

Do you wish to have that printed in the hearing record?

Dr. MOERTEL. Senator Nelson, I did not submit that reprint to you.

I would be very pleased to have it printed though, if this is the desire of the committee.

Senator NELSON. It addresses itself to these studies.

The title is "Relief of Pain by Oral Medications, a Controlled Evaluation of Analgesic Combinations."

Dr. MOERTEL. This is undoubtedly a reprint of the second study of which I referred, but as I said, I did not provide that reprint to the committee.

Senator NELSON. We will review it, and if it adds to your testimony, we will simply print it in the record.

[The prepared statement and supplemental information of Dr. Moertel follows:]

TESTIMONY BEFORE THE SELECT COMMITTEE ON SMALL BUSINESS, U.S. SENATE,  
CHARLES G. MOERTEL, M.D., MAYO CLINIC, ROCHESTER, MINN.

Studies involving Darvon and its combinations conducted at the Mayo Clinic have primarily involved treatment of the patient with advanced cancer. For these patients our single most overriding responsibility is relief of pain. Unfortunately in this vital area we as physicians frequently perform rather poorly. In our medical schools instruction in the practical use of drugs is often inadequate. Our judgment in prescribing drugs for pain is quite comparable to the public's judgment in purchasing over the counter drugs for pain. Both are largely governed by advertising. We as doctors are no less vulnerable than the public at large to the persuasive influence of Madison Avenue. For vivid evidence of this you only have to look at the Physicians Desk Reference. This is a manual distributed free of charge to all physicians each year by the Pharmaceutical Manufacturers Association. It lists all prescription drugs promoted by pharmaceutical companies. In the 1978 edition there were 149 drugs advertised for relief of pain by oral route of administration.

More than a decade ago, because we were disturbed by our ineptitude in the management of pain of the cancer patient, we initiated at the Mayo Clinic carefully controlled research studies to evaluate the relative effectiveness of the many medications for pain that were available to us. Our only vested interest was our patient in pain and these studies were not paid for by any drug company.

To insure that the results of these studies could not be in any way influenced by us or by any preconceived ideas of our patients, we double blinded the studies. By this I mean that all of the pain medications we gave to the patients looked exactly alike and were identified only by code number. Neither we nor the patients could tell which was which. The drugs were administered in randomized sequences and we only broke the code when the entire study was completed.

In our first study we looked at analgesic drugs in their pure form and this study compared nine different analgesics as well as placebo or sugar pill. It involved close to 600 drug evaluations. Our results with the four drugs that are pertinent to this hearing are displayed in Table 1. As in all studies, even with cancer pain, there will be a substantial number of patients who claim relief with sugar pills. Darvon showed some advantage over sugar pills, but this was small and not statistically significant—that is the difference could easily have occurred by accident. Acetaminophen or APAP—commonly marketed as Tylenol or Datril—showed a much more substantial degree of relief; and surprisingly, leading the pack, two simple aspirin tablets. The superiority of aspirin over Darvon was statistically significant—by that I mean that the odds are greater than 20 to 1 that this difference did not occur by chance alone. These results were quite startling to us because at that time Darvon led the market in prescription drug sales.

It can reasonably be argued that although interesting these results really aren't a fair evaluation of Darvon. Although Darvon is sold in pure form, it is usually marketed in combination with aspirin or APAP or with APC as the so-called Darvon compound. In a second study we, therefore, looked at aspirin alone compared to aspirin plus a variety of other drugs that are commonly marketed in aspirin containing drug combinations. This study involved 100 patients in 1000 separate drug evaluations. In Table 2 you can see that again