INTERNATIONAL JOURNAL OF LEPROSY

PUBLISHED AS THE OFFICIAL ORGAN OF THE INTERNATIONAL LEPROSY ASSOCIATION WITH THE AID OF THE LEONARD WOOD MEMORIAL

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Entered at the Post Office at Cleveland as second-class matter.

Vol. 15 No. 1 1947

EDITORIALS

Editorials are written by members of the Editorial Board and opinions expressed are those of the writers.

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THIS TIME — LET'S HAVE THE PROOF!

Sufficient has been learned of results with certain sulfones — promin, diasone, and promizole — to justify a demand for the most thorough clinical trials of these and related compounds. Clinicians with large experience, although cautious in their conclusions, have quite consistently published accounts of beneficial effects even in lepromatous cases of long duration.

Nevertheless, leprologists will recall the remarkable results attributed to chaulmoogra oil and its derivatives. All the world gave thanks that at last a cure had been discovered for one of the most dreaded of diseases. Now, after four decades, although it will be admitted that the early claims were greatly exaggerated, lack of adequately controlled experiments still precludes a definitive answer to the question: Has chaulmoogra any specific value in the treatment of leprosy?

This time history must not repeat itself. Popular clamor for a particular drug, stimulated by those who do not hesitate at times to assume greater wisdom than the clinicians who are treating the patients, is a very real obstacle to controlled experimentation in medicine. In the present instance a possible solution would be to treat alternate patients with sulfa and chaulmoogra derivatives respectively. It is important that no time should be lost as there is already a feeling of high optimism in certain quarters which,

whether or not justified, will make proper clinical trials increasingly difficult.

A carefully planned cooperative research program has been successful in establishing the position of sulfa drugs and antibiotics in various diseases, and a similar program is clearly indicated in the present case. The desirability of such a procedure has already been informally discussed. Mr. Perry Burgess, President of the American Leprosy Foundation, is keenly interested. Dr. Jose Rodriguez has consulted certain manufacturers and found them open to suggestions. Others, including Drs. G. H. Faget, L. F. Badger, and Ricardo Guinto have pressed the case for controlled studies. From the pool of ideas thus collected, the following specific proposals have been formulated by the Acting Editor:

1. Leadership in a cooperative research program should be undertaken by a non-governmental organization with international experience. The organization most likely to be successful in obtaining the necessary funds is the American Leprosy Foundation (Leonard Wood Memorial). It is fitting, moreover, that an American organization should take the leadership, since the drugs in question have been produced in the United States.

2. A Nuclear Central Committee for Cooperative Clinical Research should be appointed by the organization accepting the responsibility. This committee should prepare in detail plans for clinical research. The execution of these plans would undoubtedly require the cooperation of leprologists and manufacturing chemists.

3. A fundamental requirement in each clinical trial would be an interested, unbiased, and experienced investigator. Each investigator must have skilled assistants and adequate facilities. There are probably only a small number of institutions in which the necessary combination of skilled staff and adequate facilities exists.

4. The assistance of certain manufacturing chemists would be essential. Several well known companies have been conducting extensive research on sulfa compounds for years. There are a large number of such compounds which are relatively non-toxic and which have never been tried on leprosy. New compounds are constantly being developed. Furthermore, some of these companies have had experience in cooperative clinical trials of several antibiotics and drugs. It goes without saying that the conditions of their participation in such a program must always be such as to prevent unethical or premature advertising of any product.

To the present the treatment of leprosy has been a by-product. The sulfone drugs have been produced primarily for use in tuberculosis or other diseases. As experience in treatment of leprosy

progresses, new and really specific drugs will be synthesized. This assumes the full cooperation of manufacturing chemists at every step.

5. The first duty of the Nuclear Central Committee would be to appraise the present situation, to select drugs for study and to make necessary arrangements with governments, leprologists, and manufacturers. Agreements with manufacturers should provide that the selected drugs may be distributed only by the Committee during the period of trial. Doubtless there would be pressure upon the Committee to release drugs prematurely for indiscriminate treatment. A firm policy would have to be adopted in this matter.

The Committee should lay down in detail the plan under which each trial would be conducted. If possible, the principle of random sampling should be adopted in every study. There should be uniformity in clinical classification and in the form of reports which would be submitted to the Committee.

The Nuclear Central Committee should have power to add to its number especially in the direction of including outstanding leprologists from all parts of the world.

Let us proceed in faith and hope. But let the faith and hope be tempered with the leaven of science. There must be no turning back. This time—LET'S HAVE THE PROOF!

J. A. Doull