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Medical Monitoring of Medical Devices: An Industry-Based Solution Provides the Best Results

By Ian Gallacher

The design, manufacturing, and sale of implantable medical devices² is a large and growing industry in this country.³ Despite the advances made in design and manufacturing over the years, the medical device industry inevitably experiences failure of at least some of its products in any given line.⁴ The United States Code requires manufacturers, physicians, and medical institutions to report product failures when they become known.⁵ When failures become numerous, the products are frequently recalled,⁶ either voluntarily by the manufacturer, or pursuant to the FDA's regulatory power.⁷ These recalls often occur in a blaze of publicity, and are invariably a prelude to mass litigation.⁸

The combination of a high income industry, inevitable product failure, and high publicity recalls has created a target-rich environment for the plaintiffs' bar. There are a number of highly skilled attorneys, well armed with an array of sophisticated legal weapons, who make a lucrative practice of stalking the medical device industry and attacking companies whose products have run into trouble. One of the newer armaments available to such attorneys is a form of relief known as "medical monitoring."

Medical monitoring can be defined as the expense related to the periodic diagnostic evaluation of an individual or group of individuals in order to detect and/or prevent an anticipated medical outcome. It can also include scientific research necessary to deter-

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mine the root cause of a particular product failure, as well as, research exploring more efficient methods of diagnosis. Medical monitoring does not typically include the cost of treating the medical outcome if it emerges, or the cost of medical or surgical intervention to prevent the outcome.

Medical device medical monitoring litigation developed from cases involving exposure to toxic substances. The first case to explicitly permit recovery for medical monitoring is generally considered to be *Ayres v. Township of Jackson*⁹. In this toxic exposure case, the New Jersey Supreme Court permitted plaintiffs to recover for medical monitoring even though the plaintiffs had not demonstrated any physical injury from the toxic exposure. Although *Ayres* is the first case to recognize a medical monitoring remedy, earlier cases have recognized relief for diagnostic testing, not all of them toxic exposure cases.¹⁰

Medical monitoring suits are often brought as class actions.¹¹ Class actions permit the aggregation of claims against the defendant thereby increasing the efficiency of the medical monitoring effort¹² and arguably increasing the attorney's fee.¹³ Also, medical monitoring is, at least facially, an appealing concept since it introduces a means of preventing people from becoming ill before they have to sue, and provides them with diagnostic care at no expense. Yet this facial appeal disguises a myriad of legal and policy problems which render court-ordered medical monitoring a less appropriate mode of recovery in medical device cases than an industry based solution with FDA oversight.¹⁴

This article will review the public policy concerns addressed by the toxic exposure cases and discuss why an industry based initiative is a more appropriate solution for dealing with

product failure of medical devices. This article will also explore whether medical monitoring is properly viewed in terms of legal damages or equitable relief, and discuss how the nature of the relief effects a defendant's right to a trial by jury, and the type of class action which may be certified under the Federal Rules of Civil Procedure. In addition, this article will address the legal problems which complicate and may prevent medical monitoring relief, including how the FDA's regulatory oversight role may conflict with the doctrines of preemption and separation of powers. Finally, this article will explain why the most efficient and beneficial method of resolving medical monitoring issues is for the medical device industry to make medical monitoring a part of device recall programs.

I. The policy considerations implicated by medical device monitoring support an industry based solution rather than litigation

While medical monitoring might be an appropriate remedy in toxic exposure litigation, the translation of this type of relief to the medical device arena is an uneasy one. In particular, certain policy considerations might justify the imposition of court-ordered medical monitoring relief in toxic exposure situations. These public policy concerns are better addressed in medical device cases by keeping the medical monitoring in the hands of the manufacturers of the devices, and combined with regulatory oversight by the FDA.

Toxic exposure cases differ fundamentally from medical device cases since toxic exposure cases involve the unintended and involuntary exposure to hazardous environmental agents.

In specific, individuals exposed to toxic substances are most likely unaware of their exposure and would have no reason to seek diagnostic or preventative medical care, while an individual who receives a medical device is aware of possible complications that may result from the implant. Further, the potential health hazards resulting from exposure to toxic substances have protracted latency periods. Accordingly, courts have identified public policy considerations which support the creation of court-ordered medical monitoring relief in toxic exposure cases.¹⁵ Quoting from a California Supreme Court case, the court in *Day v. NLO* cited four public policy considerations supporting medical monitoring relief in toxic exposure cases:¹⁶

First, there is an important public health interest in fostering access to medical testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease, particularly in light of early diagnosis and treatment for many cancer patients.

Second, there is a deterrence value in recognizing medical surveillance claims...

Third, "[t]he availability of a substantial remedy before consequences of the plaintiffs' exposure are manifest may also have the beneficial effect of preventing or mitigating serious future illness and thus reduce the overall costs to the responsible parties."¹⁷

Finally, societal notions of fairness and elementary justice are better served by allowing recovery of medical monitoring costs. That is, it would be inequitable for an individual wrongfully exposed to dangerous toxins, but unable to prove that cancer or disease is likely to have to pay the expense of medical monitoring when

such intervention is clearly reasonable and necessary.¹⁸

With the exception of the "deterrence" factor¹⁹, the public policy considerations identified by the courts are better addressed in medical device cases within the context of a voluntary program initiated by the device manufacturer and regulated by the FDA. Simply put, the medical device manufacturer working in cooperation with the FDA can more efficiently and quickly provide medical monitoring to affected individuals at no cost to the individual.

An industry-based medical monitoring program would combine the manufacturer's knowledge of the device, and its ability to act quickly to analyze the problems in a device, with the regulatory oversight and enforcement power of the FDA. Such an approach would meet the immediate medical needs of the affected individuals, and would involve less expense to the industry. Moreover, an industry-based medical monitoring program would reduce the transaction costs to manufacturers, thus encouraging them to invest more resources in a voluntary monitoring program.

Furthermore, given the heavy economic and time costs of litigation, both the public health interest in early diagnosis and the reduction of the overall costs to the responsible parties are better protected by a voluntary industry program regulated by the FDA. The glacial pace of litigation in this area can mean that plaintiffs might not obtain a medical monitoring program, even by settlement, until years after the discovery of the problem which caused the litigation. The public policy concerns discussed by the courts, including fostering access to medical testing for the affected individuals and the prevention or mitigation of serious illness, are meaningless if they are not

achieved quickly enough to be of any benefit. In addition, the collection and analysis of data is a process which should begin immediately upon the realization that a problem exists, rather than waiting for a court order that could be delayed for years. It is clearly in the patients' best interest for the manufacturer to initiate a voluntary program of monitoring-type activities as soon as possible without waiting for a court to order such activity.

II. NASPE promulgated a model guideline for managing medical device recalls

The North American Society of Pacing and Electrophysiology ("NASPE"), a group of physicians and pacing professionals, supports the development of an industry-based medical monitoring program and has outlined a model monitoring program for intracardiac devices. In a "NASPE Policy Statement," published in 1996, NASPE articulated guidelines for managing an intracardiac device recall.²⁰ Although aimed specifically at a narrow group of medical devices, the NASPE article provides a model outline of how to manage all medical device recalls.

Although NASPE focuses on the responsibilities of each party to a recall, including the patient, the hospital and the media, the analysis of a manufacturer's responsibilities during a product recall is particularly relevant and is worth quoting at length.

A manufacturer's primary responsibility is the design and manufacture of reliable and safe devices. Preclinical testing, however, cannot mimic the hostile environment of prolonged endovascular exposure. Regulatory oversight during premarket approval may be inadequate

as well, "Man is imperfect and therefore his devices (may be) imperfect." . . . The manufacturer is responsible for postmarket surveillance; device failures may be random or systematic and the latter can only be determined by analysis of performance trends. This may be difficult if the failures are not time dependent or are confined to only certain production lots. Once a device problem is identified, the failure rate, mechanisms, and possible associated patient risk must be evaluated with the help of an expert panel convened by the manufacturer.

After recognition of a problem and its magnitude, a notification process begins with the identification of physicians, patients and hospitals, along with recommendations on device disposition and patient management. Communication with regulators, physicians and hospitals is essential as well as accountability for all devices manufactured, with retrieval of nonimplanted devices. It is the manufacturers' responsibility to ensure that the recall process is complete and that physicians have been advised of clinical management options. Problems with patient identification and device tracking arise when a recall device (e.g., a lead) is connected to a competitor's device (e.g., a pulse generator). Cooperation between manufacturers is essential, but may be problematic. recalls pose difficulties for the manufacturer because of these multiple responsibilities and pressures. The manufacturer also faces significant costs, lost business, opportunistic actions of competitors, loss of a positive image in the physician community, and possible legal and regulatory actions.²¹

The NASPE article also sets forth the steps that a manufacturer should take to meet its obligations in a recall situation.

1. Identification of a problem.
2. Confirmation by a Physician Advisory

Panel (PAC).

3. Classification of a recall.
4. Prompt notification to device regulatory body or federal agency of all relevant clinical and technical data, including recommendations for management.
5. Provision of model and serial numbers of all affected hardware to regulatory agencies.
6. Direct registered mail notification to National Pacemaker Registry, implanting physicians, follow-up physicians, and directors of pacemaker clinics.
7. Notification to competitors with a request for identification of affected hardware registered in their database.
8. Recommendations for management by Physician Advisory Panel.
9. Provision of ongoing support: technical, warranty, credit, financial (expenses not covered by insurance), referrals to centers of excellence (special problems), timely updates on incidence, screening techniques.
10. Request updates/feedback of relevant information from affected pacemaker clinics.²²

The NASPE recommendations provide an outline for a paradigmatic medical monitoring program which can be followed by every manufacturer of a medical device. Adherence to this outline, with the addition of FDA oversight, would supply all the benefits of court-ordered medical monitoring, but would provide them years earlier than a court-ordered program and at significantly less expense. Further, NASPE's proposal adequately meets the public policy goals outlined by the courts.

Understandably, the public may have concerns about the independence of the program, and therefore its reliability. Two separate

independent entities would have a role in the management of a recall, including a Physician Advisory Panel consisting of independent experts with no incentive to provide cover for the manufacturer, and the FDA, an organization which is in no way an apologist for the medical device industry. The role of an independent Physician Advisory Panel and the FDA should alleviate any public concerns over the reliability of a voluntary program.

Not only is an industry based medical monitoring program, as outlined above, the most beneficial and efficient means of meeting the needs of patients, it may also be the only appropriate method of obtaining a medical monitoring program. Judicially-imposed medical monitoring obtained by means of litigation is a form of relief which involves significant and potentially insurmountable legal obstacles.

III. Difficulties in determining whether medical monitoring relief is equitable or legal in nature and the implications for the parties to a medical device suit

A court imposed medical monitoring remedy has characteristics both legal and equitable in nature. Whether medical monitoring relief may be properly classified as equitable relief or legal relief is a question with serious implications for the parties of a medical device suit. The resolution of this question affects issues as central as the right to a jury trial and the type of class which a court may certify.

Any consideration of the nature of a form of relief must begin with an analysis of the Seventh Amendment. The Seventh Amendment

provides that “[i]n Suits at common law, where the value exceeds twenty dollars, the right of trial by jury shall be preserved.”²³ A suit in common law is one in which legal rights alone are asserted as opposed to those in which equitable rights are asserted.²⁴ The distinction between legal and equitable remedies has been maintained, even after the merger of law and equity.²⁵

To determine whether a particular form of relief is legal or equitable under the Seventh Amendment, a court must go through a two part test. First, the court must determine the nature of the issues involved by comparing the action being brought with like actions brought in 18th century England before the merger of the courts of law and equity; and second, the court must examine the remedy sought.²⁶

In order to determine the nature of the claim when no such claim existed in 18th century England, the court must look for an analogous cause of action that did exist at that time.²⁷ Medical monitoring did not exist as a claim in 18th century England.²⁸ In searching for an analogous claim, the court in *Barnes v. Am. Tobacco Co. Inc.* concluded that medical monitoring is similar to a negligence action for future medical expenses. Thus, the *Barnes* court placed medical monitoring squarely in the legal damages camp.²⁹ The court reached this conclusion because under Pennsylvania law, in order to recover for common law medical monitoring, a plaintiff must establish that he was exposed to hazardous substances because of the defendant’s negligence.³⁰ Because negligence-based causes of action, both in 18th century England and in the United States today, are actions at law, the court reasoned that it would be appropriate to conclude that a medical monitoring claim raises primarily legal issues.³¹

The *Barnes* court had greater difficulty determining the nature of the remedy sought in medical monitoring cases. The problem, as explained by the court, is in determining what the plaintiffs are truly seeking. If they seek compensatory damages, then their request is for money, and is legal in nature. If, on the other hand, the plaintiffs “seek the establishment of a court-supervised medical monitoring program through which the class members will receive periodic examinations, then plaintiffs’ medical monitoring claim can be properly characterized as [a] claim seeking injunctive relief.”³²

As the *Barnes* court noted, the distinction between these two positions is a fine one.³³ The court relied on the analysis of Judge Spiegel in the *Day* case:

Relief in the form of medical monitoring may be by a number of means. First, a court may simply order a defendant to pay a plaintiff a certain sum of money. The plaintiff may or may not choose to use that money to have his medical condition monitored. Second, a court may order the defendants to pay the plaintiffs’ medical expenses directly so that a plaintiff may be monitored by the physician of his choice. Neither of these forms of relief constitute injunctive relief as required by Rule 23(b)(2).

However, a court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced is utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the Court to address issues as

they develop during the program administration. Under these circumstances, the relief constitutes injunctive relief as required by Rule 23 (b)(2).³⁴

Accordingly, the *Barnes* court concluded that, in the case before it, the plaintiffs' request for medical monitoring relief seeking periodic diagnostic examinations was "paradigmatic" of injunctive relief under a medical monitoring claim.³⁵

Having therefore determined that the nature of the medical monitoring relief depends on how the plaintiffs plead – a request for money means that the relief is legal in nature, whereas a request for a funded program means that the relief is equitable – the *Barnes* court then concluded that such a distinction unfairly placed the defendants' right to a jury trial in the hands of the plaintiffs. The court based this conclusion on the long-standing doctrine that a plaintiff cannot invoke the powers of equity where there is an adequate remedy at law available.³⁶ Because the court had concluded that medical monitoring relief was available as a matter of law, it was bound to hold that, although possible to analyze medical monitoring as either legal or equitable, the action is a legal one for purposes of the Seventh Amendment.³⁷

Just as the legal versus equitable nature of medical monitoring in litigation presents complicated legal questions of a defendant's right to a trial by jury, the certification of a medical monitoring class action is an equally difficult question. So much so, that once again the appropriateness of medical monitoring litigation is brought into question.

Barnes again illustrates this point as the court attempted to reconcile its previous finding of medical monitoring as legal relief for purposes of the Seventh Amendment with

its certification of a Rule 23 (b)(2) class action; an action that seeks injunctive or other declaratory relief as opposed to monetary, legal damages.³⁸

Under Rule 23(b)(2), certification is appropriate where equitable and injunctive relief is the sole or primary relief sought and 'does not extend to cases in which the appropriate final relief relates exclusively or predominantly to money damages.' . . . Thus, in order to establish a right to Rule 23(b)(2) certification, it need only be shown that the relief requested is not predominantly money damages. This inquiry has nothing to do with whether one's constitutional right to a jury trial has been implicated by the underlying nature of the claim. Indeed, the bar for determining whether the nature of a claim is equitable or legal for Seventh Amendment purposes is much higher than it is under Rule 23(b)(2) analysis. Under Seventh Amendment analysis, the right to a jury trial must be upheld even if the legal issues are characterized as "incidental" to equitable issues. . . . For this reason, decisions holding that medical monitoring claims may be certified under Rule 23(b)(2) are not dispositive for purposes of the right to a jury trial. In theory and practice, courts can certify a class pursuant to Rule 23(b)(2) and yet find that the parties are entitled to a jury under the Seventh Amendment.³⁹

The *Day* court's analysis, however, contradicts the above conclusion in *Barnes*. According to *Day*, a request for injunctive relief is necessary to certify a class under Rule 23(b)(2), therefore, the *Barnes* court's previous conclusion that medical monitoring relief is legal in nature precludes the certification of a

Rule 23(b)(2) class, regardless of other considerations. If, on the other hand, medical monitoring is, in fact, equitable in nature, then the case cannot be placed before a jury.⁴⁰

Under Rule 23(b)(2), a class is mandatory, or non opt-out.⁴¹ All individuals who fall within the definition of the class are bound by any court ruling.⁴² Indeed, there is no need for a class notice to be sent out informing such class members of their membership in a class,⁴³ although failing to notify class members of the existence of a medical monitoring class would, to be sure, defeat the purpose for which the class was certified. By contrast, Rule 23(b)(3), the class structure which was established to permit class members to seek primarily money damages, permits class members to opt-out of the class.⁴⁴ If too many people opt-out of a medical monitoring class, however, the class loses its rationale – economies of scale are lost, together with cost maintenance and the ability to develop a cohesive strategy for the medical monitoring of the class as a whole.

Since a Rule 23(b)(2) certification creates a non opt-out class, both plaintiffs and defendant's may prefer this certification for convenience purposes. Convenience, however, cannot serve as justification for the certification of a Rule 23(b)(2) class in medical monitoring cases: as the *Barnes* court has correctly determined, medical monitoring is primarily a legal remedy. The considerations of how a case can be certified as a class action should not drive the determination of the nature of the relief being sought. If medical monitoring is a legal remedy, however, then plaintiffs run into a significant, potentially insurmountable, obstacle on their way to recovery – their absence of current injury precludes the necessary finding of liability

IV. Medical Monitoring Suits Must Be Brought As Product Liability Claims Thereby Making Recovery Difficult For Plaintiff's Who Have Not Suffered Injuries

The sine qua non of a medical monitoring claim in the context of medical device litigation is that the individual, or group of individuals, has a device which has shown a propensity to fail in others, but which has not yet failed in that individual's case, and has therefore not yet caused any injury. In such a case, the individual is seeking the medical monitoring in order to prevent or mitigate injury when and if it occurs. In order to recover for medical monitoring damages, a plaintiff must establish the defendant's liability under a product liability theory in order to recover damages against that defendant. Under most states' product liability laws, however, a plaintiff who has no injury cannot, as a matter of law, prove that he or she has a cause of action against the defendant. In other words, medical expenses are not themselves injuries – rather, they must be incurred in connection with an already-existing compensable injury.⁴⁵ Accordingly, courts are reluctant to award a medical monitoring remedy to plaintiffs who have suffered no injury.

The notion that an individual who has a product which has not yet failed cannot recover against the manufacturer is widely accepted.⁴⁶ In a recent Alabama case, the Alabama Supreme Court concluded that regardless of how a plaintiff pleads, a claim for recovery because a medical device might someday fail is, in fact, a product liability claim. Further, a plaintiff may not evade this result by attempting to bring a fraud claim rather than a claim for product liability in medical device cases.⁴⁷

Indeed, the statute of limitations for product liability claims typically will not begin to run until after the predicate injury has manifested itself.⁴⁸

The United States Supreme Court recently reviewed this issue in the context of a Federal Employers' Liability Act ("FELA") case.⁴⁹ After a careful analysis of the policy considerations involved, and a recognition that the courts which have analyzed this question have come to different conclusions, the Court failed to find "sufficient support in the common law for the unqualified rule of lump-sum damages" that was before it.⁵⁰ The Court reached this conclusion, despite its obvious sympathy for the plaintiffs, because of its concern over "the potential systemic effects of creating a new, full-blown, tort law cause of action – for example, the effects upon interests of other potential plaintiffs who are not before the court and who depend on a tort system that can distinguish between reliable and serious claims on the one hand and unreliable and relatively trivial claims on the other."⁵¹

The Supreme Court's concerns are real and well-founded. A class-wide medical monitoring program could be a significant expense to a defendant⁵² which should only be incurred after liability for the design, manufacture and/or labeling of a defective product has been established before a jury. Only in this way can the system prevent abusive suits filed without proof that a medical device is, in fact, defective. An individual seeking a judicially-imposed medical monitoring program, however, will almost inevitably not have suffered the predicate injury necessary to permit recovery for the damages the individual is seeking.⁵³ Accordingly, there should be no liability for a medical monitoring program, as a matter of law in most cases. This does not mean that

individuals with recalled medical devices should not be entitled to medical monitoring,⁵⁴ merely that their chances for recovery through litigation are so tenuous that their interests are better served by an industry-based initiative.

V. The doctrine of the separation of powers creates a conflict between judicially-imposed medical monitoring and the FDA's regulatory role.

A judicially-ordered medical monitoring program also raises serious Constitutional and doctrinal concerns that threaten the success of any recovery through litigation. In specific, a court mandated medical monitoring remedy implicates the fundamental principle of the separation of powers.

The doctrine of separation of powers is intended as a safeguard against the encroachment of one branch of the federal government into the affairs of another branch, or the aggrandizement of one branch at the expense of another.⁵⁵ In particular, the judicial branch of the federal government should neither be assigned nor allowed tasks that are more properly accomplished by other branches.⁵⁶

Given the FDA's Congressionally-mandated role in the regulation of medical devices, regardless of the device's marketing status, it is almost inevitable that it will become involved in regulatory activity once a device begins to show problems.⁵⁷ Although the FDA has broad powers, it is likely that at least part of this regulatory activity will consist of ordering a recall of the device, if a recall has not been voluntarily undertaken by the manufacturer. If the manufacturer has already initiated a recall, the FDA can demand that recall-related activities continue. Once the FDA becomes involved in the recall of a medical device, its presence

creates separation of powers issues for medical monitoring litigation. Congress has granted the FDA far-reaching policy making authority and regulatory power to take whatever steps as are necessary to protect the public health, and courts should not attempt to interpose themselves into the FDA's Congressionally-mandated area of expertise and authority.

The FDA is an agency within the Department of Health and Human Services⁵⁸ which is in turn a branch of the Executive branch.⁵⁹ Congress has delegated to the FDA, through the Medical Device Amendments to the Food, Drug and Cosmetic Act ("MDA"), the comprehensive authority to regulate the conduct of medical device manufacturers and to take such steps as are necessary to protect the public health in regards to medical devices. As a result of its Congressional mandate, the FDA has built up years of experience in dealing with the medical device industry, making judicial deference to its actions particularly appropriate.⁶⁰

Of course, before any separation of powers conflict arises, the FDA must have asserted itself into a medical device recall. The MDA grants the FDA jurisdiction to oversee the post-market surveillance of any medical device which is permanently implanted into a person, and may cause serious, adverse health consequences or death if the device fails.⁶¹ The FDA's involvement is particularly useful during the early stages of a product recall when a manufacturer might wish to contact the individuals who use the medical device. Section 518(a) of the MDA provides that the FDA can order direct notification to specific appropriate third parties, including doctors and patients, where there is a determination that a medical device presents an unreasonable risk of substantial harm and that notification may elimi-

nate such risk.⁶² The FDA's review of the language of these notification letters, and of the notification letters which are sent out to all physicians who might come into contact with patients with the recalled device, is valuable as a means of ensuring as disinterested and informative a notice as possible, and again demonstrates the fairness with which an industry-based, FDA regulated solution could be implemented.

Although it would probably be an overstatement to say that the medical device industry welcomes the FDA's involvement in recall-related activities, such involvement is accepted by the industry since it is arguably mandated by statute, and presumably functions for the benefit of patients who have received medical devices. The FDA's involvement, however, creates a Constitutional impediment to patients who seek a judicially-imposed medical monitoring program. In addition, the FDA's regulation of the recall activities of the device manufacturer could preempt any court-ordered monitoring activity.

VI. Regulatory action by the FDA might preempt state law causes of action

The preemption doctrine is closely related to the separation of powers doctrine and can have the same preclusive effect on a plaintiff's attempt to impose court-ordered medical monitoring on a medical device manufacturer. Although the Supreme Court appeared to have foreclosed the use of the preemption doctrine as it pertains to medical devices, there is still some room for its application in this type of litigation.

As the Supreme Court has noted, "the States traditionally have had great latitude

under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”⁶³ Yet the value of the federal government’s power to impose blanket regulation in many areas has become increasingly important in recent years. “[I]n recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people.”⁶⁴ In order to protect these societal advantages, preemption has become an important element in areas which are heavily regulated by the federal government.

The threshold requirement for the application of the preemption doctrine is the intent of Congress to preempt the field, and there is no question that Congress intended the MDA to have at least some preemptive effect. Section 360k(a) of the Act provides that “no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (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 a device under this chapter.” Parsing the meaning of this passage, and particularly the meaning of Congress’ chosen term “requirement,” has caused considerable difficulty, however.

The Supreme Court undertook the task of analyzing the meaning of the MDA, and its preemptive scope, in 1996. Unfortunately, the Court’s opinion in *Medtronic, Inc. v. Lohr* left many questions unanswered. Without becoming mired in a detailed account of the fractured *Lohr* opinion and the many possible meanings the opinion could have, one thing at least is clear – according to a majority of the Court, preemption occurs “only where a particular

state requirement threatens to interfere with a specific federal interest.”⁶⁵

State requirements must be “with respect to” medical devices and “different from, or in addition to” federal requirements. State requirements must also relate “to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device,” and the regulations provide that state requirements “of general applicability” are not pre-empted except where they have “the effect of establishing a substantive requirement for a specific device.” Moreover, federal requirements must be “applicable to the device” in question and, according to the regulations, pre-empt state law only if they are “specific counterpart regulations” or “specific” to a “particular device.” The statute and regulations, therefore, require a careful comparison between the allegedly preempting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and the regulations.⁶⁶

The *Lohr* opinion analyzed the preemptive effect of the MDA in connection with the process by which medical device manufacturers receive permission to market their products. The Court’s analysis, however, is equally applicable in the medical monitoring context. When the FDA has imposed itself into the recall of a specific medical device, and has issued orders regarding the conduct of the recall of that device, it has imposed requirements which are device-specific onto a manufacturer. Any attempt to impose a court-ordered medical monitoring program, therefore, is an attempt to impose requirements predi-

cated upon state law which are “with respect” to a specific device, and are “different from or in addition to” those requirements imposed by the FDA. Accordingly, once the FDA begins the regulation of a medical device recall, court-imposed medical monitoring is preempted, and continues to be preempted as long as the FDA is regulating the recall.

This result, which comports with the FDA’s own narrow view of the preemptive effect of its activities,⁶⁷ is particularly desirable when the possibility of conflicting requirements is considered. Where a court-imposed medical monitoring program co-exists with a recall program being regulated by the FDA, it is entirely possible for a manufacturer to be required to, for example, provide certain information to doctors or patients by the court, yet be prohibited from providing such information by the FDA. To the extent that recall and monitoring activities could be coordinated in order to prevent such conflicts would negate the need for two programs because one would merely be duplicating the efforts of the other.⁶⁸ In such a case, no physician would order the second, court-imposed, medical monitoring program. Medical or scientific necessity is one of the fundamental pillars of medical monitoring relief. Although it can be argued that judicially-imposed medical monitoring is necessary in order to mandate compliance, this argument ignores the teeth carried by the MDA, in the form of civil and criminal penalties for failure to comply with an FDA order.⁶⁹

Thus, the FDA has the mandate to involve itself in the recall of medical devices, the power to regulate the activities of a manufacturer when such a device specific recall is initiated, either voluntarily by the manufacturer or under FDA orders, and has the power to enforce its regulations. Under these circum-

stances, and in light of *Lohr*, it is difficult to conclude that litigation-based medical monitoring, sought under the application of State law, is not preempted by the FDA’s device-specific regulation.

VII. Conclusion

The medical monitoring of patients with a defective medical device should be conducted with the best interests of the patients in mind. Patients with defective medical devices should receive an analysis of data surrounding their problem, recommendations regarding clinical management of the problem, and reimbursement of expenses associated with diagnostic and therapeutic treatment as early as possible. Not only are there serious, if not insurmountable, legal obstacles to obtaining judicially-imposed medical monitoring, such legally obtained relief does not inure to the benefit of the plaintiffs. The interests of patients are best served by a voluntary program initiated by the manufacturer with regulatory oversight from the FDA. In this way, a plan for the clinical management of the problem can be developed as efficiently, quickly, and inexpensively as possible, without the significant transaction costs associated with litigation-based medical monitoring, a form of relief which, in any case, might not be available to prospective litigants.

Endnotes

² The term “device” is defined in § 321(h) of the Federal Food, Drug, and Cosmetic Act of 1938 as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related

article, including any component, part, or accessory, which is (1) recognized in the official National Formulary or the U.S. Pharmacopoeia or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure of any function of the human body or bodies of other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." 21 U.S.C. § 321(h).

³ According to the Health Industry Manufacturers Association ("HIMA"), U.S. production of medical devices and diagnostic products reached \$61.2 billion in 1996 and was projected to reach \$71.4 billion in 1998. Medical device exports accounted for \$12.9 billion in 1996 and imports amounted to \$6.4 billion. The U.S. medical device industry employed 280,760 people in 1996. HIMA projects industry growth for 1998 as follows: market size up 7%; production up 8%; exports up 9%; imports up 6%; trade surplus up 17%; and employment up 2%. HIMA U.S. MEDICAL TECHNOLOGY INDUSTRY FACT SHEET (1996).

⁴ The body is a hostile environment for engineered devices, with numerous anticipated and unanticipated strains placed on any device by the motion of the body as well as the body's natural defenses to foreign objects. Taking the artificial components of a pacemaker system as an example, physicians have concluded that "All components of the pacemaker system . . . have continued to have reportable failures. . . . These findings were observed for all five of the leading manufacturers. We conclude, therefore, that despite technological advances, formal monitoring of permanent pacemaker systems continues to be necessary on the basis of such evidence of continuing device imperfections." David T. Kawanishi, et. al. *Failure Rates of Leads, Pulse Generators, and Programmers Have Not Diminished Over the Last 20 Years: Formal Monitoring of Performance is Still Needed*, 19 PACING AND CARDIAC ELECTROPHYSIOLOGY ("PACE") 1819 (1996).

The U.S. General Accounting Office ("GAO"), in a 1992 study of the performance of implantable pacemaker leads noted that a 7% failure rate appears to be the trigger percentage for regulatory action on previ-

ously recalled or safety-alerted leads, although the report also notes that some experts believe that the number should be somewhere between 1% and 5%. U.S. General Accounting Office, *Medical Technology: For Some Cardiac Pacemaker Leads, the Public Health Risks Are Still High*, GAO/PEMD-92-20, Sept. 1992, ("GAO Report") at 14-15.

⁵ See 21 U.S.C.S § 360i (1997).

⁶ A medical device "recall" can be defined as "the removal from the market of a particular product, correction of a marketed product, or correction of a marketed product, or correction of labeling or of promotional material that FDA considers in violation of the laws if administers. FDA has designated three classes of recall in descending order of the potential degree of health risk from class I to class III." *GAO Report* at 48(citation omitted).

⁷ See 21 U.S.C. § 360a(e)

⁸ The failure of several different medical devices has resulted in litigation. See, e.g., *Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992) (dealing with the fracturing of heart valves); *In re Cordis Corp. Pacemaker Product Liability Litigation*, MDL 850 (S.D. Ohio 1992) (dealing with defective pacemakers); *Rall v. Medtronic, Inc.* 1986 WL 22271 (D. Nev. 1986) (dealing with defective pacemaker leads); *Spitzfadden v. Dow Corning Corp.*, No. 97-1011 (La. App. 4th Cir. 2/11/98) (dealing with breast implants); *In re Am. Med. Sys. Inc.*, 75 F.3d 1093 (6th Cir. 1996) (dealing with penile implants).

⁹ See *Ayres v. Township of Jackson*, 525 A.2d 287 (N.J. 1987). The Court held that "the cost of medical surveillance is a compensable item of damages where the proofs demonstrate, through reliable expert testimony predicated upon the significance and extent of exposure to chemicals, the toxicity of the chemicals, the seriousness of the diseases for which individuals are at risk, the relative increase in the chance of onset of disease in those exposed, and the value of early diagnosis, that such surveillance to monitor the effect of exposure to toxic chemicals is reasonably necessary." *Id.* at 312.

¹⁰ See *Friends For All Children v. Lockheed*

Aircraft Corp., 746 F.2d 816 (D.C. Cir. 1984) (granting a preliminary injunction which required defendant to create a fund to pay for diagnostic examinations). *But see*, Reed v. Phillip Morris Inc., No. 96-5060, slip op. at 35 (D.C. Sup. Ct. Aug. 18, 1997) (holding that medical monitoring is a compensable element of damages, not a cause of action).

¹¹ Class actions are typically sought in federal court pursuant to one of the subdivisions of Fed. R. Civ. P. 23. This paper will only analyze class questions in terms of the federal rules. Traditionally, federal courts have been receptive to the class action device making federal courts the forum of choice in medical monitoring litigation. *See, e.g.*, Phillips Petroleum Co. v. Shutts, 472 U.S. 797, 822 (1985) (holding that it is unconstitutional for forum state to apply its own substantive law in nationwide class action to claims of class members residing in other states unless forum state has legitimate state interest in each such claim).

However, federal courts have become increasingly less receptive to class actions. *See, e.g.*, Amchem Products, Inc. v. Windsor, 117 S.Ct. 2231 (1997); Valentino v. Carter Wallace, Inc., 97 F.3d 1227 (9th Cir. 1996); Castano v. American Tobacco Co., 84 F.3d 734 (5th Cir. 1996); In re American Medical Systems, Inc., 75 F.3d 1069 (6th Cir. 1996); Matter of Rhone-Poulenc Rorer, Inc., 51 F.3d 1293 (7th Cir. 1995) (all rejecting class certification of mass products liability litigation). *But see*, Matsushita Electric Industrial Co. v. Epstein, 116 S.Ct. 873 (1996) (holding that state class action judgments are entitled to full faith and credit, even though they resolve claims which are exclusively federal and could not have been brought in state court). Accordingly, it is unclear whether, in the future, state law medical monitoring class actions may assume greater importance than they have until now.

¹² Class certification is only efficient, however, when a mandatory class can be certified. The certification of a medical monitoring class under the provisions of Fed. R. Civ. P. 23(b)(3), which permits class members to opt-out of the class and pursue individual remedies, would be counter-productive, as opting-out of unified relief would detract from any efficiency gained by class certification.

¹³ The attorney's fees which can be generated from a settlement involving medical monitoring class

certification are not insubstantial and can be the source of collateral litigation. *See, e.g.*, *Bowling*, 132 F.3d 1147 (1998) (requiring defendants to pay \$75 million into a Patient Benefit Fund, \$80 to \$130 million into a Medical and Psychological Consultation Fund (the final amount depending on the number of claims), and \$500,000 to \$2 million for each U.S. claimant into the Fracture Compensation Mechanism)

¹⁴ This paper is limited to a discussion of the medical monitoring issue in the context of medical device litigation. It takes no position on the propriety of medical monitoring relief in the area of toxic exposure.

¹⁵ *See Day v. NLO*, 851 F.Supp 869, 881

¹⁶ *See id.* at 881 (quoting *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 824 (Cal. 1993)).

¹⁷ The potential costs are considerable. The GAO Report, for example, observed that 86% of pacemaker recipients are elderly and eligible for Medicare coverage for pacemaker-related procedures. "If a lead fails, there are two types of expense: the replacement operation and additional transtelephonic monitoring of patients who did not receive a replacement lead. . . . We estimate that the minimum total cost beyond routine Medicare coverage for all five models [analyzed in the survey] would be \$50 million; this would rise to \$56 million if another potentially problematic model were found to experience significantly high failure rates" *GAO Report* at 15. The cost model, assumptions, and findings of the cost model upon which the GAO Report is based can be found at Appendix V of the GAO Report.

¹⁸ *See Day*, 851 F.Supp at 881.

¹⁹ A medical device manufacturer faces almost certain national, and potentially international litigation as soon as a medical device is recalled. Such litigation often includes a punitive damages component. In addition, a manufacturer who has failed to meet its obligation under the MDA is subject to civil and criminal penalties. If the prospect of these punishments is insufficient to deter the manufacturer from acting negligently, court-ordered medical monitoring will unlikely be of any additional threat.

²⁰ Bernard S. Goldman et. al, *Management of Intracardiac Device Recalls: A Consensus Conference*,

19 PACE 7 (1996).

²¹ *Id.* at 9.

²² *Id.* at 10.

²³ U.S. Const. amend. VII.

²⁴ *See* *Chauffeurs, Teamsters & Helpers, Local No. 391 v. Terry*, 494 U.S. 558, 564 (1990) (quoting *Parsons v. Bedford*, 3 Pet. 433, 447 (1830)).

²⁵ *See, e.g.,* *Beacon Theaters, Inc. v. Westover*, 359 U.S. 500, 501 (1959), the court held that "Maintenance of the jury as a fact finding body is of such importance and occupies so firm a place in our history and jurisprudence that any seeming curtailment of the right to a jury trial should be scrutinized with the utmost care" (citations omitted); *See also*, *Matter of Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293 (7th Cir. 1995), the court held that "The protection of the right conferred by the Seventh Amendment to trial by jury in federal civil cases is a traditional office of the writ of mandamus. . . . When the writ is used for that purpose, strict compliance with the stringent conditions on the availability of the writ (including the requirement of proving irreparable harm) is excused." (citations omitted).

²⁶ *See Terry*, 494 U.S. at 565.

²⁷ *See id.*

²⁸ *See Barnes v. the Am. Tobacco Co.*, 989 F.Supp. 661 (E.D. Pa. 1997), *appeal docketed*, No. 97-1844 (3d Cir. Oct. 29, 1997).

²⁹ *See id.*

³⁰ *See id.* The Pennsylvania Supreme Court held that the elements of a common law claim for medical monitoring are:

- (1) exposure greater than normal background levels;
- (2) to a proven hazardous substance;
- (3) caused by the defendant's negligence;
- (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease;
- (5) a monitoring procedure exists that makes the

- early detection of the disease possible;
- (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and
- (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Id. (quoting *Redland Soccer Club, Inc. v. Department of the Army*, 696 A.2d 137, 145-46 (Pa. 1997)).

³¹ *See Barnes*, 989 F.Supp. at 662.

³² *See id.* at 663. The *Barnes* court failed to refer to state law for information regarding the nature of medical monitoring claims. Several states have concluded that medical monitoring is an element of legal damages, to be recovered after liability is established under an underlying tort theory such as negligence or strict liability. *See, e.g.,* *Fleming v. Knowles*, 130 So. 2d 326 (Ala. 1961); *Burns v. Jaquays Mining Corp.*, 752 P.2d 28 (Ariz. 1988); *Potter v. Firestone Tire and Rubber Co.* 863 P.2d 795 (Cal. 1993); *Riche v. City of Baton Rouge*, 541 So. 2d 905 (La. App. 1988); *Thomas v. Fay Bearing Corp., Inc.*, 846 F.Supp. 1400 (W.D.Mo. 1994); *Ball v. Joy Mfg.*, 755 F.Supp. 1344, (S.D.W.Va. 1990). New Jersey, by contrast, has concluded that medical monitoring relief is equitable in nature. *See Ayres*, 525 A.2d at 314. "In our view, the use of a court-supervised fund to administer medical surveillance payments in mass-exposure cases. . . . is a highly appropriate exercise of the Court's equitable powers." *See id. Compare Redland Soccer*, 696 A.2d 137 (Pa. 1997) (approving of medical monitoring relief, but outlining a series of elements which plaintiffs must prove in order to prevail on what it termed a "common law claim for medical monitoring." *See id.* at 145. The differences between state laws on this issue, at the least, make class certification of a medical monitoring claim inappropriate.

³³ *See Barnes*, 989 F.Supp. at 665.

³⁴ *Day*, 144 F.R.D. at 335-36.

³⁵ *See id.*

³⁶ *See, e.g.,* *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992).

³⁷ See *Barnes*, 989 F.Supp. at 666. The court's conclusion was strengthened by the policy considerations underlying the principle that equitable relief should only be available where there is no adequate legal remedy. The Supreme Court has held that the purpose of this provision is "to guard the right of trial by jury preserved by the Seventh Amendment and to that end [it] should be liberally construed." *Ross v. Berhard*, 396 U.S. 531, 539 (1970)(citation omitted).

³⁸ Fed. R. Civ. P. 23(b)(2) provides as follows: "An action may be maintained as a class action if the prerequisites of subdivision (a) are satisfied, and in addition: (2) the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole. . . ."

³⁹ *Barnes*, 989 F.Supp. at 666 (citations omitted).

⁴⁰ The *Barnes* court noted that other courts had "repeatedly" sent medical monitoring claims to the jury. See *Barnes*, 989 F.Supp. at 667, citing *In re Paoli R.R. Yard Litig.*, 35 F.3d 717 (3d Cir. 1994); See, e.g., *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829 (3d Cir. 1990); *Herber v. Johns-Manville Corp.*, 785 F.2d 79 (3d Cir. 1986); *Day v. NLO* 851 F.Supp. 869 (S.D. Ohio 1994). The *Barnes* court observed, however, that these courts did not directly examine the issue. At least one court declined to certify a mandatory medical monitoring class which was sought in conjunction with the largest class ever certified. "Certification of the medical monitoring class in this case under Rule 23(b)(2) would infringe on the constitutional right to a jury trial, The Court cannot and will not infringe on that inviolate right." *Castano v. American Tobacco Co.*, 160 F.R.D. 544, 552 (E.D.La. 1995). One potential solution to this conflict is to impanel a jury for all issues of law and impanel the same jury as an advisory jury pursuant to Fed. R. Civ. P. 39(c), which provides that "[i]n all actions not triable of right by a jury the court upon motion or of its own initiative may try any issue with an advisory jury or, except in actions against the United States when a statute of the United States provides for trial without a jury . . . may order a trial with a jury whose verdict has the same effect as if trial by jury had been a matter of right." Fed. R. Civ. P. 39(c).

⁴¹ Fed. R. Civ. P. 23(c)(3) provides, in pertinent part, as follows: "The judgment in an action maintained as a class action under subdivision (b)(1) or (b)(2), whether or not favorable to the class, shall include and describe those whom the court finds to be members of the class." By contrast, the remainder of Fed. R. Civ. P. 23(c)(3) provides that "[t]he judgment in an action maintained as a class action under subdivision (b)(3), whether or not favorable to the class, shall include and specify or describe those to whom the notice provided in subdivision (c)(2) was directed, and who have not requested exclusion, and whom the court finds to be members of the class."

⁴² Although the Rule would appear to be clear on this point, it is true that some courts have permitted opt-outs in supposedly mandatory, or non opt-out, (b)(1) or (b)(2) class actions. See, e.g., *Eubanks v. Billington*, 110 F.3d 87, 94 (D.C.Cir. 1997) (finding that "[T]he language of Rule 23 is sufficiently flexible to afford district courts discretion to grant opt-out rights in (b)(1) and (b)(2) class actions.") citing *Crawford v. Honig*, 37 F.3d 485 (9th Cir. 1995); *County of Suffolk v. Long Island Lighting Co.*, 907 F.2d 1295 (2d Cir. 1990); *Williams v. Burlington Northern Inc.*, 832 F.2d 100 (7th Cir. 1987); *Holmes v. Continental Can Co.*, 706 F.2d 1144 (11th Cir. 1983); *Penson v. Terminal Transport Co.*, 634 F.2d 989 (5th Cir. 1981).

⁴³ Fed. R. Civ. P. 23(c)(2) provides, in pertinent part, as follows: "In any class action maintained under subdivision (b)(3), the court shall direct to the members of the class the best notice practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort. When a class is certified, however, all class members are entitled to notice. Rule 23(e) provides that "[a] class action shall not be dismissed or compromised without the approval of the court, and notice of the proposed dismissal or compromise shall be given to all members of the class in such manner as the court directs." Accordingly, when a medical monitoring class is certified pursuant to settlement, all class members will be notified in the best manner practicable under the circumstances.

⁴⁴ See *supra* note 40.

⁴⁵ See, e.g., *Bourgeois v. A.P. Green Indus., Inc.*, 1997 WL 728529 (La. Ct. App. 1997) (affirming trial

court's holding that medical monitoring damages could not be recovered where plaintiffs failed to allege present injury).

⁴⁶ See, e.g., *Pfizer, Inc. v. Farsian*, 682 So.2d 405, 408 (Ala. 1996); *Walus v. Pfizer, Inc.*, 812 F.Supp. 41, 44-45 (D.N.J. 1993); *Angus v. Shiley, Inc.*, 989 F.2d 142 (3rd Cir. 1993); *Murphy v. Shiley, Inc.*, 940 F.2d 668, text in 1991 WL 135505 (9th Cir. 1991); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991); *Lauterbach v. Shiley, Inc.*, 1991 WL 148137 *4 (S.D.Tex. Mar. 29, 1991) *Pryor v. Shiley, Inc.*, 916 F.2d 716, text in 1990 WL 159582 *3 (9th Cir. 1990); *Spuhl v. Shiley, Inc.*, 795 S.W.2d 573, 580 (Mo. Ct. App.); *Sill v. Shiley, Inc.*, 735 F.Supp. 337, 340 (W.D.Mo. 1989); *Brinkman v. Shiley, Inc.*, 732 F.Supp. 33, 35 (M.D.Pa. 1989); *Kent v. Shiley, Inc.*, 1989 U.S. Dist. LEXIS 8962, *4-5 (D.Or. Jan. 23, 1989); *O'Brien v. Medtronic Inc.*, 439 N.W.2d 151 (Wis. Ct. App. 1989) *Taylor v. Medtronic, Inc.*, 861 F.2d 980, 988 (6th Cir. 1988); *Hagepanos v. Shiley, Inc.*, 846 F.2d 71, text in 1988 WL 35752 *1-2 (4th Cir. 1988);

⁴⁷ See *Farsian*, 682 So. at 407. Alabama has passed a product liability statute that subsumes within it claims of negligence and strict liability. The *Farsian* court concluded that regardless of how a plaintiff pleads the claim, a claim for recovery because a medical device might someday fail is, in fact, a product liability/personal injury claim. "Alabama courts have never allowed a recovery based on a product that . . . is and has been working properly." *Id.*

⁴⁸ See, e.g., *Cacciacarne v. G.D. Searle & Co.*, 908 F.2d 95 (6th Cir. 1990). If this rule were otherwise, it would create the impossible situation of a plaintiff being required to file suit without any evidence that a malfunction in the medical device had, or might, occur, in order to avoid a potential barring of the litigation if the device malfunctioned after the running of the applicable statute of limitations.

⁴⁹ See *Metro-North Commuter R.R. Co. v. Buckley*, 117 S.Ct. 2113, 2115-16 (1997). Although this case involved FELA, the Court observed that it had found no other FELA decisions on this issue, and instead based its decision on its canvassing of state law cases "that have considered whether the negligent causation of this kind of harm . . . by itself constitutes a

sufficient basis for a tort recovery." *Id.* at 2122.

⁵⁰ See *id.* at 2124.

⁵¹ *Id.*

⁵² Such programs are certainly expensive in the aggregate. Whether, on the other hand, a medical monitoring program when viewed as an expense per individual would be particularly expensive is another issue. This has implications for federal suits filed under the federal courts diversity jurisdiction. The jurisdictional amount in controversy for diversity cases is now \$75,000. See 28 U.S.C. § 1332. Whether each class member would be able to make a claim for individual medical monitoring in a particular case is an issue which would require careful scrutiny on a case-by-case basis. Class members may not aggregate their claims in order to meet the jurisdictional amount. See *Snyder v. Harris*, 394 U.S. 332, 335 (1969). This same rule applies in class certification claims for injunctive relief brought under Rule 23(b)(2). *Pierson v. Source Perrier, S.A.*, 848 F.Supp. 1186, 1188 (E.D.Pa. 1994); *Smiley v. Citibank (South Dakota), N.A.*, 863 F.Supp. 1156, 1163 (C.D.Cal. 1993). Each representative plaintiff in a class suit must meet the jurisdictional amount set by Congress. The force of the Supreme Court's opinion in *Zahn v. International Paper Co.*, 414 U.S. 291 (1973) has been somewhat undermined by the careless drafting of the language of the Judicial Improvements Act of 1990, codified as 28 U.S.C. § 1367. The drafters of this Act, by error, omitted Rule 23 from the list of Rules of Civil Procedure unaffected by the portion of the Act which provides for supplemental jurisdiction over all other claims that are so related to claims in the action within the court's original jurisdiction that they form part of the same case or controversy. (For more surrounding the drafting of the 1990 Act see, Thomas C. Arthur & Richard D. Freer, *Close Enough For Government Work: What Happens When Congress Doesn't Do Its Job*, 40 EMORY L.J. 1007 (1991)(describing the Act as a "nightmare of draftsmanship").

Even though the 1990 Act throws some of the Court's holding in *Zahn* into, at best, a state of confusion, the Court's holding that each representative plaintiff in a class suit must meet the jurisdictional amount is undiminished. See also, *In re Abbott Laboratories*, 51 F.3d 524, 526-27 (5th Cir. 1995). This holding is particularly significant in cases involving medical

monitoring, where there is, or should be, no deviation between the relief sought by the representative and the other, passive, members of the class.

⁵³ In some cases, courts have found that no physical injury is necessary in order to seek medical monitoring relief. *See, e.g.,* Gibbs v. E.I. DuPont de Nemours & Co., Inc., 876 F.Supp. 475 (W.D.N.Y. 1995); Bocook v. Ashland Oil, Inc., 819 F.Supp. 531 (S.D.W.Va. 1993). Moreover, in the case often cited as the herald of product liability based medical monitoring programs – *Friends for all Children, Inc. v. Lockheed Aircraft Corp.* – the plaintiffs had suffered physical trauma as a result of a plane crash in which they were passengers. *See also,* Hagerty v. L & L Marine Services, Inc. 788 F.2d 315, *modified*, 797 F.2d 256 (5th Cir. 1986); Simmons v. Pacor, Inc., 674 A.2d 232 (Pa. 1996) (in both cases plaintiffs suffered traumatic impact). For this reason alone, these cases are distinguishable from the paradigmatic medical monitoring situation presented by medical device litigation.

⁵⁴ *See infra* section I.

⁵⁵ *See* Buckley v. Valeo, 424 U.S. 1, 122 (1976).

⁵⁶ Morrison v. Olson, 487 U.S. 654, 680-81 (1988).

⁵⁷ Although FDA has not indicated a threshold of device failures, the GAO observed, based on the regulatory action that the FDA had taken on recalled pacemaker leads, that a minimum failure level of 7% appeared to be the trigger percentage for regulatory action. *See supra* note 3 at 14..

⁵⁸ *See* 21 U.S.C. § 393(a).

⁵⁹ *See* 5 U.S.C. § 101.

⁶⁰ *See, e.g.,* United States v. 9/1 KG. Containers, 854 F.2d 173, 176 (7th Cir. 1988) (finding that the phrase “necessary for the public health” in the FDCA requires the FDA “to make a judgment where the public interest lies,” and courts must defer to the FDA when it is acting pursuant to its statutory mandate;) Washington, Dept. of Ecology v. United States Env’tl Protection Agency, 752 F.2d 1465, 1469 (9th Cir. 1985) (concluding that Judicial deference to agency action is particularly appropriate

where a full understanding of the force of statutory policy in a given situation depends upon “more than ordinary knowledge respecting the matters subjected to the agency regulations.”) (citations omitted).

⁶¹ *See* 21 U.S.C. § 360i(a).

⁶² Section 518(a) of the MDA has been codified as 21 U.S.C. § 360h(a).

⁶³ ⁶² *See* Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2245 (1996) (quoting Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756 (1985)).

⁶⁴ *Id.* at 2245.

⁶⁵ *See id.* at 2257.

⁶⁶ *Id.* at 2257

⁶⁷ The FDA is understandably, and properly, concerned about having broad preemptive powers. The present regulation pertaining to this issue provides, in pertinent part, that “[s]tate or local regulations 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 Food and Drug Administration requirements.” 21 C.F.R. § 808.1(d). The preemption of medical monitoring relief once the FDA has become involved in the regulation of a device recall is entirely consistent with the FDA’s position in this regulation.

⁶⁸ Judicially-imposed medical monitoring program would carry with it heavy transaction costs in the form of attorney’s fees whereas the FDA-regulated recall would not, thus making such parallel programs unnecessary.

⁶⁹ Section 301q(1)(a) of the MDA provides statutory authority for the imposition of civil and criminal penalties for non-compliance with FDA requirements.

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