Brit. J. Psychiat. (1974), 124, 498–502

Book Reviews

ESSAY REVIEW

Thalidomide and the Power of the Drug Companies. By HENNING SJÖSTRÖM and ROBERT NILSSON. Harmondsworth: Penguin. 1971. Pp. 281. Price 40p.

In an affair as emotive as the thalidomide disaster, it is important to identify the viewpoint of the authors of any book on the topic. Nilsson is a Swedish scientist who participated as main scientific adviser and technical co-ordinator of the thalidomide trials in Scandinavia on behalf of the plaintiffs (the parents of thalidomide children). Sjöström is a lawyer who has dealt with many thalidomide cases, again for the plaintiffs. Nevertheless, the authors state that their assertions are backed by documentary evidence from the transcriptions of the court proceedings and from documents seized by the German police from the firm that introduced thalidomide, Chemie Grünenthal.

The outlines of the story are fairly well-known. In 1957, thalidomide was introduced as a sedative on the West German market. By 1958 the publicity campaign to promote it was massive, and eventually thalidomide was sold by licensees in eleven European, seven African, seventeen Asiatic and eleven American countries. The first serious adverse effect to be documented was a case of polyneuritis which occurred during one of the clinical trials in 1956. By late 1959, several cases had been described, and by 1960 'a wave of polyneuritis reports reached the company from every corner of the Federal Republic'. Nevertheless, the company continued to promote the drug as 'non-toxic' and 'harmless', and even in November 1960 when it acknowledged that such reactions could occur it claimed that they were 'allergic' and would disappear on 'immediate withdrawal of the drug'. The company tried to delay publication of case reports and 'resorted to denigration of the scientific competence' of the doctors who drew attention to the polyneuritis. The controversy grumbled on.

Meanwhile, the far more devastating effect of the birth of deformed children to mothers who had taken thalidomide during early pregnancy was coming to light. By 1961 many cases of phocomelia had been reported, and in November of that year Dr. Lenz of Hamburg traced an association to thalidomide. Again the company resorted to 'delaying tactics'. On 26 November 1961 the newspaper *Welt am Sonntag* published the whole affair and Chemie Grünenthal immediately decided to withdraw the drug from the market, being afraid 'of the strength of public opinion which might be created' by the article. In most other countries where it was marketed thalidomide was also withdrawn but only after a delay of 3 months in Canada and 10 months in Italy and Japan. In some countries, for instance Canada, the authorities had to insist on the drug's withdrawal.

The U.S.A. escaped the disaster (except for some babies born of mothers who obtained special supplies) because the Food and Drug Administration refused to license thalidomide. The impression has been created that this was due to their inertia, but this book makes it clear that their official, Dr. Kelsey, was genuinely dissatisfied with the evidence that it was safe. The reports of polyneuritis reinforced her reservations and she was concerned about the possible teratogenic properties of the drug. That thalidomide was excluded from the U.S.A. shows that licensing authorities can act intelligently and with forethought.

Much of the book is taken up with an account of the legal tussles in the German Federal Republic which makes the recent legal proceedings in the U.K. involving the Distillers Company seem a very gentlemanly affair. The entire legal system in Germany emerges with very little credit. Compared with the recent settlement in England, Chemie Grünen-

thal seem to have escaped lightly with respect to paying compensation. The inertia and lack of interest by governments in various countries is still a major scandal.

What should concern us as doctors is to ensure that the likelihood of such a disaster happening again is as low as possible commensurate with the development and introduction of effective new drugs. The acceptability of a drug depends on the evaluation of its effectiveness, the seriousness of the condition for which it is indicated, and the severity of its unwanted effects. The first two aspects can be assessed before a drug is introduced, and many of the more common unwanted effects will be detected at this stage of early clinical evaluation. However, the incidence of some serious effects is very low and may not be appreciated until the drug has been fairly widely used. Hence the need for notification systems for adverse reactions on a national or international scale. The main requirement is to limit the numbers of new drugs introduced, because it is impossible to guarantee that another disaster on the thalidomide scale might not happen again.

One solution which has been advocated is the nationalization of the pharmaceutical industry. Underlying this proposal is the concept that it is somehow immoral to profit from an illness. This argument applies equally to housing and food, but in political terms nationalization is indeed a solution to the problem. It is not a good solution in medical terms because drug production and drug licensing would both be State responsibilities and a conflict of interest could easily arise.

The most obvious criticism of the drug industry is its insistence on introducing a dreary and apparently inexhaustible line of chemical congeners—the 'me-too drugs'. These involve minor molecular manipulations in order to get round the patents of other manufacturers or in order to replace the manufacturer's existing lucrative product whose lease of patent protection is almost ended. With the length of time it takes to develop a drug to the point of marketing, there may be only 5 or 6 years left before the expiration of the patents. Also, drug companies feel it necessary to make high profits on a drug not so much to recoup its research and development costs as to provide funds for the development of the next one. The pharmaceutical industry is highly competitive and a company high in the sales league one decade can have faded away by the next one.

An alternative to State control of drug development which would stem the flow of 'me-too' new drugs would be for the drug licensing authority to insist that a drug be shown to be appreciably *superior* to existing drugs before licensing is allowed. This procedure should be coordinated on an international scale so that the drug company would be involved in the minimum number of submissions. Data on drugs are difficult to assess, but it is not that much more onerous for a licensing authority to decide whether a new drug is superior to older ones than, as is current practice, to pronounce on its relative safety. The result of such regulations would be a great diminution in the number of new drugs licensed, and all would be genuine innovations. Because of these drugs' superiority, doctors would prescribe them widely and any unsuspected untoward effects would be quickly apparent. The drug company would be rewarded by a protected market until a further substantially improved product was developed: patents would be irrelevant. Thus, the industry could concentrate on more fundamental research instead of superficial minimal improvements in composition and formulation of their existing products.

To return to the book, it is written in a clear style and it grips the reader. It should be read by all doctors who prescribe medicines to warn them that they cannot absolve themselves of all responsibility for the disaster by regarding it as unavoidable or by attributing it to the mistake of a drug company or to the laxity of governmental agencies. Even now there are drugs available on prescription which are obsolete, ineffective or habit-forming. Only by the voluntary limitation of prescribing, as has occurred with the amphetamines and in some areas with the barbiturates, can the physician demonstrate his resistance to the pressures of drug companies and their advertising agencies.

MALCOLM LADER.