

The MER/29 Story—An Instance of Successful Mass Disaster Litigation

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THE MER/29 STORY is more than an unusual account of the marketing of a prescription drug which injured thousands of users. It is a case history of the legal response to the problems of mass litigation. In particular, it shows how plaintiffs' attorneys banded together voluntarily and without court control to dispose of approximately fifteen hundred civil suits filed by injured drug users who sought aggregate punitive damages by which the defendant manufacturer claimed it would be destroyed. Finally, the story describes how the Food and Drug Administration handled the drug, how the United States Congress investigated it, and how the federal government successfully prosecuted the manufacturer for submitting false data.

Part I of this Article presents the scientific and economic background of the marketing of MER/29. Part II deals with the organization of the litigation and the role of the plaintiffs' group. The disposition of the litigation is covered in Part III, and the last Part considers the implications of the litigation to the legal profession, to other interested groups, and to the public.

I

THE MER/29 STORY

A. The Medical Background

In the mid-1950's many physicians believed that high levels of cholesterol, a fatlike substance in the blood and tissue, significantly contributed to atherosclerosis, or hardening of the arteries. Since atherosclerosis in turn led to heart attacks, these physicians believed that lower cholesterol levels would mean fewer deaths from heart attacks.¹ Because low-cholesterol diets were generally recognized as inefficient in reducing cholesterol, many pharmaceutical houses and scientists were searching during the 1950's for a drug either to prevent the formation of cholesterol in the

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¹C. MOSES, *ATHEROSCLEROSIS: MECHANISMS AS A GUIDE TO PREVENTION* (1963); Owen, *Efficacy of Drugs in Lowering Blood Cholesterol*, in 48 *MEDICAL CLINICS OF NORTH AMERICA*, 347 (1964); Editorial, *Hypercholesterolemia and Cholesterol-Lowering Drugs*, 266 *N. ENG. J. MED.* 1009 (1962).

body or to destroy it after formation. It was imperative that such an anti-cholesterol drug, like any new drug intended for so fundamental a use, meet the dual requirements of safety and efficacy.²

One company actively seeking a compound to lower cholesterol effectively and safely was the Wm. S. Merrell Co. of Cincinnati, a small, old-line drug company that was part of one of the major, diversified pharmaceutical manufacturers in this country, Richardson-Merrell, Inc. of New York.³ In 1956, Merrell laboratory scientists developed and patented a series of compounds which did appear to reduce cholesterol levels in lower animals. One of these compounds was later to be marketed under the trade name of MER/29.⁴

B. Testing and Marketing the Drug

In order to understand the criminal and civil litigation which followed Merrell's marketing of MER/29, it is important to know how drugs were tested, approved and marketed in the United States between 1956 and 1962, the time period involved.⁵ Using animal and human data, Merrell had to convince the Food and Drug Administration (FDA) that the new drug MER/29 was at least safe, if not necessarily effective.⁶ The safety data, submitted as a new drug application, had to show the drug to be relatively nontoxic in animals and without serious side effects in humans. The Food and Drug Act required the manufacturer to provide the FDA with "full reports of investigations which have been made to show whether or not such drug is safe for use."⁷ On this basis, the FDA would approve the drug for sale in interstate commerce, by prescription only and under approved labeling conditions.

² See R. GOODMAN & P. RHEINGOLD, *LAWYERS DRUG HANDBOOK* (1967); Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 *RUTGERS L. REV.* 947, 960 (1964).

³ Richardson-Merrell, Inc. was the name assumed in 1960 by the old Vick Chemical Company, at a time when the Wm. S. Merrell Co., formerly a corporate subsidiary, was made an operating division.

⁴ The compound had the laboratory code number of WSM 5052 and the generic name of triparanol. A review by Merrell of its program and its discovery of MER/29 is contained in Palopoli, *Basic Research Leading to MER/29*, 2 *PROGRESS IN CARDIOVASCULAR DISEASE* 489 (1959). This issue of the journal is a special publication on a major conference, known generally as the "Princeton Conference," held by Merrell on MER/29 in December 1959.

⁵ See Rheingold, *supra* note 2, at 959-61. In 1963 the procedure was substantially revised. Kefauver-Harris Drug Amendments Act of 1962, 76 Stat. 780, 21 U.S.C. §§ 301-92 (1964). Good lay commentary on the role of the FDA in the approval of new drugs is in M. MINTZ, *THE THERAPEUTIC NIGHTMARE* 230-47 (1965), printed in revised form as *BY PRESCRIPTION ONLY* (1967).

⁶ The current efficacy requirement was added by the Kefauver-Harris amendments. 21 U.S.C. § 355(b) (1964).

⁷ Federal Food, Drug, and Cosmetic Act § 505, 52 Stat. 1052 (1937), *as amended*, 21 U.S.C. § 355(b) (1964).

From 1956 to 1959 Merrell scientists conducted MER/29 tests on animals and humans, with an eye both to FDA requirements and to later promotion of the drug to prescribing physicians. The biochemistry department studied how and to what degree MER/29 lowered cholesterol; the toxicology department administered it in varying dosages to rats, dogs and monkeys to test any toxic effects on tissues and organs; and, thereafter, physicians in the medical department of Merrell approached doctors, known as clinical investigators, to have them test the drug on their patients.⁸ The Merrell scientists conducting these tests were responsible to the management of Merrell, including a vice president-scientific director, a plant manager, and a president. The Merrell president in turn reported to the management of the parent company in New York.

Although the precise facts concerning the conduct of this animal and human testing in the Merrell laboratories will never be known, it is clear that something very wrong did occur.⁹ As a result of Merrell's conduct, a grand jury indicted the company and its chief scientists, and a federal judge convicted them.¹⁰ Well over a thousand injured persons brought private suits alleging that the conduct far exceeded mere negligence and amounted in fact to fraud.¹¹ The then Senator Humphrey, investigating

⁸ On clinical investigation in the development of new drugs, see Rheingold, *supra* note 2, at 954-55. The clinical investigator is a private physician, independent of the drug company. He is often supported in his work, however, with grants and free supplies of the drug from the manufacturer.

⁹ Perhaps the ideal account of the MER/29 litigation should be written by someone with equal access to the knowledge and tactics of both sides. That must remain an ideal, however, since the full story from the defendant's point of view will certainly never be told, due to the corporate policy and criminal aspects of the litigation. Thus, the exact amount of claims and monies paid out are known only to the defendant, who has never seen fit to disclose this data. Nor could the impartial reader (any more than a juror) today be able to determine exactly what happened at Merrell in the 1956-1962 period. While the transcripts of the cases tried or the briefs of the parties upon appeal present the opposing constructions of the events as presented in litigation, they do not produce a clear understanding of what actually transpired. Facts presented in this Article relating to internal events at Merrell over the years are drawn from the records on appeal in two of the cases, *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967), and *Ostopowitz v. Wm. S. Merrell Co.*, No. 5879-1963, N.Y.L.J., Jan. 11, 1967, at 21, col. 3 (Sup. Ct., Westchester County, N.Y.), *appeal docketed sub. nom. Ostopowitz v. Richardson-Merrell, Inc.* (App. Div., 2d Dept., Apr. 26, 1967).

¹⁰ *United States v. Richardson-Merrell, Inc.*, Crim. No. 1211-63 (D.D.C., June 4, 1964). See text accompanying notes 16 *infra*.

¹¹ In *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 850 (2d Cir. 1967), the Second Circuit stated that the record showed

countless instances of carelessness and even of wilfulness by subordinate officials and of failure to exercise proper supervision and possible bad judgment by higher ones. Granted that few human endeavors would escape without blemish from such searching scrutiny, the picture is not a pretty one.

MER/29, intimated that both Merrell and the FDA had been unusually lax.¹²

Detailed review of the evidence against Merrell produced in the criminal and civil cases is unnecessary in an article on the use of mass litigation, but the author believes that a few examples of the proof relating to misconduct in the administration of the drug to animals and humans, concededly given from the plaintiff's viewpoint, will help explain the vigor with which the cases were both prosecuted and defended.¹³

Evidence concerning animal tests included flagrant examples of misconduct. A chart submitted to the FDA was redrawn to show a monkey as having gained weight, when actually he had lost twenty-five percent of his body weight. When two dogs developed cataracts (the subsequent human injury), the fact was recorded on their autopsy sheets but omitted in the report to the FDA; similar cataract development in rats was also excluded from FDA reports. While MER/29 was on the market, another drug company reported to Merrell that cataracts had developed in animal tests involving synthesized MER/29, but Merrell did not relay the data to the FDA.

The attitude of the Merrell management toward human testing and the marketing of the drug was similar. For example, when doctors inquired whether the drug might be causing a certain side effect in their patients (such as cataracts or hair loss), the company untruthfully claimed no knowledge or prior reports about such effects in animals or humans. Company salesmen were directed to respond to similar inquiries from doctors by suggesting that some other drug was causing the harm. Other evidence of misconduct included interoffice memoranda indicating a desire not to report fully to the FDA and admitting that data had been withheld. Finally, except for the warning letter required by the FDA, the company promoted the drug, until its withdrawal, as "entirely safe" and free of side effects.

Merrell's June 1959 application for permission to market MER/29

See further discussion of the case in text accompanying notes 56-57 *infra*. A California court of appeal stated:

From all of the evidence the jury could find that appellant acted recklessly and in wanton disregard of possible harm to others in marketing, promoting, selling and maintaining MER/29 on the market in view of its knowledge of the toxic effect of the drug.

Toole v. Richardson-Merrell Inc., 251 A.C.A. 785, 810-11, 60 Cal. Rptr. 398, 416 (1967).

¹² See *Hearings Before the Subcomm. on Reorganization and International Organizations*, 88th Cong., 1st Sess., pt. 3, at 1256-57 (1963) [hereinafter cited as *Humphrey Hearings*] (remarks of Senator Humphrey). See also S. REP. NO. 1153, 89th Cong., 2d Sess. 132 (1966).

¹³ The examples are taken primarily from the records cited in note 9 *supra*.

was approved in April 1960, and within two months the company was promoting MER/29 as the "first safe" drug to lower cholesterol. Rapidly accepted, the drug had been used by roughly 400,000 persons by December 1961. In mid-1961 Merrell amended its labeling to warn of hair loss, and in December 1961 it mailed a so-called "Dear Doctor" warning letter, approved by the FDA, to all practicing physicians. This letter for the first time warned that cataracts, baldness, severe forms of dermatitis, and less common side effects might result from use of the drug.¹⁴

In April 1962 the company voluntarily withdrew MER/29 from the market as reports of side effects increased and sales diminished. One week before withdrawal of the drug, the FDA inspected Merrell's records and discovered for the first time that it had received erroneous animal data from Merrell. In May 1962 the FDA suspended the new drug application for MER/29 on the basis of clinical experience demonstrating that the drug was not safe for human use.¹⁵ This terminated the company's right to remarket the drug, and it has not been sold since.

C. *The Legal Aftermath*

Subsequently, the Department of Justice investigated Merrell's conduct. In 1963 a Washington, D.C., grand jury was presented with evidence of Merrell's submission of false testing data to the FDA in violation of federal statutes. The grand jury subpoenaed Merrell laboratory records, some 107,000 in number, took testimony from former employees and others, and had as a consultant an FDA doctor who had been assigned to follow MER/29 when it was on the market. These same sources were also to be the starting point for the plaintiffs in the civil litigation.

On December 20, 1963, the grand jury returned a particularly detailed indictment for submitting false animal data to the FDA and for withholding data that the law required the company to furnish.¹⁶ Indicted were

¹⁴ Warning letter from Carl A. Bunde, Director of Medical Research of Wm. S. Merrell Co., Dec. 1, 1961, copy on file with *California Law Review*.

¹⁵ MER/29 New Drug Application Suspension Order, Food and Drug Administration, May 22, 1962, copy on file with *California Law Review*. In conjunction therewith, on May 7, 1962 the Medical Director of the FDA, Dr. W. H. Kessenich, issued a confidential memorandum to FDA doctors stating in part:

As you may know, we have recently obtained evidence that the Wm. S. Merrell Co. falsified data submitted as part of the New Drug Application for MER/29. In view of this we cannot consider the information submitted by this firm as reliable without thorough verification.

Humphrey Hearings, *supra* note 12, at 908.

¹⁶ *United States v. Richardson-Merrell, Inc.*, Crim. No. 1211-63 (D.D.C., June 4, 1964). The indictment was based on violation of the federal false writing statute, 18 U.S.C. § 1001 (1964), and not upon violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.

Richardson-Merrell, Wm. S. Merrell, and three of its scientists who had been intimately connected with the animal experiments. All defendants entered a plea of *nolo contendere*, no doubt with an eye to the coming civil litigation. The corporate defendants were fined a total of 80,000 dollars, the maximum under the law, and the scientists received suspended sentences.

Although the number of persons injured by MER/29 will never be known, the author's conservative estimate exceeds 5,000. The number was probably much higher, because many persons never attributed their injuries to the drug. The worth of the drug which produced these injuries must be measured by balancing its side effects against its efficacy in preventing atherosclerosis. MER/29 had intolerable side effects, the most serious being cataracts, which developed in users aged eight to eighty. In addition, even at the time of its withdrawal from the market, there remained doubt as to MER/29's basic efficacy. At least some doctors felt that lowering cholesterol in general would have no effect on heart attacks, and that in addition MER/29 could not be effective because it replaced cholesterol with another fatty substance equally conducive to atherosclerosis.¹⁷ The drug which occasioned the mass litigation described here was thus of doubtful worth.

II

THE CIVIL CASES AND THE MER/29 GROUP

Individual cases based on MER/29 injuries were first filed in 1961; the number filed increased annually in 1962, 1963 and 1964, and are still being filed as of this writing in 1967. Computation of the number of cases filed depends upon how one counts derivative suits, suits by multiple plaintiffs in a death action, or a consolidated action for a number of injured drug users. In any case, over 1,500 suits were eventually filed. In addition, hundreds of claims were disposed of one way or another short of suit. MER/29 cases were begun in almost every state and in many different courts, both state and federal, within most states.¹⁸

§§ 301-92, as amended, (Supp. IV, 1963). See Rosner, *Criminal Liability for Deceiving the Food & Drug Administration*, 20 FOOD DRUG COSM. L.J. 446 (1965) (discussing the MER/29 situation).

¹⁷ See 2 MEDICAL LETTER 81 (1960); Herndon & Siperstein, *Desmosterol Deposition in Human and Experimental Atherosclerosis*, 12 CIRCULATION RESEARCH 228 (1963). The FDA itself had adopted the policy that role of cholesterol in heart disease had not been established. 24 Fed. Reg. 9990 (1959).

¹⁸ There was no strong correlation between a state's population rank and the number of cases filed therein. Some of the factors which may have led to the commencement of less than a statistically expectable number of suits in one state and more in another are

A. Formation of the Plaintiffs' Group

Given the number of cases filed, some sort of group effort among plaintiffs' attorneys was inevitable.¹⁹ Not only would knowledge about one case aid other lawyers, but also joint preparation of cases would result in economy of effort and expense. Such economy was particularly desirable in the MER/29 cases, which involved relatively small injuries, because a case potentially worth about 50,000 dollars, for example, did not justify trial expenses of 10,000 dollars.

In April 1963, one year after withdrawal of MER/29 from the market, 33 lawyers with MER/29 cases met in Chicago at the instigation of several well-known personal injury lawyers who had been in contact with the products liability exchange maintained by the American Trial Lawyers Association (then known as NACCA) in Boston.²⁰ The MER/29 Group, as it came to be known, originally agreed to undertake three primary functions: to disseminate information about litigation in progress, possibly by newsletter, through a central clearinghouse; to investigate the feasibility of joint preparation of cases; and to hire medical consultants. It was determined at the first meeting that each member should be assessed \$100 to defray costs. A "trustee" to hold the money and act as a clearinghouse was chosen.

Both the structure and function of the MER/29 Group changed rapidly after the 1963 Chicago meeting. While a chronological description of this change would make interesting reading, the Group's activities can be more concisely presented from a topical standpoint, as is done in this Part and in Part III below.

the varying popularity of the drug with doctors, the awareness of the bar as to what constitutes a good cause of action, and the flow of law business to the large cities and large law firms.

¹⁹ The group activity that is discussed here is among lawyers and not injured persons or the public. Unfortunately, there was not at the time nor is there now any organization to provide information to persons injured by MER/29 and needing to evaluate the idea of making a claim against the manufacturer. While a few organizations that write up health and medical news for the laity carried information about MER/29 side effects, such as Health Bulletin, of Emmaus, Pa., a person suspecting that he had an injury or a claim would have learned nothing by writing to the American Medical Association, the FDA, or other governmental agencies, including supposedly consumer-oriented commissions like the National Safety Council, the Better Business Bureaus, or the American Bar Association.

²⁰ It should be emphasized that the MER/29 Group was neither part of nor operated by the American Trial Lawyers Association. As described in the text, the latter merely furnished a list of lawyers having cases which was used as an invitation list for the Chicago meeting. Membership in the Group was open to all lawyers, including those who generally did defense work. In fact, approximately half the members of the Group could not be identified as plaintiff's personal injury attorneys.

B. Operation of the MER/29 Group

The MER/29 Group grew to some 288 member lawyers or law firms by 1967.²¹ In addition to the \$100 originally paid in, most members paid an additional assessment of \$200 per firm, which was used to finance the discovery program. Subsequent additional assessments varied with the number of cases being handled by each member, with a maximum assessment of 1,000 dollars for a firm representing 18 or more plaintiffs.²² The Group collected a total of approximately 70,000 dollars, an amount largely spent in 1964-1966. The bulk of the money was used for the discovery program, for the printing and photocopying of newsletters and documents, and for advice from medical consultants. Lawyers who performed services for the Group, including the trustee, were paid for their time on an hourly rate.

The clearinghouse function was performed primarily by issuing group newsletters prepared by the trustee. Some twenty-six issues covered news of developments in trials and settlements, the proof being assembled by the Group, new medical knowledge, and current developments in the industrial and regulatory fields.²³ New members joining the Group at any stage received, in addition to the backlog of newsletters, the "MER/29 Package"—several hundred pages of background documents, pleadings, answered interrogatories, medical reports, and outlines of the depositions taken. As time went by, other packages were assembled for the use of members and were supplied generally at the cost of copying. Such packages included a set of the "key" documents from the Merrell files for use in proving liability, the depositions taken with exhibits, the MER/29 new drug application, a medical analysis of cataracts prepared by an ophthalmologist hired by the Group, transcripts of previous trials, and a "trial

²¹ The membership added members to the original 31 as follows: balance of 1963—119; 1964—77; 1965—34; 1966—19; 1967—7. By 1967 the Group had completed its work and existed only to provide copies of previous papers to new members and to answer questions. The author does not know what percentage of lawyers with MER/29 cases joined the Group, nor what percentage of the total number of cases filed were within the Group. It seems fair to conclude that at least 75% of the lawyers, and a greater percentage of the cases, were involved. With only a few exceptions, the firms with MER/29 cases that were recognizable as specialists in personal injury cases joined in.

²² Four firms had over 20 cases apiece: one firm in Chicago, one in San Francisco and two in New York City. One of the latter had over 100 cases. The majority of the members had only a single case.

²³ The newsletters were marked and intended to be confidential and for the use of the members only. As time went by, however, the defendant did come into possession of the letters, undoubtedly from one of the members. No particular harm was done, however, since nothing truly confidential was included in the letters, and in fact later issues were written somewhat for the defendant's consumption.

package" containing outlines of previous trials, suggestions for the examination of witnesses, and trial and motion briefs previously used.²⁴

The day-to-day operations of the MER/29 Group and the carrying out of its objectives were increasingly the responsibility of the Group's "trustee." More important policy decisions were sometimes formulated at occasional meetings of members during concurrent national bar association meetings, or by a steering committee of seven members chosen at one of these meetings. More often, however, decisions of all sorts were made on an ad hoc basis by vocal members of the Group, by the trustee, or by members of the trustee's firm. This central operation of a plaintiffs' group had advantages over attempts by the members to divide up responsibility and assign specific tasks to various firms or teams. Because of its central direction, the MER/29 Group could work quickly and according to a unified, comprehensive scheme.

Such unified action by the plaintiffs served to counteract the defendant's natural advantages. The defendant in any mass disaster situation is inherently well organized to deal with multiple litigation. It can coordinate its activities and to an extent even control the course of litigation. As in almost all personal injury litigation, however, insurance coverage meant that the MER/29 defendant consisted of two forces, not always working in tandem. Solving the problem fairly well, the insurance carriers hired local defense counsel (until the insurance ran out), and Merrell was represented at a national level both by Richardson-Merrell house counsel and by a Wall Street firm acting as "national counsel" in both criminal and civil litigation. Although the plaintiffs regarded the formation of their group as only a device to give them equal strength with the defendant's organization, it was the defendant's expressed attitude that by the formation of the Group, the plaintiffs somehow gained an unfair advantage.²⁵

Negotiations between the Group and the defendant were carried on at frequent meetings at which the trustee and one or two other members generally represented the Group, and counsel from the national defense firm, sometimes with a representative of house counsel and the insurance carrier present, represented the defendant.

²⁴ As part of the clearinghouse activity, the trustee answered questions requiring responses which ranged from explanations of some part of the Group's work to a hand-holding sort of relationship with attorneys unsure about how to handle a products liability case. The time spent for this was paid for out of the Group's treasury.

²⁵ Speech by Sherwood E. Silliman, Counsel for Richardson-Merrell Inc., before the annual meeting of the Section on Food, Drug & Cosmetic Law of the New York State Bar Association, Jan. 26, 1965; Costello, *Multiple Drug Litigation—The Defendant's Viewpoint*, 22 FOOD DRUG COSM. L.J. 145 (1967).

C. Consolidation of Cases and Concerted Action

Perhaps the most basic decision for the plaintiffs and the defendant in the MER/29 litigation was whether to consolidate the pending cases, either for all or for a limited number of purposes. The concept of "consolidation" could involve legal joinder of multiple cases for all purposes, including trial, or for some purposes, such as joint discovery, or it could involve extrajudicial cooperation between the plaintiff Group and the defendant by agreement on group procedures. For the defendant there were important considerations on both sides. Consolidation or any form of formal group effort would diminish its law work, reduce the time which its scientific personnel spent in giving discovery, and reduce the chances of inconsistent rulings and trial decisions. On the other hand, consolidation or concerted action by the plaintiffs would also facilitate the plaintiffs' discovery, lend strength through union to the plaintiffs' Group, and probably improve many plaintiffs' cases.

For the plaintiffs, the benefits of concerted action outweighed the dangers in almost every attorney's mind. The individual lawyer was afraid only that he might lose control of his case, which would consequently be less well prepared, or that he would suffer professionally or economically through consolidation. In retrospect, these concerns were not well founded. Far from losing financially, a lawyer in the MER/29 Group enjoyed inexpensive (300 dollars at the most) yet careful preparation of the liability issues which cost the Group as a whole tens of thousands of dollars. No plaintiff's lawyer who resisted joining the Group because he feared loss of identity as an able personal injury lawyer in fact gained anything.

Members were unenthusiastic, however, about consolidating cases for trial purposes, or about any form of Group decision that would directly shape the trial. For every member disappointed because the Group did not take over his case there were dozens who felt themselves perfectly capable of handling their own cases. Thus, concern for one's identity as a trial lawyer and for the potential economic consequences of group trial took real form at the trial stage.

An early drive toward legal consolidation came in fact from the defendant, who made an abortive attempt to have the Judicial Conference of the United States²⁶ interest itself in the MER/29 litigation. In 1961 the Judicial Conference had created the Co-ordinating Committee for Multiple Litigation of the United States District Court, which was to consider all problems arising from multiple litigation with common witness and

²⁶ Established by 28 U.S.C. § 331 (1964).

documents problems.²⁷ Pursuant to these powers, the committee took over control of the then pending electrical price fixing cases, involving some 1,900 cases in thirty-five district courts.²⁸ National counsel for Merrell proposed in November 1963 that the committee take control of all pretrial phases of the MER/29 litigation in like fashion. Chief Judge Alfred P. Murrah, chairman of the committee, declined to involve the committee, although in a letter he noted that individual district courts were free to take any action toward unified discovery which they might deem proper.²⁹ Certainly one factor in the committee's decision was that more than half of the cases were pending in state courts, over which the committee had no jurisdiction.

Pretrial consolidation having been refused by the federal courts, the defendant adopted an approach tolerating group action in the MER/29 cases but opposing actual joinder of cases for trial purposes. For example, the defendant cooperated with the plaintiffs in pretrial discovery and frequently proposed assignment of all cases pending in one court to one judge, as discussed below. On the other hand, the defendant objected when one plaintiff's attorney sought to consolidate a large number of cases for all purposes, including trial. In the latter case, counsel for Merrell were concerned about the prejudicial effect of bringing to one jury's attention in a consolidated trial the fact of a large number of injuries (a fact which was bound to come out anyway during a trial). The court ruled against consolidation, stating:

The conglomerate mass effect might easily excite the jury to the detriment of the defendant, let alone lessen a true appreciation and assimilation of each claim to be decided separately.³⁰

On motion or sua sponte, a number of federal district courts did impose some control upon the MER/29 cases in their jurisdiction. For example, the United States District Court for the Southern District of New York, where some seventy-five cases were pending, assigned one judge to

²⁷ See 1961 JUD. CONFERENCE OF U.S. REP. 61; 1962 *id.* at 27; 1963 *id.* at 49. The power of the federal courts over multiple litigation would be strengthened by the enactment of S. 159, which would add § 1407 to 28 U.S.C., creating a Judicial Panel on Multidistrict Litigation. This panel would allow for the consolidation of pretrial discovery where common questions of fact are involved. 8 *U.S. Cong. & Adm. News* at xiii (Sept. 20, 1967).

²⁸ Neal & Goldberg, *The Electrical Equipment Antitrust Cases: Novel Judicial Administration*, 50 A.B.A.J. 621 (1964); Rheingold, *Mass Litigation Affecting Many Persons*, TRIAL, Dec. 1965, at 29.

²⁹ Letter from Chief Judge Alfred P. Murrah to Andrew J. Graham (Nov. 27, 1963), on file with the author.

³⁰ Goldblatt v. Wm. S. Merrell Co., CCH PRODS. LIAB. REP. ¶ 5173, 51 N.Y.L.J. No. 5, at 13, Jan. 8, 1964 (Sup. Ct. N.Y.), *modified*, 22 App. Div. 2d 886, 254 N.Y.S.2d 940 (Sup. Ct. 1964).

handle all of the cases for all purposes, pursuant to a local rule, without specifically directing how the cases should be tried.³¹ The assigned judge did not use his powers to consolidate cases for trial and exercised any power sparingly; he merely made himself available for consultation with the parties and agreed at the plaintiff's request to bring on for trial a pilot case in advance of its normal position on the calendar.

Across the street from the federal court, the New York trial court for Manhattan and the Bronx found itself with over 300 MER/29 cases pending. Upon the defendant's motion, the New York Appellate Division ordered the cases assigned for all purposes to one trial court judge with plenary powers to handle the litigation.³² Although his appointment assured uniformity of pretrial rulings, once again there was little or no affirmative direction of the litigation by the court. It seems fair to state that the courts exercised only minimal control over the MER/29 litigation, despite its size, because of the successful, comprehensive scheme worked out voluntarily between the plaintiffs and the defendant.³³

D. Group-Conducted Discovery

The MER/29 Group's primary achievement was management of mass pretrial discovery. By agreement with the defendant, all discovery carried out by the Group's representatives was made applicable to all cases in the MER/29 Group, even those entering the Group after completion of discovery. The defendant benefited greatly from this arrangement, as indicated above, but had the Group's size and power been less, the defendant might reasonably and profitably have decided to force the plaintiffs to seek court-by-court piecemeal orders to sanction cooperative discovery.

The physical arrangements for group discovery were worked out by a number of letters of agreement and stipulations.³⁴ Any member of the Group wishing to participate would sign the agreement and return copies

³¹ On March 14, 1964, the District Court by Chief Judge Sylvester Ryan assigned all pending MER/29 cases (then 25) to Judge Thomas Croake pursuant to local rule 2. Thereafter, on motion of the defendant without objection from the plaintiff, cases subsequently filed in the court were transferred to Judge Croake.

³² *Goldblatt v. Wm. S. Merrell Co.*, 22 App. Div. 2d 886, 254 N.Y.S.2d 938, 939 (1964): "The orderly administration of justice requires that a single Justice of the Supreme Court be given jurisdiction over and supervise and preside over all phases of all such actions . . ."

³³ In California, lead defense counsel in Los Angeles wrote Chief Justice Phil S. Gibson on Nov. 11, 1963 asking the state supreme court to establish a plan of uniform pretrial procedure and preparation in the various county courts to avoid disorder which the defendant anticipated with the then some 45 pending cases. The supreme court took no statewide action, but judicial supervision of the type described in the text was given by judges in Los Angeles and San Francisco counties.

³⁴ These stipulations and other papers relating to the MER/29 Group are on file with the author and are available for examination.

to representatives of both parties, thus agreeing to certain terms included in the overall package of agreements between the Group and the defendant. The member agreed not to carry on solo discovery repetitive of Group efforts, to look to the Group and its trustee rather than to the defendant for the production of documents, and to provide the defendant with full medical data on his case regardless of what local court rules required. It is interesting to note that the few attorneys who, fearful of these terms, did not give timely notices for participation later sought re-admission. Because of its novelty, the group discovery is explained below in some detail.

1. *Depositions*

Twelve group depositions were taken in three sets.³⁵ The first set dealt with officers of the defendant: the former president of Merrell, at the time of the deposition a vice-president of the parent, whose deposition ran eleven days,³⁶ another Richardson-Merrell vice-president, and the Merrell vice-president who had been in charge of promotion. In addition, a single deposition was taken of a Merck & Co. scientist who had performed an outside test on MER/29 and had reported its results to Merrell. This was taken pursuant to a three-way stipulation, counsel for Merck also participating.³⁷

³⁵ In the agreements covering these depositions, the parties anticipated the problems which would be created if one side wanted to seek any sort of protective order. It was agreed that all such matters would be heard before the federal judge in the Southern District of New York who had been assigned supervision of all of the cases pending in that District, as described in note 31 *supra* and accompanying text. The depositions were captioned in the case then pending before him and were conducted pursuant to the Federal Rules. While there was no agreement by the parties to be bound nationally by the ruling of the district judge, in practice there was no challenge to his rulings elsewhere.

³⁶ During the course of this deposition, two protective motions were made by the defendant before Judge Crooke, see note 31 *supra*. In one motion, the defendant sought to preclude any questioning of the president about matters relating to the wrongdoing of the company on the ground that the criminal matter was then still pending. The court, with good precedent, upheld the application of the privilege of self-incrimination to civil litigation, but only until disposition of the criminal action. Motion heard Mar. 13, 1964.

In another motion, the plaintiff sought to compel answers about thalidomide, another drug being developed by Merrell at the same time that it was working on MER/29. The Court indicated that questions might be asked about thalidomide, but suggested that it be referred to at trial as another drug, unnamed, because of its highly emotional impact. Motion heard Feb. 1964.

³⁷ When after the deposition further questions arose, Merck consented to answer sets of interrogatories and counterinterrogatories submitted by the parties, and the parties agreed these could be used any place where the primary deposition was in use. It is interesting to note that Merck, being concerned about the possibility of nonmembers repeatedly wishing to take its deposition, attempted through its counsel to notify all lawyers with cases about the pending deposition and to encourage them to participate if they desired. None did.

Eight depositions were then taken pursuant to an agreement allowing each side an equal number of nonparty deponents. The agreement thus enabled the defendant to put into every member's case the depositions of four defense witnesses. The plaintiffs' four deponents included two former Merrell scientists, who testified to the changing of laboratory records at Merrell; the FDA physician who had been in charge of following MER/29 and who later testified on the FDA and MER/29 before the Humphrey Committee;³⁸ and the chief ophthalmologist of the National Institute of Health, a branch of the Department of Health, Education and Welfare, who had performed MER/29 animal experiments which produced cataracts.³⁹ The defendant, choosing its four deponents on a rebuttal basis, deposed two other ex-employees, one of whom was one of the scientists who had been convicted; a clinical investigator for the company whose attitude toward MER/29 was still favorable; and a young scientist who had done some recent animal experiments with MER/29.⁴⁰

In all these depositions, the defendant was represented by its national defense counsel and the plaintiffs' Group by its trustee, sometimes with another attorney. There was virtually no appearance, let alone participation, by other Group members, and after the depositions were taken no member of the Group sought for any reason to retake any of them. In fact, no lawyer outside of the Group, even though aware of the Group's activities, sought to take these depositions. In addition, few if any members sought to take depositions of other witnesses.

2. Documents

Because the grand jury had subpoenaed all the defendant's files relating to MER/29, those files of some 107,000 documents were available on sixty-five rolls of microfilm. The defendant voluntarily agreed to produce these microfilms for the Group for use only once. A representative of the

³⁸ The FDA at first resisted the deposition of any employee, citing a housekeeping rule which purported to ban it, 21 C.F.R. § 4.1 (1967). The agency finally agreed, however, with the stipulation that the plaintiffs withdraw any request for the production of FDA records and not inquire into matters that the doctor learned only while a consultant to the grand jury investigating Merrell.

³⁹ Counsel for the Department of Health, Education and Welfare objected to the deposition on the ground that it would consume the time of a government employee. Plaintiff moved in a Maryland federal district court under Federal Rule 37 for an order compelling the witness to testify. After a hearing, the court ruled orally that the witness must appear and respond to all questions, including those relating to his opinion, but limited the deposition to two days. Ruling made Oct. 28, 1964.

⁴⁰ Neither side, it may be noted, took the deposition of the man who had been the chief of toxicology at Merrell during the relevant times and had actually performed the altered tests, even though he was in the center of the vortex in every regard and had been indicted and convicted in Washington. He had been released by Merrell in 1962. Nor did he ever testify at any trial.

Group would examine them and members of the Group would thereafter seek copies of documents from the Group rather than from the defendant. The Group's trustee spent virtually two summers reading and copying pertinent documents on the film, even then reading only half.⁴¹

By offering voluntarily its entire file, the defendant spared itself the time and expense of responding frequently to differently-worded requests for production of records. In retrospect, however, it appears that this procedure may have harmed the defendant by giving to the plaintiffs documents which they could never have obtained through routine discovery procedures, even if they had suspected their existence.⁴² In a lesser case, however, a defendant may swamp the plaintiff by producing all its records; the Group, for example, never read half the documents produced by Merrell.

3. *Interrogatories*

After maneuvering on both sides, the plaintiffs in the Group agreed to submit a standard set of interrogatories, to which the defendant agreed to provide uniform answers, but only where state procedure allowed the use of interrogatories. The questions dealt mainly with matters left unanswered by the depositions and with issues raised by the previous documentary discovery.

III

THE DISPOSITION OF THE LITIGATION

While the Group had a direct role in the pretrial phases of the MER/29 litigation, its role in the settlement, trial or other disposition of the cases was only indirect. As noted, the members of the Group were not on

⁴¹ In addition, the defendant provided separately the new drug application and its sales and promotional literature. Not content with the Merrell new drug application, the plaintiff's Group sought to discover the FDA's version of the application, on the ground that it had no way of knowing whether Merrell had provided a complete and accurate copy of all of the correspondence. On the FDA's motion, the Group's notice was orally quashed because the plaintiffs had no proof that the applications differed, which was, the court felt, a condition for the discovery of government records. The defendant supported the FDA's position. Lack of access to the FDA files on MER/29 as a result of this motion and as a result of the FDA's position when its doctor's deposition was taken, note 38 *supra*, was a serious handicap to the plaintiffs. The FDA's attitude of secrecy toward its files pervades all of its dealing with the public, including the medical profession. While it has been criticized by Senator Humphrey, *Humphrey Hearings, supra* note 12, pt. 5, at 2864, and others, the FDA has indicated that it will not change its policy, despite passage of the Freedom of Information Act, 80 Stat. 250 (1966). See Manana, *FDA's Obligations under the 1966 Public Information Act*, FDA Papers, Sept. 1967, at 16.

⁴² In one document, for example, an Inter-Department Memo dated March 24, 1961, the president of the parent corporation had scribbled in the margin "also desirable to play ball with Talbot [the FDA doctor who was then handling the MER/29 drug application] who got #29 through over protest. Talbot has authority to OK."

the whole interested in consolidation for trial, nor did many of them favor the proposal of a traveling plaintiffs' team to try each case as it came up. Even intermediate proposals failed to work, such as categorization of cases on their medical facts by the Group and the defendant, so that some scale of values might be attached thereto. In the latter case, meetings were held but fundamental differences in approach barred any possibility of agreement.

As a rule, therefore, disposition of the cases was the product of a "free enterprise" system. Without pressure from the Group or from the courts, the lawyer could handle his case as he wished.⁴³ The members did, however, avidly await from the Group information about other members' cases, including the minutest details available concerning settled cases and the type of trial being put on by both sides. Since Group newsletters could not adequately convey to individual members the Group's collective knowledge about the trial of a MER/29 case, the "MER/29 School," as it was known, came into being. Four two-day sessions were held, operated by the trustee and not the Group, for a total of approximately thirty members. Such was its success, that a member began a trial the day after attending the school—and won.

The "free enterprise" system returned the balance of power to the defendant at the trial stage. The defendant could and did select the cases it wanted tried. Good cases approaching trial were settled. Finally, when a series of cases came up which favored the defendant because of their facts or for other reasons, the defendant could bring these on to trial. The success of these tactics is evident in verdicts for the defendant in the first three cases tried. Meanwhile, able plaintiff's attorneys with cases buried on long calendars had to wait impatiently for a chance to try a case on their own terms. On the whole, however, members of the Group were not discouraged by the defendant's initial three victories after explanations of the conduct of the trials.

The "free enterprise" system also meant that plaintiffs' attorneys varied widely in their determination to try cases or willingness to settle, in their assessment of a fair settlement value, and in the skill and preparation with which they tried cases. These immense differences in the abilities of plaintiffs' counsel, typical of personal injury practice today, are unfortunately ignored by the bar, which continues to resist the idea of specialization by lawyers.⁴⁴

⁴³ The same was true at the pretrials. The Group's role here was confined to providing members with copies of pretrial orders and rulings made in other actions, together with the key documents on liability which could be marked at the conferences. The courts did not work out consolidated pretrials.

⁴⁴ See note 75 *infra* and accompanying text.

A. Trials

By the fall of 1967, eleven MER/29 cases had been tried to a jury verdict, two had resulted in a hung jury, and in six others a jury was selected but the case was settled during trial. Relevant data on the eleven cases tried to a verdict is set forth in the accompanying table. The disposition of well over 1,000 cases with only eleven tried, less than one per cent, is obviously significant. In the author's opinion, the chief factors contributing to the low rate of trial were an awareness on both sides that liability was clear and that the cases were long and expensive to try and willingness by too many plaintiffs' counsel to avoid trial by taking a marginally adequate settlement.

As the trials continued, they became progressively more expensive and time consuming to try, as is partly indicated in the table. The extreme was reached in the upstate New York case tried in 1967 which ran, with days off, from the middle of February to the middle of May.⁴⁵ The patience of judge and jury in this case was commendable, but it was a poor way to try a personal injury case. The defendant had four counsel in full-time attendance, and its costs, including witness fees, undoubtedly exceeded 100,000 dollars. The plaintiffs' costs themselves approached the jury's verdict of 20,000 dollars.

Given the great expense and clear liability, the author can only suggest reasons why any cases were tried at all. In some cases, genuine medical disputes left the outcome in doubt, or the demanded amount was regarded as too high for the type of case involved (cases 5, 9, 11 in the table). Occasionally, the defendant was simply unwilling to recognize its great exposure (cases 4, 6, 7, 8). Finally, the defendant felt in some cases that it faced an unprepared plaintiff (cases 1, 2, 3, 10). It is apparent that big verdicts were returned only in the second class of case.

Both the size of the verdict and the outcome of the trial were greatly influenced by the size of the city and surrounding metropolitan area in which the case was tried. The general belief that large city juries bring in big verdicts was supported by the outcome of these trials. The plaintiff won every case tried in a city or metropolitan region of over 150,000 population and lost or got verdicts under 50,000 dollars elsewhere. Later interviews with jurors indicated that small-town jurors felt they should not decide if the defendant should be punished by more than compensatory damages. That presumably was for the government. In large cities, the average juror welcomed the opportunity to speak out against the conduct of this avaricious appearing corporation.⁴⁶

⁴⁵ *Space v. Richardson-Merrell, Inc.* (Sup. Ct., Broome County, N.Y., May 15, 1967).

⁴⁶ An enterprising reporter for the Washington Post, Morton Mintz, interviewed several

TABLE OF MER/29 CASES TRIED TO VERDICT

Plaintiff	Court (Federal or State)	Year	Weeks	Group		Result at Trial, on Appeal
				Case	Case	
1 Lewis	Eugene, Ore. (S)	1964	2	no		defense verdict, affirmed ^a
2 Ellerbe	Crosset, Ark. (F)	1964	2	no		defense verdict, no appeal ^b
3 Curdmore	Dallas, Tex. (S)	1965	2	no		defense verdict, affirmed ^c
4 Toole	San Francisco, Calif. (S)	1965	5	yes		\$675,000, affirmed after remittitur ^d
5 Silette	W. Palm Beach, Fla. (S)	1965	2	yes		defense verdict, on appeal ^e
6 Roginsky	N.Y., N.Y. (F)	1966	5	yes		\$117,000, reversed in part ^f
7 Golden	Seattle, Wash. (F)	1966	2	yes		\$150,000, settled for \$125,000 ^g
8 Ostopowitz	White Plains, N.Y. (S)	1966	5	yes		\$1.2 million, on appeal ^h
9 Ward	Reno, Nev. (F)	1967	4	yes		\$45,000 verdict, satisfied ⁱ
10 Montcrief	Los Angeles, Calif. (S)	1967	1	no		\$20,000 verdict, satisfied ^j
11 Space	Binghamton, N.Y. (S)	1967	12	yes		\$20,000 verdict, satisfied ^k

^a 243 Ore. 317, 413 P.2d 400 (1966). See text accompanying note 59 *infra*.

^b (D. Ark., June 18, 1964) (four plaintiffs).

^c 398 S.W.2d 640 (Tex. Civ. App. 1965) (first trial ended in mistrial). See text accompanying note 60 *infra*.

^d 251 A.C.A. 785, 60 Cal. Rptr. 398 (1967). See text accompanying note 54 *infra*.

^e No. 64 L 499B (15th Jud. Cir. Ct., Palm Beach County, Fla., July 28, 1965), *appeal pending*, No. 552-553 (Dist. Ct. App., 4th Dist., Fla.).

^f 378 F.2d 832 (2d Cir. 1967). See text accompanying note 57 *infra*.

^g Civ. No. 5992 (W.D. Wash., April 7, 1966). The verdict was wholly compensatory, as punitive damages are not allowed in Washington. Spokane Truck & Dray Co. v. Hoefer, 2 Wash. 45, 25 P. 1072 (1891).

^h No. 5879-1963, N.Y.L.J., Jan. 11, 1967, at 21, col. 3 (Sup. Ct., Westchester County, N.Y.), *appeal docketed sub. nom.* Ostopowitz v. Richardson-

Merrell, Inc., (App. Div., 2d Dept., Apr. 26, 1967). See text accompanying note 58 *infra*.

ⁱ No. 1715 (D. Nev., Mar. 25, 1967).

^j No. C 844053 (Super. Ct., Los Angeles County, May 18, 1967).

^k (Sup. Ct., Broome County, N.Y., May 15, 1967).

A second major factor determining the outcome in the cases tried, as examination of the table indicates, was whether or not the plaintiff's attorney was a member of the Group. The skill of the plaintiff's attorney was important and in a few instances the most significant factor in producing the result. Finally, two other relevant factors were the plaintiff's appeal to the jury as an injured person and the degree to which his injuries and medical proof agreed with descriptions of the effects of MER/29 in the medical literature.

Most of the trials were handled for the defendant by local counsel hired by the insurance carrier. Of the three New York cases, however, two were tried by counsel from the national defense firm and the third by a well-known defense expert hired specially for the fray. Informed attorneys from the company's house staff or from the national defense firm were at almost every trial to offer assistance and on occasion to help with cross-examination of liability witnesses. On the plaintiff's side, four of the ten cases were tried by one firm, and another firm started a number and tried one to completion. The Group's trustee assisted the plaintiff's counsel in two trials—one won, one lost—and was compensated by the attorney rather than the Group.

B. Punitive Damages and Appeals

Had the defendant's liability in the MER/29 cases been less clear, an earlier disposition of the whole litigation would have been likely. The liability picture looked so strong to the plaintiffs, however, that they felt they had a strong punitive damages claim. The whole quest for punitive damages, in fact, caused great inobilization of effort on both sides. The Group's extensive discovery outlined above centered on proving the necessary elements of a punitive damages claim, existence and proof of the basic negligence case for compensatory damages being taken for granted. The trials themselves included no real proof of carelessness but focused on showing intent or reckless indifference on the part of the defendant.

Exemplary damages undeniably had a dual attraction to the plaintiffs and their counsel. The first attraction was the money itself, and the second originated in the moral righteousness which grew in the minds of almost every person exposed to the facts of the MER/29 case. As members of the Group prepared their cases, they passed from amazement at the defendant's alleged acts to anger at the defendant, an attitude which is

of the jurors in the New York case which produced the \$1.2 million verdict (see table p. 133 and note 58 *infra*) as to their motivation for making what was the highest personal injury verdict in New York's history. Mr. Mintz quoted one juror as saying that the jury felt the company "had to be punished not only for what they had done, but also as a warning to all drug companies, that they could not do things like this." *Washington Post*, Dec. 12, 1966, at 12, col. 1.

warmly human but may interfere with a trial lawyer's objectivity. Many of the jurors in these cases also developed this sense of indignation, fulfilling the purposes of punitive damages by making awards on this motivation.⁴⁷

The defendant saw the rapidly rising claims for punitive damages, totaling hundreds of millions, as a threat to the corporation's financial well-being. Certainly if many of the pending cases had resulted in sizeable punitive damages awards, the assets of Richardson-Merrell, which were in the 150-200 million dollar range,⁴⁸ might have been totally liquidated, with or without insurance.⁴⁹

The merits of imposing punitive damages upon Richardson-Merrell in these particular cases, and indeed the whole topic of the viability of the punitive damages concept, is much beyond the scope of this Article.⁵⁰ However, the MER/29 litigation did raise a few fairly novel questions of punitive damages which bear some comment. The appeals in the MER/29 cases will be discussed simultaneously because they so often involved the question of exemplary damages.

Although seeking punitive damages in a products liability case was unusual, it was by no means unprecedented; the novel punitive damages issues therefore revolved primarily around Richardson-Merrell's ingenious defenses. The defendant argued that punitive damages should never be awarded against drug companies, which have the special role of making new drugs for sick people.⁵¹ It argued that imposition of punitive damages by a civil jury was so similar to a criminal fine that criminal procedural safeguards, including a burden of proof beyond a reasonable doubt and the benefits of double jeopardy provisions should be required.⁵² Fi-

⁴⁷ See note 46 *supra*.

⁴⁸ Richardson-Merrell, Inc., Annual Statement, for the Fiscal Year 1965-1966. At the end of fiscal 1965-1966, the tangible assets were \$148 million.

⁴⁹ On the coverage in this case, see text accompanying note 63 *infra*.

⁵⁰ See discussion in Morris, *Punitive Damages in Personal Injury Cases*, 21 OHIO ST. L.J. 216 (1960); Morris, *Punitive Damages in Tort Cases*, 44 HARV. L. REV. 1173 (1931); Ornstein, *Criminal Safeguards and the Punitive Damages Defendant*, 34 U. CHI. L. REV. 408 (1967); Note, *The Imposition of Punishment by Civil Courts: A Reappraisal of Punitive Damages*, 41 N.Y.U.L. REV. 1158 (1966). General counsel for the defendant also wrote an article. Silliman, *Punitive Damages Related to Multiple Litigation Against a Corporation*, 16 FED. INS. COUNSEL 91 (1966).

⁵¹ The only court which responded to this argument was the majority of the panel of the Second Circuit in *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 851 (2d Cir. 1967) which only made an observation in passing.

⁵² Again, the only serious consideration given to this was by the Second Circuit in *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 850-51 (2d Cir. 1967), in which the majority concluded that it would be more proper to require at least that the plaintiff prove the punitive damages case by clear and convincing evidence, as compared to a mere preponderance.

nally, the company argued that it should not have to pay punitive damages more than once for the same basis conduct.

The question of multiple punitive damages attracted the most attention, inspiring good arguments on both sides. The defendant argued that it would be bankrupted because each jury acting without knowledge of others would award punitive damages undiminished by any previous awards, although the company had done only one wrong and should therefore be punished only once. The plaintiffs argued that there were multiple wrongs, as measured by the multiple injuries, and that verdicts collectively bankrupting the defendant only represented society's judgment on the corporation.⁵³

The MER/29 appeals left these issues largely unresolved, because most cases were settled and only three juries awarded punitive damages. In the California case,⁵⁴ the trial judge cut the punitive damages verdict of 500,000 dollars to 250,000 dollars because many untried cases were pending. The appellate court affirmed, without discussing multiple punitive damages.⁵⁵ In the New York federal case,⁵⁶ the trial court allowed a punitive damages award of 100,000 dollars, finding such an amount not excessive considering the defendant's conduct. On appeal, a majority of a panel of the Second Circuit reversed as to the punitive damages award, partly on the basis that multiple punitive damages were unfair and could destroy the company.⁵⁷ In the New York state case,⁵⁸ the trial court reduced the 850,000 dollar punitive damages award to 100,000 dollars because the jury did not know and could not have known about other cases

⁵³ An interesting subsidiary issue here is whether the defendant may inform the jury about previous punitive damages it has paid or a previous criminal fine in order to mitigate damages. Such a declaration cuts two ways: Some jurors might view it as an indication that they, too, should award punitive damages, whereas others might feel that there was no need to make further awards. If the latter reasoning is valid, announcing previous awards to the jury would be a simple way to avoid the dangers of multiple punitive damages awards. That mitigation of this sort is allowed, see 22 AM. JUR. 2D *Damages* § 248 (1965).

⁵⁴ *Toole v. Richardson-Merrell Inc.*, 251 A.C.A. 785, 60 Cal. Rptr. 398 (1967), *petition for hearing by the California Supreme Court denied* (Sept. 7, 1967). The judgment was satisfied with costs and interests for \$501,306 in 1967.

⁵⁵ *Toole v. Richardson-Merrell, Inc.*, 251 A.C.A. 785, 60 Cal. Rptr. 398 (1967).

⁵⁶ *Roginsky v. Richardson-Merrell, Inc.*, 254 F. Supp. 430 (S.D.N.Y. 1966).

⁵⁷ *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967). The court affirmed the \$17,000 compensatory verdict. The specific ground given for the reversal on the punitive damage award was that there was no evidence in the record that management had participated in the concededly wrongful conduct. On the same record, the California court in *Toole v. Richardson-Merrell, Inc.* came to the opposite conclusion as to management's knowledge and in a footnote acknowledged the New York decision, stating "We respectfully differ from that holding." 251 A.C.A. 785, 811 n.3, 60 Cal. Rptr. 398, 416-17 n.3 (1967).

⁵⁸ *Ostopowitz v. Wm. S. Merrell Co.*, No. 5879-1963, N.Y.L.J., Jan. 11, 1967, at 21, col. 3 (Sup. Ct., Westchester County, N.Y.), *appeal docketed sub. nom. Ostopowitz v. Richardson-Merrell, Inc.* (App. Div., 2d Dept., Apr. 26, 1967).

pending. The court set a fairer amount based on the precedent of the New York federal case.

Thus at the time of this writing, the defendant, for all of the mobilization of the parties, has paid punitive damages in only one case. Perhaps, therefore, the obvious sympathy for the defendant evident in the Second Circuit opinion's reference to the possibility of "overkill" was misplaced.

In an appeal not involving punitive damages, the Supreme Court of Oregon was afforded an opportunity to comment at length upon its newly-announced rule of strict liability and to refuse to apply it, on the record before it, to the case of a "pure" and "nondefective" product, a drug.⁵⁹ The Texas Court of Appeals on a plaintiff's appeal gave short shrift to any claims of error.⁶⁰ In addition to appeals after trials, MER/29 cases involved decisions on various subsidiary issues.⁶¹

C. Settlements

Over ninety-five per cent of the MER/29 cases were settled between 1962 and 1967, the year in which almost all the then pending cases were settled. Settlements over this five-year period gradually increased in size. In the "typical MER/29 case"—good medical proof of cataracts and hair and skin change in a man under 60, but with no earnings loss and only slight medical expenses—settlements grew from approximately 25,000 dollars in the early period, to 75,000 dollars in the mid-period, to 125,000 dollars near the end.

Several factors influenced the gradual rise in value of the cases. Because of crowded dockets in the metropolitan areas, cases in the rural states and areas of the country were the first to come up for trial and

⁵⁹ *Lewis v. Baker* [and *Richardson-Merrell, Inc.*], 243 Ore. 317, 413 P.2d 400 (1966). Whether and to what extent the new doctrine of strict liability in tort in products liability cases should apply to a pure prescription drug is a question unsettled in the law. Contrary to the position taken in *Lewis* are *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159 (D.S.D. 1967); *Toole v. Richardson-Merrell, Inc.*, 251 A.C.A. 785, 60 Cal. Rptr. 398 (1967); *Russell v. Community Blood Bank, Inc.*, 196 So. 2d 115 (Fla. 1967). See James, *The Untoward Effects of Cigarettes and Drugs: Some Reflections on Enterprise Liability*, 54 CALIF. L. REV. 1550 (1966); Note, *The Manufacture, Testing and Distribution of Harmful New Drugs: The Applicability of Strict Liability*, 28 U. PITT. L. REV. 37 (1966).

⁶⁰ *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex. Civ. App. 1965), *cert. denied*, 385 U.S. 1003 (1966).

⁶¹ *Bennett v. Richardson-Merrell, Inc.*, 231 F. Supp. 150 (E.D. Ill. 1964) (action for breach of implied warranty could be maintained); *Tytel v. Richardson-Merrell, Inc.*, 37 F.R.D. 351 (S.D.N.Y. 1965) (ordering discovery of documents); *Knowles v. Vick Chemical Co.*, 240 Ark. 125, 398 S.W.2d 204 (1966) (no retroactive effect granted where cause of action accrued before new law allowed breach of warranty action); *McLeod v. Wm. S. Merrell Co.*, 174 So. 2d 736 (Fla. 1965) (drugstore which sold MER/29 not strictly liable); *Krohn v. Richardson-Merrell, Inc.*, 406 S.W.2d 166 (Tenn.), *cert. denied*, 386 U.S. 978 (1966) (wife has no right of consortium where husband rendered impotent by MER/29).

hence for settlement. Thus at a time when there were few cases still pending in the states with the smallest populations, almost no cases had been disposed of in Illinois, California and New York—the very areas where ultimately the largest amounts in settlement were paid. In fact, by early 1967, the majority of cases in New York City, particularly in Manhattan, were still pending.

A second factor accounting for the rise in the value of the cases was the course of the trials, inevitably the best guideline for a case's settlement value. Big verdicts pushed the defendant into offering larger settlements to avoid similar exposure in the future. While the 1.2 million dollar verdict in New York survived, plaintiffs often wanted at least one-tenth of it. Of course, reverses suffered by plaintiffs had the opposite effect, and both sides were inhibited by the fact, known to all, that the cases were very expensive and time consuming to try.

The ability of the plaintiff's counsel was a third factor influencing the settlement amount. Some lawyers were obviously better negotiators than others. Some, finding themselves at trial and unprepared, settled for whatever the defendant would pay or the court would coerce from the defendant. Throughout the litigation, in fact, there were settlements for little more than nominal sums or nuisance value—one case settled for 1,500 dollars was indistinguishable from another one settled at the same time by skilled plaintiff's lawyers for 60,000 dollars. On the whole, attorneys in the Group who generally represented defendants or who were not known as personal injury lawyers settled for less than did habitual plaintiff's personal injury lawyers. Certainly nonmembers did much more poorly in settlements than did members of the Group. In the author's opinion, these nonmembers, most of whom did not want to pay 300 dollars to join, not only did a distinct disservice to the clients whom they represented, but were also economically shortsighted, since the increase in value of the case meant in the long run an increase in the fee many times the 300 dollar investment.

All of the settlements were denominated compensatory damages, creating a certain tax advantage for the plaintiff.⁶² Tax consequences to the defendant were the same for both compensatory and exemplary damages. Moreover, categorization of the settlements was insignificant from the standpoint of insurance coverage, as is explained below. From a psycho-

⁶² Generally, punitive or exemplary damage recoveries are taxable, whereas compensatory damages are not. *Commissioner v. Glenshaw Glass Co.*, 348 U.S. 426 (1955).

Settlement might also become more attractive than usual in a case where a healthy portion of the expectable verdict at trial was going to be punitive damages and hence taxable income. For example, a nontaxable settlement of \$125,000 would be better than a verdict of \$50,000 compensatory and \$100,000 punitive, and plaintiff's counsel felt obligated to so advise.

logical viewpoint, however, the defendant certainly wished to be seen as paying out only compensatory money; if plaintiffs had seen that settlements were including a punitive damage "premium," labeled as such, demands would undoubtedly have been raised.

D. Insurance; Nature of the Defense; Number of Suits

Central to the MER/29 litigation was the defendant's knowledge that its insurance coverage was inadequate to meet the MER/29 claims. Richardson-Merrell was insured for all its Merrell products on an annual basis.⁶³ The insurance was written for a relatively small amount of primary coverage and several layers of excess coverage. This reportedly amounted to some five million dollars a year, or a pool of roughly 15 million dollars to cover the years of injury.⁶⁴ Payment by insurers of this total for a single product's damage was probably an industry record.

At the start, the insurance carriers involved applied their usual hard-nosed approach toward settlement to the MER/29 cases. This attitude was justifiable in the early days of the litigation because of the unusual precedential value any large settlement would have upon the bulk of pending cases.⁶⁵ As time passed and several juries brought in verdicts greatly in excess of the carrier's previously estimated maximum, the attitude toward settlement became more favorable. As the insurance money began to run out, the tempo of settlements and their amount increased. The carriers after all had to pay for defense counsel out of their own funds until the Merrell coverage was exhausted.

Insurer and insured had different attitudes toward punitive damages. If these were not covered by insurance, then the insured would want to concede great negligence but deny any intent. The insurer, however, did not want to admit fault of any sort. Whether Richardson-Merrell was in fact expressly insured for punitive damages is unknown; even if it had been, a case might have arisen in a state which held such insurance to be

⁶³ A claim would be assigned to a particular year's coverage according to the time when injury was first experienced. Only in two of the three years involved was the coverage wholly exhausted, July 1, 1960-June 30, 1962. Because Merrell's insurance was for all products, it also covered the claims which were filed in this same period for thalidomide injuries, especially the teratological injuries to fetuses. While these were very few in number, the potential damages were large. No thalidomide case has been tried at this writing, although several have been settled.

⁶⁴ Basic Analysis of Richardson-Merrell, Argus Research Corp., N.Y., March 14, 1967, copy on file with *California Law Review*. In addition, it was announced in 1967 that the company also had some additional insurance coverage, which would take effect only after it had paid a certain amount out of its own funds.

⁶⁵ In seeking to prevent settlements from becoming precedents, the defendant at times exacted from a plaintiff's counsel an agreement not to "publicize" a settlement, preventing the disclosure of the amount to the plaintiffs' Group.

against public policy.⁶⁶ This issue was rendered moot, however, by the exhaustion of insurance before the payment of any punitive damages.

Having anticipated that its large coverage would eventually be exhausted, Richardson-Merrell had allocated part of its past years' earned surplus to a special pool for payment of claims. As of early 1967 when Merrell began paying out of its own pocket, it had some 42 million dollars in this pool, certainly more than adequate for the company's outstanding liabilities. In the period from February to September 1967, 7 million dollars was paid out of this.

Once the defendant itself took over the defense of the cases, a great impetus to settle became apparent. Not only did it desire to avoid the great expense of carrying the cases, but it also desired to finish the litigation because of its effect on the stock of the company⁶⁷ and on the morale of its personnel. In this last phase, the plaintiffs also became increasingly interested in disposing of pending cases. This rational spirit of compromise in 1967 contrasted sharply with the several earlier years of emotionalism during which cases were unnecessarily tried.

The author believes, with the advantage of hindsight, that the defendant and its carriers paid out millions of dollars which they might have saved by adopting a different attitude toward the litigation in the 1962-1964 period. Had the defendant simply settled the cases as they sprang up in the early periods of the litigation, even at the then allegedly exorbitant rates of 25,000 to 35,000 dollars, there would have been few if any 100,000 dollar settlements and no million dollar verdicts. However, the defendant's early attitude that the injuries were slight and that most of the cases were frauds brought by persons wishing to blame all of their ills on MER/29 stiffened the resolve of the plaintiffs considerably. The early litigation drew attention to the fact of the suits, encouraging persons to sue who did not otherwise know or believe they had a valid claim. Thus the typical defense-insurance company suspicions, although natural, were in the long run expensive.

Another factor in the defendant's unwillingness to recognize its responsibility for its injurious conduct and to dispose of the cases may have been a mildly paranoid attitude that all too frequently arises when large corporations are sued. The company management sees the suits as an at-

⁶⁶ Compare *Northwestern Nat'l Cas. Co. v. McNulty*, 307 F.2d 432 (5th Cir. 1962), with *Carroway v. Johnson*, 245 S.C. 200, 139 S.E.2d 908 (1965).

⁶⁷ See Hoddeson, *Richardson-Merrell is Suffering The Aftereffects of MER/29*, *Barron's*, June 15, 1964, at 3. The stock fell from over \$100 a share in 1962 to the high 40's in 1964. As the MER/29 litigation has been disposed of, the stock has climbed back to 100 in the fall of 1967.

tack upon its reputation and integrity and as a form of "blackmail." The moralistic urge to defend at all costs replaces a level-headed economic approach to the disposition of the litigation.⁶⁸ The banding together of the plaintiffs in the MER/29 cases may well have intensified this attitude, as no doubt did the company's preexisting ideas that it had made a miracle drug, only to have competition in the drug industry and the FDA blacken the name of the drug and force it off the market.

Certainly MER/29 injured more persons than any product marketed in recent years, and no doubt as high a percentage of those injured sued as have ever sued for product-connected injuries. At the same time it is true that a relatively small percentage of people sue for injuries sustained through the use of or contact with a product,⁶⁹ even, as with MER/29, when there is wide publicity about the company's wrongdoings. There are relatively few suits because some people do not know they have been injured; some do not know that they took the drug or their doctors tell them later that they did not take it.⁷⁰ Some do not consult an attorney since they believe that they cannot sue or they do not want to sue and appear litigious;⁷¹ some consult lawyers and are advised that they cannot sue a drug manufacturer. Most unhappily of all, some consult an attorney for the first time after the statute of limitations has run.⁷²

⁶⁸ These points are further discussed in Rheingold, *Multiple Drug Litigation—The Plaintiff's Viewpoint*, 22 FOOD DRUG COSM. L.J. 136 (1967).

⁶⁹ In drug "disasters" similar to MER/29, with dozens or even hundreds of persons injured, only a handful of suits may be filed against the manufacturer. An example involves the drug Orabilex, a contrast dye, withdrawn in 1964 from the market after the FDA claimed that false data had been sent to it and that it had reports of many persons injured through its use. M. MINTZ, *THE THERAPEUTIC NIGHTMARE* 111-24 (1965).

⁷⁰ In numerous instances, prescribing doctors initially denied that they had even prescribed MER/29, only to admit later when their records were obtained that they had done so. A major loophole in the drug laws today is the absence of a provision requiring the druggist to put a drug's brand name on the label when he sells prescription medicine.

⁷¹ MER/29 injured a number of person who apparently felt that it would be improper for them to sue, including a judge, a congressman, a high ranking officer, an editor, and an entertainer.

⁷² One of the most aggravating aspects of the MER/29 litigation to the plaintiffs was the short statute of limitations. Why so many plaintiffs came to lawyers' offices for the first time only after the statute had apparently run is a mystery, but the fact remains that it happened often and sometimes quite unjustly. Some cases brought in tardily were "saved" by unusual theories of liability, like warranty or fraud, or by devices for tolling the statute, or by a mild amount of forum shopping. Certainly statute of limitations laws are antiquated when they do not take into consideration the usual time lapse before a plaintiff discovers his injuries and realizes that they are due to a specific product. A routine provision for tolling the operation of the statute until the plaintiff discovers the source of his injuries is desirable in every state. See Rheingold, *Solving Statutes of Limitation Problems*, in 4 AM. JUR. TRIALS 441 (1965).

IV

SIGNIFICANCE OF THE MER/29 LITIGATION

A. *To the Bar, in Handling Mass Disasters*

The primary achievement of the MER/29 Group was to demonstrate that attorneys all over the country handling the same sort of case could cooperate voluntarily and without court control or supervision in the joint preparation and ultimate disposition of a mass of cases. Partial precedents for the Group in the handling of earlier mass disasters like ship sinkings, airplane collisions, or great explosions and fires involved simpler organizations and operations, since the disaster was in a single place, there was one fact situation, and usually there was direct judicial control over the progress of the cases.⁷³ The MER/29 Group proved that lawyers with cases pending all over the country, involving varying fact situations, could join together and do the work efficiently and yet voluntarily, in cooperation with the defendant.

The need for and desirability of group handling of multiple tort claims arising out of modern mass disasters is quite apparent today. Group action lessens the costs of preparing cases, which in the usual disaster case are great, and hence gives the injured and often indigent plaintiff representation that he might otherwise not have. It gives the plaintiff bargaining power that he might lack were his case the only one pending. Further, it reduces the work of the courts and thus may help to shorten trial dockets.

In addition, group cooperation in multiple litigation assembles the best skill available in the personal injury trial bar. All too often the counsel hired in big cases arising from catastrophes, mass or personal, are not experienced in the handling of big cases, and indeed may not be experienced in handling any sort of personal injury suits. As mentioned earlier,⁷⁴ the attitude that all lawyers are interchangeably able to handle any case that clients bring to them is seriously out-of-date; the time for specialization is no doubt at hand.⁷⁵

⁷³ See A. ROSENTHAL, H. KORN & S. LUBMAN, *CATASTROPHIC ACCIDENTS IN GOVERNMENT PROGRAMS* (1963); Rheingold, *Mass Litigation Affecting Many Persons*, *TRIAL*, Dec. 1965, at 29; Note, *Consolidation in Mass Tort Litigation*, 30 *U. CHI. L. REV.* 373 (1963).

⁷⁴ See text accompanying note 44 *supra*.

⁷⁵ On the merits of specialization, see G. GREENWOOD & R. FREDERICKSON, *SPECIALIZATION IN THE MEDICAL AND LEGAL PROFESSIONS* (1964).

One might inquire with interest how the MER/29 cases would have fared under a workmen's compensation scheme for handling personal injury cases, like that proposed in R. KEETON & J. O'CONNELL, *BASIC PROTECTION FOR THE TRAFFIC VICTIM* (1965). Certainly, the amounts would have been much less. Most of the cataract victims had no earnings loss and medical expenses not exceeding \$1,500. Hence, under some proposals, the awards would have been \$1,500, nothing being allowed for the impact of cataracts and the removal of the

The extent to which the work of the MER/29 Group will set a pattern for future formation of plaintiffs' groups to handle similar litigation remains to be seen. At least a half dozen groups have been formed in the last several years, dealing with products which cause widespread injuries, particularly drugs.⁷⁶ The success of any new group will rest in part upon the willingness of the lawyers involved to share their information, experts and thoughts on trial tactics and thus apparently to sacrifice personal gain for the good of the plaintiffs involved.

The significance of the MER/29 cases to the developing law of both products liability⁷⁷ and punitive damages⁷⁸ has already been noted. Although the validity of punitive damages against drug manufacturers or any defendants may be questioned, the author believes that with drugs, as with other products, the threat of punitive damages prevents antisocial behavior by the manufacturer that other forms of compulsion may be grossly inadequate in controlling. The maximum criminal fine imposed upon Merrell was 80,000 dollars, barely a drop in the bucket compared to the company's profits from selling the drug. Initial FDA regulation was inadequate, as is explained below. The idea that concern for the company's reputation would keep it from putting matters of profits above concern for health, a factor actually cited by one judge,⁷⁹ is simply not borne out by the facts. This is not to say, however, that the law of punitive damage may not need some basic reform.⁸⁰

B. To the Defendant, Drug Industry and Insurance Carriers

The impact of the MER/29 disaster upon the manufacturer, Richardson-Merrell, is unmeasurable. Its stock fell disastrously; its earnings and profits declined; earned surplus usually available for expansion was used to pay off claims after the insurance was exhausted; and the company's

lenses upon the whole man. The MER/29 cases apparently required no sort of basic protection plan in order to ensure some recovery by all plaintiffs, since so extraordinarily high a percentage of litigants made a recovery.

⁷⁶ The drug groups include Aralen, birth control pills, Sabin polio vaccine, Parnate, drugs which produce teratogenic (monster) effect in fetuses, and Esidrix and HydroDIURIL.

⁷⁷ See note 58 *supra*.

⁷⁸ See text following note 50 *supra*.

⁷⁹ Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 841 (2d Cir. 1967).

⁸⁰ Courts and jurors may regard punitive damages with doubt as basically a windfall to the plaintiff, except where the exemplary damages, so denominated, are really extra compensation for a tort like libel, for which the actual compensatory loss cannot be adequately measured. Punitive damages would have the same deterrent effect on defendants if the money paid went to the court, or to some charity of the plaintiff's choice. The plaintiff, however, might then have no incentive to seek punitive damages. A plan could be worked out, however, in which some of the recovery went to the plaintiff, such as the payment of his attorney's fees (not otherwise assessed against the compensatory award), with the balance to charity.

standing with its regulatory agency, the FDA, fell considerably. The company was not hurt, however, in the eyes of its purchasing public, the medical profession, which continued to prescribe its other products, as is discussed in the next section below. Responding to these adverse effects, Richardson-Merrell undoubtedly took steps to avoid "another MER/29" within its system. The extent of its reforms, however, became a point of debate at trial when Merrell raised the defense of mitigation of damages by showing that it had turned over a new leaf.

MER/29 also left its mark on the pharmaceutical industry as a whole. A series of congressional investigations had already revealed the industry to be a high-profit group often not as vitally concerned with health as the investigators might have expected it to be,⁸¹ and MER/29 was an additional black eye for the drug industry. Its practical effect on the industry, however, is unclear. Post-MER/29 revelations of companies withholding from the FDA data which it described as obligatory,⁸² and criticisms by the present FDA Commissioner⁸³ dispel any immediate hope that the industry is seeking to prevent another MER/29 within its ranks or that manufacturers are voluntarily ceasing to conceal side effects from the Government and the public.

The expenditure of nearly 15 million dollars in insurance coverage, leaving the insured with a large amount to pay in remaining claims, undoubtedly has led to reevaluation of insurance risks and premiums and has led potential defendants to increase their coverage.⁸⁴

⁸¹ See Humphrey Committee Report, S. REP. NO. 1153, 89th Cong., 2d Sess. (1966); Kefauver Committee Report, S. REP. NO. 448, 87th Cong., 1st Sess. (1961); *Hearings Before the House Subcomm. on Government Operations*, 88th Cong., 2d Sess. (1964-66) [hereinafter cited as *Fountain Committee Hearings*]. See the discussions in R. HARRIS, *THE REAL VOICE* (1964); M. MINTZ, *supra* note 69.

⁸² Orablix is one example. See note 66 *supra*. Another is Elipten, a drug to control epilepsy, which was removed from the market in 1966 because of the FDA's discovery of the alleged withholding of animal side effect data from it. *New York Times*, Feb. 16, 1966, at 54. A 1964 FDA investigation into Parnate, an antidepressant, disclosed that the company had received many reports of strokes in humans but had not relayed them to the FDA as required. *Fountain Committee Hearings*, *supra* note 81, pt. 3, at 1408.

⁸³ FDA Commissioner James L. Goddard stated last year that he was shocked that in the data the FDA was receiving from manufacturers there were "clear attempts to slip something by us," and that there was a practice of "conscious withholding of unfavorable animal or clinical data." *New York Times*, April 7, 1966, at 24. He repeated such comments, coupled with a plea to the manufacturers that they stop concealing reports of adverse reactions, in "Clamp Down on the Drug Industry—Its Meaning," *U.S. NEWS & WORLD REPORT*, May 16, 1966, at 76.

⁸⁴ See *Richardson-Merrell Drug Damage Suits Stress Value of Products Liability Insurance*, *THE WEEKLY UNDERWRITER*, March 19, 1966, at 20. In connection with the numerous products liability suits against Cutter Laboratories in the late 1950's for polio due to the administration of its polio vaccine, the defendant, with six claims remaining, has paid \$1.05 million in addition to \$2 million in coverage. *How Cutter Came Back*, *BUSINESS WEEK*, Feb. 24, 1962, at 139.

C. To the Medical Profession

Viewed as an example of a whole profession being hoodwinked by a drug company, the conduct of the doctors in the MER/29 episode is perhaps not startling. However, the layman who expects doctors to have some degree of scientific curiosity, some sophistication about new drug promotion, and some sensitivity for injuries from products which they prescribe must certainly find their conduct in the MER/29 situation surprising.

MER/29 was aggressively promoted by Merrell during its two years on the market. The initial advertising campaign for doctors included distribution of 100,000 copies of a Western Union manual about MER/29, publication of an eight-page advertisement in leading medical journals, and a series of monthly ads and direct-mail pieces. In true Madison Avenue form, all this material had one simple message: MER/29 had been proved safe, nontoxic and free of side effects. Salesmen on the routes and even a free handout movie repeated the message. Although proving intent to mislead the doctor was therefore easy in the MER/29 cases, it remains surprising that doctors did in fact rely on the advertising. MER/29 thus proved the oft-made criticism that the medical profession has come to rely for its education on drug sellers rather than on its own studies or common sense.⁸⁵

Whether brainwashed by the manufacturer or too busy treating conditions to ask their cause, the medical profession performed poorly in the detection of side effects. The proof showed, to be sure, that doctors faced a company that concealed its knowledge of side effects and provided false answers to routine inquiries about them, but nevertheless the doctors appear to have lacked the normal scientific curiosity that should have led to an early realization that MER/29 was a toxic drug. Some continued to prescribe MER/29 even after a patient had developed cataracts and had been operated on! In fact, without the detective work of the Mayo Clinic in 1961,⁸⁶ MER/29's side effects might have remained undetected even longer.

Perhaps the most incredible aspect of the medical profession's performance was its reaction to the revelations made by Merrell's indictment and conviction and by the subsequent civil litigation. Few reports of the company's wrongdoing ever appeared in the medical press. The average doctor is not even aware of the identity of MER/29's manufacturer, much

⁸⁵ See Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 965 (1964).

⁸⁶ See Achor et al., *Cutaneous Side Effects from Use of Triparanol (MER/29): Preliminary Data on Ichthyosis and Loss of Hair*, 36 PROCEEDINGS OF STAFF MEETINGS OF MAYO CLINIC 217 (1961); Kirby, *Cataracts as Possible Complications of Treatment with Triparanol*, 67 ARCH. OPHTHAL. 543 (1962).

less of the manufacturer's improper acts.⁸⁷ This reaction may not be so surprising, however, in view of the dependence of the medical press upon its advertising, which almost totally involves promotion of prescription drugs.⁸⁸

Finally, law-medicine relations in the MER/29 story involved the role of the doctors in the civil litigation. Their aid to the plaintiffs' Group and to individual cases were almost nonexistent. No qualified doctor agreed to act for the plaintiffs as a paid consultant. Only a handful, none of them associated with the drug industry in any way, would testify on the liability issue—the company's violation of existing standards. Prescribing and treating doctors were hesitant to come to court, and some even attempted to dissuade the patient from suing. Some in fact refused to admit that they had ever prescribed MER/29. The defendant apparently had no such difficulties in obtaining medical experts. The profession cooperated nobly. In one case, the director of the American Medical Association's Division of Drugs testified for the defense that the company had done nothing unusual,⁸⁹ and one former clinical investigator for MER/29 testified in almost every trial for a fee approaching 5,000 dollars per time.

D. To the FDA and Government Regulation of the Industry

The MER/29 episode also proved that the FDA was not functioning well in the years involved, 1959-1962. This was the emphatic conclusion of the FDA itself,⁹⁰ of Senator Humphrey,⁹¹ and of critics of the industry.⁹² The FDA as then operated could not deal with a MER/29-type sit-

⁸⁷ This lack of awareness by the medical profession is aptly illustrated by the testimony upon cross-examination of an expert who had been called in a MER/29 trial to testify for the defendant that the company had done nothing wrong. The witness, when confronted for the first time during cross-examination with numerous instances of fraudulent reports, stated that he could not answer if these showed a deviation from the standard of care because he refused to believe that any drug company would have done these things! Testimony of Dr. Jean K. Weston, Record on Appeal at 2024, *Ostopowitz v. Wm. S. Merrell Co.*, No. 5879-1963, N.Y.L.J., Jan. 11, 1967, at 21, col. 3 (Sup. Ct., Westchester County, N.Y.), *appeal docketed sub. nom.* *Ostopowitz v. Richardson-Merrell, Inc.* (App. Div., 2d Dept., Apr. 26, 1967).

⁸⁸ See L. LASAGNA, *THE DOCTORS' DILEMMAS* 162 (1962); M. MINTZ, *supra* note 69.

⁸⁹ Testimony of Dr. Jean K. Weston, Record on Appeal at 1929, *Ostopowitz v. Wm. S. Merrell Co.*, No. 5879-1963, N.Y.L.J., Jan. 11, 1967, at 21, col. 3 (Sup. Ct., Westchester County, N.Y.), *appeal docketed sub. nom.* *Ostopowitz v. Richardson-Merrell, Inc.* (App. Div., 2d Dept., Apr. 26, 1967).

⁹⁰ FDA Deputy Commissioner John L. Harvey, speaking in San Francisco before the Division of Food, Drug, and Cosmetic Law of the American Bar Association, Aug. 8, 1962, stated: "In retrospect, it is apparent that the drug should not have gone on the market in the first place." *Humphrey Hearings*, *supra* note 12, pt. 2, at 380, 383. Dr. Nestor of the FDA concurred, in testimony before the Humphrey Committee. *Id.*, pt. 3, at 777-78.

⁹¹ See note 12 *supra*.

⁹² M. MINTZ, *supra* note 69, at 230-47. See also Cavers, *Administering That Ounce of*

uation, as indicated by its initial approval of the drug on inadequate data, by its failure to suspect from numerous clues that data was being withheld from it, by its compromise at the top level of the agency in accepting a warning letter by the company when even its own medical officers wanted the drug off the market, and by its great delay in eventually forcing withdrawal of the drug.

The central question is whether the government could today detect a similar attempt by a manufacturer to conceal its knowledge about toxicity from the Government. The author believes it could not. Even the major improvements in reporting created by the 1962 drug amendments⁹³ do not compel a company to be candid. The FDA relies today, as always, on a company's honesty and integrity in submitting accurate and complete data on all studies performed. Even if every manufacturer had to send its most basic, raw data from animal tests to support its conclusions, that raw data could be slanted. Two improvements which would tend to reduce substantially the risk of another MER/29 would be performance of premarketing tests by the Government or medical institutions (to be paid for by the drug companies) and better organized collection of side effect data from the medical profession.

The United States Congress performed admirably in the MER/29 episode as a watchdog of both the FDA and the industry it is supposed to regulate. Senator Humphrey's committee took testimony on MER/29, published numerous confidential FDA memos (which otherwise would not have been available to the civil litigants), and pinpointed the weaknesses of the review system on numerous occasions.⁹⁴

E. To the Public

Describing the impact of the MER/29 fiasco upon the drug-consuming American public involves summarizing in general terms the whole litigation and group effort. The author believes that through concerted activity the injured plaintiffs received better representation from the bar and fuller, quicker settlements than they would have obtained had every plaintiff and his counsel gone his own way.

The author believes that the net result of the litigation has been to bring home to the pharmaceutical industry and all manufacturers the public's demands that careful thought go into the formulation, production and marketing of products. This is, after all, the significance of the New York

Prevention: New Drugs and Nuclear Reactors, 68 W. VA. L. REV. 109 (1965) (discussing MER/29).

⁹³ See note 5 *supra*.

⁹⁴ See note 12 *supra*.

jury's award of 850,000 dollars in punitive damages.⁹⁵ If regulation by the FDA, Congress, the medical profession, and the industry itself does not result in improvement, then the private enterprise system of civil litigation will provide the solution.

⁹⁵ See note 46 *supra*.