

## EDITORIAL

### DRUG CONTROL IN THE AMERICAS<sup>1</sup>

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This Seminar on Drug Control in the Americas could not have been held 20 years ago. Not because the human values that inspire it did not exist, but rather because the circumstances precluded those values from overcoming other interests, in order to create a public awareness of the problem. Today, every undertaking is appraised in terms both of its contribution to development and the economy, and of its adverse effects on man and his environment. As with all movements inspired by the common good, the initial phases have seen exaggeration, excessive caution, precipitous action, and in general, the predominance of emotion over reason. Although the pendulum is now swinging the other way, the motivating force has not lost its meaning. And what motivates it is a convergence of diverse currents of opinion that have appeared spontaneously to reaffirm the inalienable rights of man in society. Men must not be the victims of technology, but its beneficiaries; not slaves of machines, but their masters; not at the mercy of material objects, but in command of them for man's welfare. And profit cannot be sought at the price of others' health.

A new image of the consumer—as one who demands to know what he is buying, to take part in development planning, to contribute to that eternal process of learning known as progress—is now taking shape. Already we have examples of this new attitude. It is no longer acceptable for industry to neglect the safety of workers and to contribute to pollution of the air, water, and soil. Nor can additives be used in food to make it more attractive or palatable, when their effects on health are unknown. Nor can crops be sprayed at random with insecticides in disregard of their possible long-range consequences. Nor can automobiles and other passenger carriers be built with defects that may cause accidents later. And now society expects each medication to have the declared composition and to exert the therapeutic activity claimed for it.

In summary, what is sought is the humanization of development—or, in Fromm's poetic words, "the revolution of hope." What seizes our attention is that there are some who are surprised by, and even react violently to these demands of consumers who will not remain impassive when their natural rights are threatened. Such demands signal an attempt to create a more just and healthier society, ruled by values that should ever be our guide, whatever may be the level and nature of our progress.

We are being asked to practice what we preach; to let our actions prove our words; to make our convictions prevail over our interests and the common good over individual enrichment.

Within this conceptual framework, the purposes of your Seminar come into

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<sup>1</sup>Statement delivered at and published in the proceedings of the *Seminar on Drug Control in the Americas (Maracay, Venezuela, 15-20 November)*, *Scientific Publication PAHO 225* (1971), 7-9. Appearing also in *Boletín de la Oficina Sanitaria Panamericana*, Vol. LXXI, No. 5 (November 1971), pp. 375-377.

sharper focus, for they concern one of the most sensitive areas of social life and one of the most essential instruments for the prevention and cure of illness, the lengthening of life, and the pursuit of happiness. If we note further that in Latin America the industry produces over \$1.2 billion of drugs at manufacturer's prices each year, we can understand even better the ethical, biological, and ecological importance of your task.

The surveys taken by our Organization show that in general the systems used to evaluate the quality of medicines in the majority of the countries are below the level of technical development required to test the volume of drugs resulting from domestic production and importation. There is a shortage of personnel—whose training must be improved continuously because of the intensive research conducted by the industry itself—of equipment, materials, and even of physical facilities. Legislation is not always up to date, nor does it provide educational standards that will make the consumer a responsible and active participant. Let us keep in mind that a large proportion of accidents involving children are due to the ingestion of excessive quantities of drugs or toxic substances at home, left within their reach by parents.

It should be added that control is terminal, i.e., when the preparation is either on the market or about to be placed there. In other words, only in a few cases are the intermediate stages analyzed to guarantee the final result. What is more, industry does not always have testing laboratories, nor do government services examine their records to assure accuracy.

Funding of the government drug control services is as inadequate as it is essential. We should make special note here of the steps taken by the Government of Argentina to earmark 0.75 per cent of the proceeds of sales of all pharmaceutical substances for the Governmental Department of Quality Control. The Governing Bodies of our Organization have recommended that similar procedures be adopted in accordance with each country's circumstances.

In the search for a drug there is a series of stages, the mere enumeration of which reveals the complexity of the production process. It begins with chemical investigation designed to extract the substances from nature, analyze them, and—if appropriate—synthesize them. This is followed by biological research, which involves tests, either in the laboratory or on experimental animals, of the action of the substance, that is, its pharmacology; of its harmful effects, or toxicology; and its effects on offspring, i.e., genetic studies. If no adverse effects are observed, the substance must be provided with the best possible medium to transform it into an effective, stable, and well-tolerated medication; this stage is known as galenic research. Then comes the final or clinical stage, the purpose of which is to test the drug's therapeutic action on ill persons who are willing to take part. After this comes mass production, or—as it has been well put—“the jump from milligrams to tons.” Above all we wish to stress once again the preventive or curative action that prolongs life and fosters well-being and happiness. Whether the preparation of medical substances is a state or a private activity, control aimed at guaranteeing the safety, purity, and efficacy of those substances must be exercised with all scientific, technical, and moral rigor.

The tremendous progress of the last 30 years in the identification and preparation of drugs and pharmaceuticals is due in large measure to the efforts of industry. While the universities of the technologically advanced countries, as well as their Governments, have concentrated on the study of basic functions in normal and pathological states (the most conspicuous example of which is molecular biology), private enterprise has devoted its greatest attention to therapeutic effects and to production. We are convinced that a sound industry, genuinely interested in

social well-being as a prelude to and an ultimate consequence of development, prefers that the Governments have efficient and well-equipped institutions to control the quality of drugs, as regards both their composition and their pharmacological effects. When it has its own laboratories, industry cooperates in the implementation of the laws in force.

It is this spirit that led the World Health Assembly and the Governing Bodies of the Pan American Health Organization to include in their policies the provision of advisory services to the Governments in this sensitive field which affects many of their activities. The standards recommended for manufacture and quality inspection of drugs,<sup>2</sup> the system proposed for certification of the quality of pharmaceutical products destined for international trade,<sup>3</sup> the encouragement of the organization of quality control laboratories to serve one or more countries, and the center for international surveillance of adverse reactions to drugs, are manifestations of the universal interest of Governments in this problem. In my judgment, they all reflect the movement now taking shape to motivate the consumer to lay aside his passive role and claim his right to get exactly the article he pays for.

Your Seminar is a first step down a long road. As you proceed you will be subject to misunderstandings, to misinterpretations, to unspoken attitudes, to pressures of every sort. May you constantly find your inspiration in the image of that society we all seek, and in the comforting vision of children you will have helped to save and adults whose happiness you will have fostered.

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<sup>2</sup>Resolution WHA22.50. *Off. Rec. Wld Hlth Org.* 176 (1969), 24-25.

<sup>3</sup>*Ibid.*, pp. 104-105.