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In re Products Liability NEWSWIRE

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NANO LAW

Small Is the New Big: Eye on Nanotechnology Regulations in the U.S. and EU

In past issues, we have discussed the growing use of nanotechnology in a wide array of consumer, medical, food and industrial products.[1] Among other things, we've noted that the incorporation of nanoparticles — which may be as small as several molecules — into such products has led to expressions of concern by scientists and regulators about the safety of such novel substances, particularly when used in products intended for human consumption.

Nanotechnology is one of the fastest growing commercial technologies — one eventually expected to cut a very wide swath across the global economy — and many public agencies and academic institutions are launching comprehensive efforts to understand its benefits and potential risks. Recently, both the U.S. FDA and the European Union have issued reports concerning nanotechnology and product safety. Both bodies largely conclude that private industry must consider the special risks of nanotechnology in complying with existing regulatory requirements — even though official nanotechnology-specific regulatory regimes are likely a long way off.

FDA Nanotechnology Task Force Report

In 2006, the FDA commissioned a Nanotechnology Task Force to look into a wide range of nanotechnology issues falling within the FDA's regulatory ambit. Following public hearings, "Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force" was issued on July 25, 2007 ("Report").[2] The Task Force was appointed partly in response to vocal calls for FDA regulation of nanomaterials by public interest groups, such as the International Center for Technology Assessment.

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1 See, e.g., "Nanotechnology Law & Commerce: Doing Business at One-Billionth of a Meter," *In re* Products Liability at 12 (July 2007); "Nanotechnology: A Regulatory Void," *In re* Products Liability at 17 (April 2007); "Uncharted Products Liability Waters: Nanotechnology," *In re* Products Liability at 10 (Nov. 2006).

2 See http://www.fda.gov/nanotechnology/taskforce/report2007.html.

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No Call — Yet — For Product Labeling

The FDA Nanotechnology Task Force largely concluded that — for now — current FDA regulatory and rule-making authority is sufficient to address health risks that may emerge from nanotechnology-based products. Notably, in light of the limits of current science, it specifically declined to recommend the adoption of any new labeling rules requiring identification of the presence of nanoscale materials.

> Because *the current science does not support a finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials*, the Task Force does not believe there is a basis for saying that, as a general matter, a product containing nanoscale materials must be labeled as such. *Therefore the Task Force is not recommending that the agency require such labeling at this time.*

Report at 35 (emphasis added).

Scientific State of the Art Still Too Immature for Consensus Building

In reaching its conclusions, the Task Force stressed the current lack of scientific and regulatory consensus both as to what constitutes a "nanoparticle" and how to determine whether "nanomaterials" might implicate special health concerns. More to the point, it concludes:

> Identifying precisely what qualifies as a nanoscale material is difficult and currently a subject of substantial discussion in the scientific, regulatory, and standards communities. As a result, developing a comprehensive description of products that are currently produced with nanotechnology, or may be produced with this technology in the future, would be difficult at best, and likely infeasible.

Id. at 7.[3]

Notwithstanding an appreciation that the reduction and manipulation of materials at the nanoscale range can substantively alter their physical properties and "inter[action] with biological systems," the Report concludes that there are no intrinsic properties of nanoscale materials that automatically raise health and safety concerns as such. To wit:

> The available information does not suggest that all materials with nanoscale dimensions will be hazardous. Furthermore, if all nanoscale materials are compared to all non-nanoscale materials, whether larger or smaller, it is not apparent that the nanoscale materials as a group would have more inherent hazard. *However, consideration of the basic science of how materials interact with biological systems does indicate that a material's properties can change when size is increased or decreased into, or varied within, the nanoscale range*.

Id. at 11 (emphasis added).

Calls for FDA Guidance and Industry Data-Gathering

Nonetheless, the Report suggests specific FDA action with regard to emerging issues of safety and health pertaining to the use of nanotechnology. In this regard, its recommendations to the FDA include a proposal that the agency issue industry guidance for the identification of particle size in OTC drugs, food and color additives as well as certain dietary supplements. It also recommends that the FDA request data from regulated entities in order to identify previously approved food and color additives and OTC drug products now containing nanoscale versions of previously approved ingredients. *Id.* at 30.

Regarding prescription drugs and biologic products, the Report notes that existing FDA regulations already require agency notification when changes to the composition or manufacture of such products have "a substantial potential" to create "an adverse effect" on the product. It notes, too, that "[c]hanges to a product to introduce nanoscale ingredients or processing would trigger change notification chemistry supplements and permit [the] FDA to review and approve the revised formulation. Depending on the change, the resulting product might be considered a new product for which a new approval is needed." *Id.* at 23.

The FDA, of course, is already authorized to require "particle size data" in support of new drug applications. As the Report notes, the FDA requests information on particle size when the agency considers such information relevant to determining whether a particular human drug product or class of human drug products is safe and effective. If the FDA determines such data are needed for a class of drugs, FDA may issue guidance to applicants recommending that they be submitted in the original application. *Id.* at 22. Although FDA authority is somewhat limited in respect of products "not subject to premarket authorization" requirements, the Report adds that "the agency's authority is comprehensive with regard to products subject to premarket authorization such as drugs, devices, biological products, and food and color additives." *Id.* at 30.

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[3] The Woodrow Wilson International Center's Nanotech Project maintains a publicly accessible database identifying products labeled as containing nanoscale materials. See http://www.nanotechproject.org/index.php?d=44&id=44&action=view&p=17 (last visited Oct. 3, 2007).

A Post-Script to Consumers from the FDA on Nanotechnology

Summarizing the Report's findings, the FDA highlighted the Task Force's conclusion that current FDA regulations already require manufacturers to ascertain and report risks attributable to the incorporation of certain nanomaterials, and — further — that products straddling the borders of its regulatory authority would be regulated as "combination products."

> For the most part, FDA experts believe that nanotechnology products present challenges similar to those FDA faces for products of other emerging technologies. FDA experts recognize, however, that product safety and effectiveness can change as size goes up or down within the nanoscale, adding additional complexity to the product review. It's also possible that nanotechnology will be used in a wide variety of products, such as foods, drugs, cosmetics, and medical devices. The agency expects that many of the nanotechnology products it will regulate will span the regulatory boundaries between drugs, medical devices, and biologics. These, then, would be regulated under the rules established for 'combination products.'[4]

The REACH Protocol and the EU Action Plan for Nanotechnology

Recently, the European Union passed a regulation closely regulating chemicals and other substances manufactured in or exported to EU nations. Known as REACH (for "Registration, Evaluation and Authorization of Chemicals"), it requires that extensive registration, data-sharing and technical evaluations be filed with the appropriate EU and member-state agencies for a wide array of chemicals and substances, including those involving nanotechnology.[5]

The REACH system establishes a single regulatory framework for the registration, evaluation and authorization of chemicals coming to or from the EU. Beginning June 1, 2008, it will require corporations to gather and disclose information on the properties of substances which they manufacture in or import to the EU in an amount of at least one ton per year and to demonstrate safety of use.[6] (Previous legislation required member-state regulatory authorities to prove the existence of a risk in order to ban a substance.) This information must then be sent to the European Chemicals Agency, located in Helsinki, Finland, which will manage the registration of these substances by setting up a database. Unregistered substances may not be manufactured in or exported to the EU. Thereafter, EU member states must assess the registration dossiers and grant or refuse authorizations for substances considered to pose a risk to health or the environment. Adopted at the end of 2006, the REACH system replaces 40 prior national legislative acts of EU member states.

REACH and Nanotechnology

As for nanotechnology specifically, EU regulatory and scientific advisory groups have reached conclusions essentially identical to those of the FDA Nanotechnology Task Force: more study is required before the development of nanotechnology-specific regulatory regimes can be formulated, but, in the meanwhile, existing regulations put the onus on industry to identify and address the potential hazards of nanotechnology as nanomaterials are incorporated into products entering the stream of commerce.

To this end, on September 6, 2007, the EU issued a report called, "Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009: First Implementation Report 2005-2007" ("EU Report").[7] This report discusses the findings of the EU's primary consultative body for nanotechnology risk assessment — the Scientific Committee on Emerging and Newly Identified Risks. Endorsing this group's finding, and echoing the FDA Nanotechnology Task Force's approach, the EU Report states:

> [A]lthough the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with nanoparticles, they may not be sufficient to address all the hazards. Because of uncertainties, the current risk assessment procedures require modification for nanoparticles. Knowledge gaps have been confirmed in areas such as nanoparticle characterization, detection and measurement; their fate and persistence in humans and the environment; and all aspects of the associated toxicology and ecotoxicology. These should be addressed to allow satisfactory risk assessments for humans and ecosystems.

EU Report at 9.

Summary: Regulation by Litigation?

Both the FDA and the EU have attempted to put the immediate burden on industry to identify and describe safety and health issues posed by nanotechnology under existing regulatory

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4 See www.fda.gov/consumer/updates/nanotech072507.html.

5 See *REACH in Brief*, http://ec.europa.eu/enterprise/reach/overview_en.htm.; see also www.ec.europa.eu/enterprise/reach/faq_en.htm.

6 After December 1, 2008, existing substances that have not been pre-registered under REACH can no longer be sold in the EU.

7 See ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/com_2007_0505_f_en.pdf.

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schemes designed to address traditional risk/benefit profiles of substances and consumer products. Both bodies make clear that regulatory regimes specific to health concerns unique to nanotechnology will not emerge anytime soon. At the same time, each notes the need for continued scientific study and development of definitions, standards and risk profiles for specific classes of nanomaterials prior to the development of any such regulatory regimes.

What this means, unfortunately, is that until such time as clear nanotechnology-specific regulatory guidelines are forthcoming, innovative manufacturers and others are likely to be subjected to uncertainty, which could lead to regulation by litigation.

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NANOTECHNOLOGY LAW & COMMERCE:
BUSINESS AT ONE-BILLIONTH OF A METER

January 31, 2008

Chadbourne & Parke LLP
30 Rockefeller Plaza
New York, New York

THE AGENDA

Opening Remarks

The Honorable George E. Pataki
Governor of New York (1995-2007)
Counsel, Chadbourne & Parke LLP

An Introductory Trivium: Understanding Nanotechnology NanoScience 101

Dr. Alain E. Kaloyeros
Vice President and Chief Administrative Officer
Professor of Nanosciences, Nanoengineering and Physics
University at Albany — SUNY, Albany, NY

Nanotechnology Risk Profile & Perception

Dan M. Kahan
Elizabeth K. Dollard Professor of Law & Deputy Dean
Yale Law School, New Haven, CT

Panel Discussion: Debating The Promise and Challenge of Nanotechnology

Issue I: Financing & Underwriting
Issue II: Public Policy & Politics

Reception

For registration and other information, please contact:

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PUNITIVE DAMAGES

The Punitive Damages Wheel Turns Post-*Williams*: Ninth Circuit Remands Products Suit For Second Retrial of Punitive Damages *Quantum*

See *White v. Ford Motor Co.*, 2007 WL 2445952 (9th Cir. Aug. 30, 2007)

Overview

For the second time, the Ninth Circuit has ordered a retrial on punitive damages in this products liability case against Ford — holding, this time, that a Nevada district court failed to provide constitutionally mandated limiting instructions preventing the jury from awarding punitive damages based on evidence and argument of non-party harm. The decision in *White* came six months after the U.S. Supreme Court held that punitive awards based "in part upon the desire to *punish* the defendant for harming persons who are not before the court (*e.g.*, victims whom the parties do not represent)" constitute an "unconstitutional taking of 'property' from the defendant without due process." *Philip Morris U.S.A. v. Williams*, 127 S. Ct. 1057, 1060 (Feb. 20, 2007); see also *id.* at 1065 ("the Due Process Clause prohibits a State's inflicting punishment for harm caused strangers to the litigation").[1]

The Facts: A Truck "Rollaway," A Death And The First Trial

Two Nevada parents brought suit against Ford for the death of their three-year old son "who was killed when Mr. White's parked Ford F-350 pickup truck rolled over [the child] in the family driveway." *Id.* at *1. After climbing into the cab of the truck, the boy allegedly "knocked the gearshift into neutral," which somehow released the parking brake and sent the truck rolling down the sloping driveway. *Id.* at *3. When plaintiffs' son "fell or climbed out of" the truck, its "rear dual wheels rolled over and crushed" him. *Id.*

The accident occurred in October 1994, two months *before* Ford — in response to pressure earlier that year from the National Highway Traffic Safety Administration — issued a recall notifying vehicle owners of the need to install a "protective wedge" in the parking-brake mechanism as "a precautionary

[1] We discussed *Williams* earlier this year. 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 at 1 (April 2007).

measure" against its "spontaneous disengagement" and vehicle "rollaway" problems. *Id*. at *3. Although Ford told federal regulators it had "decided to recall 884,400" vehicles on August 30, 1994 — including plaintiffs' — it did not issue its recall notice until early "December 1994, two months *after*" the death of plaintiffs' son. *Id*. at *4 (emphasis in original).

After a trial in federal district court in Nevada, the jury returned a verdict against Ford for failing to warn consumers of the parking brake-related "rollaway" problem (but not defective design), and awarded plaintiffs more than $2 million in compensatory damages, and just over $150 million in punitive damages. It also found that plaintiffs were 40 percent contributorily negligent for failing to supervise their son carefully. *Id*.

On post-trial motions, the trial court found the punitive award "constitutionally excessive" and entered remittance at just over $69 million, reasoning that the resulting 30:1 ratio between punitive and compensatory damages comported with the largest one ever approved by a Nevada court. *Id*.

Ford's First Trip To the Ninth Circuit

On Ford's initial appeal to the Ninth Circuit, the court affirmed *liability* for both compensatory and punitive damages, but reversed and remanded for a new trial on the *quantum* of punitive damages — because the jury instructions (contrary to *State Farm*) "unconstitutionally allowed a Nevada jury to punish Ford for out-of-state conduct" by failing to state expressly that it could not award punitive damages "to protect people or punish harm outside of Nevada." *Id*. at *5.[2]

The First Punitive Damages Retrial

The punitive damages retrial was presided over by the same trial judge, but tried to a new jury. This jury was not told either the amount of the compensatory damages previously awarded against Ford or about plaintiffs' contributory negligence. *Id*. But because, in closing argument, plaintiffs' counsel referenced Ford's knowledge that at least 54 others had been injured by similar "rollaways" involving its vehicles — and decided not to "tell[] people the truth" — Ford sought a limiting instruction at the charge conference to prevent the jury from punishing it "not just for the harm to these plaintiffs, but for harm to other plaintiffs, whether in state or out-of-state." *Id*. at *6 (internal citations omitted). The trial court refused this request.

Following an eight-day trial, this jury awarded $52 million in punitive damages, which the district court concluded was constitutionally permissible, notwithstanding that the award remained more than 22 times greater than the cost of Ford's compensatory liability (at $2.3 million).

Ford's Second Trip To the Ninth Circuit

Ford then returned to the Ninth Circuit, arguing that the punitive award was unconstitutionally excessive, in addition to instructional and evidentiary errors. After oral argument, however, the U.S. Supreme Court issued its landmark punitive damages decision in *Williams* on February 20, 2007, leading the Ninth Circuit to set the matter for rehearing to consider "the implications of *Williams*." *Id*. at *6.

The Ninth Circuit Orders Second Punitive Damages Retrial

While "sympathetic to the difficult task that both district court judges and counsel face in maneuvering through [the] ever-shifting area" of the constitutional dimensions of punitive damages jurisprudence, the court was "compelled to reverse" in the light of *Williams* and the trial court's failure to give "a harm to nonparties instruction," which created a "significant risk" that the jury punished Ford for harm to nonparties — in violation of Ford's due process rights.[3] *Id*. Although, as plaintiffs argued in support of their harmless-error point, the jury was instructed not to consider harms *outside of Nevada,* the court ruled that this extraterritorial instruction — while possibly "mitigating" the risk of unconstitutional punishment — did not eliminate that risk since "the jury may have interpreted the . . . instruction as allowing damages for harm to [other] people residing *inside* Nevada." *Id*. at 7 (emphasis in original).

Guidance for the Second Punitive Damages Retrial (and Third Overall)

The court then issued the district court instructional guidance for purposes of the third trial overall in this case on the *quantum* of punitive damages.

First, the court rejected Ford's argument that due process requires a "reasonable relationship" or proportionality instruction. *Id*. at *8. Per the Ninth Circuit, "nothing in *State Farm* precludes

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[2] Because the court determined that a new trial on punitive damages was warranted as a matter of procedural due process, it did not address whether the original or subsequently remitted punitive awards were unconstitutionally excessive as a matter of substantive due process. *Id.* at *5.

[3] The court considered that a new trial — and not a reduction in the amount of punitive damages — is the only appropriate remedy for constitutionally inadequate jury instructions. Coincidentally, in a breach-of-contract decision issued the next day, another Ninth Circuit panel similarly concluded that "[w]hile remittitur may remedy a [punitive damages] jury award deemed unconstitutionally excessive . . . it seems less appropriate where the constitutional error stems from misguidance regarding the way the jury may use evidence in setting the amount." See *Merrick v. Paul Revere Life Ins. Co.*, 2007 WL 2458503, at *8 (Aug. 31, 2007).

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courts from ensuring proportionality through a post-verdict review, rather than with pre-verdict jury instructions." *Id.* at *8.

Second, Ford was constitutionally entitled to have the punitive damages jury know the amount of compensatory damages awarded plaintiff. Indeed, without such knowledge, the *White* court reasoned, "the punitive damages jury could not have come to a reasoned conclusion as to the amount of additional damages necessary to deter Ford from similar conduct in the future." *Id.*

Third, Ford was also constitutionally entitled to have the punitive damages jury know that plaintiffs had been found 40 percent responsible for their son's death, since Ford's "reprehensibility" must be "judged in relation to the conduct and actions of others, not merely by looking at Ford's conduct in the abstract." *Id.* at *10.[4]

Is it Time Yet for an Alternative Approach to Punitive Damages?

As we commented earlier this year, see *supra* f.1, the whole question of "harm to non-parties" in punitive damages jurisprudence — which is a relevant consideration for purposes of finding "reprehensibility," but *ultra vires* for purposes of actually setting the amount of punitive damages — seems to have created more mist than clarity.

In brief, if the only relevant "potential harm" for "reprehensibility" purposes is that to which plaintiff was subjected, see *Williams* Majority Op. (citing *State Farm*), why bother with the plainly confusing business of "others" at all, much less the application of the often vexing, constitutional mechanisms of punitive damages jurisprudence: calibration and adjustment for "reprehensibility," "reasonable relationships," and "excessiveness" (filtering what "shocks the conscience")? See *In re* Products Liability at 10 (April 2007). Instead,

> [p]erhaps 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 trebled damages on proof of certain aggravating factors (*i*.e., egregiousness) by clear and convincing proof. Such an approach would also seem a more direct way of arriving at already agreed constitutionally permissive punitive/compensatory damage ratios of single digits (by simply tripling compensatory damages in certain circumstances, rather than analyzing ratios for reasonableness and the like).

Id. Food for thought.

[4] Because it ordered a new trial on punitive damages, the court did not address "whether the jury's $52 million award was constitutionally excessive." *Id.* at *12.

PREEMPTION

Senator Leahy Pushes Back Against Bush Administration's Preemption Policies in Judiciary Committee Hearings

See *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?* Hearings of the S. Comm. on the Judiciary, 110th Cong. (Sept. 12, 2007)

Introduction

The doctrine of federal preemption has figured prominently in products liability litigation for decades. More recently, in 1992, the doctrine was given new salience in products liability law during the early days of the third wave of modern tobacco litigation — in the form of the plurality, landmark decision delivered by the U.S. Supreme Court on the facts of *Cipollone v. Liggett Group*, 505 U.S. 504 (1992). We have been following the continuing thread of this line of jurisprudence, particularly in the pharmaceutical context.[1]

The issue has recently surfaced in Congress. Last month, Sen. Patrick Leahy (D-Vt.) — Chairman of the Senate Judiciary Committee — convened a hearing on the Bush Administration's stance on federal preemption. He did so under the somewhat provocative title of "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?"[2]

Opening hearings on September 12, 2007, Senator Leahy took direct aim at what he called the Bush Administration's "aggressive legal theory" of preemption, which he said was "threaten[ing] devastating consequences for American con-

[1] See, e.g., "Sorry, Charlie! — Informal and Light FDA Regulatory Touch Preempts Methylmercury Litigation in New Jersey," *In re* Products Liability at 8 (April 2007); "Preemptive Effect Owed FDA Pharmaceutical Labeling Rule Generates Debate," *In re* Products Liability at 8 (Nov. 2006).

[2] See http://judiciary.senate.gov/hearing.cfm?id=2935 (contains Sen. Leahy's opening remarks and copies of each witness's prepared statement).

sumers." As his launching pad, he used the case of *Levine v. Wyeth*, 2006 WL 3041078 (Vt. Oct. 27, 2006), which we discussed last year in these pages. See *supra* n.1.

He described Ms. Levine as "a successful musician" whose arm was amputated after she developed an infection following an "IV push" administration of Phenergan — a Wyeth pharmaceutical. He then summarized the gist of Wyeth's motion to dismiss Ms. Levin's subsequent failure-to-warn claims under the doctrine of federal preemption, taking the line that Wyeth's position supposedly illustrated how federal preemption "is being invoked to shield corporations from culpability and prevent injured Americans from obtaining redress for their injuries." *Id.*

Holding in *Levine v. Wyeth*

Vermont's high court held that "Congress intended the [Food, Drug and Cosmetic Act] to preempt only those state laws that would make it impossible for manufacturers to comply with both federal and state requirements." 2006 WL 3041078 at ¶ 32. More particularly, it declared that because "federal labeling requirements create a floor, not a ceiling, for state regulation," *id.* at ¶ 6, it was possible for Wyeth to comply with both FDA regulations and duties imposed by Vermont law — by issuing a stronger warning against "IV push" administration — and, consequently, there was no conflict between federal and state law warranting preemption. *Id.* at ¶¶ 32-34.[3] (But as the First Circuit Court of Appeals opined in general Circuit skirmishing over preemption prior to *Cipollone* — in a decision overtaken by subsequent events — plaintiffs' theory that defendants had a "choice of how to react" was "akin to the free choice of coming up for air after being underwater." See *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 627 (1st Cir. 1987), *abrogated by Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)).

While Senator Leahy agreed with the Vermont Supreme Court's holding, he expressed concern that the U.S. Supreme Court was using federal preemption to close the courtroom door to plaintiffs.

The Witnesses Called by Senator Leahy

Senator Leahy then gave the floor to the witnesses, including: Ms. Donna Stone, a Delaware legislator and President of the National Conference of State Legislators; Ms. Collyn Peddie, a private practitioner; Professor David Vladeck, a Georgetown University law professor; Mr. Alan Untereiner, a Supreme Court practitioner, on behalf of the U.S. Chamber of Commerce; and Professor Viet Dinh, also of Georgetown University.

The Plaintiff's Perspective: Federal Legislation Is Necessary to Limit Preemption

Ms. Stone generally endorsed Sen. Leahy's opening remarks. See Stone Statement. In her view, federal agencies have preempted — in a wholly inappropriate fashion — "established bodies of state law in the absence of underlying statutory authority through the rulemaking process." *Id.* In illustrating her point, Stone focused on the FDA's preemption position in regard to prescription drug labeling. *Id.;* see generally M. Yelenick, *Client Alert: New FDA Rule on Prescription Drug Package Inserts* (Feb. 2006) (outlining FDA's then-new prescription drug labeling regulations) (available at http://www.chadbourne.com/publications/index.html).

Positing a substantial detrimental impact on states from preemption, Stone advocated the need for Congressional legislation balancing state and federal interests. See Stone Statement (advocating that "individual liberties can be protected by dividing power between levels of government; in other words, division of power between federal and state governments also serves as a check on the power of each").

Ms. Collyn Peddie took a similar position, describing the preemption "problem" as follows: "[i]ncreasingly, those injured by prescription drugs are seeing their right to seek compensation in court eliminated entirely by the preemption doctrine" (as if a litigant's "day in court" were an absolute right — coinciding principles of jurisprudence notwithstanding). See Peddie Statement. Focusing specifically on FDA labeling regulations allowing state failure-to-warn claims to be preempted, Peddie identified the number of cases in which federal courts had dismissed — wrongly in her view — failure-to-warn claims as a "critical mass." *Id.*

Elaborating, she claimed that these cases illustrate "an emerging pattern of judicial and executive legislating, and nullification of federal and state laws permitting tort claims against pharmaceutical companies," which, in the end, only increases the FDA's regulatory burden (as "the only game in town" when it comes to the business of ensuring drug safety). *Id.* To solve this "problem," Peddie says congressional intent should be made clearer, that congressional oversight of the FDA and other safety agencies should be increased, and that legislation expressly limiting preemption is required. *Id.* (explaining that "[t]o avoid usurpation of its powers by the FDA, Congress must speak clearly on the issue of preemption of pharmaceutical claims"). At the same time, she proposed that well-settled common law rules of statutory construction be jettisoned in favor of congres-

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3 On March 12, 2007, Wyeth petitioned the U.S. Supreme Court for *certiorari*, with The Products Liability Advisory Council and the U.S. Chamber of Commerce filing *amicus* briefs. On May 17, 2007, the U.S. Supreme Court invited the Solicitor General to express "the views of the United States" on the subject in connection with Wyeth's *certiorari* petition. See *In re* Products Liability at 14 (July 2007). Thus far, the U.S. Supreme Court has not granted Wyeth's petition.

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sional legislation dictating uniform rules for how courts should construe federal statutes. *Id*. ("By providing more guidance to the Courts and agencies in interpreting federal statutes, particularly with regard to preemption, Congress can increase the likelihood that state and federal courts will follow established principles in interpreting federal law.").

Georgetown's Professor Vladeck took a similar tack, claiming that:

> [A]gencies are attempting to stake out the scope of preemption with little or no guidance from Congress. In so doing, agencies have strayed from their proper function of applying the law as defined by Congress into the constitutionally impermissible role of making the law on their own — untethered by guidance from Congress, unconstrained by the political process and using backdoor means that escape serious oversight — all in an effort to eliminate state law.

Id. at 4. He used the FDA's preemptive actions in regard to prescription drug labeling and medical devices as an example of how federal agencies are supposedly deciding themselves — in the pages of the *Federal Register*, he neglects to note — the boundaries between state and federal law (with Congress supposedly unaware of these developments).

Vladeck worries that "the FDA does not have the resources to perform the Herculean task of monitoring the performance of every drug on the market" or "single-handedly protect[ing] the American people against defective and dangerous medical devices." *Id.* at 9-10 & 14. His answer is "[s]tate damages litigation," which he believes "helps uncover and assess risks that are not apparent to the agency" in the course of a congressionally mandated FDA approval process. *Id.* at 11. "Above all else," he stated, "Congress should not let the Executive Branch arrogate these decisions to itself and then tell the American people that it is *Congress* that has determined to take away these rights." *Id.* at 25 (emphasis in original).

For the Defense: No Circumscribing Preemption Legislation Is Needed — Congress Speaks for Itself

Taking the opposite view were Mr. Untereiner and Professor Dinh. Untereiner attested to the overriding importance of the preemption doctrine to the national economy and commerce at large. See Untereiner Statement. He began by describing the massive number of local governmental units in the United States — 87,500 — and then explained how preemption "streamlines the legal system, reduces the regulatory burdens on business, and helps to create a unified national marketplace for goods and services," as opposed to the confusing patchwork quilt of conflicting regulation that would otherwise prevail in its absence. *Id.* Taking issue with calls for federal legislation that would sterilize the doctrine of federal preemption, Untereiner testified:

> Contrary to the suggestion of some, the law of federal preemption as it stands today is not in need of radical revision — and, indeed, it would be unwise to place additional limitations on the preemption doctrine, as some have proposed. Such additional limits would impair the ability of Congress and administrative agencies to bring about the many significant benefits that flow from preemptive statutes and regulations.

Id.[4]

Professor Dinh agrees. Proffering the benefit of his constitutional scholarship, he opined that he could find no support for any presumption against preemption. See Dinh Statement.

More specifically, he explained that if Congress prefers to preserve state law, it can either decline to legislate, "preserve state law by including an express savings provision" in legislating, or "enact background rules . . . [expressly governing] how it will preempt state law in the future." *Id*. He cautioned, however, that the latter approach "would upend constitutional supremacy and create a presumption in favor of overlapping regulation by multiple jurisdictions." *Id*. Also, in his view, asking Congress to "predict developments in state common law or anticipate the future legislative agendas of States and localities" would be impossible. *Id.*

Conclusion

This debate will continue to play out, with the next hand — on the scope of FDA medical-device preemption — being dealt by the U.S. Supreme Court this Term in *Riegel v. Medtronic, Inc*. See generally "*The Federalist Papers*: Medical Equipment Makers Take Dispositive Preemption Question to the U.S. Supreme Court," *In re* Products Liability at 1 (July 2007). ◎

4 Untereiner described several benefits of preemption. Among other things, it "reduces the burdens to new entry by small businesses and lowers the cost of doing business (which in turn can result in reduced costs of goods and services to consumers)[; and it] . . . ensures that the legal rules governing complex areas of the economy or products are formulated by expert regulators with a broad national perspective and needed scientific or technical expertise rather than by decision makers — such as municipal officials, elected state judges, and lay juries — who have a far more parochial perspective and limited set of information. *Id.*

Third Circuit Holds State Consumer Fraud Claims Preempted By FDA's Prescription Drug Labeling Regulations

See *Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.*, No. 05-5340, 2007 WL 2376312 (3d Cir. Aug. 17, 2007)

Background

In the first federal court of appeals decision to address federal preemption of claims based upon prescription drug advertising, the Third Circuit recently held that state-law consumer claims brought by a union trust fund (and two individuals), were preempted by regulations promulgated by the Food and Drug Administration (FDA). Plaintiffs in *Pennsylvania Employees* filed a putative nationwide class action against Zeneca and AstraZeneca (hereinafter Zeneca) alleging that Zeneca had engaged in deceptive, unlawful advertising practices under the Delaware Consumer Fraud Act — as well as the consumer protection laws of the other 49 states — in its promotion of Nexium (a proton-pump inhibitor used to treat acid reflux disease). Plaintiffs claimed Zeneca "misleadingly" advertised Nexium as an improvement over Prilosec, another Zeneca pharmaceutical, because the Prilosec patent was set to expire in the near future. *Id.* at *1.

Claims Not Exempted by Provision of Delaware Consumer Fraud Act

The first issue confronted by the Third Circuit was whether the FDA's "approval of prescription drug labeling and regulation for advertising" brought plaintiffs' claims within the Delaware consumer fraud statute's exemption for "advertising or merchandising practice" that otherwise complies with "the rules and regulations[] of [,] and the statutes administered by, the Federal Trade Commission." *Id.* at *2.

As is typical of much state consumer fraud legislation, the Delaware statute at issue in this case expressly proscribes:

> [t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby[.]

Id.

Although the federal district court concluded that Zeneca's conduct was protected against state law proscription — because the advertising at issue "related to the safety and efficacy of Nexium" and was consistent with FDA-approved labeling — the Third Circuit disagreed, holding that the plaintiffs' claims were indeed actionable under Delaware law. In support of this holding, the court cited the limited reach of the state's consumer fraud law exemption — which carved out only "practices that are compliant with *FTC* rules and regulations," not, it held, practices subject to the rules and regulations of the *FDA*, the only agency in fact now responsible for "regulating the advertising of prescription drugs [including Nexium and] independent of any delegation [of authority] from the FTC." *Id.* at * 3 (emphasis added).

Following this strict-constructionist line of reasoning, the Third Circuit declined defendants' invitation to broaden the Delaware statute's reach by allowing its FTC-exemption to reach FDA regulations — since the "FDA is not referenced in [the statutory exemption], nor does the FDA act as a proxy for the FTC in its regulation of prescription drug advertising." *Id.* at *10.

But FDA Regulations Nevertheless Support Implied Conflict Preemption

This detour (regarding the Delaware statute's exemption provision) was all of no moment, however, given that the Third Circuit ultimately upheld the lower court's dismissal of plaintiffs' claims on the basis that they were impliedly preempted by federal law. *Id.* at *6.

Embarking upon an implied-conflict preemption analysis to determine whether Delaware consumer fraud law posed "an obstacle to the FDA's congressionally-mandated [sic] regulation of prescription drug advertising," the court reviewed the FDA's congressional mandate (under the Food, Drug and Cosmetic Act) "to promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" — to the end of ensuring that prescription pharmaceuticals are "safe for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof" (under 21 U.S.C. §§ 393(b), 355(d)). See *id.* at *6.

Finding that the FDA had, "[p]ursuant to its regulated authority over prescription drug advertising[,] . . . promulgated regulations that lay out the specific requirements for advertising prescription drugs," *id.* at *7, the Third Circuit staked the necessary grounding for application of the doctrine of federal preemption on the basis that the FDA requires manufacturers to submit prescription drug advertisements to it when those advertise-

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ments are initially published — coupled with the "degree of discretion" it retains under its regulations in regard to post-marketing monitoring of drug labeling and advertising. *Id.*

State Consumer Fraud Laws Pose Obstacles to Pertinent FDA Regulations

Despite the lack of any explicit preemption provision in either the FDA's enabling legislation or its regulations, the court held that "state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority." *Id.* at *8. Referring to the U.S. Supreme Court's conflict-preemption analysis in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) — where the Court found the "existence of . . . federal enactments [to be] a critical element in [the plaintiffs' case]" and allowed the claims to proceed — the Third Circuit reasoned that the Food, Drug and Cosmetic Act was not "clearly a 'critical element,' *because plaintiffs may not need to show non-compliance with the FDCA in order to prevail.*" *Id.* at *9 (emphasis added). It held that allowing plaintiffs' "claims to proceed would unnecessarily frustrate the [the enabling statute's] purpose and FDA regulations, as the extent of agency involvement in regulating prescription drug advertising is extensive and specific." *Id.*

Finding the requisite "high level of specificity in federal law and regulations with respect to prescription drug advertising" necessary to conclude that "Congress intended to give the FDA exclusive authority to regulate prescription drug advertising," the Third Circuit concluded that plaintiffs' state consumer fraud claims were preempted. Characterizing the FDA's advertising regulations as sufficiently "specific," the Third Circuit concluded:

> To allow generalized state consumer fraud laws to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users. Accordingly, the state consumer fraud laws are preempted by the extensive federal legislative and regulatory framework.

Id. at *10. Put differently, "the purpose of protecting prescription drug users in the [FDA's enabling legislation] would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the validity of statements approved by the FDA." *Id.* at *9-*10.

The Dissent

Circuit Judge Cowan filed a strongly worded dissent taking issue with every aspect of the majority's preemption analysis — echoing in detailed fashion, many of the same points made by the witnesses who took Senator Leahy's position in the hearings he chaired last month as Chairman of the U.S. Senate Judiciary Committee on the subject of "regulatory preemption." See *supra* at 6.

Taking a much more circumscribed view of federal preemption than the majority did, and focusing on the comparative nature of Nexium ads (as allegedly superior to competitor's products), he wrote:

> Given that there are limitations to the FDA's oversight over prescription drug advertisements — both congressionally imposed limitations, such as the lack of authority to require pre-approval . . . and practical limitations attendant to the sheer volume of drug advertisements in the media . . . — the supplementation of state-law remedies would seem to aid the FDCA's objectives and purposes, not frustrate them.

Id. at *14 (citations omitted).

Summary

Circuit Judge Cowan's view pretty much sums up the divide between the proponents of FDA preemption on the one hand, and its opponents, on the other. We summarized this issue in the context of *Riegel* and the pre-market approval of medical devices — a case now before the U.S. Supreme Court — just a few months ago. See "*The Federalist Papers*: Medical Equipment Makers Take Dispositive Preemption Questions to U.S. Supreme Court," *In re* Products Liability at 1 (July 2007) (reprinted in *Mondaq,* on Aug. 30, 2007, and *Product Liability Law 360,* on Sept. 24, 2007).

New York City's Regulatory Response to So-Called "Obesity Epidemic" Fails

See *New York State Rest. Ass'n v. New York City Bd. of Health*, 2007 WL 2593025 (S.D.N.Y. Sept. 11, 2007)

Introduction

Adopted by the New York City Department of Health and Mental Hygiene in December 2006, New York City Health Code § 81.50 ("Regulation 81.50") would require New York City

restaurants (including, especially, chain restaurants such as McDonald's) *voluntarily* making calorie-content information of their menu items publicly available, to make the same information available on their in-store menu boards and menus. *Id*. at *1. The New York State Restaurant Association (NYSRA), representing some 7,000 restaurants, recently challenged the regulation, as expressly preempted by the federal Nutritional Labeling and Education Act of 1990 (NLEA), 21 U.S.C. §§ 301, 343, 343-1 (2006). *Id*.

Granting NYSRA's motion for summary judgment, the Southern District of New York held that the City of New York "has adopted a regulatory approach that puts it in the heartland of [the NLEA] and has subjected its regulation to preemption." *Id*. at *10.

While the litigants argued extensively about the desirability of Regulation 81.50 as an effective means of reducing obesity and improving public health, the legal issue was whether the regulation fell within the City's regulatory province or was instead exclusively a matter for federal regulation. *Id*. at *3. Because the City employed a regulatory approach that imposed different obligations than federal regulation with respect to *voluntary* nutritional claims made by restaurants, the court found Regulation 81.50 preempted by the NLEA. *Id*.

Local Law and Regulation 81.50

Regulation 81.50 would require restaurants that choose to publicize the caloric value of their food to "post on menu boards and menus the calorie content values . . . for each menu item next to the listing of each menu item . . . in a size and typeface at least as large as the name of the menu item or price, whichever is larger." *Id*. at *1. The City claimed Regulation 81.50 was needed to combat, among other things, an "obesity epidemic" in New York. *Id*. at *2.[1] NYSRA objected to the City's "choice of methods for combating obesity," arguing that the NLEA preempts Regulation 81.50. *Id*. at *2, *3. It also contended that by specifying the location and size of such information displays, the regulation would make menu boards confusing and likely have an adverse impact on restaurants to which the regulation applies. *Id*. at *2.

Federal Law and the NLEA

The NLEA was enacted in 1990 "to clarify and to strengthen the Food and Drug Administration's [FDA] legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." *Id*. at *4 (citing 1990 U.S.C.C.A.N. 3336, 3337) (internal citations omitted). The NLEA subsection addressing the making of *voluntary* nutrient content claims, 21 U.S.C. § 343(r), designates a food as misbranded "if a claim is made in the label or labeling of the food which expressly or by implication . . . characterizes the level of any nutrient" unless "the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary." *Id*. at *5 (quoting 21 U.S.C. §§ 343(r)(1)(A), (2)(A)(i)).[2] Pursuant to § 343(r) of the NLEA, the FDA enacted regulations governing nutrient content claims — including uniform descriptor definitions (*e.g.*, "lite" or "contains") and claims describing particular nutrients (*e.g.*, "calorie free" or "reduced sodium"). *Id*. (citing 21 C.F.R. §§ 101.10, 101.13, 101.54-65 (2007)).

Under these FDA-administered regulations, if a restaurant chooses voluntarily to make a nutrient-content claim in labeling its food (including on menus), its claim must comply with FDA regulations. *Id*.[3] The court emphasized that the foregoing applied only to voluntary claims, and that states are not precluded from establishing requirements for mandatory nutritional labeling of restaurant food, since the NLEA itself specifically exempts food served in restaurants from mandatory nutritional labeling. *Id*. at *5-6.

In the end, the fact that New York City's Regulation 81.50 applied only to voluntary claims by restaurant proved its undoing.

Express Preemption under the NLEA

In conducting its preemption inquiry, the court first observed that the NLEA explicitly forecloses the possibility of implied preemption. *Id*. at *4 (the NLEA "shall not be construed to preempt any provision of State law"). Consequently, any preemptive effect would have to be expressly provided for in the NLEA. *Id*.

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1 California, Hawaii, Illinois and Massachusetts have introduced similar nutritional labeling measures. *See, e.g.*, S. 120, 2007-08 Leg., Regular Sess. at § 2(c) (Cal. 2007) (the "California Uniform Retail Food Facilities Law," passed the California Senate on September 12, 2007, requiring that "[e]ach food facility that uses only a menu board shall provide on the menu board the total number of calories per item in a size and typeface that is clear and conspicuous"); H.R. 54, 2007 Leg., 24th Sess. at § 321 (Haw. 2007) ("Menu Education and Labeling Act" would require restaurants to "maintain nutritional information on each standard menu item," including, among other things, calories, grams of saturated fat and trans fat and grams of carbohydrates); H.R. 389, 2007-08 Leg., 95th Gen. Assem. at § 10 (Ill. 2007) ("Menu Education and Labeling Act of 2007" would require restaurants to post a sign stating "Certain foods on the menu may be high in calories, . . ."); S. 1290, 2007-08 Leg., 185th Sess. at § 3(1)(a) (Mass. 2007) ("Menu Education and Labeling (MEAL) Act of 2008" would require restaurants to "provide nutritional information . . . including but not limited to the total number of (1) calories; (2) grams of saturated fat plus trans fat; (3) grams of carbohydrates; and (4) milligrams of sodium").

2 Examples of such claims include "low sodium" or "lite." *Id*.

3 Citing C.F.R. § 101.13(q)(5) ("A nutrient content claim used on food that is served in restaurants . . . shall comply with the requirements of this section.").

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The express preemption provision applicable to restaurants was found in 21 U.S.C. § 343-1(a)(5), which provides that

> *no State or political subdivision of a State may directly or indirectly establish under any authority . . . any requirement respecting any claim of the type described in § 403(r)(1) made in the label or labeling of food that is not identical to the requirement of § 403(r),*

except in circumstances not applicable in the underlying litigation. *Id*. at *6 (emphasis added). As such, states are precluded from establishing requirements for labeling "claims," including those made by restaurants, unless the requirements are identical to federal requirements. *Id*.

After analyzing the NLEA and attendant regulations, the court found that the voluntary disclosure of calorie information by restaurants triggering Regulation 81.50 may be a "claim" (subject to misbranding charges by the FDA) under § 343(r) of the NLEA. *Id*. at *8. In this regard, it observed that "[a]n expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, *e.g.*, 'low sodium' or 'contains 100 calories.'" *Id*. at *7 (quoting 21 C.F.R. § 101.13(b)(1)). The court also referenced the preamble to the enabling regulations, in which the FDA stated "that section [§ 343(r)] of the act and therefore these final regulations apply to statements of the amount of a nutrient in food [*e.g.*, '5 grams fat'] as well as to statements of the level of a nutrient in food [*e.g.*, 'low fat']." *Id*. at *8 (internal citation omitted).

NYC Regulations Inconsistent with Federal Law

In reaching its holding that Regulation 81.50 "seems to impose obligations . . . not imposed by or contained in the federal regulation of nutrient claims under § 343(r)," *id*. at *9, the court first observed that — pursuant to 21 C.F.R. § 101.10 — a restaurant which voluntarily makes a nutritional claim is permitted to publish the nutrient amount that is the basis for the claim "in various forms, including those provided in § 101.45 [shelf labels, signs, posters, brochures, notebooks, or leaflets] and other reasonable means." *Id*.

Regulation 81.50 by contrast, would require a restaurant choosing to make calorie information available also to post the amount of calories "on menu boards and menus," too. *Id*. Further, pursuant to 21 C.F.R. § 101.10, a restaurant may determine the nutrient amount "by any reasonable bases," whereas Regulation 81.50 requires the calories level to be "calculated in accordance with 21 C.F.R. § 101.9(c)(1)(i)." *Id*. Explaining the conflicting duties imposed on restaurants by the NLEA and Regulation 81.50, the court held:

> If a food purveyor chooses to make a nutrient content claim, then it is subjected to mandatory regulations under § 343(r) regarding the nature and content of its voluntary claim. Likewise, if a restaurant chooses to make calorie content information available, then it is subjected to a mandatory requirement under Regulation 81.50 of posting such information on menu boards and menus. *By making its requirements contingent on a voluntary claim, Regulation 81.50 directly implicates § 343(r) and its corresponding preemption provision.*

Id. at *10 (emphasis added).

Conclusion

In short, although New York City has the authority (consistent with the NLEA) to *mandate* nutritional labeling by restaurants, it did so "in a manner that offends the federal statutory scheme for voluntary nutritional claims," by making the *voluntary* disclosure of such information the trigger for its application. *Id*. at *1. As such, Regulation 81.50 was preempted by the NLEA. *Id*.

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N.J. Supreme Court Upends Nationwide Vioxx Cost-Recoupment Class Action on Failure of "Predominance" and "Superiority"

See *International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc.*, __ A.2d __, 2007 WL 2493917 (N.J. Sept. 6, 2007)

Background

As previously reported, see "N.J. Court Affirms Nationwide Class in Vioxx Recoupment Litigation," *In re* Products Liability at 7 (July 2006), a New Jersey trial court certified — and an intermediate appellate court affirmed — a nationwide class action of third-party payors seeking to recover the purchase price of pain medication marketed under the trade name Vioxx. At issue were plaintiffs' claims that Merck had fraudulently misrepresented and concealed information regarding the comparative safety and efficacy of Vioxx to justify premium pricing, thereby forcing plaintiffs to pay higher prescription costs than would have been the case absent Merck's alleged fraud.

On September 6, 2007, the New Jersey Supreme Court

reversed and ordered decertification, finding that the lower courts had erred in holding that "common questions of fact and law predominate." *Id.* at *1.

Factual Overview

This recoupment action was brought by a union trust fund — for itself and similarly situated others — that provided various health-care benefits to its members, including a prescription drug plan. More particularly, plaintiff provided health care benefits to its members through an independent health insurance company which, in turn, outsourced management of the trust fund's prescription drug plan to an independent prescription benefit manager (PBM). *Id.* at *3. Plaintiff's prescription plan, as is so with virtually all such U.S. plans, was governed by the PBM's drug formulary, which lists the prescription drugs covered by the plan and the prices paid for those drugs. Each PBM tasks its own Pharmacy and Therapeutics Committee ("P&T Committee") with reviewing and evaluating the "effectiveness, safety and cost of each available medication" for purposes of developing a formulary. *Id.* at *3.

Plaintiff's Theory of Liability

Plaintiff complained that Merck marketed Vioxx as a safer and more effective alternative to other pain medications in order to inflate its market price relative to competitor products. It supposedly did this "through an aggressive marketing campaign undertaken at a time when defendant [not only] was aware that its product was neither more effective nor safer than other available products," but that Vioxx might actually have been more dangerous than the other available pain medications. *Id.* at *1. In particular, plaintiffs asserted that although (as early as 1998) Merck's clinical studies "demonstrated a link between [Vioxx] and adverse cardiovascular side effects," the company nevertheless "continued its marketing and promotional campaign and concealed those adverse findings" for some six years — "until the product was withdrawn from the market in September 2004." *Id.* at *2.

Lower Courts Agree Certification Emphasizing Defendant's Conduct

In granting class certification, the trial court concluded that the claims presented common questions of fact and law that predominated over any questions affecting only individual members. Specifically, it found that the facts relating to Merck's marketing campaign, alleged suppression of adverse information, and its efforts to have Vioxx included in formularies were common to all members of the proposed class of third-party payors.

While acknowledging that the decision by any particular P&T Committee, PBM, or third-party payor to include Vioxx in its formulary was an "individual one," the trial court largely focused its analysis on Merck's conduct — that is, its supposed broad sowing of fraud generally — to reason itself to the conclusion that the "facts relating to the marketing campaign itself and the information distributed by defendant to those decision-makers was common to all class members." *Id.* at *6. It further found common questions of law to predominate based upon, among other things, its conclusion that New Jersey's Consumer Fraud Act, see N.J.S.A. 56:8-1 to -166, could properly be applied to the claims of all class members — regardless of their residency.

New Jersey's Appellate Division affirmed, chiefly on the view that common questions of law predominated because New Jersey's consumer fraud statute could be applied to the class nationwide. See *Int'l Union of Operating Eng'rs Local # 68 Welfare Fund v. Merck & Co.*, 384 N.J. Super. 275, 350 (App. Div. 2006). In reaching this conclusion, the intermediate appeals court glossed over the individual decision-making processes plainly engaged in by PBMs and class members alike, finding sufficient common questions of fact and law on the belief that the New Jersey's consumer fraud statute's "ascertainable loss" requirement (a proxy for reliance) — and causal nexus — "could be proven on a class-wide basis through expert testimony" alone. *Id.* at *7. Merck then pressed its case to New Jersey's Supreme Court.

New Jersey Supreme Court Reverses by Instead Emphasizing Effect on Plaintiffs

Assuming for appeal purposes only that it agreed with the holdings below that New Jersey's consumer fraud statute could be applied nationally,[1] the New Jersey Supreme Court noted its obligation to "consider, in light of the requirements of our [Consumer Fraud Act], what questions of fact or law are common and whether those questions predominate in the sense required for certification of a class." *Id.* at *9. In the process, the court found not only the requisite "predominance" lacking, but — surprisingly, given typical judicial treatment of the issue — "superiority" as well.

Absence of Predominance

Traveling a road often noted (but rarely taken) by courts, New Jersey's highest court focused its analysis more upon the *class members' exposure and reaction* to defendant's alleged fraud than it did upon *defendant's conduct* (which most courts tend to

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[1] The high court described Merck's arguments for reversal on the choice-of-law question as "strong," but ultimately did not need to reach them given its adjudication of the predominance question. *Id.* at *12, f.3.

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treat rather abstractly, as if it takes place in a vacuum). Along this road, the New Jersey Supreme Court discovered far too much diversity among the members of the proposed class for certification purposes. *Id*. at *9. Summarizing its reconnoitering of the factual landscape, it said:

> The available information makes it plain that [the class members] are a diverse group of entities. *More important to our analysis, however, plaintiff does not suggest that each of these proposed class members, receiving the same information from defendant, reacted in a uniform or even similar manner*. Rather, the record speaks loudly in its demonstration that each third-party payor, relying on PBMs and P&T Committees, made individualized decisions concerning the benefits that would be available to its members for whom Vioxx was prescribed. The evidence about separately created formularies, different types of tier systems, and individualized requirements for approval or reimbursement imposed on various plans' members and, to some extent, their prescribing physicians, are significant. *That evidence convinces us that the commonality of defendant's behavior is but a small piece of the required proofs. Standing alone, that evidence suggests that the common fact questions surrounding what defendant knew and what it did would not predominate*."

Id. at *9.

The Court also accepted Merck's argument that plaintiff's plan to prove "ascertainable loss" on a class-wide basis by "expert analysis alone" — to the effect that Merck's alleged marketing scheme "created an effect on the price of Vioxx" — amounted to an impermissible "fraud on the market" theory under New Jersey law. *Id.* at *10. As such, "the theoretical basis" for plaintiff's common question of law assertion was stripped away.

"Superiority" and a Return to the Original Parameters of Class Actions

Finally, and rather significantly, the New Jersey Supreme Court also applied a "rigorous" analysis to the "superiority" prong of its class action rule — as required by its recent decision in *Iliadis v. Wal-Mart Stores, Inc.*, 922 A.2d 710 (N.J. 2007).

Harking back to the original roots of class actions — as a tool for giving "disadvantaged" litigants or those with small (i.e., negative) value claims access to judicial relief — the Court distinguished the "hourly wage earners" in *Iliadis*, who were seeking compensation for "relatively small units of time" against a "large corporate defendant," from the union trust fund (and others) behind the Vioxx recoupment litigation. On this basis, it found the putative class action lacking in superiority. *Id.* at *11-12. More to the point, it said:

> Unlike the individual wage earners [in *Iliadis*], plaintiff and, by extension, all of the members of the class, allege that they have been damaged in *large sums*. Unlike those hourly wage earners, plaintiff and the other third-party payors are *well-organized institutional entities with considerable resources*. Unlike in *Iliadis*, here we see *no disparity in bargaining power* and no likelihood that the claims are individually so small that they will not be pursued. *In short, we find no ground . . . to conclude that this proposed nationwide class meets the test for superiority that we have traditionally required.*

Id. at *12 (emphasis added).

Welding Fume Litigation Update: Another Blow for Plaintiffs — This Time on Medical Monitoring Claims

See *In re Welding Fume Products Liability Litigation*, ___ F. Supp. 2d ___, No. 1:03-17000, 2007 WL 2701925 (N.D. Ohio Sept. 14, 2007)

Introduction

With thousands of plaintiffs from across the country, a large pool of deep-pocket defendants, and active multidistrict litigation — which at its height encompassed over 10,000 cases — the welding fume litigation seemed poised to become the next asbestos. Only a few pro-plaintiff developments, however, have held against a strong tide of defense rulings and verdicts nationwide, and yet another blow to plaintiffs was delivered on September 14, 2007, when Judge O'Malley — the federal district court judge overseeing the multidistrict litigation — denied certification of a medical-monitoring class action.

The MDL Proceedings

More than four years ago, the Judicial Panel on Multi-District Litigation conferred multi-district status on "welding fume" lawsuits filed in federal court on the ground that welding fume suits allegedly "share[d] factual questions concerning, inter alia, whether exposure to welding fumes cause[d] the conditions complained of by plaintiffs and whether defendants knew or

should have known of any health risks associated with exposure to welding fumes." *Id.* at *1.

As a general matter, these plaintiffs have alleged — on liability theories sounding in strict liability, negligence, fraud, and conspiracy — that: (1) they inhaled fumes produced by welding rods; (2) these fumes contained manganese; and (3) this exposure caused them permanent neurological injuries and other harm. More generally, they uniformly allege that manufacturers, suppliers, and distributors of welding rod products failed to warn plaintiffs of "the health hazards posed by inhaling welding rod fumes containing manganese and, in fact, conspired to affirmatively conceal these hazards from those engaged in the welding process." *Id.* at *1.

After more than four years of litigation, only two MDL cases have been tried, with both producing defense verdicts.

Transfer of the Putative Medical Monitoring Class Action

On January 18, 2006, the Judicial Panel on MDL transferred *Steele v. A.O. Smith* from the Northern District of California to the *Welding Fume* MDL in the Northern District of Ohio. As with the complaints preceding it, *Steele* named a large number of manufacturers, suppliers, distributors, and consumers of welding rods as defendants — alleging negligence, strict liability, fraud, and aiding and abetting claims in connection with their involvement with or movement of welding rod products in the stream of commerce. *Id.* at *2. Unlike other welding fume complaints, however, the *Steele* plaintiffs did not allege existing physical injuries caused by inhaling the manganese or other welding fumes, but medical monitoring claims instead — on the basis that welders:

> have been exposed to welding fumes containing manganese in excess of the [Threshold Limit Value] and will continue to be exposed to manganese in welding fumes, and thereby suffer, and will continue to suffer, *a significantly increased risk of serious neurological and neuropsychological injury*.

Id. at *2 (emphasis added). Abjuring monetary damages, the *Steele* plaintiffs sought a variety of injunctive and declaratory relief — primarily a medical monitoring program to "account for their allegedly increased risk of developing welding-fume-induced brain damage." *Id.* at *2.

The Certification Battle

Urging certification, plaintiffs asserted that common questions of fact and law entitled them to proceed to trial on an aggregate basis. In support, they advanced 17 purported common questions of law and fact including: whether (1) defendants' conduct caused class members to be exposed to manganese in welding fumes; (2) whether defendants' conduct put members at an increased risk of developing neurological injuries in relatives to non-welders; (3) whether defendants intentionally or negligently failed to warn class members of the true risks associated with manganese exposure in welding fumes; and (4) whether defendants engaged in a course of conduct to suppress, conceal or misrepresent facts relating to the dangers of exposure to manganese in welding fumes. *Id.* at *3.

Following a thorough analysis of class certification requirements under the Federal Rules of Civil Procedure, the *Steele* court ultimately denied certification on the basis of plaintiffs' failure to satisfy Rule 23's typicality requirement. Seizing on two elements of any medical-monitoring cause of action — namely, the need to establish that exposure was caused by defendants' negligence and that the exposure generated an increased risk of disease — the court determined that plaintiff's claims involved too many individualized questions of fact and law to merit class certification. More particularly, it reasoned that plaintiff's claims spun far too many atypical generalities that could not be decoupled from plaintiff's assertion that exposure equals risk. This is because:

> [n]ot every exposure to manganese fumes is toxic; the level of exposure is critical to the question of whether an increased risk of illness occurs. [Not insignificantly, too,] the product came with warnings. Thus, whether the defendants were negligent . . . depends not simply on whether any given plaintiff suffered exposure, but on whether the warning supplied by the defendant sufficiently apprised the plaintiff of the risk of exposure. Similarly, whether a given plaintiff suffers an increased risk of illness depends not simply on the fact of welding fume exposure, but on the degree of exposure, and whether there was more exposure than might have otherwise occurred due to the failure of the warning. *These circumstances change dramatically the degree of typicality of evidence and issues among plaintiffs in this case, because of the great variety of products, manufacturers, warnings, employers, and workplaces involved.*

Id. at *19-*20. Closing the analytical circle to deny plaintiffs' motion for class certification, *Steele* concluded that "*there is ultimately no single course of conduct* by all of the defendants [necessarily applicable to all or a majority of plaintiffs]. In sum: there is insufficient typicality." *Id.* at *20 (emphasis in original).

Is The Writing on the Wall for Welding Fume Litigation?

Notwithstanding plaintiffs' efforts to manufacture a welding

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fume epidemic, the future of this litigation seems less than certain. With back-to-back defense trial verdicts, an MDL that has seen the number of claims systematically winnowed from over 10,000 to less than 2,000 claims today, *id.* at *1, and this latest development — defendants would seem to have the advantage. ◎

FORUM NON CONVENIENS

On a "Close Call," U.K. Found to Offer Adequate Alternative Forum for Adjudication of Tainted Blood-Product Claims

See *In re Factor VIII or IX Concentrate Blood Prods. Liab. Litig.*, 484 F.3d 951 (7th Cir. 2007)

Background

The nature of the U.S. legal system — including the availability of jury trials, liberal discovery rules, contingency fees, neglible costs exposure and the availability of generous damage awards (especially punitives) — makes the U.S. court system singularly appealing to foreign plaintiffs. Perhaps more than most nowadays, pharmaceutical defendants have found themselves at the front line of an intense campaign by foreign litigants to gain access to American juries and (through them) corporate purse strings. See generally D. Wallace, *The Commercial Risk of International Trafficking in American-Style Tort Litigation,* Bloomberg's Weekly Law Reporter (Oct. 29, 2007).

In re Factor VIII or IX Concentrate Blood Prods. Liab. Litig. — hereinafter *In re Factor VIII* — highlights the issue. In this litigation, citizens of the United Kingdom, Italy, Germany, Israel, Argentina and Nebraska brought claims in U.S. federal court against the manufacturers of various blood-clotting products. *Id.* at 953. Plaintiffs — hemophiliacs and their spouses — alleged that they contracted either the HIV virus or the Hepatitis C virus from exposure to contaminated blood-clotting products manufactured by defendants. *Id.* at 953-54; see also *In re Factor VIII or IX Concentrate Blood Prods. Litig.*, 408 F. Supp. 2d 569, 570-71 (N.D. Ill. 2006). More particularly, they claimed that defendants (a) failed to disclose the known risks of their products, (b) failed to use available treatments for killing the viruses in the plasma of their products, and (c) continued to export non-heat-treated "factor concentrates" overseas after adopting safer methods for the sale of similar products in the U.S. See *In re Factor VIII*, 484 F.3d at 953.

Defendants moved for dismissal in the district court under the doctrine of *forum non conveniens*. Concluding that the U.K. courts would be a more appropriate forum in which to handle the U.K. plaintiffs' claims, and that its interest in this litigation substantially outweighed that of California (where the case was initially filed), the district court severed the U.K. claimants and granted defendants' motion to dismiss. *Id.* at 953, 959. Calling it a "close call," the Seventh Circuit affirmed. *Id.* at 959.[1]

Alternative Forum's "Unfavorable Law" Not Enough To Avert *Forum Non Conveniens* Dismissal

The starting point for the Seventh Circuit's analysis was the holding of *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 255-56, 266 (1981), in which the U.S. Supreme Court held that an "otherwise appropriate" *forum non conveniens* dismissal should not be rejected simply because it would lead to an application of law unfavorable to plaintiff in the alternative forum (which was plaintiff's rebuttal argument in the *In re Factor VIII* litigation). *In re Factor VIII*, 484 F.3d at 956. Under *Piper*, unfavorable law in the alternative forum is only given substantial or even dispositive weight when the *remedy* it provides is clearly inadequate. *Id.* Ultimately, an alternative forum is deemed adequate "when the parties will not be deprived of all remedies or treated unfairly." *Id.* at 957 (quoting *Kamel v. Hill-Rom Co.*, 108 F.3d 799, 802 (7th Cir. 1997)).

Based on *Piper*, the Seventh Circuit rejected plaintiffs' principal ground for reversal: that the U.K. was not an adequate alternative forum because "the U.K. legal system strictly adheres to the 'but for' principles of causation and does not acknowledge market share or its variants that are available in the U.S." *Id.* (quotations omitted).

In reaching this result, the court found that the decision by the House of Lords in *Fairchild v. Glenhaven Funeral Servs., Ltd.*, (2003) 1 A.C. 32 (H.L.), undercut plaintiffs' argument — since *Fairchild* allowed recovery in an asbestos case, notwithstanding plaintiff's inability to prove which of several prior employers had exposed him to injury-producing asbestos fibers. What is more, it did so by expressly modifying the U.K.'s strict "but for" rules in asbestos litigation. See *In re Factor VIII*, 484 F.3d at 956. While acknowledging that no U.S. court could say for certain whether a U.K. court would extend and apply *Fairchild* to the blood-products claims at issue, the Seventh Circuit explained that the requisite *forum non conve-*

[1] Defendants separately moved to dismiss the claims of the Argentine plaintiffs on June 4, 2007, but the district court has not yet ruled. The claims of the Italian, German and Israeli plaintiffs are still pending.

niens analysis did not require as much. Thus, the district court was within its discretion in finding that, after *Fairchild*, the U.K. courts offer an adequate alternative for the U.K. plaintiffs. *Id*. at 957-58.

Procedural Impediments Unique to U.K. Legal System — Including "Loser Pays" Rule — Not Enough To Avoid Dismissal Either

The Seventh Circuit next rejected plaintiffs' assertion of "extreme impediments" to their ability to fund and run the litigation if it were to proceed in the U.K. — largely due to the sting of the "loser pays" rule[2] — since if it were to find dismissal improper for this reason, it would "risk gutting the doctrine of *forum non conveniens* entirely," the U.S. being one of the few jurisdictions where each party pays its own attorney's fees. *Id*. at 958.[3]

"It Could Have Gone Either Way"

Still, the Seventh Circuit expressed ambivalence about affirming — stating that its ruling "easily could have gone either way." *Id*. More particularly, in balancing the respective U.K. and California interests, the court noted that three defendants were headquartered in California, one defendant had its main manufacturing plant there, and that the plasma collection process took place in California. *Id*. While these were "not trivial local interests" from the court's perspective, what may have tipped the decisional balance for the court was its observation that the U.K. government had shown considerable interest in the plight of hemophiliacs infected with HIV and Hepatitis C from treatment with contaminated blood products, and provided plaintiffs' medical care. *Id*.

Summing up, the court explained:

> In the end, a rational person might come to either conclusion on this record: some might think that the greater interest lies in the place where the companies operated and allegedly committed the wrongs; *others might find a greater interest in the place where the victims suffer from those wrongs and where the financial impact of the consequences will fall.*

Id. (emphasis added). In this case, it was the latter fact that carried the day for defendants.

Conclusion

The *In re Factor VIII* litigation is yet another example of U.S. courts applying the principles of *forum non conveniens* to salutory effect. It prevents courts with little to no nexus to a dispute from becoming mired in a flood of litigation owing more to forum shopping (than it does to bromides about "access to justice"), while at the same time respecting the sovereign right of other nations — through their courts — to set and enforce the legal standards applicable to products sold and consumed within their borders. See generally *In re* Products Liability at 3-5 (Nov. 2006)(discussing the "migratory tort phenomenon" and New Jersey state court's dismissal of Vioxx claims on *forum non conveniens* grounds). ◎

FOREIGN LAWS

A Look Behind the Tide of Foreign Litigants Hitting U.S. Courts: British Pharmaceutical "Group Claim" Founders On Procedural Conditions Attached to Legal Aid Funding

See *Multiple Claimants* v. *Sanifo-Synthelabo Ltd & anr*, [2007] EWHC 1860 (High Ct., Q. B. 2007)

Background

In these pages, we have previously chronicled the continuing push by foreign litigants to prosecute products liability claims in the U.S. court system.[1] More often than not, the doctrine of *forum non conveniens* defeats these efforts. The campaign continues, however, for a variety of reasons — chief among which is the general lack of contingency fees outside the U.S., and the brake it puts on entrepreneurial plaintiff lawyering of the American sort.

While moves are afoot in places abroad to allow private funding of litigation — through contingency fees and variants, such as "success fees" — widespread systemic change is still far off. Although commercial funding outfits stepped into the breach a few years ago in the U.K., the policies they were under-

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[2] In this vein, it might also have mentioned the lack of punitive damages.

[3] In terms of private-interest factors, the court held that the U.K. was an adequate, and preferable, forum for adjudicating the dispute — including (a) the defendants' ability to join as third-party defendants various non-U.S. parties, (b) access to evidence and (c) ease of discovery. *Id*. It found the public-interest factors ultimately a "neutral" point, as the record was essentially "silent about the relative administrative advantages or disadvantages of California and the United Kingdom." *Id*. at 958.

[1] See, e.g., "Citing 'Interests of Justice,' N.J. Court Dismisses British Vioxx Claim on Grounds of *Forum Non Conveniens*," *In re* Products Liability at 3 (Nov. 2006); "A Look Into the Migratory Phenomenon," *In re* Products Liability at 4 (Nov. 2006); see also P. Wilkinson, "Is the Tide Shifting for Foreign Plaintiffs Wishing to Litigate Product Liability Claims in the U.S. Courts?" *Scrip World Pharmaceutical News* (Aug. 2007).

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writing to advance and insure the cost of litigation were subsequently barred by statute due to "considerable consumer detriment."[2] As a result, for the most part, litigants must petition government for legal aid — public funding — in order to cover the cost of running individual or group actions in the civil courts. But without the prospect of winning punitive damages, and against the prevailing backdrop of generally modest compensatory damage awards and governmental budgetary constraints (coupled with exposure to fees and costs under the "loser pays" rule), the risk is often too great even for government to assume.

A current effort in the English courts to litigate products liability claims against the maker of an epilepsy drug sheds some light on the impetus for the push by foreign litigants for access to U.S. courts.

Betwixt a Rock and a Hard Place: The Epilum Case

A group of U.K. claimants seeking damages in the English courts for birth defects allegedly caused by their pre-natal use of Epilum sued Sanifo-Synthelabo Ltd. — makers of an anti-seizure epilepsy drug sold under the brand name Epilum. Acknowledging timely notice of the birth-defect risks associated with the use of Epilum by pregnant women, plaintiffs' liability theory is grounded on the assertion that they had no choice but to take the drug to avoid seizures during pregnancy.

Legal Aid — "Yes, You Have It; No, You Don't; Well Maybe..."

The Legal Services Committee initially agreed to fund their claim through legal aid and a "group claim" was subsequently ordered in August 2006. In an about-face that very same month, however (fearing the potentially massive costs of prosecuting a well-defended pharmaceutical lawsuit), the Legal Services Commission decided to revoke public funding for the suit. Following confidential judicial review quashing the decision, the Legal Services Committee amended its position in May 2007 and agreed to provide limited funding contingent upon preliminary judicial determination of the question whether Epilum is defective within the meaning of the Consumer Protection Act — that is, general causation.

Thereafter, claimants moved for an order allowing their case to proceed on a trial limited to a preliminary testing of plaintiffs' general causation theory (based on a variety of assumptions posited by claimants). More specifically, plaintiffs asked the court to assume that Epilum (a) is not safe for use by pregnant women, (b) is necessary for epileptic women of child-bearing age to prevent seizures, (c) has no safe alternative and, further, (d) that there is no way of knowing in advance whether a fetus will be adversely affected by pre-natal exposure to Epilum.

Trial Court Refuses Preliminary Proceeding As Valueless

This proposal was rebuffed by the trial court, which refused to grant the application for the following reasons:

First, the court deemed the assumptions advanced by claimants to frame a determination of the preliminary issues as too ambiguous, imprecise and simplistic to be litigated fairly and efficiently without the need for leading and evaluating a significant amount of scientific evidence — thereby defeating the claimed procedural efficiencies of the proposed preliminary proceeding. More to the point, in this regard, it said:

> Particularly in a case of such complexity as this, it is necessary that the assumptions are precise and unambiguous. Otherwise, the assumptions provide no adequate foundation for the enquiry, they need to be expanded and explained by evidence and much of the purpose of having preliminary issues is lost. Of course, it is recognized that it might be necessary to supplement the assumptions with some limited evidence, but the more that is required, particularly if it is necessary to have complicated scientific and pharmacological evidence, the less attraction of the proposal for preliminary issues.[3]

Second, the court held that plaintiffs' proposed liability assumptions would not necessarily allow for sufficient judicial scrutiny of the merits of the preliminary issues, and thus rendered the preliminary issues unsuitable. More specifically, and with respect to the defect issue, it stated: "I do not understand that it is suggested that this question is suitable for a preliminary issue by itself. As the formulation indicates, it was designed to present a conclusion from earlier [assumptions and] does not seem to me suitable as a preliminary issue."[4]

Conclusion

As a practical matter, the court's rejection of claimant's proposed procedural shortcut — a position taken by plaintiffs solely to secure government legal aid funding in order to get to a decision on the merits — would seem to defeat the underlying claims at the starting line.

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2 See C. Hodges, *The Americanization of European Civil Justice Systems*, Univ. of Oxford Centre for Socio-Legal Studies at 3 (2006) (available at www.europeanjusticeforum.org) (last visited Sept. 7, 2007).

3 *Id.* at ¶ 48.

4 *Id.* at ¶ 63

Legal Alchemy: "Gross Negligence" and Corporate Manslaughter in Britain

See *Corporate Manslaughter and Corporate Homicide Act 2007* (c. 19) (Eng.)

In the hands of inventive, aggressive plaintiff's lawyers in the U.S., the principle of "gross negligence" can be turned into Monopoly-money punitive damage awards against the manufacturers of consumer products. Beginning next year in Britain, it is possible that the same principle could be used by like-minded Crown prosecutors to charge manufacturers of consumer goods with corporate manslaughter under the Corporate Manslaughter and Corporate Homicide Act 2007.[1]

History of the Bill

Prior to the enactment of this legislation, a company could only be convicted of manslaughter in Britain, if a "directing mind" of the organization — basically a member of the board of directors, the managing director or other senior officers who speak and act on behalf of a company — were also guilty of the offense.[2] This was known as the "identification principle," which required proof of *mens rea* (or a guilty mind) by senior officers — the "directing minds" — and then imputted that state of mind to the company.

One of the perceived shortcomings of the "identification principle" in practice, however, was that it did not permit Crown prosecutors to establish a corporate *mens rea* by aggregating the collective state of mind or knowledge of senior corporate officers.[3] In most cases, especially when dealing with medium- and large-sized companies, there was insufficient evidence to convict the senior officer and, as a consequence, the company could not be prosecuted.

In response, the Law Commission issued a proposal to facilitate the prosecution of corporate entities for involuntary manslaughter under the head of a 1996 report called "Legislating the Criminal Code: Involuntary Manslaughter."[4]

Enter, some years on now, The Corporate Manslaughter and Corporate Homicide Act 2007, which received Royal Assent on July 26, 2007, and enters into force on April 2008. Among other things, the Act does away with the prior requirement that an individual "directing mind" be convicted before a corporate entity could be prosecuted for corporate manslaughter. Instead, liability for the new offense of "corporate manslaughter" in England, Wales and Northern Ireland — and "corporate homicide" in Scotland — turns upon a finding of "gross negligence" by "senior management" in the corporation's operations that is a "substantial element" in causing an individual's death.[5]

The key elements of the offense follow:

- The organization must owe a *"relevant duty of care"* to the victim under the law of negligence, including those owed in connection with the supply of goods or services (whether for consideration or not). Moreover, traditionally exculpatory common law rules, such as primary assumption of risk (or *volenti non fit injuria*), do not apply.
- *"Gross negligence"* is established by evidence, among other things, (a) that the organization failed to comply with health and safety legislation applicable to the product, or (b) that there were attitudes, policies, systems or accepted practices within the organization likely to have encouraged any such failure, or to have produced tolerance of it. Additionally, a finding of "gross negligence" can be supported by consideration of any health and safety guidance notes relating to the alleged breach.[6]

The Costs of Conviction

Upon "conviction on indictment" of corporate manslaughter, the court can impose an "unlimited fine" (Section 1.6).[7] In addition, the court is authorized to issue remedial orders requiring an organization to take specific steps to rectify any management failures found to have proximately caused death by "gross negligence" (Section 9). Finally, the court is empowered to order a convicted organization to publicize — in a manner and by terms specified by the court — the fact of its conviction, the particulars of the offense, the amount of any fine imposed and the terms of any remedial order entered (Section 10).

Looking Forward

While the scope and manner of this Act's eventual enforcement remain to be seen, it certainly merits careful scrutiny.

1 A copy of this statute can be downloaded at http://www.opsi.gov.uk/acts/acts2007/pdf/ukpga_20070019_en.pdf.

2 See *Tesco Supermarkets Ltd v. Nattrass [1972] AC 153*.

3 See *Crown v P & O European Ferries Ltd* [1990] 93 Cr App R.

4 See Law Commission Report (1996): "Legislating the Criminal Code: Involuntary Manslaughter" (LC237, 1996) (available at http://www/lawcom.gov.uk/docs/lc237.pdf).

5 "Senior management, relation to an organization, means the persons who play significant roles in (i) the making of decisions about how the whole or a substantial part of its activities are to be managed or organized, or (ii) the actual managing or organizing of the whole or a substantial part of those activities."

6 "Corporate manslaughter" is "indictable only in the High Court of Justiciary," with trial before a jury (Section 1.7).

7 See Explanatory Notes at ¶ 19.

Et cetera

Publications

- David Wallace will publish "The Commercial Risk of International Trafficking in American-Style Tort Litigation," in *Bloomberg's Litigation Reporter* (Oct. 29, 2007).
- David Wallace and Nicholas Booke will publish "Small is the New Big: Nanotechnology and the Challenge of Doing Business at One-Billionth of a Meter," in *Product Liability Law & Strategy* (forthcoming Nov. 2007).
- David Wallace and Philip Pfeffer published "Eleventh Circuit Holds That Beryllium Sensitization May Be Cognizable 'Injury'" in *Mondaq* (Aug. 30, 2007), which was reprinted in *Products Liability Law360* (Sept. 24, 2007).
- Phoebe Wilkinson published "Is the Tide Shifting for Foreign Plaintiffs Wishing to Litigate Product Liability Claims in the US Courts?" in *Scrip World Pharmaceutical News* (Aug. 17, 2007).
- David Wallace and Benjamin Rubinstein published "The Dispositive Preemption Question," in *Product Liability Law360* (July 30, 2007).
- Phoebe Wilkinson and Gretchen Werwaiss co-authored "Defending Warnings-based Claims Against Manufacturers," in *For the Defense* (July 2007).

Speaking Engagements

- On November 1-2, 2007, Phoebe Wilkinson will be speaking at the Fourth Annual Drug and Medical Device Litigation Seminar, in New York, New York.
- On February 6, 2008, David Wallace will address the topic of "Managing Production in Foreign Countries and Related Global Litigation," at DRI's 2008 Product Liability Conference — *Product Liability in the Global Economy* — in Scottsdale, Arizona.

Appointments

- David Wallace has been named to the Board of Editors of *Product Liability Law & Strategy*, a monthly newsletter published by American Law Media.

***To view the full articles**, please visit Chadbourne's on line publications at http://www.chadbourne.com/publications/index.html.*

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