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An Ad Hoc Inquiry Into the Feasibilities and Impracticalities Associated With Class Certification Of Blood Glucose Monitor Users

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Table of Contents

1	Author's Statement	4
2	Blood Glucose Monitors	5
2.1	History	5
2.2	Industry.....	6
2.3	Accuracy.....	7
2.4	Regulatory Environment.....	8
2.5	Warranties	9
3	Commencing the Action	10
3.1	Choosing the Court	10
3.1.1	<i>Riegel v. Medtronic, Inc.</i>	10
3.1.2	<i>Wyeth v. Levine</i>	14
3.1.3	<i>Implications of Lohr, Riegel and Wyeth</i>	16
3.1.4	<i>Legislative Redress</i>	23
3.1.5	<i>Conclusion</i>	24
4	Class Certification.....	26
4.1	The Importance of a Personal Injury Claim	28
4.1.1	<i>In re West Virginia Rezulin Litigation</i>	30
4.1.2	<i>Davis v. American Home Products Corporation</i>	31
4.1.3	<i>In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation</i>	33
4.2	Numerosity	36
4.3	Commonality	36
4.4	Typicality.....	36
4.5	Adequacy.....	36
5	Conclusion	36
	APPENDIX A.....	Error! Bookmark not defined.

Table of Cases

<i>AKS v Bennett</i> , 150 F.R.D. 187, 191 (D Kan 1993)	42
<i>Alm v. Aluminum Co. of America</i> , 717 S.W.2d 588, 592 (Tex. 1986).....	19
<i>Amchem Prods. v. Windsor</i> , 521 U.S. 591 (U.S. 1997)	passim
<i>Becton Dickinson v. Usrey</i> , 57 S.W. 3d 488 (Tex. App. 2001)	29
<i>Benner v. Becton Dickinson & Co.</i> , 214 F.R.D. 157 (S.D.N.Y. 2003).....	39
<i>Bostick v. St. Jude Med., Inc.</i> , 2004 U.S. Dist. LEXIS 29997, 19-20 (W.D. Tenn. Aug. 17, 2004)	41
<i>Brown v. Am. Home Prods. Corp. (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.)</i> , 2000 U.S. Dist. LEXIS 12275 (E.D. Pa. 2000).....	43
<i>Crosby v. Social Sec. Admin.</i> , 796 F.2d 576 (1st Cir. Mass. 1986).....	39
<i>Davis v. Am. Home Prods. Corp.</i> , 844 So. 2d 242, 247 (2003).....	1, 22, 33, 36
<i>General Telephone Co. of Southwest v. Falcon</i> , 457 U.S. 152, 102 S.Ct. 364 (1982).....	29
<i>General Telephone Co. v. E.E.O.C.</i> 446 U.S. 318, 330, (1980).....	38
<i>Georgine v. Amchem Prods.</i> , 83 F.3d 610, 625 (3d Cir. Pa. 1996).....	39
<i>Goodman v. Lukens Steel Co.</i> , 777 F.2d 113, 124 (3d Cir. 1985)	43
<i>Hansen v. Haff</i> , 65 F.2d 94 (9th Cir. Cal. 1933)	38
<i>Harris v. Purdue Pharma, L.P.</i> , 218 F.R.D. 590, 595 (S.D. Ohio 2003)	28
<i>Hofts v. Howmedica Osteonics Corp.</i> , 597 F. Supp. 2d 830 (S.D. Ind. 2009)	24, 25
<i>Hoxworth v. Blinder, Robinson & Co.</i> , 980 F.2d 912, 923 (3d Cir. 1992)	42
<i>In re Agent Orange Prods. Liab. Litig.</i> , 818 F.2d 145, 166-67 (2d Cir. 1987).....	40
<i>In re American Medical Sys.</i> , 75 F.3d 1069 (6th Cir. 1996)	38, 41, 42
<i>In re Medtronic Sprint Fidelis Leads Prods. Liab. Litig.</i> , 592 F.Supp.2d 1147 (D.Minn.,2009) .	22, 23, 24
<i>In re Rezulin Prods. Liab. Litig.</i> , 210 F.R.D. 61(S.D.N.Y. 2002).....	passim
<i>In re School Asbestos Litig.</i> , 789 F.2d 996, 1010 (3d Cir. 1986).....	40
<i>In re St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.</i> , 2004 U.S. Dist. LEXIS 149, 4-5 (D. Minn. 2004)	1, 34, 35, 36
<i>In re W. Va. Rezulin Litig. v. Hutchison</i> , 214 W. Va. 52, 59 (W. Va. 2003)	32
<i>In re West Virginia Rezulin Litigation</i> , 585 S.E. 2d 52 (W. Va. 2003).....	1, 32
<i>Johns v. DeLeonardis</i> , 145 F.R.D. 480, 484 (ND IL 1992).....	43
<i>Lewallen v. Medtronic USA, Inc. et al.</i> 2002 WL 31300899, No. C01-20395 (N.Cal.2002).....	29
<i>Marisol A. by Forbes v. Giuliani</i> , 126 F.3d 372, 375 (2d Cir. N.Y. 1997)	40

<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (U.S. 1996)	passim
<i>Meredith v Mid-Atlantic Coca Cola Bottling Co</i> , 129 F.R.D. 130, 133 (ED Va 1989).....	42
<i>Niemiera v. Schneider</i> , 114 N.J. 550, 559 (1989)	19
<i>Ortiz v. Fibreboard Corp.</i> , 527 U.S. 815 (U.S. 1999)	28, 29
<i>Perez v. Wyeth Labs Inc.</i> , 734 A.2d 1246 (N.J. 1999)	21, 22
<i>Reichman v. Bureau of Affirmative Action</i> , 536 F. Supp. 1149 (M.D. Pa. 1982)	38
<i>Riegel v. Medtronic, Inc.</i> , 128 S. Ct. 999 (U.S. 2008)	passim
<i>Rivera v. Wyeth-Ayerst Labs.</i> , 283 F.3d 315 (5th Cir. Tex. 2002).....	30, 31
<i>Robidoux v. Celani</i> , 987 F.2d 931, 936-37 (2d Cir. 1993).....	40
<i>Scott v. University of Delaware</i> , 601 F.2d 76 (3d Cir. Del. 1979).....	38
<i>Simon v Eastern Kentucky Welfare Rights Org.</i> , 426 U.S. 26, 40 n 20 (1976).....	42
<i>State ex rel. Johnson & Johnson Corp. v. Karl</i> , 647 S.E.2d 899, 910-11, 914 (W. Va. 2007).....	21
<i>Valentino v. Carter-Wallace, Inc.</i> , 97 F.3d 1227 (9th Cir. Cal. 1996)	38
<i>Wyeth v. Levine</i> , 173 L. Ed. 2d 51 (U.S. 2009).....	passim

1 Author's Statement

My grandfather is a diabetic. Like many, he is the type of diabetic that routinely, if not obsessively, monitors his blood sugar with a blood glucose meter (BGM) that was prescribed to him by his doctor. From the time he was diagnosed, he has meticulously kept notes on the readings from this meter. He uses the meter at least five times a day, in the morning (fasting); in the evening; and before each meal. Based on the meter's readings, he decides what to eat and how much medication to take. While not insulin dependent, he takes pills to help keep his blood sugar regulated.

If the readings show that his sugar is high, he will stay away from the foods that are prohibited and increase his medication dosage. If the readings are low, he will eliminate the medication altogether and eat more sugary foods. In truth, his entire lifestyle is based on the little digital number that appears on the blood glucose meter.

Several months ago, my grandfather came to me with two BGM's. He conducted measurements with both devices. One BGM listed his blood sugar at 87, within normal range, and the other listed it at 149, above normal. We repeated the tests. This time the first BGM read 117 and the second read 161. At this point, my grandfather asked me to contact the manufacturers of these devices and ask them to replace these obviously malfunctioning devices. I proceeded to do this and was met with customer service representatives who offered to replace the devices at no cost.

Roughly two weeks later, the new units arrived. I, myself, loaded and programmed them in the hopes that their inaccuracy was a result of my grandfather's inability to do so properly. However, repeated testing showed that both machines were inconsistent with each other, and even with themselves a large part of the time. My

grandfather wanted to know how he could safely take his medication without an accurate reading. Why was he told by his physician to rely on this device when it offered little guidance on his dosing?

This series of events got me thinking. How many millions of people were dependent on these devices, like my grandfather? What were the responsibilities of the manufacturers to the user? Why were no promises of accuracy made to the consumer?

Following is a brief foray into some of the answers to these questions.

2 Blood Glucose Monitors

2.1 History

The history of blood glucose monitors for home use dates back to the 1960's. In 1965, a company named AMES developed a stick that a patient would apply a drop of blood to. The stick would change color based on the amount of glucose in the blood and compare it to a chart to find out their reading. Then, in 1970, a man by the name of Anton H. Clemens developed the first blood glucose meter based on this method. It consisted of a light meter that read reflected light on those same sticks. The darker the color, the less light reflected. That reflected light was sent to a photoelectric cell, which swung a needle. This added a degree of accuracy, as the machine was able to detect change in light and dark better than a person. This type of testing is still used today in urine tests for glucose.

Today, most meters use an electrochemical method. Test strips absorb a drop of blood, which reacts with an enzyme electrode and generates an electrical current.

The amount of charge that passes through the electrode results in a reading proportional to the amount of glucose in the blood.

Over time, the changes in technology have led to smaller, more accurate meters that rely on less blood for their results. However, even in their modern state, most meters are accurate 85% of the time at best, with many factors adding to their inaccuracy.

2.2 Industry

Currently, the market for blood glucose meters is estimated at \$3 billion dollars per year worldwide and growth continues. The National Diabetes Information Clearinghouse estimates that, in 2007, 23.6 million people were diabetic in the United States with the total cost for US diabetic care reaching \$174 billion. The market will also continue to benefit from evidence that frequent monitoring can greatly reduce serious and even fatal consequences of uncontrolled blood glucose levels in patients, as reported by the Diabetes Control and Complications Trial (DCCT).¹

The market for whole blood glucose strips is highly concentrated with four companies holding ninety percent of the market. Roche Diagnostics is the overall market leader with LifeScan, a Johnson and Johnson Company, second, benefiting from sales of the ONE TOUCH Ultra introduced in 2001. The Ultra is approved for alternative site testing and is providing stiff competition for Roche's Accu-Chek Compact, also approved for alternative site testing. Bayer's Ascensia monitors and Abbott Laboratories' Medisense are lesser, but important players in this market.

¹ *DCCT and EDIC: The Diabetes Control and Complications Trial and Follow-up Study*, NIH Publication No. 08-3874, May 2008, <http://diabetes.niddk.nih.gov/dm/pubs/control/>.

2.3 Accuracy

The accuracy of blood glucose meters is a widely discussed topic in both the medical community and in medical technology settings. Even when used optimally, the meters offer results that are within a 10%-15% range of accuracy, on average. However, accuracy is greatly affected by a great number of factors including the condition of the test strip, user error, size and quality of the blood sample, environmental factors and a whole host of other factors that could lead to the degradation of accuracy.

Inaccuracy is widely accepted as part of the normal operations of BGM's. So much so that in 1987 a team of doctors developed a method for analyzing these inaccuracies called the Clarke Error Grid.²

The grid breaks down the accuracy of meter readings into five categories:

1. Region A are those values within 20% of the reference sensor.
2. Region B contains points that are outside of 20% but would not lead to inappropriate treatment.
3. Region C are those points leading to unnecessary treatment.
4. Region D are those points indicating a potentially dangerous failure to detect hypo- or hyperglycemia.
5. Region E are those points that would confuse treatment of hypoglycemia for hyperglycemia and vice-versa.

² Clarke WL, Cox D, Gonder-Frederick LA, Carter W, Pohl SL: *Evaluating clinical accuracy of systems for self-monitoring of blood glucose*. Diabetes Care 10:622–628,1987.

In 2000, this grid was improved, with the categories changing slightly³ in order to determine a better method for measuring and analyzing the inaccuracy of BGM's because:

As long ago as 1987, the ADA stipulated that the accuracy of SMBG should be sufficient to exclude errors of 15%. Since then, it has become apparent that tight control of BG levels is a crucial parameter in the management of diabetes. It has been shown, for example, that an intense treatment regime, compared with conventional treatment, can reduce the risk of retinopathy, neuropathy, and nephropathy by 50–70% for type 1 diabetic patients. Similar benefits have been demonstrated for type 2 diabetes. These results suggest that normalization of BG levels may effectively eliminate or greatly reduce these dire complications of diabetes. Thus, the ADA now recommends at least 3 or 4 SMBGs per day for type 1 diabetic patients.

Also, in 1987, the ADA proposed a goal for SMBG: total error (system plus user error) should be $\pm 10\%$ for all SMBG systems for BG values between 30 and 400 mg/dl. Our data indicate that this seemingly modest goal remains elusive. How important are these shortcomings in the measurement of BG values to the treatment of diabetes? The ADA guideline offers one criterion, but it does not recognize that all BG measurement errors of a given percentage do not have equal clinical significance.⁴

2.4 Regulatory Environment

Blood glucose meters are classified as Class II medical devices.⁵ They are regulated by the FDA under the Department of Health and Human Services. The

FDA reviews all glucose meters and test strips before they can be marketed to the public. This FDA "premarket" review process requires the manufacturer of the meter to show that the meter system provides acceptable accuracy and consistency of glucose measurement at high, medium and low levels of glucose as compared to glucose meters already being sold. The quality of software is an increasingly important feature of

³ Parkes JL, Slatin SL, Pardo S, Ginsberg BH. *A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose*. *Diabetes Care*. 2000; 23(8):1143–1148.

⁴ *Id.*

⁵ 21 CFR 862.1345

glucose meters since it controls the testing and data storage and controls the displays that the user sees and uses when testing.⁶

The FDA also considers possible interference from over-the-counter medications, prescription medications, and vitamin supplement and asks for data showing how well the meter has performed during actual use (a type of human factors study). BGM's are reviewed under the 510(k)⁷ review process, a process the FDA defines as :

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to PMA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the Act.⁸

2.5 Warranties

All BGM's appear to carry a standard consumer warranty. (See Appendix A).

⁶ Food and Drug Administration Center for Devices and Radiological Health, *Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology*, available at <http://www.fda.gov/cdrh/ode/gluc.html>; Food and Drug Administration Center for Devices and Radiological Health, *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*, available at <http://www.fda.gov/cdrh/humfac/1497.pdf>.

⁷ Food and Drug Administration Center for Devices and Radiological Health, *Premarket Notification 510(k)*, available at <http://www.fda.gov/CDRH/DEVADVICE/314.html>.

⁸ *Id.*

3 Commencing the Action

3.1 Choosing the Court

3.1.1 *Riegel v. Medtronic, Inc.*⁹

In February, 2008 the Supreme Court handed down a crucial decision in *Riegel v. Medtronic, Inc.*,¹⁰ involving medical devices regulated by the FDA. The case began in 1996 when an FDA-approved balloon catheter burst during Mr. Charles Riegel's angioplasty. As a result, Mr. Riegel experienced a complete heart blockage and had to undergo emergency coronary bypass surgery. Mr. Riegel sued Medtronic Inc., the manufacturer of the catheter, and claimed that the device was negligently designed, manufactured and mislabeled under New York state law.

The U.S. district court dismissed most of Mr. Riegel's claims on the ground that they were pre-empted by the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetics Act, which bars any state from establishing a requirement for a device "which is different from, or in addition to, any requirement" established under the MDA. The 2d U.S. Circuit Court of Appeals upheld that ruling, and the case was appealed to the Supreme Court, which addressed the question of "[w]hether the *express* preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration."¹¹

⁹ 128 S. Ct. 999 (U.S. 2008)

¹⁰ *Id.*

¹¹ *Id.* (*emphasis added*)

The Court denied Mr. Riegel's claims against Medtronic, and asserted that the catheter had been subject to an intensive approval process resulting in detailed federal requirements relating to the design, manufacture and labeling of the device. The Court held that the premarket approval process imposed "requirements" under MDA because the FDA required devices that received premarket approval to be made with almost no deviations from the specifications in the approval application. Further, the Court held that New York's tort duties constituted "requirements" under the MDA. Thus, petitioners' negligence and strict liability claims that related to safety and effectiveness were based on New York "requirements" with respect to the catheter that were "different from, or in addition to" the federal requirements. The Court rejected the contention that the general common-law duties were not requirements maintained "with respect to devices."¹²

The Court followed its own reasoning in a prior pre-emption decision in *Medtronic v. Lohr*,¹³ where the court asserted that the MDA, particularly 21 U.S.C.S. § 360(k), preempted state common law actions against the manufacturer for negligent manufacturing or failure to warn, but allowed claims based on negligent design. In *Lohr*, court rejected *Medtronic's* position that the MDA preempts all common-law claims against manufacturers for damages caused by medical devices and that design-defect claims involving section 510(k) devices are not preempted. The Court also ruled that claims based on a manufacturer's failure to comply with duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations were not preempted. The Court reasoned that § 360(k) did not deny a state the right to provide traditional remedies for violations of common law duties when those duties paralleled

¹² 128 S. Ct. 999 (U.S. 2008).

¹³ 518 U.S. 470 (U.S. 1996).

federal requirements. “Pre-emption would have had the effect of granting complete immunity from design defect liability to an entire industry that needed stringent regulation because there was no explicit private cause of action against manufacturers in the MDA.”¹⁴ Legislative history also showed that it was not Congress's intent to preempt most general common law duties enforced by damages actions. The federal requirements reflected generic concerns about device regulation generally, not concerns regarding a specific device that the statute was designed to protect from potentially contradictory state requirements.¹⁵

Riegel is distinguishable from *Lohr* in that the device in question in the *Lohr* case, a pacemaker, was grandfathered into the FDA's approval under a process that permitted manufacturers to submit to the FDA devices that are equivalent to devices that had been on the market prior to the passage of the MDA in 1976.¹⁶ Thus, it was not subjected to the FDA's rigorous testing protocol. This lack of rigorous premarket approval was the basis for the court's finding that this category of devices should remain open to state tort law, the only law that could constrain manufacturers in any way. Hence, the *Riegel* device, whose every aspect had been considered by the FDA before it received premarket approval as a new Class III device, no longer needed the protections of the state, having been thoroughly vetted and approved federally.

In *Riegel*, the court's analysis forayed even deeper, into notions of public policy and specifically to a consideration of whether the FDA or a state court could best

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ 518 U.S. 470, 482

determine the safety and effectiveness of medical devices.¹⁷ The defendant's device was subjected to an exhaustive premarket approval (PMA) process, under which manufacturers submit results of clinical studies and other extensive documentation for FDA review. Further, a device company submits an application for PMA typically only after investing thousands of hours and millions of dollars in developing and testing its new device. In turn, the FDA's internal scientists and engineers spend on average 1,200 hours assessing the device, may refer the application to a panel of outside experts and frequently request additional data from the manufacturer before granting PMA. Hence, it is unreasonable that a lay jury would be better equipped to determine the operational safety of a medical device than a legislatively appointed body that is expressly chosen to.¹⁸

The 8-1 decision in *Riegel* was borne directly from the express language of 21 U.S.C.S. § 360(c). By acknowledging congressional intent through the plain meaning of the statute, the court was bound by the specific clause preventing state law from preempting the FDA's premarket approval process. In fact, the pre-emption clause was included specifically to prevent states from forcing companies to tinker with their products after the FDA has approved a device. The statute reflects this, disallowing states from imposing "any requirement" on devices. Thus, the court ruled in favor of upholding "express pre-emption."

¹⁷ 128 S. Ct. 999, 1011

¹⁸ *Id* at 1008.

3.1.2 *Wyeth v. Levine*¹⁹

Most recently, in March of 2009, the Supreme Court issued another decision relating to pre-emption in which the court decided that the FDA's drug labeling requirements did not pre-empt state law product liability claims. In *Wyeth v. Levine*.²⁰ Ms. Levine, a musician, was injected with an anti-nausea drug via the "IV-push" method, whereby a drug is injected directly into a patient's vein. The drug entered Ms. Levine's artery and caused her arm to become gangrenous and later, amputated.²¹

Ms. Levine brought a state-law damages action in Vermont, alleging that Wyeth, the manufacturer of the drug, had failed to provide an adequate warning about the significant risks of administering the drug by the IV-push method. The Vermont jury determined that Ms. Levine's injury would not have occurred if the drug's label had included an adequate warning, and it awarded damages for her pain and suffering, substantial medical expenses, and loss of her livelihood as a professional musician. Wyeth argued that Ms. Levine's failure-to-warn claims were pre-empted by federal law because the drug's label had been approved by the federal Food and Drug Administration (FDA). The Vermont Supreme Court affirmed.²² The Supreme Court granted certiorari.

In this case the drug in question was approved by the FDA for sale under the Food, Drug, and Cosmetic Act ("FDCA") because it was deemed "safe and effective" by the agency in 1955. When a drug is approved under the FDCA, not only the drug itself is approved, but so is the exact language of the label and any material included with the

¹⁹ 173 L. Ed. 2d 51 (U.S. 2009)

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

drug's packaging. Over the subsequent years, the label was modified with the FDA's approval. One of the modifications it approved was a warning that stated that extreme caution should be used when directly injecting the drug (a method known as "IV push," as opposed to using an IV drip) since it can cause gangrene when accidentally injected into an artery.

Wyeth argued implied pre-emption based on impossibility. Specifically, that federal law preempts the state-law claims because the label of a prescription drug cannot be changed without FDA approval. A manufacturer can only change a drug label if it acquires new information, and because Wyeth did not acquire any new information about the risks of the drug, Wyeth argued that it would have had no authorization to change the drug's label without FDA approval.²³ In response, Ms. Levine argued that Wyeth must show that there was clear congressional intent to have federal law preempt state law in this situation because, unlike the regulation in *Riegel*, neither the FDCA nor its amendments contain an express provision for preemption for cases involving prescription drugs.²⁴ Further, that the absence of an explicit provision "strongly signals [Congress's] intent to preserve state-law remedies against pharmaceutical manufacturers."²⁵

The Court held that a state tort jury, rather than the FDA, is responsible for regulating warning labels for prescription drugs. The 6-3 majority held that the evidence was insufficient to show that the FDA would have barred Wyeth from changing its label. Justice Stevens added, however, that if the FDA had rejected "the kind of warning

²³ *Id.* at 3, 27.

²⁴ *Id.* at 21.

²⁵ *Id.* at 27–28.

required by the Vermont jury," then Wyeth would have faced a classic "impossibility" dilemma, no different than the dilemma it would have confronted if Vermont had passed a statute requiring warning language on the label that would have been rejected by the FDA.²⁶

3.1.3 Implications of *Lohr*, *Riegel* and *Wyeth*

3.1.3.1 The 510(k) Process

Although on the surface, it may appear that the decision in *Riegel* limits a patient's right to sue under state tort claims, the decision is limited in its scope. Most medical devices, including blood glucose monitors, go through what is known as the 510(k) process, the process reviewed in *Lohr*, which differs from the PMA process the court so closely relied upon in *Riegel*. There is a substantial difference between the 510(k) process and the PMA process. The PMA process is a substantive, in depth analysis of a device's safety and effectiveness, whereas a 510(k) process establishes that the device is substantially equivalent to a predicate device; that is, a device that is already legally marketed in the US. Whether a device is reviewed under a 510(k) or a PMA is based on the risk-based regulatory classification of the device, which means almost all Class I and Class II devices are reviewed under the 510(k) process. In *Riegel*, the Court reaffirmed the distinction between the exhaustive "federal requirements" of the PMA process and the looser scrutiny of 510(k) notification. This means that 510(k) devices—which vastly outnumber PMA devices—remain fully exposed to mass-tort liability, as the Court held in *Lohr*.

²⁶ *Id.* at 65.

3.1.3.2 *Manufacture Defect Claims*

Also, the *Riegel* decision does not bar manufacture defect claims - meaning manufacturers are still at risk for being sued when their products do not meet FDA guidelines.²⁷

3.1.3.3 *Learned Intermediary Doctrine*

Under the learned intermediary doctrine, manufacturers of medical devices can fulfill their duty to warn by sufficiently advising physicians of the potential risks associated with the use of their products. The physician then acts as an intermediary between the manufacturer and the final consumer (the patient). So long as the warning conveys adequate information to the physician concerning the product's risks and indications, the product is not defective. In short, it is not necessary for the manufacturer to warn the patient directly.^{28, 29} Most states and courts, including New York have adopted the doctrine.³⁰ In addition to prescription medicines, the doctrine has been applied in numerous cases involving medical devices, including catheters, pacemakers, breast implants, bone plates and screws, etc.³¹ However, if the information provided to that physician through that product's FDA-approved labeling differs from the information

²⁷ *Id.*

²⁸ *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989) ("a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities")

²⁹ *Alm v. Aluminum Co. of America*, 717 S.W.2d 588, 592 (Tex. 1986) ("when a drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the drug")

³⁰ Diane Schmauder Kane, J.D., *Construction and Application of Learned Intermediary Doctrine*, 57 ALR 5th 1 (1998)

³¹ *Id.* at 73-77 (citing cases).

provided to the physician by the manufacturer's representatives or other materials, the doctrine will not apply.

This issue of physician and consumer education proves crucial to any discussion of blood glucose monitors. Numerous studies have found, and the FDA agrees, that improper use of the device is a major factor in the inaccuracy of the results.³² Although the FDA regulates the labeling of all medical devices, its statutory authority does not extend to regulation of advertising of all medical devices. Specifically, the FDA regulates the advertising and promotion only of restricted medical devices, consisting of Class III and some Class II devices. The advertising regulation of all other devices falls under the purview of the FTC. Hence, the FDA's oversight of blood glucose monitor advertising is nonexistent, allowing manufacturers to freely promote their products to both the intermediaries and the end user. It is important to note that blood glucose monitors are not prescription medical devices and can be purchased over the counter. Despite being available over the counter, blood glucose monitors are predominantly distributed through prescription and therefore a discussion of the doctrine is merited.

Some courts have recently held that in cases where the product is directly marketed to consumers, the manufacturers are liable, not the physicians. In *Perez v. Wyeth Labs., Inc.*,³³ the New Jersey Supreme Court restricted the learned intermediary doctrine, and required manufacturers' warnings in the direct-to-consumer advertising

³²See Food and Drug Administration, *Glucose Meters and Diabetes Management*, available at <http://www.fda.gov/diabetes/glucose.html#13>; Bhubendra Rasaiah, *Self-monitoring of the blood glucose level: potential sources of inaccuracy*, *Can Med Assoc J.* 1985 June 15; 132(12): 1357-1359, 1361.

³³ 734 A.2d at 1246-47 (N.J. 1999)

context.³⁴ The court remarked that today managed care organizations provide medical services, patients can buy drugs in various locations outside of the traditional pharmacy, and most importantly, that sellers frequently advertise products to consumers directly "on the radio, television, the Internet, billboards on public transportation, and in magazines."³⁵

In 2007, the West Virginia Supreme Court agreed in *State ex rel. Johnson & Johnson Corp. v. Karl*,³⁶ and declined to adopt the learned intermediary "exception" to a general warning responsibility.³⁷ Here, the court held that direct-to-consumer advertising precludes the premises upon which the learned intermediary doctrine rests: "... (1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of 'doctor knows best' of need for the patient's informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject."³⁸ In his article³⁹, Mr. Kyle Fogt points out:

"the central theme, consistent among all of the cases finding an exception to the learned intermediate doctrine, is that the physician-patient relationship is not the same as in typical treatment scenarios."⁴⁰ When this premise, upon which the learned intermediary doctrine is built, is not

³⁴ *Id.* at 1257

³⁵ *Id.* at 1246-47

³⁶ 647 S.E.2d 899, 910-11, 914 (W. Va. 2007)

³⁷ *Id.*

³⁸ *Id.* at 910 (quoting *Perez*, 731 A.2d at 1255)

³⁹ Kyle T. Fogt, *The Road Less Traveled: West Virginia's Rejection of the Learned Intermediary Doctrine in the Age of Direct-to-Consumer Advertising*, 34 Iowa J. Corp. L. 587, 591-592

⁴⁰ Jeffrey J. Wiseman, *Annual Survey of South Carolina Law: Tort Law: Another Factor in the "Decisional Calculus": The Learned Intermediary Doctrine, the Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. Rev. 993, 1009 (2001).

present, a court may require the drug manufacturer to deliver a warning directly to the consumer.⁴¹

The West Virginia Supreme Court continues to be the only court that has outright rejected the doctrine, but there is a consensus among scholars and those involved with this aspect of product liability litigation, that as the scope and frequency of direct to consumer advertising continues, the learned intermediary doctrine will continue to come under scrutiny and remain a viable outlet for those seeking to bring state tort claims.

3.1.3.4 Is Preemption Applicable When an FDA Approved Medical Device Is Recalled?

If the FDA's PMA process serves as the foundation for preemption of state law, what happens when that process is negated in a recall? This question was recently addressed in a Minnesota Federal Court. In *In re Medtronic Sprint Fidelis Leads Product Liability Litigation*,⁴² twenty seven patients brought an action against the manufacturers of the Sprint Fidelis implantable cardiac defibrillator (ICD), which was implanted in patients' chests to monitor heart rates and correct arrhythmias by delivering electrical shocks to the heart muscle.⁴³ The FDA granted Medtronic's application for supplemental pre-market approval of the device in 2004. In 2006, patients who had been implanted with the ICD began to report that the device was delivering painful and unnecessary shocks, and several physicians reported that there were fractures in the leads. On October 15, 2007, Medtronic issued a Class I recall of the product. At the time of the

⁴¹ *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding that a manufacturer must ensure that warnings about its prescription vaccine reach consumers who are offered the vaccine at mass immunization clinics).

⁴² 592 F.Supp.2d 1147 (D.Minn.,2009)

⁴³ *Id.* at 1155

recall, some 257,000 Sprint Fidelis leads remained implanted in patients.⁴⁴ After the recall, the growing number of lawsuits was consolidated into one action.

Medtronic argued that the plaintiff's complaint was entirely pre-empted under 21 U.S.C. § 360k(a) and relied wholly on the *Riegel* decision to uphold the notion that the remedies sought by plaintiffs' state tort claims were "different from, or in addition to" MDA requirements. Plaintiffs argued that Medtronic could not avail itself of the protections offered under *Riegel*, because the product had been recalled therefore the PMA process annulled, and also, since Medtronic had failed to adhere to certain specifications of the PMA, preemption was not applicable because their claims were "parallel" to federal requirements.

The Minnesota federal court held that *Riegel* supports preemption for recalled devices. In applying the law of *Riegel* to the facts of *Sprint Fidelis*, the court held that a recall is not the same as voiding or negating a PMA.

The FDA, too, recognizes the distinction between the recall of a device and the revocation of a device's PMA – it has noted that "[w]hen a company recalls a medical device; it . . . takes action to prevent the problem *from happening again*." There cannot be an "again" for a recalled device if the recall invalidated the device's PMA.⁴⁵

In addition, since the PMA was in place at the time the leads were implanted, a subsequent invalidation of the PMA would be irrelevant because liability hinged on whether the devices were defective at the time of implantation. Finally, the courts rejected plaintiffs' argument that their claims were parallel to federal interests on the

⁴⁴ *Id.*

⁴⁵ *Id.* at 1157

basis of preemption and held that plaintiffs' claims imposed requirements that were different from, or in addition to, those imposed under federal law.⁴⁶

Contrary to *Sprint Fidelis*, in *Hofts v. Howmedica Osteonics Corp.*⁴⁷, an Indiana federal court recently ruled that the plaintiff's claims could proceed. In this case, the judge argued that preemption only applied to claims that an approved device "violated state tort law *notwithstanding compliance with the relevant federal requirements*"—in other words, if a device were later found to have *violated* its approved requirements, it would no longer qualify for protection from state tort claims.⁴⁸ The court's ruling relied on the fact that *Riegel* did not overrule *Lohr*, in that some state-law claims may still be permissible as "identical or parallel to the FDA's federal requirements." In the court's view, "[i]f the law were otherwise ... then *Riegel* and the [Medical Device Amendments to the Food Drug and Cosmetic Act] would be turned upside down and *Lohr* would be overruled."⁴⁹

In *Sprint Fidelis*, the court directs the plaintiffs to seek redress through congressional means. "Congress has decided to limit medical-device manufacturers' liability in order to spur innovation, even though individuals are sometimes injured when using medical devices. Plaintiffs' remedy, therefore, lies with Congress, and not with this Court (or any other court)."⁵⁰ The *Hofts* decision does not, instead distinguishing the *Sprint Fidelis* ruling as "unusually stringent," and expressing its disapproval of what it perceives to be efforts "to stretch *Riegel* beyond recognition" by "transforming its

⁴⁶ *Id.* at 1158

⁴⁷ 597 F. Supp. 2d 830 (S.D. Ind. 2009)

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

protection for FDA-approved devices that *comply* with federal law into a grant of civil immunity for FDA-approved devices that *violate* federal law." ⁵¹

Thus far, *Hofts* represents a minority view among post-*Riegel* decisions, virtually all of which have dismissed the plaintiffs' claims as preempted. To the extent other courts follow this court's reasoning, there may be little or no drop in filings against device manufacturers, since most mass-tort device litigation involves recalled products.

In the realm of blood glucose monitors, recalls have occurred in almost one hundred instances since 2002.⁵² In most cases, the calibration of the machines was incorrect. It is important to examine the applicability of *Riegel* in light of these.

3.1.4 Legislative Redress

On March 5, 2009, Sen. Edward M. Kennedy (D-Mass.), chair of the Senate Health, Education, Labor and Pensions Committee, introduced a bill into the Senate to forestall the *Riegel* decision. ⁵³ The Medical Device Safety Act of 2009 would amend Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) by adding the following language:

(c) No Effect on Liability Under State Law- Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.

(b) Effective Date; Applicability- The amendment made by subsection (a) shall--
(1) take effect as if included in the enactment of the Medical Device Amendments of 1976 (Public Law 94-295); and
(2) apply to any civil action pending or filed on or after the date of enactment of this Act.⁵⁴

⁵¹ *Id.*

⁵² Food and Drug Administration, *Medical Device Recall Database*, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>

⁵³ Medical Device Safety Act of 2009 (Introduced in Senate), S 540 IS, 11th Cong. (2009).

⁵⁴ *Id.*

Sen. Kennedy was also the sponsor of the bill that resulted in the passage of the MDA, and he does not believe the *Riegel* opinion follows the will of Congress, nor does he feel that there is clarity in light of the *Wyeth* decision.⁵⁵ He and Rep. Henry A. Waxman (D-Calif.), chair of the House Committee on Oversight and Government Reform, have both vowed to legislate against the Supreme Court's decision.

The new legislation, should it succeed, would have the power to eliminate the preemption protection the decision grants to the premarket approval devices. The legal concept behind preemption is straightforward: Congress has the power under the Constitution to "preempt" state laws and regulations that conflict with or exceed the requirements of federal law. Generally speaking, Congress must say it intends a federal statute to override comparable state laws, although in some circumstances the federal requirements may be so comprehensive and exhaustive that they "occupy the field" and "impliedly preempt" states from implementing their own rules. State interference with federal law is not limited to statutes and regulations; the Supreme Court has held that verdicts and court decisions under state common-law are just as disruptive, and therefore also subject to preemption.

3.1.5 Conclusion

While the decisions above may cast a doubt as to whether an action can successfully be brought against the manufacturers of blood glucose monitors, they by no means eradicate any chance of successfully pursuing an action at least as to the question of preemption. BGM's are Class II devices, subject to a 510(k) review and

⁵⁵ Committee on Energy and Commerce, *Health Leaders Introduce Legislation Reversing Supreme Court's Medical Device Decision*, available at http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1518

available both through a physician and over the counter. As such, these devices fall well within the carved out niches of *Lohr*, *Riegel* and *Wyeth*. In addition, BGM's and test strips are often the subject of FDA recalls, arguably negating the little scrutiny they receive under 510(k). Having overcome, or at least somewhat scaled, the issue of preemption it is important to now determine the viability of any such action in the field of class actions.

4 Class Certification

Medical devices are frequently the subject of class action cases, most of which are brought in federal court. The Supreme Court has handed down several decisions⁵⁶ that make certifying a product liability class more difficult. The Court calls for “caution when individual stakes are high and disparity among class members is great.”⁵⁷ Relying mainly on concerns reflected in 1966 amendments to Rule 23, the Court held that mass torts are “ordinarily not appropriate” for class treatment.⁵⁸ Federal and state courts tend to tread lightly before certifying a class in a medical device product liability suit, noting the likelihood of attracting a great deal of publicity as well as claimants that may or may not have been able to pursue a traditional tort cause of action on their own.

The overwhelming issues associated with claimants’ personal injuries tend to make medical device class actions unmanageable. The cases require extensive investigations into claimant’s medical histories including their interactions with the devices in question.⁵⁹ In addition, the same plaintiff often seeks to represent both symptomatic and asymptomatic claimants.⁶⁰ In addition, and of most importance in the case of blood glucose monitors, it is inherently and practically difficult to establish whether class members were properly warned, including the problem of educating the

⁵⁶ *Amchem Prods. v. Windsor*, 521 U.S. 591 (U.S. 1997), *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (U.S. 1999)

⁵⁷ *Amchem*, 521 U.S. 591, 625

⁵⁸ FED R. CIV. P. 23, notes of Advisory Committee on 1966 Amendments to Rules, *reprinted in* 39 F.R.D. 69, 103 (1966)

⁵⁹ *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 66-67 (S.D.N.Y. 2002)

⁶⁰ *Amchem*, 521 U.S. at 591

jury about the intricacies of the learned intermediary doctrine.⁶¹ Medical device litigation introduces additional individual issues such as variations in product models and varying uses under each class member's individual circumstances.⁶²

Despite this, class actions are almost always pursued in instances of product recalls, and many times when the product is still marketed. Few federal courts have certified a class in medical device cases, but it is not impossible. Previously, classes have been certified in federal court for recipients of pacemakers, heart valves, tobacco users, and people exposed to asbestos and many more in state courts nationwide. In response to these difficulties, new theories of injury and causation have emerged to make class cases appear more manageable. Further, some courts continue to certify even personal injury claims.⁶³

In defending a class action, the single most important motion facing a defendant is the plaintiff's motion to certify a class. Rule 23(a) requires that the plaintiff demonstrate numerosity, commonality and typicality, and that the class members will be adequately represented, and must additionally demonstrate that the action satisfies Rule 23(b). The class action requirements of Rule 23 are mandatory. Thus, class certification requires that the prospective class representative satisfy the elements set forth in Rule 23(a), as well as the elements of Rule 23(b) be met.⁶⁴

The plaintiff has the burden of proving that a class should be certified.⁶⁵

⁶¹ *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 595 (S.D. Ohio 2003)

⁶² *See, e.g., Benner v. Becton Dickinson Co.*, 214 F.R.D. 157 (S.D.N.Y. 2003); *Becton Dickinson v. Usrey*, 57 S.W. 3d 488 (Tex. App. 2001); *Lewallen v. Medtronic USA, Inc. et al.* 2002 WL 31300899, No. C01-20395 (N. Cal., August 28, 2002)

⁶³ *Amchem*, 521 U.S. 591 (1997); *Ortiz*, 527 U.S. 815 (1999).

⁶⁴ *General Telephone Co. of Southwest v. Falcon*, 457 U.S. 152, 102 S.Ct. 364 (1982) (reversing class certification for failure to analyze Rule 23 requirements).

⁶⁵ *Amchem*, 521 U.S. 591

4.1 The Importance of a Personal Injury Claim

In recent years, ⁶⁶ plaintiffs have begun to reject personal injury claims in lieu of medical monitoring, statutory consumer fraud, or unjust enrichment claims based merely on an "enhanced health risk."⁶⁷ In addition, they are seeking economic loss damages limited to such amounts as the return of their product purchase price.⁶⁸ The associated theory of product liability is that the product has a latent propensity to increase one's risk of harm, that the alleged risk has been concealed from the public through campaigns of false or deceptive marketing, and that the plaintiffs have, in effect, been denied the benefit of their bargain because no one would have purchased a potentially dangerous product if they had "known the truth."⁶⁹

Most at risk in these "no injury" tort theories are the defendants. The plaintiff does not have to show that any person was, in actuality, harmed by the product – in fact, in many cases few consumers have been harmed – yet the plaintiff can still assert a claim and have it aggregated. In addition, an "enhanced risk" implies commonality while simultaneously avoiding issues of personal injury causation. The defendant must respond to these specious allegations, but cannot concede that the defect is fodder for class certification. In addition, the defendant must battle the claim in the prying eyes of the media whose tendency is to highlight the danger, not safety, of a litigated product.

This approach to class certification is not without its problems. In order to prevail, the plaintiffs must still meet the burden of proof and therefore must still be subject to the

⁶⁶ *Rezulin*, 210 F.R.D. at 67-69, *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. Tex. 2002)

⁶⁷ *Rezulin*, 210 F.R.D. at 67-69

⁶⁸ *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. Tex. 2002)

⁶⁹ *Id.*

same inquiries into medical histories, an already heavily burdened process weighed on more so by any product that is available over the counter.⁷⁰ Additionally, in order to receive damages equivalent to even the purchase price of the product requires evidence that the purchaser received value less than what was bargained for.⁷¹ Thus, the issues of causation and personal injury remain the same.

In *Rezulin*, plaintiffs sought only the return of their purchase price and claimed an “enhanced health risk” while maintaining that *Rezulin*, a diabetes medication, caused liver damage and death.⁷² The court held:⁷³

To obtain restitution of the purchase price of *Rezulin*, plaintiffs and class members would be obliged, at least in many jurisdictions, to prove some kind of harm.... [T]he question of whether an individual class member got his or her money's worth is inherently individual. Indeed, it involves very much the same question as would a claim for money damages for personal injury."

Similarly, plaintiffs who challenged the anti-inflammatory drug *Duract*, while alleging that the product causes liver failure and death, limited their claim to return of purchase price because, in view of the purported product risks, they had been denied "the benefit of the bargain" when they purchased and used *Duract*. Here, the court questioned whether a claim of “enhanced health risk” was a viable tort theory that raised a justiciable case or controversy.

Lost "expectations" or lost "benefit of the bargain" claims arise in contract, not in tort. The latter requires injury and, since the plaintiffs could not claim

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Rezulin*, 210 F.R.D at 68

⁷³ *Id.*

they suffered any of the alleged ill-effects of Duract, the court finds that no Article III standing existed to prosecute a product liability action.⁷⁴

4.1.1 *In re West Virginia Rezulin Litigation*

In *In re West Virginia Rezulin Litigation*,⁷⁵ plaintiffs sought to certify a class of all persons who either consumed Rezulin in West Virginia or consumed the drug after having it prescribed or sold to them in West Virginia. The trial court denied certification, but the West Virginia Supreme Court of Appeals reversed and remanded. Here, plaintiffs claimed the makers of Rezulin, a diabetes drug, were responsible for claimants' increased liver damage and allegedly fraudulent marketing campaign.⁷⁶ Plaintiffs asserted that the manufacturer actively hid clinical data showing the danger of Rezulin and sought relief for statutory consumer fraud in the form of medical monitoring.⁷⁷ The plaintiffs generally asserted that the defendants knowingly put a defective chemical - a drug - on the market, which they knew or should have known was defective at the time. The plaintiffs contended that the defendants' product caused the plaintiffs to be subject to an increased risk of liver disease and injury.⁷⁸

Defendants asserted that plaintiffs were unable to identify anyone else in the state "who suffered a Rezulin-related injury"⁷⁹ and that there could be no class cohesion under such circumstances, and thus any commonality, typicality, adequacy or

⁷⁴ *Rivera*, 283 F.3d at 319-21

⁷⁵ 585 S.E. 2d 52 (W. Va. 2003).

⁷⁶ *Id.*

⁷⁷ *Id.* at 53

⁷⁸ *In re W. Va. Rezulin Litig. v. Hutchison*, 214 W. Va. 52, 59 (W. Va. 2003)

⁷⁹ *Id.* at 67

predominance of common issues.⁸⁰ The court held these arguments to be improper attacks on the merits.⁸¹

The court found class action status appropriate and held that “The plaintiffs are primarily seeking relief relating to medical monitoring. The plaintiffs are not required, at the class certification stage, to identify the specific injuries of each class member, and it was error for the circuit court to so hold.”⁸² The court went on to use bargain analysis to conclude that plaintiffs' consumer fraud claims could be resolved on a class basis: “If the consumer proves that he or she has purchased an item that is different from or inferior to that for which he bargained, the ‘ascertainable loss’ requirement [of the West Virginia statute] is satisfied.”⁸³ Finally, the court dismissed while the issue of actual personal injury claims as merely “individual damage issues that do not ordinarily preclude certification.”⁸⁴

4.1.2 *Davis v. American Home Products Corporation*

In *Davis v. American Home Products Corporation*,⁸⁵ the plaintiffs requested the certification of a class action, claiming strict liability for an allegedly defective product, the Norplant implant contraceptive device, manufactured by American Home Products Corporation d/b/a Wyeth Ayerst Corporation (“Wyeth”).⁸⁶ Wyeth appealed the trial court's judgment that granted the plaintiffs' motion for class certification and provided the definition of the class, but the fourth circuit affirmed and granted class certification.

⁸⁰ *Id.*

⁸¹ *Id.* at 63

⁸² *Id.* at 67

⁸³ *Id.* at 75.

⁸⁴ *Id.* at 72.

⁸⁵ *Davis v. Am. Home Prods. Corp.*, 844 So. 2d 242, 247 (La.App. 4 Cir. Mar. 26, 2003)

⁸⁶ *Id.*

In this case, approximately 1800 Louisiana women implanted with the Norplant contraceptive device and experienced a range of physical symptoms. They claimed that “the Norplant device was defectively designed because the time-release mechanism for the drug distributed highly concentrated amounts of the drug throughout a user’s body during the first twelve to eighteen months of use.”⁸⁷

The court reasoned that the static nature of the device, an implant, constituted one device with the same dosage and thus its effect could be equally measured across the class.

Only one category exists: women who were or are living in Louisiana, who used the Norplant implant, and who suffered from the 15 side effects that Wyeth listed in the labeling of the Norplant implant product.”⁸⁸

The court when on to reason:

The issue is whether the one product, Norplant implant, produced by one manufacturer, Wyeth, is defective because the product had the above characteristics and caused injury to the class members. As stated by the plaintiffs, ‘Certification of the class is proper because it essentially boils down to one fundamental question: Is the Norplant contraceptive device a defective product?’ There should be one answer to this question, and the only practical vehicle that can effectively arrive at one consistent answer is the class action procedure.⁸⁹

The court noted that the case involved only personal injury plaintiffs, as opposed to a mixture of personal injury and asymptomatic plaintiffs, and that the class was restricted to female residents of Louisiana, instead of women spread across the country.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

4.1.3 *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation*

In *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation*,⁹⁰ the United States District Court for the District of Minnesota certified two classes in a medical device product liability suit. The first class consisted of those members who received the implanted device and suffered injury and the second class consisted of those members that were asymptomatic.

In this case, the defendant manufactured an artificial heart valve called the "Silzone" valve. The Silzone valve was approved by the FDA and implanted into over ten thousand individuals in the United States. The valve was voluntarily recalled after its safety and efficacy were called into question. Plaintiffs brought a motion seeking certification of two classes. Class I, the monitoring class, was to include every patient in the United States who still has a Silzone valve implanted. Class I sought injunctive relief, in the form of medical monitoring. Class II, the injury class, was to consist of all people in the United States who received a Silzone valve and who have sustained physical injuries due to the valve, including but not limited to injuries requiring explantation surgery and injuries resulting in death. Class I sought injunctive relief only, while Class II sought money damages.⁹¹

The Court found that both proposed classes "met the threshold requirements of Rule 23(a)", that common issues of law and fact predominated, a class action was the "superior way to adjudicate the claims" and certified plaintiffs' common law claims for both Class I and Class II pursuant to Rule 23(b)(3) and (c)(4). The Court also

⁹⁰ *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation*, 2004 U.S. Dist. LEXIS 149, 4-5 (D. Minn. 2004)

⁹¹ *Id.*

conditionally certified the medical monitoring claims of the Class I plaintiffs, pursuant to Rule 23(b)(2).⁹² Additionally, the Court determined that “common issues of law and fact predominated in plaintiffs' claims under Minnesota's consumer protection and deceptive trade practices acts and that a class action was the superior method of adjudicating those claims.”⁹³ The Court went on to certify plaintiffs' claims under those statutes pursuant to Rule 23(b)(3).

The court found that personal injury issues were curtailed in light of the fact that the case, much like *Davis*, involved only one product, whose defects and exposures were reasonably measurable. Furthermore, the court found that “individual issues of causation were not overarching,”⁹⁴ and remarked that the valve had already been recalled. As for the medical monitoring issues, the court found that:

Unlike claims involving uncertain levels of exposure and an uncertain number of potential individuals exposed, the medical monitoring class here is certain and discrete. In addition, in contrast to cases involving environmental toxins, the Court will not face issues of length or amount of exposure. Finally, because the Court defines the class narrowly to include only asymptomatic individuals, this case does not present issues of causation.⁹⁵

The court said that even “persons with a proven increased risk of harm, even if unmanifested, would be entitled to medical monitoring”⁹⁶. The court was satisfied with plaintiffs' expert testimony, which showed a plausible link between increased risk of valve leaks and use of the Silzone valve.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.* at 6-7

⁹⁵ *Id.* at 13

⁹⁶ *Id.* at 9-11

In January 2004, the *St. Jude* court partially reversed itself⁹⁷ and decertified the personal injury class because of variations in state law. The court ruled that because the plaintiffs' relied on numerous theories of liability, the litigation was unmanageable.

However, plaintiffs state six liability theories. Each of those six theories will require at least two subclasses (resulting in twelve subclasses). Perhaps twelve subclasses could be manageable; however, the difficulty does not stop there. The Court is persuaded that no two states' law is substantially alike when the Court considers all of plaintiffs' substantive claims; therefore the Court faces the proposition of managing upwards of 25 subclasses. Despite plaintiffs' conviction that the subclasses might be managed with special interrogatories and verdict forms, the Court simply cannot fathom a workable trial plan, given the sheer number of subclasses.

In reference to individual fact issues, the court stated:

After fully considering the variations in all the states' laws, it is relatively clear that no two states apply substantially the same law to all of the plaintiffs' claims. Although the Court is not convinced that it is per se impossible to certify and successfully try a class action involving the laws of 50 states, the Court does find that given the magnitude of the variations in these particular claims, the class action is not the superior method of adjudication in this dispute.⁹⁸

The court then proceeded to narrow the medical monitoring class to subclasses of states that have expressly recognized such claims.

It is a remarkable occurrence for a federal court to certify a class action and rarer still for one to be certified in the products liability/personal injury arena. However, as is indicated above, there exists the possibility of such a certification. Therefore, in order to fully understand the feasibility, it is necessary to explore in detail the pre-requisites to a class action as they relate to FDA approved medical devices.

⁹⁷ *Id.*

⁹⁸ *Id.*

4.2 Numerosity

DELETED TO CONFORM TO OSCAR FILE SIZE LIMITS

4.3 Commonality

DELETED TO CONFORM TO OSCAR FILE SIZE LIMITS

4.4 Typicality

DELETED TO CONFORM TO OSCAR FILE SIZE LIMITS

4.5 Adequacy

DELETED TO CONFORM TO OSCAR FILE SIZE LIMITS

5 Conclusion

There is strong support for the idea that careful monitoring of blood sugar with the use of blood glucose monitors can lead to marked improvements in health and wellness for those suffering from both Type I and Type II diabetes. Both the scientific community and the regulatory body agree that both improper use and the malfunction of these devices can have a seriously adverse affect on a user's health.

Recent developments in pre-emption law have outlined the requirements for bringing an action against a manufacturer of an FDA approved medical device. Specifically, devices that undergo the 510(k) approval process remain a viable target for state tort claims. In addition, devices that are the subject of recalls may also be the objects of such actions. Finally, because of the enormous impact of recent court decisions on the mass tort field, Congress has stepped in with the aim of legislating back the consumers' right to bring actions against malfeasant manufacturers.

However, even once the preemption stumbling block is overcome, the issue of class certification looms large. In order to satisfy the prerequisite requirements of class

certification, the class must show that it satisfies the numerosity requirement. Although there are some caveats to this requirement, the sheer number of users would, in all likelihood, satisfy this requirement. However, the vast range of users and the huge assortment of diseases that they suffer from make the other three requirements, commonality, typicality and adequacy, difficult to surmount.

It is important to note that the actual claims that could be brought have not been discussed within the confines of this writing and could, on their own, fill many pages, but in order to truly determine the success or failure of such an endeavor, these would need to be examined in detail.