

over-the-counter drugs which are sold in even greater quantities. I think just the volume itself speaks somewhat to the problem.

The subject of adverse reactions to drugs is an important subject. This complication rate has been estimated at some 10 percent, and further that approximately 5 percent of all patients admitted to general hospitals are admitted because of some form of drug reaction.

As I have indicated in my testimony, studies have shown that the average hospital patient receives between eight and 10 drugs per hospital admission and this, of course, may go much higher.

I think all of these indicate, to a degree, the magnitude of the problem we are talking about this morning.

Mr. GORDON. You also state:

We have a responsibility to do what we can to assure that Federal purchasers are fully informed about the products they buy.

What have you done to keep the Government agencies informed about the merits and demerits of drugs on an absolute as well as relative basis?

Dr. EDWARDS. Well, as you know, at least as it relates to the current drug efficacy study, we have sent to each of the purchasing agencies in the Federal Establishment that purchases drugs, our list of drugs classified by NAS-NRC as "ineffective." We intend to keep them up to date on this.

We also intend at the completion of this study to publish a document on the study per se listing all the drugs and their classification by the National Academy of Sciences.

In terms of our day-to-day activities, and Dr. Simmons might want to address himself to this particular question, I do not believe we notify Federal agencies on a day-to-day basis of the new drugs we have approved. Is that correct?

On a periodic basis they are notified but not with each drug as it is approved by the Food and Drug Administration.

Senator NELSON. What kind of a response, if any, have you gotten from any of the professional organizations, the medical profession, or from individual physicians across the country when you have listed a drug that has been widely used and then taken off the market as "ineffective" or "possibly effective?" Those two categories go out of the market forthwith, if they are classified as such; is that right?

Dr. EDWARDS. Possibly. In the case of those drugs classified as "ineffective", the manufacturer has 30 days in which to submit new evidence to us to justify a change in that classification. With "possibly effective" drugs, 6 months are allowed for submission of new evidence; and for the "probably effective" drug 1 year is allowed.

Senator NELSON. Of those that have been removed from the market because they were found to be ineffective or because companies could not come up with evidence to sustain any claim that they were effective, what kind of a response have you heard from the profession?

Dr. EDWARDS. I suspect it is a little early to make any blanket statements. We have certainly heard from the American Medical