The UN System's War on the Drug Industry

Harry Schwartz

THERE IS A CERTAIN IRONY in the fact that the Western pharmaceutical industry is under increasingly virulent attack from the United Nations system and the third world countries that dominate it. After all, the industry's products have been the source of virtually all important advances in medical therapy in modern times, and the peoples of the third world have been among the major beneficiaries.

Thus, as a recent *Scientific American* article has pointed out, the gain in average life expectancy in the developing countries in the fifteen years from 1950 to 1965 equaled the whole gain achieved in Western Europe in the seventy years from 1800 to 1870. The new drugs and insecticides introduced into the developing countries soon after World War II, according to the authors (Davidson Gwatkin and Sarah Brandel of the Overseas Development Council), "made it possible to control many communicable diseases and appear to be responsible for roughly half of the increase in life expectancy in the Third World." And a more subjective—and more forceful—statement on the same theme comes from Ghana's Jerry Rawlings, who explained in a radio speech that he had ousted the previous regime because it was corrupt and particularly because profiteering and hoarding of pharmaceuticals had turned Ghana's hospitals into "graveyards."

Surely the would-be regulators at the United Nations (UN) do not want hospitals in the developing countries turned into graveyards. Yet, in the past decade, an unwary observer could easily be forgiven if he gained the impression that the United Nations in general and the developing countries in particular would like to do away with the Western pharmaceutical industry entirely. A few years ago, for example, the director-general of the World Health Organization (WHO), Dr. Halfdan Mahler, accused the multinational drug companies of carrying on "drug colonialism" in the third world, and called their activities indecent. A December 1981 report from UNCTAD (the UN Conference on Trade and Development) praised Cuba as a model for developing countries, citing the fact that "all drug production has been in the public sector since 1961, and private prescription and distribution of drugs were abolished in 1960." And a well-known 1975 UNCTAD report on the transfer of pharmaceutical technology to developing coun-

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tries (by Sanjaya Lall, who has since repudiated some of its key ideas) even argued against pharmaceutical innovation on the grounds that it produced dangerous monopoly power in the industry.

At one and the same time, there have been complaints that the pharmaceutical companies greatly overcharge their third world customers, as well as complaints that the companies use African nations (to quote the Zimbabwe minister of health's remarks to an April 1982 WHO meeting) as "dumping grounds for cheap preparations which will throttle our nascent pharmaceutical industry." Both claims have some validity. That is to say, pharmaceutical prices in the third world are higher than in most Western countries (thought not much higher than in, say, New Zealand), chiefly because of transportation and other distribution costs; but those prices are lower than they would be if the developing countries were doing the manufacturing themselves. (Indian streptomycin prices have been as much as ten times world streptomycin prices.) Even so, when the pharmaceutical companies are attacked for having prices that are simultaneously too high and too low, it is hard to escape the conclusion that they are really being attacked for existing at all.

But the attacks continue, for all that, and various UN agencies have come up with some suggested responses. They are three in number: (1) the creation of "essential drug" lists, patterned after WHO's model list but adapted to specific local needs, (2) the effective abolition of drug patents in developing countries, and perhaps worldwide, and (3) the imposition of an international marketing code for pharmaceuticals. All three schemes seem to have, as an underlying assumption, the view that pharmaceutical development has already gone about as far as it can or should go.

The Essential Drug List

For most of the past decade, the World Health Organization and other UN bodies have been pushing the idea that poor nations should buy only "essential" drugs and the associated idea that the essential drugs should be bought in the cheapest generic form instead of from research-oriented manufacturers. The objective is to eliminate needless duplication, to facilitate bulk purchasing of lowest cost drugs, and to provide guidelines for the manufacturing decisions of the national pharmaceutical enterprises many countries are creating or hope to create. Supporters of the idea argue that pharmaceuticals often account for 35 to 40 percent of some poor nation's annual health expenditures and that drug prices must therefore be exorbitant. What is ignored here is that many countries allocate only a minuscule portion of their GNP to health, and that drugs represent such a large part of that because so little is spent on doctors, nurses, and hospitals. It makes sense for developing countries to focus on medicines because they are by far the most cost-effective means of preventing, curing, or palliating diseases. (Look at the results, for example, with smallpox and polio.) It does not make much sense, however, for these countries to complain about the percentage of their health funds that they spend on medicines.

Nor does the essential-drug-list approach make much sense for all parts of the third world. For the desperately poor countries—those with annual per capita incomes under, say, $200—the essential drug list may admittedly be the counsel of despair. But many third world countries — Venezuela, Saudi Arabia, South Korea, Singapore, for example—are far from such abject poverty. In such countries as these (and there are a few dozen of them), there is a strong case to be made against primary dependence, let alone exclusive dependence, on any limited list. If, for every disease, there were one and only one drug that would cure, prevent, or palliate the disease, for each and every person suffering from it—and if such drugs had been discovered for all diseases —then one would not have to go beyond the essential list of such drugs. But, in fact, a particular drug may help, say, nine out of ten victims of a disease, while a different drug (or a combination of different drugs) may be required to help the tenth. Moreover, any limited drug list would necessarily exclude medicines needed for infrequent or very rare diseases. The more varied the medicines available to a nation's patients, the greater the percentage of patients who can be helped.

The idea of an essential drug list is often linked, as we have noted, to the idea that generic drugs are preferable (because cheaper) to pharmaceuticals carrying brand names and

trademarks. But some developing countries have learned to their sorrow that this is not true: the lower cost of generic drugs may be more than offset by poor quality and late delivery. In 1977, a major UNCTAD publication (by S. Bibile) hailed the great savings supposedly made by Sri Lanka when that country established a monopoly drug import agency and began buying generic drugs from "non-traditional sources," including the Soviet bloc. Only later did it become public knowledge that the agency had grossly exaggerated its savings and failed to mention the losses suffered because of the poor quality of some of its generic drugs. The monopoly was ended after Sri Lanka's socialist government was defeated at the polls in 1977.

Nevertheless, the drive to convince developing nations to focus on essential drugs continues, as though the mere fact of restricting the drug formulary would work magic. Along with this drive goes the neglect of related—and very pressing—issues, particularly the need for a system of distributing medicines, for ensuring that drugs are discarded when they have lost their potency, and for seeing to it that drugs requiring special handling (refrigeration, for example) receive it. In many developing nations, medicines are plentiful only in the capital city, which often has a major hospital with Western-trained specialists and expensive Western equipment for the most modern diagnostic and surgical procedures. Yet, in rural areas a dozen miles away, there are few drugs and fewer doctors, and the pharmaceutical famine grows more acute as the distance from the capital lengthens.

To get drugs and doctors to the people of the developing countries has become a matter of increasing concern to the pharmaceutical manufacturers. In early 1980 the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) told the World Health Organization that some members of IFPMA were willing to negotiate low concessionary prices for sales to the most poverty-stricken countries. In January 1982 (after two years of bureaucratic delay) WHO suddenly announced that the IFPMA offer was being received with great satisfaction, and the May 1982 meeting of the World Health Assembly reacted with similar favor. Forty-six of IFPMA's member companies have now agreed to sell some 230 drugs and vaccines (of which 135 are on the model WHO list of essential drugs) to some of the poorest developing countries at prices the IFPMA executive vice-president has called "favorable." The exact figures are to depend on quantity, pack sizes, dates of delivery, and the like.

In addition, some Western pharmaceutical firms have begun to train citizens of some of the least-developed countries to solve problems of drug logistics and distribution—a step whose proliferation throughout the world is likely to prove more valuable in the long run than the IFPMA initiative (even though that initiative seems more in line with UN desires). Among pilot projects now under way are those sponsored by U.S. firms in Gambia and Swiss firms in Burundi.

Both the essential-drug-list approach and the attempts to build infrastructure have in common the assumption that the important thing is delivering the drugs we have rather than developing new drugs. But the latter is important too, and that is where the real trouble begins.

The War against Trademarks and Patents

Brand names and trademarks establish a manufacturer's responsibility for its products and assure customers of quality—an assurance for which the customers are willing to pay a premium. To the foes of transnational pharmaceutical companies, however, trademarks are simply a device for giving firms intolerable market power. Typical of what some parts of the UN bureaucracy would like to achieve are the recommendations of an August 1981 draft report of the World Intellectual Property Organization. Arguing that trademarks on pharmaceuticals may be redundant and may increase prices, the report urged that serious consideration be given to limiting or prohibiting the use of such trademarks, especially in developing countries. (Given that even the political parties in such countries must use trademarks on the ballot for the benefit of a largely illiterate mass of voters, one wonders what the trademarks on pharmaceuticals will be replaced with.)

This drive against trademarks is supported by such influential third world countries as India, Yugoslavia, and Mexico, which have

significantly limited the use of international trademarks in their own national markets. In fact, the World Intellectual Property Organization, established within the UN as the successor to previous international bodies created to defend the rights of those who own intellectual property, has increasingly become a forum for third world calls to confiscate intellectual property. The tendency to use it in this way is strengthened by the fact that many third world leaders have their eyes firmly fixed on the advantages to them of creating domestic pharmaceutical industries, while the Western nations are represented by diplomats generally keeping at least one eye on their standing with the third world. In addition, some Western countries (France, for example, whose minister of health is a Communist, or Sweden, or Holland) agree with the third world on ideological grounds.

The war against trademarks is only half the story—and the less important half. With it we are still in the realm of already existing drugs. It is the war against patent protection that takes us into the area of greatest danger.

The basis of existing international patent protection is the Paris Convention of 1883, whose provisions have fostered technical innovation and the prompt spread of innovation throughout the world for a century. But in October 1981, the Nairobi Diplomatic Conference for revision of the Paris Convention tentatively approved two changes relating to actions a developing country can take in the event of "failure to work" a patent. Only the United States expressed active opposition. One change would allow a developing country to give an exclusive compulsory license for the use of a particular patent to anyone it wishes if, two-and-a-half years after the patent has been granted, the granting country determines that it has not been worked adequately. An even more drastic change would give developing countries the right to revoke a patent five years after granting it, if the compulsory license granted earlier has not brought about what the country involved regards as adequate working of a patent.

While these changes would apply to all patents, their impact on the innovative pharmaceutical industry would be particularly crippling. First, working a drug patent means manufacturing the drug, all the way from initial raw materials to the final formulation ready for sale and consumption. It must be emphasized that, even if a pharmaceutical company has a multimillion dollar plant in a developing country, one that is manufacturing different dosage forms of a drug from imported intermediate chemicals, this would not be considered "working a patent" in that country. Even under the milder of the two provisions, a firm that discovered a new medicine and was manufacturing dosage forms of that medicine in a given country for distribution in that country could find the exclusive right to manufacture the drug assigned to someone else, making it illegal for the company to continue manufacturing its own drug.

Second, the effect of these two provisions would be especially great because of the character of the drug approval process. Application for a patent on a new drug is made as soon as possible after discovery, and the patent is (mostly) granted in due course. But the drug itself cannot be marketed until it has been cleared by the appropriate national body—the Food and Drug Administration (FDA) in the United States, for example. The process of winning approval for marketing can and often does take even longer than five years, certainly in the United States where the FDA's slowness in granting approvals has created the much publicized U.S. "drug lag." Thus the Nairobi proposals would seriously threaten the pharmaceutical companies with loss of their patent rights because they have not yet begun the manufacture of an unapproved drug.

One reason the Nairobi proposals got almost automatic approval from most countries represented there is that in most other industries there is no need for the pre-marketing approval process required for pharmaceuticals—or, at least, that is my conjecture. It is also worth noting that Canada, Australia, New Zealand, Spain, Portugal, and Turkey—three of them clearly first world countries and the other three borderline—declared at Nairobi that, in relation to pharmaceuticals, they regard themselves as developing countries entitled to these special developing-country rights. (Countries like these, incidentally, which do not suffer from the third world diseases for which adequate medicines are still to be developed, would benefit much more than the third world from a successful attack on pharmaceutical patents.)

Why should weakening patents for new medicines disturb the general world community? An eloquent answer emerges from a recent book *attacking* the multinational pharmaceutical industry. Milton Silverman, Philip Lee, and Mia Lydecker, in their *Prescriptions for Death,* give this unequivocal judgment for patent protection:

> It seems to us that wiping out patent protection for new drugs would be a short-term boon for some countries but a long-term disaster for the world. It would effectively choke off much if not most of the industry's research and the development of better drugs. Some industry critics have countered that much of the industry's research is wasteful and needless, and that the important investigations can be taken over easily by university and government laboratories. For the last thirty or forty years, however, the record is clear that although some of these nonindustry institutions have contributed magnificently to basic research, they have turned out few important products. Certainly in difficult economic times with tight budgets, few government agencies or university research centers would be willing to take the gamble of investing the enormous resources and the many years now required in modern drug development.

The countries of the third world should be taking those words to heart.

The International Marketing Code for Pharmaceuticals

Finally we turn to the third prong of the UN attack, a code on marketing practices to be formulated and promulgated by the World Health Organization or some other UN body. The precedent would be WHO's adoption of a stringent marketing code for infant formula. And the basic assumption would be that the drive for private profit by multinational drug companies, as the Lall report put it, "is not compatible with the well-being of the vast majority of the world's population." Those pushing for such a code know well, or should have learned from the infant formula battle, how easy it is to arouse Western public opinion to moral outrage through a well-orchestrated campaign attacking alleged industry abuses.

At this point we should perhaps step back and view the issue in some perspective. The Western pharmaceutical industry sells its products in well over 100 countries, where the levels of cultural, educational, economic, and medical development vary enormously, as do the local practices and standards of political morality. It would be unrealistic to assume that pharmaceutical marketing in the third world is unaffected by a national or local atmosphere of cynicism, or tolerance of corruption, or probably (in some cases) the virtual necessity of *baksheesh.* There have, indeed, been dismaying instances of abuses in pharmaceutical marketing in the third world.

Many of these abuses have involved the sale of medicines for whose efficacy extravagant claims have been made and about whose potential dangers too little or nothing has been said. Lack of properly controlled distribution networks in developing countries may have contributed to the problem. Another contributing factor may be that the Western pharmaceutical companies are accustomed to prescriptions written by doctors and filled by registered pharmacists, while third world countries often do without prescriptions and are interested in getting medicines to as many people as possible—a situation not ideally suited for safeguards. Both factors can produce an element of carelessness in an area where any carelessness may be too much.

But carelessness is not the only abuse. Drug sales in various countries are often made through friendship, "contacts," the giving of samples—a very personal kind of marketing network. In countries where personal gifts usually accompany business deals, the line separating bribery from custom is pretty uncertain.

That does not excuse companies clearly on the wrong side of the line. But are we to impose on the developing countries a marketing code whereby every drug (1) should be sold in every country only for the purposes approved by the FDA in this country, (2) should be accompanied by all the warnings in our *Physician's Desk Reference,* (3) and should be sold without any advertising or other marketing effort aimed at doctors and/or patients? Supporters of the code, by and large, want roughly that. But apart from imposing our own "drug lag" on the world at large (and perhaps even wind-

ing up with requirements that a drug for a disease that does not exist in the United States would have to be tested and approved in the United States), it is hard to see what the first of these provisions would do. The second is unlikely to do much harm, but it is also unlikely to do much good. It is certainly arguable that it is not particularly important to cite (in, say, Paraguay or Uganda) a 1-in-40,000 chance of a given side-effect when the immediately important thing is curing the 40,000. Even worrying about a 1-in-100 side effect may be a luxury when one is trying to eliminate a disease attacking much of the population in a given country (as schistosomiasis). And as for arms-length marketing, we may ask whether Sri Lanka would not have been better off succumbing to pharmaceutical company blandishments and getting better-quality drugs on time.

All this having been said, it is nevertheless true that Western public opinion expects—and has a right to expect—a high standard of conduct from its major corporations. The pressure of this expectation has already brought some significant changes. Last year IFPMA adopted a voluntary marketing code that pledges "full candor in dealings with public health officials, health care professionals, and the public" and requires that "information on pharmaceutical products should be accurate, fair and objective, and presented in such a way as to conform not only to legal requirements but also to ethical standards and to standards of good taste." Also, in an oblique reference to charges of bribery, "scientific objectives should be the principal focus" in arranging medical symposia, and "entertainment and other hospitality shall not be inconsistent with such objectives." Early this year, in response to charges that its voluntary code lacked enforcement mechanisms, IFPMA established a committee consisting of its president, executive vice-president, and two vice-presidents to oversee the code. "The major sanction against any company that transgresses the code will continue to be the sanction of adverse publicity." (IFPMA has also noted its willingness to supply foreign governments with current issues of the *Physician's Desk Reference*, or its British, French, or West German counterparts.)

In spite of these measures, many still expected a historic confrontation over WHO's proposed code at the May 1982 meeting of the World Health Assembly in Geneva. The reality was quite different—a near consensus in favor of giving the industry's voluntary code a chance. In part this happened because Secretary of Health and Human Services Richard Schweiker addressed the meeting, making quite plain the Reagan administration's opposition to this and other needless UN meddling in the pharmaceutical field. Many of his listeners must have remembered how the United States had pulled out of the International Labor Organization for three years (1977–80) and stopped paying its very substantial dues, returning only after the ILO's policy had become more sensible. There were few in Geneva who wanted WHO to be a second victim of such American wrath. Only the hardliners—notably Cuba and Romania, scarcely nonaligned third world countries—spoke out directly in favor of UN-imposed regulation of world pharmaceutical marketing.

Clearly, the IFPMA marketing code and the industry's offer to sell some drugs at concessionary prices have brought about a temporary truce. This development was underscored at IFPMA's biennial convention in Washington, D.C., in June, when Director-General Mahler of WHO hailed "the new era of cooperation" and won a standing ovation from the audience of pharmaceutical executives. Neither side at the meeting ignored the points of continuing friction, but both gave much evidence of wanting to get along.

Truce or Peace? Where Do We Go from Here?

It is difficult to predict how long this era of relative good feeling will persist. It is all too easy to imagine future developments that would again poison the atmosphere. Certainly many in the UN bureaucracy and in positions of power in the developing countries will continue to distrust the drug companies. But whatever the future holds, the present gives ground for modest hope—especially if the international patent system is not wrecked. The results should be better health in the developing countries—along with continued profits from drug innovation which in turn will help pay for further research into debilitating third world diseases.

If what we have is really peace. ■