

**REGULATORY ENFORCEMENT** Actavis  
injunction sought P. 21

**PRODUCT WATCH** Animas insulin pump  
recalled due to power glitch P. 24

### **\$16.5M Awarded In Illinois State Court Fentanyl Patch Trial**

CHICAGO — An Illinois state court jury on Nov. 17 awarded \$16.56 million to the family of woman who allegedly died from an overdose from a leaking Duragesic fentanyl patch. **SEE PAGE 4.**

### **\$13.3M Awarded In Florida State Court Fentanyl Patch Trial**

SANFORD, Fla. — A Florida state court jury on Oct. 28 awarded \$13.3 million to the family of a woman who allegedly died of an overdose from a defective Duragesic fentanyl pain patch. **SEE PAGE 5.**

### **\$12.9M Awarded In 3 New Jersey Accutane IBD Cases**

ATLANTIC CITY, N.J. — A New Jersey state court jury on Nov. 19 awarded \$12,895,500 to three plaintiffs who claim that their inflammatory bowel disease was caused by Hoffman-La Roche Inc.'s acne drug Accutane. **SEE PAGE 7.**

### **Self-Critical Privilege Claim Denied In State Kugel Cases**

PROVIDENCE, R.I. — A Rhode Island state court judge on Oct. 27 refused to recognize a self-critical analysis privilege for defense documents in four Kugel surgical mesh cases. **SEE PAGE 9.**

### **State Judge Rejects 'Product Line' Successor Liability**

WATERBURY, Conn. — A Connecticut state court on Oct. 20 declined to adopt a "product line exception" to the state's successor liability law in a hip implant case. **SEE PAGE 11.**

### **Michigan Drug Shield Law Applied To Lipitor Claims**

NEW YORK — A New York appeals court on Nov. 20 affirmed that Michigan state law applies to the Lipitor injury claims of three plaintiffs and that they had not provided a foundation for their argument that their claims fell under the fraud exception to Michigan's drug shield law. **SEE PAGE 11.**

#### **Knee Implant Case Found Preempted; No Parallel Claims Found**

CHICAGO — An Illinois federal judge on Nov. 26 ruled that a Zimmer knee implant plaintiff's claims are preempted and that she did not produce evidence of any state law tort claim that parallels federal requirements.

Orthopedic Devices  
P. 12

#### **Human Tissue Plaintiffs Seek Appeal Certification Of Expert Exclusion**

NEWARK, N.J. — Plaintiffs in the human tissue multidistrict litigation have asked the judge to certify for appeal his Oct. 22 decision to exclude expert testimony that certain viruses or diseases can be transmitted by bone and tissue recovered from unsuitable corpses.

Human Tissue  
P. 17

#### **Zicam Class Rejected; Question Too General; Class Size Speculative**

SPOKANE, Wash. — A Washington federal judge on Oct. 31 denied certification of a class of people who allegedly lost their sense of smell and/or taste from using Zicam zinc-based cold remedies.

Zicam  
P. 18



### Counsel

Grange is represented by Charles W. Miller and James C. Orr Jr. of Heygood, Orr, Reyes, Pearson & Bartolomei in Dallas and Nancy A. Mismash of Robert J. Derby & Associates in Salt Lake City.

Mylan is represented by Clem C. Trischler of Pietragallo, Gordon, Alfano, Bosick & Raspanti in Pittsburgh and Tracy H. Fowler and Kamie F. Brown of Snell & Wilmer in Salt Lake City. ■

### Duragesic Claims Up 66 Percent, Johnson & Johnson Reports; Ortho Evra Claims Down

NEW BRUNSWICK, N.J. — Claims involving the Duragesic fentanyl transdermal patch increased 66 percent from August to November, Johnson & Johnson (J&J) reported last month in its Form 10-Q report to the U.S. Securities and Exchange Commission.

In August, J&J reported that there were 60 lawsuits or claims involving Duragesic. In November, it reported that the number was 100.

Duragesic is made by J&J's Ortho-McNeil Janssen Pharmaceuticals division. Plaintiffs have alleged that the defects in the patches allowed fentanyl gel to leak out and cause overdoses.

#### Ortho Evra Cases Down

J&J also reported that suits and claims involving the Ortho Evra birth control patch have declined 66 percent between August and November. The number of cases reported in August was 2,000. The number reported in November was 1,200.

Plaintiffs allege that the Ortho Evra patch exposed them to excessive amounts of hormones, causing blood clots or strokes.

Claims or lawsuits involving the atypical antipsychotic drug Risperdal were down 6 percent between August and November, J&J said. It reported 570 claims in August and 535 in November.

Plaintiffs allege that Risperdal causes excessive weight gain, hyperglycemia and diabetes.

### Charite Disc Claims

J&J reported that claims or suits involving the Charite artificial spinal disc increased 2.8 percent from August to November. There were 280 claims reported in August and 288 reported in November.

Plaintiffs allege that the Charite disc does not improve spinal conditions and may lead to revision surgery. ■

### \$12.9M Awarded In New Jersey In 3 Accutane IBD Cases; Were 1st To Involve Non-surgical Injuries

ATLANTIC CITY, N.J. — A New Jersey state court jury on Nov. 19 awarded \$12,895,500 to three plaintiffs who claim that their inflammatory bowel disease (IBD) was caused by Hoffman-La Roche Inc.'s acne drug Accutane (Kelly Mace v. Hoffman-La Roche Inc., et al., No. ATL-L-199-05 MT, Jordan Speisman v. Hoffman-La Roche Inc., et al., No. ATL-L-196—05 MT, Lance Sager v. Hoffman-La Roche Inc., et al., No. ATL-L-197-05 MT, N.J. Super., Atlantic Co.; See 11/13/08, Page 13).

(Verdict forms in Section B. ■ Document #28-081204-105V.)

The verdict was the first in IBD cases in which a plaintiff did not have his or her colon partially or totally removed.

Kelly Mace, 25, Lance Sager 28, and Jordan Speisman, 27, all of Florida, each took Accutane as teenagers to treat acne and claimed that it caused IBD, including ulcerative colitis and Crohn's disease. Mace and Sager must take drugs to manage their conditions. Speisman may require surgical removal of his colon. All also claim to be at risk for colon cancer because of Accutane.

The plaintiffs sued Hoffman-La Roche in a New Jersey Superior Court, and their cases were transferred

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to an Accutane mass tort docket in Atlantic County. Theirs were the first to be tried as a group after two earlier single-plaintiff trials.

### Jury Questions

An eight-member jury was asked four questions for each plaintiff:

Did Hoffman-La Roche Inc. (Roche) provide adequate warning to Mace's doctor about the risk of IBD that Roche knew or should have known of before July 1999: seven "yes," one "no." Did it provide adequate warning to Sager's doctor for risks known before January 1998: seven "yes," one "no." Did it provide warning to Speisman's doctor for risks known before November 1999: seven "yes," one "no."

Is Accutane a cause of IBD in some people who take it: 7-1 in all cases.

Would a stronger warning have prevented the plaintiffs from taking Accutane: 7-1 in all cases.

Was Accutane a substantial factor in causing IBD in the plaintiffs: 6-2 for Mace and 7-1 for Sager and Speisman.

### Damage Awards

On a 6-2 vote, the jury awarded Mace \$128,000 out of a maximum of \$132,500 for future medical expenses and \$1.5 million for pain, suffering and disability.

On a 7-1 vote, the jury awarded Sager the maximum of \$125,000 for future medical expenses and \$2.5 million for pain, suffering and disability.

On a 7-1 vote, the jury awarded Speisman the maximum of \$142,500 for future medical expenses and \$8.5 million for pain, suffering and disability.

### Experts

Plaintiff experts included: Cheryl Blume, Ph.D., of Pharmaceutical Development Group in Tampa, Fla., and Alan Bess, M.D., of the Mount Sinai School of Medicine in New York.

Defense experts included Lorraine J. Gudas, Ph.D., of Cornell University Medical College in New York; Lloyd Mayer, M.D., of Mount Sinai Medical Center

in New York; Gerald A. Faich, M.D., M.P.H., of Narberth, Pa.; and Jerry F. Hardisty, D.V.M., of Research Triangle Park, N.C.

A plaintiff source told Mealey Publications that in addition to evidence and testimony presented in two earlier New Jersey IBD trials, the Mace, Sanger and Speisman trial included evidence that Accutane was "internally contraindicated" for IBD.

### Roche Will Appeal

In a statement, Roche said it was disappointed by the verdict and planned to appeal. Roche maintains that Accutane's label has warned of IBD for more than 20 years and that there is no reliable scientific evidence that the drug causes IBD.

The trial lasted five weeks from opening arguments. The panel deliberated a reported 4-1/2 hours before returning its verdict. Judge Carol Higbee presided.

In the first IBD case to go to trial in New Jersey, McCarrell v. Hoffman-La Roche Inc. (No. ATL-L-1951-03, N.J. Super., Atlantic Co.; See 7/1/08, Page 10), a jury awarded \$2.6 million. That case is on appeal to the Superior Court Appellate Division.

The second case, Kendall v. Hoffman-La Roche Inc. (No. ATL-L-8213-05, N.J. Super., Atlantic Co.; See 6/19/08, Page 26), resulted in a \$10.5 million verdict. Post-trial motions are pending in the trial court.

### Prior Motions, Rulings Applied

All five cases have shared the same pretrial rulings and experts, including denial of federal preemption and allowance of Roche internal causality reports on Accutane adverse events. Judge Higbee earlier denied Roche's motion to stay the ongoing trial pending resolution of the McCarrell case.

The plaintiffs are represented by Michael Hook and Steve Bolton of Hook Bolton in Pensacola, Fla., David R. Buchanan of Seeger Weiss in New York and Mary Jane Bass, Jack Lurton and Jack Zoesch of Beggs & Lane in Pensacola.

Roche is represented by Michael R. Griffinger and Michelle M. Bufano of Gibbons in Newark, N.J.; Michael X. Imbroscio and Paul W. Schmidt of Covington & Burling in Washington, D.C.; Russell L.

Hewit of Dughi & Hewit in Cranford, N.J.; and Lee David Thames of Butler, Snow, O'Mara, Stevens & Cannada in Jackson, Miss. ■

## Rhode Island Judge Declines To Find Self-Critical Privilege In Kugel Surgical Mesh Cases

PROVIDENCE, R.I. — A Rhode Island state court judge on Oct. 27 refused to recognize a self-critical analysis privilege for defense documents in four Kugel surgical mesh cases (*Barbara Brokaw, et al. v. Davol Inc., et al.*, Nos. 07-5058, 07-4048, 07-1706 and 07-3666, R.I. Super., Providence; 2008 R.I. Super. LEXIS 146).

(Opinion in Section D. ■ Document #28-081204-114Z.)

In 2007 Barbara Brokaw, Raymond Mutz, Tammy Oakley and Delza Young sued Davol Inc. and C.R. Bard Inc. in the Providence Superior Court for injuries from the Kugel surgical mesh patch. The defendants filed a privilege log that included a confidential audit report on the defendants' quality systems conducted by an outside consultant. The defendants claimed a self-critical analysis privilege.

The plaintiffs moved to compel and asked the court to declare that the self-critical analysis privilege is not valid under Rhode Island law. The defendants asked the court to adopt such a privilege, saying there is a strong public interest in encouraging companies to conduct voluntary quality audits. The voluntary actions would be chilled, the defendants said, if they were disclosed in litigation.

In addition, the defendants argued that under the self-critical analysis privilege, the audit would be protected under *Hickman v. Whirlpool Corp.* (186 F.R.D. 362, 363 [N.D. Ohio 1999]).

### State Rejected Remedial Privilege

Judge Alice Bridget Gibney said the Rhode Island Supreme Court's reluctance to recognize new privileges is "well-settled." "In addition," she wrote, "the Court is persuaded that the adoption of a self-critical analysis privilege would run counter to the policies under-

lying Rhode Island Rule of Evidence 407 regarding subsequent remedial measures."

Judge Gibney noted that though Federal Rule of Evidence 407 does not allow evidence of subsequent remedial measures to encourage safety improvements, Rhode Island rejected that policy. "Defendants' argument, therefore, that disclosure of self-evaluative analyses may deter businesses from conducting similar candid reviews in the future is in clear conflict with public policy favoring liberal discovery expressed in Rhode Island Rule 407," the judge wrote.

"Accordingly," she continued, "Defendant has not met its burden of showing a compelling public policy interest in protecting self-evaluative reports from discovery. The Court, therefore, declines to recognize the self-critical analysis privilege as a valid privilege under Rhode Island law."

In light of her refusal to find the new privilege, Judge Gibney said she did not have to address whether the documents would be protected under *Hickman*. ■

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