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## A COMMENT ON *PRIVACY AND ACCOUNTABILITY IN BLACK-BOX MEDICINE*

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Human institutions and activities cannot avoid failures. Anxiety about them often provokes governments to try to prevent those failures. When that anxiety is vivid and urgent, government may do so without carefully asking whether regulation's costs justify their benefits. *Privacy and Accountability in Black Box Medicine* admirably labors to bring discipline and rationality to thinking about an important development — the rise of “black-box medicine” — before it causes injuries regulation should have prevented and before it is impaired by improvident regulation. That is, *Privacy and Accountability* weighs the costs against the benefits of various forms of regulation across the many kinds of black-box medicine.

*Privacy and Accountability*'s enterprise is rewarding because (as the article says) black-box medicine offers major hopes for much progress in many fields. *Privacy and Accountability* is exemplary in identifying early the range of reasons for and against regulating black-box medicine and the range of ways it might be done adroitly. This task, of course, is as daunting as it is desirable: Identifying the costs and benefits of black-box medicine and of its regulatory alternatives is hardly possible, if only because so many sorts of elusive data are needed. However, a more searching and skeptical inquiry might advance the article's search for systematic, disciplined, realistic, and thus (I believe) cautious ways to regulate black-box medicine.

First, the ardor with which we should regulate black-box medicine depends, as the article says, on how much good it can do. The authors acknowledge that the quantum of good is some form of “a lot,” but they describe the good blandly — as “innovation.” That anodyne term hardly brings home what is at stake. If black-box medicine attains anything like the article's expectations, many people will live who would otherwise die, many people will enjoy health who would otherwise endure disease, and many people will escape suffering who would otherwise bear it. A clearer, fuller statement of the promise of black-box medicine might better reveal how much death, disease, and suffering it might diminish and thus what over-regulation might cost.

Second, regulation gains allure if the regulatory choice is between a safe status quo (current treatments that work) and risky future (innovations that

might fail). The authors are too sophisticated to think this is actually our choice, but it's how they often appear to talk and what many people clearly think. Yet if black box algorithms are blocked until regulators are satisfied, algorithms will ordinarily not go away, for health-care decisions generally rest on algorithms of some sort. Many algorithms go unexamined and slip insidiously into medicine under, for example, rubrics like "my clinical experience." Even examined algorithms are often unsupported by satisfactory evidence (if only because they are the best our present ignorance permits).

Third, arguments for regulation too often seem to assume that regulators will work acutely and wisely. *Privacy and Accountability* could usefully ask more rigorously whether regulation will correctly identify good and bad algorithms and products and then properly sort them. If, as the article vigorously argues, evaluating these algorithms and products is nastily hard, how accurate can regulators be? How well have similar regulators — like the FDA and the system of Institutional Review Boards that I will shortly discuss — done separating wheat from chaff?

Fourth, and critically, the article does not really undertake the (admittedly arduous) work of assessing the actual risks of black-box medicine and thus may make too much of its special dangers. Consider the article's ominous account of privacy risks. Although the privacy literature is massive, we are not proffered evidence about the actual privacy consequences of black-box medicine. Rather, we are vaguely warned that "losses of patient privacy . . . can cause significant harms" and that "people consider health information to be especially sensitive." The article then lists four harms breaches of medical privacy can inflict. The article does not, however, estimate how often medical privacy is breached or show that "breaches" harm patients.

Despite the lack of evidence (or even speculation) about such fundamental questions, in its crucial Part IV ("Reconciling Privacy and Accountability") the article repeatedly advocates often-restrictive regulation because privacy concerns are weighty. The article advocates "a system of specific restrictions on the collection, use, or disclosure of patient health information" because "the privacy interests . . . are so great." [39] The article advocates "independent gatekeepers" because "the privacy interests . . . are so great." [43]. Among the reasons for updating regulations "continuously" is that the cost of privacy breaches is "so high." And the article wants specially stringent "safeguards" because "the potential privacy harms . . . are so great." [48]

The absence of evidence is particularly bothersome because medical research evaluating evaluate black-box medicine — or most other kinds of medicine — cannot easily cause damaging breaches of privacy. In most research "the risk of inadvertent or damaging disclosure of sensitive infor-

mation is extremely low.”<sup>1</sup> Long before HHS blessed us with HIPAA, a survey of over two thousand research projects found only three confidentiality breaches “that had harmed or embarrassed a subject. And of 729 behavioral projects, only four reported ‘harmful effects.’ ”<sup>2</sup> Richard Campbell could find “very few” confidentiality breaches.<sup>3</sup> Green knew of “no instances of harm from unauthorized disclosures” in observational health-services research. Georgetown’s Health Privacy Project did not document any.<sup>4</sup> An HHS advisory committee found no confidentiality breaches in researchers’ use of records.<sup>5</sup>

Harm, after all, hangs on an attenuated chain of events: Information people want secret must be collected, but most research does not do so. The information must be revealed, but researchers have few incentives to release it and many reasons not to. The information must reach someone able and willing to misuse it. Who is that? The modal fear is insurance companies using genetic information to deny people coverage. But doing so is illegal, and Hall and Rich report that there has not been and is unlikely to be “serious adverse selection” and that “[m]ultiple, independent sources refuted” or could not “document, any substantial level of genetic discrimination.”<sup>6</sup> Another study found no evidence of insurers cancelling policies in this way.<sup>7</sup>

This actually makes sense. A researcher would need a lot of information about the insureds of a particular company. It would have to be reliable information about factors significantly affecting insurability (and most genetic information is low on the list). Furthermore, confidentiality is an old principle of medicine and research. An AAUP subcommittee found privacy concerns” entirely met by long-standing departmental and disciplinary practice.”<sup>8</sup> Furthermore, confidentiality is an old legal duty. The Association of Academic Health Centers argues that HIPAA may offer no “greater protec-

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1. Academy of Medical Sciences, *Personal Data for Public Good: Using Health Information in Medical Research* 41 (Jan 2006), <http://www.acmedsci.ac.uk/viewFile/publicationDownloads/Personal.pdf>.

2. Zachary M. Schrag, *How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965-1991*, 21 *J Policy History* 3, 29 (2009).

3. Richard T. Campbell, *Risk and Harm Issues In Social Science Research*, Human Subjects Policy Conference at 7 - 8 (April 2003).

4. Lee A. Green et al, *IRB and Methodological Issues: Impact of Institutional Review Board Practice Variation on Observational Health Services Research*, 41 *HSR: Health Services Research* 214, 225 (2006).

5. William Burman & Robert Daum, *Grinding to a Halt: The Effects of the Increasing Regulatory Burden on Research and Quality Improvement Efforts*, 49 *Clinical Infectious Diseases* 328, 329 (2009).

6. Mark A. Hall & Stephen S. Rich, *Laws Restricting Health Insurers’ Use of Genetic Information: Impact on Genetic Discrimination*, 66 *American J Human Genetics* 293, 305 (2000).

7. Karen J. Wingrove et al, *Experiences and Attitudes Concerning Genetic Testing and Insurance in a Colorado Population: A Survey of Families Diagnosed With Fragile X Syndrome*, 64 *American J Medical Genetics* 378, 380 (1996).

8. AAUP, *Research on Human Subjects* at 4.

tion than current longstanding effective regulation,”<sup>9</sup> like FDA and NIH rules and state privacy law. Before HIPAA there was no “explosion of improper disclosures” or any “systematic unwillingness to deal with the problems that do arise.”<sup>10</sup> HHS’s rationale for HIPAA centrally relied on nine anecdotes, like health-insurance claims forms blowing out of a truck or an employee stealing a health-department disk. Unfortunate events, but while laws already penalize negligence and theft, winds still blow and employees still steal.

Nor is it clear that black-box medicine touches unusually sensitive privacy questions. Some people, for example, are voluble about their abortions but taciturn about their money. Releasing the information used in identity thefts harms many people much more than disclosing medical information. And while if asked if they value privacy people say “yes,” they are worthily willing to risk privacy to promote research. For example, in one “community-based primary care practice, only 3.6% of the patients refused to allow their medical records to be used in research.”<sup>11</sup> Even groups widely thought to distrust medical researchers — like African Americans and rural Africans — generously contribute information to research.<sup>12</sup>

*Privacy and Accountability* argues that black-box medicine specially endangers privacy because it is so greedy for data: “The more information that’s collected, disclosed, and used, the greater the raw material for future privacy problems and the more serious those problems are likely to be when they do occur.” [38.] This is logically plausible but experientially implausible. Indeed, as the article acknowledges, the reverse may be true. The flood of information needed may make damaging use of private information *less* likely, since fishing a datum out of flood and then finding some way to abuse it are so hard. Researchers working with such floods rarely care about any individual’s droplet. What matters is the large numbers, not single data points.

*Privacy and Accountability* buttresses its argument for “accountability” for black-box medicine because its products are “classic credence goods.” Perhaps its consumer products are, but the rest are ordinarily used or dispensed by doctors, who should not take such things on faith. *Privacy and Accountability* also wants accountability because black-box medicine is specially hard to evaluate. Is it really? Much medical thinking has been dis-

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9. Association of Academic Health Centers Press Release, *HIPAA Creating Barriers to Research and Discovery: HIPAA Problems Widespread and Unresolved Since 2003*, Association of Academic Health Centers 1, 6 (June 16, 2008).

10. Richard A. Epstein, *HIPAA on Privacy: Its Unintended and Intended Consequences*, 22 *Cato J* 13, 23 (2002).

11. Barbara P. Yawn et al, *The Impact of Requiring Patient Authorization for Use of Data in Medical Records Research*, 47 *J Family Practice* 361, 363 (1998).

12. E.g., David Wendler et al, *Research on Stored Biological Samples: The Views of Ugandans*, 27 *BMJ* 1, 1 (2005).

credited in recent decades, and much treatment is unsupported by decent evidence. Is black-box medicine so different that it needs special scrutiny? True, algorithms can be “so complex as to defy understanding.” But how much understanding is needed? Theories about how the body and medicine work are notoriously contestable, and the real test of medicine is its effect (whatever its theory).

Finally, *Privacy and Accountability* does not explain why its elaborate array of regulatory devices is necessary when so many of them are already law and when there are regulators the article generally excludes from its analysis. The article focuses on only two basic regulators — the FDA and patients, providers, and insurers. But the enterprises that produce algorithms are also regulated by, for instance, tort law and the market (which the article discusses obliquely in examining providers and insurers). Given the calamitous consequences of lost tort suits and of bad publicity about products, it’s hard to regulate well without accounting for tort law and market forces.

Nor is it clear why researchers are not included in the list of evaluators of black-box medicine. They actually do the evaluative work, and their careers depend on doing it competently. There are certainly many problems with researchers’ work, but those are problems that presumably apply to research about all kinds of medicine, not just black-box medicine.

Finally, there is already extensive government regulation in many of the areas the article addresses. As I have intimated, medical privacy is protected by so many kinds of government agencies and rules that some of them — HIPAA, for instance — provoke bitter humor from physicians, patients, and researchers. Not least, most of the regulatory methods *Privacy and Accountability* canvasses are already used by the Institutional Review Boards that approve vast stretches of human-subject research. IRBs have regulated that research — and especially the privacy concerns it raises — so fiercely and, it must be said, foolishly<sup>13</sup> that it is hard to see why black-box medicine should be entangled in further restrictions and why we should believe that the new regulators *Privacy and Accountability* anticipates will do better.

*Privacy and Accountability* stands out in the literature on regulating medical research because it is conspicuously more willing to weigh the benefits of research against its costs, because it is conspicuously more sensitive to the breadth of both medical research and regulatory methods, and because it is conspicuously less bound by the dogmas of the literature. Because it succeeds so estimably in these essential ways, I hope that the authors continue working yet more intensively and freshly along the lines that they have richly opened.

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13. For a thorough analysis of this conclusion, see Carl E. Schneider, *The Censor’s Hand: The Misregulation of Human-Subject Research* (MIT Press, 2015).