No. 14407

IN THE SUPREME COURT OF THE STATE OF MONTANA

1979

VICTOR F. HILL and MINNIE M. HILL,

Plaintiffs and Appellants,

-vs-

SQUIBB & SONS, E.R., A FOREIGN CORPORATION; and FREDERIC S. MARKS, M.D.,

Defendants and Respondents.

Appeal from: District Court of the Thirteenth Judicial District,

Honorable Robert Wilson, Judge presiding.

Counsel of Record:

For Appellants:

Kelly and Foley, Billings, Montana William T. Kelly argued, Billings, Montana

For Respondents:

Crowley, Haughey, Hanson, Toole & Dietrich, Billings, Montana Jack Ramirez argued, Billings, Montana Anderson, Symmes, Brown, Gerbase, Cebull & Jones, Billings, Montana

Submitted: February 8, 1979

Decided: APR -6 1979

Filed: APP - 1974

Thomas J. Kearney

Mr. Chief Justice Frank I. Haswell delivered the Opinion of the Court.

This is an appeal by plaintiffs from judgments entered in the District Court of Yellowstone County on a directed verdict in favor of defendant Squibb & Sons, a partial directed verdict in favor of defendant Frederic S. Marks, and a jury verdict rendered in favor of Dr. Marks on the remaining claims against him.

plaintiff Victor F. Hill suffers from severe allergic reactions (contact dermatitis) to a variety of substances and most severely to petroleum based products. Hill was a mechanic by trade, and thus was subject to constant exposure to those products. He was first treated by defendant Dr. Marks in 1952, at which time the flareups of his dermatitis were occurring only about twice a year. By the mid-1960's, however, plaintiff's condition had worsened to the point where he was seeing Dr. Marks three or four times a month. After 1969, the visits to Dr. Marks averaged about two times a month.

A well recognized treatment of skin problems is the use of a class of drugs known as steroids, a kind of synthetic cortisone. Cortisone and all cortisone related drugs have significant and well-known side effects.

Dr. Marks initially treated plaintiff with injections of ACTH, a chemical which stimulates natural production of cortisone by the adrenal glands. The ACTH was administered in conjunction with topical steroid creams applied directly to the affected areas and prescriptions for steroid pills to be orally ingested. In 1965, Dr. Marks began using an injectible steroid called Kenalog-40 which had recently been put on the market by defendant Squibb & Sons. From 1965 to 1970, Dr. Marks gave plaintiff injections of Kenalog-40, together with oral and topical steroids, at approximately two week intervals. Occasional injections of ACTH were also given to plaintiff during that period.

In the summer of 1970 plaintiff spilled brake fluid over a large part of his body, causing an extremely severe flare-up of the dermatitis. Dr. Marks increased the steroid treatments by supplementing the ACTH and Kenalog-40 injections with more oral steroids. Over the last five months of his treatment by Dr. Marks, up to his final visit on January 18, 1971, plaintiff was treated with a total of 1450 mg. of sterane, an oral steroid, and 440 mg. of Kenalog-40 by injection.

At his last visit to Dr. Marks in January 1971, plaintiff was referred by Dr. Marks to the Billings Clinic. Plaintiff had some facial swelling which Dr. Marks wanted the clinic to check into. On January 20, 1971, the Billings Clinic referred plaintiff to its staff dermatologist, a Dr. Smoot. Upon learning of plaintiff's history, Smoot immediately discontinued the injections of steroids because he "could see nothing but problems down the road." Dr. Smoot continued to prescribe oral steroids and steroid creams, gradually tapering them off. As the steroid treatment was lessened, the dermatitis worsened, until in July 1971 it was so bad Hill was disabled completely and had to give up his job.

In March 1971, while under treatment at the Billings Clinic, Hill first noticed blurring vision and in the fall of that year he required surgical removal of cataracts. In 1973, he developed back pain and was diagnosed to have osteoporosis, a loss of calcium in the bones. Cataracts and osteoporosis of the types that plaintiff exhibited are both characteristic side effects of steroid treatment.

On September 9, 1974, a complaint was filed in Yellow-stone County District Court by Victor and Minnie Hill alleging that plaintiff's cataracts and osteoporosis were the result of the actions of Squibb & Sons and Dr. Marks. The claim against Squibb & Sons was framed in three counts, alleging negligence,

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strict liability in tort, and breach of express and implied warranties. The central theory of the claim was that Squibb's Kenalog-40 was negligently marketed and was a defective product because the package inserts provided with the drug did not warn specifically enough of its dangerous side effects. As to Dr. Marks, the complaint alleged, in summary, negligence in failing to fully advise plaintiffs in regard to the risks associated with steroid treatments and in failing to properly monitor the effects of the treatment on Victor Hill over the nearly twenty year period in which steroids were administered to him.

After a period of extensive discovery, jury trial was had on the matter before Judge Robert H. Wilson. Plaintiffs testified that Dr. Marks had never told them of the side effects of steroid treatment, and that if he had, then Victor Hill would have quit his job to avoid exposure to the substances which caused his dermatitis. Dr. Marks and his nurse, on the other hand, testified that while the specific side effects were never enumerated, plaintiffs were informed many times that steroid treatment was dangerous, that Dr. Marks hesitated to continue using it, and that Victor Hill should get another job. There was evidence that plaintiff did, in fact, try to seek other employment but had no alternative skills. There was also testimony that plaintiff's condition was a severe one, that long-term steroid therapy, while risky, was not entirely unheard of, and that the decision to undertake such therapy is a matter of informed judgment by the treating physician after weighing the risks and benefits.

At the close of plaintiffs' case, defendant Squibb & Sons' motion for directed verdict was granted on the ground that there was no expert testimony that the package insert Squibb included with Kenalog-40 was inadequate in warning of its side effects. Defendant Marks also moved for directed verdict, raising the statute of limitations as a bar and arguing further that plaintiff

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had failed to establish a prima facie case because there had been no expert testimony that Dr. Marks had failed to act as a reasonably prudent physician in the area would have acted in the same circumstances. The court denied Marks' motion, holding that in regard to the statute of limitations there was a question of fact for the jury as to when plaintiffs' claim arose; and that while lack of expert testimony was fatal to the plaintiffs' claim in regard to the question of malpractice, the issue of lack of informed consent should go to the jury because the question of whether plaintiffs had been told enough to make their own judgment as to continuation of the treatment was a question "readily ascertainable by the layman." The case was submitted to the jury in that posture, and a verdict in favor of defendant Marks was returned. The verdict was rendered in a general form; it does not appear from the record whether the jury found the statute of limitations issue to be determinative or if it was rather the merits of the informed consent question that controlled. On appeal, plaintiffs raise the following issues: 1. Whether the filing of an ex parte trial brief by defendant Squibb was a violation of plaintiffs' due process rights. Whether the trial court erred in granting a directed verdict in favor of defendant Squibb. Whether the trial court erred in excluding from evidence certain of plaintiffs' proposed exhibits.

- 4. Whether the trial court erred in granting a directed verdict in favor of defendant Marks on the issue of malpractice.
- 5. Whether the trial court erred in submitting the issue of the statute of limitations to the jury rather than treating it as a matter of law to be decided by the court.

Plaintiffs first objected to Squibb's ex parte trial brief in the lower court in a motion for a new trial. Plaintiffs' specific objection was that Squibb's ex parte brief had compromised

plaintiffs' case in that it failed to cite many pertinent decisions and distorted plaintiffs' evidence and the applicable law. Plaintiffs also objected to the practice of allowing ex parte trial briefs in general, contending that it violates a party's right to an adversary hearing.

Rule 19 of the Rules of Practice of the District Court of the Thirteenth Judicial District specifically allows the filing of trial briefs to be used solely for the benefit of the trial court and not divulged to opposing counsel. There is little authority addressed to the propriety or impropriety of this practice.

The ABA Code of Professional Responsibility, DR 7-110(B), contemplates submission of trial briefs without service on opposing counsel where "authorized by law". "[I]n the absence of statute, rule, direction of the court, or agreement between counsel requiring service on opposing counsel, it is not necessary, and indeed not wise, to exchange trial briefs because of the possibility of educating opposing counsel as to the lawyer's theories in regard to his case." 5 Am.Jur.Trials p. 92-93. The literature on preparation for trial in products liability cases strongly recommends filing of trial briefs by plaintiffs in such actions. Cf. 12 Am.Jur. Trials p. 121.

We recognize that theoretically a rule allowing for the filing of <u>ex parte</u> briefs may be suspect in that it conflicts with the spirit of openness and cooperation underlying the modern rules of civil procedure. Nonetheless, judges have a right to secure a trial brief from the attorneys in a cause and, indeed, in a complex case such a brief may be indispensible to inform the judge of the nuances of the arguments that will be forwarded at trial. In our opinion, if the fact that the contents of the brief will be divulged inhibits counsel from accomplishing that

end and thereby impedes the ability of the judge to be fully informed, then a rule allowing for <u>ex parte</u> trial briefs is defensible.

In any event, plaintiffs' attack on the rule here on constitutional grounds is not persuasive. Plaintiffs themselves could have filed such a brief if there were matters they felt were in need of clarification or explanation. Plaintiffs presented testimony for eight days, at the conclusion of which Squibb moved for directed verdict. Thereafter, both the attorney for Squibb and the attorneys for plaintiffs were given ample opportunity to argue the motion. Under these circumstances, we cannot find that plaintiffs were denied due process. Furthermore, our reading of the trial brief in conjunction with the record and our review of the authorities cited in it does not indicate that plaintiffs' case was in any way compromised thereby. We find no error on this point.

We now turn to the second issue on appeal; alleged error in the directed verdict for Squibb & Sons. Squibb maintains that the directed verdict was proper because plaintiffs failed to produce expert testimony that the package insert in Squibb's product inadequately warned of dangers. Squibb contends that because of this failure plaintiffs did not establish a <u>prima facie</u> case. We agree.

As a general rule, the duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given to the physician who prescribes it. Dyer v. Best Pharmical (Ariz.App. 1978), 118 Ariz. 465, 577 P.2d 1084; Terhune v. A. H. Robins Co. (1978), 90 Wash.2d 9, 577 P.2d 975; McEwen v. Ortho Pharmaceutical Corp. (1974), 270 Or. 375, 528 P.2d 522; Davis v. Wyeth Laboratories, Inc. (9th Cir. 1968), 399 F.2d 121; 28 C.J.S. Drugs & Narcotics Supplement §57. By logical extension, then, since the warning is directed to physicians,

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only they or someone with similar expertise concerning pharmeceuticals would be qualified to determine whether or not the warning was adequate.

There are no Montana cases specifically holding that a plaintiff must produce expert testimony to sustain an action against a drug company for failure to warn adequately of side effects of its products. There are, however, numerous Montana decisions to the effect that, in a malpractice suit against a doctor or dentist, expert evidence is the only proper guide and without it a plaintiff cannot recover. Cf. Llera v. Wisner (1976), 171 Mont.254, 557 P.2d 805, 33 St.Rep. 1211; Collins v. Itoh (1972), 160 Mont. 461, 503 P.2d 36; Callahan v. Burton (1971), 157 Mont. 513, 487 P.2d 515; Negaard v. Feda (1968), 152 Mont. 47, 446 P.2d 436. We hold that the reasoning of these decisions extends to the situation involved here.

In matters "with respect to which a layman can have no knowledge at all, the court and jury must be dependent on expert evidence." Callahan, 157 Mont. at 520, 487 P.2d at 518-519. adequacy of a warning directed to physicians is such a matter. This conclusion is consistent with the only other case we have found where on similar facts an attempt was made to reach the jury without expert testimony that the warning was inadequate. Carlsen v. Javurek (8th Cir. 1975), 526 F.2d 202. a directed verdict in favor of the manufacturer/ an anesthetic was upheld on appeal. Here, as in Carlsen, there was no expert testimony that the warning was inadequate. On the contrary, the only expert testimony on the issue was that of Dr. Marks, who stated that in his opinion the warning was adequate. Therefore, even viewing the evidence in the light most favorable to plaintiffs, we find that the directed verdict in favor of Squibb & Sons was correct.

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The third issue on appeal involves alleged error in exclusion from evidence of several of plaintiffs' proposed exhibits. The contested items are a 1977 Handbook of Practical Pharmacology stating that osteoporosis could be a complication of long-term steroid treatment, and a Contac package. We find no error in the exclusion of the former because a 1977 publication is no proof of knowledge that could be imputed to Squibb & Sons during the period 1965 to 1971 when plaintiff was being treated. Plaintiffs argued that the Handbook should have been admitted under Rule 407, Mont.R.Evid. That rule has no application here because the Handbook did not originate with Squibb and was not a subsequent remedial measure taken by Squibb. As to the Contac package, plaintiffs apparently offered it as an exhibit because defense counsel in his opening statement noted that Kenalog-40 was "like a Contac pill" in that the drug is suspended in the bloodstream and dissolved into the system over a period of time. From this, plaintiffs sought to use the warning on the Contac package that it is "not for frequent or prolonged use" as evidence of inadequacy of the warning on the Kenalog-40 package insert for lack of that phrase. Plaintiffs' argument is without merit. The Contac package warning has no relevance because Contac is a nonprescription drug and the warning is not intended for the informed use of a physician but for the patient himself. The District Court properly excluded both exhibits.

The fourth issue under consideration concerns the directed verdict for Dr. Marks on the issue of malpractice. The District Court held that plaintiffs! failure to produce expert testimony in that regard was fatal to their cause of action. Plaintiffs contend that this was error because Dr. Marks allegedly admitted that he had violated the applicable standard of care and thereby provided against himself sufficient expert testimony to establish a prima facie case.

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It is true that in several recent cases we have cited with approval Evans v. Bernhard (1975), 23 Ariz.App. 413, 533 P.2d 721, for the proposition that third party expert testimony is not necessary if a defendant doctor's own testimony establishes the standard of care and departure from it. Montana Deaconess Hospital v. Gratton (1976), 169 Mont. 185, 545 P.2d 670; Llera v. Wisner (1976), 171 Mont.254, 557 P.2d 805, 33 St.Rep. 1211. Further, in Thomas v. Merriam (1959), 135 Mont. 121, 337 P.2d 604, we indicated that negligence of a doctor may be shown by his own admissions. The crux of this issue is, then, did Dr. Marks in fact testify what the standard of care was and that he had violated it? We find that he did not.

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In urging that Dr. Marks did so testify, plaintiffs rely primarily on the following exchange that occurred during cross-examination:

"Q. Is it fair to say that with respect to Vic Hill, from the standpoint of the standard of care, you didn't apply to him in administering Kenalog that standard of care that you think you should have, is that correct? A. In retrospect.

"Q. The answer is yes? A. Yes."

This short colloquy taken out of context does not, however, when read in balance with the rest of Dr. Marks' testimony, have the conclusive effect plaintiffs would give it. It does not appear that Dr. Marks ever established what the standard of care was, or admitted that he violated it. At one point he says "I was the standard of care", since he was the only doctor in the community with specialized training in the treatment of disorders like that of Victor Hill. He also testified that in Victor Hill's case, in his best medical judgment, there were no alternatives to the treatment he gave. Plaintiffs' contentions in this regard are not borme out by Dr. Marks' testimony, and the District Court did not err in directing a verdict in his favor on the malpractice claim for lack of expert testimony.

In conjunction with the directed verdict on the malpractice

issue, Dr. Marks has asked us to review the trial court's denial of his motion for directed verdict on the issue of informed consent. Marks contends that the trial court erred in submitting the issue of informed consent to the jury in view of the fact that there was no testimony, expert or otherwise, that an ordinarily prudent physician would have been more specific in warning of the possible side effects of steroid treatment. Marks maintains that even though he has not cross-appealed on this matter we can review the denial of his motion for directed verdict on the informed consent issue under Rule 14, M.R.App. Civ.P. From our research into the authorities construing the statutory predecessors of Rule 14, M.R.App.Civ.P., it does not appear that Marks comes within either its scope or its purpose on the circumstances present here. Francisco v. Francisco (1948), 120 Mont. 468, 191 P.2d 317, 1 ALR2d 625; J. M. Hamilton Co. v. Battson (1935), 99 Mont. 583, 44 P.2d 1064, 101 A.L.R. 520; 5 Am Jur 2d Appeal and Error §653. Therefore we decline to undertake the review requested by Dr. Marks in this regard.

Nonetheless, we note in passing that the doctrine of informed consent is one concerning which there is significant confusion caused by a failure in many of the reported cases to recognize distinctions. See 36 Ford.L.Rev. 639 (1968). "In most cases involving this issue, courts have held that expert testimony is necessary to establish the existence and scope of a physician's duty to inform his patient of the risks of a proposed treatment. The type of expert testimony required is testimony as to the degree of risk or, more commonly, testimony as to the standard medical practice to disclose risks under the same or similar circumstances or, similarly, testimony as to whether a reasonable medical practitioner would have disclosed a given risk under the same or similar circumstances." Annot. 52 ALR3d 1084, 1088. Montana follows the latter version of the majority rule.

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Negaard v. Feda (1968), 152 Mont. 47, 446 P.2d 436; Doerr v. Movius (1970), 154 Mont. 346, 463 P.2d 477; Llera v. Wisner (1976), 171 Mont. 254, 557 P.2d 805, 33 St.Rep. 1211.

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The trial court judge in this case was aware of these Montana decisions when he ruled on Dr. Marks' motion for directed verdict. He allowed the issue of informed consent to go to the jury despite the absence of expert testimony because he felt that the circumstances of the case came within language from Llera, that expert medical testimony is not necessary if "the conduct complained of is readily ascertainable by a layman." Llera v. Wisner, 557 P.2d at 811, 33 St.Rep. at 1217-1218. We note that this language from Llera goes to the question of the establishment of a standard of care to demonstrate negligence generally rather than to a standard of sufficiency of the physician's disclosure. In our opinion, there are different considerations involved. Cf 36 Ford.L.Rev. 639 (1968). In any event, since the jury found for Dr. Marks, if there was error in submitting the informed consent issue to them it was harmless error. Therefore, any further discussion of the correctness or incorrectness of the distinction drawn by the trial court judge would be inappropriate here.

by the court in submitting to the jury the question of whether plaintiffs' claim was barred by the statute of limitations. Plaintiffs contend that in Montana the application of the statute of limitations is to be determined by the court as a matter of law. In support of that position plaintiffs rely on Hornung v. Richardson-Merrill, Inc. (D.Mont. 1970), 317 F.Supp. 183. Hornung was a products liability action against a drug manufacturer where the defendant's motion for summary judgment on the statute of limitations was denied because there was an issue of fact as to when the plaintiffs should have become aware of the causal connection between the damages at issue and the defendant's product. Judge

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Russell Smith stated that on the trial of the case the Court would resolve that issue of fact on the basis of the evidence presented. In a footnote to that statement, Judge Smith noted:

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"I would have thought that the fact problems surrounding the application of a statute of limitations would be resolved by a jury in a jury case, but apparently the rule is otherwise." Hornung, 317 F.Supp. at 185.

The cases cited in support of that footnote are Falls Sand & Gravel v. Western Concrete, Inc. (D.Mont. 1967), 270 F.Supp. 495, and Owens v. White (9th Cir. 1965), 342 F.2d 817. Our review of those decisions and the cases cited in them indicates that they represent a line of authority that was inapplicable to the circumstances, and that the initial thought mentioned by Judge Smith in his footnote was correct.

Falls Sand & Gravel, supra, was a case involving alleged negligent misrepresentation by a contractor of the amount of materials to be furnished by a supplier. The court equated negligent misrepresentation with fraud and cited several Montana fraud cases holding that the time at which there has been a discovery of facts constituting fraud to start the running of the statute of limitations is a question of law. Kerrigan v. O'Meara (1924), 71 Mont. 1, 227 P. 819; Ray v. Divers (1928), 81 Mont. 552, 264 P. As to Owens, supra, that was a malpractice action, but it was a decision construing Idaho law under which the issue of when a plaintiff's claim accrued for purposes of the statute of limitations is apparently a preliminary matter of law in every case "and like all issues of law must be resolved by the court even though this will require evidence." Owens, 342 F.2d at 819.

In relying on <u>Falls Sand & Gravel</u> and <u>Owens</u>, the court in <u>Hornung</u> overlooked the line of authority which controls here and should have been controlling there. Accordingly, plaintiffs' reliance on <u>Hornung</u> here is inappropriate. The rule in Montana and in the majority of jurisdictions is that whether an action is

barred by the statute of limitations is for the jury when there is conflicting evidence as to when the cause of action accrued. Stagg v. Stagg (1931), 90 Mont. 180, 300 P. 539; 54 C.J.S. Limitations of Actions §399. That was the case here. Plaintiffs made some unsubstantiated allegations that Dr. Marks had somehow concealed their cause of action from them, but there is no evidence in the record that would support application of the special rule in fraud cases here. We hold that the District Court properly submitted the issue of the statute of limitations to the jury.

None of the specifications of error raised by plaintiffs have merit. The judgments entered by the District Court are affirmed.

Chief Justice

• • • • • • Justice John C. Sheehy, specially concurring: I concur with the foregoing opinion, but I want to express my disapproval of Rule 19 of the Thirteenth Judicial District, or any rule like it which permits the filing of ex parte briefs with the Court. I do not find in this case that the filing of the ex parte trial brief deprived the plaintiff of due process, but I can conceive of situations in which substantial harm would be done to a party's case where trial briefs (in effect, private communications to the trial court that are not served upon the other party) deprive the District Court of the benefit of the adversary process. The spirit of the federal rules of civil procedure, upon which the Montana rules of civil procedure are based, is full and open disclosure of fact and law. That spirit is best expressed in Burton v. Weyerhaeuser Timber Company (D.C. Oregon 1941), 1 F.RD 571, where the trial court said:

". . . I can sympathize with the desire of counsel, experienced in the older forms of practice, to withhold disclosure of such dramatic issues until the midst of trial, but it must be made clear that surprise, both as a weapon of attack and defense, is not to be tolerated under the new federal procedure. . .

"Faithfully administered in spirit, as my senior colleague and I are endeavoring to administer them, the new rules outlaw the sporting theory of justice from Federal courts." 1 F.R.D. at p. 573.

All attorneys practicing under the Montana Rules of Civil Procedure should come to know that the guidepost of practice under the rules is full disclosure of law and fact. This is most effectually done by adherence to pretrial procedure. At that time, as the Court said in Burton, supra:

Parties are expected to disclose all legal and fact issues which they intend to raise at trial, save only such issues as may involve privilege or impeaching matter. As to these two exceptions, disclosure may be made to the judge conducting the pretrial hearing without disclosure to opposing counsel, and a ruling will be made on the exception claimed.

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"The test to be applied on impeaching matter or any factual issue, which counsel feels should not be disclosed to his opponent in advance of the trial, is the simple one--whether disclosure or nondisclosure will best promote the ends of justice. That is for the judge conducting the pretrial hearing to determine. " 1 F.R.D. at 572.

The day is gone when the prototype old fashioned attorney produced the hidden witness at trial or the uncited but decisive case and left the opposing attorney lying bloody on the courtroom floor. Justice is achieved, under the spirit of our modern rules, by full and open disclosure of The statements in Burton were approved in law and fact. the Ninth Circuit Court of Appeals in Walker v. West Coast Fast Freight Inc. (9th Cir. 1956), 233 F.2d 939.

Justice Justice