Response to Dreyfus and Sobel

To the Editor: While disagreeing with some of their views, I applaud the letter by Jennifer C. Dreyfus and Mark E. Sobel.[1] They framed the debate aptly—as a debate about civil rights—and made an effort to provide legal support for their position. Bioethical discourse has been largely silent about civil rights, even though bioethicists are keenly attentive to civil-rights-related issues such as privacy, discrimination, stigmatization, and the need to be informed when consenting to uses of one's data.[2] A vibrant, legally grounded debate about genomic civil rights is overdue, and I thank the *American Journal of Human Genetics* for hosting it.

Dreyfus and Sobel characterize my earlier article[3] in *The Journal* as a proposal. For stylistic reasons, the editors and I chose to format it as a Commentary instead of a Review. It is always hard to force the square peg of a legal review into the round holes of science journal formats. I apologize if this created a false impression that my article is an opinion piece. It addresses how federal law currently *is* and not how it *ought to be*. Its findings reflect thorough legal research performed by a licensed attorney (me) with pre-academia experience as a partner in the regulatory practice of a large law firm. The legal sources and documents I reviewed are itemized in the 355 footnotes of a longer law review article, now forthcoming in the well-regarded *William & Mary Law Review*.[2]

The protections afforded by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule[4] are civil rights. This is not a provocative new idea that I am proposing. It is a present fact with a long history. On December 28, 2000, the day that the US Department of Health and Human Services (HHS) first promulgated the Privacy Rule, HHS Secretary Shalala delegated her HIPAA-related responsibilities to the Office for Civil Rights within HHS.[5] There was no question then, nor is there now, that the Privacy Rule is a civil-rights regulation.

Does the Social Security Act Limit HIPAA's Individual Access Right?

I respectfully disagree with Dreyfus and Sobel's theory that title XI, part C, section 1171(4) of the Social Security Act (SSA)[6] limits the scope of genetic information that is protected by the Privacy Rule (and is thus subject to HIPAA's individual access provisions[7]).

The SSA's title XI, part C, sections 1171–1179 were created by the 1996 HIPAA statute.[8] The SSA's section 1171 established Congress's definitions for key terms later used in the Privacy Rule, such as "health information" and "individually identifiable health information."[9] In December 2000, HHS faithfully inserted these section 1171 definitions into the original Privacy Rule at 45 C.F.R. § 160.103.

By citing section 1171(4), Dreyfus and Sobel are referring to the definition of health information that Congress, back in 1996, wanted the Privacy Rule to protect. In 2008, Congress expanded that definition by enacting the Genetic Information Nondiscrimination Act of 2008 (GINA).[10] Section 1171(4) of the SSA is, therefore, not a separate statutory constraint that limits how much genetic information is subject to the Privacy Rule's protections.

Section 102 of GINA defined the term "genetic information" by amending the Public Health Service Act at 42 U.S.C. § 300 gg-91. GINA's definition includes information from genetic tests of a person or their family members as well as information about manifest disease in the family members, and it expressly includes genetic services (testing, interpretation, and counseling) done as part of clinical research. This is a broad definition, including virtually any information a clinical or research genetic or genomic test reveals about a person.

The crux of our current debate is how much of that genetic information is protected by the Privacy Rule—and hence subject to its individual access right—after GINA. Dreyfus and Sobel feel that "it would be reasonable" for the Privacy Rule to protect genetic information only if it meets Congress's old 1996 definition of health information. Sadly, the US Congress does not always do what good citizens believe is reasonable. Congress has already acted to reject their position.

Section 105 of GINA adds a new section 1180 to the SSA. It states, "Genetic information shall be treated as health information described in Section 1171(4)(B)." In other words, Congress deems genetic information (as broadly defined by GINA at 42 U.S.C. § 300 gg-91) to meet the constraint that appears in section 1171(4)(B) of the SSA. That constraint says that information is health information if it "relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual." Section 1180 of the SSA is a congressional determination that all genetic information satisfies this condition and, therefore, is health information protected by the Privacy Rule (under the assumption, of course, that the information is held by a HIPAA-covered entity).

HHS later confirmed its own understanding that "section 105 of Title I of GINA contains new privacy protections for genetic information, which require the Secretary of HHS to revise the Privacy Rule to clarify that genetic information is health information."[11] This statement by HHS is entitled to very strong deference by federal courts because HHS made it in the preamble to a final regulation that was promulgated by notice-and-comment rulemaking.

Dreyfus and Sobel's theory thus lacks legal support. Their theory would nullify GINA's expansion of privacy

protections for genetic information. Even before GINA, genetic information was already protected by the Privacy Rule if it was clinically significant health-related information that met Congress's 1996 definition of health information. That was the same approach that Dreyfus and Sobel advocate now. Congress does not enact statutes that do nothing, and Congress did not enact GINA's privacy provisions merely to provide the same genetic privacy protections that already existed before GINA.

The recent ethical controversy surrounding the use of genetic data to identify the Golden State Killer[12] highlights the concerns that led Congress to place non-health-related genetic information under the protections of the Privacy Rule. Ancestry testing services generally are not HIPAA-covered entities, so the Privacy Rule's protections did not apply in that case. Under Dreyfus and Sobel's approach, non-medically significant genetic data, such as forensic identifiers, would not be protected by the Privacy Rule even when held by a HIPAA-covered entity, such as a hospital or clinic. Non-medically significant data would be excluded not only from HIPAA's individual access provisions but also from its privacy protections, potentially eroding public trust. People need access to their genetic data files, for example, to know whether they contain data that might implicate loved ones in a crime. When designing HIPAA's access right, HHS recognized that there can be no informed consent for secondary research uses of people's health records if people have no idea what the records contain.[13] Informed consent does not just mean telling people how researchers plan to use their data. It also means letting people inspect the records you want them to share so they can make an informed decision about how risky it could be if others see what is in those records.

Can People Waive HIPAA Access as a Condition of Research?

Dreyfus and Sobel recommend that investigators should be able to ask people to waive their HIPAA access rights as a condition of participating in research. They are correct that people are generally free to waive their civil rights unless law prevents it. When people plead guilty to a crime, they waive important rights such as their right to a jury trial, their right against self-incrimination, and often their right to an appeal. People waive many of their free-speech rights when accepting a job or signing a nondisclosure agreement. Yet giving a person something of value in exchange for waiving their right to vote would be suspiciously close to vote buying, which is illegal in every state. So the question is whether waiving HIPAA's individual access right as a condition of enrolling in research is analogous to vote buying, at least in the sense that law places limits on individual choice.

In the context of research, it is ethically and legally problematic to ask prospective participants to waive a civil right instrumental to their privacy, their informed consent to future data uses, and their right to withdraw from research. The Common Rule proscribes the use of exculpatory language that requires people to surrender their legally protected rights as a condition of research participation.[14] Consistent with this ethical norm, the Privacy Rule treats individual access to one's own data as somewhat like the right to vote and limits people's ability to waive it in research contexts.

The Privacy Rule has an access exception that allows HIPAA-covered research sites to suspend research participants' HIPAA access rights temporarily during a clinical trial[15] lest participants get their data and "un-blind" the trial. This exception lets research data be withheld temporarily and only if the individual agreed to the denial of access when consenting to the research.[13] Access must be reinstated upon completion of the research,[13] so data from completed studies is never eligible for this exception. If HIPAA-covered research sites choose to maintain individually identifiable research data past the end of a clinical study, people will have access to their designated record sets (the subset of the data to which HIPAA allows access).

Elsewhere, I traced the legal history to try to understand why policymakers gave so much weight to the access right, and curious readers are referred there.[2] HIPAA's individual access right is consistent with 50 years of US federal laws and policies that protect information privacy and support individual access in other contexts, such as access to one's financial and credit information.[2] The EU's General Data Protection Regulation, effective as of May 2018,[16] and the earlier directive it replaced also treat access to one's own data as an essential part of privacy protection. Against this background, efforts to reverse HIPAA's access right would be difficult. Efforts to strip research participants of a federally protected privacy right have unsavory optics and run counter to the regulations protecting participants in research.

Other Concerns

Those who recoil from the reality of HIPAA's individual access right need to explain, much more clearly than has been done, why this right seems so horrifying. Is the real concern that researchers could face tort liability or be overwhelmed with follow-up questions from research participants? Is it the perceived cost of responding to requests for data access—something a number of labs are already doing without financial ruin? Is the concern that participants could take medical action based on research data, even though medical action normally requires a clinician who seemingly has a duty to seek clinical confirmation of research results before proceeding? Once the concerns have been aired, there could be ways to resolve them.

Or is this about investigators' desire to control the data? If so, caution is warranted: blocking people's access to their data fuels pressures for state legislators to pass laws giving people property rights to their data. Such laws could seriously threaten informational research as we now know it. HIPAA and the Common Rule defer to more stringent state laws, so investigators could find themselves having to negotiate licensing agreements with their past research participants just to buy back the right to use the data

that investigators already have on file. HIPAA's individual access right is a vaccine against deleterious state laws on data ownership—but only if HIPAA access works.

On a personal note, I share Dreyfus and Sobel's support for policies that will make data available for research and preserve research data to create medical knowledge commons.[17] Where we might differ is that I accept that individual data access, which admittedly entails some nuisances, is a necessary part of such policies. For 9 years I have fought state legislation that would grant individuals legal ownership of their data to the detriment of research. Those who seek to undermine people's HIPAA access right are not making that fight easier.

I disagree with various other statements that Dreyfus and Sobel made, but space constraints bind. In brief, it is a serious legal and conceptual error to treat HIPAA access and the return of interpreted results as synonymous. One is an established and legally enforceable civil right; the other is emerging as an ethical and possibly legal right but is still being defined. HIPAA access is a "data-only" right that does not require genetic counseling; the return of results often does include counseling. Also, I do not agree with the statement, attributed to me, that there is a conflict between the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[18] and HIPAA's access right. A document available on the website of the Center for Medicare and Medicaid Services suggests that there is a conflict.[19] I am on record as questioning whether that document is consistent with CLIA and various other laws.[2]

I appreciated the opportunity to respond to the concerns that Dreyfus and Sobel raised.

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