THE Flexner DISCOVERY LECTURE SERIES

Upcoming Discovery Lecture:

KERRY J. RESSLER, M.D., PH.D.
Emory University

September 27, 2012
208 Light Hall / 4:00 P.M.

THE Flexner DISCOVERY LECTURE SERIES

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R. ALTA CHARO, J.D.

FASTER, SAFER, BETTER:
THOUGHTS ON PHARMACEUTICAL DEVELOPMENT

SEPTEMBER 20, 2012
4:00 P.M.
208 LIGHT HALL

VANDERBILT UNIVERSITY
MEDICAL CENTER

FASTER, SAFER, BETTER: THOUGHTS ON PHARMACEUTICAL DEVELOPMENT

It has long been assumed in public debates that pharmaceutical development involves a zero-sum game in which speed of development is traded for enhanced safety of the approved drugs. But is this so? Clinical trials have long been criticized as overlong and prohibitively expensive. And given the known shortcomings of pre-market clinical trials at identifying risks and benefits -- the artificially homogenous study populations, the absence of significant co-morbidities, the short duration of the studies, to name but a few -- many critics have called for more emphasis on ever more rigorous post-market review. But post-market surveillance tends to focus on risks in the real-world patient population without equal attention to benefits. And in a system that rewards R&D investment almost entirely with opportunities for extended market exclusivity (and therefore, higher profits to offset development costs), it is difficult to restrict promotion or withdraw drugs from the market without significant resistance from a variety of interested parties. Is it possible to construct a regulatory system that eases this tension and encourages both speedier approval and superior ability to ensure the best possible risk-benefit balance in marketed drugs? This presentation will focus on some of the legal issues that need attention in order to achieve this result, including First Amendment considerations and forms of economic market protection.

R. ALTA CHARO, J.D.

ASSOCIATE DEAN FOR ACADEMIC AFFAIRS

WARREN P. KNOWLES PROFESSOR OF LAW AND BIOETHICS

UNIVERSITY OF WISCONSIN LAW SCHOOL

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R. Alta Charo is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison, where she is on the faculty of the Law School and the Medical School's Department of Medical History and Bioethics. She offers courses on bioethics, biotechnology law, food & drug law, torts, and legislative drafting. In 2005, she was elected as a fellow of the Wisconsin Academy of Sciences, Arts and Letters and in 2006 she was elected to membership in the National Academies' Institute of Medicine. Professor Charo's voluntary national service includes membership on the NIH Human Embryo Research Panel, President Clinton's National Bioethics Advisory Commission, and President Obama's transition team. She has also been employed as a legal analyst for the congressional Office of Technology Assessment, policy analyst for the US Agency for International Development, and senior policy advisor in the Office of the Commissioner at the US Food & Drug Administration. In addition to service on a number of other National Academies boards and committees, in 2005-2006, she served on its committee to review the FDA and the U.S. national system for the assurance of drug safety. At present she is completing her 6-year term as a member of the IOM Board on Population Health and Public Health Practice.