

TEACHING LAW STUDENTS TO BE POLICY-MAKERS: THE HEALTH AND SCIENCE POLICY WORKSHOP ON GENOMIC RESEARCH

Benjamin E. Berkman*

Karen H. Rothenberg**

* Benjamin E. Berkman, J.D., M.P.H, is a faculty member in the NIH Department of Bioethics and the Deputy Director of the Bioethics Core at the National Human Genome Research Institute.

** Karen H. Rothenberg, J.D., M.P.A., is the Marjorie Cook Professor of Law, founding Director of the Law & Health Care Program, and former Dean of the University of Maryland Francis King Carey School of Law. During the 2011-2012 academic year, Professor Rothenberg is on leave as Special Advisor to the Director, National Human Genome Research Institute and is a Visiting Scholar at the NIH Department of Bioethics.

The opinions expressed in this article are those of the authors. No statement in this article should be construed as an official position of the National Human Genome Research Institute, National Institutes of Health, or Department of Health and Human Services.

I. Introduction

There comes a time, often towards the end of college, when young adults start thinking about their career paths. Science and medicine are popular areas of interest, but the reality of blood and cadavers, or pipettes and centrifuges, has a tendency to discourage some potential doctors or scientists from pursuing these options. There has thus emerged a trend of using law school as a vehicle for engaging in a health- or science-related field. However, this legal career path is not as well traveled as the more common law firm route. Many students interested in combining law and health or science express an interest in “doing health policy,” yet often have little understanding about what that entails and how to best develop the analytic skills needed to succeed in a policy environment.

This should not be surprising, given the disagreement about how to define policy and how best to teach students to do policy analysis. Nevertheless, law schools have a responsibility to prepare these students for a variety of legal roles (e.g., drafting and implementing legislation, regulations, advocating on behalf of clients, working with industry, etc.) by finding creative ways to expose them to the complex (and often messy) world of policy-making and doing so in a structured and mentored environment that emphasizes learning and skill development. Classroom education, and its emphasis on legal theory, is insufficient to prepare law students with an interest in health and science policy for future careers in this field.

In response to this pedagogical challenge, we designed our “Health and Science Policy Workshop: The Regulation of Genomic Research.” This innovative educational experience allowed law students to engage with actual policy-making. The course was not designed as a mere academic exercise. Rather, it grew out of our recognition that the National Human Genome Research Institute (NHGRI) was being asked to provide ethical and regulatory guidance to

scientists, ethics review boards, and research institutions, all of which were struggling with the appropriate way to incorporate next-generation genomic sequencing technology into research protocols.

We were in a unique position to design a policy workshop on this topic because both of us straddle the legal academic and health policy spheres. At numerous points throughout her career, Professor Rothenberg has been involved as an active participant in policy-making at the National Institutes of Health (NIH), including taking time off from teaching to spend sabbaticals at NHGRI and the National Institute for Child and Human Development (NICHD). As part of Professor Berkman's joint appointment between NHGRI and the NIH Department of Bioethics, he has extensive protected research time to produce independent academic and policy papers, which inform (and are informed by) his institutional research ethics and science policy service requirement. He also has years of experience teaching law school courses.

With these backgrounds, we were able to forge a unique collaboration between the Law and Health Care Program at the University of Maryland Francis King Carey School of Law (UM Carey Law) and the NIH. This workshop gave students practical exposure to cutting-edge regulatory and science policy questions currently facing NIH. Under our supervision, students worked with bioethicists, policy-makers, and scientists from NHGRI and the NIH Department of Bioethics to analyze an emerging set of legal, ethical, and regulatory questions related to the evolving field of genomic science.

In this article, we will begin by briefly framing the scientific and ethical issues that served as the foundation for the issues explored in the course. In the subsequent section, we will describe the novel way in which the workshop was designed and structured to achieve a defined set of pedagogic goals. The final section will analyze the strengths and weaknesses of this

model, with an emphasis on the challenges and opportunities of generalizing our teaching method to a wide range of academic settings.

II. The Legal and Ethical Implications of Rapidly Evolving Genomic Science

The past few decades have been dominated by a targeted genetic research paradigm; with limited ability to produce genetic sequence data, scientists had to focus their attention on a handful of the most promising genes or genetic regions.¹ The past few years, however, have been marked by a transition into a new phase of research that focuses on the genome as a whole.² This shift has been driven by the development of next-generation sequencing technology, which makes it feasible for laboratories to generate huge amounts of genomic sequence data inexpensively and efficiently. A whole exome sequence (all of the protein coding regions of the genome, i.e., genes) now costs less than \$1,000 commercially, and whole genome sequences are available for only five to ten times that cost.³ Researchers are rapidly and enthusiastically adding next-generation sequencing capacity to their research.

This transition is potentially problematic. The ethical, legal, and social concerns previously associated with targeted genetic research are amplified by the magnitude and types of information generated by large-scale genomic sequencing.⁴ Concerns that had been rare are becoming more prevalent and more complex, and institutional review boards (IRBs) are being called upon to evaluate the ethics of research involving the use of these emergent, cutting-edge technologies in research with human subjects prior to the development of ethical consensus and regulatory guidance about the use of these technologies.

To cite a prominent example, genomic research with human subjects raises complicated questions about the management of incidental or secondary findings. Incidental findings are

research results concerning an individual research participant that have potential health or reproductive importance and are discovered in the course of conducting research but are beyond the aims of the study.⁵ For example, while analyzing a subject's genomic data to help answer scientific questions about the underlying genetic causes of diabetes, an investigator could learn that the subject is at elevated risk for breast cancer or Alzheimer's disease, or that they are a carrier for cystic fibrosis. As researchers are increasingly adopting next-generation sequencing technology into their studies, the likelihood vastly increases of discovering an incidental finding.⁶ The question is no longer whether, but how many, incidental findings will be uncovered for a given participant.⁷

Given this new reality, there has been a controversial debate about how, to whom, and under what circumstances to return incidental results.⁸ There is a widely-held (although disputed) perception that there is an emerging trend towards accepting some ethical obligation to disclose some categories of incidental findings,⁹ and many investigators have decided (or are being required by their IRBs) to incorporate a plan for managing incidental results within their protocols. Unfortunately, the contours (or limits) of the obligation to disclose incidental results remain poorly defined. Beyond distinctly ethical questions, the problem of incidental findings also raises some very interesting and important legal and regulatory questions.

III. Course Design

Structure

The goal of our workshop was to use this emerging area of genomic science as an opportunity for students to analyze a series of interrelated ethical, legal, and social issues. The five-credit course included weekly seminar sessions, meetings at NIH in Bethesda, and field

work. Students were assigned individual paper topics, each of which analyzed a specific ethical, regulatory, and/or policy issue, with the goal of presenting a concrete proposal to provide guidance as to how NIH should proceed on that issue. Students also worked in collaboration to produce a workshop consensus document that synthesized their individual research to be presented to high-level policy-makers. Additionally, the class observed and critiqued IRB deliberations and, as part of their field work, participated in a qualitative study of IRB member attitudes relating to the return of incidental genetic research findings. Students had an opportunity to interview experts in the field, including NIH lawyers, researchers, and policy-makers. Enrollment was limited to eight students to ensure that each student received sufficient guidance and supervision.

The course began with an intensive primer to orient the students to the scientific, ethical, and legal issues that would serve as a starting point for their analysis. Given the limits of a single semester, we assigned a list of background readings for the students to read over the winter break, prior to the first class. These readings included scientific primers to help them understand the evolving nature of genomic science and research, and a representative selection of articles from the research ethics literature to provide context for the extant bioethics and policy debate. Our intention was to make the students responsible for getting themselves up to speed before the semester began, so that we could summarize the most salient details of the state of the science and ethical debate, and then quickly transition to a discussion of options for the open policy questions that lacked clear answers.

As the semester progressed, the students worked individually and in groups to develop an analysis of their policy questions. We had regular meetings with each student to discuss progress and work through any issues that arose. Toward the end of the semester, each student gave a

series of detailed presentations to the class, each of which was followed by extensive discussion and critical feedback. Through an intensive negotiation process, the students reconciled and synthesized their individual work into an Institute of Medicine (IOM)-style consensus document that detailed their collective recommendations. The semester culminated in a two-hour presentation of the students' recommendations to twenty high-level NHGRI leaders and policy-makers, including the NHGRI Director, Dr. Eric Green.

Substantive Topics Explored

The topics of inquiry (see Table 1) were chosen after months of negotiation between the two of us: we synthesized the literature in the field, generating a set of questions that was responsive to NHGRI's needs and that would also have clear pedagogic value. Even though the topics were chosen ahead of time, every effort was made to match students to topics that interested them. The topics fell into three broad categories, but were all interrelated and sometimes were difficult to divide. For example, strengthening arguments about an ethical requirement to disclose incidental findings can influence the scope of the related legal obligation.

The first category included a set of more conceptual topics that explored incidental findings from a purely ethical perspective. Given the uncertainty around the extent to which there is an ethical obligation to disclose incidental findings, we wanted the students to synthesize the existing bioethics literature, and then to try their best to articulate and defend a position relating to pressing unanswered policy questions. For example, it is unclear how investigators should define and determine the category of "clinically relevant" information that is important enough that it can or should be disclosed as an incidental finding. It is similarly uncertain how much time and effort is required to satisfy an obligation to look for incidental findings, and the

extent to which resource limitations can mitigate the obligation to look for and return incidental genetic research results.

The second category included topics related to emerging or unanswered legal and regulatory issues. For example, while there is consensus that any information returned to individual subjects must first be verified, the existing regulations under the Clinical Laboratory Improvement Act (CLIA) are unevenly applied and may not be the best regulatory framework for genomic research.¹⁰ Some early empirical research is starting to suggest that fear of liability for failing to disclose important information is one of the reasons that many researchers are devising plans to return incidental findings. Does this fear of liability stand up to a robust legal analysis? Finally, most people agree that you should only disclose desired genetic information. Next-generation sequencing is forcing a re-examination of this assumption, prompting scholars and policy-makers to ask whether there is a legally enforceable right not to know genetic information about oneself.

The third category was more generally related to the practical realities of research ethics. This category included questions about the evaluation of group risks associated with genetic and genomic information and the challenge of how best to obtain informed consent in a genomic research context.

Pedagogic Aims

In creating the course, we had a number of specific pedagogic aims. First, we hoped to help fill what we perceived as a serious gap in the legal education of future health lawyers: access to policy-making experience. Law school curriculum provides ample opportunity for students to engage in traditional legal analysis and robust exploration of the conceptual

underpinnings of the law. Except for a few law schools with strong health-focused clinical and/or externship programs, however, there is a dearth of opportunities for students to engage in real-world application of their developing skills and knowledge base.¹¹ Even in those law schools with robust clinical and externship opportunities in policy-making settings, externship supervisors may not be as well equipped as law professors to include rigorous pedagogical training as part of the policy-making experience. While an externship in a policy-making setting can provide wonderful hands-on exposure to the role of lawyers as policy-makers, externships generally provide students with exposure to the specific handful of policy issues tackled by their supervising agency. Our workshop was designed to go beyond this relatively narrow view of policy-making by giving students training in how policy is developed – from research to negotiation to presentation. Further, in our workshop, students engaged in the policy-making themselves rather than working as a law clerk for their policy-making externship supervisor. The skills learned in the workshop are highly translatable to other policy-making settings.

Our hope was to expose the students to the complete range of steps that comprise an actual policy-making experience, complete with the opportunities and challenges inherent in such an endeavor. We wanted to make this experience as realistic as possible; students had to grapple with shifting deadlines, complex political and institutional limitations on what could be publically proposed, and the challenge of interpersonal negotiation and disagreement among themselves.

Second, we wanted to incorporate empirical techniques into the students' educational experience. Unlike a traditional law school clinic, this interdisciplinary workshop combined legal and policy analyses with qualitative and quantitative research methodologies. Understanding the role of empirical data, policy analysis, interdisciplinary perspectives, and

collaborative teamwork are all important for enhancing the role of the lawyer doing the legal and regulatory analysis of the issues, but law school curriculums do not often prepare students to understand statistical analysis and qualitative or quantitative study methodology. While a single upper-level law school course obviously does not provide the time and space to rigorously train students in statistical and social science methodology, our hope was twofold. We wanted to demonstrate the role that data plays in policy-making. We also wanted to illustrate that to succeed as a health policy-maker, students will need to acquire an ability to understand, interpret, and sometimes generate empirical data.

Third, we wanted to expose these students to the idea that careers in health law can take a variety of forms. Students interested in health law often express an interest in using their legal training to build non-traditional (i.e., non-law firm) careers, but they often lack a sense of the different directions such a career could take. While this course illustrated only one possible path, our aim was to show the students how stimulating and rewarding a non-traditional legal career could be, and to inspire them to do the hard work of looking for a job that meshes well with their passions and intellectual interests. UM Carey Law offers health law clinics and externships, and this course took experiential learning one step further by creating a course that pushed the students' evolving legal skill past their comfort zone, forcing them to adapt their legal training to an applied-science policy context.

Finally, in the context of our Law and Health Care Program, we hoped that a course like this could serve as a capstone to the health-focused law school experience. We accepted only third-year students, most of whom were obtaining their certificate in health law. This intensive course might have been inappropriate for a student earlier in their educational trajectory, but for these students, it represented a culmination of the past three years of hard work and dedication.

IV. Discussion

The Health and Science Policy Workshop was a unique opportunity to explore what might happen when legal educators push law students beyond their comfort zones. Predictably, this resulted in successes and failures, a number of which we share here. This analysis is grounded in a process of honest self-reflection, as well as the anonymous feedback provided by the students after the course. We also discuss the barriers to generalizing the course, focusing on the challenges associated with exporting the course structure to other topics and institutions.

Successes

The students clearly enjoyed the opportunity to interact with scientific experts who are leaders in their field. Genomic research methodologies are in the early stages of adoption, and many of the scientists that the students had an opportunity to interview are at the cutting edge of this work. This interaction accelerated the students' understanding of the necessary scientific background, and it provided the real-world context to motivate students to appreciate the importance of their work. As one student noted, "The course provided a rare opportunity to work on cutting-edge, unsettled issues along with the chance to meet those in the field at NIH." These conversations helped to make their experience much less abstract and academic, illustrating the coming genomic research revolution and the ethical, legal, and social issues that needed to be solved. Similarly, the students expressed a positive view of the opportunity to interact with policy-makers actively working on this issue. They felt that their work might actually influence real policies.

This interaction with experts also had unexpected consequences, mainly in the form of benefits resulting from the pressure of presenting their recommendations to a non-legal audience.

The end product was not a paper or exam that would be evaluated by a single professor, judge, jury, or legislature. The students had to present their ideas to a group of important scientists, experts, and leaders in their field, who generously took two hours out of their day to hear what this group of students had to say. This was a five-credit class, and we expected a commensurate time commitment. The students went well beyond our expectations, in large part because of their collective desire to impress (or fear of) their ultimate audience. The students also impressed us in their ability to adapt their legal and ethical analyses into language that non-lawyers could easily understand.

It should also be noted that the students performed admirably as a group, and they seemed to appreciate the opportunity to engage in collective and individual work. This sentiment flowed in part from the intense and intimate nature of the small class. It also had to do with the specific focus on genomic research, an emerging field with a rich literature that still has many controversial and unanswered questions. The topic area was broad enough that each student could feel like they were tackling a discrete and important question. At the same time, the papers were related enough to give the students a sense that they were working together to build a comprehensive and cohesive set of recommendations.

Additionally, the course presented students with an opportunity to contribute to legal scholarship. From the beginning of the course, we made it clear that we would work to publish papers with those students who produced work of sufficiently high quality. The students appreciated the opportunity to develop new ideas that addressed actual policy problems, and they were excited by the prospect of making a real contribution to the literature. Of the eight students, our hope is that four or five will eventually be able to produce a published piece.

Challenges

The course required students to work outside of a typical law student's skill set. First, most of the students had little or no background in genetic science, and it was difficult to develop quickly the necessary background knowledge to engage effectively in a sophisticated analysis of the ethical and legal issues raised. Second, the majority of students had never worked in a policy environment, where a premium is placed on clear and concise communication. This was most evident during the difficult process of translating each of their thirty-page papers first into a thirty-minute presentation, then a five-minute summary. It is no easy task to articulate a position on a controversial topic effectively and convincingly in such a short amount of time, particularly for law students who have been taken out of their world of statutes, regulations, and case law. Third, the class was forced to grapple with a new force: politics. The course was structured such that NHGRI was the (unofficial) "client" and the class was responding to the client's questions and concerns. In response to the political reality about what a federal institution like NIH can or cannot say, the students were occasionally frustrated by the amount of care that had to be given to how things were framed and what could or could not be proposed.

As with any group, we sometimes had to navigate interpersonal dynamics. Group work inherently creates the risk of free-riders and turf battles, and the intimate class size had the potential to exacerbate any personality conflicts. Many of the topics overlapped at their margins, and on occasion, students would encroach into each other's topics, particularly when there were interesting foundational questions or assumptions that had an impact on the direction of everyone's conclusions. We had to help the students negotiate how to delineate each of their topics such that they each had a discrete set of ideas to develop, while giving them some room to influence each other's thinking on issues with broader import for the entire group.

Even more difficult was the challenge of dealing with substantive disagreement and the need to reach consensus. In addition to their individual papers, we asked the students to produce an IOM-style consensus document that provided a unified summary of their views across the entire range of policy questions we had explored. Predictably, consensus was sometimes hard to come by. For example, the students were split about the question of whether traditional conceptions about the “right not to know” are appropriate in a genomic research context. The standard position is that researchers should only disclose genetic information that is desired by the participant, but some of the students subscribed to an emerging view that there are some (limited) circumstances where it might be ethically appropriate to override an individual’s expressed wish not to know genetic information about themselves.

The students looked to us to help resolve their disagreements. We resisted doing so for pedagogic reasons, and also because we often held different views. Some students commented that this made them feel like they were getting “conflicting guidance” or that there was “confusion as to what the professors wanted.” Eventually, they came to realize that this was by design and that it reflected the reality of the often messy policy-making process. As one student noted, “Even though having professors with different opinions made it hard sometimes, it probably accurately reflected the policy-making process and was very effective at forcing us to come together to figure things out.”

Time also presented a challenge. As noted earlier, this was a five-credit course, and we made it clear before the semester began that it would require a substantial commitment, including time outside of the defined class period. The students understood and agreed to this commitment, but the realities of a law school semester and personal lives, combined with sometimes unpredictable scheduling and deadlines of our course, created tension with other

obligations. This led to logistical barriers: group collaboration was often required, but scheduling meetings outside of class was extraordinarily difficult. It also led to elevated stress levels. In normal courses, students have some ability to control the pacing of their semester (for example, completing a research paper before a pressure-filled exam period begins).

Unfortunately, the back-loaded structure of our course meant that we were asking our students to work the hardest just when they were beginning to get distracted by end-of-semester anxiety.

In fact, one of the most common critiques we received had to do with the time pressure created by the back-loaded structure of the course. Multiple students expressed the view that it would have been better to spread out the intensive work more evenly over the entire semester. While this is a fair criticism, it was not unanticipated. When planning the course, we made a conscious decision to devote what we felt was the time necessary to bring students up to speed, knowing that this would result in a compressed schedule towards the end of the semester. We knew that the students would have a challenging end-of-semester – particularly given that they were all approaching graduation – but we were unwilling to sacrifice the early foundational preparation for fear that students would not be prepared to engage in sophisticated analyses of a complex set of issues. This problem might be avoidable with a two-semester model, where more time can be spent on background and bringing everyone up to speed.

Finally, we had to grapple with reputational concerns. It was ambitious to expect a group of law students, with a range of abilities, to master a complicated area of science, and then to propose solutions to a controversial set of open legal and ethical questions. Our worry was that the students would appear naïve, or ill-prepared, if we exposed them to our scientific colleagues too early. A poor first impression would make it harder to convey their eventual recommendations persuasively. We opted to delay the fact-finding interviews with experts until

later in the semester to make sure that they had sufficient background knowledge to ask thoughtful and productive questions. We wanted them to establish what they could not figure out on their own before engaging with the experts. While defensible, perhaps this approach was too conservative; the students impressed us with their interview questions, and we received extremely positive feedback from our scientific colleagues.

Conclusion

In evaluating the positive and negative aspects of our course, we recognize that this educational experience was the product of a fortunate (and somewhat unique) partnership between NIH and UM Carey Law. Depending on the resources available, it might be difficult for other law school faculty to generalize this experience to their institutions. Access to NIH is not easy to replicate, and it can be difficult to find instructors who straddle the academic and policy worlds. We acknowledge that our experiences are not typical. We both had substantive knowledge about cutting-edge science policy issues that were under active debate, and we had extensive support from the NIH policy-making community.

The lack of existing access to these resources can be a challenge, though it is not necessarily insurmountable with sufficient creativity and planning. Law school faculty will always be part of a larger academic institution, and they can develop partnerships in their own state or local community (e.g., stage agencies or state legislatures). We imagine that there are faculty members in health-related disciplines working on interesting scientific issues that want to extend their work to a wider policy audience. It could also be feasible to identify institutes and centers that have access to grant funding or have the infrastructure to obtain outside support. All universities will have their areas of expertise and preeminence, and it makes sense to focus

energy on leveraging those intellectual resources as sources of material and expertise around which to structure a course.

In the context of a law and health care program with many existing health-related clinics and externships, we wanted to build on existing infrastructure to create something different. With this class, our hope was to give a group of health law students exposure to the complex reality of a policy-making process. We wanted to start giving them the tools that would help them thrive in a variety of health-related legal roles. We viewed the workshop as a culmination of our rigorous health law certificate curriculum – an experience that would help them transition from being law students with an interest in healthcare to being lawyers engaged in the making of health and science policy.

Table 1

Topics of Inquiry

➤ **Category 1: The contours of an ethical obligation to return incidental research results**

1. How should we define and determine what constitutes clinically useful information?
2. How much time and effort is required to satisfy an obligation to look for incidental findings? Does the answer change depending on the specific researcher's expertise and relationship to the subject?
3. To what extent does the "resource excuse" mitigate the obligation to look for and return incidental genetic research results?

➤ **Category 2: Legal issues raised by incidental research results**

4. What are the strengths and weaknesses of potential legal arguments (e.g., duty to warn, contractual, professional responsibility, right to access personal information) that might be used to support or defeat an obligation to return incidental genetic research findings?
5. What legal and ethical concerns might flow from an individual's right not to know incidental genetic research findings?
6. How does the Clinical Laboratory Improvement Amendments (CLIA) interact with the return of incidental research findings, and does the law need to be revised given new genomic research technologies?

➤ **Category 3: Ethics review of genomic research**

7. Are the current regulations adequate to protect against possible group harms, and do advances in genomic research technology raise new concerns about group harms?
8. What are the challenges associated with obtaining informed consent in an era of genomic research?

¹ Benjamin E. Berkman and Sara S. Hull, "Ethical Issues in Genomic Databases," In Encyclopedia of Ethics (2010).

² Eric E. Green and Mark S. Guyer, "Charting a Course for Genomic Medicine from Base pairs to Bedside," *Nature* 470: 204-213 (2011).

³ Illumina, "Illumina Reduces Price of Whole Human Genome Sequencing through Illumina Genome Network," May 2011, at <http://investor.illumina.com/phoenix.zhtml?c=121127&p=irol-newsArticle&ID=1561106&highlight=>; Illumina, "Illumina Announces Bold Steps to Accelerate the Adoption of Individual Genome Sequencing," June 2011, <http://investor.illumina.com/phoenix.zhtml?c=121127&p=irol-newsArticle&ID=1572084>.

⁴ Holly K. Tabor, Benjamin E. Berkman, Sara C. Hull, and Michael J. Bamshad, “Genomics Really Gets Personal: How Exome and Whole Genome Sequencing Challenge the Ethical Framework of Human Genetics Research,” *American Journal of Medical Genetics Part A*, Epub ahead of print. (2011).

⁵ Wolf, S.M., et al., *Managing incidental findings in human subjects research: analysis and recommendations*. J Law Med Ethics, 2008. 36(2): p. 219-48, 211.

⁶ See Tabor, *supra* note 4.

⁷ Id.

⁸ See, e.g., Wolf, *supra* note 5; Bredenoord, A.L., et al., *Disclosure of individual genetic data to research participants: the debate reconsidered*. Trends Genet, 2011. 27(2): p. 41-7; Clayton, E.W., *Incidental findings in genetics research using archived DNA*. J Law Med Ethics, 2008. 36(2): p. 286-91, 212; Miller, F.G., M.M. Mello, and S. Joffe, *Incidental findings in human subjects research: what do investigators owe research participants?* J Law Med Ethics, 2008. 36(2): p. 271-9, 211; Shalowitz, D.I. and F.G. Miller, *Disclosing individual results of clinical research: implications of respect for participants*. JAMA, 2005. 294(6): p. 737-40; Richardson, H.S., *Incidental findings and ancillary-care obligations*. J Law Med Ethics, 2008. 36(2): p. 256-70, 211; Ravitsky, V. and B.S. Wilfond, *Disclosing individual genetic results to research participants*. Am J Bioeth, 2006. 6(6): p. 8-17.

⁹ See, e.g., Beskow, L.M. and W. Burke, *Offering individual genetic research results: context matters*. Sci Transl Med, 2010. 2(38): p. 38cm20; Fabsitz, R.R., et al., *Ethical and practical guidelines for reporting genetic research results to study participants: updated guidelines from a National Heart, Lung, and Blood Institute working group*. Circ Cardiovasc Genet, 2010. 3(6): p. 574-80; Wolf, *supra* note 5.

¹⁰ Clinical Laboratory Improvement Act, Pub. L. 90-174, 81 Stat. 536 (1967) (current version 42 U.S.C. § 263a (2006)).

¹¹ David Segal, “What They Don’t Teach in Law School: Lawyering,” New York Times, November 19, 2011.