reverse despite the abundant legislative history that this factor cannot be considered by the FDA in approving new drugs. The FDA has refused to approve labeling allowing the marketing of dicloxacillin for streptococci, pneumococci and sensitive staphylococci because it has been shown to be better than penicillin G and penicillin V in the treatment of bacterial infections in that it is effective against penicillin G-resistant staphylococci.

It is urged, therefore, that the FDA either immediately discard the theory by deleting its elements from the labeling for semi-synthetic penicillinase-resistant penicillins or apply it even-handedly by requiring it in the labeling for all antibiotics which are indicated for use in the treatment of infections caused by pneumococci, streptococci and staphyococci. After that, we hope the FDA should appoint a joint industry-government-academic advisory panel to decide whether the reserve drug theory itself should be finally and uniformally imposed or discarded.

MARCH 28, 1968.

To: William H. Stewart, M.D., Surgeon General, PHS
From: James L. Goddard, M.D., Commissioner of Food and Drugs
Subject: Dicloxacillin as a subject of hearings by the Nelson committee

Reference is made to inquiries directed to you by Mr. Thomas Corcoran, attorney representing Bristol Laboratories, regarding the origin of suggestions that the drug, Dicloxacillin, be considered by the Nelson committee.

In early March the Nelson committee staff contacted the Administration with the request that information be furnished the committee on the investigational drug, MER–29, and on a number of marketed drugs approved post-1962. These requests were handled by the Office of Legislative and Governmental Services of the Food and Drug Administration.

The allegation of Mr. Corcoran that the drug, Dicloxacillin, was suggested for consideration by Dr. Robert McCleery is false; a fact we have verified by interview with Dr. McCleary. The request for information on this drug came from the committee staff.

We recently prepared an information memo for Dr. Lee, dated April 18, 1968, which summarizes the history of Administration position on Dicloxacillin. A copy is attached. This memorandum provides insight into the pressures imposed by drug firms on the Administration in its clearance of new drugs for marketing.

Answering your request for our views about whether you and Dr. Lee should meet with Mr. Corcoran:

There is nothing in FDA's handling of this matter that requires such a meeting. We see no objection to a meeting at which the facts are laid before the attorney. If there is a meeting, the Department should not be apologetic for its position of Dicloxacillin. We have a sound position and should adhere to it.

To: Dr. Philip R. Lee, Assistant Secretary for Health and Scientific Affairs
From: James L. Goddard, M.D., Commissioner of Food and Drugs
Subject: Labeling of semisynthetic penicillins

Recently, Mr. Thomas Corcoran, an attorney representing Bristol Laboratories, questioned the action FDA has taken with regard to a semisynthetic penicillin produced by Bristol.

The attached staff paper gives in considerable detail the FDA position and the manner in which we reached it. I believe we have a sound position and think that we should adhere to it.

Mr. Corcoran is in error when he implies that we are discriminating against his client. You will note from the staff paper that we are taking steps to achieve uniform administration of the statute to the semisynthetic penicillin manufacturers.

MAY 23, 1968.

COMMENTS ON BRISTOL'S "DYNAPEN" LETTER

1. The headline characterization of the drug as a "—High Potency Pencillin— for Skin and Soft Tissue Infections" on envelope and letter is inconsistent with the limited approved indications for the drug. It is indicated, in Skin and Soft Tissue Infections, but only those due to Pen-G resistant staph.