

SEPTEMBER / OCTOBER 2004

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## OIG CROSSHAIRS SHIFT TO MEDICAL DEVICE MANUFACTURERS

Aggressive federal and state scrutiny of and enforcement against pharmaceutical companies and providers for anti-kickback violations and healthcare fraud and abuse have been well publicized. With the closing of many of these investigations, the government is now shifting its focus to another healthcare sector — manufacturers of medical supplies and devices — and is pursuing the device industry with the same zeal witnessed in the provider and pharmaceutical industries. Lewis Morris, the chief counsel to Office of the Inspector General (OIG) of the Department of Health and Human Services, recently stated that there are plans to accelerate investigations of alleged fraud and abuse by medical device companies.<sup>1</sup> The government's commitment to pursuing healthcare fraud in the device industry is further evidenced by the government's establishment of a straw medical distributorship as part of an undercover sting operation targeting device manufacturers.<sup>2</sup>

In fact, the Department of Justice (DOJ) has already achieved enforcement success in the device sector. In 2003, Abbott/Ross paid civil and criminal fines totaling \$614 million for allegedly paying kickbacks and encouraging customers to submit bundled claims for enteral feeding products;<sup>3</sup> Guidant paid civil and criminal fines of \$92.4 million for allegedly failing to report to the FDA malfunctions with its Ancure Endograft System;<sup>4</sup> and, more recently, Augustine Medical paid \$12.7 million in criminal and civil fines after pleading guilty to conspiracy to defraud the government.<sup>5</sup> Moreover, reports indicate that, currently, the DOJ is investigating the alleged payment of kickbacks to doctors by a subsidiary of Medtronic, Inc.;<sup>6</sup> the billing and coding practices of a subsidiary of the Stryker Corporation;<sup>7</sup> and the relationships with healthcare professionals of a subsidiary of Cochlear Limited.<sup>8</sup>

### **Enforcement Authority Applied in Device Context**

While the government has many legal tools available to investigate and prosecute

healthcare fraud, the primary legal authorities the government will use against medical device companies will be the same ones used to pursue pharmaceutical companies and providers: the Anti-Kickback Statute, the federal False Claims Act, and the threat of exclusion from federal programs.

Importantly, there are systemic and fundamental differences between the medical device industry and other sectors of the

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## FTC CONSENT SETTLEMENTS CONTINUE CLOSE SCRUTINY OF PHARMACEUTICAL INDUSTRY

Two recent FTC consent agreements — the first involving the pioneer manufacturer of a product designed to combat breakthrough cancer pain (BTCP) and the other concerning a maker of OTC children's liquid ibuprofen — demonstrate that the FTC continues to apply close scrutiny to pharmaceutical industry participants and to activities and practices within the industry. The FTC and the DOJ Antitrust Division can be expected to continue to closely monitor and take enforcement actions against life sciences industry companies, as outlined in their recent, voluminous joint report on *Improving Health Care: A Dose of Competition* (July 2004) (available at [www.usdoj.gov/atr/publichealth\\_care/204694.htm](http://www.usdoj.gov/atr/publichealth_care/204694.htm)).

### **In the Matter of Cephalon, Inc. and CIMA LABS, INC.**

In this case, the consent agreement allows Cephalon, Inc. to conclude its \$515 million acquisition of CIMA LABS, INC., under the

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## OCTOBER 2004 SPONSORED EVENTS

- 4 **Pennsylvania Biotech 2004**  
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healthcare industry that may increase the former's exposure to liability under the Anti-Kickback Statute and the False Claims Act. For example, device companies typically have extended sales and marketing negotiations for high-cost products, complex product financing arrangements, training and certification programs for healthcare providers, beta-testing, equipment installation and site demonstrations, and contractual commitments for servicing, warranties and customer discounts, and then often furnish coding, coverage, and reimbursement advice.

In addition, an important characteristic of the enforcement strategy against medical device companies is the expansive use of "regulatory" violations such as for GMPs, product promotion, MDR reporting, etc. under the federal Food, Drug, and Cosmetic Act as a basis for False Claims Act liability.

### Kickbacks

As it applies to medical device companies, the Anti-Kickback Statute prohibits either offering or receiving anything of value that is intended to induce the purchase, lease or recommendation of a company's products. Violation of the law will occur even if the intention to induce referrals is only one among many otherwise legitimate commercial reasons for the activity or program.

Examples of problematic or questionable conduct include offering customers and prospective customers entertainment, free or below-market-priced consulting services or excessive training, free goods or loans, or grants for business assistance or other non-medical purposes. In addition, providing non-fair-market-value business deals such as excessive discounts, multi-product discounts, generous financing or favorable lease arrangements may also draw scrutiny.

### False Claims

The federal False Claims Act typically applies directly to the providers and suppliers that file claims for payment with the government. Although many medical device companies do not file claims, the government may still pursue False Claims Act violations if the government finds that a medical device company "caused" the filing of a false claim. Causing the filing of a false claim can be as simple as providing coverage and coding advice to customers, or providing inappropriate discounts or other compensation to providers.

An actionable claim can either be facially false, meaning that the falsity is contained on the face of the claim, or tainted by a kickback or a fraudulent course of conduct that caused or attempted to cause the government to pay the claim. Pursuing false claims under the "tainted" claim theory is extremely favorable to the government since it allows the government to combine all company activities the government finds objectionable into one integrated broad-based "scheme" to defraud and renders false every claim submitted under the scheme,

which increases exposure to liability and potential recoveries.

### Compliance Readiness

One of the most effective ways for a medical device company to avoid violating the Anti-Kickback Statute, the False Claims Act, and other healthcare fraud statutes is to implement an effective compliance program. A compliance program provides a basis for ethical business practices, and assists in corporate risk management. A device company compliance program should be consistent with the published OIG models, the (proposed) new Sentencing Guidelines, and AdvaMed ethical guidelines. In order to be effective, the compliance program must integrate audit processes and contain verifiable outcome measures.

There are steps that medical device companies can take today to either avoid or be prepared for a healthcare fraud investigation. Because sales approaches, customer demands, and promotional opportunities vary so significantly in the device industry, each company must carefully scrutinize its promotional and marketing practices and create a compliance program and auditing system that fits the particular unique aspects of that company.

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### Endnotes:

- <sup>1</sup> See [http://www.boston.com/business/globe/articles/2004/05/19/us\\_picking\\_up\\_pace\\_of\\_device\\_inquiries](http://www.boston.com/business/globe/articles/2004/05/19/us_picking_up_pace_of_device_inquiries).
- <sup>2</sup> See <http://www.belleville.com/mld/belleville/news/5192768.htm>.
- <sup>3</sup> See [http://www.abbott.com/news/press\\_release.cfm?id=587](http://www.abbott.com/news/press_release.cfm?id=587).
- <sup>4</sup> See [http://www.usdoj.gov/usao/can/press/html/2003\\_06\\_12\\_endovascular.html](http://www.usdoj.gov/usao/can/press/html/2003_06_12_endovascular.html).
- <sup>5</sup> See <http://pubs.bna.com/ip/BNA/hfr.nsf/is/a0a9d3n5n4>.
- <sup>6</sup> See <http://twincities.bizjournals.com/twincities/stories/2003/09/08/daily5.html?t=printable>.
- <sup>7</sup> See <http://ir.thomsonfn.com/InvestorRelations/PubNewsStory.aspx?partner=2275&storyId=100381>.
- <sup>8</sup> See <http://www.cochlear.com/PDFs/RequestforInfo.pdf>.

Unique medical device industry characteristics may increase exposure under the Anti-Kickback Statute and the False Claims Act.

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## SPEECHES & ARTICLES

### BUSINESS AND FINANCE/SECURITIES

#### Pennsylvania Biotech 2004

*"Fundamental Business & Legal Strategies"*

Manya S. Deehr

*"Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside"*

Randall B. Sunberg

October 4–5, 2004, Philadelphia

#### Licensing Executives Society Annual Meeting

*"Pharma-Biotech Collaborations & M&A: Protecting the Deal While Protecting Your Interests"*

Randall B. Sunberg

October 17–21, 2004, Boston

### PHARMACEUTICALS/BIO TECHNOLOGY/MEDICAL DEVICES

#### Biotechnology Industry Organization's Human Resources Conference

*"Employment Law Update"*

Carol R. Freeman

October 27–29, 2004, San Francisco

### INTELLECTUAL PROPERTY

#### Maximizing Pharmaceutical Patent Life Cycles

*"Industry Commentary on the MMA"*

Brian P. Murphy

October 4–5, 2004, New York

#### AusBIO 2004

*"How to Benefit or Impede a Global Company's Program Through Technology Transfer Decisions Made by the Private Sector"*

Kathryn Doyle

November 7–10, 2004, Brisbane, Australia

#### Western Regional Meeting of the American Chemical Society

*"Protecting the Product Life Cycle — Patent Law for Chemists"*

Jeffrey S. Mann, Richard G.A. Bone, Elizabeth C. Weimar, Erich E. Veitenheimer,

Kathryn Doyle, Sarah A. Key, Victor N. Balancia

October 28, 2004, Sacramento

### FDA/HEALTHCARE REGULATION

#### New Initiative on Food and Biotechnology: Biotech Bugs

*"An Examination of Applicable International Laws as They Could Apply to GM Insects"*

Mark Mansour

September 20–21, 2004, Washington, D.C.

## FTC CONSENT SETTLEMENTS CONTINUE CLOSE SCRUTINY OF PHARMACEUTICAL INDUSTRY — continued from page 1

condition that Cephalon grant Barr Laboratories, Inc., a manufacturer of generic pharmaceuticals, an irrevocable license to manufacture and sell a generic formulation of ACTIQ, Cephalon's fentanyl-based BTCP medication. At present, Cephalon is the only company selling that type of medication in the United States. According to the complaint, CIMA, although not currently offering a similar product, was positioned to be the next entrant in the market for BTCP drugs.

The FTC alleged that the U.S. market for BTCP drugs was the relevant market for examining the proposed transaction. The Commission distinguished BTCP drugs from other types of pain relievers by observing that BTCP drugs (1) help to reduce or eliminate the spikes of severe pain that cancer patients experience; (2) provide a faster onset of pain relief than other treatments; and (3) can be self-administered in convenient and portable doses. Under this definition, the market for drugs used to treat BTCP is a monopoly, with Cephalon marketing the only BTCP medication that has been approved by the FDA for such use. CIMA, although not currently manufacturing or selling a BTCP product, is developing OraVescent fentanyl (OVF), and intends to seek FDA approval by late 2004 or early 2005. OVF is a fast-dissolving, effervescent fentanyl tablet that is expected to enter the U.S. market in either 2006 or 2007 and is the BTCP

drug best positioned to compete with Cephalon's ACTIQ. Both ACTIQ and OVF are formulations of the same readily available, nonpatented active ingredient, fentanyl.

Having defined the market as consisting only of Cephalon and the potential entrant CIMA, the FTC asserted that the proposed acquisition would violate Section 5 of the FTC Act and Section 7 of the Clayton Act because it would cause significant anticompetitive harm in the U.S. market for BTCP products. The FTC further asserted that, with only one firm currently marketing a BTCP drug to U.S. consumers, CIMA's entry likely would increase competition, absent the contemplated transaction. As a result, allowing Cephalon to control both ACTIQ and OVF would effectively eliminate competition, resulting in consumers having to pay

higher prices for BTCP medication. Also, according to the complaint, the FTC feared that Cephalon's ownership of both products would allow it to undermine generic ACTIQ entry by shifting patients to the patent-protected OVF product prior to generic launch, thus depriving consumers of the full benefits of generic competition.

According to a three-person majority of the FTC commissioners, the proposed consent agreement alleviates the allegedly anticompetitive impact in the U.S. market for BTCP drugs of Cephalon's acquisition of CIMA by requiring Cephalon to grant a third-party company, Barr, a fully paid, irrevocable license to make and sell a generic equivalent of ACTIQ in the United States that will be launched as soon as the FDA approves OVF,

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and in any event no later than February 2007. The proposed consent in this matter also contains a number of provisions designed to help Barr jump-start its entry into the putative market for BTCP. First, Cephalon must transfer the know-how and intellectual property related to all versions of ACTIQ to Barr immediately under a licensing and supply agreement. Second, if Barr is unable to manufacture an FDA-approved version of ACTIQ by the date the license takes effect, Cephalon would be required to supply Barr with a version of ACTIQ that it can market in generic form. Third, the consent agreement prohibits Cephalon from making certain regulatory filings that would delay FDA approval of Barr's generic ACTIQ to ensure that Barr will be in a position to launch its generic no later than Cephalon's launch of CIMA's OVF.

The Commission approved the consent order by a 3-1-1 vote, with Commissioner Pamela Jones Harbour recusing herself, and with then Commissioner Mozelle Thompson dissenting. In his dissent, Commissioner Thompson criticized the majority for its apparent willingness to tolerate a merger between the only two pioneer companies manufacturing a BTCP product, assuming CIMA successfully launches its product, thereby eliminating potential pioneer competition in an effort to facilitate the entry of a generic product.

*Cephalon was represented before the FTC by Washington, D.C.-based Antitrust Practice*

*partner Willard K. Tom (wtom@morganlewis.com), former Deputy Director of the FTC Bureau of Competition.*

### **FTC v. Perrigo Co. and Alharma Inc.**

In this case, Perrigo and Alharma agreed to settle charges arising from a 1998 agreement between the two companies concerning OTC store-brand children's liquid ibuprofen. Under the agreement, Perrigo will pay \$3.75 million and Alharma will pay \$2.5 million to the FTC. The companies will pay an additional \$1.5 million to state attorneys general to resolve claims arising out of the same matter.

The circumstances giving rise to this action date back to 1996, when Perrigo and Alharma each filed ANDAs with the FDA for approval to sell store-brand versions of children's liquid Motrin. In anticipation of FDA approval, expected by the companies in June 1998, both Perrigo and Alharma sought to establish a customer base for their respective products. According to the FTC's complaint, this head-to-head duel led to substantially lower prices for store-brand OTC children's liquid ibuprofen. In April 1998, however, FDA regulations were modified in a manner that resulted in Alharma receiving 180 days of market exclusivity, i.e., the FDA would not approve Perrigo's product until 180 days after Alharma began marketing its product.

As alleged by the FTC, Perrigo, faced with Alharma's regulatory advantage, approached Alharma and sought to negotiate an

agreement that would allow it to sell its product during the exclusivity period. The parties failed to reach such an agreement, but then, according to the complaint, the parties signed an agreement in June 1998 that had the effect of allocating to Perrigo the sale of OTC children's liquid ibuprofen for seven years. In exchange for agreeing not to compete, Alharma received an up-front payment and a royalty on Perrigo's sales of children's liquid ibuprofen. The complaint further asserts that Perrigo proceeded to launch its children's liquid ibuprofen product in January 1999 and that, within six months of launch, Perrigo raised prices to those customers who had obtained lower prices when Perrigo and Alharma were competing for customers.

According to the FTC, Perrigo and Alharma are still the only two companies to obtain FDA approval for an OTC version of liquid ibuprofen that is bioequivalent to children's liquid Motrin. To date, Alharma has not marketed its product, despite having received FDA approval to do so in April 1999. The complaint further contends that the 1998 agreement between Perrigo and Alharma unlawfully drove up prices for wholesale customers — including supermarkets, drug chains and mass merchandisers — and violated the FTC Act.

The complaint in this matter, authorized by a 5-0 vote of the FTC commissioners, is of special note because of the disgorgement remedy sought from both parties. According to a press release issued by then FTC Chairman Timothy Muris, "[t]his case is the first Commission implementation of the disgorgement policy statement issued by the FTC in July 2003." The disgorged funds are to be used by the FTC to compensate customers harmed by the companies' alleged misconduct. The proposed consent settlement bars each company from repeating the alleged unlawful conduct, subject to certain exceptions identified in the orders. The proposed consent settlement also contains certain recordkeeping provisions to allow the FTC to monitor compliance.

*Perrigo was represented in this matter by Washington, D.C.-based Antitrust Practice partner Scott A. Stempel (sstempel@morganlewis.com).*

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