The Legality of Abortion Pills

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[00:00:00] Jeffrey Rosen: Judges in Texas and Washington State have handed down dueling decisions on the legality of mailing the abortion pill, mifepristone, which is used in over 50% of abortions in the United States. In Texas, a district judge has invalidated the Food and Drug Administration's approval of mifepristone for mailing. While in Washington, a district judge ordered the FDA to make no changes to the availability of mifepristone in 17 states. Together, the two cases create a legal clash for the FDA, which means the cases may go to the Supreme Court.

[00:00:36] Jeffrey Rosen: Hello, friends. I'm Jeffrey Rosen, President and CEO of the National Constitution Center, and welcome to *We The People*, a weekly show of constitutional debate. The National Constitution Center is a nonpartisan, nonprofit chartered by Congress to increase awareness and understanding of the Constitution among the American people. In today's episode of *We the People*, we'll break down the Texas and Washington decisions on abortion pills.

[00:00:59] Jeffrey Rosen: We'll ask, first if mailing mifepristone violates the Comstock Act, second, if the FDA's approval of the drug violated the Administrative Procedure Act, and third, if the courts had jurisdiction to rule on these cases in the first place. Joining us to help understand the legal stakes of these important cases are two leading scholars of abortion law. Thomas Jipping is Senior Legal Fellow for the Edwin Meese III Center for Legal and Judicial Studies at the Heritage Foundation. He co-authored a report for the Heritage Foundation arguing that the federal law bars mailing abortion drugs. Tom, welcome to *We The People*.

[00:01:35] Thomas Jipping: Thanks, Jeff. Great to be here.

[00:01:38] Jeffrey Rosen: And Rachel Rebouche is Dean of Temple University, Beasley School of Law. She's written articles about mifepristone regulation and slate, the Columbia Law Review, and has a forthcoming article in the *Stanford Law Review* about abortion pills. Rachel, it's wonderful to welcome you to We The People.

[00:01:55] Rachel Rebouche: Thank you. Thanks for inviting me on.

[00:01:57] Jeffrey Rosen: Let's begin with the, the facts of these complicated cases. Tom, tell us about the 2016 FDA regulations that at the moment are enjoined by the Texas Court of Appeals. What are those regulations and what do they do?

[00:02:15] Thomas Jipping: Well, I'd, I'd like to start a little bit before that because the FDA approved mifepristone in 2000, uh, but they did so under a very, um, specific process that itself imposed safety restrictions. From the very beginning, the FDA's actions have always reflected the need for extra safety precautions. That initial approval was challenged two years later, the law allows citizens to file petitions asking the FDA to change what it's done. And the law requires the FDA to respond within 180 days. For whatever reason, the FDA didn't respond for 14 years.

[00:03:01] Thomas Jipping: So that brings us to 2016, where the FDA then denied the 2002 petition and at the same time dropped a number of safety precautions that, uh, had been in place all along. And those included extending the use of mifepristone from 7 to 10 weeks decreasing the number of in-person doctor's office visits from three to one, allowing non-doctors to prescribe or ad- or to dispense or administer mifepristone and dropping the requirement that physicians report nonfatal medical complications.

[00:03:45] Thomas Jipping: Each of theseI think three of those four, uh, actions or decisions, um, really factored into, uh, the later litigation and even the Fifth Circuit's decision. So the March 16 action was to drop a number of the safety precautions, uh, that had been in place since 2000.

[00:04:10] Jeffrey Rosen: Rachel, how would you describe, uh, the significance of the 2016 changes, which are the ones that are at the moment, uh, enjoined? And what facts should listeners understand about what their legal significance is?

[00:04:24] Rachel Rebouche: Thank you. So I, I think that the 2016 changes reflected a deep consensus about the safety of mifepristone and its appropriate use. So take, for example, extending from 7 weeks to 10 weeks, providers were commonly prescribing mifepristone off label beyond 7 weeks because it's safe and effective to do so. It's, it's similar to currently providers, um, with a gestational limit of 10 weeks prescribed through 12 weeks for the same reasons and the ability to prescribe off label is not new, it's not specific to mifepristone.

[00:05:04] Rachel Rebouche: And it reflects the providers and the medical community's judgment that, um, about the safe use of a drug. I'd add that another change that's, that's been an issue in this litigation happened in 2021. So, the 2016 changes were, were significant for the uptake of mifepristone as part of a medication abortion and I guess I'd clarify for listeners that medication abortion is a two-drug regimen. Mifepristone is the first drug that one takes first and then misoprostol is the second drug, a set of pills people take 24 to 48 hours later.

[00:05:44] Rachel Rebouche: And it's only mifepristone that's regulated as Tom said through and, through the FDA process. Misoprostol is not subject to the same, uh, regulations. You know, I think it's also, uh, an important change that has also impacted and influenced the use of medication abortion happened in 2021. I suspect we'll dig into this in a little bit more detail, but that was the FDA decision to lift another restriction, which required patients to pick up the pills at a healthcare facility.

[00:06:24] Rachel Rebouche: Lifting that restriction after a court case, uh, there had been a previous, uh, investigational drug study. The FDA have used its enforcement discretion to suspend the rule during the pandemic, uh, to reduce provider patient contact. That decision in the same vein of the 2016 amendments to mifepristone's regulation allowed providers to mail medication abortion for the first time on a broad scale. And, uh, the FDA also announced that it would allow certified pharmacies to dispense medication abortion. So that, that's also another change that's been significant and is at the heart of the litigation we're seeing out of Texas.

[00:07:08] Jeffrey Rosen: Thanks to you both for clarifying that the changes that are at issue involve both the authority to mail mifepristone and the conditions for dispensing it. Alright, let's now jump into the substance of the legal challenges to these changes. They involve, first, a statutory claim that mailing abortion pills violates the Comstock Act. Second, there's a claim that the Food and Drug Administration acted arbitrarily in proving the change. And, and then third, there are question invo- involving standing.

[00:07:40] Jeffrey Rosen: Let's begin with the, the heart of the matter, which is the claim that, uh, mailing abortion drugs violates the Comstock Act, which forbids mailing every article or thing designed, adapted, or intended for producing abortion. Tom, you've been a central voice in arguing that the Comstock Act violates mailing abortion pills. Tell us why.

[00:08:03] Thomas Jipping: Well, you just read it. Um, the, the plain text of the statute, uh, clearly includes the abortion drugs that we're talking about today. That's why the FDA approved them for that purpose. I don't know anybody who would argue that mifepristone is not designed intended for producing abortion. Of course, it is. The fact that it's a 19th century statute means that critics will call it arcane suggesting that somehow old statutes don't have to be followed or the fact that it hasn't been enforced for many, many years.

[00:08:44] Thomas Jipping: Also, the suggestion is, well, if we haven't enforced it in the past, we shouldn't enforce it now. But the legal question, and everyone can read the statute for themselves, it's 18 USC Section 1621. And everyone should read it for themselves because ... And I worked on the United States Senate for 15 years. This is one of the clearest statutes that I've ever seen and it prohibits mailing abortion drugs. That's significant because, uh, as Rachel described, um, the April 2021 changes from the FDA allowed the dispensing by mail and through mail order pharmacies.

[00:09:24] Thomas Jipping: And that, that's where the conflict with the c- uh, Comstock Act comes in. The Department of Justice issued in opinion through the Office of Legal Counsel a few months back creating a fictional like version of the Comstock Act that requires what it doesn't require, and everyone can read that on its face. I think that was an attempt to try to spin the Comstock Act away from being an obstacle to expanded abortion access, but, uh, the statutes clear. It prohibits mailing abortion drugs and therefore it's a significant part of the legal regime that, that we're working with today.

[00:10:06] Jeffrey Rosen: Rachelas Tom said, the Office of Legal Counsel has issued an opinion arguing that it's not a violation of the Comstock Act to mail mifepristone. It cited decisions dating back to the one packet decision from 1936 by Judge Augustus Hand, and many,

decisions after *Roe* and *Casey*, which held that there was not a violation of the Comstock Act to, mail abortion pills. Tell us about the Justice Department's argument and whether or not you think it's correct.

[00:10:38] Rachel Rebouche: Thank you. So I, I think I might disagree with Tom [laughs] about the applicability of the Comstock Act, just totally fine. People could disagree. Because I actually am persuaded by the Office of Legal Counsel's argument interpreting the cases and reading the cases that interpreted the Comstock Act in the '30s. At a time before *Roe* and *Casey*, it's clear that courts read the act with an eye toward understanding its applicability and the breadth of how it applies.

[00:11:11] Rachel Rebouche: Um, there are lots of laws that are very clear, uh, texturally clear about what they provide. And yet courts interpret them, uh, to make sense for what their application would mean, uh, per the, the, the, the intent of Congress. So one thing that came out of those decisions was a narrow reading of Comstock Act b- to apply to the intent to procure illegal abortions, unlawful abortions. Because if the Comstock Act applied, uh, just as read literally by its text, it would prohibit all, uh, almost everything that's used in an abortion from being mailed.

[00:11:50] Rachel Rebouche: I agree with Tom, it certainly would apply to medication abortion, it certainly would apply to mifepristone. But it could also apply to forceps, it could apply to a surgical gear, although their surgical abortions are a very small percentage of abortions in this country to the devices using an aspiration abortion. So, I think the intent of courts and interpreting the Comstock Act was to say there's got to be some line drawing here. And where we should draw the line is people who are seeking to procure illegal abortions or unlawful abortions.

[00:12:27] Rachel Rebouche: And I think that the Office of Legal Counsel makes the argument that it would be very hard to determine when the purpose of mailing medication abortion is to procure an illegal or unlawful abortion. Not impossible, of course, but that that is something that intent driven test is something that in most cases, will be hard to prove because there are lots of lawful reasons to mail medication abortion. Indeed, in the '30s, mailing abortion instruments or articles had a lawful purpose if it was an abortion to save the life of the pregnant person.

[00:13:06] Rachel Rebouche: And so that is the, that is some the genesis of the thinking around the Office of Legal Counsel's opinion. And now I think it is an issue that is clearly teed up by the, uh, district court and Fifth Circuit for further review.

[00:13:22] Jeffrey Rosen: Tom, what is your response to the argument that the purpose and legislative history of the act, as construed by judges like Judge Hand in one packet suggests that physicians do have the right to prescribe contraception for the health of their patients, as Judge Hand said, and Judge Hand held that the design of the act was not to prevent the importation carriage or mail of things which might be implied by conscientious physicians for the purpose of saving lives or promoting the wellbeing of their patients. And he also invoked an exception in the original version of the Comstock law which would have accepted physicians. What's your argument about all this?

[00:14:03] Thomas Jipping: Well, Judge Hand was talking about a statute that doesn't exist, in the Comstock Act, the first section of it when it was enacted referred to unlawful abortion. And the second one, which is what we're talking about, did not. I'm Rachel would agree that it's a standard principle for interpreting statutes that if you have two sections of a statute, one that uses a term like that and the other that doesn't, that indicates that Congress did not intend that limitation to exist in that second provision.

[00:14:36] Thomas Jipping: Congress repeatedly revisited the Comstock Act and never inserted this unlawful intent requirement in it and end on a few occasions when amendments were offered in to insert that intent requirement, Congress did not choose to do so. And, again, read the Comstock Act. It's about things. It's about articles. It's not about senders. It's not about recipients. Those words don't even appear in the Comstock Act.

[00:15:10] Thomas Jipping: The Postal Service which was the, the entity that asked the Office of Legal Counsel for its advice and then that produced this opinion, the Postal Service, go to their website. They have always had regulations about things that may not be put into the mail because of the nature of what those things are. That's been the case throughout the entire history of the Postal Service. And that's exactly the kind of statute that the Comstock Act is.

Thomas Jipping: I, I would disagree with Rachel that those appeals court decisions that were cited in the OLC opinion, uh, clearly interpret the Comstock Act the way she suggests in the Fifth Circuit. And the district court disagreed with that. I don't think that's a fair reading of those cases. But the bottom line is, um, courts are supposed to interpret congressional statutes starting with the text of the statute and, and figure out what Congress intended by what Congress enacted. Congress said what they meant and they meant that you can mail abortion drugs.

[00:16:19] Jeffrey Rosen: Rachael, Tom is arguing that there's a strong textualist argument for the enforcement of the Comstock Act. Tell us more about the history of that act. This, of course, was a broad 19th century law that prohibited the mailing of obscene materials and it was part of a campaign against, uh, contraception, pornography and, and abortion. It hasn't been enforced for much of the 19th century, and especially post *Roe*, it was not enforced. What relevance is this history in the construction of its meaning? And do you believe that the textualist justices on the Supreme Court would accept Tom's reading or not?

[00:16:58] Rachel Rebouche: So, I think the history, as you say, of the Comstock Act is as an anti-vice act that was passed on a wave of popular support for, uh, federal intervention in policing and enforcing actions against vices - contraceptives, abortion, lewd, lascivious material. And, I think the Comstock Act was enforced. I think Tom's has much more background in the history of the Comstock Act, but my reading about its enforcement was that it was enforced for about 40 years after its passage.

[00:17:33] Rachel Rebouche: But then really, after the 1930s the federal government did not enforce the Comstock Act in terms of articles and, and whatnot shift. And I just clarify that the example I gave, the breadth of the Comstock Act applying, the examples are things that are used in, you know, everyday abortion care that aren't necessarily medication abortion, but are used in

clinical care, generally those articles and things. And so the, the federal government stopped enforcing the Comstock Act and after these, uh, these 1930s opinion.

[00:18:11] Rachel Rebouche: And then, of course, it- it's not surprising that there wasn't much attention paid to the Comstock Act after *Roe* v. *Wade* was decided and there was a constitutional floor for abortion rights for *Dobbs* last June. So, I think that even a textualist judge, and I think all judges would say they, they pay attention to a statutes text and they start with a text interpreted, still have to rely on congressional intent the applicability of the text, particularly when dealing with a statute that has been in disuse, that has not been applied, and that is 150 years old.

[00:18:50] Rachel Rebouche: And so that, that even reading the text on its face requires interpreting the law applying it and understanding what was the intent in passing the law. And I think that that is a persuasive argument for why Congress intended at a time when passing it to apply to unlawful abortions. At the time, almost all abortion was unlawful though it's, I think there's also some contestation about the history of those prohibitions and the timing and pregnancy at which they applied.

[00:19:29] Rachel Rebouche: But that is not the world we live in now. We have a much more complicated legal landscape after *Dobbs*. And any court would have to read this law using textualist analysis and understand, uh, what is its applicability in 2023. And courts could disagree. I mean, absolutely…We're going to see disagreement. [laughs] Going to see courts who disagree with the Fifth Circuit's interpretation just as we see disagreement between, uh, you know, Judge Kacsmaryk and the OLC.

[00:20:01] Jeffrey Rosen: There will indeed be disagreement and you're both laying it out quite well. Tom, as I mentioned, you've been one of the leading proponents of this textualist reading of the Comstock Act. Tell us about when it was first pressed, how after Dobbs came down, you thought it was relevant, and whether or not you think of the textualist justices on the court will, will be persuaded by it or not.

[00:20:21] Thomas Jipping: Welll, it was passed in 1873. And, I think as you alluded to, Jeff, it covers both things that can be put to immoral use, that's some of the language in it. And there's two categories. One is literature, written material and there's a whole bunch of adjectives, lewd, lascivious, and all of that. And then there's this clear statement, any article or thing that can be that is designed, intended, or adapted to produce abortion, its enforcement over the next 40 years.

[00:20:57] Thomas Jipping: And it's named after Anthony Comstock, who was a well-known anti-vice crusader. He actually was appointed a special agent of the Postal Service to enforce this law, which probably made him really happy. It was enforced with regard to that first category of material obscenity advertisements for various things you know, that type of thing. It was not enforced, with regard to abortion. In fact, I think there's only one of the cases that the OLC cites in its opinion that even related to abortion as the Supreme Court had rulings with regard to the First Amendment and its application to pornography or obscenity, cultural views and opinions changed, what have you.

[00:21:51] Thomas Jipping: Certainly, *Roe v. Wade* meant that the Comstock Act, if there was, if there had been interest at that time and enforcing it with regard to abortion they probably put that on hold. I don't think you, you could have enforced the Comstock Act at that time with regard to abortion under *Roe versus Wade*. But it is certainly applicable today. As you mentioned at the top, Jeff, that chemical abortions that are the majority of abortions today and that majority is probably growing. And so that puts that other part of the Comstock Act, I think, on the table.

[00:22:27] Thomas Jipping: I would disagree a little bit with, with Rachel that when a statute is clear, the Supreme Court has held many, many times that when the statute's text…when the plain and ordinary meaning of the text is unambiguous that courts have to stop, the interpretation is over, the construction is done. They may not go then further outside the statute to find things to inject into it, to change what the plain, ordinary, and unambiguous text show that is Congress' intent. The Supreme Court has held that many, many times and, and that's as applicable to the Comstock Act as to any other statute I've ever seen.

[00:23:16] Jeffrey Rosen: Rachel, you have a forthcoming article in the Stanford Law Review, uh, that you've written with David Cohen and Greer Donley called Abortion Pills, where you talk about how a revival of the long unenforced Comstock Act is central to the strategy to, to stop the mailing of abortion pills. Is this a case that's, sort of, teed up for the textualist justices to accept or, or given all the precedent against enforcement along these lines and the concern about the massive invasions of privacy that the Comstock Act in its original incarnation, uh, precipitated, uh, where people have their mail spied on and so forth might lead to a different result.

[00:23:50] Jeffrey Rosen: And, and also, maybe talk about the complexities of trying to figure out what the intent of the person who's mailing the pill is when you're sending the pills into a state that bans abortion, is that automatically, um, intent to, uh, support an unlawful abortion or not?

[00:24:05] Rachel Rebouche: So, you know, I, I think that this will be the question for the Supreme Court, is the interpretive lens to bring to, uh, thinking about the application of the Comstock law and how and if it applies. Um, because, uh, you know, I j- I think that Tom and I just disagree that, uh, you, you, uh, you could have a textualist approach that is, um, that still, uh, has to reckon with the fact that over two-thirds of the country permit abortion, allow it to be is, uh, have, have, uh, decided that abortion is legal.

[00:24:39] Rachel Rebouche: And there will have to be some, uh, clarity, uh, if the Comstock law is indeed good law, uh, to how it applies in those places, uh, where people rely on mail for all kinds of, uh, articles and instruments and, and aids in, in abortion, medication abortion, uh, not just mail pills, but also abortion that occurs in brick and mortar facilities. Um, uh, you know, that, a textualist approach has to incorporate the, you know, the, the common sense application of law. And so I, I don't know, uh, what the Supreme Court would decide or h- what its take on the Comstock will be.

[00:25:21] Rachel Rebouche: Um, but I do think differing opinions, uh, their, you know, m- minds can differ about how this law, uh, should be bred. Um, so the article that you reference with Greer Donley and David Cohen is, um, is essentially our take on what we think, uh, is our

now r- re- the, the, the present reality of abortion, uh, conflict and debate in the country. And we, we argue that it's really has to center on medication abortion and abortion pills as the subtle name on the paper. [laughs]

[00:26:00] Rachel Rebouche: So just, uh, because mailing, you know ... I think the reason we're talking about this and the reason it's a live issue for the Texas District Court for the Fifth Circuit and probably, ultimately, the Supreme Court is that the ability to mail abortion pills the, uh, future of, the potential future of certified pharmacies dispensing it, uh, people ordering medication abortion from outside the country, through groups like Aid Access. It really I think, is changing and shaping the nature at least for early abortion services.

[00:26:36] Rachel Rebouche: So in that first trimester, between 10 and 12 weeks, um, for, you know, it, it's, it, it is, there's a prol- there, I think we argue that there will be a proliferation of pills and then the legal battles and the practical, the access problems or issues, uh, for abortion in the, in the future are going to revolve around trying to open access to medication abortion or closed down access to medication abortion. And I think the application of the Comstock law is part of that conversation.

[00:27:11] Rachel Rebouche: It's part of, uh, people who either, you know, uh, seek to apply the Comstock law so that mailing of abortion pills, um, is prohibited or suggests that the Comstock law does not apply or moves to repeal the Comstock law, uh, because of the, the way in which medication abortion has evolved into something that people, uh, really, uh, can't administer on their own. And so that, that's the heart of the argument.

[00:27:42] Rachel Rebouche: And we go through, not just the Comstock Act, but we think about the efforts to promote pills, what the FDA has done, what informal networks are doing, uh, what, what's changed about telehealth for medication abortion, uh, uh, and the like, um, the proposals to have pharmacists prescribe, uh, the, uh, proposals to have, uh, advanced provision of medication abortion pills, so no pregnancy tests but, uh, provision of medication abortion before pregnancy, um, as well as efforts to, uh, police or penalize the use of p- pills, so efforts to remove mifepristone from the market, uh, how the location of abortion is, uh, described, um, you know, potential efforts to target patient conduct or, or information bans, misinformation. So, that's what the paper does it. It, it, I think it's trying to, to map out, uh, what the potential future of debates and challenges overmedication abortion might look like.

[00:28:48] Jeffrey Rosen: Thank you for identifying those potential battlegrounds. And, uh, We The People listeners can check out the paper abortion pill 76 Stanford Law Review and it's online. Uh, Tom, let's turn to the question of the Administrative Procedure Act. And the second big holding in the Texas district court decision was that the FDA acted arbitrary and capriciously in lifting certain, uh, safety regulations and, and that its approval of mifepristone for mailing, uh, wasn't legally justified. Tell us about that part of that holding and whether or not you agree with it.

[00:29:27] Thomas Jipping: Um, well, the, the, the original challenge to the 2000 approval or the original response was 2002, two of the medical associations that are plaintiffs in the Texas litigation today asked the FDA to change or to reverse that 2000 approval, and a couple of things

that were controversial about it. Federal law requires that the, um, the entity or the company seeking FDA approval must provide substantial evidence of its safety and effectiveness for the, the intended use under the conditions that it's proposing.

[00:30:06] Thomas Jipping: And the FDA, um, uh, e- even a few months before it approved mifepristone, um, told, uh, Danco labs which was the company producing the c- the, the branded version of mifepristone called Mifeprex, uh, that there wasn't sufficient evidence. And then suddenly, uh, in September of 2000, the FDA approved the drug under a, a, a s- a, a unique set of regulations intended for, uh, drugs that treat life-threatening illnesses, such as HIV and cancer. Um, pregnancy complications may be life-threatening, but pregnancy itself is not, uh, a life-threatening illness.

[00:30:53] Thomas Jipping: And yet that was the track, uh, the accelerated fast track in which the FDA, uh, approved mifepristone. Uh, and it, it approved it for all women, there was no age restriction, but there was no evidence of mifepristone's impact on women under the age of 18. So that, so it's not that there was a lack of substantial evidence, there was no evidence, uh, as to how it would impact women, uh, under 18. And, um, there were other similar kinds of, of problems where the FDA's approval, uh, was based on, uh, evidence that, um, either was lacking or far less than substantial with regard to, um, the, the criteria that the FDA had to apply.

[00:31:44] Thomas Jipping: And so it was controversial from the start. And for the next, until the, just the last few years, the FDA has always imposed significant safety restrictions because of the, um, potential harms. The Fifth Circuit pointed out that, you know, uh, by the FDA's own data and information, there, there have been and will continue to be hundreds of thousands of adverse, uh, complications that will need to be treated by doctors, a couple of the controversial changes where non doctors can administer, uh, this abortion drug.

[00:32:20] Thomas Jipping: And doctors don't have to report, uh, complications that are, that do not result in death. Both of those things, especially in combination, mean that physicians then will have, will, will actually, it'll, uh, the risks that a physician will have to then treat the complications go up, which is why the court in the Washington case, the district court case in Washington, uh, actually, was critical of, uh, the FDA, uh, for, um, wanting to eliminate all of the, uh, the restrictions. When in fact, uh, that would only raise the danger and the potential of complications for women.

[00:33:00] Thomas Jipping: So it's th- it's that kind of decision making. I, I, I would emphasize, uh, we talk as if, uh, any of these individual cases is going to be the last word on the FDA's approval of abortion drugs. If abortion drugs are so safe and all the evidence, at least today, is there, uh, the FDA, if they f- once follow the law, uh, c- could well come to the same conclusion, but at least based on the kind of evidence that the law requires them to consider. They did not consider that kind of evidence in 2000. Uh, and therefore their decision to approve the drug, anyway, was arbitrary and capricious.

[00:33:38] Jeffrey Rosen: Rachel, what is your evaluation of the Texas district judge ruling on the question of the Administrative Procedure Act? Tom mentioned the judges objection, that drug was approved under the wrong category because pregnancy is not a life-threatening illness

and it was approved for women under 18 without considering evidence of the effects on their health. Um, tell us about your view on all that and, and also how that Supreme Court is likely to review the FDA's determinations about medical safety.

[00:34:08] Rachel Rebouche: Uh, uh, you know, I think this is the, one of the more challenging aspects of talking about this case. Because just as the Texas decision and the Washington decision, they're just mere opposite takes on mifepristone's safety and effectiveness. Um, you know, I disagree with Tom, uh, that there is a, a, a hidden history of mifepristone being an unsafe or risky drug. I think there's copious evidence that mifepristone is safe. Um, and the FDA has relied on that evidence for over two decades.

[00:34:41] Rachel Rebouche: I think that the analysis of, uh, the FDA, uh, of the term illness being used by the FDA, which it has used before for other conditions outside of pregnancy, um, to, in order to, uh, under that time, uh, uh, issue, um, issue an approval that was subject to restrictions, which is what subpart H provided, uh, which was then later replaced by another system by which the FDA could approve drugs but attach restrictions to their use and dispensation. That is the risk evaluation and mitigation strategies or what we've been calling the REMS.

[00:35:20] Rachel Rebouche: Um, and each of these moments, the FDA sought to attach restrictions to mifepristone. Uh, the FDA's history with the drug has been one of careful review. Um, there have been multiple reports, you know, such as an almost 60-page report by the GAO, the Government Accountability Office. Um, there has been countless studies about the, the use and effectiveness of mifepristone. And in each turn, the FDA has it arguably and, uh, uh, uh, as the, um, another federal district court, the one in Washington suggestion, suggested, um, has overregulated mifepristone based on its safety record.

[00:36:02] Rachel Rebouche: And so it's, it's, the, the, the trouble I have, uh, uh, at, you know, when the, the issue of safety, um, comes up is how to discuss what has been, uh, for many, for many folks, uh, a pretty clear safety record, uh, that's been turned upside down. And I understand that folks can disagree about a whole lot. But as someone who teaches health care law, as someone who, um, has, uh, studied, uh, the FDA, as someone who, um, has thought that the FDA has treated mifepristone somewhat exceptionally, very exceptionally, um, i- it's hard for me to see the evidence of mifepristone's safety and understand an argument that it is a unsafe and risky drug.

[00:36:54] Rachel Rebouche: Now, the, the argument about what the FDA, how the FDA applied its statute and like, that's an argument around, uh, the deference to an agency and applying its process. But I think it is, again, should be clear that the FDA has, uh, at all points of mifepristone's approval and regulation attached restrictions to the drug, because of the argument. Because, you know, better to be safe than sorry in, in some sense. And that's the wrong phrase.

[00:37:21] Rachel Rebouche: But, um, in response to concerns about, uh, potential risks that have not materialized, if this was a drug that it was approved last year and there was a lot we didn't know about it or how it works and why it works and, um, and how people should use it, that would be one thing. But it is not. This is, you know, almost a quarter of a century of

regulation. And I think that that says a lot, uh, you know, and I think that, that is, you know, this will be at the heart of, uh, uh, courts evaluation of the FDA's, uh, role and the FDA's authority.

[00:37:56] Rachel Rebouche: But of course, this is not just about mifepristone's safety or efficacy. This is also a question of what kind of deference the FDA should be given, how its power to review and to, uh, attest to a safety of a medication, uh, should be respected. It's not a mistake that major pharmaceutical companies have come out and said, well, wait a second, if a federal district court can suspend in a sense, uh, FDA approval from 23 years ago, um, what does that mean for our ability to invest and, uh, and trust, uh, in the approval process for any drug? Uh, so there are much bigger questions. Uh, but at the heart of them, I think there is just fundamentally, fundamental disagreement about what the science and facts say about mifepristone's safety.

[00:38:48] Jeffrey Rosen: Well, we come now to the question of standing. We the People listeners know that we always leave this, uh, till the end because it tends to be really technical. But here, it's related to the question of whether or not the mifepristone is dangerous. Uh, Tom, tell us about what the Texas District Court held about why physicians have standing because they claim that mifepristone is dangerous, could create more work for them in emergency rooms, and whether or not you think that that standing theory is likely to, uh, persuade the Supreme Court?

[00:39:19] Thomas Jipping: Uh, well, I would like to make two sharp points in response to, um, what, what Rachel had said. Number one, the issue was not whether, um, mifepristone is safe. The issue is whether the FDA followed the law in 2000 when coming to its, uh, approval decision. Uh, second, in the 2016 changes that we discussed, uh, the FDA said, you know, no one has to report nonfatal complications and then in 2021 turned around and said, there's no evidence of nonfatal complications, so we're saying it's safe. That's a bait and switch that they can have both ways.

[00:39:56] Thomas Jipping: And then third, uh, you know, the, the Washington State district you judge, Judge Thomas Rice, um, was very critical of the FDA and its assessment of mifepristone's, uh, safety. Uh, I'm quoting here, it says, "The FDA did not assess whether mifepristone qualified for the REMS, for the safety risk based on the criteria set forth under federal statute. The record demonstrates potentially internal, inconsistent FDA findings regarding mifepristone's safety profile, so." There are serious issues going to the merits of the FDA's APA claims.

[00:40:32] Thomas Jipping: So I, it's not as smooth and uninterrupted, I think, uh, as Rachel suggested. On the standing issue, um, uh, the plaintiffs in the Texas case were a few individual doctors and several medical association. So there were, uh, the question is whether the organizations and the individuals each had standing. The 2016 change that I just referred to, the fact that non-doctors can dispense mifepristone and the complications from the use of mifepristone, if they don't kill people, don't have to be reported are exactly the kind of changes that result in a significantly increased burden on emergency room physicians.

[00:41:15] Thomas Jipping: Who, who has to deal with them, the complications, the non-doctor who, who gave the abortion drug out? Of course not. Uh, and so the doctors argued and, and the associations argued on behalf of their doctor members, uh, that, um, these changes and the use of this drug, uh, result in not only significantly, uh, increased situations where the physicians themselves have to, um, treat these patients, but also the organizations when they're trying to inform the public about this drug and its potential complications.

[00:41:52] Thomas Jipping: If the law no longer requires the actual reporting of nonfatal complications, the, the, the very information that these organizations need and that the public needs to know don't exist. And frankly, it also complicates getting informed consent from, uh, patients when the, the very information that would be needed, uh, for that informed consent no longer has to be reported. So, Judge Kacsmaryk and the Fifth Circuit agreed that there is both associational standing and standing of the individual doctors to challenge this.

[00:42:27] Thomas Jipping: Um, I think that the Washington State case where the plaintiffs were states, uh, I think there's, that, that, that presented a very different and unusual standing kind of an argument. Um, but that issue of standing whether the litigants are the right ones to go into court, that's a very important one. And, and we'll certainly be, uh, litigated as the cases go forward.

[00:42:49] Jeffrey Rosen: Just to sum up where we are, the Washington State case involve liberal states who wanted to enjoin FDA rule changes from going into effect because they fear that a pharmacy certification requirement would reduce availability of mifepristone for their residents. And, uh, the, the Washington decision was about these new rules that the FDA issued, which lifted the in-person dispensing requirements.

[00:43:13] Jeffrey Rosen: Um, uh, Rachael, uh, those who are opposing standing, uh, in the Texas case, say, this is a version of the Advil theory of standing, that if there's any drug that might have possible small health effects, you can claim that it would overrun emergency rooms and get into court, even if you're not dispensing that drug on your own. Tell us more about that and what, whether or not you're persuaded by the argument against standing.

[00:43:36] Rachel Rebouche: So just to be clear, the attorneys general in Washington had asked the court to, um, essentially, uh, enjoin any action by the FDA that would try to remove or suspend approval for mifepristone and then to remove all the restrictions on mifepristone. Um, so it's, it's not just, it's not about certification or, uh, uh, you know, only, it's that, um, the, what the plaintiffs asked for there was for the court to essentially enjoin the FDA from restricting mifepristone through provider certification, through certified pharmacies, through the other ways in which mifepristone's distribution and, uh, use is, uh, restricted.

[00:44:23] Rachel Rebouche: Um, and, and just a quick point that relates to standing, you know, a- again, I just disagree with Tom. I think we agree that the issue is whether the FDA follow the law. But I think it is just as strong an argument that subpart H in 2000 was the regulatory tool that the FDA created to the agency's sluggish approval of new drugs, uh, particularly at the height of the HIV/AIDS epidemic. The FDA never relied on subpart H to accelerate approval of mifepristone.

[00:44:54] Rachel Rebouche: In fact, it rejected the drugs approval twice before finally approving it three years after the manufacturer submitted its application. And at the time in 2000, the REMS program I mentioned did not exist. Subpart H was the primary avenue that the agency had from limiting the distribution of new drugs after it approved them. So in other words, the agency used its subpart H authority to regulate mifepristone more harshly than the vast majority of drugs, not more leniently as the Texas, uh, order suggests.

[00:45:25] Rachel Rebouche: And that's important because I think there's also important for our listeners, it, it shouldn't be suggested that there's just some void of information about mifepristone's safety, that, um, the FDA's, uh, uh, uh regulations about what providers have to or do not have to report back to the agency, um, says nothing about all the evidence that I mentioned earli- earlier, that has been submitted to the FDA over the years that has been conducted in this country by independent, reputable, uh, knowledgeable experts, uh, clinic and otherwise, that show that mifepristone is safe.

[00:46:01] Rachel Rebouche: Um, you know, uh, uh, again, I know we disagree on the point, but underlying the comments about the FDA's failure to apply subpart H, uh, correctly is this allegation that it's, it's so hastily, leniently, and contrary to what has been known for decades about mifepristone. So the standing issue is interesting because there is absolutely no evidence that doctors are overwhelmed treating patients in ER because of medication abortion. I don't, uh, the, there's been no credible study that shows that's true.

[00:46:36] Rachel Rebouche: Um, and, you know, I think your, your version of, of how standing should apply, y- might cut either way, uh, given, uh, the public interest in this topic. But the idea that, um, there is a concrete harm to physicians across the country, uh, because they are inundated with, uh, requests for care from people who are taking medication abortion is just false.

[00:47:01] Jeffrey Rosen: Well, it's time for closing thoughts in this important, uh, discussion. And, Tom, the first one is to you, uh, maybe sum up for We The People listeners why you think that the FDA's approval of mailing mifepristone violates the Comstock Act and whether or not you think the Supreme Court will and should strike that down?

[00:47:20] Thomas Jipping: Well, I encourage people to read the Comstock Act. Um, uh, uh, I, I think, uh, the arguments that Rachel has raised, uh, are all arguments that should be directed to Congress for perhaps repealing the Comstock Act. But judges do not have the authority to effectively rewrite statutes. The Comstock Act prohibits any article or thing intended, designed, or adapted for producing abortion. Uh, it makes those such articles or things unmailable. Um, I don't know anyone who would misunderstand that language.

[00:47:59] Thomas Jipping: Uh, law- and the lawyers are trained to make words mean many different things, uh, but that's what Congress said and that's what Congress meant. If Congress wants to change the law, eliminate it to had opportunities to do so in the past and chosen not to do so, uh, it can, but judges don't have the authority to do that. Um, and I think regardless of what you think about abortion or abortion drugs, um, or policies about this or that, uh, I, I think we all, I hope we would all agree that judges don't have the power to, to change statutes.

[00:48:36] Thomas Jipping: That's what the Department of Justice tried to do in its opinion, trying to put language into the Comstock Act that just isn't there. I think judges ought to faithfully and impartially construe it for what it says and for what Congress clearly meant and if Congress want to then respond by changing it, it can.

[00:48:55] Jeffrey Rosen: Rachel, the last word in this important discussion is to you. Tell We The People listeners why you think that the FDA's approval of mifepristone does not violate the Comstock Act and, and why you think the Supreme Court should not enjoin it.

[00:49:07] Rachel Rebouche: I, you know, I, I agree with Tom that there is a question now for the public about whether this law should stay on the books and, uh, people who think that it should not should, uh, you know, uh, mobilize to, uh, have the law repealed. Um, I disagree that the Comstock Act, uh, uh, you know, if it's up, uh, you know, as a court would apply it, that a court, um, could not read the text of the law and understand that it is a law intended to apply to unlawful abortion.

[00:49:37] Rachel Rebouche: It is not a law that is intended to penalize, uh, uh, the mailing of as, as, as broad as languages that, that Tom just read, articles things, you know, that, that two, two-thirds of the country in which there is lawful abortion, all, all, all forms of abortion. Um, I think that courts, um, could faithfully read the text and understand that as Congress passed it 150 years ago and as it's been in disuse, for much of that history, um, that as applied in 2020, that text, uh, means something, uh, th- means that the, the law, if applied, applies to unlawful abortion.

[00:50:20] Jeffrey Rosen: Thank you so much, Thomas Jipping and Rachel Rebouche, for a civil deep and illuminating discussion of the legality of mailing mifepristone. Uh, Tom, Rachel, thank you so much for joining.

[00:50:34] Thomas Jipping: Thanks for the opportunity.

[00:50:36] Rachel Rebouche: Thanks so much.

[00:50:38] Jeffrey Rosen: Today's episode was produced by Lana Ulrich, Bill Pollock, and Sam Desai. It was engineered by Dave Stotz and John Pop. Research was provided by Sophia Gardell, Sam Desai, and Lana Ulrich. Please recommend the show to friends, colleagues, or anyone anywhere who's eager for a weekly dose of constitutional illumination and debate. You can also sign up for our newsletter at constitutioncenter.org/connect, uh, and get more of our content, uh, and keep in touch with the center.

[00:51:06] Jeffrey Rosen: It's so meaningful to hear from all of you and it would be wonderful to have you as, as part of the Constitution Center Community. Always remember that the National Constitution Center is a private nonprofit, we rely on the generosity, the passion, the engagement, the dedication to lifelong learning from people across the country who are inspired by our nonpartisan mission of constitutional education and debate. Support the mission by becoming a member at constitutioncenter.org/membership or give a donation of any amount to support our work, including the podcast at constitutioncenter.org/donate. On behalf of the National Constitution Center, I'm Jeffrey Rosen.