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KAREN ROTHENBERG’S (NOT SO) SECRET ROLES AND CONTRIBUTIONS AT THE U.S. NATIONAL INSTITUTES OF HEALTH

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I. INTRODUCTION

As the metaphorical ‘center of the biomedical research universe,’ the U.S. National Institutes of Health (NIH) regularly attracts the best and brightest minds to help the agency pursue its mission – that is, “to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.” Achieving that mission in a socially responsible fashion depends on establishing and maintaining a strong ethical and legal framework, something of profound interest and concern to Professor Karen Rothenberg throughout her lengthy career as a prominent legal scholar. It was, therefore, perhaps inevitable that NIH and Karen would connect in highly productive and meaningful ways.

Karen’s interactions involved distinct parts of the NIH – specifically, the National Human Genome Research Institute (NHGRI) and the Clinical Center’s Department of Bioethics – and occurred intermittently over two decades, being most intense during two periods. The first of these occurred in the 1990s, during which Karen served as a valued ad hoc advisor to a then-adolescent NHGRI. At that time, Francis Collins was the NHGRI Director, the field of genomics was young and growing rapidly, and the Human Genome Project (HGP) was in full swing. The second of these involved a more formal role from 2011 to 2015, during which Karen served as a Special Advisor to the NHGRI Director (Eric Green) and was also an Adjunct Faculty Member in the Clinical Center’s

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Department of Bioethics. During both of these stints, Karen's ability to straddle the academic and policy divide allowed her to contribute as an advocate, advisor, educator, scholar, and mentor.

II. ADVOCATE

Until the HGP came along, few if any scientific fields had sought to anticipate the ethical, legal, and social consequences of their work, much less analyze the societal implications and recommend legislative action – all long before major advances from that work were realized. But starting in 1990, that is precisely what the National Center for Human Genome Research (later renamed NHGRI) did. At that time, an important issue emerged that, if not dealt with effectively, could limit the societal benefit of genomics research: there needed to be an effective way to prevent genetic discrimination.

To be successful, this effort required bold leadership. Karen's vision, passion, and deep expertise made her ideal for this role. As the Marjorie Cook Professor of Law and Director of the Law and Health Care Program at the University of Maryland Law School, she had the legal gravitas and personal commitment to turn policy goals into concrete actions. As the National Action Plan on Breast Cancer (NAPBC) came alongside as a natural partner in this policy effort, Karen was appointed to NAPBC's organizing body and quickly became a leading voice at workshops and public discussions focused on avoiding genetic discrimination. This led to her co-authoring a landmark 1995 *Science* paper on genetic information and health insurance¹ and subsequently a 1997 *Science* paper that provided specific recommendations to avoid workplace discrimination on the basis of genetics.²

Those two articles became the foundation for everything that followed. Though none of us thought that it would take more than a decade for effective federal legislation to become law, we all celebrated in May 2008 when the Genetic Information Nondiscrimination Act (GINA) was signed into law. Along with an amazing team of scientists, advocates, legal scholars, and policy experts, Karen had helped birth legislation with consequences so significant and profound that Senator Edward Kennedy called GINA “the first major new civil rights bill of the new century”.³

1. Kathy L. Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, 270 *SCIENCE* 391 (1995).

2. Karen H. Rothenberg, et al., *Genetic Information and the Workplace: Legislative Approaches and Policy Changes*, 275 *SCIENCE* 1755 (1997).

3. Kathy L. Hudson et al., *Keeping Pace with the Times – The Genetic Information Nondiscrimination Act of 2008*, 358 *NEW ENGLAND J. MED.* 2661 (2008).

III. ADVISOR

Upon his appointment as NHGRI Director in 2009, Eric Green immediately accelerated an ongoing round of strategic planning at the Institute. At several key meetings related to the crafting of NHGRI's 2011 strategic plan,⁴ Karen contributed important and thoughtful input to intense discussions about the future of NHGRI's then-mature Ethical, Legal, and Social Implications (ELSI) Research Program. Those contributions led to Karen playing a larger role advising the new NHGRI Director on the reorganization and 'modernization' of the Institute. Karen's experience as the Dean of a major law school brought a valued perspective, along with remarkable wisdom and sound judgment, to her role as a Special Advisor.

While Karen's advice related to multiple parts of NHGRI, her efforts were most focused on the Institute's Extramural Research Program (ERP). The ERP oversees the funding of researchers outside of NIH and is responsible for roughly three-quarters of the funds allocated to NHGRI by the U.S. Congress. For many years, NHGRI's ERP was laser-focused on the HGP, requiring a relatively simple organizational structure. By the time of Karen's arrival as a Special Advisor (nearly a decade past the completion of the HGP), the breadth of scientific areas covered by the NHGRI ERP had grown substantially. Managing such a diverse program required a different organizational model. Ultimately, a new configuration emerged that converted the NHGRI ERP from a single large entity into a thematically defined four-division structure, one that then required the appointment of four new division directors. Needless to say, this involved a substantial amount of 'change management,' something that was greatly aided by Karen's sage advice and counsel.

Karen's experience and expertise were particularly well-suited for helping with one component of NHGRI's ERP, the ELSI Research Program (which by congressional mandate, is associated with 5% of the Institute's research budget). The Institute's reorganization in 2012 provided the opportunity to elevate the ELSI Research Program by making it the centerpiece of a new division (the Division of Genomics and Society). Karen urged that the new Division embrace a larger scope of activities beyond the ELSI Research Program, including a major 'ELSI consultative role'⁵ and opportunities for its staff to participate in scholarly and outreach activities. With these added responsibilities, Karen recognized that the Division would need ongoing advice over time. Towards that end, she helped to establish a standing advisory body, the Genomics and Society Working Group; the work of this group ensured that appropriate attention is paid to ELSI research

4. Eric D. Green et al., *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204 (2011).

5. Jean E. McEwen et al., *The Ethical, Legal, and Social Implications Program of the National Human Genome Research Institute: Reflections on an Ongoing Experiment*, 15 ANNUAL REV. OF GENOMICS AND HUM. GENET. 481 (2014).

within NHGRI's ever-growing research portfolio. Karen's valued input also aided the Division of Genomics and Society's first permanent Director, Lawrence Brody. Finally, Karen advocated for the Division to take a holistic approach to its work. While ethical, legal, and social research can easily (and often does) occupy three unconnected academic silos, Karen urged NHGRI to join these silos and develop approaches for scholars in each of these areas to work together. This highly collaborative approach to ELSI research represents a lasting contribution of Karen's advice.

IV. EDUCATOR

The University of Maryland Law School is renowned for its health law program, but Karen was inspired to move beyond the normal law school pedagogic focus on abstract legal theory by providing law students with an opportunity to gain real-world experience in health policy at NHGRI. Specifically, she developed the idea for an intensive workshop where students would research and analyze a range of ethical, legal, and policy questions raised by the increasing prevalence of human genome sequencing in research. Do investigators have an ethical or legal duty to look for secondary findings? Does the CLIA regulatory regime make sense in an era of genomic research? How should institutional policies be structured to grapple with the challenges inherent in obtaining informed consent to sequence an individual's genome? How could we strengthen laws protecting people against genetic discrimination? In close consultation with NHGRI scientists and policy-makers, the students developed meaningful insight about these (and other) real ethical and policy problems that NHGRI was actively confronting. The intensive NHGRI policy experience was so successful that Karen then created an ongoing NHGRI externship course (which just completed its fourth year) in which law students are embedded in various NHGRI groups for a semester. These innovative educational experiences have been quite successful, but they were only possible because of Karen's unique position straddling the academic and policy worlds.

As another example of Karen's creativity in expanding pedagogic boundaries, she turned her passion for theater into a tool for teaching bioethics. In collaboration with Lynn Bush (Columbia University), Karen recognized that many of the ethical issues raised by genomics research and genomic medicine have a substantial emotional component and require more than just detached normative analysis. The duo wrote and staged innovative plays designed to immerse an audience into the ethical debate, staging these plays at academic conferences and local theaters. She even organized a conference at NHGRI where playwrights were exposed to scientific and bioethical issues to serve as inspiration in their own work. Karen and Lynn eventually wrote a book about

this experience, which hopefully will be a useful tool as the scientific world continues to grapple with difficult issues inherent to genomic advances.⁶

V. SCHOLAR AND MENTOR

As an Adjunct Faculty Member in the NIH Clinical Center's Department of Bioethics, Karen contributed her wisdom and expertise as a scholar in residence and mentor. Through active discussion and collaboration, she helped to sharpen her colleagues' arguments. For example, Karen co-authored an article with Department of Bioethics colleagues analyzing the liability issues raised by the return genomic incidental findings to research participants.⁷ Published by the highly ranked *Georgetown Law Journal*, this paper provided a framework for courts to grapple with the potential onslaught of cases that inconsistent return of results policies would likely provoke.

Through disagreement and combative collegiality, Karen's advice and critique of bioethics projects proved invaluable to strengthening colleagues' scholarly work. As an example, one of us (BEB) has written extensively with skepticism about the idea that people should have a strong right not to know medically important genomic information about themselves.⁸ Karen emphatically disagreed, arguing that individuals should be able to refuse information about their genome, particularly information resulting from genetic tests. The ensuing debates were instrumental for identifying and addressing weaknesses in this controversial argument. While still on different sides of the academic debate to this day, Karen's unfettered willingness to engage in high-level scholarly debate were undeniably helpful.

VI. A LEGACY OF VALUED CONTRIBUTIONS

Karen is a noted health law scholar and leader in the ELSI research community, but her career has also included a less well-known but equally important public service role as an advisor to NHGRI and NIH. In this role, Karen has effectively drawn on her experience in legal academia to provide invaluable insight to the emerging fields of genomics and genomic medicine. Karen's distinct combination of enthusiasm and wisdom helped to ensure that genomics research was built upon a foundation of ethical and legal scholarship. Her work continues to influence the field to this day.

6. KAREN H. ROTHENBERG AND LYNN BUSH, *THE DRAMA OF DNA: NARRATIVE GENOMICS* (2014).

7. Elizabeth R. Pike et al. *Finding Fault?: Exploring Legal Duties to Return Incidental Findings in Genomic Research*, 102 *GEO. L. J.* 795 (2014).

8. Benjamin E. Berkman, *Refuting the Right Not to Know*, 19 *J. Health Care L. & Pol'y* 1 (2017).