

FDA Hit on Failure to Ban Drug Serc

By Jack Anderson

Congress has caught the Food and Drug Administration allowing a drug company to sell prescription pills whose only proven worth is for treating obesity of the patient's pocketbook.

The official responsible for the ruling is a former lawyer for some of the nation's wealthiest drug companies. He is articulate Peter Hutt, the FDA's general counsel, whose previous clientele led consumer advocates to question when he got the job whether he could get tough with the pharmaceutical industry. The answer appears to be "No."

In a confidential report, the General Accounting Office has said Hutt's actions are so "inconsistent with (the law) as to constitute abdication by the FDA of its functions . . ."

And Rep. L. H. Fountain (D-N.C.), the gristly chairman of the House Intergovernmental Relations Subcommittee, has taken the drastic step of going over Hutt's head to Health, Education and Welfare Secretary Elliot Richardson in order to stay Hutt's hand.

At issue is a precedent-setting case involving a dubious anti-dizziness drug called Serc. Evidence shows the drug's original FDA approval was based on a study later found by FDA to be "untrue" and grossly "defective."

FDA ordered the drug off

the market but gave Serc's maker, Unimed, a break and let it continue peddling the drug while the order was on appeal. In February, the courts ruled against Serc, and federal laws say such drugs "shall" be taken off the market.

But to Fountain's amazement, Hutt insisted that "shall" really means "may." He allowed Unimed to go on peddling Serc in interstate commerce, with the excuse that the profits were needed to finance other tests of the drug.

Fountain, a lawyer himself, asked the General Accounting Office for a confidential opinion on the situation. We have copies of two GAO documents which say flatly that Hutt's citations do not "have the slightest relevance to any matter here in issue."

In unusually stern language, the GAO says "the present General Counsel's legal position thus completely disregards the express and unequivocal language . . . of the Food, Drug and Cosmetics Act as well as the legislative history of this provision . . . The failure of the FDA to (ban the drug) was clearly contrary to law."

Alarmed by the potential for mischief in Hutt's strange ruling, Fountain wrote Richardson that the "law is being flouted . . . But more importantly," he went on, "FDA's

improper actions, if allowed to stand, will set a precedent which could completely undermine the new drug provisions of the Act."

In other words, the importance of Hutt's action is not really Serc, which has only about \$1 million in sales a year, but the tens of millions of dollars worth of potentially useless drugs from bigger firms that can be foisted off on the sick, the poor and the elderly.

Footnote: Hutt strongly feels that a court order, allowing untested drugs to remain on the market if there is a "compelling" medical reason for doing so, should apply in the case of Serc. Actually, there is no definite proof that Serc helps the dizziness it is prescribed for.

Washington Whirl

Tomato Tumult—The great gassed green tomato controversy continues to ripen. We revealed earlier how the Agriculture Department and Florida's big corporate tomato men had connived to favor ethylene-treated "gassed greens" over vine-ripened tomatoes from Mexico. Both Agriculture and the tomato growers blasted us. Now, the Consumers Union and other consumer groups have charged in the courts that Agriculture has shown about as much regard

for the housewives of America as a hornworm shows for a tomato plant. The suit, based on expert research, contends that the housewife is being robbed of the better tasting, more nutritious vine-ripened tomatoes by unlawful and invalid Agriculture Department actions.

Cantankerous Cabinet—Vice

President Agnew, in his capacity as chairman of the President's Marine Sciences Council, tried to stop disagreements between the Cabinet members who served on the council. To keep them in line, he wanted an advance script of the meetings. This is revealed by the council's former executive secretary, Prof. Edward Wenk, now at the University of Washington, in a new book, "The Politics of the Ocean." Agnew instructed his staff, writes Wenk, "to have the Executive Secretary prepare a scenario for all members at future Council meetings so that the outcome would be known; otherwise, he would not preside. I registered the impracticability of that demand. Trying to write script for any Cabinet officer with a guarantee that he would follow it was beyond my capabilities." Agnew eventually abandoned his quixotic plan.