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Expert Analysis

Concerns Heighten Over the Prospect of 'Responsible Corporate Officer' Prosecutions Against Drug and Device Manufacturers

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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.

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.

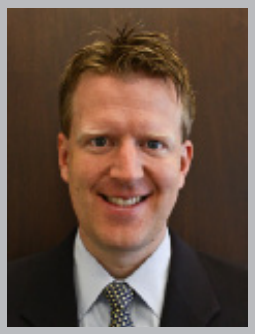
[19] *Conwed Corp. v. Union Carbide Corp.*, 443 F.3d 1032, 1038 (8th Cir. 2006).

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

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

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



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