tol was advised that recertification could be effected only after the remedial ad had appeared in the same journals as the original ad.

The events following these decisions are reflected in the remedial letter and the correct ads, copies of which are included for the record—exhibits K and L.

Senator NELSON. They will be included in the record.

(The information referred to follows:)

EXHIBIT K

BRISTOL LABORATORIES,
Syracuse, N.Y.

DEAR DOCTOR: The Food and Drug Administration has asked that we call your attention to our letter of May 17, 1968 which announced the coming availability of Dynapen (sodium dicloxacillin monohydrate). The Food and Drug Administration has expressed concern that our discussion of this drug in terms of treating skin and soft tissue infections created misleading impressions concerning the proper use of Dynapen in its limited appropriate indications.

Therefore, we wish to specify the indications and limitations for use of this drug in detail as follows:

1. The prinicpal indication for Dynapen is in the treatment of infections known to be due to penicillinase-producing staphylococci which have been shown to be sensitive to it.

2. If antibiotic therapy is considered necessary in potentially serious infections while awaiting reports of cultures and sensitivity studies, Dynapen may be used to initiate therapy in such patients in whom a penicillinase-producing staphylococcus is suspected. (See Important Note below.)

Important Note

Bacteriologic studies to determine the causative organisms and their sensitivity to dicloxacillin should be performed. When it is judged important that treatment be initiated before definitive culture and sensitivity results are known the choice of Dynapen should take into consideration the knowledge that its has also been shown to be effective only in the treatment of infections caused by pneumococci, Group A betahemolytic streptococci and penicillin G-sensitive staphylococci. In serious, life threatening infections oral preparations of the penicillinase-resisant penicillins should not be relied on for initial therapy.

Methicillin, a compound working through a similar mechanism against penicillin G-resistant staphylococci, has been available for nine years. It is a fact that strains of staphylococci resistant to methicillin have existed in nature and it is known that the number of these strains reported has been increasing. It has been demonstrated that such strains are almost always resistant to other penicillinase-resistant penicillins, such as the isoxazole group of which Dynapen is a member. When such a strain is isolated, use of routine antibiotic discs cannot be relied on to differentiate relative sensitivity. Such strains of staphylococci have been capable of producing serious disease, in some instances resulting in fatality. Because of this, the Food and Drug Administration is concerned that widespread use of the penicillinase-resistant penicillins in infections other than those due to penicillin G-resistant staphylococci may result in the appearance of an increasing number of staphylococcal strains which are resistant to these penicillins.

Therefore, if the bacteriology report indicates the infection is not due to a penicillin G-resistant staphylococcus, the physician is advised to continue therapy with a drug other than Dynapen or any other penicillinase-resistant semi-synthetic penicillin.

Indicated surgical procedures should be performed.

Contraindications

A history of allergic reactions to penicillin should be considered a contraindication.

Information in our announcement letter, or that you may have received from one of our sales representatives, should be carefully considered in light of the preceding clarification.

We have discontinued the advertising in question. Future advertising will be appropriately modified. The drug is not available for prescription at this time. We will notify you when it becomes available.

Sincerely,

H. C. PELTIER, M.D.,
Vice President, Medical Director.