

RISMED 00168

Book Review

Milton Silverman, Mia Lydecker, Philip Lee. *Bad medicine: the prescription drug industry in the third world*. Stanford University Press, \$29.95. ISBN 0-8047-1669-2

Once more Silverman and his colleagues have looked at the role of the pharmaceutical industry in developing countries. In earlier studies, such as *Pills, Profits and Politics*, *The Drugging of the Americas* and *Prescriptions for Death and The Drugging of the Third World*, they exposed the abuses of the pharmaceutical industry in the course of marketing and promoting their products. In this volume they look at what has happened since the multinational companies have come under heavy attack from consumerists, the media and government officials. A wide range of topics are discussed.

In the first place they look (again) at the situation of *misinformation*, i.e. unsubstantiated claims about efficacy and attempts to cover up hazards. Publicly available and widely used information sources containing information approved by governmental agencies were checked for 40 single drug entities or fixed combinations, covering 1500 products from 400 Western companies and 74 Third World Companies. The Physician's Desk Reference was used for the US, and MIMS (Monthly Index of Medical Specialties) in the UK, but they examined also the editions produced for a large number of countries in Asia, the Middle East, French and English speaking Africa, Central America and Southern America. The results are shown in 40 tables. The multinational companies appear to have changed their ways. Efficacy claims are today more restricted to what can be scientifically substantiated. More warnings are given about side effects. The authors describe the changed situation of the (multinational) pharmaceutical industries. The dwindling of profits, the few new important drugs emerging per year and governmental restrictions have all made the business more expensive. The development and implementation of the Essential Drug List of WHO and the accompanying Drug Action Program have, after initial protests by the industry, been accepted for public health though they are still opposed in the case of the private sector.

The rise of the *generics* is reviewed. The strong reaction of brand name producers, which has in the mean time abated, passes the review. That approval of generics can involve problems is shown in the description of the Dingell Hearings (1989) where irregularities within the FDA in accepting bribes from major producers of generics in the US were exposed. This led to proposals for new and strict legislation to prevent and punish such practices. In the Philippines a law was passed in 1988 that all drugs imported, manufactured, distributed, prescribed, or

marketed there should use the generic name. Despite heavy pressure from multinational companies and pressure through U.S. diplomatic channels the law was enacted. However, a number of problems remain to be solved. There is a long delay in the approval of generics; moreover there are indications that prices for generics are higher than before.

In a number of *case studies* the authors make clear how changes have been wrought and some of the problems involved. A good example of the latter is the case of *dipyrrone*. When it became clear that this drug might be associated with agranulocytosis the producer, Hoechst, came under pressure to withdraw it from the market. It was then decided to carry out a multinational epidemiological study of the occurrence of agranulocytosis among dipyrrone users, led by well recognized experts. The study was carefully designed. However, the results were unclear. In some countries the risk of agranulocytosis was related to dipyrrone use, in other countries no such association could be detected. The enormous differences in the results led to doubts about hidden bias or other methodological problems. The authors describe how Hoechst used the results in one way, while drug authorities took another view and scientists all over the world expressed doubts about the results. The confusion remains; dipyrrone is still on the market in many industrialized and Third World countries. Another case, the use of *high dosage estrogen-progesterone products* for pregnancy tests, induction of abortion or other menstruation-related problems, illustrates that consumerists can be successful. The campaign against this type of product in India is extensively discussed, with special attention to the different tactics used. Noticeable here, as in other cases described, is how professionals in the countries involved support the industry in advancing claims that are not accepted in the medical world in industrialized countries.

The same happened in Bangladesh when that country courageously implemented an *Essential Drug Programme* despite powerful opposition by the pharmaceutical industry liaised to physicians (who defended their absolute autonomy to prescribe) and pharmacists (who feared to lose their business). It is difficult to make firm conclusions about the effect of the Bangladesh project because of lack of reliable data, and disagreement remains. It is pointed out, however, that, despite threats to the contrary, major multinational companies still operate in the country, physicians are still practicing and pharmacists are still in business.

In the book attention is paid to the problem that appears to be increasing, the production and marketing of *spurious, fraudulent or counterfeit products*. In these instances an imitation of the real product is made with absolute uncertainty about the content of active ingredients. The multinational companies are generally not involved in this; more often domestic producers are involved. Cases are described in Indonesia (where as much as 30% of the drugs in circulation are estimated to be fraudulent products), India and Brazil, but the authors emphasize that these are just a number of examples and that similar cases occur elsewhere.

Silverman e.a. not only look at the faults of the industry, but also pay extensive attention to *positive developments*. They note an increase in investments in drugs for tropical diseases and better cooperation between industry and governments. The development of ivermectin against river blindness by Merck Sharp and Dohme

– which later made it available free of charge to public health programmes – is described as an illustration of the first aspect. Development of a better chain of drug supply and education programmes in Africa are examples of the latter. Special attention is paid to Servipharm, a subsidiary of Ciba-Geigy that produces generics at low prices for Third World countries with quality guaranteed and supports the development of other aspects (such as a drug quality control laboratory) of the drug chain. Despite criticism that such endeavours inhibit the development of local firms, Servipharm has proved its value in many countries.

The book exemplifies the recent history of the *efforts of consumer organisations* all over the world to better the drug situation, especially in Third World countries. Probably the most effective bodies are IOCU (The International Organisation of Consumers Unions) and Health Action International. The latter is especially active in trying to enforce an international code for drug marketing. A special case is that of clioquinol, a drug that causes SMON, resulting among other things in paralysis and irreversible blindness. Clioquinol, a product of Ciba-Geigy, had numerous victims. The fight to get it off the market took many years. Damage suits started in Japan in 1971 yet it took until 1982 before it was taken off the market worldwide. The fight between consumers and Ciba-Geigy was bitter and although many negotiations took place no acceptable solution on how to deal with the situation could be found. Important, however, was that drug industry representatives and consumer leaders did find ways to communicate whereby a basis was laid for communication in the future.

The essential role of government in protecting consumers' rights is made again abundantly clear by looking at the role of the FDA in the registration process. More recent is the involvement of the government in regulations concerning the export of drugs, resulting at best in a ban on the export of unapproved drugs to Third World countries. In the US such exports have been curtailed, but notably in Europe consumers have not been able to do so, despite efforts in the mid eighties.

In their last chapter the authors emphasize that the accomplishments made so far, small though some of them may be, are the result of the efforts of many. They express their concern that the professionals involved in Third World countries, physicians as well as pharmacists, have shown so little interest in the matter of promoting rational drug use - with some notable exceptions. Moreover, serious difficulties in all facets of the drug sales process still exist, including exaggerated claims, irrational drugs, irrational dosing forms as do serious problems associated with dispensing of drugs, such as the dispensing of prescription-only drugs without a physician's agreement. They plead for the development of quality assurance programmes for developing countries and implementation on a much wider scale of essential drug programmes. They call for strategies of negotiation instead of confrontation between industries and consumerists.

The book contains a wealth of knowledge. Learning from cases in the past may help us to deal better with the problems of tomorrow. The book is of value to all concerned with rational drug use and with the spending of public funds to secure the greatest benefit for the public. Countries new to market economies, such as the Eastern European states, though of course facing different problems, may learn

from this book about the pitfalls. The lesson that collaboration may function better than confrontation seems to be learned already. A Foundation has been set up in which governments of the countries of the former Soviet Union and the multinational pharmaceutical industry work together with independent experts in trying to solve the problems of that part of the world. Its development deserves to be followed carefully; it could augur well for the future.

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