

# A Change is Gonna Come: How Will the New HHS and FDA Affect Pharmaceutical and Medical Device Companies?

Cathy L. Burgess

Robert Roth

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# Topics for Discussion

- Selection of Tom Daschle as HHS Secretary. What does this say about the Administration's view of pharmaceutical and medical device companies?
- Selection of CMS Administrator and FDA Commissioner. When will they be selected? What is the significance to industry?
- Will President Obama's Administration reverse preemption? What other current FDA principles are likely to change?
- What is the likelihood of the enactment of broad health care and/or Medicare reform in 2009?
- How could President Obama's expanded access plan impact Medicare and third party reimbursement?

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# HHS Secretary Tom Daschle

- Health and Human Services
  - Tom Daschle, Secretary of DHHS; confirmed
    - William Corr, Deputy Secretary of DHHS; nominated

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# Selection of CMS Administrator

- Charlene Frizzera, Acting Administrator
- Possibly Under Consideration
  - Jeanne Lambrew, Senior Fellow, Center for American Progress and member of Obama Transition Team
  - Dan Mendelson, President, Avalere Health
  - Robert Berenson, Urban Institute
  - Judy Feder, Georgetown University
  - Ken Thorpe, Emory University

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# Selection of FDA Commissioner

- Frank Torti, Acting Commissioner; Deputy Principal Commissioner and Chief Scientist
- Under Consideration
  - Steven Nissen, MD: Cleveland Clinic
  - Josh Sharfstein, MD: Baltimore Department of Health
  - Michael Taylor, JD: Research Professor, GW School of Public Health and Health Services
  - Susan Wood, Ph.D.: Research Professor, GW School of Public Health and Health Services
  - Robert Califf, MD: Professor of Cardiology, Duke Univ.
  - Mary Pendergast, JD, LLM: Consultant
  - Others????

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# Preemption - Background

- During the campaign, President Obama said that he would end "attempts to protect drug companies from product liability.
- Last year, Obama cosponsored a Senate bill that would have overturned a U.S. Supreme Court decision in favor of **preemption** for some medical devices. His new White House Chief of Staff, Rahm Emanuel cosponsored the House version while he was a member of Congress .

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# Preemption

- On January 20<sup>th</sup>, Emanuel notified federal agencies of an immediate freeze on all pending regulations.
- The freeze would allow the Obama Administration to strike preemption language from any proposed rule or final rule that has not gone into effect.
- Example: FDA's proposed rule on drug labels and pregnancy, which would preempt tort suits in which the plaintiff sued a drug manufacturer for failing to warn about risks specific to pregnant or nursing women.

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# Preemption – Other Possibilities

- Executive Order, which would create a presumption against preemption, i.e. a presumption that state laws do not conflict with federal law unless shown otherwise. (recommended by the Center for Progressive Reform)
- New rulemaking
- Congressional action supported by Administration

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# Changes at FDA – Guiding Principles

- FDA needs to refocus as a strong, science based agency
  - Lost the confidence and trust of the public and Congress
- FDA is sorely under-funded and under-resourced to carry out its mandates
  - GAO Biannual Report, January 22, 2009
    - FDA Oversight of Medical Products Inadequate
- IT is dysfunctional. Needs to keep pace with needs of the Agency and industry
  - Foreign establishment inventory
  - Imports

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# Changes at FDA –What Can We Expect?

- Commissioner appointment is a high priority
  - Recognition that FDA needs strong leadership
- Increased funding and resources
- Greater emphasis on enforcement possible
  - The Agency typically focuses on consumer protection during a Democratic administration
  - Oversight may shift from the Agency to Industry

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# Changes at FDA –What Can We Expect?

- Stronger emphasis on High risk Device product approvals
  - GAO Report: FDA Should Take Steps to Ensure High Risk Devices are Approved Through Most Stringent Premarket Review process
- Stronger emphasis on postmarket safety
  - GAO Report: New High Risk Areas: Monitoring Postmarket Safety

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# Changes at FDA –What Can We Expect?

- Greater emphasis on imports and foreign inspections
  - Recent Draft Guidance on Good Importer Practices
  - GAO Report on Drug Safety; More inspections needed to strengthen FDA’s Foreign Drug Inspection Program
- Greater oversight/monitoring/review of promotional materials
  - Final Guidance on Good Reprint Practices on off-label use
  - GAO Report: New High Risk Areas: Reviewing Promotional Material for Medical Products

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# Changes at FDA – The Crystal Ball Says...

- Tobacco legislation
  - Bipartisan support; President Obama co-sponsored leg as Senator
  - William Corr (nominated) is Director Kids for a Smoke Free America
- Drug reimportation bill
  - Reintroduce 2007 bipartisan bill; President Obama supported; Drug must be FDA approved and manufactured in FDA inspected facility

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# Changes at FDA – The Crystal Ball Says...

- **Additional FDA offices to open overseas**
  - Increase FDA worldwide visibility, provide guidance and build relationships with foreign counterparts
  - No extra-territorial authority
- **Increase foreign inspections**
  - FDA provided budget increase to strengthen foreign inspection program
  - Increase oversight over Supplier Quality issues
    - Pilot Secure Supply Chain program for drugs (100 applicants)

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# Changes at FDA – The Crystal Ball Says...

- **Biosimilars**
  - Congressional interest growing for FDA to regulate these generic biologics
- **Import safety legislation**
  - Increase oversight and accountability of foreign firms
  - Improve IT to facilitate imports, and coordinate with other FDA databases to facilitate holistic Agency decisions
  - Reduce opportunity for “port shopping”
  - Streamline import statute in certain circumstances to reduce burden on FDA process
- **Review recent Guidance on Good Reprint Practices**

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# What Can We Expect from Health Care Reform?

- Focus on reducing costs, expanding access, and promoting prevention
- Likelihood of action in 2009

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# President Obama's Expanded Access Plan

- Guaranteed eligibility
- National Health Insurance Exchange
- Tax Credits for Families and Small Businesses
- Employer Contribution
- Required Coverage for Children
- Expansion of Medicare and SCHIP
- Increased Flexibility of State Plans

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# Impact of the President's Expanded Access Plan: Third Party Reimbursement

- What will be the effect of 46 million more people with health insurance
- Will the growth in prescription drug prices be closer to the 1.4% for 2007 or the 3.5% for 2006?
- Will the growth in retail prescription drug spending be closer to the 4.9% in 2007 or the 8.6% in 2006?

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# Changes at CMS – What Can We Expect From Medicare Reform?

- Allow Medicare to Negotiate Prescription Drug Prices
- Increased “Transparency” in Part D Plans
- Closing the Part D “Doughnut Hole”
- Reduction in Payments to Medical Advantage Plans
- Likelihood of Action in 2009

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# Wrap-Up

QUESTIONS AND ANSWERS

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