recall it from the marketplace. This was with Esidrex-K, Ciba, and Merck & Co., Inc. did the same with Hydro-diuril-Ka.

In the case of Darvon, that announcement was made, as you indicate in 1969, I believe, and we did not have a press release at that time. We are trying to be more alert to the important drugs as they come out to attempt better communication. But the NAS–NRC evaluations themselves are made available both to the press and to the affected people and anyone else who is interested enough in them at the time they are published in the Federal Register.

Dr. EDWARDS. We have established a working relationship with the AMA Medical News in which weekly or every other week they will publish in that publication a list of products that were found ineffective. In the case of Darvon we are currently again revising the labeling on Darvon, but——

Mr. GORDON. Is this information reaching the hands of every doctor in the country?

Dr. EDWARDS. Probably not. I suspect that we should be using far more than we have the "Dear Dr." letter, and our new "Current Drug Information" letters which as you know, we started in 1970. We are working to publish that more frequently on a number of different subjects. The "Dear Dr." letter is another, of course, mechanism for communicating with the practicing physician. We have not been totally impressed with the value of this as such. It is a very expensive way of doing it.

We are trying to come to grips with what method is the most dollar wise—considering the limited dollars that are available in the Agency, what is the most effective way of communicating with physicians. It is a tough problem to come to grips with.

Mr. GORDON. How about States and municipalities? They have a similarity of interests, do they not?

Dr. EDWARDS. This information was sent to State purchasing officials, Secretary of State Departments of Health, and Secretary of State Boards of Pharmacy.

Mr. GORDON. We are not sure doctors are getting this information, are we?

Dr. EDWARDS. No, we are not, very frankly. It is a weakness and one that I can only say at this time that we are trying to correct. I think over the years the practicing physician has not looked to the FDA enough for reliable drug information and this is one of the areas in which we have got to reestablish our image as being in fact the center for reliable, meaningful drug information. Unfortunately, in the past I think it has tended to be the drug detail man and in our judgment, we have to swing this back.

Senator NELSON. What is the legal status of a dosage form that is no more effective than a placebo? In other words, NAS–NRC says a 32 milligram tablet of propoxyphene hydrochloride, that is Darvon, was shown to be no more effective than a placebo. It is in the marketplace. What is the legal aspect of that?

Mr. GOODRICH. The legal aspects are that any claim of effectiveness for any type of drug must be supported by substantial evidence as we have indicated. As I understand the justification for the 32 milligram, it is to permit some dosage flexibility, but this is a matter that we must look into in terms of going over the claims.