to be printed in a journal in 2 weeks, a document which is not given to others for review despite the known controversy which exists. Then the AMA calls a prepublication press conference, and announces an article that is to be printed in 2 weeks, and the result is a headline which appears in papers throughout the country which speaks of 15,000 people dying each year, which has nothing whatsoever to do with any of the material to be published. I think it is irresponsible, and I am extremely disappointed that the AMA has seen fit to take this measure; I can only ascribe it to some naivete, they never should have functioned in this manner.

The CHAIRMAN. I have not, by the way, seen either the editorial, nor have I yet seen the report of the Biometric Society.

Mr. CHAYET. You ought to read it. It is most interesting, particularly the editorial.

The CHAIRMAN. Well, I have not seen it.

Mr. CHAYET. Senator, I am sorry to go on for so long, but you said something previously about the legal aspects involved in this matter, and you referred to the Food, Drug and Cosmetic Act. I would like to address myself to this aspect of this very important question.

We have depended on a regulation of the FDA itself, which reads as follows:

> The existence of a difference of opinion among experts qualified by training and experience, as to the truth of a representation made or suggested in the labeling is a fact the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representations.

What this means is, if a manufacturer seeks an NDA and he knows that there is controversy over his product, he has a duty to come forward, if there is a material weight of opinion against his drug, and inform the FDA. Why does not the Government have a similar obligation to inform physicians that there is a material weight of opinion contrary to its findings? Why has the Government sought to repeal this regulation when the case was returned to the agency by the court of appeals? Does this principle exist only for the manufacturers? If there is material weight of opinion against a position why is it stifled and not reflected—just because it is the Government position? That is my question. I have not yet received an appropriate answer.

The CHAIRMAN. Well, just let me say—if we are addressing ourselves to the same thing—that I carry no brief for everything the FDA does, but, as a matter of fact, they have in a very massive way done exactly what you say they have not done. In accordance with the 1962 amendments to the Kefauver Act, the FDA contracted with the National Academy of Sciences-National Research Council which set up panels on all kinds of drugs. These panels evaluated thousands of drugs and then made recommendations. And the FDA took very positive action on a large number of drugs, perhaps as many as 6,000 of them.

Mr. CHAYET. That is true.

The CHAIRMAN. Informing the public about their deficiencies.

Mr. CHAYET. I do not want to imply that the FDA does not do anything proper at all. The FDA has done a great deal of fine, very valuable, very important work, and I never want to deprecate that