point where only effective claims are used but the point of the regulation is that any time a claim rated other than effective is used in promotion during this interim period of implementation, that is the 6- and 12-month period, there must be an appropriate qualification of that claim.

Now, the other point you are addressing is, of course, an important point. Where the prescribing profile of the drug is basically changed, should there be some method of communicating to the physician?

The answer, of course, has to be yes. But whether it should be in that ad which covers only effective claims, we do not think so. There should be other mechanisms of communicating the new prescribing profile for, let us say, the sulfonamides or even the tetracyclines.

Dr. EDWARDS. This will be, as I mentioned earlier this morning, all in a document that we intend to publish as soon as this is complete on all of the drugs that were considered by the National Academy of Sciences and their particular recommendation.

Senator NELSON. Thank you very much, Dr. Edwards. We appreciate your taking time to come.

The hearing will resume in this room at 10 a.m., tomorrow, with the Comptroller General.

(Whereupon, at 11:55 a.m., the hearing was recessed, to reconvene at 10 a.m., Tuesday, January 19, 1971.)

(Upon the direction of the chairman, information pertaining to the hearings follows:)

[Press release dated Jan. 14, 1971]

NEWS OF ELI LILLY & CO.

Senator Gaylord Nelson has attacked the medical value of Darvon® (propoxyphene hydrochloride, Lilly) and criticized government agencies for buying it in a low dosage form he contends is "ineffective."

The Senator quoted the National Academy of Science/National Research Council finding that the "32 mg. dose has often been found indistinguishable from placebo." He added that experts believe there is "no particular reason to use it (Darvon) routinely in preference to (other analgesics)."

The Lilly Company makes the following reply:

The smaller dose (32 mg.) of Darvon® (propoxyphene hydrochloride, Lilly) is made for special situations. It gives flexibility of dosage, enabling the physician to tailor the amount to the needs of the individual patient. Some patients find the 32 mg. dose quite adequate, although a 65 mg. strength is most frequently used. In short, Darvon is effective in the way physicians use it.

The fact that some investigators failed to show a difference between 32 mg. of Darvon and a placebo, or "sugar pill", is not surprising. All analgesics give similar results at their lower ranges of effectiveness. Thus a placebo often performs as well as a single aspirin tablet. This does not mean that the aspirin tablet is a placebo. It merely shows that analgesia research, being based on subjective evidence, is not at all that precise at the lower ranges of dosage.

As for the view that Darvon should not be prescribed "routinely" in preference to other analgesics, we agree. No analgesic should be prescribed except after consideration of the particular needs of the particular patient.

[From the New York Times, Dec. 21, 1970]

MANY DOCTORS IGNORE U.S. LIST OF HAZARDOUS OR USELESS DRUGS

(By David A. Andelman)

A list of 369 drug products considered ineffective or hazardous by the Food and Drug Administration apparently is being ignored by a large number of doctors and their patients across the country. Some doctors go so far as to say they consider the Federal agency's action in issuing the list unethical.