

*HealthBlawg :: David Harlow's Health Care Law Blog*

**Interview of Prof. Marc Rodwin, JD, PhD, Suffolk University Law School  
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David Harlow: Hello. This is David Harlow on HealthBlawg and I have with me today Marc Rodwin, Professor at the Suffolk University Law School in Boston, who has a piece published in the current issue of JAMA, the Journal of the American Medical Association, regarding the case for public ownership of patient data. Good afternoon Marc.

Marc Rodwin: Good afternoon, David. Nice to speak with you.

David Harlow: Thank you for being with us. The case that you make is a compelling one and I wonder if you could lay it out in brief for our listeners and readers.

Marc Rodwin: Sure, maybe I should give a little background.

David Harlow: Thank you.

Marc Rodwin: There is a new emerging market in patient data -- de-identified or anonymized data, aggregate data -- and it's growing particularly because of the move to electronic medical records. The significance of this is that it will now be much easier to do all sorts of analysis of public health, of marketing trends, of valuation of healthcare systems, of hospitals, epidemiological research and so it's a very valuable development.

David Harlow: Yes and that's part of the background for the push to add electronic medical records to our healthcare system.

Marc Rodwin: Right, but what hasn't been discussed very much -- it's been overshadowed by the talk of confidentiality issues or technology or making this happen -- is how to make this work for the public and for private parties too, and the main question that's been ignored is who owns this data, who should own it and what is the consequence of the law on ownership in this area and in fact there is an area of great uncertainty because the law has really been established to decide ownership of medical records, tangible property in the past and there, there is a pretty clear resolution of records pretty much in most states owned by providers but patients have access to the records and their limits on provider use of it for confidentiality. But with electronic data you don't necessarily have exclusive ownership and it's not really clear what its status is. There are a few parameters so it's pretty clear from what's been said so far that this is not something that the law would normally allow to be copyrighted or patented because it doesn't involve (the raw data on patients) creativity and it's not an invention but there is some referring to data that comes from a billing record or a patient record something that's been produced there and in that sense it's not protected. On the other hand, what has happened so far is people who have been selling the data they have both for-profit

firms, not-for-profit hospitals, insurance companies and they have often used contracts in selling it to restrict others from using it and they have put the data in -.

David Harlow: Just to be clear we are talking about aggregated de-identified data for the most part.

Marc Rodwin: Yes, absolutely, I thought I said that up front. So there is an effort to really make this a private property and there have actually been some people out there in the policy world suggesting that it should be private, not public: The Heritage Foundation in a brief a while ago said that government shouldn't have any privileged access and so they have to buy it and other groups that have looked it have said don't think about ownership, just about access. But if there isn't some provision set up to make it public, publicly available, then it's going to be treated quite possibly as private property and that's going to create problems most with the public and for private development is my argument. Now for the public the problem is this: if individual insurance companies and hospitals have a right to own the data, they can restrict who uses it and they can not make it available, they can sell it only on terms that they want, and even if it's made sellable to public health authorities it maybe simply to expensive to get. The problem is larger than you might think, because the value of this data is particularly if you have a comprehensive database; so fracturing it into parts owned by lots of different entities makes it much harder to collect together and to use, and even the transaction cost -- if you have the money -- would impede use, so that would really limit many of the public health and research functions of it. We have seen this happen in other areas there has been some discussion of patenting genes, Lori Andrews and others have written about that and there is actually an economic literature that discusses what's called "the tragedy of the anti-commons" and the basic idea is that if you allow private ownership but such that the values are really downstream it becomes very hard for private owners to collect them together and get the beneficial uses. That's what I am saying is going to occur here and why I recommend that there be a mandate to have reporting of certain aggregate data to say HHS or a new government entity and that that data then be made available to the public. Now there actually are some precedents for that in limited ways: California requires hospital discharge data to be reported for all hospitals, Medicare requires all hospitals to report certain cost data -- so this is not a totally new approach or a radical approach. The other thing that is important to know is making this publicly available doesn't impede commercialization of sorts, it just makes a better market for it because once that's public you can have different firms take the data, analyze it and put it into software in different ways, do all the kind of things that make it valuable and usable, the only thing that happens when its public is you prevent these parties that analyze the data from having a monopoly and applying and kind of having that tie in with the data ownership in their analysis.

David Harlow: So whatever the value they add in terms of analysis would be added in, and you create a market for that sort of analysis.

Marc Rodwin: Sure so if Harlow and Rodwin Associates does very good graphics on the data and puts it into a usable friendly format, we could sell that. But given that the data is

out there and others could do it we wouldn't be able to sell it with a monopoly profit based on our having the data or on having an inferior product that no one else could compete with. Someone else down the street, Tom Jones, could say I can do that even better, or sell it with different unit pricing and make it and compete with you so you can actually have two or three folks developing the analysis and delivery in certain ways and none would be able to require that you only go to them for their services because you have to buy the services with the data. So I can say a bit more, but why don't I let you ask some questions.

David Harlow: What I was going to ask next is: Would you see the sort of protection of rights or protection of the usability of this data, as something that could fit in with the framework for meaningful use that's been articulated under the Recovery Act?

Marc Rodwin: Well I don't think it's been sufficiently articulated yet and I think it's yet to be articulated with regulation.

David Harlow: There is a draft definition or working definition if you will out there for comment and I guess one of the ways that's being framed is: What are the health outcomes or policy priorities that are going to be advanced by a definition of meaningful use and you have articulated a very important one which is the use of all of this data for population-based, evidence-based healthcare.

Marc Rodwin: Yes, we will see what comes out in the regulations and how they develop, but what I am suggesting is a broadest possible definition, possible and that would require that it all be made available and what worries me is that "meaningful use" might significantly restrict it in different ways and the approach I am taking is that it's all reported and made -- through a government entity -- available to everybody who wants to use it once it's protected, and that would preclude anyone not making something available or making it available later or on less favorable terms and for broader than just population data, conceivably. While I am very interested in the public health uses, it would be also usable for a subpopulation, for the Boston area population or for studying of one hospital system or one HMO.

David Harlow: Or for a particular disease.

Marc Rodwin: That's right and so I think there is a value to having some mandatory reporting which will certainly get the data out there in a way that's saying the data has to be made available to those who request it or in certain circumstances that puts the cost of collecting it elsewhere. Right now we have done this with Medicaid data in California and there are certain times you just have to report certain things and maybe there should be some compensation for that but basically we are talking about people reporting things that they already have and do report to others so if you have to turnover information already for billing or for Medicare cost data and the like, we are not talking about a lot more burden to make that same data available more broadly.

David Harlow: Now in this piece you have highlighted the fact that some data sellers will draft agreements that limit buyers of the data from further disseminating that information and I guess the question I would have on that front is whether you are aware of law suits or decisions that have addressed the enforceability of those agreements? Take the case that the work that's done in manipulating that data doesn't really create something that copyrightable. So the question is can the seller really enforce an agreement that requires someone to not disseminate that information further?

Marc Rodwin: Right, well I am not aware of decisions that have ruled on it but there is a difference between the copyrightability and enforceability of a contract. It could be, I assume, the evidence I have, it's not copyrightable. A breach of copyright would mean someone could claim a copyright infringement for use and you have the remedies there, a breach of contract is a different matter and even if they can't copyright the data they might be able to, under the terms of the contract, have contract remedies. It's also quite possible that simply having that clause in contracts is going to chill and limit what different people do with their data and limit access there, and in addition what I have been reading about and told is that people are trying to put this data into software in ways to limit its access. But the tension is basically here: if the data really is available publicly, you are going to have less of a primary market in people buying it from others without the analysis and the fact is if you want to buy certain data now there are known sellers and they can deliver a database and certain kind of databases and there really aren't a lot of alternatives at this point.

David Harlow: Right, so you are talking about encouraging a much more robust secondary use of the data.

Marc Rodwin: Yes, that's what I think would be beneficial.

David Harlow: Now, do you see patient rights activist is being opposed to this sort of approach?

Marc Rodwin: Well you know it doesn't fit into standard categories and I think a lot of people's initial reaction is that you don't want something public -- with the idea that it's safer when it's private, in the sense that it's confidential. But I think that misconstrues what's going on, because public doesn't mean that it's not protected in terms of confidentiality, nor does not public or private mean that it is. In fact there are, of course, risks any time there is data available, whether it's publicly available or private, on a private market, that there will be a breach of confidentiality. If the data is not properly coded or if it's broken down in certain ways and there's other information you can combine with it, you might be able to then identify patient information, but my point is that that's equally a problem if there is a private market where you can buy this data, where firms have exclusive ownership interests in the data and in a situation where it's available through a government entity like HHS. So it hasn't really been broached; as far as I know much of the public and patient rights groups haven't been talking about this so far, they have been talking about privacy as a separate issue.

David Harlow: So we are talking about privacy and control of health records and I was getting at the question of whether you think some folks would see this putting of records into public hands as a concern when some patient advocacy groups who prefer to see rate of patient control of records.

Marc Rodwin: Right, there are some people out there that talk about patients owning the data: that's a proposal, that's not what current law is and the current situation is that even if you would like patients to own data and stop others from doing anything with it that's not happening now, and the law is not allowing it. And it's not the public access that's the problem; if there is a problem it's private firms appropriating it without consulting them and without any oversight, and I think to the extent that this is made public it's going to have to be done through a statute that will design what the limits are and the uses in confidentiality in a way that they can guarantee much more safety for patients and currently exists.

David Harlow: Do you think that the current legislative debate on healthcare reform provides a vehicle for such a statute?

Marc Rodwin: Well, it provides a vehicle for doing it but it's not what's the focus of most people's attention so it's unlikely to. At this point the center of the debate in the editorials in the press and the like is elsewhere. It may well be that when there is, if there is, a major bill in Congress someone there will slip in something that relates to this but it's not an issue that's been debated at all, and that's a little bit worrisome, because I think there is a significant chance that some groups that are doing well with the current situation will try to put in some kind of legislation to do the opposite: to make it private, to not allow public access, and since a lot of the public is not aware of this issue yet they won't see what's happening and they won't be able to prevent that.

David Harlow: All right -- so that could be a surprise. Well hopefully we don't get a surprise like that. I appreciate very much you taking the time to discuss this issue with me, it is an interesting topic and a very interesting proposal, a valuable proposal and perhaps that can get some traction of the current environment as we are discussing this.

Marc Rodwin: Well wherever you come out on it, it's worth thinking about, it's a major policy issue, it's opening up, it's new and it will make a big difference.

David Harlow: Yes, well, Professor Marc Rodwin, thank you very much for taking the time with HealthBlawg today, I appreciate your thoughts and your insights and thank you again for being with us.

Marc Rodwin: It's my pleasure; thank you.