Because the majority of antacids are used for treatment of chronic conditions, patient acceptability and psychosomatic considerations are particularly important. Many gastric problems originate with or are aggravated by stress. Having settled on a satisfactory prescription, the physician will frequently find that the patient becomes conditioned to the use of exactly that medication, and unexpected changes in its appearance can generate patient reactions of a magnitude not seemingly in direct relationship to that of the change. Consequently, our essential characteristics for these items are particularly sensitive to flavor, palatability, and color.

Other factors also have a major bearing on our choices among this family of drugs. I mentioned that we provide a range of antacids in order to allow a deliberate choice. We must do this because of the medicolegal responsibilities of the physician as they relate to drug usage.

Through the use of our individual hospital formularies, and the medical stock list, we encourage our physicians to prescribe generically. The Surgeons General endorse this procedure so long as we can exercise adequate quality control and quality assurance procedures throughout the entire supply system, from type classification of the item to consumption of the drug by the patient. We have, to the best of our ability, assured ourselves that these products are safe, efficacious, and economical. But what of the individual physician?

On 31 March, 1 and 2 April 1969, the Drug Information Association in collaboration with the American College of Clinical Pharmacology and Chemotherapy, American Medical Association, American Therapeutics Society, and the American Society for Pharmacology and Experimental Therapeutics conducted a symposium on "Formulation Factors Affecting Therapeutic Performance of Drug Products". Dr. Don Harper Mills, M.D., JD, clinical professor of forensic medicine and pathology, School of Medicine, University of Southern California at Los Angeles, presented a paper which stated most succinctly the problem of the medical practitioner. Dr. Mills notes the significant increase of malpractice suits in recent years, and speculates that certain statistics project that theoretically, ". . . a physician who practices for ten years faces a 100% chance of being sued." It is the duty of the physician to exercise judgment, to select, to choose—he determines what laboratory test, to consult or not consult, which consultant, what diagnosis, and finally, what therapy. It is the exercise of his judgment in the latter area which is of concern to us today. In his paper, Dr. Mills emphasizes that the duty of the physician to choose a drug which, of his own knowledge, is effective, safe and proper, is an affirmative one, and must be suceptible of proof in court. Dr. Mills includes as a fact requiring personal knowledge, the therapeutic equivalency (or biological availability) of the chemically equivalent drugs available.

We in the Department of Defense have been aware for some time of clinical indications that not all chemically equivalent drugs appeared to be therapeutically equivalent. Like most of the profession, we had originally no scientific documentation or studies. It was primarily a clinical impression supported by a large body of the profession over the same general time frame and substantiated by therapeutic experiences.

In 1966, we became sufficiently concerned that we began to search for a means of evaluating the question. The services are neither staffed nor funded for the conduct of formal clinical studies. In this connection, section 203 of title 2 of the fiscal year 1970 Defense Authorization Act (research and development) required a restriction on our medical R&D efforts to studies involving military-related diseases. The FDA did not at that time appear informed in this area, and we were somewhat reluctant to set ourselves up as experts purely on the basis of clinical indications. We chose a very small scale approach similar to that ultimately adopted by the National Academy of Science/National Research Council Task Force on drugs. We planned to obtain all possible clinical and stability data from the originator of a product and the FDA. We would then search the literature, and other possible sources such as the Intragovernmental Professional Advisory Council on Drugs and Devices (IPADD), and attempt to reach conclusions which would be supported by scientifically acceptable evidence. Limited resources precluded advancing beyond the planning stage.

DOD is grateful that it has been spared the necessity of conducting its own study. Recent widespread concern has resulted in the NAS/NRC study of drugs, which has now been reported to FDA.