OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

D00266

United Nations Industrial Development Organization

Distr.
LIMITED

ID/WG.37/17
22 January 1970

ORIGINAL: ENGLISH

Expert Working Group Meeting on the Establishment of Pharmaceutical Industries in Developing Countries

Budapest, 4 - 10 May 1969

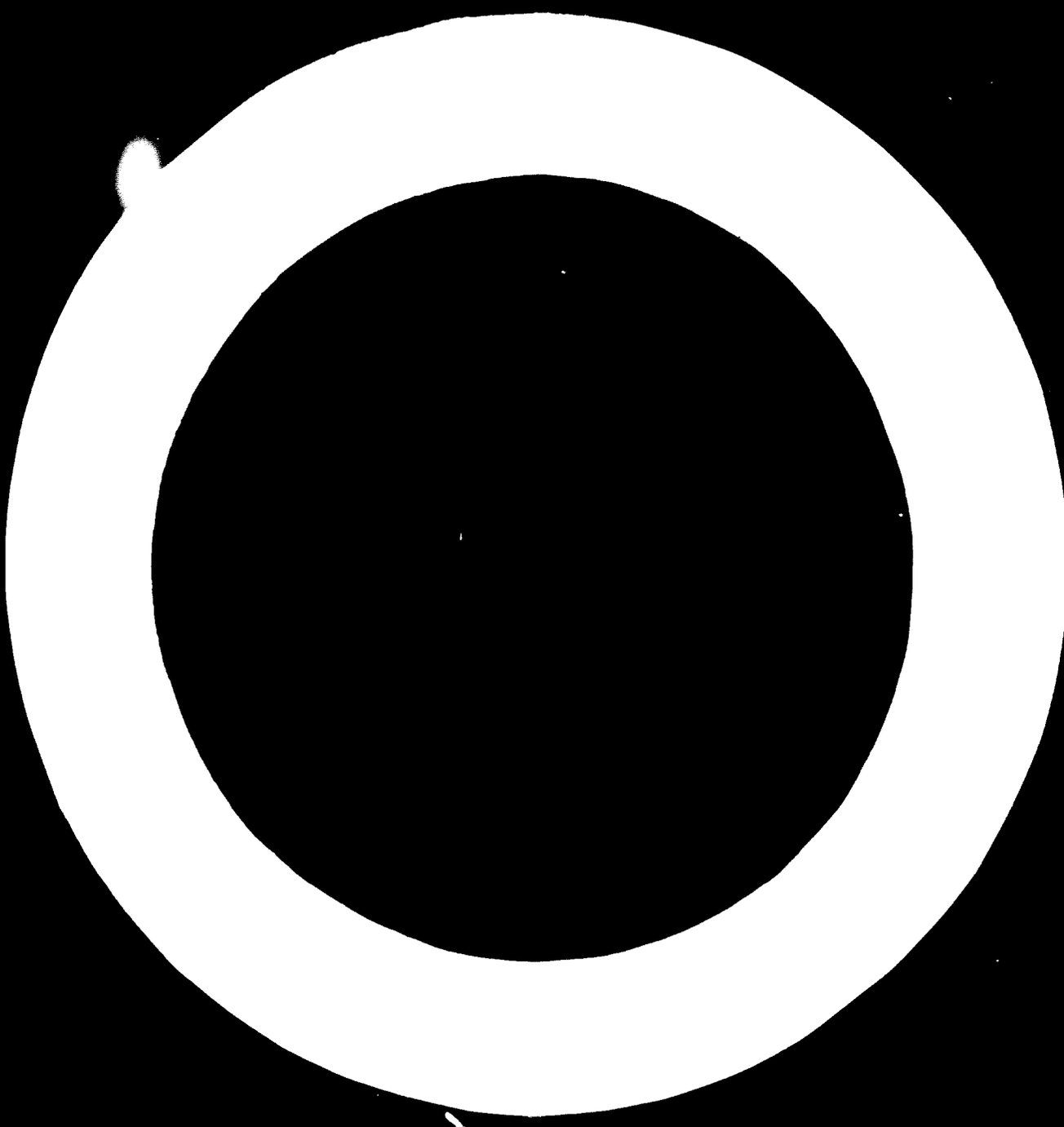
THE IMPORTANCE OF ACCURATE DRUG INFORMATION 1/

by

Julius Segal
National Institute
of Mental Health
Washington D.C.
United States of America

1/ The views and opinions expressed in this paper are those of the author and do not necessarily reflect the views of the secretariat of UNIDO. This document has been reproduced without formal editing.

id.70-387



In every period of history, man has sought to use pharmacological products as a means of promoting health, reducing pain, and improving the well-being of his community. When early man derived a juice from a succulent leaf to apply to a wound, he was practicing this ancient art. In the book of Exodus, Moses was directed by the Lord to prepare "an ointment compound after the art of the apothecary". Ancient Assyrian tablets list drugs used in early times derived from food, seeds, flowers, bark, and roots of plants, and in ancient Babylonia, parts and organs of animals were used as drugs.

Scientific use of drugs was not achieved until the last half of the 19th century. Since then, understanding of drugs and their use has increased greatly as the science of chemistry has developed, and as our knowledge of how to conduct careful scientific experiments has increased. Whereas earlier, there was no organized body of scientific knowledge to guide the medicine user in the appropriate application of drugs, today the field of pharmacology has advanced significantly.

Today, for example, the U.S. Government sponsors a large scale psychopharmacology research programme through the National Institute of Mental Health. Through this programme a broad range of studies - from basic research on mechanisms of drug action to controlled clinical trials

.../...

of drugs - are pursued in hundreds of laboratories and hospitals in the U.S. and other countries. The results of this effort are evident, for example, in the remarkable strides made in the treating of mentally ill patients through tranquilizer and anti-depressant drugs.

Despite the rapid increase in data about drug action and effects - perhaps because of it - a new problem has arisen. The problem of maximising the usefulness of the information about drugs that already exists. The proliferation of drugs and their uses has challenged our ability to apply them safely and efficiently. The task today is to provide to the public accurate, quick, and straightforward data regarding drugs. It is of the utmost importance that available information regarding drugs and their uses and abuses be made available to the medical practitioner and to the consumer.

Only by presenting accurate information on drugs to the consumer can his health be protected. It is essential that populations avoid the negative results that maybe brought about by confusion and delayed information about drugs. It is clear that today, countless persons use a variety of drugs without accurately knowing the implications. Many people use powerful hypnotic and sedative drugs, for example, for passing and minor sleep disturbances. Individuals must begin to take responsibility for their welfare in consuming drugs - and only accurate and comprehensive data, available to both doctor and patient in understandable form, will solve the dilemma.

The importance of accurate and consistent information about drugs is perhaps most dramatically emphasized by the case of the drug thalidomide - an episode in 1961 in which incalculable harm resulted to many innocent victims. In the United States at that time, Dr. Frances Oldham Kelsey, now Acting Director, the Division of Scientific Investigations of the Food and Drug Administration, was instrumental in her refusal to release thalidomide, a drug then used widely in other parts of the world. The evidence was beginning to accumulate that this drug, when used by the

.../ ...

pregnant woman, would harm the developing fetus It has been estimated that if she had consented, about 10,000 American babies would have been born malformed - legless or armless - by the time the mistake was discovered. Nonetheless, despite furor over thalidomide in the United States, babies were being deformed in other countries, where people bought the drug under other trade names.

The confusion arose from a lack of accurate information - from the fact that local brand names masked the actual generic name of the drug. Had correct information been available in countries outside the United States, many babies around the world would have been spared lifelong difficulty.

A more current and pervasive example lies in today's inappropriate use of sedatives and tranquilizers. Millions are now regularly taking minor tranquilizers and sedatives for symptoms that relate to insomnia. Although these drugs are mild and often helpful, one must take some caution in their casual use from studying the experience of those who have used major tranquilizers in mental hospitals.

The advent of major tranquilizing drugs in the last decade and a half has revolutionized the care and treatment of victims suffering serious mental illness. These drugs have become the mainstay of many psychiatric hospitals and have so muted the symptoms of psychosis that thousands of chronically disturbed patients have returned to their homes, and are now treated in their own communities.

Only in 1967 did we begin to learn, however, that some of these very tranquilizers could, in isolated instances, produce serious illness after long use. Although cases are admittedly rare, prolonged use of potent tranquilizers can cause diseases of the blood or liver, or the symptoms of Parkinson's disease. The ravages of mental illness clearly warrant the continued calculated use of major tranquilizing drugs. The usual hospital patient taking such drugs, however, is under medical supervision.

.../...

Unfortunately, however, one in every twelve adults regularly takes tranquilizers. Upwards of 30 million Americans now cope with anxiety, insomnia, tension, and emotional distress by taking drugs - often without close contact with their doctors. Many Americans are using heavy doses of drugs that create risks hardly commensurate with their complaints.

One American psychiatrist in Baltimore, Maryland, Dr. Frank Ayd, Jr. is unusually well-acquainted with the problems of drug information. Ayd single-handedly published a monthly newsletter, reviewing the current material on drugs. He is no alarmist, but he says: "today's medicine involves polypharmacy. Patients come into my office, some of them taking 6 different medications a day. Others take as many as 16 different drugs a day. They suffer from multiple drug interactions". The patient may be complicating an already intricate guessing game by medicating himself. He buys over-the-counter drugs - antihistamine, cough medicine, aspirin. Which human doctor could outguess all the possible interactions? Some day, perhaps, doctors will have electronic computers to help them. The patient's age, weight, drug reactions, history, and symptoms will be programmed into a computer along with the extensive list of all the drugs he is taking. It might be possible for a computer to process all this information and produce a sensible suggestion. Only a computer could store in its memory the vast amount of data about drugs and their combined effects so as to predict the outcome of particular combinations.

For the first time, a group of doctors took a quick look in 1966 at the way in which physicians actually did handle drugs. Dr. Anthony Kales surveyed 102 doctors in the wealthy Beverly Hills residential area and in West Los Angeles. How do middle-class doctors prescribe sleeping pills? What kind of information do they obtain from patients? A questionnaire asked the doctor what drugs he prescribed, and for how long. Who were the patients receiving the pills? The replies were chastening. They demonstrated that most general practitioners, even in

.../...

very wealthy and educated neighborhoods, very close to a laboratory devoted to sleep research, knew almost nothing about the new work relating drug impact to sleep. Little of this information had become available to them. What, then, should be expected of doctors in other regions?

The need for reliable and accurate drug information is demonstrated by the continuing efforts in the U.S. to provide standard reference works which will identify for both doctor and patient the uses, the efficacy, and the side effects of drugs.

Libraries in hospitals, universities, and medical associations almost inevitably include a huge and basic reference volume on drug therapy known to doctors and every medical student: The Pharmaceutical Basis of Therapeutics, edited by Louis Goodman and Alfred Gilman. It is a compilation of detailed reviews by the country's leading experts in pharmacology, and includes the range of possible risks and complications.

A common reference on drugs on the desk of many doctors is the Physician's Desk Reference, known as the "PDR". This book is published by Medical Economics, Inc. and distributed without charges to all registered medical doctors in the United States. Many thousands of drugs are listed in its 1500 triple-column pages. It offers advice on application, symptoms, dosage, and side effects. This is an expensive and useful book - offered free to the physician through information supplied by drug companies. There is some evidence that users are unaware of, or even are favourably disposed to, its commercial sponsorship.

The fact is that doctors have few references at present that give up-to-date information on specific drugs - only the references made available to them directly by the drug companies. "Each day the drug manufacturer bombards his target through the mails with a barrage of attractive and eminently readable but far from disinterested literature which he regularly follows up with the direct attack of his detail men,

.../...

"Walter Modell has written. Dr. Phillip R. Lee, Assistant Secretary of Health, Education, and Welfare, told the Senate Monopoly Subcommittee in the fall of 1960 that "many if not most physicians rely primarily" for information about the drugs they prescribe "on the advertising and promotional activities of drug companies". Dr. Lee called this a matter of "grave concern" for the public as well as the medical profession. Dr. Lee - himself a physician - testified that doctors generally get "scant and insufficient" education in drug therapy while in medical school, and that in private practice a majority of them either is unaware of or ignores the small number of publications which provide "comparative, objective data".

What about the Federal Government's role? The pharmacist sells and dispenses drugs within the provisions of the food and drug laws of the country in which he practices. These laws recognize the existing national pharmacopoeia as the standard for drugs. The pharmacopoeias of the various nations are compiled and published according to the respective local national procedures. The World Health Organization of the United Nations published the first volume of the Pharmacopoeia Internationalis in 1951. Its purpose is to standardize, as far as possible, medication with drugs throughout the world. Furthermore, the Pharmacopoeia Internationalis provides standards for drugs for smaller nations that have no national pharmacopoeia.

In effect, a government pharmacopoeia should provide, for a specific political area, standards of identity, quality and strength for those medicinals which represent the best practice and teaching of medicine. The primary function of a pharmacopoeia is to describe each drug of the approved list in such a way that whenever dispensed it meets the standards of quality and strength established for it. As such, the provisions of the Pharmacopoeia in force are binding on all those who produce drugs and who dispense them. The Pharmacopoeia is potentially, therefore, a fundamental safeguard to public health.

.../...

In practical terms, is the government today an effective direct source of data?

Largely not. In the United States, for example, the Federal government references are neither current nor useful in prescribing drugs in the doctor's office. It is only every five years that the Pharmacopoeia of the United States is reissued. There is also a National Formulary which is no longer kept up-to-date. Even if they were current, these Government volumes cannot help the doctor find out who manufactures a drug, how much it costs, what symptoms it helps, nor how it acts in the body. No busy doctor can afford to make a research project out of every prescription. Thus he has to rely upon the drug manufacturers for most of his information.

Former United States Food Chief Goddard long sought a comprehensive drug compendium. "I really think the time has come when the American physician deserves a source of drug information that is unbiased, that would be put together by the top scientists in given specialty fields, not FDA employees. I wish the critics would learn what we have proposed. People who say it is impossible to produce a compendium and update it four times a year simply don't understand modern technology".

In September of 1966, the last step was taken. A special task force on prescription drugs appointed by the Department of Health, Education, and Welfare recommended the publication of a national drug compendium, listing all lawfully available drugs, their uses and effects, good and bad. The report insists that doctors need objective, up-to-date guidelines on the use of drugs in treating patients.

The foregoing is to convey the continuing attempt to satisfy the consumer's need for accurate drug information. If history is the best teacher, then the lesson should be well learned, and the experience of the United States and its citizens in its growing need for better and more available drug information is one which can be used as a basis for

.../...

avoiding pitfalls and planning intelligent dissemination of drug information in developing countries.

That such a need exists can no longer be questioned. Physicians from leading medical schools have testified that many practitioners don't understand the potent drugs they use, that their postgraduate education is deficient, that their choice of drugs is often confused by an over-emphasis on brand names, and that for drug information they rely too much on drug industry sources.

Dr. James M. Faulkner, chairman of the Massachusetts Medical Society committee that publishes the prestigious New England Journal of Medicine, told the subcommittee that "medical education has failed to grasp the significance of the vast proliferation of new drugs that has taken place over the last couple of decades." Now, he said, "the practicing physician finds himself obliged to choose between a bewildering array of drugs for which competing claims are made, and more often than not he finds himself not only ill-prepared to make correct judgments but at a loss to know where to turn for unbiased information."

It is very difficult to watch people who go once or twice to a doctor's office and continue to buy without renewing prescriptions. But often, too, a doctor has not learned about a drug's effects for some time after the drug is on the market. Communication is slow. The information drifts slowly from individual physicians as each one publishes his case histories in medical journals. All too often, a doctor, with due caution, and knowing that his colleagues will otherwise criticize him, fails to publish a paper because he feels that one cannot draw conclusions from three cases. It may take a long time and quite a few tragedies before the journals, the drug houses, and the Government learn that a particular drug has dangerous effects.

In our advanced technology, drugs are quickly dispensed to millions of people; yet communication among doctors is still slow and primitive. No central service exists upon which a doctor can

.../...

call for the specific information he needs about a particular drug for a particular patient. Instead, the helpless physician is inundated with drug advertising and samples, with more information than he can possibly absorb or has any use for.

Indeed, it is surprising how hard it is to demonstrate that many popular drugs accomplish more than a placebo. It is partly for this reason that the FDA has undertaken its review of over 3500 drugs placed on the market between 1938 and 1962, when legal requirements for drug testing were tightened; involved is the scrutiny of around 40,000 claims for efficacy.

The use of an ineffective drug might remain only a waste of time and money if it had not other effects. Unhappily a drug can cause unpleasant side effects and may even induce dependency without ever conquering the symptoms for which it was taken.

Although the protection of the health of the consumer is of primary concern, another important reason for the transmission of accurate data about drugs is to serve the economic interests of the consumer. Correct and accurate information about drugs is also crucial to protect the consumer from having to pay more than is necessary for a particular drug. In his 1968 message on health to the Congress of the United States, President Johnson recommended that a manual of drugs be developed and made available to both doctors and consumers, such a manual would present information regarding the cost of a drug under its generic name - as contrasted with the cost of the same drug when marketed under a brand name by a particular manufacturer.

Most people could save themselves both confusion and money if they knew the generic names of the drugs they take. The difference between buying a drug under its generic and under its brand name can amount to twenty dollars a bottle. Neither research nor production warrant such prices in most cases. The only valid reason for the higher cost is better quality - which is only sometimes the case. A study of 175 million prescriptions written

.../...

for elderly people in 1966 showed that $41.5 million could have been saved if the doctors had prescribed by generic name rather than brand name, the U.S. Health, Education, and Welfare Department has said.

Clearly, both the physical and economic well-being of the consumer depends on accurate and speedy information about the true value of available drugs. The provision of such information in a comprehensive fashion remains a primary task for any health oriented program.


4. 4. 72