

Mr. GORDON. You say that there is no convincing evidence that controlling blood sugar prevents or retards the vascular complications resulting from diabetes.

In that case, then, is there any sense in using drugs that are harmful to accomplish something that we don't know is helpful?

Dr. FELIG. Patients may derive some benefit from oral agents by virtue of their effects on the acute or short-term consequences of the high blood sugar. When the blood sugar rises to the point of causing excessive urination, as Dr. Chester has indicated, the depletion of certain essential body minerals, electrolytes, is harmful. In that circumstance, there are patients who, because of their total unwillingness to use insulin, could benefit from the oral drugs in the sense that they could have symptomatic relief. So, in that short-term or limited sense, one could ascribe a therapeutic benefit from these drugs. Whether or not that outweighs the consequence or the potential risk is something that is the essence of clinical judgment.

Mr. GORDON. We have asked Dr. John Davidson, who is director of the diabetes clinic in Atlanta, Ga., what percentage of the people using these drugs should actually be using them. He stated that maybe 1 percent of the people who are using them should be using them; or, 99 percent should not be using them. We asked Dr. Bradley who is one of the proponents of the use of this drug—or at least so he seems to be—the same question. He said that about 80 percent of the people who were using them should not be using them. Then I asked Dr. Winegrad the same question on the telephone, and he estimated about 90 percent of the people. So, you see, you have from 80 percent to 99 percent of those who are using them that should not be using them.

Would you gentlemen care to make any estimates, given your experience, given the fact that maybe 1½ million people are using these drugs?

Dr. FELIG. I am firmly convinced that there is overutilization, and we think that the figure of 80 percent represents a very conservative estimate of overutilization. We estimate that probably somewhere in the neighborhood of 90 percent should be treated with means other than the oral agents.

Mr. GORDON. Would the others agree with you?

Dr. CHESTER. I would.

Dr. LARNER. I would think 90 percent or more.

Dr. SIMS. I think it is a game of selecting a figure. But it is worth emphasizing that, if there is a minute percent in which the drug is indicated and the drugs are allowed to remain on the market for that reason, the realities are that it will continue to be used on many more patients. I believe it is for that reason that the FDA and others have to play an active role in education, as was emphasized at the hearing yesterday.

Mr. GORDON. Dr. Felig, please proceed.

Dr. FELIG. It is thus clear, I think, from what the other experts here have said, as well as from what is generally recognized, that these drugs are useful in a very limited number of patients with adult-onset diabetes; namely, those with symptoms due to an elevated blood sugar in whom dietary measures have failed and in whom insulin is impractical or refused by the patient. While some