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Technology Change Raises New Legal Issue

- Electronic Medical Records (EMRs) allow us to tap patient data. They create great potential benefits as well as risks.

- How the law defines ownership of patient data will shape whether its benefits can be developed and affect patient confidentiality.
Use of Patient Data

• National, longitudinal data would allow monitoring and responding to public health problems not possible now.

• E.g., Tracking adverse drug reactions.
Current Law

• Treats medical *records* as physical property owned by doctors or hospitals.

• Allows patients and insurers access to records.

• Providers don’t have exclusive ownership of record’s data.

• Providers own records but not the *data*. 
Current Commercial Practice

Organizations with patient data sell it.

- They employ contracts that limit purchasers from disseminating data to third parties.
- They use technology that restricts use of data.
CONFIDENTIALITY

Patient data stripped of personal identifiers

Referred to as:

Anonymized data (or)

De-identified data.
Does compiling data create intellectual property (IP)?

Not today (in U.S.A.).

• IP law protects only original creations or inventions.
• But, commercial firms want to turn patient data into their property.

• And, even without copyright, there are obstacles to access to patient data.
Argument

• Treating patient data as private property precludes forming comprehensive databases required for public health and safety uses.

• Private ownership allows monopolies that will limit competition in the market for data derived services.
Proposal

1) Require providers to report anonymized patient data to public authority.

2) Public authority then:
   • Create aggregate data bases to promote public health, patient safety, and research.
   • Make data available for private parties to develop data-derived services.
Argument

There is no need to create private property to encourage production of patient data. It already exists.

Providers and medical organizations will collect this data to perform their work, whether or not they must disclose it, and even if they cannot sell it.
Public ownership would ensure the aggregation of patient data.

Private ownership would preclude most public uses and restrict many private uses.

The risks to privacy are no greater with public than with private ownership.
The Rise of Patient Data Markets

Firms, foundations and government policy all promote private data markets.

Conventional wisdom supports private ownership of patient data or maintaining current default rules.
• 2006 Heritage Foundation report advocates private ownership and contends that governmental authorities should have to purchase patient data on the same terms as all other parties.
AMIA in 2007 advocated that stakeholders voluntarily adopt guidelines for data stewardship, an shared access.

Stakeholders, with data access data include:

Provider organizations; personal health record service providers; insurance companies; health data exchanges; and health data banks patients, but not Public Authorities
The standards that these private entities develop will reflect the interests of those who want to sell data but not the interests of patients or the public.
Transform Your Commercial Model.

Your organization knows it needs to change its go-to-market strategy, but where do you start? And how?

About Us

IMS plays a central role in advancing global healthcare — revealing the insights within the most comprehensive market intelligence available.

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Headlines

IMS in the News: Launch Experience in Study Featured in IN VIVO

IMS Forecasts Global Pharmaceutical Market Growth of 5-8% Annually through 2014; Maintains Expectations of 4-6% Growth in 2010

IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $350.3 Billion

IMS in the News - Specialty Pharmaceuticals: Shifting Specialties, Medical Marketing & Media

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Events

IMS to Present at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Annual International Meeting
May 15, 2010

IMS to Present at Pharmaceutical Business Intelligence and Research Group (PBIRG) Annual Meeting
May 16, 2010

IMS Webinar: The Future of Commercial Models in Pharma
May 25, 2010

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• IMS over $2 Billion a year selling data
The Case for Public Ownership

1) No need for private ownership.

Physicians necessarily generate patient data as part of their work, to provide medical care, comply with health care regulations, and to receive payment.
2) *Value of Public Ownership*

- Patient data display network effects.
- Value of patient data in public domain.
Public Ownership Better Ensures Data Collection and Availability

• Public ownership is more efficient way than private ownership to collect data

• Without public ownership it may be impossible to create population wide-patient data.
Private Ownership Obstacles

Some data owners won’t sell or share data

- More profitable not to sell;
- Want to conceal information to protect themselves
Private Ownership: Collection Bias

• Private firms will only collect most profitable data
  – Selected information and populations

• Once such profitable data collected its harder to collect the rest.
Private Ownership: Unreliability

**Unreliable Source of Data**

• Can not ensure a stable source of data.

• Fluctuations in market demand can result in certain data not being collected
Private Ownership—No Single Data Base

• Antitrust law would preclude any single firm from owning all data make it hard to create a national data base.
Private Ownership—High Transaction Costs

• Creating multiple large competing data bases would be expensive.

• Each aggregator would have to negotiate with the data seller over price and other terms.

• Hold outs.
Private Ownership Restricts Use

Data owners tie data purchase to purchase of related services and products.

- Restrict competition for data services.
- Charge monopoly prices.
- When data publicly owned, multiple firms compete in market for data services.
Example of Private Restrictions 1

TRIPS restricts clinical trial data use by generic competitors to prove drug safety/effectiveness.

• Rewards investment in research.

• But conceals information on health risks.
Example of Private Restrictions 2

• Many drug firms delayed or blocked disclosure of research data on drug risks.
  — Led to requirement to register clinical trials.

• Doctors and medical firms have incentive to limit the data as protection from competition/oversight.

• Private firms that sell own data seek limits on government making data available.
Private Ownership Restrictions 3

• Anti-Commons Problem
• Patent Thickets
• Hold Out
Tragedy of Commons

• If a non-renewable resource is public and individuals don’t pay for their use, they lack incentive to use the resource prudently.

  – E.g. overgrazing/ over fishing
Tragedy of Anti-Commons

When “multiple owners each have a right to exclude others … and no one has an effective privilege of use.”

• E.g. Rusia post Soviet Union

• E.g. biomed research when ownership of basic building blocks for innovations are divided among numerous parties.
Anti-Commons for Patient Data

• Private ownership of patient data would fracture population data.

• Aggregators must purchase data from each individual.

• High transaction costs.
Can Markets Resolve Anti-Commons Problems?

• Kieff and Paredes and Hall argue that even when multiple parties can block a project, they still have incentives to cooperate to share net gains.
Rodwin turns a critical eye to the current proposals, ... suggests new directions for reform ... [and] offers important advice that policy makers must heed if we are to restore trust in our profession.” — Jerome P. Kassirer, M.D., Editor-in-Chief Emeritus, New England Journal of Medicine

“Superb, comparative, fascinating... A valuable historical study which is also a major contribution to conflict of interest debates in US and international health care policy, suggesting practical alternatives for the future.” — Rosemary A. Stevens, DeWitt Wallace Distinguished Scholar, Weill Cornell Medical College, New York City

“A wise, powerful, broad-ranging guide to saving the relationship between doctors and patients. Conflicts of Interest is meticulously researched and beautifully written. It explores the past, illuminates the present, and points us toward a promising future. We ignore Marc Rodwin at our peril.” — James Morone, co-author of The Heart of Power: Health and Politics in the Oval Office and author of Hellfire Nation

“Rodwin, whose earlier classic on medical conflicts of interest contributed importantly to the public debate, has deepened his analyses in a comparative perspective... He again enlarges and enlightens the debate and offers useful policy alternatives.” — David Mechanic, Director, Institute for Health, Health Care Policy, and Aging Research, Rutgers University

“This book specifies the ways in which both government and medical professionals and organizations must change if we are to adequately protect patients. Rodwin’s analysis is thoughtful and thorough; his recommendations can help guide us to more effective public policies.” — Thomas Rice, Professor, UCLA School of Public Health

“A fitting sequel to Rodwin’s pathbreaking Medicine, Money, and Morals. His analysis of conflicts of interest in medicine in France, Japan, and the U.S. is both fascinating and sensible.” — Timothy Stoltzfus Jost, Robert Willett Family Professor, Washington and Lee University School of Law

“The medical profession, the market, and the state exist in a delicate and dynamic balance. By explaining how this balance is maintained or lost in three countries, Rodwin is able to diagnose the ills of American medicine and suggest appropriate treatment.” — John D. Lantos, M.D, Professor of Pediatrics, University of Missouri, and author of Do We Still Need Doctors?
Marc A. Rodwin.  
Conflicts of Interest  
and the Future of Medicine:  
The United States, France and Japan  
(New York: Oxford University Press, 2011)