

the NAS-NRC noted that most of the current package inserts require significant revision. As I say, that is being done. Too often they are promotionally slanted. They sometimes are models of clarity when it comes to claims of effectiveness, but models of obscurity in the discussion of limitations, side effects, contraindications, et cetera. In our judgment, our interim labeling regulations will help to correct this problem.

Our first task here is to develop uniform labeling for classes of drugs so that the prescriber will understand that tetracycline, for example, by whatever trade name it is sold has the same indications and the same warnings, et cetera. We are developing such labeling in the course of the NAS-NRC reviews.

We have also increased our advertising surveillance to make sure that the appropriate message, as approved in the package insert, is reflected in the important phases of promotion.

We and the manufacturers involved are studying the problem of detailing, to attempt to assure a balanced oral message to the busy practitioner.

And finally, we have the important problem of adverse reaction reporting from the prescribers themselves and of communicating the experience so reported in a timely fashion to others who use the drug. We can offer no solution to this at the moment, but we are in the process of planning and developing the system necessary to solve this problem.

Communication to other Federal officials involved in drug purchasing, of course, is a simpler problem.

The Federal Register is the official vehicle through which we first publish our position with respect to the safety and efficacy of drugs. We have recently supplemented this in an effort to make sure that affected people are notified with a list representing those drugs which lack substantial evidence of effectiveness, or that an unfavorable benefit-risk ratio exists.

Mr. GORDON. Dr. Edwards, do you tell the press about important actions which you announce in the Federal Register?

Dr. EDWARDS. Practically all of the time a press release is prepared when any important drug or other important announcement is placed in the Federal Register.

Mr. GORDON. I am thinking specifically of the potassium thiazide combination diuretics about which you had some kind of an agreement with the industry recently. You had a notice in the Federal Register but I did not notice anything in the press. I did not even know about it until someone told me about it. And then also the Darvon. I did not even know that there was a statement in the Federal Register about Darvon, which I understand appeared in April 1969, until I got the NAS-NRC report last summer.

Mr. GOODRICH. On the thiazide diuretics, the two leading brands in the market, Esidrex-K, Hydro-diuril-Ka, were removed from the market soon after the *Panalba* case was decided back in the spring of last year. One product still is in controversy with us, a Squibb product under which they have submitted some data.

I do not know what you have in mind in terms of an agreement. The agreement was that they would take the product off the market,