In the patent provisions of the original S. 1552, Kefauver proposed that a patent application for "any molecular modification of any patented or unpatented drug or for any combination of two or more drugs" would not be granted a patent unless "the Commissioner (of patents) * * * determined that the change from the prior art made by the modification or combination would not have been obvious to a person having ordinary skill in the art, and (B) the Secretary (of HEW) has determined that the therapeutic effect of such a modification is significantly greater than that of the drug so modified or that *the therapeutic effect of such drugs taken in combination is significantly greater than the therapeutic effect of such drugs when taken separately*". [My emphasis.]

The legislation I have in mind would simply substitute for patent application a new drug application and in place of granting a patent, granting a license to market. Like the efficacy provisions of the 1962 legislation I would make the legislation retroactive. In determining the definition of significantly greater therapeutic effect I would again be guided by the definition of efficacy that appears in the Kefauver-Harris Amendments of the Drug Act, "substantial evidence means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could be fairly and responsibly concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof".

In brief, the legislation I have in mind has already been written. Making it applicable to drug combinations requires changing a few words. I am not unrealistic enough to believe that such legislation could get past the PMA and AMA lobbies without a Gargantuan struggle. Nonetheless it is required if we are going to put teeth into the drug act.

A valid objection that would be raised is that prescriptions for two or more drugs would cost more. This is a moot point and we must weigh it against the fact that a combination such as Achrocidin is prescribed for at least 10 patients who do not need it, for one who may need it and all patients pay for the antibiotic they may or may not need. The antibiotic constitutes the major part of the cost of the combination. The argument that rational prescribing would cost more than irrational prescribing is, in my opinion, inane and I do not believe that it could survive in any fair debate over the issue

Raising the question of the cost of drugs, I am reminded that I intended to clarify the question of whether licensing, inspection, and strict quality control would raise or lower the cost of drugs. The Task Force Report states: "Any company, large or small, brand name or generic name producer, can institute and maintain an effective quality control program, and most companies have apparently done so. The cost of such a program has been estimated to be about 2.4% of sales for a large company, but may be somewhat more for a smaller firm".

The term "somewhat more" is vague but I believe we can satisfy it if we multiply 2.4% by more than four times and assume that strict quality control for a generic drug would raise its price by 10%. The Committee is aware that the spread between brand name and generic drugs can be in the order of ten times or more, but these are extreme examples. Let us take an average example with which I am well acquainted. Generic Sodium Pentobarbital sells for approximately $4 per thousands. In the catalogues sent to me (a copy of which is enclosed) by wholesale houses the price has varied from $3.85 to $4.40. This is an umbrella price at which I can buy the drug in quantities of 1,000. The pharmacist probably pays less; he certainly does not pay more. In the same catalogue the price of Nembutal (Abbott's brand name for the same drug) remains fixed at $17.00 per thousand. If we assume that the generic brand is not quality controlled and that the institution of quality control would raise the price by 10% we still have a figure of $4.40, or at most, $5.00 per thousand. Even an idiot can conclude that in a competitive market the $17.00 brand would have to lower its price to meet the competition or be forced off the market. It is conceivable that it could be reserved for the carriage trade since there are those people who automatically conclude that anything that costs more must be better. The physician who writes prescriptions for patients cannot and should not indulge in this luxury.

While the relative wholesale price of brand name drugs as compared with generic drugs is just as available to other physicians as it is to me, any attempt to translate these prices into the price the patient pays for his prescription