

Drugs on the Docket Podcast

Season 1 Episode 2 – *Ruan v. United States* and the intersection of healthcare, criminal law, and the opioid crisis with Jenn Oliva and Kelly Gillespie

TRANSCRIPT:

Hannah Miller: If you've paid any attention to the news these last few years, you've probably heard the name Sackler. The Sackler family owned and ran Purdue Pharma, a drug company that was ultimately prosecuted for the role it played in fueling the opioid crisis. Purdue Pharma invented OxyContin. When OxyContin was approved by the Food and Drug Administration in 1995, it was hailed as a miracle drug for people who suffered from chronic pain. But Purdue Pharma's aggressive promotion of the drug to prescribing physicians contributed to the drug's frequent misuse. As the Justice Department explained at the time of resolving multiple criminal and civil complaints, Purdue admitted that it marketed and sold its dangerous opioid products to health care practitioners, even though it had reason to believe those providers were diverting them to abusers.

Purdue also paid kickbacks to providers to encourage them to prescribe even more of its products. As the scope of the opioid epidemic and the role of opioid prescribing came into focus, Government officials at a local, state and federal level have developed a range of legal responses. With a focus on health care practitioners, these responses have included setting formal limits of when and how opioids can be prescribed, revoking the prescribing or practicing licenses of doctors, and even criminally prosecuting doctors for acting essentially as illicit drug dealers. These responses have also posed challenges to doctors caring for patients struggling with pain. Most troubling to many practitioners has been the threat of criminal prosecution, should they come under the scrutiny of their state's medical board or the Federal Drug Enforcement Administration.

This very issue made its way to the U.S. Supreme Court in 2022, in the case of *Ruan v. United States*. The *Ruan* case involved the prosecution of two doctors who prescribed a large amount of opioids but who claim they did so for legitimate medical purposes. The case called into question what federal prosecutors must prove about a doctor's mental state in order to convict them of unauthorized distribution of controlled substances. The court ruled in favor of the doctors, saying they could only be convicted of federal criminal drug offenses if prosecutors could prove they actually, subjectively knew that there was no legitimate medical purpose for their prescribing.

Considering how much urgency there is to combat the opioid crisis, what other means might the government use going forward to limit opioid access? Is focusing on prescribing and medical practices really the best way to address substance misuse and overdose deaths?

From the Drug Enforcement and Policy Center at The Ohio State University, this is *Drugs on the Docket*. Each episode will tell the story of how U.S. court decisions impact drug law and policy and continue to shape the War on Drugs. I'm your host, Hannah Miller. Today, we're exploring the intersection of health care, criminal law and the opioid crisis. If you like what you hear in today's episode, visit go.osu.edu/drugsonthedocket to follow the series.

So it seems, it seems very odd to say that I'm excited to talk about opioids, but there's really no other way to put it. I'm actually very excited to talk about opioids and I'm equally excited to have Professor Patti Zettler as my co-host today. Say hey, Patti.

Patricia Zeller: Hi, everyone.

Hannah Miller: So Patti is a nationally recognized expert on food and drug law and policy. She currently serves as an associate professor of law at The Ohio State University Moritz College of Law, and is an affiliated faculty member of the Drug Enforcement and Policy Center. Patti, would you do the honors of introducing not just a guest, but guests, plural, for today's episode?

Patricia Zettler: I would be delighted to. Today, we are so lucky to be joined by two absolute superstars in the health law world. The first guest I'll introduce is Jenn Oliva. Jenn is a professor at UC Hastings Law whose teaching interests include health law and policy. She's earned numerous awards for her scholarship, teaching and service and coauthored an amicus brief in support of the petitioner and in *Ruan v United States*, the case we'll be talking about today, along with our second guest, Kelly Gillespie. Jenn, can you go ahead and say hello?

Jenn Oliva: Thanks to you, Patti and Hannah, for having me here today.

Patricia Zettler: So, Kelly, our second guest, is a professor of law and director of the Health Law Program at Creighton University School of Law, where she teaches health care law, bioethics, torts and holds public health law seminars focused on pandemic ethics and drug policy. Welcome, Kelly. And if you could say hello briefly as well, that'd be great.

Kelly Gillespie: Hello, great to be here. Thanks again.

Hannah Miller: For listeners unfamiliar with the Ruan case and its journey to the U.S. Supreme Court. Would either of you care to summarize?

Jenn Oliva: The petitioner in this case, Dr. Ruan, practiced medicine as a board-certified interventional pain specialist in Mobile, Alabama. As our country's drug overdose crisis has worsened over the last two decades, government agencies like the Federal Drug Enforcement Administration that are charged with controlled substances regulation, including prescription opioid oversight, have enhanced their surveillance of pain clinic practices like Dr. Ruan's who frequently prescribe prescription opioids. And subsequent to a DEA investigation, Dr. Ruan was indicted by a federal grand jury. He was charged with violations of Section 841 of the federal Controlled Substances Act, which criminalizes the unlawful distribution of controlled substances.

And Section 841 is a very broad provision which makes it a federal felony for any person to knowingly and intentionally distribute a controlled substance except as, "otherwise authorized under the Controlled Substance Act." Physicians like Dr. Ruan are authorized to prescribe controlled substances under the statutes applicable regulations, so long as those prescriptions are, and this is another quote, "issued for a legitimate medical purpose in the usual course of the physician's professional practice." Prescribing behavior that's merely been deemed outside the standard of care has long been viewed the purview of state, civil and regulatory law, and not that of the federal criminal legal system.

This federal felony statute that I'm talking about here, prescribers face up to life in prison and \$1,000,000 fine if they're found guilty. So it's a severe penalty. Most of the federal courts until recently have read an implied good faith defense into the Section 841. This means that doctors cannot be convicted of the felony distribution provision so long as they have a good faith belief that their prescribing practices fell within legitimate medical practice.

In other words, they're acting as a medical professional, not as a drug trafficker or a drug dealer in the traditional way we think about that. Dr. Ruan invoked that good faith offense in his criminal trial. Unfortunately, the district court rejected it and provided the jury with an objective standard that we describe in our pleadings as a mere negligence standard. The case was appealed to the 11th Circuit, and the 11th Circuit confirmed. So Dr. Ruan at that point was facing more than 20 years in prison. He petitioned for certiorari or review of the case to the United States Supreme Court. And it was at this stage of the proceedings that Professor Gillespie and I got involved in the case.

The law firm called me and said, "Hey, do you know anybody who would write amicus brief from the health law policy perspective?" And I put them on hold and called Kelly. There were a lot of great amici at the merit stage when we shifted strategies as made sense. But at the petition stage, Kelly and I were the only brave souls because the petition was due right around Christmas Eve.

Hannah Miller: I see this amicus brief. I can imagine, like the two of you being like, we got to do this, we have to do this.

Kelly Gillespie: And then we were like, do we have to do this right? And why? Why did we think we had to do this? Do we still have to do this? Oh, yes, we have to do this. And then like, yes, we have to do it.

Jenn Oliva: It's probably totally because of us, and the health law professors brief that all of this went the way that it did. I'm just kidding.

But we were the only amicus. So, we were also challenged in that sense that we were trying to cover a lot of things just to try to get them to grant cert.

Kelly Gillespie: Right.

Jenn Oliva: And since we were alone, that was a little more challenging. It was a little easier for us to flex in our areas of expertise on the merits, the second round.

Kelly Gillespie: Yeah.

Jenn Oliva: The Supreme Court ultimately ruled in Dr. Ruan on favor, nine zero, by holding that in order to convict a physician who is authorized under the Controlled Substance Act to prescribe controlled substances, a felony unlawful distribution, the government is required to prove beyond a reasonable doubt that the physician knew or intended that the prescription was unauthorized. That is to say, knew that it was not being issued for a legitimate medical purpose in the course of professional practice.

Kelly Gillespie: Part of the reason that this had been so urgent is that in the years immediately preceding this case, some of the circuits really began eroding their previously adhered to standards. So, like in the Ruan case, what had once been called the so-called objective good faith defense, where doctors could not be convicted if they could show that they had a reasonable belief that they were acting as a doctor in the usual course of professional practice, that circuit had essentially taken that standard, which was already a little bit tenuous because their belief wasn't just a subjective, honest belief, but it had to be a reasonable one. But they eliminated that as well.

To apply the reasonableness essentially to the act of the prescribing, all the government had to show is that the person had acted outside the usual course. And as our briefs discuss, and I have to give all the credit to Jenn, the standards for expert testimony are so different in these federal criminal trials. What the standard of care is, this sort of generally accepted national medical standard. So, it's less tailored to the physician's practice than in most states. And it's much easier to see an expert. If you're in a malpractice case, you have to prove harm to a patient. And in these cases, of course, harm to a patient is not an element. In fact, it had become much easier to convict a prescribing practitioner under the felony distribution statute than it would be for them to have a finding of liability in a malpractice trial. And that seems to just turn things on its head.

The 11th, 10th and Fourth Circuit in particular, had really eroded their standards in different ways, but essentially had gotten to the point where all you had to prove is that the doctor had acted, or the prescriber had acted, outside the usual course, judged by this sort of pseudo standard of care assessment, which is problematic, obviously because of the harsh penalties involved and felony conviction. Right? Over a million dollars in fines and up to a lifetime in prison.

Patricia Zettler: If I can follow up on what you said, Kelly. I teach legislation and regulation, so I'm always trying to teach my law students that statutory interpretation is actually really important to a lot of the issues we really care about. And I gather from what you just said, that you and Jenn were not compelled to submit an amicus brief just because you're passionate about statutory interpretation and maybe some other concerns that you have. So, I'm wondering if you could talk a little bit more about why it is you felt it was important to file an amicus brief in this case?

Kelly Gillespie: Jenn and I have written about the harms that had come from the policy response to the so-called opioid crisis. But the initial response was to focus almost exclusively on prescription medications and prescription medications for people with chronic pain, and how reactions by providers and institutions to laws that perhaps didn't have the right focus or weren't addressed at the right underlying harms necessarily, how those laws and responses actually induced harm in their own right. So, for example, in 2016, the CDC came out with guidance on beginning prescription opioids in patients with chronic pain for primary care providers. And it was very clearly stated this was guidance, these were guidelines, that decisions had to be made at the bedside in the context of clinical care in those very nuanced situations. And then people from insurance companies to state lawmakers enshrined those in laws. And patients who had been on opioids for a really long time found themselves abruptly cut off, abandoned, voluntarily tapered. And there's been some pretty good empirical work since then that found that those patients were at a higher risk of suicide and that there were actually more harm that came from those decisions than had they been left on the medication that they were on.

And I also was interested in working on this just from my pre-law life experience, which was I was a nurse and my last job in nursing, I worked with a population of patients who had chronic pain and badly needed help, and I saw patients

who did really well on long term opioid therapy and certainly some for whom it wasn't a great choice. But these decisions are complicated and complex and don't respond well to the blunt force of the criminal law.

Hannah Miller: If you're not in the medical space or the legal space or the policy space, you're not really paying attention to how these other agencies might be impacting the overall system and how people respond to the system or practice as a result of these guidelines. What misconceptions do you think there are about opioids in the public sphere?

Kelly Gillespie: Just the word opioids has taken on this sort of almost mystical quality, right? Absent context for like bad, opioids equals bad, right? Opioids equals danger. And the truth is, of course, far more complicated. They're a prescription medication, just like lots of other prescription medications. Like all prescription medications, they hold the promise of benefit for the right patient under the right circumstances. And they also can be an agent of harm under the wrong circumstances. Right? And it's making that decisions always nuanced, a balance between benefits and risks. And yet I feel like they've become sort of a heuristic or a rule of thumb in their own right to sort of stand in for harmful or evil or bad. And they just don't have that much power. Right? It all has to be evaluated contextually.

Hannah Miller: Jenn, do you have anything to add about the 2016 guidelines? What changes are going to be made to these guidelines so that it minimizes the unintended negative consequences on chronic pain patients or others who are currently prescribed opioids?

Jenn Oliva: The big criticism of the guidelines was that they quotes unquotes recommended that clinicians use hard metrics like dosage thresholds and day supplies caps, right, when they were treating people with chronic and persistent pain. And the CDC argued, and they're technically correct, that like, look, these recommendations are like the pirates code, ok? They're not the law, they're not ossified, they're merely guidelines. But what ended up happening was everybody else, the states, insurance companies, ossified these rules and adopted them. And then we had a cascade of downstream harms that, quite frankly, if you know anything about drug policy, were entirely predictable.

First, by setting these explicit thresholds, they undermined prescribers' ability to prescribe based on individual patient assessments. This is one of the things the AMA has really emphasized in the rewriting of the guidelines. Some patients need higher doses, some patients need different treatment regimens, and the standard of care is to provide individual care, so they really interfered with physician ability to do that. Second, in response to the guidelines in these state laws I'm talking about, as well as the heightened law enforcement scrutiny that I alluded to earlier, prescribers just started getting out of the pain management business. It's simply too risky. It's long been stigmatized. And if they didn't do that, they significantly limited their opioid prescribing part of their practice, right, to avoid scrutiny. This, in turn, created an access to care crisis for patients that were dependent on opioids, these legacy patients that have long been on opioids, right? They were rapidly tapered, they were abandoned, etc., etc.

And as the supply of prescription opioids decreased, the illicit opioid products, you guys know this, the three waves, right? Heroin first, and then really, unfortunately, illicit synthetic fentanyl quickly supplanted prescription opioids as the primary driver of our current polysubstance overdose crisis.

So why did I say this was all predictable? Well, the illicit drug market behaved consistent with how it's always behaved, which is a comporting with the Iron Law of Prohibition. Richard Cohen coined that term in 1986, and it stands for that as law enforcement and scrutiny become more intense regarding a particular substance, the potency of that class of substances increases. He puts it this way: the harder the enforcement, the harder the drugs. So heroin is much more potent, right, than prescription opioids and fentanyl, orders of magnitude more.

And I just want for the people out there listening, I know that's a hard concept to grasp because it seems so intuitive that if we just cut the supply, we're going to be able to solve the problem. But we witnessed the exact same dynamic during alcohol prohibition, where many Americans switched their beverage of choice from beer and cider to hard liquor and high proof spirits. Why was that, right? Those were easier to smuggle and conceal.

So the bottom line is prescribing is way down. I read a recent statistic that said it's back down to the mid-nineties or 1999 levels, but overdose deaths are way up. In 2021 we had over 107,000 deaths in the United States, which was the record calendar year in U.S. history, and the previous records were set in the previous two years, 2020 and 2019. So the bottom line is that I understand that some of this stuff's not intuitive, but drug markets were working here as they've always worked, and sometimes that's complex and nuanced and difficult to understand.

Patricia Zettler: Thanks for that, Jenn. And I want to build on something you said, which was to talk a little bit about health care practitioners', you know, legitimate concerns about criminal enforcement and how difficult it is to be a prescriber and kind of moving away from prescribing. And Kelly, you mentioned earlier that you used to practice as a nurse before your career in law. And I know you also have a doctorate in health care ethics. So, I'm wondering if you can reflect a little bit on what your sense is of how aware health care professionals actually are of the Ruan decision and what this decision might mean on the ground for providing care to patients? Are we going to see health care professionals feel a little more comfortable that they're not going to be the target of criminal enforcement? Do they even know about this?

Kelly Gillespie: My sense is that not a ton of health care professionals on the ground know about this decision, at least not as many as ought to. And I'm hoping that we can get the word out more and more. If you're working hard as a health care provider and you're working in one of these areas, especially addiction care for caring for people with chronic pain, not only are you working with a highly stigmatized patient population, but the providers that work in those fields also have a sort of association stigma. When I worked with that patient population, other health care providers would frequently say like, I don't know how you can stand working with "those people". And so I think because of that, there is an extra drive to not want to be associated with being a, "bad doctor." And so that makes us all want to separate ourselves like, okay, I am a good provider, doing the best to provide good care. And it makes me feel better to think of those doctors that have been criminally prosecuted as sort of bad doctors, because the fear is potent.

For those that are really in the know, it should provide some reassurance because one of the big concerns is, and you'll hear this, you talk to health care providers, like I'm worried about my license first, because the first thing they consider is, is their ability to practice. But the scariest thing, of course, is criminal investigation and prosecution. If it's not clear what the mens rea or guilty mind requirement is, and the behavior, the actus rea, right, the act that you have to perform to commit a crime, is one that could be lawful or unlawful, depending on the circumstances, it's really hard to know what the line is between lawful and unfulfilled conduct. Right? And so the fact that the court really focused on, no, this is a specific intent crime right, we need knowledge or intent to exceed your authorization to prescribe not in the usual course of professional practice. That should provide some real reassurance because it's a that's a far stretch from accidental, mistaken or even negligent decisions. Right? So it really should provide some reassurance that if you're out there and you're thinking about your patients, like a mistake is not going to end up under criminal scrutiny. You are actually protected.

Patricia Zettler: So are attorneys at health care institutions part of the audience you're talking to or, you know, how do you communicate that information? Because I imagine also, you know, health care practitioners perceptions of what they can and can't do are influenced by the policies of the institution in which they practice when they're at a larger institution. I don't know if you're comfortable sharing what you've been doing on that sort of communication front, but I'd be curious to hear more about that too.

Kelly Gillespie: We've got a short piece coming out in the Health Affairs Forefront, and that'll reach some people for sure. We would like to do more in terms of targeted explanations at health care providers. So, we have an article that'll come out in the Ohio State Journal of Criminal Law and some other some other things in the works. But I think that's important.

I mean, it's hard for lawyers. It is hard for practitioners to understand this because prescribing decisions that involve controlled substances, there's just so many legal remedies. So, one course of conduct, you can find yourself dealing with both state and federal administrative issues, state civil law issues, right, state criminal and federal criminal law issues. There's just so many possible legal consequences for providers for one course of conduct that it is hard to keep track of. And then you layer into that all of the policy pieces that many institutions have, prescribing policies and then health insurers and third party payers have their own set of rules and so-called hard and soft edits from the insurance companies. It's really hard for anybody to understand what is the law?

Patricia Zettler: I will encourage my students to listen to that part, that it's always really hard to understand, what is the law?

Kelly Gillespie: I like to say there are no secret laws, but sometimes I feel like in this there might be.

Hannah Miller: Something that I realized as I was reading a little bit more on this topic is for every doctor that a criminal charge is brought against them, there are plenty of doctors who surrender their certificate of registration because they're scared. It's almost like a plea deal for, for practitioners who have certificates of registration with the

DEA in order to prescribe opioids. When the DEA starts putting pressure on them or there's any hint that their actions are suspicious, they just surrender their certificate of registration, because, as you said, Kelly, they are first and foremost concerned about their license to practice. Do you have any sense of how common it is for certificates of registrations to just be like surrendered as opposed to practitioners who are criminally prosecuted and lose their license and certificates of registration that way?

Jenn Oliva: Yeah, you could actually come up with that exact number by looking on the DEA's website. They're very proud of their enforcement actions and they publicly disclosed what they've been doing. But I want to back up one more step because whereas I've never practiced medicine or served as a nurse, I was a military police officer for years. And I think that sometimes people don't understand what actually happens when the DEA shows up and it's criminal time. What happens is they show up with a U-Haul at your practice, blows the doors down, come in, rip patients out of patient rooms, isolate the doctor and start collecting up all the records and throwing them in the U-Haul. It's a terrifying experience. If you see this happen to a colleague, you won't forget it. Trust me. And then they get into the bargaining around the registration.

We're not on here to give legal advice to anybody. But I will say this, you're not obligated to give up your registration without administrative proceeding. You do not have to give that up in exchange for making deals and bargains with the DEA on site. It's always best to call an attorney and proceed with caution. Many times people will surrender the registration, in my understanding, and many practitioners have bolstered this understanding over the years, the DEA will frequently say this may not need to go any further, it may not need to go to indictment if you'll go ahead and relinquish voluntarily your registration right now. We may not pursue anything else. And you can always apply to get it back. And that's how some practitioners just feel like I just want to be cooperative and go ahead and do that. But you do have a right to an administrative hearing. And the DEA, it takes a lot of time and resources for them to actually do that work. So it's just another thing to think about.

Moreover, and I just want to emphasize that anybody who's been indicted will have at least had their registration suspended by the DEA, so they will not be holding an active registration while they're going through the criminal process. These criminal felony prosecutors that we're talking about do not revolve around the DEA's Administrative Licensure and Registration Authority. They have plenty of tools in their toolbox on that. They don't even need to go to the distribution, selling, distribution provision. Those are completely separate matters. So I hope that that's some somewhat helpful, but that's sort of what practitioners are facing down, boots on the ground, on the police side of things.

Kelly Gillespie: We have to remember, first of all, back to what I said earlier about there being myriad remedies. There are many, many ways that a prescriber that is viewed as careless to the point of being dangerous can be stopped from ever practicing medicine again, including prescribing controlled substances. So that's one thing. But the other thing is having your certificate of registration to prescribe, which is the federal permission that gives you a DEA number, that affects your ability to practice at all.

We forget often or don't understand how integral and intertwined the prescribing of controlled substances is to the everyday practice of medicine. So, if you're a family doctor, right, you're a surgeon, you're a palliative care doctor, I mean, you name it, almost anything, any particular practice you're going to find, you're going to have patients for whom a controlled substance is medically indicated. You can find niches, I guess, where you're working in cooperation with somebody who has to write the controlled substances prescribing for your patients, or maybe you just do like wellness physicals all day long. That's about the only example I can think of of medical practice where controlled substance prescribing isn't sort of part of the everyday practice of medicine. Right? We have to remember how perilous this can be because it's not just those doctors who for whom it's like 80% of their practice. It's, it's every doctor or advanced practice provider. And then the part with the sort of bargaining that also happens, like with the state medical boards, for example, where there may be just informal early agreements about what you prescribe or taking classes or things as a condition. So that happens too. But the vast, vast majority of health care providers are trying to do their best by their patients.

Hannah Miller: How will the decision in the Ruan case impact the DEA's federal enforcement powers or even tactics? Will it change the dynamic that currently exists between the DEA and state agencies, for instance, like the state medical boards?

Jenn Oliva: In a couple of ways, it might. None of this decision directly implicates the day-to-day scope of authority or duties of state medical boards. On the regulatory side of the DEA's authority, this opinion also does not affect that.

Right? They still maintain all of their ability to conduct regulatory investigations, suspend the license and have to follow that administrative process to suspend, revoke, authorize this kind of practice.

What may happen, and all we can do is speculate, we're going to watch this, a lot of these cases, at least in their inception, involve messy paperwork. The DEA is suspicious about something, for example, you're in pain management practice and you're prescribing a lot of opioids. That has just been targeted for obvious reasons in this crisis. Right? So, Dr. Ruan fell into that. Now the DEA goes and it starts poking around and they see less than desirable, adequate paperwork for certain patients when there's gaps in the medical records. Now they're becoming even more suspicious. Those kinds of failures of not documenting an examination of a patient in a given instance on your prescribing or something could be cause to bring this kind of distribution charge against the doctor previously. And it's still could going forward. But that kind of carelessness, the DEA now is going to at least have to think about. What's the circumstantial evidence here that suggests that the doctor wasn't just super busy or a little bit careless or a little bit negligent in checking boxes or filling out forms. They're going to have to show some kind of pattern or practice here or something with this individual patients' treatment plan that indicates intent, that indicates knowledge that they're outside the scope. So I do think that it will have some adjustments on how the DEA conducts these investigations. And again, I'm purely speculating because this is all new and I actually really love to hear Kelly's thoughts on that.

Kelly Gillespie: Yeah, I mean, I think that's right. It's always true, but it's particularly true whenever anything changes in drug policy. The devil's in the details and how it actually gets carried out. I do think it's going to give investigators, and then prosecutors making decisions, a little bit of pause in May in fact, think, oh, this this is going to be hard to show actual knowledge and the intent. It was very clear from the oral arguments in their briefing they were not interested in having the mens rea of knowledge or intent apply to these cases. And because they know that's harder for them to prove, it takes more, and so we'll have to see how it plays out on the ground.

I'm trying to think in oral argument the term they actually used. I think they called it the egotistical doctor because they had their sort of own, not completely stated, but categorizations of the kinds of doctors that they prosecute. And they describe this sort of egotistical doctor who cared too much for his or her own good and just thought they were trying to do right by their patients and maybe made some not great decisions. And they use that as an example of people they want to prosecute and who should be convicted and go to jail. And I think this ruling makes very clear that that's no longer a target. Life in prison is not the appropriate remedy for a doctor who might be a little misguided. This is a felony drug distribution charge. This is not the criminal penalty for not being wonderfully and perfectly careful at all times.

Patricia Zettler: Building off those reflections about the DEA is enforcement authorities, and Jenn, I really appreciated your perspective on what it's really like on the ground when law enforcement comes to a physician's office for a criminal case. You know, the Ruan case, of course, is about one specific statutory provision in the Federal Controlled Substances Act relating to DEA's enforcement authority. But there's been a lot of talk recently about other areas where health care may fear criminal enforcement, maybe most notably with respect to reproductive health care, now that the Supreme Court is overturning Roe v Wade and we see states moving to criminalize the provision of abortion care. So I'm wondering, recognizing that this case is about the federal Controlled Substances Act and how we interpret that statute, if you nevertheless see any parallels between this case and what health care practitioners in other fields may be facing?

Jenn Oliva: There's so many parallels, and I'm going to see maybe a little critical in my commentary, so I just want to go ahead and be completely honest with the audience. I don't think that I could be more pro-choice or more pro reproductive justice. But the first thing that is like parallel that I think is super important, that I already alluded to earlier, is the general public and a lot of policymakers egregious misunderstanding about the health care conditions that they're trying to manage or regulate, right. Opioid use disorder, we've brought up the etiology of that is extremely nuanced and complex. Experts aren't good at it, so we know for sure the public can't be too good at it and policymakers probably can't be too good at it, since the experts really struggle. This is also extremely true with chronic and persistent pain. This is a condition, especially when it presents in women or people who are racialized or minoritized, that is psychosomaticized. It's often viewed as a psychiatric disorder or condition. It takes a long time to get the treatment regime right. We're not good at it, guys. We're just not good at it.

And here I have to admit, I have been shocked because I hadn't thought about these cases this way. But most of the post-Dobbs debate has exposed that like drug use and these other things are talking about, a shockingly high

percentage of the American public do not realize how risky pregnancy often is for pregnant people, nor how often pregnancies are unsuccessful and result in miscarriages of births. It's estimated that about one in four pregnancies end up with these unfortunate and unintended results.

The debate always sort of centers around unwanted pregnancies and these other sort of moralizing things, which we also see again in drug policy. But there isn't nearly enough discussion about these wanted pregnancies that have complications and end up with these medical interventions. So the bottom line is that the first parallel is where a considerably high number of policymakers and judges do not understand the underlying health conditions at issue, whether it's chronic pain, opioid use disorder, pregnancy complications. We are likely in this country to enact no one policy and make judicial decisions that exacerbate rather than mitigate harm.

The second area for me that I just want to touch on real quick is near and dear to my heart, which is health data privacy and surveillance. I've made a fuss for years about how poorly protected health information is generally, and particularly stigmatizing health information is in the United States. I jumped up and down when the United States government, to the tune of hundreds of millions of dollars, funded these state surveillance programs, these AI-powered, you know, algorithm-driven state databases that collect up all controlled substance information because I saw danger down the road.

It's been years that people have been complaining. Really honestly since 2001 when the when the rule was enacted about HIPAA's holes when it comes to law enforcement investigations, right. To this day in the United States, hospitals drug test post-delivery patients and their newborns for illicit substances, often without consent, and immediately run down to the local police department or Child Protective Services, which instigate a cascade of really horrific things for those individuals. But my arguments have fallen on deaf ears. And my criticism, I guess here is that seems like the pendulum may have shifted all of a sudden, even when the Dobbs opinion was leaked, I was seeing all of this stuff up online: how to protect yourself, how to disable your period tracking apps, watch out for these HIPPA gaps, here's what hospitals are not allowed to do with your health data in clinics. So I was really emboldened by that. The federal government after US issues HIPPA guidance saying here's what hospitals have to do and here's what they can resist doing from law enforcement. Really strong statement from the federal government who doesn't go around very often, I don't think ever has before, issued guidance suggested like resist the law enforcement investigation to medical providers. I've never heard them say it before. I was thrilled to hear it. So my second observation is that there are some of these privacy concerns that involve the folks we're talking about that are implicated by these controlled substance prescribing cases, Patti, and reproductive rights surveillance. We have built up an infrastructure and a law and policy system that is not favorable to these folks. And that's a huge parallel.

I'm going to mention two other things just quickly, so I won't be remiss. The health equity and disparate impact issues are very similar. Not all of us will suffer the same. You know, folks who are relatively resource poor, again, racialized minoritized women and pregnant people will suffer obviously more than other folks. That's the same with these other conditions. And again, this is just yet another example of the criminalization of very intimate choices that often happen at the point of access to care for people who are marginalized and stigmatized.

Patricia Zettler: Thanks, Jenn. Kelly, do you have anything you want to add?

Kelly Gillespie: I think you see a lot of parallels where ever laws are carved out of what are really deeply entrenched moral, social, cultural issues. And when we try to settle those broader disputes by penalizing and even criminalizing practitioners and patients in need of care, the people that lose are always the patients most in need, and the patients who have the least means to actually get that appropriate care.

Criminalization of patients in need of care is state sanctioned stigma, state sanctioned discrimination. And that's definitely what we have had going on here in the context of reproductive health care. And whenever the law tries to regulate these particularly nuanced areas of care, and especially when it has to do with areas like sex and drug use and all of these issues, sort of the regulation of vice, not only is it always the patients that lose, but what we're doing is we're forcing practitioners into this horrible spot where they don't necessarily know the line between lawful and unlawful conduct, and they're being forced every day to choose between good and ethical patient care and self-preservation. And that is no place to put people, because then we're forcing them to choose to become martyrs just to do what they've been trained to do and to take good care of people. And it's a terrible place for the law to be. And it's deeply concerning.

People are already, again, throwing up the term unintended consequences of some of the state laws that are coming out in the aftermath of Dobbs. But none of these are unintended. The harm to the people most in need of help will come from these laws is certainly foreseeable, if not foreseen, and implicitly at least reflects a decision about who and what matters most. It comes down to reinforcing the power imbalances, and at a minimum, it's deeply unethical.

Hannah Miller: Do you think that Ruan tells us anything about how other drug policy questions might fare in this Supreme Court?

Kelly Gillespie: I think the answer is probably no. It doesn't tell us much. But I will say that drug policy is one of those unique areas where those who tend to view the world through a more liberal lens and those who have a more libertarian bent, the beliefs seem to converge there. And to the extent that that libertarian bent runs through some of the justices that are rightly or wrongly described as more conservative, I do think that there may be some potential for some outcomes that don't for their sort of drug exceptionalism, meaning treating things that involve drugs differently than any other context.

Jenn Oliva: Patti actually was totally right earlier when she was talking about this is a super narrow provision of an enormously complex and involved statutory scheme that intersects with any number of other agencies and all sorts of things. But I will say this, I went back and read the oral argument. I was actually quite shocked by the fact that the court never once suggested, well, isn't most openly prescribing suspicious? No one took that view. And this could be, look, we think that the court has a cell phone bias, maybe they have a doctor bias. There's all sorts of ways to explain this stuff. But they did take the absolute view, and Justice Alito adopts this and he waits to the bitter end to give it to me, but he adopts this at the end of his concurrence even, these provisions were not intended for anything beyond, you know, drug trafficking. And what we really think this agency is supposed to be going after drug cartels and serious drug distributors. They're basically giving doctors the benefit of the doubt here. And that line ran through the oral argument and is reflected in the opinion, although it's a little more obscure, because Alito is not happy about a bunch of other things before he gets there.

Maybe in some ways, in addition to this being cross boundary with libertarians and progressives issue drug policy, this also comports with delegation issues that this court has, anti-regulatory issues of this court has writ large in the executive branch. So there may be some connection there. If you just look at this term and what's been recently done in administrative law, I've been thinking about that even though this is a criminal case, I've been thinking about the connections there a lot.

Patricia Zettler: I had the exact same thought, Jenn, I was going to ask a similar question, which is I wonder if the right framing is not that the Supreme Court has a pro-physician bias, but rather has an anti-agency, or at least a healthy skepticism of agencies extending their statutory authority to reach things that may not be clearly within their statutory authority.

Jenn Oliva: Yeah, majorness and clearness not unknown to us. But I will say we'll use this for the rest of our lives when we talk to you and pretend like we anticipated this because we did go pretty hard core state's rights at the end of that brief. And I don't know if that helped or hurt, but we thought that might get a couple justices to see it from that perspective.

Hannah Miller: Well, thank you so much for your time today, Jenn and Kelly. It'll be interesting to see how things play out over the next few years as a result of the decision of Ruan v. United States. And Patty, thank you so much for co-hosting today's show.

Patricia Zettler: Thank you. And I want to reiterate, Kelly and Jenn, Hannah's thanks. It's just a delight to talk with you and learn from your expertise. And we really appreciate you taking the time.

Kelly Gillespie: Of course. Thank you.

Jenn Oliva: Thank you both so much.

Hannah Miller: Drugs on the docket is a production of the Moritz College of Law, Drug Enforcement and Policy Center. This episode is produced by me, Hannah Miller and Holly Griffin. Doug Berman is our editorial advisor. The music is composed by Joe DeWitt.