

10428 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

us that: " * * * the Department of Defense has been casting clouds over the nation's drug supply for the last several years with statements made by some of their spokesmen." [See page 10164.]

The subcommittee would appreciate hearing the comments of the representative of the Department of Defense on the testimony of the Food and Drug Administration, the U.S. Pharmacopeia, and the National Formulary respecting the charges that have been made by Mr. Feinberg, and then later we would also like comment on the special standards which are established for drugs purchased by the DOD and which are claimed by Mr. Feinberg to be higher standards than those required by the Food and Drug Administration.

I am sorry to take so much time reading such a long introductory statement, but since the matter is of very great importance, because the Department of Defense is very prestigious and its name is being used, I think it is necessary to lay the whole record out and clarify it, if possible.

Please proceed.

STATEMENT OF MAJ. GEN. GEORGE J. HAYES, MEDICAL CORPS, U.S. ARMY, PRINCIPAL DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH AND ENVIRONMENT); AND LT. COL. THEODORE D. WOOD, DIRECTOR OF MATERIEL, OFFICE OF THE SECRETARY OF DEFENSE (HEALTH AND ENVIRONMENT)

General HAYES. Mr. Chairman, I would say your statement is like a breath of fresh air coming into a crowded room. This has cleared up confusion caused by some of the prior statements, and I would like at a later time to give some perspective on that. But I agree with everything you said in the statement.

I can now only say in response to Mr. Feinberg's speeches, I think it is only fair to recognize that Mr. Feinberg began his work at the DPSC at a time when there were questions about the quality of drugs in the open market. He did a great deal early on to help set standards, and actually some of those standards have been incorporated by the USP and the FDA.

Mr. Feinberg is a perfectionist. He also—I guess it is sort of like some of us old souls—he is fighting past wars and recounting the tales and sort of losing the historical perspective of then and now.

In your statement there is one comment that I would like to make to clarify and again get a perspective on the digoxin situation.

In March 1965, the U.S. Naval Hospital, Saint Albans, and in October 1965, Brooke General Hospital both complained that their physicians had noticed an unsatisfactory clinical response to a specific manufacturer of digoxin. Testing of this digoxin manufacturer revealed unacceptable lack of tablet content uniformity. The specific lots of digoxin were withdrawn from the system. In September of 1965, the USP, XVII, revised its recommended testing procedures for assays of individual tablets of various drugs of