

**Regulatory Realities:**

**Comprehensive Solutions to Developments in Compliance**

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# Current Environment

## **Life Sciences Industry is Experiencing a Fundamental Shift**

- Unprecedented change in regulation of drugs, medical devices, and enforcement of cGMP and other practices
- Tremendous impact, billions of dollars in flux
- Services market is highly fragmented
- Industry focus on total product lifecycle solutions

**Fragmented approach is sub-optimal: Need for a Comprehensive, Integrated Solution**

# Critical Industry Drivers: New World, New Challenges

2000 – 2009

2010 – 2020

510(k)  
Process

Well understood,  
often perfunctory

New requirements,  
increased burden

PMA Process

Cumbersome, but  
manageable

More, better data,  
perfect execution

Post-Market  
Surveillance

Required, but not  
enforced

Active enforcement,  
new FDA tools

Compliance  
and GMP

Inconsistent, limited  
reporting of failures

Safety concerns to  
drive new standards

Global  
Supply Chain

New, manageable

Industry-wide,  
enforcement required

Off-label  
Promotion

Illegal, but loosely  
enforced

FDA/DOJ active  
pursuit of cases

Off-label Use

“Practice of Medicine”

- FDA Reform
- Legislation
- Whistleblowers



- Litigation
- Cost Pressures
- Patient Safety

# Focus on Enforcement: Legislation as the “Lab”

- Food Safety and Modernization Act (2011)
  - FDA authority to order mandatory food recalls
- Dodd-Frank Wall Street Reform and Consumer Protection Act (2010)
  - Whistleblower protection
- False Claims Act & Anti-Kickback Act Amendments (2010)
  - Allows easier, indirect whistleblowing; expands definition of false claims
- Amendment to Corporate Culpability Provisions of US Sentencing Guidelines (2010)
  - Compliance officers should have “direct reporting obligations” to Board or other senior executives
- Enforcement of Park Doctrine (2010)
  - Executives can be liable for violating FDCA even without knowledge or intent

# How Serious is FDA About Compliance?

- FDA Commissioner Hamburg's new policies:
  - Enforcement action can proceed without a Warning Letter
  - 400 new investigators
  - 10 offices OUS
  - Aggressive Criminal Prosecution Guidelines
  - Expand healthcare fraud-related investigations
  - Reorganized FDA, August 2011

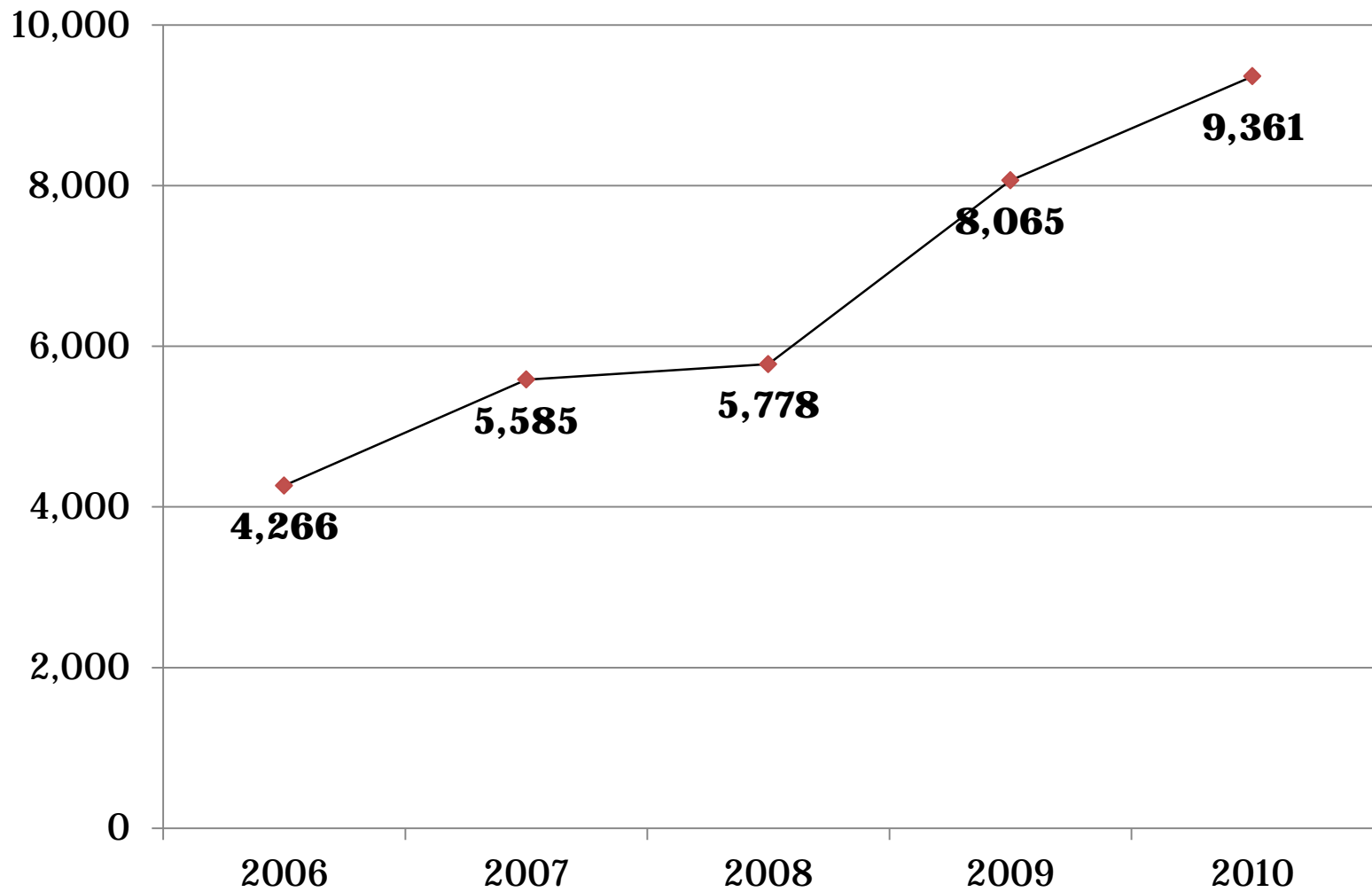
*“Companies must have a realistic expectation that if they are crossing the line, they will be caught; if they fail to act, we will.”*

*“....FDA will be prepared to act swiftly and aggressively to protect the public... If we find that we must move quickly to address significant health concerns or egregious violations, we will consider **immediate** action...”*

FDA Commissioner Margaret A. Hamburg, MD

# How Serious is FDA About Compliance?

## Recalled Products



# The Significance of Compliance

- Compliance issues are the most significant and potentially devastating risks to any pharmaceutical or medical device company.
  - Client X had three hundred employees until a single consent decree. Now they have four.
- FDA and the US Department of Justice are increasing their compliance scrutiny.
  - Ready to penalize companies with fines of nearly a billion dollars for promoting unapproved use (Company M paying \$950 million).
- FDA is increasingly looking OUS for compliance issues.
- By instituting strong compliance systems as a priority at every stage of development, companies invest in security and peace of mind.

# New Target: OUS Activities

- FDA is seeking to expand its compliance scrutiny internationally
- Dedicated offices focused on China, India, Africa and Asia, Latin America, Middle East
  - FDA has doubled its regulatory agreements with foreign counterparts in the past five years to over 100 formal agreements
  - These agreements allow for the sharing of inspection reports and joint inspections
- Release of the “Pathway to Global Product Safety and Quality” in 2011
  - Stated Goal: “FDA will transform itself from a domestic agency operating in a globalized world to a truly global agency fully prepared for a regulatory environment in which product safety and quality know no borders.”

# FDA International Actions

- Inspections of overseas drug manufacturing plants increased from 333 in 2007 to 424 in 2009
- Currently working over the next 12 months to create “global coalitions of regulators” in order to expand the reach of FDA
- Company R in India
  - FDA cited manufacturing defects at two of the company’s plants in India
  - Barred from selling 31 different drugs in the US
  - Shares fell 8.7% after reports that the company may have to pay over \$1 billion to settle the dispute with FDA

# FDA International Harmonization

- FDA is an active participant in the Global Harmonization Task Force (GHTF) and the International Conference on Harmonization (ICH)
- The GHTF not only works to converge regulatory rules, but it also “serves as an information exchange forum” for medical device regulatory practices
- Companies need to prepare their international activities for this type of harmonized overhaul of regulation

# Negotiation vs. Escalation

- Company leadership must respond to compliance issues by actively initiating discussion directed towards a solution.
  - They increasingly lose control of the situation by anticipating FDA's suggestions.
- FDA wants immediate and demonstrated action.
  - If FDA does not see the action they expect, they quickly escalate to a warning letter.
  - Waiting for FDA's next move only works to your disadvantage; this puts the ball in their court in a game where you must play by their rules.

Do not expect a chance to negotiate. You need to respond with immediate and aggressive action.

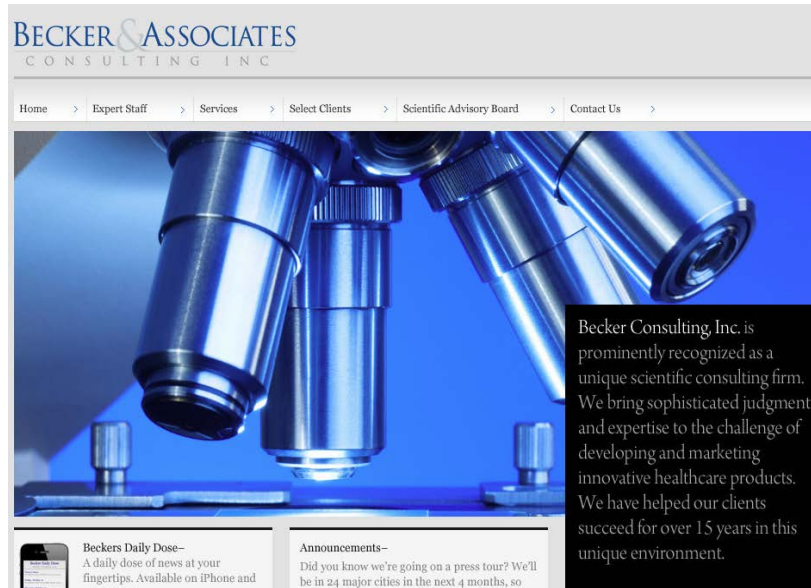
# The Necessity of a Total Compliance Strategy

- Companies can protect themselves from ruinous compliance-related issues by making compliance a first priority
  - A small investment in compliance protection can be the difference between a blockbuster product and a billion dollar fine and criminal charges.
- Total Product Lifecycle Approach
  - Institute comprehensive and interconnected systems at every stage of product development
  - Facilitate communication within the stages such that each informs the other
  - Begin with strong and trustworthy data, manufacture with well-designed and robust systems, conclude with well-formulated and honest labels.
  - Innovate with integrity → market with integrity.

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