additionally, the government stated that they wished to have the jury instructed on willful blindness in that "would have allowed [the jury] to find that Reichel knew a fact if he 'deliberately closed his eyes to a fact that otherwise would have been obvious to him.'"[53] Reichel objected and the court sustained in favor of jury instructions that read:

> Since an essential element of the offense is that it be undertaken "knowingly" and "willfully," it follows

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[47] Indictment ¶ 9, United States v. Reichel, No. 1 1:15cr10324 (D. Mass. 2016).
[48] U.S. Dep't of Justice, *Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme*, (Oct. 29, 2015), http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.) [hereinafter "Warner Chilcott Pleads"].
[49] Indictment ¶ 9, United States v. Reichel, No. 1 1:15cr10324 (D. Mass. 2016).
[50] *See* Giampetruzzi, *supra* note 46 (citing Brian Amaral, *Bribery Case Against Ex-Warner Chilcott Exec Heads to Jury*, LAW 360 (June 16, 2016), https://www.law360.com/articles/807929/bribery-case-against-ex-warner-chilcott-exec-heads-to-jury).
[51] *See* Warner Chilcott Pleads, *supra* note 48.
[52] *See* Giampetruzzi, *supra* note 46.
[53] Government's Proposed Instructions No. 21, United States v. Reichel, No 1:15cr10324 (D. Mass. 2016)).

> that good faith on the defendant is a complete defense. It is for you to decide whether or not the defendant acted in good faith, but if you decide that at all relevant times he acted in good faith, it is your duty to acquit him.[54]

Over the next two days, the jury deliberated and ultimately acquitted Reichel of all charges.[55] As one commentator pointed out, "Had he been convicted, Reichel faced up to five years' imprisonment and mandatory exclusion from all federal healthcare benefit programs, such as Medicare and Medicaid."[56] He further stated, "In a case that everyone seemed to be watching, and had a *Yates* imprint all over it, the government had come up short against an individual."[57] This case is a clear demonstration of the challenged faced by federal prosecutors in charging corporate individuals as they bear the burden of proof to establish both the executive's knowledge and his or her intent to break the law. Despite this setback, the Department of Justice will not forgo prosecution of corporate executives, but will instead work to improve the quality of their evidence and sources of information, primarily the mandated corporate cooperation.[58]

In a similar case, GeneScience Pharmaceutical was investigated for a period of three years and ultimately was charged, along with the founder, Lei Jin.[59] GeneScience pled guilty to a felony charge of illegally distributing human growth hormone in the United States.[60] GeneScience was sentenced to pay a settlement of $3 million towards a clean competition fund, which supports drug-free sports, and $7.2 million in criminal forfeitures.[61] However, Lei Jin entered a guilty plea and was sentenced to 5 years' probation.[62]

Another challenge faced by the Department of Justice when prosecuting corporate executives is not only the burden of proof, but also overcoming the hurdle of the attorney-client privilege. In 2011, GlaxoSmithKline made headlines when they agreed to plead guilty and pay a record $3 billion to resolve fraud allegations and failure to report safety data.[63] In addition to corporate responsibility,

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[54] Final Jury Instructions at 6, United States v. Reichel, No 1:15cr10324 (D. Mass. 2016).
[55] Docket at No. 245, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016)).
[56] Giampetruzzi, *supra* note 46 (citing 18 U.S.C.S. § 371; 42 U.S.C.S. § 1320(a)).
[57] *Id*.
[58] *Id*.
[59] Duff Wilson, *Drug Maker From China Pleads Guilty*, N.Y. TIMES (Oct. 6, 2010), *available at* http://www.nytimes.com/2010/10/07/business/07drug.html.
[60] U.S. v. Lei Jin, No. 10CR00144 2010 WL 3936987 (D.R.I. Oct. 1, 2010).
[61] *Id*.
[62] Jesse C. Vivian, *New FDA Strategy: Criminal Charges Against Pharma Executives*, U.S. PHARMACIST (June 20, 2011), https://www.uspharmacist.com/article/new-fda-strategy-criminal-charges-against-pharma-executives.
[63] Duff Wilson, *Glaxo Settles Cases With U.S. for $3 Billion*, N.Y. TIMES, (Nov. 3, 2011).

prosecutors alleged that a high-ranking attorney obstructed an FDA investigation into whether the company marketed one of their anti-depressant drugs, Wellbutrin SR, for the off-label use of weight loss.[64] Prosecution alleged that the attorney made false statements during an investigation in which she denied having any knowledge that the company was promoting the drug for such uses.[65] The difficulty arises when prosecutors are attempting to prosecute an attorney representing a client for a criminal offense because the bulk of the communications between the attorney and client are privileged and cannot be compelled for disclosure. "While there have been a few drug company executives who have pled guilty to criminal and/or civil charges relating to the unlawful marketing of a product, this strategy of suing corporate executives, who almost always rely on the advice of their attorneys, is very problematic."[66]

Following the Warner Chilcott case, federal prosecutors filed suit in a Massachusetts federal court against William Facteau, former CEO of Acclarent, and Patrick Fabian, former Vice President of Sales. Like many others, this case arose out of a qui tam suit filed under the federal False Claims Act by a former sales representative who worked for Acclarent from 2007 to 2011.[67] The relator alleges that Acclarent received FCA clearance for its "Relieva Stratus MicroFlow Spacer" (Stratus) device, a device which utilized saline to open a patient's sinuses following surgery.[68] However, allegedly, this was not the true purpose of this device. Following FDA clearance, Facteau and Fabian intended to use Stratus as a drug-delivery device and marketed Stratus for that purpose even after, in 2007, when the FDA rejected the request to promote Stratus for such purposes.[69] Following this rejection, the relator alleged that between 2008 and 2011, Facteau and Fabian engaged in a scheme to develop and marked Stratus rapidly in order to generate sales and make the company, Acclarent, an overall desirable target for acquisition or an IPO.[70]

The relator further alleged that, as part of the scheme, sales employees were praised promotion and trained only in the off-label

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[64] Indictment ¶ 25-26, United States v. Stevens, No. RWT 10 CR 0694 2010 WL 4530135 (D. Md. 2010).
[65] *Id*.
[66] Vivian, *supra* note 62.
[67] Laurence Freedman, *Another Jury Acquits in One of the First Few Prosecutions of Health Care Executives Following DOJ's Yates Memo*, MINTZ LEVIN, (July 27, 2016) https://www.healthlawpolicymatters.com/2016/07/27/another-jury-acquits-one-first-prosecutions-health-care-executives-following-dojs-yates-memo/.
[68] U.S. Attys Off., U.S. Dep't of Justice, *Former Acclarent, Inc. Executives Convicted of Crimes Related to the Sale of Medical Devices* (Jul. 20, 2016), https://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-convicted-crimes-related-sale-medical-devices.
[69] Freedman, *supra* note 67.
[70] Indictment ¶ 15, United States v. Facteau, No. 1:15-cr-10076-ADB (D. Mass. 2015).

use of the Stratus device and were encourages to discuss with physicians the benefits of the off-label uses of the device with steroids.[71] Their efforts paid off and made them a desirable target for acquisition when in 2010, Johnson & Johnson acquired Acclarent for $785 million.[72] Despite being told to discontinue the promotion of the Stratus device for off-label uses, Acclarent continued to promote the device and ultimately allegedly caused several doctors and other health care providers to bill federal health care programs for unapproved uses of the device. In May 2013, Acclarent made the decision to discontinue the use of the Stratus device.

Despite discontinuing the device, both Facteau and Fabian were indicted for "felony wire fraud and conspiracy, as well as a number of misdemeanor counts related to introducing a misbranded and adulterated device into interstate commerce."[73] The prosecution argued, at trial, that the two parties hid the truth of their device's purpose from the FDA. The defense countered, and jury agreed, that they had not hid the truth, but had rather applied for several years to have the off-label use cleared by the FDA, but had not received any approval beyond the initial saline use. The jury agreed and acquitted them of the singular felony charge. "Facteau and Fabian did not escape trial unscathed, however, and were convicted on 10 misdemeanor counts of introducing a misbranded and adulterated device into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act." [74] Johnson & Johnson agreed to pay $18 million to resolve any civil allegations that it caused health care providers to submit false claims to the federal health care programs.

In the most recent, and ongoing, development of the Yates memorandum, a former senior executive of Tenet Healthcare Corp, John Holland, has been indicted on charges of participation in a scheme to bribe physicians for patient referrals, enabling the healthcare corporation to fraudulently bill Medicaid programs in excess of $400 million.[75] Holland was senior vice president for Tenet's southern states between 2006 and 2013 and has been accused by federal prosecutors of paying $12 million in kickbacks to Clinica de la Mama, a clinic serving predominately undocumented pregnant women in Georgia and South Carolina. In these states, the clinic referred expecting mothers to local Tenet

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[71] Freedman, *supra* note 67.
[72] *Id*.
[73] *Id.*
[74] *Id*.
[75] U.S. Dep't of Justice, Office of Public Affairs, *Former Executive of Tenet Healthcare Corporation for Alleged Role in $400 Million Scheme to Defraud* (Feb. 1, 2017), https://www.justice.gov/opa/pr/former-executive-tenet-healthcare-corporation-charged-alleged-role-400-million-scheme-defraud.

hospitals. In return, Tenet would bill Medicaid, and in some cases, Medicare, for the total of $149 million in reimbursement from the referrals.[76] The indictment also alleges that Holland falsified compliance reports to the Department of Health and Human Services, violating Tenets previous 2006 settlement agreement in which Tenet agreed to pay $900 million for over inflating charges to Medicaid. Holland, facing four charges of mail fraud, health care fraud, and major fraud against the United States plead not guilty in federal court in Miami.

Holland is likely the first of several managers and executives at Tenet Healthcare to be charged. In the past year, Tenet Healthcare reached a $514 million settlement to resolve the criminal and civil claims that came from a whistle-blower lawsuit filed more than 10 years ago. Richard Deane, attorney for Holland, stated that"[t]he allegations relate to contracts from more than 10 years ago that were openly reviewed and approved at multiple levels of the company, including by their lawyers, was released on a $3 million bond late Wednesday."[77] If convicted, John Holland could face up to 50 years in prison with his homes in Dallas and Park City also facing seizure. However, Holland's attorney believes that his client is innocent, that the jury will find him so, and "the company's resolution", of the issue, "should have ended the matter."[78] Acting Assistant Attorney General, Blanco said that the "charges underscore our continued commitment to holding both individuals and corporations accountable for the fraudulent conduct. We will follow the evidence where it takes us, including to the corporate executive ranks."[79] Although juries have not entirely sides against corporate executives in the various cases and charges levied against them, considered together, they raise questions about the willingness of juries to hold individuals personally accountable for the actions or wrongdoings of their companies, despite the government's "recommitment to prosecuting individual's as professed in the Yates Memo."[80]

V. CONSIDERATIONS TO COMBAT THE INEFFECTIVENESS OF THE YATES MEMORANDUM

Laws without teeth are merely words. Historically, monetary penalties have done little to effectively curb the trend of corporate violation of federal administrative regulation from the Federal Food, Drug, and Cosmetics Act to the Anti-Kickback Statute. The billions

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[76] *Id*.
[77] *Former Tenet Vice President Faces Prison Time for Role in $400 Million Scheme,* MODERN HEALTHCARE (Feb. 1, 2017) http://www.modernhealthcare.com/article/20170201/NEWS/170209987.
[78] *Id.*
[79] *Id*.
[80] *Id*.

imposed as federal sanctions are written off as insignificant means to reach the end of realized exponential profits. The Yates Memorandum is sound in both idea and scope, but the goals and language have not been effectuated in the most efficient ways. The number of corporate senior executives that have been charged individually following the memo has grown. However, the number of convictions of criminal charges is small. It is more likely that a middle manager or sales representative will face the full force of criminal charges, and even jail sentences, than the majority of charged senior executives.

The state of American healthcare and regulation is always in flux, but that has never been truer than now. While we are in the early stages of a new administration, it will be interesting, as time goes on, to see the impacts that will be made on the prosecution of corporate executives. The following are considerations on what might be done to remedy the ineffectiveness found in the application of the Yates Memorandum. Time will tell whether future administrations will continue to pursue accountability by using the same methods or if they will make changes, from minor to major, to potentially empower prosecutors to fully perform all of the goals set forth in the memorandum.

The first potential solution to accomplish the goals set forth by the Yates memo is to further empower federal prosecutors. In doing so, it would be necessary to call for further cooperation by corporations involved in investigations. In order to qualify currently for the cooperation credit, a corporation must disclose to the Department of Justice all relevant facts about an individual's misconduct. "The company must identify any individuals involved or otherwise responsible for the misconduct at issue, regardless of their position, status, or seniority, and provide to the Department all facts relating to that misconduct."[81] The revision should include further calls for corporate transparency and full disclosure. Federal prosecutors face the burden of often having to prove individual *mens rea* and *actus reus* without all of the necessary facts and as their cases have suffered as a result. By fully disclosing all relevant information to the misconduct at hand, and employees who are connected to such misconduct, federal prosecutors might be able to build stronger cases reinforced by this additional evidence which might be able to prove the intent and knowledge of corporate executives.

By revising the current or issuing a new memorandum to reflect this first proposal, federal prosecutors might be empowered to overcome the challenges of acquiring sufficient evidence to hold individual corporate executives accountable. With more access to evidence, federal prosecutors will not only be able to better show

[81] *See* Yates, *supra* note 35, at 3.

the knowledge of misconduct or intent of the corporate executive, but will also be able to better advocate their cause to the jury. As it has been noted previously, juries have shown a hesitancy to convict individuals for the wrongs of their companies. However, with enough information, stemming from full and transparent cooperation by corporations, juries will be better able to understand the role that executives play in the misconduct or why they should be held vicariously liable for the acts of the corporation that they knew, or should have known, were illegal.

Finally, a more immediate proposal would be to revise the Department of Justice's approach to monetary penalties. If the profits that can be made by the sale of pharmaceuticals or services billable to federal healthcare programs can justify the financial penalties imposed on the means utilized to realize them, as the cost of doing business, then it would be wise for the Department of Justice to seek, and impose, higher monetary settlement and sanctions against these violative corporations. If evidence fails to show cause or juries are too hesitant to hold individuals accountable for the wrongdoings of the corporation, then, perhaps, it is best left to the shareholders to rectify noncompliance. If the Department is able to advocate for and impose far higher monetary penalties, then it would be wise for shareholders, acting in the best interest of their investments, to remove habitually offending executives and managers who are threatening their return on investment by continually incurring billions of dollars in settlements for regulatory violations.

THE EXPANSION OF THE "RIGHT TO DIE": PHYSICIAN-ASSISTED SUICIDE, CONCEPTS OF STATE AUTONOMY & THE PROPER POLITICAL PROCESS FOR LEGALIZATION

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I. AN INTRODUCTION: PHYSICIAN-ASSISTED SUICIDE & THE "RIGHT TO DIE"

Physician-assisted suicide has been the subject of fierce debate over the past few decades, and there is no doubt that it is an extremely sensitive issue with compelling arguments from both its detractors and its supporters. Its opponents usually refer to the practice of physician-assisted suicide by either that name, simply "suicide," or euthanasia.[2] Advocates of physician-assisted suicide term the procedure as physician-assisted death, physician aid in dying, or "death with dignity."[3] This Note will use the term "physician-assisted suicide," as that seems to be the most neutral way to term the practice. In order to make sure that the connotations behind this term are expressed correctly and persuasively, it is important to begin with a discussion of various terms related to the broader concept of "the right to die," of which physician-assisted suicide is one subcategory.

The "right to die" has developed through case law (the progression of which will be addressed later), and its expression typically refers to a patient's right to refuse medical treatment or to have medical treatment withdrawn, even if either of those actions result in the patient's death.[4] This right is subject to heightened evidentiary standards that courts may impose on patients and/or their representatives.[5] The underlying rationale behind allowing patients or their representatives to make such irreversible decisions is that patient autonomy and the preservation of dignity are implicit in the concept of an individual's liberty rights.[6] Be that as it may, the concept of the "right to die," as opposed to the legal term, encompasses voluntary euthanasia, non-assisted suicide, and physician-assisted suicide.[7] It is important to note that physician-assisted suicide is simply a subset of this broader concept, and it is being developed through both courts and legislatures throughout the country.[8] Additionally, the major distinction between the general

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[2] Annette E. Clark, *Autonomy and Death*, 71 TUL. L. REV. 45, 100 (1996).
[3] Katherine A. Chamberlain, *Looking for a "Good Death": The Elderly Terminally Ill's Right to Die by Physician-Assisted Suicide,* 17 ELDER L.J. 61, 65 (2009).
[4] *Physician-Assisted Suicide and the Right to Die with Assistance*, 105 HARV. L. REV. 2021, 2021 (1992).
[5] *See generally* Cruzan v. Missouri, 497 U.S. 261 (1990).
[6] Jennifer Porter, *Who Lives? Who Dies? Who Decides?*, 14 GEO. J. L. & PUB. POL'Y 599, 600 (2016).
[7] Lara L. Manzione, *Is There a Right to Die?: A Comparative Study of Three Societies (Australia, Netherlands, United States*), 30 GA. J. INT'L & COMP. L. 443, 444 (2002).
[8] *Id.*

"right to die" as it is understood in the United States and physician-assisted suicide as it is understood generally is that the "right to die" is mostly passive, while physician-assisted suicide requires the physician to take an active role in helping the patient achieve the goal of his or her death.[9]

"Euthanasia" is defined as "the act or practice of killing or permitting the death of hopelessly sick or injured individuals (as persons or domestic animals) in a relatively painless way for reasons of mercy."[10] As with the "right to die," physician-assisted suicide is simply part of this definition, although many incorrectly consider "euthanasia" and "physician-assisted suicide" synonymous.[11] However, using the terms interchangeably is a misnomer and ignores the various procedural safeguards in place for the latter.

Relatedly, "assisted suicide" is defined as "suicide committed by someone with assistance from another person."[12] Without the prefatory term "physician," this could include all persons rendering suicidal aid to another, ranging from a physician to a friend to a complete stranger being paid for a "mercy killing."[13] By contrast, "physician-assisted suicide" is defined as "suicide by a patient facilitated by means (as a drug prescription) or by information (as an indication of a lethal dosage) provided by a physician aware of the patient's intent."[14]

This demonstrates the importance of utilizing the correct terminology when referring to this practice and placing it in the public sphere for discourse and debate, which is, as this Note will demonstrate, where these arguments properly belong.

A. Current Legal Status of Physician-Assisted Suicide

Physician-assisted suicide is legal in a few foreign countries, and it is lawful in even fewer American states.[15] The most liberal of such laws are in Belgium, a country that allows children to request

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[9] *See generally* Washington v. Glucksberg, 521 U.S. 702 (1997).
[10] "euthanasia." Merriam-Webster Online Dictionary. 2017. https://www.merriam-webster.com/dictionary/euthanasia (last visited February 2, 2017).
[11] *See generally* John Deigh, Physician-Assisted Suicide and Voluntary Euthanasia: Some Relevant Differences, 88 J. CRIM. L. & CRIMINOLOGY 1155 (1998).
[12] "assisted suicide." Merriam-Webster Online Dictionary. 2017. https://www.merriam-webster.com/dictionary/assisted%20suicide (last visited February 2, 2017).
[13] Need cite and explain "mercy killing" if it is in quotes.
[14] "physician-assisted suicide." Merriam-Webster Online Dictionary. 2017. https://www.merriam-webster.com/dictionary/physician-assisted%2Bsuicide (last visited Febuary 2, 2017).
[15] Christina Sandefur, *Safeguarding the Right to Try*, 49 ARIZ. ST. L.J. 513, 515-16 (2017).

physician-assisted suicide as long as they are competently able to understand the consequences of the request.[16] By contrast, the statutory rights that have been created in the various jurisdictions within the United States where physician-assisted suicide is legal are incredibly strict and contain a number of procedural safeguards. Physician-assisted suicide is currently a statutory right in Oregon, Washington, Vermont, California, Colorado, and the District of Columbia.[17] It is legal at common law only in the state of Montana.[18] Before assessing these safeguards as indicating the best approach to obtaining and implementing physician-assisted suicide within the states, a brief historical overview is necessary to place the progression of the law in this area in its proper context.

B. Supreme Court Jurisprudence & The "Right to Die"

The first case ever to be heard by the United States Supreme Court regarding the issues related to "right to die" was *Cruzan v. Director, Missouri Department of Health*.[19] The plaintiff, Nancy Cruzan, was a woman who, as a result of a car crash, was left in a persistent vegetative state.[20] Surgeons placed a feeding tube in her arm for long-term support, and her parents objected to the feeding tube once it became apparent that Nancy would not regain her mental faculties.[21] When her parents asked the hospital to remove the feeding tube, the hospital stated that it could not do so without a court order, which the parents subsequently sought.[22] The trial court initially approved the court order based on evidence that Nancy had told a friend earlier that year that she:

> expressed thoughts at age twenty-five in somewhat serious conversation with a housemate friend that if sick or injured she would not wish to continue her life unless she could live at least halfway normally suggests that given her present condition she would not wish to continue on with her nutrition and hydration.[23]

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[16] *See* Charlotte McDonald-Gibson, *Belgium Extends Euthanasia Law to Kids*, TIME (Feb. 13, 2014), http://time.com/7565/belgium-euthanasia-law-children-assisted-suicide.
[17] *See supra* note 15.
[18] *Id.*
[19] Cruzan v. Missouri, 497 U.S. 261, 277 (1990).
[20] *Id.* at 266.
[21] *Id.*
[22] *Id.* at 267.
[23] *Id.* at 268.

The State of Missouri, as well as Nancy's guardian ad litem, immediately appealed the decision.[24] The Missouri Supreme Court reversed, ruling that in the absence of a legitimate living will or clear and convincing evidence, a person may not refuse treatment for another, even a family member.[25]

Nancy's parents then petitioned the Supreme Court of the United States for a writ of certiorari, and the Court agreed to hear the case.[26] The Supreme Court of the United States held that the State of Missouri's "clear and convincing" evidence standard did not violate the Due Process Clause of the Fourteenth Amendment.[27] Writing for the majority, Chief Justice Rehnquist recognized a competent individual's right to refuse life-saving medical treatment.[28] However, the Court ruled that it was not a violation of the Fourteenth Amendment for a third party seeking to refuse life-saving medical treatment for an incompetent individual to bear a higher burden of proof.[29] The Court stated, "An incompetent person is not able to make an informed and voluntary choice to exercise a hypothetical right to refuse treatment or any other right."[30]

In her concurrence, Justice O'Connor wrote separately to address the issues that the Court did not decide; namely, that the Court was simply addressing a standard of proof as not in violation of the Constitution; and the Court was not deciding whether the Constitution required the several states to follow the directions of the patient's duly appointed surrogate.[31] She also noted that the Court also did not address the propriety of states developing other methods of safeguarding an incompetent individual's liberty interest in refusing medical treatment.[32] Justice O'Connor's concurrence focused on the majority's narrow holding.[33] The line that perhaps best expresses the implication of the Court's silence was this: "Today we decide only that one State's practice does not violate the Constitution; the more challenging task of crafting appropriate procedures for safeguarding incompetents' liberty interests is entrusted to the 'laboratory' of the States."[34] O'Connor observed that the issue was a delicate one.[35] As this was the first case that the Supreme Court heard regarding the "right to die," it is significant

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[24] *Id.*
[25] *Id.*
[26] *Id., cert. granted*, 492 U.S. 917 (1989).
[27] *Id.* at 286.
[28] *Id.* at 278.
[29] *Id.* at 280.
[30] *Id.*
[31] *Id.* at 289
[32] *Id.* at 290-92
[33] *Id.*
[34] *Id.* at 292.
[35] *Id.*

that the highest court in the federal judicial system was quick to defer to state interpretations of the "right to die," and indicates, from the beginning of the Court's jurisprudence, a willingness to leave such decisions up to the individual state.

Following *Cruzan*, the next major development in Supreme Court jurisprudence on the "right to die" specifically addressed the narrower, related issue of physician-assisted suicide in a pair of companion cases decided on the same day – *Washington v. Glucksberg*[36] and *Vacco v. Quill*.[37] In *Glucksberg*, the plaintiffs were physicians, terminally ill patients, and a non-profit organization called "Compassion in Dying."[38] They challenged Washington's ban against assisted suicide, claiming that it was a liberty interest protected by the Due Process Clause of the Fourteenth Amendment to the United States Constitution.[39] On writ of certiorari, the Supreme Court held that the Due Process Clause did not protect the right to assistance in committing suicide.[40] The Court reasoned that the State of Washington had an "unqualified interest in the preservation of human life" that was not to be weighed differently according to "the medical condition and the wishes of the person whose life is at stake."[41] The Court rejected such a "sliding-scale approach" and gave substantial deference to the "number of state interests" implicated by Washington's assisted suicide ban in reaching its holding.[42]

In *Vacco*, the plaintiffs were physicians, and they challenged a newly enacted prohibition in the state of New York against physician-assisted suicide, which criminalized the action.[43] The plaintiffs claimed the prohibition was a violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, because it treated patients with a terminal illness who are on life support differently than those who were not on life support.[44] Upon writ of certiorari, the Supreme Court held that states have a legitimate interest in outlawing assisted suicide, and that "liberty" does not include a right to physician-assisted suicide."[45] The Court again delineated a number of legitimate state interests that New York used to justify the ban, and further reasoned that Equal Protection was not violated because all individuals were subject to

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[36] Washington v. Glucksberg, 521 U.S. 702, 707-08 (1997).
[37] Vacco v. Quill, 521 U.S. 793, 797-98 (1997).
[38] *Washington*, 521 U.S. at 707-08.
[39] *Id.*
[40] *Id.* at 735.
[41] *Id.* at 729.
[42] *Id.*
[43] Vacco, 521 U.S. 793 at 797-98.
[44] *Id.* at 798.
[45] *Id.* at 807-09.

the statute and thus the prohibition did not treat individuals differently.[46] The Court said:

> On their faces, neither New York's ban on assisting suicide nor its statutes permitting patients to refuse medical treatment treat anyone differently from anyone else or draw any distinctions between persons. Everyone, regardless of physical condition, is entitled, if competent, to refuse unwanted lifesaving medical treatment; no one is permitted to assist a suicide. Generally speaking, laws that apply evenhandedly to all "unquestionably comply" with the Equal Protection Clause.[47]

In addition to court cases, some states have addressed the issue of "right to die" through state statute. The first state to legalize physician-assisted suicide, Oregon, did so through a ballot measure, but a lengthy injunction delayed implementation of the law until 1997.[48] The Ninth Circuit Court of Appeals lifted the injunction and determined that several patients, doctors, and residential care facilities (all from the State of Oregon) lacked the "injury-in-fact" required for standing to bring a challenge to the law, and thus the federal court had no jurisdiction to decide any related constitutional issues.[49] The Supreme Court denied certiorari on the standing issue,[50] potentially because it had already expressed its opinions about the "right to die" and state autonomy in developing it. The United States Supreme Court was silent on the issue for several years.

The next Supreme Court case on this issue was brought in 2006. In *Gonzales v. Oregon*, after Oregon's Death with Dignity Act was passed, United States Attorney General John Ashcroft issued an Interpretive Rule that physician-assisted suicide was not a legitimate medical purpose and that any physician administering drugs to that effect violated the Controlled Substances Act.[51] Oregon, along with a physician, pharmacist, and several terminally ill patients from Oregon, challenged the rule.[52] The district court issued an injunction against the enforcement of the rule, which the Ninth Circuit Court of Appeals affirmed.[53] Upon granting the Attorney General's writ of certiorari, the United States Supreme Court affirmed.[54] The Court held that the Interpretive Rule was not entitled to deference under several prior deferential standards established by the Court, since in

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[46] *Id.* at 799-800.
[47] *Id.* at 800.
[48] Lee v. Oregon, 891 F.Supp. 1439, 1439 (D. Oregon 1995).
[49] *See* Lee v. Oregon, 107 F.3d 1382 (9th Cir. 1997).
[50] *Lee v. Harcleroad, cert. denied*, 522 U.S. 927 (1997).
[51] Gonzales v. Oregon, 546 U.S. 243, 254 (2006).
[52] *Id.* at 255.
[53] *Id.*
[54] *Id.* at 275.

order to be given deference, "the rule must be promulgated pursuant to authority Congress has delegated to the official."[55] The Court viewed his Interpretive Rule as an improper use of power, stating:

> The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.[56] . . . The Government, in the end, maintains that the prescription requirement delegates to a single executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality. The text and structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance and the congressional role in maintaining it.[57]

Following that decision, the Supreme Court has been silent on the issue, and it seems well-settled that the Courts have, at least incidentally, adopted Justice O'Connor's approach in *Cruzan*, deferring to the states as to what falls within the constitutional bounds of the "right to die." What follows is a history of the various states that have legalized physician-assisted suicide within the United States.

II. PHYSICIAN-ASSISTED SUICIDE IN THE UNITED STATES

Discussions of the legalization of physician-assisted suicide through statute began to take place as early as 1906, when a woman named Anna Hill, whose mother had died a particularly painful death from cancer, inspired legislation in Ohio that contemplated legalizing "voluntary euthanasia" for competent adults who were fatally wounded, terminally ill, or suffering from extreme pain.[58] Ultimately, the bill was defeated.[59] In the following years, various

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[55] *Id.* at 258
[56] *Id.* at 258.
[57] *Id.* at 275.
[58] Thane Josef Messinger, *A Gentle and Easy Death: From Ancient Greece to Beyond Cruzan Toward A Reasoned Legal Response to the Societal Dilemma of Euthanasia*, 71 DENV. U. L. REV. 175, 189 (1993).
[59] *Id.* at 190.

individuals (both physicians and laypersons) were prosecuted for assisting suicides.[60] The public's attitude toward the issue vacillated based on the current political climate; for instance, euthanasia was utilized quite frequently in Nazi Germany, leading many Americans to abhor physician-assisted suicide as tantamount to the same horrible practice.[61] As the right to refuse life-saving medical treatment began to develop, public opinion began to shift as well, with constituents beginning to more actively discuss the issue.[62] In fact, a Gallup poll conducted in 1973 reported an increase in favorable views toward physician-assisted suicide.[63]

Of course, no discussion of physician-assisted suicide would be complete without the man who invokes a knee-jerk thought when the practice is discussed – Dr. Jack Kevorkian.[64] The publication of Dr. Kevorkian's activism and criminal prosecution sparked a fair amount of public discourse.[65] Dr. Kevorkian's arguably most famous statement, taken (almost ironically) from a book on Christian ethics, perhaps best embodies the attitude of the states that have legalized physician-assisted suicide since 1994 – "Dying is not a crime."[66]

A. Progression of Valid Physician-Assisted Suicide Laws

In 1994, Oregon became the first state to allow its residents suffering from terminally ill diseases or conditions to obtain lethal doses of medication from their treating physicians for the purposes of self-administering the doses and thereby ending their own lives.[67] Oregon accomplished this through the establishment of the aptly-named "Oregon Right to Die" political committee, consisting of various businessmen, lawyers, and medical professionals.[68] The committee drafted several variations of the bill before settling on

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[60] *Id.*
[61] *Id.* at 199.
[62] *Id.* at 206.
[63] *Id.*
[64] *Id.* at 212-13. Dr. Jack Kevorkian was an American pathologist who rose to infamy by assisting terminally ill patients with ending their lives. He had a significant impact on the modern debate about physician-assisted suicide.
[65] *Id.* at 213.
[66] Samuel Wells & Ben Quash INTRODUCING CHRISTIAN ETHICS. 329 (John Wiley and Sons 2010).
[67] *See* Center for Disease Prevention & Epidemiology – Oregon Health Division, *Physician-Assisted Suicide*. 1997. http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/CDSummaryNewsletter/Documents/1997/ohd4623.pdf (published on November 11, 1997).
[68] *See* Death with Dignity, *Oregon Death with Dignity Act: A History*. https://www.deathwithdignity.org/oregon-death-with-dignity-act-history/ (last visited February 17, 2017).

"Measure 16," which is what is now referred to as the "Death with Dignity Act."[69] Oregon voters approved of the Death with Dignity Act by a margin of 51.31% to 48.69%.[70] The Act made physician-assisted suicide legal within the state of Oregon under certain circumstances, and it provided a number of safeguards to prevent abuse, mistake, and coercion.[71]

The Oregon Death with Dignity Act (the "Act") allows a patient to request a prescription for a lethal dose of medication that would terminate the patient's life.[72] A patient requesting this must have been diagnosed with a terminal illness that would otherwise kill the patient within six months, and the request must be made twice orally and once in writing.[73] The two oral requests must be separated by a period of at least 15 days, and the written request must be signed in the presence of two witnesses.[74] The requests must all be voluntary and initiated by a competent patient who has reached the age of majority.[75] The physician who will prescribe the medication must consult with another physician to determine the diagnosis of the illness as terminal.[76] Moreover, a medical professional potentially involved in this process is allowed to refuse to participate on moral grounds.[77] The request must be attested to by two disinterested witnesses, one of whom must not be a family member.[78] There are various procedural safeguards in place to ensure that the terminally ill patient is making this decision voluntarily and competently.[79] Further, the patient may retract the request at any time during the process.[80]

As mentioned above, the enactment of the Act was accomplished through a ballot measure. A subsequent ballot measure to overturn the prior one was unsuccessful.[81] In fact, the margin by which the measure to repeal the Act passed was greater than the initial measure.[82] Initially, a federal district court judge placed a temporary injunction on the implementation of the Act; the

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[69] OR. REV. STAT. § 127.800 (2016).
[70] Oregon Secretary of State, *Initiative, Referendum and Recall: 1988-1995*, Oregon Blue Book. http://bluebook.state.or.us/state/elections/elections21.htm (last visited February 20, 2017) [hereinafter "Initiative, Referendum and Recall"].
[71] *See generally* OR. REV. STAT. § 127.800 *et seq.* (West 2017).
[72] OR. REV. STAT. § 127.800 § 2.01 (West 2017).
[73] OR. REV. STAT. § 127.800 § 3.06 (West 2017).
[74] OR. REV. STAT. § 127.800 § 3.08-.09 (West 2017).
[75] OR. REV. STAT. § 127.800 § 2.01 (West 2017).
[76] OR. REV. STAT. § 127.800 § 3.02 (West 2017).
[77] OR. REV. STAT. § 127.800 § 4.01 (West 2017).
[78] OR. REV. STAT. § 127.800 § 3.09 (West 2017).
[79] OR. REV. STAT. § 127.800 § 3.01-.14 (West 2017).
[80] OR. REV. STAT. § 127.800 § 3.07 (West 2017).
[81] *See* Initiative, Referendum and Recall, *supra* note 69.
[82] *Id.*

injunction became permanent in August 1995, and both parties appealed on various legal issues.[83] In 1997, the United State Court of Appeals for the 9th Circuit dismissed the claim on jurisdictional grounds, effectively terminating the injunction and deferring to Oregon's right to develop its own laws.[84] Although there have been various attempts to repeal the Act or withhold the lethally prescribed drugs, Oregon's Death with Dignity Act remains the law.

Over a decade passed before physician-assisted suicide was legalized in another state. In 2008, Washington submitted for a vote "Initiative 1000," which is what is now referred to as Washington's own "Death with Dignity Act."[85] Unlike the initial ballot measure in Oregon, Initiative 1000 was approved by a greater margin – 57.82% to 42.18%.[86] A similar measure submitted to the public in 1991 had been rejected by the voters[87], but unlike that measure, which would allow the physicians to administer the lethal doses of medication, Initiative 1000 required the patient to self-administer the medication.[88]

The law contains similar procedural safeguards to the Oregon Act and some opt-outs.[89] For instance, individual hospitals can choose to refuse to participate in physician-assisted suicide as long as it explicitly states its position to do so in the policies and procedures that the hospital makes available to its staff.[90] Like the Oregon statute, the Washington Death with Dignity Act contains requirements of competency, a series of requests, and some waiting periods between requests and prescription of the medication.[91] Upon a close reading of Washington's Act, it appears that it closely mirrors the Oregon Act due to similarly tracked language.

The next state to legalize physician-assisted suicide, Montana, did so in a different way – through a court ruling. Robert Baxter was an elderly, retired truck driver residing in Montana who had been diagnosed with terminal lymphocytic leukemia.[92] As he

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[83] *See* Lee v. Oregon, 869 F.Supp. 1491 (D. Or. 1994; *affirmed by* 891 F.Supp. 1439 (D. Or. 1995).
[84] *See* Lee v. Oregon, 107 F.3d 1382 (9th Cir. 1997).
[85] *See generally* R.W.C.A. § 70.245 *et seq.* (West 2017).
[86] *See* Washington Secretary of State, *Initiative Measure 1000 concerns allowing certain terminally ill competent adults to obtain lethal prescriptions,* http://results.vote.wa.gov/results/20081104/Initiative-Measure-1000-concerns-allowing-certain-terminally-ill-competent-adults-to-obtain-lethal-prescriptions.html (last visited February 15, 2017).
[87] *See* Death With Dignity, *Washington Death with Dignity Act: A History*, https://www.deathwithdignity.org/washington-death-with-dignity-act-history/ (last visited February 15, 2017).
[88] R.W.C.A. § 70.245.010 (West 2017).
[89] R.W.C.A. § 70.245.190 (West 2017).
[90] *Id.*
[91] R.W.C.A. § 70.245.020 to .130 (West 2017).
[92] Baxter v. Montana, 354 Mont. 234, 237 (2009).

began to receive chemotherapy treatments, they became less and less effective.[93] Without a cure and with no prospect for recovery, Mr. Baxter wanted to ingest a lethal dose of medication that he could self-administer at the time of his choosing in order to end his pain and suffering.[94] He filed an action along with four physicians and an organization called "Compassion & Choices" seeking to establish a constitutional right to receive and provide aid in dying.[95] The state argued that Montana's constitution conferred no such right.[96] The district court ruled in favor of the plaintiffs, and Mr. Baxter died that same day.[97] The district court held that "constitutional rights of individual privacy and human dignity, taken together, encompass the right of a competent, terminally-ill patient to die with dignity."[98]

The Montana Supreme Court vacated the district court's resolution of the constitutional issues and declined to state its holding on that basis. Rather, it based its holding on an alternate statutory basis.[99] Namely, the court said that physicians may use the state's consent statute as a defense, stating, "[t]he consent of the victim to conduct charged to constitute an offense or to the result thereof is a defense."[100] The court dismissed the Appellants' argument that the exception to this type of consent as "against public policy" was inapplicable because "courts that have considered this issue yields unanimous understanding that consent is rendered ineffective as 'against public policy' in assault cases characterized by aggressive and combative acts that breach public peace and physically endanger others."[101] The court stated that there was "nothing in Montana Supreme Court precedent or Montana statutes indicating that physician aid in dying is against public policy."[102] Although there have been attempts to circumvent the 'court's determination through the legislature, these have been unsuccessful, and physician-assisted suicide remains legal at common law.

A few years after the Montana decision, Vermont became the fourth state to legalize the practice.[103] Prior to the passage of the law, a poll conducted indicated that 74% of voters in that state favored "mentally competent, terminally ill patients with less than six months to live to be able to end their life in a humane and dignified manner, using prescription medications they can self-

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[93] *Id.*
[94] *Id.* at 238.
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] *Id.* at 250-51.
[100] *Id.* at 239; *See also* MONT. CODE ANN. § 45-2-211 (West 2017).
[101] *Id.* at 241.
[102] *Id.* at 250.
[103] 12 V.S.A. § 5281 *et. seq.* (West 2017).

administer."[104] Unlike Oregon and Washington, however, Vermont did not put it to a vote of the people. In May 2013, the Vermont General Assembly voted to approve "Act 39," which is more commonly referred to as the "Patient Choice and Control at the End of Life Act."[105] This was a departure from the practice of citizens drafting the bill and proposing it as a ballot measure. Instead, it was designed by lawmakers and put to a vote in the state legislature.[106]

This Act is also extremely similar to the statutes passed in Oregon and Washington. The various waiting periods and methods of requesting the prescription, as well as the physician's role in the process, bear a striking resemblance to the related statutes in those two other states.[107] Like the other two states that had legalized physician-assisted suicide prior to Vermont's Act, the Vermont required residency and stated that insurance companies may not deny benefits that would be otherwise conferred simply because a patient acts in accord with the Act.[108] However, a patient loses his or her protections if he or she takes the prescribed medication outside of Vermont's jurisdiction.[109] This might implicate the patient's insurance rights, as the death may be ruled a suicide in a state where ingesting the medication is illegal.

On June 9, 2016, the California legislature passed the "End of Life Option Act," making it the fifth state to legalize physician-assisted suicide.[110] In November 2016, Colorado joined the fold as the sixth state and its citizens approved ""the "End of Life Options Act," with 64.87% of those who voted in favor of the ballot measure.[111] Polling in both of these jurisdictions indicated that a majority of the voters polled supported physician-assisted suicide in the circumstances anticipated by the statutory language.[112] These Acts also contained the same requirements and safeguards as those of other states, and they were mainly guided by those states in both

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[104] *See* Compassion & Choices, *Polling on Voter Support for Medical Aid in Dying for Terminally Ill Adults*, https://www.compassionandchoices.org/wp-content/uploads/2016/07/FS-Medical-Aid-in-Dying-Survey-Results-FINAL-7.21.16-Approved-for-Public-Distribution.pdf (July 21, 2016).
[105] *See* Vermont Department of Health, *The Patient and Control at End of Life Act, Frequently Asked Questions*, http://www.healthvermont.gov/sites/default/files/documents/2016/11/Act39_faq.pdf (revised June 2015).
[106] 2013 VERMONT LAWS NO. 39 (S. 77) (2013).
[107] *See* VT. STAT. ANN. tit. 18, § 5281 *et. seq.* (West 2017).
[108] 12 V.S.A. § 5287 (West 2017).
[109] *Id.*
[110] CAL. HEALTH & SAFETY CODE § 443.1 *et. seq.* (West 2017).
[111] COLO. REV. STAT. § 25-48-101 *et. seq.* (West 2017).
[112] *See supra* note 105.

the drafting of the legislative/ballot measures and the implementation thereafter.[113]

Finally, the most recent jurisdiction to legalize physician-assisted suicide was the District of Columbia. The bill, named the Death with Dignity Act, was introduced in the Council of the District of Columbia (the unicameral legislative body of that district),[114] signed by the Mayor, and sent to the United States Congress for review. Ultimately, attempts to oppose the bill's passage were unsuccessful, and the law became effective on February 20, 2017.[115] It is worth noting that, as of the date of this Note, seven jurisdictions have legalized the practice of physician-assisted suicide, and six of these have done so within the past decade. So, it appears that the momentum of legalizing physician-assisted suicide is on the rise, at least for now.

In all other jurisdictions, physician-assisted suicide remains prohibited under state law. Before examining the various justifications and defenses both in favor of and against the practice, it is necessary to briefly examine the current legal status of physician-assisted suicide in all jurisdictions but these seven.

B. Prohibitions Against Physician-Assisted Suicide

In January 2014, New Mexico looked as if it would join Montana as the second state to have physician-assisted suicide legalized at common law.[116] The plaintiffs were physicians and a patient who was currently in remission from uterine cancer, but feared its return and wanted the "'peace of mind' of knowing that aid in dying would be an option available to her if she [found] her suffering in the terminal stage of her cancer unbearable."[117] The State objected and emphasized that the state had a compelling interest in criminalizing physician aid in dying.[118] A district court judge ruled that physicians who rendered aid in dying to their patients could not be prosecuted under the state's Assisted Suicide Statute.[119] The court stated:

> "This court cannot envision a right more fundamental, more private or more integral to the liberty, safety and happiness of a New Mexican than the right of a competent, terminally

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[113] *See* CAL. HEALTH & SAFETY CODE § 443.1 *et. seq.* (West 2017); COLO. REV. STAT. § 25-48-101 *et. seq.* (West 2017).
[114] D.C. ST. 7-661.01 *et. seq.* (West. 2017).
[115] *Id.*
[116] Morris v. Brandenberg, 2014 WL 10672986 *2 (N.M. Dist. 2014).
[117] *Id.*
[118] *Id.* at *7.
[119] *Id.*

> ill patient to choose aid in dying. . . . If decisions made in the shadow of one's imminent death regarding how they and their loved ones will face that death are not fundamental and at the core of these constitutional guarantees, then what decisions are?"[120]

Several days later, the court entered a declaratory judgment and an injunction to that effect.[121] The State of New Mexico appealed, and the Court of Appeals of New Mexico held that physician-assisted suicide was neither a fundamental liberty interest protected by due process nor inherent in an individual's right to life, liberty, and happiness.[122] Upon writ of certiorari to the Supreme Court of New Mexico, that court affirmed the decision of the appellate court below, and thus physician-assisted suicide was prohibited by court ruling on June 30, 2016.[123]

On January 30, 2017, a "death with dignity" bill, styled the "End of Life Options Act," was introduced in the New Mexico House of Representatives.[124] A companion bill was also introduced in the New Mexico Senate.[125] As of the date of this Note, no significant developments have taken place with respect to the progression of this legislation.[126]

In all other states, physician-assisted suicide remains illegal. If a physician gives renders any assistance to a patient in terminating the patient's own life, the physician can be (and most assuredly will be) both criminally and civilly liable. In the states where all physician-assisted suicide is against the law, the debate rages on, with those on both sides of the issue approaching it from various angles.

i. Arguments Against Legalization

The arguments against the legalization of physician-assisted suicide are not merely moral or religious objections. The potential for fraud and abuse, as well as the possible difference in statutory interpretations that might be given where the statute is ambiguous, are worthy of attention and belong in any discussion about whether the practice should be legalized in that particular jurisdiction.

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[120] *Id.*
[121] Morris v. Brandenburg, 2014 WL 10672977 (N.M. Dist. 2014).
[122] 356 P.3d 564, 585 (N.M. Ct. App. 2015).
[123] 376 P.3d 836, 857 (N.M. 2016).
[124] 2017 NM H.B. 171 (January 18, 2017).
[125] *Id.*
[126] *See* New Mexico Legislature, *https://www.nmlegis.gov/Legislation/Legislation?chamber=H&legType=B&legNo=171&year=17* (last visited March 2, 2017).

Of course, there is the moral opposition to the procedure, and in a nation that is vastly religious (whether it be Christian or otherwise), the gravity of that certainly should not be downplayed as (at the very least) a passive influence on opponents of physician-assisted suicide and the debate in general. Various denominations and sects are split on their views regarding the practice of physician-assisted suicide.[127] Most adherents to Christianity oppose the practice, claiming that God is the ultimate judge and that the determination of when and in what manner to die is left to Him, not human preferences.[128] Buddhists believe that assisted suicide runs contrary to the basic tenet of Buddhism that one should not kill another living being, but followers of the religion recognize feel differently about refusal of medical treatment, especially when pointless.[129] Several other religions also decry the practice under a "slippery-slope" argument, whereby physician-assisted suicide could extend from the very terminally ill to other vulnerable populations based on preconceived notions of self-worth and social status.[130]

Unrelated to moral and religious objections are the practical difficulties that may arise; for instance, determining the competency of individuals. What distinguishes a competent individual from an incompetent one can sometimes be easy. For example, an ambulatory person with terminal cancer may still be able to speak and reason, and so would likely be competent, whereas the injured in Cruzan was in a permanent vegetative state and obviously

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[127] *See infra* note 129, 130, 131.

[128] John B. Mitchell, *My Father, John Locke, and Assisted Suicide: The Real Constitutional Right*, 3 IND. HEALTH L. REV. 45, 92-93 (2006) ("In his work, John Locke specifically said that we have no right to commit suicide. In doing so, Locke had both a theological and a conceptual ground. The basis of this theological argument [is] a form of Thomas Aquinas' classic argument against suicide: Our lives are not ours, but are God's property.").

[129] Damien Keown, *Suicide, Assisted Suicide and Euthanasia: A Buddhist Perspective*, 13 J.L. & RELIGION 385, 404 (1998-99) ("Buddhism may thus be thought of as adopting a middle way between two opposing positions. The first is the doctrine of vitalism, which holds that life is an absolute value to be preserved at all costs. At the other extreme is the quality of life view, or the belief that life has no intrinsic value and can be disposed of when its quality drops below an acceptable level. Buddhism occupies the middle ground, holding that the value of life is neither absolute nor does it fluctuate. While life must never be intentionally destroyed, there is no obligation to preserve it at all costs.").

[130] Margaret Somerville, *Is Legalizing Euthanasia an Evolution or Revolution in Societal Values?*, 34 QUINNIPIAC L. REV. 747, 773 (2016) ("A chilling example of the logical slippery slope is the euthanizing, in December 2012, of 45 year old twins in Belgium. Deaf since childhood, Marc and Eddy Verbessem were facing the additional disability of blindness. Accepting that they were irremediably suffering, their physician euthanized them.").

incompetent.[131] However, difficulties arise when the lines are blurred. For instance, many individuals may experience periods called "lucid intervals" where they are fully competent for purposes of legal efficacy.[132] During a lucid interval, a person may fully understand the implications of his or her decision, as well as the gravity of his or her situation, and wish to seek aid in dying from the physician in a completely competent state.[133] There are obvious difficulties with this factual scenario that indicate that the presence of a cognitive disorder alone cannot be determinative of the competency level necessary to request physician-assisted suicide.[134]

The various areas of the law where a competency determination is a prerequisite for carrying out some sort of legally significant act does not bring clarification to this issue. There are varying degrees of competency required to enter into a contract, to marry, to divorce, to write a living will, etc.[135] Which one is the best, and why is it the best?[136] There are arguments to be made at all competency levels, and the fact that such arguments are out there introduces wrinkles into determining competency for such an irreversible decision.[137] Opponents of physician-assisted suicide

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[131] Cruzan v. Missouri, 497 U.S. 261, 277 (1990).

[132] Joshua C. Tate*, Personal Reality: Delusion in Law and Science*, 49 CONN. L. REV. 891, 929 (2017) ("As stated in the Restatement (Third) of Donative Transfers, an individual who is 'mentally incapacitated part of the time,' but has 'lucid intervals during which he or she meets the standard for mental capacity' has the power to execute a valid will during such a lucid interval.") (internal citations omitted).

[133] *Id.*

[134] Catherine S. Shaffer, Alana N. Cook, and Deborah A. Connolly, *A Conceptual Framework for Thinking About Physician-Assisted Death for Persons With A Mental Disorder*, 22 PSYCHOL. PUB. POL'Y & L. 141, 147 (May 2016) ("Moreover, although problems in decisional capacity have been demonstrated in those with a severe mental disorder, decisional capacity is relatively unimpaired in those with mild or moderate forms of mental disorders. Similarly, some individuals with a mental disorder may only have impaired decisional capacity when they are experiencing acute symptoms of their disorder and may otherwise be competent when experiencing a remission.").

[135] *Id.*

[136] *Id* at 147-48. ("The law recognizes numerous distinct competences (i.e., driving capacity, marriage capacity, testamentary capacity, financial capacity, criminal capacity) that differ based on the abilities required for the task and consequences of the decision. Given the gravity of end-of-life decisions, should we set a higher standard of competence for PAD decisions than other routine health care choices? If so, what criteria or standards should apply? Are different criteria and standards of competence justifiable in cases where a mental disorder is the primary or sole diagnosis versus when the individual is not suffering from a mental disorder?").

[137] *Id.* ("The standard of competence required to request PAD is heavily contested in the literature. If the bar is too high, an individual's decision-making autonomy is infringed upon. If the bar is too low, sufficient protection for incompetent decision-makers is not provided.").

maintain that these wrinkles bolster their reasoning for statutes against physician-assisted suicide, since "competency" is seemingly vague.

Many medical professionals consider the practice of physician-assisted suicide to violate the Hippocratic Oath.[138] The Oath states, "I will give no deadly medicine to anyone if asked, nor suggest any such counsel."[139] Opponents of physician-assisted suicide argue that the practice runs contrary to the Hippocratic Oath, which is prominently displayed to the public as well as revered by most who practice medicine.[140]

ii. Arguments in Favor of Legalization

Proponents of physician-assisted suicide contend that a person should be able to die with dignity.[141] The terminally ill cancer patient that continues to suffer day in and day out should be able to die on his or her own terms, not continue to suffer in front of family, friends, and caretakers, and thus be subjected to indignities. In fact, the legislation passed in Oregon, Washington, and the District of Columbia all contain the word "dignity" in the Act, and that is part of the justification given for their passage. Supporters of physician-assisted suicide laws argue that states should not force people to depend on others for even the most menial of tasks or to powerlessly sit by and watch the hours tick by as they count down to their impending demise.[142]

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[138] Dr. Raanan Gillon, *Physician Assisted Suicide—Sympathy and Skepticism*, 75 U. DET. MERCY L. REV. 499, 507.

[139] *See supra* note 139 at footnote 20.

[140] Dwight G. Duncan and Peter Lubin, *The Use and Abuse of History in Compassion in Dying*, 20 HARV. J.L. & PUB. POL'Y 175, 182 (1996) ("The Oath expressly forbids administering poisons to patients even when requested. A clearer rejection of physician-assisted suicide cannot be imagined. What is important is not only the Oath itself, but also its wide acceptance, in so many countries, over so long a period, as the solemn accompaniment to full-fledged admission to the profession of medicine.").

[141] Kristen Loveland *Death and Its Dignities*, 91 N.Y.U. L. REV. 1279, 1311 (2016) ("Within the concept of individual dignity as it appears in the assisted suicide context may sit both a right to assisted suicide and a responsibility to the community that facilitates the individual's death. To the extent possible, then, an individual seeking assisted suicide should feel constrained by a responsibility to respect collective dignity in choosing how to die. Even as it provides for assisted suicide, a legislature may be justified in limiting the means by which it is achieved.").

[142] Leslie Meltzer Henry, *The Jurisprudence of Dignity*, 160 U. PA. L. REV. 169, 212 (2011) ("There is surely an argument that competent individuals who opt for a physician's assistance in ending their lives are defining their existence and unraveling 'the mystery of human life.'" [quoting Planned Parenthood v. Casey, 505 U.S. 833 (1992)]).

Moreover, autonomy in choosing when one will die, when it is determined that one will inevitably die within a specified time period, is important to advocates of physician-assisted suicide because it allows competent individuals to request the expedition of their death.[143] Terminally ill patients are already severely lacking in their own personal liberties, so extending this right to them as a form of liberty can be benign and sympathetic while also remaining within the constitutional confines of personal liberty.[144] Proponents of physician-assisted suicide liken prohibitions against terminally ill patients requesting aid in dying to be a severe deprivation of personal liberty: "The exercise of the right to privacy (in the personal autonomy sense), can become a means to protecting dignity, and protecting dignity in this context can assure that one of our most important private choices is secure. The two rights provide complementary protections."[145]

There are several procedural safeguards in the states that have extended the right to physician-assisted suicide, and several of them are identified above. These include: a minimum age, voluntariness with the opportunity to rescind, the requirement that the patient competently make the request more than once, encouragement to seek counseling, and several others.[146] While opponents of this idea have suggested that people will flock to these states—that reality is not borne out by the data—primarily because these state statutes also contain a residency requirement.[147] Moreover, the number of people that may seek physician-assisted suicide and obtain it is severely limited by the fact that at least one physician must diagnose the patient with a terminal illness that will kill the patient within six months.[148] These standards and requirements are so exacting and strong that they are subject to no more abuse than any other statute guaranteeing a personal liberty, and arguably, they are subject to less abuse.

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[143] *See supra* note 3.

[144] Erwin Chemerinsky, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 871, 876 (4th ed. 2011). ("Ultimately, the question of whether there should be a right to physician-assisted death, like all difficult constitutional questions, turns on one's view of constitutional interpretation and the role of the judiciary. Should this be regarded as one of the most important aspects of personhood and autonomy, as the Ninth Circuit concluded? Or is this a matter appropriately left to the political process, as the Supreme Court ruled?").

[145] Matthew O. Clifford and Thomas P. Huff, *Some Thoughts on the Meaning and Scope of the Montana Constitution's "Dignity" Clause with Possible Applications* 61 MONT. L. REV. 301, 330 (2000).

[146] OR. REV. STAT. § 127.800 *et seq.* (West 2017); R.W.C.A. § 70.245 *et seq.* (West 2017); 12 V.S.A. § 5281 *et. seq.* (West 2017); CAL. HEALTH & SAFETY CODE § 443.1 *et. seq.* (West 2017); COLO. REV. STAT. § 25-48-101 *et. seq.* (West 2017); D.C. ST. 7-661.01 *et. seq.* (West. 2017).

[147] *Id.*

[148] *Id.*

iii. Comparison with Other Legal Standards

In some states and countries, a criminal charged with an offense punishable by death may, once sentenced to death, forego all of his appeal rights and "volunteer" to let the death sentence be carried out.[149] Some scholarly articles have suggested that this act is comparable to physician-assisted suicide.[150] The death row inmate knows that, in all likelihood, he will presumably face death; he is statutorily allowed to face it as soon as plausible if he foregoes his appeal rights. That reasoning fits squarely with the terminally ill patient who knows she is about to die as well.[151] In order for a prisoner to abandon all appeals in this manner, the Supreme Court has required that he make a knowing, voluntary, and intelligent waiver of his rights to appeal and be mentally competent.[152] Mental competence is not a high bar.[153] The Supreme Court recognized that this standard permits even severely mentally ill defendants to be found competent to waive certain trial rights, even if they are otherwise mentally incompetent in other respects.[154] Thus, prisoners have less procedural protections than terminally ill patients seeking to die in states where physician-assisted suicide is legal, and yet courts have said that even these minimum protections for prisoners do not violate the Constitution.

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[149] Nicole F. Dailo, *"Give Me Dignity By Giving Me Death" Using Balancing to Uphold Death Row Volunteers' Dignity Interests Amidst Executive Clemency*, 23 S. CAL. REV. L. & SOC. JUST. 249, 293 (2014) (""Death row inmates, though convicted of perhaps the worst crimes imaginable, deserve to have their choices respected, particularly because an assertion of their dignity, expressed through their autonomous legal decisions, is often all they have left. Further, if our society values life as much as it claims, it must necessarily respect any individual's assessment and decision about the quality and direction of his or her life. For death row volunteers, this means providing them with the means to carry out their sentences, especially when a state's blanket reprieve or moratorium is problematic.'").

[150] *Id.*

[151] Jason Iuliano, *Why Capital Punishment is No Punishment At All"*, 64 AM. U. L. REV. 1377, 1411 (2015) (""As a society, we would not permit assisted suicide or voluntary euthanasia if we believed that the medications used in the procedure caused significant suffering. Today, seventy percent of Americans support euthanasia. Indeed, opponents of assisted death have advanced many arguments against the practice, but not a single one claims that assisted death should be banned because it causes the individual to experience pain. If we believe that euthanasia is a peaceful, humane exit for our close relatives and pets, there is no reason to believe that lethal injection is a painful event for criminals.'").

[152] *See generally* Godinez v. Moran, 509 U.S. 389 (1993).

[153] Meredith Martin Rountree, *Volunteers for Execution: Directions for Further Research into Grief, Culpability, and Legal Structures*, 82 U.K.M.C. L. REV. 295, 300 (2014).

[154] Indiana v. Edwards, 554 U.S. 164, 178 (2008).

Another area in which the law has developed more thoroughly in an analogous way is the issue of abortion rights.[155] As with physician-assisted suicide, abortion rights allow a woman to maintain autonomy in choosing the manner, method, and time in which to deliver her child (if she choose to do so at all). The Supreme Court uses the "fetal viability" standard to determine whether a woman's rights to seek an abortion are being infringed upon.[156] The rationale behind allowing abortion in limited circumstances (which many of the most staunch pro-life advocates offer as justifiable causes for doing so) – such as rape, incest, and the endangerment of the mother's life – can be properly extended to physician-assisted suicide as well because of the exigent circumstances that must exist (in the states that allow physician-assisted suicide) for a patient to request such action. Certainly, inherent in these exceptions that pro-life and pro-choice advocates have carved out is the "freedom to choose." The woman who was raped wants to be able to choose to have a child rather than have it foisted upon her; the woman who is having a child as a product of incest desires the freedom to have a baby that is healthy and without the many genetic abnormalities that are more likely to arise as a result of mating within one's own gene pool; and the mother whose life is in danger due to complications during delivery may wish to preserve her own life over the life coming into being. The reasoning is similar in that a patient knows that he is going to die, and he simply wants the freedom to choose a more expeditious death process.[157]

III. STATE PATHWAYS TO LEGALIZATION

Thinking back to Justice O'Connor's concurrence in *Cruzan*, she believed that states should be free to retain and develop a basic constitutional "right to die" that is inherent in due process considerations.[158] She believed the interpretation of this right,

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[155] Carrie H. Pailet, *Abortion and Physician-assisted Suicide: Is There a Right to Both?*, 8 LOY. J. PUB. INT. L. 45, 60 (2006) (""There is a legal link between abortion and physician-assisted suicide. Both procedures have relied on the same legal argument, that to prohibit either choice is a violation of an unspecified, constitutionally protected, liberty interest that one may make decisions affecting one's own body free from legal interference. The argument expounding a right to privacy gradually became focused as a right to autonomy - the right to make decisions regarding one's body and healthcare without interference from the State."").

[156] Planned Parenthood v. Casey, 505 U.S. 833, 870 (1992).

[157] *See generally Assisted Suicide and Reproductive Freedom: Exploring Some Connections*, 76 Wash. U. L.Q. 15 (1998).

[158] *Cruzan*, 497 U.S. at 292.

including how far to extend the right, is best left to the states.[159] This is markedly different than the Court's other forays into foisting the widespread adoption of certain liberties on all states through preempting state action through a court ruling.[160] In an age where the Tenth Amendment is mostly a truism due to federal regulation and oversight, leaving issues like this up to states is a means of giving the states back the powers that they should have rightly been exercising in the first place. There is an inevitable tension that arises when thinking about whether to expand a federal right, for expanding a federal right always places burdens upon states, as they must observe it regardless of their own statutes or state constitutions. As this issue has been left (at least for now) within the discretion of the states, the states that are considering whether to legalize the practice of physician-assisted suicide must decide the best approach to handling the issue, especially if a state's ultimate decision is to authorize the practice.

A. Legislative Action vs. Judicial Activism

There are two methods whereby physician-assisted suicide can be legalized – through legislative action (whether it be representative democracy or pure direct democracy) or through judicial review. Currently, only one state has indirectly authorized physician-assisted suicide in certain situations through the judiciary.[161] There is a separation of powers consideration inherent in discerning whether a constitutional issue like physician-assisted suicide should be decided by the legislature or the judiciary[162]. For a number of reasons, the judiciary is not the proper place to resolve this important question. Judicial action exists to determine the constitutionality and validity of laws,[163] but with a controversial

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[159] *Id.*

[160] *See* Roe v. Wade, 410 U.S. 113 (1973) (holding that all states must recognize a woman's right to seek an abortion prior to the third trimester of pregnancy); Obergefell v. Hodges, 135 S.Ct. 2584 (2015) (holding that all states must recognize a right to same-sex marriage).

[161] *See* Baxter, *supra* note 93

[162] Natalie Haag, *Separation of Powers: Is There Cause for Concern?*, 82- J. KAN. B.A. 30, 36 (2013) ("When state officials and legislators complain about "judicial activism" regarding a particular judicial opinion, they are really contending the judicial branch made law rather than interpreted the law passed by the legislature. If true, that would amount to an encroachment by the judicial branch into the powers of the legislative branch.").

[163] Martin Edelman *Written Constitutions, Democracy and Judicial Interpretation: The Hobgoblin of Judicial Activism*, 68 ALB. L. REV. 585, 588 (2005) ("[J]udicial review enlists the power of an independent judiciary to authorize or limit governmental action by virtue of its authority to interpret the fundamental law of the land.").

topic involving states' rights that are not necessarily well-settled, the more proper place is the legislature.[164]

Five states have now implemented ballot measures that have received a majority of votes in favor of physician-assisted suicide.[165] This is a states' rights issue, and the Supreme Court implicitly held as much in *Gonzales v. Oregon* when it deferred to Oregon's Death with Dignity Act.[166] The Act, contained in a ballot measure, came under fire with a subsequent attempt to repeal by another ballot measure three years later.[167] As the latter measure was rejected by a much greater margin than the first measure passed,[168] this is proof that the legislature embodies the will of the people, and as the country and states are founded on concepts of democracy, it would be best to let the people decide how to run their states.

By now, states like Oregon and Washington have empirical data on the usage and effects of the legislative measures they have passed legalizing physician-assisted suicide in certain circumstances. Contrary to the argument that residents would flock to utilize these procedures en masse, since 1997, only 1,749 people have been prescriptions written under Oregon's statute; only 1,127 of those have died as a result of consuming the prescribed dose (64.4%).[169] With respect to more recent data obtained in Oregon, in 2016, only 204 people received lethal doses of medication in compliance with the statute.[170] During that year, 133 people died as a result of ingesting this medication; of those, 19 that died has been prescribed the medication during previous years.[171] During 2016, the patients who received the prescriptions were mainly those 65 years of age or older (80.5%) and (likely with some overlap) those suffering from a terminal form of cancer (78.9%).[172] The data showed that the three most frequently mentioned end-of-life concerns for patients who obtained prescriptions in 2016 were loss of autonomy (89.5%), decreasing ability to participate in activities

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[164] Erwin Chemerinsky, *The Vanishing Constitution*, 103 HARV. L. REV. 43, 77, 103 ("In developing a theory of judicial review, the crucial question is which issues are best suited to legislative, executive, or judicial resolution. . . .Particularly for constitutional norms that the judiciary does not enforce, legislative and executive implementation becomes imperative.").
[165] *See supra* note 147.
[166] *See* Lee, *supra* note 85.
[167] *Id.*
[168] *See* Initiative, Referendum and Recall, *supra* note 69.
[169] Pub. Health Div., Ctr. for Health Statistics, Oregon Death with Dignity Act, Data summary 2016, OREGON HEALTH AUTHORITY (Feb. 10, 2017). https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/year19.pdf (February 10, 2017).
[170] *Id.*
[171] *Id.*
[172] *Id.*

that made life enjoyable (89.5%), and loss of dignity (65.4%).[173] This is consistent with data from previous years.[174] Most notably, in 2016, *zero* physicians were referred to the Oregon Medical Board for failure to comply with statutory requirements.[175]

Although Washington's Death with Dignity Act was passed more recently, annual reports can still be found containing somewhat similar data. From 2009 (the first year the medication was available) until 2015 (the most recent obtainable data), 938 people received prescriptions for the medication.[176] Of those, 917 ingested the medication and died (97.8%).[177] This is somewhat higher than Oregon, but there appears to be no reason why some take the medication and some do not.[178] During 2015, the patients who received the prescriptions were mainly those 65 years of age or older (73.9%) and (likely with some overlap) those suffering from a terminal form of cancer (72%).[179] The data showed that the three most frequently mentioned end-of-life concerns for patients who obtained prescriptions in 2016 were loss of autonomy (85.8%), decreasing ability to participate in activities that made life enjoyable (86.3%), and loss of dignity (68.5%); this is consistent with data from previous years.[180] No data was available to determine whether any physicians had been referred to the Washington Medical Board for failure to comply with statutory requirements.[181]

The laws passed in Vermont, California, Colorado, and the District of Columbia are simply too recent and simply do not have enough data to conduct a proper analysis of the law's' effects. It will be interesting to see if these states produce reports bearing similarities to Oregon and Washington as the conversation continues in states where the practice is still against the law. Similar data would indicate the propriety of leaving the legalization of physician-assisted suicide in the hands of the legislature.

By contrast, medical professionals in the State of Montana have been left in a situation tantamount to "legal purgatory,"

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[173] *Id.*
[174] *Id.*
[175] *Id.*
[176] *See*.Wash. State Dep't of Health *Washington State Department of Health 2015 Death with Dignity Act Report, Executive Summary*, WASHINGTON STATE DEPARTMENT OF HEALTH, http://www.doh.wa.gov/portals/1/Documents/Pubs/422-109-DeathWithDignityAct2015.pdf (2015).
[177] *Id.*
[178] *Id.*
[179] *Id.*
[180] *Id.*
[181] *Id.*

because there is no guidance.[182] As the *Baxter* case did not decide the constitutional question, but rather focused on determination guided by public policy in the absence of statutory language or case law on the issue, there are no clear standards by which a physician can be sure that his conduct in rendering physician-assisted suicide to a patient does not violate a criminal or civil statute. Unlike the procedural safeguards in Oregon, Washington, etc. that guide the physician in complying fully with constitutional and statutory law, there is no guidance under this nebulous court ruling. Even though the Journal of Palliative Medicine has undertaken to give physicians in Montana some guidance, there is still no legal regulatory framework for medical professionals practicing in that state to follow.[183]

Seven years have now passed since Montana's highest court decided the case, and it is becoming clear now that the lack of data and analysis of the effects of the case stem from the physicians making individual choices, under the circumstances, with no regulatory scheme to direct them. There are no reports, and thus no data to express demographics, prevalence of the practice, or a patient's underlying motivations for seeking the procedure.

Because of the disparity in analyzing the effects of the legalization of physician-assisted suicide in jurisdictions where it is a statutory right versus the jurisdiction where it is legal at common law, legislation is a preferable approach, as it creates a framework for discussions among medical professionals as well as society-at-large.

B. Representative Democracy vs. Direct Democracy

Several mechanisms exist by which a bill can become a law, but the fundamental democratic dichotomy is whether to create a statutory right through representative democracy or pure democracy. The six jurisdictions with statutes providing for physician-assisted suicide are split in the manner in which they got there. Oregon, Washington, and Colorado instituted their laws through ballot measures drafted by experienced professionals and submitted to the people for a vote.[184] Vermont, California, and the District of Columbia drafted bills and introduced them directly to

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[182] Sen. Jim Shockley & Margaret Dore, *No, Physician-assisted Suicide is Not Legal in Montana*, 37- MONT. LAW. 7, 25 (2011) ("Baxter has created confusion in the law, which has put Montana citizens at risk. Neither the legal profession nor the medical profession has the necessary guidance to know what is lawful.").
[183] David Orentlicher, Thaddeus Mason Pope, and Ben A. Rich, *Clinical Criteria for Physician Aid in Dying*, J. OF PALLIATIVE MED., Vol. 16, No. 3 259, 260 (2016).
[184] OR. REV. STAT. § 127.800 *et seq.* (West 2017); R.W.C.A. § 70.245 *et seq.* (West 2017); COLO. REV. STAT. § 25-48-101 *et. seq.* (West 2017).

their respective legislative houses.[185] While there are certainly valid concerns regarding representative democracy, pure democracy was not envisioned by the Framers of the Constitution.[186] Senator John C. Calhoun once put this consternation quite succinctly, when he said, "The Government of the absolute majority instead of the Government of the people is but the Government of the strongest interests; and when not efficiently checked, it is the most tyrannical and oppressive that can be devised."[187] Although certainly special interest groups and political contributions are concerns of representative democracy, James Madison considered a republican form of government the most desirable form of government for checking the power of democracy.[188] Further, the right to every state to have a "republican form of government" is manifested explicitly in the United States Constitution.[189] If the Framers of the Constitution considered representative democracy the best form of state governance, then it seems that representative legislative action is more suitable to decide a constitutional issues left to the discretion of the states than pure direct democracy.

C. Potential Positive Future Effects of Widespread Adoption

Up until this point, this Note has not opined about the effects of widespread adoption among the states of physician-assisted suicide in certain circumstances and subject to the various procedural safeguards provided above. However speculative an analysis of these possible effects may be, there is at least some indication that providers and patients alike have benefitted in the jurisdictions where the possibility of physician-assisted suicide is available.

Although it may seem initially insensitive, there can be no doubt that health care costs remain high within the United States, and long-term care costs pose a problem in particular.[190] This is not to suggest that an individual should take into consideration the

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[185] 12 V.S.A. § 5281 *et. seq.* (West 2017); CAL. HEALTH & SAFETY CODE § 443.1 *et. seq.* (West 2017); D.C. ST. 7-661.01 *et. seq.* (West. 2017).
[186] Steve C. Briggs, *Colorado Bar Association President's Message to its Members*, 33COLO. LAW. 47, 47 (2004).
[187] *Id.* (quoting John C. Calhoun, "Against the Force Bill," speech given on the Senate floor (Feb. 16, 1833)).
[188] *Id.*
[189] U.S. Const. Art. IV § 4.
[190] Eriko Sase and Christopher Eddy, *The Millennials in an Aging Society: Improving End-of-Life Care by Public Policy*, 21 GEO. PUB. POL'Y REV. 1, (2016) ("Millennials may also be personally affected by the relative unaffordability of long-term care insurance, coupled with the shift towards chronic, debilitating disease that is a consequence of increasing lifespans and lifestyles.").

effects of his cost burden on American society when determining whether to request a lethal dose of medication for his terminal illness. It is simply a note that allowing individuals in certain circumstances, many of whom do require quite expensive long-term care, will have an incidental effect of decreasing long-term health care costs in the long run, as the medication itself is relatively inexpensive by comparison.[191] A widespread adoption could plausibly lead to lower long-term health care costs as people exit the market.

Widespread adoption could also decrease forum shopping. Although states statutes do thus far contain a residency requirement, the actual determination of whether a person is a resident for purposes of the statute is left to the physician's discretion. For example, in Oregon, such factors include: "an Oregon Driver License, a lease agreement or property ownership document showing that the patient rents or owns property in Oregon, an Oregon voter registration, or a recent Oregon tax return."[192] Additionally, there is no minimum residency requirement.[193] Although the data does not show thousands of terminally ill people flocking to Oregon or Washington to establish residency for the sole purpose of obtaining lethal medication, it is certainly reasonable to posit that at least a few have done so.[194] A widespread adoption would reduce forum shopping or "doctor shopping," and those who truly wish to end their lives in a dignified and autonomous manner would be able to do so with physicians who have been treating them from the onset of their respective illnesses.

Although this list is certainly not an exhaustive inventory of the prospective benefits of widespread adoption, one final consideration is allowing physicians more mobility. A physician who primarily provides long-term care may receive several requests from patients with terminal illnesses (who meet all the criteria discussed earlier) to help them end their lives. However, in jurisdictions where such a remedy is unavailable, the physician will be unable to comply with the patient's request. The physician may not wish to move to any of the seven jurisdictions where the practice is legal. A widespread adoption by the states of physician-assisted suicide legislation would give physicians autonomy and, as noted in the statutes above, physicians who have moral objections would be able to remove themselves from the process without fear of

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[191] Death with Dignity, *FAQs*, https://www.deathwithdignity.org/faqs/ (last visited March 3, 2017).
[192] Oregon Public Health Initiative, *FAQs about the Death with Dignity Act*, https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/faqs.pdf (last visited March 3, 2017).
[193] *Id.*
[194] *See supra* note 6.

retribution. There are still other considerations (and of course, accompanying counter-arguments), but a widespread adoption would leave state autonomy intact while providing both direct and incidental benefits on federal and state levels.

IV. CONCLUSION

Physician-assisted suicide is a controversial issue that implicates significant constitutional issues, and the United States Supreme Court has indicated that it is best left to each state to determine whether and to what extent the "right to die" within that state encompasses physician-assisted suicide. After seeing how it has played out in the jurisdictions that have legalized the practice, the best option seems to be to pass a legislative measure codifying the methods and procedures whereby physician-assisted suicide may be legally carried out. Not only does this offer guidance for physicians contemplating whether they are able to be involved in such a practice, but it provides empirical data and statistical analysis in a way that a nebulous legal status at common law is simply unable to do. The information gathered from a jurisdiction that guides its physicians in this limited-circumstance implementation will serve to guide other jurisdictions as they continue to have conversations, about whether the "right to die" should allow a patient to die with dignity. Perhaps this issue could even serve as a reminder of the importance of state autonomy, and maybe then, the Tenth Amendment could come back into greater focus as more than just a truism.