APPENDIX II

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FDA CRACKDOWN—GOVERNMENT, INDUSTRY CLASH OVER BID TO CURB COMBINATIONS OF DRUGS—AGENCY CALLS FOR WITHDRAWAL OF 100 ANTIBIOTIC PRODUCTS; MAKERS DEFEND EFFICACY—LONG TERM EFFECT ON PROFITS

(By Jonathan Spivak, staff reporter of the Wall Street Journal)

WASHINGTON.—A new struggle, with high economic and political stakes, is looming between the nation's drug manufacturers and Uncle Sam.

The focal point this time is the medical merits of combination drugs—widely used prescription products that contain two or more active ingredients.

Government and academic experts increasingly contend that many of these mixtures unnecessarily expose patients to several drugs at once, permit physicians to avoid careful diagnosis and prevent tailoring of prescriptions to the patient's particular needs.

Drug company executives challenge these assertions and point to the long and extensive popularity of combinations among physicians and patients. They insist the products offer effectiveness, economy and convenience.

The Food and Drug Administration is bringing the conflict to a head by ruling that almost 100 antibiotic combinations are ineffective and proposing to remove them from the market. Democratic Sen. Gaylord Nelson of Wisconsin, who has been holding months of hearings hostile to the drug industry, is seizing on the FDA's action in an effort to embarrass the drug makers further; his small business subcommittee will air criticisms of the antibiotic combinations in a new set of hearings starting today.

SETTING PRECEDENTS

The action against antibiotics could set precedents for FDA policy toward many other kinds of drug mixtures, including pain-killers, cough and cold preparations, compounds used against high blood pressure, and arthritis and ulcer remedies. Some of these combinations may come under attack on grounds of ineffectiveness.

"I don't think the pattern will evolve as a general anticombination bias of this agency," says FDA Commissioner Herbert Ley Jr. "But I think where these combinations are irrational and illogical there will be a confrontation."

It's likely that the FDA will prevail in forcing the most questionable products off the market. But other long-established remedies may escape unscathed. And industry-Government compromises may be reached for others, permitting continued marketing with restrictions on claims for their effectiveness.

The Government's objective is to enhance the quality of health care received by the American public. But industry spokesmen argue that in the end its action could tend to curb drug-company profits and development of new products. Certainly the stakes for the industry are large. Dr. Ley estimates that retail sales of the antibiotic mixtures alone total $200 million or more a year. Combinations comprise about 40% of all drugs on the market.

SUBCOMMITTEE'S PLANS

In the short run, the attack on the combinations may simply tarnish further the image of the pharmaceutical industry. Sen. Nelson, a persistent and powerful critic of the industry, has invited academic medical men and FDA regulators to air their objections to the antibiotic mixtures; the manufacturers may not get an equal chance to defend their products. The subcommittee hopes to show that the drug companies frequently foist costly and valueless products on the public by needlessly combining already available drugs. Physicians are then persuaded to prescribe them through high-pressure promotion, the critics will charge.

Particular attention will probably focus on the Upjohn Co.'s widely promoted Panalba, a mixture of the antibiotics movobiocin and tetracycline. Panalba is one of the compounds the FDA wants to remove from the market. The company has adamantly resisted, urging physicians to write the agency in protest.

Many infectious-disease experts argue that Panalba and other antibiotic combinations are useless and potentially dangerous. They claim the mixtures need-