

## TRANSCRIPT: THE CASE FOR NATIONAL POLITICAL (RATHER THAN STATE OR JUDICIAL) REGULATION OF HEALTH CARE

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My perspective on all of this will track a lot of what Ernie<sup>1</sup> said, actually. Except Ernie is a big fan of states and their ability to experiment and skeptical of federal power; and I, in the field of health care in particular, am a big fan of federal power, and I'm somewhat skeptical of how much states can contribute in experimentation or otherwise. This is still a very controversial position to take. I'm assuming that in this room it's an even more controversial position to take because I know we have a lot of state legislators and other state politicians here. But let me try to make the case briefly that federal regulation has some superiorities to state regulation in the field of health care and then I will move on to thinking about *Sorrell*<sup>2</sup> and also the ACA [Patient Protection and Affordable Care Act]<sup>3</sup> litigation in a little bit.

My view on federal regulation is that there are certain things, particularly in health care, that the federal government brings to the table that the states are incapable of replicating for themselves. One, we like uniformity of rules across state lines for the sake of entities—private entities, regulated entities—that have presences in multiple states. Pharmaceutical corporations are a good example of this, right? So we like the idea of federal tort reform for pharmaceutical rules, and federal preemption and FDA regulation in this field, because pharmaceutical companies need to have consistent standards across state lines in order to operate most efficiently. Otherwise compliance costs are going to be much higher as they try to tailor their labels and their safety standards to fifty different legal regimes. States are not capable of creating that uniformity except very expensively through horizontal federalization, where they have to coordinate with each other and set the same legal standards in all fifty

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† Please note that the Speaker reviewed and edited this Transcript. Language added by the *Vermont Law Review* appears in brackets, and ellipses indicate omissions of language.

1. Ernie Young, Alston & Bird Professor, Duke Law School.

2. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

3. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified in scattered sections of 26, 29, & 42 U.S.C.).

states. That is a lot more expensive than just having Congress do it, which is why we have Congress.

Second, the federal government can correct interstate spillovers. If one state has a weaker regime than another state in terms of regulation, and draws a whole bunch of companies into that state at the expense of other states, then there might be something like a race to the bottom where states will compete to have the least restrictive regime possible; where maybe that kind of non-restrictiveness, that kind of libertarianism, is at the expense of safety regulations and things that are helpful. So the federal government can set a uniform standard in order to set the optimal level of regulation where states would compete in an adverse way that would either under-regulate or over-regulate compared to what is optimal.

All of that is not to say that states do not bring anything to the table. Obviously we like state control for the sake of experimentation. We like state control for the sake of diversity, voice, and exit, which are liberty-protective virtues of state control. If different states have different regulatory regimes, then Ernie doesn't have to go live in a single-payer system in Vermont. He can stay in North Carolina. And I can live in Massachusetts with my individual mandate; I don't have to move to those crazy places where they're OK with adverse selection. So it allows for individual residents to choose the policy realm that they like best.

My perspective on all of that is that the federal government is capable of capturing those same advantages of federalism and is capable of doing it even better than the states, through various tools that the federal government currently uses, and uses in health care regulation regularly. So for experimentation, Medicare runs demonstration projects on a regular basis.<sup>4</sup> It is capable of demonstration projects that are targeted to demographically representative areas instead of saying, "oh, single payer worked in Vermont so we should go use that now in Texas," even though we can't regress out all the differences between Vermont and Texas to know whether or not that's actually going to work—whether the translation is going to hold up. In fact, the experiment in Vermont tells us very little about whether or not the policy approach works or will work elsewhere. If instead the federal government says, "we're going to have single-payer systems in the following ten communities that are roughly representative of the United States and see what works and what doesn't," we might be able

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4. *Demonstration Projects and Evaluation Reports*, CTRS. FOR MEDICARE & MEDICAID SERVS., [http://www.cms.gov/DemoProjectsEvalRpts/01\\_Overview.asp](http://www.cms.gov/DemoProjectsEvalRpts/01_Overview.asp) (last visited Mar. 20, 2012).

to get much better experimentation. The federal government doesn't experiment like that today because it doesn't see that as its goal or as its role, but I think it could and I think it could do a much better job than state experimentation, which is all sort of uncoordinated.

Second, with diversity, voice, and exit, we're seeing that happen right now with HHS's [Health and Human Services] implementation of the ACA. As states are resisting the individual mandate and various other aspects of the ACA, HHS is saying, "OK, we'll give you waivers to get out of the things that you really hate." And so to the extent that there are citizens [who] are really, really resistant to what the federal government wants to do, the federal government can say, "OK, you can get out of the things that you really hate but you're going to do it through a federal control that at least has the capability of looking around and saying, 'Well what is OK to let states get out of and where do we need uniformity? Where do we need spillover prevention? Where do we need more consistency in the policy approach that's being taken?'" So in my view the federal government is in a position to be able—particularly in an information age where we can get better information about what policy preferences are, where we can get information about what the right policy, what the optimal policy approach is—the federal government is in a position to do a really good job of capturing all the benefits of a federal system without needing strong state policymaking authority—strong state sovereignty.

All of that said, I really don't like *Sorrell* as an opinion and I'm actually more comfortable with the idea of having the Supreme Court invalidate the ACA under the Commerce Clause.<sup>5</sup> So why? There's something worse than having states be in charge and that's having courts be in charge. If courts are putting themselves in a position to review the policy approach that we're taking to try to regulate something as complicated as health care, they have to do it on a case-by-case basis—where the courts are looking at something discrete that's being challenged in front of them and asking, "Is it OK for you to prohibit data mining?" To answer that question well, we need to look at it in the context of a much bigger regulatory approach to drugs, drug policy, generics, branded drugs, and safety standards—most of which happens through FDA regulation. There are so many moving parts to that regulatory scheme beyond just, "Is this commercial speech that should be protected under the First Amendment?"

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5. U.S. CONST. art. I, § 8, cl. 3.

And courts don't have that wide-angle lens that they can take to something like health care regulation.

So if we use the First Amendment as a way of stopping the states from experimenting—by the way, the First Amendment is not a federalism doctrine at all, right?—the First Amendment will also stop the federal government from experimenting in exactly the same way. So I don't mean to say that this was a federalism case at all, but by using the First Amendment to try to get rid of health care regulations we don't like, we're putting courts in a position of evaluating the usefulness of those regulations. Under strict scrutiny, compelling state interest is an inquiry that the courts have to make. So if we use the First Amendment to get rid of a suspicious regulation, the courts will put themselves in a position of evaluating the usefulness of every regulation compared to the threat to First Amendment liberties, and I don't think judges are very good at that—at evaluating what health care policy should be.

What if instead we use structural doctrines to create barriers and to raise enactment costs of things that look substantively suspect? Here we go back to what Ernie was saying: the ACA litigation is really about a threat to liberty. It's really about something *Lochner*-like,<sup>6</sup> where what we don't like is forcing someone to buy something. That to me is a good reason to say that the federal government should not do this *yet*. This is something that's suspect, this is something that just on a quick sniff test looks like maybe we're not ready for it, so let's stop the federal government from doing it. The states can do it if they want. Massachusetts, you're fine. If that's the approach that you like then, you know, keep going with it. All that that's doing is raising the enactment cost of the particular approach that the judges are a little bit suspicious of by making fifty states act independently if the suspicious regulatory approach is going to be enacted nation-wide. The holding, though, allows the states to try it.

Furthermore, the holding even allows the Congress to try it in different forms, maybe, that are politically harder to pass. So it would be OK to pass a tax deduction to accomplish the exact same result of the individual mandate, right? The holding might be, "You can't penalize people for failing to buy insurance, but you can reward people for successfully buying insurance and carrying insurance." That looks like what the courts are saying at the lower level. But it's politically harder to pass a reward for

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6. *Lochner v. New York*, 198 U.S. 45 (1905).

having insurance because that requires raising everyone's marginal tax rate to give them back a deduction. That's going to make it much harder to pass.

So when judges use structural doctrines of these kinds to try to get rid of suspect policies, all they're doing is making the policies harder to pass, but not making them impossible to pass, and not putting themselves in the position of evaluating the cost-benefit balance of the particular regulatory approach—not putting themselves in the position of doing strict scrutiny. So for me, I like the structural doctrines, the federalism doctrines, better than the substantive doctrines as a way of trying to push back on potentially problematic policies. Particularly in the area of health care where it seems to me that, because everything is interconnected, we need a holistic approach that only legislatures are really capable of putting into place.

That said, the other thing that Ernie mentioned: One place where judges are becoming increasingly involved is in dormant Commerce Clause cases, and it would have been possible to issue the exact same holding in *Sorrell* by using dormant commerce analysis. To make the exact same challenge (it would have been up to the litigants, but) it would have been possible to present a similar challenge on dormant Commerce Clause grounds and to have said that this creates uneven regulation for pharmaceutical companies that need to craft different marketing approaches for different states according to different rules about what kinds of data they're allowed to use and not allowed to use. And that interferes with interstate commerce from the point of view of the pharmaceutical company. That holding would have been better in my opinion than the First Amendment holding<sup>7</sup> because it would have allowed Congress to step in and say, "Well, we want this approach or that approach to try to regulate health care." So from my perspective the *Sorrell* opinion is more problematic than a potential ACA opinion despite the fact that I like federal control better than state control. I like political control better than judicial control even more.

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7. *Sorrell*, 131 S. Ct. at 2659.