

Senator NELSON. In other words, if you need a mild analgesic, isn't the drug of choice aspirin, unless there is some reason for selecting another analgesic?

Dr. EDWARDS. That would be my analysis. I am sure that there are those who would say Darvon is necessary.

Senator NELSON. Oh, good heavens. Wholesale sales amount to \$80 million worth or about \$140 million in the retail marketplace. Apparently doctors prescribe it day-in and day-out with no indication that you ought to have Darvon instead of aspirin. I think that is what the promotion is all about. How they make a decision to prescribe something that costs the patient 100 times as much as aspirin is another example of the power of promotion and advertising.

Is there any reason that you know for routinely prescribing Darvon as a mild analgesic?

Dr. EDWARDS. No. I think it is exactly why we are taking these various steps to better educate the physician. In this regard, although the cost of the medication is not the direct responsibility of FDA, nevertheless, we have to take it into consideration.

Mr. GORDON. In the articles which appeared in the Medical Tribune on April 19 Dr. Edward Freis said: "There are excellent new anti-hypertensive agents available to clinicians in Europe but not in the United States. The Bethanidine, for example, can be prescribed for patients in Great Britain and the Scandinavian countries, but not here."

Dr. Lasagna in the same issue of the Medical Tribune cited the availability of carbenoxalone "the drug of choice in gastric ulcer management in Great Britain, and in a recent poll of United Kingdom experts," Dr. Lasagna said, "this was rated as their therapeutic maneuver number one. If that is so, that means that our patients are being deprived of an important drug."

"We have one beta-blocker in the United States," Dr. Lasagna noted. "There are several in the United Kingdom. And even the one that we have is not approved for use in high blood pressure or angina, although the evidence suggests that it could be of benefit for those indications."

I wonder if you could comment on those statements?

Dr. SIMMONS. Yes, Mr. Gordon. I think that if you examine carefully the charges that have been made, you will find that they are unfounded. The drug to which Dr. Lasagna referred is available in England.

Senator NELSON. What kind of a drug is it?

Dr. SIMMONS. It is an ulcer drug that is available in England. There have been recent reports of a high incidence of side effects from this drug, including hypertension and heart failure. For this and other reasons we and other experts in this country feel further studies are necessary. We think it warrants carefully conducted trials. Nobody has given us the judgment that this drug should be generally available for use in this country before these trials are completed.

Senator NELSON. There has been no application submitted to FDA to market it in this country?

Dr. SIMMONS. To the best of my knowledge; no. As to the beta-blocker problem, we have run into adverse effects produced by several of these experimental drugs in animal systems. Because of this and with the advice of our advisory committee, we are limiting studies