COURT OF APPEALS OF WISCONSIN
PUBLISHED OPINION

Case Nos.: 97-0192 & 97-0194

Complete Title of Case:

97-0192
STEVEN STAUDT, ON BEHALF OF HIMSELF AND ALL OTHERS SIMILARLY SITUATED,

PLAINTIFF-APPELLANT,

V.

FROEDTERT MEMORIAL LUTHERAN HOSPITAL, SENTRY INSURANCE, WISCONSIN HEALTH AND HOSPITAL ASSOCIATION, OHIO HOSPITAL INSURANCE COMPANY, AND WISCONSIN PATIENTS COMPENSATION FUND,

DEFENDANTS-RESPONDENTS.

97-0194
DENNIS DVORAK, ON BEHALF OF HIMSELF AND ALL OTHERS SIMILARLY SITUATED,

PLAINTIFF-APPELLANT,

V.

COLUMBIA HEALTH SYSTEM, INC., COLUMBIA HOSPITAL, INC., WISCONSIN HEALTH CARE LIABILITY INSURANCE PLAN, ST. PAUL FIRE AND CASUALTY, CONTINENTAL INSURANCE COMPANY, AND WISCONSIN PATIENTS' COMPENSATION FUND,

DEFENDANTS-RESPONDENTS.

Opinion Filed: March 17, 1998
Submitted on Briefs: February 3, 1998

JUDGES: Fine, Curley and Myse, JJ.
Concurred:
Dissented:

Appellant
ATTORNEYS: On behalf of the plaintiffs-appellants, the cause was submitted on the briefs of *Ronald S. Goldser* of *Zimmerman Reed, P.L.L.P.*, of Minneapolis, Minnesota.

Respondent
ATTORNEYS: On behalf of the defendants-respondents Froedtert Memorial Lutheran Hospital and Sentry Insurance, the cause was submitted on the brief of *John A. Nelson* and *Terry E. Nilles* of *von Briesen, Purtell & Roper, S.C.*, of Milwaukee.

On behalf of the defendant-respondent Wisconsin Patients Compensation Fund, the cause was submitted on the brief of *William H. Levit, Jr., Michael B. Apfeld, Winston A. Ostrow,* and *Sarah B. Ludwick* of *Godfrey & Kahn, S.C.*, of Milwaukee.

On behalf of the defendants-respondents Columbia Health System, Inc., Columbia Hospital, Inc., and Wisconsin Health Care Liability Insurance Plan, the cause was submitted on the brief of *Lori Gendelman* and *Jeffrey J.P. Conta* of *Otjen, Van Ert, Stangle, Lieb and Weir, S.C.*, of Milwaukee.

COURT OF APPEALS
DECISION
DATED AND FILED

March 17, 1998

Marilyn L. Graves
Clerk, Court of Appeals
of Wisconsin

NOTICE

This opinion is subject to further editing. If published, the official version will appear in the bound volume of the Official Reports.

A party may file with the Supreme Court a petition to review an adverse decision by the Court of Appeals. *See* § 808.10 and RULE 809.62, STATS.

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STATE OF WISCONSIN **IN COURT OF APPEALS**

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DEFENDANTS-RESPONDENTS.

APPEAL from judgments of the circuit court for Milwaukee County: CHRISTOPHER R. FOLEY, Judge. *Affirmed.*

Before Fine, Curley and Myse, JJ.

FINE, J. Steven Staudt and Dennis Dvorak appeal from the trial court's summary-judgment dismissal of their claims against Froedtert Memorial Lutheran Hospital, its insurers, and Columbia Hospital and its insurers. Staudt's and Dvorak's cases were consolidated for decision before the trial court, and are consolidated on appeal. We affirm.

Summary judgment is used to determine whether there are any disputed facts that require a trial, and, if not, whether a party is entitled to judgment as a matter of law. RULE 802.08(2), STATS.; ***U.S. Oil Co. v. Midwest Auto Care Servs., Inc.***, 150 Wis.2d 80, 86, 440 N.W.2d 825, 827 (Ct. App. 1989). Although assisted by the trial court's well-reasoned written decision, our review of a trial court's grant of summary judgment is *de novo*. *See* ***Green Spring Farms v. Kersten***, 136 Wis.2d 304, 315–317, 401 N.W.2d 816, 820–821 (1987).

These cases arise out of the use of surgical screws by the plaintiffs' respective physicians to treat the plaintiffs' back problems. Neither Staudt nor Dvorak was enrolled in a clinical investigation of the screws' efficacy or safety.

They claim that they were injured as a result of the operations, and brought these actions against the hospitals where the surgeries were performed—not the manufacturer of the screws or their physicians.

Plaintiffs' claims are predicated on what they contend was a violation of the hospitals' duties to them: to tell Staudt and Dvorak that the Food and Drug Administration had not approved the screws for the specific procedures for which the screws were used; to warn them of risks inherent in the use of the screws; and to ensure that Staudt and Dvorak were enrolled in a clinical investigative trial before the screws would be used in the surgeries. As conceded by plaintiffs' counsel before the trial court, the legal viability of these claims depends on plaintiffs' contention that use of the screws in their surgeries violated the FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. § 301, *et seq*., as amended by the MEDICAL DEVICE AMENDMENTS OF 1976, Pub. L. 94-295. The trial court held that the hospitals were not liable to the plaintiffs because physicians have the right, within the exercise of their medical judgment and discretion, to use a medical device for purposes that have not been approved by the Food and Drug Administration as long as the FDA has approved use of the medical device for some purpose. On our *de novo* review, we agree.

The Food and Drug Administration regulates the use of medical drugs and devices. FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. § 301, *et seq*., as amended by the MEDICAL DEVICE AMENDMENTS OF 1976, Pub. L. 94-295. Once a drug or device has been approved for any purpose, physicians may use that drug or device for purposes that have not been approved. ***Ortho Pharmaceutical Corp. v. Cosprophar, Inc.***, 32 F.3d 690, 692 (2d Cir. 1994) (drug); ***Weaver v. Reagen***, 886 F.2d 194, 198 (8th Cir. 1989) (drug); ***Femrite v. Abbott Northwestern Hosp.***, 568 N.W.2d 535, 540 (Minn. App. 1997) (device). Indeed, the medical devices at

issue here, screws approved by the Food and Drug Administration for use in long bones, have been lawfully used by at least some physicians as they were used here—in the vertebral pedicle—as "'an "off-label" use--that is, using an approved device for an unapproved indication.'" ***Femrite***, 568 N.W.2d at 542 (quoting a Food and Drug Administration document). *See also* Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems, 60 Fed. Reg. 51,946, 51,947 (proposed Oct. 4, 1995). As noted by the Food and Drug Administration, permitting such "unapproved" use defers to the physician's medical judgment: "'In general, a physician who engages in off-label uses has the responsibility to be well informed about the device, and to base the decision to use it on sound medical evidence and a firm, scientific rationale.'" ***Femrite***, 568 N.W.2d at 542 (quoting a Food and Drug Administration document).

Although hospitals must give certain information to those of their patients participating in clinical investigations of "off-label" uses of medical devices, *see* 21 C.F.R. pts. 50, 56, & 812, the hospital need not give this information to patients who are not part of such an investigation, even though their physicians are treating them with the device in an identical "unapproved" way. ***Femrite***, 568 N.W.2d at 542–543. As noted, neither plaintiff was taking part in a clinical investigation. Moreover, the duty to get informed consent from a patient rests with the physician and not the hospital. ***Scaria v. St. Paul Fire & Marine Ins. Co.***, 68 Wis.2d 1, 18, 227 N.W.2d 647, 656 (1975); § 448.30, STATS. (subject to certain exceptions, physician must inform patient about "benefits and risks" of "all alternate, viable medical modes of treatment"). That the "informed consent" is in connection with the "unapproved" use of a medical device that has been approved for other purposes does not alter this principle. ***Femrite***, 568 N.W.2d at 543. Indeed, the Investigational Devices Exemptions Manual, published by the

Food and Drug Administration in June of 1992, recognizes the applicable paradigm:

> Good medical practice and patient interests require that physicians use commercially available devices according to their best knowledge and judgment. If a physician uses a device in the practice of medicine for an indication not in the approved labeling, he or she has the responsibility to be well informed about the product, to base its use on a firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a device in this manner as part of the "practice of medicine" does not require the submission of an [Investigational Devices Exemption], or review by [a hospital Institutional Review Board], unless such review is required by the institution in which the device will be used.
>
> The investigational use of an approved, marketed device differs from the situation described above. "Investigational use" suggests the use of an approved device in the context of a study protocol. When the principal intent of the investigational use of a device is to develop information about its safety or efficacy, submission of an [Investigational Devices Exemption] is generally required.

U.S. DEP'T OF HEALTH & HUMAN SERVS., INVESTIGATIONAL DEVICE EXEMPTIONS MANUAL 49. Plaintiffs have not referred us to any evidence that either Froedtert Hospital or Columbia Hospital has internal procedures that require that patients who are not part of a clinical study receive the type of information or warnings that plaintiffs contend the hospitals should have given them. Additionally, plaintiffs have pointed to no statute or regulation that requires hospitals to ensure that every patient whose physician uses an approved drug or medical device for an "unapproved" purpose first enroll that patient in a clinical study.

The overriding issue on this appeal is whether medical decisions on how to treat patients will be made by those patients' physicians, who are, of

course, subject to liability if they commit malpractice, or whether additional layers of review will be interposed between patient and physician. Plaintiffs have cited to us no statute, regulation, or court decision that prevents a physician in the course of his or her medical practice from using an approved drug or medical device for an "unapproved" purpose.[1] The only reported court decision presenting the issues that are the subject of this appeal, ***Femrite***, recognizes the need to respect the physician-patient relationship, including deferring to medical judgment as to when an approved medical device should be used for an "unapproved" purpose. As we have seen, the Food and Drug Administration, which has general regulatory authority over drugs and medical devices, agrees. Until Congress changes the law to prohibit the "unapproved" use of drugs or medical devices that are approved for some purposes, or until the legislature of this state—if consistent with the Constitutionally mandated supremacy of federal law, *see* U.S. CONST. art. VI, cl. 2—alters the current calculus with respect to the use of drugs and medical devices, responsibility for the plaintiffs' alleged injuries as a result of their spinal operations does not lie with the hospitals in which the surgeries were performed.[2]

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[1] The Department of Health and Human Services does have the authority to prevent the use of any medical device "[i]f the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death." 21 U.S.C. § 360h(e)(1). No such finding was made with respect to the screws involved in these cases.

[2] Plaintiffs also contend that the hospitals: violated standards promulgated by the Joint Commission on Accreditation of Health Care Organizations; failed to provide "Administrative Services"; were guilty of "Fraudulent Concealment"; and were guilty of "Administrative Negligence," "Simple Negligence," and "Corporate Negligence." Insofar as these contentions stray beyond plaintiffs' arguments that the use of the screws in their surgeries was unlawful, the contentions are undeveloped; insofar as they do not stray, they are foreclosed by our conclusion that the use of the screws here was not unlawful. We do not address arguments that are not developed. *See* ***Barakat v. Department of Health & Soc. Servs.***, 191 Wis.2d 769, 786, 530 (continued)

By the Court.—Judgments affirmed.

N.W.2d 392, 398 (Ct. App. 1995) (appellate court need not consider "amorphous and insufficiently developed" arguments); *see also* ***Libertarian Party of Wisconsin v. State***, 199 Wis.2d 790, 801, 546 N.W.2d 424, 430 (1996) (appellate court need not address issues that lack sufficient merit to warrant individual attention). Significantly, in the course of their contentions that the hospitals should have prevented the plaintiffs' physicians from using the screws in their surgeries, plaintiffs concede that "a physician is not bound by the FDA's requirements concerning the use of medical devices." Moreover, plaintiffs have not even alleged that their physicians were negligent in connection with their surgeries. Imposition of liability on the hospitals under the circumstances here would, anomalously, compel hospitals to stop physicians from doing what the Congress and the Food and Drug Administration say they have the right to do—use approved drugs and medical devices in "unapproved" ways.