Jones Walker E*Zine

Products Liability
May 2001 Vol. 5

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Supreme Court Rules That Fraud-On-FDA Claims Against Manufacturer Are Preempted

Buckman Co. v. Plaintiffs' Legal Committee,
121 S.Ct. 1012, 148 L.Ed.2d 854, 69 USLW 4101 (2001)

On February 21, 2001, the U.S. Supreme Court ruled that a medical device company and its consultant cannot be sued by patients claiming that FDA approval was obtained by fraud. (See Newsflash, Feb. 2001, vol. 2.)

The case involved individuals who claim they were injured by the use of orthopedic bone screws in the pedicles of their spine. The plaintiffs alleged that the defendants, AcroMed Corp, the manufacturer of the “Variable Screw Placement Spinal Plate Fixation System”(VSP), and Buckman Co., a consulting firm for medical device manufacturers, made fraudulent misrepresentations to the FDA in order to obtain approval for marketing bone screws used in spinal surgery.

Buckman twice sought FDA approval of AcroMed's VSP for use in spinal surgery; but the FDA rejected both applications. Buckman then sought and won approval to use the VSP in arm and leg bones. The suit claims that Buckman sought and won FDA approval even though the defendants always expected that doctors would use the product for spinal surgery.

Chief Justice William H. Rehnquist said, “[S]tate-law fraud-on-the-FDA claims inevitably conflict with, and therefore are impliedly pre-empted by federal law.” “The FDA ... has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the agency.” Chief Justice William H. Rehnquist further stated that this flexibility was a “critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives.”

For example, “off-label” use of medical devices is “an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine,”Rehnquist said. State law claims for off-label use would subject a manufacturer to “unpredictable civil liability”. Additionally such claims would “deter off-label use despite the fact that the FDCA [Federal Food Drug and Cosmetic Act] expressly disclaims any intent to directly regulate the practice of medicine.”

According to Chief Justice Rehnquist, plaintiffs' reliance on *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238 (1984), was misplaced. *Silkwood* was based on principles of traditional state tort law (the duty of care owed by an employer to employee), not a fraud-on-the-agency theory. Also, unlike the federal statutory and regulatory scheme governing the development and utilization of atomic energy analyzed in *Silkwood*, there “is clear evidence Congress intended the MDA [Medical Device Amendments] be exclusively enforced by the federal government.”

Similarly, Chief Justice Rehnquist said the claims in *Medtronic Inc. v. Lohr,* 518 U.S. 470 (1996), arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely a violation of the FDCA requirements. “In sum, were the plaintiffs to maintain their fraud-on-the agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case,” Chief Justice Rehnquist concluded.

- Robert L. Walsh

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Summary Judgments Granted Within 10 Days Of Trial Will Be Vacated

Lassere v. State,
2000-0306 (La.App. 1 Cir. 3/28/01), ___ So.2d ___, 2001 WL 293698.

The First Circuit will enforce the deadlines set forth in the summary judgment Code article, to the extent of vacating summary judgments granted when those deadlines are not observed.

In this case the defendant filed its motion one month in advance of trial, but failed to serve the plaintiff until the day before the hearing. This violated Article 966(B)'s requirement that summary judgments be served at least ten days before the time specified for the hearing. The trial judge attempted to cure the problem by giving the plaintiff additional time to submit his opposition memorandum and deciding the motion on the papers. However, this in turn caused a further delay with the result that on the date of the judge's decision granting the summary judgment, only five days remained until trial. This violated Article 966(D)'s requirement that judgments on summary judgment motions “shall be rendered at least ten days prior to trial.”

The First Circuit rejected the approach taken by some other courts that encroachments on the ten day time period will only affect the validity of judgments if the opponent can show prejudice. They also rejected the defendants' plea that they would be greatly prejudiced by having to try a case when no material issues of fact existed. Finding the deadlines of Article 966 to be mandatory the court held that, “the mover who seeks to avoid trial by summary judgment proceedings must comply with the procedural safeguards outlined therein.”

While the court's strict reading of the rule appears to be correct, it does point out a problem with Article 966. The ten day pre-trial deadline which was inserted in the 1997 revisions to the article was intended to help the parties avoid trial preparation expenses in cases in which summary judgment was merited by forcing trial judges to make their decisions early. However, when a trial judge delays a decision to within the ten day period, whether by the fault of the parties or not, the parties are forced to incur not only trial preparation expenses, but also the expenses of actually trying the case, even though the case should have been dismissed on summary judgment.

As a practical matter, one wonders how this case will be handled on remand. Will the trial court try the case, or will it simply set a trial date several months out and then rehear the summary judgment and issue the same decision sufficiently in advance of the trial? Also, should a trial court continue a case when it receives a summary judgment which appears meritorious, if there is not enough time to render a decision ten days in advance of trial? We will follow this issue to see how trial courts work with the summary judgment deadlines. Meantime, the lesson of this case is to file your summary judgment motion early.

- Madeleine Fischer

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Employer's Pre-1996 Fault Must Be Quantified, Then Reallocated

Fleniken v. Entergy Corp.,
2000-1824 (La.App. 1 Cir. 2/16/01), ___ So.2d ___, 2000 WL 133205

Considering an accident which occurred in February, 1996, the Louisiana First Circuit holds that when an employer's negligence contributes to an accident, the employer's percentage of fault must be assessed by the fact finder. However, that percentage must then be reallocated among all other persons at fault in the accident.

Wilburn Fleniken was injured when he walked into a low-hanging electrical distribution line. Fleniken, an independent contractor truck driver, was inspecting a trailer on premises owned by TMI at the time of the accident. Reversing certain jury findings, the First Circuit found that the accident was caused by the fault of three entities: 1) TMI, the owner of the premises; 2) Entergy, the utility operator; and 3) Safeway, the company which contracted with Fleniken for his truck driving services. The Court allocated fault in the following percentages: TMI - 40%; Entergy - 20% and Safeway - 40%.

The First Circuit also determined that even though plaintiff Fleniken was an independent contractor, because his work for Safeway predominately included manual labor, Safeway was entitled to immunity from tort liability under the Louisiana Worker's Compensation Act. Having found that Safeway could not be required to pay 40% of the jury award because of its immunity, the Court was faced with the issue of how to dispose of Safeway's 40% in the judgment.

The Court reviewed Louisiana Supreme Court decisions bearing on this issue from 1991 to the present, noting that the Supreme Court had several times changed its views on the question. Articles 2323 and 2324 of the Louisiana Civil Code were both amended effective April 16, 1996, after the date of Fleniken's accident. Article 2323, Comparative Fault, was amended to clarify that the fault of all persons causing or contributing to an injury or death must be quantified regardless of whether the person is a party to the action, insolvent, unable to pay, immune by statute, or even unidentified. Article 2324 was amended to abolish solidary liability under most circumstances, providing that no one could be held liable for more than his own percentage of fault. The Louisiana Supreme Court has held that Article 2323 is procedural and is to be applied retroactively, but that the pertinent part of Article 2324 is substantive and may only be applied prospectively.

Applying these principles the First Circuit concluded that Safeway's 40% had to be reallocated proportionately between the two remaining tortfeasors, Entergy and TMI. Since TMI was originally allocated twice the fault of Entergy, after reallocation, their percentages of the judgment were 66.67% and 33.33% respectively.

Although this case is not a products liability case, such cases often involve co-existing fault of an employer, particularly in the toxic tort and asbestos context. If the First Circuit's ruling stands, then the holding of this case will apply to all cases arising out of incidents occurring prior to April 16, 1996 -- at least in that jurisdiction. After April 16, 1996 the amended Article 2324 applies and the result will be different: an employer's fault once assessed will not be reallocated to any other party.

- *Madeleine Fischer*

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Remember that these legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:

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