opening page of my prepared statement, and I will dispense with a recitation of them.[1]

Mr. Chairman, I am grateful for your invitation to discuss with you the question proposed by your subcommittee, namely, how well is the quality of the Nation's drug supply being monitored and protected by our system of compendial specifications and standards coupled with FDA's enforcement of them. My answer, in brief, is that the system is working quite well, comparatively speaking, but that it could and should be working much better. I should like to enlarge upon that response in several dimensions.

In the first instance, if we consider progression on a time scale, there can be no doubt that the standards and specifications of the United States Pharmacopeia are far more perceptive and more demanding than they were 35 years ago. Similarly, the potentialities of the Food and Drug Administration in monitoring the quality of our drug supply has been considerably extended during that time.

The regulatory powers of the Food and Drug Administration have been significantly strengthened by several amendments to the Federal Food, Drug and Cosmetic Act of 1938—most notably the Kefauver-Harris Amendments of 1962, and the Good Manufacturing Practice provisions of that amendment.

Furthermore, the remarkable advances in all of the pharmaceutical sciences during the past 3 decades and particularly in drug analysis and biopharmaceutics, have stimulated the adoption of more exacting requirements in governmental and pharmacopeial standards, and in manufacturers' drug quality control programs.

Second, if we compare the quality of the drug supply and the effectiveness of drug regulation in the United States with those encountered elsewhere, we can again affirm that we have much to which we can point with pride. The drug industry of the United States, the U.S. Food and Drug Administration and the United States Pharmacopeia are generally cited as the hallmarks of preeminence in pharmaceutical circles throughout the world.

Only Canada, Scandinavia and parts of Western Europe—and I should add Japan—approach or equal the levels of excellence that we have established. None of them surpass us to a significant degree.

Senator NELSON. Well, outside of Scandinavia, which countries in Western Europe?

Dr. BANES. Great Britain. The United Kingdom is at the stage where it is about equivalent to, or approaches, the standards set by the United States.

Senator NELSON. In addition to Canada and Scandinavia, does England have safety and efficacy requirements?

Dr. BANES. Yes, sir. They do. The British laws have been modified during the past few years, and they have approached the system now in effect in the United States.

Senator NELSON. How about the question of advertising?

Dr. BANES. In some respects advertising is even more restricted in some of these countries than in the United States. Furthermore,

[1] See page 10748.