

2. "Based on my experience of drug plants, it is my firm conviction that the primary problem lies in the fact that many producers in the business today are in gross violation of FDA's good manufacturing practices regulations. Those same firms are manufacturing drugs on a daily basis."

3. "We have seen totally unacceptable housekeeping conditions involving dirt, filth, and rodents. We have reviewed production records that showed noncompliance with the companies' own standards. We have found instances where ingredients and finished products are not adequately tested."

4. With respect to problems of digoxin tablets—"This was no surprise to the drug specialists in DPSC because we know of many other examples demonstrating that compliance with laboratory standards is not necessarily indicative of clinical effectiveness."

On January 17 of this year, the subcommittee requested the Department of Defense to supply us with the names of the firms and the dates on which they allegedly committed "gross violations" of FDA's good manufacturing practices regulations; if and when these were reported to the FDA and other government purchasing agencies; and if so, when and in what detail, and the exact description of the violation. In addition, the subcommittee asked for an explanation of how the 45 percent plant and 42 percent product rejection rates were derived, as well as other information to support the claims that Mr. Feinberg had been making for several years.

Starting on January 30 and on several subsequent dates, the Department of Defense supplied us with a considerable amount of material which I shall place into the record of these hearings, together with an analysis by the United States Pharmacopeia and the American Pharmaceutical Association. The Food and Drug Administration also studied the material supplied to us by the DOD and sent members of its Office of Compliance to the DPSC Center in Philadelphia to ascertain precisely what kind of data could have been the basis of Mr. Feinberg's many speeches and articles.

What did the data show?

1. That the DPSC, in fact, surveys only about 10 percent of their prospective contractors and that this 10 percent is the result of a conscious selection process. In other words, DPSC has already concluded that the remaining 90 percent constitute prospective contractors who are fully capable—in the judgment of DPSC—of performing satisfactorily under the terms of the proposed contracts. So the rejection rate is only 4.5 percent of all prospective contractors, not 45 percent. Mr. Feinberg did say that the rejection rate on DOD plant inspections is 45 percent, but he did not mention that the inspections were performed on only 10 percent of the prospective contractors and that fully 95.5 percent of the contractors submitting a bid were judged by DPSC to be capable of performing under the terms of the proposed contracts.

But what about the 4.5 percent rejection rate? How serious were the alleged violations? What was the quality of the plant inspections?