have said. There has also been a good deal of evidence on the other side. And this is not a generic brand issue, Senator, it is a question of the competence and the capabilities of the manufacturers of drugs, no matter how they market their products. It is a question of the current competence and capability of FDA to inspect and insure good manufacturing practices. It is a question of the sufficiency of the standards of compendia and those things, incidentally, were all reviewed in the OTA report which you are familiar with. And they did not come up with the conclusions you stated. They found problems.

Just this last week on the issue of FDA competence, the House Appropriations Subcommittee has indicated in its report—not yet published but available for review—that there are very serious questions about the inspection capabilities and performances during the last 2 years by the FDA.

Now, we don't announce this with pride. We have problems with that too. And we have appeared before the Appropriations Committee and have asked that the FDA be given more inspectors and more money. But nevertheless, GAO report of 2 years ago, and the report here now of this week indicate that anybody in FDA who says they have got the inspection problems in hand are not giving you the whole story. There are problems there, serious problems. And that is why we say, you cannot make an assumption across the board that drug producers or their products are of equal value and safety and effectiveness. There are two sides distinctly to that issue.

The CHAIRMAN. Of course, you will never achieve perfection. There will be drugs that will fail tests no matter who the manufacturer is. But the fact is that the best testimony we have received is that of drugs going into the marketplace, there is no significant difference between them. So if the end results of the tests and studies that FDA is making, those that are being made, indicate that there is no significant difference, that doesn't mean we shouldn't have more inspections, and inspectors, and it doesn't mean that it isn't necessary from time to time for compendial standards to change. But it also means that all of those drugs coming out in the marketplace for all practical purposes are equivalent in their quality and their standards of manufacturing. So why fuss about it?

Mr. STETLER. That is a big guess, incidentally, on the part of FDA. They do not know that.

Let me give one specific. Over 2 years ago they issued for comment their regulations on bioavailability. Now, this is just to announce the standards that they expect manufacturers to comply with. To this day final regulations have not been published. A lot of the statements they make before congressional committees say that "we will be able to" or "we are going to." But certainly any final promulgation of MAC would have to await at least the issuance, and hopefully some assurance of compliance with bioavailability regulations. They haven't even been issued yet.

Now, in the absence of such regulations, how they can say manufacturers are in compliance? I am not able to understand.[1]

[1] These regulations entitled "Requirements Relating to Bioequivalence and Bioavailability of Drug Products," were published by the Food and Drug Administration on June 20, 1975, in the Federal Register, pages 26142–26171.