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President John F. Kennedy to Senator James O. Eastland, 10 April 1962

John F. Kennedy

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THE WHITE HOUSE

WASHINGTON

April 10, 1962

Dear Senator:

In the message I sent to the Congress on March 14, I called attention to the need for new legislative authority to advance and protect the interests of consumers in the marketing of drugs.

S. 1552, which is now pending before your Committee, incorporates the major recommendations I made. It will strengthen and broaden existing laws in the food and drug field, contribute toward better, safer and less expensive medicines, and establish a better system of enforcement. As you know, the bill is the outgrowth of twenty-eight months of intensive investigation and hearings by your Subcommittee on Antitrust and Monopoly. I believe that early passage of this legislation will substantially improve the ability of the drug industry to serve the Nation and help provide consumers with quality drugs at low competitive prices.

I understand that the members of the Subcommittee on Patents have decided that the compulsory licensing feature of the legislation requires further study and consideration. I would hope that this would not, however, delay enactment of the other provisions of the bill -- provisions which will establish necessary safeguards to assure the reliability and effectiveness of drugs placed on the market, provide for standardization of drug names, and thereby encourage physicians to prescribe drugs by nonproprietary rather than by brand names, require disclosure of adverse as well as beneficial effects of drugs in drug promotion, and assure consideration of therapeutic effectiveness in the granting of patents for drugs that are modifications of other drugs.

The message I sent to the Congress made several other suggestions which, it would seem to me, might appropriately be included in the bill now before your Committee. They are:

1. Drug manufacturers should be required to keep records on and report to the Department of Health, Education and Welfare any indications of adverse effects from the use of a new drug or antibiotic.

2. The Department of Health, Education and Welfare should be empowered to withdraw approval of a new drug on the basis of a substantial doubt of its efficacy or safety.

3. The provisions requiring drug manufacturers to maintain facilities and controls to assure the reliability of their product, and to institute more effective inspection to determine whether drugs are being manufactured in accordance with the law, cannot feasibly be limited to a particular class of drugs and should therefore be made applicable to over-the-counter as well as prescription drugs.

4. An enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines should be provided.

The need for these amendmends is based upon the accumulated years of experience of the Food and Drug Administration, and they appear to be properly within the scope of the subject matter dealt with in the extensive hearings of the Subcommittee on Antitrust and Monopoly.

In addition, I recommend two minor procedural changes:

1. In the section having to do with the rendering of advisory opinions by the Department of Health, Education and Welfare to the Patent Office on the therapeutic effect of modifications and combinations, I suggest that the requirement providing the applicant with an opportunity for a plenary hearing be deleted. Under the provisions of S.1552 in its earlier form, the Secretary's finding was conclusive and therefore should have required a formal hearing. But since the bill in its present form requires no binding decision to be made by the Secretary, the requirement of the hearing seems inappropriate and would tend to unduly delay the rendition of the Secretary's purely advisory opinion to the Commissioner. The action of the Commissioner is, of course, subject to well established de novo judicial review.

2. The provision requiring the filing of patent agreements with the Commissioner of Patents should more properly be in the form of an amendment to the Patent Act rather than the Sherman Act.

I have asked the Department of Health, Education and Welfare to transmit to you promptly any additional recommendations to strengthen, clarify, or improve the bill that it may have and that will not require additional hearings or substantially delay action on the bill.

It would not appear that the consideration of these proposed changes should occasion any further delay in the approval of this important measure.

With the above changes, S. 1552 adequately deals with the most pressing problems in the drug field, and it is my sincere wish that it be enacted during the current session of the Congress. Your cooperation and assistance to this end will be greatly appreciated.

Sincerely

Honorable James O. Eastland
United States Senate
Washington, D. C.