I think it is a clear example of a situation where we need further research before we can make a definite decision whether this drug should be removed from our formulary.

Senator NELSON. You can't come up with carefully controlled studies that demonstrate that it is effective, is that correct?

Dr. COHN. I think that the controlled studies that have been done so far are unfortunately on too small a group of subjects to take a categorical position about its effectiveness.

Senator NELSON. Would the controlled studies that have been done qualify it under the effectiveness provision of the Kefauver 1962 statute—substantial evidence of effectiveness?

Dr. COHN. I think that at the moment—there is no demonstrated substantial evidence of effectiveness, but there is no clear-cut proof of ineffectiveness. There have also been controlled studies of nitroglycerine which is a drug which almost all physicians accept as effective in treatment of angina. There have been in the past controlled studies of nitroglycerine which have shown this drug to be no better than a placebo. There have been other controlled studies which have shown it to be effective and physicians today use this drug with a rather firm feeling that the drug is effective. And we have not really—this drug has not come into conflict because it is generally used.

Peritrate is in the status of a drug which some controlled studies have shown to be ineffective but not enough studies have been done in a large enough series that all physicians are willing to accept the data from these controlled studies.

Senator NELSON. Well, what do you say about Darvon?

Dr. COHN. I think I should turn that over to someone else.

Senator NELSON. The testimony of medical experts, which remains uncontradicted—though there may be somebody in the country who can contradict it—is that the drug of choice for a mild analgesic is aspirin. Of course, there may be special cases where if somebody was allergic or something, you may use Darvon, and they recited a couple of special cases. The witnesses could not explain the substantial, very large purchases of Darvon by DOD and VA. I think DOD bought more than four and a half million dollars' worth and nobody could explain why they would buy that much, when you could have bought the same amount of aspirin for $180,000. You could have saved about four and a half million dollars.

Well, what is going on in the Department of Defense purchasing and VA purchasing to get all this Darvon?

Dr. WELLS. Mr. Chairman, may I ask Mr. Statler, our Chief of Pharmacy, to take up this point.

Mr. STATLER. Yes, Senator. On Darvon, VA's purchases in the past year admittedly have been around 51 million doses of Darvon and we are not trying to defend the large use of this drug.

In the same period of time, however, we did buy around 110 million doses of other analgesics, notably aspirin. In the drug efficacy study reports which the NAS–NRC sends to FDA are these extracts in addition to the comments which we frequently heard about 32 milligram dosage not being as effective as a placebo.