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On the front lines for safety
FDA insider Peter Barton Hutt speaks at UB

In an era of growing suspicion toward “big government,” a long-time Washington insider came to the University at Buffalo on Oct. 26, 1998, to deliver a highly charged account of one federal agency’s activist role in American life: the federal Food and Drug Administration.

Peter Barton Hutt, who grew up in Kenmore, N.Y., served as chief counsel for the FDA from 1971 to 1975. Now he specializes in food and drug law in his practice with the Washington law firm Covington & Burling, and teaches on that subject at Harvard and Stanford law schools. At his lecture in the Center for the Arts, jointly sponsored by UB Law School and the university’s dental school, Hutt told how an agency that began in the 1830s as a minor offshoot of the U.S. Patent Office has since grown to become “the single most important component of government that we have in our society. The FDA regulates 25 percent of the American economy,” he said. “That is a staggering figure when you think of it.”

Its charge is to regulate foods, drugs and medical devices, but far from its activist role of today, the early FDA served as a “policeman” forcing food manufacturers and distributors to clean up their act and prevent adulteration of the nation’s food supply. It was after 120 people died in one day in September 1837, when the introduction of a new drug proved poisonous, that Congress passed laws requiring that the government be notified before new drugs were introduced to the marketplace.

What followed was a steady expansion of the FDA’s powers, Hutt said, as the agency broadened its reach to control pesticide residues on food, food additives and colorings, introductions of new drugs, and finally medical devices.

Congress decided that none of these drugs and devices should go on the market without FDA approval, hence the agency’s powerful new role as gatekeeper and rule-maker to this lucrative industry.

“These were statutes,” Hutt said, “that usually were created in a crisis atmosphere, because of one tainted product or one consumer who was made sick.”

For decades, he said, the agency was the focus of debate over the “drug lag” — many drugs widely available in Europe were not sold in the United States, a fact many blamed on the great number of FDA regulations governing the testing and approval of pharmaceuticals. “It is unclear,” he said, “whether the drug lag’s net effect is positive or negative. One opinion is that the American people must be protected at all costs, and if the cost of that is delay in the introduction of new medical technology, so be it. You can always find a drug or device that has hurt someone. Those are real people and you can find them. What you can’t find, and what no newspaper ever emphasizes, are those people who are harmed by the delay in medical technology.”

The issue came to the forefront in the late 1980s and early 1990s, he said, largely because of grass-roots activism by the gay community in response to the AIDS crisis. “People began to realize the drug lag is not an abstract problem,” he said. Gay activists marched on the agency, some even chaining themselves to the front door of the FDA building in Washington, demanding accelerated approval for promising anti-AIDS drugs. The agency responded, and in subsequent years advocates for other ill Americans, suffering from such maladies as cancer and heart disease, added their voices to the chorus pushing for faster drug approvals.

Meanwhile, Hutt said, the Republicans’ Congressional “budget revolution” was flattening FDA’s spending allocation. At the same time, the White House has proposed such new programs as a food safety initiative, and next-generation issues such as gene therapy and cloning are demanding attention. The agency, squeezed for resources, broke with tradition and began to charge user fees for new-drug applications. The FDA hired 500 new drug reviewers and cut its review time for applications in half — a huge savings for drug companies, he said. Because it is so expensive to introduce a new drug, faster approval increases the firms’ return on investment rapidly.

Hutt told the audience of about 65 people that the latest revision in the agency’s work, the FDA Modernization Act of 1997, among other things allowed the sale of dietary supplements without FDA approval — a blow to the agency, which had waged a 75-year war against such products as being useless.

Other reforms have been enacted, and more have been urged by various interests, but still, Hutt said, “we have in a true sense no coherent pharmaceutical policy in this country. The FDA is trying hard to do its job the same way it has done for the past century. The single greatest need is leadership at the top of the FDA. We need a leader who does not see regulation as confrontation, but rather as cooperation and negotiation.

“After all, it is the health of the American people we are talking about.”