

# Inre Products Liability

NEWSWIRE

July 2008/Issue 8

## PUNITIVE DAMAGES

### U.S. Supreme Court Slashes *Exxon Valdez* Punitive Award From \$2.5 Billion To \$500 Million — Declares 1:1 Ratio An “Upper Limit” Under Federal Common Law

See *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 WL 2511219 (U.S. June 25, 2008)

Almost 20 years after the *Exxon Valdez* — piloted by an intoxicated captain with a known history of alcohol abuse — spilled millions of gallons of crude oil off the coast of Alaska into Prince William Sound on a foggy night, the U.S. Supreme Court has finally determined what that spill will cost Exxon in punitive damages. That final number is \$507.5 million, or roughly the equivalent of what the company had already paid in compensatory damages to the plaintiffs — individuals who were “dependent on Prince William Sound for

their livelihoods.” *Id.* at \*4.<sup>1</sup> In reducing the punitive damages award (which the Ninth Circuit had affirmed) from \$2.5 billion to \$500 million, the Court ruled that as a matter of federal maritime common law, a 1:1 ratio

*/ continued page 2*

#### THE AGENDA

- 1 PUNITIVE DAMAGES
  - *Exxon Valdez* Punitive Award Slashed
  - *Williams* Returns to U.S. Supreme Court
- 5 NANO LAW
  - Mediating the Uncertainty of Nanotechnology
  - Carbon Nanotubes — Risk, Regulation and the Shadow of Asbestos Litigation
- 10 PUBLIC NUISANCE
  - Verdict Against Lead Paint Manufacturers Reversed
- 12 MEDICAL MONITORING
  - No Medical-Monitoring Claims Without Present Injury
- 14 FOREIGN LAWS
  - The “Rome II” Regulation on Cross-Border Torts
  - The EC’s Annual RAPEX Report
- 18 PREEMPTION
  - Pharmaceutical Preemption Rumble Continues
  - Preemption in Generic Drug Case
- 22 CONSUMER FRAUD
  - Merck Settles Consumer-Protection Actions Against Vioxx

1 As the Court noted, Exxon had already (1) “spent around \$2.1 billion in cleanup efforts,” (2) “pleaded guilty to violation of the Clean Water Act, the Refuse Act, and the Migratory Bird Treaty Act and agreed to pay a \$150 million dollar fine, later reduced to \$25 million plus restitution of \$100 million,” (3) entered into a consent decree to resolve a civil action by the United States and the State of Alaska, which resulted in the company agreeing “to pay at least \$900 million toward restoring natural resources,” and (4) “paid another \$303 million in voluntary settlements with fisherman, property owners, and other private parties.” *Id.* at \*5. All told then, prior to this ruling Exxon had already paid over \$3 billion dollars as a result of this environmental disaster. The remaining civil cases were consolidated into this lawsuit, where Exxon had “stipulated to its negligence in the Valdez disaster and its ensuing liability for compensatory damages.”

For more information about our practice, contact

- Garyowen P. Morrisroe  
+1 (212) 408-5100, gmorrisroe@chadbourne.com
  - Allison M. Alcasabas (London)  
+44 (0)20 7337-8000, aalcasabas@chadbourne.com
- or visit us at [www.chadbourne.com](http://www.chadbourne.com)

## PUNITIVE DAMAGES

*continued from page 1*

between punitive and compensatory damages “is a fair upper limit.” *Id.* at \*21.

*Exxon Shipping* will almost certainly reverberate well beyond the parochial contours of common law admiralty principles that gave it life, as other civil litigants seek to extend and shoehorn its holding — what Justice Ginsburg called its “1:1 solution” — into the due-process prong of punitive-damages law. Interestingly, last year in these pages we argued the benefit of precisely this more quantitative approach to punitive damages, writing:

Perhaps the law of punitive damages might be generally simplified and reformed by borrowing the example of the antitrust and RICO statutes, among others. Give plaintiffs the right to recover[, say,] trebled damages on proof of certain aggravating factors (i.e., [egregiousness]).... Such an approach would also seem a more direct way of arriving at already agreed constitutionally permissive punitive/compensatory damage ratio of single digits ... rather than analyzing ratios for reasonableness and the like[.]

See “U.S. Supreme Court Says Jurors May Not Use ‘Reprehensibility’ to Punish Defendants for Harm to Non-Parties — Leaves Procedural Safeguards to Laboratory of Lower Courts,” *In re Products Liability 3* (April 2007).

### Exploring the Historical Roots and Evolution of Punitive Damages

The Court began its detailed and methodical common-law analysis by examining the historical roots of punitive damages,<sup>2</sup> noting that “exemplary” damages were originally “justified as punishment for extraordinary wrongdoing” aimed at deterring such conduct in the future. *Id.* at \*12. As another early justification for exemplary damages (as a variety of compensatory damages), it cited the need “to compensate for intangible injuries, compensation which was not otherwise available under the narrow conception of compensatory damages prevalent at the time.” *Id.* (citation and quotation omitted). As the common law expanded to provide compensatory damages for a broader and broader array of injuries (including, most significantly in this regard, pain and suffering), the Court

noted that “American courts tended to speak of punitive damages as separate and distinct from compensatory damages.” *Id.*

Whatever their historical roots, the Court explained that punitive damages today serve (as a criminal-law analogue) the dual objectives of “retribution and deterring harmful conduct.” *Id.* With these modern day, criminal-law objectives in mind, the Court observed, juries and judges tend to impose greater punishment for more morally blameworthy conduct. Thus, the Court acknowledged that as opposed to conduct that is merely reckless, conduct “taken or omitted in order to augment profits represents an enhanced degree of punishable conduct, as of course does willful or malicious action, taken with a purpose to injure.” *Id.* at \*13. The Court also explained, as it has done previously, that higher punitive damages are often “thought to be justifiable when wrongdoing is hard to detect” or when misconduct results in “only a small amount of economic damages” — wholly apart from the gravity of the wrongful conduct at issue. *Id.* (citation and quotation omitted).

Following its historical overview of punitive damages and their modern day policy justifications, the Court next surveyed how various U.S. states have approached punitive damages, taking particular note of the fact that many cap punitive damages at a set amount or as a ratio relative to compensatory damages — “ranging from 5:1 to 1:1.” *Id.* It also noted that various empirical studies have found that “the median ratio of punitive to compensatory awards has remained less than 1:1.” *Id.* at \*15.

### The 1:1 Solution

After examining the historical, empirical and policy-based factors that would ultimately inform its analysis, the Court expressed skepticism that verbal formulations, superimposed on general jury instructions, are the best insurance

<sup>2</sup> Before determining what the appropriate amount of punitive damages should be under maritime common law, the Court had to resolve two antecedent arguments made by Exxon for why punitive damages were not warranted. First, the Court divided 4 to 4 (Justice Alito had recused himself from the decision) on the question of whether Exxon could be held derivatively liable for punitive damages for the acts of the ship’s captain, leaving undisturbed the Ninth Circuit’s holding that it could be. *Id.* at \*9. Second, the Court rejected Exxon’s argument that the Clean Water Act preempts maritime punitive damages at common law, finding “no clear indication of congressional intent to occupy the entire field of pollution remedies.” *Id.* at \*10.

against unpredictable “outlier” punitive damages awards. *Id.* at \*18. In fact, it was “doubtful that anything but a quantified approach” to limiting punitive damages awards would work. *Id.*<sup>3</sup> It therefore concluded that “to protect against the possibility (and the disruptive cost to the legal system) of awards that are unpredictable and unnecessary, either for deterrence or for measured retribution, we consider that a 1:1 ratio, which is above the median award [of punitive damages in all cases that have awarded them, according to several published, academic studies], is a fair upper limit in [] maritime cases.” *Id.* at \*21.

### The Dissent

According to the dissent by Justice Stevens, the majority failed to exercise appropriate “judicial restraint in the absence of” a clear congressional mandate for punitive awards to be categorically capped at an amount no greater than the compensatory award in all maritime cases. *Id.* at \*22. In responding to this view for the majority, Justice Souter reasoned that the judiciary has historically “accepted primary responsibility for reviewing punitive damages and thus for their evolution,” and that, “it is hard to see how the judiciary can wash its hands of a problem it created, simply by calling quantified standards legislative.” *Id.* at \*19.

### The Case’s Knock-On Import Is Uncertain

Unlike other U.S. Supreme Court punitive-damages cases, which have all “examined outlier punitive damages awards” for “excessiveness” through a constitutional lens, *Exxon Shipping* “differs from due process review because the case arises under federal maritime jurisdiction.” *Id.* at \*16. For that reason, the Court reviewed the jury’s punitive damages award “for conformity with [federal] maritime law, rather than” for purposes of determining whether the award would comport with the “outer limit allowed by due process.” *Id.*

Ultimately, this unique jurisdictional feature of the case may limit its influence over how lower courts and state legisla-

tures police outlier punitive damages awards, but the Court does appear to be signaling its distress over “the stark unpredictability of punitive awards” and the need for guidelines that make such awards more “reasonably predictable” in terms of their potential severity — “so that even Justice Holmes’s ‘bad man’ can look ahead with some ability to know what the stakes are in choosing one course of action or another.” *Id.* at \*15 - \*16. The need for such guidance and predictability after all is hardly unique to admiralty law.

It may just be, however, that the Court is embarking on a course that will eventually lead it to abandon the imprecise, nuanced, verbal standards that have marked its due process jurisprudence to date — and confounded lower courts — in favor of “the 1:1 solution.” *Id.* at \*28 (Ginsburg, J., dissenting). ©

## Once More Into the Breach: *Williams v. Philip Morris* Returns To U.S. Supreme Court For (Yet Another) Punitive Damages Tutorial

See *Philip Morris USA Inc. v. Williams*, 128 S. Ct. 2904 (2008)

The U.S. Supreme Court recently accepted *certiorari* to review — for the third time in five years — a long-simmering punitive damages battle pitting the spouse of a deceased smoker (and the Oregon appellate courts) against Philip Morris (and the U.S. Supreme Court). On this trip, the high Court will consider the more limited question of whether:

after [it] has adjudicated the merits of a party’s federal claim and remanded the case to state court with instructions to ‘apply’ the correct constitutional standard, the state court may interpose — for the first time in the litigation — a state-law procedural bar that is neither firmly established nor regularly followed.

*Philip Morris’s Petition for a Writ of Certiorari*, 2008 WL 795148, at \*1 (“*Id.*” hereafter). This limitation makes it unlikely that *Williams III* will produce any further illumination of the constitutional strictures applicable to the assessment and quantum of punitive damages.<sup>1</sup> In the meanwhile, the significance of the Court’s recent punitive-damages decision in *Exxon*

/ continued page 4

<sup>3</sup> Drawing an analogy to criminal law, the Court noted that federal criminal sentencing guidelines over the last 25 years have rejected a discretionary system for sentencing in favor of adopting “a system of detailed guidelines tied to exactly quantified sentencing results . . .” *Id.* at \*18.

## PUNITIVE DAMAGES

*continued from page 3*

*Shipping*, reported elsewhere in these pages, will almost certainly continue to be debated and litigated.

### Procedural Background: “What a Long Strange Trip It’s Been”

As previously described, *see* “The Devil’s in the Details: Courts Diverge on Punitive Damages Post-*Williams*,” *In re Products Liability* 6-8 (April 2008), the U.S. Supreme Court first reviewed and remanded this case to the Oregon Supreme Court in 2003, after the landmark punitive-damages decision in *State Farm*, which held that “few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process.” *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2003). On that initial remand, the Oregon Court of Appeals and the Oregon Supreme Court both concluded that a 97 to 1 ratio between Philip Morris’s punitive liability (\$79.5 million) and compensatory liability (\$821,000) comported with due process.

In February 2007, the U.S. Supreme Court again remanded the case, this time with instructions for the Oregon courts to employ “procedural safeguards” to prevent “an unreasonable and unnecessary risk” that the jury might “punish a defendant [with punitive damages] on account of harms it is alleged to have visited on nonparties.” *Philip Morris USA v. Williams*, 127 S. Ct. 1057, 1064-65.

On this second remand, however, the Oregon Supreme Court avoided its superior’s mandate and never addressed whether the trial court’s jury instructions failed to provide the “procedural safeguards” required to protect Philip Morris’s due process rights. Instead, the Oregon Supreme Court announced — for the first time in the litigation — an “independent and adequate” state-law procedural basis for affirming the punitive damages award. Specifically, it ruled that since a portion of Philip Morris’s proposed punitive damages charge — which was completely unrelated to ensuring that the jury refrained from assessing punitive damages based on harms to nonparties — was erroneous (that is, not “clear and correct in all respects, both in form and in substance, and . . . altogether free from error” as a matter of Oregon law), Philip Morris had failed to preserve its federal due-process objection. *Williams v. Philip Morris, Inc.*, 344 Or. 45, 56 (Or. Jan. 31, 2008).

### “Wait A Minute:” The Arguments Presented In Philip Morris’s Certiorari Petition

According to Philip Morris’s petition, the Oregon Supreme Court improperly invoked a “state ground” for affirming the punitive-damages award in the case. In particular, Philip Morris argued that the procedural rule employed by the Oregon Supreme Court “is unreasonable, inconsistently applied, and nothing more than a pretext for [its] refusal to protect Philip Morris’s due process rights.” *Id.* at \*3. It requested that the U.S. Supreme Court take the case for a third time “to prevent state courts [like Oregon’s] from deploying state procedural rules to evade this Court’s constitutional decisions, and to protect this Court’s role as the final arbiter of federal constitutional rights.” *Id.*

As Philip Morris explains in its briefing, the two claimed charge “errors” cited by the Oregon Supreme Court — (i) urging the jury that it “may” rather than “shall” consider various statutory factors in awarding punitive damages, and (ii) asking the jury to consider whether Philip Morris’s conduct was motivated by “illicit” profits, as opposed to simply the desire to make any profits — were never mentioned “by either the Oregon Court of Appeals or the Oregon Supreme Court in [the] nine years of appellate litigation” that preceded the 2008 decision by the Oregon Supreme Court following the U.S. Supreme Court’s most recent remand. *Id.* at \*12. Philip Morris argues that the Oregon Supreme Court’s use of these errors in avoidance of the U.S. Supreme Court’s constitutional mandate demonstrates that there was “no adequate and independent state ground” to support the Oregon courts’ earlier affirmance of the punitive-damages award against Philip Morris. *Id.* at \*16. Put differently, it says that “where a state court does *not* indicate that its decision rests on state-law grounds . . . it is impermissible for a state court to invoke a state-law ground for the judgment for the first time *after* [the U.S. Supreme] Court has ruled on the federal issue.” *Id.* at \*17 (emphasis in original). According to Philip Morris, the Oregon Supreme Court did just that.

<sup>1</sup> The high Court declined to review the second issue on which *certiorari* was sought: “Whether a punitive damages award that is 97 times the compensatory damages may be upheld on the ground that the reprehensibility of a defendant’s conduct can ‘override’ the constitutional requirement that punitive damages be reasonably related to the plaintiff’s harm.” *Id.*

Philip Morris further argues that the rule of procedure invoked by the Oregon Supreme Court marked “the first time in any reported Oregon decision that an appellate court has rejected an instruction on one subject, after the trial judge considered the subject separately at the charge conference, merely because it appeared under the same heading as a defective instruction *on an entirely distinct point of law.*” *Id.* at \*27 (emphasis in original). Instead, Philip Morris points out, the historical norm for Oregon reviewing courts has been to “consider the correctness” of a charge on a topic-by-topic basis. *Id.* (citing cases). In its departure from the normal rules of appellate review in the state, Philip Morris maintains that the Oregon Supreme Court did not follow a “firmly established and regularly followed” state rule of procedure otherwise constituting an independent and adequate state ground for affirming the punitive damages award, much less ignoring a U.S. Supreme Court constitutional mandate. *Id.* at \*25.

Although *Williams III* will not likely add further definition to punitive-damages jurisprudence, the U.S. Supreme Court’s decision in this matter will almost certainly make interesting reading. ☺

## NANO LAW

# Mediating the Uncertainty and Abstraction of Nanotechnology Promotion and Control: “Late” Lessons from Other “Early Warnings” in History

### Introduction

Nanotechnology presents all stakeholders something unique in regard to high-tech innovation generally: the chance to get things right the first time, by building on the lessons of past societal experience with transformative technology. There are enough published accounts to avoid repetition here — genetically modified foods, civilian nuclear power, and, more recently, biofuels. The common denominator is lack of public trust — confidence — in the ability of government, science and industry to characterize and manage the human health and environmental risks of new technology effectively, all the

more so considering the exponential scale and pace of nanoscale science and engineering advancement.

## 20th Century Regulatory Paradigms Meet 21st Century Science

In this regard, it is intuitively difficult to assume — on the basis of “substantial equivalence” or otherwise — that early 20th century regulatory models rooted in the peculiar nature and scale of 19th century industrial development can keep pace with something as robust and dynamic as nanoscale science, on all counts. This seems especially significant in light of the novel nature of nanotechnology itself, which one observer recently likened to “rediscovering the periodic table of elements.”

On close study, one failing of past regulatory oversight of emergent technologies has been chiefly the closed nature of its decision-tree structure. Except through the relatively limited, passive filter of representative democracy, and “open public meetings,” there has been little true multi-stakeholder dialogue in regard to the business of managing the risk landscape of so-called “megasciences,” from biotechnology to nanotechnology. As a vestigial part of an earlier industrial age, regulators and risk managers typically take a classic risk assessment approach, grounded on the operating premise that *x* amount of health risk, environmental harm and associated costs, narrowly defined, is (or is not) outweighed by *y* amount of consumer benefit, industrial commerce, and revenue. The relevant calculus in regard to megasciences like nanotechnology, however, is more complicated. In the first instance, the risks and benefits are largely undefined — unknown — rendering their full quantification largely impossible. This, and failing to account sufficiently (or at all) for what Donald Rumsfeld once famously called “unknown unknowns” (uncertainty) arguably takes one a long way to understanding how to improve the chances of successfully commercializing nanotechnologies, while at the same time balancing risk and benefit — broadly speaking.

## New Promotion and Control Paradigms: Constructive Technology Assessment

Clear and coherent nano-specific regulatory oversight is probably years off, which is almost certainly too long when one considers that “a nanosecond is to a second as a second is to 30 years” (Sarnoff, 1964). In brief, there is not enough quantita-

/ continued page 6

## NANO LAW

*continued from page 5*

tive certainty surrounding nanotechnology to satisfy traditionally linear risk assessment parameters — *control* models — at any point in product or process lifecycles. Further, market forces — commercialization — cannot (and will not) await the arrival of nano-focused regulatory oversight. With nanotechnology, there is simply too much opportunity to be lost awaiting the arrival of clarifying regulatory sanction, standards or guidance.

In the meanwhile, companies in the field can either follow uncertainty (uncertainly) or proactively lead on the basis of bold, new governance — promotion and control — paradigms every bit as innovative and transdisciplinary as the nature of nanotechnology itself. More specifically, nano interests should consider establishing defensive positions on the foundation of classic technology assessment (TA) tools supplemented by

to the table for transparent, participative discourse on matters that are ultimately as much about the social sciences as they are the so-called hard sciences.

As part of this process, one of the voices that must be heard — in many respects the most important nanotechnology stakeholder — is the public's, since it is public perception that ultimately drives, *first*, investment (in the markets) and, *second*, consumer acceptance of nano-based products in the context of perceptions of nanotechnology's wider social costs. In short, the public should be brought into the risk management process at the earliest opportunity. Without it, the risk is that the nanotechnology bridges already being built on many fronts will become bridges to nowhere. There is, further, much litigation peace to be won (and costs to be saved) on the basis of seeking multi-actor dialogue and collaboration from the outset — (a) in the framing of relevant risk assessment questions, (b) for the marshalling of evidence representing broadly

**In the meanwhile, companies in the field can either follow uncertainty (uncertainly) or proactively lead on the basis of bold, new governance — promotion and control — paradigms every bit as innovative and transdisciplinary as the nature of nanotechnology itself.**

what is called constructive technology assessment (CTA), which includes social and environmental considerations as factors relevant to the integration of new technology into society. With CTA, the goal is understanding and managing technological risk on a more pro-active, inclusive, transdisciplinary, and collaborative multi-stakeholder basis — bridge building basically — than has been standard governmental or industrial practice to date. *See generally* A. Rip, T. Misa and J. Schot (eds.), *Managing Technology in Society: The Approach of Constructive Technology Assessment* (London: Pinter Publishers, 1995) (collecting essays outlining CTA in theory and practice).

### **Public Perception is Critical to Investment in and Consumer Acceptance of Nanotechnologies**

One lesson of past experience is the need to open the deliberative process to different perspectives and inputs — by bringing all interested and otherwise impacted stakeholders

diverse societal interests to better inform socially responsible answering action, and (c) in terms of how the integration of nanosciences and products into society — the balancing of *promotion and control* — might be managed for the widest possible good.

The U.S. is an example, where the process of reauthorizing the National Nanotechnology Initiative has exposed a deeply polarized debate over the amount of federal nanotechnology dollars that should be devoted to further research and better understanding of the environmental, health and safety (EHS) risks of nanotechnology as a percentage of the nation's total nanotechnology spend annually — some \$1.5 plus billion federal dollars for 2008. But only \$76 million of this outlay has been earmarked by the White House for EHS-related research of nanotechnologies (significantly less than the annual payroll of a number of major league baseball teams). Early in the debate, there were calls to require that ten percent of the fed-

eral government's nanotechnology R&D budget be set aside for EHS-related study, which was vigorously opposed by the White House and ultimately deleted from the House bill. Plainly, however, there must be better balance between government's promotion and control of nanotechnologies if their integration into society is to succeed.

Instead of assigning arbitrary values or percentages to EHS research, therefore, a better alternative might be to run all federally and privately funded nanotechnology research and development work using a combination of classic TA and the new paradigm of CTA for risk assessment and management purposes — accounting for EHS and other risks throughout, and as an integral part of, the promotion process. Adding a CTA (qualitative) component to traditional (quantitative) risk management could help to shape public understanding and acceptance of nanotechnologies from the earliest possible state of the product development cycle.

### Concluding Thoughts

In the end, with or without the intervention of clear regulatory oversight, the management of technology in society is about the democratic process — the consent of the people (*i.e.*, impacted stakeholders). Of overriding importance in the mediation of uncertainty inherent to the process of technological innovation, is the need to capture diverse, outcome-directed decisional inputs on a multi-stakeholder basis through a transparently deliberative process. While industry decision-makers and risk managers may not have the luxury of awaiting regulatory guidance in the ongoing race to market, neither are they necessarily without precedent for being more proactive about the issue of EHS risk management in the interim.

Careful study of the “late lessons” of man's experience with innovative technologies since the late 1800s generally suggests that the methodology of traditional technology assessment (TA) — treating technological innovation as “black boxes” to be opened only by “expert” scientists in relatively closed-network discourse with government and industry leaders — is not enough by itself to reduce potential liabilities. See generally European Environment Agency, Environmental Issue Report No. 22, *Late Lessons From Early Warnings: The Precautionary Principle 1896-2000* (Copenhagen, 2001) (cataloguing international experience with the regulation of new technologies). This history counsels need to consider new paradigms for managing the socio-environmental risks of techno-

logical innovation like nanotechnologies. In light of these considerations, active multi-actor and public engagement over the competing spheres of nanotechnology *promotion* and *control* — in recognition of the fact that new technologies are endogenous, not exogenously imposed on society from without — may be the best risk mitigation strategy from both a civil litigation and regulatory enforcement perspective.

While regulators outside of the Netherlands and Denmark (where CTA is official policy) are unlikely to adopt it in the near term, nanotechnology firms could in the meanwhile strive for greater market stability — and avoidance of *post hoc* operational disruptions (in the form of PR problems, litigation, and *ad hoc* regulation) — by proactively combining classic technology assessment tools with those of constructive technology assessment to better inform and guide product promotion and control efforts from the earliest stages of nanotechnology product lifecycles, beginning with design.

This recommendation reflects the observation of Rip *et al.* (1995) — and the “late lessons” of other “early warnings” in regard to the integration of technology into society — that the social and environmental impacts of technological innovation are not abstract externalities subsequently attaching to the products of technological innovation in the marketplace after the fact. They are instead factors actually co-produced by the very products born of technological innovation in the first place, and should ideally be managed from this perspective. ☉

## Carbon Nanotubes, EHS Risk and Regulation, and the Long, Dark Shadow of Asbestos Litigation

See *The National Nanotechnology Initiative Amendments Act of 2008* (H.R. 5940)

### Nanotechnology and Lawmaking

On June 5, 2008, the U.S. House of Representatives passed by an overwhelming margin the National Nanotechnology Initiative Amendments Act of 2008.<sup>1</sup> This bill amends legislation from 2001 that created the National Nanotechnology

*/ continued page 8*

<sup>1</sup> See H.R. 5940.

## NANO LAW

*continued from page 7*

Initiative, a broad mandate for the creation of scientific standards for nanotechnology, coupled with government support of nanotechnology research into environmental, health and safety (EHS) concerns that have arisen over the now-ubiquitous use of nanotechnology in a broad array of consumer, medical and industrial products.

According to the U.S. House of Representatives Committee on Science and Technology, this legislation “does not substantially alter NNI, but makes adjustments to some of the priorities of the program and strengthens one of the core components — environmental and safety research.”<sup>2</sup> However, while the bill sets goals and proposes the creation of additional bureaucratic infrastructure for addressing potential nanotechnology-related EHS risks, some authorities in the field have advocated that EHS matters still must be addressed more vigorously.

Although the U.S. Senate has yet to pass its own legislation, its Subcommittee on Science, Technology, and Innovation recently held hearings on amendment of the NNI. One of the witnesses, David Rejeski, Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, expressed concern about issues that he says are not yet adequately addressed by current regulatory regimes, including a rise in the marketing of products with claimed “antibacterial” properties attributed to nano-engineered silver particles, products for children containing nanoparticles, and consumer products containing unverified therapeutic claims.<sup>3</sup>

### Nanotechnology and Science

Recently, scientists have identified potential health risks posed by one of the most common substances created by nanotechnology — carbon nanotubes. This is particularly significant given estimates that the global carbon nanotube market could exceed US\$1.9 billion by 2010.<sup>4</sup> Carbon nanotubes are used in a variety of industrial and consumer products and can also be purchased in bulk without warning labels or suggested safety measures; under U.S. product regulatory regimes, carbon nanotubes are largely treated as being identical to graphite in pencils.<sup>5</sup>

Scientific studies, however, have suggested that carbon

nanotubes — in particular, the long-fiber variety — may act like asbestos fibers, causing localized inflammatory reactions that can lead to disease and cancers, including mesothelioma.<sup>6</sup> Other researchers studying the biological behavior of a variety of carbon nanotubes and other nanoparticles also claim to have found some similarities to the behavior of asbestos particles — including deposition in pulmonary and abdominal tissues and the evocation of distinct host responses.<sup>7</sup>

These and like reports have prompted calls for warning labels and the need to use safety equipment in handling carbon nanotubes. The National Institute of Occupational Safety and Health recently raised the issue and is devoting further study to it. In this regard, one of its scientific consultants, Dr. Vladimir Murashov, cautions:

[w]hile the mechanisms of biological responses to carbon nanotubes are not yet fully understood, recent studies such as those from Japan and the UK add to the growing body of peer-reviewed scientific literature and remind the occupational safety and health community that carbon nanotubes should be handled prudently to minimize potential exposures in the workplace and to prevent potential adverse health effects in workers.<sup>8</sup>

Since protective handling measures have already been developed for asbestos fibers, some suggest that it may be prudent

<sup>2</sup> See <http://science.house.gov/press/PRArticle.aspx?NewsID=2185> (accessed July 8, 2008).

<sup>3</sup> See Testimony of David Rejeski (April 28, 2008) (available at [http://commerce.senate.gov/public/\\_files/RejeskiWrittenTestimony.pdf](http://commerce.senate.gov/public/_files/RejeskiWrittenTestimony.pdf)) (accessed July 8, 2008).

<sup>4</sup> See <http://www.electronics.ca/presscenter/articles/640/1/Global-Carbon-Nanotubes-Market-to-Exceed-1.9-Billion-by-2010/Page1.html> (accessed July 8, 2008).

<sup>5</sup> See Testimony of Andrew D. Maynard, Ph.D., Chief Science Advisor Project on Emerging Nanotechnologies, before the U.S. House of Representatives Committee on Science and Technology, at 25 (Oct. 31, 2007) (available at [http://democrats.science.house.gov/Media/File/Commdocs/hearings/2008/Full/16apr/Maynard\\_Testimony.pdf](http://democrats.science.house.gov/Media/File/Commdocs/hearings/2008/Full/16apr/Maynard_Testimony.pdf)) (accessed July 8, 2008).

<sup>6</sup> See, e.g., Poland, *et al.*, “Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study,” *NATURE NANOTECHNOLOGY* 423-28 (2008).

<sup>7</sup> Seaton *et ano.*, “Nanoscience, Nanotoxicology, and the Need to Think Small,” *LANCET* 923-24 (2005).

<sup>8</sup> See [http://www.cdc.gov/niosh/blog/nsb052008\\_nano.html](http://www.cdc.gov/niosh/blog/nsb052008_nano.html) (accessed July 8, 2008).

to adopt and adapt these off-the-shelf protocols for carbon nanotubes — while the scientific community continues to study and quantify the EHS aspects of carbon nanotubes and nanotechnologies generally.

### Nanotechnology and Commentators

Many commentators have noted the need to prevent another asbestos-type litigation nightmare potentially concerning not only carbon nanotubes, but nanotechnology-engineered products as a whole. They suggest that industry and regulators can help by ensuring that due investigation and account is made of emerging evidence regarding possible EHS risks from nanotubes. Previously in these pages, we have suggested that the immense complexity of nanotechnology means that the arrival of nano-specific governmental regulation will likely take considerable time — indicating that nanotechnology undertakings will have to operate for a period without clear EHS regulations or a liability framework.<sup>9</sup>

### Nanotechnology and Lawyers

Lawyers involved in asbestos personal-injury and abatement litigation know that the price of asbestos litigation over past decades (and continuing) has been astronomical — bankrupting countless entities along the way.<sup>10</sup>

One problem was that the liability case against the major asbestos manufacturers was fairly clearly established early in the litigation (especially atmospherically) — owing chiefly to the disclosure of corporate documents evidencing a lack of due care by defendants, leaving only individual issues of medical causation and environmental risks for litigation. This precedent has created a system rife with abuse potential.<sup>11</sup> More recently, we have seen this pattern repeat itself in regard to claims in respect of silica exposure, where thousands of dubious medical claims were filed against a backdrop of alleged corporate failure to determine safe levels of exposure in industrial settings.<sup>12</sup> Indeed, nanotechnology firms are already facing criticism from the insurance sector for alleged failures to adequately disclose possible EHS risks stemming from nanotechnologies.<sup>13</sup> Past experience counsels that such omissions in the context of tort litigation can be especially problematic — even when the scientific facts establish that concomitant risks are small or outweighed by significant social benefits.

### Concluding Thoughts on Nanotechnologies and Business at One-Billionth of a Meter

Nearby in these pages, we offer commentary on how nanotechnology firms might creatively and proactively manage the EHS aspects of nanotechnologies pending the development of nano-specific laws and regulations. To this end, every effort must be made to avoid repetition of the asbestos model — which (all things considered) has benefited few as much as it has the plaintiff's bar — and to ensure the development of a promotion and control environment conducive to “responsible investment in and commercialization of nanotechnologies through their infancy — free of potentially ruinous litigation exposure.”<sup>14</sup>

Among other things, liability caps, some limited degree or form of immunity, and mandated insurance coverage — some of which have been used to nurse development of the civilian nuclear power industry, for instance — could help to cabin the asbestos template's reach. What is needed most, however, is bold, out-of-the-box thinking equal to the innovative, evolutionary nature of nanotechnology itself. In fact, law has stood at this crossroad before.

In the 1960s, at the dawn of today's highly commercialized, mass consumption and Internet-driven society, the California Supreme Court began the modernization of American tort law with the invention of strict liability. Half a century on, one wonders whether nanotechnology will produce any significant developments in products liability law to accommodate the reality of doing business at one-billionth of a meter.<sup>15</sup> ©

<sup>9</sup> See “Small is the New Big: Eye on Nanotechnology Regulations in the U.S. and EU,” *In re Products Liability* 1-4 (Nov. 2007).

<sup>10</sup> See “Nanotechnology Law & Commerce: Doing Business at One-Billionth of a Meter,” *In re Products Liability* 12 (July 2007) (putting the price tag at some US\$200 billion).

<sup>11</sup> See L. Brickman, “An Analysis of the Financial Impact of S. 852: The Fairness in Asbestos Injury Resolution Act of 2005,” 27 *Cardozo L. Rev.* 991-1033 (2005).

<sup>12</sup> See *In re Silica Products Liability Litigation* (MDL No. 1553), 398 F. Supp. 2d 563 (S.D. Tex. June 30, 2005) (Order No. 29) (detailed judicial finding of thousands of fraudulent medical diagnoses of plaintiffs reached only for purposes of litigation without proper investigation).

<sup>13</sup> See Lloyd's of London, *Nanotechnology: Recent Developments, Risks and Opportunities* (2007).

<sup>14</sup> See *In re Products Liability*, *supra*, at 12 (July 2007).

<sup>15</sup> *Id.*

## PUBLIC NUISANCE

### Taming the “Public Nuisance” Monster: Rhode Island Supreme Court Holds Line to Reverse Landmark Verdict Against Lead Paint Manufacturers

*See State of Rhode Island v. Lead Indus. Ass’n, Inc.*, Nos. 2004-63-M.P., 2006-158-Appeal, 2007-121, 2008 WL 2605396 (R.I. July 1, 2008)

#### Mapping Progress: “Here Lie Monsters”

The evolving effort by the plaintiff’s bar to sidestep long-established tort law principles by repackaging garden-variety injury claims as public-nuisance actions has been dealt another serious blow in Rhode Island, following several other appellate decisions in Missouri and New Jersey state courts.

The February 2006 jury verdict in favor of the State of Rhode Island, holding lead paint pigment manufacturers<sup>1</sup> responsible for the adverse health effects associated with lead paint, was groundbreaking on several levels. *First*, it marked a significant departure from the lead paint industry’s two-decade-long record of successfully defending itself against liability. *Second*, it raised the specter of potentially bankrupting liability costs, with the abatement price tag for the more than 240,000 homes at issue in the litigation (mostly in and around Providence) estimated at in excess of \$1 billion. *Finally*, the verdict was predicated on a novel theory of liability — that Rhode Island’s lead paint problems and related health issues constituted a public nuisance for which lead paint manufacturers were responsible. This result raised significant implications not only for the paint industry itself (in terms of similar suits pending elsewhere), but for product manufacturers generally given the subjectivity and vagueness with which public-nuisance theories of liability are riddled. *See* “Public Nuisance Liability ‘Monster’ Threatens to ‘Devour’ Lead Paint Makers,” *In re Products Liability* 10-11 (July 2006).

As the trial judge who first dismissed the case in July 2003 observed, unless rightly restricted to its origins and elemental keystones, public-nuisance theories of liability threaten to “become a monster that would devour in one gulp the entire law of tort.” *Id.* at \*11.

These concerns subsided earlier this month, however, when, on July 1, 2008, the Rhode Island Supreme Court over-

turned the verdict, holding that the trial judge was wrong to deny a motion by Sherwin-Williams, NL Industries Inc. and Millennium Holdings LLC to dismiss the case — that the case never should have proceeded to trial at all. Specifically, the court reversed the judgment of the Superior Court because:

the state has not and cannot allege any set of facts to support its public nuisance claim that would establish that defendants interfered with a public right *or that defendants were in control of the lead pigment they, or their predecessors, manufactured at the time it caused harm to Rhode Island children.*

*Id.* at \*2 (emphasis added). At bottom, the case failed for plaintiff’s inability to establish defendants’ control over the alleged nuisance instrumentality at the time injury occurred.

#### The Law of Public Nuisance: What It Is and What It Isn’t

Conducting an exhaustive survey of the genesis and evolution of public-nuisance law to set the table for its analysis, the Rhode Island Supreme Court identified three principal elements essential to the establishment of public-nuisance liability: (1) an unreasonable interference; (2) with a right common to the general public; (3) by a person or people with *control* over the instrumentality alleged to have created the nuisance *when the damage occurred*. In addition, plaintiff must prove that defendant caused the public nuisance. *Id.* at \*13.

Holding that defendants’ motion to dismiss should have been granted, the court observed that the State had failed to allege facts supporting each of these elements — and, indeed, could not do so as a matter of law. Specifically, the complaint alleged simply that “[d]efendants created an environmental hazard that continues and will continue to unreasonably interfere with the health, safety, peace, comfort or convenience of the residents of the [s]tate, thereby constituting a public nuisance.” *Id.* at \*20. The State, however, failed to allege that defendants interfered with a “public right” as that term long

<sup>1</sup> The first trial of this matter ended in a mistrial in 2002 and was followed by a four-month jury trial. *Id.* at \*7-9. The jury found defendant manufacturers, NL Industries, Inc. (formerly National Lead Co.), The Sherwin-Williams Co., and Millennium Holdings LLC (Millennium) (collectively defendants), liable under a public-nuisance theory. *Id.* at \*9. Other companies targeted in the suit eventually settled or were dismissed from the litigation.

has been construed as a matter of public-nuisance law. Equally fatal to the State's claim was its failure to allege that defendants exercised control over the lead pigment at the time it caused harm to children. *Id.*

### For Public Nuisance Purposes, the Scope of Actionable “Public Rights” Is Narrowly Circumscribed

With regard to the “interference with a public right” prong of the public-nuisance liability standard, the court said the rights at issue must be “those indivisible resources shared by the public at large, such as air, water, or public rights of way” and, further, that “[t]he interference must deprive *all* members of the community of a right to some resource to which they otherwise are entitled.” *Id.* (emphasis added). Continuing its analysis, it found that the public's alleged right to be free from the harm of unabated lead paint fell “far short of alleging an interference with a public right as that term traditionally has been understood in the law of public nuisance.” *Id.* at \*21. That's because “[t]he term public right is reserved more appropriately for those indivisible resources shared by the public at large.” *Id.* Reasoning further, the court rightly worried that rejiggering the definition of “public right” to include conditions present in a finite number of private residences “would be antithetical to the common law and would lead to a widespread expansion of public nuisance law that never was intended.” *Id.* Doing so would be:

wholly inconsistent with the widely recognized principle that the evolution of the common law should occur gradually, predictably, and incrementally. Were we to hold otherwise, we would change the meaning of public right to encompass all behavior that causes a widespread interference with the private rights of numerous individuals.

*Id.* In short, notwithstanding its oft-stated sympathy for the victims of lead paint exposure (more often than not children), the court explained that it had no choice as a court of law but to draw the lines necessary to tame and keep the public-nuisance liability monster at bay.

### “Control” Over the Nuisance at Time of Injury Is Also Critical

The Rhode Island Supreme Court also held that the State's

complaint failed — fatally — to allege any facts to support a conclusion that defendants were in control of the lead pigment at the time it harmed Rhode Island's children. *Id.* at \*22. Put differently, “[f]or the alleged public nuisance to be actionable, the state would have had to assert that *defendants not only manufactured the lead pigment but also controlled that pigment* at the time it caused injury to children in Rhode Island — and there is no allegation of such control.” *Id.* (emphasis added). In further support of this holding, the court noted that the Rhode Island General Assembly had already passed abatement legislation “recogniz[ing] defendants' lack of control and inability to abate the alleged nuisance [by] plac[ing] the burden on landlords and property owners to make their properties lead-safe.” *Id.* at \*2. More particularly, the Rhode Island legislature:

recognized that *landlords, who are in control of the lead pigment at the time it becomes hazardous, are responsible for maintaining their premises and ensuring that the premises are lead-safe.* Quite tellingly, the General Assembly's chosen means of remedying childhood lead poisoning in Rhode Island did not include an authorization of an action for public nuisance against the manufacturers of lead pigments.

*Id.* at \*25 (emphasis added).

### A Word to Bench and Bar on the Limits of Public-Nuisance Law

Concerned with the State's effort to dress a products-liability claim in the garb of public-nuisance theory — to avoid the more rigorous burden of proving either defect or fault and the causal connection to injury that are required in traditional products liability actions — the court offered the following guidance on the need to keep public nuisance and products liability claims separate and distinct from one another:

The proper means of commencing a lawsuit against a manufacturer of lead pigments for the sale of an unsafe product is a products liability action. The law of public nuisance never before has been applied to products, however harmful. Courts in other states consistently have rejected product-based public nuisance suits against lead pigment manufacturers, expressing a concern that allowing such a lawsuit would circumvent

/ continued page 12

## PUBLIC NUISANCE

*continued from page 11*

the basic requirements of products liability law . . . Public nuisance focuses on the abatement of annoying or bothersome activities. Products liability law, on the other hand, has its own well-defined structure, which is designed specifically to hold manufacturers liable for harmful products that the manufacturers have caused to enter the stream of commerce. Undoubtedly, public nuisance and products liability are two distinct causes of action, each with rational boundaries that are not intended to overlap.

*Id.* at \*23-\*24 (emphasis added).

In making these observations, the court was careful not to minimize the severity of the harm that thousands of children in Rhode Island had suffered as a result of lead poisoning, noting that its hands were tied — as the law does not necessarily provide redress for all injuries. “Our hearts go out to those children whose lives forever have been changed by the poisonous presence of lead. But, however grave the problem of lead poisoning is in Rhode Island, public-nuisance law simply does not provide a remedy for this harm.” *Id.* at \*2.

### Conclusion: Alternative Remedies Available

The Rhode Island Supreme Court further justified its ruling on the grounds that reversal of the jury’s verdict did not leave Rhode Islanders wholly without remedy at law or equity. Specifically, the court explained that: (a) an injunction requiring abatement could be sought against landlords who allow lead paint on their property to decay; (b) Rhode Island’s Lead Poisoning Prevention Act provides for penalties and fines against those property owners who violate its rules or procedures; and (c) Rhode Island’s Lead Hazard Mitigation Act further authorizes a private cause of action to be brought on behalf of households with at-risk occupants to seek injunctive relief to compel property owners to comply with the act. *Id.* at \*25.

In the end, the Rhode Island Supreme Court’s dismissal of the state’s public-nuisance action — its adherence to the rule of law — could well have a chilling effect on not only the surge in lead paint litigation that was expected to follow the Rhode Island verdict, but as well the many other dubious and problematical uses to which the plaintiff’s bar of late has been seeking to put public-nuisance law. ©

## MEDICAL MONITORING

### New Jersey Supreme Court Disallows Products Liability-Based Medical Monitoring Claims Without Present Injury

See *Sinclair v. Merck & Co., Inc.*, 2008 WL 2340280 (N.J. June 4, 2008)

The New Jersey Supreme Court’s recent decision in *Sinclair* illustrates how courts are increasingly unwilling to allow medical monitoring claims to proceed when plaintiffs are unable to demonstrate true physical injury. We’ve previously reported extensively on developments in this area of the law, including the decision by the intermediate appellate court in *Sinclair* to allow plaintiffs’ medical monitoring claims to proceed notwithstanding the lack of manifest physical injury.<sup>1</sup>

### Background

In *Sinclair*, plaintiffs filed a putative products-liability class action against Merck and a number of others on behalf of Vioxx users, alleging theories of negligence, breach of warranty, unjust enrichment and violations of the New Jersey Products Liability Act (PLA or Act) and the New Jersey Consumer Fraud Act (CFA). *Id.* at \*1.

Specifically, plaintiffs alleged that “as a result of their direct and prolonged consumption of Vioxx, they [were] at enhanced risk of serious undiagnosed and unrecognized myocardial infarction . . . and other latent and unrecognized injuries.” *Id.* at \*2. In addition to seeking punitive damages, plaintiffs sought “medical monitoring relief paid for by defendants” — specifically, “a court-administered screening program to provide medical diagnostic tests for each member of the proposed class and follow-up with

<sup>1</sup> See “Claimed Beryllium Exposure Alone — Without Actual Physical or Mental Injury — Cannot Support Medical Monitoring Suit Under Mississippi Law,” *In re Products Liability* 7 (Apr. 2007). See also “Eleventh Circuit Holds That Beryllium Sensitization May Be Cognizable Injury,” *In re Products Liability* 3-4 (July 2007); “Illinois Appeals Court Disallows Medical Monitoring Claim Based on Absence of Present Physical Injury,” *In re Products Liability* 5 (July 2007); “Louisiana Appeals Court Cuts Class Action Award, But Otherwise Affirms ‘Damages’ To Fund Court-Supervised Smoking Cessation Program,” *In re Products Liability* 5 (Apr. 2007); “Oregon Appellate Court Rejects Medical Monitoring Claim,” *In re Products Liability* 6 (Nov. 2006).

an epidemiologist.” *Id.* Significantly, none of the plaintiffs alleged “any known adverse effect as a result of taking Vioxx.” *Id.*

The trial court granted Merck’s motion to dismiss for failure to state a claim, reasoning that the New Jersey Supreme Court had not yet applied “a medical monitoring remedy to a pure products liability action where the PLA applies” and that “the CFA only allows for recovery of economic damages.” *Id.* The Appellate Division — based on its belief that the state’s “limited medical monitoring jurisprudence” did not necessarily compel dismissal — reversed and remanded for discovery, holding that plaintiffs should be “accorded an opportunity to demonstrate ‘harm’ cognizable under the [PLA]” before those claims could be dismissed. *Id.* at \*2.

### Prior New Jersey (Toxic Tort) Decisions Allowing Medical Monitoring

The question before the New Jersey Supreme Court on appeal was whether “plaintiffs may recover the costs of medical monitoring despite their failure to allege a physical injury,” *id.* at \*1, prompting a review of its “limited authority for medical monitoring,” consisting of several toxic tort decisions in which it had allowed the recovery of medical-monitoring costs in the absence of a physical injury in certain circumstances — albeit none in the context of a products-liability claim, which proved to be the decisive factor in the end. *Id.* at \*3.

In *Ayers v. Township of Jackson*, 525 A.2d 287 (N.J. 1987), for example, New Jersey residents sued their town under the Tort Claims Act for water contamination allegedly caused by the operations of a municipal landfill. Reinstating an award of annual “medical surveillance” costs that was struck down by the Appellate Division, the New Jersey Supreme Court reasoned that:

[T]he 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 reasonable and necessary.

*Ayers*, 525 A.2d at 312. It cautioned, however, that going forward

funds should be established to disburse such benefits, as opposed to the payment of “lump-sum” medical surveillance damages.

Just two years later, in *Mauro v. Raymark Indus. Inc.*, 561 A.2d 257 (N.J. 1989), the court decided a case involving a repairman suing asbestos manufacturers for “injuries allegedly sustained as a result of inhalation of asbestos fibers.” *Id.* at \*4. Although advised that the results of “his physical examination and lung function test were normal,” plaintiff also was told that he had “bilateral thickening of both chest walls and calcification of the diaphragm” and that his exposure to asbestos increased his risk of developing lung cancer. *Id.* In addition to claims for emotional distress and an increased risk of cancer, therefore, plaintiff sought to recover the “cost of future medical surveillance.” *Id.* While overturning the jury award for enhanced risk of cancer, the New Jersey high court held that “[r]ecognition of present claims for medical surveillance and emotional distress realistically address[] significant aspects of the present injuries sustained by toxic-tort plaintiffs, and serve[] as an added deterrent to polluters and others responsible for the wrongful use of toxic chemicals.” *Id.*

Lastly, in *Theer v. Philip Carey Co.*, 628 A.2d 724 (N.J. 1993), plaintiff had sued asbestos manufacturers for the death of her husband and for her *indirect* exposure to asbestos through her husband’s clothes. Reviewing and distinguishing *Ayers* and *Mauro*, and characterizing medical monitoring as a “special remedy,” the court held that plaintiff was not entitled to damages for medical surveillance because the remedy applies only to those “*directly* exposed to hazardous substances.” *Id.* at \*5 (emphasis in original).

### Manifest Physical Injury Necessary Under PLA

Next, the court reviewed the provisions of the PLA to determine whether it restricted plaintiffs’ attempt to recover medical-monitoring damages. With the statute defining “harm” (in pertinent part) as “personal physical illness, injury or death,” Merck argued that plaintiffs’ claims failed because “physical” modified both “illness” and “injury,” whereas plaintiffs urged that the Act did not limit compensable injury to physical harm. *Id.* Siding with Merck, the court read the statute “to require physical injury” — noting that prior to its enactment, New Jersey had adopted the Restatement (Second) of Torts § 402A, which required physical harm for strict liability in tort for defective products. *Id.* Further, the court could find nothing in the Product

/ continued page 14

## MEDICAL MONITORING

continued from page 13

Liability Act's legislative history to suggest that "the Legislature intended to eliminate that physical component." *Id.*

Because plaintiffs were admittedly without a manifest physical injury (as required by the PLA's definition of "harm"), the court ruled that their claim for medical-monitoring damages — sounding in products liability — failed. *Id.* at \*7.

### No Claim Under the CFA Either — Product Liability Act Provides Sole Remedy

In an effort to avoid the strict requirements of the PLA, plaintiffs also recast their claims in an effort to bring them under the umbrella of the Consumer Fraud Act. Rejecting this tactic, the court held that "the Legislature expressly provided in the PLA that claims for 'harm caused by a product' are governed by the PLA 'irrespective of the theory underlying the claim.'" *Id.* at \*7 (citing N.J.S.A. 2A:58C-1b(3)). Since plaintiffs' case "obviously" involved a product liability claim, it fell squarely and unavoidably within the scope of the PLA, which is the exclusive source of relief and remedy for all "harm caused by a product" under New Jersey law. *Id.*

In reversing the Appellate Division and remanding for reinstatement of the trial court's judgment of dismissal, the court explained:

The language of the PLA represents a clear legislative intent that, despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product. *The heart of plaintiffs' case is the potential for harm caused by Merck's drug. It is obviously a product liability claim.* Plaintiffs' CFA claim does not fall within an exception to the PLA, but rather clearly falls within its scope. Consequently, plaintiffs may not maintain a CFA claim.

*Id.* at \*7 (emphasis added).

### The Dissent — Harm Threshold Was "Vaulted"

Justice Long filed a dissent taking issue with what he considered the majority's restrictive reading of "harm" under the Product Liability Act to require a "manifest injury." *Id.* at \*8. As he put it, "if the majority is correct in declaring that plaintiffs are excluded from recovery because they have not suffered 'harm'

under the PLA, they fall outside the PLA, which defines a 'product liability action' as 'any claim or action brought by a claimant for harm caused by a product.'" *Id.* at \*9. As such, they are entitled to proceed under the "common law theories that were also pleaded in the complaint." *Id.*

Beyond this, Justice Long faulted the majority for "concluding that plaintiffs failed to vault the harm threshold in the PLA." *Id.* He did so based on his belief that with the PLA, the legislature had enacted "an all-encompassing definition of harm that mirrored common law principles," and, further, that nothing in the Act "directly or inferentially signals a retreat from the common law notion that increased risk of injury that creates a need for medical surveillance is a cognizable harm." *Id.* at \*11. For these reasons, he would have reinstated plaintiffs' complaint for medical surveillance damages. ☺

## FOREIGN LAW

### The "Rome II" Regulation on Cross-Border Torts: Conflict of Laws Resolved?

*See Regulation (EC) No 864/2007 of the European Parliament and of the Council — Rome II — (July 11, 2007)*

Similar to the U.S., an EU Member State presently uses its own conflict-of-law rules<sup>1</sup> to determine the applicable law in respect of cross-border torts.<sup>2</sup> Some countries follow the *lex loci delicti* (place of the wrong) rule,<sup>3</sup> while others follow different tests — for instance, the place with the "most significant relationship" to the tort. Briefly, there is no coherent set of rules applied throughout the European Union, which can create uncertainty for multinational corporations. Furthermore, the

<sup>1</sup> Conflict-of-law rules, also known as "private international law" in civil law jurisdictions, regulate the applicable law in situations where the (inconsistent) laws of more than one nation-state are arguably applicable to a lawsuit or interpretation of a document.

<sup>2</sup> For contract-related disputes, the relevant regulation in the EU is the "Convention on the Law Applicable to Contractual Obligations" ("Rome Convention"), which came into force on April 1, 1991.

<sup>3</sup> In England, the rules set out in Part III of the Private International Law (Miscellaneous Provisions) Act 1995 apply for tort-related conflict-of-law issues. The general rule is that the applicable law is that of the country in which the events constituting the tort in question occurred (*lex loci delicti*).

incongruence creates disparate results and the uncertainty it generates can increase insurance costs.

In an effort to address these problems, EU Member States have been debating the text of a regulation on conflict of laws for some time. In July 2007, after years of discussion,<sup>4</sup> the final text of the Rome II Regulation — a measure to harmonize conflict-of-law rules throughout Europe — was agreed by the European Parliament and the Council.<sup>5</sup> It comes into force on January 11, 2009. *See Official Journal Of The European Union*, L199/40-49 (July 31, 2007).

Rome II will apply to non-contractual obligations raising conflict-of-law issues, save those involving a state’s public liability, family matters, estate, negotiable instruments, trust, corporate issues, nuclear damage and privacy disputes.<sup>6</sup>

### The General Rule — *Lex Loci Damni*

Under Article 4, the general choice-of-law rule in the setting of all non-contractual obligations is *lex loci damni* — the law of the place where the damages occurred:

[t]he law applicable to a non-contractual obligation arising out of a tort/delict shall be the law of the country in which the damage occurs irrespective of the country in which the event giving rise to the damage occurred and irrespective of the country or countries in which the indirect consequences of that event occur.

*Id.* at 44.

There are two exceptions. The *first* provides that when both parties have their “habitual residence in the same country at the time when the damage occurs, the law of that country shall apply.”<sup>7</sup> The *second* is the so called “escape clause” of Article 4(3), which provides:

[w]here it is clear from all the circumstances of the case that the tort/delict is manifestly more closely connected with a country other than that indicated in paragraphs 1 [place of injury] or 2 [habitual residence], the law of that other country shall apply.<sup>8</sup> A manifestly closer connection with another country might be based on a pre-existing relationship between the parties, such as a contract, that is closely connected with the tort in question.

*Id.*

The objective is a flexible framework of conflict-of-law rules that enables courts to treat individual cases in an appropriate

manner. Articles 5 to 9 of the regulation set up particular rules for specific areas of tort law, including product liability.<sup>9</sup>

### Product Liability

Rome II proposes that the conflict-of-law rule in matters of product liability (Article 5) should meet the objectives of: (i) fairly spreading the risks inherent in a modern high-technology society; (ii) protecting consumer health; (iii) stimulating innovation; (iv) securing undistorted competition; and (v) facilitating trade. (*See* Recital 20.)

To achieve these objectives, Rome II establishes what it calls a “cascade system of connecting factors, together with a foreseeability clause.” Under this system,

[t]he first element to be taken into account is the law of the country in which the person sustaining the damage had his or her habitual residence when the damage occurred, if the product was marketed in that country.

*/ continued page 16*

- <sup>4</sup> On July 22, 2003, the European Commission proposed a regulation on the “Law Applicable to Non-Contractual Obligations” [COM (2003) 0427 final]. In February 2006, the European Commission’s proposal was modified to incorporate certain amendments passed by the European Parliament [COM(2006) 83 final].
- <sup>5</sup> *See* EC Regulation 864/2007 of the European Parliament and of the Council on the ‘Law Applicable to Non-Contractual Obligations’ (“Rome II”).
- <sup>6</sup> Specifically, Rome II does not apply to revenue, customs or administrative matters or to the liability of the State for acts and omissions in the exercise of State authority “*acta iure imperii*,” nor does it apply to obligations arising out of family relationships, matrimonial property, property regimes of relationships deemed by the law applicable to such relationships to have comparable effects to marriage, wills and succession, bills of exchange, cheques and promissory notes and other negotiable instruments; law of company; settlors, trustees and beneficiaries of a trust created voluntarily; nuclear damage; violations of privacy and rights relating to personality, including defamation. (*See* Article 1.)
- <sup>7</sup> *See* Article 4(2). For the purpose of this regulation, the habitual residence of companies is the place of their central administration.
- <sup>8</sup> Article 14 gives parties freedom to agree or stipulate to “the law of their choice” either “after the event giving rise to the damage occurred” (subsection 1(a)) or, in commercial settings, “by an agreement freely negotiated before the event giving rise to the damage occurred” (subsection 1(b)) — in both instances subject to the proviso that the choice does not “prejudice the rights of third parties.”
- <sup>9</sup> *See, e.g.,* Article 6 (unfair competition), Article 7 (environmental damage), Article 8 (infringement of intellectual rights) and Article 9 (industrial action).

## FOREIGN LAW

*continued from page 15*

See *Official Journal of the European Union, supra*, at 44 (Article 5(1)(a)) (emphasis added). Failing that, the applicable law shall be “the law of the country in which the product was acquired, if the product was marketed in that country” (Article 5(1)(b)), or — failing that — “the law of the country in which the damage occurred, if the product was marketed in that country” (Article 5(1)(c)).

These conflict-of-law rules are subject to a foreseeability clause (favoring defendants), which provides that the applicable law “shall be the law of the country in which the person claimed to be liable is habitually resident if he or she could not reasonably foresee the marketing of the product . . . in the country” whose law would otherwise apply under the terms of Article 5(1). These rules, however, can be overridden in the case of torts “manifestly more closely connected” with a particular country. (See Article 5(2).)

Parenthetically, it should be noted that the 1985 EU Directive on liability for defective products<sup>10</sup> — which harmonizes the applicable law on claims for defective products across the EU — generally does not allow Member States to derogate from the Directive’s terms.<sup>11</sup> As a consequence, conflict-of-law issues become somewhat less relevant in cases falling under the scope of the Directive, as the substantive law on defective products has already been unified throughout Europe.

### Punitive Damages

Large punitive damages or exemplary damages awards are rarely seen in Europe. Rome II recognizes that this is a delicate area, however, in which harmonization might not be the best approach, and therefore creates a public-policy exception. More directly, Recital 32 recognizes that while Member State courts

<sup>10</sup> EU Directive 1985/374 on the Approximation of the Laws, Regulations and Administrative Provision of the Member States Concerning Liability for Defective Products.

<sup>11</sup> Member States, for instance, are not authorized to maintain more stringent provisions in order to secure a higher level of consumer protection. See European Court Judgment of April 25, 2002 in Case C-183/00, *María Victoria González Sánchez and Medicina Asturiana S.A.*, which states that Article 13 of the Directive must be interpreted as meaning that the rights conferred under the legislation of a Member State on the victims of damage caused by a defective product may be limited or restricted as a result of the Directive’s transposition into the domestic law of that State.

may, “in exceptional circumstances,” award “non-compensatory exemplary or punitive damages,” awards of an “excessive nature” falling from the application of any Rome II choice-of-law provision “may, depending on the circumstances of the case and the legal order of the Member State of the court seized, be regarded as . . . contrary to the public policy (*ordre public*) of the forum.” This issue is covered in Article 26 — under the heading “public policy of the forum” — which allows courts to refuse application of laws specified by Rome II’s conflict-of-law “cascade system” when “such application is manifestly incompatible with the public policy (*ordre public*) of the forum.”

### Looking Forward

The legislative journey of Rome II has not always featured clear sailing and it remains to be seen how European courts will interpret this regulation. In regard to product liability, however, this measure seems to strike the requisite equilibrium. ©

## A European Regulatory Success Story? The European Commission’s Annual RAPEX Report

See *Keeping European Consumers Safe: 2007 Annual Report on the Operation of the Rapid Alert System for Non-Food Consumer Products* (Luxembourg: Office of Official Publications of the European Communities, 2008)

In 2004, the EU established RAPEX — “the internal market’s safety net,” a rapid alert system intended to facilitate better intra-EU surveillance of and response to dangerous consumer products, excluding food and pharmaceutical products.<sup>1</sup> Its legal framework was established by the EU’s Directive on General Product Safety in 2001, and RAPEX requires the exchange of information about dangerous products “only if there is evidence or reasonable suspicion that these products can be found on the markets of at least two countries participating in the system.”<sup>2</sup>

### RAPEX and the “Summer of Recalls”

Following the now infamous “summer of recalls” in 2007, in which a tremendous number of Chinese imports (primarily toys, but also such things as diethylene glycol-tainted toothpaste) were found to be unsafe, the European Commission’s most

recent Annual RAPEX Report reported a 53% rise in the number of dangerous products removed from the European market in 2007 over 2006, and that since RAPEX went in effect in 2004, the number of dangerous products in the European market had more than tripled — climbing from 468 in 2004 to 1,605 in 2007.<sup>3</sup> By contrast, in 2006 “the total number of notifications rose by 24% compared to 2005.”<sup>4</sup> The European Commission characterizes this increase as a positive trend.

### Commission Says Increase in Dangerous Goods Means RAPEX is Working

The 2007 Annual RAPEX Report ascribes these higher numbers to “an increased effectiveness of product safety enforcement by national authorities, increased awareness by businesses as regards their responsibilities, the EU enlargement in 2004 and 2007, as well as to general network-building actions coordinated by the Commission.”<sup>5</sup> The higher number of apparently dangerous goods floating in the European stream of commerce is not attributed to the possibility that the quality of products on European shelves has simply fallen. While an overall decrease in quality is unlikely to be the main cause of the increase in dangerous goods being detected, it’s a possibility arguably warranting closer scrutiny and pointing to “room for improvement,” which the European Commission acknowledges:

The European Commission carried out a thorough review of the EU global product safety system in the latter half of 2007, following the high-profile, worldwide alerts involving key consumer products. This review focused on existing legislation, enforcement capacity in the Member States, the obligations of economic operators and cooperation with third global partners. It confirmed that the EU product safety system is solid and guarantees a high level of consumer protection, while allowing the smooth overall functioning of global trade. *There is, however, room for improvement, and a package of initiatives to reinforce our product safety net was identified.*<sup>6</sup>

### “Hands Across the Water” — Sino-EU Cooperation

On the positive side, there has been a notable increase in cooperation between Chinese and European authorities since the recall of numerous Chinese products last year. In 2004, a “RAPEX China” system was established for the rapid transmission of data between EU and Chinese authorities. This system

actually requires input from Chinese authorities on a quarterly basis, and the European Commission considers its operation positive — noting that the incidence of Chinese authorities investigating reports of dangerous goods and taking corrective actions is markedly up. Redoubling this effort, the Commission is now helping “the Chinese authorities in setting up a domestic alert system, similar to the European RAPEX, to better track sub-standard and dangerous products, especially toys.”<sup>7</sup> At the same time, the Commission is deepening and expanding “cooperation with [the EU’s] major trading partners — the United States and China.”<sup>8</sup>

Looking at Chinese goods specifically, however, where according to the RAPEX system more than half of all reported dangerous goods originated, the European Commission dismisses the possibility that the quality of Chinese goods has been falling in recent years by explaining that the apparent increase “does not necessarily mean that there were a greater number of dangerous goods on the European market in 2007. [Instead,] certain products which had been notified in previous years as being of unknown origin were notified in 2007 as being of Chinese origin.”<sup>9</sup> As European Consumer Commissioner Meglena Kuneva explains in a Foreword to the report: “the exchange of RAPEX information with China has revealed tremendous capacity and potential for improving product safety upstream in the supply chain and in fostering a culture of safety and market surveillance outside Europe. Thus becoming a valuable, ‘must know’ reference for international cooperation tools on product safety.”<sup>10</sup>

### Conclusion

If the European Commission’s report is correct, then the EU’s

*/ continued page 18*

<sup>1</sup> *Id.* at 9. Food, feed, medical devices and pharmaceuticals are excluded because they are otherwise covered by specific pan-European alert systems. Information about dangerous food and feed, for instance, is exchanged through the Rapid Alert System for Food and Feed (RASFF). *Id.* at 10.

<sup>2</sup> *Id.* at 11.

<sup>3</sup> *Id.* at 15-16.

<sup>4</sup> *Id.* at 16.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* at 7 (emphasis added).

<sup>7</sup> *Id.* at 32.

<sup>8</sup> *Id.*

<sup>9</sup> See <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/252&format=HTML&aged=0&language=EN&guiLanguage=en>.

<sup>10</sup> 2007 Annual RAPEX Report, *supra*, at 3.

## FOREIGN LAW

*continued from page 17*

regulatory and policy approach to product safety appears to be working as intended — and may well be achieving what Commissioner Kuneva has stated as its goal: “The point of RAPEX and our other safety mechanisms are to ensure that EU citizens can shop in peace, without having to worry about distinguishing safe products from dangerous ones.”<sup>11</sup> On the other hand, the European Commission may have just as much at stake in terms of promoting greater consumer confidence in the Commission itself, which it is developing “roadmaps to restore.”<sup>12</sup> ©

<sup>11</sup> See n.9.

<sup>12</sup> 2007 Annual RAPEX Report, *supra*, at 31-32.

## PREEMPTION

### Pharmaceutical Preemption Rumble Continues — Next Stop, U.S. Supreme Court

See *McDarby v. Merck & Co., Inc.*, 2008 WL 2199871 (N.J. Sup. Ct., App. Div., May 29, 2008)

#### Commentary

U.S. Supreme Court review next Term of *Wyeth v. Levine* (see 128 S. Ct. 1118 — granting *certiorari*) and, with it, definitive word whether prescription-drug failure-to-warn claims are preempted by the federal Food, Drug and Cosmetic Act cannot arrive soon enough. While last Term’s decision in *Riegel* finally ended skirmishing over the preemption question in regard to the Medical Device Act, preemption issues continue to bedevil pharmaceutical-labeling litigation — splitting circuits, states and Congress, and burdening manufacturers, insurers, investors, litigants and sundry other interests with uncertainty.

There is much at stake, with markets (for treatments and cures) hanging in the balance, and the issue playing out in various venues, not just the courts. Congressman Waxman and Senator Leahy have convened hearings on pharmaceutical preemption — the latter in the wake of lower court decisions in *Levine v. Wyeth*, out of the Vermont state court system.<sup>1</sup> At the

same time, state regulators (sometimes through state AGs) are getting into the act, bringing pharmaceutical firms to litigation or the bargaining table over their business practices, as *über*-regulators — wresting multi-million dollar settlements and voluntary injunctions from firms on a nationwide basis. Merck’s recent settlement of Vioxx-related marketing claims run in the form of coordinated, multi-state AG litigation — covered elsewhere in this issue — is a recent example. The template was tobacco litigation and the Master Settlement Agreement of 1998, the litigation “peace” that cost the tobacco industry an estimated US\$280 billion spread over the first 25 years — basically an annuity in perpetuity.

In so many ways, warning litigation in the prescription-drug context is a tailor-made venue for preemption fights — bringing all these issues together in a way most health-effects litigation does not. At the head of it all is a strong, expert federal agency — the FDA — charged by Congress with regulating food, drug and cosmetic safety through the development and enforcement of *national* standards. Jockeying for position at the same time are state regulatory authorities, including AGs, and the plaintiff’s tort bar. In the middle, are commercial interests of various stripes, but chiefly prescription-drug manufacturers.

Although the U.S. Supreme Court decided *Riegel* 8-1, it was about the Medical Device Act’s provision of express preemption. And *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), a draw (with Justice Alito’s recusal), was about “fraud on the FDA” in the context of a Michigan immunity statute and New York conflict-of-law rules. Neither is dispositive of the issues at stake in *Wyeth*. On balance, however, federal preemption of pharmaceutical failure-to-warn claims is probably — under most circumstances — a necessary and good thing, but the issue is not as straightforward in *Wyeth* as it was in *Riegel*, given the nature of their respective preemption provisions.

One of the key issues in current pharmaceutical-warning litigation is the Preamble issued by the FDA in January 2006, abandoning a decades-old statutory interpretation against preemption to announce that FDA authority in fact preempted competing state-warning requirements — by regulators or juries. Also in play is the meaning of FDA regulations regarding “changes being effected” or CBE Supplements applicable to newly discov-

<sup>1</sup> See “Senator Leahy Pushes Back Against Bush Administration’s Preemption Policies in Judiciary Committee Hearings,” *In re Product Liability* 6-8 (Nov. 2007).

ered adverse health-effects information. Wading into the statute, its purpose, its legislative history and its attendant regulations, some courts have found implied or conflict preemption, while others have returned from this journey to write of finding just the opposite — that FDA authority instead constitutes but a floor or minimum standard that state authorities (courts included) are free to second-guess, or to raise additional regulatory superstructure upon, in the interest of *greater* public safety.

CBE Supplements, however, are not the license for pharmaceutical undertakings (much less juries and judges) to re-label prescription drugs that a large number of courts have declared them to be. To the contrary, FDA regulations and guidelines seem to say, quite clearly, that this amendatory vehicle should only be used to advise the FDA of *new* categories or magnitudes of adverse health effects (*viz.* “newly discovered”) for which the FDA is not already on notice as part of the drug approval

that CBE Supplements enabled drugmakers to comply with both federal and state prescription-drug safety requirements, thereby defeating the argument in favor of conflict preemption.

*McDarby* (and *Cona*, with which it was decided) were individual actions brought by Vioxx users against Merck on claims sounding in fraud and products liability, under New Jersey’s Product Liability Act (PLA) and Consumer Fraud Act (CFA). The gravamen of each was inadequate warning by Merck of Vioxx’s cardiovascular risks.

***A Statutory Rebuttable Presumption of Warning Adequacy and the Proverbial Writing on the Wall in Regard to Preemption***

Significantly, New Jersey’s PLA sets up a rebuttable presumption making all FDA-approved prescription-drug warnings *prima facie* “adequate” as a matter of law. *Id.* at \*25 (quoting N.J.S.A. 2A:58C-4). As the New Jersey Supreme Court held in *Perez v. Wyeth*

**At the same time, state regulators (sometimes through state AGs) are getting into the act, bringing pharmaceutical firms to litigation or the bargaining table over their business practices, as über-regulators — wresting multi-million dollar settlements and voluntary injunctions from firms on a nationwide basis.**

process, and not simply other instances of effects already considered by FDA regulators in approving specific types or classes of prescription drugs.

As a backdrop to this debate, by all accounts the FDA is understaffed, underfunded, and overworked — spread too thin, lending the case against labeling preemption (led by “reinforcements” FDA says it doesn’t want or need) a degree of superficial appeal. However, the confusing mosaic of contradictory requirements and standards that would surely follow a finding that state law was not preempted in this setting cannot be underestimated. It would be impossible for commercial interests to navigate these waters without considerable economic and social costs (micro/macro; internal/external) and uncertainty.

Next stop, the U.S. Supreme Court. [DLW]

**Analysis**

A brief discussion follows of *McDarby*, a typical state-court appellate decision from New Jersey of recent vintage — finding

*Labs. Inc.*, 734 A.2d 1245 (1999), assuming “that the duty to consumers is met by compliance with FDA regulations helps to ensure that manufacturers are not made guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs, a result that could have a ‘significant anti-utilitarian effect.’” *Id.* at \*25. For this reason, evidence of “deliberate concealment or nondisclosure” has been traditionally required to overcome the presumption of warning adequacy. *Id.* at \*25-26.

Seeking to overcome this presumption, plaintiffs marshaled “evidence of Merck’s strenuous, economically driven, opposition to the inclusion of cardiovascular risks in the ‘Warnings’ section of the Vioxx label, despite the universal opinions of the FDA’s advisory committee.” *Id.* at \*29. Explaining that its reviewing focus rested “solely upon plaintiffs’ claims of Merck’s economically-driven *manipulation of the post-market regulatory process* (and specifically declining to ground its decision “upon any claim of fraud on the FDA,)” *id.* at \*26 (emphasis added), the court turned to a piece of law review advocacy by former FDA

/ continued page 20

## PREEMPTION

*continued from page 19*

Commissioner David Kessler. *Id.* (quoting Kessler & Vladeck, “A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims,” 96 *Geo. L.J.* 461 (Jan. 2008)). In particular, the court focused on his contention that FDA “determinations about labeling ought not be subject to re-examination by courts or juries in failure-to-warn cases” *until the day after a new drug is approved*. Put differently, in his view, absent fraud on that agency, FDA preemptive authority should exist for all claims predicated on facts up to “the day of new drug approval.” *Id.*

Citing what Kessler & Vladeck catalogued as “flaws in the FDA’s control over *post-market labeling* in the years that Vioxx was on the market,” the *McDarby* court then concluded:

[W]e are unwilling to accept Merck’s position [based on N.J. Supreme Court precedent] that the presumption of adequacy of a prescription drug’s label can be overcome only upon proof of deliberate concealment or nondisclosure . . . [,] such a restriction is too narrow.

*Id.* at \*28 (emphasis added). Finding sufficient evidence to rebut the presumption of warning adequacy, and without ever mentioning the Noerr-Pennington doctrine or the right to petition government, it held:

In this regard, we particularly note evidence of Merck’s strenuous, economically driven, opposition to the inclusion of cardiovascular risk in the “Warnings” section of the Vioxx label, despite the universal opinions of the FDA’s advisory committee and medical reviewers — and indeed, initially, the FDA regulators themselves — that a warning was appropriate.

*Id.* at \*29. In other words, Merck lost the advantage of a rebuttable presumption of warning adequacy at law because it (a) was motivated by economics, and (b) disagreed with government regulators.

### *The Killing of Preemption*

In dispensing with Merck’s preemption argument, the court —

- (1) Dismissed FDA’s 2006 Preamble as lacking “preemptive force” and irrelevant because it “does not constitute a regulation, duly adopted after notice and comment, but is merely an expression of opinion, reflective of current Administration views, on the part of the FDA.” *Id.* at \*24;

- (2) Reasoned that plaintiff’s challenge of the adequacy of Vioxx’s warning label was “consistent with, and indeed relies upon, FDCA regulations that, at the time, required labeling to be revised “to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.” *Id.* at \*20 (quoting 21 C.F.R. § 201.57(e) and § 314.70(c)(2)(i) — regarding CBE Supplements). As such, Merck’s duty of care was not “simply” a “state-law construct[,]” but one that “mirrored” and was “premised upon a federal obligation.” *Id.* Neither, therefore, did it involve the classic “Hobson’s choice of either complying with federal regulations and continuing to be subject to damages in state tort actions or providing additional warnings and thereby violating federal law.” *Id.* at \*21; and

- (3) More specifically, there was no conflict preemption because plaintiff’s proposed “labeling changes” were entirely “consonant” with federal requirements concerning “changes being effected” or CBE Supplements, under 21 C.F.R. § 314.70(c), which prescription-drugmakers can — under limited circumstances — implement labeling supplements on notice to, but without pre-approval by, the FDA. The court never mentions these limiting circumstances, however (discussed above), presumably because Messrs. Kessler and Vladeck do not elaborate on them in the law review article upon which *McDarby* placed so much stress.<sup>2</sup> According to *McDarby*, therefore, “[p]rior FDA approval is not required” whenever “the manufacturer seeks to ‘add or strengthen a contraindication, warning, precaution, or adverse reaction’ to the labeling.” *Id.* at \*23.

This portion of the FDA regulations — relating to CBE Supplements — is likely to be a good part of the tipping point in terms of whether state-law “failure to warn” claims are preempted in the pharmaceutical setting. It’s down now to the U.S. Supreme Court. ☹

<sup>2</sup> The court comes closest with its citation of a 17-year-old New Jersey Supreme Court case — *Feldman I* — which concluded: “[i]t would seem anomalous for the FDA to have prevented a drug manufacturer from advising the public immediately of a newly discovered danger while waiting for FDA approval.” *Id.* at \*22. In fact, the FDCA does not do such thing. Unfortunately, the *McDarby* court failed to follow the meaning of “newly discovered danger,” which is a special term of art according to FDA regulations.

## California Federal District Court Finds Preemption in Generic Drug Case

See *Gaeta v. Perrigo Pharmaceuticals Co.*, No. C 05-04115 (N.D. Cal. June 13, 2008)

The preemption debate surrounding the labeling of FDA-approved drugs marches on in courts around the country, as the third in a trio of FDA preemption cases, *Wyeth v. Levine*, is scheduled to be argued before the U.S. Supreme Court next term.<sup>1</sup> Adding to this preemption mix is a recent federal district court decision from California that granted summary judgment, on preemption grounds, to the maker of a generic over-the-counter (OTC) drug.

### Background

In *Gaeta*, plaintiffs alleged that after their son underwent minor surgery, he was given generic OTC ibuprofen manufactured by the Perrigo Pharmaceuticals Company. *Id.* at 2. Within days of ingesting the ibuprofen, the boy was diagnosed with septic shock, dehydration and liver failure, necessitating a liver transplant. *Id.* Necrotic tissue on his fingers and toes eventually required amputation. *Id.* Plaintiffs sued Perrigo and others on theories of strict products liability, breach of warranty, and negligence.

### Labeling Requirements for Generic Drugs

Perrigo sought summary judgment arguing that plaintiffs' claims were preempted by the Food, Drug, and Cosmetics Act (FDCA). Under the FDCA, drug manufacturers are required to obtain approval from the Food & Drug Administration prior to public sale, which requires submission of a new drug application (NDA). In the Drug Price Competition and Patent Term Restoration Act of 1984, however, Congress relaxed the procedure for obtaining FDA approval to market and sell a generic drug — permitting

generic drug makers to submit an abbreviated NDA (ANDA). The ANDA must certify that the generic manufacturer will produce the bio-equivalent of a listed drug, labeled just as the listed drug is, including warnings. *Id.* at 3 (citing 21 U.S.C. § 355(j)(2)(A)).

If the FDA finds that the labeling for the drug is “no longer consistent with that for the listed drug,” or if the label “is false or misleading,” the agency may withdraw approval for the ANDA. *Id.* at 6-7 (quoting 21 C.F.R. § 314.150(b)(3), (b)(10)). While for non-generic drugs it is proper to use a CBE Supplement to amend the label in certain circumstances, they may not be used for drugs approved under an abbreviated NDA. *Id.* at 7. Rather, generic drugs must conform to the approved labeling for the listed drug in all material ways. *Id.* In other words, the generic manufacturer “cannot change its label to add a warning or contraindication without FDA approval.” *Id.*

### Modernization Act — “Savings Clause” Doesn’t “Save” Claim

In analyzing whether plaintiff's claims were preempted by the FDCA, the district court first reviewed the Food and Drug Modernization Act of 1997 (Modernization Act), which expressly preempts state laws regarding non-prescription OTC drugs. *Id.* at 5. The Modernization Act, however, contains a savings clause to the effect that preemption does not apply to “the liability of any person under the product liability law of any State.” *Id.* (quoting 21 U.S.C. § 379r(e)). While hardly a model of clarity, a California appellate court previously ruled that this “savings clause” did not apply to all “common law and statutory actions imposing liability on commercial sellers of products.” *Id.* (quoting *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 790-91 (2002)). In the event, the *Gaeta* court noted that savings clauses generally do not bar “the ordinary working of conflict pre-emption principles,” and that courts should “decline to give broad effect” to them when doing so “would upset the careful regulatory scheme established by federal law.” *Id.* at 5 (citing U.S. Supreme Court decisions in *Geier* and *Locke*).

In considering whether conflicts between state and federal laws upset the regulatory scheme of the FDA, the *Gaeta* court acknowledged that it must give deference to the FDA's interpretation of the scope of its authority to regulate absent clear authority to the contrary. *Id.* at 8 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-44 (1984)). Thus, “state tort law which would hold a generic drug manufacturer liable for failing to modify a label” necessarily conflicts with the FDCA and is preempted. *Id.* (citations omitted).

/ continued page 22

<sup>1</sup> See generally “FDA Stakes Position in Face of Looming Preemption Battle in *Wyeth v. Levine*,” *In re Products Liability* 4 (April 2008). *Levine* is a drug-labeling case in which the Vermont Supreme Court held that FDA regulations regarding CBE (or “Changes Being Effected”) Supplements allow unilateral changes to drug labels whenever the manufacturer believes it will make the drug safer. The other FDA-related cases receiving recent U.S. Supreme Court scrutiny were *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (an 8-1 victory for medical-device manufacturers), and *Warner-Lambert Co., LLC v. Kent*, 128 S. Ct. 1168 (2008) (a 4-4 draw leaving undisturbed a Second Circuit decision finding no preemption of “fraud-on-the-FDA” claims).

## PREEMPTION

*continued from page 21*

### Preemption of Plaintiffs' Claims

Plaintiffs' claims were based, at least partially, on allegations that defendants failed to warn adequately of the risks associated with the use of the ibuprofen, including the risk of acute liver failure. *Id.* The district court found, however, that the FDA had approved Perrigo's over-the-counter ibuprofen under the ANDA process in 1987, indicating that the agency considered the drug safe as labeled. *Id.* at 9. Subsequently, in 2002, the FDA performed a comprehensive review of ibuprofen and determined that a warning about the risk of liver injury was not scientifically supported by available data. *Id.* Although the agency concluded that OTC ibuprofen labels should include a warning about the risk of acute renal failure, it has not yet approved that warning. *Id.*

Since Perrigo's ibuprofen contained the warnings mandated by the FDA for OTC ibuprofen, the district court concluded that Perrigo had complied with the relevant FDA labeling requirements. As such, because plaintiffs' failure-to-warn claims (if successful) would put Perrigo's abbreviated NDA approval in jeopardy for non-conformance with FDA requirements regarding the labeling of OTC ibuprofen, plaintiffs' claims were preempted — justifying summary judgment. *Id.*

The district court's analysis in *Gaeta* differed somewhat from many recent preemption cases, since the case involved a generic OTC drug rather than a prescription pharmaceutical, and may serve as a foundation for any preemption-based analysis in any future cases implicating OTC generics. ☺

## CONSUMER FRAUD

### Merck Settles AG Consumer-Protection Actions Against Vioxx

*See Oregon ex rel. Hardy Myers, Attorney General for the State of Oregon v. Merck & Co., Inc.* (Cir. Ct. Or., Marion Co., May 20, 2008)

#### Background

What began with tobacco litigation in the mid-1990s, state attorneys general banding together nationwide under the

National Association of Attorneys General (NAAG) to pursue tobacco companies (collectively), has predictably expanded to ensnare other manufacturers for recovery of health-care costs allegedly caused by their products. *See* D. Wallace, "A Dispatch from America's Tobacco Litigation Ranks: Primary Assumption of Risk and Personal Responsibility in a Comparative Fault Age," *Zeitschrift Für Stoffrecht: The European Journal For Substances And The Law* 85 (May 2006). This relatively new trend — regulation by AG litigation — is now engulfing the pharmaceutical industry.

On May 20, 2008, Merck & Co., Inc. (Merck) announced its entry into a Stipulated General Judgment (SGJ or Agreement) with attorneys general from 29 states and the District of Columbia that resolved state investigations under state consumer protection laws related to Vioxx, an anti-inflammatory drug allegedly linked to thousands of heart-attack deaths.<sup>1</sup> According to the states, Merck launched a deceptive advertising campaign back in 1999, misrepresenting the safety of and improperly concealing the increased risks associated with Vioxx, and continued to do so up until its voluntary withdrawal of Vioxx from the market in 2004. Under the Agreement, the largest ever for a multi-state consumer-protection drug case, Merck agreed to pay a total of \$58 million to the settling states.

The Agreement resolves issues purportedly raised by Merck's promotional and marketing practices regarding Vioxx — as well as Merck's practices related to Data Safety Monitoring Boards (DSMBs), publication of clinical trials, and the support of continuing medical education. *See* SGJ ¶ 1(a). The following highlights some of the Agreement's salient provisions.

#### Settlement Payments

Under the Agreement, and without admitting any liability, Merck's lump-sum \$58 million payment will be divided for direct payment to each state in an amount designated by a "Multistate Executive Committee" — comprised of attorneys general representing Arizona, California, Florida, Illinois, Ohio, Oregon,

<sup>1</sup> Merck reached settlement with 29 states and the District of Columbia, including: Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Nebraska, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington and Wisconsin. *See State of Oregon ex rel. Hardy v. Merck & Co., Inc.*

Pennsylvania, Texas and Vermont. See SGJ ¶¶ 1(h) & 23. These payments are to be used by the states for attorneys' fees and other costs of litigation and investigation — or to be placed in, or applied to, a consumer protection enforcement fund, consumer education, or some other consumer aid fund — and for other permissible purposes to be determined by each state at the sole discretion of its attorney general. *Id.* ¶ 23.

### Clinical Trials

The SGJ requires Merck to register its clinical trials with, and submit results to, the federal clinical trial registry and results data bank established by the FDA Amendments Act of 2007, Public Law No. 110-85. See SGJ ¶¶ 1(c) & 3.

### Marketing and Advertising Restrictions

The heart of the Agreement centered on restrictions of Merck's promotional activities. Over the next ten years, Merck will delay direct to consumer (DTC) television advertising for "any Merck Product" — *i.e.*, any Merck prescription drug or biological product manufactured, distributed, sold, marketed or promoted in the U.S. — if such a delay is sought in writing by the FDA. See SGJ ¶¶ 8, 10. In addition, Merck will, over the next seven years, submit all new DTC television campaigns for FDA approval before running the campaign, and will modify the advertising consistent with any written comments from the FDA. *Id.* ¶¶ 9, 10.

The Agreement also places significant restrictions on Merck's ability to present, in promotional materials, information regarding clinical studies involving Merck products. Merck may not, for example, (i) present information or conclusions from a study that is "inadequate in design, scope, or conduct to furnish significant support for such information or conclusions" (*id.* ¶ 11; see also *id.* at ¶ 13), or (ii) use statistical analysis "on a retrospective basis to discover and cite findings not soundly supported by the study." *Id.*

### Continuing Medical Education

The Agreement further provides that any person who promotes a Merck product going forward must, as a condition of his or her contract with Merck, disclose to any continuing medical education (CME) participants the existence and nature of his or her relationship with Merck if: (1) the product the speaker promoted is in the same therapeutic category as the subject of the CME program; and (2) the CME program occurs within twelve

months of the speaker performing work for or receiving compensation from Merck. SGJ ¶ 14. Thus, any doctors who receive promotional payments from Merck must disclose that fact whenever they address a CME audience.

### Prohibition on "Ghostwriting"

In response to claims that Merck paid allegedly unaffiliated scientists to attach their names to studies actually authored by Merck scientists (sometimes referred to as "ghostwriting"), the Agreement requires all named authors on Merck-sponsored research to have made a substantial contribution to the conception and design of the study or the interpretation of its data, and to have been involved in the drafting/revision of the article. SGJ ¶¶ 19-20.

### Data Safety Monitoring Boards

Merck agreed to impose conflict-of-interest rules on members of external DSMBs (impartial groups that oversee clinical trials), including a prohibition against (i) holding more than \$25,000 worth of Merck stock (exclusive of mutual fund holdings) (see SGJ ¶ 16(a)), (ii) trading in Merck stock during DSMB service (*id.* ¶ 16(b)), (iii) serving as a clinical trial investigator in a trial being monitored by the DSMB (*id.* ¶ 16(c)), and (with certain exceptions) (iv) consulting for or being employed by Merck during DSMB service (*id.* ¶ 16(d)).

### Conclusion

This Agreement should serve as a reminder of the ever-expanding willingness and ability of states, in the absence of federal action, to regulate an entity's or industry's conduct through the use of state-generated investigations and the (threatened) application of state consumer-protection statutes with generally relaxed burdens of proof and enhanced damages provisions (including, typically, attorneys fees and trebled damages). In this case, in addition to requiring substantial monetary payments, the Agreement fundamentally alters the marketing landscape for Merck for many years to come by, among other things, making Merck's DTC promotion subject to FDA approval. The "success" of this Agreement, and the continued need for state revenue, will no doubt only increase the desire of states to become super-regulators of company conduct. ☉

## Et cetera

### Publications

- David Wallace published “Chadbourne on Nanotechnology: The Need for New Policy and Business Paradigms,” in *Product Liability Law & Strategy* (July 2008).

### Speaking Engagements

- On June 17-18, 2008, David Wallace addressed the topic of “Mediating Nanotechnology Uncertainty and Abstraction: Lessons from Recent History and the Case for New Paradigms,” at Credit Suisse’s *Global Nanotechnology Conference*, in London, England.
- On May 4-6, 2008, David Wallace served as the moderator for the topic “Nanotechnology Tools: Advancements in Characterization and Fabrication,” at the *NanoBusiness Alliance Conference*, in New York City.
- On June 24-25, 2008, Phoebe Wilkinson gave a presentation on “Cross Examining a Plaintiff’s Regulatory/FDA Expert” at the *2nd Annual Drug & Medical Device On Trial Conference* in New York City.
- On September 23-24, 2008, Phoebe Wilkinson will be co-presenting at the Drug and Device Forum in Philadelphia, Pennsylvania, on *Defending Consumer Fraud Economic Injury Claims* and will speak on the following topic: “Preventative Medicine: Uncovering Business Practices That Are Warning Signs to Consumer Fraud Litigation.”
- On October 23-24, 2008, David Wallace will be speaking on class-action law at a conference sponsored by the Quebec Bar Association’s Continuing Education Service, entitled *Recours Collectif: Developpements Recents au Quebec, au Canada et aux Etats-Unis*, at the Hotel Omni Mont-Royal, in Montreal, Canada.
- On November 13, 2008, Gretchen Werwaiss will co-chair the ABA Section of Litigation Products Liability Committee’s *Ninth Annual Women In Products Liability Regional CLE Workshop*, being held at the offices of Chadbourne & Parke in New York City.
- On November 13, 2008, Mary Yelenick will serve as the co-moderator of a panel that will address how manufacturers can deal with situations that can occasion a consumer-product recall, at the ABA Section of Litigation Products Liability Committee’s *Ninth Annual Women In Products Liability Regional CLE Workshop*, being held at the offices of Chadbourne & Parke in New York City.
- On November 14, 2008, Phoebe Wilkinson will co-chair the ABA Section of Litigation Products Liability Committee’s *Pharmaceutical Litigation Regional CLE Workshop*, being held in New York City.

Contributors to this edition of *In re Products Liability* are: David L. Wallace, Joseph G. Falcone, Ellen A. Black, Nicholas S. Booke, Timothy F. Burke, Cassandre L. Charles, Maria E. Martinez, Philip A. Pfeffer, and Benjamin C. Rubinstein.

### PRODUCTS LIABILITY GROUP

Garyowen P. Morrisroe, Chair

#### Partners

Allison M. Alcasabas, *London*  
Thomas E. Bezanson  
Thomas E. Butler  
Joseph G. Falcone  
Jay Henneberry, *Los Angeles*  
Gregory M. Loss  
Thomas J. McCormack  
Dennis R. Neutze, *London*  
Thomas E. Riley  
Bruce G. Sheffler  
Donald I. Strauber

David L. Wallace  
Phoebe A. Wilkinson  
Mary T. Yelenick

#### Counsel

Peter K. Eck  
Danielle P. Langhoff  
Lawrence E. Savell  
Susan St. Denis, *Los Angeles*  
Gretchen N. Werwaiss

#### Associates

Ellen Black  
Nicholas S. Booke  
Timothy F. Burke, *London*

Cassandre L. Charles  
Amy H. Chung  
S. Jean Kim, *Los Angeles*  
Michael R. Kelly, *London*  
Joaquina M. Lazaro  
Maria E. Martinez, *London*  
Alexandra K. Nellos  
Philip A. Pfeffer  
Morghana Richardson  
Benjamin C. Rubinstein

***In re Products Liability*** is published by Chadbourne & Parke LLP for general information purposes only. It does not constitute the legal advice of Chadbourne & Parke LLP and it is not a substitute for fact-specific legal counsel. For complimentary copies or changes of address, please contact Kate Clark at [kclark@chadbourne.com](mailto:kclark@chadbourne.com).

For more information about our practice, contact Garyowen P. Morrisroe at +1 (212) 408-5100 ([gmorrisroe@chadbourne.com](mailto:gmorrisroe@chadbourne.com)), Allison M. Alcasabas in London at +44 (0)20 7337-8000 ([aalcasabas@chadbourne.com](mailto:aalcasabas@chadbourne.com)), or visit us at [www.chadbourne.com](http://www.chadbourne.com).

### Chadbourne & Parke LLP

**New York**  
30 Rockefeller Plaza  
New York, NY 10112  
+1 (212) 408-5100

**Washington**  
1200 New Hampshire Ave., NW  
Washington, DC 20036  
+1 (202) 974-5600

**Los Angeles**  
350 South Grand Ave., Suite 3300  
Los Angeles, CA 90071  
+1 (213) 892-1000

**Houston**  
1100 Louisiana, Suite 3500  
Houston, TX 77002  
+1 (713) 571-5900

**Mexico City**  
Paseo de Tamarindos, No. 400-B Piso 22  
Col. Bosques de las Lomas  
05120 México, D.F., México  
+52 (55) 3000-0600

**London**  
Chadbourne & Parke  
a multinational partnership  
Regis House, 45 King William Street  
London EC4R 9AN, UK  
+44 (0)20 7337-8000

**Moscow**  
Riverside Towers  
52/5 Kosmodamianskaya Nab.  
Moscow 115054 Russian Federation  
+7 (495) 974-2424  
Direct line from outside C.I.S.:  
(212) 408-1190

**St. Petersburg**  
Stroganovskiy Business Centre  
19A Nevskiy Prospect  
St. Petersburg 191186 Russian Federation  
+7 (812) 332-9300

**Warsaw**  
Chadbourne & Parke  
Radzikowski, Szubielska and Partners LLP  
ul. Emilii Plater 53  
00-113 Warsaw, Poland  
+48 (22) 520-5000

**Kyiv**  
11 Mykhailivska Street, 4th Floor  
Kyiv 01001, Ukraine  
+380 (44) 230-2534

**Almaty**  
Dostyk Business Center  
43 Dostyk Avenue, 4th floor  
Almaty 050010, Republic of Kazakhstan  
+7 (727) 258-5088

**Dubai**  
City Tower I, Sheikh Zayed Road  
P.O. Box 23927, Dubai, United Arab Emirates  
+971 (4) 331-6123

**Beijing**  
Beijing Representative Office  
Room 902, Tower A, Beijing Fortune Centre  
7 Dongsanhuan Zhonglu, Chaoyang District  
Beijing 100020, China  
+86 (10) 6530-8846

© 2008 Chadbourne & Parke LLP  
All rights reserved.

[www.chadbourne.com](http://www.chadbourne.com)