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**Alicia Hall
(California State University, Fresno)**

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**

Dennis J. Mazur
Department of Veterans Affairs Medical Center
Oregon Health and Sciences University

Dennis J. Mazur’s paper covers a wide range of important issues related to informed consent. Starting from the idea that citizens have a right to “full and open disclosure of risk information related to medical products,” Mazur touches upon a number of problems that prevent the full exercise of this right. The most significant of these seem to be, first, the availability of data from clinical trials; and second, the fact that some adverse effects of a medical product may not show up until well after the clinical trials have ended.

First, Mazur argues that the full data from all clinical trials—including all of the raw data as well as the research alternatives that were rejected before settling upon the hypothesis to be tested—need to be made publicly available for reanalysis and confirmatory studies. Mazur makes a strong argument for the need for this universal availability of clinical trial data and availability, and his argument raises a number of interesting questions. For instance, he writes that “citizens may need the help of interested experts—unrelated to industry and unrelated to government regulators—to help reexamine and reinterpret the ‘raw data’ of science for citizens.” I agree that something like this would be necessary in order to make all of this data meaningful to patients, and that anyone doing this would need to be independent. I wonder if Mazur could say something a little more specific about what he has in mind here—who would these interested experts be? Will they just be other researchers or doctors deciding on their own which

studies to evaluate, or does he have something more official and systematic than this in mind?

Related to this issue, Mazur raises a very good question: who should be considered the owners of the data gained through clinical studies? Many researchers often view this data as proprietary, as being the product of their labors, but since such data could not come about without the cooperation of research participants, Mazur is right to question this traditional view. Of course, making a strong argument for wide access to this data is not necessarily enough to bring this state of affairs about. While recent legislation (as part of the FDA Revitalization Act) requires researchers to register information about their trials, what they are required to disclose is far less than Mazur argues is needed. Many research sponsors would strongly object to requirements that they disclose all of their data, arguing that some of the financial incentives for conducting research would be lost by making their data so widely available. How would Mazur respond to arguments like this?

A separate but related issue is the concern about severe outcomes of a new medical product that do not show up until after clinical trials have ended and the product is being used in the patient population. Mazur states that “citizens as patients are study participants in informal N-of-1 trials as the now-approved drug is prescribed in patient care.” Patients are thus research participants, but, as Mazur points out, without the stronger standards for informed consent that are held for official research studies. So the problem seems to be that, even if we did have full access to the raw data from these studies, the research does not really end when the official study ends and the drug gains approval. What are we to do about this? Individual doctors might adopt a policy of not prescribing new drugs until a year or so after they have been on the market and some more of these adverse effects are known, but this wouldn’t seem to improve patient awareness or autonomy. Some patients, whose doctors do not have such a policy, would be unwitting research participants, while others would not. If this period of early post-trial prescribing really is research, this would be a far too arbitrary and non-transparent way of conducting research. What does Mazur suggest should be done about this? Should we apply the same rigorous informed consent standards for the initial period of prescribing any new drug?

Overall, Mazur makes a strong argument for the need for far more disclosure if we are to protect patients’ right to make informed decisions about their treatment. Too many factors—from the lack of full data about all trials, to the manipulation and selection of data in journal articles and direct-to-consumer advertisements, not to mention conflicts of interest in prescribing and industry-sponsored research—stand in the way of the patient’s ability to

make wise and informed decisions. Mazur's solution may be an ideal, but since we so often fall short of the mark when putting things into practice, aiming at the ideal may be the best way to go.