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## The Federal Preemption Battle Has Just Begun

Law360, New York (October 24, 2008) -- After the Supreme Court's decision in *Riegel v. Medtronic Inc.* on Feb. 20, 2008, there was widespread applause by manufacturers, retailers, chambers of commerce and the defense bar.

After all, with only Justice Ginsburg dissenting, the Court struck a strong blow against state common-law tort and product liability claims – and consequently, also against growing personal injury damage awards and the plaintiffs bar.

By holding that the Food and Drug Administration's (FDA) premarket approval process for Class III medical devices established federal requirements, and that those requirements preempted state tort and product liability claims pursuant to Section 360k(a) of the Medical Device Amendments of 1976 (MDA), the Court signaled that it was willing to expand federal preemption law to reign in state tort and product liability litigation.

But, the applause did not end there. The Court also granted certiorari earlier this year in the case of *Wyeth v. Levine*, which will be argued on Nov. 3, 2008. Similar to the *Riegel* case, the issue before the Court is whether certain approvals by the FDA preempt state product liability claims.

More specifically, *Wyeth* argues that FDA's drug labeling approvals and requirements should preempt state product liability claims because they may effectively place conflicting requirements on drugs.

But, unlike the *Riegel* case, the legal framework involved in *Wyeth* does not include a specific statutory provision providing for preemption. Nonetheless, the cheerleaders are on the sidelines anticipating another favorable ruling on federal preemption.

But, a more detailed analysis of *Riegel*, the statutory and regulatory framework of the different FDA approval processes, and current legislation pending in both the U.S. House of Representatives and the U.S. Senate may cause those cheerleaders to postpone their victory party.

First, the holding in Riegel is not as broad as portrayed by some commentators and industry articles. It is limited strictly to those Class III medical devices that pass through the FDA's premarket review process – a process that includes a voluminous application, a detailed review and risk analysis by the FDA, and approval of any proposed labels.

It does not include Class III medical devices that are either grandfathered by law (sold before the MDA's effective date) or are approved by the FDA under the substantial equivalence process of Section 510(k).

This is important because, as the Court recognized, the vast majority of new medical devices used today were approved under the Section 510(k) process.[1]

More significantly, the MDA expressly provides for preemption of state requirements. Section 360k of the MDA provides:

(a) General rule

Except as provided in subsection (b) of this section, 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 the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

Thus, the Court's holding is really based on two fundamental findings: first, the FDA's premarket approval process, which focuses on safety, was found to place federal requirements that are specific to individual medical devices; and second, state common-law tort and product liability actions also place requirements on those same devices.

The Court's opinion has very little discussion about whether requiring something over and above the FDA's requirements would be permissible if not in conflict, and also has very little discussion on the Court's traditional wariness of finding broad federal preemption.

Instead, using the rather plain, broad language of Section 360k of the MDA, the Court affirmed the Second Circuit's finding of federal preemption.

As Justice Ginsberg points out in her dissent, however, the preemption scheme in Section 360k may not have been intended by Congress to broadly preempt state tort and product liability claims for medical devices.

For, when the MDA was enacted in 1976, there was widespread tort and product liability litigation throughout the country relating drugs, labels, and medical devices, including the Dalkon Shield cases.

But nowhere in the MDA does Congress specifically address state common-law tort and product liability actions (including notably in the preemption language of Section 360k), and nowhere in the legislative history of the MDA is there a clear indication that Section 360k was intended to curtail that type of litigation.

More pointedly, Congress clearly was aware that some states had developed separate approval and regulatory schemes for medical devices because the legislative history even includes a discussion of California's then-existing approval and regulation of medical devices. H.R. Report No. 94-853.

It thus appears more likely that Section 360k was enacted to preempt potentially inconsistent state regulatory and approval schemes for medical devices – not state tort and product liability actions.

This interpretation is supported by the fact that Congress did nothing to address the significant state tort and product liability litigation over drugs and additives, which also was widespread at that same time.

And, in 1976, Congress only needed to provide preemption of state regulatory and approval schemes for medical devices in Section 360k because no states had such schemes for drugs.

But, as Justice Stevens recognizes in his concurrence, the drafters of Section 360k simply drafted a statutory provision that goes beyond its intended coverage.

Nowhere on its face is it limited to requirements imposed by state approval processes for medical devices, and clearly other proceedings at the state level can and will result in “requirements” being imposed.

Thus, it was relatively easy for the Court in *Riegel* to interpret Section 360k to preempt state tort and product liability claims for Class III medical devices approved by the FDA pursuant to its premarket approval process.

In doing so, however, *Riegel* took basic liability issues impacting citizens out of the hands of the states, and placed them solely in the hands of the scientists, politicians and staff at the FDA.

Consequently, Congress has demonstrated an intent to act to reverse the direction set by *Riegel*. Bills have been introduced in both the U.S. House of Representatives (H.R. 6381) and the U.S. Senate (S.R. 3398) to make it clear that Section 360k of the MDA does not preempt state common-law tort and product liability actions.

Specifically, as currently drafted, the legislative language is simply the following:

Sec. 2 Liability Under State And Local Requirements Respecting Devices.

(a) Amendment.—Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by adding at the end the following:

“(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.

This “fix” is squarely intended to rectify what some in Congress believe is the wrong interpretation of the statutory preemption provision in Section 360k.

Given that the Democrats are likely to add seats in both the House and Senate this election cycle, the Democratic-sponsored Bills have a much greater chance of passing in the next Congress.

And, given that Republicans should be worried about legislation that erodes states’ rights and long-standing principles of federalism, the Democratic-sponsored Bills might even have Republican support.

This brings us now to the upcoming *Wyeth v. Levine* case, which is set to be argued in the Supreme Court on November 3rd, one day before the presidential election. This

case is on appeal from the Vermont Supreme Court, and involves the use of a Wyeth drug, Phenergan, in a push IV injection.

This method of administration was permissible on the drug's FDA-approved label, but the label also included a warning of risks accompanying this method, including the gangrene unfortunately experienced by the plaintiff.

Wyeth argues that the FDA's approval of the label under the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. 301 et seq., preempts state product liability claims.

Interestingly, Wyeth's position is, in part, based on the fact that the FDA itself believes its approval of labels should trump state common-law claims.

In its Preamble to a 2006 rulemaking (71 FR 3934), the FDA states:

FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.

But, this preemption position is not supported by a regulation promulgated pursuant to notice and comment, nor by legislative language.

Rather, the FDA is trying to dictate that its requirements for labels on drugs no longer are simply minimum ones – a “floor” so to speak – but instead are the only ones.

Under Chevron and frankly common sense, the FDA's own interpretation of the reach and import of its approvals and requirements should not be given deference by the Supreme Court.

And, it would be a strong defeat for principles of federalism and states' rights if the Court used this particular case to expand federal preemption – and concurrently wipe out most avenues of redress for parties to seek damages under state tort and product liability laws.

There is undoubtedly a very deep bucket full of frivolous lawsuits, excessive damage awards, greedy plaintiffs' lawyers, unfair sentiment in juries, and state court judges and rulings that stack the deck against well-meaning corporate defendants.

In fact, we have seen and successfully defended against many of these cases, which simply serve to raise costs in our society each and every day.

But, making the FDA the only guarantor of safety for a subset of drugs and medical devices cannot be the solution.

And, allowing federal agencies to decide if and when their approvals, requirements and actions preempt long-standing state common-law also cannot be the solution.

In Riegel, the Court took the plain, broad language of a statutory preemption provision, and threw the long preemption ball allowed by that language. That play is likely to get called back by the umpires in Congress.

In Wyeth, on the other hand, the Court risks converting the regulatory compliance defense into a regulatory compliance bar against state product liability claims.

With the FDA's declaration of preemption tucked in a preamble of a rulemaking, and with the broad spectrum of government approvals and requirements by other agencies that could quickly come into play, the Supreme Court should not use this case to continue down the field of federal preemption.

An expansion of federal preemption using the Wyeth case risks tearing down important principles of federalism, and also runs the risk of creating precedent that may have an impact far beyond drug and medical device personal injury litigation.

And, the cheerleaders on the sidelines right now may not like that expansion – especially if election day – the day after argument in the Wyeth case – delivers a Democratic White House and stronger Democratic Congress. Simply put, that would be a game changer.

With the possibility of broad-sweeping Democratic legislation, and new directions and agendas by federal agencies, the expansion of federal preemption may have entirely new groups providing the applause.

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