AREEDIA/ZOMETA

Supreme Court won’t disturb punitive damages award against Novartis in Areedia/Zometa Case

The U.S. Supreme Court has refused to disturb an award of punitive damages to the estate of a woman who claimed the Novartis bone-strengthening drugs Areedia and Zometa caused the destruction of her jawbone.


The high court denied review of what Novartis Pharmaceutical Corp. said was a federal appellate court ruling that mistakenly left standing a $861,000 punitive damages award for the estate of Rita Fussman (see Westlaw Journal Pharmaceutical, Vol. 29, Iss. 2).

Novartis argued that a Feb. 8 decision by the 4th U.S. Circuit Court of Appeals improperly let the punitives award stand based on a finding that the Supreme Court said such an award complies with federal law under Wyeth v. Levine, 555 U.S. 555 (2009).

CONTINUED ON PAGE 16

AREEDIA/ZOMETA

Tennessee woman can’t link Areedia/Zometa warning to jaw bone death

A woman failed to show that data about the risks of osteonecrosis of the jaw on Areedia and Zometa warning labels would have altered her doctor’s decision to prescribe the drugs to her, a Tennessee federal judge has ruled in dismissing an injury lawsuit.


Areedia and Zometa, manufactured by Novartis Pharmaceuticals Corp., are prescription bisphosphonate medications used to reduce cancer patients’ risk of bone fracture from bone metastasis.

The drugs were approved by the FDA in 1996 and 2002, respectively, and are still on the market, according to the opinion by U.S. District Judge Curtis L. Collier of the Eastern District of Tennessee.

Several years after the drugs’ market release, some patients developed osteonecrosis of the jaw, or bone death, which can lead to the loss of jaw bone.

According to the opinion, Charlotte Payne, diagnosed in 1998 with breast cancer that
TABLE OF CONTENTS

Aredia/Zometa: Novartis Pharm. Corp. v. Fussman
Supreme Court won't disturb punitive damages award against Novartis in Aredia/Zometa Case (U.S.) ................................................................. 1

Tennessee woman can't link Aredia/Zometa warning to jaw bone death (E.D. Tenn.) ......................... 1

Commentary: By Patrick J. Hurd, Esq., LeClairRyan
Charting a prudent course on off-label promotion of drugs and devices ........................................ 3

Children's Tylenol (Remand): Moore v. J&J
Tylenol wrongful-death suit stays in Pennsylvania federal court (E.D. Pa.) ........................................... 6

Securities Fraud: In re Omnicare Sec. Litig.
Omnicare shareholders argue for reinstatement of securities fraud claims (6th Cir.) ......................... 7

Zyprexa Overdose (Hospital Negligence): Coggins v. HCA Health Servs.
Prescription error caused mom's overdose death, woman claims (Va. Cir. Ct.) ................................. 8

Niaspan: In re Niaspan Antitrust Litig.
Philadelphia federal judge to lead Niaspan antitrust multidistrict proceeding (J.P.M.L.) .................... 9

Chantix
Anti-smoking drug Chantix may be safe with treated depression, study says ................................. 10

Skin Care Lotion: Cortez v. Unilever United States
Chicago man says Vaseline lotion caused 'cosmetic disfigurement' (Ill. Cir. Ct.) ............................. 11

Commentary: By James Schurz, Esq., Morrison & Foerster
Consumer class actions take another hit: Supreme Court rules class-action arbitration waiver covers antitrust claims ............................................. 12

Advisory
Recent labeling changes ......................................................................................................................... 15

News in Brief ........................................................................................................................................ 18

Case and Document Index .................................................................................................................. 19
COMMENTARY

Charting a prudent course on off-label promotion of drugs and devices

By Patrick J. Hurd, Esq.
LeClairRyan

To what extent can pharmaceutical and medical device companies promote off-label uses of their products without fear of reprisal from federal regulators? Unfortunately for the industry — and, arguably, for patients and doctors in need of accurate facts about the safety and efficacy of specific off-label uses — there is not yet a definitive answer to this critical question.

After all, federal regulators have yet to issue their final guidance on off-label promotions, and the U.S. Supreme Court has yet to resolve a host of conflicting decisions from the lower courts. But does this mean drug and device companies should simply refrain from ever discussing off-label uses of their products in ways that could be construed as promotional? Not necessarily.

This is because, taken together, three rulings from the past few years do suggest a framework for charting a prudent course on off-label promotions. They also help clarify the conditions under which the free speech clause of the First Amendment is likely to protect such discussions. This article takes a brief look at the implications of these three cases:

- United States v. Caputo, 517 F.3d 935 (7th Cir. 2008)
- United States v. Caronia, 703 F.3d 149 (2d Cir. 2012)
- United States v. Harkonen, 510 F. App'x 633 (9th Cir. 2013)

HOW WE GOT HERE

As legal scholars have pointed out, the promotional materials drug and device companies use are among the most heavily regulated communications in the world. And this is no idle scrutiny — by all accounts, regulators continue to aggressively pursue civil and criminal enforcement of perceived violations related to drug and device misbranding and off-label promotion, with at least 24 Justice Department settlements from 2004 to 2011.

In fiscal year 2012, the department recovered nearly $2 billion in cases alleging false claims for drugs and medical devices and obtained 14 criminal convictions and $1.5 billion in criminal fines and forfeitures under the Food, Drug and Cosmetic Act.\(^1\) This enforcement push, moreover, has been characterized by an expanded use of non-prosecution and corporate integrity agreements aimed at driving huge settlements running into the hundreds of millions or even billions of dollars.\(^2\)

And yet, given that no law prevents doctors from freely prescribing FDA-approved drugs and devices for off-label uses, and that both patients and doctors clearly need a thorough understanding of, and solid scientific evidence about, the safety and efficacy of such off-label uses, one might wonder why regulators feel compelled to maintain such unrelenting scrutiny of these communications.

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Arguably, the horrendous histories of two products in particular, thalidomide and the Dalkon Shield, go a long way toward explaining the hyper-cautious approach that continues to prevail at the FDA. Here is how the agency described a part of this history in an October 2012 website article commemorating the 50th anniversary of one of its proudest moments: passage of the landmark Kefauver-Harris Amendments:

[T]halidomide, a sedative used to treat morning sickness in pregnant women, ... was causing birth defects in Europe, Canada and other countries. Fast federal action to prevent that kind of devastation from happening in the United States came in the form of the 1962 Amendments to the Federal Food, Drug and Cosmetic Act. Commonly called the Kefauver-Harris Amendments, they were sponsored in Congress by Sen. Estes Kefauver (D-Tenn.) and Rep. Oren Harris (D-Ark.). Once signed into law by President Kennedy on Oct. 10, 1962, the amendments established a framework that required drug manufacturers to prove scientifically that a medication was not only safe, but effective.\(^3\)

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Before this, the FDCA had basically given drugmakers a free hand to introduce new products. The FDA lacked the authority to enforce good manufacturing processes, for example, and companies could take virtually any drug to market as long as regulators did not try to stop the marketing within a 30-day deadline period.

Thalidomide, originally approved as a tranquilizer, had caused unspeakable birth defects when given to pregnant women off-label as a relief for morning sickness. More than a dozen companies had brought the infamous drug to market across the globe, but not in the United States, where the FDA’s Dr. Kathleen O. Kelsey doggedly refused to authorize thalidomide because of her concerns about its potential to cause nerve disease. The FDA had managed to avoid disaster, and the agency developed a new mantra: “Better to be extremely safe than sorry.”

These cases illustrate that communications about off-label uses of drugs and devices can indeed constitute protected, commercial speech, provided they constitute truthful and lawful promotions of off-label uses for FDA-approved drugs and devices.

**UNITED STATES V. CAPUTO**

The holdover effects of this difficult history are still visible at the FDA. A recent example is the FDA memorandum filed in 2009 during the course of an off-label promotion case that was later dismissed. The FDCA legislative history, regulators argued, shows that “drug manufacturers, when left to their own desires, frequently make untruthful claims about new uses.”

The overall feeling at the FDA seems to be that doctors must be protected from biased information provided by drug and device manufacturers and that this is possible only through the intercession of an independent government agency.

The occasional malefeasance of present-day bad actors tends to reinforce this view. In the 2008 case United States v. Caputo, for example, executives at Abtox Inc. were convicted of multiple counts of fraud, sentenced to prison terms and ordered to pay restitution of $17.2 million to 144 hospitals. The case hinged on off-label claims about Plazlyte, a device formerly used to sterilize medical instruments. According to the government, Abtox executives ignored studies showing product failures and aggressively marketed Plazlyte for unsafe uses even in the face of FDA warning letters.

“Essentially, both defendants viewed the FDA as a regulatory nuisance that could be neutralized through various misleading and false submissions,” the trial judge said at sentencing. “Both defendants were motivated by individual economic greed and the desire to capture market share, and they placed these goals over and above our nation’s complex regulatory scheme, which protects the health of our country. ... It is hard to imagine a more egregious corporate crime.”

The defendants appealed to the 7th U.S. Circuit Court of Appeals, arguing, among other things, that their First Amendment rights had been violated. The court rejected their free speech argument. “Unless the machine itself could be sold lawfully,” the court noted, “there were no lawful off-label uses to promote. And the jury found, by its verdicts on both the fraud-on-the-United States count and the misbranded-device counts, that the [sterilizer device] could not be sold.”

Bear in mind, the defendants in this case were hard-pressed to argue that their false and misleading statements somehow passed the Supreme Court’s four-pronged test for whether “commercial speech” was entitled to First Amendment protection. One of the requirements for that test, after all, is that the speech in question concerns a lawful activity and is not misleading.

The high court ruled that decisions on First Amendment protection of commercial speech should include determinations that:

- The speech is “not misleading and must concern lawful activity.”
- “The asserted government interest must be substantial.”
- The applied regulation “must directly advance the government interest asserted ‘to a material degree.’”
- The regulation “must be narrowly drawn and may not be more extensive than necessary to serve the interest.”

**UNITED STATES V. CARONIA**

In stark contrast to Caputo, the 2012 case United States v. Caronia helps illustrate the conditions under which drug and device makers can feel more confident about discussing off-label uses. Here, a sales representative and a paid-consultant physician were charged in August 2008 with two counts of misbranding after they promoted off-label uses of the narcolepsy drug Xyrem to a government informant who was wearing a wire.

Convicted by a jury, the defendants appealed to the 2nd Circuit, arguing that the misbranding provisions in the FDCA violated the First Amendment by preventing the drug company representatives from engaging in speech related to off-label promotion. For its part, the government argued that its use of the provisions was about demonstrating intent, not restricting speech.

The 2nd Circuit, however, chose to apply the Supreme Court’s four-pronged test for protected, commercial speech and concluded that the government “simply ... cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.”

In Caronia the court found that the FDA’s criminal prosecution of these individuals was impermissible under the free speech clause of the First Amendment, in part because it created an artifice in which some people, namely, doctors, could speak about the off-label use of an FDA-approved drug, but others could not. The court said there was no rational basis for this distinction and noted that, because the statements in question were truthful, they could not be deemed criminal.

Had the defendants been lying, cherry-picking data and engaging in craven acts akin to those in Caputo, the story here would have
been quite different. But the 2nd Circuit, at least, clearly saw the value in allowing drug companies to provide scientific evidence substantiating both the safety and efficacy of an off-label use. And indeed, while the FDCA makes it a crime to misbrand a drug, neither the statute nor the implementing regulations expressly prohibit or criminalize off-label promotion. The court did point out, however, that its conclusions should not be applied to FDA-approved drugs for which off-label use is specifically prohibited.

**UNITED STATES V. HARKONEN**

*United States v. Harkonen*, which is among the most recent cases to deal with off-label promotion, highlights the potential for illegal conduct to trump any assumed protections of speech. On March 4, the 9th Circuit affirmed the trial court decision by focusing on the defendants’ fraudulent conduct in the case — namely, issuing a press release full of false and misleading statements about off-label uses of the immune system booster Actimmune, thereby engaging in wire fraud.

While the appeals court essentially punctuated on elaborating any further about First Amendment issues in play here, the trial court had found that the First Amendment does not shield fraud and that this case was as much about fraudulent conduct, which is well within the purview of the FDCA, as it was about speech.

**Conclusions**

While the Supreme Court has provided a four-pronged test for determining commercial speech protected by the free speech clause of the First Amendment, the court has yet to deal head on with the issue of off-label promotion and its validity. Likewise, drug and device companies are still waiting for the FDA’s final, long-promised guidance on this issue. (Hearings were first held in 2009).

And so, until a higher degree of clarity and granularity on off-label promotions is available, the prudent course for drug and device makers is to be conservative and cautious.

Still, these cases illustrate that communications about off-label uses of drugs and devices can indeed constitute protected, commercial speech, provided they constitute *truthful and lawful* promotions of off-label uses for *FDA-approved* drugs and devices. The corollary, then, is that any false and fraudulent communications about off-label uses may not merit First Amendment protection.

This is clearly the prevailing view in the 2nd Circuit and even in the 7th Circuit, where the eloquent Chief Judge Frank H. Easterbrook wrote:

> If a given use is lawful and thus can be written about freely in newspapers or blogs, and discussed among hospitals, doesn’t it make a good deal of sense to allow speech by the device's manufacturer, which after all will have the best information? Why privilege speech by the uninformed? The manufacturer has an incentive to slant the speech in its favor and may withhold bad news, but many listeners, especially those professionals such as physicians, understand this and can discount it appropriately.9

The average citizen enjoys freedom of speech under the First Amendment. Nonetheless, citizens cannot yell “Fire!” in a crowded theater and expect to enjoy protection for such reckless speech. Likewise, drug and device makers cannot mislead the public in ways that could cause harm. But this does not mean they must keep their lips sealed. Following the rationale of the 2nd Circuit in *Caronia*, when doctors want the facts, companies should have the right to speak up, as long as they speak the truth and stick to the to the scientifically proven facts, as supported by unbiased studies dealing with off-label uses.  

**NOTES**


4. Id.


A Philadelphia federal judge has declined to send a product liability suit over Children’s Tylenol back to state court because the plaintiffs live in Washington state and the remaining defendants are citizens of New Jersey, giving the court diversity jurisdiction.


Plaintiffs Daniel and Katy Moore, residents of Yakima, Wash., allege their 2-year-old son River died from taking contaminated Children’s Tylenol on July 23, 2010. They sued manufacturer McNeil–PPC Inc., located in Fort Washington, Pa.; parent company Johnson & Johnson, based in New Jersey; a number of individual McNeil and J&J executives; and Costco, the Washington retailer that sold the Tylenol.

The Moores filed the suit in the Philadelphia County Court of Common Pleas in 2011 because they claimed McNeil made the contaminated Tylenol at the Fort Washington plant, making Pennsylvania the jurisdiction where the injury occurred.

The defendants removed the case to the U.S. District Court for the Eastern District of Pennsylvania on the basis of diversity of citizenship, which establishes federal jurisdiction in cases where the plaintiffs and defendants are citizens of different states and the amount of damages being sought is likely to exceed $75,000.

Judge McLaughlin based her decision on the U.S. Supreme Court’s holding in *Hertz Corp. v. Friend*, 130 S. Ct. 1181 (2010), which held that “the place where the corporation’s high-level officers direct, control and coordinate the corporation’s activities, i.e., its nerve center,” is its headquarters.

The judge agreed to reconsider her initial ruling but, in her Sept. 20 memorandum opinion, she found no reason to overturn it. She also declined to allow the case to be taken to the 3rd U.S. Circuit Court of Appeals on interlocutory appeal because she said several other cases against McNeil and J&J are pending in the Eastern District of Pennsylvania. Such an appeal would not advance the resolution of this case, she said.

**Attorneys:**
- **Plaintiffs:** Irene M. McLafferty and Joseph L. Messa Jr., Messa & Associates, Philadelphia
- **Defendants:** Christy D. Jones, Butler Snow O’Mara Stevens & Cannada, Ridgeland, Miss.; David M. Abernathy and Melissa A. Graff, Drinker Biddle & Reath, Philadelphia

**Related Court Document:**
Memorandum opinion: 2013 WL 5298573
Omnicare shareholders argue for reinstatement of securities fraud claims

Shareholders of Omnicare Inc. are seeking reinstatement of their securities fraud lawsuit asserting the pharmaceutical company’s top officials knew about audits that revealed it was not in compliance with government billing procedures.


In March, U.S. District Judge David L. Bunning of the Eastern District of Kentucky dismissed claims that the company’s executive-level employees made materially false statements in violation of Sections 10(b) and 20(a) of the Securities Exchange Act.

The judge said company statements about legal compliance are “soft information” that are not actionable unless the defendants knew the statements were untrue when made.

In their appeal, the shareholders say the judge erred in dismissing their suit because Omnicare’s officials were aware of three audits that found substantial violations of Medicaid and Medicare reimbursement requirements.

The shareholders say Omnicare’s audit results show that the defendants knew their statements about legal compliance were false.

They contend the audit results showed the defendants knew that their statements about legal compliance were false.

The plaintiffs originally alleged in their complaint that Omnicare officers and directors misled investors about alleged kickbacks from other drug companies and false claims made to Medicare and Medicaid.

These accusations were based on a whistle-blower lawsuit over the alleged Medicare fraud that led to a government investigation.

The shareholders said Omnicare’s failure to disclose the problems artificially inflated the stock price until the truth was revealed by the suit alleging violations of the False Claim Act.

The investors said Omnicare was paying and receiving illegal kickbacks and, as a result, subsequently entered into large civil settlements with various federal and state authorities.

The proposed class period is from Jan. 10, 2007, to Aug. 5, 2010.

But the defendants argue that the whistle-blower complaint was filed by a disgruntled former Omnicare employee, John Stone, and was promptly disclosed by the company in August 2010.

The whistle-blower complaint did not result in any judgment, finding or admission of wrongdoing, Omnicare says.

Moreover, the defendants point out that Stone’s action was dismissed with prejudice on the grounds that the alleged “document deficiencies” in claims for reimbursement would not make those claims false or fraudulent.

The company also says the shareholders cannot show that its top officials had scienter, or the required intent to deceive, when they said Omnicare was in material compliance with government reimbursement requirements.

According to the defendants’ brief, Omnicare disclosed in each of its quarterly filings with the Securities and Exchange Commission that “its own internal compliance program ... from time-to-time has identified overpayments and other billing errors.”

The company also contends that revelation of the whistle-blower suit did not cause investors’ losses and that the securities fraud claim were properly dismissed.

Oral argument on the appeal has not yet been scheduled.

Omnicare shareholder disputes have been before the 6th Circuit previously. In May the court reinstated claims over alleged misrepresentations Omnicare’s 2005 stock offering materials based on the same allegations of fraudulent billing practices.


Attorneys:


Related Court Documents:
Appellees’ brief: 2013 WL 4648111
Appellants’ reply brief: 2013 WL 5290563

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ZYPREXA OVERDOSE (HOSPITAL NEGLIGENCE)

Prescription error caused mom’s overdose death, woman claims

A doctor and pharmacist at a Virginia hospital failed to detect a prescription error that led to an elderly dementia patient’s overdose and eventual death from the antipsychotic medication Zyprexa, the patient’s daughter alleges in a $10 million state court lawsuit.

Coggins v. HCA Health Services of Virginia Inc. et al., No. 2013-14603, complaint filed (Va. Cir. Ct., Fairfax County Sept. 19, 2013).

Karen P. Coggins seeks survivor damages on behalf of her mother’s estate for “inappropriate” prescription of the drug, injuries and mental anguish.

The complaint filed in the Fairfax County Circuit Court says a psychiatrist prescribed a daily dose of 2.5 milligrams of olanzapine, also known as Zyprexa, to Patricia M. Coggins in summer 2012 as treatment for anxiety and depression related to mild dementia.

Zyprexa packaging contains a “black box” warning from the Food and Drug Administration that says it is not approved for the treatment of dementia-related psychosis and carries an increased risk of death for patients with dementia.

When Patricia felt ill and experienced mental fogginess Aug. 4, 2012, Coggins took her to the emergency room at Reston Medical Center, where she was diagnosed with mild pneumonia, according to the suit.

Coggins allegedly brought her mother’s medications to the hospital, where nurse Celina X. Wan recorded them and incorrectly noted the prescribed daily dose of Zyprexa as 25 milligrams instead of 2.5 milligrams, the suit says.

Patricia’s attending physician, Dr. Xuwan Liu, failed to recognize the error and ordered that 25 milligrams of the drug be given to Patricia each day, the complaint says.

Pharmacist Linda D. Canady received and filled the order, and nurse Bernice M. Rechlis administered the “massive” dose of Zyprexa to Patricia, who became incoherent and unable to follow commands or move her legs, according to the suit.

None of the health care providers recognized the error until the next day when Patricia’s son Michael looked at the Zyprexa bottle his sister had brought to the hospital and noticed the discrepancy in dosage, the complaint says.

Patricia allegedly suffered permanent debilitation of her mental status from the overdose and never recognized her family again, according to the suit. She transferred to a rehabilitation facility, where she suffered several falls related to the overdose and died Nov. 9, 2012.

Coggins alleges that Wan, Liu, Canady and Rechlis breached the standard of care by ordering and administering Zyprexa to a dementia patient and failing to prevent the dosage error.

HCA Health Services of Virginia, operator of Reston Medical Center, is also a defendant in the suit.

Liu was grossly negligent by failing to independently verify the dosage on the first bottle and by ordering the drug without first consulting with Patricia’s physician or a pharmacist, the complaint says.

Canady should have known the prescription was an error because the maximum daily dose of Zyprexa is typically 20 milligrams, but she acted with gross negligence by failing to discuss the prescription with Liu, according to the suit.

Coggins seeks $5 million in compensatory damages for negligence and wrongful death, and $5 million in punitive damages for gross negligence.

Attorneys:

Related Court Document:
Complaint: 2013 WL 5402408
Philadelphia federal judge to lead Niaspan antitrust multidistrict proceeding

A Philadelphia federal judge will oversee consolidated pretrial proceedings in eight suits accusing Abbott Laboratories, Teva Pharmaceuticals and other companies of using “reverse payment” agreements to stall the arrival of generic competition for Abbott’s brand-name cholesterol-management drug Niaspan.


The Judicial Panel on Multidistrict Litigation selected the U.S. District Court for the Eastern District of Pennsylvania to host the proceedings, noting that seven of the eight pending antitrust cases alleging manipulation of the market for the drug are pending there.

In its transfer order, the panel said that the eighth case, from the District of Rhode Island, will join the other cases in Philadelphia despite arguments by the plaintiff, the City of Providence, that the consolidation occur there.

Handling the cases in Philadelphia will be Senior U.S. District Judge Jan E. DuBois, who the panel described as “an experienced transferee judge who we are confident will steer this litigation on a prudent course.”

The plaintiffs, mainly employee labor unions or drug co-operatives, allege Abbott intentionally delayed the September debut of a Niaspan generic (niacin extended-release tablets).

They say Abbott and Kos Pharmaceuticals Inc. (the previous Niaspan makers) were central to a web of private agreements and reverse-payment deals between Abbott it, Barr Pharmaceuticals, Duramed Pharmaceuticals Inc., Duramed Pharmaceuticals Sales Corp., AbbVie Inc., and Teva.

The drug is designed to raise the levels of HDL, or “good” cholesterol, and lower LDL, or “bad” cholesterol, and triglyceride rates in patients with difficulty controlling their cholesterol.

Name-brand Niaspan is now sold by AbbVie Inc., while Teva holds the right to market the first generic version, with other generics firms expected to follow suit.

The panel said that among the common issues to be decided by the MDL will be whether Abbott, Kos and their affiliates allegedly agreed to pay Teva in return for its agreement to delay the entry of a Niaspan generic, the effect of any such agreement on the Niaspan market, and the measure of damages incurred by direct and indirect purchases who were forced to pay top-dollar for the name brand version longer than necessary.

In an order written by JPML chairman John G. Heyburn II the panel said it knows of at least eight similar cases that may soon join the initial batch before Judge DuBois.

Related Court Document:
Transfer order: 2013 WL 5239728
Anti-smoking drug Chantix may be safe with treated depression, study says

(Reuters Health) – In a trial among people with a history of depression, those taking the quit-smoking aid varenicline — marketed in the U.S. as Chantix — were no more prone to depression or thoughts of suicide than those on a placebo, according to a new study.

In 2007 the U.S. Food and Drug Administration announced reports of serious side effects, including suicidal thoughts and erratic behavior in some people taking Chantix to stop smoking. The agency and Chantix manufacture Pfizer Inc. said at the time it was unclear whether the symptoms were caused by the drug or by nicotine withdrawal.

Two years later the FDA added a “black box warning” about these possible side effects to packages of Chantix and to another drug prescribed for smoking cessation, Zyban.

But the new trial results showing no greater depression risk while quitting smoking with Chantix, even in depression-prone patients, are not surprising according to lead study author Dr. Robert Anthenelli of the Veterans Affairs San Diego Healthcare System in California.

“Our prior experience using the medication in smokers with and without mental health disorders, and the results of more than 15 placebo-controlled randomized clinical trials found no such association,” he told Reuters Health.

About half of smokers seeking help in quitting are depressed or have suffered from depression and related disorders in the past, Anthenelli’s team points out in the Annals of Internal Medicine. Yet previous trials of drugs to aid smoking cessation have generally excluded people taking antidepressants or antipsychotic drugs to treat mental disorders, they write.

To test whether varenicline would help such patients quit smoking without exacerbating depression, Anthenelli and his fellow researchers, many of whom work for Pfizer, randomly assigned 525 adult smokers to take varenicline or a placebo.

All the trial participants had stable treated current or past major depression and no recent cardiovascular problems. They ranged in age from 18 to 79 and two thirds were women.

About three quarters of participants regularly used antidepressants and anti-anxiety drugs during the study, but people using other smoking-cessation medications, non-cigarette tobacco products or marijuana were excluded, as were people taking antipsychotic medications.

During the three-month treatment phase of the study, half the participants took Chantix, 1 milligram twice daily, and the other half got dummy pills. Afterward, all participants were followed for 40 weeks during which they no longer took the pills.

During the final month of taking the drug or placebo, participants took breath tests to detect carbon monoxide and verify whether they had abstained from smoking. Among those taking Chantix, 35 percent had not smoked, compared to 15 percent of the placebo group.

Previous studies have found that Chantix is “very effective” for quitting smoking, Anthenelli noted. Smokers who take the medication are two to three times more likely to successfully quit long-term than those who take a placebo, he said.

Participants taking Chantix were more likely to suffer from mild side effects like nausea, headache and abnormal dreams, and twice as many on Chantix reported insomnia compared to the placebo group. But there were no significant differences in mood or anxiety between groups and no worsening of depression in either group, according to the results.

Researchers monitored mood changes during the treatment phase and suicidal thinking or behavior for an additional 40 weeks after smokers stopped taking the medication.

At the beginning of the study, 88 people in the group taking varenicline reported any lifetime history of suicidal thoughts or attempts compared to 89 people in the placebo group.

At the start of the study, six people in the varenicline group and one in the placebo group had suicidal thoughts.

During the final 30 days of the three-month treatment phase, 15 people taking varenicline and 19 on placebo reported suicidal thoughts, and one placebo participant exhibited suicidal behavior.

There were two deaths among the participants during the 40-week follow up: one caused by an accidental fall, and the other by an overdose of morphine and another prescription medication.

It’s uncertain whether that overdose, which involved one of the participants who took varenicline, was a suicide, according to the researchers. But it happened 10 weeks after
participants stopped taking varenicline, so the death was not considered treatment-related, the authors write.

The study was funded by Pfizer and Anthenelli and some of his co-authors were supported by funding from the U.S. National Institutes of Health and other sources.

“This study addresses a critical gap in the literature by targeting smokers with major depression,” said Brian Hitsman, who studies cigarette smoking and depression at Northwestern University Feinberg School of Medicine in Chicago.

Smokers with depression would be especially vulnerable to any mood changes as a result of the drug, Hitsman told Reuters Health.

But the drug’s effects for people with untreated depression could be different and need to be studied as well, he cautioned.

Most smokers are not at an increased risk of depressive episodes after quitting, Anthenelli said.

“However, because depression is an episodic illness prone to recurrence, and since a minority of smokers with past histories of depression may be at increased risk after quitting, it’s important for clinicians to remain vigilant and monitor their patients closely,” he said.

People with depression are more likely to start smoking than others, and smokers with a history of depression are more likely to have severe withdrawal symptoms than those without depression, Anthenelli said.

“The bottom line is that close monitoring is still required when using varenicline to treat smokers with mental illness, even those with major depression, but it’s becoming increasingly clear that varenicline is safe and well-tolerated in this underserved population,” Hitsman said. WJ

(Reporting by Kathryn Doyle)

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SKIN CARE LOTION

Chicago man says Vaseline lotion caused ‘cosmetic disfigurement’

A Chicago man is seeking unspecified damages in an Illinois state court lawsuit alleging he suffered permanent “cosmetic disfigurement” after using Vaseline brand men’s skin care lotion.

Angel Cortez says he purchased the “fast absorbing” variety of Vaseline Men Body and Face Lotion from a CVS pharmacy in October 2011 and developed a rash and permanent skin damage from using it.

In a complaint filed in the Cook County Circuit Court, Cortez names as defendants the lotion’s makers, suppliers and distributors, including Unilever United States Inc., Unilever U.S., Unilever Supply Chain Inc., Unilever Illinois Manufacturing LLC, Unilever Foods & HPC Inc.


Cortez says his injuries stem from the defendants’ failure to properly develop and manufacture the product. He is seeking damages for medical expenses and current and future lost wages.

The suit also alleges the Unilever companies failed to properly warn users of the product’s potential health risks.

National pharmacy chain CVS LLC is also a defendant because the company “negligently and carelessly failed to evaluate and control its skin care products” in a way to prevent injury to the public.

CVS “knew or should have known” that its sale of the skin care product would cause injury and damage, the suit says. WJ

Attorneys:
Plaintiff: Randall F. Peters & Associates, Chicago

Related Court Document:
Complaint: 2013 WL 5428790
COMMENTARY

Consumer class actions take another hit: Supreme Court rules class-action arbitration waiver covers antitrust claims

By James Schurz, Esq.
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In American Express Co. v. Italian Colors Restaurant, No. 12-133, 133 S. Ct. 2304 (June 20, 2013), the U.S. Supreme Court dealt another blow to consumer class actions. The high court ruled that federal courts cannot overturn a class-action arbitration waiver simply because it would cost plaintiffs more to arbitrate the claim than they could possibly recover.

In a 5-3 decision, the justices held that the Federal Arbitration Act, 9 U.S.C. § 1, bars courts from invalidating such waivers even where pursuing a federal antitrust claim on an individual basis would be prohibitively expensive.

The decision is a critical extension of AT&T Mobility v. Concepcion, 131 S. Ct. 1740 (2011), which enforced a class-action waiver in an arbitration clause in a standard customer agreement. The Concepcion decision was criticized as a “devastating blow to consumer rights” and a major setback for people who lack the resources to challenge big companies. The other shoe has now dropped.

The Supreme Court’s decision in American Express removes the last significant defense to avoiding an individual arbitration clause when a consumer would prefer to pursue a class action. Counsel for plaintiff Italian Colors Restaurant, Deepak Gupta of Gupta Beck, said the Supreme Court’s most recent term “was a near blood-bath for class-action plaintiffs’ lawyers.”

Justice Elena Kagan was only slightly less dramatic, observing: “To a hammer, everything looks like a nail. And to a court bent on diminishing the usefulness of [Federal Rule of Civil Procedure] 23, everything looks like a class action, ready to be dismantled.”

The combined impact of Concepcion and American Express on consumer class actions is transformative. And we can expect to see a shift in consumer class-action lawyers’ tactics in its wake.

**AMEX V. ITALIAN COLORS RESTAURANT**

The case began when a group of merchants sued American Express over the fees they had to pay each time a customer charged a purchase. Italian Colors Restaurant, an eatery in Oakland, Calif., sought to team up with other merchants to argue that American Express was violating antitrust laws.

According to the merchants, American Express used its monopoly power in the charge cards market to force merchants to accept its less popular credit cards. Charge card transactions must be paid in full each billing cycle. Credit cards allow customers to carry a balance based on making a required minimum payment. The merchants asserted that American Express credit cards force them to pay rates that are 30 percent higher than Visa’s and MasterCard’s.

American Express violated the Sherman Act, 15 U.S.C. § 1, by “tying” the less popular credit cards to the charge cards, according to the merchants.

American Express has a standard agreement with merchants requiring all disputes between the parties be resolved by arbitration. The agreement also provides that “[t]here shall be no right or authority for any claims to be arbitrated on a class action basis.” So when the merchants filed their antitrust action in federal court, American Express moved to compel individual arbitration under the Federal Arbitration Act.

The merchants argued that the costs associated with pursuing individual antitrust cases far exceeded any potential recovery. They sought judicial approval to pursue the claim as a class action in federal court as the only means to effectively vindicate federal statutory rights.

The 2nd Circuit sides with the merchants

The 2nd U.S. Circuit Court of Appeals sided with the merchants — three times — before the Supreme Court took the last word. And the dialogue between the Supreme Court and the 2nd Circuit tells us a lot about the Supreme Court’s reasoning.

In Amex I, 554 F.3d 300 (2d Cir. 2009), the 2nd Circuit said the merchants could proceed in federal court. The appeals court relied on a “vindication of statutory rights”
analysis, finding that enforcing the class-action waiver “would grant Amex de facto immunity from antitrust liability by removing the plaintiffs’ only reasonably feasible means of recovery.” For this proposition, the court relied on its determination that the plaintiffs had successfully shown they would incur prohibitive costs in individual actions.


The American Express v. Italian Colors ruling is the “worst Supreme Court arbitration decision ever,” according to some consumer advocates.

Stolt-Nielsen said class-action arbitration cannot be compelled where the arbitration clause makes no mention of class arbitration. The Supreme Court reasoned that class-action arbitration changes the nature of the proceedings so much that it cannot be presumed the parties consented to it when they agreed to arbitrate.

The 2nd Circuit in Amex II, 634 F.3d 187 (2d Cir. 2011), responded that Stolt-Nielsen did not affect its original decision. Stolt-Nielsen said parties cannot be forced into class arbitration when they have not agreed to it. But according to the 2nd Circuit, that did not mean the presence of a class arbitration waiver made the clause per se enforceable. And the appeals court concluded Amex’s clause was unenforceable because the prohibitive costs of individual action effectively denied the merchants the opportunity to vindicate their rights.

The Supreme Court responded again, this time through Concepcion.

Concepcion held that the Federal Arbitration Act preempts state contract law that conditions enforceability of arbitration clauses on the availability of certain procedures. At issue was California’s common-law unconscionability doctrine, the Discover Bank rule.3 This doctrine invalidated many class-action waivers if the court found they were included in adhesion contracts involving claims of relatively small amounts. The Supreme Court concluded this doctrine was preempted by the FAA’s liberal policy favoring arbitration, declaring “states cannot require a procedure that is inconsistent with the FAA, even if it is desirable for unrelated reasons.”

The 2nd Circuit requested the Amex parties to submit briefs on the impact of Concepcion in Amex III, 667 F.3d 204 (2d Cir. 2012), the appeals court concluded (for the third time) that the class-action waiver in the arbitration clause was unenforceable.

The court distinguished Concepcion based on the nature of the underlying right: Concepcion dealt with FAA preemption of state law doctrine, but the Amex case was about vindication of a federal statutory right.

So in Amex III, the 2nd Circuit reasoned Concepcion has no application where the class-action waiver precludes plaintiffs’ ability to vindicate a federal statutory right.

The Supreme Court granted certiorari to consider “[w]hether the Federal Arbitration Act permits courts ... to invalidate arbitration agreements on the ground that they do not permit class arbitration of a federal-law claim.”

**EFFECTIVE VINDICATION OF THE RIGHT TO PURSUE A CLAIM**

Since it has been more than four years since Amex I, it would be reasonable to assume there was a thicket of issues for the Supreme Court to untangle. Not really. The majority opinion is relatively simple and short.

In overturning the 2nd Circuit, Justice Antonin Scalia wrote for the majority that the individual arbitration requirement in the American Express clause was not a barrier to pursuing claims, but a limitation on the means of pursuit. “The antitrust laws do not guarantee an affordable procedural path to the vindication of every claim,” Justice Scalia reasoned. He further observed that the antitrust laws make no mention of class actions: “The fact that it is not worth the expense involved” to prove a claim does not eliminate the right to pursue such a claim.

The “effective vindication” exception relied upon by the 2nd Circuit is not so elastic as to encompass the costs of proving a particular claim, the majority wrote. Instead, it is limited to the right to pursue statutory remedies. The Supreme Court explained the exception would “certainly cover a provision in an arbitration agreement forbidding the assertion of certain statutory rights.”

The exception could also cover “filing and administrative fees attached to arbitration that are so high as to make access to the forum impracticable.” But so long as the parties have a right to pursue their federal statutory rights in an arbitration forum, a class-action waiver will stand.

Writing for the three dissenters, Justice Kagan found this reasoning unpersuasive, bordering on the outrageous. She explained that the Amex arbitration clause “imposes a variety of procedural bars that would make pursuit of the antitrust claims a fool’s errand.”

“So if the arbitration clause is enforceable, Amex has insulated itself from antitrust liability — even if it has in fact violated the law,” she wrote. “The monopolist gets to use its monopoly power to insist on a contract effectively depriving its victims of all legal recourse.”

She summarized the majority’s holding as “admirably flaunted rather than camouflaged: Too darn bad.”

**LOOKING TO THE FUTURE**

The American Express v. Italian Colors ruling is the “worst Supreme Court arbitration decision ever,” according to some consumer advocates. “The Supreme Court took another big step down the road of permitting companies to use arbitration agreements to entirely insulate themselves from class-action liability,” professor Brian Fitzpatrick of Vanderbilt Law School said. “The writing is on the wall now more clearly than ever: There is little future for consumer and employment class actions, and even shareholder class actions may not survive.”

Are consumer class actions really over? No. But we can expect the following trends to accelerate.

*Expect increase in class-action waivers in consumer and employment contracts.*

Given Concepcion and American Express, we can anticipate the increased use of class-action waivers in a broad variety of business contracts. It is already happening. This development will likely strain administering organizations such as the American Arbitration Association, which are generally ill-equipped to handle
identical claims in different jurisdictions. Interests of confidentiality pose further obstacles to ensuring consistent, predictable results. Expect to see redesigned due process protocols from alternative dispute resolution organizations for arbitration of consumer disputes.

Consumer-friendly provisions in arbitration agreements are not necessary.

AT&T designed its consumer arbitration procedures to ensure that individual customers would be motivated to bring their claims. This was accomplished through a series of cost-shifting provisions, minimum recovery for consumers and other measures. Although the 9th Circuit noted these provisions in its analysis in Concepcion, the Supreme Court paid little attention to them. American Express makes it clear these protections are of no consequence. While such protections may have salutary benefits in terms of customer relationships, it is irrelevant to the issue of enforceability under the FAA or application of the “effective vindication” exception.

Offer and acceptance will be the principal battleground.

In light of the Supreme Court’s narrowing of the “effective vindication” exception, we can expect to see increased attacks on issues relating to contract formation. In both Concepcion and American Express, the court reaffirmed its position that the FAA is not implicated when a party successfully challenges the formation of the arbitration agreement, such as by proving fraud or duress. In the consumer arena, proving offer and acceptance is often complicated given the varied distribution channels: online, third-party distribution partners, brick-and-mortar stores. Expect to see increased scrutiny from courts that may be reluctant to send claims to private dispute resolutions systems where there is no clear manifestation of assent.

Expect increase in class actions for products that do not involve adhesion contracts.

In recent years, there has been an increase in class actions alleging misrepresentation and unfair business practices involving everyday products, such as toiletries, cosmetics and food. Expect that trend to continue. As claims over certain categories of products are directed to individual, private dispute resolution procedures, there likely will be a shift to those products that do not have standard terms of sale.

More regulations are likely from Consumer Financial Protection Bureau.

Recent efforts to restrict arbitration in the consumer context have stalled in Congress. But expect to see increased pressure on the Consumer Financial Protection Bureau to propose regulations that limit or restrict the use of arbitration in consumer financial services agreements.

NOTES

4 Paul Bland, The Worst Supreme Court Arbitration Decision Ever, PUBLIC JUSTICE (June 20, 2013), http://publicjustice.net/blog/worst-supreme-court-arbitration-decision-ever,
Recent labeling changes

The Food and Drug Administration announced that as of Sept. 26, the following products had modifications to their labeling in August, including “boxed warnings,” contraindications, warnings, precautions, adverse-reaction sections or patient package inserts.

Ablavar (Gadofosveset Trisodium) injection
Aerospan (flunisolide) inhalation aerosol
Amaryl (Glimepiride) tablets
Avelox (Moxifloxacin Hydrochloride) tablets and injection
Cipro (Ciprofloxacin Hydrochloride) tablets and oral suspension
Cipro IV (Ciprofloxacin Hydrochloride) injection
Cipro XR (Ciprofloxacin extended-release) tablets
Colyte (Peg-3350 & electrolytes) for oral solution
Crestor (Rosuvastatin Calcium) tablets
Daliresp (Roflumilast) tablets
Desoxyn (Methamphetamine Hydrochloride) tablets
Doxil (Doxorubicin HCL) liposome injection
Factive (Gemifloxacin Mesylate) tablets
Firmagon (Degarelix for injection)
Halaven (Eribulin Mesylate) injection
Intuniv (Guanfacine) Extended-release tablets
Letairis (Ambrisentan) tablets
Levaquin (Levofloxacin) tablets, oral solution and injection
Lialda (Mesalamine) delayed-release tablets
Mirena (Levonorgestrel-releasing intrauterine system)
Noroxin (Norfloxacin) tablets
Omniscan (Gadodiamide) injection
Optimark (Gadoversetamide) injection
Quillivant XR (Methylphenidate) extended-release oral suspension
Relistor (Methylnaltrexone Bromide) subcutaneous injection
Ryalto (Atazanavir Sulfate) capsules
Septra and Septra DS (Trimethoprim and Sulfamethoxazole) tablets
Sirturo (Bedaquiline) tablets
Skylla (Levonorgestrel-releasing intrauterine system)
Strattera (Atomoxetine Hydrochloride) capsules
Sutent (Sunitinib Malate) capsules
Votrient (Pazopanib) tablets
Xarelto (Rivaroxaban) tablets
Xgeva (Denosumab) injection
Zevalin (lbritumomab Tiuxetan) injection

CLASS ACTION

This reporter covers the proliferation of the class action lawsuit in numerous topic areas at the federal, state, and appeals court levels. Topics covered include consumer fraud, securities fraud, products liability, automotives, asbestos, pharmaceuticals, tobacco, toxic chemicals and hazardous waste, medical devices, aviation, and employment claims. Also covered is legislation, such as the 2005 Class Action Fairness Act and California’s Proposition 64, and any new federal and state legislative developments and the effects these have on class action litigation.

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Novartis
CONTINUED FROM PAGE 1

the appellate court mistakenly cited Levine, which involved only compensatory damages, the company said.

“We are disappointed that the United States Supreme Court has denied the Novartis petition and that we won’t have the opportunity to present our case to the court at this time,” Novartis spokeswoman Julie Masow said in an emailed statement.

According to Herbert Fussman’s Supreme Court opposition brief, his late wife, Rita, began taking Aredia in June 2001 to treat bone cancer that had spread from her breasts. He said his wife’s oncologist soon switched her to Zometa, a new Novartis bone-strengthening medication that, like Aredia, is product from the family of bisphosphonate drugs.

The Fussman suit claims that Novartis knew of the risk of developing osteonecrosis of the jaw, or bone death due to lack of blood supply, linked to the drugs before his wife started taking them, but failed to timely alert the medical community or general public.

Fussman said his wife used Zometa used until 2005. In the interim, she had two teeth extracted, causing dental problems, which led to her March 2003 diagnosis of osteonecrosis of the jaw.

Rita Fussman died in 2009 just as the case was going to trial before Judge James A. Beaty of the U.S. District Court for the Middle District of North Carolina. Herbert Fussman was substituted as plaintiff, both personally and as representative of her estate.

A jury ruled for Fussman, awarding $12.6 million in punitive damages plus $287,000 in compensatory damages. Citing North Carolina law, Judge Beaty reduced the total award to $1.2 million, including punitive damages of $867,000.

Although Novartis filed three post-trial motions for a new trial and motions for judgment as a matter of law on all counts, Judge Beaty let the awards stand. He said Fussman had submitted more than 150 documents supporting his claim that Novartis knew of the risk of ONJ posed by Aredia and Zometa but failed to adequately warn consumers (see Westlaw Journal Pharmaceutical, Vol. 26, Iss. 10).

Novartis appealed to the 4th Circuit, seeking a new trial. The company said Judge Beaty erred in admitting into evidence a series of 2004 emails between Novartis and two doctors on the osteonecrosis risk factors linked to bisphosphonates. The company also said the judge should have barred from evidence data on a 2007 change in the Zometa warning label. The revised label bore tougher language on jaw damage, compared with the 2003 label that was used when Rita Fussman took the drug.

On Feb. 8 the appeals court rejected Novartis’ claims, upholding the award. It said the possible error of admitting data on the 2007 label revision did not prejudice Novartis because other significant evidence signaled Novartis’ awareness of Zometa’s dangers.

Novartis petitioned the Supreme Court for review May 9, saying the Food and Drug Administration’s authority over the drug approval process bars private litigation that seeks to compel new warnings on FDA-approved drugs. Novartis also said federal law prohibits the use of such suits to “punish a manufacturer for alleged failures to properly communicate with the FDA during the drug approval process.”

Fussman told the high court the rulings below should stand and that the 4th Circuit properly rejected Novartis’ claims that the FDA already has “ample power” to punish and that allowing what Novartis called punishment of FDA-approved conduct was improper.

“The ability for juries to impose punitive damages against FDA-compliant manufacturers of prescription drugs threatens the availability of necessary and often lifesaving medications for patients around the world,” Masow added. “NPC believes that the Fussman petition took an important first step in raising this issue with the court, and we anticipate that the court will address the arguments raised in the petition in the future.”

Attorneys:

Related Court Documents:
Cert petition: 2013 WL 1912100
Opposition brief: 2013 WL 3930513
Petitioner’s reply: 2013 WL 4049444

See Document Section A (P. 21) for the certiorari petition and Document Section B (P. 36) for Novartis’ opposition brief.
Jaw bone death
CONTINUED FROM PAGE 1

metastasized to her bones, was prescribed Aredia in 1999 by oncologist Darrell Johnson.

Johnson provided no warnings about Aredia as he was then unaware of the link between ONJ and bisphosphonates, the opinion says.

After Payne had been on Aredia for two years, Johnson, still unaware of the ONJ risk, switched her to Zometa, according to the opinion.

In reviewing a 2005 bone scan, Johnson observed an abnormality in Payne’s mandible, or jaw bone. He referred her to a dentist and suspended her Zometa treatments as he had by then learned of a link between ONJ and bisphosphonates, according to the opinion.

Several of Payne’s teeth were removed by an oral surgeon, who diagnosed her with bisphosphonate-induced ONJ, the document says.

Payne’s mandible and maxilla were later removed. Although she stopped using Zometa in 2005, she still suffers from jaw problems, according to the opinion.

Payne sued Novartis in 2008, asserting strict liability, failure to warn, breach of the warranty of merchantability and fraud. Her husband, Brent, tendered a claim for loss of consortium.

The Paynes said Novartis should have warned Johnson of the possible link between ONJ and bisphosphonates.

Novartis moved for summary judgment, and Judge Collier granted the motion.

Under Tennessee law, “even if an inadequate warning is found to render a product defective or unreasonably dangerous, a plaintiff must still establish proximate causation between the failure to warn and her injury,” the judge said, quoting from *Hurt v. Coyne Cylinder Co.*, 956 F. 2d 1319, 1329 (6th Cir. 1992).

Since Tennessee law applies the “learned intermediary doctrine” by which a physician effectively replaces a patient to whom a duty to warn is owed, the plaintiffs must show that a different warning would have altered the prescribing physician’s conduct, the judge explained.

The evidence shows that even if Novartis had warned Johnson of the ONJ risk before he prescribed Payne’s bisphosphonates, he would have done so anyway, Judge Collier said.

Attorneys:


Related Court Document:
Opinion: 2013 WL 4779571
NEWS IN BRIEF

FTC WEIGHS IN AS AMICUS IN EFFEXOR XR SUIT

In an amicus brief filed in the Effexor XR antitrust litigation, the Federal Trade Commission argues strongly against the defendants’ assertion that antitrust liability can arise from an agreement to settle Hatch-Waxman patent litigation only if it involves a cash payment. The U.S. Supreme Court’s recent decision in FTC v. Activis, 133 S. Ct. 2223 (June 17, 2013), would be seriously undermined if branded drug companies were able to sidestep antitrust review by using noncash payments to delay generics from entering the market, the agency says. In a series of suits filed in the U.S. District Court for the District of New Jersey, direct and indirect purchasers of Effexor XR accuse Wyeth LLC of an anticompetitive scheme to block generic versions of the depression and anxiety treatment from entering the market.


FDA CAUTIONS ON PROPER DISPOSAL OF ‘PAIN PATCHES’

The Food and Drug Administration is reminding the public to properly dispose of fentanyl-containing pain patches to avoid exposing children and others to the drug. The agency said in a Sept. 23 alert that since it issued a similar warning in April 2012, two children have died from accidental exposure to the patches, which release a potent narcotic opioid. Consumers should fold used patches — sticky side together — and flush them down the toilet, not placed them in trash cans accessible to children and pets, the alert said. The FDA said it will now require the manufacturers of the brand-name Duragesic pads and its generic counterparts to print the name and strength of the drug more clearly on each patch in long-lasting ink, so patients can easily find patches that have fallen off.

MICROBIAL CONTAMINATION PROMPTS CHILDREN’S’ SUNSCREEN RECALL

W.S. Badger Co., a manufacturer of organic and natural body care products, is recalling all lots of its SPF 30 Baby Sunscreen Lotion and one lot of SPF 30 Kids Sunscreen Lotion. The company says the lotions, all sold in four-ounce tubes since February at pharmacies and independent food co-ops, were found to contain Pseudomonas aeruginosa, Candida parapsilosis and Acremonium fungi. Badger announced the recall through the Food and Drug Administration on Sept. 25. The New Hampshire-based firm’s website says the sunscreen passed all presale microbiological testing but contamination was found in routine post-production screening. The statement says there have been no adverse effects reported in relation to the issue. Customers can return the product to its place of purchase for a refund or contact the company at 800-603-6100 for more information.
# CASE AND DOCUMENT INDEX

Coggins v. HCA Health Services of Virginia Inc. et al., No. 2013-14603, complaint filed (Va. Cir. Ct., Fairfax County Sept. 19, 2013) ................................................................. 8

Cortez v. Unilever United States Inc. et al., No. 2013-L-010844, complaint filed (Ill. Cir. Ct., Cook County, Law Div. Sept. 30, 2013) ........................................................................................................ 11

In re Effexor XR Antitrust Litigation, No. 11-cv-5479, amicus brief filed (D.N.J. Sept. 13, 2013) ........................................................................................................ 18

In re Niaspan Antitrust Litigation, MDL No. 2460, 2013 WL 5239728 (J.P.M.L. Sept. 17, 2013) ........................................................................................................ 9

In re Omnicare Inc. Securities Litigation, No. 13-5597, reply brief filed (6th Cir. Sept. 12, 2013) ........................................................................................................ 7


**Document Section A** .................................................................................................................................................................................. 21

**Document Section B** .................................................................................................................................................................................. 36