

policies and methods I am by no means always in complete agreement. In this case, however, it is difficult to categorize their action as punitive when the demand is simply to provide evidence, thus far unavailable, that these drugs are effective for the claims they are purported to have. I am confident some pharmaceutical groups involved in this controversy will attempt to provide such evidence. These data should be evaluated critically, objectively, open mindedly, and reevaluations of efficacy considered and accepted, regardless of whether they agree or differ from the ones which now stand. I emphasize why with Dr. Kunin.

The implication that a large number of practicing physicians have gathered evidence which is valuable with respect to evaluation of drug efficacy and which has not been adequately considered by the panels deserves brief examination. It might be appropriate to consider the type of contribution which the practicing physician can best make which is valuable in the advancement of scientific and medical knowledge. It is a practical impossibility to project reliably all the results, good and bad, from extensive drug usage with the necessarily somewhat limited scientific investigations of each agent prior to its public release. To accomplish this might not always but often would work to the public detriment and unnecessarily delay the availability of many valuable drugs for the treatment of human ills. What may happen, however, is exemplified by the bone marrow toxicity of chloramphenicol producing usually fatal loss of white blood cells. This became clear only several years of general use and it was actually only a few years ago that the toxicity of chloramphenicol for premature infants was recognized.

Dr. Bryan Williams, now a practicing physician in Dallas, Tex., and myself published one of the first extensive clinical investigations of chloramphenicol and noted that the white blood count in several patients fell to low normal or low levels following cure of their infection. Although the implications may be clear in retrospect we were not sufficiently insightful to recognize them at the time.

It remained for the use of the drug by practicing physicians to make clear the importance of this phenomenon. Another example is provided by an agent which prevents manufacture of cholesterol, MER-29, from which the serious side effects requiring its removal from commercial distribution were appreciated only after its introduction into medical practice.

Mr. GORDON. May I correct you there. As I understand it, Richardson-Merrill knew about the side effects of MER-29 before it went on the market, but withheld the information from the FDA and from the medical profession. They were subsequently convicted in a criminal case for violating the Food and Drug Act.

Dr. HEWITT. I stand corrected.

Senator NELSON. As to the question of chloramphenicol, as I recall it, the first time evidence of serious damage to blood occurred was in 1954, and I think it came on the market in 1949.

Dr. HEWITT. Yes. The reference to this article of Dr. Williams and myself is 1950.

Senator NELSON. The point I wanted to raise is this: It is correct, is it not, that the scientific community has been aware, since the mid-