Certification:
Diplomate of the American Board of Surgery.
Diplomate of the American Board of Psychiatry and Neurology (Psychiatry).
Memberships:
American Psychiatric Association.
Society of University Surgeons.
American Group Psychotherapy Association.
New Jersey State and Mercer County Medical Societies.
Alpha Omega Alpha.
Publications:
15 Papers dealing primarily with Hypertension and the Sympathetic Nervous System.

STATEMENT BY A. DALE CONSOLE, M.D.

INTRODUCTION

Before presenting my prepared statement I should like to make some introductory comments. I have prepared my statement with the understanding that representatives of the drug industry, the PMA and the AMA either have had or will have their days in court. The drug industry and its friends have demonstrated in the past that they are more than able to speak for themselves. I do not exect them to support my views of the problems. I feel no need to support theirs.

I also wish to make it clear that I am not an academician. For almost ten years I have devoted 90% of my time to the private practice of psychiatry, and my contact with the so-called "white towers of medicine" has been minimal. During those ten years I have held only one academic position and that is a part-time one, Research Association in Psychiatry at Cornell Medical College.

I speak for myself and myself only. The primary justification for my appearance here derives from a degree of expertise I gained during the six and one-half years I spent as Associate Medical Director and Medical Director of E. R. Squibb & Sons.

LICENSING AND INSPECTION

I have always found it curious that a process that started in late 1959 as an investigation of "administered prices in the drug industry" ended in 1962 with the passage of legislation that had no effect on drug prices. Actually no one who was knowledgeable expected that the Kefauver-Harris Amendments of the Drug Act would affect prices and it seems clear that the late Senator Kefauver accepted the bill in its final form only because it was the best compromise he could get at the time. Even so he made a last-ditch effort to introduce a patent amendment and was defeated.

The record is clear and it demonstrates that the attack on drug prices had two prongs. One of these was contained in the patent provisions. The other was directed against the allegation that generic equivalents are inferior and unreliable drugs. In drafting S. 1552, Kefauver and his staff sought to increase price competition by encouraging generic prescribing. Realizing that they could not accomplish this unless assurance was given that any drug on the market had to meet standards of purity, safety, and efficacy determined by the FDA, they drafted Section 508. Let me quote some of the pertinent language: "Paragraph (b) provides that no license shall be granted unless the applicant demonstrates that the establishment . . . meets such standards . . . to insure . . . the purity, safety, and efficacy of the drug. . . . When the Secretary (of HEW) determines that the establishment no longer meets the standards, he shall revoke or suspend the license."

The intent of the language is crystal clear, and it was emphasized in Kefauver's opening statement in the first session of the hearings on S. 1552. Referring to the licensing and inspection provisions, he said, "These provisions *put real teeth into the Food and Drug Act.* By realizing that any firm which produces inferior drugs can have its license to do business suspended or revoked, the physician should gain assurance that any drug sold in the country, whether produced in this country or abroad, whether made by large companies or small companies, and whether marketed under a brand name or generic name, *is of adequate and acceptable quality*" (emphasis mine).