R. ALTA CHARO, J.D.

FASTER, SAFER, BETTER:
THOUGHTS ON PHARMACEUTICAL DEVELOPMENT

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

Upcoming Discovery Lecture:

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

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