TRANSCRIPT: *SORRELL V. IMS HEALTH* AND THE SHIFT TO REGULATION BY PAYMENT

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I would first like to thank the organizers for putting this conference together. This is a great conference in a few dimensions. For one thing, it is a joint venture between two law schools. For another, there also is a good mix of scholars and folks who have actually been involved in the litigation.

I teach both constitutional law and health law. My remarks will veer a bit more toward the health law and pharmaceutical policy directions. In keeping with that theme, and to place the Supreme Court's *Sorrell v. IMS Health*[1] decision in context, I want to start with a century-old quotation from Roscoe Pound, who talked about the distinction between "the law in books" and "the law in action."[2] I think that distinction helps us have perspective on the *Sorrell* case and related cases.

This is an instance, of course, where the law in books is in a very canonical book—the Supreme Court Reports—and from a canonical institution of constitutional law—the Supreme Court. It touches upon an issue of policy that is among the most pressing and important that we face: health care policy and the effort to control and manage health care costs. Therefore, one would think the Court's decision in *Sorrell* is very important.

I assert that it is less important than we might think, and the reason it is less important says much about our federal system—and not just about the vertical dimension of federalism, but rather about the elastic, redundant, multi-modal form of the American legal system. To put it more simply, while *Sorrell* may have blocked one means toward the ends of health care and pharmaceutical cost control, there are alternative—and perhaps more effective—pathways to achieve these ends. Even during the pendency of the litigation, we see government beginning to go down these alternative pathways. In other words, the lesson that we can draw from *Sorrell* is that the American federal system offers multiple and redundant pathways to achieve policy goals. In this way, the Supreme Court's controversial disabling of one policy mechanism might merely force policymakers to think about other means to achieve the same end.

This suggests that we as legal scholars perhaps focus too much on the Supreme Court and too much on certain areas of highly visible doctrinal

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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. Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011).
2. Roscoe Pound, *Law in Books and Law in Action*, 44 AM. L. REV. 12, 15 (1910).

constitutional law. In the federalism context, it suggests that we focus too much on a concept of mutually exclusive state and federal jurisdiction, which is very prevalent in the debates over the Affordable Care Act.[3] We perceive that something is either a federal question or a state question, when in fact the vast majority of American regulatory policy plays out in a concurrent, overlapping, and much more complex regulatory space. In the area of pharmaceutical regulation and pricing, that is clearly true.

The last lesson I draw from *Sorrell* is that it illustrates that we are in the middle of a fundamental paradigm shift in the way both federal and state governments regulate primary behavior. In the older "New Deal paradigm"—which is what the Supreme Court operated on and disabled in the *Sorrell* case—the government acted as a command-and-control regulator of primary conduct through generally applicable laws. By contrast, the newer, twenty-first century model—what I call "regulation by payment"—relies much more heavily on the government as spender or payer. Under this model, the government attaches regulatory strings to funding medical care and paying doctors, such that it can simultaneously pay for patients' medical care while incentivizing certain kinds of purchases. We are only at the beginning of this dimension in the health care area, and particularly in the Medicare and Medicaid systems. Ultimately, I think this shows that we're moving from a realm of regulation by broad-based rule to a realm of regulation by payment, at both the state and federal level.

On this theme, I want to discuss a different case from about ten years ago where the Supreme Court notably disabled another policy initiative in the health care area. That case related to the FDA's efforts under President Clinton and Commissioner Kessler to regulate cigarettes in the middle and late 1990s.[4] You will remember the FDA's ambitious legal jurisdictional claim that, for the first time in over half a century, it had the authority to regulate tobacco.[5] You will also recall that a few years later, in the 2000 *FDA v. Brown & Williamson Tobacco* decision, the Supreme Court assertively—although by a hotly divided 5-4 margin—denied the FDA's jurisdiction to regulate tobacco and smoking.[6] I think that I am one of the few people who supported greater smoking regulation who also thinks the Supreme Court was probably right in that ruling, largely for the reasons that Justice O'Connor laid out in the majority opinion.

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3. Patient Protection & Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010), *amended by* Health Care & Education Reconciliation Act, Pub. L. No. 111–152, 124 Stat. 1029 (2010).

4. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125 (2000).

5. *Id.* at 127.

6. *Id.* at 133; *see also id.* at 161 (Breyer, J., dissenting).

However, what is interesting in light of all this legal debate was the really ambitious policy claim the FDA made when it promulgated its tobacco control regulations in 1996. It had a wealth of data to support its belief that smoking was a problem.[7] It asserted its intent to regulate tobacco more intensively and to reduce youth smoking by 50% between 1997 and 2003.[8] This was a very ambitious goal—to cut smoking in half among people under eighteen—for an addictive product backed by a big industry. Of course, the Supreme Court later held that the FDA could not regulate tobacco. Interestingly, what happened to youth smoking rates over that very same time period is that they dropped at a rate almost equal to what the FDA suggested its authority was necessary to achieve. In other words, youth smoking rates—without the FDA's help—dropped almost 50% in the six-year period between 1997 and 2003.[9]

Why is that? The reasons behind this drop, I think, are relevant to the discussion surrounding the *Sorrell* case today. In fact, other institutions and other legal forms in American law operated simultaneously to put pressure on the tobacco industry to change norms and practices. There were tax policies that placed higher taxes on cigarettes.[10] The states also played a crucial role. A number of state Attorneys General filed and settled lawsuits against large tobacco companies, and a number of state public health departments engaged in aggressive anti-smoking campaigns.[11] Ultimately, there was this multi-modal, eclectic mix of power brought to bear that achieved the very same goal the FDA claimed could only be achieved through its own regulatory apparatus.

That story, I think, fits with the assertion I am making: that the U.S. legal system—both in its vertical federal dimension and in its horizontal, multi-modal dimension, between common law, agency rule, and spending power—operates in a redundant and a pliable way, at least as to policy goals that are broadly accepted. In the case of anti-youth smoking campaigns, that appears to have happened. I see the same thing happening now and would predict further responses in the realm of prescription drug pricing, even in the wake of the *Sorrell* decision.

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7. *See id.* at 134–35.

8. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,397, 44,573 (Aug. 28, 1996).

9. Centers for Disease Control & Prevention, *Cigarette Use Among High School Students–United States, 1991-2009*, 59 (26) MORBIDITY & MORTALITY WKLY. RPT. 797, 798–99 (2010), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm.

10. Centers for Disease Control & Prevention, *CDC Grand Rounds: Current Opportunities in Tobacco Control*, 59 (16) MORBIDITY & MORTALITY WKLY. RPT. 485, 487 (2010), http://www.cdc.gov/mmwr/pdf/wk/mm5916.pdf.

11. *Id.* at 488–89.

So in that sense, I think the decision is important: we ought to discuss it, critique it, and analyze it. However, it may be "walled-off" from the actual behavior that state, federal, and private payers engage in when deciding whether or not to pay for branded versus generic drugs. At bottom, for all the discussion of the First Amendment and physician privacy—which are clearly important topics—the New Hampshire and Vermont laws prohibited the sale of data to data miners in an effort to control drug costs.[12] At the time these statutes were passed, prescription drug costs were one of the most rapidly rising components of our national health care expenditure.[13] As we sit here today, drug costs are not among the more rapidly rising components of our national health care expenditure. Indeed, during the pendency of this litigation, generic drug use has increased dramatically, both in the medical system at large and specifically in the Medicaid system of the various states. At the time these laws were passed in the middle of the last decade, about 60% to 70% of total prescription drug sales paid for were generics.[14] Today, upwards of 75% of total prescription drug sales paid for are generics.[15] Even outside the Medicaid system, five or six years ago, about 50% of the drug prescriptions were generics; today, that figure stands at about 70% and rising.[16] We see a correlative benefit in the sense that the part of our health care expenditure matrix that is rising at the lowest rate—and that has actually flat-lined in the last few years—is prescription drug expenses, while physician services, hospital rates, and the like continue to go up and up.[17]

This suggests a few things. First, the Court's assertiveness (it is assertiveness, and perhaps even activism, as my co-panelists explicated very well) is important within "the law in books," as we speak—the law of constitutional doctrine. It may be less important, at least in this issue area, for the ultimate end goal of these statutes: to control drug costs. The reason this is so is because both federal and state governments have other means—indeed, much more effective means—to achieve the goal of cost control. Here I come back to the power of the purse and the government's ability to regulate through payment.

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12. *See* Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2660–61 (2011); IMS Health, Inc. v. Ayotte, 550 F.3d 42, 47 (2008).

13. *See* KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS 1 (2010), *available at* http://www.kff.org/rxdrugs/upload/3057-08.pdf; *see also* NAT'L CONFERENCE OF STATE LEGISLATORS, HEALTH COST CONTAINMENT & EFFICIENCIES: USE OF GENERIC PRESCRIPTION DRUGS & BRAND NAME DISCOUNTS (2010), *available at* http://www.ncsl.org/portals/1/documents/health/GENERICS-2010.pdf

14. *See* NAT'L CONFERENCE OF STATE LEGISLATORS, *supra* note 13, at 1–2.

15. *Id.*

16. *Id*.

17. *See* KAISER FAMILY FOUND., *supra* note 13, at 1.

Much was made in the *Sorrell* litigation about the vast amount of money that the pharmaceutical industry spends on detailing. The estimates vary, putting this figure at anywhere between $30 and $50 billion per year.[18] Even if we assume that the larger figure, $50 billion, is accurate, that number is dwarfed by the amount of money that public and private payers spend for prescription drugs in the United States, which runs to almost $300 billion.[19] When you consider government payers by themselves, Medicare and Medicaid spend over $80 billion on prescription drugs.[20] The point here is obvious: Reading the *Sorrell* opinion, the state's justification for this law was focused on the quite significant and quite frightening clout of the prescription drug industry in inducing prescriber behavior and thereby driving these costs up even further.[21]

However, there is quite a degree of centralized public and private power on the payer side to induce, incentivize, or even—through a refusal to pay for branded drugs—command compliance from prescribers. That ought to counteract the pressures of the detailers. And data would suggest that we have seen a policy response using that spending power. In the Veterans Affairs system, for instance, states and private payers have implemented prescriber restrictions, refusing to pay full price for branded drugs and imposing co-payments on patients in private or Medicaid structures for branded drugs versus generics.

Finally, I would like to close with some general thoughts. First, I think this notion of "regulation by payment"—as opposed to regulation by centralized command-and-control regulation—is the policymaking trend, at least in the health care area, for the foreseeable future. I would predict by the year 2025, the most important federal drug regulatory agency will not be the FDA—the flagship twentieth century agency—but the Center for Medicare & Medicaid Services—the one that decides for which drugs the government will pay. That transformation is already underway, and the big private insurance companies are making the same kind of formulary decisions.

The last concluding point that connects with my colleagues' excellent remarks is that we have—to use Ernie's vocabulary—a different double standard here. It's a double standard where the Supreme Court and the other

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18. *See* PEW PRESCRIPTION PROJECT, ACADEMIC DETAILING: EVIDENCE-BASED PRESCRIBING INFORMATION 1 (2009), *available at* http://www.mainemed.com/academic/resources/fact-sheet.pdf.

19. *National Health Expenditures: Historical*, CTR. FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.htm (last visited May 17, 2012) (scroll down and click on link for "National Health Expenditures by type of service and source of funds").

20. *Id.*

21. Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2661 (2011).

federal courts have nowhere articulated any kind of limitation or restraint on this phenomenon that I call "regulation by payment." There is a famous case that we all teach called *South Dakota v. Dole*.[22] In that case, states that took federal highway funds had to raise their drinking age to twenty-one-years old, or they would lose 5% of their total potential funding.[23]

Over a vehement dissent by Justice O'Connor, the Court sort of hand-waved at any serious federalism concerns and locked in place this "regulation by payment" paradigm: If the federal government pays or sends money down to the states, they can force the states to comply with the strings attached to that money.[24] The same principle holds if federal or state governments distribute money to physicians or universities: The government may attach really significant strings to the use of that money. The case that comes to mind is *Rust v. Sullivan*, in which the Court upheld a government regulation forbidding physicians who received Medicaid funds from discussing abortion.[25] Ask yourself which is really the greater burden on speech: Is it *Rust*, or is it not being able to sell one's data? Doctrinally, however, the Medicaid "gag rule" on abortion is okay, and this pharmacy law is not okay—and that distinction has everything to do with the receipt of government funds.

This is the new double standard. The new paradigm for the twenty-first century is the government regulating as payer rather than as first-order regulator, and the real neo-Lochnerism, in that vein, would be a reversal of *South Dakota v. Dole* and the Court really attempting to police the strings that come along with spending. I do not foresee that and I do not advocate for that, but it would truly subvert twenty-first century regulation. Thank you.

22. South Dakota v. Dole, 483 U.S. 203 (1987).
23. *Id.* at 205.
24. *Id.* at 206–09.
25. Rust v. Sullivan, 500 U.S. 173, 196–200 (1991).