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COMMENTARY ON:

**Full Disclosure of the “Raw Data” of Research on Humans: Citizens’
Rights, Product Manufacturer’s Obligations and the Quality of the
Scientific Database**

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Dennis Mazur’s paper is a call for clarity in the publication and use of research data. In keeping with the conference theme of ‘breaking down barriers,’ he aims to identify practices of researchers and product manufacturers which prove a hindrance to the interests of research participants, patients, and further scientific research. He concludes that, “added precision to the contents of the scientific database of generalizable knowledge will allow for better patient care decision making in the present and better development of research hypotheses and research designs in the present and future.”

This is a sensible and laudable assertion, but the argumentation by which Mazur reaches this conclusion would itself benefit from greater clarity and connection to the work being undertaken in other disciplines. Work across boundaries means applying the attentions and expertise of different disciplines to the same problems. Insofar as the work Mazur advocates is already taking place in research governance and publishing¹, his analysis of

¹ See for instance PLoS Clinical Trials www.plosclinicaltrials.org , and their inaugural editorial: Smith, Richard and Ian Roberts, ‘Patient Safety Requires a New Way to Publish Clinical Trials.’ PLoS Clinical Trials e6 (May 2006):1-3; Hrynaszkiewicz, Iain and Douglas G Altman, ‘Towards agreement on best practice for publishing raw clinical trial Data’ *Trials* 2009, 10:17; Piwowar HA, Becich MJ, Bilofsky H, Crowley RS, on behalf of the caBIG Data Sharing and Intellectual Capital Workspace: ‘Towards a data sharing culture: recommendations for leadership from academic health centers,’ *PLoS Med* 2008, 5:e183.

direct-to-consumer advertising through the lens of the law can be a timely and helpful addition.

In the case of medicinal product research, development, advertising and implementation, there are not only boundaries to be overcome but distinctions which have been inappropriately blurred. A conflation of constituencies, sleight of hand with forms of expertise and communication, and imprecision as to what is owed to whom, only muddies the picture. Mazur recognises some of these ambiguities even as he falls victim to others. Bringing some of these blurred boundaries into focus may afford points for contact with other disciplines in pursuit of a common goal of improved research, development and marketing practice.

Defining Roles

Mazur is concerned with citizens' rights to full disclosure of risk factors vis-à-vis medicinal products and their manufacture. 'Citizen' is used at some times to refer to study volunteers and at others to patients or consumers. It may be that the term is serving as a convenient collective noun, but the grouping is both too wide and too narrow. As Mazur himself recognises, research participants have different motivations and expectations than patients receiving a therapeutic treatment. Nonetheless, he writes, "I will argue that citizens are owed these rights [of full risk disclosure] because citizens are the study participants upon whom research is conducted in medical product testing." He seems in this to be arguing that the work of some – the study participants – results in an obligation to others – patients – by virtue of a shared but undefined citizenship. This connection is not obvious, nor indeed even necessarily understood to exist among the 'citizen' groups. The basis of his assertion needs further development.

Citizenship may also be too narrow a term. It is typically tied to a country or a passport, and yet research is multinational. Increasingly, study participants may be in developing countries. Do these differences of citizenship, as typically understood, have any impact on those so grouped together in his argument? If a participant in a developing country bears the risks of research to develop a drug to a safety level acceptable in the developed world, does the patient who benefits owe anything to the common 'citizen' who has taken this risk putatively 'on their behalf'?

Mazur puts great weight on the voluntary nature of research participant involvement. As noted, he seems to suggest it creates obligations in researchers and product manufacturers not only to those participants but to other 'citizens.' Similarly, he suggests that the time, effort and possible

burden of risk voluntarily undertaken by participants puts them in a privileged position with regard to the resulting raw data – the observations and measurements made of them. This privilege is once again translated to a wider citizen constituency of which participants may or may not be a knowing part. Such an emphasis on the source of the data neglects, however, the relationship between the participant and the researcher. It does not take into account the purposes and expertise of the researcher who is stimulating, observing and measuring what participants exhibit. It also does not acknowledge the participants' possible relation to the furthering of 'generalisable knowledge' which Mazur outlines at the end of his article.

Information and its communication

Mazur suggests disclosure of raw data to 'citizens' (in this instance, presumably consumers) because it is non-manipulated. The assumption seems to be that access to 'true' numbers, constitutes respect of the 'right' to full disclosure. This gets back to the necessary distinctions between the production, ownership and consumption of information. There is also a distinction to be drawn between data and its meaning.

By 'raw data,' the author refers to information collected during a study and recorded in the research study's database. Mazur is advocating broad access to data in this form: before analysis is conducted, before any interpretation of that analysis is made, and "before any conclusions [are] drawn from the analysed and interpreted data." Analysis and interpretation, then, are stages between an alleged purity of 'raw' data and conclusions that may be further 'manipulated' in pursuit of commercial, non-scientific ends.

The importance of not confusing full disclosure of raw data with meaningful information, and the importance of ensuring appropriate communication is made clear in Mazur's account of the 'learned intermediary defense.' This describes the attempt by product manufacturers to opt out of any obligations to disclose full information to patients by asserting they only have obligations to disclose risks to physicians. It is the role of the physician – the learned intermediary – to interpret and weigh the risk, and decide whether and what to communicate to the patient. This may be the case where pharmaceuticals only have contact with physicians, but does not apply when they appeal to patients as consumers through direct-to-consumer advertising. The courts found, Mazur notes, "that manufacturers of prescription drugs are subject to the same duties to warn consumers about the risks of their products as other manufacturers." In this instance, reinstatement of boundaries serves as a protection for individuals.

Mazur spells out well the new complexities that arise as patients increasingly become consumers. He writes, “The precise boundaries of what can be said and what cannot be said related to the science of the medical product in commercial advertising are not straightforward.” In advertising, scientific data is being put to a different, possibly distorting purpose. It is possible that, when it is being used to sell a product, scientific data is being smuggled across boundaries. It moves out of the genre of scientific clinical trial reporting and into the genre of marketing. The marketing relies on the reputation of science and the scientific method to bolster its less objective commercial claims. Mazur rightly identifies the dangers to trust and accountability – to the stature of scientific research itself – that results from such a blurring of communication contexts.

Distinctions allow us to judge information according to genre and to adjudicate sources on the basis of stated or assumed aims. While the raw data are useful to other researchers for reanalysis and confirmatory studies, it is not obvious that it will be meaningful to less numerate non-scientific citizens – whether participants, patients or consumers – in pursuit of risk and treatment guidance. Mazur acknowledges this when he asks, “How is one to develop an assessment tool to measure the extent to which various forms of scientific information can achieve a level of accuracy and a level of understandability in communications to citizens for their decision making?” It is here that the most important work across boundaries is still waiting to be done.