we believe, is for medical conditions for which the drug is not indicated or for which it is expressly prohibited, such as acne, the common cold, simple infections and the like. We are disappointed by a current advertisement in the *Readers Digest* by the Pharmaceutical Manufacturers Association, which describes chloramphenicol as a prime member of a "class of drugs that fights 100 diseases" and characterizes it as a "broad spectrum" antibiotic effective against dozens of diseases, causing only occasional and sometimes serious side effects in some patients.

The exact number of patients who have suffered a serious or fatal blood disease as a result of the indiscriminate use of chloramphenicol is not known.

Various estimates place the incidence rate of blood dyscrasias from chloramphenicol at one (1) person in ten thousand (10,000) to one (1) person in one hundred thousand (100,000) who receive the drug.

Despite the risks associated with the use of chloramphenicol, if one may judge from the sales figures, use of the drug continues to be excessive. Where have the FDA, the manufacturer, and the medical profession failed? Is the general medical community unaware of, or unconcerned about, the risks associated with this drug? What must be done now? These are most difficult questions, and the answers do not come easily.

The "box warning" in the labeling is strongly worded and tells the physician quite bluntly the dangers of the drug, yet it has not accomplished its intended purpose.

What other steps might be taken? We have considered restricting the use of chloramphenicol to hospitals. However, aside from the legal problems involved, we have learned that more than half the chloramphenicol distributed in this country is purchased by, and presumably used in, hospitals.

In addition, restriction of the drug to hospital use alone would pose an undue hardship on some patients for whom the drug is properly prescribed. There are fewer than 1,000 cases of Typhoid Fever in this country each year, but the majority occur in rural areas which may not be served by hospitals and a few patients may require continual use of the drug after their hospital discharge. Some persons, therefore, would be deprived of appropriate treatment unless they undergo the inconvenience and expense of a hospital confinement.

Other measures have been suggested, such as requiring that every prescription for chloramphenicol be countersigned by a second physician or requiring permission by a board of physicians before the drug could be used. Such measures are not possible under current law, nor does it seem to me that such systems would be practical, desirable, or possible to enforce.

It has also been suggested that this drug, along with other "dangerous drugs," be restricted to use by physicians registered with the Government in much the same way that narcotics are handled. This is not possible under the present law, nor is it particularly desirable. Most drugs are potentially dangerous, even when properly used and certainly when misused. Where should the line be drawn? Establishing this group of drugs would, it seems to me, create more problems than it would solve.

It has also been suggested that detailed records, other than those kept by the pharmacist, be maintained for every patient in a hospital who receives this drug. The doctor would write his diagnosis and it would be kept in the hospital record. A copy of this record would be sent to the AMA, the PHS, or the FDA for review. Again, this is not possible under current law, nor is it practical for any such group to monitor prescribing practices to preclude misuse.

What then is the best way to approach this problem? How do we reach the physician with this most important prescribing information? These hearings, I believe, have created an atmosphere of interest throughout the country, and have made many physicians take notice of the grave risks involved in misuse of chloramphenicol.

We know additional action is necessary; we will not delay in taking this action. We plan to move with every means at our disposal to curb the misuse of chloramphenicol. We are taking, or soon will take, the following steps:

1. We are revising the chloramphenicol labeling so the indications for use are more restrictive and more clearly stated. We are revising the warnings to include the incidence of risk estimates of aplastic anemia developed by the California Medical Society. We are adding warnings against use of the drug in late pregnancy or in lactation. Leukemia also is to be listed as a possible side effect.