Former FDA chief cites pressure by drug makers

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WASHINGTON — Dr. Herbert L. Ley Jr., the ousted food and drug commissioner, said he was under "constant, tremendous, sometimes unmerciful pressure" from the drug industry while he headed the nation's largest consumer protection agency.

"Some days I spent as many as six hours fending off representatives of the drug industry," Ley said during an interview in which he detailed, the troubles that swirled around him during his three years with the Food and Drug Administration.

During this time, at least 300 drugs were taken off the market as ineffective, while crises arose involving birth control pills, artificial sweeteners, pesticides and food additives.

Ley, who previously had been a professor of medicine at Harvard, joined the FDA in 1966 as director of its bureau of medicine. Last year he became commissioner of the agency that regulates more than $100 billion worth of products yearly, but three weeks ago Robert H. Finch, secretary of health, education and welfare, named Dr. Charles Edwards to replace him.

Sitting in the living room of his split-level home in suburban Bethesda, Md., Ley reflected on the agency's past problems and future challenges. He was not optimistic.

"The thing that bugs me is that the people think the FDA is protecting them — it isn't," he said. "What the FDA is doing and what the public thinks it's doing are as different as night and day."

Ley said the FDA's professional staff is both inadequate and filled with "retreads," that motivation is lacking to do an effective job of consumer protection, that more money is needed to allow the agency adequately to fulfill its mandated functions and that Finch has failed to support the agency.

"There has been a total lack of topside support from the current administration," he said, insisting that "unless you have complete support you can't operate."

As an example, Ley said, when Wilbur J. Cohen, the previous secretary of health, education and welfare, was in office the FDA commissioner and other agency officials routinely sat in on weekly HEW staff meetings. "This ended last January when Mr. Finch took over," he said.

"John Gardner (Cohen's predecessor) told Finch that FDA was important but he apparently didn't listen," Ley said.

Cohen was credited by Ley for resisting drug industry pressure when the FDA made major decisions restricting the use of some pharmaceuticals, a major and still unresolved regulatory battle that has been going on for most of this decade.

Under the 1962 Harris-Kefauver amendments to the Food, Drug and Cosmetic act, drug makers were ordered to show that their products were not only safe but also effective for the uses stat-

Ley recalled that the greatest amount of pressure over restrictions on an individual drug involved Dynapen, an antibiotic made by Bristol Laboratories of Syracuse, N.Y., a division of the Bristol-Myers Co.

"Dynapen is an excellent drug for use against inrections of some kinds of staphylococci that are resistant to penicillin," Ley said. But he added that Bristol Laboratories wanted to use Dynapen for most staph infections, and objected when the FDA decided that other antibiotics were more effective and restricted the use of dynapen to penicillin-resistant staph infections.

"Bristol brought tremendous pressure on me," Ley recalled. "The bugging was unmerciful at times, with as many as five phone calls a day from Bristol people or their representatives."

Ley said, "There also has been a lot of pressure during the last 18 months involving the drug efficacy review of the National Research Council," on whose recommendations the 300 products have been taken off the market. He said the reason for the protests and pressure was money "pure and simple."