

appearance, it is quite another matter to seem to suggest that the workability of competition is not an important issue. On the contrary, the chief purpose of S. 1552 was to make the drug industry more workably competitive; it was not designed, for example, to stimulate or retard turnover in sales rank as an end in itself, or otherwise. But the point need not be labored.

B. *Senate Judiciary Committee Action*

S. 1552 was reported out of Senator Eastland's Judiciary Committee as a much more innocuous document than when it was submitted.⁴⁴ All the patent provisions had been rejected. The other contemplated reforms were considerably attenuated. The request for public control over generic names on the part of the Secretary of the Department of Health, Education, and Welfare survived in modified form: under certain circumstances, the Secretary is to hold hearings and establish generic names for certain drugs. The request that the FDA pass on the efficacy of drugs became a provision that drug efficacy claims be supported by substantial evidence, but the wording adopted limited its jurisdiction only to initial claims made subsequent to approval. The licensing requirement became mere registration, but the FDA was granted greater power to inspect plants. The requirement that advertisements contain generic names and statements on efficacy and side effects was entirely rejected.

Kefauver and other members of the Subcommittee majority noted that the amended bill would perhaps improve the quality of drugs, but would have little if any effect on prices, and indicated their intention to propose several amendments to the bill in order to salvage some of its economic impact. First, they proposed that all drug patent license agreements be filed with the Commissioner of Patents. It will be recalled that PMA had expressed willingness to make private patent interference settlements a part of the public record; the amendment would not require public filing, but would extend to all patent licensing agreements. Second, it was proposed that the compulsory patent licensing feature of the original bill be retained, but that it be invoked only where wholesale drug prices exceeded 500 per cent of factory costs. Third, it was pointed out that the wording of the current bill would not restrict drug claims to demonstrated efficacy after the approval of a new drug application, and requested the necessary modification in wording. Fourth, a compromise on the contents of drug advertisement was put forth: generic names need appear in type face only half as large as brand names, and summaries, rather than complete statements, of efficacy and side effects should be included.⁴⁵

C. *Congressional action*

On August 3, 1962, the late President Kennedy communicated to Senator Eastland a list of amendments for the Committee to consider, relating chiefly to drug safety. The Committee met a few days later, and in addition to adopting some of the amendments suggested by the President, accepted Kefauver's amendments regarding advertising content and efficacy claims, but rejected his patent amendments. The bill was then transmitted to the House of Representatives, where further amendments were proposed. A conference report of October 3, 1962 shows that the conference between the Senate and House managers of the bill resulted in the substantial adoption of the Senate version, with only minor changes, except that the requirement that the Secretary of HEW publish and distribute to physicians all the detailed information required by law to be included in the drug package was dropped.⁴⁶ No reason is given for omitting this important provision. In the absence of information regarding motive or influence, the deprivation of easy access by the physician to the best information on drugs can only be interpreted as an act of disinterest misanthropy.

V. CONCLUSIONS AND POLICY RECOMMENDATIONS

The amended bill was passed by both houses and became law on October 10, 1962, as the "Drug Amendments of 1962," more frequently referred to as the Kefauver-Harris Act. It will serve to improve the quality of drugs, but its impact on competition will be slight. Requiring evidence of efficacy will, if properly en-

⁴⁴ Rt. on S. 1552, op. cit., pp. 1-8.

⁴⁵ *Ibid.*, pp. 38-48.

⁴⁶ Drug Amendments of 1962: Conference Rept. No. 2526, House of Representatives, 87th Cong., second sess., Washington, D.C., Government Printing Office, Oct. 3, 1962 pp. 10-18.