

desirable than individual dosages were eliminated; a requirement that the combination be effective for the duration of dosage was removed; and a requirement that the combination be advantageous for "most" patients was changed to require that combinations be "safe and effective for a significant patient population."

"We won the fight on combination drugs," said William C. Cray, PMA's vice president for public relations. "The final guidelines were quite reasonable."

New FDA lawyer: The drug industry's status with FDA also has been enhanced by the May 31, 1971, retirement of William W. Goodrich as the FDA's top lawyer. His exact title was assistant general counsel for food, drugs and environmental health in the Department of Health, Education and Welfare.

Goodrich, who had served in the government for 32 years, was not held in high esteem by the drug industry. Goodrich helped shape FDA policy against combination drugs, and it was Goodrich who defended the agency in court when the industry challenged—unsuccessfully—the removal from the market of the combination drug, Panalba. Panalba's manufacturer, the Upjohn Co., was joined by PMA in that fight.

"He was basically anti-industry," Cray said of Goodrich. "He tended to inject policy into the legal area, and he was influential in shaping that policy."

Brennan expressed relief that Goodrich is gone. "From where we sit, that can't hurt," he said.

Goodrich's successor is Peter Barton Hutt, who took over Sept. 1. Hutt was a partner in the prominent Washington law firm of Covington and Burling, where he specialized in representing food, drug and cosmetic firms in dealings with the government.

Hutt has a better perspective on government regulation, and he understands the industry point of view, Cray said. He and Brennan both said that Hutt is less interested in FDA policy, and they expect him to handle FDA court cases strictly from a legal standpoint, with much less regard for policy than Goodrich had.

But the PMA representatives said they respect Hutt as a top-notch lawyer who will be anything but a pushover. "Hutt is in there now, but let me tell you, he is not industry's man in that job," Brennan said. Cray said, "Hutt will be hard, but fair."

Hutt disagreed with the PMA's assessment that the drug industry is better off with Goodrich gone. "Let's wait five years and ask them again."

"My new client is the general public through the Food and Drug Administration, and I intend to represent that client as well as any lawyer can," he said. "I don't regard myself as a friend of anybody but the agency."

Hutt said he definitely is interested in policy and said he would consider policy and morality together with the law in carrying out his new responsibilities. "I've never been able to separate them," he said.

Congress: A year ago, the PMA was watching the progress of several bills in Congress. PMA President C. Joseph Stetler testified against four that were before the Senate Labor and Public Works Subcommittee on Health, including the bills (S 3096, S 3651 and S 3652) introduced by Sen. Nelson. The bills, which would have required new drug coding and labeling and more frequent plant inspection, all died in the 91st Congress and have not been introduced again.

Sen. Russell B. Long, D-La., chairman of the Senate Finance Committee, also had aroused PMA interest by reintroducing an amendment to the Social Security Act (49 Stat 622) to limit reimbursement under medicare and medicaid to those drugs approved by a government-sponsored committee and within an acceptable price range. Long's bill (Amendment 929 to HR 17550), was killed by his own committee and has not been introduced this year.

Nelson's new bill: In introducing his comprehensive new bill Nov. 4, Nelson told the Senate that its provisions were urgently needed to protect the public against dangerous and unnecessarily expensive drugs.

The bill would establish a national drug testing and evaluation center to clear new drugs before they are marketed; it would provide for publication of a compendium listing all drugs and their characteristics to help doctors in prescribing them; it would establish a committee to compile a formulary of recommended drugs (similar to the Long amendment); it would strengthen drug labeling and certification rules; and it would curtail certain types of drug promotion by manufacturers.

The bill, if it became law, would be the most far-reaching legislation aimed at the drug industry since the 1962 Kefauver-Harris Amendment.