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The Opioid Epidemic: Regulation, Responsibility, and Remedies

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THE OPIOID EPIDEMIC REGULATION, RESPONSIBILITY, AND REMEDIES

Tricia Herzfeld
Gerald Stranch
Zack Buck

MR. GROVES: My name is Alan Groves. I served as the Editor in Chief of the *Tennessee Journal of Law and Policy* from February 2017 until just a few weeks ago. My successor Editor in Chief will be moderating our second panel this afternoon. Our first panel discussion today is going to focus on some of the questions you all were asking at the end of the last session about regulation, responsibilities and remedies. So, our first two panelists to my immediate right come from the firm of Branstetter, Stranch and Jennings located in Nashville, Tennessee. In the past year, their firm has filed three different lawsuits in Tennessee against several opioid manufacturers. Tricia Herzfeld is a 2001 graduate of George Washington University Law School and is now a partner at Branstetter, Stranch and Jennings. Ms. Herzfeld has previously served as Legal Director of the American Civil Liberties Union of Tennessee where she successfully litigated dozens of high-profile civil rights cases in state and federal courts. She has also served as a public defender in Miami where she conducted over 80 criminal trials. In 2012, she was selected as one of the nation's Super Lawyers, and among

those with that honor, she attained Rising Star status in 2013.

Her colleague, Gerald Stranch, received his law degree from Vanderbilt University. He is now the managing member of Branstetter, Stranch and Jennings and chairs the firm's complex litigation team. He oversees the firm's securities, class actions, antitrust, shareholder derivative, mass tort and consumer class cases. Mr. Stranch also served as an adjunct professor at Vanderbilt University School of Law. He was named the top 40 under 40 from the National Trial Lawyers Association and was named the Mid-South Rising Star by Super Lawyers.

And finally, Professor Zack Buck at the end of the table, teaches a variety of health law classes at the University of Tennessee College of Law, including a bioethics and public health seminar, torts, health care finance and organization, health care regulation and quality, and health care fraud and abuse. His scholarship examines governmental enforcement of laws affecting health and health care in the United States. Before joining UT, Professor Buck taught at Mercer University School of Law, Seton Hall University School of Law and the University Pennsylvania School of Law. He also practiced complex commercial litigation at Sidley Austin in Chicago.

So, with this distinguished panel now introduced, let's just jump right into our first question, and we are going to start off where the last panel ended talking about remedies and particularly the search for a cause of action in some of these lawsuits that have been filed.

So, Ms. Herzfeld, I'll throw this first question to you. Can you talk to us a little bit about the suits that your firm has filed and particularly why you chose to bring those causes of action that you did, the statutory and the common law public nuisance claims and then also a cause of action under Tennessee's Drug Dealer Liability Act.

MS. HERZFELD: Sure. Thanks very much for having us. We appreciate the opportunity to talk about our lawsuits. Lawyers always like to talk about their lawsuits, so we can answer any questions you all have, and we happily do so. Our lawsuit that we brought— we have actually brought three different lawsuits throughout Tennessee. They have been filed in the Tennessee state courts. So that means our lawsuits are a little bit different than the vast majority of them across the country. Those have been filed primarily in federal court or have been moved to federal court. So, we made a very, very rational, I think, and determined decision that we wanted to keep our cases in state court, and there were some reasons for that. We don't think that a federal judge, with all due respect to the federal judiciary in Cleveland, Tennessee, where the multi-district litigation is, is going to have the same understanding of the real day-to-day impact of the opioid crisis. So, we really made a point to file our cases in Tennessee.

So, the first case that we filed is in Sullivan County, Tennessee, so up in the very, very top corner in the Appalachian region where it is really ground zero to the opioid epidemic here in Tennessee. They have the number one statistics for births of children that are born dependent on opioids, and so those children are classified as having neonatal abstinence syndrome, and that was the primary reason that we decided to file that first case there. Our cases are a little bit different than many of the others, because ours has primarily been filed by District Attorney Generals, and I think you are going to hear from one of our clients a little bit later today. We did that because we have a somewhat unique— I say unique, sort of— statute in Tennessee called the Drug Dealer Liability Act. Now, the Drug Dealer Liability Act initially was put together by an organization called ALEC. Has anybody heard of ALEC? American Legislative and Exchange Council.

So, they put together somewhat conservative proposed legislation and kind of pushed that legislation out throughout the country. I think it was 23 states ended up passing various versions of the Drug Dealer Liability Act back in the day, and Tennessee was one of them. Now, initially the Drug Dealer Liability Act was supposed to— I think the thought process at that point was, there was a crack cocaine epidemic, and the idea was to be able to go after the higher-level drug dealer chain, not just the person you're buying from or the person at the drug house, but kind of going up until you get to the suppliers and the producers, further and further. So, we took that law and decided, well, it kind of seems like the same thing for opioids; right? You have the street-level dealers. You have the people that they are getting them from. You have the pill mill doctors who are supplying them, which is often without a legitimate prescription; that's mostly how that happens. They get them from various pharmacies, who get them from distributors, who ultimately get them from producers. And why is that any different than a drug cartel? So that's why we decided to file under the Drug Dealer Liability Act, because, truthfully, we think the opioid epidemic and the way that it's impacted Tennesseans and most of the state, it really is illegal drug activity; right? That's really what we're talking about. It may have the veneer of being legal, because there are legal uses for opioids, but the legal uses of opioids are not what is causing this epidemic and causing so many people to die. It's the illegal uses.

So, we're really trying to tackle it from that way. Now, the Drug Dealer Liability Act has a lot of benefits to it. One of them that we really like is, there's not that level of causation. So, the principles of this law are more actually rooted in antitrust, so it's market participation. So, all we have to prove— all we have to prove— is that someone or a corporation knowingly participated in the illegal drug market, and as you have heard earlier, with those numbers, how could you not have known; right? I

mean, the diversion is clear, the news stories are clear; we simply have to prove that they knowingly participated in this illegal drug market. Now, a lot of other causes of action have been filed, a bunch of other different lawsuits across the country. They are more of a traditional negligent standard, where you would have to prove in this context that this individual got this pill from this person, there was a duty, there was a breach, and you're going to have to work your way all the way up pill by pill all the way through. That's not required under the Drug Dealer Liability Act. So that's why we chose that cause of action. The other one that we filed is, we filed under common law and statutory nuisance, and you will see nuisance showing up in a lot of the lawsuits throughout the country. Specifically, for us, our District Attorneys typically file nuisance lawsuits. They are the ones who file those. They shut down houses of prostitution. They shut down crack houses. They do this stuff all the time. So, it meshed very well with an additional cause that is typically within their purview of fighting crime. So, the purpose of our lawsuit is to focus less kind of on consumer protection, more to really focus on the fact that these drugs are now being used illegally and everybody knows it.

MR. GROVES: Mr. Stranch, I'll throw the next question to you. Ms. Herzfeld just talked about the state law claims that your firm has brought, the Tennessee Drug Dealer Liability Act and then the common law and statutory public nuisance claims. Some attorneys for the opioid manufacturers have argued that federal regulations actually preempt any state law claims. So, what is your response to that argument?

MR. STRANCH: Those defense lawyers are saying anything and everything they can to try to shut this litigation down. They are absolutely shameless. They are even attacking whether cities and counties have the

authority to bring the lawsuit or to hire outside counsel to do it. Their entire strategy right now is delay, delay, delay as long as possible. I don't think the federal regulations preempt anything in our litigation in particular, because we have specific state statutory claims that don't talk, reference or have anything to do with federal regulations. One thing that's clear is, this is not a complete preemption area like an ERISA where any claim at all would be preempted— field preemption is what it's called. They have not really raised federal preemption in our case in the motion to dismiss that we already argued. They did throw in the rest of the kitchen sink, though. Some of the other cases that are out there might have more of a federal preemption issue, particularly with the distributors; the McKessons, the Cardinals, the AmerisourceBergens, those entities, because those claims are often based on— you have this federal duty that you have to report when certain key things occur, you didn't report, so now I've got a cause of action against you, and so you might run into some preemption issues on that. We have chosen not to file the distributor cases yet until we can get the discovery so we can point to exactly what they knew and when they knew it so that we can plead around and avoid any possible problems with preemption. But, again, it's not really as much of an issue for our case, because we are not trying to prove you knew about this through federal regulation. We are saying, hey, look, you not only participated in the illegal drug market because you continued to ship pills to known diversion sources. So, it's completely outside of that realm. And so, we're a little bit different in what we do. But, yes, they are raising any and all defenses that they can to delay this as long as possible.

MR. GROVES: Thank you. Ms. Herzfeld, you mentioned the remedies that are available for some of these causes of action. Can you talk about what kind of damages that you are hoping to obtain for the clients that

you represent, and are there any procedural or legal obstacles that you face in obtaining those damages?

MS. HERZFELD: So, we are hoping to obtain really big damages for our clients, huge, huge, and there's a lot of reasons for that, not because anybody is trying to get rich; right? When you look at these towns and you look at— Sullivan County, Tennessee, is a great example. I think someone in the audience said earlier that the towns are emptier. They are full of people that can't get jobs, because nobody can pass a drug test, and that's nobody's fault; right? I mean, it's not because you decided that you were going to become a drug addict and that's how you wanted your world to end up. Nobody intends to become a drug addict. But you did have a workplace injury because you worked in the coal mines or you worked wherever it is, and your doctor gave you these drugs. Nobody intends to get addicted. Nobody intends to become a drug addict. And the consequences of that are just devastating, especially in a small town. We know that there are employers that have jobs they can't fill because they cannot find sufficient people to pass a drug test. So, our case not only includes damages for the town, which I'll talk about more specifically in a minute, but also claims for babies. So I think our case is the only case in the country, at least the last time I checked, where we have included claims on behalf of particular infants, and these are individual children whose identities are sealed; I know who they are, but their identities are sealed, and they were babies that were born dependent on these drugs, so their birth mothers took the drugs during pregnancy and at some point gave birth to these children who suffered enormously.

So, I would like to talk about their damages first. What we know about the children that are born with neonatal abstinence syndrome is actually, pardon the pun, in its infancy. It's not something that has been studied for an extraordinary amount of time, but this

phenomenon, neonatal abstinence syndrome and opioids, hasn't been around that long. Here's what we know: When these babies are born, they shake, they cry uncontrollably, you cannot sooth them. That is the one thing you will hear everyone say. They scream and scream and scream to the point where their volunteers whose only job is to cuddle the babies. They just walk and cuddle and rock and walk and cuddle and rock. And why is it? Because the children have had a constant supply of these highly-addictive medications in utero, and once they are born, it's discontinued. Do you know how they treat those babies? Morphine. They have to give those babies morphine. In the first days of their life, they are given a bit and then they wean them down and they wean them down and they wean them down, and so they end up in the neonatal intensive unit and they are being given controlled doses of morphine to wean them down. So that's the first few weeks, which is crying and shaking and rocking and horrible. But then what comes next? You have a lifetime of learning disabilities: oppositional defiant issues, inability to concentrate, emotional outbursts that they don't understand why that is happening; the parents, the grandparents, foster parents, no one understands why this child is just not behaving in a way that makes sense, and what we're finding, through the studies, is that most of that can be taken back to this exposure in utero. Babies are developing; there's stuff that happens there. So, we are trying desperately to get damages for those babies. We know that they will have a lifetime of medical needs, a lifetime of special needs. They need early intervention. The educational costs, imagine the educational costs of taking a child with needs. We don't quite understand through essentially 20 years. We don't know what that is going to look like. And Tennessee has the highest number of babies born with neonatal abstinence syndrome due to opioid addiction.

MR. STRANCH: It's a baby born every other day dependent on opioids.

MS. HERZFELD: It's so bad that the Children's Hospital up there had to open up its own wing, its own wing with its own beds just for these babies. So, I don't want to lose sight of that. Of course, we're filing through District Attorneys who are seeking truth and justice and going to get the bad guys and drug dealers out of their districts; right, and that's true and important and amazing, but also, it's the babies; right? It's the people who are raising the babies. It's the families that are broken and destroyed by the fact that now the grandmother or the auntie or the cousin that's raising these babies. And when you take that, and you multiply that not just from a one-family perspective, but from an entire community, the devastation is extraordinary. So what kind of damages are you hoping to get? Well, let's see, prosecutors have to spend more time prosecuting, cops have to spend more time arresting, more Narcan, more ambulance costs, more emergency room costs, more overdose costs, more educational costs. Court system costs go up; right? Everything exponentially goes up. Those resources might have been used for other things, positive things, but instead they are all being diverted to deal with this completely overwhelming crisis.

So, what are the damages? Good question. They are enormous. The other thing we have asked for, in addition to damages to fix all the stuff that's happened in the past, is, we have asked for injunctive relief going forward, and that sounds crazy; right? How do you get injunctive relief on a pill epidemic, an illegal pill epidemic? But that's what we want. We want the drug manufacturers to stop. That's just the answer, stop, stop doing it. You know what you are doing, you know what the harms are, stop putting profits over people, stop. And if that means that they have to pay for remediation in order to make these things happen, in order to not only

make the communities whole for the past damages, but to pay for rehab beds, education, different drug courts, these types of things going forward to kind of help fix that damage, special ed students, all these things, they all need to pay that going forward. So, the damages are huge, and I think it will probably be a bit challenging to figure out exactly how big, because there's a lot of zeros there.

MR. STRANCH: One of the things you need to know about that, like in Hawkins County, the sheriff did an analysis at the jail. Eighty-eight percent of the jail population, which was full, was there because of pills, either DUI while high on pills, stealing to buy pills, domestic violence while high on pills. It's all pills. It's 88 percent of the jail in Hawkins County. And so, we really can't emphasize enough how bad this is in the communities. It's easy when you're in a city like Knoxville to miss exactly what's going on in some of these smaller communities.

MS. HERZFELD: We missed it. We didn't know; right, until we knew? I mean, we didn't know until we knew. It's devastating.

MR. GROVES: Professor Buck, we have heard a little bit about the suits against these drug manufacturers. Just from a broader public health perspective, what are the similarities in this type of litigation against the drug manufacturers to the litigation that occurred against Big Tobacco in the 1990s, and are there any differences?

MR. BUCK: Sure. So, focused on manufacturers for a minute and talking federal regulations. I think there's one kind of major similarity, and that is, in many of these claims that are the federal claims, there is a core to them that focuses on some kind of fraudulent

advertising. So the drug companies are actually advertising these drugs either direct to consumer or in doctors' offices in some way that can be alleged to be fraudulent, and in that way we have a similarity with Big Tobacco in the 1990s. You know, they're burying bad science, they're minimizing poor results from clinical trials, and they may be actually misbranding these drugs through their misleading advertising. But beyond that, there are a lot of differences, and in particular there are three that I was able to kind of come up with in thinking. First, opioids have a lot of regulation around them to begin with. They actually are FDA approved to treat chronic pain, and we have been talking a lot about misuse of opioids and illegal use of opioids, but I think it's important to also recognize that through the last generation of health law and policy, there's been a lot of discussions about how chronic pain in this country is undertreated and how individuals have a stigma attached to them who are facing chronic pain, as well as the individuals who prescribe those drugs, and that's complicating the regulation of these drugs in a way that never complicated the regulation of tobacco. Tobacco was not subject to FDA approval until 2009 in this country. Drugs that are sold in this country are approved by the FDA, and so we have a regulatory structure in place from the federal perspective that is different than tobacco in that regard. The second I guess you could say a way that these are very different is that these drugs are subject to a number of antifraud tools at the federal level when we're talking about manufacturers. So, the most potent, you can talk about the False Claims Act.

The federal government is able to go after manufacturers who misbrand their drugs, who advertise their drugs to doctors in ways that are untrue, because the federal government pays for these drugs through Medicare and Medicaid, and these programs allow the federal government to empower the Department of Justice to go after manufacturing companies who make

untrue statements in their advertisement. The problem, of course, with this way or this pathway is that there's often a desire to settle these cases, particularly of course from the drug companies' perspective, but also from the Department of Justice. There's been a reliance on Corporate Integrity Agreements over the last couple of years that are put in place to try to govern drug companies' behaviors going forward and check in every quarter on pricing or advertising. And I think the biggest challenge here is that misbranding is really profitable for these manufacturing companies. So if you're a manufacturing company and you have gotten your drug approved for a narrow segment of the population, but you can go into a doctor's office and allegedly talk about an off-label use that the FDA has not approved your drug for, which is the case in the Purdue case around Oxycontin, they were minimizing the addictive effects of the drugs to the doctors; that's the allegation. There's a huge market out there for which you do not have to go through the FDA to seek approval. You can get doctors to prescribe your drug off label, and often doctors will do so. It's a very profitable thing, if you are a private company and you owe a duty to your shareholders to maximize profits and you see that you can open up the market by eight, nine, ten billion dollars and the statutory penalties might only amount to a two or three-billion-dollar settlement, that's a calculation that many drug manufacturing companies make. And so, I guess the thing that I would say about this is that our enforcement and regulatory system here is not potent enough and that we settle too much with drug companies in this respect.

Of course, there's also a challenge that if you take a drug company to trial for one of these cases, what faces them, in the event of a bad verdict from their perspective, is exclusion from Medicare or Medicaid, and that means they can't basically do any business with anybody related to the American healthcare system, to which they make the argument to the Department of Justice this is

something that will hurt a lot of people. Like the Pfizers of the world going to court and saying we do a lot of good, so you can't exclude us because think about all the patient harm that will come. And I know I'm blowing that out of the perspective there, but that's the heart of the argument from the pharmaceutical company. The final thing, the third I think big difference is going back to a point that I had made earlier, which is a lot of these drugs— and this is what makes this problem so complicated and much more complicated than the tobacco problem— is that, again, these drugs, some of them are indicated, some of them are legitimate. We can't categorize them all in one way or the other. And we built the system, at least in this country, around prescription drugs that values professional autonomy, and it complicates the regulation of prescription. We trust our doctors and we give them a lot of authority and discretion to make determinations about our drugs. And so, the best way I think we can try to go about this problem is to go after the manufacturers using the tools I mentioned. I think those are the things that complicate the analysis when we're comparing it to tobacco.

MR. GROVES: Mr. Stranch, Professor Buck just talked a little bit about the federal government's involvement from a regulatory perspective, but let's talk about what the Justice Department has done just in the past year. In August of 2017, the Justice Department announced the formation of the Opioid Fraud and Abuse Detection Unit, which will temporarily provide financial resources to 12 of the 94 U.S. Attorney's Offices for the purposes of prosecuting health care fraud and abuse, and the Eastern District of Tennessee U.S. Attorney's Office was selected to participate. So how significant of a development is this in your mind, and in general what should the role of the federal government be in combatting this crisis?

MR. STRANCH: I mean, they're putting drapes on a burning house. You're not going to arrest your way out of this problem. It's way too big. The time to do that was 25 years ago. And the federal government, there's been a complete failure of the regulatory system to do anything about this, both at the state and at the federal level. I can tell you, from representing District Attorney Generals, that they are absolutely underwater with pill problems. I mean, it's the number one thing they deal with. We have even got one DA that we've talked with who says, look, if I dig hard enough on any case that comes into my office, there's going to be pills in there somewhere, I've just got to dig deep enough to find it, and I take a little slightly view, I say maybe in 99 percent of the cases, but he's adamant it's a hundred percent. That's how bad the problem is. So, some funding to help find opioid fraud and abuse and maybe shutdown a pill mill here or there, it will be nice, it will help, but it's— I mean, you're standing at a breaking dam and you're sticking your finger in a crack. It's going to take the full weight of the federal government, the state government, the court system through private litigation and the legislature in changing laws if we're actually going to try to get ahead of this problem, because right now we have not even hit the crest of the tidal wave. It is still coming. It is still getting worse. Every year there's more babies born dependent on opioids. Every year there is a rise in the number of deaths due to overdoses. And even in places where we have seen the overdose deaths start to level out, what we are seeing is a number of overdoses have continued to rise anyway, and what it is a reflection of is, now they have Narcan in the cop cars, now they have Narcan in the ambulances, so they can deploy immediately when something happens.

We have got districts that we're working with where they're putting it in schools because kids are overdosing at school on opioids. So, a couple of million bucks from the Department of Justice to put five or six

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people looking at pill mills is not going to change anything. I mean, it's a window dressing so that someone can stand up and say, look, we're doing something, but they are not really doing anything at all. I will speak briefly about Purdue for a second. They pled guilty to misbranding back in 2006, and they admitted to what I call the Holy Trinity of Lies. They said we told people that if you have true chronic pain, you will not become addicted to our pills. We told doctors and people if you have true chronic pain, you won't develop a tolerance to our pills. And we told people if you have true chronic pain, you won't go through withdrawal when the pills are taken away. They admitted in their criminal guilty plea that those statements were all false and they knew they were false at the time they made them, and these are statements that they were training their people to go out and detail doctors and tell them this over and over and over again, and it went on for over a decade before the federal government got involved on it. And during that time, Oxycontin use went from a mid-eight figure drug to a billion dollar drug every single year and created an entire generation of doctors that believe these scientific facts that are not facts that are in fact false, and it created an entire generation of addicts, and despite that guilty plea, despite paying \$600 million that they paid as part of that and agreeing that they're not going to do that and submitting to all these monitoring programs with states and the federal government where they're supposed to submit, here's the list of doctors that are prescribing our pills at certain levels, there's been no enforcement action on that at all, and they have continued to do the exact same thing. At the time we filed our first complaint, they were still pushing OxyContin for use in chronic pain, for people that have a history of substance abuse and saying they probably would not get addicted or less likely to get addicted. This is on web sites that they run that they host with their name on them that are designed for doctors to answer their questions

about the drugs. The regulatory world failed, and they have done nothing about it. And having a couple more people in the U.S. Attorney's Office who are focused on pill detection and finding street-level drug dealers, it's going to do nothing.

MR. GROVES: In the second half of the discussion I want to talk about some legislative policy proposals that are percolating in the Tennessee General Assembly, but before we get to that, Professor Buck, I'm going to throw the ethics question at you. Rule 1.6(c)(1) of the Tennessee Rules of Professional Conduct requires lawyers to review information relating to the representation of a client to the extent the lawyer reasonably believes disclosure is necessary to prevent reasonably certain deaths or substantial bodily harm. So, what are the implications of this rule for attorneys that are representing the pharmaceutical companies?

MR. BUCK: Well, I think that the reasonably certain deaths or substantial body harm in 1.6(c)(1) probably is not as applicable as you might think when you take a look at it, because the individual that 1.6 contemplates is identifiable, and it's hard to make that causal link if you're representing a pharmaceutical company. I think that the ethical question that is perhaps more interesting is, what if you find yourself representing a pharmaceutical company that wants to engage in some kind of activity that you think is fraudulent. This happens a lot in the health care world when I talk to people who practice, and it's one of the things that keeps them up at night. If our client determines that they have gotten overpaid by Medicare or if they find that some of their scientific statements aren't defensible, what is my role as the attorney?

Tennessee's rules are permissive in that instance, so you, as the attorney, have the ability to disclose, it's not required, but it is available to you if you think that

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you need to in order to prevent an ongoing crime or fraud. And withdrawal also is permissible, and so in the event that you might find yourself advising a client that's unwilling to reconsider a course of action, the withdrawal would be permissive. There are cases in which withdrawal is required, and that is when you know that your client is using your services to perpetrate a crime, so the line between those two standards is pretty blurry, but usually there's a lot of discretion given to the attorney to decide what he or she needs to do in that instance, but it is not an easy place to be in, and it happens I think fairly regularly, so it's worth thinking about when you're talking about the topic.

MR. GROVES: Now we will make that transition and we're going to talk more about legislative policy proposals. As many of you might know, Governor Haslam recently announced his Tennessee Together Plan, which proposes a host of legislative and regulatory efforts to fight this epidemic, and the plan emphasizes three different strategies: prevention, treatment and law enforcement. So, I want to spend the rest of our time talking about this, and then at about 2:00, 2:05 we will open it up to audience questions; you can be writing those down. So, Ms. Herzfeld, some lawmakers in the General Assembly have suggested that one way to prevent future opioid addiction is to limit the supply and dosage of opioid prescription such as what was mentioned earlier, limiting new patients to a five-day supply. Others are calling for prevention education in public schools. What is your reaction to some of these preventative policy proposals?

MS. HERZFELD: I think they are all really good ideas, and they are very, very well intentioned, but I think as Gerald has made it clear, we are really just kind of nipping around the edges at this point. Legislation alone isn't going to fix the problem. I like the

three-or-five-day limit on the ability to get those pills. That is something that we have noticed is a really big deal. The stuff that we have reviewed, I mean, just the sheer number of pills that are given to folks, it's crazy. I mean, it's a crazy amount, when you're getting a 30-day supply and five pills a day and four refills and doctors don't even worry about it; sure, you want another refill, no problem. I had my tonsils out a couple years ago and they had given me hydrocodone, I think, and of course I had taken it for two days. I had my tonsils out; right, in my 30s, and it was painful, but after the second day, I was like my God, get me off of this stuff, like please.

When I went for my follow-up a week after, the doctor is like do you want more hydrocodone? And I'm like oh, my God, no. They just hand it out to you so easily. And, again, I don't think they mean anything by it. I think they're trying to be helpful, at least in some circumstances. So, limiting that and limiting who can prescribe I think is really another important thing. You have a lot of nurse practitioners— and this is not to get down on nurse practitioners— but you have a lot of nurse practitioners who don't have sufficient supervision who are running things kind of on their own and you are seeing an extraordinary number of these pills getting into the system that aren't necessary, they are not medically necessary, it's too much, it's overkill, and a lot of that is coming through nurse practitioners. So, there's a lot of things. There needs to be accountability; what is the enforcement mechanism if somebody is violating. There needs to be monitoring. There needs to be limitations on all that. I don't think it can just kind of be one thing and here's a little bit of education and we're going to take the pills and make it for five days. It has to be a more omnibus kind of gigantic regulatory scheme to even begin to make a dent.

MR. GROVES: Mr. Stranch, I was going to ask you if you thought \$25 million was enough to fund

treatment and recovery services, but I think I know your answer to that.

MR. STRANCH: Twenty-five million bucks won't even run a quality facility in one area of the state for a year. Again, window dressing is all it is. What you need to know about addiction when you're dealing with opioids such as this, you actually have multiple levels of addiction you have to break. You have to break the chemical dependency. For many people in Tennessee, that is actually broken while they are in jail, because they lose the opioids, they go through withdrawal in jail. Oftentimes they receive little to no medical care or therapy as part of that process. They just literally detox, go through the shakes, horrible diarrhea, headaches, nausea, throwing up in the jailcell. That's how it normally goes. Once you break the chemical dependency, you still have a behavioral dependency that has to be broken as well, and your brain won't go back to the way it was before you started taking opioids for 12 to 18 months after you have broken the chemical dependency, and so that's why you have so many people that relapse in that first year, because their brain is still not back to normal and they're feeling depressed, the hormones and things inside your brain and the way it works and the receptors are not working right again. They're still not back to normal, so it's easy to slide back to the addiction, because that feels good at that point. And so, if you really wanted to do this correctly, I mean, you can look at programs like the Tennessee Medical Association; they have an assistance program for doctors that become addicted.

It's a multi-year program once you enter it, and you lose your medical license if you don't complete it. They have an 85-percent cure rate, but it's a multi-year program. You have to go inpatient depending on the level of your addiction. You have regular meetings with people. You have regular drug tests. You have therapy on a

regular basis, not like 12-step-type stuff, but like sit down and talk about what's going on in your life, what are your triggers, help to identify your triggers so you can deal with them, and \$25 million is not going to let you do that for a couple hundred thousand Tennesseans that are currently addicted right now. Twenty-five million is not going to let you do it for 400 or 500 Tennesseans in one small area, and it's certainly not going to provide the aftercare once you break those addictions and you're trying to re-enter society as— as my father would always say for me, I just want you to be a taxpayer— try to become a taxpayer again. There's no support services for that. Twenty-five million dollars is nothing.

MR. GROVES: Professor Buck, part of the Tennessee Together Plan also involves law enforcement, and so the question that I have is, how do we enforce criminal laws that are already on the books with respect to users and distributors while also not re-enforcing the negative stigma that is associated with addiction or prescribing?

MR. BUCK: I think it's a very hard question to answer, so I'm just going to take up a couple minutes and then we can go to the audience. But going back on what was previously said, I mean, we don't think about this as a holistic problem, you think about physicians or dentists prescribing these drugs and you ask yourself, well, why would they? Well, first of all, they are seeking to treat some symptom that you might have, but also, they are incentivized to do that. We pay them to prescribe in this country. Medicare pays more for drugs that are more expensive to those doctors. They get a higher cut of the cost. And so, until we actually look at our own laws that actually create some of this problem in the first place and reverse them, we're not really going to make any dent in the problem. In talking about the criminal aspect, I mean, these issues that are so interesting find

themselves on the line between public health and criminal law, and I think part of the challenge is to adequately calibrate the response.

Is it a public health problem or is it a criminal law problem? I'm somebody who approaches these issues from kind of a health policy perspective, and so I'm much more likely to treat them at least on the addict side as a public health problem. It reminds me of the case where the students, common law students in here or others who recently graduated, Ferguson versus the City of Charleston that you might do in common law. It becomes a Fourth Amendment case, but in that case the issue is a hospital is testing the blood of pregnant women who comes to the hospital against their consent, and then for women who test positive, they are given the option of either entering a drug counseling program or going to jail. Now, if you think about that and apply a public health lens, that's a terrible program, because not only does it penalize people who might need medical assistance, but it deters people who need prenatal care from coming to the hospital in the first place. So, the first thing I would say to the governor is, do no harm, don't have a system in place that deters people from seeking help that they need. And so, in that perspective, a public health perspective, would say let's put more money on drug rehabilitation centers, let's expand Medicaid in this state, let's provide care for people who need it who don't have access to these services, but I don't think that's the total answer. I think the other part of it is, you have got to calibrate the penalties for those that have the ability to change their behavior, and that's the manufacturers, it's the drug companies, it's the distributors, and maybe it's the doctors; maybe we need to change the way we pay physicians in this country, and also think about what we can do to the regulatory mechanism. Is it really doing enough to deter the pharmaceutical companies in this country to think twice about advertising their drug in a way that they can alleged to be fraudulent, even if it's the

case that they stand to make a lot more money if they do so. So, I think we need to think about it from more of a holistic perspective. I think you have to be really careful that you don't harm providing care for people who need it by leaning too far toward criminality for those who are struggling from addiction.

MR. GROVES: We will open it up to questions now. I believe we have a couple of microphones that are going to be walking around, so if you will just raise your hand and I'll call on you. I think right here in the front.

UNIDENTIFIED SPEAKER: Thank you. As an attorney, if I'm working with the DPR and I'm being accused of knowingly lying three times with regard to relevant facts, even if I'm cooperating and remorseful, I'm going to lose my license for some period of time at least, and why do the manufacturers not lose their license for some period of time at least when they knowingly mislead and fraudulently tell things like that?

MR. STRANCH: Because our government is not in the business of shutting down big business. They cut a deal with them, they take some money, they let them move on. I'll give you an example of how bad it is. In our lawsuit, we sent requests for admissions. Each one of the facts that they admitted in that criminal guilty plea, we asked them just to admit it in our lawsuit, and they refused. They denied each one of them, said they are not true facts.

UNIDENTIFIED SPEAKER: I was just wondering, you had mentioned that there are kids overdosing in schools now and I was wondering are those primary, middle or high schools? What's the frequency that you all are seeing this now and where in the state, which schools, what area is that happening?

MR. STRANCH: It's actually happening across the country. It's showing up in high schools. So, one of the big things that's going on is, school boards are now discussing whether they want to deploy Narcan in the high schools, because there's been about a dozen or more overdoses that have occurred in high schools where kids would go to school, take a couple pills to help float their math class and OD. It's particularly becoming a problem with the introduction of fentanyl and carfentanyl, which is dangerously potent, and you don't really know how strong it is, because they're pressing out pills to make it look like something, sticking a little fentanyl in it, and sometimes you're getting a dose that's ten times what you think you're getting. They had an outbreak down in Florida recently where I think it was 12 students OD'd and died where they were all taking the same pills that were supposed to be one strength but were actually about 10, 12 times that strength. And so, yeah, it's happening in high schools all over the country. I know there's been a couple of deaths in Ohio. There were the deaths in Florida. We have talked to a couple people here in Tennessee that are looking into it for their high schools as well, as to whether they ought to be deploying Narcan for suspected overdoses in the school. It's a real problem.

MR. GROVES: We have another question down here.

UNIDENTIFIED SPEAKER: This might be more of a rhetorical statement or rhetorical question. I'm thinking somewhat of an analogy to what's happened with the groundswell against the NRA for what happened I guess a week and a day ago in Florida where at least the kid seemed to be -- there seems to be some friction, some impetus to fix. So, here's my analogy, and I'm not sure it works, and I'm wondering what you think about it. So if I'm a doctor in Sullivan County, or a dentist, and I'm figuring I've got, off the top of my head,

a hundred colleagues, maybe 50, and I'm going to the local county club once a month to meet with them just to -- I don't understand how the doctors in a smaller community like that, why there can't be some groundswell from them that would be effective in preventing this or something.

MS. HERZFELD: I think with a lot them, there actually is. We have talked to an extraordinary number of doctors who actually have an incredible amount of remorse, who have unwittingly participated in this and not realized. We were just talking about --Gerald and our other law partner, Jim, were telling the same story about doctors who have said I have prescribed so much opioids, I have given all these things, and now I'm looking back going, oh, my goodness, how many people did I hook, how many people did I harm, and they were talking about two different doctors and two completely difference conversations, which is wild; right? But it's not. There's been a million articles-- you can Google it-- of doctors sitting down and saying did I contribute to this, how did I do this, and how do I get out of it, because now you have patients coming to these doctors, and I'm talking about the legitimate ones, I'm not talking about the Fentanyl pill mills; that's a drive-through business. It's different. It's criminal. But for legitimate doctors, I mean, they are now trained to ask what is your pain level; right? When I was growing up, nobody asked that. It was how are you feeling, what's your blood pressure, looked at your heart rate, blah, blah, blah.

But now it's please rate your pain. So, we as a society now expect the doctors to keep us out of pain, and if you go to your doctor and say I'm in pain and I have got this root canal, you haven't given me enough medication, you're mad at your doctor for keeping you in pain, and the truth of the matter is, he's actually good; right? I mean, not all the time and not an extraordinary amount, but it is natural. There is a thing about pain. Sometimes

you're going to be in pain. That root canal is going to hurt. So, I think that friction between the doctors and the patients of I'm expecting you to make me feel better and the doctor doesn't want to give you something but yet needs to give you a little something and there's a dance there. There have been some extraordinary things written that you can find online where doctors talk about that struggle.

MR. STRANCH: By the way, the whole focus on pain and how we should never have pain, there's all these groups, Americans Against Pain, the American Society for the Prevention of Unnecessary Pain, I mean, they are all front organizations that have been funded by the opioid manufacturers, and that's what started this fifth vital sign of your pain, because they want to be able to — they have something that they can justify, but it's completely subjective. My grandmother, for example, every time she goes to the doctor — she's on her fifth bout with cancer — doctor says what's your pain on a level of one to ten. It's ten. Every time it's ten. The doctor finally says to her, well, it's always ten. She says, well, yeah, either it hurts or it doesn't. That's what it is. That's the way she views it. And so, what this pain thing is, it gave the doctors the ability to write down in the chart pain of eight, oxycodone and give support for it, when it's just a completely subjective measure. There's nothing objective about it. It's not like your blood pressure or your white blood cell count or your temperature. It's just a complete subjective thing that is used to justify prescribing pills. And they use these front groups to go in and train and to talk to doctors that people should not be feeling pain on a day-to-day basis. You should not ever feel pain, pain is bad. Well, that was an actual sea change in the way doctors view things.

I blew my knee out playing rugby in the '90s and had to have a knee surgery. When the surgery was done, the doctor said to me afterwards, look, I'm going to give

you this five-day prescription for pills, but I only want you to take them when the pain gets to be too bad. The pain is supposed to be your guide. It tells you what you can and can't do with your knee. If it hurts, stop doing what you're doing, because you're going to over-extend and reinjure yourself. That's what the purpose of the pain is. It's a warning sign to you to don't do that. And they have completely changed that. And the doctor told me you should probably only be taking these pills at night, because you're going to be worn out, your knee is going to be hurting and it will help you fall asleep. That was it. A friend had a very similar surgery last year. He got a 30-day supply of Oxycontin and the doctor said, "And if you feel any pain at all, you call me, and I'll get you something stronger." That's the change, and it's this emphasis on pain that is not created through the medical community by doctors doing largescale studies, blind studies, double blind studies, observational studies, longitudinal studies, it was created by a bunch of front groups that the opioid manufacturers supported, because that's how they can push their pills.

UNIDENTIFIED SPEAKER: The first ten years after law school, I did plaintiffs' asbestos work and so I know what's in front of you and I wish you well. I'm interested in causation and damages. Addicted children, they don't all have these horrible effects later in life. Now, I'm in family law and I know that. So the test that we were stuck with is, if you're going to say— we were faced with this: Okay, yeah, this guy has had all this asbestos exposure, he has a much, much higher risk of contracting cancer later on, but you have got to prove it's more likely than not that this guy is going to have cancer, so how are you going to, A, prove that this baby is going to have learning disabilities and obstructive disorder eight, nine, ten years from now and there are kids that have learning disabilities and obstructive disorder who never were exposed to opioids? So, you have got to get over that too,

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that it's this and he wouldn't have just already had it, and I can't imagine how you're going to do that. So how are you going to do that?

MR. STRANCH: For starters, the Drug Dealer Liability Act has a specific section that deals with assigning claims to babies that are exposed in utero. So, they have a specific test already for what you can do, and we know for the kids that we filed, they already have those problems now. They already have impulse control problems now.

UNIDENTIFIED SPEAKER: How old are they?

MR. STRANCH: They range in ages. Most of them are close to school age or in school.

UNIDENTIFIED SPEAKER: Some of them will graduate from college before you're through.

MR. STRANCH: More than likely, more than likely. But one of the things that what we believe the current state of medicine to be on this is, look, if you're exposed to significant amounts of opioids in utero, you're going to have impulse control problems later in life, period, full stop, that's going to happen. The question becomes, are you able to deal with it, control it or not, which is kind of ironic for someone with impulse control problems, but the way it works is, you have to do early childhood intervention and you have to work with the children from day one and you have to provide them with a stable environment so that they cannot have external stressors. One of the problems of the opioid epidemic is, of these babies that are born with NAS, like 25 percent of them end up in foster care within a year. Many of them end up bouncing in and out of foster care.

So, they don't have a stable environment to start with, which only causes to exacerbate the impulse control

problems. Now, if a kid gets adopted straight out of coming out of the NICU, goes to a stable, loving family and they take care of him and they provide all of the early childhood intervention, you may see a child that is going to graduate and, as my dad said, become a taxpayer. Greatest thing you could ever want for your kid is to become a taxpayer. But that doesn't mean that there's not going to be problems and struggles and the behavioral therapy and other stuff that's going to have to be done along the way. We also know from another child we represented that it can be much more than just impulse control problems. It can literally be a question of will this child ever be able to be a functioning member of society without having to have an adult doing things for them and overseeing them.

UNIDENTIFIED SPEAKER: The corporate boys are going to say prove that this kid doesn't need \$1,000 worth of treatment rather than the \$500,000 worth of treatment that you say he needs ten, 15 years from now.

MR. STRANCH: We're still struggling to get them to admit they're selling opioids. They're not admitting anything. But we're going to have our experts that are going to go through and that are going to talk about what's facing these kids, what's going to happen, what money is going to have to be spent on them, the problems they're going to have, and they're going to have their experts, like in all cases where you have medical experts, who are going to say this kid was never harmed, and if there was any harm, it was because the dad had bad genetics or the mom had bad genetics and they all preexisted and had nothing to do with this, and by the way, would you like some opioids?

I mean, that's what they're going to do. And I just think our experts are going to be more believable than theirs, because we're going to be putting them in front of a jury that is going to be living in a community where

they're seeing this on a day-to-day basis, where they're seeing the disruption in the classroom through their kids and their neighbors' kids. Our first hearing that we went to in our case, there was three divorces on the docket, and two of them was because the spouse ran off because she was addicted to pills. These communities know this, and they are not going to be very impressed with a medical doctor that comes in and says there's no long-term harm damage from shooting up opioids during pregnancy and that these kids are not going to have any problems, and if they do, it's because they didn't have a stable home life beforehand and they've got bad genetics.

UNIDENTIFIED SPEAKER: Baby Doe is a very sympathetic plaintiff.

MR. GROVES: That's about all the time that we have for this panel of discussion. Join me in thanking our panelists for joining us.

