

# Compliance: Don't Be Too Late Getting Your House in Order

Presented by:  
Mark DuVal, President, DuVal & Associates, P.A.  
for LifeScience Alley  
January 13, 2011



**DUVAL & ASSOCIATES**

drug, device & food law

# Agenda

- **Understanding the Lessons of Compliance**
- **Knowing the Essentials**
  - **OIG Compliance Guidance**
  - **Applicable Statutes (FDCA, AKB, FCA, FCPA, etc.)**
- **Tailoring the Compliance Program to Your Organization**
- **Questions**









# The Avatar is now on our side

- Michael Loucks retired
- Here's his trophy room (\$6.8B):

Year	Defendant	Payment
2009	Pharmacia & Upjohn Company (Pfizer)	\$2,300,000,000
2009	Aventis Pharmaceuticals, Inc.	\$96,579,241
2007	Bristol-Myers Squibb Co., Apothecon, Inc.	\$515,000,000
2006	Schering-Plough Corp., through its subsidiary Schering Sales Corp.	\$435,000,000
2005	Serono, Inc.	\$704,000,000
2005	SmithKline Beecham Corp., d/b/a GlaxoSmithKline	\$150,000,000
2005	Boston Scientific Corp.	\$74,000,000
2004	Pfizer Corp., subsidiaries Warner Lambert, Inc. & Parke-Davis	\$430,000,000
2003	Bayer Corp.	\$257,200,000
2003	SmithKline Beecham Corp., d/b/a GlaxoSmithKline	\$87,600,922
2001	TAP Pharmaceutical Products, Inc.	\$875,000,000
2000	National Medical Care	\$486,000,000
1997	Damon Clinical Laboratories, Inc.	\$119,000,000
1994	C.R. Bard, Inc.	\$61,000,000



(Former US Attorney-Mass., Michael Loucks. He netted 30% of the settlements in the last 15 years)



# The Players

- **FDA – FDCA**
- **CMS – False Claims Act (FCA)**
- **Office of Inspector General (OIG) of DHHS –**  
Anti-kickback, FCA and Foreign Corrupt Practice Act (FCPA) – Civil and Administrative
- **Federal Prosecutors –** the litigators for everything  
– Department of Justice (DOJ)
- **States –**  
--State Attorneys General – Civil and criminal  
--Medicaid Fraud Control Units – Civil and criminal referrals



## Federal judge rejects \$296 million Guidant plea deal

April 27, 2010 by *MassDevice staff*

A federal judge in Minnesota rejects a guilty plea and \$296 million penalty Boston Scientific Corp. would have paid to settle a case against its Guidant Corp. subsidiary over faulty defibrillators.

4

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A federal judge today rejected a \$296 million plea agreement between the U.S. Justice Dept. and Boston Scientific Corp. (NYSE:BSX) subsidiary Guidant Corp. over faulty implantable defibrillators.



Earlier this month the Natick, Mass.-based medical devices giant, which paid \$26 billion for Guidant in 2006, agreed to plead guilty to a pair of misdemeanor criminal charges for withholding information from the Food & Drug Administration: specifically, to making a materially false statement about its Ventak Prizm 2DR implantable defibrillator in a required submission and to failing to notify the agency of a "correction" to its Contak Renewal defibrillators. Several patients died due to flaws in the devices that Guidant knew about and moved to correct without notifying the

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September 29, 2010

## Justice Dept, Inspector General To Target Individuals In Off-Label Cases

Article preview from ["The Gray Sheet"](#) - September 29, 2010

The government's chief litigators are not mincing words: They plan to hold more health care execs personally responsible for crimes at their firms.

### Justice Dept, Inspector General To Target Individuals In Off-Label Cases

Article preview from ["The Gray Sheet"](#) - September 29, 2010

By *Jessica Bylander*

The Department of Justice and Department of Health and Human Service's Office of Inspector General will join FDA in shifting the focus to individual liability in cases such as off-label promotion of devices and drugs.

FDA plans to more aggressively pursue misdemeanor prosecutions of CEOs,



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## AG Coakley Announces \$1.35 Million Settlement with Stryker Biotech

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BOSTON, Aug. 26 – The Massachusetts Attorney General issued the following news release:

Stryker Biotech, a Hopkinton-based medical device company, will pay \$1.35 million to the Commonwealth to resolve allegations that it marketed certain orthopedic products for uses that had not been reviewed and approved by the U.S. Food & Drug Administration (FDA) and misled health care providers about the appropriate uses of its products, Attorney General Martha Coakley announced today.

As a result of a multi-year investigation, the Attorney General's Office alleged that Stryker Biotech LLC (Stryker) violated the state's Consumer Protection Act by engaging in unfair and deceptive trade practices that boosted sales of certain products used in orthopedic procedures to strengthen and promote growth of bones. Under the terms of a settlement filed yesterday in Suffolk Superior Court, Stryker will pay \$325,000 in civil penalties, \$875,000 to fund efforts to combat unlawful marketing and other programs to benefit health care consumers, and \$150,000 to cover attorneys' fees and investigative costs.

# Sorin Group Announces Full and Final Settlement of Investigation by Department of Justice



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*Full and Final Settlement Ensures Focus on Plan for Cardiac Rhythm Management Business Unit in United States*

MILAN--(BUSINESS WIRE)-- Sorin Group, (MIL:SRN) (Reuters Code: SORN.MI), a global medical device company and a leader in the treatment of cardiovascular diseases, announced today that it has concluded a full and final settlement of the United States Department of Justice investigation into sales and marketing practices of its subsidiary Ela Medical, Inc. and of former independent sales representatives. Tentative settlement had been previously announced by the Group on March 12th, 2010.

The Company will immediately pay \$10 million (€7.2 million) to the United States Government. A provision for this amount had been booked in the 2009 financial accounts, therefore the settlement will have no impact on either the Company's fourth quarter or its full year 2010 financial statements. The settlement will also not impact year-end 2010 guidance for consolidated net debt (€150 million), which has already taken into account the settlement cash-out.

Andre-Michel Ballester, Chief Executive Officer of Sorin S.p.A., said, "As we announced in March this comprehensive settlement avoids the uncertainty of protracted litigation and ensures focus on our future plans for CRM in the United States."

Commenting on the completion of the settlement, Dan Hackman, Ela Medical, Inc.'s Senior Vice President for US Cardiac Rhythm Management commented, "Closure of this investigation places this legacy issue firmly behind us and clearly enhances our ability to execute on our plans for CRM in the United States. Our commitment to provide patients and healthcare providers with life-saving and life-enhancing innovation, and to conduct our business in a highly ethical manner is stronger than ever."

## About Sorin Group

Sorin Group ([www.sorin.com](http://www.sorin.com)) is a global, medical device company and a leader in the treatment of cardiovascular diseases. The Company develops, manufactures and markets medical technologies for cardiac surgery and for the treatment of cardiac rhythm disorders. With 3,600 employees worldwide, the Group focuses on three major therapeutic areas that include: cardiopulmonary bypass (extracorporeal circulation and autotransfusion systems),

- **Knowing the Essentials**
  - **OIG Compliance Guidance**
  - **AdvaMed Code**
  - **Applicable Statutes (FDCA, AKB, FCA, FCPA, Sunshine Act, state laws, etc.)**

# OIG Guidance--Elements for an Effective Compliance Program

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.



# AdvaMed Code



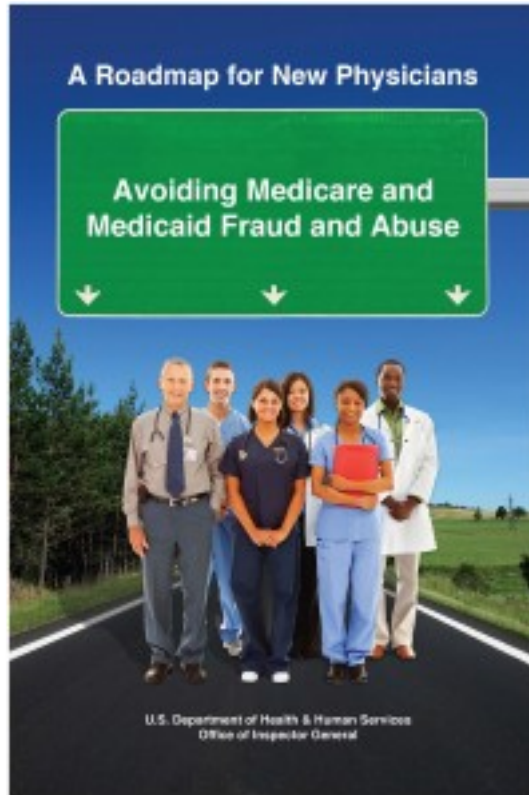
- Persuasive authority, not law, but it might as well be
- Helpful for analysis of your relationships
- Consider it as a code of conduct if you don't have one
- Includes for example:
  - Consultancies – make sure they are bona fide, FMV
  - Meals – keep them modest
  - Gifts – no branded items, make them educational in nature
  - Reimbursement – don't help upcode, miscode, etc.
  - Grants and donations – make sure they are bona fide
  - CMEs – bona fide, NOT selected by sales and marketing
  - Sales and Promotional Meetings, etc., etc.



# HHS-OIG Issues “Roadmap” to Help New Physicians Steer Clear of Fraud and Abuse

November 28, 2010 by Kate Greenwood · [Leave a Comment](#)

Filed under: [Fraud & Abuse](#), [Health Law](#)



As others have noted, earlier this month the HHS-OIG issued “A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse,” a

pamphlet which students, resident abuse law. The 2010 survey it co of the nation’s m the topic. The R around the relati payers, with an e health care provi chosen “case ex those relatio concludes with a a list of steps to

**The Roadmap is sensibly organized around the relationships physicians have with (1) payers, with an emphasis on Medicare, (2) fellow health care providers, and (3) vendors. It uses well-chosen “case examples” to make the rules governing those relationships concrete. The Roadmap concludes with a helpful list of additional resources, a list of steps to take “[i]f you are engaged in a relationship you think is problematic or have been following billing practices you now realize were wrong,” and a plug for the HHS-OIG’s Provider Self-Disclosure Protocol.**

relationship you think is problematic or have been following billing practices you now realize were wrong,” and a plug for the HHS-OIG’s Provider Self-Disclosure Protocol.

As David Harlow points out on his [HealthBlawg](#), the release of the Roadmap coincides with an effort by the federal government to re-think current fraud and abuse laws to facilitate the development of accountable care organizations and other efforts to better organize and pay

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Center for Policy and Research  
Releases new Guantánamo Rep  
DRUG ABUSE: AN EXPLORATION  
OF THE GOVERNMENT’S USE OF  
MEFLOQUINE AT GUANTANAM

# State Laws:



- Connecticut, Vermont, Massachusetts, Nevada, California, Minnesota, D.C., West Virginia and Maine all have special laws for drugs (some devices)
  - These states have special requirements and consequences for non-compliance
  - Some only cover drug companies
- Some require annual reporting
  - Massachusetts (report transfers of value > \$50)
  - Vermont (report nearly everything)
  - Various other requirements
  - More onerous for drug companies



# Sunshine Provision



- Passed as part of the Health Care Reform Law
  - Have to report any “transfer in value” to a physician greater than \$10, or > \$100 per year
  - Must report all such transfers by March 31, 2013 for 2012
  - Harsh penalties: \$1000-\$100,000 per occurrence
  - Some exclusions, e.g. discounts, samples, et al.
- Visit [www.duvalfdalaw.com](http://www.duvalfdalaw.com) for our Client Alert on this new law



# Tailoring the Compliance Program to Your Organization

- **Process:**
  - Analyze remuneration to Health Care Practitioners
  - Review existing and new:
    - Consultancies
    - Royalty payments
    - Clinical programs (especially physician-initiated trials)
    - Sales and marketing programs (co-marketing, referral dinners, product bundling, off-invoice price concessions, sales to clinical groups, etc.)
    - CME, speaker's bureaus, publication planning



# What does the Government want to see?

- Code, SOPs and policies in place and someone *in charge* of them
- A promotional review process
- Train management and sales and marketing on FDCA, AKS, FCA, FCPA (where applicable):
  - Must cover position on off-label discussion/dissemination and reimbursement advice
  - Company Code, SOPs, policies/approval procedures
- Compliance
  - ensure adherence to policies, SOPs and procedures by dealing swiftly and fairly with offenders
- Audits
  - in-house and the field
  - Regular management review
- Get ahead of the Sunshine Provision
- ***Stay current***



# QUESTIONS?

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