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**MEDIA ADVISORY ----- INVITATION TO COVER ----- MEDIA ADVISORY**

**SETON HALL UNIVERSITY SCHOOL OF LAW AND THE NEW JERSEY INTELLECTUAL PROPERTY  
LAW ASSOCIATION TO DISCUSS HATCH-WAXMAN DEVELOPMENTS**

**WHO/WHAT:** Bruce Kuhlik, senior vice president and general counsel of Pharmaceutical Research and Manufacturer of America (PhRMA), will deliver a lecture titled *Recent Hatch-Waxman Developments*.

**WHERE/WHEN:** The lecture will run from **6 to 8 p.m. Thursday, Oct. 21**  
Seton Hall University School of Law, One Newark Center, Newark, N.J.  
(on the corner of Raymond Blvd. and McCarter Highway)

**BACKGROUND:** Hatch-Waxman was Congress' attempt to reach a balance between generic drug makers and original patent holders. It allows approval of generic products through Abbreviated New Drug Applications (ANDA). Through this application, the developer of a generic drug can rely on the safety data supplied by the original manufacturer -- provided it can demonstrate that both drugs are equal. It also allowed development of generic versions while the reference product is still protected so that the generic version can be released on the day the patent expires. Kuhlik will discuss the issues that surround Hatch-Waxman and the impact that court decisions have had on it.

Before Hatch-Waxman, only 35 percent of pioneer drugs had generic competition after patents expired. Now, almost all innovator drugs face such competition, according to the According to the Pharmaceutical Research & Manufacturers of America.

Kuhlik directs PhRMA's activities relating to domestic intellectual property rights. Prior to joining PhRMA, he was a partner in the Washington, D.C., office of Covington & Burling where he served as the coordinator for the food and drug and healthcare practice groups. He authored numerous publications on food and drug law and intellectual property rights and is a frequent speaker on issues facing the pharmaceutical industry. Kuhlik graduated *summa cum laude* from Harvard College with a degree in Economics in 1978 and *magna cum laude* from Harvard Law School in 1981.

***To secure press credentials, please contact Christine Q. Bland at (973) 642-8724  
by 5 p.m. Monday, Oct. 18, 2004.***