SORRELL V. IMS HEALTH INC.:
HEALTH CARE INFORMATION COMES BEFORE
THE U.S. SUPREME COURT

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Cory Andrews: Good afternoon, welcome to the Washington Legal Foundation’s (WLF) Web Seminar series. I’m Cory Andrews. I’m Senior Litigation Counsel here at WLF and this is our second web seminar for 2011. I would like to thank all of you who are joining us live via our simultaneous webcast. As always, today’s program will be permanently archived and available for future viewing on our website.

For those of you that may not be familiar with the Washington Legal Foundation we're now in our 34th year of free enterprise legal advocacy. We started out as a litigating group exclusively and a vibrant Supreme Court practice remains at the core of our mission to promote the concepts of liberty and limited government. We've pursed amicus and original actions in over 1100 suits in federal and state court. Twenty-five years ago we decided to add a publishing arm, our Legal Studies Division, which publishes throughout the year in eight free-standing formats on a wide range of issues and our communications arm frequently produces Media Briefings, web seminars such as these as well as podcasts and other programs including our LegallyBrief short video series. We also maintain The Legal Pulse which is our legal blog. And we invite you after today’s program to explore our main website at http://wlf.org.

Two weeks from today, and on the next to the last day of the term, the U.S. Supreme Court will hear oral arguments in the case of Sorrell v IMS Health. This is one of those cases that has been somewhat overlooked in the popular media but is really quite a significant case. And in the interest of full disclosure, I should mention that WLF has filed three amicus briefs in the case in support of IMS, one in the trial court, one with the Second Circuit Court of Appeals and most recently in the U.S. Supreme Court.

The case involves a long time practice of pharmacies, which is to collect the prescription history of prescribers, doctors, and physician's assistants, and then make that data public for a variety of uses. Those uses include public health uses and prevention and disease control by the federal government, academic medical research by scholars, and a commercial use, namely the marketing of prescription drugs to physicians. Now, all of the information that is collected is de-identified under HIPAA, which means that any patient-identifying information is already stripped out although the prescriber's identity is retained.

In recent years, the New England states of Vermont, Maine, and New Hampshire have passed laws severely restricting the use of such data— but only by drug manufacturers for marketing purposes. Section 17 of Vermont Act number 80, which was passed in 2007, prohibits the use of such data by drug companies for marketing to physician
prescribers, unless those prescribers sign and file a written consent with the Vermont Department of Health. Now Vermont claims that the law is necessary to protect the patient-doctor relationship and to help control health care costs.

And so is this a privacy case? What First Amendment protections extend to exchanges of valuable data if any? Would Vermont’s loss of this case strengthen or weaken the doctor-patient relationship? These are only some of the questions we hope to answer today. Before introducing today's speakers, a quick programming note: If any of our online viewers have questions they would like to put to our group of esteemed experts, they can do so by emailing their questions to interactive@wlf.com. And we'll try to include those questions during the Q and A at end of today’s program. We've got a great panel for you today, and I will introduce the speakers in the order in which they'll speak.

First, Deven McGraw. Ms. McGraw is the director of the Health Privacy Project at the Center for Democracy and Technology (CDT) which is focused on developing and promoting workable privacy and security protections for electronic personal health information. Ms. McGraw is active in efforts to advance the adoption and implementation of health information technology and electronic health information exchange to improve health care. She was one of three persons appointed by the U.S. Secretary of Health and Human Services to serve on the health information technology policy committee, a federal advisory committee established in the American Recovery and Reinvestment Act of 2009. Prior to joining CDT, Ms. McGraw was a chief operating officer at the national Partnership for Women and Families. She's also worked as an associate in the public policy group at Patton & Boggs and in the health care group at Ropes & Gray.

Following Ms. McGraw will be John Verdi. Mr. Verdi is senior counsel to the Electronic Privacy Information Center (EPIC) and director of EPIC’s Open Government Project. His work focuses on legal issues relating to consumer privacy, digital security, government surveillance, and open government. He supervises ethics litigation programs, litigates FOIA requests, and files amicus curiae briefs in the Supreme Court and federal circuits. He's co-editor of Litigation Under the Federal Open Government Laws 2008, and regularly speaks on privacy issues at conferences and in the media. Before joining EPIC, Mr. Verdi was a civil litigator in Washington, D.C., and his experience includes matters relating to federal and state open-record statutes, APA claims regarding federal oversight, and tort cases involving digital information, misappropriation, and misuse.

And batting cleanup, Richard Samp. Mr. Samp is chief counsel of the Washington Legal Foundation. He regularly litigates in federal court in support of broad First Amendment protection for commercial speech rights. Some leading Supreme Court commercial speech cases in which he has played an active role include Nike Inc. v. Kasky, and Greater New Orleans Broadcasting Association v. United States. He has authored WLF briefs in cases involving challenges to state laws prohibiting the commercial use of prescriber identifiable data, including all of the amicus briefs filed in this case. He’s a 1974 graduate of Harvard College, and received his law degree from University of Michigan in 1980. Before joining WLF in 1989, Mr. Samp was a litigator in the Washington D.C. office of Shaw Pittman. Deven, we'll start with you.
Deven McGraw: I don't think I've been at a podium that looks quite like this since my moot court argument in the first year of law school. Suddenly I'm going to get really nervous. And, thank you for that kind introduction. Thank you for allowing us to be here. We are probably the only party sitting at the table that did not actually file a brief in this case. But we do think that there are important issues to discuss that are raised by the briefs. Our issue was that we didn't actually care who won necessarily in terms of whether the statute is or isn't upheld so we didn't field a brief on one side or the other but we have done some significant work on HIPAA de-identified data. We had a stakeholder forum in 2009 and issued a paper as a result of that talking about how de-identified data, the standards under HIPPA, for which there are some, which I think we have to level set at the beginning. But there are standards for de-identification of health data that comes out of HIPAA-covered identities, which is the bulk of the data at issue in this case. There are no such standards for anonymization or de-identified data that comes out of the Internet.

And it's a significant distinction that's an important one to raise. Because many of the instances of re-identification that are raised in some of the briefs that take place in the Internet context, in fact, that data probably wouldn't survive but for the de-identification analysis, because that standard doesn't apply in that space. So, we have a great interest in cases that are about de-identified issue data. We have a great interest in having regulators pay a bit more attention to de-identified data than they have. But I want to keep my remarks focused to this case. And we have two main points to make here. One is that we actually share the concerns that are expressed by Vermont and amici, including John's organization EPIC, about the potential expansion of the corporate free speech doctrine to invalidate statutes that are legitimately enacted to protect individual privacy.

The problem here is that we don't think this statute was legitimately enacted to protect individual patient privacy in particular here are overbroad and the assertion of a prescriber's rights to privacy is misplaced. Behavior of physicians and other prescribers is routinely scrutinized by federal and state regulators, licensing boards, and accrediting organizations. Private organizations like Health Plans routinely look at the behavior of prescribers in an effort to improve the quality of our health care system and reduce costs. This is really critical work, that if there were a broadly-recognized interest in prescriber privacy, as asserted by some in this case, would be hugely problematic to conduct some of those activities. So, we're very concerned about the potential for the Court to recognize a prescriber right of privacy in this case, and what the parameters of that would be for the future of some of these very important initiatives.

Now, with respect to the patient privacy issues, we actually...let me step back and say that we have raised concerns about the HIPAA de-identification standard. We do not think that it's in exactly the right place that it needs to be. We are gravely concerned that the safe harbor method which is one methodology for de-identifying data, just requires the removal of 18 specific identifiers, and you have reached the nirvana of de-identification. And when you've reached that, it falls completely out of regulation. Even
though it is acknowledged to be de-identified data, no matter how stringently you de-
identify it, it never raises zero risk.

So a completely hands-off approach to regulation makes absolutely no sense here, and
we need to do some work on this standard. First of all if we're going to have a safe
harbor standard, we need to be continually examining it to make sure that it continues
to be robust enough to reduce the risk of re-identification to that very low level, which is
the one we want, in order to free its use, for a lot of other important purposes. And we
need prohibitions against re-identification. We don't have those because we sort of treat
it as though it's non-regulable.

As a result, if someone were to inappropriately re-identify it, we would have no legal
means other than potentially breach of contract where such a contract exists in order to
hold people accountable. And that's not a good legal environment for actually
encouraging the use of de-identified data which is really what we ought to be doing.
Data use in less identifiable form when it's protected against re-identification raises far
less risk, and we have a lot of important uses of health data, that are beyond treatment.
They all fall into that bucket of secondary uses that people talk about, whether it's
research, whether it's public health, whether it's back office operations, or business
analytics. They're all driven and made better by data.

And far better for us to be using this in de-identified form, the least identifiable form
possible, to protect patient privacy than to use it in fully identifiable form. And I fear
that, in some cases, people have used the perceived weaknesses, and some of the attacks
on the de-identification standard, as suggesting that the two types of data have now
been conflated and they're all the same. I actually don't think anybody sitting in at this
presentation believes that but that has certainly been asserted by a number of folks and
it's very dangerous for setting up a set of privacy policies that allow us to use data for a
range of very important public benefit purposes without it being identifiable in raising
undo privacy risks.

Now, having given my schpeel about de-identified data and how we really feel about it,
are those issues actually implicated in this case which sort of takes the Vermont statute
takes the HIPAA de-identification data standard as a given? It's only HIPPA de-
identified data that they are approaching in this case. It's prescriber identified as Cory
stated, it's patient de-identified, they take the HIPAA standard as a given and then
regulate it on the prescriber identifiable standpoint.

The statute does absolutely nothing to address the weaknesses that we have exposed,
and others have exposed in the de-identification standard. And in fact, one could,
because the statute permits the use of the data for marketing purposes, as long as the
prescriber has consented and doesn't prohibit any other uses of patient de-identified
data, one could argue that it's not actually aimed at patient protection at all. So, because
of that we are very concerned if in fact were the Court to suggest that patient privacy is
at issue, and that was one of the primary reasons why the Vermont legislature enacted
this statute. It then becomes very dangerous from our point of view to have the Court
potentially striking it down on First Amendment grounds, because from a privacy
advocate standpoint the worst thing that could possibly happen in this case is for there
to be legitimate patient privacy rights recognized as being protected by this legislation and nevertheless they be trumped by a stronger corporate First Amendment right that has set a very dangerous precedent for legitimate privacy regulation that would be very difficult to overcome.

So with that I will close. I’m looking forward to the questions. Thank you very much.

**John Verdi:** Thank you. First of all, a word about EPIC. I am senior counsel of the Electronic Privacy Information Center, and we are a Washington D.C. nonprofit dedicated to advancing constitutional interests and privacy rights. We’ve been around since about 1994. For the purposes of my discussion today, I’m going to assume that the speech at issue here is commercial speech, and that the court is going to apply or at least attempt to apply the *Central Hudson* analysis.

Now, other *amici* in this case have argued that these data flows are not speech at all, they’re not commercial speech and they’re not any kind of speech. And they may be right in that analysis. It’s certainly outside of my expertise to have an informed discussion about whether that’s true or not. And some folks have suggested that this case might be an opportunity for the court to revisit, or even overturn the *Central Hudson* framework. Given my lack of a Bat Phone connection to the Supreme Court and lack of ability to predict what the Justices are going to do in any particular instance, I’m going to take no position on that possibility and assume that *Central Hudson* is still good law in the minds of at least five of these Justices.

So the real question is whose privacy is at stake here. Certainly physicians’ privacy is at stake. Their names are on these prescription records and these prescriber-identifiable records are explicitly regulated by the statute at issue. Other *amici* have addressed their support for the law on that basis and I would leave it to them to discuss that in great detail. EPIC’s brief, however, focuses on patients, which is the other group of individuals who we believe have privacy interests at stake here.

First of all, we think there’s a clear privacy interest that patients have in their prescription records. I think as a baseline matter that is undeniable. And the reality is that you either cannot, or companies like IMS and Verispan do not, collect prescription information concerning prescribers, without collecting prescription information concerning patients as well. And the question arises – alright, why do patients have an interest in this? Isn’t this data anonymized or de-identified anyway?

It’s a good question, but the reality is that this data is not *anonymized*, as Deven said, this information is *de-identified*, which is different from anonymization. What happens is the patient’s name and other personally identifiable information on the prescription record are de-identified by using a cryptographic algorithm to obscure the name itself, but to maintain a unique identifier. So that individuals looking in this particular database would be unable to tell on its face whether or not John Verdi had prescription records in this database. But if I did, my prescription unique identifier 19225 would be accurate and accurately tie all of my prescriptions together across a number of different prescribers. And what that means is that the data is more useful to pharmaceutical companies and others who want to get a snapshot of how prescription practices
interrelate across patients and how they interrelate across prescribers. But it also makes this practice dangerous. So rather than actual anonymization, what you have is de-identification and the particular de-identification technique that’s implemented in this case by IMS Health, the plaintiff in the original matter, is a cryptographic technique called MD5, and they use MD5 to hash or obscure the names and some other data and to assign this unique identifier. The trouble of course is that this particular cryptographic technique is deeply flawed. Security analysts and security professionals have called into question the efficacy of MD5 for a number of years. And as recently as 2008 and 2009, there have been a number of demonstrations of individuals’ ability to circumvent or crack the MD5 algorithm. Such an attack on the prescription data that is contained in these databases would essentially allow the complete re-identification of all the patients in the databases because it would take away the de-identification, it would take away any semblance of anonymity, and it would be a disaster from a patient privacy perspective.

Now even if the MD5 de-identification technique were perfect, even if it were mathematically and cryptographically unassailable, patients are at a real risk of re-identification from this sort of record regardless of the efficacy of that particular algorithm. A number of security experts have done very influential work in the re-identification field. They’ve noted that you can re-identify medical records to a very high degree of certainty using only three factors: gender, zip code, and date of birth. That essentially enables an individual to be re-identified to high degree of certainty even though their home address and their proper name is not revealed by the prescription record, and in this particular case, it’s clear that the prescription records continue to contain gender, zip code, and age, which is a fairly good proxy for date of birth. It’s not perfect, but it would enable re-identification to a slightly lower degree of certainty. You also have techniques that could include a combination of prescriber IDs and drug IDs that could be used to re-identify patients particularly in a small sample like the state of Vermont. You have a small pool of prescribers, you have a relatively small pool of patients relative to the country as a whole, and re-identification based on those sorts of techniques is possible.

There are several public examples of re-identification of supposedly de-identified databases. Individuals have been re-identified and de-identified databases released by America Online, released by Netflix, released by other Internet companies who took steps to cryptographically de-identify that data. Yet enough personally-identifiable information was preserved that individuals were able to be re-identified. Not every individual was re-identified in these cases, but some were. And these sorts of databases containing prescriber information and prescription information pose the same risk to patients. All of these risks are heightened when you have a small sample like the state of Vermont. And I think it’s instructive that the three states that have enacted these laws, Vermont, New Hampshire, and Maine are not only regionally similar, but they are also similar from a population perspective. These are small states dealing with relatively small pools of prescribers, relatively small pools of patients. And re-identification in those cases is slightly easier than it would otherwise be in large cases.
Now, why does this matter? It matters because, this law is flawed. It's not a perfect law from EPIC's perspective and certainly if we were enacting in the Vermont legislature a prescription privacy law focused on patient privacy, it would not hinge on the prescriber's ability to opt out, or a requirement to opt in, to that sort of disclosure would not hinge on a proxy. In addition, it would not relate to only disclosure of marketing purposes. I think for a meaningful medical privacy legislation at the state level in this area, you really have to look at laws that regulate the use of prescription data that can be used to identify, or re-identify patients, for all purposes. And you need to give patients the legal right to ensure that their privacy is protected in those areas regardless if it's used for marketing or for another purpose. Just because the statute is flawed, doesn't mean that it does not provide some protection to patients. Or that it does not implicate patients' privacy issues at all.

And the critical question that needs to be asked, I think, by the justice system in this case, by the Vermont legislature, and by the lawyers who are arguing it, is to what extent corporate free speech, commercial free speech is going to prevent state legislatures and Congress from legislating privacy protections in the information age. When lots of products, including marketing data and other information and other deliverables are digital in nature and are essentially data flows, if the Court finds in this case, that commercial-free speech trumps the prescriber's privacy interest, the patient's privacy interest. Then, we are in, and I think everyone would agree, a very difficult position, a very unenviable situation in which lawmakers will not be able to regulate and impose common sense standards on the sort of data flows that we are seeing as drivers for the new economy. And I think that that is what is at stake here. And I think it's a critical case for both patient privacy and for prescriber privacy rights.

Thanks.

**Richard Samp:** Both I and the Washington Legal Foundation over the years have focused on First Amendment rights and I don't pretend to know the ins and outs of privacy rights to the extent of either Deven or John and I'm not going to try to take issue with anything that John said about the ability to crack various algorithms that had been developed under HIPAA to protect privacy. But I am here to say that I don't think that this case really is about privacy and certainly not about the privacy rights of patients. And I can say that confidently because the lower courts never at any time addressed issues of patient privacy. And for that reason it would be highly unusual for the Supreme Court to take the sort of steps that Deven fears, where the Court says yes this is about patient privacy, but nonetheless we don't think patient privacy is very important at all. That is not this case. That's not what's going to happen.

What's at stake here, to the extent that it's a privacy case at all, is the privacy rights of doctors versus the First Amendment rights of people who want to speak truthfully, and also the societal interest in making sure that information that's very valuable for a whole host of reasons other than marketing prescription drugs is allowed to be freely disseminated. Now from a First Amendment perspective, I am very interested in this case because it is really the first time in probably a decade that the U.S. Supreme Court has taken a careful look at commercial speech issues. Just very briefly commercial speech is basically advertising and the Supreme Court up until about 1977, said that
advertising really didn't have any First Amendment protection at all. Starting with the Virginia Board of Pharmacy decision in 1977, the Court has looked at a long series of commercial speech cases, but as I said, none in about the last decade. And what the Court has said is that advertising as long as it is truthful is entitled to significant First Amendment protection. But protection that's at somewhat less than what we consider fully protected speech, typically speech about issues of public importance.

Now, some people have been critical of what's been known as the Central Hudson test, which the Supreme Court has developed in order to balance commercial speech rights versus other interests that states may have. Some people have wanted to change the definition of what constitutes commercial speech. Others have suggested that perhaps there is reason to simply eliminate the distinction between commercial speech and more fully protected speech and to impose the same stringent standards on suppression of commercial, truthful speech that we will also regularly impose on other types of speech.

Frankly, I don't think that's going to happen in this case. I think that the Supreme Court is going to say that given that we have a case where even applying the reduced First Amendment protections that are usually invoked for commercial speech, that even under those standards, the Vermont law is highly suspect. The Court is likely to say we will assume that this really is commercial speech although the plaintiffs in this case argue strenuously that it is not. That they're not advertising. That they're simply conveying truthful information not for any purpose of selling a product but for the purpose of conveying truthful information that others can use for a variety of purposes. But the Court is going to assume for purposes of this decision that this is commercial speech, and it will most likely find that the law is none-the-less invalid under those standards.

And the reason that I'm reasonably confident about that is the Vermont legislature, in pushing this statute, didn't really intend to make this a privacy statute at all. As a matter of fact Vermont repeatedly said that its principal goal in adopting this statute was to correct an imbalanced market place of ideas. Vermont was very concerned that pharmaceutical companies were having too much, say, when it came to what kind of drugs doctors prescribed. As far as Vermont was concerned, it was interested in holding down health care costs. It thought that pharmaceutical companies were working against the interests of reduced costs by pushing doctors to prescribe new drugs that tend to be protected by patents, and therefore, whose prices are higher. As far as Vermont was concerned, it preferred that doctors would prescribe generic drugs that had been on the market for a long time. They weren't exactly the same drugs as the ones that were being pushed by brand name drug companies, but they cost a lot less money. From Vermont's point of view, these generic drugs would be almost as good, and certainly for the cost involved, it would be much better from the state's perspective if they were the ones prescribed.

Of course Vermont is very free to, if it wants to, to tell doctors that they ought to be prescribing these generic drugs. And in fact through use of formularies that's something that insurance companies do all the time. They say to a doctor: if you want to prescribe the more expensive drug for this particular use, we're not going to absolutely tell you you can't, but we're going to make you jump through a lot of hoops as a way of
encouraging you to prescribe the less expensive drug or else to justify to us why in your professional opinion the more expensive drug is required.

But Vermont is not satisfied with simply pushing its view as to proper prescription practices within the state because it feels as though there's this imbalance in the marketplace. The drug companies have a lot more money than the state does to push its view that the newer drugs are very often times better, and they're worth the extra cost. And so Vermont decided, well, if we can suppress the amount of speech that drug companies are using to promote their drugs, then perhaps we would have a better balance within the marketplace. And so Vermont decided that if we can stop drug companies from getting their hands on this prescriber-identifiable data, so that they can't know what particular doctors are prescribing, that'll be tougher for them to make their sales pitches. And so, that is the principle rationale for Vermont's law as well as the laws in Maine and New Hampshire. And, in fact, in the lower courts, that was the principal grounds on which Vermont defended its law. And it was only when it came to the Supreme Court that Vermont hired a new attorney, who realized, that this was going to be somewhat indefensible grounds under the First Amendment. Vermont has changed its tune and has been talking much more as though this is a case about privacy. Given the Supreme Court's repeated statements throughout its commercial speech cases that it is unwilling to allow states to prohibit truthful speech for the purpose of correcting imbalances in the marketplace of ideas. I can say with some confidence that the Court is going to be very skeptical of Vermont's efforts to turn this into a privacy case.

Well let me just very briefly talk about some of those privacy interests. And it is true, that Vermont did say in its legislation that one of its interests was an interest in protecting the privacy of doctors. But if what we're talking about is the privacy of doctors and not the privacy of patients, it has been proven throughout American history, that commercial entities have received far lesser degree of privacy protection than individuals. The cases throughout the common law have said that individuals have a right of privacy in what they do in their own homes and in what they do when it comes to their private affairs. But the moment that they step out into the commercial world or into the political world, and hold themselves out to the public, the public really does have an interest in the kinds of activities that those individuals are engaged in. And, the United States has filed a brief in this case, on the side of Vermont, but it very clearly says that we agree with those who say that doctors have significantly reduced privacy expectations.

In fact, of course, in this day and age, most doctors engage in the practice of medicine in the corporate form. And one of the black letter laws of privacy law is that corporations have no right of privacy, *per se* that an individual has the right of privacy, but corporations do not. And one of the reasons is that corporations tend to be entities that are engaged in commercial activity. Therefore, they have significantly reduced privacy expectations. Now that's not to say that states can't, if they want, change the common law, and pass the statute that provides new privacy expectations that did not exist in the past. But certainly the Supreme Court when it comes to balancing First Amendment rights against privacy rights will regularly look at what is the pedigree of those privacy
rights so that if the Supreme Court, as I expect in this case, decides that First Amendment rights to speak truthfully about the information that’s at issue here, which is the prescribing habits of doctors, that those First Amendment rights outweigh the privacy interests of doctors. That there is no reason for anybody to fear that somehow that will put at jeopardy the privacy rights of patients because historically, those two sorts of privacy rights have never been put on the same level.

One or two other points and then I will open this up to questions. There has been an argument raised that the First Amendment is not at issue at all, and the reason is that the government simply is denying access to information that the government has the right to control.

And that simply isn't the case here. If you have situations where the government has its own records and it doesn't want to share it with anybody, the failure of the government to release information has never been thought to be an infringement of First Amendment rights. However, the information that pharmacies and others have in this case about prescription habits of doctors is not government information. That's information that's within the private sector that pharmacies have long had access to and therefore, any time the government wants to deny the right of pharmacies and others to disseminate truthful information that's already in their possession, the First Amendment is fully applicable in those kinds of cases.

Now, the Supreme Court has had a few occasions to balance First Amendment rights against privacy rights, most prominently in a case called Bartnicki where the radio station wanted to broadcast truthful information except the truthful information consisted of telephone conversations that had been illegally wire tapped and the Supreme Court did have to engage in a balancing process, and I suspect that the court will have to engage in a similar sort of balancing process but just as in Bartnicki where the Supreme Court said that when we're talking about truthful information and when the speaker had nothing to do with the supposedly nefarious means by which the information was obtained that in that case, the First Amendment rights were thought to trump any privacy rights that were at issue. Well, I think again, so long as in this case, we're not talking about any privacy rights of patients and while John says they may be at issue, they were not raised below, that's not this case. I suspect in the end when the court does engage in its balancing process it will cite the Bartnicki case, and it will say the that whatever minimal rights that commercial entities have to personal privacy that those will be trumped by the right to speak freely about First Amendment issues. Thank you.

Cory Andrews: Before we begin Q & A, I just wondered is there anything on the panel that you would like to respond to or pick up on. I'll start with you, Deven.

Deven McGraw: I think, I wish I were quite so confident that the Court would not pick up the privacy claims that have been raised by Vermont. But I hope you're right again. Because I'm on John's side in seeing some serious concerns with corporate First-Amendment jurisprudence being expanded, and the balancing tests going in favor of the corporate First-Amendment interests in a statute that the Court somehow recognizes as
raising some privacy interest to be protected whether that's on the privacy or on the patient's side.

I think the other thing I'll say is that I read with great interest actually, EPICs brief and the criticisms of the cryptographic hashing methodology used by one or more of the respondents in that case, and we did mention in a piece that we wrote—of course, we did not submit a brief, again, as I said that these are concerns that we think that regulators ought to pay attention to and quite frankly, if in fact that methodology does not meet the de-identification standard under HIPAA, which it would be required to because this is data subject to HIPAA. We have, actually, legal mechanisms to prohibit the use of that data for a whole range of purposes including marketing. In fact you can't sell identifiable data for this purpose now under the law based on a change to HIPAA that congress made in 2009.

So, you know, I guess I'll say it again. There are some issues that need to be resolved with de-identification policy generally including whether the methodologies are sound, including whether a hands-off approach to regulation is the right way to do it. We just don't think they're raised in this case, and it would be dangerous for the Supreme Court to be raising it absent, sort of a full record developed in front of it to resolve it appropriately.

**John Verdi:** I'll tack on to what Devon said in terms of re-identification. One of the concerns that you often see in the cryptographic community is the idea of future-proofing. You try to future-proof cryptographic algorithms. You try to future-proof hashes. You try to future-proof other techniques. But the difficulty, of course, is that technology moves forward at a rapid pace. And the way that that implicates the issues specifically here are two attacks on this sort of de-identification process. One is the attack on the MD Five Hash itself. As computers get faster it inevitably becomes easier to crack than it is today even someone with a laptop can could crack it this afternoon. The second is that we don't know what publicly available databases are going to come online in the coming years and one of the techniques that's often used in re-identification is comparing de-identified data to publicly available data bases to try to figure out whether you can get matches between some of the tidbits of information and then in a particular confidence interval be able to re-identify that data. So not only do we have a problem with future proofing in the technology and in the math and in the functions. We also have a problem with future proofing because we don't know with the electronic health records that are coming online public and the other information that's coming online what publicly available health info is going to be out there either aggregate, de-identified, anonymized or explicitly just identifiable. And that attack could also become much easier in the coming months and years.

**Richard Samp:** If I could briefly respond? The kinds of information that the plaintiffs in this case want to convey, as far as I know, there is absolutely no evidence that some of the fears that John has raised have ever come to pass. There has been no history of patient information becoming identifiable as a result of the limited distribution of prescriber information that's at issue here. And in fact, the evidence is overwhelming that that's not the issue that Vermont looked at, and that it really wasn't adopting a privacy statute. I think the best evidence of that is that there's a hundred uses that you
can make of this prescriber identifiable information and Vermont didn't ban 99 of them. It said they're all fine. But the one kind of information, the one use you can't make of this information is you can't provide it to a drug company, so that the drug company can use it for marketing purposes. So that for example, if someone didn't like a particular doctor and thought that he had suspect prescribing practices, they could write an article in the Vermont daily newspapers about his prescribing practices and that would be just fine.

So, it seems to me we ought to await a real privacy statute before we decide that the privacy interests that have been expressed today are going to trump First Amendment rights.

**Cory Andrews:** Kind of picking up on that point Rich, is it true that there's nothing in the Vermont law that would prevent say a media outlet from obtaining all the prescriber identifiable data, and then publishing it on the Internet.

**Rich Samp:** I agree with that 100 percent but I'd be interested if John could respond.

**John Verdi:** Yeah, as long as it, as I said the Vermont laws specifically targeted at marketing and there's nothing in there now, that may come to prior, that may come into question under other statues but that...

**Cory Andrews:** Right but doesn't that take the wind out of the sails of the privacy argument that Vermont is making in this particular case?

**John Verdi:** You know, I don't think so because what it points out is the reality that the statute is imperfect, and there are lots of imperfect statutes out there that still pass constitutional muster. It doesn't mean that the privacy interest isn't sufficiently great and the statute doesn't address it in any specific way so that it weighs on the scale of the statute as against a commercial speech interest. There are lots of imperfect privacy statutes out there. In fact, I haven't yet seen a perfect one. Now I don't know whether you have. Perhaps you could introduce me to them after the panel.

**Cory Andrews:** No.

**John Verdi:** But simply because a statute is imperfect or a legislature did not get everything right, that doesn't give corporations a constitutional veto over the substance of the session.

**Cory Andrews:** Deven, I think you referenced this in your remarks, but many *amicus* briefs that were filed in the case in support of Vermont seek to obliterate this distinction between identifiable data, and de-identified data.

**Deven McGraw:** Right.

**Cory Andrews:** And they seek to do so in furtherance of patient privacy. Do you think that obliterating that distinction...would be helpful or harmful to patient privacy?
**Deven McGraw:** We think the distinction is very important. And again you know health data the primary purpose for which it's generated and used is treatment – treatment of individuals. But if we were to stop there and suggest that the data couldn't be used for other purposes we would be missing enormous opportunities from a public health perspective, from a research perspective, from a quality of health care improvement, and cost control perspective much less allowing health care entities to become more efficient businesses we'd lose all those opportunities essentially or we'd have to allow them to be done with more identifiable data versus creating a class of data, or classes, actually would be preferable, of data that can be used for purposes beyond treatment. But that, protect patient privacy by masking or stripping of identifiers.

Now, again, having said that, it's a really delicate balance from a policy standpoint. Because you cannot assume that this data, when you've stripped identifiers off of it. Whether it's through cryptographic hashing, or through the removal of identifiers that in the past have been used to identify people.

You cannot then assume that there is never going to be a risk to that data, and unfortunately that's the policy situation that we find ourselves in today. And that really motivates people to say, hey, this data, there really isn't a meaning, as meaningful a distinction or the distinction that used to exist is becoming less and less meaningful over time.

If we want to preserve the ability to use de-identified data, we need to protect that thing like a national treasure and stop treating it as though it raises no risk, put some regulation on it at a minimum to protect it, to have penalties for re-identification and maybe some, at least greater, transparency about its uses. Otherwise, we're going to continue to come up against these questions because people are really suspicious.

**Cory Andrews:** John, I know EPIC's brief focuses on the risk that prescriber-identifiable records can then be later used to re-identify patients. Putting aside that, you said in your remarks that you do believe that prescribers themselves have a recognized privacy interest upon which Vermont could rely here. I wondered if you might flush out what is a prescriber's interest in privacy, given, I guess as Rich points out, they're engaged in commerce, they're heavily regulated by the state, and they're engaged in matters that greatly impact public health.

**John Verdi:** Well, sure. I think a lot of those factors that you just described could equally apply to attorneys. Attorneys are engaged in commerce, they engage in matters that impact justice in the courts of a very real public interest. And yet no one questions whether or not attorneys and clients have confidential communications, have a right to engage in privileged communications concerning their ongoing litigation whether or not an attorney holds a work product privilege concerning the work that they do for a client. Now, certainly there are exceptions to that.

In legal malpractice suits, those sorts of privileges can be broken. Those privileges can be waived by attorneys and their clients but the idea that prescribers give up their right to privacy simply because they engage in a business, well let me tell you: we're not going to see doctors going out there and offering their services for free just to maintain their
privacy. These folks are engaged in commerce as much as a lawyer is as much as a builder is as much as anybody else is and yet at the same time they occupy a space of trust with their patients and I think that patients have an expectation that their doctor will be able to affect their privacy rights that their doctor will be able to stand as a proxy against others who want to transmit that sort of data and certainly there is regulation of narcotics prescriptions and other data there are insurance companies who have contractual relationships with doctors. The doctors enter those contracts freely. This sort of information the doctors aren’t operating the pharmacies. They aren’t consenting to the releases of the information. In fact, Vermont law allows doctors to opt in and consent to this sort of thing. All it does is require pharmacies and pharmaceutical companies and IMS Health and others to respect the wishes of prescribers concerning this sort of dissemination of their prescriber information.

**Cory Andrews:** Rich, you mentioned that one of the reasons that Vermont gave for the law was to “correct an imbalance in the market place of ideas.” It struck me remembering my days in law school, isn’t that one of the Supreme Court’s tests for whether you're engaged in view point discrimination or not, and isn't view point discrimination subject to strict scrutiny?

**Richard Samp:** In general, the Supreme Court has been very skeptical of any statutes that are not viewpoint neutral. In other words, the Court from time to time will say we will allow speech to be proscribed even though it's not content neutral for example we can ban speech within 100 feet of a polling place because it’s unseemly to allow people to get too near to the polling place so long as the state doesn't say that okay you can hand out literature for Republicans within a hundred feet of the polls, but you can't do it for Democrats. The moment that you are no longer viewpoint neutral in that way by allowing one side to speak but not the other side, that's considered viewpoint discrimination and the Supreme Court has virtually never upheld that, and that's exactly what is happening here. Vermont has what they call a counter detailing program where they go out and they try to provide information to doctors to stop them from prescribing more expensive drugs and in fact Vermont has access to the very prescriber identifiable information that's at issue in this case. Yet Vermont wants to deny that information to drug companies so that drug companies won’t be able to make the opposite arguments and that kind of viewpoint discrimination is generally considered an anathema under the First Amendment.

**Cory Andrews:** Seems that one of the questions that underlies all of this discussion is a premise. And I wonder if the premise has been sort of proven out by research or evidence. And the question that I'll just throw it out there is what evidence is there that the marketing of brand name prescription drugs to doctors will necessarily or even likely to result in those doctors prescribing drugs that are too expensive or that negatively impact public health. Does anyone know if doctors actually are making bad prescription decisions for their patients in Vermont after a visit from a detailer? Or whether this law would change that in any way, shape, or form? Or did Vermont ever make such a claim? Or did it ever try to establish this through any sort of investigation or findings?

**Deven McGraw:** I haven't exhaustively reviewed the record on this point, but I do recall seeing materials in amicus briefs filed by AARP as well as Vermont. And certainly
I saw it in the lower court case of IMS v. Ayott, where a similar New Hampshire statute was at issue. And I do think that the legislative record has evidence that was submitted by the proponents of the legislation indicating that in fact health care costs were raised by marketing of brand name drugs now whether that link was appropriately made in a statistically significant way in terms of whether all of the environmental impacts that drive a prescriber to prescribe one drug over the other. I do not know. I can't evaluate the evidence, on that basis, but I do know that it was submitted at the lower court level. At least, with respect to some of the other cases that have come up on similar statutes.

**Richard Samp:** I would like to make a couple of quick comments on that point. I think it's fair to say that companies don't spend a lot of money on advertising if they did not think that it would result in more of their products being sold. The problem with the findings of Vermont in this case is not that they were trying to say that increased advertising leads to increased sales, and therefore higher Medicaid reimbursement costs. Rather Vermont was saying, that if we can deny information to drug companies then they won't be able to advertise and market as well as they would otherwise. In other words there are no limitations imposed in this case on the right of the drug companies to knock on the doors of doctors and to try to sell their drugs. And of course there's nothing that stops doctors from saying, go away, I don't want to speak to you.

But what Vermont did was to make findings that if we can deny this information that somehow there will be less advertising going on and therefore less promotion of drugs. And we'll have less sales of these drugs and that causal link has never really been established other than Vermont in its legislation, legislative findings that uh saying by ipsi dixit that yes, that is so. And in fact most people assume that if drug companies cannot target doctors as well because they don't know exactly who it is that among cardiologists who are most likely to be prescribing their new cardiology drug. Therefore, they'll be doing more advertising. So it will be less efficient advertising, but there will be more of it, and there still will be increased sales. So, the idea that, that Vermont's law will accomplish its cost saving purpose, I think it's a very tenuous suggestion.

**Cory Andrews:** We do have some questions from our viewers and one of them is from actually the executive editor of the New England Journal of Medicine. And it's addressed to Mr. Samp, and it says “Mr. Samp, who is the speaker in this situation; who is it in your view who should have First Amendment protection is this speech or is this commercial conduct and can you comment on the distinction between speech and conduct in this case?”

**Richard Samp:** Well, when people move their lips and utter words, I generally consider that speech. There are two sets of plaintiffs in this case. There are the pharmaceutical companies that are claiming that by denying them information, it violates their First Amendment rights, but this case is known as IMS Health. IMS Health is a company that's in the business of collecting and analyzing information from pharmacies, then providing it to an assortment of people including medical researchers and universities, but also they provide to as their principal, the principal user of their information is drug companies. So, in my mind, the First Amendment rights of both of those groups are at issue. But given that the principal speaker is in this case, companies
like IMS, I would think that they are the ones, perhaps, that are the primary victims of the violation of First Amendment rights.

**Cory Andrews:** And another question, I’ll just throw it out there to everyone. If the Vermont law is upheld is there any danger that other types of information will fall under government regulation? And what dangers might be associated with that? So, I guess that's a slippery slope argument.

**John Verdi:** Sure. I wouldn't necessarily characterize it as a danger. I think that, certainly, if the Vermont law is upheld, I certainly think that other sorts of commercial speech might become subject to the same regulation or similar regulation. I think. The question you've got to ask yourself, though, is that this sort of “commercial speech” has been out there for a very long time. Governments are certainly not reticent to regulate in this area. And yet you have seen little regulation of this sort of commercial speech. So I don't know whether particular lawmakers, whether it's Congress or the states has, you know, a desire to regulate in this area. I will say that there's a very real danger that, as I said in my opening remarks as physical products, you know, the advertising billboard that you see as you go down the street, the magazine catalog that you get in the mail simply become data flows. There is a very real risk that a decision by the Supreme Court striking down the Vermont Law and incorporating in its analysis patient’s privacy interests here would open the door to an unregulated market in personal data online the likes of which we have not seen because there are certain baseline common sense regulations that the Federal Trade Commission enforces, concerning online data flows and online advertising concerning deceptive practices, fair practices that could come under constitutional scrutiny if the Vermont law is struck down so I don't necessarily see it as a danger but I do think there's a real possibility depending on how the court crafts its decision that this could have implications beyond the health care realm.

**Deven McGraw:** And I think going back to the points that I've been making repeatedly about sort of de-identified data, you know, the privacy issues that have been raised by Vermont and amici in this case on de-identified data, I see those questions coming up repeatedly. Over and over again. And yet we've so far not had any real genuine response to the concerns that have been raised from the policy makers. And so as a result, you're ending up with these cases being not exactly shoehorned, but these issues being, really I guess I will say being shoehorned into a case where we don't think they belong. Raising the very real risk that they could be decided in ways that could have, cause all kinds of problems for us down the road with respect to legitimate privacy legislation. As I said, if we continue to ignore the regular policy circles, where these issues really ought to be debated and considered and get full public transparency, we'll continue to sort of face problems like this one where we, it's a tertiary issue that might, in fact not be well treated in this forum.

**Richard Samp:** The real danger in this case is not the danger that privacy is going to be invaded because I think that the Supreme Court has a healthy respect for the privacy rights of individuals. Rather the danger is that we more and more see governments thinking that they can regulate truthful speech because they think that the consumers are better off not hearing certain sorts of truthful information. For example, the cigarette advertising is already pretty much totally prohibited. And we're constantly
seeing proposed legislation to limit advertising of other types of products whether it's cereal for children has sugar in it, whether it's advertising of products that supposedly contribute to the obesity epidemic in this country. There are any number of government regulators, if given the opportunity, would ban advertising on those subjects. And if you uphold the speech ban in this case, it seems to be that it would be a very easy thing for governments to say we can also step into those other areas.

**Cory Andrews:** We're just a little bit over time. I'm going to wrap up with one final question. Again, just, everyone's free to take a crack at it. If Vermont is. If the concern here is really about re-identification of patients, is there perhaps a better way for Vermont to prevent re-identification than this law? Which basically prevents the use of all prescribed identifiable information for marketing purposes?

**Deven McGraw & John Verdi:** Yes.

**Richard Samp:** I would say yes as well. I think where John and I would disagree is that John would say it's an imperfect law, but it still doesn't violate constitutional norms because it's better than nothing. And my view is that the Supreme Court has repeatedly said that an under-inclusive law is very suspect under the First Amendment. That if you're not really going to be protecting privacy that calls into question the legitimacy of your privacy rationale in the first place and therefore given the strong protection that the Constitution provides for the First Amendment, that we're not going to allow these sort of half-hearted laws. If you're going to protect privacy make sure that you really do it.

**Cory Andrews:** Thanks everybody. That's all of our time for today. We appreciate you being here.