No. 10-15222

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ALEXIS DEGELMANN, *et al.*,

Plaintiffs-Appellants,

v.

ADVANCED MEDICAL OPTICS INC.,

Defendant-Appellee.

On Appeal from the United States District Court
for the Northern District of California
(No. 4:07-cv-03107-PJH, Hon. Phyllis J. Hamilton, U.S.D.J.)

BRIEF FOR AMICUS CURIAE PUBLIC CITIZEN, INC., SUPPORTING PLAINTIFFS-APPELLANTS' PETITION FOR REHEARING EN BANC

Allison M. Zieve
Adina H. Rosenbaum
Scott L. Nelson
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

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Attorneys for Amicus Curiae

CORPORATE DISCLOSURE STATEMENT

Public Citizen, Inc. is a non-profit, non-stock corporation. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

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INTEREST OF AMICUS CURIAE[1]

Public Citizen, Inc., a consumer-advocacy organization founded in 1971, appears on behalf of its more than 225,000 members and supporters before Congress, administrative agencies, and courts on a wide range of issues and works for enactment and enforcement of laws protecting consumers, workers, and the general public. Public Citizen attorneys have represented plaintiffs or amici curiae in numerous cases involving the issue of federal preemption of state-law claims, and acted as lead counsel in the two U.S. Supreme Court cases interpreting the scope of the express preemption provision of the Medical Device Amendments of 1976 (MDA) to the Food, Drug, and Cosmetic Act, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). In addition, Public Citizen, through its Health Research Group, has significant experience working with Food and Drug Administration (FDA) regulations and procedures.

Public Citizen submits this brief because it is concerned that the Panel's decision in this case greatly expands the preemptive scope of the MDA and misunderstands the nature of guidance documents issued by the FDA. By holding

[1] A motion for leave to file this amicus brief is being submitted concurrently with this brief. Counsel for appellants consented to the filing of this brief, and counsel for appellees did not consent. No party's counsel authored this brief, in whole or in part, and no party or counsel for a party contributed money intended to fund the preparing or submission of this brief. No person, other than amicus curiae, its members, or its counsel, contributed money intended to fund the preparation or submission of the brief.

that non-binding guidance imposes preemptive "requirements" within the meaning of the MDA's preemption provision, the decision threatens to eliminate a broad range of state-law claims that, under the MDA and Supreme Court precedent, should be permitted to go forward.

BACKGROUND

Although the Food and Drug Administration (FDA) has extensively regulated prescription drugs since enactment of the Food, Drug, and Cosmetic Act in 1938, the FDA did not regulate medical devices until passage of the Medical Device Amendments of 1976 (MDA). *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76 (1996). The MDA divided medical devices into three categories—Classes I, II, and III—and established a tripartite scheme for their regulation. *See id.* at 476-77. Class I devices include such basic items as bandages and tongue depressors. Class II devices include more complex or potentially more dangerous products, such as hearing aids and tampons, for which performance standards, post-marketing surveillance, and other tools establish sufficient assurance of safety and effectiveness. Class III devices, such as heart valves, stents, and pacemaker leads, treat serious medical conditions and/or pose serious risks of causing injury to patients. 21 U.S.C. § 360c(a)(1)(C).

The MDA requires that the FDA grant premarket approval to most Class III devices before they can be marketed. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312,

317 (2008). The premarket approval process involves a detailed review of a device's safety and efficacy. *See id*. When the FDA grants approval, its order conditions the manufacturer's ability to sell the device on its conformity to detailed design specifications and to the label approved by the agency. *See id*. at 319.

In contrast, Class I and II devices, as well as Class III devices already on the market when the MDA was enacted, are subject to less stringent standards: such devices, as well as devices that are their "substantial equivalents," may remain on or enter the market through a truncated review process generally referred to as the "§ 510(k) process" (named after the relevant section of the MDA). Section 510(k) review does not entail a thorough examination of the device's safety and efficacy. *Riegel*, 522 U.S. at 317.

The MDA contains an express preemption provision stating that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement" that is "different from, or in addition to, any requirement applicable under this chapter to the device, and [that] relates to the safety or effectiveness of the device or to any other matter included in a [federal device] requirement." 21 U.S.C. § 360k(a). The Supreme Court has twice considered the scope of this provision. First, in *Lohr*, the Supreme Court held that state-law claims involving devices that receive marketing approval through the § 510(k) process are not preempted by § 360k(a) because that process does not

establish federal *requirements* applicable to the device. 518 U.S. at 494, 501. Later, in *Riegel*, the Court held that the premarket approval process that applies to certain Class III devices establishes requirements concerning the design and labeling of devices, because of the thoroughness of the FDA's safety and effectiveness review and because FDA marketing approval for such devices is contingent on use of the approved design and labeling. Accordingly, *Riegel* held, § 360k(a) preempts state-law claims involving devices that have premarket approval if the claims challenge design or labeling that complies with the federal *requirements* imposed as a condition of premarket approval. 552 U.S. at 323.

ARGUMENT

I. The Panel Decision, Misunderstanding the Nature And Effect Of FDA Guidance Documents, Presents An Issue Of Exceptional Importance Because, If Allowed To Stand, It Will Lead To Incorrect Outcomes In A Large Number Of Cases.

As *Lohr* and *Riegel* agree, preemption under § 360k(a) turns on the existence of a federal medical device "requirement"—that is, a mandatory federal standard specifically applicable to the design or labeling of the product. The Panel found such a requirement in the FDA's 1997 guidance for contact lens care products. According to the Panel, that guidance document "mandates" criteria for a contact lens solution to be labeled a disinfecting solution. Panel Op. 18568. The Panel found, therefore, that "with regard to the labeling at issue in this suit, the FDA has

promulgated specific requirements, which [the product] met," *id*. 18569, and that the plaintiffs' state-law claims are preempted.

In fact, FDA guidance does not establish "requirements," as the FDA has explicitly and repeatedly stated. Because the Panel's decision turned on a misunderstanding of the nature of guidance documents, rehearing should be granted to correct the error and forestall a broad expansion of MDA preemption based on that error.

A. Guidance documents are "prepared for FDA staff, applicants/sponsors, and the public [to] describe the agency's interpretation of or policy on a regulatory issue." 21 C.F.R. § 10.115(b)(1). Unlike statutes and regulations, guidance documents are not "law." Rather, as explained in an FDA regulation, "[g]uidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA." *Id*. § 10.115(d). And every guidance document must "[p]rominently display a statement of the document's nonbinding effect." *Id*. § 10.115(i)(1)(iv). Further, "[g]uidance documents must not include mandatory language such as 'shall,' 'must,' 'required,' or 'requirement,' unless FDA is using these words to describe a statutory or regulatory requirement." *Id*. § 10.115(i)(2).

The guidance at issue here reflects these features: the express disclaimer of legal effect is set forth in the second paragraph, and the paragraph about

disinfecting solutions on which the Panel focused uses "should" and "may," not "shall" or "must." *See* FDA, *Guidance Document for Contact Lens Care Product Manufacturer* at 1, 30 (May 1, 1997), *cited in* Panel Op. 18568-69 (attached as Exh. B to Pet. for Rehearing) (hereafter "FDA Guidance").

Numerous aspects of guidance documents reflect their informal and non-binding nature. To begin with, they are not promulgated in accordance with the rulemaking procedures of the Administrative Procedure Act, 5 U.S.C. § 553. Rather, the FDA publishes a notice in the Federal Register saying that draft guidance is available online or from the FDA, but it does not publish the guidance itself. 21 C.F.R. § 10.115(g). Even final guidance documents are not formally published, but are instead posted online and made available on request. And more generally, because of their informal and non-binding nature, agency guidance documents do not get *Chevron* deference—the high degree of deference afforded to an agency when it speaks with the force of law. *See Christensen v. Harris County*, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference."); *see, e.g., Precon Dev. Corp., Inc. v. U.S. Army Corps of Eng'rs*, 633 F.3d 278, 290 n.10 (4th Cir. 2011) (refusing to afford *Chevron*

deference where government's view set forth "only in a non-binding guidance document").

Although guidance documents do not establish requirements, this is not to say that the FDA cannot establish requirements, as required for preemption under the MDA, for a Class II device. For instance, this Court in *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997), held that FDA *regulations* setting forth the specific text of warnings that must accompany tampons (which are Class II devices) establish preemptive requirements. Nonetheless, although the FDA *can* issue regulations for Class II devices, it did *not* do so here. Instead, it proceeded through guidance that expressly disclaims any binding effect and explicitly says that manufacturers need not follow the approach stated in the guidance, but must satisfy the "requirements" of the statute and regulations. *See* FDA Guidance, *supra*, at 1.

B. The Panel's error in holding that an FDA guidance document "mandates" that certain "requirements" be met, Panel Op. 18568-69, has potentially broad significance because the FDA has issued hundreds of guidance documents with respect to medical devices, including many that specifically address Class II devices, such as the one at issue here. *See* FDA, *Comprehensive List of Guidance Documents at the FDA*, 75 Fed. Reg. 48180, 48204-21 (2010) (listing current FDA guidance documents regarding medical devices). Because, as explained above,

these documents do not set forth "requirements," they should have no preemptive effect under *Lohr* and *Riegel*. Yet the Panel decision would expand the preemptive scope of the MDA to encompass the non-binding content of these hundreds of documents.

II. The Panel's Decision Conflicts With Decisions Of Other Circuits And Is Inconsistent With Supreme Court Precedent.

In holding that a guidance document established "requirements," Panel Op. 18569, the Panel decision conflicts with decisions of other courts, which have recognized that where an agency "does not impose any legal obligations" on a regulated entity, the agency's action "has no preemptive effect." *Mwantembe v. TD Bank, N.A.*, 669 F. Supp. 2d 545, 553 (E.D. Pa. 2009); *see Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 245 (3d Cir. 2008) (no preemption because FDA consumer advisory, "backgrounder," and compliance policy were insufficient to establish "binding and exclusive application of federal law"); *Molycorp, Inc. v. EPA*, 197 F.3d 543, 546 (D.C. Cir. 1999) (agency guidance stating that it "is intended solely to provide information to the public and the regulated community regarding the wastes that are potentially subject to the requirements of this title" does not create binding requirements); *see also Wilderness Soc'y v. Norton*, 434 F.3d 584, 595-96 (D.C. Cir. 2006) (discussing distinctions between statements of policy and codification of binding rules).

The Panel's decision is also inconsistent with U.S. Supreme Court precedent defining "requirement" as "a rule of law that must be obeyed." *Bates v. Dow Agro-Sciences, LLC*, 544 U.S. 431, 445 (2005). This common-sense definition cannot be squared with a decision holding that a document that "does not create or confer any rights," "does not operate to bind the FDA or the public," and allows manufacturers to use an "alternative approach" (FDA Guidance, *supra*, at 1) sets forth preemptive requirements. The Panel decision is also inconsistent with cases holding that state law on a topic is not preempted where an agency chooses not to issue regulations on that topic. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) ("quite wrong" to view decision not to issue federal regulation as "functional equivalent" of prohibition against state regulation of the subject matter); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995) (where agency had no standard either requiring or prohibiting antilock brakes, state common-law claim regarding antilock brakes not preempted).

Rehearing this case would enable the Court to resolve the tension between the Panel decision and other court of appeals and Supreme Court precedent.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for rehearing en banc and reverse the Panel's holding on the issue of preemption.

Respectfully submitted,

/s/ Allison M. Zieve

Allison M. Zieve
Adina H. Rosenbaum
Scott L. Nelson
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Attorneys for Amicus Curiae
Public Citizen, Inc.

November 14, 2011

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Circuit Rule 40-1, I certify that the foregoing brief is proportionally-spaced, has a type-face of 14 points, and, as calculated by my word processing software (Microsoft Office Word 2010), contains 2,073 words.

November 14, 2011

/s/ Allison M. Zieve
Allison M. Zieve

CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2011, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system. I further certify that I mailed the foregoing document by First-Class Mail, postage prepaid, to the following non-CM/ECF participant:

Mark P. Robinson
Robinson Calcagnie & Robinson
Suite 700
620 Newport Center Dr.
Newport Beach, CA 92660

November 14, 2011

/s/ Allison M. Zieve
Allison M. Zieve