

# Trends in Medical Device Cases

Michael K. Loucks  
First Assistant U.S. Attorney  
United States Attorney's Office  
District of Massachusetts

The views expressed here are the personal opinions of the author and do not represent official positions of the Department of Justice.

# Relevant Laws

Anti-kickback statute

False claims cases, criminal and civil

- Medicaid Pricing Crimes
- Medicare Billing Fraud

Food, Drug and Cosmetic Act crimes

- Manufacturing process crimes
- Off-label promotion crimes

Conspiring to defraud an agency by interfering with its lawful functions through trickery, fraud and deceit

# Resolutions > \$1,000,000 (305)

Four year Period Ending	Total Amount Recovered	Criminal Fines	Settlements Less than \$10,000,000	Settlements More than \$99,999,999
12/31/199 4	\$602,000,000	\$97,300,000	1	2
12/31/199 8	\$1,676,837,748	\$93,600,000	21	7
12/31/200 2	\$4,642,527,772	\$603,593,600	45	7
12/31/200 6	\$8,218,577,264	\$956,147,866	96	18

Total: \$15,866,250,180; criminal fine: \$1,770,821,466

# Breakdown of Cases

Sector	No. of Cases	Recovery
Pharma Products	42	\$6.187 billion
Hospitals	103	\$4.043 billion
<b>Medical Devices</b>	<b>12</b>	<b>\$1.067 billion</b>
Dialysis Providers	5	\$943.6 million
Laboratories	17	\$872.7 million
Nursing Homes	12	\$518.2 million
Home Health Care	17	\$465.3 million
Carriers/intermediaries	14	\$420.5 million
Insurers	7	\$386.9 million
Rehabilitative services	6	\$341.6 million

Industry Sector	Total Settlements	Settlements since 1/1/2004
Carriers/intermediaries	14	7
DME	28	10
Home Health Care	17	6
Hospitals	103	45
Laboratories	17	2
<b>Medical Devices</b>	<b>12</b>	<b>3</b>
Nursing Homes	12	6
Pharma products	42	18
Physicians	16	8
Retail Pharma	10	7

# Relator Payments

Total payments to relators exceed \$1 billion dollars (unofficial estimate; official estimate through 2005: \$812,479,422)

Relator in TAP case was also relator in Astra-Zeneca matter: gained \$110,000,000

Relators are almost always insiders or former insiders

# Twenty largest

\$257 million to \$900 million

Sector breakdown:

- 9, pharmaceutical products
- 5, hospitals
- 2, dialysis
- **1, medical device**
- 1, insurer
- 1, rehabilitative services

# Doing it Right

Pressures from:

- Competitors on pricing, quality
- Customers on service, delivery, pricing
- QC on following the processes
- Regulatory affairs on following the rules

What happens:

- Cutting of corners
- Sloppiness, rushing can become criminal
- Need to provide things of value to gain product acceptance

Growing culture of acceptance

# Then versus now

The more things change the more they stay the same.

Today's hot trend of off-label promotion prosecutions is identical to prosecutions from the past.

Problems persistent today in bad corporate cultures match problems from the past.

- **Bard, 1987-1990**
- **Serono, late 1990s**
- **Canova, 2000s.**

# C.R. Bard, Inc.

## FDCA violations in the distribution of adulterated heart catheters

- One device suffered a failure as a result of a use that was off-label : **2 cm tip broke off**
- Company made changes in devices without seeking new approvals from the FDA

Conduct: 1987-1990; company charged October 1993; pled guilty and sentenced, April 1994, paid \$61,000,000.

# Off-label promotion issue

Restriction in labeling: affected use

Following the rules = loss of sales

Marketing pamphlets, handouts, sales rep statements: all pushed off-label use

Sales force, while aware of the label, not told the reason for restriction

Doctors followed promotion, used device off-label

# Bard

The labeling provided to the FDA stated "Warning: Do Not Turn the Probe II device more than one rotation (360 degrees) in the same direction."

In fact, physicians were routinely being told by USCI personnel in the human clinicals that the device could be rotated 15 times.

# Bard

— First Objective: to verify that the Probe B design may be freely rotated and/or define when rotation compromises performance.

Dr. King was anxious to use the redesigned probe in this case and checked with me several times to be sure... we could turn it ten revolutions in one direction.

# Bard

ISSUE: We have ... had several Probe failures involving the loss of the spring tip ... and/or loss of the entire neck extension ...

Physicians have been told "You can twist this thing 15 times and nothing will happen."

# Bard

The issue that we have been struggling with is how to remain committed to that precept [quality product] when we face the daily struggle of meeting sales objectives in a highly competitive environment. I agree that we have slipped. I concur that several of the decisions including the Mini, 3 Lumen and Probe were weighted too heavily with commercial interest.

**Memo by President of the catheter division to his boss**

# Bard

The USCI culture was "not keeping corporate in New Jersey totally informed about what was going on."

"Cutting corners became a way of life. That became a way of life. Or, we'll do the testing on human beings. None of us in this room would want to be the person tested on. We cut corners which were bad. We knew things were happening and we didn't tell corporate."

# Bard

[W]e never give our people enough time to accomplish their jobs but rather rush the program to the next step before it is ready. .. We feel enormous pressure from upper management and marketing to continue despite the unsolved technical issue. .. We chose not to address these design flaws but rather to begin production and fix these things on the way. We now find ourselves in the most uncomfortable position of trying to decide what to sell without adequate tests in place to identify the quality of our results. ... Does asking tough questions or making waves put one in the political shithouse?

# Serono

Criminal conduct: 1996-2002

FDCA violations in the distribution of a drug, serostim, and a medical device, a bio-impedance analysis machine

Faced with a rapidly diminishing market, Serono undertook to “expand” the definition of AIDS wasting to encompass newly emerging symptoms exhibited by AIDS patients and then promoted Serostim to treat these symptoms, even though the FDA had not evaluated or approved the safety and efficacy of the drug for such treatment.

# Serono

Despite knowing that the devices lacked FDA approval, Serono Labs promoted the use of BIA technology to physicians, patients, state Medicaid agencies and other third-party payors as an appropriate tool for determining whether Serostim should be prescribed and reimbursed.

# Serono

The approved label described the studies Serono Labs had performed on the drug, indicating that the trial demonstrating efficacy:

- had been performed on patients with "AIDS wasting"
- who had "unintentional weight loss of at least 10% or
- weighed less than 90% of the lower limit of ideal body weight."

# Serono

During the approval process, the FDA had objected to Serono's request to lower the 10% weight loss figure as the benchmark of AIDS wasting; Serono then agreed to continue to use the 10% weight loss criterion.

Serono also raised the possibility of measuring changes in "body cell mass," or "BCM," instead of "lean body mass," or "LBM," as done in the study. When the FDA objected, Serono dropped that proposal and agreed to continue to measure changes in LBM.

# Serono

However, in marketing the product, Serono claimed it was not possible to tell whether patients were wasting simply by looking at them and asserted:

- even if patients were not losing weight - and had actually *gained* weight – they could still be wasting if you looked at the BCM and not their LBM
- BCM could *only* be measured by performing BIA tests in tandem with certain software.

# Serono

Sales reps were required to report - and were rated on - their "BIA hit rate":

- *i.e.*, the number of BIAs performed that resulted in Serostim prescriptions.

To meet sales goals, sales reps manipulated testing and test results by:

- changing the patient's height, weight, and the numerical "resistance" and "reactance" readings generated by the BIA itself, so that the test showed patients to be wasting when they were not.

# United States v. Canova

Transtelephonic cardiac pacemaker testing

- 30-30-30 second intervals: testing of the pacemaker in three thirty second intervals
- Medicare paid on a per test basis
- Time requirements prevented “acceleration” of testing

Vice President, Operations: increased employee quotas from 32 to 40 per day

# Employee Testimony

Former plant manager: “If we were far behind on target, John would be pretty animated ... what we were going to do to get close to being on target”

Technicians: to meet quota, the last 30 second interval had to be cut to 10-15 seconds

From predecessor, when told employees were out of compliance: “everyone had to be in compliance [but] nothing [i.e., quotas] could suffer.”

# Employee Testimony

Another manager: [I told Canova] that “technicians were not performing the entire 30-30-30 testing all the time.”

Another manager: [I told him] “We’re not doing it period ... no one’s doing it.”

After seeking an “interpretation” from a Medicare carrier employee that the last 30 seconds didn’t mean 30 seconds, Canova and another employee decided on their own “there was in fact a loophole” that did not require a thirty second tape.

# What to watch for

Are the normal processes being followed?

Are there pressures to increase productivity, output, sales that are unrealistic for the resources available?

Are employees being told to stay in compliance and to meet production/sales demands that are not realistic for the resources at hand, or in light of the rules governing either production or sales?

Has someone offered a novel or new or suddenly discovered justification?

Are there budgets with few controls that can be used to provide incentives to customers?

Is a manager ignoring warnings from subordinates?