



FOLEY & LARDNER LLP

# FDA Enforcement in 2012

Lisa M. Noller

Medmarc Loss Control Webinar Series

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# Overview

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- Enforcement statistics
- The “Responsible corporate officer doctrine”

# FDA Enforcement Statistics Summary

## Fiscal Year 2011

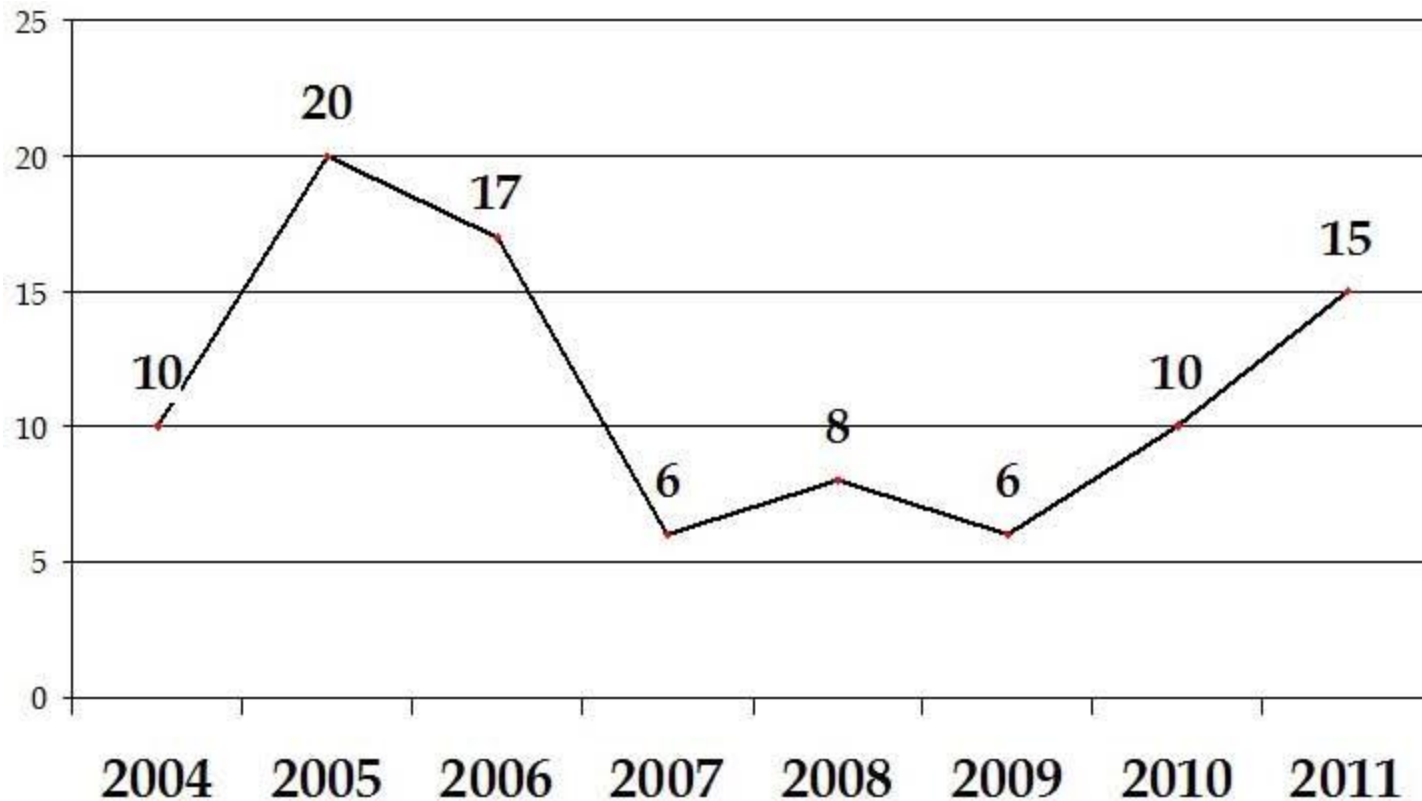
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Seizures	15
Injunctions	16
Warning Letters	1720
Recall Events	3640
Recalled Products	9288
Debarments	16

# FDA Seizures

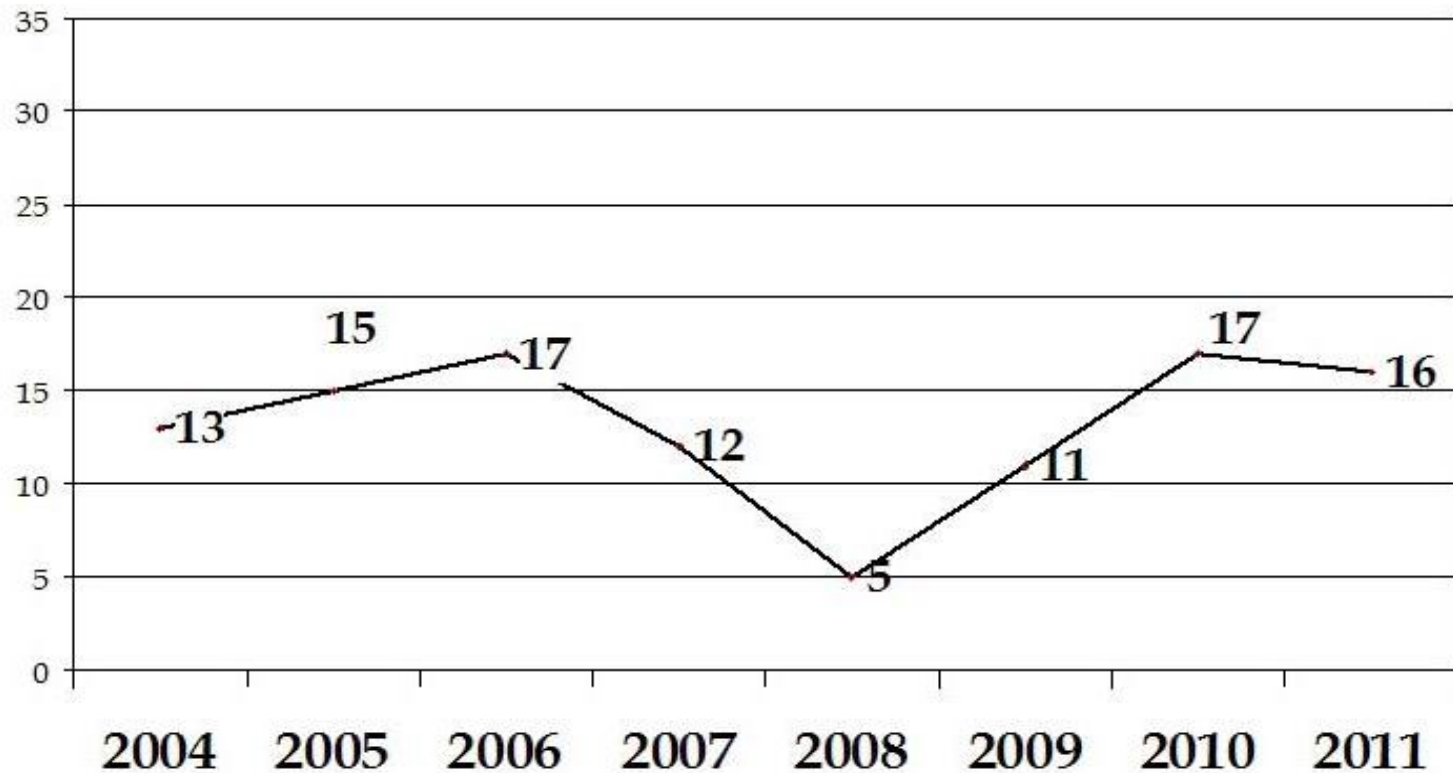
## Fiscal Years 2004-2011

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# FDA Injunctions Fiscal Years 2004-2011

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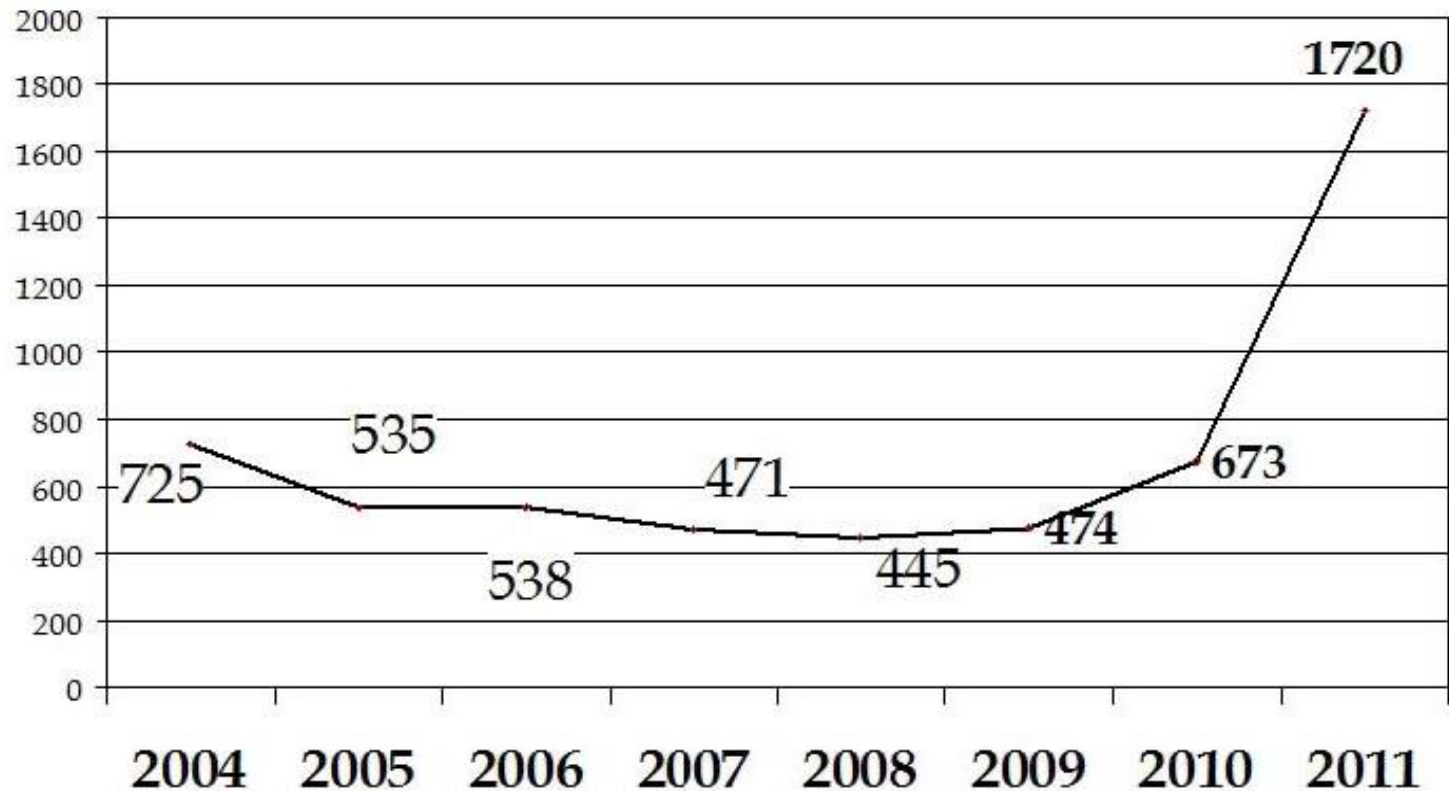
# FDA Enforcement Actions Summary

## Fiscal Year 2011

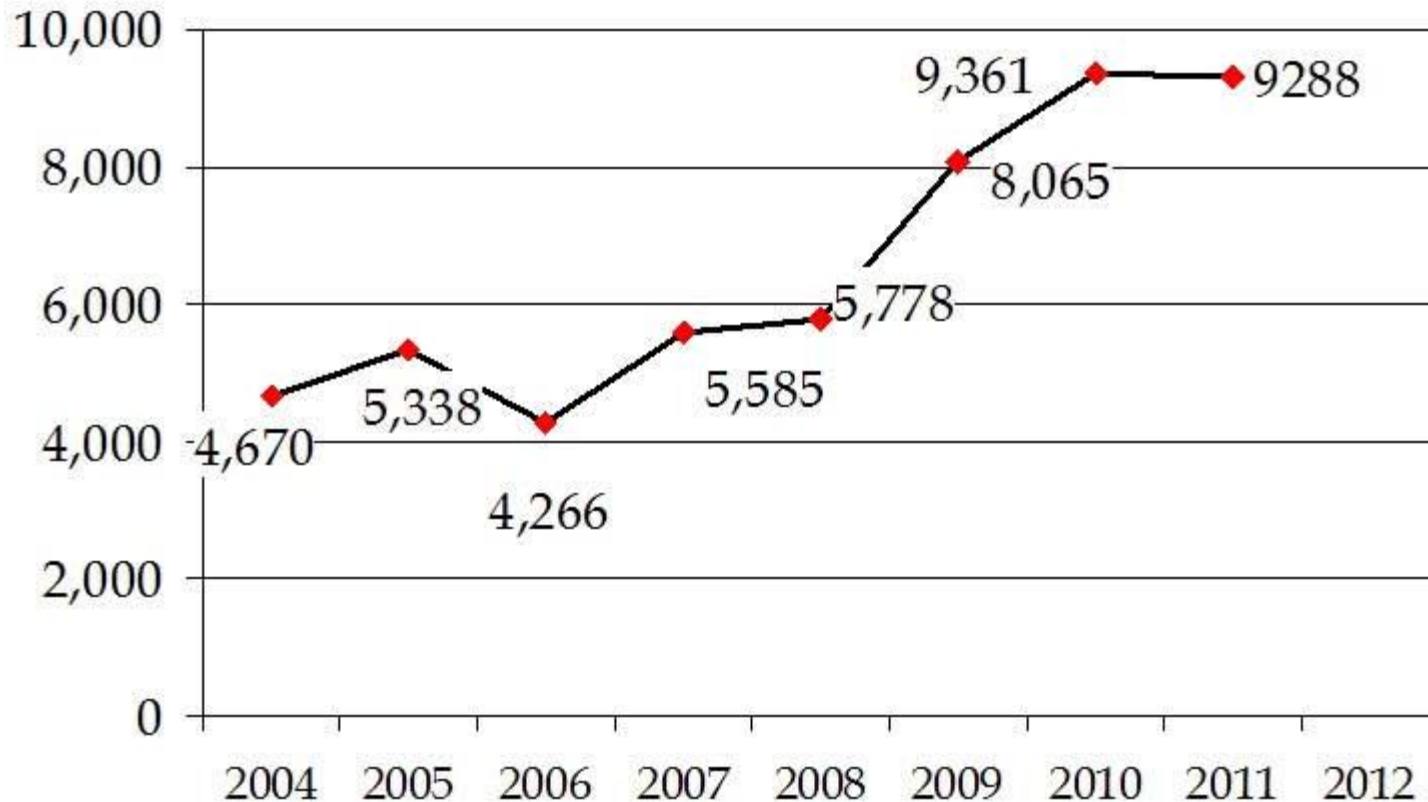
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- Pharma – 3
  - Deltex (+ RCOs)
  - McNeil-PPC (+ RCOs)
  - H&P (+ RCOs)
- Food/drink – 9
  - Processing/distribution – 4
  - Manufacturing - 2
  - Warehouse – 1
  - Handler – 1
  - Hauler – 1
- Dietary supplements - 1

# FDA Warning Letters Fiscal Years 2004-2011



# Recalled Products – All Centers Fiscal Years 2004-2011



◆ Recalls: Class I, II, and III

# Transparency Initiative

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- Launched in June 2009. Web portal launched in May 2011
- Publicizing more information about inspections and court actions
  - Summary of most common Inspectional Observations of objectionable conditions or practices
  - Inspections database
  - Provide more information to the public about:
    - Company practices that “may jeopardize public health”
    - Recall and enforcement activities
    - Inspection results
    - Food products not subject to recall

# Current Enforcement Climate

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- “ I don’t know when, where or how many cases will be brought . . . But if you are a corporate executive – or counsel advising such a client – I would not wait for the first case to decide now is the time to comply with the law. They won’t get a mulligan on their conduct”
  - Eric Blumberg, FDA Litigation Chief (Oct. 2010)
- “I do think we’re going to see an increasing number of cases [brought] against individuals”
  - Mary Riordan, senior counsel, HHS-OIG (Sept. 26, 2011)
- “As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue. . . . One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, **either directly or because of their positions of responsibility in the company** that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.”
  - *Testimony of Lewis Morris, Chief Counsel to the Inspector General, House Committee on Ways and Means, Subcommittee on Oversight (March 2, 2011).*

# Framework

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- “Responsible Corporate Officer Doctrine” encompasses several paradigms
  - Food Drug and Cosmetic Act of 1938
    - 21 U.S.C. Sections 331 (prohibited acts), 333(a)(1) (misdemeanor), 333(a)(2) (felony)
  - Supreme Court Cases
    - *Dotterweich* (1943) and *Park* (1975)
  - HHS-OIG Exclusion Authority
    - 42 U.S.C. Section 1320a-7(b)(15) (1977)

# Responsible Corporate Officer Doctrine

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- “The offense is committed . . . by all who do have such responsible share in the furtherance of the transaction which the statute outlaws...”
  - *United States v. Dotterweich*, 320 U.S. 277, 284 (1943)
- “. . . the Act imposes not only a **positive duty to seek out and remedy violations** when they occur, but also, and primarily, a **duty to implement measures that will ensure that violations will not occur**. The requirements of foresight and vigilance imposed upon responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and wellbeing of the public that supports them.”
  - *United States v. Park*, 421 U.S. 658, 672 (1975)
- RCOD eliminates the need to prove “consciousness of wrongdoing”

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- “In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted.”
    - *Dotterweich*, 421 U.S. at 670-71.

# “The good sense of prosecutors”?

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- Recent DOJ prosecutions
  - Purdue Frederick Co.
  - Synthes, Inc. / Noridian Corp. (subsidiary)
  - Ethex Corp.

# The good sense of administrators?

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- Recent Exclusions
  - Purdue Frederick Co.
  - KV Pharmaceutical Co.
  - Forest Laboratories (sort of)
  - InterMune

# “The wise guidance of trial judges”

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- Is the RCO doctrine constitutional?
  - SCT has said yes, where CEO was involved in the violation (*Dotterweich*), or admitted the buck stops at his desk (*Park*)
- HOWEVER,
  - Exclusion is akin to a criminal sanction
  - Criminal penalties are typically imposed only where requisite *mens rea*
  - Due process concerns raised in both SCT dissents
- Need an excluded RCO to challenge sanctions (injunction?)

# Mandatory HHS-OIG Exclusions

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- 4 bases (all derivative of a conviction)
  - Federal Health Care Program-related offenses
  - Patient abuse or neglect
  - Felony health care fraud offenses
  - Felony controlled substances convictions
- “Conviction” defined broadly
- OIG has no discretion regarding whether to impose a mandatory exclusion

# Permissive HHS-OIG Exclusions

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- Authorization to permissively exclude individuals who own, control or direct a sanctioned entity at the time of the proposed exclusion
  - Not limited to the time of the event
    - Though RCOs might not have held a duty
- Direct or indirect ownership or control
- More than 15 bases (mostly derivative)
  - Misdemeanor fraud conviction
  - Obstruction conviction
  - Misdemeanor controlled substance conviction
  - License revocation or suspension
  - Entities controlled by excluded individual (and vice versa)
- Permissive exclusions vest authority to impose exclusion in an OIG exclusions official whose discretion is not reviewable

# Section 1128(b)(7) Exclusions

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- Affirmative (not derivative), permissive exclusion authority
- OIG must establish at hearing before ALJ
- Often basis for negotiated exclusion agreements
  - Emmanuel Bernabe: Nursing home executive; Agreed to permanent exclusion in July 2009
  - Alleged substandard care provided at nursing facilities under his direction

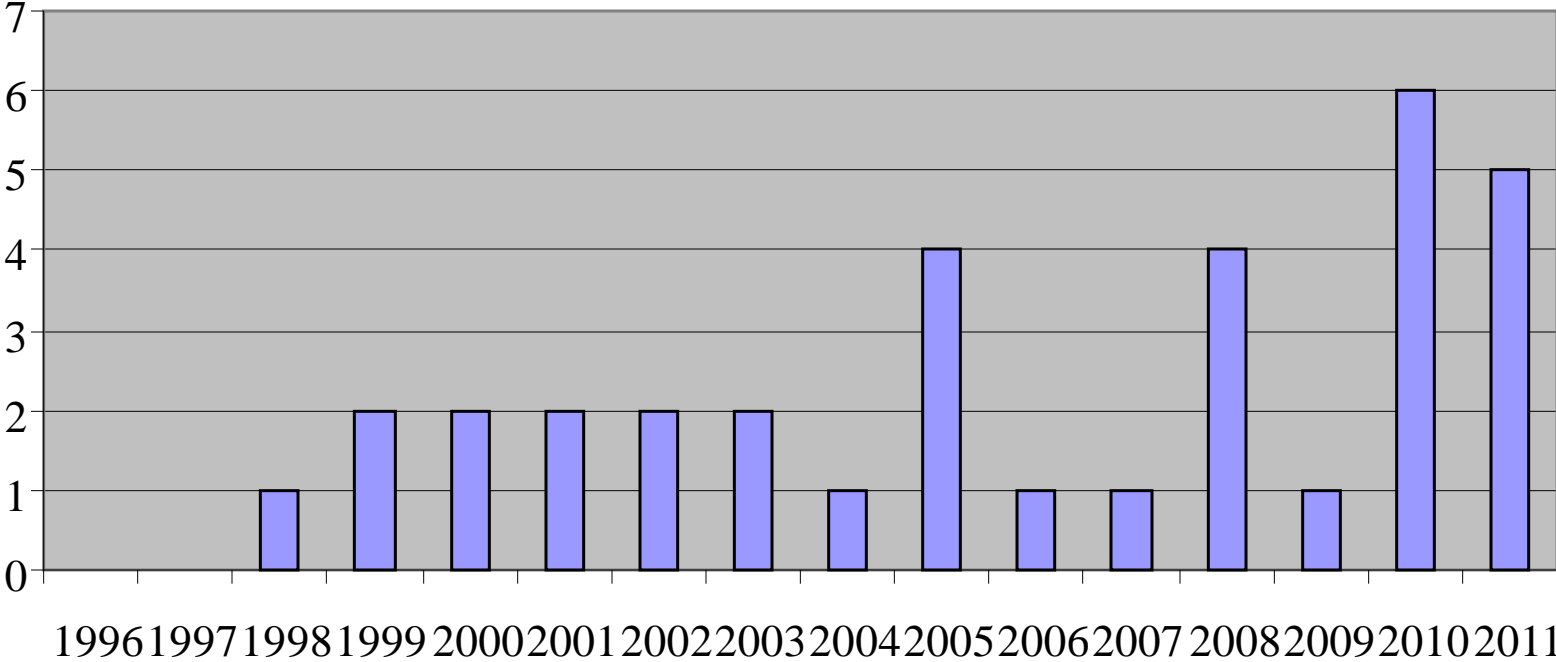
# Section 1128(b)(15) Exclusions

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- Authority since 1996
  - An individual with an ownership or control interest in a sanctioned entity and who knows or should have known of the action constituting the basis for the sanction; or,
  - An individual who serves as an officer or managing employee of the sanctioned entity (*i.e.*, **no knowledge element**)
- 34 current exclusions reported
  - Including drug companies, drug suppliers and pharmacies
- Congress: where an entity or individual is convicted or excluded from the Medicare program, a culpable individual may also be subject to exclusion, *even if he himself has not been convicted or excluded*

# OIG's Use of Section 1128(b)(15)

Section 1128(b)(15) Exclusions



# Other Exclusion Authorities

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- Conviction-based authorities have been used when individuals are personally convicted as part of global prosecution
  - Purdue executives excluded under Section 1128(b)(1) (misdemeanor fraud) and (b)(3) (misdemeanor controlled substances)
  - Former CEO of Intermune, Scott Harkonen, M.D., excluded under Section 1128(a)(3) based on wire fraud conviction

# HHS-OIG Internal Agency Guidelines

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- Basis for criminal conviction or exclusion of the entity
- Any other conduct that formed the basis for criminal, civil, administrative investigations, cases, charges, or resolutions
- Matters that involve entities that are or were related to the convicted entity
- Circumstances of the misconduct
- Seriousness of the offense
- Individual's role at the entity
- Individual's actions in response to misconduct
- Information about the entity

# FDA Weighs In

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- FDA announced in March, 2011 it would recommend RCO prosecutions in certain instances, based on:
  - Individual's position in the company
  - Individual's relationship to the violation
  - Whether the individual had the authority to prevent or correct the violation
- Follows *Park* and HHS-OIG

# FDA Weighs In

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- FDA Regulatory Procedures Manual factors:
  - Actual or potential harm to the public
  - Obvious vs. hidden violation
  - Violation reflects a pattern of illegal behavior and/or failure to heed prior warnings (*Park*)
  - Widespread vs. isolated incident
  - Serious violations
  - Quality of the legal and factual support
  - Prudent use of agency resources
  - Significant financial benefit to corporation
  - Evidence that simple and inexpensive correction would have prevented the conduct

# Impossibility defense?

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- Impossibility defense might be available if an RCO could show he exercised extraordinary care but nevertheless was powerless to stop the violation
  - Rick Blumberg, FDA deputy chief counsel for litigation, June 7, 2011
- So far, not so good (*United States v. Y. Hata & Co.*, 535 F.2d 508, 515 (9<sup>th</sup> Cir. 1976), *United States v. Gel Spice Co.*, 773 F.2d 427 (2d Cir. 1985))
  - Fact-specific inquiry

# Responding to the RCO Doctrine

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- Implement written policies, procedures, standards of conduct
  - Communicate policies to owners, managers, executives, Board members, etc. (routine briefings)
  - Encourage them to embrace an active role in compliance
  - Mandate training for (b)(15) individuals
- Designate a compliance officer or compliance committee
  - Responsible for updating policies, training individuals
  - Written charters, mission statements
  - Provide adequate resources for compliance
- Educate!
  - Train RCOs on compliance issues and responsibilities, including conflicts of interest
  - Specialize training for RCOs re. compliance principles

# Responding to the RCO Doctrine

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- Implement anonymous reporting mechanisms
  - Develop an action plan for responding
- Enforce standards through well-known disciplinary policies
- Identify risks and routinely address them
  - Auditing, monitoring, reviewing
  - Routine review of compliance policies, procedures
  - Report results to RCOs
- Promptly investigate and remediate potential and actual compliance problems

# Seven Components of an Effective Program

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- Contains standards and procedures
- Governing authority is on board
- Excludes criminals as decision-makers
- Communicates standards and procedures
- Reasonably ensures program is followed, effective and anonymous
- Includes incentives and disciplinary measures
- Takes reasonable steps to respond to and remedy problems

# Negotiating with the government

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- Challenge (b)(15) exclusion in settlement agreements, CIAs, plea agreements
  - Add recitals
- Memorialize any “side agreements” or discussions
- Affirmatively raise any issues with agency counsel, AUSA
- Affirmatively raise any issues with RCOs
- Be prepared to explain why entity conviction or exclusion is sufficient

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- Best defense is conduct that never invites scrutiny
  - Second best defense is showing the government the RCOs did everything possible to prevent misconduct



FOLEY & LARDNER LLP

# Thank You!

Lisa M. Noller  
Foley & Lardner  
321 N. Clark St.  
Suite 2800  
Chicago, IL 60654  
(312) 832-4363  
lnoller@foley.com