The US Medical Device Safety Act – Legislation Too Far

A US bill is seeking to overturn the 2008 Supreme Court ruling in *Riegel v Medtronic* that bars state product liability lawsuits against manufacturers of certain medical devices. *Tripp Haston* questions the rationale behind the legislation and argues that it would be detrimental to the interests of patients.

When the US Congress enacted the Medical Devices Amendments to the Federal Food, Drug, and Cosmetic Act in 1976, it recognised that medical devices were different from other products subject to the FDCA.

US legislation includes an express pre-emption provision for certain high-risk medical devices

Specifically, it included within the MDA an express pre-emption provision for certain high-risk medical devices. This provision prohibits states from establishing any "requirement" that is "different from" or "in addition to" any federal requirement, or that "relates to safety or effectiveness of the device" included in a requirement applicable under the MDA[1].

In 2008, the US Supreme Court in *Riegel v Medtronic* relied on this express pre-emption provision as its primary basis in concluding that medical devices approved through the Food and Drug Administration's rigorous premarket approval process were largely immune from state tort liability due to the pre-emptive effect of the MDA and the role of the FDA[2]. In contrast, largely because the underlying FDCA contains no such express pre-emption provision for the other products it covers, the Supreme Court reached the opposite conclusion earlier this year for a case involving pharmaceuticals. It decided in *Wyeth v Levine* that prescription pharmaceutical products, with notable exceptions, largely are not immune from state tort liability, despite rigorous approval processes and postmarketing safety oversight by the FDA[3].

Thus, the law in the US today treats PMA-approved medical devices and pharmaceuticals disparately in terms of state tort liability, based, largely, on the express pre-emption provision of the MDA.

The MDSA and efforts to reverse *Riegel*

Congressional opponents of "medical device pre-emption" argue that the distinction between the two types of products does not make sense and are seeking to eliminate the effect of the legislative difference between the two. As such they introduced in Congress in March this year a bill that seeks to eviscerate state tort immunity for all medical devices. The Medical Device Safety Act of 2009 contains an operative provision that is uncomplicated[4]. The provision provides that:

The Medical Device Safety Act of 2009 is seeking to eviscerate state tort immunity for all medical devices…

> *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.*

Identical versions of the MDSA exist in both the House of Representatives and the Senate. Similar bills were introduced in Congress in 2008 but failed to pass. However, this year's bills have progressed further in the legislative process.

All eyes now rest on Congress as the MDSA proceeds through the legislature. In the House of Representatives, the health subcommittee of the House Committee on Energy and Commerce held public hearings on the matter on 12 May and 18 June. The May hearing focused on the impact of the *Riegel* decision on medical device safety considerations, while the June hearing focused on the adequacy of current medical device regulations to ensure patient safety.

…but there is debate over its rationale and value

It is too early to predict whether the bill will succeed or fail. However, it raises three key questions that have sparked debate over its rationale and have cast doubt over its value. These questions are:

- Does *Riegel* represent a dramatic legal shift or is it consistent with established law?
- Why should PMA medical devices be afforded pre-emptive status and pharmaceuticals denied the same?
- Would eliminating pre-emptive protection advance medical device patients' interests?

Dramatic legal shift or consistent with established law?

In life, timing is everything – especially when it comes to successful passage of legislation. In a bid to create a basis and a rationale for the MDSA, the bill's sponsors have cast it as one that would

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"overturn a 2008 Supreme Court decision that, *for the first time*, denied patients injured by certain medical devices the right to seek compensation through state product liability lawsuits". What is at odds with this statement is that the bill does not simply seek to change a judicial act, it also seeks to change a congressional act, in that it would withdraw the effect of the express pre-emption provision contained within the MDA.

One argument is that Riegel represented a departure from established law

At the 12 May health subcommittee public hearing, committee chairman and MDSA sponsor Henry Waxman (Democrat – California) asserted that *Riegel* represented a departure from established law. He made the following observation in his opening remarks[5]:

> *Until February of last year, when Americans were injured by defective medical devices, they had a remedy. In most states, they were able to sue the manufacturer of that product for damages in state court. In fact, the only way patients can obtain compensation is to bring a lawsuit under state law.*
>
> *Ironically, the decision applies only to the most dangerous and most complex devices. The kind of devices that, when they malfunction, often result in death or severe physical impairment.*
>
> *The Court's decision was bad for Americans in another way too. It has destroyed one of the most powerful incentives for safety – the possibility of liability.*
>
> *The [MDSA] does nothing more than to simply return things to the status quo before last year's Court decision.*

Six separate witnesses appeared at the 12 May hearing and provided the committee with testimony concerning the pending legislation. David Vladeck, professor of law at Georgetown University, provided testimony consistent with Representative Waxman's assertion that *Riegel* departed from established law. Professor Vladeck claimed that the MDA's express pre-emption provision was not intended to pre-empt state tort liability, but rather merely intended to[6]:

> *…formalise the allocation of responsibilities between FDA and state regulators, and to ensure that FDA had the final say over a PMA device's design … [n]othing in [the MDA express pre-emption provision] says that Congress is acting to nullify existing state damages claims. There are federal statutes that do just that. But they do so in unmistakable terms and generally provide a federal remedy in lieu of displaced state remedies.*

In stark contrast to the comments of Representative Waxman and Professor Vladeck, Richard Cooper, chief counsel of the FDA during President Carter's administration observed that[7]:

An alternative argument is that Riegel was not an innovation in the law and was decided correctly

> *Riegel was not an innovation in the law, and was decided correctly … [t]he decision was anticipated by a substantial majority of the federal courts of appeals that had considered the issue.*

Mr Cooper cited a long line of Supreme Court precedent interpreting express pre-emption provisions to make the point that such provisions routinely result in decisions akin to *Riegel* in narrowing or eliminating conflicting state law claims. Mr Cooper observed that:

> *Moreover, Riegel and the cases that foreshadowed it did not come out of the blue. Rather, they reflect widely supported mainstream trends in judicial and scholarly understanding of products-liability law and of the role of federal agencies in administering regulatory statues enacted by the Congress.*
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> *In fact, the Riegel decision itself was not a departure from the underlying decisions of lower courts; the Court affirmed both the US District Court and the US Court of Appeals for the Second Circuit's initial decisions dismissing the claims based on the operation of the express pre-emption provision of the MDA.*

Finally, included in Mr Cooper's comments were the following portions of a *Harvard Law Review* article on the *Riegel* decision:

The Medical Devices Amendments via its express pre-emption made the FDA the only arbiter of appropriate regulation

> *Through the MDA, Congress created a superseding federal system of regulation to ensure the safety of medical devices. In so doing, Congress vested the FDA with the power to approve – through a rigorous process – new devices before they may be marketed. Through its express pre-emption, the MDA made the FDA the only arbiter of appropriate regulation … As Justice Scalia argued [in Riegel], to allow state common law claims to proceed against a properly screened medical device in the face of the pre-emption provision would grant a single jury greater power than even state legislatures – a "perverse distinction" not mandated by the MDA. By precluding some tort suits, Riegel accepted that some consumers hurt by pre-approved products will be uncompensated, which is a necessary cost of prioritising the federal system.*

Contrary to the claims of Representative Waxman and Professor Vladeck, it is clear that the *Riegel* decision flowed naturally from the congressional intent expressed by inclusion of the express pre-emption provision of the MDA. The MDSA sponsors, rather than choosing to simply and honestly address a decision by a prior Congress to include such a provision and identify any alleged changed circumstances that justify its nullification, have wrongfully opted to vilify the Supreme Court for "incorrectly" deciding *Riegel.* Undoubtedly, this is due to the fact that there are no changed circumstances since the MDA's passage that justify the MDSA.

Affording pre-emptive status to devices but not to drugs

The US now treats PMA-approved devices and pharmaceuticals disparately with regard to state tort liability

As already mentioned, the current regulatory and legal environment in the US now treats PMA-approved devices and pharmaceuticals disparately with regard to state tort liability. While eight Justices in the *Riegel* decision found in favour of federal pre-emption for devices under the MDA, six Justices in the *Levine* decision found, with notable exceptions, no such blanket pre-emption for pharmaceutical products approved under the FDCA. Four Justices (specifically, Justices Kennedy, Souter, Breyer and Stevens), who were in the majority for both decisions, therefore, saw a distinction between the legal issues concerning the two classes of products.

In *Levine,* the Supreme Court addressed the question of whether state law failure-to-warn claims conflicted with the objects and purposes of the FDCA in establishing a uniform system of warnings for a particular pharmaceutical product. Had a majority of the court have found such a conflict, it would have resulted in a decision that pharmaceuticals enjoyed the same broad pre-emptive immunity from most state tort liability that the *Riegel* decision found for PMA-approved devices.

The level of scrutiny and review involved in the regulatory approval procedure for pharmaceuticals is at least as intense as, if not greater than, that for the PMA procedure for medical devices. The PMA procedure – which is used for medical devices perceived to be of high risk to patients (ie Class III devices) – requires the FDA to review a product's design, labelling and manufacturing specifications and to determine that those specifications provide a reasonable assurance of safety and effectiveness. Moreover, the postmarketing safety surveillance system for pharmaceuticals is equally as rigorous as that for PMA-approved devices.

Distinguishing between the approval procedures for pharmaceuticals and devices based on the role of the FDA, therefore, makes no sense. Those Justices who were in the majority of the *Riegel* opinion, but in the dissent in *Levine* (specifically, Chief Justice Roberts and Justices Alito and Scalia), made precisely that point in their opinion[8].

The majority opinion in *Levine* relied heavily on the absence of an express pre-emption provision in the FDCA, in contrast to the inclusion of such a provision in the MDA for PMA-approved medical devices. Thus, the distinction between the two opinions and the two types of products is largely legislative according to the majority opinions in *Riegel* and *Levine.*

One cannot rationally distinguish a justification for broadly exempting medical devices but not pharmaceuticals from state tort liability

Given the greater level of regulatory oversight the FDA applies to the approval and postmarketing safety surveillance of pharmaceuticals compared with Class III medical devices, one cannot rationally distinguish a justification for broadly exempting one but not the other from state tort liability. Indeed, even in *Levine*, while refusing to recognise blanket immunity from state tort liability, the court allowed that, in certain instances where a clear conflict between state and federal requirements existed, pharmaceuticals could be exempt from most state tort liability[9].

Given the rigorous approval and postmarketing safety surveillance processes, both pharmaceuticals and PMA-approved devices are deserving of blanket immunity from state tort liability. Simply because the *Levine* court refused to recognise this blanket immunity is no justification for rolling back such protection for PMA-approved medical devices.

Medical device pre-emption and the interests of patients

The regulation of medical devices involves striking a balance between safety and efficacy. Lean too hard on safety matters and important medical device therapies would be impeded from coming to market, depriving certain patients of potentially life-saving therapies. Lean too hard on efficacy and effective products with potentially unacceptable risks would enter the market.

A fundamental assumption underlying the MDSA is that state court juries are better positioned than the FDA to ensure patient safety. The bill's sponsors argue that medical device companies need the threat of state tort liability exposure to keep them adequately focused on patient safety. Furthermore, they wish to ensure the potential of economic recovery via the tort system for a patient harmed by a medical device.

Between the state tort system and the FDA, it is unquestionable that specialists from the FDA who have a macro-view of safety and efficacy in a broad patient population are better positioned to serve as gatekeepers for the initial approval of medical devices. The question is whether

institutionally the FDA is capable of adequately monitoring postmarketing safety on a macro-view, rather than the macro-implications of juries serving as postmarketing safety monitors in the micro-view of an individual patient's jury trial.

Two witnesses offered differing views on the impact the Medical Device Safety Act would have on patients

At the May hearing, two witnesses offered differing views on the impact the MDSA would have on medical device patients. *Washington Post* columnist Michael Kinsley, who suffers from Parkinson's Disease and whose symptoms are relieved through an intra-cranial implanted device, recognised the tension between the FDA system of postmarketing safety surveillance and that of the state tort system. He said[10]:

> *We all want the government to protect us from dangerous drugs and devices. But we don't want the government to prevent us from getting helpful or even lifesaving drugs and devices. Yet the most important drugs and devices are both. They save lives, and they can cost lives. The government's job is to weigh the risks against the benefits.*
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> *And here's where it gets messy. We have two completely independent systems for making the same decision of whether a drug or device should be approved for sale. One is the Food and Drug Administration – a national government agency staffed by experts and mandated to take into account both the potential benefits and the potential dangers. The decisions it makes set a uniform standard for everyone in every state. The other system is tort law, administered by thousands of non-expert judges and jurors in 50 state courts. The same issue can and does get re-litigated dozens of times. Differences in state law or just the randomness of juries produce dozens of different answers. Some plaintiffs hit the jackpot; most victims never even sue. The direct cost is horrendous: delivering a dollar to a victim costs far more than a dollar in expenses – mostly lawyers' bills.*
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> *The indirect cost is immeasurable. Lawsuits focus on the victim of some medical product. By their nature, they undervalue the benefit that same product has brought to other users, or even to the victim herself.*
>
> *Forced to choose between these two systems for making essentially the same decision, I believe that anyone sensible would choose the FDA. But in real life, the situation is even crazier: we have both systems simultaneously. And basically, whichever one draws a more restrictive line, wins. Add to this the fact that product manufacturers have no idea when or how the standard might change, and you have a perfect arrangement for discouraging drug and device manufacturers from developing new products, like the ones that allow people like me to go about our business, which is making trouble for people like you.*

One witness said that the differences in state law or just the randomness of juries produce dozens of different answers

On the other hand, a young mother who experienced adverse effects from an implantable heart defibrillator followed by a general decline in health, told the May hearing that her device had been the subject of hundreds of complaints prior to the manufacturer's decision to withdraw the product[11]. She observed that it was "wrong" for her health insurer or government programmes like Medicaid or Medicare to be responsible for healthcare expenses for the adverse effects and alleged consequences when those costs should properly be borne by the device manufacturers. She concluded that, though her healthcare costs related to the adverse event were covered by private insurance, she found it "discouraging and demoralising" that she had no recourse for her injuries, and that a company that manufactured a defective product that had harmed her and thousands of other individuals "had no accountability".

The other witness said it was "discouraging and demoralising" to have no recourse for her injuries

Opponents of the MDSA argue that its adoption would discourage medical device innovation and the costs incurred by medical device manufacturers via the state tort system would merely be passed on to patients and insurers via increased costs of the devices. A white paper on the economic impact of eliminating federal pre-emption of medical devices on patients, innovation and jobs was released in April[12]. The paper asserts that the MDSA would have a variety of negative effects both on the interests of individual patients and on the overall healthcare system in general. With regard to the impact on patients' interests and medical technology innovation, the paper claims that adoption of the MDSA would result in:

- reduced patient access to devices and the health benefits they provide;
- unreliable, inconsistent patient access to devices and the health benefits they provide as varying state regulations and tort liabilities discourage or eliminate products in some regions but not others;
- increased medical costs and lower net public health compared to what could be achieved with increased medical device innovation and product introductions;
- increased defensive medical practices by physicians to avoid possible litigation, raising health costs and exposing patients to greater risks from the added unnecessary procedures;

- reduction in the number of products being developed as manufacturers and their investors respond to greater uncertainty regarding product approval and economic sustainability; and
- transfer of health regulatory decisions to untrained, non-expert juries who are exposed to only a biased fraction of the scientific fact base on which to base their decisions.

The paper also asserts that passage of the MDSA would negatively impact employment within the medical device industry by increasing costs and discouraging innovation, and reducing research and development pipelines. Finally, it claims that the act would result in increased government spending due to a fall-off in innovation, a rise in tort-related costs, and increased court's budgets due to an anticipated rise in medical device lawsuits.

The Medical Device Safety Act would negatively impact employment in the medical device industry by increasing costs and discouraging innovation

While some might question the extent of such costs, there can be little doubt that America's state tort system generally results in added costs in all other sectors of the economy. Given the costs attendant with litigation, it is hard to imagine a credible argument that asserts that exposing individuals and organisations to state tort liability results in a systemic cost savings. The question is, are the added costs justified because of any measurable societal benefit?

On balance, the evidence presented to date on the question of whether the interests of patients are best advanced by eliminating medical device pre-emption is decidedly negative. Subjecting medical device manufacturers to myriad, inconsistent and sometimes arbitrary results from the state tort system will unquestionably discourage innovation and raise costs. Those costs will be borne directly and initially by medical device manufacturers but ultimately by taxpayers through higher device and societal costs passed on by the manufacturers.

Conclusion

The MDSA, if enacted, would roll back the protections afforded to manufacturers of PMA-approved medical devices both from the original MDA as well as its interpretation by the *Riegel* court. Its sponsors have failed to provide a compelling rational for the legislation. Subjecting device manufacturers to additional and inconsistent regulation via the state tort system fails to advance the interests of patients and would, in fact, be detrimental to their interests.

Subjecting device firms to additional regulation via the state tort system fails to advance the interests of patients

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