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SAVING THE WORLD HEALTH ORGANIZATION FROM A POISON PILL

INTRODUCTION

The World Health Organization deservedly has been respected as one of the most effective and dedicated international agencies grouped under the United Nations umbrella. WHO has led victorious battles against smallpox, diphtheria, tetanus, whooping cough, poliomyelitis, measles, and tuberculosis. Whether WHO will achieve future victories, however, is a matter of mounting concern.

WHO has become an instrument of those countries and groups that already have eroded the effectiveness and legitimacy of many other U.N. agencies. They seek to use the U.N. and its agencies to regulate the globe's natural, financial, economic, and informational resources. Advocates of such global regulation will be massing later this month at a WHO meeting in Nairobi. There they are preparing to give WHO a poison pill. They will seek adoption by WHO and forwarding to WHO's governing body, the World Health Assembly, at its annual meeting next May, a proposal recommending that nations enact drug legislation containing a "medical needs" clause. Such a clause would determine which drugs would be approved for marketing in both developed and developing countries.

The standard that these groups seek to impose would allow on the market only drugs that are either therapeutically superior to or cheaper than available products. Drugs already approved would be reevaluated periodically according to these criteria, which would be superimposed on the traditional requirements of safety, efficacy, and quality.

In theory, these new criteria seem innocent and even commonsensical. In practice, they could be a nightmare. If followed by both developed and developing countries, they could significantly slow progress in pharmaceutical and medical research. This would happen since few, if any, pharmaceutical companies would risk investing in research and development without some assurance of being able to market the resultant products if they were safe and useful. The current costs of bringing a new drug to market, including important clinical trials, are about $100 million.

If followed primarily by developing countries, the "medical needs" approach would have a somewhat limited effect on research and development, since developing countries provide only around 12 percent of the total sales market for the international pharmaceutical industry. Yet the criteria would reduce enormously the incentive to pharmaceutical manufacturers to develop therapies needed in developing countries where severe health problems are especially widespread. The victims would not be the pharmaceutical firms but the poor populations of the developing world, who are most in need of these therapies.

Adoption of a "medical needs" clause would achieve a long-sought goal of the regulatory activists in WHO: strict limitation of the activities of Western pharmaceutical manufacturers in the developing world.[1] With only one version of a drug available, for instance, there would be no need for marketing. In effect, competition among pharmaceutical products would end in the developing world.

This would not serve "the attainment by all peoples of the highest possible level of health,"[2] the goal for which WHO was founded, which the U.S. currently supports with $130.6 million--25 percent of its 1984-1985 budget.

U.S. representatives to the Nairobi meeting thus should save WHO from the poison pill of the "medical needs" criteria by pressing WHO to reject these proposals. WHO should stick to its original intent and build on its fine record for proposing concrete steps to improve general health care systems in developing countries.

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1. Anwar Fazal, former head of the International Organization of Consumer Unions (IOCU), indicated clearly in 1983 that the real target of the activists' draft marketing code is the developed world's "leading 110 companies which manufacture almost 90 per cent of the world pharmaceuticals and control technology and trade in drugs." See: Harry Schwartz, "A War on Drugs, New Order Style," The Wall Street Journal, March 24, 1983.

2. United Nations, Department of Public Information, Everyone's United Nation (New York: United Nations, December 1979), p. 361.

THE U.N.'S WAR ON THE PHARMACEUTICAL INDUSTRY

A key development last year in the U.N. campaign against the pharmaceutical industry was a decision by the World Health Assembly to convene an experts' conference in 1985 to discuss "the means and methods to ensure the rational use of drugs." The results of this conference, scheduled for Nairobi, from November 24 to 29, are to be reported to the 1986 World Health Assembly. This meeting is widely viewed by consumer activists and their supporters in WHO as an opportunity to launch a major effort to convince WHO to begin work on a Marketing Code on drugs.[3]

Halfdan Mahler, WHO's Danish Director-General, so far has resisted efforts to adopt a code. Yet pressure for such a code is mounting from powerful regulatory activists, led by such groups as Health Action International (HAI).

Encouraged by several governments and some members of the WHO staff, the activists have developed a vehicle to attain their goal without actually calling for a "code." They are pushing a proposal recommending that national legislation governing the marketing and distribution of drugs in developed and developing countries include a "medical needs" clause. If the regulatory activists have their way, the only medicines permitted on the global market will have to be either "therapeutically superior" or cheaper than other available medications. If a "medical needs" clause were widely adopted by WHO member governments, the traditional standards to demonstrate safety, efficacy, and quality prior to marketing would be inadequate, and a newly developed drug would have to undergo an economic "litmus test" that would keep it off the market if it were shown to be even slightly more expensive than an existing drug.

By adopting a "medical needs" clause, countries in effect would be stating that, at the time the clause takes effect, they have all the medicines they will ever need for whatever purpose. Keeping new medicines off the market, unless they could meet the "medical needs" test, would stifle competition and innovation in the international pharmaceutical industry.

The "medical needs" concept is a misnomer. What are claimed to be "medical" criteria are in fact economic factors. The introduction of a new drug into a market, as for any other commodity, would depend on its price relative to the price of available alternatives already on the market--which might be other drugs or medical procedures altogether. The introduction of the new drug would be prevented if it

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3. Harry Schwartz, "Forcing Drug Firms into Third World Triage," The Wall Street Journal, August 24, 1984, p. 20.

were more expensive than or, at the moment of introduction, therapeutically equal or inferior to available remedies. Moreover, the product would be denied an opportunity to demonstrate its potential effectiveness in treating a particular disease under unique environmental conditions or in treating other illnesses for which it was not originally indicated.

The producer of the drug already on the market thus would have no incentive to innovate or to lower prices, since his product would be insulated from competition by the "medical needs" clause. The regulatory activists and their supporters within the World Health Organization hope that, by couching their attempt to drive the international pharmaceutical industry out of the developing world in the appealing guise of "medical needs," they will gain the support of the experts and WHO officials in Nairobi, and eventually the governments of developing countries.

PROBLEMS WITH THE "MEDICAL NEEDS" CONCEPT

A wide range of scientific and economic evidence refutes the arguments of those who would impose the "medical needs" criteria on developing country governments, health planners, and physicians.

The proposal, for example, assumes that it is possible to reach a definitive judgment on the therapeutic value of a product before it is introduced onto the market. It further assumes that, if the decision made at that time is against registration of the new medicine, no sacrifice of any future therapeutic benefit will ever occur.

These assumptions are unjustified. The full therapeutic potential of many medicines becomes apparent only after their introduction. This is because new and valuable uses for a product often are established only after its introduction. Use of a medicine, moreover, may lead to a better understanding of the disease process, to new and better treatment of the disease, and to preventive measures.

An example of the "later benefit" phenomenon is provided by the beta blocker propanolol which was introduced as an "anti-arrhythmia" drug and subsequently as medication for angina. Only after considerable time on the market was it recognized that propanolol and other medications in its class were highly effective anti-hypertension agents. In fact, they have become very widely used and have revolutionized the treatment of hypertension. More recently, their benefit in preventing second heart attacks revealed, in addition, their lifesaving potential.

Good medical care in developing and industrialized countries alike requires a broad spectrum of medicines from which to select the

best therapies. In the developing countries, in particular, differences in genetic constitution, diet, infectious organisms, and the local structure of health care services all need to be taken into account in selecting the most appropriate treatments. The broad adoption of the "medical needs" criteria would limit severely the options in this selection and, therefore, have devastating effects on the quality of medical care in the developing world.

The adoption of a "medical needs" clause also would interfere with the economic aspects of innovation within the pharmaceutical industry. Successful pharmaceutical research and development is very costly because it demands long-term continuity of effort by a multidisciplinary team of scientists, collaborating closely in a series of diverse research projects. On the average, 10,000 compounds are studied and rejected for every new drug that reaches the market; currently, these development costs average about $100 million.[4]

The objective of these projects generally is to develop a major "breakthrough" drug. In practice, however, this research typically yields a series of minor, rather than major, advances. Such minor advances constitute a vital component in pharmaceutical innovation, providing worthwhile improvements over previous therapy. Minor advances also help build a base of knowledge from which significant gains occasionally arise. A "medical needs" policy, on the other hand, would dry up the source of pharmaceutical innovation by keeping even minor advances in medication off the market. This could, in turn, destroy the base for future major breakthrough medication and would involve a severe deterioration of medical care in the developing world.

A "medical needs" policy also would reduce the incentive of rival firms to develop competing products, thus ensuring a monopoly position for a breakthrough product throughout the life of its patent, and probably beyond it. By providing a competitive challenge to the market position of an innovative drug, the introduction of a new product offering even minor advantages over that drug could result in lower prices and even stimulate further product improvements.

"Medical needs" criteria in addition would provide national drug registration authorities with a convenient, extra pretext for erecting nontariff barriers against imported medicines.

There is no convincing evidence that a "medical needs" restriction on the number of drugs available would reduce the consumption of medicines or lower their costs. It is clear, however, that such a restriction would limit competition, slow the rate of pharmaceutical innovation, impede the practice of medicine, and raise

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4. Schwartz, August 24, 1984, op. cit.

the overall cost of illness in human and economic terms, particularly in the developing world.

RECOMMENDATIONS

Pharmaceutical distribution systems in developing countries are deficient in many respects, as are their general health care systems and their standards of hygiene and nutrition. The question that should be addressed by U.S. experts attending the World Health Organization meeting in Nairobi later this month is how best to improve these deficiencies. International codes, economic regulations, or "medical needs" clauses are not the way to improve these systems.

The U.S. experts in Nairobi should press senior WHO officials and other conference delegates to oppose endorsement of "medical needs" clauses. The U.S. experts should propose steps to improve developing country pharmaceutical marketing and distribution systems and the proper utilization of medications. These include:

o National (rather than international) drug legislation requiring marketing approval based on safety, efficacy, and quality and outlining a proper distribution system. Some developing countries do not have this basic legislation.

o Greater use and expansion of the existing WHO "Certification Scheme for Pharmaceuticals Moving in International Commerce," which provides an importing country with information on the marketing status of a product in the exporting country and the required compliance of the manufacturer.

o Use of the International Federation of Pharmaceutical Manufacturers Association (IFPMA) Code of Pharmaceutical Marketing Practices, adopted in 1981 by the 48 national pharmaceutical industry associations represented in the Federation.

o Training in pharmaceutical quality control for developing country government officials.

o Increased education in the proper use of pharmaceuticals for health care providers in developing countries.

Capitulating to the demands of the health activists in Nairobi would provide none of the benefits of improved medical care and access to safe and reliable pharmaceutical products that could be gained by undertaking these measures. Conceding to the activist champions of the "medical needs" clause stands to deprive developing country populations of the many medical services they so badly need.

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