MASS TORT LITIGATION IN HEALTH CARE

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I. INTRODUCTION AND OVERVIEW

"Mass tort" is defined as a group of cases with common characteristics, most notably a large number of claims associated with a single product and a large number of parties with claims arising from a common event. *See* NEW JERSEY MASS TORT (NON-ASBESTOS) REFERENCE BOOK (July 2005). While not all mass tort cases are class action lawsuits, many class action lawsuits involve mass torts. Mass tort litigation encompasses a wide variety of practice areas, including toxic torts, product liability and health care. From fen-phen to Vioxx to medical devices, hospital billing practices, insurance premiums and even medical marijuana, developments in the field of mass tort litigation greatly impact the delivery of healthcare products and services.

This paper focuses on mass tort litigation in the context of health care, beginning with a brief discussion of the fen-phen and Vioxx cases, as well as the effect the outcome of such litigation may have on defense strategies for mass tort litigation in the future. This paper also discusses medical device lawsuits, concentrating on the rise of federal preemption as a defense to state common law claims and the likely impact of such preemption. Additionally, this paper discusses recent federal legislation aimed at curbing the cost and prevalence of class actions and the likely impact therefrom. Finally, this paper provides examples of mass tort claims that while out of the ordinary, nevertheless impact the delivery of healthcare products and services.

II. FEN-PHEN - A CAUTIONARY TALE

A. Introduction

The pharmaceutical company Wyeth was responsible for two medications, Pondimin and Redux, that, taken in combination with a third drug, were known as "fen-phen." Fen-phen was a prescription cocktail with the purpose of suppressing appetite and promoting weight loss. Widely prescribed, fen-phen first encountered trouble in July of 1997 when doctors at the Mayo Clinic discovered an association between diet drugs and heart valve disease. *See* Alison Frankel, *The Fen-Phen Follies*, THE AMERICAN LAWYER, March 1, 2005. Just months later, Wyeth withdrew Pondimin and Redux from the market at the request of the Food and Drug Administration. By 1999, almost 20,000 lawsuits had been filed against Wyeth in state and federal court, as well as over 100 putative class actions. *See id.*

B. Early Litigation

The initial individual fen-phen lawsuits resulted in poor outcomes for Wyeth. One trial resulted in a verdict of $150 million in compensatory damages for five plaintiffs in Mississippi. *See* David J. Morrow, *American Home to Settle Some 1,400 Fen-Phen Suits*, N.Y. TIMES, December 23, 1999, at C2. Seeking to halt further losses, Wyeth (then American Home Products Corp.) agreed to pay $350 million to settle 1,400 fen-phen cases brought in Mississippi. *See id.* As a result of early defeats, Wyeth sought to enter into a "global resolution" to the fen-phen litigation so to effectively cap the litigation. Frankel at 2.

C. Class Action

Wyeth entered into negotiations with a plaintiffs' negotiating committee in an effort to achieve agreement on a class action program. These negotiations resulted in a class action settlement approved by a court on August 28, 2000. In the settlement, Wyeth conceded the causation issue. The settlement also included, among others, the following characteristics:

- fen-phen users were required to register claims by a certain date;
- individuals identified through screening provided within the class action would be required to resolve their claims through the class action trust fund;
- five levels of injury were established, with Level I constituting the least serious injury and Level V the most serious;
- Level V individuals were expected to receive up to $1.3 million, while Level I individuals were expected to receive approximately $7,500;
- two payment schedules were established, one for the long-term fen-phen users (full payments) and another for individuals who either took fen-phen for less than two months or had alternative medical explanations for heart valve disease;
- a "medical model" whereby, instead of every claimant being screened by the trust, claimants would submit to the trust echocardiograms conducted under physician supervision, along with documents referred to as "green forms" on which cardiologists would attest to the claimant's medical condition; and

- despite the "medical model," Wyeth still had the right to ask its own physicians to review echocardiograms submitted by claimants.

See id. Wyeth's approval of the class action settlement structure was based in part on two key assumptions. First, Wyeth predicted that approximately 35,000 claimants would collect payments from the trust. *See id.* at 3. Second, Wyeth estimated that the trust would pay approximately $2.55 billion to the estimated 35,000 claimants. *See id.* Both of these assumptions proved to be inaccurate.

By 2002, the trust anticipated that between 75,000 and 85,000 claimants would demand payment - far greater than the 35,000 anticipated. *See id.* The low initial estimate was due in part by Wyeth's failure to account for an aggressive advertising effort by plaintiff's lawyers to sign-up potential claimants. *See id.* Additionally, Wyeth failed to anticipate the type of claims filed. Scientific evidence showed a much stronger link between fen-phen use and aortic valve damage than fen-phen use and mitral valve damage. Additionally, aortic valve damage was fairly rare, while mitral valve damage was a common condition among overweight individuals. *See id.* Therefore, Wyeth anticipated seeing more aortic valve claims. However, mitral valve claims vastly exceeded aortic valve claims. *See id.*

In addition to the number and type of claims filed, Wyeth incorrectly predicted the average payment from the trust. By the summer of 2002, payments from the trust averaged over $400,000. *See id.* With more than twice as many claimants as anticipated, the total amount paid out would be closer to $10 billion, not $2.5 billion.

D. Problems with the Medical Model

The unexpectedly high number of claimants and large amount of funds being claimed prompted Wyeth's attorneys to investigate further. A review by physicians retained by Wyeth of claimant echocardiograms indicated that a large number of "green forms" were being completed by just two cardiologists, Dr. Linda Crouse and Dr. Richard Mueller. The trust then hired an expert cardiologist to review the echocardiograms submitted by Drs. Crouse and Mueller. *See id.* at 4. The results of this review led Wyeth to conclude that only $3.2 million should be paid out to certain plaintiffs - not the $50 million the trust anticipated paying out to such plaintiffs at the time. *See id.*

Following these conclusions, a hearing took place in September 2002. Among the evidence presented at the hearing was the following:

- Dr. Mueller received $1,500 from a law firm representing plaintiffs whenever a claimant he reviewed submitted a "green form" to the trust;

- Dr. Crouse had evaluated 725 echcardiograms at a fee of $1,000 each;

- Dr. Crouse spent only 2 to 3 minutes reviewing each echocardiogram;

- Dr. Crouse found that 60%-70% of the echocardiograms she reviewed for law firms showed sufficient heart valve disease to qualify for payment from the trust, compared to 5% in a blind clinical study in 1998; and

- Dr. Crouse signed "green forms" without reviewing patients' medical records.

See id. As a result of the evidence presented at the September 2002 hearing, the judge allowed every claim of significant damages to be audited by the trust, writing "[c]ommon sense compels the conclusion that something may be seriously amiss." *Id.* at 5.

By March of 2004, auditors reviewed approximately 4,600 claims and disqualified almost two-thirds of them. Almost 50 law firms had more than 50% of their claims rejected. *See* REPORT BY WYETH ON MATRIX CLAIMS AND FUND A BENEFITS PROCESSING BY THE AHP (2004). As lawyers representing claimants retaliated against the trust with more litigation, payment of claims nearly came to a halt.

The major obstacle preventing the settlement agreement from operating as intended was the unanticipated number of Level I and Level II claims. The surprisingly large number of Level I and Level II claims were clogging the system and giving rise to accusations by Wyeth that echocardiograms were being manipulated to show injury, as well as accusations by plaintiffs' firms that Wyeth was to blame for constructing an inaccurate medical model. *See* Frankel at5.

E. The Seventh Amendment

In an attempt to salvage the class action settlement, lawyers with Wyeth and plaintiffs' firms engaged in discussions that ultimately led to the "Seventh Amendment" to the settlement agreement. Under the terms of the Seventh Amendment, Level I and Level II claimants were transferred out of the old trust and into a new $1.275 billion fund with its own medical review process. *See id.* All claimants who passed the medical review were to divide the funds on a pro-rata basis. *See id*.

F. Impact on Future Mass Torts

As a result of the Seventh Amendment, Wyeth's initial estimate of $2.55 billion was increased by only $1.275 billion. *See id.* at 6. Although this may appear to be a modestly successful effort to achieve a global solution to the fen-phen litigation, the inefficiency and potential for abuse created by the class action settlement serves as a cautionary tale and valuable lesson for those attempting large-scale class action settlements of pharmaceutical mass torts.

As Michael Fishbein, a class action attorney and leader of the plaintiffs' class action negotiating committee stated, the low standard of proof and high compensation to plaintiffs common in large-scale class actions creates "a huge incentive to push [dubious] claims." *Id.* When safeguards and audits are added to guard against abuse, "[t]he class mechanism becomes less effective than the tort system." *Id.* As the Vioxx experience outlined in the next section demonstrates, perhaps defendants in pharmaceutical mass tort litigation would be better served by adopting a case-by-case approach to defending lawsuits.

II. SUMMARY OF VIOXX TRIALS

A. Background

More than 20 million people took the painkilling drug Vioxx between 1999 and 2004. In September 2004, Vioxx's manufacturer Merck took the drug off the market after a clinical trial showed that the drug raised the risk of heart attack and stroke. Since then, over 14,000 federal and state lawsuits have been filed against Merck, covering approximately 27,000 plaintiffs. *See* Alex Berenson, *Legal Stance May Pay Off For Merck*, N.Y. TIMES, August 4, 2006 at C1. This section will provide a brief summary of the Vioxx lawsuits that have gone to trial to date, as well as an analysis of the legal ramifications of the verdicts.

1. Brazoria County

In August of 2005, a jury in Brazoria County, Texas awarded a total of $253.5 million in damages to the widow of a man who took Vioxx. *See* Alex Berenson, *The Vioxx Decision: The Overview, Jury Calls Merck Liable in Death of Man on Vioxx*, N.Y. TIMES, August 20, 2005 at A1. This amount included $24.5 million in compensatory damages and $229 million in punitive damages. *See id.* Under Texas law, damage caps limited the total award to $26.1 million. *See id.* In *Ernst v. Merck*, the plaintiff's husband took Vioxx for a period of seven months and then died in 2001 of an arrhythmia. *See id.* Initially, many commentators believed this case to present significant causation problems for the plaintiff, as clinical trials had not linked Vioxx to arrhythmias. However, the plaintiff's lawyer, Mark Lanier, successfully argued that decedent's arrhythmia was actually caused by heart attack brought on by a blood clot caused by Vioxx. *See id.*

2. Atlantic City

The second trial against Merck regarding the drug Vioxx took place in the fall of 2005 in Atlantic City, New Jersey. The judge overseeing this case was tasked with overseeing over 2,900 lawsuits filed in New Jersey state court against Merck for injuries allegedly caused by Vioxx. *See* Alex Berenson, *Jury Begins To Deliberate*, N.Y. TIMES, November 2, 2005 at C1. Unlike the plaintiff's verdict in Texas, Merck won the jury trial 8-1. *See id.* This case involved a less sympathetic plaintiff, a 60 year old man who took Vioxx for less than two months before suffering a heart attack, which he survived. *See id.*

3. Federal Court - Houston

The third Vioxx trial against Merck took place in federal court. Although the court was scheduled to preside over this case in New Orleans, Louisiana, this trial was conducted in Houston, Texas as a result of the damage inflicted by Hurricane Katrina. *See* Alex Berenson, *A Mistrial is Declared in 3rd Suit Over Vioxx*, N.Y. TIMES, December 13, 2005 at C1. This case involved a plaintiff who died at age 53 after taking Vioxx for less than one month. *See id.* After two days of deliberations, the court declared a mistrial. *See id.* Many commentators viewed this result as a blow to Merck, as causation was viewed as a weakness of plaintiff's case.

4. Federal Court - New Orleans

As with the third trial, the fourth Vioxx trial against Merck took place in federal court. In a retrial of the

federal case in Houston, Texas, a jury in New Orleans, Louisiana returned a defense verdict after deliberating for less than four hours. *See Federal Jury Clears Merck in Death of Vioxx Patient*, N.Y. TIMES, February 18, 2006 at C4. Plaintiff's problems satisfying the element of causation were too difficult to overcome, as the jury concluded plaintiff never proved any link between Vioxx and the heart attack. *See id.* This verdict represented a major win for Merck.

5. Atlantic City

The fifth Vioxx trial against Merck took place in Atlantic City, New Jersey. The jury found that Vioxx significantly contributed to a heart attack suffered by a 77 year old man. *See No Verdict on Penalty in Vioxx Case*, N.Y. TIMES, April 11, 2006 at C3. The jury awarded $4.5 million in compensatory damages. *See id.* Additionally, the jury awarded $9 million in punitive damages, finding that Merck mislead the Food and Drug Administration about the dangers of Vioxx and acted with wanton disregard for patients taking the drug. *See* Alex Berenson, *Vioxx Jury Adds More in Damages*, N.Y. TIMES, April 12, 2006 at C1.

Notably, this verdict constituted the first punitive damages award against a drug company in the state of New Jersey. *See id.* Under New Jersey law, because punitive damages were awarded the case was automatically referred to the state attorney general for a possible criminal investigation of Merck's conduct. *See id.* Additionally, the verdict in this case made it difficult for Wyeth lawyers to claim the company was the victim of a "runaway jury," as the jury found only one of the two plaintiffs was injured as a result of using Vioxx. *See id.*

6. South Texas

Texas state court in Rio Grande City, a small town near the Texas border with Mexico, served as the venue for the sixth Vioxx trial against Merck. On April 21, 2006, a jury awarded $32 million in damages to the family of Leonel Garza, a 71 year old retiree who died of a heart attack in 2001 after using Vioxx for a short period of time. *See* Alex Berenson, *Merck Loses Vioxx Suit in Texas*, N.Y. TIMES, April 22, 2006 at C1. Due to Texas law governing punitive damages caps, this award was automatically reduced to $7.75 million. *See id.* This verdict was viewed by many as an unexpected blow to Merck, as the plaintiff was thought to have difficulty proving causation. Although plaintiffs claimed Mr. Garza took Vioxx for 25 days before his heart attack, records only showed he took Vioxx for seven days. *See id.* Additionally, Mr. Garza had suffered a heart attack in 1981, underwent quadruple bypass surgery in 1985 and was an overweight smoker with high blood pressure. *See id.* Nevertheless, the jury reinforced the "plaintiff friendly" reputation of South Texas by returning a plaintiff's verdict.

7. Atlantic City

In the seventh Vioxx trial against Merck, the venue was New Jersey state court in Atlantic City, New Jersey for the third time. *See Merck Wins Vioxx Case in New Jersey*, N.Y. TIMES, July 14, 2006 at C4. On July 13, 2006, the jury found Vioxx did not contribute to a heart attack suffered by a 68 year old woman. *See id.* Additionally, the jury found that Merck had warned the patient's doctor about the risk of Vioxx and did not defraud consumers. *See id.* However, Merck lost one part of the jury verdict, as the jury found that Merck failed to warn the patient herself about the drug. *See id.*

8. Los Angeles

The eighth Vioxx trial against Merck took place in state court in Los Angeles, California. On August 2, 2006, a jury found Merck not liable for injuries to a 71 year old man who began taking Vioxx "as needed" in 1999 and suffered a heart attack in 2001. *See Merck Wins Vioxx Case in Los Angeles*, N.Y. TIMES, August 3, 2006 at C9. Additionally, the jury found Merck did not conceal information regarding the health risks associated with Vioxx. *See id.* Of note, more than 2,000 Vioxx lawsuits filed in California have been consolidated in Los Angeles by the judge who presided over this case. *See id.*

9. New Orleans - Federal Court

The third Vioxx trial against Merck in federal court, and the ninth Vioxx trial against Merck overall, took place in New Orleans federal court. The jury found that Merck's negligence caused the heart attack of Gerald Barnett, a 62 year old former FBI agent. *See* Janet McConnaughey, *Next Vioxx Trial Set to Get Under Way*, THE WASHINGTON POST, September 10, 2006. Mr. Barnett took Vioxx for 2 ½ years. *See id.* The jury awarded plaintiffs $51 million in damages, although the Court ordered a new trial on damages. *See id.*

10. New Orleans - Federal Court

On September 26, 2006, Merck achieved a defense verdict in the third Vioxx case against Merck in New Orleans federal court. The plaintiff was a 56 year old obese man with a history of cardiovascular problems who had taken Vioxx for four months before his heart attack. *See id; see also Merck Wins Federal Vioxx Product*

Liability Case: Smith v. Merck & Co., Inc., http://www.merck.com/newsroom/press_releases/corporate/2006_0926.html. Notably, this was the first Vioxx case against Merck to be tried in which the patient began taking Vioxx six months after the label was changed to say that the drug might increase the risk of heart attack. *See* McConnaughey.

B. Likely Impact of Verdicts on Trial Strategy

After ten trials, Merck has achieved a defense verdict in five, with four plaintiffs' verdicts and one mistrial. Additionally, one New Jersey state case has recently been overturned by the court, as the judge granted a new trial. *See id.* Nevertheless, this degree of success appears to vindicate Merck's consistent strategy of trying Vioxx cases individually, instead of working to settle the cases as a package or entering into a settlement. Therefore, Merck will likely continue to utilize a case-by-case strategy in defending Vioxx lawsuits.

The judge overseeing the Vioxx cases in federal court in New Orleans has said he wants to achieve a global settlement for the 5,700 Vioxx cases on his docket. *See id.* Still, even if the Vioxx cases are ultimately resolved through a global settlement, each defense verdict decreases the value of such settlement. To date, by trying each Vioxx case individually, Merck has avoided the problems inherent in a large-scale settlement evidenced by the fen-phen settlement.

III. MEDICAL DEVICES

A. Introduction

In addition to lawsuits involving drugs, plaintiffs have also initiated many lawsuits pertaining to medical devices. As one example, there is a line of cases where plaintiffs allege pacemakers have failed, leading to emergency open heart surgery. Another line of cases question whether balloon catheters used in angioplasties failed, causing injury to cardiac patients. A third line of cases pertain to whether stents used to treat abdominal aortic aneurysms malfunctioned, necessitating open heart surgery. A fourth example of medical device litigation pertains to collagen compounds which act as a replacement for soft tissue that as been lost due to scarring. A fifth example pertains to whether hip and knee implants were defective, causing infection.

These cases are often filed in state court. Generally speaking, state court is a more favorable venue for plaintiffs than federal court. Typical claims against medical device manufacturers include state common law claims such as negligence and strict liability for failure to warn, breach of warranty, and defective design, among others. Defense lawyers often prefer to remove state law cases to federal court in hopes of finding a more favorable venue. Federal law preemption of state law claims has become an increasingly common vehicle for dismissal of state common law causes of action in medical device cases throughout the U.S.

The basis of federal preemption of state law claims is found in the U.S. Constitution. By virtue of the U.S. Constitution's Supremacy Clause, it has long been settled that "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)(quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) and citing *M'Culloch v. Maryland*, 17 U.S. 316, 427 (1819)). In recent years, federal courts around the country have been considering the issue of whether Section 360k(a) of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (hereinafter "FDCA"), 21, USC § 301, *et seq.*, preempts certain state common law causes of action regarding medical devices that have entered the market through the Food and Drug Administration's pre-market approval process. This section provides a brief overview of the FDCA, including the FDA's approval process, as well as a detailed discussion of the holdings of various circuit courts on the issue of state common law preemption. This section concludes with a brief summary of the likely impact of these holdings on medical device manufactures.

B. Medical Device Approval Process

Amendments to the FDCA pertaining to approval of medical devices were enacted in 1976 in order to "provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). These amendments group medical devices into three categories - Classes I, II and III. Class I devices present no unreasonable risk of injury or illness and are subject only to "general controls." 21 U.S.C. § 360c(a)(1)(A). Class II devices pose a greater risk than those in Class I, and they must comply with "special controls" but may be marketed without advance approval. *Id.* at § 360c(a)(1)(B). Class I and II devices, ranging from elastic bandages to powered wheelchairs, are subject to fewer FDA controls than Class III devices. Class III devices are those that either "present a potential unreasonable risk of illness or injury" or are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 USC § 360c(a)(1)(C)(ii). Class III devices must be approved by the FDA prior to being marketed. Examples of a Class III device include a pacemaker, replacement heart valves

and implanted cerebella stimulators. *See* http://fda.gov/cdhr/devadvice/3132.html.

The two most common avenues for obtaining FDA approval of Class III medical devices are through the 510(k) process and the pre-market approval (hereinafter "PMA") process. The appropriate avenue for approval depends on the nature of the particular medical device. The 510(k) process applies to medical devices shown to be substantially equivalent to devices that entered the market prior to the 1976 Medical Device Amendments and were not subject to FDA approval. Therefore, if a manufacturer establishes that a new device is "substantially equivalent" to a device that entered the market prior to the 1976 Amendments, such manufacturer may market the new device without undergoing a lengthy PMA. However, if a manufacturer cannot meet this "substantially equivalent" test, the 510(k) process is not available and the manufacturer must follow the PMA process.

The PMA process requires the medical device manufacturer to submit a detailed PMA application to the FDA containing, among other things:

- reports of all clinical and non-clinical studies of the safety and effectiveness of the device;
- a statement of the device's components;
- ingredients, properties and principles of operation of the device;
- a description of the methods used in the manufacture and processing of the device;
- details regarding any marketing of the device;
- information about performance standards;
- samples of proposed labeling; and
- any other information requested by the FDA.

21 U.S.C. § 360e(c).

After reviewing an application, the FDA has the authority to either approve, deny, or impose modifications. 21 CFR § 814.44(c). Once the FDA approves a medical device, the applicant must comply with the FDA's approval order, containing the specific conditions of approval. 21 CFR § 814.80. Further, the applicant is required to submit subsequent changes to the device to the FDA for approval, through a PMA supplement. 21 CFR § 814.39(a).

C. 1976 Amendments Preemption Clause - 360k(a)

In addition to stating the PMA process, the 1976 Amendments contain an express preemption clause, which states in part:

> [N]o state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use 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.

21 USC § 360k(a). Because the statute does not define the term "requirement," it is unclear whether Congress intended the provision to preempt state common law claims. The FDA has promulgated regulations interpreting Section 360k(a), which state:

> [s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d). Therefore, the scope of Section 360k(a) has been the subject of numerous court rulings.

D. Court Cases Interpreting Scope of 360k(a)

1. Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

In *Lohr*, the United States Supreme Court considered the scope of Section 360k(a). Specifically, the Court addressed the issue of whether Section 360k(a) preempted state common law claims pertaining to medical devices that entered the market through the 510(k) approval process. The *Lohr* case pertained to the alleged failure of a pacemaker, requiring the plaintiff to undergo emergency surgery. The plaintiff brought numerous state common law claims for negligence and strict liability. *See Lohr*, 518 U.S. at 471-72.

With regard to plaintiff's negligence and strict liability claims, the Court unanimously held that plaintiff's design defect claims were not preempted because the 510(k) approval process does not impose any "requirements" under 360k(a), but instead merely establishes whether a new device is substantially equivalent to a pre-1976 Amendments device. *See id.* at 500.

With regard to plaintiff's manufacturing and labeling claims, however, the Court was divided. A five Justice majority held that Section 360k(a)'s reference to "requirements" means that only device-specific FDA requirements can give rise to preemption. *See id.* Because the FDA manufacturing and labeling requirements covering the device were general in nature and not specific, these justices concluded that plaintiff's manufacturing and labeling claims were not preempted. *See id.* Four Justices disagreed, concluding that any FDA requirements, whether general or device-specific, give rise to preemption. *See id*. at 513-14.

The Court was also split with regard to the broader question of whether common law duties may ever constitute "requirements" under Section 360k(a). Four Justices found that common law actions, just like state statutes, impose requirements on manufacturers and are thus preempted by Section 360k(a), to the extent they differ from FDA requirements. *See id.* at 509-10. While Justice Breyer did not join in that opinion, he agreed that the word "requirement" may be read as "including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 504. Four Justices disagreed with the others, opining that "few, if any, common law duties have been preempted" by Section 360k(a), and that it would be "rare, indeed" for preemption to occur. *Id.* at 502-03. Although the *Lohr* Court did not specifically address preemption of state claims involving medical devices approved through the PMA process, the majority of circuit courts who have addressed this issue have relied on the *Lohr* Court's interpretation of Section 360k(a) in holding that such claims are preempted.

2. Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001).

In *Martin*, the Fifth Circuit addressed the issue of whether Section 360k(a) preempted state common law claims pertaining to medical devices that entered the market through the PMA process. The *Martin* case pertained to the alleged failure of a pacemaker, causing injury to plaintiffs. *Martin*, 254 F.3d at 574. Similar to the claims in *Lohr*, the plaintiffs in *Martin* sued on state law claims, alleging both negligence and strict liability claims for defective design, failure to warn and negligent manufacturing. *See id.* at 578.

At the outset, the Fifth Circuit stated that the issue before the Court had been previously addressed in *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (5th Cir. 1993). In *Stamps*, the court held that similar state product liability claims were preempted. *See id.* However, the Fifth Circuit acknowledged that it was bound to follow the Supreme Court majority's opinion in *Lohr*. Nevertheless, the Court conceded that it could not "fully grasp the opinion's interpretation of when state common law requirements are considered 'specifically developed with respect to medical devices' without Justice Breyer's concurrence. *Id.* at 581-82. Relying on Justice Breyer's position that there is no preemption in *Lohr* because there is no conflict between the Section 501(k)(a) process and common law duties, the Fifth Circuit concluded that the Supreme Court may take a less assured view of the generalities of common law duties in comparison to the specific federal requirements of the PMA process. *See id.* at 582. Further, the Fifth Circuit held that *Lohr* is limited to "a finding that the Section 501(k)(a) process does not create specific federal requirements that conflict with state tort actions" *Id.* at 584. Thus the Fifth Circuit found that the *Lohr* opinion did not overrule *Stamps*. *See id.*

The Fifth Circuit held that the PMA process will preempt state tort law claims when the substantive requirements imposed by those claims potentially conflict with PMA approval. *See id.* Therefore, plaintiffs' tort claims relating to design, manufacturing process, and failure to warn were preempted by the MDA. *See id.*

3. Mitchell v. Collagen Corporation, 126 F.3d 902 (7th Cir. 1997).

In *Mitchell*, the 7th Circuit considered the same question. The *Mitchell* case pertained to the alleged injuries suffered by a patient who was injected with collagen compounds (Zyderm or Zyplast, hereinafter collectively "Zyderm"). *See* 126 F.3d at 905. Zyderm acts as a replacement for soft tissue that as been lost due to scarring and is classified as a Class III medical device. *See id.* The plaintiffs alleged various state law claims, including negligence, strict liability, fraud, mislabeling, misbranding and breach of warranty. *See id.* at 906.

At the outset, the 7th Circuit noted that the factual situation before the court in *Mitchell* was substantively different than the factual situation in *Lohr*. The court held that the PMA process, as opposed to the 510(k) process described in *Lohr*, can constitute a specific federal regulation of a product that can have a preemptive effect. *See id.* at 911. The court held that all

of plaintiff's claims were preempted, as the claims alleged that defendant was negligent despite its adherence to the standards required by the FDA and the PMA process. *See id.* at 913-15.

4. Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001).

In *Brooks*, the 8th Circuit addressed the issue of Section 360k(a) preemption of state common law claims pertaining to medical devices approved through the PMA process. The *Brooks* case pertained to a surgical technician who was diagnosed with occupational asthma allegedly attributable to vapors released during a bone cement mixing process. *See* 273 F.3d at 787. Bone cement is used to bond with bone or prosthesis in orthopedic surgeries. *See id.* The plaintiff subsequently brought a failure to warn claim against Howmedica, Inc., the manufacturer of the bone cement called Simplex. *See id.* Simplex is categorized as a Class III medical device. *See id.* at 789.

After analyzing the Supreme Court's holding in *Lohr*, the court held that the Simplex package labeling was subject to "meticulous and ongoing federal regulation" and that the FDA imposed specific requirements through the PMA process. *Id.* at 799. Because the specific state requirement plaintiff sought to establish with her common law claim of failure to warn would interfere with specific federal requirements, plaintiff's claim was preempted under Section 360k(a). *See id.*

5. Riegel v. Medtronic, Inc., 451 F.3d 104 (2nd Cir. 2006).

In *Riegel*, the 2nd Circuit considered the same issue. The *Riegel* case involved a cardiac patient who sued the manufacturer of a balloon catheter used in his angioplasty, asserting state law claims including strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, sale and manufacture. *See* 451 F.3d at 107.

The court divided its analysis into two parts. First, the court considered whether when the catheter was approved under the PMA process, it became subject to a federal device-specific requirement. *See id.* at 117. Second, the court considered whether there was a conflict between plaintiff's tort claims and any FDA device-specific requirements. *See id.*

The court commented that the PMA approval process differed greatly from the approval process at issue in *Lohr*. The court found that medical devices approved under the PMA process are subject to device-specific requirements. *See id.* Additionally, the court found that plaintiff's state common law claims would result in state "requirements" that differed from PMA process standards. Because the premise of plaintiff's claims was that the balloon catheter was defective, and such device had already undergone the PMA process, the court found plaintiff's claims to be preempted. *See id*. at 120-122.

6. Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999).

In *Goodlin*, the 11th Circuit addressed the same issue regarding preemption of state common law claims pertaining to medical devices approved through the PMA process. The *Goodlin* case pertained to the alleged failure of a pacemaker, causing plaintiff to undergo open-heart surgery. *See id.* at 1369. Similar to the claims in *Lohr*, the plaintiff in *Goodlin* sued on claims of negligent design and strict product liability. *See id.*

The 11th Circuit addressed whether the PMA process imposed any specific federal requirements on a particular device. Differing from the majority of circuits, the court concluded that the PMA process "concerns the manufacturers' ability to market minimally safe devices but makes no attempt to announce substantive safety standards that might determine the outcome of a product liability suit." *See id.* at 1380. The court concluded that the FDA's approval of a medical device pursuant to the PMA process "imposes no specific federal requirement applicable to a particular device and, therefore, has no preemptive effect under section 360k(a) of the MDA." *Id.* at 1382.

E. Impact of Preemption on Defense of Medical Device Claims

The Supreme Court decision in *Lohr* is very confusing, both due to the complicated regulatory subject matter, as well as the multiple plurality decisions. Additionally, two new justices have taken the bench since the case was decided in 1996, so the *Lohr* ruling may be in doubt if the Supreme Court was to reconsider its ruling. Therefore, it is difficult to predict the likely impact of *Lohr* on medical device preemption litigation.

Most, but not all, circuit courts favor preemption of state common law claims within the context of medical device litigation. Therefore, when defending medical device mass tort cases, practicioners must be mindful of the particular circuit within which a lawsuit has been filed and develop arguments emphasizing that particular

circuit's rulings, if federal preemption of state common law claims is the goal.

IV. CLASS ACTION FAIRNESS ACT OF 2005

Congress enacted the Class Action Fairness Act of 2005 (hereinafter "CAFA") on February 18, 2005. *See* to remedy alleged "abuses of the class action device." Pub. L. No. 109-2, § 2(a)(2), 2005 U.S.C.C.A.A.N. (119 Stat.) 4 (codified in scattered sections of 28 U.S.C.). The stated purpose of CAFA is "to assure fairer outcomes for class members and defendants." *Id.* (preamble). CAFA's provisions are complex and include both significant as well as minor changes in class action practice. Generally, important changes in class action litigation due to the passage of CAFA include: (1) the expansion of diversity jurisdiction; (2) expansion of the authority to remove cases from state to federal court; and (3) enactment of new requirements for federal class action settlements. *See* ATLA ANNUAL CONVENTION REFERENCE MATERIALS, Volume I, at page 2 (July 2005).

A. Expansion of Diversity Jurisdiction

CAFA expands diversity jurisdiction by implementing three new requirements applicable to class actions commenced after February 18, 2005. First, diversity jurisdiction now exists where the proposed class has at least 100 members. *See* 28 U.S.C. § 1332(d)(5). Second, diversity jurisdiction exists were any one plaintiff and any one defendant are citizens of different states. *See* 28 U.S.C. § 1332(d)(2). Third, diversity jurisdiction is met where the amount in controversy exceeds $5 million. *See id.* While this third requirement raises the previous amount in controversy requirement of $75,000 significantly, the claims of individual class members shall be aggregated to reach the $5 million threshold. *See id.*

While CAFA's new requirements for diversity jurisdiction are sweeping, there are a number of exceptions. These exceptions include "local controversy," "home state controversy," "state action," "covered securities," and "interests of justice." *See* Ronie M. Schmelz, *The Class Action Fairness Act of 2005: An Overview of CAFA and The Early Decisions*, P.L.I., July 2006, at 3.

1. Local Controversy Exception

Under the "local controversy" exception, a district court must decline jurisdiction under the following circumstances: (1) greater than 2/3 of the class members are citizens of the state in which the class action was originally filed; (2) at least one defendant is a citizen of the state where the action was originally filed and is both (i) a defendant from whom significant relief is sought and (ii) a defendant whose conduct forms a significant basis for the claims asserted; (3) the principal injuries suffered by each defendant were incurred in the state where the action was originally filled; and (4) during the three year period preceding the filing of the class action, no other class action was filed asserting the same or similar allegations against any of the defendants on behalf of the same class. *See* 28 U.S.C. § 1332(d)(4)(A).

2. The Home State Controversy Exception

Under the "home state controversy" exception, a district court cannot accept diversity jurisdiction where at least 2/3 of the members of the proposed class, as well as the primary defendants, are citizens of the state in which the action was originally filed. *See* 28 U.S.C. § 1332(d)(4)(B).

3. The State Action Exception

Under the "state action" exception, a district court must decline jurisdiction in any class where the primary defendants are states, state officials or other government entities against whom the district court may be foreclosed from ordering relief. *See* 28 U.S.C. § 1332(d)(5).

4. The Covered Securities Exception

Under the "covered securities" exception, CAFA does not apply to any class action that solely involves a claim concerning a covered security, as defined under the Securities Act of 1933 and the Securities Exchange Act of 1934, or relates to any rights or duties pertaining to any security. *See* 28 U.S.C. § 1332(d)(9)(A).

5. The Interests of Justice Exception

The "interests of justice" exception is a discretionary exception to the diversity requirements under CAFA. Under this exception, a district court may "in the interests of justice and looking to the totality of the circumstances," decline to exercise diversity jurisdiction over a class action where more than 1/3 but less than 2/3 of the members of the proposed class and the primary defendants are citizens of the state in which the action was originally filed. *See* 28 U.S.C. § 1332(d)(3).

B. Removal from State to Federal Court

CAFA also sets forth rules relaxing the standard for removal of cases from state to federal court. Generally, any civil action brought in state court over which federal

courts have original jurisdiction may be removed within 30 days of defendant receiving the pleading which places defendant on notice that the case is removable. *See* 28 U.S.C. §§ 1441, et seq. CAFA institutes many significant changes regarding the removal of class actions to federal court.

First, CAFA removes the one year time limit found in 28 U.S.C. § 1446(b) for removal of class action cases and does not proscribe a time limit under which class action cases must be removed to federal court. *See* 28 U.S.C. § 1453(b). Additionally, under CAFA a class action case may be removed to federal court even if many defendants are residents of the forum state, as long as at least one defendant is diverse. *See id.* Further, class action defendants are not required to obtain approval from co-defendants prior to removal of class actions to federal court. *See id.* Also, under CAFA remand orders in class action cases may be appealed immediately, subject to the appellate court's agreement to accept the case. *See* 28 U.S.C. § 1453(c).

C. Class Action Settlements

CAFA includes significant provisions pertaining to class action settlements. Section 3 of CAFA sets forth a "Consumer Class Action Bill of Rights and Improved Procedures for Interstate Class Actions." 28 U.S.C. §§ 1711-1715. These provisions provide for, among other things, new procedures for obtaining judicial approval for class action settlements as well as setting forth the basis upon which coupon settlements will be approved by a court. *See* 28 U.S.C. § 1712(a). With regard to attorney's fees in coupon settlements, CAFA provides that the portion of attorney's fees attributable to the award of coupons must be based on the value to class members of the coupons that are redeemed. *See id.*

D. Likely Impact of CAFA on Mass Torts in Health Care

As CAFA is recently passed legislation, its long term effects cannot be fully evaluated at this time. However, initial court decisions applicable to all class actions, including health care mass torts, shed light on the potential effect of CAFA on mass torts. One frequent area of litigation pertains to the meaning of "commencement" under CAFA. Many circuit courts have held that the term "commencement" refers to when an action is originally filed in state court, rather than when it is removed. *See, e.g. Pfizer, Inc. v. Lott*, 417 F.3d 725, 726 (7th Cir. 2005); *Pritchett v. Office Depot, Inc.*, 420 F.3d 1090, 1094 (10th Cir. 2005). Additionally, courts are split on whether CAFA shifts the burden of proof to plaintiffs to prove federal jurisdiction does not exist on removal. *See, e.g. Berry v. Am. Express Publ'g Corp.*, 381 F. Supp.2d 1118, 1122-23 (C.D. Cal. 2005)(concluding that burden of proof lies with party opposing removal because of legislative history suggesting the same and CAFA's purpose to expand federal jurisdiction); *but see Eufaula Drugs, Inc. v. TDI Managed Care Servs., Inc.*, 2006 WL 986976, at *3 (M.D. Ala. Apr. 14, 2006)(court refused to consider the Senate report on CAFA and instead applied the traditional burden). However, despite the number of cases that have dealt with aspects of CAFA since its passage in 2005, many important provisions have yet to be fully explored by courts. CAFA provisions pertaining to class action settlements have yet to be fully interpreted. *See* Schmelz, at 13.

V. ATYPICAL MASS TORT LITIGATION

In addition to litigation regarding drugs and medical devices, plaintiffs bring a wide variety mass tort lawsuits pertaining to health care. Many of these mass torts, while atypical, seek to affect change in the delivery of healthcare products and services just as drug and medical device litigation does. Below is a summary of three such atypical mass torts.

A. Uninsured Patients

A recent class action settlement took place in Los Angeles County Superior Court, California, pertaining to uninsured and some underinsured patients of Tenet Healthcare Hospital (hereinafter "Tenet") who either paid out of pocket expenses or owe money for treatment during the period of June 15, 1999 to December 31, 2004. *See* Notice of Proposed Settlement with Tenet Healthcare Corporation. Plaintiffs claimed Tenet charged uninsured and some underinsured patients a full, non-discounted rate. *See id.* at 1. Plaintiffs alleged that such actions were excessive and unconscionable, as well as a violation of unfair competition and consumer protection laws. *See id.*

Tenet eventually reached a settlement agreement with the plaintiffs. As part of the settlement agreement, Tenet denied all allegations of wrongdoing and maintained the class action had no merit. *See id.* Additional terms of the class action settlement included the following:

- cash refunds by Tenet for uninsured patients who received treatment at Tenet and paid their hospital bills, in accordance with a specified formula;

- a revised discounted hospital bill for uninsured patients who received treatment at Tenet and owe

money, but have not paid Tenet for such treatment, in accordance with a specified formula;

- payment by Tenet of $4 million to a non-profit organization whose purpose is to aid the underinsured with health care costs, such organization to be recommended by plaintiffs with court approval;

- discounted pricing for uninsured patients seeking treatment at Tenet;

- disclosure of estimated charges for any anticipated treatment required to be paid by any uninsured patient; and

- establishment by Tenet of criteria to be satisfied prior to initiating litigation for the purposes of collecting on any uninsured patient accounts.

See id. at 2.

B. Medical Marijuana

In a more unusual health care mass tort, over 160 individuals from 49 states filed a class action lawsuit in Philadelphia federal court requesting laws prohibiting the medical use of marijuana be struck down as unconstitutional. In late 1999, the court dismissed the lawsuit. *See Judge Dismisses Medical Pot Suit*, ASSOCIATED PRESS, December 4, 1999. At issue in the case was the U.S. government's "compassionate use" program, begun in 1970, which allowed certain individuals to use marijuana for medical reasons. *See id.* The program has slowly been phased out. *See id.* According to press reports, as of 1999 only eight percent of patients nationwide still receive marijuana under the "compassionate use" program, some of whom have glaucoma or cancer. *See id.* Lawrence Hirsch, an attorney representing the plaintiffs, argued that everyone should be free to smoke marijuana "without control or interference" from the government. *Id.* Hirsch argued "[i]f the government allows eight people to get it, then all people who need it should be able to get it." *Id.* Nevertheless, the lawsuit was not a complete loss for medical marijuana advocates, as the court ruled that those involved in the "compassionate use" program prior to 1992 should retain the right to use marijuana until their deaths. *See id.*

C. Insurance Premiums

On September 19, 2006, 51 year old Richard B. Cort filed a class action lawsuit in Baltimore City Circuit Court against CareFirst BlueCross BlueShield (hereinafter "CareFirst"). *See* Alan Zibel, *CareFirst hit with class action suit over premiums*, BALTIMORE BUSINESS JOURNAL (September 19, 2006), http://www.bizjournals.com/baltimore/stories/2006/09/18/daily15.html. The suit alleges CareFirst overcharged members with individual coverage by prematurely raising their rates. *See id.* Mr. Cort claims that when CareFirst raised his premium when he turned 50, it charged him at the increased rate for the entire month instead of for the remainder of the month after his birthday. *See id.* While this conduct allegedly resulted in an overcharge of only $78.60, plaintiff's counsel Andrew D. Levy estimates that damages for the entire class of plaintiffs could be in the millions of dollars "when you consider how many people CareFirst insures and how most of those policyholders do not have birthdays that occur on the first day of the month." *Id.*

In response to the lawsuit, CareFirst announced on September 20, 2006 that it would send refund checks to policyholders whose premiums were raised at the beginning of the month when they reached a certain age rather than on their birthday. *See* M. William Salganik, *CareFirst Plans Birthday Refunds*, BALTIMORE SUN, September 20, 2006 at 2D. Additionally, CareFirst will cease charging a full month's increased premium to policyholders whose birthdays are not on the first of the month, at least until amendments to future policies are filed explicitly contemplating such an increase. *See id.*