



**KEY ENFORCEMENT ISSUES -
The Government's Perspective**

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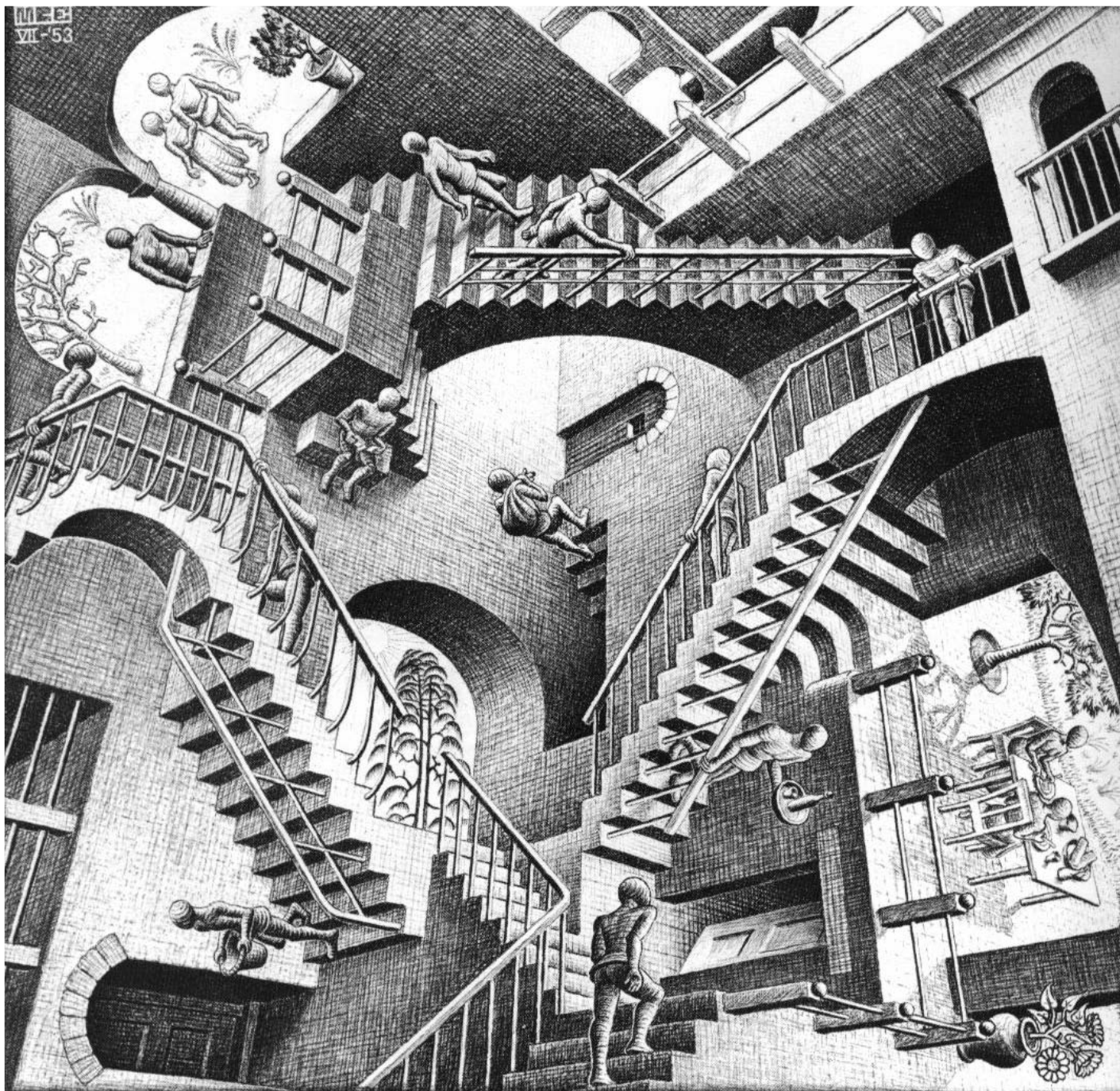
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KEY ENFORCEMENT ISSUES - The Government's Perspective

- Increasing Scrutiny by OIG/DOJ/US Attorney's Offices/FDA/ State Attorneys General
 - Federal Food, Drug & Cosmetic Act – misbranding violations (strict liability offense – criminal)
 - Federal and State False Claims Acts (qui-tam cases, i.e., whistleblowers – civil penalties)
 - Anti-Kickback Law (Fraud & Abuse Statute - criminal)
 - State Fraud & Consumer Protection Laws

VI-53



Cases, Fines Soar In Fraud Probes Of Drug Pricing

Drive May Net \$1 Billion From Firms Overcharging Public Health Programs

By JOHN R. WILKE

Months before a new law kicks in that will dramatically escalate government spending on drugs, state and federal prosecutors are investigating 150 cases that involve alleged pricing fraud by some of the world's largest drug makers and could produce more than \$1 billion in criminal fines and civil penalties this year.

The cases are part of an expanding industrywide investigation of drug pricing that has produced scores of lawsuits currently under seal in courts around the country. They are focused on allegations that drug companies cheat state and federal health-care programs by inflating prices, offering undisclosed rebates to distributors or marketing drugs for unapproved uses, according to lawyers and officials involved in these cases.

A half-dozen major drug makers have already paid fines and penalties to settle charges in the past two years. At least three more—Seroquel Inc., Abbott Laboratories Inc. and King Pharmaceuticals Inc.—are expected to face similar allegations and possible criminal fines or civil penalties this year.

Prosecutors also could force these companies to accept "corporate integrity agreements" that include tough federal oversight of the way the companies price and market drugs under government-paid health-care programs, including Medicaid and Medicare.

The recent surge in cases reflects increasing scrutiny of drug makers' pricing practices and a sharp rise in federal and state prosecutions of health-care fraud. Prescription drugs represent an ever-larger share of the nation's health bill, and the federal government is preparing for a huge increase in spending when the new Medicare drug benefit goes into effect in January.

It will cover prescription drugs for the first time for more than 40 million Americans and will cost an estimated \$70 billion in its first 10 years. With these huge increases on the way, Senate Finance Committee Chairman Charles Grassley, an Iowa Republican, has pressed the Justice Department to step up fraud enforcement.

While the criminal and civil penalties and settlements represent a small fraction of drug-company profits, they are rising

fast. Fines and penalties this year could amount to almost twice the totals paid in each of the past three years, officials said.

Peter Keisler, who oversees the Justice Department's civil-fraud unit, said that "the most frequent defendant in fraud cases today is in health care" and that the industry now accounts for "the lion's share of fraud, both in number of cases and dollar amounts—and those numbers are going up."

Mr. Keisler wouldn't discuss individual cases. But he said the number of separate civil and criminal investigations under way stands at 150 and involves nearly 500 drugs. "We've been focusing on pharmaceuticals intensively over the past year, to coordinate the massive number of cases with others in law enforcement, the states and federal agencies," he said.

The scope of the investigation and the cooperation involved suggests that what had appeared to be scattered moves in the past few years has coalesced into a broad

Costly Remedy

Criminal or civil penalties already paid by selected drug companies to settle allegations of pricing fraud:

COMPANY/ DATE SETTLED	TOTAL FINE, IN MILLIONS	PRODUCT(S)
Pfizer May 2004	\$430	Neurotin
AstraZeneca June 2003	355	Zoladex
Schering-Plough July 2004	345	Clarithin
Bayer April 2003	257	Cipro, Adalat
GlaxoSmithKline April 2003	68	Pacl, Ponase

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Whistle-blowers' spotlight falls on drug companies

Federal rules allowing big payouts pressure life-sciences industry

By Mark Siefert

Federal prosecutors report a sharply rising rate of private lawsuits filed in federal court seeking the prosecution of former whistleblowers against their own firms, especially drug companies. The cases in those cases—up 60 percent in 2004 to 2005—include 20 percent of the 2005 cases reported on the state's last governing life-sciences industry.

That means for the government side of cases, while prosecutors say federal rules allowing a cap on payouts to plaintiffs who whistleblow on the public.

Perhaps the most famous was a former drug executive who was awarded \$7 million for helping trigger a recall of tainted 6175 tablets sold worldwide with TAP Pharmaceuticals Inc. The case and others have led to more than 100 federal court cases in federal and state courts, and Robert M. Thomas, generally an ambivalent DOJ attorney in addition to who prosecuted white-collar cases.

Thomas heads the office, and he says up, where more people aware of the "over" and Thomas, says, Justice attorney who prosecutes in private suits who receive no public funds.

Nearly all these cases are filed under seal and often aren't disclosed by the Justice Department, he says. He says more would be disclosed.

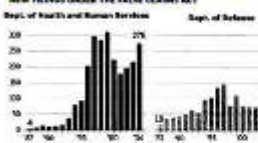
Michael J. Sullivan, US attorney for the District of Massachusetts, says such cases don't represent the volume of pending investigations. But he also says he has seen 10 lawsuits filed in the past 12 months, which he says he has not yet received.

"The Justice objective here isn't to do, and he says, but to change industry practices," Sullivan said. "That will have a much more significant impact over the long term than just a few cases."

Case-load boom

The number of lawsuits targeting drug makers and other government health contractors has exploded since a federal corporate crime bill took effect in the fall.

NEW FILINGS UNDER THE FRAUD CLAIMS ACT



Source: DOJ, review of cases at the civil division of the Justice Dept. and the Dept. of Defense, which tracks cases filed since 2003 as early as 50 years ago. The Justice Dept. also tracks the cases filed in the past 10 years. The Justice Dept. also tracks the cases filed in the past 10 years.

The rise in the number of cases is a sign of the industry's growing reliance on the federal government for health care. The industry's reliance on the federal government for health care is a sign of the industry's growing reliance on the federal government for health care.

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Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

DOJ reports 500 drugs now under investigation — sweeping enforcement initiatives expected in 2005

Experts predict rough year ahead for pharma as public confidence in industry crumbles

Assistant Attorney General for the Civil Division of the U.S. Department of Justice Peter Keisler recently reported that more than 500 drugs are currently under investigation by state and federal prosecutors. That comes on the heels of a separate estimate by an Assistant U.S. Attorney that over 100 pharma qui tam cases are now under seal. Whatever the exact number, all sides agree it is certain to be a very challenging year for the pharmaceutical and medical device industries on a range of fronts.

As one Assistant U.S. Attorney put it last month, "There is no question that right now pharmaceutical companies are in the crosshairs of the prosecutorial gunfight." However, the full scope of emerging investigations is still unclear. "We believe many very large fraud cases are still under seal," says James Moorman, president of the Taxpayers Against Fraud Education Fund. According to Moorman, who has close ties to Sen. Charles Grassley, the more than \$2.4 billion already recovered from drug manufacturers is "just the tip of the iceberg."

That is just one of the troubling predictions for pharma in 2005. Conversations with dozens of current and former state and federal prosecutors, defense counsel, and senior industry executives reveal at least ten broad themes (see next page). This issue looks at several of these areas including DTC advertising and continuing medical education as well as some broad trends. The next two issues will examine the new risks associated with drug pricing, off-label promotion, and sample accountability as well as growing threats facing the medical device sector.

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Two new publications coming shortly

In order to adequately cover two areas related to pharma sales and marketing compliance — implementation of the new Medicare drug benefit and emerging drug safety/risk management issues — two new publications will be announced shortly. Rx Compliance Report subscribers will receive the premiere issue of each publication at no cost. We look forward to your feedback.

KEY ENFORCEMENT ISSUES - The Government's Perspective

Concerns with off-label marketing and use:

- FDA regulations permit companies to “market” off-label in very limited circumstances under FDA regulations (e.g. WLF articles)
- Doctors free to prescribe for off-label use, and companies and doctors are allowed “scientific interchange”
- Doctors base decisions on studies/data
- System breaks down if studies not disclosed or if data is affirmatively misrepresented



KEY ENFORCEMENT ISSUES - The Government's Perspective

Concerns with kickbacks:

- System also breaks down if doctors' independent judgment is compromised because of unlawful remuneration
- Safe Harbors – available for a range of activities, but often the parameters are unclear, or the safe harbor is susceptible to abuse (e.g., personal services contracts)

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Recent Cases - Oxycontin (Purdue Pharma):

- \$600 million in civil and criminal penalties paid – May 2007
- Three Company executives, including corporate counsel, pled guilty to “misbranding” under FD&C Act
- Aggressive marketing campaign to promote powerful narcotic drug to wide groups of physicians – claim that product’s delayed release made it less addictive and less prone to abuse
- However, claims not true, and drug became widely abused, resulting in significant addiction, criminal activity and death

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False Claims Act

- Significant civil penalties for making or causing a false claim to be made on the government
- Applies to wide range of activities – billing, reimbursement and rebating activities as well as kickbacks are the most common false claims
- Many cases are civil AND criminal

KEY ENFORCEMENT ISSUES - The Government's Perspective

- False Claims Act and the Pharmaceutical Industry
 - Since 2000 – Total recovery against the industry – over \$ 5 billion
 - Other examples – off label promotion/kickback cases
 - Pfizer – Neurontin - \$430 MM
 - Astra-Zeneca - \$355 MM
 - TAP - \$855 MM
 - Eli Lilly – Evista - \$36 MM
 - Serostin – (Serono) - \$704 MM

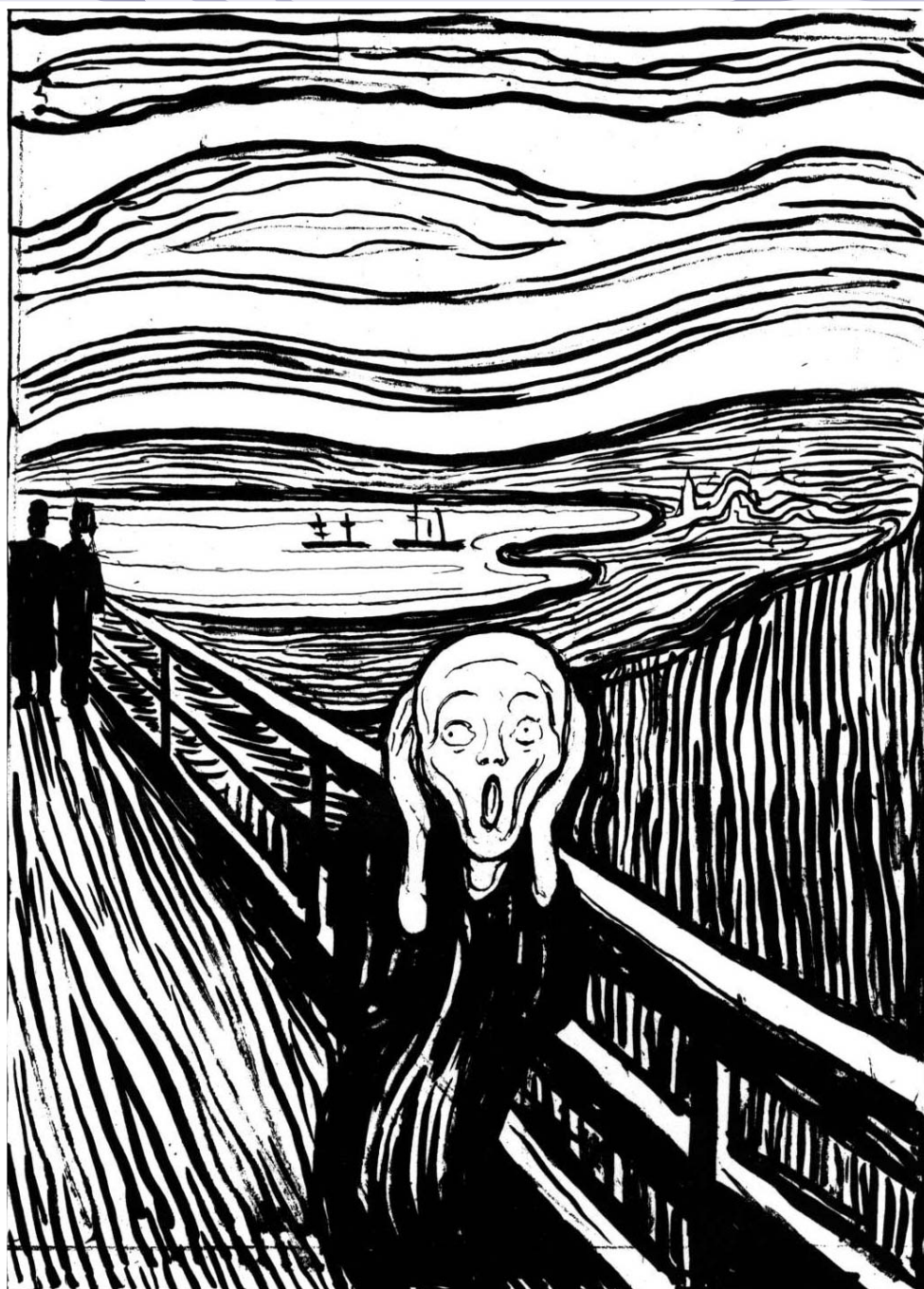
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Consistent Themes

- Threat of patient harm, generally caused by or related to corruption of medical judgment – via kickbacks or via dissemination of incomplete, misleading or false clinical information
- Adding Costs to the System – important, but more compelling where there is a questionable benefit to patients compared to risk

OIG's Compliance Program Guidance for Pharmaceutical Manufacturers

- Issued May 2003 – Cite:
- <http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>
- Applies to wide range of activities – beyond traditional “marketing” programs
- Specific Mention of Research Funding as an “Area of Concern” – this is becoming an increasing focus of regulatory/prosecutorial activity



KEY ENFORCEMENT ISSUES - The Government's Perspective

- Maintaining Quality and Compliance in today's environment is critical to long and short term organizational success
- Increasing visibility of "compliance," "compliance officers" and compliance programs since the introduction of the Sentencing Guidelines
- What drives adherence in an organization?
 - Culture is very important; actions and rewards are more telling than corporate policy statements and mandatory training programs

KEY ENFORCEMENT ISSUES - The Government's Perspective

- ☛ Is compliance a staff function, detached from the day-to-day business operations?
- ☛ Governance – Independent?
- ☛ Is the compliance adequately resourced – in terms of number of personnel and appropriate expertise?
 - Business experience and auditing experience are both needed to understand the overall ramifications of operational activities
 - What is the compliance officer's role vis-à-vis the outside world, including prosecutors and regulators?

