

Fighting the high cost of health care

Both insurers and consumers have an interest in widely available, low-cost generic drugs. The big pharmaceutical companies have stymied competition from makers of generic alternatives. Trial lawyers have joined forces with insurers to stop them.

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According to statistics from the U.S. Census Bureau, roughly 85 percent of Americans have some type of health insurance.¹ Some people get coverage through government-subsidized programs, but most have employer-provided or independently purchased private insurance.

That most insurance comes from private companies should be no surprise—it's a fact that grows out of this country's failure to adopt a comprehensive national health insurance program. Accordingly, private insurers play a vital role, partly because of the sheer number of people who rely on them, and partly because of skyrocketing health care costs, which can be financially devastating to a family when a loved one becomes seriously ill.

Because they shoulder a significant financial load,² health insurers and other third-party payors (TPPs), including health and welfare funds and self-insured employers, have an abiding in-

terest in keeping health care costs down. Recently, in addition to more traditional cost-saving measures, TPPs have found that litigation can be an effective way to recoup some costs. Insurance companies are certainly no strangers to the courtroom, but in this context, TPPs are occupying the plaintiffs' seat, closest to the jury box. The dynamic is nontraditional; the results are mixed and compelling.

Third-party payors generally pursue two types of actions: antitrust cases against manufacturers of brand-name prescription medications and actions against medical device manufacturers. Although different in theory, the goal of both types of lawsuit is the same: to obtain reimbursement from companies that wrongfully line their coffers at the expense of those who ultimately bear the ever-increasing cost of health care.

The manufacture and sale of prescription drugs is one of the most prof-

itable industries in the United States. American consumers account for approximately 45 percent of the world's prescription pharmaceutical revenues,³ and the cost of prescription drugs has been rising at a rate of 14 percent to 18 percent per year. In 1997, over \$97 billion worth of prescription drugs was dispensed in the United States. By 2005, that figure had ballooned to about \$200 billion.⁴

In short, the market for prescription drugs is huge—one of the largest in our economy—and brand protection has become a top priority for drug companies. When companies that make brand-name drugs go too far in their attempts to block competition from bioequivalent generics, TPPs seek to recover the unrealized cost savings from the entry of these lower-cost alternative treatments.

To ease the entry of generic drugs into the market, Congress enacted the Drug Price Competition and Patent

Term Restoration Act of 1984, also called the Hatch-Waxman Act.⁵ Under Hatch-Waxman, a company seeking FDA approval for a generic alternative drug may file an Abbreviated New Drug Application (ANDA) that relies on, but need not independently replicate, the FDA's previous findings about safety and efficacy for the comparable patent-protected drug. The ANDA must include a certification that the proposed generic drug would not infringe on existing valid patents by its manufacture, use, or sale.⁶

If the generic applicant claims that the patent is invalid or will not be infringed by its product, it must submit a certification to the FDA and notify the patent holder.⁷ This is known as a "paragraph IV" certification. The first applicant to submit an acceptable ANDA with a certification for a generic version of a brand-name drug receives a 180-day period of exclusivity before other ANDAs for the same drug can be approved by the FDA. Thus, the first generic ANDA applicant has the opportunity to compete directly with the brand-name manufacturer for 180 days without the threat of competition from other generic manufacturers.⁸

The "branded" patent holder has 45 days after this notification to bring a patent infringement suit against the applicant. If the patent holder does file suit, the FDA's approval of the ANDA is automatically delayed for 30 months or until the patent is declared invalid or not infringed.

This stay is automatic, regardless of the lawsuit's merits.

'Working' Hatch-Waxman

The Hatch-Waxman Act was designed to stem the rising cost of prescription drugs and bring less expensive generic drugs into the market more quickly.⁹ Studies have found that the first generic competitor typically enters the market at a price 70 percent to 80 percent of its brand-name counterpart's price.¹⁰ Average generic-drug

prices are 25 percent below the retail price of the branded alternative and within one year capture as much as 44 percent of branded sales.¹¹

Some makers of brand-name pharmaceuticals have tried to unlawfully extend patent protection for their most lucrative drugs. They have learned to "work" the Hatch-Waxman system by filing baseless patent litigation in response to paragraph IV certifications.¹²

From an economic perspective, a patent illegally extended is no different from a patent illegally obtained. Both actions impose anticompetitive costs on third-party payors and consumers.

As noted, merely filing an infringement suit forecloses competition—and preserves monopoly profits—for up to 30 months.

Pharmaceutical companies have abused this provision of the Hatch-Waxman Act, costing the TPPs—and, ultimately, consumers—billions of dollars. Studies estimate that generic competition after successful patent challenges involving just four major brand-name drugs (Prozac, Platinol, Taxol, and Zantac) has saved TPPs and consumers more than \$9 billion.¹³

In response to this manipulation of the law, TPPs have increasingly turned to the courts for redress, filing antitrust actions against the makers of the brand-name pharmaceuticals. These lawsuits rest on two primary claims. The first is a claim that the brand-name manufacturer used "sham litigation."

In *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, the Supreme Court established a two-part test for determining whether litigation can be considered a sham: "First, the lawsuit must be objectively baseless, in the sense that no reasonable litigant could realistically expect to succeed on the merits"; second, the lawsuit must "conceal[] 'an attempt to interfere di-

rectly with the business relationships of a competitor' [emphasis added], through the 'use [of] a government process—as opposed to the *outcome* of that process—as an anticompetitive weapon' [emphasis in original]."¹⁴

For example, plaintiffs in the *Wellbutrin* antitrust case made multiple sham-litigation claims against Glaxo-SmithKline (GSK).¹⁵ These lawsuits were based on the latter's filing of patent

infringement suits against five competitors that issued paragraph IV certifications for generic versions of its blockbuster antidepressant.

After a favorable decision for one of the generic companies, GSK withdrew the remaining infringement cases. The *Wellbutrin* plaintiffs alleged that GSK knew its lawsuits were frivolous but used litigation to obtain the mandatory stay and unlawfully extend its monopoly. The court denied GSK's motion to dismiss the sham-litigation claims after finding that plaintiffs had alleged facts sufficient to support them.

The second type of claim TPPs bring alleges fraud by the brand-name manufacturer on the U.S. Patent and Trademark Office (PTO). In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, the Supreme Court held that the maintenance and enforcement of a patent obtained "by knowingly and willfully misrepresenting facts to the Patent Office" may form the basis of monopolization claims under §2 of the

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Sherman Act.¹⁶

An example of a TPP case using this theory is *In re Metoprolol Succinate Antitrust End-Payor Litigation*, where the plaintiffs brought *Walker Process* claims for AstraZeneca's actions in obtaining patents for Toprol-XL, a medication used to treat angina, hypertension, and congestive heart failure.¹⁷

AstraZeneca neglected to disclose to the PTO its involvement in a contest over the inventorship of metoprolol succinate and failed to name the correct inventors in its prosecution of the rele-

high. Given the stakes, future litigation in this arena appears inevitable.

Generic drug payoffs

"Exclusion payment" cases (also called "reverse payment" cases) are a fast-growing area of pharmaceutical antitrust litigation, and some of them have garnered national attention. In these cases, the generic companies and the brand manufacturer settle the patent litigation: The brand manufacturer pays the generic-drug maker in exchange for the latter's agreement

extend beyond the full patent term. The Supreme Court declined to hear the case.

Litigation involving the breast cancer drug Tamoxifen produced a similar result.²⁰ First, the district court dismissed the plaintiffs' complaint alleging that AstraZeneca's agreement to give Barr Laboratories a payment of \$21 million to keep Barr's generic product off the market was anticompetitive. The Second Circuit affirmed the lower court's ruling in a 2-1 decision, finding that such payments are valid if the generic's entry is not delayed beyond the patent term and if the infringement litigation is not a sham. The Supreme Court recently declined to hear the case.

The Second Circuit judges were not concerned by the exclusion payments, reasoning that settling an infringement suit with one generic competitor would have no effect on other companies challenging the patent.²¹ In fact, the court noted:

There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. *We doubt, however, that this scenario is realistic.*²²

That skepticism proved to be anything but prescient. Contrary to the Second Circuit's prediction, makers of brand-name drugs have been settling not only with the first generic company to file an ANDA, but with all potential generic entrants. This trend is perhaps best illustrated by *Pennsylvania Turnpike Commission v. Cephalon, Inc.*—an antitrust action involving Cephalon's alertness drug Provigil.²³

In that case, Cephalon "bought the field" by settling patent infringement claims with all four generic companies that—in exchange for collective licensing payments of \$136 million—agreed not to market their generic versions of Provigil until 2011. After the deal was struck, Cephalon's CEO remarked that it enabled the company "to get six more years of patent protection. That's \$4 bil-

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vant patents. The plaintiffs claim these material omissions would have negatively affected the patent examiner's decision to issue the patents.

Further, AstraZeneca violated the doctrine of nonstatutory double patenting (also known as "obviousness-type" double patenting), which prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant. The plaintiffs allege that AstraZeneca wrongfully concealed from the PTO that a prior patent anticipated the subject patents, which contained only a slight modification, thereby rendering them unenforceable. The court has yet to rule on AstraZeneca's motion to dismiss.

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Although these claims carry a high burden of proof, TPPs have had a series of successes resulting in substantial recoveries. That said, the incentives for pharmaceutical companies to aggressively protect their brand are extremely

to refrain from manufacturing its alternative drug.

While these agreements between companies benefit the parties involved, they clearly injure individual consumers and TPPs. As Federal Trade Commissioner Jon Liebowitz noted recently, "The increased costs resulting from anticompetitive agreements that delay generic competition harm all those who pay for prescription drugs: individual consumers, the federal government, state governments trying to provide access to health care with limited public funds, and American businesses striving to compete in a global economy."¹⁸

Third-party payors have filed suits attacking these payoffs as anticompetitive. Despite the clear harm to third-party payors and consumers, plus the support—and administrative enforcement actions—of the Federal Trade Commission (FTC), courts have been reluctant to strike down these deals.

In *In re Schering-Plough Corp.*,¹⁹ the FTC found that Schering's agreement to pay Upsher-Smith Laboratories and ESI Lederle, Inc., to delay the entry of their generic products was an illegal restraint of trade. But the Eleventh Circuit reversed that decision, holding that such payments are legal if the delay does not

lion in sales that no one expected.²⁴ Defendants' motion to dismiss is currently pending before the court.

If courts refuse to heed the FTC's warnings about the harm that arises from providing blanket judicial protection to these anticompetitive agreements, "generic entry" will become a meaningless term and the Hatch-Waxman Act nothing more than a drug-patent-extension vehicle that spreads continuing monopoly profits among a few companies—instead of cost savings to TPPs and the general public.

The courts' failure to discourage exclusionary payments has led to legislative action. Recently, Reps. John Dingell (D-Mich.), Bobby Rush (D-Ill.), Henry Waxman (D-Cal.), Ed Markey (D-Mass.), G.K. Butterfield (D-N.C.), Mike Doyle (D-Penn.), and Jan Schakowsky (D-Ill.) introduced a bill that would stem this practice.²⁵ The legislation broadly prohibits as anticompetitive ANDA paragraph IV litigation settlements where the generic manufacturer receives something of value and the ANDA filer agrees not to "research, develop, manufacture, market, or sell its generic drug." The bill does contain specific exclusions for this general prohibition when the value received by the generic applicant equates to nothing more than the right to sell a generic version of the branded drug prior to patent expiration.

The bill provides further flexibility by allowing the FTC to adopt rules exempting certain agreements from the general prohibition. It also provides that a generic-drug maker would forfeit its exclusivity if it receives something of value under the terms of a settlement with the brand-name drug manufacturer. Clearly, members of Congress have recognized the restrictive effect these agreements have on competition, at the expense of TPPs and consumers.

Medical device litigation

Medical devices must undergo lengthy review and testing before the FDA will approve them for sale. These stringent regulations and the manufacturers' assurances lead consumers and

TPPs to trust that the devices are safe and effective. But when these products turn out to be defective, the consequences for consumers' health can be devastating and the economic harm to TPPs astronomical.

In 1976, Congress amended the federal Food, Drug, and Cosmetic Act, enacting the Medical Device Amendments (MDA) to intensify FDA regulation of medical devices.²⁶ The statute broadly defines a medical device as any health care product "which does not achieve its primary intended purpose through chemical action . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes."²⁷

The MDA divides medical devices into three separate classes for purposes of FDA approval and regulation, depending on the degree and nature of the risk the device presents.²⁸ Class III devices, subject to the most stringent regulatory control, are of particular concern to TPPs because they usually are surgically implanted.

When a Class III device is found to be defective and must be replaced, the attendant medical costs are significant. They include removal and replacement of the device and ongoing medical monitoring of the patient.

Companies that manufacture, promote, and sell defective medical devices have been sued for wrongfully shifting the economic burden of replacement to public and private TPPs.²⁹ The most egregious examples are manufacturers that attempt to sidestep responsibility for paying these costs even though they released a device knowing it was defective. TPP plaintiffs have fought hard in court to ensure that such violators bear the full consequences of their actions or inactions.

In *In re Medtronic, Inc., Implantable Defibrillators Products Liability Litigation*, TPPs have made multiple claims seeking monetary relief for the economic harm they incurred from the recall of approximately 87,000 Class III implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds).

The allegations against Medtronic

include claims that the ICDs and the CRT-Ds contained faulty batteries and/or capacitors that made the devices unreasonably dangerous. TPP plaintiffs also asserted state law claims under Minnesota's False Statements in Advertisement Statute,³⁰ Deceptive Trade Practices Act,³¹ Prevention of Consumer Fraud Act,³² and the 50 states' consumer protection statutes.

The plaintiffs in the litigation argue that Medtronic used deception in the design, development, manufacture,

To understand the basis of manufacturers' preemption challenges in cases involving medical devices, a basic understanding of the Class III approval and regulatory process is helpful.

Class III devices are subject to a rigorous premarket approval (PMA) process or a less stringent premarket notification (PMN) process—also known as a “§510(k) process”—before they can lawfully be marketed and sold.³⁶ The PMA applicant must demonstrate a “reasonable assurance” that the device

PMA approval process, and circuit courts are divided on the issue. Several have concluded that the MDA preempts state law claims that impose additional or inconsistent requirements for a PMA-approved device.⁴² The Eleventh Circuit has adopted a contrary position, ruling that the MDA does not preempt state law causes of action in these circumstances.⁴³

Last year, in *In re Medtronic, Inc.*, the Minnesota district court considered—and rejected—Medtronic's motion for summary judgment based on its claim that federal preemption bars state common law claims for devices approved through the PMA process.⁴⁴ The court determined that the TPP plaintiffs' claims that the company failed to comply with FDA regulations merely impose parallel requirements, but no requirements different from or in addition to the federal ones. Therefore, the court concluded, their claims are not preempted.

The court explicitly found that the *Medtronic* plaintiffs produced “credible evidence indicating that—after Medtronic discovered the design defect and confirmed the discovery through patients' device failures, and after obtaining FDA approval for the modified battery—Medtronic continued to ship and sell devices containing the defective battery.”⁴⁵

The court went a step further, stating that “if the court adopted Medtronic's view [of preemption], once a medical device manufacturer obtains PMA approval, it would be insulated from liability even if it chose to conceal data from the FDA to maintain its PMA approval.”⁴⁶ The court had previously denied Medtronic's motion to dismiss the TPP plaintiffs' claims on all counts.⁴⁷

The legal landscape for TPP antitrust and consumer fraud claims is novel and challenging, with inconsistencies and adverse rulings to overcome. But the latest developments are encouraging for TPPs and consumers alike. The FTC has taken a strong stance against exclusionary payments, and the Supreme Court may review these settlements in the *Tamoxifen* case. Similarly, the favorable district court decision in *Medtronic* is prom-

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promotion, and sale of the ICDs and CRT-Ds. They also cite common law claims for unjust enrichment, negligence, strict liability, and breach of warranty.

The manufacturers raise every conceivable defense, including that federal law preempts such claims. In considering a preemption challenge, the court must consider whether a “state rule conflicts with or otherwise ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives’ of the federal law.”³³ Preemption may be express or implied, as preemption “is compelled whether Congress's command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.”³⁴

The MDA contains an express preemption clause, providing that

no state . . . may establish or continue in effect with respect to a device . . . any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.³⁵

This type of preemption is also known as “360k(a) preemption.”

is both “safe . . . [and] effective under the conditions of the use prescribed, recommended, or suggested in the proposed labeling thereof.”³⁷ A company must request FDA approval through a supplemental premarket approval application (SPMA) before it can make a modification that affects safety or efficacy in a device that has already obtained PMA approval.³⁸

A Class III device may qualify for review under the less rigorous PMN process if the manufacturer can establish that its device is “substantially equivalent” to one that was legally marketed before May 28, 1976.³⁹

In *Medtronic, Inc. v. Lohr*, the Supreme Court, considering a defective-design claim involving a device with PMN approval, provided a framework for applying 360k(a) express preemption to state law tort claims. The Court held that the MDA does not expressly preempt all state common law causes of action and that any state common law claims that mirror federal requirements are not preempted.⁴⁰ The Court concluded that the §510(k) process did not impose any specific federal requirements that could conflict with state law principles.⁴¹

But the Supreme Court has not addressed the preemptive effect of the

ising and could signify an important shift in the way courts approach the preemption defense.

Without question, this area of the law, in which the stakes are high for everyone involved, will see vigorous litigation. And plaintiff lawyers have a vital role to play, advocating for TPPs in the face of pharmaceutical companies' apparent willingness to go to any length to unfairly extend their patents and constantly increase their profits. ■

Notes

1. Carmen DeNavas-Walt et al., U.S. Census Bureau, *Income, Poverty, and Health Insurance Coverage in the United States: 2003* at 14, www.census.gov/prod/2004pubs/p60-226.pdf (Aug. 2004).
2. Henry J. Kaiser Family Found., *Health Care Spending in the United States and OECD Countries*, exhibits 1, 3 & 4, www.kff.org/insurance/snapshot/index.cfm (Jan. 2007) (click on title). The report notes, for example, that health expenditures per capita in the United States were \$5,711 in 2003; between 1980 and 2003, health expenditures per capita grew a staggering 4.4 percent annually; and total health expenditures in 2003 represented .2 percent of the country's gross domestic product for that year.
3. IMS Health, *IMS Country Sales Report* (2004); IMS Health, *World Review* (2001). See generally IMS, www.imshealth.com.
4. See Aaron Catlin et al., *National Health Spending in 2005: The Slowdown Continues*, 26 *Health Affairs* 142 (2007).
5. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. §§68b n.-70b (2000); 21 U.S.C. §§301 n.-55 n. (2000); 28 U.S.C. §2201 (2000); and 35 U.S.C. §§156-282 (2000)).
6. 21 U.S.C. §355(j)(2)(A)(vii)(IV).
7. *Id.*; 21 U.S.C. §355(j)(2)(B); see also Fed. Trade Comm'n., *Generic Drug Entry Prior to Expiration Date: An FTC Study* 6-8 (presenting in chart form the relevant requirements of the ANDA applicant), www.ftc.gov/os/2002/07/genericdrugstudy.pdf (July 2002) (hereinafter "2002 FTC Study").
8. 21 U.S.C. §355(j)(5)(B)(iv).
9. The amendments were balanced, also taking into account the extensive research, development, and testing done by the original drug patent holder by, in certain circumstances, extending the patent term for certain drugs. See 2002 FTC Study, *supra* n. 7, at 4-5.
10. See Cong. Budget Off., *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii, www.cbo.gov/ftpdoc.cfm?index=655&type=0&sequence=2 (July 1998) (hereinafter "CBO Study"). See generally David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 *Rev. Econ. & Stats.* 37, www.ftc.gov/be/workpapers/industrydynamics_reiffenwp.pdf (Feb. 2002).
11. CBO Study, *supra* n. 10.
12. See e.g. 2002 FTC Study, *supra* n. 7 at 14 (describing the high percentage of lawsuits filed by brand-name drug manufacturers on receipt of paragraph IV certifications).
13. Sen. Comm. Commerce, Science & Transp., *Generic Pharmaceuticals: Marketplace Access and Consumer Issues*, 107th Cong. 12 (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Assn.), http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:90155.pdf (Apr. 23, 2002).
14. 508 U.S. 49, 60-61 (1993) (quoting *E. R.R. Pres. Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) and *Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991), respectively).
15. *In re Wellbutrin SR Antitrust Litig.*, 2006 WL 616292 at *3 (E.D. Pa. Mar. 9, 2006).
16. 382 U.S. 172, 177 (1965).
17. No. 06-CV-00071 (D. Del. filed Feb 2, 2006).
18. H.R. Subcomm. on Commerce, Trade & Consumer Protec. of the Comm. on Energy & Commerce, *Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry*, 108th Cong. 5 (statement of Jon Liebowitz, FTC Commissioner), www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf (May 2, 2007).
19. No. FTC 9297, 2003 WL 22989651 (Dec. 8, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).
20. *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 2007 WL 1802162 (June 25, 2007).
21. *Id.* at 395 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 534 (E.D.N.Y. 2005)).
22. *Id.* (emphasis added).
23. No. 06-CV-2020 (E.D. Pa. filed May 12, 2006).
24. John George, *Hurdles Ahead for Cephalon*, *Phila. Bus. J.*, <http://philadelphia.bizjournals.com/philadelphia/stories/2006/03/20/story1.html> (Mar. 17, 2006).
25. H.R. 1902, 110th Cong. 1 (Apr. 17, 2007).
26. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified in various sections of 21 U.S.C.).
27. 21 U.S.C. §321(h)(3) (2000); see also 21 C.F.R. §60.3 (2007).
28. 21 U.S.C. §360c.
29. See e.g. *In re Medtronic, Inc., Implantable Defibrillators Prods. Liab. Litig.*, No. 05-MDL-1726 (D. Minn. filed Dec. 8, 2005); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, No. 05-MDL-1708 (D. Minn. filed Nov. 8, 2005).
30. Minn. Stat. §325F.67 (2004).
31. Minn. Stat. §325D.44-48.
32. Minn. Stat. §325F.69-70.
33. *Livadas v. Bradshaw*, 512 U.S. 107, 120 (1994) (quoting *Brown v. Hotel & Rest. Employees & Bartenders Int'l. Union Local 54*, 468 U.S. 491, 501 (1984)).
34. *Metro. Life Ins. Co. v. Mass.*, 471 U.S. 724, 738 (1985) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).
35. 21 U.S.C. §360k(a).
36. 21 U.S.C. §360e.
37. 21 U.S.C. §360e(d)(2)(A), (B); see also 21 U.S.C. §360c(a)(1)(C), 360(k); 21 C.F.R. §§807.81, 807.85.
38. 21 C.F.R. §814.39 (2005); Ralph F. Hall, *To Recall or Not to Recall, That Is the Question: The Current Controversy over Medical Device Recalls*, 7 *Minn. J.L. Sci. Tech.* 161, 166 (2005).
39. 21 U.S.C. §360e(b)(1); see also 21 U.S.C. §§360c(i), 360(k), 360(o); 21 C.F.R. §§807.87, 807.92, 814.1(c).
40. 518 U.S. 470, 486-89, 492-501 (1996).
41. *Id.* at 492-502.
42. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 118 (2d Cir. 2006), *cert. granted*, 2007 WL 1802109 (June 25, 2007); *Gomez v. St. Jude Med. Diag. Div., Inc.*, 442 F.3d 919, 929-30 (5th Cir. 2006); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 487-90 (7th Cir. 2005); *Horn v. Thoratec Corp.*, 376 F.3d 163, 169-73 (3d Cir. 2004); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226-28 (6th Cir. 2000).
43. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).
44. 465 F. Supp. 2d 886, 895 (D. Minn. 2006).
45. *Id.*
46. *Id.*
47. See also *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 484 F. Supp. 2d 973 (D. Minn. 2007), *reconsideration granted in part*, 2007 WL 2028137 (D. Minn. May 9, 2007), where the court dismissed TPP plaintiffs' claims, finding a lack of standing under Article III of the Constitution.

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