



PRODUCT SAFETY & LIABILITY



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REPORTER

NOVEMBER 10, 2008

HIGHLIGHTS

U.S. Supreme Court Hears Arguments in Drug Preemption Case

A highly engaged U.S. Supreme Court bench questions lawyers representing drug manufacturer Wyeth, injured plaintiff Diana Levine, and the United States about whether the Food and Drug Administration's approval of Wyeth's Phenergan label impliedly preempts Levine's failure-to-warn claims. Levine, whose arm was amputated due to gangrene that resulted when an intravenous injection of the nausea drug Phenergan inadvertently entered an artery, won a multimillion-dollar judgment that was upheld by the Vermont Supreme Court. Observers tell BNA the tenor of the oral argument did not suggest that the court will render a sweeping preemption ruling. Their predictions range from a narrow, fact-based win for Wyeth to an affirmance of the result favoring Levine. **Page 1116** . . . An Analysis & Perspective article examines preemption cases before the Court. **Page 1133**

Industries Urge CPSC to Exempt Products Without Lead From Testing

Citing the economic ramifications, industry representatives urge the CPSC to exempt from testing products with no lead or with no accessible lead under requirements specified in new lead regulations of the CPSIA. The burden would come from the cost of testing thousands of items that may not need testing, they say. **Page 1123**

Court Grants Judgment for Defense, Says Suicide Warnings Were Adequate

Suicide warnings on the acne medication Accutane were legally adequate under New York law, a federal trial court rules. The court grants summary judgment to defendants Hoffmann-LaRoche Inc. and Roche Laboratories Inc. in a suit by a father whose son committed suicide after treatment with Accutane. **Page 1119**

NuvaRing Defendants Seek Master Complaint in Birth Control Device MDL

Defendants in multidistrict litigation over the NuvaRing contraceptive device ask the court overseeing the MDL to order the plaintiffs to file a master consolidated complaint that would bring together their common claims and liability theories. **Page 1120**

Analysis & Perspective

The U.S. Supreme Court Takes on Four Preemption Cases

For more than two decades, Public Justice has been fighting against preemption. In this Analysis & Perspective, Public Justice staff attorney Leslie A. Brueckner recalls the history of the preemption cases and addresses the issues in matters currently before the Supreme Court, including the just-argued *Wyeth v. Levine* case. The new cases underscore the huge threat posed by federal preemption of plaintiffs' remedies, and the importance of continuing the fight, Brueckner says. **Page 1133**

ALSO IN THE NEWS

COSMETICS: Federal courts in New Jersey and Illinois throw out putative class actions over lead content in lipstick. **Page 1119**

MEDICAL DEVICES: A federal trial court dismisses a lawsuit brought by seven plaintiffs who claimed that their saline breast implants deflated. **Page 1120**

FOIA: A plan to reduce backlogged Freedom of Information Act requests sets goals to speed the time it takes to process agency FOIAs, the CPSC says. **Page 1124**

CRASH TESTS: Under a new European New Car Assessment Programme (Euro NCAP) star rating system, which advises consumers about the safety performance of new cars sold overseas, vehicles must have electronic stability control to score highly. Beginning in 2009, the system will challenge manufacturers to improve safety features as vehicles are subjected to tougher and more comprehensive crash tests. **Page 1126**

RECALL REPORT

LISTING: A compilation of automotive equipment, consumer products, and motor vehicles recalled in October. **Page 1127**

**BNA**

PRODUCT SAFETY & LIABILITY REPORTER

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Product Liability

Phenergan

Supreme Court Hears Preemption Arguments Over Vermont Drug Safety Suit

A highly engaged U.S. Supreme Court bench questioned lawyers for drug manufacturer Wyeth, injured plaintiff Diana Levine, and the United States Nov. 3 about whether FDA approval of Wyeth's Phenergan label preempts Levine's state tort claims, which led to a multimillion dollar verdict affirmed by the Vermont Supreme Court (*Wyeth v. Levine*, U.S., No. 06-1249, argument 11/3/08).

The advocates responded to questions about whether a conflict between federal and state obligations existed at all; whether the FDA actually considered the risk at issue in this case—that a patient could develop gangrene from injection of Phenergan directly into a vein with a syringe, known as the “IV push” method; and what a drugmaker must show in order to change a label.

The tenor of argument did not suggest the court will render a sweeping preemption ruling, experts told BNA. Predictions ranged from a narrow win for Wyeth to affirmance of the Vermont result favoring Levine.

Lawyers for the parties gave the court very different views of the case. “The conflict presented here is stark,” Seth P. Waxman argued on behalf of Wyeth. The FDA approved a label calling Phenergan safe and effective for all uses, yet a state jury concluded the precise wording of the label rendered Phenergan unreasonably dangerous, he said.

Deputy Solicitor General Edwin S. Kneedler argued that the FDA always has required a showing of new risk information to justify a manufacturer's changing a label without prior agency approval.

But David C. Frederick argued for Levine, “The idea that [an approved] label is set in stone for all time misunderstands the way the process works.” He also contended that Wyeth knew by 1970, and certainly by the 1990s, about the dangers of administering Phenergan by IV push.

Cure Worse Than Disease. Levine, a professional guitar player, was given Phenergan at a clinic in April 2000 to combat nausea associated with migraine headaches. A physician's assistant administered it via IV push. The drug entered Levine's artery, leading to gangrene and the amputation of her arm.

A Vermont state jury awarded Levine \$7.4 million, later adjusted to \$6.7 million. The Vermont Supreme Court affirmed the judgment, rejecting Wyeth's argument that FDA actions preempted the claims. The Vermont court said the jury's verdict did not conflict with the labeling requirements for Phenergan because Wyeth could have warned against IV push administration without prior FDA approval.

Wyeth took its case to the U.S. Supreme Court, arguing in its brief that Levine's suit was impliedly preempted for two reasons. First, the company said, it could not comply with both FDA labeling requirements and state tort duties. Second, it said, a state-law duty would stand as an obstacle to the objectives of Congress because Congress intended the FDA to make judgments about a drug's risks and benefits.

'I Don't Understand.' At the outset of Waxman's presentation, Justice Anthony M. Kennedy said, “You argue that it's impossible for Wyeth to comply with the state law and at the same time with the federal label. As a textual matter, as a logical matter, I just—I don't understand that. I think I could design a label that's completely consistent and that meets the requirements that the Respondents wish to urge.”

Justice David H. Souter referred to Kennedy's question—“Where is the conflict?”—and checked with Waxman whether the label was the “standard of conflict” regardless of whether Wyeth tried to change it. That is, he said, “if there is a difference between them, there is a conflict. Am I right about your argument?”

“Yes, you are right,” Waxman responded. He added, “We cannot have a world in which the very day after an intensive [FDA] process, . . . either, A), manufacturers can just run in and change the label . . . or B), that a state jury . . . or 50 state legislatures can decide” to impose a label-changing obligation on manufacturers.

Serious Risk. But Justices Samuel A. Alito Jr. and Ruth Bader Ginsburg both wondered, as Alito put it, “How could the FDA conclude that IV push was safe and effective when on the benefit side of this you don't have a life-saving drug . . . , and on the risk side you have the risk of gangrene?”

Waxman responded that there had been testimony about circumstances in which IV push administration was indicated, and that the labeling was directed at “medical professionals” who would make judgments about what method to use.

As the government began its presentation, Justice Ginsburg asked Kneedler whether the FDA has changed its policy regarding preemption.

Kneedler said, “The FDA, to my knowledge, has never taken a position that, as a general matter, a manufacturer may change a label without the existence of new information that justifies a revision. . . . But we are not arguing for the proposition that tort remedies are preempted as a general matter.” He referred to situations where state and federal standards were the same, for example, cases of drug adulteration.

Justice Antonin Scalia explored the possibility of tort remedies for injuries when a manufacturer failed to bring risk information to the attention of the FDA.

No preemption in that case, Kneedler said.

New Information. The nature of “new information,” which Wyeth and the United States argued was the basis for any unilateral label changes under the “changes

being effected,” or CBE, regulation, occupied several exchanges the justices had with Kneedler and with Frederick.

Justice Stephen G. Breyer asked, “Why isn’t the fact that some . . . number of people are getting gangrene, why isn’t that new information?”

Kneedler answered, “New information means new information about a risk that is greater in severity or frequency.”

Breyer complained that the manufacturer had not raised the issue of new information at trial; “If you simply read the regulation, you won’t find any of all this complicated stuff about certain kinds of new information.” After some exchanges, he warmed to his theme: “[Y]ou say new information of a certain kind would be okay, nobody argued it. You read the reg, and it doesn’t seem to make all these distinctions. End of case.”

Souter asked Frederick, Levine’s attorney, to confirm that he disagreed with the FDA’s position that new information is required to justify a label change.

Frederick answered, “I think that the dispute is [over] what constitutes new information, because we don’t take issue with the notion that new information can be new analysis” of older data.

Consideration of Risk. Scalia and Chief Justice John G. Roberts Jr. questioned Frederick sharply about whether the FDA specifically considered the risks of IV push. “When they determine that it’s safe to use it under those circumstances, that necessarily includes a consideration of the risk,” Roberts said.

But Frederick maintained that “there was no way FDA could have made this determination because the risks of IV push are so catastrophic.”

“Well, you’re just contradicting the label,” Scalia said.

Ultimately, Kennedy asked, “If we conclude that new information is the criterion for deciding this case . . . , can this verdict be sustained?”

Frederick said it could. “Wyeth knew or should have known about [the] comparative risks [of IV push versus an IV drip method of administration]. It should have had a basis for changing its label or proposing to FDA a different label, and that would be sufficient to satisfy the federal standards as well as the state duty of due care.”

In a rebuttal, Waxman stressed that this was not a case of new information because the risk of gangrene from inadvertent arterial contact with Phenergan had been known for years.

Experts Weigh In. “I think things went very well,” said David Vladeck, a professor at Georgetown Law Center who filed a brief in the case on behalf of two former FDA Commissioners, Dr. Donald Kennedy and Dr. David A. Kessler, in support of Levine. “Only two justices seemed opposed to Levine’s position,” he said, referring to Roberts and Scalia.

“The justices were interested, active, and well-prepared,” attorney Andrew Tauber, who practices with Mayer Brown in Washington, D.C., told BNA. Tauber submitted a brief on behalf of the Product Liability Advisory Association Inc., a manufacturers’ association, in support of Wyeth. “Were I forced to make a prediction, I’d say the court is likely to issue a narrowly written decision that upholds preemption.” Tauber said he expects the ruling to be narrow because of the extent of the questioning on such issues as

whether a manufacturer must have new information about risks to change a label unilaterally.

“There’s no question the justices are interested in this case,” said Jayne Conroy, who represents plaintiffs in pharmaceutical cases at Hanly Conroy Bierstein Sheridan Fisher & Hayes LLP in New York, N.Y., and attended the argument. “There was drama in the room. . . . It was more fact-specific than I expected.” She said it went relatively well for the plaintiff.

Andrea Bierstein, also attending from Hanly Conroy, added, “The decision may be carefully drawn and not sweeping,” based on the nature of the questioning.

Attorney James Huston, who has a defense practice at Morrison & Foerster LLP’s San Diego, Calif., office, told BNA after reviewing the transcript, “My prediction is they’re probably going to affirm the Vermont Supreme Court verdict.” He said the justices “seemed troubled by the facts,” which were “good for both sides”: a sympathetic plaintiff and outsized risks, but also an “attractive” preemption argument because Wyeth argued the risk was known and warned against. But he said the court showed interest in a limited form of preemption, such as where the FDA considered the risks at issue. And he said he did not see evidence in this case that the FDA had considered the risks of gangrene from IV push administration.

Observers also highlighted the court’s discussion of what exactly the FDA considered. Justices Samuel A. Alito Jr. and Anthony M. Kennedy were “skeptical of the idea that the FDA specifically considered the risk,” Vladeck said, adding that he thinks Wyeth overstated the degree to which the FDA considered the risk from the IV push method of administration.

Conroy commented, “There seemed to be a lack of common language about what the FDA does or doesn’t do, and . . . that’s at the core of the case. . . . It seemed as though the court could benefit from a more thorough understanding of how the process works.”

FDA oversight, Bierstein said, has been “left behind by the explosion in the pharmaceutical industry.”

In Tauber’s view, the court’s questioning suggested it might find preemption in cases where “there are no allegations that the manufacturer has withheld information from the FDA; the FDA specifically considered the particular risk at issue; and the FDA specifically rejected stronger warnings.” He said he was satisfied that those conditions existed in Levine’s case.

Huston said he doesn’t think the case will bring about much change in pharmaceutical litigation. In a new political landscape, he suggested, Congress could pass a law to reduce the effect of a ruling finding preemption.

Waxman is with Wilmer Cutler Pickering Hale and Dorr LLP in Washington, D.C.

Frederick practices with Kellogg, Huber, Hansen, Todd, Evans & Figel PLLC, also in Washington, D.C.

By MARTINA S. BARASH

Paxil

Court Won't Revisit No-Preemption Ruling But Grants Motion for Interlocutory Appeal

A federal trial court in Pennsylvania refused Oct. 29 to reconsider its earlier decision rejecting a preemption defense in a failure-to-warn suit by parents of a teenager who committed suicide while under treatment with the antidepressant Paxil (*Knipe v. SmithKlineBeecham d/b/a GlaxoSmithKline*, E.D. Pa., No. 06-3024, 10/29/08).

The U.S. District Court for the Eastern District of Pennsylvania, however, granted defendant Glaxo-SmithKline's request for interlocutory review to the U.S. Court of Appeals for the Third Circuit, which has ruled—in a different fact setting—that Food and Drug Administration approval of a drug warning label preempts state tort claims.

Although the court said it does not begrudge the defendant's "repeated and vigorous efforts to dismiss this case on preemption grounds, the simple fact remains that no conflict existed between federal and state law, such that the addition of plaintiffs' proposed warning to the Paxil label prior to September 2002 would have subjected Defendant to some form of sanctions," the opinion said.

Youth Commits Suicide in 2002. Marion L. Knipe and Harold L. Garrison Jr. sued GSK after their 16-year-old son committed suicide in September 2002. The court noted that its Aug. 28 memorandum and order fully and completely explained its rationale for distinguishing *Colacicco v. Apotex Inc.*, 521 F. 3d 253 (3d Cir. 2008), which the U.S. Court of Appeals for the Third Circuit found preemption based on the regulatory history of Paxil, specifically the FDA's determination that the warnings sought by the plaintiffs lacked scientific basis and would be false and misleading (36 PSLR 364, 4/14/08).

At the time Paxil was prescribed for decedent Jake Garrison in September 2002, the Food and Drug Administration had not publicly stated a position regarding a link between pediatric use of the drug—an off label use—and an increased risk of suicidality, the U.S. District Court for the Eastern District of Pennsylvania said. *Colacicco*, therefore, did not control the case, it said (36 PSLR 842, 9/8/08).

GSK sought reconsideration, or, alternatively, certification of an interlocutory appeal.

Refusing to grant reconsideration, the court said, "Defendant now presents nothing other than evidence that could have previously been presented to the Court; requests for the Court to rethink issues over which it has already labored; and attempts to raise new issues with the benefit of hindsight provided by the Court's prior analysis."

Interlocutory Appeal Granted. Under 28 U.S.C. § 1292(b), a non-final order may be certified for interlocutory appeal if the court determines that it: (1) involves a "controlling question of law"; (2) for which there is a "substantial ground for difference of opinion"; and (3) which may "materially advance the ultimate termination of the litigation" if appealed immediately.

The plaintiffs argued that the issue of preemption is fact-intensive and, thus, not a pure question of law amenable to interlocutory review. But this argument disregards the nature of the conflict preemption analysis, which turns precisely on whether two laws or regulations—one federal, one state—conflict. The Third Circuit repeatedly has said preemption, by its nature, lends itself to interlocutory appeals, the district court said. The preemption issue here is undoubtedly a controlling issue of law.

Under the second element, there is a "substantial ground for difference of opinion" about an issue when the matter involves "one or more difficult and pivotal questions of law not settled by controlling authority."

The particular question at issue in this case, whether the FDA effectively preempted a state law claim for failure to warn of the risk of suicide among pediatric Paxil patients—has generated only one other judicial opinion, which found preemption in the face of highly distinguishable facts, the court said, citing *O'Neal v. SmithKlineBeecham Corp.*, 551 F. Supp. 2d 993 (E.D. Cal. 2008) (36 PSLR 137, 2/11/08).

Therefore, this preemption decision involves a rather novel question of law, which the Third Circuit has not yet had the opportunity to address, the court said. "The court would be remiss to ignore the ongoing pendency of nationwide litigation involving this precise issue."

Moreover, the contours of preemption in the context of pharmaceutical litigation generally "remains a pressing and hotly disputed topic," the court said. Given these facts, the court found that a substantial ground for difference of opinion exists.

Third, the court said an interlocutory appeal would materially advance the termination of this litigation.

In light of the wealth of exhibits produced in support of the *Daubert* motions, the court said the trial in this case is likely to be long and complicated. Should the Third Circuit reverse this preemption decision, the case would be dismissed. "In the face of such potentially long proceedings," the court said, "an interlocutory appeal may very well spare time and expense for both court and litigants."

The U.S. Supreme Court heard arguments Nov. 3 in a case involving federal preemption of tort suits against drug manufacturers. (See related story, this issue). However, legal experts suggested the Supreme Court is likely to issue an opinion tied to the facts of that case, which do not involve off-label use of a drug.

Judge Ronald L. Buckwalter wrote the opinion.

The plaintiffs are represented by Bijan Esfandiari, Kate E. Gillespie, Cara Luther, George W. Murgatroyd III, Frances M. Phares, of Baum Hedlund Aristei & Goldman in Los Angeles.

GSK is represented by Andrew T. Bayman, Franklin P. Brannen Jr., Todd P. Davis, Robert B. Friedman, S. Samuel Griffin, Heather M. Howard, of King and Spalding in Atlanta; Cindy K. Benes, Peter D. Braun, Robert E. Glanville, and Thomas S. Wiswall of Phillips Lytle in Buffalo, N.Y.; Mark S. Brown in Washington, D.C.; and Melissa R. Margulies of Lavin O'Neil Ricci Cedrone & Disipio in Philadelphia.

Cosmetics

Lipstick Wearers Did Not Allege Loss Due to Lead Content, Two Courts Say

Federal courts in New Jersey and Illinois threw out putative class actions over lead content in lipstick Oct. 23 and Oct. 28 (*Koronthalay v. L'Oreal USA Inc.*, D.N.J., No. 2:07-cv-05588, 10/23/08; *Frye v. L'Oreal USA Inc.*, N.D. Ill., No. 1:08-cv-00213, 10/28/08).

Judge Robert W. Gettleman of the U.S. District Court for the Northern District of Illinois reasoned that the plaintiff, a woman named Don's Frye, did not allege actual damages in the form of the cost of the lipstick and could not bring an action, under Illinois law, for medical monitoring or the enhanced risk of contracting a disease.

The U.S. District Court for the District of New Jersey denied plaintiff Ruth Koronthalay's motion for reconsideration, reiterating its earlier holding that she could not support an argument that her lipstick had a lower value because of its lead content. She had also "provided no authoritative evidence that the lead levels in [defendant L'Oreal USA Inc.'s] lipstick products constitute a dangerous amount or [are] in some way prohibited." Nor would she be allowed to amend her complaint, the court said.

Gettleman distinguished Frye's case from another decided in the same district, *Stella v. LVMH Perfumes and Cosmetics USA Inc.*, 564 F. Supp. 2d 833 (N.D. Ill. 2008), based on different defense arguments. But "[t]o the extent that the decision in the instant case differs with *Stella*, this court respectfully disagrees with our distinguished colleague," Judge Elaine E. Bucklo, Gettleman wrote.

Frye alleged that she bought and used L'Oreal's "Colour Riche True Red" and "Colour Riche Classic Wine" lipstick, and that these contained levels of lead well above the regulated level for candy and were dangerous. She brought a claim under an Illinois consumer fraud statute, as well as implied warranty, strict liability, and negligence claims (36 PSLR 64, 1/21/08).

These all require that the plaintiff allege actual damages, Gettleman said. Frye alleged she would not have purchased the lipstick had she known of the lead, Gettleman said. "But she does not allege that she would not have purchased lipstick, that she would have purchased cheaper lipstick, or that the lipstick in question had a diminished value because of the lead. Simply put, there is no allegation that the presence of lead in the lipstick had any observable economic consequences," he wrote.

Although the Illinois Supreme Court "has not yet accepted" causes of action for medical monitoring or "enhanced risk," a federal court in Illinois predicted it would uphold a claim for medical monitoring. But that claim would require the plaintiff prove monitoring is "probably, not just possibly, necessary," Gettleman wrote.

Similarly, Judge Dannis M. Cavanaugh, in federal court in New Jersey, said Koronthalay "does not allege facts that could support an argument that the value of Defendants' lipstick products is less because of their lead content. Lost value to her is "a purely subjective allegation of harm," he said.

Daniel R. Lipinski and Philip A. Tortoreti of Wilentz, Goldman & Spitzer PC in Woodbridge, N.J., represented Koronthalay.

Aaron Ross Walner, Lawrence Walner, and Michael S. Hilicki of Lawrence Walner & Associates Ltd. in Chicago, Ill., represented Frye.

James Holsey Keale and others at Sedgwick, Detert, Moran & Arnold LLP in Newark, N.J., and New York, N.Y., represented L'Oreal in the New Jersey action; Anthony J. Anscombe and others at Sedgwick's Chicago office represented the company in Illinois.

Accutane

Court Grants Judgment to Defendants, Says Suicide Warnings Legally Adequate

Suicide warnings on the acne medication Accutane were legally adequate under New York law, a federal trial court ruled Oct. 30, granting summary judgment to Accutane defendants Hoffmann-LaRoche Inc. and Roche Laboratories Inc. (*Snyder v. Hoffmann-LaRoche Inc.*, M.D. Fla., No. 07-1282, 10/30/08).

The U.S. District Court for the Middle District of Florida rejected claims by William Snyder, whose son, Joseph, committed suicide after having used Accutane.

Joseph Snyder's dermatologist, Dr. Robert E. Kalb, first prescribed Accutane to Snyder in February 2000. He completed several courses of Accutane treatment over the next few years, and stopped taking Accutane in April 2003. On Feb. 28, 2005, Snyder committed suicide.

Snyder, asserted various claims, each based on the defendants' alleged failure to warn that Accutane could cause his son to commit suicide.

The defendants sought summary judgment, arguing that the warnings given to Snyder's physician were exactly the same as the warnings the court had held were adequate under Wisconsin law in *Stupak v. Hoffmann-LaRoche Inc.* (35 PSLR 811, 9/3/07).

Standards Under New York Law. The court, which oversees federal multidistrict litigation, observed it must now consider whether the Accutane warnings were adequate according to New York law.

Under New York law, a manufacturer must warn of "all potential dangers in its prescription drugs that it knew, or in the exercise of reasonable care, should have known to exist."

New York courts have adopted the learned intermediary rule, under which a manufacturer's obligation to warn runs to the prescribing physician, not directly to the patient.

Warning Adequacy. A court may hold a prescription drug warning to be adequate as a matter of law if it provides specific and detailed information on the risks of the drug. In considering the adequacy of a warning, a court must examine whether the warning is accurate, clear, and consistent on its face; and whether it portrays with sufficient intensity the risk involved in taking the drug.

According to the plaintiffs, the warnings are not direct, unequivocal and sufficiently forceful to convey the risk of suicide. Snyder argued the defendants' warnings equivocate in stating that Accutane "may" cause depression and suicidal ideation, that emotional instabil-

ity “may bear no relation to therapy,” and that the side effect of suicide is “uncommon” and/or “rarely” occurs.

Moreover, Snyder argued that the statement that “no one knows if Accutane caused these [suicidal] behaviors” dilutes the warning.

But the court disagreed.

The February 1998 warnings specifically caution that Accutane treatment may cause suicide. Statements that Accutane “may” cause suicide, or that such a result “rarely” occurs, do not diminish the seriousness of the warning, the opinion said.

Moreover, updated warnings provided to Dr. Kalb in a January 2001 Dear Healthcare Provider letter, the Informed Consent/Patient Agreement, and the Medication Guide specifically warned that some Accutane patients had ended their own lives despite a lack of depressive symptoms.

Taken as a whole, the warnings clearly, accurately, and consistently conveyed to Dr. Kalb that Accutane might cause suicide, with or without prior symptoms of depression, the court said. The adequacy of the warning entitles defendants to summary judgment on all of the plaintiff’s claims.

Judge James S. Moody wrote the opinion.

Attorneys for the plaintiff included Brian A. Goldstein of Cellino & Barnes, PC, in Buffalo, N.Y.

Defense attorneys included Rafael Cruz-Alvarez of Shook, Hardy & Bacon, in Miami, Fla.

Contraceptives

NuvaRing Defendants Seek Master Complaint In Birth Control Device Multidistrict Litigation

Defendants in multidistrict litigation over the NuvaRing contraceptive device asked the U.S. District Court for the Eastern District of Missouri Nov. 3 to order the plaintiffs to file a master consolidated complaint (*In re NuvaRing Products Liability Litigation*, E.D. Mo., No. 4:08 MDL 1964, motion filed 11/3/08).

Organon USA Inc., Organon Pharmaceuticals USA Inc., Organon International Inc., and Schering-Plough Corp. argued in a memorandum in support of their motion that, “because the allegations in the individual complaints are vague, a master consolidated complaint would give Plaintiffs an opportunity to clearly allege the common causes of action.” Additionally, they said, the filing of a master consolidated complaint will promote the goals of multidistrict litigation by conserving judicial resources, decreasing litigation costs, promoting uniformity of law in pretrial rulings, and serving the convenience of the parties.

Defendants said their request is “simple”; they merely want the court to order plaintiffs to file a single complaint that brings together their common claims and liability theories, the memorandum said. “Master consolidated complaints are commonplace in MDL proceedings, primarily because they facilitate the efficient and fair processing of similar actions through the pretrial phase,” defendants asserted.

At the same time, they said, a master consolidated complaint maintains individual plaintiffs’ rights—it does not “merge” the lawsuits into a single case or change the parties’ rights. A master consolidated complaint merely becomes the “operative” complaint in the

case, and does not dissolve the individual lawsuits, they said.

Additionally, because plaintiffs’ cases involve “virtually identical claims,” requiring defendants to file pretrial motions and responses to each and every complaint will result in redundant filings, defendants argued.

In August, the Judicial Panel on Multidistrict Litigation transferred and consolidated the NuvaRing product liability lawsuits for pretrial proceedings. Judge Rodney W. Sippel, of the Eastern District of Missouri, was assigned to supervise the action (36 PSLR 822, 9/1/08). Numerous plaintiffs had sought consolidation, and the JPML found that their cases shared common fact questions relating to the manufacture, sale, and safety profile of the contraceptive device.

The NuvaRing is a prescription pharmaceutical birth control device that uses hormones to prevent pregnancy. Users of the device have alleged that it caused them to suffer multiple symptoms, including chest pains, irregular heart rhythms, and pulmonary embolisms.

Melissa A. Geist, of Reed Smith LLP in Princeton, N.J.; Barbara R. Binis, of Reed Smith LLP in Philadelphia; and Sonja S. Weissman, of Reed Smith LLP in Oakland, Calif., filed the motion for defendants.

Full text of memorandum is at <http://op.bna.com/hl.nsf/r?Open=mapi-714mq5>

Medical Devices

Claims Against Faulty Breast Implant Maker Dismissed for Lack of Diversity Jurisdiction

The U.S. District Court for the Southern District of Texas Oct. 27 dismissed a lawsuit brought by seven plaintiffs who claimed that their saline breast implants, made by French company Poly Implant Protheses, deflated (*Ewert v. Poly Implant Protheses*, S.D. Tex., No. H-07-3065, 10/27/08).

In an opinion by Judge Ewing Werlein Jr., the court found that it lacked subject matter jurisdiction because there was not complete diversity of citizenship between the parties—at least two of the plaintiffs and Poly’s U.S. distributor, P.I.P./USA Inc., resided in Florida.

Plaintiffs’ first and second amended complaints both named P.I.P. as a co-defendant in the action. When the court pointed out the diversity problem, plaintiffs proposed to amend their complaint yet again. The proposed third amended complaint dropped P.I.P. from the caption and requested damages solely against “defendant” Poly, but continued to refer to defendants in the plural in other parts of the complaint.

The change in the caption alone was not enough to cure the problem, the court said. To determine the identity of the parties, a court looks beyond the caption to the substance of the complaint to see whose conduct is the subject of the claim and against whom the action is alleged, it said.

Here, plaintiffs alleged that Poly “manufactured, marketed, distributed and/or sold” the allegedly defective implants. They also asserted that P.I.P. “marketed, distributed and/or sold” the implants and, additionally, “gave a 10-year warranty.” Also, although plaintiffs’ complaint sought judgment against “defendant,” else-

where in the same sentence they asked the court to require “defendants” to appear and answer.

“The Court gains an impression from all of this that some sleight of hand is being attempted,” it wrote. Although the caption named only Poly, it appeared from the substance of the complaint that plaintiffs also were seeking to hold P.I.P. liable, it said.

If plaintiffs were seeking relief from the Florida company, then there was no diversity of citizenship, the court said. Also, it noted, if plaintiffs were not seeking relief from the Florida company, but the French parent company’s liability was being premised on the Florida’s company’s conduct in the United States on behalf of its parent, then the French company “takes on the Florida citizenship of its alter ego subsidiary,” and diversity was still lacking.

Plaintiffs failed to establish that there was complete diversity of citizenship between the parties; therefore, the court dismissed the action for lack of subject matter jurisdiction.

Charles Rene Houssiere III, of Houssiere Durant in Houston, represented plaintiffs.

Sharla J. Frost, of Powers Frost LLP in Houston, represented Poly.

Medical Devices

Medtronic MDL Special Master Recommends Approval of Common Benefits Attorneys’ Fees

Magistrate Judge Arthur J. Boylan, acting as special master in the multidistrict product liability litigation involving Medtronic Inc.’s implantable defibrillators, Oct. 20 recommended that the court approve a common benefit attorneys’ fees fund of \$18.25 million and distribute the fund among counsel who made common benefit contributions to the litigation (*In re Medtronic Inc. Implantable Defibrillator Product Liability Litigation*, D. Minn., MDL No. 05-1726, report and recommendation 10/20/08).

Boylan’s report and recommendation followed an Aug. 20 hearing at which members of the common benefit attorneys’ fees committee argued in favor of the amount. The committee, appointed May 13, was charged with reviewing and recommending how common benefit attorneys’ fees should be allocated. Boylan said the fund should be distributed as determined by the committee, as stated in a supplemental affidavit filed by attorney Daniel Gustafson Oct. 14.

Claimants in this litigation were individuals who received surgically implanted cardiac defibrillators made by Medtronic. The company recalled the defibrillators pursuant to a Food and Drug Administration field action, based on the possibility that certain models were subject to premature battery depletion.

Medtronic announced the settlement of the litigation related to its “Marquis” line of implanted cardiac defibrillators on Dec. 21, 2007. The company specifically agreed to pay \$18.25 million into a fund designated for common benefit attorneys’ fees. The attorneys’ fees fund is completely separate from a fund designated for claims resolution.

Single Objection. Only one claimant objected to the distribution of the common benefit attorneys’ fees fund, Boylan said. He dismissed her objections, holding that

the negotiation of the separate fee agreement was not unethical, nor was the amount unreasonable. Boylan was “persuaded that common benefit counsel dedicated time and resources sufficient to support the size of the fees claim in light of discovery and document review, depositions, court appearances, briefing on non-dispositive and pre-emption motions, selection of bellwether cases, extensive settlement negotiations, and claims administration duties.”

Additionally, the special master said contingent fee arrangements between claimants and attorneys entitled to share in the common benefit attorneys’ fees fund should not be disturbed, although he would limit contingent fees to 33 and one-third percent. Boylan said he saw no “compelling reason” to undertake the “chore” of surveying various retainer agreements, and would presume the arrangements reasonable so long as they did not exceed one-third of the gross award allocated to the claimant.

The common benefit attorneys’ fee committee is chaired by Dan Gustafson, of Gustafson Gluek PLLC in Minneapolis. Other committee members are: Charles S. Zimmerman, of Zimmerman Reed PLLP in Minneapolis; Diane Nast, of RodaNast PC in Lancaster, Pa.; Gale Pearson, of Pearson, Randall & Schumacher PA in Minneapolis; Richard J. Arsenault, of Neblett Beard & Arsenault in Alexandria, La.; Neil Overholtz, of Aylstock, Witkin & Sasser PLC in Pensacola, Fla.; Nicholas J. Drakulich, of the Drakulich Firm in San Diego; Yvonne Flaherty, of Lockridge Grindal Nauen PLLP in Minneapolis; and Kenneth M. Seeger, of Seeger Salvas LLP in San Francisco.

Full text is at <http://op.bna.com/hl.nsf/r?Open=mapi-7kwnmt>

Contrast Dyes

District Court Remands Gadolinium Cases To State Court, Rejects ‘Misjoinder’ Claims

A removed complaint that contains product liability claims against diverse medical device makers and medical malpractice claims against nondiverse defendants must be remanded to state court, the U.S. District Court for the Northern District of Ohio ruled in two separate decisions Oct. 21 and Sept. 12, refusing to apply the doctrine of “fraudulent” or “procedural” misjoinder to salvage federal jurisdiction (*Rodriguez v. Tyco Healthcare Group LP*, N.D. Ohio, MDL No. 1909, No. 1:08-GD-50327, 10/21/08; *Geffen v. General Electric Co.*, N.D. Ohio, MDL No. 1909, No. 1:08-GD-50212, 9/12/08).

According to the court, the doctrine of fraudulent misjoinder may apply when a plaintiff tries to defeat the federal court’s diversity jurisdiction by alleging, in the same complaint, claims against nondiverse party defendants that are unrelated to claims alleged against diverse party defendants.

But the doctrine is not universally accepted in the federal courts, the court said. In two separate opinions by Judge Dan Aaron Polster, the court said the fraudulent misjoinder doctrine has been adopted by only one circuit, that a number of other federal courts have “outright rejected” it, and that there are myriad reasons not to adopt the doctrine.

Nephrogenic Systemic Fibrosis. Both cases were transferred to the Ohio-based district court as part of multi-district litigation involving gadolinium-based contrast agents used in medical imaging procedures. The plaintiffs, Udele Rodriguez and Priscilla Geffen, alleged that they developed Nephrogenic Systemic Fibrosis (NSF) after they received injections of contrast agents made by various defendants, including Mallinckrodt Inc., Tyco Healthcare Group LP, Covidien Inc., and General Electric Co.

In addition to stating various product liability causes of action against the medical device makers, the complaints filed in state court alleged medical negligence claims against the clinics and physicians who administered the contrast agents. The clinics and physicians were residents of the same states as the plaintiffs.

The device company defendants removed the actions to federal court based on diversity jurisdiction. Under federal procedural rules, federal courts have jurisdiction over actions between citizens of different states where the amount in controversy exceeds \$75,000. However, there must be complete “diversity” in such cases. In other words, none of the defendants can have a common residency or citizenship with any of the plaintiffs.

Rodriguez and Geffen each moved to remand their cases to state court on the basis that complete diversity was lacking in both lawsuits due to the presence of the clinic/physician defendants. Mallinckrodt opposed remand on the basis that the nondiverse defendants had been fraudulently joined or that the claims against them had been fraudulently misjoined solely for the purpose of defeating federal jurisdiction.

Removal Improper. As an initial matter, the court remanded Rodriguez’s claims to Texas state court because the device company defendants did not obtain consent of all defendants before removal. The rule of unanimity requires all defendants to agree prior to removal, and a failure to show such consent results in a defective removal, the court said. Additionally, the court found that Rodriguez had not fraudulently added the nondiverse defendants to the action.

The *Rodriguez* court also rejected Mallinckrodt’s fraudulent misjoinder argument, citing its earlier decision in *Geffen*. Geffen was a California citizen, as were all three “medical” defendants, and she originally filed her suit in California state court.

The Ohio federal court explained Mallinckrodt’s theory: that the medical malpractice claims asserted by Geffen against the medical defendants should not have been alleged in the same complaint as the products liability claims asserted against the manufacturer defendants because the medical malpractice claims were factually and legally distinct from the products liability claims. Mallinckrodt asserted that the two sets of claims ought to be severed, with the court retaining jurisdiction over the products liability claims but dismissing or remanding the medical malpractice claims.

Fraudulent Misjoinder Theory. The court noted that this theory of “fraudulent misjoinder” first was articulated in a subsequently abrogated Eleventh Circuit decision and has been adopted by only one federal circuit court, the Fifth Circuit. The Northern District of Ohio’s governing circuit, the U.S. Court of Appeals for the Sixth Circuit, has not adopted the doctrine of fraudulent mis-

joinder, it said, and the few district courts within the Sixth Circuit that have addressed it have reached divergent conclusions. Federal district courts throughout the country—including those in California—either have declined to apply the fraudulent misjoinder doctrine or have rejected it outright, the court added.

Absent controlling Sixth Circuit authority, the Northern District of Ohio opted not to adopt the doctrine. “Conducting fraudulent misjoinder analysis in this case necessarily requires the Court to wade into a thorny thicket of unsettled law; disagreements exist as to numerous questions about the doctrine, and ‘the last thing the federal courts need is more complexity,’” it wrote.

“Whether to apply the doctrine in the first place, whether the doctrine requires egregious misjoinder or some other level of bad faith before it can be invoked, whether to apply state or federal joinder law, and whether a federal court should be deciding issues of state joinder law in the first instance are among the unresolved inquiries the Court declines to decide here,” it said.

The “better course of action,” the court concluded, would be to allow the state court to rule on the propriety of the joinder under the state’s joinder law. The California court “is in the best position to determine” whether Geffen’s medical malpractice claims properly were alleged in a complaint that also alleged product liability claims against the manufacturer defendants, it said.

Absent a finding of fraudulent misjoinder, the court said it was left with a complaint alleging viable claims against both diverse and nondiverse defendants. Under such circumstances, the court had no subject matter jurisdiction, it said, remanding the action to California state court.

In the *Rodriguez* case, David Abrego, of the Law Office of David Abrego in Corpus Christi, Texas; and Arthur Gonzalez, of Brent Coon in Corpus Christi, represented Rodriguez.

Kathleen Anne Frazier and Elmore James Shepherd III, of Shook Hardy & Bacon LLP in Houston; and Deborah A. Moeller, of Shook, Hardy & Bacon LLP in Kansas City, Mo., represented the manufacturer defendants.

Jay H. Henderson, of Cruse Scott Henderson & Allen in Houston, represented defendant Radiology & Imaging of South Texas LLP.

In the *Geffen* case, Christina A.L. Fountain, Ramon Rossi Lopez, and Jason Edward Ochs, of Lopez McHugh, Newport Beach, Calif., represented Geffen and her husband, Joel Geffen.

Stephanie Achsah Hingle and Deborah C. Prosser, of Kutak Rock, Los Angeles, and Heidi L. Levine and Christopher M. Strongosky, of DLA Piper in New York, represented the GE defendants.

Deborah A. Moeller, of Shook, Hardy & Bacon in Kansas City, Mo.; and Frank C. Rothrock and Thomas A. Woods, of Shook, Hardy & Bacon in Irvine, Calif., represented Mallinckrodt. John C. Kelly, of Carroll Kelly Trotter Franzen & McKenna in Long Beach, Calif., represented the nondiverse defendants.

Full text of *Rodriguez* is at <http://op.bna.com/hl.nsf/r?Open=mapi-7kwsq2> on the Web.

Full text of *Geffen* is at <http://op.bna.com/hl.nsf/r?Open=mapi-7kwsqx>

Product Safety

Consumer Products

Lead

Industries Urge CPSC to Exempt Products Without Lead From Testing, Cite Economics

Representatives of industries that will be required to comply with new lead regulations urged the Consumer Product Safety Commission Nov. 6 to exempt from testing products that have no lead, or no accessible lead.

They cited harrowing economic ramifications from the cost of testing thousands of items that may not need it.

Frederick Locker, attorney with Locker Greenberg & Brann, said CPSC should address how to avoid testing materials that are not at risk.

People are facing a "tremendous regulatory burden" and they do not know what is expected of them, Locker said. While toys have always been regulated, the Consumer Product Safety Improvement Act of 2008 (CPSIA) has come as a shock to other industries, he added.

Locker and others made their comments at a CPSC meeting on lead requirements mandated by the Consumer Product Safety Improvement Act of 2008.

Congress, in the CPSIA, mandated that the agency make allowances for certain products, Locker said. Those allowances should be addressed up front, and should not be done piecemeal, he added.

The potential for harm to the economy is very significant, Locker said, because of the costs to manufacturers.

The main goal of industries, whether they are the toy, electronics, or fabric industries, is to eliminate the risk to children, Locker said. However, the problem is defining where there is a risk and where there is no risk.

Most Electronics Not Children's Products. Chris Cleet, director of Environmental Affairs for the Information Technology Industry Council gave a presentation on lead in electronics, and said that most electronics are not children's products.

Lead is used because it has a specific purpose or use. "We've gotten lead out of a lot of applications, but not all of them," Cleet said.

"The big question," according to Cleet, is whether the industry can get lead in electronics down to 600 parts per million, 300 ppm, or 100 ppm. "We just don't know at this point whether we can get it down further," he said.

The electronics industry has spent significant resources minimizing or eliminating the use of lead in electronics, Cleet said. Most remaining lead use in electronics is covered by the EU RoHS Directive (Restriction of the use of certain Hazardous Substances in electronics).

The RoHS sets lead levels at 1,000 ppm for a couple of reasons: because a total avoidance of lead is impossible to achieve; and because the level was considered to ensure a high level of protection, Cleet said.

He recommended that CPSC develop an exemption process for specific uses of lead, relying on the EU RoHS exemptions. He also said CPSC and industry should coordinate to further develop the ASTM F963 standard.

Low Lead Use in Apparel Industry. A representative of the American Apparel & Footwear Association (AAFA) said that lead does not exist in fabrics, although it may be present in other components of a garment, such as buttons, and could be in the shanks and steel toes of footwear.

AAFA members already are testing components, such as zippers and buttons on children's clothing for lead. AAFA Executive Vice President Steve Lamar noted that the industry has developed guidance.

He recommended that the statute exclude items where there is no lead contamination. Lamar pointed out that a 100 percent cotton T-shirt does not have any lead, yet manufacturers are being told they have to test for lead. CPSC also should require testing at the component level, and not the entire product, he said.

A button could be tested for lead, requiring a limited number of tests. However, if the test is applied to garments, then the manufacturer must send 40 garments to be tested. When fabrics and dyes and yarns are added to the mix, thousands of tests could be required. Such testing would become an incredible burden and strain the capability of industry laboratories, Lamar said.

It is important for CPSC to revisit the implications of retroactivity for inventory. "It is difficult and extraordinarily costly to assure that products are compliant with a standard we didn't know about when we contracted out," Lamar said.

Products in the apparel industry have about a one-year lead time. When there is less than a year it is difficult to plan for. The sooner manufacturers can get clear written guidance, the better it will be, Lamar added.

CPSC Seeking Information. CPSC staff is seeking comments from industry on children's products and electronics, including:

- what products or components have lead content of more than 600 ppm (or 300 ppm or 100 ppm);
- what lead-containing components are inaccessible;
- what products already comply with other standards or regulations for lead content; and
- whether it is technologically feasible for electronic devices to meet the lead content limit.

The CPSC Web site provides information on the CPSIA, including frequently asked questions about lead in children's products.

The current lead paint is limited to 600 parts per million for children's products. But those levels will drop to

meet deadlines mandated by the CPSIA. Some key dates include:

- Nov. 12, after which general conformity certification under the lead paint ban is required for manufactured products;
- Dec. 21, after which third-party testing and certification is required for products under the lead paint ban;
- Feb. 10, 2009, after which children's products may not contain more than 600 parts per million of lead, and a general conformity certification is required;
- March 2009, third-party testing and certification required for children's metal jewelry;
- Aug. 14, 2009, after which children's products may not contain more than 300 ppm of lead and not more than 100 ppm *if technologically feasible*; and lead-containing paint must be reduced to 90 ppm.

Memorandum on Inventory. Manufacturers and retailers will be prohibited from selling any children's products—including items in their inventory—that exceed mandated lead limits after a new law goes into effect in February 2009, CPSC announced in a Sept. 12 memo. General Counsel Cheryl A. Falvey wrote the memorandum in response to a request by Acting Chairman Nancy A. Nord for guidance on product inventories, which arose from a Sept. 3 meeting on the Consumer Product Safety Improvement Act of 2008 (Public Law 110-314) (36 PSLR 902, 9/22/08). Part of that meeting's discussion addressed how the law will apply to stock inventory, and whether provisions of the act will apply retroactively (36 PSLR 853, 9/8/08).

"While Congress may never explicitly state that the lead ban applies retroactively to inventory, it did not condition the applicability of the lead ban to products manufactured after a certain date as it did in other sections of the statute," Falvey said in the memo. However, read as a whole, the CPSIA suggests that the statutory provisions on lead limits apply to inventory, she added.

The act makes it illegal for anyone to "sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product" that is banned under the Federal Hazardous Substances Act, the memo said.

A member of the audience said that it is not possible, as a practical matter, to eliminate inventory in that time, adding that it would also have a catastrophic economic effect.

Additional information on various aspects of the CPSIA can be found on the CPSC Web site at <http://www.cpsc.gov>.

BY ELLEN BYERRUM

FOIA

CPSC Freedom of Information Plan Aims To Speed Response to Backlogged Requests

A plan to reduce backlogged Freedom of Information Act requests sets goals to speed the time it takes to process agency FOIAs, according to a Consumer Product Safety Commission document posted on its Web site Oct. 28.

Since January, CPSC has taken steps to implement an electronic FOIA processing application (FOIAX-

press) and new document scanning procedures, the document said.

The backlog reduction plan updates information in an Aug. 1 CPSC memo to Clay Johnson, chairman of the President's Management Council (36 PSLR 784, 8/18/08).

In November 2007, CPSC said it expected to receive approximately 4,500 FOIA requests each year for the next three years. At that time, the agency said its goal was to process 4,575 FOIA requests each year, FY 2008 through FY 2010, which would address some of the backlog.

Federal agencies were directed by a December 2005 executive order (E.O. 13392) to take a number of steps to help improve their internal operations for responding to FOIA requests. The steps included appointing high-level FOIA officers and public liaisons, establishing FOIA service centers at each agency to assist requesters, and submitting reports to the attorney general and the Office of Management and Budget on how well each agency handles FOIA requests.

An Electronic System. The FOIAXpress process is now automated—from the receipt of the request to its completion—according to the plan. The requests are forwarded electronically to the program offices, and the response is submitted back to the FOIA office electronically as well.

At first, the staff "learning process" on the automated system "temporarily and significantly slowed down our processing, thereby creating an increase in the backlog," the plan said.

However, after completing the initial and follow-up training, "everyone involved with usage of the new system is proficiently utilizing the system as intended," the document pointed out.

"In addition to being more efficient, the automated system also provides accountability for all FOIA requests processed because it maintains an activity log which describes all actions and individuals involved with the processing of a request," the plan said.

In addition, the CPSC FOIA reduction plan anticipates:

- reducing the allotted response time for program offices to the FOIA office from 10 to seven working days;
- reducing the backlog [from a backlog of 220 in December 2007] to 200 by Dec. 31, 2008; and
- focusing efforts on the oldest requests.

The CPSC Freedom of Information backlog reduction plan is available at <http://www.cpsc.gov/library/foia/foia102808.pdf>.

Import Safety

China Orders Increased Inspections Of Animal Feed for Traces of Melamine

BEIJING—China's government has ordered tightening of quality checks on animal feed, after officials acknowledged that feed products are routinely tainted with melamine—the inedible chemical blamed for a spate of illnesses and deaths in recent months.

In a statement posted on the agency Web site Nov. 1, the head of the Ministry of Agriculture announced that the ministry would increase in frequency and number of tests performed on feed for melamine. Though government regulations bar adding melamine to animal feed and human food, testing up until now has been limited or nonexistent.

The government is changing that practice, however, after melamine was found in eggs first in Hong Kong, then later in mainland China—apparently a by-product of melamine-laden feed given to chickens. Melamine, a plastic binding agent, falsely boosts protein content in tests and hence allows producers to earn more with diluted nutrients. The chemical was blamed for thousands of dog and cat deaths in North America last year, linked back to Chinese-made pet food.

“The ministry will tighten its supervision of the feed industry and crack down on producers who add melamine to their products,” Wang Zhicai, director of the livestock division of the agency, said in the Web statement.

This summer and fall, government agencies have admitted that nearly 60,000 children were sickened with kidney ailments caused by melamine-tainted infant formula. Four children died. As government regulators struggled with the crisis, which spread through the dairy industry to other milk products, tainted eggs were found in Hong Kong.

In comments reported by the government’s Xinhua news agency, Agriculture Minister Sun Zhengcai, however, said the tainted eggs were an anomaly and not a widespread concern.

“The tainted eggs were found in some batches of egg products made by certain manufacturers,” Sun said.

Still, Wang said, China will step up content testing on animal feeds under a regulation implemented after the pet food scandal last year. The rules limit the amount of melamine allowed in animal feed to 2 milligrams per kilogram.

BY KATHLEEN E. McLAUGHLIN

Product Recalls

Fabric Coating, Children’s Toys Recalled For Respiratory, Lead-Exposure Hazards

The Consumer Product Safety Commission announced recalls Nov. 4 of a fabric spray that can pose a serious respiratory hazard to consumers, and children’s toys made in China and Hong Kong that violate the federal lead paint standard.

The Sherwin-Williams Co., of Cleveland, Ohio, is recalling an estimated 75,000 units of Krylon “Outdoor Spaces” UV fabric protector, which is an aerosol coating used to protect fabric.

The company received one report of a consumer who experienced coughing and difficulty breathing that required overnight hospitalization, CPSC said.

The Krylon fabric protector comes in a tan, 11-ounce aerosol can. Part number 2900 is printed above the UPC (724504029007) on the side of the can. The product was sold at Wal-Mart, Ace Hardware, and other retail stores nationwide from January 2006 through September 2008 for about \$7.

Consumers may return the Krylon to the store where it was purchased for a full refund.

Toy Xylophones. King Import Warehouse, of Dallas, Texas, is recalling about 144 toy xylophones made in China because the surface paint contains excessive levels of lead.

The miniature toy xylophone, item KW20119, measures about 12 inches long by 5 inches wide. It has a lavender frame, a lavender mallet, and four bars which are orange, yellow, green, and white. The toy was sold at Dollar Zone “giant,” Sam 99 Cent Store, and 99 Cents Mart in Texas from December 2007 through February 2008 for about \$1.

The stores are offering a replacement toy.

TV Toys. OKK Trading, of Los Angeles, Calif., is recalling approximately 2,100 “Mini-Telesvisor” toys made in Hong Kong because they contain excessive levels of lead.

This plastic TV toy has a microphone and is powered by two AA size batteries. The toys were sold at OKK Trading’s Web site at www.okktoys.com from July 2008 through September 2008 for about \$1.

CPSC advised consumers to contact OKK Trading for a refund or an exchange.

Motor Vehicles

Defects Investigations

NHTSA Upgrades Toyota, Hyundai Probes; Opens Investigation of Dual-fuel Ford F-150s

The National Highway Traffic Safety Administration has intensified probes of Toyota Sienna minivans and Hyundai Santa Fe sport utility vehicles for steering problems, according to federal documents released Nov. 4.

The agency also has opened a preliminary investigation of Ford-150 trucks that run on compressed natural gas to address gas leaks that present a fire risk.

Corrosion Related to Steering Problems. The agency upgraded to an engineering analysis (EA) an investigation of 2004–2006 Toyota Sienna vehicles (EA 08-024) because the vehicles could experience steering intermediate shaft binding; corrosion of the steering intermediate shaft universal joint; or increased effort to turn the steering wheel.

The agency’s Office of Defects Investigation opened a preliminary probe (PE 08-041) in July in light of five complaints about 2004 models, alleging steering binding or increased steering effort caused by corrosion of steering shaft universal joints (36 PSLR 696, 7/21/08). Reports noted that the problem got worse over time, resulting in the steering suddenly binding during a turn.

Toyota told ODI that a combination of thermal damage and subsequent water intrusion could lead to corrosion of the lowermost universal joint installed on the steering intermediate shaft of the vehicles.

The 2004–2006 model vehicles have been the subject of 80 complaints and 914 warranty claims for steering

intermediate shaft replacement. No injuries or crashes have been reported.

An ODI assessment of complaints showed that approximately two-thirds of the complaints were for noise only; a similar evaluation of warranty data showed that 88 percent were related to noise.

Toyota told NHTSA it has made production changes since September 2006 to address the concerns and issued two technical service bulletins. The company has not, however, determined that a safety defect exists in the steering system. The automaker provided test data to NHTSA showing that the effect on steering is minimal, even for parts with relatively severe corrosion, ODI said.

ODI said it upgraded the investigation to conduct tests assessing the effect of the alleged defect on steering.

Approximately 585,000 vehicles are under investigation.

Steering Concerns Plague Hyundai Santa Fe. A similar problem plagues 2001–2003 Hyundai Santa Fe SUVs. ODI said the left or right rear suspension trailing arm could fail as a result of corrosion, leading to a loss of vehicle control.

The agency opened PE 08-040 in July—which also included the Toyota Sienna vans—in light of six complaints alleging failure of the rear suspension trailing arm.

In response to a request for more information, Hyundai provided ODI with 15 reports of corrosion failures, all of which alleged loss of vehicle control. Similarly, ODI has received 12 complaints of rear trailing arm failure, of which four reported loss of vehicle control.

All of the vehicles have been operated in “salt belt” states. No crashes or injuries have been reported.

Hyundai told NHTSA that it implemented a design change in the 2003 model year to address the corrosion issue. The scope of the investigation (EA 08-023) extends to approximately 100,000 vehicles manufactured in the 2001–2003 model years and sold in salt belt states.

Fuel Leaks From Regulator. ODI also has opened an investigation (PE 08-063) of Ford F-150 dual-fuel vehicles that operate on either conventional gasoline or compressed natural gas (CNG). The agency said it has received complaints of CNG leaks from the regulator from four of a fleet of 2003–2004 Ford F-150 dual-fuel trucks. The CNG regulator is located in the engine compartment of the truck. Leakage of CNG, particularly in an enclosed area, is a fire or explosion risk. CNG also is toxic to humans.

The preliminary probe involves about 50,000 vehicles.

Crash Tests

European Group Unveils New Rating Plan; Stability Control a Must to Earn Five Stars

The European New Car Assessment Programme (Euro NCAP) Nov. 5 rolled out a new star rating system to advise consumers about the safety performance of new cars.

The new ratings, in the form of a single overall star safety rating, replaces the current star ratings in use since 1997. Based on a five-star system, the new system presents manufacturers with tougher challenges to earn higher scores than the current ratings, according to a Euro NCAP news release.

With implementation of the new rating system in early 2009, vehicles tested by the organization will undergo tougher and more comprehensive assessments. The ratings are expected to provide the simplest and clearest information to consumers about the safety performance of their vehicles, Euro NCAP said.

“There is no doubt that this new overall rating will provide clear challenges to industry, but at the same time it will create opportunities for manufacturers to be rewarded for their dedication to safety,” said Michiel Van Ratingen, Euro NCAP secretary-general.

For example, a new car will no longer be able to get five stars in a tested vehicle (the highest rating for safety) without electronic stability control (ESC) as standard equipment. The reasoning: Data show that “ESC plays such a major role in reducing deaths on our roads, Euro NCAP believes no car should be able to achieve five stars without it,” the group said. The first ratings for vehicles tested under the new rating system will be released in February 2009.

Established in 1997 and backed by seven European governments, the European Commission, and automotive and consumer organizations in every European Union country, Euro NCAP says it has become a catalyst for encouraging significant safety improvements in new car designs.

Ratings Reflect Protection, Crash Avoidance. An overall rating will be taken from scores achieved in four areas of assessment: adult occupant protection, child occupant protection, pedestrian protection, and a new area, safety assist.

Safety assist will provide insight into the effectiveness of driver-assistance systems and active safety technologies, which are playing an increasingly important role in crash avoidance and injury mitigation.

To achieve a good result, vehicles will need to do well in each evaluation area, the group said. But consumers interested in a particular area of assessment, such as adult occupant protection, or child occupant protection, will be able to compare different vehicles because the individual scores that make up the overall rating will also be available on the Euro NCAP Web site.

The group already has begun testing seats of vehicles crash tested in 2008 to gauge their performance in rear impact and whiplash protection. Starting with the 2009 system, the whiplash test will be automatically included in the Euro NCAP adult occupant protection evaluation.

Euro NCAP expects to release the results for these whiplash tests Nov. 26.

Tests are released quarterly and can be found at <http://www.euroncap.com>.

Recall Report

OCTOBER 2008

This listing summarizes safety recall campaigns issued in October. Manufacturers and distributors conduct their recalls in conjunction with the Consumer Product Safety Commission or the National Highway Traffic Safety Administration. For a complete listing of recalls reported, refer to the Table of Recalls in PSLR's Index.

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GE Toasters

Approximately 210,000 General Electric toasters recalled because an electric short circuit can occur between the heating element and the bread cage, which poses a fire and electrical shock hazard to consumers (36 PSLR 969, 10/6/08). *Manufacturer:* Made in China and imported by Wal-Mart Stores Inc., Bentonville, Ark. *Models:* The recalled toasters—models 169115 and 169116—have a chrome steel body, a black plastic base, and controls with either two or four openings in the top. They were sold at Wal-Mart Stores nationwide from September 2007 through July 2008 for between \$17 and \$28. *Corrective Action:* Wal-Mart stores are offering a full refund or replacement toaster.

IKEA Chests

About 5,000 "KVIBY" chests recalled because the glass drawer knobs can break either during assembly or in use (36 PSLR 969, 10/6/08). *Manufacturer:* Made in Denmark and imported by IKEA Home Furnishings, Conshohocken, Pa. *Models:* The KVIBY chest is white, with four drawers and six glass knobs, article number 201-080-90 with a date stamp of 0817. The chests were sold at IKEA stores nationwide from August 2007 through July 2008 for about \$300. *Corrective Action:* CPSC advised consumers to contact IKEA to receive free replacement knobs and screws by mail.

Amusement Rides

About 85 "Yo-Yo" amusement rides across the country recalled for inspections and repairs following reports of two incidents that resulted in injuries to children and adults, including scraped knees and back strains (36 PSLR 993, 10/13/08). *Manufacturer:* Chance Rides Manufacturing Inc. (CRM), Wichita, Kan. *Models:* The Yo-Yo amusement ride is designed to spin riders in the sky in self-loading swings. *Corrective Action:* CRM is offering ride owners and state safety officials inspection/repair kits and new inspection and maintenance guidelines.

Rechargeable Batteries

About 13,000 rechargeable batteries recalled because they can overheat, which poses a fire hazard to consumers (36 PSLR 992, 10/13/08). *Manufacturer:* Made in China and imported by Coby Electronics Corp., Lake Success, N.Y. *Models:* The rechargeable batteries were sold with the TF-DVD 1020 portable DVD/CD/MP3 players at discount, electronics, music, toy, and office supply stores, and distributors of electronic products nationwide. The units were sold from May 2007 through July 2008 for about \$168. *Corrective Action:* CPSC advised consumers to contact the firm to arrange for a free replacement battery.

Girls' Sandals

An estimated 11,000 pairs of girls' sandals recalled because the ornamental flowers on the sandals can detach, which poses a choking hazard to young children (36 PSLR 992, 10/13/08). *Manufacturer:* Made in China and imported by Rack Room Shoes Inc., Charlotte, N.C. *Models:* The white sandals are leather with attached leather flowers and were sold under the Kids Feet name in girls' sizes 5 through 12. They were sold at Rack Room Shoes stores nationwide from February 2008 through June 2008 for about \$25. *Corrective Action:* The shoe stores are offering consumers a refund or store credit.

Play Sets

Approximately 500 outdoor play set gliders recalled because the instructions failed to say that all lock nuts should be tightened during assembly, including those attached by the manufacturer. As a result, some lock nuts were not fully fastened, which can cause the glider to detach and pose a fall hazard to children (36 PSLR 992, 10/13/08). *Manufacturer:* Made in China and imported by Backyard Play Systems LLC, Monroe, Mich. *Models:* The green plastic gliders were sold as an accessory to home play equipment marketed under the brand names Heartland Play Systems, Yardline Play Systems and Backyard Play Systems. The play sets were sold by Backyard Buildings and More and Lowe's stores nationwide, and online at Costco.com, BettyMills.com, and BackyardBuildings.com from February 2008 through July 2008 for about \$100. *Corrective Action:* Backyard Play Systems is notifying all customers directly and

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Continued from previous page

providing written instructions indicating the location of all lock nuts that must be securely fastened.

Gas Vent Dampers

An estimated 45,000 automatic gas vent dampers recalled because they could fail and leak carbon monoxide (CO), and lead to CO poisoning, which can be deadly (36 PSLR 1032, 10/20/08). *Manufacturer:* Effikal LLC, Orion, Mich. *Models:* The recall involves Effikal RVGP-PC Gas Vent Damper size 4, 5, 6, 7, 8, 9, or 10 installed with a variety of gas boiler systems. The items were sold by plumbing and heating wholesale distributors to plumbers and contractors nationwide from August 2007 through July 2008 for between \$1,000 and \$4,000 for the boilers. Gas vent dampers were sold as part of the gas boiler systems. *Corrective Action:* CPSC advised consumers to contact their installer to confirm they have a recalled vent damper and to receive a free vent damper replacement.

Wireless Headsets

About 525,000 wireless headsets in the United States and 675,000 sold outside the United States recalled because an internal short circuit can cause the lithium-ion polymer batteries to overheat, posing a fire hazard (36 PSLR 1064, 10/27/08). *Manufacturer:* GN Netcom Inc., Nashua, N.H., and battery manufacturer Amperex Technology Limited (ATL), Hong Kong. *Models:* The headsets are GN9120 wireless headsets with ATL lithium-ion polymer batteries. The headsets are intended primarily for professional use in offices and call centers. The product is sold with three components: a base station, headset, and power adapter. The affected batteries have part number 603028 and have a white plastic enclosure. The batteries are labeled "Made by ATL (Amperex Technology Ltd.)" and "(ATL P/N 603028)." Batteries sold as a replacement part are labeled "GN9120 battery replacement kit." *Corrective Action:* GN Netcom is providing a replacement battery.

Toy Speed Boats

About 200,000 battery-operated toy "speed boats" recalled because the two terminals can come into contact with each other, causing the battery to overheat, which poses a burn hazard to consumers (36 PSLR 1064, 10/27/08). *Manufacturer:* Made in China and imported by Dollar General Merchandising Inc., Goodlettsville, Tenn. *Models:* The recalled toy speed boats are lightweight plastic toy boats supported by an inflatable hull with "outboard" motors on them. The motor uses two AA batteries. The toy boat measures about 12 inches long by 8 inches wide and comes in various colors and designs. The toy was sold at Dollar General nationwide from March 2008 through July 2008 for \$3 each. *Corrective Action:* CPSC advised consumers return the toys to the store where purchased for a refund or replacement product.

Generator Fuel Valves

Approximately 13,000 Chinese-made portable generators because their fuel valve can be damaged by the

cover plate during shipment and can cause a fuel leak and fuel spillage during use, which poses a fire hazard (36 PSLR 1064, 10/27/08). *Manufacturer:* Made in China and imported by General Power Products LLC, Loveland, Ohio. *Models:* The recall includes the General Power Products 6000 Watt portable generator and the Poulan Pro 6000 Watt portable generator with serial numbers 060400483 through 060600725. The items were sold at hardware and home improvement stores primarily in Illinois, Indiana, Louisiana, Ohio, and Texas from June 2008 through September 2008 for between \$600 and \$800. *Corrective Action:* The commission advised consumers to contact General Power Products to determine if the generator's fuel valve is damaged and to arrange for a free repair kit and instructions.

Convertible Cribs

About 2,000 convertible cribs recalled because the mesh sides of the crib expands and creates a gap between the mattress and the side through which an infant can slip. This poses suffocation and entrapment hazards for young children (36 PSLR 1065, 10/27/08). *Manufacturer:* Made in China and imported by Playkids U.S.A. Brooklyn, N.Y. *Models:* The recall involves the Playkids U.S.A. convertible crib/playpen/bassinet/bed with model number PLK-909. "Playkids U.S.A." can be found on the packaging and on a label sewn into the side of the crib. The model number can be found on the packaging. The cribs were sold in juvenile product retailers in New York from March 2007 through September 2008 for about \$100. *Corrective Action:* Playkids USA is providing a full refund.

Wireless Guitars

An estimated 57,000 wireless guitars recalled because a circuit board defect can cause AA batteries used in the guitar to leak if the batteries are installed incorrectly, posing a risk of chemical burns to consumers. *Manufacturer:* Made in China and distributed by Performance Designed Products LLC, of Sherman Oaks, Calif. *Models:* The Rage Wireless Guitars are blue or white and 31 inches long. The guitar contains battery-operated LED-lighted fret buttons that go up the neck. They were sold at mass merchandisers and specialty retailers nationwide from June 2008 through September 2008 for between \$40 and \$60. *Corrective Action:* Consumers were advised to return the guitars to the place where purchased for a full refund, and not to contact or return the product to Nintendo.

Gas-Fired Boilers

Approximately 4,600 gas fired boilers recalled because they can leak gas, posing a fire hazard to consumers. *Manufacturer:* Viessmann Manufacturing Co., Canada. *Models:* The recall involves the Vitodens 200 boiler, which are white, wall-mounted and have Viessmann and Vitodens 200 printed on the exterior in silver letters. They were sold by plumbing and heating contractors nationwide from January 2002 through December 2007 for between \$4,000 and \$7,500. *Corrective Action:* Consumers were advised to contact their certified heating contractor or Viessmann for a free replacement of the boiler's O-ring.

Folding Game Chairs

About 1,700 folding game chairs recalled because the retaining washers on the legs can loosen, causing the chair to become unstable, which poses a fall hazard to consumers. *Manufacturer:* Made in China and imported by Brunswick Bowling & Billiards Corp., Lake Forest, Ill. *Models:* This recall involves the Colonial model folding wooden chairs for use with game tables. The chairs have a black seat cushion and either a cherry or chestnut finish. They were sold by authorized Brunswick dealers nationwide from March 2007 through March 2008 for about \$400 per set. *Corrective Action:* Consumers were advised to contact the dealer where the chairs were purchased to schedule a free repair.

Children's Jewelry

An estimated 12,000 children's ball and heart necklaces, portable CD players, and MP3 Players recalled because surface coatings on these products could contain excessive levels of lead, violating the federal lead paint standard. *Manufacturer:* Made in China and imported by Tween Brands Inc., New Albany, Ohio. *Models:* This recall involves a Ball and Heart Necklace with pink beads of varying sizes and a pink heart located in the center; a Portable CD Player with flowers and dots available in blue and pink; a pink MP3 Player with purple, green, blue, yellow, and red hearts; and a light blue MP3 Player with a picture of a monkey's face on the front. They were sold at Limited Too and Justice retail stores nationwide, the Limited Too catalog (catalog), and on www.limitedtoo.com from May 2007 through August 2008. The Ball and Heart Necklace sold for about \$8, the Portable CD Players sold for about \$25, and the MP3 Players sold for about \$55. *Corrective Action:* Limited Too or Justice stores are providing for a full refund and a coupon for a 15 percent discount off a future purchase.

Nerf Toys

An estimated 330,000 Nerf N-Strike Recon Blasters recalled because the plunger plunger can pull the user's skin during firing resulting in injury to the face, neck, and/or chest. *Manufacturer:* Made in China and imported by Hasbro Inc., Pawtucket, R.I. *Models:* This recall involves the Nerf N-Strike Recon CS-6 Blasters for children age 6 and up. The toy blaster is yellow with a black handle and orange plunger, trigger, and reload clip. The word "NERF" in black lettering is on both sides of the blaster and the word "ARMED" is indented on the orange plunger. The toys were sold at Wal-Mart, Target, Toys "R" Us, discount stores and toy stores nationwide from November 2007 through August 2008 for about \$20. *Corrective Action:* Consumers were advised to contact Hasbro for a free cylindrical cover to prevent additional injuries.

Bar Magnets

About 400 bar magnets recalled because surface paints on the magnets contain excessive levels of lead, which violates the federal lead paint standard. *Manufacturer:* Home Science Tools, Billings, Mont. *Models:* This recall involves Alnico 3-inch long bar magnets. Painted red and blue, the magnets were originally packaged as a pair or as a component of a science kit. The magnets were sold as item number MG-BAR3AL, by Web

retailers and by mail order between May 2008 and September 2008 for about \$6. *Corrective Action:* Home Science Tools are providing replacement magnets.

Battery Chargers

An estimated 5,300 battery chargers recalled because the plastic portion of the unit's power plug can crack or detach, posing an electrical shock hazard to consumers. *Manufacturer:* Made in China and imported by Fujifilm U.S.A. Inc., Valhalla, N.Y. *Models:* The recalled BC-50 battery chargers were included with the Fujifilm FinePix F100fd digital cameras and are identified by the production lot codes WCAA and WCAB. The battery chargers were also sold separately as an optional accessory for the FinePix F100fd and F50fd digital cameras with production lot codes of WBAD and WFBA. Battery chargers packaged with the Fujifilm Finepix F50d digital cameras are not included in the recall. They were sold at camera and photo supply retailers nationwide from March 2008 through September 2008 for about \$60. *Corrective Action:* The firm is providing a free replacement charger.

Baby Walkers

About 800 baby walkers recalled because they violate the baby walker voluntary standard and can fit through a standard doorway and are not designed to stop at the edge of a step. Babies using these walkers can be seriously injured or killed. *Manufacturer:* Made in China and imported by My Way Corp., San Juan, Puerto Rico. *Models:* Sold for babies 6 months and older, the walkers were sold in pink, red, green, blue, and ivory. "My Way Corp." is printed on a sticker on the front of the walker. The walkers were sold at independent discount stores in Puerto Rico from November 2004 through March 2008 for between \$18 and \$25. *Corrective Action:* Consumers were advised to return walkers to the store where purchased for a full refund.

Gas Grills

Approximately 47,000 gas grills recalled because they can be assembled improperly exposing the gas burner hoses to excessive heat, posing fire and burn hazards to consumers. *Manufacturer:* Keesung Manufacturing Co. Ltd. and Unisplendor Corp., of China, and imported by Fiesta Gas Grills, Dickson, Tenn. *Models:* The recall involves Blue Ember liquid propane (LP) or natural gas outdoor grills. The cabinet style grill has two doors and is silver-colored and black or silver-colored and gray. "Blue Ember" is printed on the grill's hood. They were sold at various home centers and retailers nationwide from November 2007 through June 2008 for about \$450. *Corrective Action:* If the hose is to the rear of the installed heat shield, the grill has been improperly assembled and consumers should contact Fiesta for replacement hoses, assembly instructions, and if necessary, for assistance in examining the grill.

Riding Mowers

Approximately 2,100 riding lawn mowers recalled because the two-piece fuel tanks on the riding mowers can separate at the seam, causing fuel to leak, which can pose fire and burn hazards to consumers. *Manufacturer:* Briggs & Stratton Power Products Group LLC, Wauwatosa, Wis. *Models:* The Murray front engine riding lawn mowers were sold at various riding lawn

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mower dealers nationwide from April 2008 through September 2008 for about \$950. *Corrective Action:* The dealer is providing a free repair.

Multipurpose Lighters

About 24,000 multipurpose lighters recalled because they fail to meet federal safety standards and because they might not contain a child-resistant mechanism, posing a potential fire and burn hazard to young children. *Manufacturer:* Made in China and imported by YMCA Trading Inc., Maspeth, N.Y. *Models:* The recalled Gas Match lighters have either a multicolored red/white, blue/white or green/white plastic body, and a silver-colored metal nozzle. Each lighter measures 10 inches long. The recalled Ready, Aim, Fire lighters have either a solid black, blue, red or green plastic body, and a silver-colored metal nozzle. Each lighter measures 9 inches long. They were sold at retail stores in New York State from August 2008 through October 2008 for about \$1. *Corrective Action:* Consumers were urged to contact YMCA Trading to arrange for return of the lighter for a refund.

Bicycle Wheels

Approximately 275 sets of racing bicycle wheels recalled because the rim surface and spoke hole plugs on the wheel can cause a puncture to the inner tube, resulting in a flat tire, which can cause the rider to lose control and fall. *Manufacturer:* Made by Shimano Components SDN, Johor, Malaysia, and imported by Shimano American Corp., Irving, Calif. *Models:* The Shimano Dura Ace Carbon Clincher Wheel Sets with model number WH-7850 C24CL were sold for road racing bicycles. The rim has labels that read Shimano WH-7850, Dura Ace, and Carbon 1380. They were sold at bicycle specialty stores and dealers nationwide from April 2008 through August 2008 for about \$1,300. *Corrective Action:* Consumers were advised to remove the wheels, and return them to their local bike dealer or retailer for a free inspection and repair.

Batteries and Recharging Station

An estimated 35,500 rechargeable batteries and recharging station for Didj Custom Gaming System recalled because they can overheat if the gaming system is placed into the recharging base upside down, posing a burn hazard to consumers. *Manufacturer:* Made in China and imported by LeapFrog Enterprises Inc., Emeryville, Calif. *Models:* The Recharging Station comes with two rechargeable batteries, an AC adapter, and a recharging base, and was sold as item 30676. It was sold at department stores and toy stores nationwide and on www.leapfrog.com, and other online retailers from July 2008 through October 2008 for about \$35. *Corrective Action:* Consumers were advised to contact LeapFrog for a full refund.

Computer Adapters

About 1,300 Duracell 130W Combo Power Adapters used with notebook computers recalled because the adapter can fail and overheat, which poses a burn

hazard to consumers. *Manufacturer:* Made in China and imported by Battery-Biz Inc., Camarillo, Calif. *Models:* This recall involves the Duracell 130W Combo AC/DC adapters, models EA10900, AC-6501, and DRUM130, with date codes 0804 and 0805. They were sold at www.dell.com and www.duracelldirect.com from February 2008 through March 2008 for between \$80 and \$120. *Corrective Action:* Battery-Biz has sent a direct notice to consumers with recalled power adapters.

Treadmills

An estimated 19,000 treadmills recalled because they can speed up unexpectedly while in use due to a malfunction with the lower control board, posing a fall hazard to consumers. *Manufacturer:* Cybex International Inc., Medway, Mass. *Models:* The recall involves the Cybex 445T, 455T, 530T, 450T, 500T, 515T, and 520T treadmill models. The treadmills are black and gray with rectangular uprights. The 530T style treadmill is 81 inches long by 32 inches wide. The 445T style treadmill is 72 inches long by 32 inches wide. They were sold at Cybex International and Cybex dealers nationwide from January 2001 through September 2008 for between \$5,500 and \$7,000. *Corrective Action:* Cybex is directly contacting known purchasers.

Wooden Toys

Approximately 1,000 wooden toys recalled because small parts can detach and break from the toy, posing a choking hazard to young children. In addition, the size of the rattle handle violates voluntary rattle standards. *Manufacturer:* Made in India and imported by Earth Friendly LLC, Beaverton, Ore. *Models:* This recall involves three models of wooden toys. Moe the car, Cubby the stackable bear, and the Bell rattle. The toys are painted in glossy red, orange, green, red, black and yellow. They were sold at toy specialty stores in Alaska, California, Colorado, Montana, Nevada, Oregon, and Washington from April 2008 through September 2008 for between \$12 and \$22. *Corrective Action:* Consumers were advised to contact Earth Friendly to exchange or refund the product.

Chain Saws

About 370,000 chain saws recalled because the chain brake can fail to stop the chain on its first application, posing a risk of laceration to consumers. *Manufacturer:* Made in China and imported by Homelite Consumer Products Inc., Anderson, S.C. *Models:* This recall involves Homelite brand chain saws, models UT10514, UT10516, UT10517, UT10518, UT10520, UT10540, UT10560, and UT10918. Affected chain saws have manufacture date between November 2007 and August 2008. They were sold at Home Depot stores nationwide between December 2007 and October 2008 for between \$110 and \$200. *Corrective Action:* Consumers were advised to contact Homelite Consumer Products to locate the nearest authorized service center to schedule a free repair.

Kitchen Mixers

An estimated 54,500 kitchen mixers recalled because they can unexpectedly turn on, activating the blade, which poses a serious laceration hazard to consumers. *Manufacturer:* Made in China and imported by

MEDport LLC, Providence, R.I. *Models:* This recall involves Fit & Fresh Smooth Blend Mixers with item number 770FF and model number SB-19. The white mixers have a base unit, blade assembly, blending cup and cap. They were sold at Longs, GNC and Vitamin Shoppe stores nationwide and at www.amazon.com from September 2007 through August 2008 for about \$2. *Corrective Action:* CPSC advised consumer to return the product to the place of purchase or contact MEDport LLC to arrange for a refund.

Printer Power Adapters

Approximately 17,000 power adapters used with printers recalled because the adapters can fail, causing the printer to overheat, and posing a burn hazard to consumers. *Manufacturer:* Made in China and sold by DYMO, Stamford, Conn. *Models:* The external power adapters were sold with the DYMO LabelWriter 400 series printers: DYMO LabelWriter 400, DYMO LabelWriter 400 Turbo, DYMO LabelWriter Twin Turbo, DYMO LabelWriter Duo, and DYMO Desktop Mailing Solution, with housing date code 2407, 2507, 2607, or 2707. They were sold by office supply stores, discount retailers, and various specialty retailers nationwide from September 2007 through October 2008 for between \$100 and \$250. *Corrective Action:* Consumers were advised to contact the firm to receive a free replacement external power adapter kit.

Computer Batteries

An estimated 35,000 lithium-ion batteries used in notebook computers recalled because they can overheat, posing a fire and burn hazard to consumers. An additional 65,000 batteries were sold worldwide. *Manufacturer:* Sony Energy Devices Corp., Japan. *Models:* The recalled batteries were included with, and sold separately, for use in Hewlett-Packard, Toshiba, and Dell Notebook Computers, through computer and electronics stores nationwide, and through various Web retailers for between \$700 and \$3,000. The batteries were also sold separately for between \$100 and \$160. *Corrective Action:* Consumers were advised to contact their computer manufacturer to determine if their battery is included in the recall and to request a free replacement battery. Consumers may use the AC adapter to power the computer until a replacement battery arrives.

MOTOR VEHICLES

Subaru Vehicles

Approximately 16,700 Subaru vehicles recalled because the cylinder head-side oil supply pipe and turbocharger-side pipe may have been improperly assembled. The assembly glitch could cause oil to leak, which could lead to engine fires (NHTSA Recall #08V-460) (36 PSLR 973, 10/6/08). *Manufacturer:* Subaru. *Models:* 2009 Forester, 2008 Impreza, and 2007–2008 Legacy vehicles. *Corrective Action:* Dealers will inspect for cracks or an oil leak and install an additional bracket to increase the rigidity of the pipe. Dealers will replace the pipe assembly with a modified part.

Nissan Vehicles

More than 204,000 Nissan passenger vehicles recalled to fix an air bag malfunction. A semiconductor in the passenger seat cushion could have been manufactured incorrectly. The glitch can cause an interruption of the signal between the OCS and the air bag control unit. The result could be suppression of the air bag, illumination of the air bag warning light, and inadequate occupant protection in a crash (NHTSA Recall #08V-521) (36 PSLR 1036, 10/20/08). *Manufacturer:* Nissan North America. *Models:* Nissan Infiniti EX35, G35 sedan, and G37 coupes, and Nissan 350Z, Altima, Murano, and Rogue vehicles from the 2007–2008 model years, equipped with Continental Automotive Systems. The vehicles were manufactured between March 12, 2007, and May 27, 2008. *Corrective Action:* Dealers will test the signal between the OCS and the air bag control unit and replace the seat cushion, which contains the OCS hardware, with a new cushion that has been manufactured to specifications.

Cadillac SUVs

Approximately 17,300 Cadillac SRX midsize sport utility vehicles recalled because the vehicles can shift suddenly from “park,” causing a rollaway hazard if the vehicle is parked on an incline (NHTSA Recall #08V-527) (36 PSLR 1036, 10/20/08). *Manufacturer:* General Motors Corp. *Models:* 2004 Cadillac SRX SUVs with automatic transmissions. *Corrective Action:* Dealers will replace the pawl stopper and a bushing within the shifter assembly.

Kawasaki Motorcycles

Approximately 5,800 Kawasaki motorcycles recalled to fix turn signals that can break, which increases the risk of a crash. The turn signal stalk(s) can break, causing the signal assembly to hang by the wire harness (NHTSA Recall #08V-520) (36 PSLR 1036, 10/20/08). *Manufacturer:* Kawasaki Motors Corp. *Models:* 2008 Kawasaki KL650E8F and KL650E8FL (California) motorcycles. *Corrective Action:* Dealers will replace all four turn signal assemblies.

Hyundai Elantra Vehicles

An estimated 161,000 Hyundai Elantra vehicles recalled to address air bag wiring problems stemming from cupholder spills and items placed under the vehicles' front seats that can lead to air bag failures (NHTSA Recall #08V-532, NHTSA Recall #08V-533) (36 PSLR 1066, 10/27/08). *Manufacturer:* Hyundai Motor Co. *Models:* Two recalls of the same group of vehicles with air bag wiring issues affecting a total of 150,954 model year 2001 and 2002 Hyundai Elantra vehicles produced from June 30, 2000, through Dec. 18, 2001. *Corrective Action:* Dealers will install a protective cover over the air bag control module connector, new side air bag wiring harness connector clips, and revised wiring harness attachments under the drivers' and front-passenger seats.

Chrysler SUVs

Approximately 3,700 Chrysler SUVs recalled because the parking brake lever clutch drum could distort and reduce the effectiveness of the parking brake, allowing the vehicle to move inadvertently and crash (NHTSA

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Recall #08V-525). *Manufacturer:* Chrysler LLC. *Models:* 2007–2008 Dodge Nitro and 2008 Jeep Liberty vehicles equipped with manual transmissions. *Corrective Action:* Dealers will replace the parking brake lever assembly free of charge.

Monaco Motor Homes

An unknown number of Monaco motor homes recalled because they fail to comply with the safety standard on lamps. The middle side marker lights are nonreflective (NHTSA Recall #08V-539). *Manufacturer:* Monaco Coach Corp. *Models:* 2009 Monaco Coach Camelot. *Corrective Action:* Dealers will install a reflector at the midpoint of the sides of the coach.

Damon Sport Motor Homes

Approximately 435,00 Damon motor homes recalled because a nut that retains the steering drag link to the Pitman arm may have been improperly torqued during assembly, increasing the likelihood of damage to the castle nut and compromised integrity of the connection. This could lead to problems with the directional control of the vehicle (NHTSA Recall #08V-562). *Manufacturer:* Damon Corp. *Models:* 2006–2009 Daybreak and 2009 Daybreak Sport motor homes built on Workhorse recreational vehicle chassis. *Corrective Action:* Damon is working with Workhorse to replace and properly tighten the castle nut that retains the steering drag.

AUTOMOTIVE PARTS**Aftermarket Light Sets**

Nearly 154,000 sets of headlamps, corner lights, and bumper aftermarket light sets recalled because they do not contain the required amber side reflectors. The lights also provide less illumination than the federal motor safety standard on lamps prescribes, which could result in a crash (NHTSA Recall #08E-056) (36 PSLR 997, 10/13/08). *Manufacturer:* Sonar Auto Parts. *Models:* Sets of headlamps, corner lights, and bumper lights sold as aftermarket equipment for use on various passenger vehicles. *Corrective Action:* The company is offering a refund for the noncompliant light sets.

Aftermarket Light Sets

Approximately 101,700 sets of corner and bumper lights recalled because they do not contain the required amber side reflectors (NHTSA Recall #08E-570) (36 PSLR 997, 10/13/08). *Manufacturer:* ANW Group. *Models:* Sets of corner and bumper lights sold as aftermarket equipment for use on various passenger vehicles. *Corrective Action:* The company is offering a refund for the noncompliant light sets.

Motorcycle Helmets

An estimated 2,260 Helmet City motorcycle helmets recalled because they fail to conform to impact requirements of the federal motor vehicle safety standard for motorcycle helmets. In a crash, the helmet wearer may not be adequately protected, which could result in personal injury (NHTSA Recall #08E-059) (36 PSLR 997, 10/13/08). *Manufacturer:* Helmet City Inc. *Models:* All models of Helmet City HCI 50 helmets in sizes XS through XXL. *Corrective Action:* Helmet City will notify owners and offer a full refund for the helmets.

Trailer Axles

An estimated 3,700 remanufactured aftermarket trailer axles recalled because a manufacturing glitch during the original process could lead to cracks on the internal surface of the spindle later on. Also, some axles may have insufficient or contaminated grease. The production problem could cause separation of the spindle and the attached components from the axle. Insufficient or contaminated grease could cause the wheel-end bearings to stop functioning and lead to wheel-end separation and the possibility of a crash (NHTSA Recall #08E-065). *Manufacturer:* ArvinMeritor Inc. *Models:* ArvinMeritor trailer axles shipped for aftermarket use between July 9, 2007, and Aug. 20, 2008. *Corrective Action:* ArvinMeritor will replace the affected axles.

Hub Units for Dodge Vehicles

Approximately 2,800 SKF hub units recalled because their rotor pilots may be too long, which can lead to problems in the way the wheel is seated against the hub flange face during mounting. Improper seating of the wheel can result in excessive vibration, brake rotor noise, difficulty removing the wheel after installation and operation of the vehicle, and wheel-end separation during vehicle operation, which can cause the driver to lose control of the vehicle (NHTSA Recall #08E-064). *Manufacturer:* SKF USA Inc. *Models:* SKF hub units no. BR930361, sold as a service part for 1997–2004 Dodge Dakota vehicles and 1999–2003 Dodge Durango vehicles equipped with two-wheel-drive and rear-axle antilock brakes. *Corrective Action:* SKF will replace the defective hub units.

Analysis & Perspective

For more than two decades, Public Justice has been fighting against preemption of injured victims' claims. In this Analysis & Perspective, Public Justice staff attorney Leslie A. Brueckner recalls the history of the preemption cases and addresses the issues currently before the Supreme Court, including the recently argued *Wyeth v. Levine* case, which addresses preemption of prescription drug failure-to-warn claims.

This new spate of Supreme Court cases underscores the huge threat posed by federal preemption—and the importance of fighting it with every means at our disposal, Brueckner says.

In the Eye of the Storm: The United States Supreme Court Takes On Four Preemption Cases Affecting Consumers' Rights

By LESLIE A. BRUECKNER

More than 25 years ago, the first brief that Public Justice (then Trial Lawyers for Public Justice) filed in the U.S. Supreme Court opposed federal preemption of an injury victim's claim. It urged the Supreme Court to hold that Karen Silkwood could seek punitive damages against the Kerr-McGee Corp. for contaminating her with plutonium even though the company had complied with the federal government's regulations governing the safety of nuclear power plants. The Supreme Court agreed, 5-4.

Since that time, Public Justice's Federal Preemption Project has preserved the rights of millions of Americans to hold corporate wrongdoers accountable for the injuries caused by their hazardous products. In recent years, however, companies seeking to avoid responsibility for their conduct are advancing the federal preemption defense with more vigor than ever.

Just this term, the United States Supreme Court shocked the legal world by granting review in **four** cases involving federal preemption of consumer products. One of these cases—*Riegel v. Medtronic*, which involves defective medical devices—has already been decided adversely to the plaintiffs. Another case, *Warner-Lambert v. Kent*, was also decided—in a very unusual way. The remaining two cases could have an equally dramatic impact on the ability of victims of inadequately labeled prescription drugs and so-called “light” cigarettes to seek compensation for their injuries. Public Justice has participated as or on behalf of amicus curiae in all of these cases, urging the Court to

reject the unwarranted and overbroad preemption arguments that are being advanced by corporate America.

This new spate of Supreme Court cases underscores the huge threat posed by federal preemption—and the importance of fighting it with every means at our disposal.

Riegel v. Medtronic:

In *Riegel v. Medtronic*, which was decided Feb. 20, manufacturers of defective medical devices succeeded in convincing the Court to immunize them from almost any liability for the often-horrific injuries caused by their dangerous products. We joined with the American Association for Justice in an amicus brief urging the Court to leave state law damage claims in place, just as Congress intended. Unfortunately, eight out of nine Justices turned a blind eye to victims' rights, thereby stripping many consumers of the right to seek any remedy at all for their injuries caused by defective medical devices. See 128 S. Ct. 999 (2008).

The question in *Riegel* was whether the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act bars a couple's state law claims against the maker of a balloon catheter that burst during the husband's angioplasty. In the decision below, the Second Circuit joined the majority of other federal appeals courts and state high courts in holding that the Food and Drug Administration's (FDA's) pre-market approval (PMA) of a medical device creates a “device-specific requirement” sufficient to trigger federal preemption under the MDA. In past litigation, the federal government and the FDA had said that PMA does *not* preempt state law actions seeking compensation for damages arising from defective medical devices. But in *Riegel*, the federal government flipped its position and said that PMA is sufficient to preempt state-law claims. And, in an 8-1 decision, (in an opinion written by Justice Antonin Scalia, with Justice Ruth Bader Ginsberg dissenting), the U.S. Supreme Court agreed, wiping out

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the majority of claims relating to drugs that have obtained pre-market approval from the FDA.

In so doing, the Court gave mere lip service to the fact that federal preemption analysis revolves around one all-important question: What did Congress intend? Our amicus brief in the case explained that Congress never intended to preempt state law tort claims involving hazardous medical devices. That's clear both from the history and the language of the statute that regulates medical devices, which was passed in the wake of the Dalkon Shield scandal to protect consumers from dangerous devices—not to immunize manufacturers from liability. The brief further explained the complementary roles played by the tort system and federal regulations in making the world a safer place for consumers of medical devices and other potentially dangerous products. The Court rejected all these arguments, finding that Congress must have intended to wipe out state law claims relating to PMA devices—even though it never said so and all evidence indicates to the contrary.

One of the many ironies of *Riegel* is that, in the past, the United States agreed that Congress never intended to preempt state law claims involving medical devices that had received pre-market approval. But, in *Riegel*, the Bush administration reversed the government's position and said there is preemption. The Supreme Court agreed, and now millions of Americans will be left without any remedy at all.

Warner-Lambert v. Kent:

Public Justice also appeared before the U.S. Supreme Court in *Warner-Lambert v. Kent*, fighting to prevent pharmaceutical companies from avoiding liability based on the doctrine of federal preemption. In an amicus brief filed in January, we urged the Court to affirm a Second Circuit ruling that a drug manufacturer that failed to warn the public about the dangers of its product—and may have hidden key information from the federal government regarding the risks of the drug—cannot hide behind a Michigan state law that provides immunity to prescription drug manufacturers. See *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006). On March 3, the judgment below was affirmed because the Court was evenly divided 4-4. (The Chief Justice “took no part in the decision.” See 128 S. Ct. 1168 (2008).)

Kent involved injuries caused by the diabetes drug Rezulin, which was ordered off the market in March 2000 by the FDA after it was linked to nearly 400 deaths and hundreds of cases of liver failure. The plaintiffs in *Kent* were trying to get Warner-Lambert to compensate them for injuries caused by their ingestion of the drug. They argued that Michigan's state law immunity for drug manufacturers did not apply to their claims because it contains an exception for cases where the drug manufacturer withheld or misrepresented information that would have altered the federal FDA's decision to approve the drug. Warner-Lambert countered that the fraud exception is preempted by federal law because it conflicts with the FDA's authority to regulate prescription drugs.

Public Justice joined the fight in order to rebut one of the most radical—and dangerous—arguments in favor of federal preemption that we've ever seen. In an amicus brief filed in support of the drug company, the U.S. Chamber of Commerce—which seeks to increase corporate profits by filing amicus briefs in favor of

preemption—argued that there should be no presumption against preemption in implied conflict preemption cases. If the Court had adopted this argument, it could have tipped the scales in favor of preemption in a huge number of cases involving hazardous consumer products.

Our brief argued that the Chamber's argument—if adopted—would overturn more than a century of Supreme Court jurisprudence. It would also undermine the basic federalism principles upon which this country is based—principles preserving the historic importance of state tort law in protecting the health and safety of all Americans. Fortunately, due to the 4-4 split among the Justices, the Court never reached this issue and the Second Circuit's favorable decision remains good law.

Altria v. Good:

Third on the roster is *Altria v. Good*, which involves federal preemption of consumer-fraud litigation over light cigarettes. This case arose when a class of smokers in Maine sued the maker of Marlboro Lights and Cambridge Lights—Philip Morris USA—under Maine's Unfair Trade Practices Act. The smokers alleged that Philip Morris' marketing, which describes the cigarettes as “light” and having “lowered tar and nicotine,” was deceptive because smokers may compensate for the reduced tar and nicotine by altering their smoking habits, making the products as unhealthy as “non-light” cigarettes at the end of the day. The plaintiffs sought economic damages for having been fooled into buying so-called “light” cigarettes.

The federal district court had found that the class claims were preempted by federal law because the Federal Labeling Act of 1965 gives the Federal Trade Commission (FTC) the authority to regulate all cigarette labeling and advertising that touches on the health impact of smoking. The First Circuit reversed this decision, finding that the state law claims were not preempted, emphasizing that the FTC has never adopted a formal rule governing the way companies described their cigarettes' tar and nicotine content. The First Circuit openly observed, however, that its opinion was in conflict with a Fifth Circuit opinion holding the opposite.

Philip Morris' parent company persuaded the U.S. Supreme Court to grant review, arguing that federal law preempts the rights of consumers to seek any damages relating to their inadequate labeling of light cigarettes. See *Good v. Altria*, 501 F.3d 29 (1st Cir. 2007).

Our brief, which we filed along with the Tobacco Control Legal Consortium and AARP, emphasized, among other things, the absence of any statutory basis for concluding that Congress actually intended to preempt these sorts of claims. The brief also emphasized what is always a central theme in our efforts to battle federal preemption: that, in light of the strong presumption against preemption, a court can only find preemption where Congress plainly intended it. This is especially true given that the Federal Labeling Act of 1965—like the statutes at issue in *Riegel*, *Wyeth*, and *Kent*—does not provide any mechanism for compensating the victims of defective and/or inadequately labeled products.

Wyeth v. Levine:

Finally, there is the 800-pound gorilla known as *Wyeth v. Levine*, which will decide whether the federal

government's approval of a prescription drug's label preempts a claim that the label failed to warn of a drug's significant risks. At issue is an October 2006 ruling by the Vermont Supreme Court that federal law does not preempt a claim that the manufacturer of "Phenergan" should have warned against a method of administering the drug, called "IV push," directly into a vein.

The plaintiff Diana Levine, a guitar player, was given the drug to combat nausea associated with migraine headaches. Her arm developed gangrene and had to be amputated after the drug was inadvertently injected into an artery. A Vermont state court jury ultimately returned a verdict for the plaintiff of \$6.7 million.

On appeal to the Vermont Supreme Court, the drug's manufacturer (Wyeth) argued that her failure-to-warn claim is preempted because the drug's label was approved by the FDA. The Vermont Supreme Court rejected this argument, holding that the jury's verdict did not conflict with the FDA's labeling requirements because, under the FDA's "changes being effected" regulation, Wyeth could have warned against IV-push administration without prior FDA approval. The court wrote: "The litigation at issue here does not pose a direct and positive conflict with federal law, and, thus, there is no basis for federal preemption."

Wyeth sought U.S. Supreme Court review in March 2007. Most Court watchers expected that the petition would be denied, given that the Vermont Supreme Court's ruling did not conflict with the decisions of any federal Court of Appeals or state high court. (The U.S. Supreme Court ordinarily does not take a case absent such conflict.) Even the United States Solicitor General's Office, which has switched the government's long-held position to favor FDA preemption, urged the Court to deny review given this lack of a split. But the Court reached out and took the case anyway, in an ominous move that sent shudders through the plaintiffs' bar.

Public Justice filed an amicus brief on behalf of 10 current and former editors and contributing authors of the *New England Journal of Medicine* in their first-ever legal brief, urging the Court to reject Wyeth's attempt to immunize itself from liability for inadequately labeled drugs. As a *Wall Street Journal* article highlighting the brief noted, the medical editors and writers—who have never before banded together to address a legal decision—"plunged into an escalating legal battle" with enormous national implications.

Our brief explained that the FDA is simply unable to ensure the adequacy of prescription drug labels. Among other issues, the agency, when deciding whether to approve a drug label, is limited to the information submitted by the drug manufacturers themselves. Then, when

new risks become known after a drug's label has been approved, the agency has only limited authority to force a manufacturer to change its label to reflect the newly discovered risks. The upshot is that, in many, many cases, drugs are left on the market with inadequate labels, even as the casualty statistics climb ever higher. As proof of the pudding, the brief includes case studies of three drugs—Pondimin/Redux, Vioxx, and Trasyolol—whose manufacturers withheld key information from the FDA while lobbying against stricter label warnings and while continuing to market their unsafe drugs to an unsuspecting public.

Our brief further explains that litigation is often the only way to dig up information regarding inadequacy of drug labels. This information can, in turn, spur the agency to put pressure on the manufacturers to improve the labels. But without this critical "feedback loop" generated by prescription drug litigation, the agency will not have the information that it needs to pressure drug manufacturers to improve their labels. And, without litigation, the manufacturers will neither compensate victims nor have any financial incentive to correct their labels and provide consumers with adequate warnings.

The upshot of an adverse ruling in *Wyeth* could be a disaster for public health. The scariest thing about the case is that, depending on how the Supreme Court rules, it could wipe out all failure-to-warn litigation regarding prescription drugs in this country. Victims of inadequately labeled drugs would have absolutely no recourse to seek compensation for their injuries. The FDA would be stripped of the invaluable information that is often unearthed during the course of litigation. The only winners in this scenario would be drug manufacturers, who could continue to increase their profit margins unrestrained by the risk of litigation, at the direct expense of the hapless victims of inadequately labeled drugs.

Altria and *Wyeth* should be decided by early next year. Meanwhile, it is worthwhile to note that Public Justice has already been at the forefront of the fight against preemption in a host of areas. Among other victories, we won a unanimous United States Supreme Court ruling upholding an injury victim's right to sue a manufacturer for failing to install propeller guards on its recreational motor boat engines. See *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002). We have also fought preemption for years in cases involving medical devices, prescription drugs, motor vehicle safety, flammable fabrics, and mandatory arbitration, to name but a few. In short, this is a battle that we have already joined, and we believe that it is of utmost importance that we continue to fight for the right outcome.



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THIS WEEK'S ISSUE

Listed below are the headlines and page numbers of selected articles in this issue followed by World Wide Web sites providing related information.

Industries Urge CPSC to Exempt Products Without Lead from Testing, Cite Economics (p. 1123)

Additional information on various aspects of the CPSIA can be found on the CPSC Web site at <http://www.cpsc.gov>.

CPSC Freedom of Information Plan Aims To Speed Response to Backlogged Requests (p. 1124)

The CPSC Freedom of Information backlog reduction plan is available at <http://www.cpsc.gov/library/foia/foia102808.pdf>.

Medtronic MDL Special Master Recommends Approval of Common Benefits Attorneys' Fees (p. 1121)

Full text is at <http://op.bna.com/hl.nsf/r?Open=mapi-7kwnmt>

European Group Unveils New Rating Plan; ESC Needed to Earn Five Stars (p. 1126)

Tests are released quarterly and can be found at <http://www.euroncap.com>.

NuvaRing Defendants Seek Master Complaint In Birth Control Device Multidistrict Litigation (p. 1120)

Full text of memorandum is at <http://op.bna.com/hl.nsf/r?Open=mapi-7i4mq5>

District Court Remands Gadolinium Cases To State Court, Rejects 'Misjoinder' Claims (p. 1121)

Full text of Rodriguez is at <http://op.bna.com/hl.nsf/r?Open=mapi-7kwsg2> on the Web. Full text of Geffen is at <http://op.bna.com/hl.nsf/r?Open=mapi-7kwsgx>

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Index-Summary updates for Product Safety & Liability Reporter are available on a monthly basis.

<http://www.bna.com/current/psl>

INTERNET SOURCES

Listed below are the addresses of World Wide Web sites consulted by editors of BNA's Product Safety and Liability Reporter and WWW sites for official government information.

Consumer Product Safety Commission

<http://www.cpsc.gov>

National Highway Traffic Safety Administration

<http://www.nhtsa.dot.gov>

Thomas

<http://thomas.loc.gov>

U.S. House of Representatives

<http://www.house.gov>

U.S. Senate

<http://www.senate.gov>

U.S. Code

<http://uscode.house.gov>

BNA PRODUCTS

BNA publishes other information products for professionals in a variety of electronic formats, including the titles listed below.

Product Safety & Liability Reporter

<http://www.bna.com/products/corplaw/pslr.htm>

Toxics Law Reporter

<http://www.bna.com/products/lit/txlr.htm>

Class Action Litigation Report

<http://www.bna.com/products/lit/clas.htm>

Expert Evidence Report

<http://www.bna.com/products/lit/exer.htm>

United States Law Week

<http://www.bna.com/products/lit/uslw.htm>

ABA/BNA Lawyers' Manual on Professional Conduct

<http://www.bna.com/products/lit/mopc.htm>

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