An NIH Debriefing: A Year in Review

Professor Rothenberg returns from NIH

Karen Rothenberg, Marjorie Cook Professor of Law and director of the law and health care program, returned to the law school after a nine-month leave working as special assistant to Dr. Vivian Pinn, director of the office of research on women’s health at NIH. As Pinn’s assistant she served as an advisor on a variety of legal and ethical issues arising from research on women’s health, including the inclusion of women in clinical trials and genetic testing.

In 1994, NIH promulgated guidelines to require the presence of women in clinical research. To promote this inclusion policy, the office of research on women’s health established the Task Force on the Recruitment and Retention of Women in Clinical Studies to address barriers to women’s participation in research, and commissioned the Institute of Medicine (IOM) to establish a Committee on the Ethical and Legal Issues Relating to the Inclusion of Women and Clinical Studies. Rothenberg served on both the task force and IOM committee, which served as a natural entree to her tenure at NIH.

Rothenberg’s efforts at the office of research on women’s health focused on education, outreach and consultation addressing unresolved issues arising from implementation of the guidelines. “It became clear to me that the scientific community and Institutional Review Boards needed to become more familiar with the recommendations of the task force and the Institute of Medicine,” she says. She then convened a workshop of review board members and other experts to discuss these recommendations as well as new challenges and concerns emerging during the first phase of implementation.

“There are both practical and ethical challenges to be met in addressing inclusion/exclusion criteria and recruitment practices. Historically, the fear that some women may become pregnant during the study contributed to the rationale to exclude all women of childbearing potential,” Rothenberg points out. The NIH guidelines state that women of childbearing potential should not be routinely excluded from clinical research, but do not specifically address the participation of pregnant women. Currently, data are compiled to determine the number of women enrolled in NIH-supported studies, but do not categorize whether these women are pregnant or of childbearing potential. Thus, it is not possible to document the extent of their participation or whether there have been any changes in the way the Institutional Review Boards now address this issue.

The Institute of Medicine concluded that both women of childbearing potential and pregnant women should be presumed eligible for participation and recommended that pregnant women be excluded only when there is no prospect of medical benefit or significant risk of harm to the fetus. It recommended that the Department of Health and Human Services regulations for the protection of human subjects be significantly revised and reissued to reflect the presumption that pregnant women are as competent as nonpregnant persons to weigh the risks and benefits of participation in an approved clinical study.

Review boards also face special challenges with respect to the recruitment and retention of minority women in clinical studies. Many are concerned that the historic exploitation of minorities and the poor as commodities in clinical research not be repeated. With all of these challenges to be addressed, Rothenberg intensified her efforts, co-authoring several articles on inclusion issues and making numerous presentations and consultations on the topic.

During the months that Rothenberg worked on inclusion issues, there was a flurry of developments in the field of predictive genetic testing. These developments provided another opportunity for her to expand her role at the office of research on women’s health. She completed a policy analysis of state legislative...
Cornell Law School Professor Delivers Rome Lecture
Professor Larry I. Palmer of the Cornell Law School delivered The Stuart Rome Lecture on April 11, 1996, at the Marshall Law Library. His remarks, "Paying for Suffering: The Problem of Human Experimentation," were delivered to students, faculty, staff and alumni. The Stuart Rome Lecture was established in memory of Stuart Rome, a prominent member of the Baltimore legal community who gave generously of himself to enhance health care and the arts, as well as the legal profession.

approaches addressing genetic discrimination and health insurance for a workshop she helped organize for the National Action Plan for Breast Cancer in collaboration with NIH. As a result of the workshop, recommendations were drafted for state and federal policy makers.

Rothenberg was given major responsibility to inform health professionals, as well as state and federal legislators, on the ethical and legal issues raised by the flow of genetic information. Partly as a result of her providing an analytical framework, many state and federal proposals have been drafted which integrate the workshop recommendations.

Since her return, Rothenberg has testified on genetics and public policy before the U.S. Senate, served as a U.S. delegate to draft recommendations on a variety of legal and ethical issues at the U.S.-Canadian Forum on Women's Health, and continues to make numerous presentations and author articles on genetics and women's health issues. She is also putting together a seminar on genetics and public policy for her law students that will utilize many of the resources that she had access to while at NIH. Clearly, her work at NIH will endure for many years to come.

Nancy Zibron

Bally Total Fitness and Health Scholarship Presentation
The first Charles H. Dorsey Jr./Bally Total Fitness and Health Scholarship presentation was held on March 11, 1996, at Westminster Hall. Pictured left to right are Arthur Goldberg, CEO, Bally Total Fitness Corporation; United States Senator Paul Sarbanes; scholarship recipient Schniqua Johnson; Dean Donald Gifford; Mrs. Agnes Dorsey (wife of the late Charles Dorsey); Baltimore Mayor Kurt Schmoke and UMAB President Dr. David Ramsay.

Judge Andre Davis ’78 Speaks at Commencement
Two hundred and sixty-three members of the Class of 1996 were inducted as alumni of the University of Maryland School of Law on May 23, 1996, at the Lyric Opera House in Baltimore. More than 1,800 faculty, staff, family and friends attended the School of Law Hooding Ceremony to witness the latest crop of tomorrow’s attorneys matriculate into the ranks of the country’s legal system, business world, public interest fields and other areas. As is tradition, Dean Gifford welcomed all in attendance and introduced the day and evening division class presidents who greeted their fellow classmates. The law school was honored to have United States District Court Judge Andre M. Davis ’78 as guest speaker.

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For more information, please call Carol Thompson at (410) 706-0526.