EMERGING TRENDS IN HEALTHCARE TECHNOLOGY:
DOSING DISCRIMINATION: REGULATING PMDP RISK SCORES

SPEAKER:
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[edited for reading]

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Casey Goggin: Next up, we have Professor Jennifer Oliva. Professor Oliva currently serves as an Associate Professor and the Director of the Center for Health and Pharmaceutical Law at Seton Hall University where she specializes in health law and policy, FDA law, drug policy, evidence, and complex litigation. Prior to teaching at Seton Hall, Ms. Oliva was an Associate Professor of Law and Public Health at West Virginia University, where she was selected as the College of Law's 2017-2018 Professor of the Year and the West Virginia Law Review's 2017-2018 Professor of the Year. She received her J.D. from Georgetown University Law Center where she graduated with honors and served as the Executive Notes & Comments Editor on The Georgetown Law Review. She earned her MBA from Oxford she was a Rhodes and Truman Scholar while also a cadet at the United States Military Academy. She has worked in the appellate and health/FDA practice groups at national firms and has served as the General Counsel and Vice President of a regional behavioral health care company. Please help me welcome Professor Oliva.

Jennifer Oliva: Thank you so much. Thanks for having me today and huge thanks to Professor Farringer and everybody at the Law Review at Belmont it's a true honor. I'm going to see if I can share my slides. Did that work out? Alright awesome.

I'm really appreciative of Professor Tschider's presentation earlier because I am going to do a really specific example of many of the broad-based problems that she pointed out with potential health care technology. She talked about diagnostic medicine and predictive algorithms, coercive treatment, and really importantly the knowledge gap that often exists between physicians, providers, healthcare clinicians and the software manufacturers who are developing this AI because of course those algorithms, the models, the platforms are often proprietary and clinicians have a lot less knowledge about what the proxies are, the data, the input data that's being used, and how the algorithms actually work and evolve, than the software manufacturer has on its end. So she really introduced for me, really helped me out with her wonderful talk earlier.

This paper is called "Dosing Discrimination." I am going to have that published soon, so I look forward to feedback. I'm going to stop early, I promise to take questions because I've got to get this in shape for the California Law Review which I'm working on right now. This is just my agenda for you guys for later when you look at the slides, we can go ahead and get moving. So the first thing I want to talk about is predictive algorithms and risk scoring that has been implemented in use in the United States in response to our drug

overdose crisis. Let's talk about the drug overdose crisis first and then frame this technology and its widespread introduction in the United States in response to the crisis.

So we have this drug crisis. It's frequently called, or has been called for years, "prescription overdose crisis." That was true in wave one, which we sort of trace back to 1999, started seeing an uptick in 1999. Unfortunately, and partially to blame the response, this is a shape-shifting problem that has evolved. We're now at least in phase three, some people say we moved into phase four. So you can see the prescription opioid overdose deaths going up, and then around 2010, we see a huge uptick in heroin overdose. And very quickly after that, just three years later, we see things shifting to synthetic opioids. In fact, today, synthetic opioids are responsible (and you'll see some slides on this) for the overwhelming majority of overdose deaths in United States. Why I alluded to this introduction of a wave four is we're seeing huge upticks, especially since COVID has started, in methamphetamine-related deaths, cocaine-related deaths, and many of those are also polysubstance deaths with other substances including benzodiazepines and other sedatives. So this is shifting quite rapidly and it's evolving and it's really moved away from prescription opioids, and one of the reasons why is because we have really cracked down on the availability of prescription opioids.

One other thing I wanted to show here: U.S. overdose deaths have been escalating. Our tactics right now, our responsive tactics, quite frankly have not been successful. From 1999 when we first identified this as a crisis, you see about almost 17,000 deaths and we're up to over 81,000 deaths in the last 12-month period. That's the worst 12-month period ever recorded in U.S. history for overdose deaths, and certainly COVID is a contributing factor. Again, as I've already told you, the CDC issued a "high alert "recently talking about how this is very much driven, 60, 70% of this is driven by illicit street fentanyl, not drugs that are prescribed or are obtained for medical reasons or even diverted drugs that are obtained that way. So it's becoming much more dangerous, much more concerning drugs, and a very illicit, deadly supply that is on the street in the United States right now.

I've already told you this but there's just some slides, again directly from the CDC, not my opinion. We're looking at a synthetic opioid and now a stimulant problem. So how does the US respond? Well the U.S.'s response to this overprescribing of opioids that we had starting around 1999, in response to under treatment of chronic pain conditions the United States, has been a lot of public health

rhetoric. We've heard a lot about, "Let's have harm reduction," "Let's do evidence-based reactions," "Let's get people in treatment," "This is a health care problem, it's not a criminal justice problem." However, the United States rely very heavily on law enforcement agencies to serve as "fixers" of the crisis instead of evidence-based public health professionals. As a result, law enforcement agency does one thing and one thing only with drugs: they try to control the supply. Right? They try to control the licit supply and they try to control the illicit supply. That's what the DEA's responsible for, that's their statutory mandate. So what the DEA has decided to do was heightened surveillance, and now it's very smart AI surveillance, on prescribers, dispensers like pharmacists, and patients who are being prescribed or using prescription opioids like Oxycontin.

You can see three techniques that have been used since 1999, and they get enhanced and more powerful every year and more widespread. I'm going to focus on number 3, but we have prescribing guidelines where physicians are supposed to be really careful about how many milligrams they're prescribing, the dose amount, really evaluating patients. Number 2, opioid treatment contracts. Professor Tschider talked about form and consent, all these kinds of things. Opioid patients, whether they have substance use disorder or chronic pain conditions, have to sign contracts where they agree to all sorts of types of surveillance, up to and including having private investigators check on them, coming in for random pill counts so they can't go out of town, coming in for drug tests and things like that. I'm not going to talk about that today but that's part of this. And then number 3, prescription drug monitoring programs. These are state laws, there's been an explosion in them that I'm going to talk to you about. And these are databases, smart databases driven by AI, that assess patients and prescribers in the area of controlled substances and determine how much at-risk they are for substance use disorder and flag those patients so that they're not prescribed certain drugs by prescribers.

So what's happened over time here, again with opioids, this response I just told you about has been very successful in de-prescribing. We have much less prescribing now, as you can see in 2019 here, we're below where were in 2005. The CDC concedes that opioid prescribing is down 60% since 2012, so over the last eight years. So opioid prescribing is way down in the United States. It's down in any of the metrics (I just add this slide for people who like to get into the weeds): days per person, pills per person, scripts, overall total dosage – every single one of these metrics is way down from peak prescribing.

So, let's talk about persistent pain. Persistent pain is the number one reason why, it's the number one disability in the United States. 50-100 million people, depending on how you define the term "persistent pain," which is somewhat amorphous and hard to capture. It's the number one reason why people seek treatment, and I would say why everyone should be concerned about this kind of surveillance and be in-the-know about it is because we will all have some kind of pain in life if we live long enough to be privileged to experience it. And most of us will have some sort of disability or healthcare condition as we age. It's just a process of aging, it's something that all of us will face at some point. Pain has a long history in the United States, and I have pages and pages on this in my paper but I won't bore you with it, but a long history in this country of underassessment and under treatment. Some folks like Professor Dan Goldberg who studies pain and the history of pain suggests that this comes from the sort of "Cartesian-dualism" of medicine is an objective science, pain is hard to see, objectively verify and test. So that mind-body divide creates problems for clinicians, it's much more challenging than something they can physically see and evaluate. Pain patients have been viewed as difficult to treat, we have a poor understanding of the causes of various different pain conditions. They've been viewed as malingerers and untrustworthy in the literature.

There's also sexism and racism that sort of goes through this history, which I detail in the paper. Women are often viewed as psychosomatic and hysterical. Women's pain–and this has been evaluated by any number of scientists that are way smarter than me–women's pain is usually viewed very differently than men's pain. Doctors think that when men say that they're in pain, they wouldn't come to the doctor or seek treatment or give themselves a 10/10 unless it was serious, but that women over-evaluate or over-assess or overreact to pain. Also, on racism, this dates back to slave-breeding concepts that unfortunately have persisted over time, that African Americans have a higher pain tolerance because of their physical superiority (these are all myths and not true), and therefore they do not need to be prescribed pain the same as other populations. In response to some of these things of course, it's a little bit disturbing. You'll see I have this New York Times piece here written by these two white men.[1] A lot of people have made an argument that African Americans were spared opioid use disorder because they were prescribed fewer prescriptions. So, this is widely

[1] Austin Frakt & Toni Monkovic, *A 'Rare Case Where Racial Biases Protected' African Americans*, N.Y. Times, Nov. 25, 2019, https://www.nytimes.com/2019/11/25/upshot/opioid-epidemic-blacks.html.

acknowledged that Black people's pain was undertreated comparatively. And then this is the spin on it now and I take huge issue with that in my paper, as I'm sure you can imagine.

This is one of my favorites, John Oliver, I don't know if anybody ever follows him, but he does a lot of health law stuff, so I'm able to entertain the students a bit with some of his commentary, and he did a piece in August of 2019 on bias and healthcare. And this is Wanda Sykes in the frame with him, who is a Black comedian, and she does a bit that he plays on the show here at the twelve-minute mark where she talks about having to have a prophylactic double mastectomy. And she said at the end of the surgery, she was prescribed Ibuprofen, and she goes on to make a joke, which is grounded in truth, about how because she was a Black woman, she didn't receive any serious pain medication because of these myths that exist even though at the time she had her surgery, a very painful surgery and recovery, opioids were widely prescribed to other populations. There's been all sorts of other articles about this, I'm just desperately backing myself up here with these pictures.

So, the real question is, did persistent pain patients during this sort of transition and this phase I'm talking to you about, were they at high risk for opioid use disorder overdose deaths? And really, honestly, it's exceedingly low in this population, and that makes sense because these folks have been taking the drug for a very long period of time. Studies range from 1%-8% of people with persistent pain who are legacy patients who have been taking opioids for a long time ever developed problematic opioid use disorder. It's a very low percentage. The majority of the people who developed opioid use disorder as a result of overprescribing, received those drugs outside of the medical context – they were diverted to them – and they used the drugs recreationally, not to treat a pain or other medical condition.

I say that all to say, what about these prescription drug monitoring programs, which is my AI tool here. Law enforcement developed these prescription drug monitoring programs a long time ago and their most basic form at the turn of the 20th century, New York had the first one, followed by California. Well, what happened is, you would get a highly controlled substance, a Schedule II substance like an opioid, the doctor would fill out a form and give you a prescription in triple kick carbon. The doctor would keep one, the patient would take two to the pharmacist, the pharmacist would turn in one of the slips to the state health agency so that they could control where the opiates were going and watch out for diversion.

That was the basic gist and that was what was collected, just Schedule II drugs, and it was a carbon-based paper system.

By 1999 we had 17 states that used this system, they were pretty minor in their scope and context. Today in the United States in 2020, 49 states and the District of Columbia have these systems. They collect all schedules of drugs, II through V. Many of them also collect a lot of other drugs that aren't even controlled substances or scheduled, they're called "drugs of concern." If you've had a cat or dog spayed in the United States in the last ten years, you are in the prescription drug monitoring program because those animals are prescribed a very small dose of an opioid after that surgery. They collect all sorts of other information in addition and it's a smart database. They go and pull information from people's criminal history, court records, sexual trauma history, their general medical records, etc. And every year, whatever these PMDPs are collecting are enhanced more and more and more.

They've now layered on over the last several years algorithmic functions, and what these algorithms do is that they go in and mine through all these troves of data that apply to the patient and the prescriber. To the patient, see over here, they give three scores: a narcotic risk score (you're at risk for narcotic use disorder), sedative risk score, stimulant risk score, and it's not on this slide but it's on my next one, over here you see that 650–that's your overall NARX score. So that shows whether you're at risk. These particular slides don't show it but once you hit a certain score a bunch of red flags come up. They also, by the way, do a prescriber report, that says if a prescriber is running afoul of how the algorithms view risk. So, what kinds of things are in the criteria? The number of providers you see, the number of pharmacies, the amount and strength of your medication, you can see this. And then some very odd things that I spend a lot of time critiquing from a data science perspective in my paper: the distance you have to travel to your provider, the method that you pay, sexual abuse and trauma history, and criminal history. There's the prescriber report card, just so people have it.

So, the question is, "Are PDMPs effective?" And I'm going to go right back to that criteria here in a minute. They've been great at reducing prescribing behavior, I've already showed you that. We've had a huge reduction in opioid prescribing. But they also do three other things that have been well documented. They change prescriber behavior. Prescribers are very reticent to take on complicated pain patients right now or even treat people with substance use disorder. The treatment for people with substance use disorder are opioid agonists like buprenorphine and methadone, and

those also are Schedule II controlled substances that are opioids, so that's monitored by the prescription drug monitoring program. It creates problems for both populations. They've forced rapid taper for people so that their prescribing numbers go down, so that they don't trigger concern in the system and DEA surveillance, and they've abandoned patients and said I'm no longer going to continue to treat you.

Opioid withdrawal is extremely painful, resource intensive, and can be deadly. It causes change in patient behavior, bullet number three. Patients then go and look for a new prescriber/dispenser, that makes their risk score go up, they avoid healthcare delivery system, and the worst thing is they switch to more dangerous illicit substances. The cost of somebody in the United States switching from a prescription drug to heroin is astronomical. Injection drug use has all sorts of comorbid conditions associated with it like hepatitis, bloodborne diseases, HIV, and we're seeing upticks in that compared to taking a safe, prescription drug. Safe insofar as it's been approved by the FDA and we actually know what's in it. And dispensers have refused to fill. So, we have a huge reduction in prescribing, but we have a lot of other bad things going on. We have the highest rate ever of overdose deaths, we have a lot of switching to much, much more dangerous substances that are easier to get and cheaper and are really available on the street, and we have a lot of people who have been forced into withdrawal, depression, suicidal ideation, and are suffering and no longer able to function. So, we have a tough situation.

Don't take my word for it folks, here's a 2021 Journal of Health Economics paper where these economists, who are much smarter than me, again, went in and looked at the unintended consequences of this prescription drug monitoring.[2] And they basically say that any decrease in prescription opioid deaths (only 17% of the deaths in 2020 involved prescription opioids and the majority of those, by the way, involved another substance), they're completely offset by a large increase in illegal deaths around heroin and fentanyl.

So here are my NARX score concerns. These are secret proprietary algorithms. The company that makes NARX scores called Appriss, it's a private company, it sells this platform to the states, the states use them and then they mandate that prescribers use them. So, clinicians make clinical treatment decisions about patients

[2] Bokyung Kim, *Must-Access Prescription Drug Monitoring Programs and the Opioid Overdose Epidemic: The Unintended Consequences*, 75 J. Health Econ. 102408 (2021).

based on these secret algorithms that we don't know a lot of things about. They've never been externally validated or subjected to any kind of regulation. They're completely unregulated, so we have no idea how good or bad they are. I'm actually going to tell you they're really bad in a minute, of course, based on the little bit that we do know. They purport to measure, objectively measure something, which is a patient's risk of drug misuse, overdose, but we're bad at measuring that as experts. Experts in the field are bad at predicting who's going to develop substance use disorder. It makes you ask a question: what does Appriss know that the experts in the field do not know right now? Folks in this area of expertise are very upfront about this. They concede that it's very difficult to make a risk projection around this. Certain of the criteria are automatically going to disparately impact certain groups.

Let's just go back to that criteria again, I want to spend a little bit of time on this and then take questions. Method of payment– if you pay by cash, if you have to pay by cash for your prescription, your NARX score goes way up just based on that criteria. Well, who does that impact? That impacts people who are underinsured, or uninsured because they have to pay for their prescriptions if their insurer isn't covering it or they don't have one. So we're automatically now discriminating against people who are poor and don't have robust insurance that covers this kind of treatment. Moreover, as opioids have become more stigmatized and we had the overprescribing problem, many more private providers have a lot of obstacles to covering, prior authorizations, covering these kinds of prescriptions. So, looking at method of payment and escalating someone's risk score based on that is very questionable about which groups you're targeting and why that's an appropriate proxy for risk. And like I said, Professor Tschider told you, the information that goes out–if it's garbage in, it's garbage out. So, if we're using bad proxies to assess risk, we're not doing a good job measuring it on the back end.

Distance traveled–there's some states, there's nine states in fact, Wyoming is one of them, that don't have a single methadone program for people with substance use disorder in the entire state. Why do I say that? People in Wyoming, through no fault of their own, have to leave their home state to get the drug, can only be prescribed at these facilities. So they're going to be penalized because their state doesn't have a single prescriber in-state that even does this work. That's certainly not their fault. The view is, the more you're traveling away from your home, it's surreptitious behavior and you're drug-seeking, but lots of people who live rural, and lots of people who live in these states that I'm talking about, are forced

to do this through no fault of their own. Moreover, you can imagine the compound problem we have here as more and more people want to get out of this business. It's risky, I've got law enforcement after me. The state professional licensing boards are looking at these risk scores, I don't want to treat as many patients if it challenges my livelihood as a physician or a provider. Less and less people want to do this which means that more and more people, even suburban people, have to travel further and further away from home to fins a provider that will actually provide this service. So that's a very arbitrary factor to have in there, distance traveled, and raise risk scores.

Sexual trauma and criminal history – this is very well documented in the literature, it's not my opinion. If you're going to include sexual trauma, again, if you have a history of sexual trauma, that automatically raises your risk score notwithstanding anything else. This is going to disparately impact women patients because women are more likely to report a history of sexual trauma than men are because of the stigma and all sorts of gender and sex stereotypes that go along with that. But women are much more willing to go and seek treatment for that and are much more willing to report it. So, again, seeing elevated risk scores for this kind of stuff. Criminal history–this is well documented again, this is really going to affect minorities. On every single criteria in the criminal justice system stops, arrests, incarceration, charges, people of color are way more likely than their white counterparts to have encounters in the criminal justice system even when those groups are controlled for drug use. Meaning they use a drug at the exact same amount, you're still going to see a great disparity there. So, we know that just the addition of criminal history is, again, going to double down on certain people who, again, are already under evaluated and under treated for pain. We can see this happen to women, poor people, people who live rural, people who are underinsured, people with chronic disabilities, people of color–doubling down on disparately impacting already vulnerable groups that already were under treated in the system through this long history that I described earlier.

Again, I've already said this, but I just really want to emphasize that patients are punished under these criteria for things that are completely out of their control. Even on the multiple prescribers, if your doctor simply retires, let's just make it really benign: Your doctor retires, goes to Florida, "I'm done, I'm gone." You have to find a second provider. Your risk score goes up through no fault of your own. If you have a job, if you're in the military and you move around a lot, and you have to get different providers as you move around–your risk score goes up automatically simply

because you're serving your country and you have a job that requires a lot of movement. This can get less benign when providers automatically stop treating people and they're forced to switch pharmacists and providers, again through no fault of their own, but because people are getting out of the business. But it's an important thing to understand that these risk scores are questionable and discriminatory on their face based on the other data that we know, and that the system is creating even more discrimination by incentivizing people to stop serving these patients and to deprescribe, which PDMPs are excellent at, as I've already shown you. I've told you all this stuff, I got ahead of myself.

My argument in my paper is that these NARX scores are aggravating an already atrocious situation. Here is another health economist who tried to model the Appriss model, she recreated it, and here's what she says, and I'll end on this note. The proxies that they use basically are uncorrelated with the risks that are generates. They're not helpful, they don't work, they don't produce a valid proxy for patients. And this is the only study that I know of, and it's very recent, that tries to recreate the model and the algorithms to see if they are actually accurate at producing risk. My argument in the paper is that the FDA has the authority under the Software as a Medical Device regulatory authority to regulate these things, and the FDA actually concedes that this is true in a new regulatory document. My argument is that if the FDA subjected this risk scoring platform to its robust regulatory criteria, which I've laid out here for you, the PDMPs would fail on all three of these criteria and the FDA would be required to pull it from the market. That's the paper in a nutshell and I'd be happy to take questions. Thank you so much for having me today.

Casey Goggin: Alright, so it looks like we've got a couple of questions in the chat box. We have one question, it says, "I had trouble getting opioids recently for kidney stones for twenty-four hours until I could actually go in and see a physician despite having been a patient for years and having needed surgery for a stone. It was a long period of really intense pain. Should it really be that hard to get opioid medication? Are some practices overreacting?"

Jennifer Oliva: Yeah, I mean they're overreacting because it's been forced. You have to make a decision because the DEA can immediately suspend your license and begin an investigation that affects you, your family, your livelihood, your professional reputation. You're always going to make the decision to undertreat because there is much less chance that–you're going to say I followed the guidelines, the flag popped up, I followed the

algorithm. That's what the clinician is going to say. I really appreciate this question. I have a lot of people who have contacted me who have said something exactly like this. I'm not a doctor, kidney stones are egregiously painful, bottom line, period. Kidney stones are also a side-effect of a lot of chronic pain diseases like Crohn's disease. These folks go into an emergency room and they're just left to sit there and writhe in pain because, again, these PDMPs. So I agree with that. I have had examples with children with stage four cancer and in a practice the physician not wanting to give pain medication to a small child with an egregiously painful condition because it would affect their report for law enforcement or the DEA. I cannot emphasize enough that this is the only algorithm, platform, in the history of medicine that has ever been used by clinicians that was developed for and by law enforcement for criminal surveillance and has never been validated or evaluated by medical experts.

Casey Goggin: Great, thank you. I also asked a question earlier, because you said the algorithm is secret, proprietary data, and I assume they'd be considered PHI, and Charlotte chimed in and kind of helped me with my question. Would you be able to give us a sense of whether the data would be able to be disclosed under the statutory scheme? Would I be able to get my own score, personally?

Jennifer Oliva: I'm going to try to answer this quickly, but that is a really good question. I have a paper on this called "Prescription Drug Policing" in the Duke Law Journal[3] and would be happy to send you a link. Many of the states allow law enforcement willy-nilly to just log in to these systems and just get your individual information. They collect your name, address, whoever picks up the record for you, gender, sex. And then imagine this: all of this other history is in there. In North Carolina, I'll just give you an example, the police, when they pull you over, can pull up your PDMP if they pull you over for a traffic stop.

Now, let's go to the opposite. In some states, more than half the states, they have automatic access and then it ramps up to the highest level, which is you've got to get a warrant. But the states that have a warrant protection, which the doctors asked for, have lost case after case in the courts. The DEA has issued an administrative subpoena and asked for this information in an investigation. Utah, Colorado, New Hampshire – these states have fought the DEA in court and they lost, saying you need to get a warrant and have probable cause and the DEA has persistently won under Section 876

[3] Jennifer D. Oliva, *Prescription-Drug Policing: The Right To Health Information Privacy Pre- and Post-Carpenter*, 69 Duke L.J. 775-853 (2020).

power under the Controlled Substance Act[4] because it has the right to regulate controlled substances and has worked and end-round around the warrant requirement. I would say to you that is super concerning that the police can go in and get this stuff, even on a routine traffic stop in many jurisdictions. The jurisdictions that have stronger protections, they've been undermined by this federal law. And number three, many states actually do not allow patients to access their PDMPs, some do, and so when you think about the rampant-ness of medical errors, simply in medical records – can you imagine never being able to see your own record and make corrections? Because we have to assume that any number of those records are incorrect because medical records are riddled with mistakes.

Casey Goggin: Thank you. We have one more question but unfortunately we're out of time, so I will send this to you personally if that's alright with you. I think it's a really great question, it's about studies on the effects of improving treatments. But we will have to keep going. Thank you for your time and that excellent presentation, I would love to read that paper.

Jennifer Oliva: I'll send it to you! Thank you.

Casey Goggin: Thank you.

[4] 21 U.S.C. § 801 *et seq*.