

IN THE COURT OF APPEALS OF TENNESSEE
WESTERN SECTION AT JACKSON

GARY MURPHREE,
Plaintiff,

v.

Court of Appeals No.W2004-01432

PACESETTER INC. et al.,
Defendant.

Appeal from the Circuit Court of
Shelby County, No.CT-0054-29-00-3
Honorable Karen R. Williams

MOTION SEEKING LEAVE TO FILE

BRIEF AMICUS CURIAE

IN SUPPORT OF PLAINTIFF

Amicus, Prof. James O'Reilly, requests leave to submit this brief
amicus curiae under Tennessee Rule of Appellate Procedure 31.

Statement of Interest of the Amicus Curiae

The issue before this Court is of substantial precedential magnitude
for scholars of constitutional jurisprudence of federal preemption, and
for scholars studying federal food and drug law. Amicus has prepared

this brief pro bono and with no compensation, because of the substantial public interest in proper development of the subset of constitutional and administrative law relating to medical device preemption. Amicus has no financial interest and no association with the parties and is not a litigant in any pending medical device case or in any Tennessee litigation.

Statement under Tenn. R.A.P. 31(a)

Amicus believes that the issue of federal statutory preemption under the federal Food Drug & Cosmetic Act is so rare in state appellate jurisprudence that this court would benefit from expert assistance to aid in the understanding of this highly specialized field of law.

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BRIEF AMICUS CURIAE
IN SUPPORT OF PLAINTIFF

CONDITIONALLY FILED UNDER TENN. R.A.P. 31(a)

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Background

Amicus requests that the Court consider the issues raised in this matter regarding federal preemption and state civil remedial rights. Amicus supports the position of the plaintiff and has been provided with the defendant's appellate pleading, but has never met the plaintiff or his counsel, and has no financial interest in this or any other Tennessee case. Amicus is admitted to practice in Ohio and Virginia and admitted to the bar of the U.S. Supreme Court, Federal Circuit, Sixth Circuit and other federal courts. I have taught food and drug law at the University of Cincinnati College of Law since the early 1980s; I began teaching in 1980 and have taught courses in FDA law, administrative law, systems of regulation, labor law, criminal law, and products liability. I joined the full time faculty in 1998 after serving as an adjunct for 18 years. In that capacity I advise our students who host the national moot court competition on products liability, the Rendigs Competition.

My two-volume treatise, West's **Food & Drug Administration**, has been quoted by the U.S. Supreme Court as "Experts have written...", in the 2000 decision in *FDA v Brown & Williamson*. I have been

accepted as an expert on FDA law and procedure by the U.S. District Court for the Eastern District of Virginia in 1997 in Huntingdon Laboratories v PETA and by the Circuit Court of West Virginia in 2003 in the class action Carlos Johnson v Ethicon. I have consulted and/or been deposed in numerous other actions involving FDA issues.

My work on medical device issues dates back to adoption of the first major medical device legislation in 1975-76. Amicus was involved with the medical device industry efforts to shape the legislation at the time the 1976 amendments were being debated. I served four years as Chair of the FDA Committee of the American Bar Association, four years as Chair of the Programs Committee for the Food & Drug Law Institute, one year as Section Chair of the ABA Section of Administrative Law & Regulatory Practice, and lectured widely on drug issues. I have been paid as a federal consultant on the FDA drug approval process by the Administrative Conference of the United States, and as a consultant on FDA legal issues by the Association of Food & Drug Officials of the United States, the principal professional society in the FDA field. My treatise has been widely used and cited in federal and state courts since 1979 and I am currently working on

the treatise's third edition, having written two supplements each year on the text. I have lectured in Europe and Canada and throughout the United States on FDA and medical device product liability matters. Before joining the full time faculty, I served 24 years as the principal FDA lawyer for The Procter & Gamble Company and in that role was the designated "Official FDA Correspondent" for the company. I was engaged heavily in legislative and regulatory matters relating to medical device and federal preemption issues for many years.

I have published 29 textbooks and 135 legal articles; a textbook on federal preemption is under consideration by the American Bar Association Press. Of my articles, approximately 30 have dealt with aspects of FDA law and procedure. I served on the editorial board of the Food Drug Cosmetic Law Journal and was a member of the Food & Drug Law Institute prize committee for essays in FDA law.

I am a member of the Virginia and Ohio bars and graduated from the University of Virginia School of Law, J.D. 1974, and Boston College, B.A. cum laude 1969. I currently reside in the city of Wyoming, Ohio, where I am an elected member of city council, trustee of the Ohio

Kentucky Indiana Regional Council of Governments, and member of the Select Committee on Ethics of the Cincinnati Bar Association.

Argument of the Amicus

1. Federal Preemption Should Be Narrowly Confined to the Terms of the Federal Statute

State courts historically have been open to the remediation of individual injury cases. The foreclosure of the citizen's state tort remedies by virtue of federal statutory preemption is a rare exception to the power of state courts to provide remedies to citizens of their state. The federal administrative agency power under the Supremacy Clause, Art. I sec. 9, are to be narrowly interpreted in light of the role of states as historic protectors of private rights.

The 1976 Medical Device Amendments provided that a state "requirement" would be overridden if it conflicted with a federal agency action. This case involves a private civil tort defendant's attempt to broaden the reach of "requirement" in 21 U.S.C. 360k(a).

Preemption has been called the “Big Brick Wall” of tort law, see Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal Food Drug & Cosmetic Act*, 51 Food & Drug L.J. 509 (1996). Here a private defendant has belatedly brought a helper to try to build its wall, but the lower court has consistently declined. The extensive affidavits show this subcategory of medical device approval did not reach the level of scrutiny contemplated in U.S. Supreme Court preemption decisions, and a regulator’s ipse dixit does not preclude this court from construing U.S. Supreme Court precedent.

This court has the authority to interpret the application of U.S. Supreme Court precedents to Tennessee civil cases. Defendant seeks to exploit the dichotomy left over in 1996 when the U.S. Supreme Court, in Medtronic Inc. v Lohr, 518 U.S. 470 (1996), drew its definition of a federally preempted tort action against an FDA-reviewed medical device. This court is fully capable of construing Lohr and applying its norms to a Tennessee resident’s civil action. Lohr distinguished between comprehensive federal involvement with the regulated product during the approval step, and the simpler, quicker review routinely done by means of a notification to the

government concerning a modified device. This court is capable of construing and applying Lohr to a Tennessee resident's civil tort action.

Further, a narrow construction of "requirement" in 21 U.S.C. 360k, the term on which defendant and its newfound ally pivot their argument, serves the public interest better than a broad reading. Amicus is concerned, as a veteran teacher of products liability law, that the removal of state tort actions from the available avenues of civil redress would remove a deterrent to misconduct and erode the existing protection of the public's desire for safer products. If deterrence by tort recovery is unavailable for any modification of a "transitional preamendment Class III" device, manufacturers would greatly benefit. Then the public's only protection would be the political process in Washington, which appoints officials to reflect the views of the constituency most influential with that appointing Administration. It is rare for regulators to enter private litigation to aid one side. It would best serve the interests of the injured residents of Tennessee to allow the trial court to proceed with this case.

**2. Trial Courts Should Be Encouraged to
Develop The Record Concerning
Material Disputed Facts**

Amicus believes the material disputed facts concerning this matter are in need of development in an adversary hearing. The trial court was correct in denying summary judgment. There should be an evidentiary record developed below as to the two issues, (1) the facts of whether the part of the device that had an alleged defect in design had been scrutinized to the degree of specificity defined as federally preemptive under Lohr, and (2) whether the alleged defect represented a breach of the conditions of approval, such that the noncompliance vitiated the effect of the alleged approval. Factual development under an evidentiary hearing standard such as the Daubert standard is properly the function of the trial court in this case.

Defendant's framing of the issue as "approval is all or nothing, and states get nothing to say" challenges whether state courts have any power to construe the meaning of the Lohr decision as to the degree of scrutiny that is preemptive. Defendant is asking this state court to

yield to its supposed mantle of blanket “approval”, now that it is aided by the ipse dixit of the non-party FDA. Amicus calls to this court’s attention the significance of the ceding of so much state authority to similarly situated private tort defendants in the future. It would be far more advisable to have the factual development in open court to determine whether the part of the device that had an alleged defect in design had actually been scrutinized to the level defined as federally preemptive under Lohr. This evidentiary hearing looks at defendant’s conduct and is not focused on FDA misfeasance or laxity. In a second evidentiary step, it would be appropriate to also have the factual development under Daubert of the issue of whether the alleged defect in this case reflected a product that was in breach of the conditions of approval, such that the noncompliance vitiated the effect of the alleged “approval” of the leads.

3. Defendant Seeks to Expand Lohr

Where It Does Not Reach

Amicus understands the nuances of “pre-amendment device” modifications will be extremely confusing to non-specialists. Amicus

has written extensively about these distinctions in device status, see e.g. 1 James T. O'Reilly, Food & Drug Administration §§18.07, 18.08 (West, 2d Ed., 2004 Supp.). As a lawyer involved in the 1976 legislative developments, I recognized that the transition to a full set of safety and efficacy supportive data for devices required a bridging between old and new systems. Inartful hybrid processes like the semi-notification, semi-approval that occurred herein (described in the two expert affidavits by a former FDA physician reviewer) are a sloppy administrative mechanism which ordinarily would interest only the experts in arcane administrative procedure. The confusion here is especially severe because the victim, a Tennessee resident, would be without any remedy if the game of "approval" that was being played in this approval were to be ruled against him, without ever having had his day in court to show the existence of a defect in this product. Future death case defendants would enjoy a precedent in which overstretched regulators hand out quick clearances, which then shield the design errors of the defendants from any tort plaintiffs.

The trial court properly placed the burden of developing further facts onto the defendant. The ability of the defendant in this case to turn a

routine series of quick modifications like those under section 510(k), 21 U.S.C. 360(k), into what it has labeled a “premarket approval”, without the full set of premarket approval evaluations and clinical studies that section 515 of the Act contemplates, subverts the Lohr interpretation of the 1976 preemption legislation. That legislation as read by Lohr did not envision a series of quick clearances, chronologically evolving over time, to be accorded the kind of tort immunity this defendant seeks. Lohr’s observation, 518 U.S. at 502, that preemption would be rare, occurring when there is an unambiguous mandate for preemption to occur, *id.* at 501, clashes with the mechanisms of quick review which are in controversy in the competing expert affidavits in this case.

The hybrid “preamendment device” transitional set of evolving notifications, claimed by defendant to be preemptive in this case, are not within the Lohr decision’s “rare” set of preemptive actions. If defendant prevails in this appeal, it can achieve through gaming the FDA system what the U.S. Supreme Court has not given to medical device manufacturers, an equivalent of blanket immunity from any accountability in tort for all design modifications. Truck brakes, stoves

that release fumes, and boat motors are each regulated products whose tort immunity might follow from this precedent, as their regulators are likewise overstretched and inclined to be flexible.

There was to be an important statutory distinction between the two systems of medical device market entry, first articulated in 1976 as a method of transitioning the previously loose regulation of medical devices into a post-1976 regulatory regime. Of the two methods of market entry, one was the easy and quick “me-too” clearance known as “premarket notification” under section 510(k), which does not ask deep and detailed questions about the balance of safety and efficacy for a medical device, 21 U.S.C. 360(k). The other is “premarket approval”, the much more elaborate and substantive review process that, over many months or years, painstakingly determines that the risks of the new device are exceeded by its benefits, 21 U.S.C. 360e. Lohr spoke of the latter as preemptive. For reasons of budget and staffing shortfalls, FDA allowed an ad hoc third subcategory. Here the competing affidavits show that this device was in a middle, quite muddled subcategory as a “preamendment Class III” device whose electric leads were then sequentially cleared by quickly-cleared FDA

notifications, up to the date of manufacture of the particular lead that was used on plaintiff. Physician-review officer Dr. Parisian was there and her affidavits articulate the messy regulatory trail of this product.

Use of the preemptive authority of the federal Act in order to deprive state residents of a civil remedy is especially inappropriate here.

Taking the non-moving party's supportive affidavits as correct for purposes of the appeal, here the series of routine notifications of evolving product changes were painted in the name of "approval", without the ordinarily formal detailed evaluative processes for approval (which the affidavits show did not in fact occur for this product). Only a narrow set of medical device actions satisfy the preemptive scope of Lohr, as it would be "rare indeed" for a civil court to be barred from hearing a tort case that is within its jurisdiction, Lohr at 502.

Congress considered the existence of a full, comprehensive safety review of a modified pacemaker lead important to the public interest. When it drafted the original amendments, legislators quoted a 1973 FDA report that "since the scientific review or premarket clearance

process may be the only method available to the (FDA) by which it may request and analyze data pertinent to the device's safety and efficacy ... (that) those devices which are life supporting, life sustaining or potentially hazardous to health, and which at the same time are in a stage of rapid development need premarket clearance in order to ensure their safety and efficacy. *** Pacemakers and artificial heart valves are examples of life supporting devices ... which would require scientific review.” S. Rep. 94-33, Medical Device Amendments of 1975, 94th Cong. 1st Sess. At 15 (1975). Dr. Parisian's affidavits present material facts disputing the new FDA claim that its letter of approval, ipse dixit, gives conclusive immunity.

The policy reason this issue is presented at all is defendant's attempt to extinguish civil remedies of private plaintiffs. Lohr draws a distinction that upset many industrial manufacturers who wished a total preclusion of state tort remedies. The competing affidavits as to the facts suggest a skillful manipulation by the savvy defendant of a regulatory agency's largesse while it struggled with a flood of applications and a dearth of resources. This definitional categorization by defendant of an “approval” equaling preemption for

purposes of Lohr was a legally brilliant maneuver before the administrative agency, but the fallout from the agency's acquiescence harms the Tennessee plaintiff. The lower court should be allowed to proceed to develop the record.

In the case before this court, defendant comes to the appellate level with information not submitted below. Defendant brings in to the appellate court a party that had not been present when the initial action was proceeding through the trial court stages and asks that party to interfere on its behalf to aid its defenses. FDA is not on trial here. Amicus leaves to this court the procedural irregularity of this approach under Tenn. R.A.P. 14(b).

**4. When Applying U.S. Supreme Court Precedent,
This Court Should Examine An Agency Determination
For Its Substance, Not Merely Its Title**

The "rare" preemptive coverage recognized by Lohr is not simply an attribute of the title given to an FDA letter to the defendant. Premarket approval was very carefully integrated into the Food Drug & Cosmetic

Act, as the “twin brother” of the existing “new drug application approval” for drug products, compare 21 U.S.C. 355, 360e.

Premarket approval was intended to be the exacting process of federal physicians and engineers balancing all of the available data on safety, against all the available data on effectiveness of the proposed device, and recommending a specific product by a specific manufacturer be approved on its own merits. This careful measurement of product effects, both good and bad, would consume months or years of research, clinical studies (humans) and nonclinical experimentation (animals), cycles of questions and answers, meetings and advisory panel discussions, and ultimately a specific product approval for a specific medical device maker. At the time plaintiff received his pacemaker, the FDA’s premarket approval checklist was very detailed, see Medical Device Reporter (CCH) 7641.4 (1994). Here, the affidavits raise questions about whether the defendant’s product underwent a premarket approval scrutiny up to the standard of particularized scrutiny that the Court presumed in Lohr. This is a material question of fact in a Tennessee civil case.

A premarket approval for a medical device is a valuable right, indeed so valuable that competing firms are not able to piggyback upon that approval (as, e.g. generic prescription drugs might do) unless they have performed their own rigorous testing of their comparable device, or until three full sets of data have been reviewed and three approvals given; in this respect, the medical device premarket approval mechanism serves to comprehensively evaluate the risk and effectiveness measurements for a particular device. The FDA rules on premarket approval appear in the Federal Register of July 22, 1986, 51 Fed. Reg. 26364, with a detailed preamble, and currently are found at 21 C.F.R. Part 814. This Court can take judicial notice of the extensive regulations and of their further extensive explications at the website www.fda.gov/cdrh. Then the Court should see in the competing affidavits how this modified product's modified approval process short-cut the steps that Lohr assumed were being performed.

Without bogging down this court in federal process details, the court can simply take judicial notice of the FDA's own website at <http://www.fda.gov/cdrh/devadvice/pma> : "PMA is the most stringent type of device marketing application required by FDA." This level of

detailed scrutiny was the intended scope of the Lohr case's preemptive powers. It did not occur here, with this preamendment Class III device modification, as the affidavits in the record show. The trial court should be allowed to make a determination of the facts concerning the compliance of this defendant with the Lohr criteria for preemption, including the extent of testing actually done on this model of pacer lead, and the detailed submissions that were claimed to have been actually submitted by the defendant. The court should hear testimony on the functions of the FDA review that in fact occurred; and it then can compare these functions to the set of particularized approval criteria which the U.S. Supreme Court presumed to be a basis for approval under Lohr.

Lohr remains controlling precedent. Subsequent to 1996 and the Lohr decision, Congress acted further on federal preemption, in 1997 establishing federal preemption for FDA labeling of cosmetics and for nonprescription drugs in 21 U.S.C. 579r, 579s, but it did not alter the 1976 preemption clause that had been explicated in Lohr. Indeed, the device preemption language is one of the few medical device sections left undisturbed by Congress in the 1997 legislative

changes, Pub. L. 105-115, 111 Stat. 2295 (1997), and the decision by Congress not to change provisions on medical devices has severely limiting implications for efforts to broadly construe federal medical device legislation. *FDA v Brown & Williamson*, 529 U.S. 120 (2000)(citing the amicus' treatise). By construing the scope of *Lohr*, this court is using its normal powers of application of U.S. Supreme Court case law and is not intruding on specialized expertise of the FDA.

**5. The FDA Brief Need Not Receive
Substantial Deference, As FDA and Federal
Case Law Seek Deference for Regulations
And Here FDA Chose Not to Adopt a Rule**

FDA could have adopted a binding rule expressing its preemptive force and scope for preamendments class III devices, but has chosen not to do so. “(D)eference is not appropriate for an interpretation of a regulation found in an *amicus curiae* brief.” *Moore v Hannon Food Service*, 317 F.3d 489, 494 (5th Cir., 2003). The FDA was brought into this case by Defendant to claim the benefit of judicial deference for

what Defendant hoped would impress the court as an expert agency's binding policy norms.

Federal preemption is a question of law for the courts and is not a matter of peculiar expertise of the federal administrative agencies, for it is a constitutional issue not left to bureaucratic fiat. Agencies often fail to obtain the preemption they seek for pronouncements that are less than regulations. *Fidelity Federal Savings & Loan Assn. v de la Cuesta*, 458 U.S. 141, 158 (1982). This case involves only a federal brief in private litigation and not also a notice-and-comment rulemaking. FDA itself has not listed litigation briefs as authoritative, as it has for final rules, as the official binding position of the agency. 21 C.F.R. 10.45, 10.65.

Though the line of federal case law under *Chevron USA Inc. v Natural Resources Defense Counsel*, 467 U.S. 837 (1984) is followed in federal courts, it has had relatively little use in Tennessee civil tort actions, and the present request for extraordinary relief turns the usual case of agency action against private persons on its head. *Chevron* is inapposite on these facts. The *Chevron* doctrine was

never intended to be invoked by a civil tortfeasor against an injured plaintiff to cut off a remedy long recognized by state courts. Chevron is not usually applied to agency opinions not adopted by notice and comment rulemaking, *Christensen v Harris County*, 529 U.S. 576 (2000).

Even if Chevron were applicable, the opinions expressed in a brief in private litigation are not the kind of rulemaking determinations after public notice and comment, to which Chevron deference is accorded. The U.S. Supreme Court in *U.S. v Mead Corp.*, 533 U.S. 218 (2001) and other decisions has narrowed the range of such deference in federal court review of final agency actions. This is not such an action, 21 C.F.R. 10.45(a), and agency briefs in private litigation do not receive Chevron deference.

But even if they did, the construction of the defendant's specific product clearance as being under the larger Lohr category (not preempted) or the Lohr "rare" category (preempted) is a question of law on which this court is construing the meaning of a U.S. Supreme Court decision. The Supreme Court did not limit its holding in *Lohr* to

the form of words chosen by FDA in a product approval, but carved the distinction as to functional quality of the degree of intensity of review. It is entirely appropriate for an appellate court of Tennessee to construe the meaning of a U.S. Supreme Court opinion as applied to Tennessee civil litigation.

Finally, as the news media has widely reported in national publications, the Bush Administration's appointees to the FDA have actively solicited private industrial company lawyers to offer up cases in which FDA could use the vehicle of its briefs and intervention in order to extend FDA preemption in support of manufacturers, see e.g. Anne C. Mulkern, Watchdogs or Lap Dogs? *Denver Post* 1A (May 23, 2004), James T. O'Reilly, A State of Extinction, 58 *Food & Drug L.J.* 287 (2003); Michael Kranish, FDA Counsel's Rise Embodies U.S. Shift, *Boston Globe* (Dec. 22, 2002). Amicus avers that this solicitation of private lawsuit defendants for cases, into which the federal agency could intervene, is unprecedented in his thirty years of administrative law teaching, writing and practice with FDA and other administrative bodies. Deference is a particularly dubious claim under the circumstances here.

Amicus therefore encourages this court not to preempt plaintiff and to allow the evidentiary development to proceed in the Circuit Court.

James T. O'Reilly
Visiting Professor of Law
University of Cincinnati
June 24, 2004

AFFIDAVIT OF SERVICE

I, James O'Reilly, on June 25, 2004, mailed by U.S. mail postpaid, from Cincinnati, Ohio, copies of the foregoing motion and brief amicus curiae, to Glen G. Reid, James A. Gale, Peter D. Keisler, M. B. Cotton, W. Dunlap, and Bruce Brooke, listed as counsel for the parties in this action.

James T. O'Reilly
June 25, 2004

