

Editorial

Drug approval and company liability

The notion that countries need to maintain some form of approval system for new and old drugs is almost universally accepted. In almost all industrialized countries, such systems of scrutiny exist, operating on behalf of the community as a whole but also on behalf of the health professions who cannot possibly be expected to verify all the claims which companies may make on behalf of their drug products. The knowledge that a competent agency has found a drug to be reasonably safe, efficacious, of adequate quality and credibly promoted is an important element in prescribing choice.

Inevitably, however, questions arise as to whether the community itself, in endowing a drug product with such approval, assumes thereby a degree of liability for any adverse consequences which may ensue. Rightly or wrongly, drug companies are not uncommonly brought to court by plaintiffs who claim to have been injured by their products; and it is not unknown for the defendant in such a case to point to the product licence as constituting evidence that his drug is above legal reproach. How reasonable is such a defence? And if a company is to escape liability, shall this devolve upon the drug regulatory agency?

The company defence was classically accepted by a court in Oregon more than thirty years ago in a case involving triparanol:

“... a drug, properly tested, labelled with appropriate warnings and approved by the Food and Drug Administration, and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product. Accordingly, a person claiming to have suffered adverse effects from using such a drug, unless he can prove an impurity or an inadequacy in labeling, may not recover against the seller for breach of warranty...” [1].

Although some similar decisions by American courts did follow,¹ judges more commonly felt that courts were free to reopen issues of efficacy and safety as matters of fact [4], though the consideration that a drug had been officially approved and marketed entirely in accordance with that approval could be a relevant consideration in assessing liability [5].

Learned authorities and courts in Europe have taken the view that a company's compliance with statute law and regulations does not exclude liability in civil law, since written law is only one source of a manufacturer's duties [6]. In the Netherlands, the ultimate judicial decision in the triazolam litigation in 1990 included an explicit statement by the Supreme Court that registration of a drug by the authorities did not abolish the liability of the manufacturer [7]. French Courts had held much earlier that, whatever liability might devolve on the administration, this would not replace that of the firm marketing the product.² In

¹In a case involving an approved device, a New Jersey District Court ruled that the company was entitled to a judgement in its favour as a matter of law, since the claimant was criticising FDA-required labelling and not claiming that the firm had failed to comply with the regulations. See [3].

²[8]: “... Since... the licence which is issued reflects only a scrutiny undertaken in the public interest and is not intended to provide a State warranty as to the efficacy or safety of the product, this licence will not render the manufacturer immune to any process of law which the users may bring against him... there is no reason to consider that the legislator has intended as a consequence of this scrutiny to put the liability of the State in the place of that carried by the manufacturer...”

England, case law in other fields in which regulation exists points to the conclusion that the issue of a licence "...will not render the manufacturer immune to any process of law which the users may bring against him..." [9].

If the company's liability is not lessened, what degree of liability does the agency assume? There seems to be a high degree of legal, political and administrative unanimity across the world that a drug approval agency which has performed its task conscientiously cannot be held responsible for a product's ill-effects. There are several good reasons why this should be so. An agency carries out its scrutiny at a relatively early point in a drug's career, before it has been used on the massive scale which may follow marketing and at a time when experience in detecting adverse effects is therefore still very limited. What is more, an agency is heavily dependent for its assessment on material provided to it by the manufacturing company concerned, generally on the basis of work performed within industry or with industrial sponsorship; there are well-documented instances of companies failing to make available all the data in their possession [10–12]. Finally, it can well be argued that only a small proportion of new drugs truly represent progress in medicine; they are introduced solely because they are no worse than those already available, and because the manufacturer wishes to make money from them; it would be patently absurd if society were to assume liability for any unforeseen ill-consequences.

In day-to-day judicial practice, the official approval of a drug has a rule only one consequence for litigation coming before the courts: it provides as a rule a reasonable standard against which the acts and omissions of a pharmaceutical company can be judged. A firm which has marketed its product strictly in accordance with the conditions laid down in the licence – especially those relating to product quality and the adequacy of information – will be looked upon a great deal more leniently by a court than one which has failed to do so. The standards of medical product regulation are not perfect, but they are at their best as good as society can currently make them; the community has the right to expect that a pharmaceutical company will strive to do at least as well.

References

- [1] *Lewis v. Baker*, 413 P.2d 400, 404, Or. 1966.
- [2] *McDaniel v. McNeil Laboratories Inc.*, 241, N.W.2d 822, 828, Neb. 1976.
- [3] Anon. Cu-7 victory for Searle, *Scrip* **1377**(2) (1989).
- [4] *Brochu v. Ortho Pharmaceuticals*, 642 F.2d 652 (5th Cir. 1981); *Kearl v. Lederle Laboratories*, 218 Cal. Rptr, 453, 461 (Cal. App. 1984).
- [5] *Brown v. Superior Court*, 245 Cal. Rptr. 412 (1988).
- [6] G.M.F. Snijders, Drug registration and liability, *Ned. Jur. Blad* **19** (13 May 1989), 649–652 (*in Dutch*).
- [7] *Ned. Jur. Bl.* **6** (9 February 1990), 225–229 (*in Dutch*).
- [8] Paris Court of Appeal, 12 March 1958: D.1958-2-397.
- [9] *Bux v. Slough Metals Ltd.* [1974] 1, All E.R. 262.
- [10] P.D. Rheingold, The MER/29 Story – an instance of successful mass disaster litigation, *Calif. Law Review* **56** (1968), 116 ff.
- [11] J. Braithwaite, *Corporate Crime in the Pharmaceutical Industry*, Routledge and Kegan Paul, London, 1984, pp. 184, 346.
- [12] *Scrip*, Judge deters drug "strict liability", *Scrip* **803** (1983), 12.