efficient and effective National and Government-wide program within the Agency.

A successful program necessitates that an appropriate portion of those resources now identified with quality assurance activities for drugs and biologics in the purchasing agencies be transferred to FDA in a timely fashion.

The Food and Drug Administration has received fine cooperation from DOD, VA, and Public Health Service. We are confident that we can count on their continued cooperation as we move into the implementation stages of the plan. For these reasons, we anticipate no significant problems in completing the plan on the projected dates that we have targeted.

Within our overall policy that there be one high standard of quality for medical products for the Nation, our approach with regard to the Federal procurement agencies has been the development of a comprehensive plan which we believe will meet their varied needs.

Mr. GORDON. Dr. Schmidt, one of the most important steps to assure a high quality drug supply, it seems to me, is to remove those drugs from the market which do not meet the requirements of the law that they should be safe and effective for purposes claimed.

Does this sound reasonable to you?

Dr. SCHMIDT. Yes, I believe so. That is really what the mandate of the Agency is.

Mr. GORDON. How many of these drugs have been removed from the market in the last few years.

Dr. SCHMIDT. In the last few years, of the so-called DESI drugs, we have removed about 6,300.

Mr. GORDON. Because they do not meet the requirements of safety and efficacy?

Dr. SCHMIDT. Safety or efficacy—that is correct.

Mr. GORDON. Is it not correct that there are still such drugs on the market?

Dr. SCHMIDT. Yes, there are still some on the market for a variety of reasons. Some legal, and Mr. Hutt can speak to those, and some because we are just finding out about them. I think it will probably always be the case that we will be in the process of investigating and removing some drugs. But there are some that are on the market now that probably should come off.

Mr. GORDON. In fact, as I understand it, some drug firms have taken legal action against you to prevent your taking these drugs off the market.

Dr. SCHMIDT. Mr. Hutt has told me he needs a much larger legal staff, and I think this is part of the reason. Perhaps I could refer this question to him.

Mr. HUTT. This is, to a large extent, a statutory problem, Mr. Gordon, as I believe you are aware. The statute provides that, when we wish to withdraw approval of a New Drug Application, if the company submits objections and a request for a hearing, its product, may remain on the market until all of the administrative procedures are completely and thoroughly exhausted, unless the Food and Drug Administration can determine it represents an imminent hazard to health. In the entire history of the DESI review, which as you know