

Information Technology and Innovation Foundation

Medical Data Innovation: Building the Foundations of a Health Information Economy

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Questions from ITIF Event Description

1. Do laws that burden or ban the use of de-identified data for marketing purposes also impede medical research?
2. Under the Constitution, can states that want to regulate the conduct of those who use data do so indirectly by restricting the factual data itself?
3. What would be the real-world consequences to health care and technological innovation if the laws restricting or banning particular data sets survive Constitutional scrutiny?
4. What privacy angles should be considered?
5. And more broadly, is de-identified medical data a public good or private property?

IMS Health v. Sorrell

- IMS, Wolters Kluwer Pharma Solutions, and SDI sued, alleging new VT law restricting commercial uses of prescription data violates First Amendment. PhRMA joined the case
- Trial court upheld the law. Ruling - the state interest in controlling costs and advancing public health justified its burden on speech
- Court of Appeals struck the law. Ruling - the law is an unconstitutional violation of commercial speech
- Supreme Court oral argument on April 26, 2011
- Ruling expected late June

What Data is Involved?

- Data from Prescriptions
- De-Identified as to Patients
- Identifiable as to Prescribers



Such data is **not** subject to HIPAA – HIPAA does not restrict the use of de-identified data, recognizing it poses miniscule privacy risks and its use is vital for measuring and improving health care

Issues in the Case

- Does the Vermont law violate the First Amendment?
- Which is the right Constitutional standard to judge it by?
- If the Rx data is commercial speech, does it survive the test:
 - (1) whether the speech concerns lawful activity and is not misleading;
 - (2) whether the asserted government interest is substantial; and, if so,
 - (3) whether the regulation directly advances the governmental interest asserted; and
 - (4) whether it is no more extensive than necessary to serve that interest.
- ✓ **2d Circuit ruled the law flunks the test for commercial speech**
 - ✓ Only cognizable state interest is reducing costs through more generic drug use
 - ✓ Law does not directly advance that interest (law attempts to influence prescribing by restricting speech of others)
 - ✓ Less restrictive means of advancing state goal are available, like promoting or mandating generics directly

The Supreme Court Oral Argument

- Sharp questioning of Vermont by Justices. Several “strongly suggested” the law violates free speech
 - *J. Scalia – let’s not quibble over the purpose of the law - the law’s purpose is to impede marketing of drugs*
- Discriminatory effects of law noted
 - *J. Roberts – such discrimination is problematic*
 - *J. Ginsburg – you can’t allow different decibel levels among speakers*
- Skepticism that the law didn’t use the least restrictive means
 - *J. Sotomayor – why didn’t you use an opt-out? Couldn’t doctors register for an opt-out just like consumers have registered their phones for Do-Not-Call?*
 - *J. Scalia – doctors can just say ‘go away’ to sales reps if they want*
- Vt and US argued because Rx data is mandated by law, government can control its release. Compared to privacy laws re: drivers’ license data
- Companies said HIPAA and other privacy laws are constitutional; only a narrow ruling striking VT law is needed

Public Policy Perspectives

- The state's cost control arguments
 - Generics – VT clearly wants to control costs by pushing generics over branded drugs
 - Use of generics is skyrocketing already - generics are 78% of prescriptions
 - Generics spending grew 22% in 2010 – brand drug spending declined 1%
 - The most expensive drug ≠ the most expensive overall treatment
 - Drugs that prevent surgery save \$\$\$
 - The cheapest overall treatment ≠ what is best
 - 30 – 60% of drugs ineffective today
 - 1000s of conditions lack *any* treatment
 - Death is cheapest option
- The state's public health arguments
 - Vermont says the public must be “protected” against new drugs [!!!!]
- Beneficial uses of Rx data – simply won't exist if business model for databases isn't viable

What is the Case NOT About?

Prescriber Privacy

- The laws don't actually shield prescriber privacy, for prescriber-identifiable data is still available for all other purposes except one
- Doctor cited on AMA website: "The insurers have my prescribing information, so I don't have a problem with the pharmaceutical companies having the same information."
- AMA opt-out already exists
 - only 5% have opted out
 - 96% satisfied or very satisfied with AMA opt-out

What is the Case NOT About?

Patient Privacy

- ALL the courts, including those upholding the laws, agreed patient privacy was not at issue
- Patient privacy is not jeopardized
- HIPAA de-identification standard is a high bar
- Misconceptions about HIPAA de-identification
 - Gov. Weld case
 - Netflix, AOL
- These data sets are subjected to safeguards even beyond what HIPAA de-identification requires

What is the Case NOT about?

All Privacy Laws

- **Easy to distinguish this law from genuine privacy laws**
 - **Free Speech case –**
 - Can government discriminate among speakers?
J. Roberts – problematic
 - Can government make it harder for some?
J. Ginsburg – adjusting decibel levels is forbidden
 - Was there a less restrictive way to advance the goal
J. Sotomayor – why don't you use an opt-out?
 - **Patient/consumer privacy not involved**
 - Even doctor privacy not involved
 - J. Scalia – let's not quibble – this law doesn't protect doctor privacy – at most, it protects doctors from having to say 'go away' to sales reps - the law's purpose is to impede marketing of drugs*
- **Other privacy laws that restrict speech still have to pass First Amendment scrutiny, and the vast majority do**
 - HIPAA, other laws, have already been upheld

Broader Implications for Innovation and Technology

- Troubling precedent of government restricting (and de facto eliminating) factual data streams because government disapproves of how one set of data recipients use the data
- Why block data if the goal is curtailing conduct of certain data consumers?
 - Real estate data?
 - If some realtors use MLS data for red-lining or block-busting, should MLS data be banned? Zillow data?
 - Financial data?
 - Facebook data?
 - Google data – searches? Earth? News? Maps?
 - Census data?
- Bottom line – law blocks private parties *in advance of publication* from releasing lawfully obtained, truthful, non-privacy-invasive factual data, if used in a way disfavored by the government. Moreover, these data sets are needed by patients and taxpayers to advance important health interests

For More Information

- [Amicus brief of Genetic Alliance and National Organization for Rare Diseases, U.S. Supreme Court, *Sorrell v. IMS Health et al*](#)
- [Argument recap: Yes, it's about commercial free speech](#), Supreme Court of the United States Blog
- [Hanna: US Supreme Court skeptical about Vermont's physician data mining law](#), Vermont Law School
- [Justices' Debate Turns to Privacy for Doctors](#), The New York Times
- [*Sorrell v. IMS Health et al*, Oral Argument Transcript](#) , April 26, 2011

Questions?

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