

**MARGARET** So let me show you-- and this is where I'll go to the slides-- let me show you what a typical approval pathway would look like against what we're now in, which is Operation Warp Speed. It's worth knowing that DOD is involved in this, and so you get names like Operation Warp Speed. And I'll show you in two different slides the differences. And they're significant. We're talking about differences in time of six to seven years. But let me share my screen here. And my hope is you can all see this slide here.

So the top of this slide here, with my cursor you can see, is what a traditional paradigm of a vaccine approval would look like. And then down here, this isn't actually warp speed, but it is what a paradigm should look like in a pandemic under an EUA scenario. And there are two major differences. One is you'll see-- whoops, I just moved my own slide-- one is you'll see all of these different phases are much longer.

[PHONE RINGING]

Sorry about that. Spam. And the other thing that's very important to watch is this up here, which is the stages of manufacturing that are occurring at the same time as the drug approval process is going on.

So typical approval, the first thing is you have to target what your product is going to be. In a vaccine context, typically your target is twofold. One is what disease are you trying to look at, and then the second piece is what is your platform for that. And this is an area where vaccine development has changed astronomically. It used to be you had a question of a live virus or a dead virus as your platform. We now have tens of different platforms. And we'll talk about, very briefly, the two major ones in contention right now. But even in those 46, there are probably 30 different platforms that we're talking about for the target.

Then you start with very short, first, phase one. Usually, these used to be on healthy volunteers, but in the context of the vaccine during a pandemic, we're all the healthy volunteers. So you can actually, through phase one, go quite quickly through, typically, a small number of individuals, 10 to 15. And that's a dose

escalation phase, where you're testing exactly how this vaccine is working. And your endpoints are safety only.

Then you move into phase two, which involves more volunteers. And there, too, you're still focusing mostly on safety, but you're bringing in some efficacy. And then in phase three, you have lots of volunteers. And over a period in a traditional framework of several years, you might get several thousand volunteers in that context. And then you get to a drug approval.

Now, when we look at Operation Warp Speed or a pandemic scenario, everything is squished much more tightly. So we're moving faster, and your phase one is going to include aspects of phase two. You're going to move very quickly from phase two into phase three. As an example, the Moderna vaccine right now is in phase three. It currently has 30,000 volunteers involved. Half of them getting placebo, half are getting the active vaccine.

Now, the other piece I said to pay attention to is this piece here, the manufacturing piece, the early manufacturing and scale-up, and then large-scale manufacturing. In a typical setting, remember, most vaccines are going to fail in development. You're going to have, at most, small-scale clinical trial material being developed, because you need the material to test your vaccine, but you're not even going to think of tooling up your system so that you can produce this vaccine later on, not to speak of large-scale manufacturing.

Here, all of this is actually taking place right now. And we'll talk about that. It's actually created big distribution gaps. If you actually think about what's going on with COVID testing, we have the same problems going on, the distribution for the vaccine, and likely going to be the big problem getting it out.

Now, I just want to show the next slide here gives you another view of the same process I was just talking about, but is better at seeing what kind of timeframe I'm talking about. A typical vaccine process is 73 months to completion. Operation Warp Speed is projected-- that may be an optimistic projection, but we'll see-- at 14 months to completion. And as you can see here, the same thing I was talking about, instead of having the manufacturing pieces coming at the end, they are already in place as we move through.

The other thing that's very, very different with Operation Warp Speed is the money. No one makes money by producing vaccines. The reason you do it is to have your portfolio do some good things or you're getting funding from places like the Gates Foundation to do it. But this is not your typical for-profit situation. Now, what's happened here is the government has come in, and the government has actually started funding targeted vaccines significantly.

And when I say significant, it's significant to me. We're talking \$1 to \$2 billion contracts with the main contenders. So they're already getting \$1 to \$2 billion. There are also lots of contracts with the materials, like the vials that are going to be important later on, that are going on separate from the actual producer of the vaccine so that those things will be in place.

So Operation Warp Speed is a huge-- no matter what, take all the politics out of it, it should get us to something near 14 months to completion. And so when you hear Fauci, for example, talk about the possibility of having a vaccine to an EUA at the end of the year, that's not a crazy projection. What may be a crazier projection is getting it to the place where you can distribute it to the American population. That's-- well, I'll talk that just for a moment towards the end.

So Operation Warp Speed required the government to choose just a few candidates to give several billion dollars to. And this slide here shows you who those are. One is being developed by AstraZeneca and the University of Oxford. Also the Institute of India is involved, but the two main partners are Oxford and AstraZeneca. And you probably heard about this because they had a volunteer who had a very bad reaction. And so there was some question of whether that was related to the vaccine or not. It doesn't seem to be, but people are watching it pretty carefully.

Then Moderna has gotten a lot of news. It's probably the furthest along at this point. And that's the one that's got right now a phase three trial going on with 30,000 volunteers. The one that many people think may be the first to an EUA is actually produced by Pfizer. It's still in a phase two, three stage, but it's doing well. A lot of people have been impressed with the platform, and we'll see.

But this is a race between these three, and it's a race that may not have a single

winner. It is possible-- and this is actually one of the tricky pieces of this-- that you may see EUAs for all three of these coming in by second quarter 2021. And that's going to raise a real issue of how you think about choosing between them.

Now I should also point out that, of those 46, any of the others might be better than the ones we're talking about here, especially there are many that are in very early stages. So we're still at the animal testing and stages like that. So if you look at it that way, it's not clear.

Now let's talk about-- one of the questions you asked me was efficacy. And if you talk about efficacy, that becomes an interesting question of what the standard FDA is requiring. Most people, when they hear something is effective, what they think is this will work for me. But if you've taken my FDA class, you know that's not true. The standard that FDA has set in June is that the vaccine that will get an EUA through Operation Warp Speed must show 50% efficacy. And that means 50% against a placebo.

To give you a little bit of a comparison, most flu vaccines-- and don't not get a flu vaccine when I tell you this-- most flu vaccines on a given year have efficacy between 19% and 60%. That's because the flu virus mutates so much that there are actually so many different strains of the flu virus out there that, through the manufacturing process, you actually have to guess many months before what the most prevalent strains are going to be. If you guess wrong, you get a 19% efficacy rate. If you guess well, you get a 60% efficacy rate. We're still talking about much less than what people think efficacy means.

Now, as another comparison-- and it's important, I think, for this discussion that we're going to have here-- is that, for measles and mumps and tetanus and all of the things you got when you were a kid, the efficacy rate there is between 85% and 95%. So significantly better than what we're talking about when we talk about flu. And COVID is, unfortunately, more likely to be more like flu than it is to be-- at least now, down the road, we may get to a stage where it's more like mumps and measles, but that the best we can really hope for is about a 50% efficacy rate.

So last things to think about, I mentioned distribution is going to be a problem. Some of these vaccines have to be kept at something like 70 below zero. That

makes it kind of hard to transport them and store them. Very few people have the capacity to do that. You may have heard that we had a shortage of the various requirements to make tests.

We also have, believe it or not, a global glass shortage. Without the right kind of vials, you can't actually produce the vaccine. And so the US government, in this instance, is actually trying to get in front of all the private sector pieces. There are contracts out there, but they haven't gotten in front, and there is international competition for glass right now. That's going to play a role. Last piece is using like a TB syringe for these vaccines. There is a lot of evidence that we have a shortage of those.

So last piece is, after the distribution, that mess, part of it's figuring out what the-- before we even get to mandatory, what should the priorities, who should get it. There was a National Academy report fairly recently that outlined priorities. I suggest you actually look at that, and how that will work. And that's going to play a role as we start thinking about what mandates should look like.

One of the more interesting questions we can talk about in discussion is never mind a government mandate, but what happens if your employer mandates that you get this. We're also seeing a lot of evidence that some companies are actually trying to outbid the government by establishing contracts with the likely candidates so that they can get in front of the government and get their workers vaccinated first. This is going to be-- well, not like it hasn't been a free-for-all already. So it's going to be really interesting, and sadly, 2021 has the capability of looking just as interesting as 2020. And I'll leave it at that.

**SAVANNA:**

What a cheery note to end on, Professor. Thank you.

[LAUGHTER]

Thank you so much for that. And we're going to turn it over to Professor Shepherd to talk about ethics and her recent discussion that she was quoted for in the news. So Professor Shepherd, it's all to you. And also, Drew Calamaro's on here. I know that Drew and Professor Shepherd have been working really closely on a paper that Drew is writing about this topic. So I've asked Drew to chime in where needed, because he has become quite an expert on this over the last few months.

**LOIS** Yes, Drew has really dived into this recently. So I was also going to talk about,  
**SHEPHERD:** Savanna-- I think I was also assigned to talk about the general constitutional law. Not the religious exemption so much, potentially, or the religious issues. So I guess I just wanted to start with saying that the Supreme Court-- and this isn't a big thing to say. I mean, if you know much about health law, you would know about the *Jacobson v. Massachusetts* case from 1905.

So if you read any articles or hear any news little clips about mandatory vaccines, that's the case everybody's going to cite. And that was in 1905. And the Supreme Court upheld the state of Massachusetts law that required vaccination during the midst of a smallpox outbreak, and basically said that the state has broad police powers to protect the public health and safety, and was quite deferential with respect to didn't ask too many questions about the science, was really kind of quite deferential with respect to the review that it did.

This is before, of course, the stricter scrutiny that you might find with respect to individual liberties. And so you do have to ask, well, what about today? You know, to the extent that the previous review really just focused on was it not arbitrary, was it reasonable, would it today kind of stand up? So we'll hold that thought for just a minute.

The important thing to also note about the case, though, is that medical exemptions, it was acknowledged that, if *Jacobson* was-- it was acknowledged that he was not able to prove that he had a medical condition that made it unsafe for him to get the vaccine, so implicitly saying that you could not force a vaccine on someone for whom it would be unsafe to have the vaccine.

And since then, in 1922, the Supreme Court had another case. This was about mandatory school vaccines, which actually had been in place in many states since the 1800s. And the Supreme Court also upheld that mandatory vaccination for public and private schools, even though there wasn't a public health emergency. It wasn't like the situation in *Jacobson*, when you had a smallpox outbreak.

So to get back to where we would be today with respect to *Jacobson* if you had a challenge today, I mean, I don't think there would be quite the level of deference that you had with respect to the local health authorities' discretion with respect to

the science, but there'd be a lot. I mean, there might not be as much because it was pretty much hands-off, but there would still be a lot of deference.

And then the fact that what Jacobson-- if he didn't get vaccinated, he was fined. In other words-- and this is something that we see a lot in these kinds of cases with respect to mandatory or forced medical treatment, is in general, we consider the body, intrusions of the body so anathema and a violation of really core liberties that that's what you-- to me, that's the interesting question. I mean, could we actually force people to have a vaccine?

And not that I necessarily-- I mean, it's interesting to think about what would get us to that point where a state would actually force that, rather than making a vaccine conditional on something else, or if you don't have a vaccine, you have to be isolated or quarantined, or if you don't have a vaccine, you have to be fined. Right? So some consequence from not having a vaccine, but that's different from actually forcing a vaccine on you.

And with respect to that, we've got, since 1905, many more cases, federal, state, both supporting mandatory vaccines, federal, state courts supporting mandatory vaccines, but also upholding people's liberty interests and bodily integrity interests with respect to forced medical treatment. So you have the *Cruzan* case, which acknowledged, although not directly, that there is a right to refuse. There may be, but prior decisions could include a right to refuse medical treatment, even if it were lifesaving. And we've got a number of appellate decisions that say that you cannot, even to save the life of a fetus slash baby right at term, you can't force a C-section on a pregnant woman, that that is her choice.

So you've got these cases where you've got the liberty interests and the bodily integrity interests with roots in common law, with roots in common law, battery claims that you can't do that, or you'd have to have an extremely compelling reason to do that. So that, I think, would inform how a court would look at this kind of a case today. So an example, those were cases that dealt with a person's own health for their benefit, or for the benefit of the baby. When you're starting to think about the public health, though, the state's interests are even broader. So it's a more interesting conflict, or it's not exactly answered by those cases because of

the really strong interests that the state has in protecting the public's health.

So there's an interesting case that I have in my case book from 1993. It's just a state court case about a man with tuberculosis who would not stay in his hospital room during treatment. He had a multi resistant tuberculosis. And so the city of Newark wanted to confine him to his hospital room and also force him to have the treatment.

It was intramuscular, in fact, not even intravenous, but this pretty painful treatment. And this court, just using-- and it's a pretty well written opinion drawing on analysis from *Jacobson* on down-- so this is a 1993 case-- says that they would order his isolation and confinement in the hospital but was not willing to order that he be directly subjected to the treatment.

Of course, he couldn't get well until he took the treatment. And so you can ask how much liberty he really did have. But I think that kind of hesitancy to actually intrude the body, I think that is more where we are today than in 1985. So that's one thing I would think about.

So you have the constitutional law. You have to think about, well, is it required in the sense of, what are the consequences if you don't do it, right? And so the authority for that, in addition to what is allowed in the Constitution, is going to be your state laws. So after 9/11 in 2001 and the anthrax attacks and concerns about bioterrorism, a lot of states passed a law based on the Model State Emergency Health Powers Act, which was developed by a group of experts in the field, legal experts.

But each state had a different-- it's a model statute. So they can take what parts they want. And this was because, until then, until 2001, most states didn't have some broad statute that laid out what they could do in a public health emergency. They'd have a TB statute or they'd have a smallpox statute. So when some particular disease came up, then they passed a statute for that. So this is trying to be comprehensive. And so you'd have to look at that.

Florida, for example, apparently-- I haven't looked at it directly. So I was reading about it. [INAUDIBLE] would be [INAUDIBLE] broadened in allowing the state to



require vaccinations. Other states backed away from that. So you'd have to look at that. And when the states did pass those laws, some critics of the Model State Emergency Health Powers Act, like George Annas and Ken Wing-- they were surprised at how intrusive these laws could be, I mean, how much power they were giving states to declare a public health emergency and then to do pretty draconian things with respect to isolation and quarantine.

And instead of having individualized hearings, you could have group hearings. And so there were questions about privacy, questions about due process. And the argument that they were making at that time, which I found pretty convincing, was that, if we had a situation where we had a public health emergency, what we needed to be concerned about was giving access to people, that most people would want care. What we had to worry about was access.

What we had to worry about if we wanted to quarantine people is to make sure that their job would be secure for them and that they would be able to bring in income and pay their bills and pay their rent and that we could rely on a lot of voluntary compliance or uptake of these public health measures, whether it's a vaccine or testing or isolation or quarantine or medical treatment, antivirals, because people would want to do that in their best interests.

So I was in much agreement with them in those years after 2001 when these acts were passed. And a part of me still agrees with that, and a part of me thinks, well, I'm not sure with respect to that, how big the antivaxxer movement has gotten and now the anti masks movement. And I don't know.

I think I maybe had too rosy a view of how people would want to-- the harder question was going to be questions of access. I know those are going to still be questions. And we have to solve the access problem. But I also worry that people would not voluntarily, in order to protect others, take public health measures because of what we've seen with respect to masks and the politicalization of these issues.

So I'm sure, if we did have some kind of mandatory vaccine, no matter what the consequence was, what was conditioned upon it or what the consequence or fine or however they decided to implement it was, I'm sure it will be challenged. And so

it'll be interesting to see what happens. I'm going to leave the religious issue to Micah.

**SAVANNA:** Sure, and before we switch over, Drew, I don't want to put you on the spot, but since-- well, you did [INAUDIBLE].

**DREW** I'd much rather listen to Professor Schwartz, basically.

**CALAMARO:**

**SAVANNA:** Well, if you have any thoughts at the end and if anybody wants to talk to Drew about his paper, it's very, very fascinating.

**MICAH** Savanna, you asked me earlier about slides, and I didn't think I would have any. But **SCHWARTZMAN:** maybe I have one that's worth sharing.

**SAVANNA:** Sure, I can make you a co-host so that you can share.

**MICAH** And I'll just share this.

**SCHWARTZMAN:**

**SAVANNA:** Give it a go now. It should work.

**MICAH** OK, let's do this. How's that? Can you see what I'm-- see this slide?

**SCHWARTZMAN:**

**SAVANNA:** Yeah.

**MICAH** So this is just a state run down, the most recent I could find. I had one from 2019. It

**SCHWARTZMAN:** was a little bit better shaded out, but this will do. Maine had a law on a ballot in 2019, 2020. So it's a recent conversion to no exemptions. But you'll see that most states have a religious exemption for vaccinations. And some have an exemption that's broader that includes personal belief.

States with outbreaks in recent years, like New York, have changed their laws to eliminate religious exemptions. So New York did it. Maine did it. Some states for a long time haven't had such exemptions. West Virginia, Mississippi are interesting cases. California, which has faced an outbreak, they had a problem with measles, like in New York, has no exemption.

Some states have considered repealing their religious exemptions. New Jersey came pretty close but didn't quite manage to do it. Let me show you one more slide. I gave a talk in New Jersey I guess maybe about a year ago. It seems like 10 years ago.

But the reason why they were considering or why they were considering a repeal is because they had an explosion in the number of religious exemptions claimed. This is roughly contemporaneous, this rise in the red line here, with a measles outbreak that was happening in New Jersey and New York. And as this outbreak is going on, they're seeing increases in demands for religious exemptions.

And in the midst of an outbreak, let alone a pandemic-- I'll stop sharing this-- you can see why states want to begin to reconsider whether their exemption policies make sense. I mean, I suspect that, if there had been an even broader outbreak in New Jersey, more like the one that happened in New York-- I mean, it was beginning to spill out-- I suspect the political pressure on New Jersey would have been so strong that that effort would have succeeded.

I mean, at the end of the day-- this is true now, too-- parents want to send their children to school. And measles is dangerous and extremely contagious. And so the pressure there was intense and still not quite successful. But I think that has more to do with the extent of the outbreak than anything else.

So let me step back for a second and agree with Professor Shepherd, who pointed out that this law in the public health context is still governed by *Jacobson*. I think that's still true, even though, again, though there have been changes in our constitutional recognition of due process rights to reject medical care-- and it's true that that law has developed beyond where it was in *Jacobson*.

And yet the Supreme Court-- I think there's no question that *Jacobson* is still an important precedent. Chief Justice Roberts in one of the COVID cases, *South Bay*, over the summer relied upon it in his explanation for the denial of cert in that case. I suspect it would have broader effects under pandemic conditions if a vaccination requirement were litigated.

I will say this on top of pointing out the durability of *Jacobson*. No court, to my knowledge, has ever relied on a religious freedom protection. Whether

constitutional or statutory, no federal court has relied on a constitutional or statutory provision that generally protects religious freedom to issue a religious exemption where it wasn't already authorized by state law as an exemption from some mandatory vaccination requirement.

That is, federal courts are not in the business of creating vaccination exemptions. They might exist under state law. According to the map I showed you there, they're prevalent. But courts don't tend to create them. In fact, I don't actually know-- and I haven't done an exhaustive search of this-- I don't know of any state high court that has authorized a vaccination exemption under a general religious freedom statute or constitutional provision, like a state RFRA.

There's a federal law which provides protection of religious freedom. With respect to federal laws, that's the Religious Freedom Restoration Act, which many of you may know especially from the litigation over contraception in *Hobby Lobby*. Many states have such provisions either as a matter of statute or constitutional law at the state level. And again, I don't know of any court that has interpreted one of those provisions or statutes to issue an exemption where it wasn't otherwise specifically authorized statutorily. It would be very surprising to see a federal judge, and for that matter, I think a state judge do that.

I can think of one case in New York where a state court required a school to admit a child who was exercising a religious exemption where the school didn't want to recognize that exemption. There was some controversy in New York. You had this interesting situation where the school was announcing a religious freedom claim to prevent children from coming in if they weren't vaccinated. And the parents were exercising a religious exemption on behalf of their child.

And you have these dueling religious exemptions. And ultimately, the courts did what I think most of us would expect to be sensible, which is, if there are religious claims on both sides, you're going to side with the vaccination requirement. And that's where things ended up ultimately.

That was before New York just eliminated its vaccination exemptions. That followed shortly thereafter. I mean, those cases and the elimination are, they're not even a year apart. In other words, this is really a question for the political process. And I

think the determinants of how that process go have mostly to do with how serious the public risk is.

And I think, in most states, I'd expect state legislators to be sensitive to that risk, not necessarily because they don't care about religious freedom-- I think that many do-- but because there will be such intense pressure from the public, especially from parents, who want to send their children to safe schools. And I think that pressure largely overwhelms still the antivax movement.

Although in states where there are these religious and personal belief exemptions, you can see them exploited by those who are opposed on any grounds to vaccination requirements. And in New York and New Jersey, we had some test of that. And it didn't go very well until those exemptions were constrained or eliminated.

I think, as a matter of constitutional law, there's still no question that schools could condition attendants on vaccination. I don't see that being disturbed anytime soon. A mandate by states to get vaccinated under their police power-- I think it's a slightly more complicated question today. But under pandemic circumstances, I actually don't think it's that complicated as a matter of constitutional law.

But we have a Supreme Court that is the most solicitous of religious exemptions that we have probably ever had. And so maybe I'm speaking too soon. We'll see. I think the chief is very cautious about this sort of thing, and the COVID cases should give us some encouragement about that from the summer.

But we also have a nomination or about to have a nomination that might mean that he's no longer the median voter in the Court. And so it may turn these kinds of questions on who that median voter, who the 5, 4 swing turns out to be. And right now we don't know that. So there's some uncertainty. I'm going to stop there. I'm happy to take questions or to open a discussion or however you want to proceed.

**SAVANNA:**

Sure, Drew, I see your hand is raised. And if people want to ask questions, if you could use the hand raise function, if you click on Participants, you can raise your hand on there. And I will call on people after Joe.

**DREW**

I have a question for Professor Schwartzman. Have you read *Brown v. Stone* from

**CALAMARO:** Mississippi at all or do you know of it? It was a state Supreme Court case for Mississippi.

**MICAH** No, I haven't read that decision.

**SCHWARTZMAN:**

**DREW** Well, all it is an equal protection argument for getting rid of religious exemptions.

**CALAMARO:** So you're protecting the people who are immunocompromised. What do you think about that getting developed further, I guess? Is that a viable argument do you think?

**MICAH** I'll have to take a look at the Mississippi case. I don't know when it was issues. It's

**SCHWARTZMAN:** not something I've seen. There's a background question about whether a state could grant a religious exemption without granting an exception for people who have strong philosophical or personal commitments.

My own view is that that's impermissible under the Establishment Clause, and there's some case law that points in that direction as a matter of statutory law. You have to go back to the Vietnam draft protest cases for this, *Seeger* and *Welsh*, or those cases.

But as a matter of constitutional law, there is some contrary language and *Yoder v. Wisconsin*, which is the case granting an exemption from education requirements in Wisconsin to the Amish. And there is some language in a more recent case called *Cutter v. Wilkinson*, which says that exemptions don't have to proceed in quote lockstep with benefits to those who aren't religious.

There was a case decided just within the last couple of weeks in the 7th Circuit in which a COVID related case in which Diane Wood writing for the 7th Circuit said that the state could authorize social gatherings to larger capacities for churches but not for political rallies. This looks like a problem on that equal protection theory that I think you're mentioning or a free speech theory, which says that content discrimination is impermissible.

I think that decision in the 7th is on very shaky grounds on First Amendment Speech basis. But again, this court, if you asked me to predict what five justices on this court would do, I think they're prepared to grant religious exemptions that

don't extend to those who don't have religious claims.

I've spent a lot of time arguing against that view both normatively and doctrinally. But just as a predictive matter, where do I think the Supreme Court is? Yeah, I think it's highly protective of religious accommodations and not as interested in extending those to people who've got non-religious claims. What counts as a religion might be an interesting question here? That's the kind of question that emerges when you get this division.

One last thought about this. If you look at the contraception mandate as a interesting comparison, when the Trump administration granted exemptions there, it created two exemptions-- one for those with religious objections and one for those with moral and ethical objections. Here I suspect some states won't want to do that because it greatly expands the possibility of antivax responses and exercises of those exemptions.

And so there's pressure to allow religious exemptions and only religious exemptions for that reason to narrow the category of exemptions. There's a hard line to walk there. Sorry, that was a longer answer than you might have-- but--

**SAVANNA:** No, that was a fantastic answer. Thank you so much. Oh, Professor Shepherd, go ahead.

**LOIS** Yeah, Can i follow up with that?

**SHEPHERD:**

**SAVANNA:** Yeah, please do.

**LOIS** This is a political question, not a legal question, or a constitutional question. Do you  
**SHEPHERD:** think that if states do issue a vaccine mandate of some kind-- and I'm tending to think less about children right now, although there's so much precedent for that. I think it's interesting to think about an adult mandate like we had in *Jacobson*.

But do you think that politically there would be pressure to have a religious exemption in order to get public buy in that this is something that the state should do? I mean, I felt like in Virginia that the governor has been really careful, at least originally-- I haven't kept up with it quite as much in the last few weeks-- but to say, you have to do this.

But the enforcement is really not clear. So there's a trying to get public buy in. So do you think states that otherwise wouldn't want to have a religious exemption-- so perhaps they don't have one, like for measles, mumps, and rubella for schools or whatever-- would have one for COVID?

**MICAH**

I don't know the answer to that question. It's a fascinating question. And in other

**SCHWARTZMAN:**

countries, I know there have been experiments with different types of enforcement mechanisms, where they're not mandates but you provide some kinds of incentives or public campaigns.

It's true that one way to try to help package regulations is to include religious exemptions. You see this in states that are thinking about same sex marriage providing exemptions for social service organizations and others as a way to try to create some compromise.

I think you have the same kind of problem from the slide that I showed you out of New Jersey, which is, if those religious exemptions are exploited and the numbers of them greatly expand, they begin to defeat the public health mission. If the numbers are small, if you only have a really small contingent of religious objectors, that's one thing.

But if you've got lots of antivaxxers who use religious exemptions as a vehicle for getting out from underneath the law, you have a sincerity issue. And I don't know. Some of them may have religious objections. But to the extent that they're really motivated by medical concerns and not by religious objections, the only avenue for them is through a religious exemption, and you can see how that goes. We had similar kinds of issues with conscientious objectors for conscription in the '60s.

I think a lot depends on what kind of response you end up getting to the exemption. If it's huge, I think you've got pressure to eliminate it. And you may see both efforts. I think that's what we've seen in some states. You initially grant a religious exemption. And when it turns out that tens of thousands of people want to exercise it and undermine the health policy, then the state's effectively forced to get rid of it. Or maybe even some states will see that pattern play out. That's just conjecture on my part.



**MARGARET** Savanna.

**FOSTER RILEY:**

**MICAH** Riley wants in.

**SCHWARTZMAN:**

**SAVANNA:** I was muted. Professor Riley, good ahead.

**MARGARET** So I guess what I would say on all of this, if you're talking about political buy in, I  
**FOSTER RILEY:** don't think you'd get there with a 50% efficacy rate and unknown safety profile at all. I don't think we're going to get there for several years. We may get there if we continue to be in lockdown situations for more than another year.

But I am a really pro vaccine person. And right now, you'd have to convince me to take any of the candidate vaccines. We just don't know enough about them. And if you then mandate it, frankly you might destroy our measles and even more than what we have in terms of childhood vaccines and completely throw our vaccine program up for grabs.

So I think we're a long way from *Jacobson*. In *Jacobson*, the science was-- there's a 1905 opinion, FDA opinion, McNulty, which actually says, well, science is just opinion. I think we're further down the track on what science tells us now. And I just don't see courts or legislatures saying, oh, we're just going to trust this vaccine and the state's decision to work. I think you're going to see a lot of pushback on that.

What worries me is, if we push it too fast, that pushback is going to come unreasonably when it is reasonable to get people to take the vaccine later on down the pike. I am frankly glad I'm not rolling this process out. I guess there is an election. So who knows what could happen? But you're going to have to do it with the delicacy of a dance to get it right, or we're going to have even bigger problems.

**SAVANNA:** I see a handout from Kimmy [INAUDIBLE]. I'll let you have the last word, Kimmy.

**KIMMY:** Thanks. I know it's 6 o'clock, but really interesting conversation. Just a quick question about-- I think it was Professor Shepherd who raised the idea of employers mandating vaccines. And I'm wondering if the legal doctrine changes when you're

outside the school realm. Do states have broader police powers when it comes to mandatory school vaccines for children versus in a broader public or private sense?

**MARGARET**

So she's not here, but I can answer it. So not as an issue of state law because I

**FOSTER RILEY:**

couldn't tell you the state law piece. But OSHA has allowed employers to require flu vaccinations. So for example, at UVA, the health system requires, if you're in the health system, you can be required to get a flu vaccination.

Now flu has low safety, so low efficacy rates. But we also know it's got very good safety profiles. So I don't know that OSHA would do that with a brand new COVID vaccine. But I think that OSHA, in the right context for an employer-- let's imagine we get to a point with better safety and efficacy. You get to a point a meat packer requires its employees to be vaccinated.

I think OSHA would back them up because they can't work except being in a close context. It then ties into all sorts of issues with the ADA and what's a reasonable accommodation and can you do your work within a reasonable accommodation. And every one of those cases will be fact-specific.

**SAVANNA:**

Thank you.

**MARGARET**

Drew, you want to add to me?

**FOSTER RILEY:**

**DREW**

Not to you, no. I would never. I said one thing. Everybody who's been under this new paradigm from yesterday, I guess, was Jim Ryan's announcement. And this has been going on since 1802. I look at all of this happening through this lens, which is, back in 1802, in Mississippi territory there is a smallpox outbreak. And the governor said, if anybody goes out with smallpox-- and there was like 1,400 people in this settlement and no one else around for 300 miles-- so this was a self-defense mechanism.

But he said, anybody who goes out with smallpox, you're going to get fined \$100. And that's like \$2,100 today. So whatever is happening to us, it's not as draconian as that.

**MARGARET**

Do you recommend it?

**FOSTER RILEY:**

**DREW** What's that?

**CALAMARO:**

**MARGARET** Do you recommend \$2,100 fines?

**FOSTER RILEY:**

**DREW** No, I don't have that kind of money.

**CALAMARO:**

**SAVANNA:** I think that's the point then, Drew. You would stay inside, wouldn't you? Oh, Denny, you've got one question. Professor Riley and Schwartzman, thank you guys for sticking around with us for a few minutes. This is such a fascinating topic. I'm sure we'll [INAUDIBLE] questions. So Denny, go ahead.

**DENNY:** OK, sorry, I didn't mean to [INAUDIBLE].

**SAVANNA:** No, not at all.

**DENNY:** But I was just curious. And maybe you've covered this. I had to miss part of it. A lot of the mandatory vaccine seems to be all or nothing-- or sorry, all, basically. Have they thought about implementing the minimum number of people that need to be vaccinated and target that instead?

**MICAH** How would you do it? Are you thinking about a lottery?

**SCHWARTZMAN:**

**DENNY:** I think at least from a lot of my friends, a lot of people would just volunteer. And so you'd get a good chunk of people that are already volunteer. And I think there are medical minimums, at least statistic models, 75% of people need to be vaccinated to prevent large spreads of a certain disease.

**MARGARET** 60% either have seropositive or a vaccine. I don't think you can get to 60%, though,

**FOSTER RILEY:** without some sort of additional--

**DENNY:** Coercion, motivation.

**MARGARET** I mean, and that additional motivation may be such that you get to go to UVA.

**FOSTER RILEY:**

**DENNY:** Exactly, that leads to my follow up question, which is related, which is this also seems like a problem that Calabrese brought up in his model of free riders. People obviously benefit from having a society being vaccinated.

I mean, the fines seem like a liability protection. If you don't do it, you get fined. So I mean, can you combine the two to target maximum fairness?

**MARGARET**  
**FOSTER RILEY:** So when I'm feeling snarky, there's no question that antivaxxers are free riders in the sense that they know that there's herd immunity or they think there's herd immunity. And they don't actually frankly think about it in this equation. What they say is the measles isn't a problem because they don't see any measles.

Of course, they don't see any measles because of vaccinations. And then it ends up in this whole loop. But they are, in fact, free riders. They are not consciously free riders, but they are free riders.

I see pediatricians, the way they deal with this is they fire their patients. And that works actually. So it's another way of pushing things without a government mandate.

**DREW**  
**CALAMARO:** I'd just like to add to that in terms of-- and Professor Riley, you know this. It depends on the disease. So measles, you have to get over that 95% threshold. And I think every 5% less that people who are vaccinated for the measles, you get three times the amount of measles cases.

So it's exponential, it would seem like, in terms of the amount of-- I don't know. I'm not a mathematician. I'm a lawyer here. So that's what I know. So that's why you got to get rid of religious exemptions for something like the measles. But then you have pertussis, where the herd immunity rate's way less or any one of these other disease.

I think measles really is probably the big one that you have to worry about in terms of herd immunity. And then the rest of that stuff, if you really just push in terms of communication public health wise, then you can get above herd immunity and you don't need a mandate. But yeah, that's my opinion.

**MARGARET** Well, since I like to always end on a happy note, there are other viruses coming

**FOSTER RILEY:** down the pipe that could kill us better than any of these. So remember that.

**MICAH** Thanks for that.

**SCHWARTZMAN:**

**SAVANNA:** On that note, thank you so much to everybody who joined and asked questions. And thank you to Professor Riley and Schwartzman. And Professor Shepherd had to drop off early for another meeting, busy lady. But I really appreciate you guys being here and for taking all of our questions. And it's been really insightful.