and to advertise so intensively as to prevent the products of smaller firms from coming to the attention of the physician. Much of drug research would thereby be shifted from private to public and university channels, with a probable increase in the efficiency of such efforts, since the patent-induced incentives to engage in duplicative research, molecular manipulation, and promote unpromising drugs in the interests of their sales potential rather than their efficacy, would be removed.

IV. S. 1552: FROM BILL TO ACT

A. Original provisions

Senator Kefauver, however, did not contemplate so sweeping a reform of existing practices, perhaps in view of the political difficulties. His original bill did, nevertheless, incorporate a number of valuable reforms, particularly of patents and drug nomenclature. The salient provisions of the bill may be listed as follows:

(1) Drug patents shall take effect as of the date of the new drug application (or in the case of drugs for which no new drug application is necessary, the date for filing the patent application) and shall grant unconditional monopoly power for a period of only three years, after which such patents are subject to compulsory licensings at a royalty not exceeding 8 per cent of the sales price.

(2) No patents are to be issued for compounds merely embodying molecular manipulations of existing drugs, or combinations of existing drugs, unless the Secretary of the Department of Health, Education and Welfare determines that such a drug has a significantly greater therapeutic effect than the unmodified drug, or of the combined drugs when taken separately.

(3) The Sherman Act should prohibit private drug patent interference settlements or any other private arrangements whereby parties concede patent priority claims in return for royalty-splitting agreements, differentially favorable royalty rates for participants relative to third parties, or limitation of licensing to parties to the agreement.

(4) The Food and Drug Administration should be given authority to establish generic names of drugs, with a view toward simplification and increased use of such names.

(5) The Food and Drug Administration shall pass upon the efficacy as well as safety of drugs.

(6) The Secretary of the Department of Health, Education and Welfare should publish and distribute to physicians and hospitals copies of drug firm package inserts which describe the action of drugs and give data on dosage, contraindications, and side effects. (At present, such inserts go by only to pharmacists, not physicians.)

(7) All drug firms must be licensed by the Secretary of the Department of Health, Education and Welfare, and must submit to inspections of plant and equipment. (Plant inspection regulations are also to be made more adequate.)

(8) All drug advertising shall include (a) the generic name in type face as large as the brand name, (b) a statement of the conditions for which the drug is an effective treatment, and (c) a statement of all side effects and other warnings.

The reforms contemplated are rather modest. The provision for making patents effective as of the date of filing a new drug application is intended to eliminate any incentive for delay on the part of the applicant in patent proceedings, particularly in negotiating interferences in the interest of prolonging effective patent protection, not only for the successful applicant, but also for the entire group of interim licensees. The three-year term of absolute patent monopoly is intended to allow the successful firm to recoup its research costs during an initial monopoly period of high prices and no rivals; the compulsory licensing provision during the next 14 years is tempered by allowing the patent holder to charge an 8 per cent royalty, a very high royalty by drug industry standards, the usual rates being between two and six per cent. The prohibition of drug combination or molecular manipulation patents in the absence of evidence of superior efficacy is a laudable (although administratively difficult) attempt to halt wasteful duplicative research efforts.

The proposed Sherman Act amendment is rather strict in that it entirely prohibits private drug patent interference settlements, by making it illegal to withdraw any pending drug patent application. This is desirable in that private settle-