determine, both officers were associated most particularly with the clearance—or, rather, nonclearance—of cardiovascular agents.

The responsibility for the regulation of drugs cannot be solely a negative, censorial function but must also be a positive, affrmative, scientific action. A public health regulatory agency must recognize that its mandate to regulate is not a mandate to bring therapeutic medicinal developments to a "virtual standstill in the United States." Regulation does not simply imply rejection of dangerous new drugs but, equally important, the responsibility of promoting and making promptly available the benefits of new medicines. "To regulate" is not just to slow down; it can also be used to speed up.

In 1967 Maurice Visscher protested in *Science* (April 21) the FDA's refusal over a period of months to permit the testing for "*a new purpose a potentially lifesaving drug which had already been used, without evidence of toxicity, on half a million humans in other countries for a different purpose. . . . It happens that a million or more persons a year die of ventricular fibrillation, which this drug might prevent in many instances*" (our italics). He had previously warned that "many more lives may be lost by . . . delay than might be saved by excessive caution."

A.M.S.

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## HUMAN RESOURCES—DRUG INDUSTRY LOBBY RIDING HIGH

(By Bruce E. Thorp)

Fresh from a victory with the Administration over the regulation of combination drugs, the prescription drug industry is ready for any new challenges the federal government may send its way.

The multi-billion-dollar industry, represented in Washington by the Pharmaceutical Manufacurers Association (PMA), has significantly strengthened its position with the Food and Drug Administration in the past year. The FDA backed away last summer from strict new requirements for combination drugs, after the industry protested vehemently and cultivated extensive support among doctors and Members of Congress.

PMA's relations with Congress may be better now than they have been at any time in the past 12 years. It was on Dec. 7, 1959, that the late Sen. (1949–1963) Estes Kefauver. D-Tenn., began hearings that led to the 1962 passage of the Kefauver-Harris Amendment (76 Stat. 780), a drug-regulation law that has aggravated the industry ever since.

But the PMA now is showing a confidence that indicates that the aggravation may have come to an end. Just last month. Sen. Gaylord Nelson, D-Wis., who picked up the Kefauver spirit and resumed hearings on the drug industry in 1967, introduced a comprehensive new bill (S. 2812) that would greatly increase government control over the manufacture and use of prescription drugs. The Nelson bill, which is the culmination of four years of investigation, has the PMA so unworried that Bruce J. Brennan, vice president and general counsel, says he has not even read it yet.

Combination drugs: The battle over combination drugs—those with more than one active ingredient—began in earnest last Feb. 18, when the FDA published proposed guidelines for deciding which combinations it would approve for marketing. (*For background on the drug controversy, see. No. 24, p. 1266.*)

The agency was using powers it had received from the 1962 drug amendment to review drug efficacy. Its proposed guidelines were strict, following the advice of those academic medical experts who believe that reliance on fixed-combination drugs is more dangerous than prescribing custom dosages of each drug to best suit a patient's needs.

But combination drugs are easier to prescribe, and they are very popular among doctors. The drug industry relied on this popularity in soliciting support from practicing doctors, who wrote letters of protest directly to the FDA and also to Members of Congress, who then sent inquiries to the agency.

Besieged by this opposition, the FDA modified its guidelines before publishing a final version Oct. 15. Four major changes were made in deference to opposition from medical and drug interests: Over-the-counter drugs were removed from the guidelines and handled separately; suggestions that combination drugs are less