Dr. GODDARD. That is a different problem. That is out of my province.

Senator SCOTT. Thank you, Senator Nelson.

Senator NELSON. If I understand correctly, you said that about half the New Drug Applications were for patentable products?

Dr. GODDARD. That is an estimate we have made in the past decade; that about half of them are patentable.

Senator NELSON. Do the firms usually get a patent if the drug is patentable?

Dr. GODDARD. I assume they do. We do not know. The Patent Office has a serious backlog problem, too, Senator.

Senator NELSON. Under the law, all that is necessary is that the new drug be proven safe and efficacious; is that correct?

Dr. GODDARD. Those are the general requirements, and also that they will provide us information on their quality controls and provide good manufacturing practice, et cetera.

Senator NELSON. Then, what percentage of these nonpatentable new drugs are really just molecular manipulation or a fixed combination?

Senator SCOTT. Would you excuse me, that is how we got here as a result of molecular manipulation, is it not?

Dr. GODDARD. Yes, sir, we are products of RNA and DNA, going back to earliest forms of life.

Senator NELSON. The results you get by manipulating depends on who you are and what quality you have?

Dr. GODDARD. That is right.

Senator SCOTT. The process provides a good deal of amusement to the human race.

Dr. GODDARD. Though one can't take any given year as being completely representative, last year we approved 83 New Drug Applications. Fourteen of these were new products, Senator, really new chemical entities.

Senator SCOTT. Under the criteria used——

Senator NELSON. Fourteen of——

Dr. GODDARD. Eighty-two. So 69 of them were what have been called "me too's" or molecular manipulation.

Senator NELSON. They did nothing that some other drug already on the market did not do?

Dr. GODDARD. That is right. These 69 represent another tranquilizer, another new diuretic, et cetera.

Senator NELSON. No clinical superiority of those 69 over older drugs?

Dr. GODDARD. There would be differences in levels of clinical superiority.

Senator NELSON. How many of those 69 were fixed-combination drugs?

Dr. GODDARD. If I can refer to the record here, less than a third, I would say. I am guessing now. I would like to submit that for the record to be entirely accurate.

Senator NELSON. If you would.

(The information referred to, subsequently received, follows:)

STATEMENT OF THE FOOD AND DRUG ADMINISTRATION REGARDING THE NUMBER OF FIXED COMBINATIONS APPROVED FOR MARKETING IN FISCAL YEAR 1967

Of the 69 NDA's approved in fiscal year 1967 other than those for new single chemical entities, 11 were NDA's for combination products. Seven of these were