It is not a question raised by me. It is a question raised by the Commissioner and by yourself in a subsequent speech.

Then he goes on to say:

Now, I will admit that government employees do not have a corner on all wisdom. I will admit that there are gray areas in the IND situation. But the conscious withholding of unfavorable animal or clinical data is not a gray area matter. The deliberate choice of clinical investigators known to be more concerned about industry friendships than in developing good data is not a gray area matter. The planting in journals of articles that begin to commercialize what's still an investigational new drug is not a gray area matter. These actions run counter to the law and the ethics governing the drug industry.

(Document follows:)

SHARED RESPONSIBILITIES

(By James L. Goddard, M.D., Commissioner of Food and Drugs)[1]

INTRODUCTION

I welcome very much the opportunity to speak before you today. During the past two and a half months, it's been my pleasure to chat with many of you individually. Your courtesy visits and phone calls have been much appreciated.

They were an indication to me that many pharmaceutical manufacturers were seriously interested in the future of their industry and wished to join me in developing ways through which that future would be made a good one.

As you have come to see me, so I am here today to see you. We have much to talk about together, especially in this matter of the future of the drug industry.

Both of us—you in private industry and we in Government—share the responsibility for keeping the industry viable and healthy. In this matter, we can learn from each other.

I know many of your scientific people and I respect them. And when I say that we in Government can learn from industry, I speak from personal experience with industry's medical staffs.

However, today I am not speaking to industry's physicians. I am speaking to its decision-makers. And I am asking you to consider the ramifications of some past decisions and the ramifications of your future decisions as company—and industry—leaders.

I ask this, gentlemen, because I am very uneasy about the way events are catching up with you.

I will be quite candid with you: There is a real danger that the pharmaceutical industry as you and I know it today may be altered significantly, altered beyond your present fears, and altered beyond recall.

If this sounds alarming, it is because—frankly—I *am* alarmed. Let me give you the basis for my feeling of alarm, after only ten weeks in the Food and Drug Administration. During this brief but busy period I have seen evidence that too many drug manufacturers may well have obscured the prime mission of their industry: to help people get well.

Let us agree that every industry has to make a profit for its stockholders. I am not against profit in the drug or any other industry. The profit motive—as the Russians are finally discovering—stimulates beneficial activity: competitive research and marketing, mass education, and the rise of the general standard of living.

But each industry must have some deeper dynamic of its own, something that makes the drive for profit really worth the trouble. And I would submit that the central dynamic for the drug industry has been—*and must continue to be*—the maintenance of the health of all Americans through better pharmaceutical products.

Gentlemen, we must keep our eyes on the patient. For—once you get through the medical reports and the counselors' opinions, the advertising and the marketing data, the licensing and distribution agreements, the protocols and letters of credit, the labeling and packaging, and the report by the company treasurer—once you get through all that, you reach the physician who will administer your product to a human being.

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[1] Delivered at the annual meeting of the Pharmaceutical Manufacturers Association, April 6, 1966, at Boca Raton, Florida.