Legislative and Policy Landscape 2010 and Beyond

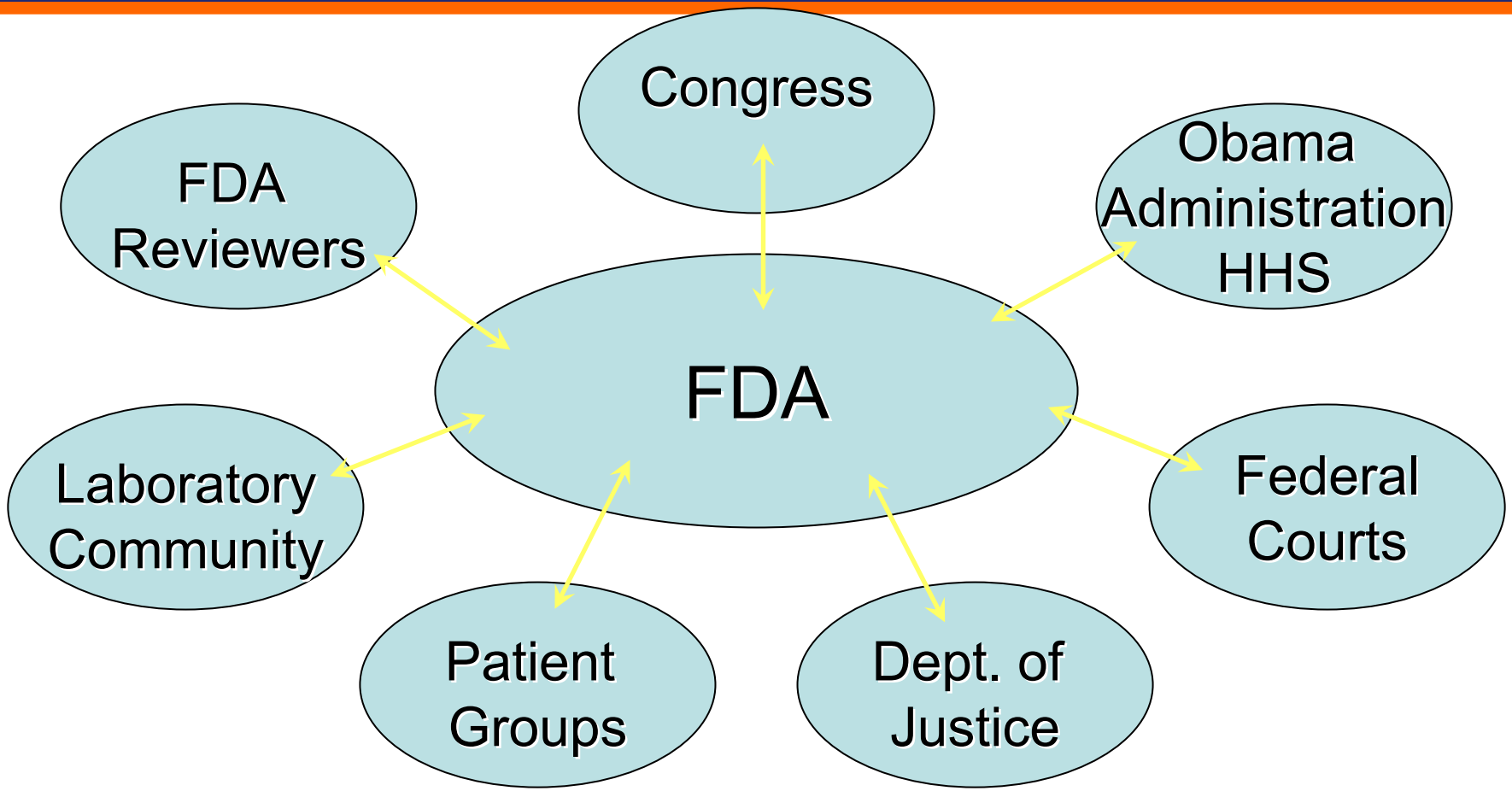
Richard Naples
VP, Corp. Reg. Affairs
and Compliance

April 23, 2010

Topics

- The Year in Review
- Policy Landscape 2010 - 2011
- Healthcare Reform
- FDA 510(k) Reform
  - Concerns
  - Reform concepts
  - Implications for Industry
- Futurescape

Stakeholders That Influence Change



The Year In Review – 2009 Insights

Top 10 Things FDA/OIVD is Most Likely to Do in This Environment

1. Pull back from close working relationship with industry?
2. Be more risk averse overall – cautious oversight of LDTs
3. More premarket data requirements – Tempered by Tier/Triage?
4. More warning letters for GMPs and other violations - ASRs
5. More conservative in deciding when to recall
6. Heightened sensitivity to adverse event reporting
7. More enforcement related to clinical trials
8. Flood of new guidelines – Companion Dx?
9. Some additional Class I/II exemptions, but limitations
10. Off-label promotion enforcement priority

Source: 2009 AMDM Annual Meeting Presentation: Legislative and Regulatory Policy Landscape; Richard Naples

BD

Something new in the headlines every day

Healthcare Issues

The Washington Post

November 24, 2009

Vaccine system remains antiquated

s the person most responsible for
uring that an optimal radiation dose
elivered safely, the medical physicist
st make sure that new machines are
up properly; that daily warm-up
cks are carried out, along with more
ensive monthly and annual evalua-
ns; and that individual treatments
administered as prescribed.
Computers can provide only so much

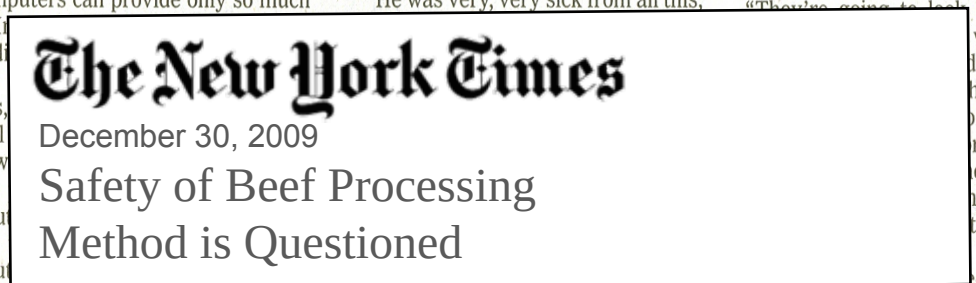
dosed and seriously injured, destroying his ability to urinate and move his bowels normally. Before two external bags were attached to collect his waste, Mr. Garst's urine leaked into his rectum because a fistula had developed. He had so many infections, his doctors had to keep trying new antibiotics to replace those that no longer worked.

"He was very, very sick from all this,"

THE WALL STREET JOURNAL.

November 19, 2009

U.S. Senate Bill Includes Lower $2 Billion Medical Device Tax



The New York Times

December 30, 2009

Safety of Beef Processing Method is Questioned

make everything right is much more
portant than it used to be," he said.
e are still grappling with how we do
t."
Hospitals sometimes aggravate the
blem, buying new technology with-
adding the employees needed to op-
te it safely, according to a report is-
d on a 2007 conference sponsored by
radiological associations and the
ional Cancer Institute.
nd hospitals complain that manufac-
ers sometimes release new equip-

devastating injuries.

The state and the commission initially told The Times that they had n
risdiction in the case since neither
first nor second treatment was by i
an overdose, even though in comb
tion they were. Despite their man
to protect patients from radiation
takes, the state and federal governm
said in essence that Mr. Garst
someone else's problem.

Had regulators investigated,
would have found reasons for concern.

The New York Times

January 7, 2010

Hospitals Could Stop Infections by Tackling Bacteria Patients Bring In, Studies Find

herself even though her husband h
died several months earlier. Seeki
reasons for her mother's suicide, M
Lilya began searching the Internet a
reached out with dozens of calls a
e-mail messages to professional grou
and government agencies.

James Gosky, a spokesman for Akr
General, said in a recent interview th
Mrs. Garman had been informed of h
overdose.

Still, Ms. Lilya said, "none of th
made any sense." So she kept pressi
— without success — for a more tho
ough investigation of her mother's ac
dent.

In a conference call last summer, s
said Lance D. Himes, assistant couns
for the Ohio Department of Health, e
plained part of the department's e
t philosophy.
ld me they don't get into a
penalties because that is wh
ice is for," she said.
esman for the state said M
enied making that statemer
ctober 2007, the state did fi
tal $4,000 for other infractio
for Mrs. Garman's overdose
ya said her investigation ha
taught her much about how hospita

government's attention, while the much more common machine-generated radiation was largely unregulated by the federal government.

Thirteen states, including California, do not require that errors involving linear accelerators be reported to state

Jared W. Thompson, an Arkansas radiation official, said he mostly worried about diagnostic radiation. "There are no limits about what can be done, how it can be used, when it is considered unsafe," Mr. Thompson said.

There are no guarantees, Mr. Whatley said, that radiological devices have been inspected and that its operators are properly trained and qualified. Depending on the state, he added, "you may get two to three times more of the

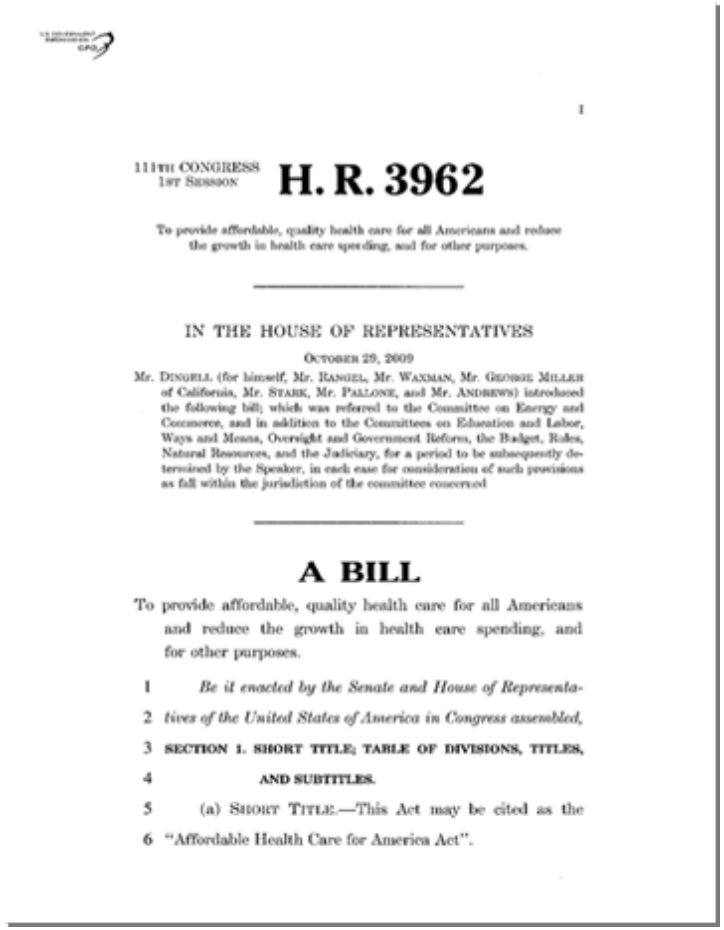
probably the single most useful im-

Healthcare Reform is a Continuous Process

Attempt to address problems that aren't going away:

- Rising healthcare costs
- Aging population
- Quality issues
- Medicare Trust Fund

Round #1 presented both opportunities and risks to industry



111TH CONGRESS
1ST SESSION

H. R. 3962

To provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 29, 2009

Mr. DINGELL (for himself, Mr. RANGEL, Mr. WAXMAN, Mr. GEORGE MILLER of California, Mr. STARK, Mr. PALLONE, and Mr. ANDREWS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Labor, Ways and Means, Oversight and Government Reform, the Budget, Rules, Natural Resources, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF DIVISIONS, TITLES, AND SUBTITLES.

(a) SHORT TITLE.—This Act may be cited as the "Affordable Health Care for America Act".

Healthcare Reform

Industry Opportunities

- Increased demand for diagnostic tests
  - Routine
  - Preventive
- HHS Action Plan to reduce Healthcare-Associated Infections (HAIs)

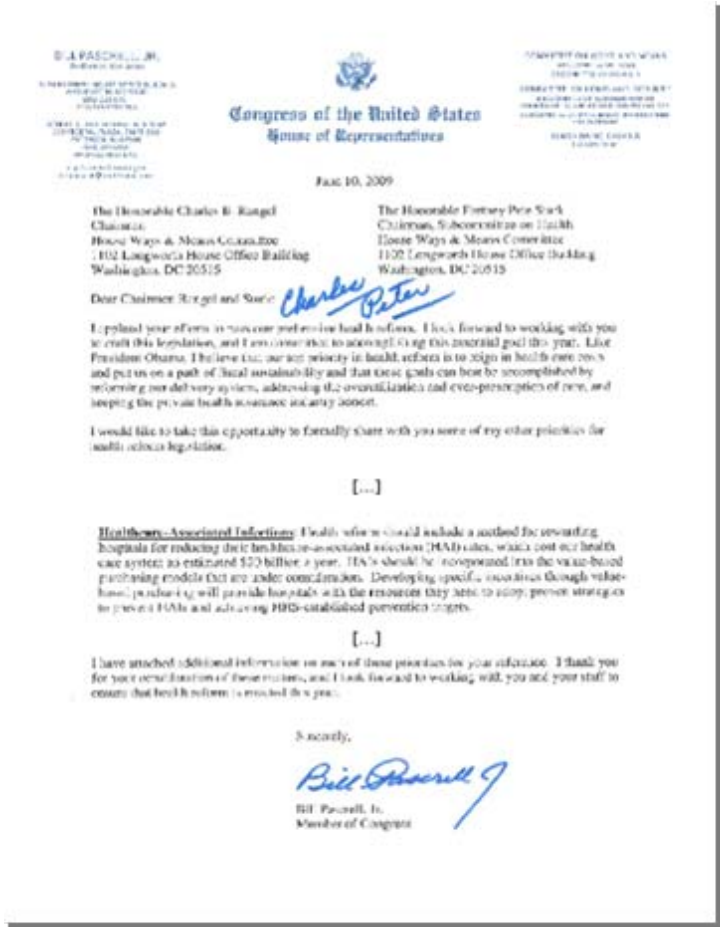
Industry Risks

- Lower profit margins for Parma companies → lower R&D spending → fewer products purchased
- Medicare/Medicaid cuts → lower hospital spending on products
- Medicare lab fee schedule cuts
- Comparative Effectiveness Research (CER)
- $2 billion/year excise tax on medical devices

BD

Value-Based Purchasing for HAIs

"Healthcare-Associated Infections: Health reform should include a method for rewarding hospitals for reducing their healthcare-associated infection (HAI) rates, which cost our healthcare system an estimated $20 billion a year. HAIs should be incorporated into the value-based purchasing models that are under consideration. Developing specific incentives through value-based purchasing will provide hospitals with the resources they need to adopt proven strategies to prevent HAIs and achieving HHS-established targets."



Congress of the United States
House of Representatives

June 10, 2009

The Honorable Charles B. Rangel
Chairman
House Ways & Means Committee
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Fortney Pete Stark
Chairman, Subcommittee on Health
House Ways & Means Committee
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairmen Rangel and Stark:

I applaud your efforts to [illegible] health reform. I look forward to working with you to craft this legislation, and I am committed to achieving this essential goal this year. Like President Obama, I believe that our top priority in health reform is to reign in health care costs and put us on a path of fiscal sustainability and that these goals can best be accomplished by reforming our delivery system, addressing the overutilization and over-prescription of care, and keeping the private health insurance industry honest.

I would like to take this opportunity to formally share with you some of my other priorities for health reform legislation.

[...]

Healthcare-Associated Infections: Health reform should include a method for rewarding hospitals for reducing their healthcare-associated infection (HAI) rates, which cost our health care system an estimated $20 billion a year. HAIs should be incorporated into the value-based purchasing models that are under consideration. Developing specific incentives through value-based purchasing will provide hospitals with the resources they need to adopt proven strategies to prevent HAIs and achieving HHS-established prevention targets.

[...]

I have attached additional information on each of these priorities for your reference. I thank you for your consideration of these matters, and I look forward to working with you and your staff to ensure that health reform is enacted this year.

Sincerely,

Bill Pascrell, Jr.
Member of Congress

BD

FDA 510(k) Process Reform

- 2/18/10: FDA public meeting
- 3/1/10: IOM public meeting; others to follow
- 5/31/10: FDA releases proposed reform plan
- 6/??/10: House hearing on FDA plan?
- 7/31/10: FDA finalizes plan
- 9/30/10: FDA implements plan
- 3/??/11: IOM releases report

FDA 510(k) Process Reform

- FDA March 1 Presentation to IOM
  - FDA 510(k) Working Group - Subteams
    - Predicates
    - Indications
    - New Technology
    - De Novo
    - Evidence
    - Modifications
    - Standards
    - Bundling
    - Third Party Review
    - Postmarket Data

Public Meeting Feb 18; FDA All Hands Meeting Feb 24;
Comment Period ended March 19; Final Report due May 31

BD

Key Issues Identified by FDA 510(k) WGs

- **Predicates** - Use of “old” predicates; subpar performance; split predicates
- **Claims** – Indications for use; off-label use
- **Clinical Data** – how much is enough?
- **Changes** – device creep; ownership changes, recalls
- **Bundling** – difficult to identify bundled products after clearance
- **Postmarket Controls** – limited authority to rescind 510(k)
- **Labeling** – final printed labeling not required

Possible FDA 510(k) Reforms

- Possible Changes
  - Limitations on choice of predicates; no more split predicates
  - Guidance on intended use vs. indications for use
  - Inclusion of final printed labeling in 510(k) clearance file
  - Regular 510(k) updates for non-significant changes
  - Limitations on bundling
  - Elimination of Abbreviated and Special 510(k)s
  - Elimination of Third-Party Review
  - Increased postmarket surveillance studies
  - Expanding FDA's 510(k) rescission authority

BD

Industry View on 510(k) Process Reform

- 510(k) process is a successful and effective program
  - Not an abbreviated process or loophole
  - We support FDA and IOM assessments
  - Need evidence that change is warranted
  - Otherwise, early 1990s history could repeat itself
- Proposals industry is contemplating
  - Improve transparency/consistency of 510(k) summaries
  - Increased scrutiny for subset of higher risk devices
    - Clinical data
    - Modifications

Implications for Industry's Risk-Based Proposal

- Do they still fit with FDA's 510(k) Reform initiatives?
  - Absolutely, Positively Yes!
  - Meets several needs -
    - Focuses FDA resources on higher risk tests
    - Supports transparency and good science
    - Foundation for high quality submissions and even more timely, predictable reviews

Issues to Watch Out For

- Congress, Obama Administration, and HHS
  - Great interest and focus on healthcare policy issues
  - Greater recognition of the value of preventive care
  - NIH/FDA focus on Genomics and Personalized Medicine
    - Genetic Test Registry
  - More hearings on the safety of medical devices
  - Legislative changes to 510(k) Process in 2011
  - Device User Fee Reauthorization
  - First steps toward regulating LDTs?

BD

Issues to Watch Out For

- FDA
  - FDA will test the boundaries of their authority. Length of review time will vary, depending on:
    - Novelty and risks associated with the device,
    - Postmarket experience with similar devices,
    - Quality of the data, and
    - The current environment in Washington.
  - Industry will be paying higher user fees for service
    - New fees for pre-submission meetings?
    - Fees applied for the first time to postmarket activities?

Issues to Watch Out For in OIVD

- FDA Interest in Tightening Blood Glucose Monitor Accuracy Specification
  - Revision of ISO TC 212 15197 pending
  - March 16 – 17, 2010 FDA Public Meeting
    - Accuracy - home use vs. hospital use
    - Interferences
  - Takeaways from Meeting
    - New FDA BGM guidance in the works
    - Restrictions on use of certain types of meters in hospitals
    - Removing older meters from the market??

What Companies Can Do Today

- Approach Congress and FDA/OIVD with sound policy ideas supported by strong rationales/evidence
- Establish and maintain positive and credible working relationship with FDA/OIVD
- Best Practices for Companies
  - Collaborate with FDA on policy issues
  - Educate reviewers on your technology
  - Utilize FDA pre-submission advice – over-communicate!
  - Good science and high quality submissions
  - Use FDA chain of command to resolve disagreements

Thank you!

Questions?