

1990

Ilo Marie Grundberg, Janice Gray v. The Upjohn Company : Petition for Rehearing

Utah Supreme Court

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INTRODUCTION

COME NOW Ilo Marie Grundberg and Janice Gray, plaintiffs and appellees, and timely file this Petition for Rehearing pursuant to Utah R.App.P.35. Appellees submit that in rendering the decision in this cause, the majority of this Court has overlooked or misapprehended certain points of law and fact which would require that the majority opinion be vacated and the minority opinion be made the judgment of this Court. To that end, plaintiffs respectfully file this petition for rehearing.

A. The Court Has Overlooked The Inefficiency Of Or Misapprehended The Efficiency Of The FDA And Abdicated Judicial Functions To The Executive Branch

This Court has issued an opinion reversing the public's longstanding right to rely upon the judicial system for an impartial airing of its grievances. Rather than relying upon the crucible that the courtroom becomes in our adversarial system, injured individuals in Utah have now been deprived by this court-made rule of the full benefit of strict products liability protection when prescribed any drug product,¹ particularly when those individual rights were already subjected to the court-made learned intermediary doctrine. In dissent, Justice Stewart observed that the Supreme Court of Utah had "little basis for abdicating judicial responsibility to the FDA." Grundberg, Slip Op. at p.19 (Stewart, J., dissenting).² Plaintiffs urge this Court

¹ This Court held that "[p]laintiffs may still recover under a strict liability claim by demonstrating that the product was unreasonably dangerous due to an inadequate warning, a manufacturing flaw, mismarketing, or misrepresenting information to the FDA." Grundberg, Slip Op. at p.24 n.8 (erroneously labeled footnote 7).

² In submitting their first brief, plaintiffs adhered to Utah R.App.P.41 and kept within the Record certified by this Court.

to reconsider the wisdom of such abdication in light of the following discussion of the FDA's efficiency and integrity.

Congressional investigations time and again have demonstrated that the FDA has repeatedly approved drugs -- many of which eventually were withdrawn from the market for reasons of public safety -- in complete ignorance of critical information either in its own files or in the published medical literature, or both, relating to the hazards of such drugs. For example, the FDA approved Oraflex on April 19, 1982, for the treatment of arthritis. Eli Lilly withdrew the drug from the market on August 4, 1982, in the wake of 11 reported deaths associated with the drug's use in the United States and 61 reported deaths in the United Kingdom. Of principal concern were reports of serious and sometimes fatal Oraflex-associated liver and kidney disease. In a report entitled, Deficiencies in FDA's Regulation of the New Drug "Oraflex", the House Committee on Government Operations, ("H.C.G.O.") a principal Congressional committee overseeing the FDA, found that in approving Oraflex for marketing, the FDA was unaware that it had received in the Oraflex clinical trials four reports of serious concomitant liver and kidney disease and two serious reports of kidney disease unaccompanied by liver injury.³ At the time the FDA approved

Defendant Upjohn ignored that Rule and submitted a voluminous Appendix. As part of this Petition for Rehearing, plaintiffs submit certain exhibits by an Appendix supporting their positions and to rebut the one-sided picture shown through Upjohn's Appendix.

³ See Deficiencies in FDA's Regulation of the New Drug "Oraflex", Fourteenth Report by the Committee on Government Operations, H.Rep.98-511, 98th Cong., 1st Sess. (1983),, pages 9 and 10. Appendix, Plaintiffs' Exhibit "A". As a consequence of its ignorance, the agency approved untruthful and misleading labeling that confined Oraflex-associated liver reactions to "liver function test abnormalities" which were "usually transient" and that denied altogether the existence of "evidence . . . of renal [kidney

Oraflex for marketing, and for several months thereafter, it was unaware of the number of reports of Oraflex-associated deaths it had received prior to its approval of the drug.⁴ Prior to approving Oraflex, the FDA made no effort to obtain information on its safety from foreign countries in which it was already marketed and was, therefore, unaware of a large number of reports of serious and sometimes fatal reactions to the drug submitted to British and Danish regulatory authorities.⁵ The FDA placed the public's health at risk by failing to enforce the legal requirement that drug manufacturers report all adverse reactions to a new drug under clinical investigation, information essential to weigh the risks against its potential benefits.⁶

The FDA approved Merital for the treatment of depression on December 31, 1984. Merital was withdrawn from the market in January of 1986 because of a large number of reports of serious immune-allergic or hypersensitivity reactions, including several fatalities, associated with its use. In a report entitled, FDA's Regulation of the New Drug Merital, the H.C.G.O. found that prior to approving Merital, the FDA overlooked clinical evidence it had received of the drug's allergy-inducing potential.⁷ The FDA also failed to ensure receipt and review of important information pertinent to the safety of Merital.⁸ The FDA's enforcement of its

toxicity in [the Oraflex] clinical studies." Id. at pp.9-10.

⁴ Id. at pages 11-12.

⁵ Id. at page 13.

⁶ Id. at page 22.

⁷ See FDA's Regulation of the New Drug Merital, Fifteenth Report by the Committee on Government Operations, H.Rep. 100-206, 100th Cong., 1st Sess.(1987), page 24. Appendix, Exhibit "B".

⁸ Id. at page 37. This deficiency included: a. important articles in the published world literature relevant to the drug's safety; and b. labeling, "Dear Doctor" letters, and other

adverse reaction reporting requirements was inadequate.⁹ H.C.G.O. concluded that the FDA exposed the American public to the potential hazards of Merital without requiring that the drug's efficacy be supported by substantial evidence derived from adequate and well-controlled studies, as mandated by law.¹⁰

The FDA approved Versed preoperative sedation, induction of general anesthesia and conscious sedation for short diagnostic or endoscopic procedures on December 20, 1985. Thereafter, Versed was associated with numerous reports of life-threatening and, in many instances, fatal episodes of cardiac and respiratory arrest, particularly when used for conscious sedation. The FDA concluded that these reactions were dose-related, but not until November of 1987, were the recommended conscious sedation doses for Versed substantially reduced. In a report entitled FDA's Deficient Regulation of the New Drug Versed, the H.C.G.O., concluding that the Versed doses originally approved for conscious sedation were excessive,¹¹ found that the recommended doses to which Versed had been reduced were identical to those reported to be effective and sufficient in several studies. When it approved Versed for marketing, the FDA was unaware of these important studies, notwithstanding that they had been prominently published in the

important regulatory information related to new drugs being marketed outside the United States that are under FDA review. Id. at pp. 37, 42.

⁹ Id. at page 71. In particular, the FDA overlooked clear evidence that Merital's manufacturer failed to submit Merital-associated safety information, as required by law. Id.

¹⁰ Id. at p.80.

¹¹ See Deficiencies in FDA's Regulation of the New Drug Versed, Seventy-First Report by the Committee on Government Operations, H.Rep.100-1086, 100th Cong., 2nd Sess. (1988), p.10. Appendix, Plaintiffs' Exhibit "C".

medical literature¹² and, in many instances, had been submitted to the agency and were, therefore, retrievable from the agency's files.¹³ H.C.G.O. also found that the FDA was not aware of the manner in which Versed was regulated in foreign nations.¹⁴ The FDA's enforcement of its reporting requirements continued to be grossly deficient. Most notably, the FDA failed to investigate the adverse reaction reporting practices of the manufacturer of Versed, notwithstanding data the agency had received from the company strongly suggesting that the firm had neglected to submit to the agency reports of Versed-associated deaths known to it prior to the drug's approval.¹⁵

The FDA approved Zomax on October 29, 1980, for the relief of mild to moderately severe pain. On March 4, 1983, marketing of the drug was halted by its manufacturer due to a very large number of allergic/anaphylactoid reactions associated with its use. Eventually, more than 2,100 such reactions were reported to the FDA. In a report entitled, FDA's Regulation of Zomax,¹⁶ the H.C.G.O. found that the FDA approved Zomax in violation of an agency policy requiring that its benefits be shown to outweigh its demonstrated carcinogenic risk.¹⁷ Again, FDA failed to make the

¹² Id. at page 20.

¹³ Id. at page 21.

¹⁴ Specifically, the agency did not know that: (a) Versed had been labeled for use abroad at substantially lower conscious sedation doses than had been approved in the United States; and (b) actions had been taken by foreign regulatory agencies to reduce the solution concentration of Versed and thereby minimize the risk of overdosing patients on Versed. Id. at page 25.

¹⁵ Id. at page 37.

¹⁶ See FDA's Regulation of Zomax, Thirty-First Report by the Committee on Government Operations, H.Rep.No. 98-584, 98th Cong., 1st Sess.(1983). Appendix, Plaintiffs' Exhibit "D".

¹⁷ Id. at page 5.

risk/benefit analysis this Court has placed within the exclusive province of the FDA. Also, the FDA's monitoring of Zomax-associated adverse reaction reports was deficient. When Zomax was removed from the market, the agency's computerized tracking system showed that the FDA had only received 270 reports of Zomax-associated allergic/anaphylactoid reactions, whereas the drug's manufacturer had actually submitted 900 to the agency.¹⁸ The FDA also failed to note evidence in its possession suggesting that Zomax posed a higher risk of serious and sometimes life-threatening allergic/anaphylactoid reactions than other drugs in its class, particularly among patients with no prior history of allergy to Zomax or any other drug.¹⁹

The FDA is neither infallible, self-informed nor omniscient. That agency, like others, depends upon the industry which it regulates, and it seldom knows that which is not highlighted in the submissions made to it. This Court should consider carefully before sanctioning the FDA as the ultimate authority speaking to the safety of prescription drugs.²⁰

Numerous articles have discussed the task of the new Commissioner of the FDA in light of the decreasing efficiency, declining morale and eroding credibility of the FDA with both Congress and consumers. In an article published at or about the time of Dr. David Kessler's appointment as Commissioner, the Washington Post reported that:

¹⁸ Id. at pages 11-12.

¹⁹ Id. at page 16.

²⁰ Halcion received final approval for marketing on November 15, 1982, a date closely aligned with the approval problems related above.

The agency's credibility was damaged last year when four FDA officials were caught accepting bribes to speed up the approval of certain generic drugs.... Several of the largest companies were caught sending the agency fraudulent information about their drugs.... Inspections of products and food and drug manufacturing plants decreased from 36,528 in 1980 to 18,592 in 1989. Seizures of contaminated foods or adulterated pharmaceuticals dropped from 539 in 1980 to 142 in 1989.... Kessler says one of his first priorities is restoring credibility to the generic drug division. "We have to be sure that the agency is clean and that everyone who deals with it is clean," said Kessler....

Thompson, L., Finally, A New Chief For the FDA, The Washington Post, Nov. 20, 1990, included in the Appendix as Exhibit "E". The Associated Press reported:

The Food and Drug Administration, its reputation tarnished by the generic drug scandal, is trying to restore its credibility by strengthening enforcement across the range of its authority, the agency's new chief [Dr. David Kessler] said Wednesday. 'There has to be a sense out there that there is a will to carry out the statute,' 'Ensuring the accuracy of the data presented to this agency is a high priority,' said Kessler.... After uncovering fraud, bribery and corruption in the generic drug industry and the FDA's generic drug division, the agency changed the drug-approval process for these products. 'The honor system is out the window,' Kessler said. FDA inspectors now audit the information in companies' drug-approval applications to verify that the data is correct.... Previously, the agency relied on companies to be truthful. But the scandal uncovered numerous instances in which companies cheated on safety and effectiveness tests required for FDA approval. Dozens of drugs were taken off the market as a result....

The Associated Press, Feb. 27, 1991, Appendix, Exhibit "F".

In these and in the numerous other articles which have been published in recent months,²¹ the relative ineffectiveness of the FDA has been noted. The articles recognize that the problems at the FDA are pervasive. "'It is glaringly apparent that the FDA

²¹ Included within the Appendix as cumulative Exhibit "G" is a collection of articles discussing the condition of the FDA and the impact of Dr. Kessler's appointment and confirmation thereon.

cannot now execute all of its statutory responsibilities within the limitations of existing resources.' said [an advisory panel in a draft report] prepared by 15 experts chosen by the agency." Newsday, April 12, 1991, included in the Appendix as Exhibit "H". "A Federal Advisory Committee appointed to study the Food and Drug Administration says the agency is overwhelmed and incapable of coping with vastly increased duties caused by the AIDS epidemic, a flood of food imports and advances in medical science and technology." N.Y. Times, April 11, 1991, included in the Appendix as Exhibit "I". "In a draft of its final report, the panel of 15 experts says that F.D.A. laboratories and equipment are in abysmal condition, that some food factories are inspected only once every eight years and that the agency no longer has adequate scientific ability to evaluate new drugs, much less keep up with 'revolutionary advances occurring in the biological and medical sciences.'" Id.

These articles reflect the consensus among Congressional leaders and scientists that the FDA has not fulfilled its mission.²² To eliminate the judicial arena as one forum wherein is considered a prescription drug product's safety and efficacy and to rely entirely upon the FDA for the resolution of such concerns is to place the well-being of the public into the bureaucratic hands of a federal agency all too subject to the vagaries of politics and

²² See also the General Accounting Office's Report to the Chairman, Subcommittee On Human Resources and Intergovernmental Relations, Committee On Government Operations, House of Representatives: FDA Drug Review-Post-approval Risks 1976-85, page 57, included in the Appendix as Exhibit "J". (51.5% or 102 of 198 drugs analyzed have serious post-approval risks requiring labelling changes or withdrawal from the market.)

personalities. Plaintiffs urge this Court to reconsider its decision establishing the FDA as the forum of last resort for the citizens of Utah.

B. The Court Overlooked Or Misapprehended The Impact of The Court's Opinion Discouraging Safer And More Efficacious Drugs.

This Court identified several policy reasons as supporting its decision to afford protection from a strict product liability claim to all prescription drugs. In dissent, Justice Stewart addressed those policy reasons and identified competing policies militating against such protection. Plaintiffs submit that Justice Stewart has provided powerful reasons not to grant prescription drugs the unwarranted protection approved by the majority.

In addition, this Court's opinion overlooks the powerful motivation such protection fosters in manufacturers to achieve the approval, at whatever costs to scientific integrity, of the FDA. While such protection might drive some manufacturers to present their data in a more forthright manner, it is equally likely that many manufacturers will conduct themselves in the manner alleged by plaintiffs in the pending products liability case against Upjohn. That is, seeing the protection to be obtained through FDA approval, many manufacturers may misrepresent in the voluminous submissions to the FDA the scientific truth about the safety and efficacy of a particular drug.

Few plaintiffs have either the technical expertise or the extensive resources necessary to evaluate the truthfulness of a drug manufacturer's submissions to the FDA. As the reports and articles discussed above indicate, even the FDA has been unable to examine for comparison purposes the accuracy and completeness of

the summaries and technical reports submitted to it by a drug manufacturer with the underlying clinical trials data. The very breadth of the protection afforded to drug manufacturers by the Supreme Court of Utah will encourage deception at the approval stage.

Moreover, granting drug manufacturers even limited protection from strict liability for all drugs upon approval by the FDA creates a disincentive to engage in research and development toward making that particular drug, or a derivative thereof, safer and more efficacious. Once approval has been obtained a drug manufacturer has little incentive to fulfill its duty to remain abreast of scientific developments. See Barson v. E.R.Squibb & Sons, Inc., 682 P.2d 832, 835 (Utah 1984). "[P]ublic policy militates against finding as a matter of law that FDA approval of a particular drug relieves a pharmaceutical company of further responsibility to continue research and testing to develop safer products." MacGillivray v. Lederle Laboratories, 667 F.Supp. 743, 745 (D.N.M..1987). The court in MacGillivray recognized that "a tort judgment against a drug manufacturer may in fact accelerate development of better, safer products Id.

The protection afforded to drug manufacturers by this Court will encourage scientific stagnation rather than promote public safety.²³ Pharmaceutical manufacturers now will rest on the FDA's approval and use it as a broad shield against liability while at the same time recognizing it as a disincentive to further reporting

²³ See Page, Generic Product Risks: The Case Against Comment K And For Strict Tort Liability, 58 N.Y.U.L.Rev. 853 (1983), as well as Wagner, Strict Liability Isn't A Problem - It's A Solution, Vol.19: 1, 13(1989). Appendix, Plaintiffs' Exhibit K.

research and development.²⁴ In light of these policies, plaintiffs urge this court to reconsider its decision.

C. The Court Has Overlooked Or Misapprehended The Traditional Focus of Strict Liability Upon The Product Rather Than Conduct.

Indeed, the approach adopted by this Court dramatically undermines the very core of the doctrine of strict liability by focusing upon the conduct of both the manufacturer and the FDA rather than upon the product itself.

In strict liability, the plaintiff is not required to impugn the conduct of the maker or other sellers[,] but he is required to impugn the product. Under section 402A, it is said that the product must be in a 'defective condition unreasonably dangerous.' This simply means that the product must be defective in the kind of way that subjects persons or tangible property to an unreasonable risk of harm.

Prosser And Keeton On Torts (5th Ed.1984), §99 at p.695.²⁵ This Court so held in Ernest W. Hahn, Inc. v. Armco Steel Co., 601 P.2d 152, 158 (Utah 1979), recognizing that a manufacturer is strictly liable even where "the [manufacturer] has exercised all possible

²⁴ Plaintiffs submit that this decision is inconsistent with current Utah law as contained in the open courts and remedies provisions of the Utah Constitution at Article I, §11. See also Berry By and Through Berry v. Beech Aircraft, 717 P.2d 670 (Utah 1985). Therein, this Court recognized the propensity of defects in drug products and injuries caused thereby to appear many years after the initial marketing or use of such products. Id. at 674.

²⁵ The rule as contained in Section 402A "renders the maker of a product strictly liable to consumers or users for harm caused to them in the course of a foreseeable use of the product by its unreasonably dangerous conditions or qualities, without respect to fault" Harper, James & Gray, The Law of Torts Vol 5, §28.15 at p.445-45 (2d.Ed.1986) (emphasis added). "In strict liability, the central issue is the character of the product, not the conduct of the parties." Lee and Lindahl, Modern Tort Law, Vol.2, §27.02 at p.546-47 (Rev.Ed.) (footnote omitted). See also Greenman v. Yuba Power Products, 59 Cal.2d 57, 377 P.2d 897 (1963) (the purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the persons who are powerless to protect themselves).

care in the preparation and sale of his product"

With its opinion, this Court has eroded the full protection of strict liability and placed burdens not envisaged by that law upon persons injured by the product, rather than upon the manufacturer of the product most able to bear such burdens and which chose to place its products on the markets for profit. It is a dangerous principle for any court to determine as a matter of law that the executive branch of government, or a regulatory agency thereof, fulfills the duties the law imposes upon that branch merely by virtue of the nature of the duties relegated to it by the legislative branch. Yet that is what this Court has done --- and not in the area of state law, but of all things, in the area of federal law.

This Court's decision disregards the traditional focus of strict products liability law and returns emphasis to the conduct of the parties. In a strict products liability case in Utah involving prescription drug products, the emphasis will no longer be upon the defective or dangerous character of the drug but upon the conduct of the manufacturer and the approval process of the FDA. Underfunded plaintiffs who fail to carry such burdens will suffer the often devastating lifelong effects of using a defective product. Plaintiffs urge this Court to return the focus to that which has caused the harm - the product.

D. The Court Has Overlooked Or Misapprehended The Impact Of This Decision On The Learned Intermediary Doctrine And The Medical Profession.

In rendering its opinion, while recognizing the viability of the learned intermediary doctrine in Utah, this Court overlooked

the effect of such decision upon that doctrine, which already serves as an impediment to an individual's action to recover for injuries sustained pursuant to his or her use of a prescription drug product. The doctrine provides that "if a manufacturer knows or should know of a risk associated with its product, it is directly liable to the patient if it fails to adequately warn the medical profession of that danger." Grundberg, Slip Op. at p.14, citing Barson, 682 P.2d at 835. In Barson, this Court stated:

The manufacturer of ethical drugs has the duty of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows or has reason to know. The manufacturer is directly liable to the patient for the breach of such duty.

Barson, 682 P.2d at 835 (footnotes omitted).

With the instant decision, this Court has held that every physician who prescribes any prescription drug to his or her patient has by definition prescribed for that patient's use an "unavoidably unsafe" product. In any action brought against such physician, the plaintiffs therein would be entitled to an instruction to the jury that the drug or other prescription product at issue is, as a matter of law, "unavoidably unsafe". Whether such conduct in any given situation violates the standard of care will be a question for the jury. That the jury has been informed that the physician-defendant prescribed an "unavoidably unsafe" product is a species of evidence likely to sway a jury.

One result of this Court's decision to afford prescription drug manufacturers protection from strict products liability, then, is a possible diversion of liability for injuries suffered pursuant to the use of prescription drugs from the manufacturer of such

drugs to the prescribing physician. Physicians will be placed in the awkward position, one which undermines the confidence critical to a meaningful doctor-patient relationship, of informing their patients that the drug product being prescribed is "unavoidably unsafe", no matter how insignificant or how serious the illness, disease or injury confronted by the patient, and no matter how dangerous or how mild the medication prescribed. Patients will then face the difficult and paradoxical decision of whether to consent to such treatment in light of this knowledge. This alteration in Utah law presents the possibility of a physician deciding against use of prescription drugs because of his potential exposure to this shifted liability, a result which furthers neither the treatment of the patient nor the development and promotion of new drug products, results which are contrary to the policies sought to be furthered by the majority's decision.

Plaintiffs submit that this Court has overlooked the impact its decision would have upon the learned intermediary doctrine in Utah and upon the medical profession. Plaintiffs urge this Court to reconsider its opinion in light of this potentially explosive situation.

Counsel for petitioners certify that this petition is presented in good faith and not for the purpose of delay.

CONCLUSION

Plaintiffs and their counsel recognize the significant issues this Court faced in its deliberations in receiving and deciding this case of first impression. While plaintiffs' views of the legal issues and the justice of their cause are reflected in the

courageous dissents, their appreciation and respect extend to all the Court, and they are confident that this Petition for Rehearing will receive this Court's continued careful consideration.

In light of the gravity of this case, the issues involved and the severe ramifications of the Court's opinion upon Utah citizens suffering drug related injuries and deaths, plaintiffs respectfully request that this Court grant plaintiffs' petition for rehearing.

Only life-threatening conditions, injuries and diseases for which a safer therapeutic alternative is not available warrant the prescription of unavoidably unsafe drugs. As its past record indicated, the FDA, upon which the majority heavily relies, is neither an effective nor an omnipotent policing, regulatory agency inasmuch as it lacks both the resources and the expertise to do so. Public policy dictates that courts should not engage in legislation in violation of the separation of powers provision of the Constitution, for if Congress had such faith in the FDA, it should pass the federal legislation needed to equal in scope this Court's present decision.

Wherefore, Plaintiffs pray that a rehearing be granted in this case, that the majority decision as rendered by this Court be vacated, and that the present minority opinion of this Court be made the unanimous judgment of this Court.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that I have this day served the within and foregoing Petition For Rehearing On Certified Questions to The Supreme Court of Utah By The United States District Court, District of Utah Central Division, Honorable J. Thomas Greene, Jr., upon counsel for defendant by delivering four copies to appellant's counsel of record to:

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This 11th day of June, 1991.



OF COUNSEL FOR PLAINTIFFS