

10208 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Honorable Gaylord Nelson

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testing. The DOD response specifically reveals that only 5% of the drug products obtained based upon contracts awarded are, in fact, subjected to laboratory testing -- the remaining 95% are judged satisfactory based upon other DOD information. Combining this response with the information provided in the second paragraph of DOD's answer to your question 15(a) -- in which they give the ratio of drug samples rejected to drug samples tested -- the composite true rejection rate in terms of total drug samples involved, amounts to less than 2.5% (that is, 42% of the 5% increment). In other words, over 97.5% of all drug product samples offered are judged satisfactory by DOD-DPSC.

No breakdown was provided by DOD relative to the 136 cases which they recommended for rejection during FY 1973; therefore, no comments can be offered relative to the severity of the alleged product deficiency or upon the appropriateness of the finding on which the rejection was based.

c. Problem Drugs

In your question 15(d) to DOD, you requested specific information relative to findings made by DPSC personnel, as well as action taken by DPSC personnel, concerning problems pertaining to digoxin tablets. You also asked DOD to name the "many other examples" referred to by a DPSC spokesman, along with other specific information pertaining to these "examples."

During my testimony before the Subcommittee on February 21, I commented specifically concerning apparent inconsistencies or peculiarities in the DOD response pertaining to digoxin tablets; since comments on this matter are already part of the hearing record, I shall not repeat them here.

With respect to the "other examples," DOD's response mentions that such information has been obtained through two sources; namely, the "published literature" and "complaint reports received by DPSC." Concerning the published literature, they cited two examples (one of which, incidentally, is published by the American Pharmaceutical Association, the organization which I represented in my testimony before the Subcommittee). Such publications are generally available, and anyone having an interest in drug quality could be expected to be as familiar with them as the DPSC spokesman. Consequently, this does not represent any special information source beyond what is widely available and already known to FDA, the official compendia, and health professionals involved in procuring or selecting drug products.