Members of New FDA Board Tied to Industry

By Joel B. Finkelstein

The Food and Drug Administration’s most recent steps toward modernizing the drug approval process have renewed some old questions about the FDA’s relationship with the industries it regulates.

Several public advocacy groups affiliated with physicians and researchers have voiced their concern over the appointment of certain members to a newly formed agency board. The groups have warned that some members may have conflicts of interest due to past or current roles as board members of pharmaceutical and biotechnology firms.

In September, Congress passed the latest version of the Prescription Drug User Fee Act—the law that established an accelerated new-drug application process funded through industry-paid fees. It included a provision requiring the FDA to establish a private-public partnership that would facilitate the Critical Path Initiative, the agency’s ongoing effort to streamline and modernize the drug approval process. The partnership, called the Reagan–Udall Foundation, will be responsible for setting goals and priorities for the Critical Path Initiative, as well as awarding grants and contracts to meet those goals, among other things.

The foundation’s board of directors, appointed by the FDA commissioner, will be largely responsible for establishing by-laws, selecting an executive director to oversee day-to-day operations, and reporting to Congress on foundation activities and operations. The federal statute stipulates that of the 14 members named to the board, four members should come from pharmaceutical and biotechnology companies, including one who is currently under investigation by the Senate Finance Committee. Tadataka “Tachi” Yamada, M.D., currently heads the Bill and Melinda Gates Foundation’s global health program but until 2006 worked as head of research for the pharmaceutical company GlaxoSmithKline. Senate investigators have uncovered evidence suggesting that, during his tenure with the company, he may have been involved in an effort to intimidate a scientist who was raising questions about the heart risks associated with the company’s blockbuster diabetes drug rosiglitazone maleate (Avandia).

In a news article published in Nature late last year, Yamada said that he had not initiated any discussion of a lawsuit against the researcher, John Buse, M.D., of the University of North Carolina, and that he had contacted Buse’s boss to check the researcher’s credentials. In the Nature article, Buse confirmed that although he felt others at the company had threatened him with a lawsuit, he never thought that any intimidation came from Yamada.

Nonetheless, in a letter to FDA head Andrew von Eschenbach, M.D., Rep. Rosa DeLauro (D-Conn.) asked him to reconsider naming Yamada to the board. “I am sure you will agree that this conduct by Dr. Yamada should not be condoned ... I believe that these allegations of Dr. Yamada’s behavior as a research chief for a drug company raise serious questions about whether the industry will attempt to influence the so-called independent research mission of the foundation,” she wrote.

According to an agency spokesperson, because the FDA does not have the authority to set conflict-of-interest policies for the foundation, the board will have to do that. However, the FDA’s response to Rep. DeLauro does not fully address her concerns, said a representative from her office.

Yamada is not the only board member whose presence has generated concern. Several other members appear to have industry ties, said Roy Poses, M.D., president of the Foundation for Integrity and Responsibility in Medicine, a small nonprofit that investigates problems in the health care system to inform policy makers and the public. In particular, Poses said he was concerned about the inclusion of William Brody, M.D., Ph.D., president of the Johns Hopkins University, and until August of last year, a director at the medical device company Medtronic.

Reagan–Udall Foundation Board Members

Mark McClellan, M.D., Ph.D., Brookings Institution (chair)
Georges Benjamin, M.D., American Public Health Association
William Brody, M.D., Ph.D., Johns Hopkins University
Helen Darling, National Business Group on Health
Cal Dooley, Grocery Manufacturers Association
Michael Doyle, Ph.D., University of Georgia
Joseph M. Hogan, GE Healthcare
Kay Holcombe, Genzyme Corporation
Sharon Levine, M.D., Permanente Medical Group
Gary Neil, M.D., Johnson & Johnson Pharmaceutical
Ellen Sigal, Ph.D., Friends of Cancer Research
Phillip Sharp, Ph.D., Massachusetts Institute of Technology
Tadataka Yamada, M.D., Bill and Melinda Gates Foundation
Diana Zuckerman, Ph.D., National Research Center for Women and Families
Phillip Sharp, Ph.D., a professor at the Massachusetts Institute of Technology and the cofounder and director of several biotechnology companies; and Ellen Sigal, Ph.D., president of the Friends of Cancer Research, which is funded largely by pharmaceutical companies.

Poses' foundation is among several watchdog groups, including the Union of Concerned Scientists and the Center for Science in the Public Interest, to voice concerns about the potential for influence of industry over the direction of the Reagan–Udall Foundation. However, supporters of the Critical Path Initiative say that the board’s makeup isn’t a problem.

“If Brody was on an advisory panel reviewing a Medtronic device, that would be one thing, but here the issues are really very academic,” said Robert Goldberg, Ph.D., vice president of the Center for Science in the Public Interest, which analyzes the efficacy and economics of medical innovations. The issue of influence cuts both ways, Goldberg said, noting that several industry members are also affiliated with universities or public advocacy groups.

A more relevant consideration may be whether the board members can advance the goals of the foundation and the Critical Path Initiative. If they can bring in money to fund important projects, then many of these concerns will go away, Goldberg said.

In an e-mail, Sharp of MIT stated that he can represent both perspectives fairly. “I have been a full-time academic for 33 years and plan to remain in the role. I also have longstanding relationships as a board member, cofounder, and advisor to a number of companies. I will bring this experience to the foundation as well,” he wrote.

However, some observers still have reservations about the foundation. “It seems to me that the primary purpose of the FDA is to promote the health and safety of the population in general by making sure that drugs, biologicals, and devices are safe and effective, and it doesn’t seem to me that it should be in the drug development and innovation business,” Poses said. “There are plenty of other organizations and companies and people in that business already.”