

particularly of the anaphylactic type, that you have encountered in your patients during or subsequent to the administration of Imferon (iron dextran injection).

Sincerely,

WILLIAM C. JANSSEN, M.D.,
Director, Clinical Research.

SMITH KLINE & FRENCH LABORATORIES,
Philadelphia, Pa., February 24, 1964.

IMPORTANT—DRUG WITHDRAWAL NOTICE

DEAR DOCTOR: Late last fall we notified you of certain hypertensive reactions that had occurred during 'Parnate' (tranlycypromine, SK&F) therapy. We pointed out that these hypertensive reactions sometimes resulted in cerebrovascular accidents, occasionally fatal in outcome. And we revised our Prescribing Information to include this material.

We also requested physicians to send us additional information as to any similar cases encountered in their practice, and as a result, we have received a number of additional reports.

After reviewing with the Food and Drug Administration the data from this country and abroad, we believe that of the hypertensive reactions reported, approximately 50 cases of cerebrovascular accidents, including 15 fatalities, may be attributable to the use of 'Parnate' (tranlycypromine, SK&F), among the more than 3½ million patients who have received the drug.

We are now informed by the FDA that because of these reactions they believed that 'Parnate' (tranlycypromine, SK&F) should be taken off the market.

With all due respect for the FDA, it is the opinion of the SK&F medical staff and the opinion of many eminent physicians whom they have consulted that the benefits of 'Parnate' (tranlycypromine, SK&F) outweigh the risks; that it is a useful and valuable drug for the treatment of a serious illness and should remain available to the medical profession. This view is supported by the recent findings of the British Safety of Drugs Committee.

Nevertheless, under protest, we are withdrawing 'Parnate' (tranlycypromine, SK&F) from the U.S. market. We are taking this step because under the present law and regulations, where there is an honest difference of medical opinion on scientific matters, there is no effective appeal to an impartial body of medical experts by whom the matter can be considered in a calm, scientific manner. Such a procedure has been strongly advocated by leading medical authorities.

In view of the withdrawal of the product, would you therefore please instruct your patients who are taking 'Parnate' (tranlycypromine, SK&F) to discontinue and to destroy whatever remaining tablets they may have. In transferring patients from 'Parnate' (tranlycypromine, SK&F) to another antidepressant, allow a medication-free interval of at least a week.

We will continue to present our views to the Food and Drug Administration and to explore with them the possibilities and procedures for having 'Parnate' (tranlycypromine, SK&F) made again available to the physician.

Very sincerely,

WALTER A. MUNNS,
President.

SMITH KLINE & FRENCH LABORATORIES,
Philadelphia, Pa., December 1963.

IMPORTANT—DRUG WARNING

DEAR DOCTOR: Although paradoxical hypertension and severe headache have always been listed among the possible side effect of Parnate (tranlycypromine, SK&F), instances of an unusually severe reaction of this type have come to our attention. The reaction is described in detail below. Reports of serious sequelae from this reaction have appeared in the foreign literature, but no reports have been published in this country. Accordingly, in our continuing effort to keep you fully informed about our products, we are passing this information on to you.

In cooperation with the Food and Drug Administration, we have revised our Parnate (tranlycypromine, SK&F) Prescribing Information, a copy of which is enclosed. Following are sections from it that have been revised either wholly or in part: