

No. 03-4213

**IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

LOUIS F. GILLIGAN; GREGORY M. UTTER;
UNITED STATES OF AMERICA *ex rel.*,

Plaintiffs/Relators-Appellees,

v.

MEDTRONIC, INC.,

Defendant-Appellant.

On Appeal From The United States District Court For The
Southern District Of Ohio, No. 98-CV-248 (Hon. S. Arthur Spiegel)

**PROOF BRIEF OF THE PRODUCT LIABILITY ADVISORY
COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT**

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**DISCLOSURE OF CORPORATE AFFILIATIONS
AND FINANCIAL INTEREST**

Pursuant to 6th Cir. R. 26.1, the Product Liability Advisory Council, Inc. (“PLAC”) makes the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? **NO**

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? **NO**

(Signature of Counsel)

November 24, 2003
(Date)

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**PROOF BRIEF OF THE PRODUCT LIABILITY ADVISORY
COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT**

INTEREST OF THE *AMICUS CURIAE*¹

The Product Liability Advisory Council, Inc. (“PLAC”) is a non-profit association with 132 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of law in the United States, with emphasis on the law governing the liability of manufacturers of products. PLAC’s perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Since 1983, PLAC has filed over 600 briefs as *amicus curiae* in both state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. A list of PLAC’s corporate members is attached as Appendix A.

Many of PLAC’s members – including manufacturers not only of medical devices, but also of pharmaceuticals, pesticides, aircraft, foodstuffs, and chemicals – are governed by comprehensive federal safety statutes and regulations. Such

¹ Plaintiffs/Relators-Appellees have refused to consent to the filing of this brief. Accordingly, this brief is accompanied by a motion for leave to file, pursuant to Federal Rule of Appellate Procedure 29(b).

uniform sets of federal regulatory standards, mandated by Congress and developed by agencies with considerable expertise in the field, are vastly superior as a matter of both common sense and public policy to a system in which an agency's carefully designed standards may be supplanted or supplemented at will by trial courts or lay juries. PLAC's members, and ultimately the consumers of their products, benefit greatly both from the certainty and efficiency that comes with federal uniformity and from the security of knowing that lay juries will not second-guess the safety decisions of expert, deliberative bodies. Accordingly, PLAC and its members have a strong interest in the proper resolution of this challenge to the authority of a federal agency under a detailed federal regulatory scheme.

ARGUMENT

Medtronic's brief explains the various ways in which the district court erred by refusing to dismiss the relators' claims. Rather than repeat those arguments, this *amicus* brief will address at greater length one point that Medtronic has raised: The district court plainly erred in concluding that a lay jury may second-guess the Food and Drug Administration ("FDA")'s decision to approve the sale of a medical device. As the Supreme Court stressed in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Federal Food, Drug and Cosmetics Act ("FDCA") allocates responsibility for the approval of medical devices *exclusively* to the FDA. Thus, allowing the relators' case to proceed would undermine the

authority of the FDA to regulate medical devices. Furthermore, the district court's analysis would apply equally to other federal regulatory schemes, thereby disrupting significant portions of the American economy.

I. THE RELATORS' CLAIMS FAIL AS A MATTER OF LAW BECAUSE THEY DEPEND ON INAPPROPRIATELY SECOND-GUESSING THE FDA'S DECISION NOT TO REVOKE ITS APPROVAL FOR MEDTRONIC'S PACEMAKER LEADS.

The essential flaw in the relators' case is that, as a matter of law, no false claims were submitted to the government; thus, there can be no liability under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* In order to understand why this is so, it is necessary to flesh out the relators' theory of False Claims Act liability. Fairly characterized, the relators claim:

- 1) The Medicare and Medicaid programs do not allow payment "for medical procedures or services performed using devices which have not been approved for marketing by the FDA." (R. 82 Pls./Rels.' Mem. Opp'n Mot. Dismiss, pg. 7, Apx. pg. __) (quoting Medicare Part A Intermediary Manual § 3151.1; Part B Medicare Carriers Manual § 2303.1; Medicare Hospital Manual § 260.1B).
- 2) Therefore, every time a doctor or hospital submits a claim for reimbursement to the government under Medicare or Medicaid, that health-care provider is implicitly certifying that the medical device used in that procedure has been approved by the FDA.
- 3) The health-care providers who implanted the pacemaker leads at issue in this litigation believed that those leads were approved by the FDA.

- 4) In fact, the FDA *had* formally approved those leads.
- 5) However, Medtronic, the manufacturer of the pacemaker leads, committed fraud on the FDA in the process of gaining approval for those leads, by lying to the agency and by not informing the agency of changes to its manufacturing processes.
- 6) This fraud had the effect of rendering the FDA's approval of the pacemaker leads illusory.
- 7) As a result, the health-care providers' implied certifications, which accompanied their requests for payment from Medicare and Medicaid, were "false claims" under the False Claims Act for which Medtronic should be held liable even though it itself never certified anything or submitted any claim for payment to the government.

There are numerous fatal flaws in relators' theory,² but this brief will focus on the one that has the broadest implications for product manufacturers: the relators' assertion that a jury has the authority to decide that the FDA's approval of the pacemaker leads was null and void (number six, in the list above). Relators have simply ignored the statutory scheme governing the FDA, under which the approval *and withdrawal of approval* of a medical device are elaborate, formal

² For example, although in *United States ex rel. Augustine v. Century Health Services, Inc.*, 289 F.3d 409 (6th Cir. 2002), this Court approved of an "implied certification" theory for liability under the False Claims Act, it does not follow that an implied certification *by one party* (health-care providers) should suffice to impose False Claims Act liability on a different party (Medtronic, the device manufacturer).

processes. As we explain below, the FDA *could* formally have withdrawn the approval for Medtronic’s pacemaker leads – but it is undisputed that the agency (despite knowledge of relators’ allegations) has not done so. Absent such formal withdrawal of approval, however, those leads remained “approved” devices, and thus as a matter of law the “claim” that those devices were approved by the FDA was not “false.” In other words, the FDA’s decision to approve the sale of, and not to withdraw approval for the sale of, the pacemaker leads cannot be challenged collaterally in a False Claims Act action.

A. The Federal Food, Drug, And Cosmetic Act Contains An Elaborate Scheme For Approving And Withdrawing Approval Of Medical Devices.

Section 515 of the FDCA, 21 U.S.C. § 360e, governs the “Premarket Approval,” or “PMA,” process, by which the FDA authorizes a manufacturer to sell a “Class III” medical device (those that either (1) are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,” or (2) “present[] a potential unreasonable risk of illness or injury,” *id.* § 360c(a)(1)(C)). The statute imposes stringent requirements on manufacturers before such approval may issue. As the Supreme Court has explained:

Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a “reasonable assurance” that the device is both safe and

effective. *See* 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this “reasonable assurance” [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996) (citations omitted). Thus, there are extensive regulations in 21 C.F.R. part 814 governing the PMA application process (*see id.* §§ 814.20-39) and governing FDA action on a PMA application (*see id.* § 814.44). After the FDA receives “reasonable assurance” of the safety and efficacy of a device, the agency must issue a formal PMA order – under 21 U.S.C. § 360e(d)(1)(A)(i) and 21 C.F.R. § 814.44(d) – approving the sale of the device.

The statute also contains a detailed scheme under which the FDA may revoke a device’s approval. That process requires that the agency consult panels of experts, hold hearings, and provide the manufacturer the opportunity for both internal agency review and judicial review under the Administrative Procedures Act (“APA”). Thus, under the FDCA,

The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 360c of this title, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application.

21 U.S.C. § 360e(e)(1); *see also* 21 C.F.R. § 814.46(a)(1). The statute specifies six grounds that would justify the FDA’s revoking a device’s PMA, including that

“such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof” (21 U.S.C. § 360e(e)(1)(A)); “the application [for the PMA] contained or was accompanied by an untrue statement of a material fact” (*id.* § 360e(e)(1)(C)); or “the applicant * * * has repeatedly or deliberately failed to * * * make reports, required by an applicable regulation under section 360i(a) of this title” (*id.* § 360e(e)(1)(D)(i)).

Recognizing the significance of the decision to withdraw approval for a medical device, the statutory and regulatory scheme governing the process of revoking a PMA includes many provisions designed to protect the rights of the manufacturer. These include:

- 1) The right to a hearing “[*b*]efore [the agency issues] an order withdrawing approval of a PMA.” 21 C.F.R. § 814.46(c) (emphasis added); *see also* 21 U.S.C. § 360e(e)(1).
- 2) Due process during any such hearing: The regulations governing hearings include detailed protections for PMA holders, including the right to counsel (21 C.F.R. § 16.62); the requirement that any decision be made on the administrative record before the hearing officer (*id.* § 16.80); and the requirement that “the Commissioner * * * issue a written decision stating the reasons for the Commissioner’s administrative action and the basis in the record” (*id.* § 16.95(b)(2); *see also id* § 814.46(d)).
- 3) Internal agency review of any revocation order: The holder of a PMA that has been revoked under Section 360e(e)(1) is entitled to have the Secretary review that determination. *See* 21 U.S.C. §§ 360e(e)(2), 360e(g)(1)(A); 21 C.F.R. § 814.46(d).

- 4) Judicial review of any revocation order: A final agency decision to revoke a device's PMA is subject to judicial review pursuant to the APA. *See* 21 C.F.R. §§ 16.120; 10.45.

In sum, the FDA has plenary authority to regulate medical devices, including the authority to revoke approval of a PMA, but that authority is constrained by appropriate due process protections for manufacturers.

B. Under This Regulatory Scheme The FDA Can Adequately Address The Relators' Allegations.

Either of the relators' theories for how Medtronic defrauded the FDA could, if proven, suffice under this statutory scheme to allow the agency to revoke the PMA for these pacemaker leads. The relators' theory that Medtronic failed to disclose flaws with its "Solution A" testing could justify revoking the approval pursuant to 21 U.S.C. § 360e(e)(1)(C), while the relators' theory that Medtronic failed to report modifications to its manufacturing process could justify revocation pursuant to 21 U.S.C. § 360e(e)(1)(D)(i).

In fact, the relators themselves were entitled to initiate a process through which the FDA would be required to consider revoking the PMA for the 4004M pacemaker lead. Under 21 C.F.R. §§ 10.25 and 10.30, any citizen may petition the FDA to take various actions, including revoking a PMA. Thus, 21 C.F.R. § 814.46(b)(2) stresses that the "FDA may use information other than that submitted by the applicant" – in other words, among other things, information

submitted in connection with a citizen petition – “in deciding whether to withdraw approval of a PMA.” Furthermore, if the relators had asked the agency to revoke the PMA for these pacemaker leads and the agency had refused to do so, the relators would even have had the right to judicial review of that decision under the APA. *See* 21 C.F.R. § 10.45.

On the other hand, as the Supreme Court has recently noted, the FDA “has at its disposal a variety of enforcement options that allow it to make a *measured* response to suspected fraud upon the Administration.” *Buckman*, 531 U.S. at 349 (emphasis added). Thus, the mere fact that a device approval may have been obtained by fraud does not mean that the PMA should be revoked; to the contrary, under the statutory and regulatory scheme, the FDA has the discretion to decide that the health benefits of the device counsel against removing it from the market and that other remedies should be pursued. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985); 21 U.S.C. § 336. The FDA has been aware of the relators’ allegations for years, but has taken no enforcement action as a result of those allegations. In fact, the Department of Justice and the Health Care Financing Administration also presumably reviewed those allegations after the relators filed this lawsuit. In response, not only did the United States decline to intervene in this litigation, but those agencies apparently did not even suggest to the FDA that it otherwise investigate or respond to the relators’ assertions.

C. The Relators' Lawsuit Is An Inappropriate Attempt To Bypass This Regulatory Scheme.

It is uncontroverted that the FDA formally approved the sale of the pacemaker leads at issue in this litigation. *See* R. 2 Compl. ¶ 52, Apx. pg. __; *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 219 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001). It is likewise undisputed that the FDA never formally revoked that approval under 21 U.S.C. § 360e(e)(1). But although the relators acknowledge these facts, they assert that the agency's approval was somehow rendered illusory, or should be held to have been revoked as a matter of law, because of Medtronic's alleged fraud on the FDA. According to the relators, the FDA's entire regulatory system can be bypassed simply by the creative lawyering technique of bringing a claim challenging the approval of a device under the False Claims Act.

This lawsuit, however, is a blatant attempt to avoid well established rules protecting the FDA's exclusive authority to regulate medical devices. Thus, in *Buckman*, the Supreme Court held that a state-law cause of action based on the allegedly fraudulent procurement of FDA approval of a medical device was preempted, because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [agency]," and allowing such claims to proceed would "skew[]" the agency's "delicate balance of statutory objectives." 531 U.S. at 348. Similarly, in *Kemp* – a case based on the same factual allegations as those

raised here, where the current relators were counsel for the plaintiffs – this Court held that “permitting a fraud claim premised on false representations to the FDA during the [pre-market approval] process [for medical devices] would conflict with well-established precedent that no implied private right of action exists under the FDCA.” 231 F.3d at 236.

The fact that the relators seek to avoid *Buckman* and *Kemp* by bringing their claims under the False Claims Act instead of under state law does nothing to rehabilitate those claims. Although in *Buckman* the Supreme Court explicitly barred only state-law causes of action based on fraud on the FDA, the logic of that decision applies equally to the claims at issue here. Any “fraud-on-the-FDA” claim second-guesses the agency’s decision-making, asserting that had the agency not been misled it would not have approved a medical device. *See Buckman*, 531 U.S. at 343 (plaintiffs’ claim was that “[h]ad [fraudulent] representations not been made, the FDA would not have approved the [medical] devices, and plaintiffs would not have been injured”). The Supreme Court refused to allow such claims to proceed. As noted above, the Court explained that 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]” (*id.* at 349 (emphasis added)):

The FDA is empowered to investigate suspected fraud, and citizens may report wrongdoing and petition the agency to take action. In addition to the general criminal

proscription on making false statements to the Federal Government, the FDA may respond to fraud by seeking injunctive relief and civil penalties; seizing the device; and pursuing criminal prosecutions.

Id. (citations and footnote omitted).

As Justice Stevens explained in his concurring opinion in *Buckman*, “an essential link in the chain of causation” in any case that relies on an alleged fraud on the FDA “is that, but for [the defendant’s] fraud, the allegedly defective [devices] would not have reached the market. The fact that the [FDA] has done nothing to remove the devices from the market, even though it is aware of the basis for the fraud allegations, [demonstrates] that this essential element of the claim cannot be proved.” 531 U.S. at 353 (Stevens, J., concurring in the judgment). Thus, the United States refused to intervene in this litigation under the False Claims Act; instead, the relators are proceeding as, in essence, bounty hunters. *See Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997).

Moreover, the *Buckman* Court also stressed that the FDA uses its enforcement authority “to achieve a somewhat *delicate balance* of statutory objectives.” *Id.* at 348 (emphasis added). “This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives.” *Id.* at 349; *see also id.* at 348 (“The balance

sought by the [FDA] can be skewed by allowing fraud-on the-FDA claims under state tort law.”).

Just as this Court concluded in *Kemp* that a “fraud-on-the-FDA” claim challenging the approval of the pacemaker leads at issue here would entail inappropriately second-guessing the agency’s “delicate balance of statutory objectives” (*Buckman*, 531 U.S. at 348), so too a False Claims Act claim that would require a jury to second-guess the agency’s decision to grant or not to revoke the approval is inappropriate. As the Court explained in *Kemp*, “allow[ing] individual juries to undertake a counterfactual FDA review [to] conclude that the FDA would not have approved [a] device” is unacceptable, because “Congress allocated the FDA responsibility to design and manage a process which would result in approval of the safest and most effective medical devices possible.” 231 F.3d at 235 (internal quotation marks and citation omitted).³

³ At the very least, the district court should have referred the question of whether the leads were approved to the FDA, under the doctrine of primary jurisdiction. *See Reiter v. Cooper*, 507 U.S. 258, 268 (1993) (“[P]rimary jurisdiction * * * is a doctrine specifically applicable to claims properly cognizable in court that contain some issue within the special competence of an administrative agency. It requires the court to enable a ‘referral’ to the agency, staying further proceedings so as to give the parties reasonable opportunity to seek an administrative ruling.”).

That the False Claims Act is a federal law rather than a state law does not minimize the interference with the scheme established by the FDCA. Rather, numerous cases have precluded private litigants from bringing federal causes of action that would in essence second-guess the FDA's decisionmaking. For example, in *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993), a drug manufacturer brought a Lanham Act claim under 15 U.S.C. § 1125(a) asserting that other manufacturers were falsely labeling drugs as “*properly* approved by the FDA,” despite the fact that the approval process for those drugs had allegedly been tainted by fraud. *See id.* at 1139 (emphasis added). The Fourth Circuit rejected this claim, holding that allowing Mylan to proceed under this theory would “permit [it] to use the Lanham Act as a vehicle by which to enforce the [FDCA] and the regulations promulgated thereunder,” despite the fact that private litigants are “not empowered to enforce independently the FDCA.” *Id.* This is the same basic explanation given by the *Buckman* Court for refusing to allow state law “fraud-on-the-FDA” claims to proceed.

Similarly, in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), *cert. denied*, 537 U.S. 941 (2002), the Federal Circuit refused to allow a drug manufacturer to use the patent laws to escape from the lack of a private right of action under the FDCA. Mylan, which had manufactured a generic version of a prescription drug, sought to challenge the “listing” of a patent obtained

by the pioneer manufacturer in the FDA’s “Orange Book” – the de-listing of which would have allowed Mylan to release its generic version of that drug up to 30 months sooner. *See id.* at 1327-1328. Mylan conceded that there was no authority in the FDCA for a private litigant to bring a “de-listing” action, but asserted that its claim could be brought under the patent-infringement laws and the declaratory judgment statute. *See id.* at 1330. The Federal Circuit rejected that assertion, concluding that Mylan’s patent-infringement “claim [was] analogous to those barred in the long line of cases precluding private rights of action under the [FDCA].” *Id.* at 1332 (citations omitted).⁴

In sum, the FDA is the *only* entity that can determine whether a medical device or drug is “approved” for sale. The fact that the relators here seek to question the agency’s decision to approve the sale of Medtronic’s pacemaker leads in litigation brought under the False Claims Act – rather than using state-law causes of action, the Lanham Act, the patent laws, or whatever other creative theory they will next devise – is of no moment. Allowing lawsuits under any of these theories of liability would interfere with the FDA’s exclusive authority to

⁴ *See also, e.g., Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-231 (3d Cir. 1990) (rejecting Lanham Act labeling claim by one drug manufacturer against another because the FDCA and the FTC Act do not create express or implied private rights of action; “what the [FDCA] and the FTC Act do not create directly, the Lanham Act does not create indirectly”).

implement its diverse and often conflicting statutory obligations. Thus, the district court plainly erred in holding that a jury could second guess the FDA's decision to approve the sale of Medtronic's pacemaker leads.

D. The Relators Are Incorrect In Asserting That We Believe Their Claims To Be “Preempted” Under *Buckman*.

The relators have consistently mischaracterized our argument, asserting that we believe that the FDCA preempts claims under the False Claims Act, in the same manner that the *Buckman* Court held that the FDCA preempts state-law tort claims. *See, e.g.*, Pls./Rels.'-Resp'ts' Opp'n To Mot. Of *Amici Curiae* For Leave To File Amicus Brs. In Supp. Of Pet. Of Medtronic, Inc. To Appeal Under 28 U.S.C. § 1292(b), pg. 3, Apx. pg. __. That is not our claim. Rather, in an appropriate instance the government (or even a relator) might well be able to sue to recover for false claims submitted to Medicare for the payment of costs associated with Class III devices.

For instance, nothing in the FDCA precludes a False Claims Act lawsuit from being initiated against a provider who filed for Medicare reimbursement for implanting a pacemaker lead but who in fact never implanted that lead. Similarly, False Claims Act liability might also be appropriate if a manufacturer or other party knowingly submitted a false claim to the government based on the misrepresentation that the FDA had formally approved the device for marketing.

Our point is quite different: It is not that the False Claims Act as a theory of liability is preempted here; rather, the necessary *precursor* to liability under the False Claims Act is a false claim, and nothing in the False Claims Act authorizes a lay jury to second-guess the FDA's decision whether to approve a Class III device. See *Buckman*, 531 U.S. at 353-354 (Stevens, J., concurring in the judgment). Thus, the relators' claims are not preempted; they are merely barred as a matter of law by the FDA's decision.

II. THE DISTRICT COURT'S RULING HAS GRAVE IMPLICATIONS BOTH FOR THE REGULATION OF MEDICAL DEVICES AND FOR NUMEROUS OTHER STATUTORY SCHEMES.

It is worth stressing the disastrous consequences that could flow from the district court's ruling. Were this litigation merely a challenge to the FDA's exclusive authority over the approval of medical devices, it would nonetheless be of great importance to the health and welfare of all Americans. If the district court's order is affirmed, the FDA would lose its ability to control the marketing of such devices, which would render the agency ineffective in protecting the public's health and safety. Every device manufacturer would be vulnerable to the claim that its products were not properly on the market, *even though* the FDA had determined that those devices were "safe and effective."

Uncertainty as to the status of medical devices, in the face of claims of "fraud-on-the-agency," would likely lead some devices to be pulled from the

market, as manufacturers would almost certainly “play it safe” and choose not to offer devices whose use might entail known risks – even if all scientific evidence demonstrated that the device was far superior to any other option. Doctors and other health-care providers also would face the burden of having to question the legal status of every device prescribed before submitting a claim to the federal government, rather than simply relying on the FDA’s approval.

And, of course, the district court’s logic is not limited to medical devices. Rather, it would apply equally to prescription drugs, which are regulated by the FDA under an essentially equivalent regulatory scheme. *See* 21 U.S.C. § 355. Furthermore, under the district court’s approach private parties could use the False Claims Act to interfere with the regulatory schemes governing countless other industries, where federal agencies must approve products before they are marketed and have discretion to choose how to enforce federal policy. We submit that the False Claims Act cannot be read to authorize lay juries to second-guess federal agencies’ decisions and to undermine federal agencies’ careful implementation of complex regulatory systems.

CONCLUSION

For the foregoing reasons, as well as those elaborated upon in Medtronic's brief, this Court should reverse the order of the district court refusing to dismiss all claims against Medtronic as a matter of law.

Respectfully submitted,

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November 24, 2003

CERTIFICATE OF COMPLIANCE

I hereby certify that – according to the word-count facility in Microsoft Word – this brief, excluding those portions omitted under Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), consists of 4364 words, which is fewer than the number specified in Federal Rule of Appellate Procedure 29(d).

Kenneth S. Geller

APPENDIX A

Corporate Members of the Product Liability Advisory Council, Inc. (as of 11/14/2003)

3M	Chevron Corporation
Altec Industries	Continental Tire North America, Inc.
Altria Corporate Services, Inc.	Cooper Tire and Rubber Company
American Household, Inc.	Crown Equipment Corporation
American Suzuki Motor Corporation	DaimlerChrysler Corporation
Amgen Inc.	Dana Corporation
Andersen Corporation	Deere & Company
Anheuser-Busch Companies	Delphi Corporation
Appleton Papers, Inc.	Dorel Juvenile Group, Inc.
Astec Industries	E & J Gallo Winery
Aventis Pharmaceuticals, Inc.	E.I. DuPont De Nemours and Company
BASF Corporation	Eaton Corporation
Baxter International, Inc.	Eli Lilly and Company
Bayer Corporation	Emerson Electric Co.
Beretta U.S.A. Corp.	Engineered Controls International, Inc.
BIC Corporation	Estee Lauder Companies
Biro Manufacturing Company, Inc.	ExxonMobil Corporation
Black & Decker (U.S.) Inc.	Federal Signal Corporation
BMW of North America, LLC	FMC Corporation
Boeing Company	Ford Motor Company
Bombardier Recreational Products	Freightliner LLC
BP America Inc.	General Electric Company
Bridgestone/Firestone, Inc.	General Motors Corporation
Briggs & Stratton Corporation	Georgia-Pacific Corporation
Bristol-Myers Squibb Company	GlaxoSmith Kline
Brown and Williamson Tobacco	GLOCK, Inc.
Brown-Forman Corporation	Great Dane Limited Partnership
Caterpillar Inc.	Guidant Corporation
CCA Industries, Inc.	Harley-Davidson Motor Company
Centerpulse USA Inc.	Harsco Corporation

Honda North America, Inc.
Hyundai Motor America
ICON Health & Fitness, Inc.
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.
Lincoln Electric Company
Masco Corporation
Mazda (North America), Inc.
McNeilus Truck and Manufacturing, Inc.
Medtronic, Inc.
Mercedes-Benz of North America, Inc.
Michelin North America, Inc.
Miller Brewing Company
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
PACCAR Inc.
Panasonic
Pentair, Inc.
Pfizer Inc.
Pharmacia Corporation
Polaris Industries, Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.
Purdue Pharma L.P.
Raytheon Aircraft Company
Remington Arms Company, Inc.
Rheem Manufacturing
RJ Reynolds Tobacco Company
Schering Corporation
Schindler Elevator Corporation
SMC Group USA Inc.
Sears, Roebuck and Co.
Shell Oil Company
Siemens Corporation
Smith & Nephew, Inc.
Snap-on Incorporated
Sofamor Danek, Medtronic Inc.
Solutia Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
The Goodyear Tire & Rubber Company
The Heil Company
The Procter & Gamble Company
The Raymond Corporation
The Sherwin-Williams Company
The Toro Company
Thomas Built Buses, Inc.
TK Holdings
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Automotive US LLC
UST (U.S. Tobacco)
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Water Bonnet Manufacturing, Inc.

Whirlpool Corporation
Wilbur-Ellis Company
Wyeth
Yamaha Motor Corporation, U.S.A.
Zimmer, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this, the 24th day of November, 2003, I served one copy of the Proof Brief Of The Product Liability Advisory Council, Inc., As *Amicus Curiae* In Support Of Appellant by overnight delivery on the following counsel:

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