

**November Program**  
**MONDAY, NOVEMBER 12, 2007**

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**TOPIC:** **An Insider's Views of the FDA: "Is It Always Raining on Me?"**

**SPEAKER:** **Sheldon Bradshaw**, Partner & Co-Chair of Food and Drug Practice,  
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The FDA could be singing the blues these days, country-style: "Seems like I've been standing under the clouds. And it's always been that way....Why does it always have to be raining on me?" (Gretchen Wilson, "All Jacked Up 2005," Sony) Many say that a basic problem at the FDA has been that the agency is caught between two conflicting political pressures: industry, the political right and advocacy group demands that drug approvals be speeded; and consumer groups and demands from the political left that the FDA show more caution.

According to a study recently completed by the Tufts Center for the Study of Drug Development, the FDA's overall approval rate for cancer drugs is 8%, although the number of new cancer drugs entering clinical development more than doubled between the early 1990s and mid-2000s. So is the FDA being too cautious these days, especially in approving drugs for fatal diseases? Or is it being a scapegoat?

Sheldon Bradshaw was Chief Counsel of the FDA until his recent resignation in September 2007. At this program, Mr. Bradshaw will share his insights about the agency, discuss the political challenges it has been facing, its future direction and possible impact of changes on the industry.

Mr. Bradshaw was appointed Chief Counsel of the FDA in April 2005. In that position, he provided legal advice to the FDA's senior leadership on a number of significant policy matters, including the agency's drug and food safety initiatives. He also formulated the legal basis for issuances of numerous FDA regulations and guidance critical to the agency's vital public health mission, including the new drug and biologic products labeling rule. He enforced the requirements of the Food, Drug and Cosmetic Act in federal court, and defended the agency's programs when they were challenged. Before joining the FDA, he was Deputy Assistant Attorney General for the Office of Legal Counsel, the U.S. Department of Justice, and provided legal advice to the White House, the Attorney General, and federal agencies, and also served as Principal Deputy Assistant Attorney General for the Civil Rights Division.