Westlaw Journal Formerly *Andrews Litigation Reporter*

MEDICAL DEVICES

Litigation News and Analysis • Legislation • Regulation • Expert Commentary

VOLUME 17, ISSUE 24 / JANUARY 18, 2011

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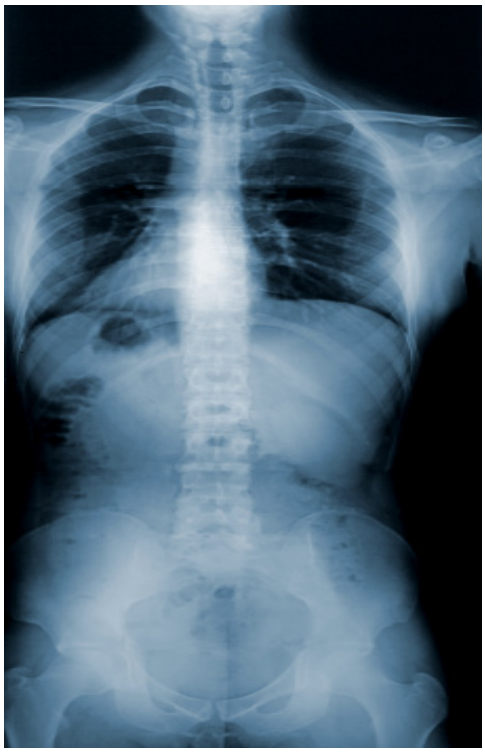
BONE STIMULATOR (FALSE CLAIMS ACT)

Fraud claims upheld against bone stimulator maker



A federal judge in Boston has ruled that Orthofix International must face claims that it defrauded the government by submitting purchase invoices for Medicare coverage of bone growth stimulators when the devices actually are used only temporarily and should have been offered for rent.

United States ex rel. Bierman v. Orthofix International NV et al., No. 05-10557, 2010 WL 4973635; United States ex rel. Laughlin v. Orthofix International, No. 08-11336, 2010 WL 4358380 (D. Mass. Dec. 8, 2010).

U.S. District Judge Edward F. Harrington of the District of Massachusetts denied the company's motion for summary judgment on charges that it violated the False Claims Act, 31 U.S.C. § 3729-3733.

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COMMENTARY

Concerns heighten over the prospect of 'responsible corporate officer' prosecutions against drug and device manufacturers

Kim Schmid and Molly Given of Bowman & Brooke and Mark DuVal and Mark Gardner of DuVal & Associates offer their insight on how consumer product and medical device manufacturers should prepare themselves to face promises from the Food and Drug Administration and the Justice Department that they intend to focus on enforcement of the "responsible corporate officer" doctrine.

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Westlaw Journal Medical Devices

Published since June 1994

Publisher: Mary Ellen Fox

Executive Editor: Jodine Mayberry

Production Coordinator: Tricia Gorman

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Westlaw Journal Medical Devices
(ISSN 2155-725X) is published biweekly by Andrews Publications, a Thomson Reuters/ West business.

Andrews Publications
175 Strafford Avenue
Building 4, Suite 140
Wayne, PA 19087
877-595-0449
Fax: 800-220-1640
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7th Circuit restores negligence suit over failed Trident hip implant

A federal appeals court has unanimously reinstated a negligence suit over woman's failed Trident model prosthetic hip, saying the trial judge erred both in finding the action federally preempted and rejecting the plaintiff's motion to amend her complaint.

Bausch v. Stryker Corp. et al., No. 09-3434, 2010 WL 5186062 (7th Cir. Dec. 23, 2010).

The 7th U.S. Circuit Court of Appeals restored Margaret J. Bausch's state law product liability and negligence action against medical device maker Stryker Corp., finding that U.S. District Judge Samuel Der-Yeghiayan should not have dismissed her original complaint.

The panel said that while medical device makers are immune from restrictions that go beyond those required under federal law, the Medical Device Amendments, 21 U.S.C. § 360(k), to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, do not preclude claims for defective manufacture that allege violation of federally approved design standards.

In March 2007 Bausch underwent a total right hip replacement with a Trident "ceramic on ceramic" joint, manufactured and marketed under an agreement among defendants Stryker Corp., Howmedica Osteonics Corp. and Stryker Ireland Ltd.

Six days before the procedure the Food and Drug Administration sent the defendants a letter indicating that the Trident implant was adulterated "due to manufacturing methods ... not in conformity with industry and regulatory standards," the complaint says.

The Trident system was recalled 10 months later, and Bausch's implant eventually failed and required replacement.

Bausch field suit in the U.S. District Court for the Northern District of Illinois, alleging that defects in the system rendered it unreasonably dangerous.

In December 2008 Judge Der-Yeghiayan granted a defense motion for summary judgment, dismissing the case on the grounds that Bausch's allegations are barred under the Supreme Court's ruling on federal preemption in *Riegel v. Medtronic*, 552 U.S. 312 (2008).

He later refused to reconsider the decision and denied Bausch's motion to amend her complaint, saying it would not cure the federal preemption issues (see *Medical Devices LR*, Vol. 16, Iss. 16).

Bausch advanced the case to the 7th Circuit, where she won a ruling declaring that her claims of product adulteration and defective manufacture in violation of federal law "are not expressly preempted by Section 360k."

Such a stance, the panel said, is consistent with *Riegel* and "numerous circuit and district court decisions that have considered similar claims based on alleged violation of federal law."

The appeals court said the Medical Device Amendments provide immunity for medical device makers, "to the extent that they comply with federal law, but it does not protect them if they have violated federal law."

The 7th Circuit rejected Stryker's defense that Bausch's allegations were expressly and impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

The panel also disagreed with Stryker's argument that there is no traditional state law tort claim for an adulterated product.

"The federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law," the appeals court said. WJ

Attorneys:
Plaintiff-appellant: David Rapoport, Chicago

Defendants-appellees: Robert M. Connolly, Stites & Harbison, Louisville, Ky.

Related Court Document:
Opinion: 2010 WL 5186062

See Document Section B (P. 22) for the opinion

> "The evidence shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient," the panel said.

Bone stimulator

CONTINUED FROM PAGE 1

He said the plaintiff, a medical billing specialist who is part of a government-backed *qui tam* case against Orthofix, offered specific detail backing his allegations that Medicare was overbilled for the bone growth stimulators.

Jeffrey J. Bierman filed the suit on behalf of the federal, state and local governments, alleging Orthofix and subsidiary Orthofix Inc. routinely billed the stimulators to Medicare and other health plans as "purchase only" items between 1993 and 2010.

The devices are used for three to six months and deactivate themselves after nine months, the suit says. Bierman said Orthofix repeatedly denied requests that the stimulators be made available on a rental basis.

Since the purchase price for an electronic stimulator is about 10 times more than a monthly rental fee, Medicaid was defrauded out of an untold amount of reimbursement money, the suit says.

Bierman, co-owner of a business that does billing services for health care providers, says Orthofix violated the FCA with each stimulator provided under such conditions.

He says the company also defrauded the government in completing the health insurance claim form and "certificate of medical necessity" required for each device sold.

Orthofix moved to dismiss Bierman's complaint, saying he failed to state a valid claim and fell short of pleading his fraud allegations with the detail required by Federal Rule of Civil Procedure 9(b).

Judge Harrington denied the motion.

He said Bierman's complaint was sufficiently pleaded to "pass muster," as it included a schedule of Medicare reimbursement claims submitted by Orthofix and co-defendant Biomet Inc. for the years in question.

The judge said that since patients typically use bone stimulators for six months at the most, Bierman's data showing that all the stimulators logged in his records were provided exclusively as "purchase items" offered substantial support for his claims against the defendants.

"Each claim in the table was reimbursed by Medicare as a purchase item. Since no rational beneficiary would ever pay for more than the nine-month rental price, there is sufficient basis to infer that beneficiaries were never offered the rental option," he wrote.

Bierman, the judge said, also sufficiently alleges that the defendants "made concerted efforts to maintain the stimulators as purchase-only items."

The complaint details "numerous instances" in which Bierman, acting as a billing service provider, "was told by the defendants' representatives, who are identified in the complaint by reference to their corporate title, that the stimulators were not for rent," according to the judge.

In November Judge Harrington dismissed a former Orthofix employee's related *qui tam* fraud claims against the firm, saying the complaint lacked the needed detail. Plaintiff Marcus Laughlin's accompanying wrongful-termination claims were allowed to proceed. *United States ex rel. Laughlin v. Orthofix Int'l NV et al.*, No. 08-11336, 2010 WL 4358380 (D. Mass. Nov. 4, 2010). WJ

Attorneys:
Defendants: Andrew C. Bernasconi, Reed Smith LLP, Washington

Plaintiff: Neil V. Getnick, Getnick & Getnick, New York

Related Court Documents:
Memorandum and order: 2010 WL 4973635
Second amended complaint: 2010 WL 3557053

See Document Section A (P. 17) for the memorandum and order.

Missouri woman can pursue federal court suit over failed Trident hip

A federal judge in St. Louis has denied Howmedica Osteonics Corp.'s motion to dismiss a suit by a Missouri woman who says her Trident hip replacement cracked because of flaws that the company failed to promptly report to the government.

Warren et al. v. Howmedica Osteonics Corp., No. 4:10-cv-1346, 2010 WL 5093097 (E.D. Mo., E. Div. Dec. 8, 2010).

U.S. District Judge David D. Noce of the Eastern District of Missouri turned back the company's arguments that Pamela Warren's strict liability and negligence claims are expressly and impliedly preempted and that the plaintiff failed to state a plausible claim.

In rejecting the motion, the judge said Warren and her husband had "concretely premised their state law claims on violations of federal regulations." Thus, the action accusing Howmedica of failing to follow federal medical device reporting rules is not preempted.

Judge Noce said Warren's claims "do not impose any additional duties on defendant" and "stem solely from defendant's alleged violation of federal regulations."

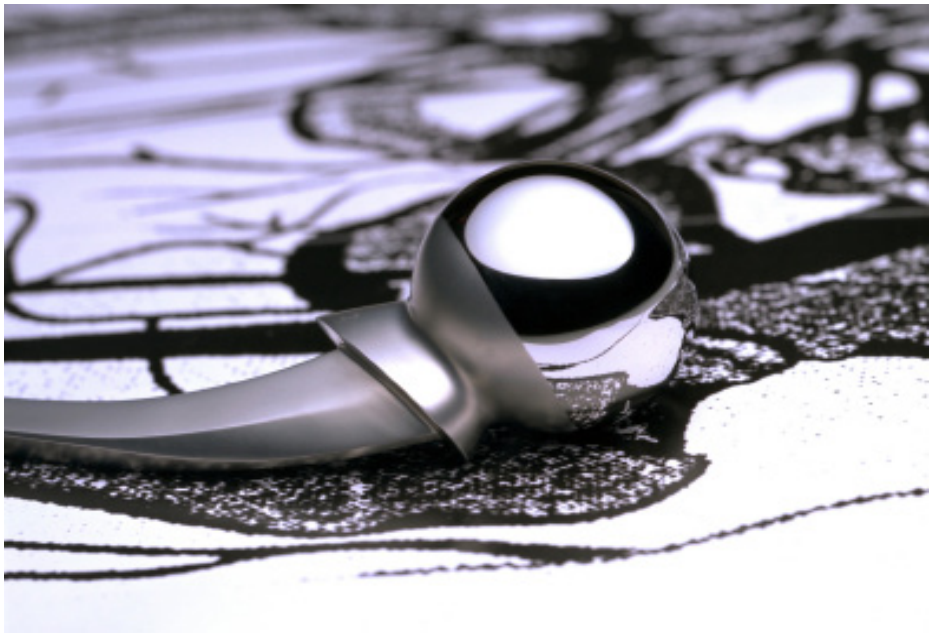
The Warrens sued Howmedica and Stryker Corp. in the St. Louis County Circuit Court, claiming that the Trident ceramic acetabular device implanted in her right hip fractured in 2007 after just three years in use.

The Trident system, which won Food and Drug Administration approval in 2003, was manufactured and marketed under an agreement between Stryker and Howmedica.

The suit says the device's ceramic lining cracked and that several shards migrated within Warren's hip area and had to be removed during a revision operation.

Howmedica announced three separate recalls of Trident components between March 2006 and January 2007, according to the suit.

Also, in 2007 Howmedica received two FDA warning letters informing it that manufacturing violations found at factories in Ireland and New Jersey rendered the Trident parts made at those plants "adulterated" under federal law, the complaint says.



The Warrens say the defendants failed to comply with federal medical device reporting rules requiring manufacturers to promptly tell the FDA of failure investigations or adverse effects stemming from the use of their products.

Citing diversity of jurisdiction, the defendants removed the action to the District Court and moved to dismiss.

The companies said:

- The action was both expressly and impliedly preempted.
- It did not assert a valid claim.
- David Warren's loss-of-consortium claim fails because of the lack of a valid underlying cause of action.

Judge Noce rejected the arguments, finding the claims valid and that federal law does not preempt them because they are based on state claims that mirror the defendants' responsibilities under federal law.

Because the Warrens had based their state law claims on federal law, the judge said their suit may proceed into the discovery phase. WJ

Attorneys:
Plaintiffs: M. Graham Dobbs, Gray & Ritter, St. Louis

Defendant: Robert M. Connolly, Stites & Harbison, Louisville, Ky.

Related Court Document:
Memorandum and order: 2010 WL 5093097

See Document Section C (P. 34) for the memorandum and order.

SPINAL FUSION SYSTEM (MALPRACTICE)

Mistrial declared after defendant doctor treats sick juror

An Arkansas federal judge has declared a mistrial after a defendant physician provided medical care to a juror who became sick in court.

Chaffin v. Eichert et al. No. 3:09-cv-00002-JLH, mistrial declared (E.D. Ark., Jonesboro Dec. 14, 2010).

Dr. Stephen Eichert rushed to the aid of the juror Dec. 13 shortly after opening argument began in the trial of plaintiff Christina Renee Chaffin's malpractice lawsuit against the physician and his practice.

After the medical emergency was over, U.S. District Judge J. Leon Holmes of the Eastern District of Arkansas declared a mistrial.

Chaffin alleged the neurosurgeon negligently breached the standard of care by failing to recognize that a defect in her spine made her an inappropriate candidate for the lumbar fusion surgery he performed in June 2006.

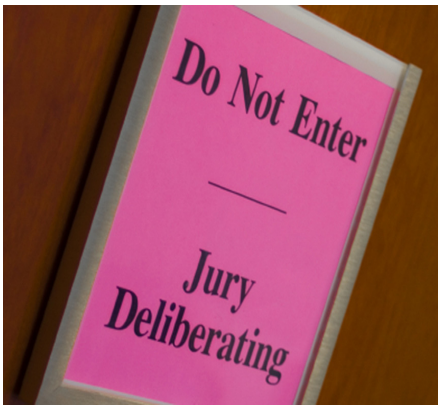
The complaint alleged Eichert negligently implanted a spinal fusion hardware system into Chaffin's lumbar spine without performing diagnostic tests that would have alerted him to her spinal defect.

According to the complaint, Chaffin consulted the defendant in January 2005 for lower-back pain, which Eichert treated conservatively through pain management therapy.

When Chaffin did not improve after nearly a year of treatment, Eichert recommended she undergo a surgical fusion procedure with the use of spinal hardware, the suit alleged.

Although Chaffin had the surgery June 14, 2006, it failed to correct her condition, according to the complaint. Eichert implanted her with Medtronic's CD Horizon Spire spinal system, using it on an "off-label" basis, meaning the device was not federally approved for the procedure.

In October 2006 Chaffin sought a second opinion and learned that her lumbar spine was unstable and that "no fusion was present." She underwent corrective surgery Oct. 18 to remove the hardware.



Before Chaffin consented to the surgery, Eichert failed to appropriately inform her of the high risk of injury and failure associated with the procedure, the complaint alleged.

Chaffin was seeking damages for her pain and suffering, the cost of both surgeries, lost wages, and mental anguish.

A retrial has been rescheduled for July 18. WJ

Attorneys:
Plaintiff: Jeffrey D. Germany, Morton & Germany, Memphis, Tenn.

Defendant: Rick T. Beard III, Mitchell, Williams, Selig Gates & Woodyard, Little Rock, Ark.

Related Court Document:
Complaint: 2008 WL 3993997

PROSTHETIC KNEE

Negligence claims restored in Alabama knee implant suit

An Alabama woman can proceed with a negligence suit against Stryker Howmedica Osteonics Corp. after a federal judge, who had provisionally dismissed the action over her failed prosthetic knee, said her recent filings contain the detail needed to support her claims.

Blackwell v. Stryker Howmedica Osteonics Corp., No. 1:10-cv-03785, 2010 WL 5139256 (S.D. Ala., S. Div. Dec. 13, 2010).

U.S. District Judge William H. Steele of the Southern District of Alabama reinstated the action, saying Emma C. Blackwell had remedied shortcomings that plagued her initial complaint against the medical device company.

Those failings led the judge to grant Stryker's motion to dismiss the suit without prejudice in October. *Blackwell v. Stryker Howmedica Osteonics Corp.,* 2010 WL 4115415 (S.D. Ala., S. Div. Oct. 18, 2010) (see *Westlaw Journal Medical Devices*, Vol. 17, Iss. 19).

In the dismissal order, however, he suggested that Blackwell refile her *pro se* complaint and include data to support her claim that her Trident TS knee system failed after less than two years because of defects.

Blackwell, whose prosthetic knee was removed and replaced in early 2010, also says the manufacturing methods for the device fell below the established standard of care.

Reinstating the suit Dec. 13, Judge Steele said that while some language in Blackwell's amended complaint and motion to reconsider was confusing, he determined that she has sufficiently pleaded her claims against Stryker.

He said it is now clear that Blackwell received an artificial knee in 2008, that Stryker made the device, that it allegedly negligently manufactured and/or designed it, "that the knee failed in less than (perhaps much less than) two years," and that Blackwell allegedly suffered damages as a result.

"A prosthesis that fails within two years may very plausibly have been negligently made or designed," Judge Steele wrote. "That other plausible explanations for the failure exist is irrelevant." WJ

Attorneys:
Plaintiff: *Pro se*, Daphne, Ala.

Defendant: Brian M. Vines, Bradley Arrant Boult Cummings LLP, Birmingham, Ala.

Related Court Document:
Order: 2010 WL 5139256

Federal judge sinks suit claiming spinal device caused user to faint, crash car

Medtronic Inc. has won summary judgment in a federal product liability suit by a Louisiana woman who says she wrecked her car when an implanted spinal stimulation device malfunctioned and caused her to black out.

Pardo et al. v. Medtronic Inc. et al., No. 10-1562, 2010 WL 5300847 (E.D. La. Dec. 15, 2010).

U.S. District Judge Ivan L.R. Lemelle of the Eastern District of Louisiana said the plaintiff had not supported her claim that the components of her Restore Ultra rechargeable neurostimulation system did not receive pre-market approval, thus negating any federal preemption protection Medtronic said it enjoys.

The judge also discarded the accompanying claim for breach of express warranty, noting that the plaintiff never alleged reliance on such a warranty.

Deborah Pardo claimed she was implanted with the Restore system to alleviate chronic nerve pain and eliminate her dependence on pain drugs but that the system was defective and did not relieve her pain.

Pardo said that on the way home from a 2009 clinic visit, where Medtronic representatives tried to adjust the stimulator, she blacked out from severe pain and wrecked her car.

Pardo sued Medtronic for product liability and breach of warranty.

Medtronic moved to dismiss. The company said the Restore system, including its neurostimulator unit, stimulator lead and lead extension kit, received pre-market approval from the Food and Drug Administration.

Therefore the Medical Device Amendments, 21 U.S.C. § 360(k), to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, preempted Pardo's state law claims, Medtronic said.

In response, Pardo said two components that Medtronic did not mention, a battery recharger and a programming unit, were never shown to have received FDA pre-market approval.

The plaintiff added that federal preemption only applies if the approved device is implanted the way in which the FDA anticipated its use. She said the doctor who implanted her stimulator did not follow the approved method, instead implanting it in her right forehead, running the leads across the back of her neck, then into her right shoulder.

However, Judge Lemelle said Pardo had not supported that claim with evidence but simply stated that federal preemption is not intended to offer blanket protection from liability, "just liability consistent with the device's approved use."

The judge rejected the argument and Pardo's accompanying warranty claim, noting that she never offered evidence that she relied on the defendant's warranty before deciding to have the system implanted.

"Plaintiff fails to allege that the warranty was ever in fact applicable," the judge said. WJ

Attorneys:
Plaintiff: Robert W. Hallack, Baton Rouge, La.

Defendant: Kelly C. Bogart, Duplass, Zwain, Bourgeois, Morton, Pfister & Weinstock, Metairie, La.

Related Court Document:
Order and reasons: 2010 WL 5300847

See Document Section D (P. 40) for the order and reasons.

> The plaintiff never offered evidence showing she had relied on a warranty from Medtronic before deciding to have the Restore system implanted, the judge said.

PAIN PUMP

Case is strong against pain pump maker, Minnesota federal judge says

A federal judge in Minneapolis has rejected what he called a "premature" and "wholly inappropriate" dismissal motion by Stryker Corp. in a suit by a man who says his shoulder was destroyed because pain pumps were improperly used to inject anesthetics after three surgeries.

Strong v. Stryker Corp. et al., No. 10-2315, 2010 WL 4967876 (D. Minn. Dec. 1, 2010).

U.S. District Judge Michael J. Davis denied Stryker's every effort to have Neil Strong's suit thrown out, saying the motion to dismiss was, in essence, a summary judgment motion that cannot be considered before discovery occurs.

Strong sued Stryker last year, alleging product liability, negligence and breach of warranty.

He says he developed chondrolysis, the complete destruction of his shoulder cartilage, because Stryker pain pumps were used to directly infuse pain drugs into his shoulder joint after operations in 2001, 2004 and 2005. Strong alleges that pain pumps are unsafe for use in or near the shoulder joint because of the cartilage issue.

Judge Davis chided Stryker for attacking Strong's complaint on the merits, which he said is a violation of the tenet that, in considering a motion to dismiss, a court accepts all factual allegations in a complaint as true.

Stryker said that despite Strong's allegations, it did not promote the use of pain pumps for use in "shoulder joint space," nor did it make any such promotions toward Strong's surgeons.

The company, which denies that the use of pain pumps causes chondrolysis, also said it "did not know, and should not have known," the risk of infusing anesthetics into a shoulder joint.

Judge Davis said Strong has "adequately set forth the factual basis for each of his claims" and offered the needed detail to support his accompanying fraud allegations.

The judge also rejected Stryker's charge that Minnesota's statutes of limitation bar any claims regarding Strong's first two procedures.

> "Plaintiff clearly pleads sufficient facts to put Stryker on notice of the basis for the fraud claims against it," Judge Davis said.

The limitation for misrepresentation and fraud claims is six years under Minn. Stat. § 541.05, subd. 1(6), while a four-year cap is placed on product liability and negligence actions, Minn. Stat. § 541.05, subd. 1(5)-2.

Strong has offered sufficient evidence to show possible fraudulent concealment by Stryker that would have kept his claims for product liability, negligence and breach of warranty from starting to run until October 2007, the judge said. WJ

Attorneys:
Plaintiff: Colin P. King, Dewsnup, King & Olsen, Salt Lake City

Defendant: Timothy P. Griffin, Leonard, Street & Deinard, Minneapolis

Related Court Document:
Memorandum of law and order: 2010 WL 4967876

See Document Section E (P. 44) for the memorandum of law and order.

REUTERS/Jason Reed

REGULATION

Invacare says it takes FDA warning letter 'seriously'

Medical equipment firm Invacare Corp. says it takes "very seriously" violations of production and operational standards detailed in a Food and Drug Administration warning letter issued after inspections at a Florida facility where it builds hospital beds.

In a statement released Jan. 4 the Ohio company said it has assembled a team of quality and regulatory experts to review the FDA's claims that Invacare failed to effectively respond to reports of fires and sparking in its electric beds, some of which involved patient entrapment and death.

The FDA's Dec. 15 letter said many of Invacare's responses to shortcomings reported to the company after a lengthy inspection at the Sanford, Fla., facility last August were inadequate.

The agency said its inspectors discovered that the manual, electric and "semi-electric" hospital beds produced there are "adulterated" under the terms of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 32(h), because Invacare's manufacturing, storage and installation processes do not comply with the FDA's "current good manufacturing practice" requirements, 21 C.F.R. pt. 820.

The beds are used in hospitals, nursing homes and rehabilitation facilities.

The FDA said Invacare does not use "appropriate statistical methodology where necessary to detect recurring quality problems" at the Florida facility, as required by 21 C.F.R. pt. 820.100(a)(1).

The letter said FDA inspectors found that files about recurring complaints over sparks and fires associated with Invacare beds "did not contain a documented determination of the action(s) needed to correct and prevent recurrence of the nonconformances."

One of the complaints, filed in April 2010, involved a fire that started at the foot of an Invacare bed and caused the user's death, according to the letter.

Other complaints reference a bed control box catching fire, forcing the treatment of two patients for smoke inhalation, and another incident in which a bed emitted a "burning smell, but no actual smoke," the letter said.

Invacare CEO Gerald B. Blouch said in the statement that the company "rigorously tests" its products and stands behind their safety.

He added that the FDA's warning letter does not say Invacare products are unsafe but deals largely with improvements needed in documentation procedures. WJ

Concerns heighten over the prospect of 'responsible corporate officer' prosecutions against drug and device manufacturers

By Kim M. Schmid, Esq., and Molly J. Given, Esq., Bowman & Brooke, and Mark DuVal, J.D., and Mark Gardner
J.D. DuVal & Associates

The recent announcement that the Department of Justice, Health and Human Services' Office of Inspector General, and the Food and Drug Administration plan to aggressively pursue individual criminal charges against executives for illegal off-label marketing deservedly caused a stir in the drug and medical device manufacturing community.[1]

High-ranking employees of pharmaceutical and medical device manufacturers are taking notice as they analyze the prospect of facing a personal criminal investigation under the "responsible corporate officer" doctrine of the Food, Drug and Cosmetic Act. However, the concern over the government's stated intent to use the RCO doctrine has implications greater than personal criminal liability because it may also provide fuel to the plaintiffs' product liability tort bar.

The results for manufacturers should government agencies forge ahead with these aggressive RCO prosecutions could be far-reaching, affecting not only manufacturers and their executives and managers, but also medical industry insurers, shareholders and, ultimately, the health care consumer.

This article outlines the contemplated enforcement actions and explores the impact that RCO prosecutions and convictions may have in the world of product liability lawsuits involving pharmaceuticals and medical devices. Industry must anticipate the likely increase in RCO prosecutions and plan accordingly.

WHAT IS THE RCO DOCTRINE?

The government intends to prosecute off-label promotion by resurrecting and seriously extending the use of the RCO doctrine, also known as the "Park doctrine," under the Food, Drug and Cosmetic Act. The doctrine is named after a CEO who in 1975 was held criminally responsible for infractions under the FDCA (a filthy and vermin-infested food warehouse) even though he was not personally involved in and lacked knowledge of the wrongdoing.[2]

The government interprets the RCO doctrine to not require proof of intent and that liability can attach vicariously. In other words, the government claims, under certain conditions the defendant can be found guilty even without personal knowledge or direct participation in the alleged off-label promotion.

By virtue of the defendant's position within the company, the CEO, executive or manager is personally responsible for regulatory compliance and for stopping and correcting any wrongdoing. Therefore, in the government's eyes, mere delegation of duties will not absolve an executive or high-ranking manager of this responsibility. The government prosecutes these off-label-promotion "crimes" under three distinct but interrelated statutes.

First, and most important, the False Claims Act, 31 U.S.C. § 3729(a)(2), makes it a civil violation to cause or induce a prescription that is reimbursed by the federal government. The government usually parlays an allegation of off-label promotion into a False Claims Act violation.

Second, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), prohibits the payment of illegal remuneration to health care providers who prescribe or refer products reimbursed by the federal government. The alleged kickback taints or biases the prescription decision, resulting in improper use of government funds.

Finally, the government uses the FDCA to prosecute illegal off-label promotion. These three statutes form the unholy triumvirate and must be considered together when reviewing promotional conduct.

Legal scholars have passionately argued that the RCO doctrine is being used improperly today. In 1975 the defendant in the Park case was fined only $250.[3] Today's prosecutors apply the law much differently.

For example, in 2007 the government accepted a misdemeanor plea entered by three pharmaceutical company executives who paid a combined $34.5 million and were barred from participating in federal health care programs for 12 years.[4] Congress did not contemplate such harsh penalties for misdemeanors without deference to *mens rea*. Nonetheless, the government continues to push for legislation and policies to make these prosecutions easier.

IS THE GOVERNMENT RAMPING UP ENFORCEMENT?

Government officials have not been shy about their intent. Last spring, newly appointed FDA Commissioner Margaret Hamburg announced that the agency would increase its misdemeanor prosecutions of CEOs, executives and managers for off-label promotion.

Ann Ravel, deputy assistant attorney general at the Justice Department, said the agency is "intent on ... prosecuting individuals when they market off-label" and that its "emphasis is going to be much increased in this area."[5]

Not to be outdone, Mary Riordan, senior counsel at OIG, said at a Sept. 21 public meeting that device and drug companies need to increase "accountability for compliance both at the board level and at the level of individual managers" because company compliance officers will not be the only employees to bear the brunt of compliance failure.[6]

The FDA also announced adding enforcement capability and expanding targets for prosecution. Deborah Wolf, the agency's regulatory counsel in charge of medical device advertising and promotion compliance, recently announced expanding her division from one person to three.[7]

In addition to traditional enforcement against companies themselves, the FDA intends to pursue enforcement against physicians and clinics who operate as agents of industry when "promoting" off-label use.[8] Penalties for off-label promotion include

civil money penalties, disgorgement of profits, imprisonment and exclusion from participating in federal health care programs.

Fair or not, prosecutors are not backing down from aggressive use of the RCO doctrine to prosecute medical device and pharmaceutical company CEOs, executives and managers for alleged off-label promotion. Indeed, even board members may be at risk. Riordan said that in recent corporate integrity agreements, board members are being required to sign off on compliance measures.[9]

In sum, in the government's eyes the ultimate responsibility for operational control and regulatory compliance is squarely within the purview of individual high-ranking company employees irrespective of personal knowledge or intent.

DOES THE FIRST AMENDMENT PROTECT OFF-LABEL SPEECH?

Some off-label prosecutions result in the juxtaposition of protected First Amendment free speech rights with the FDA's off-label enforcement rights. While the FDA has legitimate interest in prosecuting off-label promotion, the Constitution guarantees industry and the medical community the right to freely exchange medical and scientific information.

Does the Constitution afford industry and the medical community the right to exchange off-label information and, if so, are the prosecutorial policies of the FDA, OIG and Justice Department chilling protected free speech?

Importantly, the FDA *lost* a major First Amendment challenge on this issue in a series of cases filed by the Washington Legal Foundation and others in the late 1990s and early 2000s, demonstrating the tension between the government's regulatory jurisdiction and commercial free speech.[10]

In the past, the U.S. government unequivocally supported off-label uses and dissemination of medical and scientific information:

- Congressionally expressed intent in enacting Section 401 of the Food and Drug Administration Modernization Act (it has since been subject to *sunset* in September 2006).[11]
- Judicially expressed intent in the *WLF*, *Pearson*, *Western States* and *Whitaker* cases.[12]
- Administratively expressed intent in FDA guidance documents discussing off-label uses in the "practice of medicine."[13]
- Administratively expressed intent in guidance set forth by the Centers for Medicare and Medicaid Services to encourage reimbursement of medically necessary off-label uses.[14]
- Administratively expressed intent in an existing "reprint" FDA guidance document allowing dissemination of certain off-label information.[15]

Thus, despite widespread and long-standing government support for off-label uses by physicians, the FDA, OIG and Justice Department are now ratcheting up the heat on criminal prosecutions against company officials for off-label promotion.

WHAT ARE THE POTENTIAL CONSEQUENCES FOR TORT SUITS?

Given this regulatory framework and the publicity generated as of late by government agencies on this issue, can the industry expect to feel an effect of RCO prosecutions and convictions in product liability tort suits?

Absolutely. Given that the plaintiffs' bar has already attempted to use government investigations of manufacturers in parallel track or subsequent tort litigation, there is no reason to think it will not also attempt to use RCO prosecutions in tort litigation. The question then becomes, in what capacity, if any, can plaintiffs use these prosecutions to bolster claims in related product liability suits?

Discovery concerns

Given the breadth of discovery allowed under the rules and the discretion afforded to individual judges to manage their cases, plaintiffs in parallel track or subsequent litigation will almost certainly seek documents and testimony concerning a government investigation of a drug or device executive.

To the extent these documents are in the custody or control of the manufacturer, the company needs to anticipate that private litigants will seek production through discovery. Conversely, if a government investigation is ongoing or anticipated, in-house and outside litigation counsel should be wary of self-incrimination and be prepared to make savvy objections when their witnesses are deposed by plaintiffs' counsel in tort suits.

Whereas a *criminal* jury cannot draw an adverse inference from a refusal to testify,[16] a *civil* jury may be allowed to draw damaging adverse inferences from an executive's failure to testify.[17]

Non-defect, intentional-tort and punitive damages claims

First, is an RCO prosecution or conviction relevant in a subsequent tort suit? Though intentional-tort and punitive damages claims present a higher burden than defect claims for plaintiffs' lawyers in product liability cases, RCO convictions may present a formidable tool to plaintiffs in drug and device cases to both avoid summary judgment and prevail on claims of consumer fraud, misrepresentation, civil conspiracy and punitive damages.

A separate negligence *per se* claim is likely barred because of the prohibition of a private right of action in the FDCA under 21 U.S.C. § 337(a), but a conviction itself might be relevant if it supports elements of the state law claims.

For example, if an executive pleads guilty to misbranding, that tends to meet the element of making a misleading representation for a plaintiff's misrepresentation or fraud claims. Therefore, an RCO conviction would likely meet the requirements for Federal Rule of Evidence 401.[18]

Second, if the conviction is relevant, is it hearsay? Under Federal Rule of Evidence 801(d)(2)(D), "a statement by the party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship" is not considered hearsay.

Therefore a misbranding conviction may be deemed admissible to prove the truth of the matter asserted: that the executive (in their capacity as agent for the manufacturer) engaged in off-label marketing. This is damaging evidence if the plaintiff's injury is causally related to an alleged off-label use.

However, if Rule 801(d)(2)(D) does *not* apply because the executive is no longer "affiliated" with the manufacturer at the time of the plea, the conviction is not an admission by a party opponent and would be inadmissible as classic hearsay. Further, the conviction should not be admissible hearsay under

Rule 803(22) because RCO convictions are misdemeanors (carry potential prison terms of one year or less).

Of course, should plaintiffs subpoena the former executive, the conviction could be used as impeachment evidence if he or she denies any of the underlying facts. Therefore, whether or not the conviction is hearsay, there is a possibility that plaintiffs will be permitted to use guilty pleas by manufacturing executives in subsequent medical device or pharmaceutical civil tort litigation.

Third, what about unfair prejudice? Rule 403 allows courts to exclude evidence whose "probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury."

In the case of RCO prosecutions where no conviction has occurred, Rule 403 should keep out all evidence of the investigation itself. The fact of an investigation alone has minimal, if any, probative value, and yet the impact of such evidence upon a jury to confuse or mislead is undeniable. In the case where an executive has been investigated and subsequently convicted, the evidence will be much harder to keep out under a traditional 403 analysis.

Joinder of individual executives

Another related consequence of aggressive prosecution of RCO pleas: naming the executives in their individual capacity as defendants in civil tort suits. An executive may believe that the guilty plea, hefty fine and exclusion from the industry might be the end of the line for off-label promotion. However, by admitting criminal liability with a guilty plea, executives might submit themselves to individual *civil* lawsuits, too. Further, as discussed above, their convictions may become admissible as classic party admissions.

Collateral estoppel implications

Finally, plaintiffs may attempt to use the doctrine of collateral estoppel, or issue preclusion, to prevent the relitigation of off-label claims already fully litigated in a prior criminal proceeding. For example, under Minnesota law, issue preclusion works to prevent parties from relitigating issues that are "both identical to those issues already litigated by the parties in a prior action and necessary and essential to the resulting judgment."[19]

Though state law on issue preclusion varies, most states prohibit offensive use of issue preclusion against a party if the party was not actually named as a party in the first suit.[20] Therefore, the conviction of an employee may not support application of collateral estoppel against the employer. However, any statements made by the executive in the criminal proceeding may be admissible in a civil action against the manufacturer, and the conviction might be admissible to impeach the executive.

On the other hand, if the subsequent tort suit names an executive as an individual defendant, plaintiffs may attempt to apply some form of issue preclusion dependent on state law against the individual as he or she was a party to the first suit and had an incentive to aggressively litigate the issue, and a final decision on the merits was reached.

Issue preclusion against the executive may be a viable argument because the elements of an off-label RCO violation are remarkably similar to most states' common-law fraud and misrepresentation claims. Counsel in subsequent tort litigation need to carefully analyze individual state law on issue preclusion, recognizing many states allow for a prior criminal conviction to at least serve as *prima facie* evidence of tort claims, effectively shifting the burden to the executive defendants in tort cases.

WHAT CAN MANUFACTURERS DO TO PROTECT THEMSELVES?

Effective compliance programs

Prosecutors are sending a clear warning. Company executives and their board members must audit their promotional review processes, product messaging, marketing programs, grant programs, sales training, compliance programs, etc., and they must track implementation.

The government is not only looking at conventional promotion and marketing activities, but also focusing on more indirect forms of off-label "communication." These activities can include grants for continuing medical education, physician-initiated trials and the use of consultancies, such as advisory boards, among other things. Any compliance review conducted by a company must be expansive and sophisticated enough to explore and capture these nontraditional avenues of communication.

Legal challenges to RCO prosecutions

If the FDA, OIG and Department of Justice make good on their promise to aggressively pursue RCO convictions of individual industry executives, the industry must consider thoughtful legal challenges, given the outdated and constitutionally shaky ground on which they rest.[21] These challenges should occur in both the criminal and civil arena.

Criminal challenges should address congressional intent, First Amendment protections and *mens rea* requirements.[22] Defense attorneys in civil lawsuits must vehemently advocate against introduction of any investigation or conviction in a subsequent civil suit and should include the outdated and constitutionally shaky analyses in evidentiary briefing. In the meantime, industry must educate lawmakers about the unprecedented expansion of the RCO doctrine and its harsh impacts.

From a regulatory viewpoint, the unprecedented expansion of the RCO doctrine will affect business plans (especially sales and marketing plans), the use of outside consultants and corporate compliance programs. From a product liability viewpoint, plaintiffs' lawyers will liberally and aggressively attempt to use these prosecutions, and especially any resulting convictions, to pursue their claims against manufacturers.

The world of the FDA and related regulations intersect with the product liability world in serious ways, and industry has every reason to be concerned with the aggressive use of the RCO doctrine. WJ

NOTES

[1] *See* Jessica Bylander, Justice Dept, Inspector General to Target Individuals in Off-Label Cases, Gray Sheet (Sept. 29, 2010).

[2] *United States v. Park*, 421 U.S. 658 (1975).

[3] *Id.*

[4] *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 575-76 (W.D. Va. 2007).

[5] *See* Monica Hogan & Jessica Bylander, *Device Center Increases Advertising/Promotion Enforcement Staff*, Gray Sheet (Sept. 22, 2010).

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] The Washington Legal Foundation cases are a series of cases known in industry as WLF I-IV.

See Wash. Legal Found. v. Kessler, 880 F. Supp. 26 (D.D.C. Mar. 9, 1995); *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. July 30, 1998); *Wash. Legal Found. v. Friedman*, 36 F. Supp. 2d 16 (D.C.C. Feb. 16, 1999); *Wash. Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. July 28, 1999); *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. Mar. 9, 2000); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002); *Whitaker v. Thompson*, No. 01-1539, 239 F. Supp. 2d 43 (D.D.C. 2003).

[11] Pub. L. No. 105-115, 111 Stat. 2296 (1997). Section 401 described certain conditions under which a drug or medical device maker could disseminate medical and scientific information discussing unapproved uses (off-label) of approved drugs and cleared or approved medical devices.

[12] *See* note 10, *supra*.

[13] "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain record of the product's use and effects. Use of a marketed product in this manner *when the intent is the 'practice of medicine'* does not require the submission of an Investigational New Drug Application, Investigational Device Exemption or review by an Institutional Review Board. However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight." *See* FDA, 'Off-Label' and Investigational Use of Marketed Drugs, Biologics, and Medical Devices, Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update, *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.

[14] *See* Medicare Benefit Policy Manual, Ch. 15, § 50.4.3 ("Unlabeled Use of Drug"), a publication of the Centers for Medicare and Medicaid Services that discusses when off-label uses will be a covered benefit. *See also* Off-Label Coverage of FDA-Approved Drugs and Biologicals, BlueCross and BlueShield of Tennessee (Riverbend Government Benefits Administrator) (an example of how off-label uses are treated by a state carrier; it states that "Medicare recognizes off-label uses of FDA-approved drugs" and goes on to explain how off-label drugs are covered), *available at* www.codemap.com/content.cfm?id=7280&sid=59&lcd=13121.

[15] *See* FDA, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (January 2009), *available at* www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm.

[16] *Griffin v. California*, 380 U.S. 609 (1965).

[17] *Baxter v. Palmigiano*, 425 U.S. 308 (1976).

[18] This analysis applies only to actual convictions; the simple fact that a manufacturer is under investigation would be much less relevant because it does not tend to prove anything and would be unfairly prejudicial under Rule 403.

[19] *Conwed Corp. v. Union Carbide Corp.*, 443 F.3d 1032, 1038 (8th Cir. 2006).

[20] *Taylor v. Sturgell*, 553 U.S. 880, 892-93 (2008).

[21] *See* Bylander, *supra* note 1.

[22] *Park*, 421 U.S. 658.




(Pictured Left to right) **Kim M. Schmid** is a managing partner in the Minneapolis office of **Bowman & Brooke**, where she focuses her trial practice on defending medical device and pharmaceutical manufacturers in product liability litigation. **Molly Given**, an associate at the firm, focuses her trial practice on the defense against product liability claims involving medical devices and recreational vehicles. **Mark DuVal** is president and founding partner of **DuVal & Associates**, a Minneapolis law firm dedicated to counseling companies in the medical device, pharmaceutical, biotech, food and nutritional supplement industries. **Mark Gardner** is an associate at DuVal & Associates, where he focuses his practice on compliance and promotion for the medical device, pharmaceutical, biotech, food and nutritional supplement industries.

BALLOON CATHETERS RECALLED BECAUSE OF FRACTURE FEARS

AngioScore Inc. is recalling almost 18,000 balloon catheters, citing a design defect that can cause the devices to fracture and send fragments into a patient's arterial system. The company said the AngioSculpt percutaneous transluminal angioplasty scoring balloon catheter may crack or "peel" while being used to repair arterial lesions. According to the company's Jan. 5 recall announcement, pieces separating from one end of the catheter may cause "significant arterial injury which may lead to death or the need for additional surgical intervention." The recall encompasses AngioSculpt PTA catheters distributed between September 2007 and November 2010. For information on the recall, contact AngioScore's customer service department at (877) 264-4692.

ALCOHOL PADS, SWABS RECALLED DUE TO BACTERIAL INFESTATION

A firm that makes alcohol prep pads, swabs and swab sticks distributed by numerous pharmacy chains and health care supply firms is recalling the products because of concerns that they may contain a microbial contamination, *Bacillus cereus*, that could cause life-threatening infections. Triad Group, of Hartland, Wis., said Jan. 5 that the products were distributed to retail pharmacies in the U.S., Canada and Europe and sold under a number of private-label brands. The pads and swabs are individually packaged and sold in 100-count boxes in stores such as Walgreens and CVS and through health supply companies like Cardinal Health, PSS Select, VersaPro, Moore Medical and Conzellin. Despite the various brand names, the exterior boxes being recalled will identify Triad as the manufacturer. Contact Triad for a return authorization number at (262) 538-2900.

ABBOTT RECALLS 359 MILLION GLUCOSE TEST STRIPS

Abbott Laboratories has recalled some 359 million glucose test strips, saying they may give false readings that could cause varied patient health problems. In its Dec. 22 recall announcement, Abbott said the strips were sold both in retail stores and online from January through September 2010 and could give "false low" blood glucose readings. Such readings could cause patients to unnecessarily try to raise their blood sugar levels. The strips are used with Abbott's Precision Xtra, Precision Xceed Pro, MediSense Optimum, Optimum, Optimum EZ and ReliOn Ultima blood glucose monitoring devices. The test units are not involved in the recall. Consumers should contact Abbott at (800) 448-5234 to determine if their test strips are covered by the recall.

CASE AND DOCUMENT INDEX