Advocating For Reasonable Regulation

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Advanced Medical Technology Association

Steve Ubl
President and CEO, *AdvaMed*

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

March 29, 2006

AdvaMed Facts

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- World's largest association representing medical technology innovators
- Now grown to 1,300 + member companies and subsidiaries (devices, diagnostics, HIS)
- **Members manufacture 90% of – 87 B domestic market, 50% – 220 B global market**
- $21 million budget, 60 staff with global expertise
- 45 - member Board of Directors

A Healthy Industry

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- R&D 12% of sales, 4x manufacturing average, = pharma
- 80% increase in patents in last decade
- 15% average annual revenue growth over last decade
- Venture investment strong
- 90% of industry has <100 employees
- Largest industry segment represented on Forbes and Business Week's lists of fastest growing small companies
- 350,000+ jobs paying 49% more than private sector average

The Market Rewards Innovation

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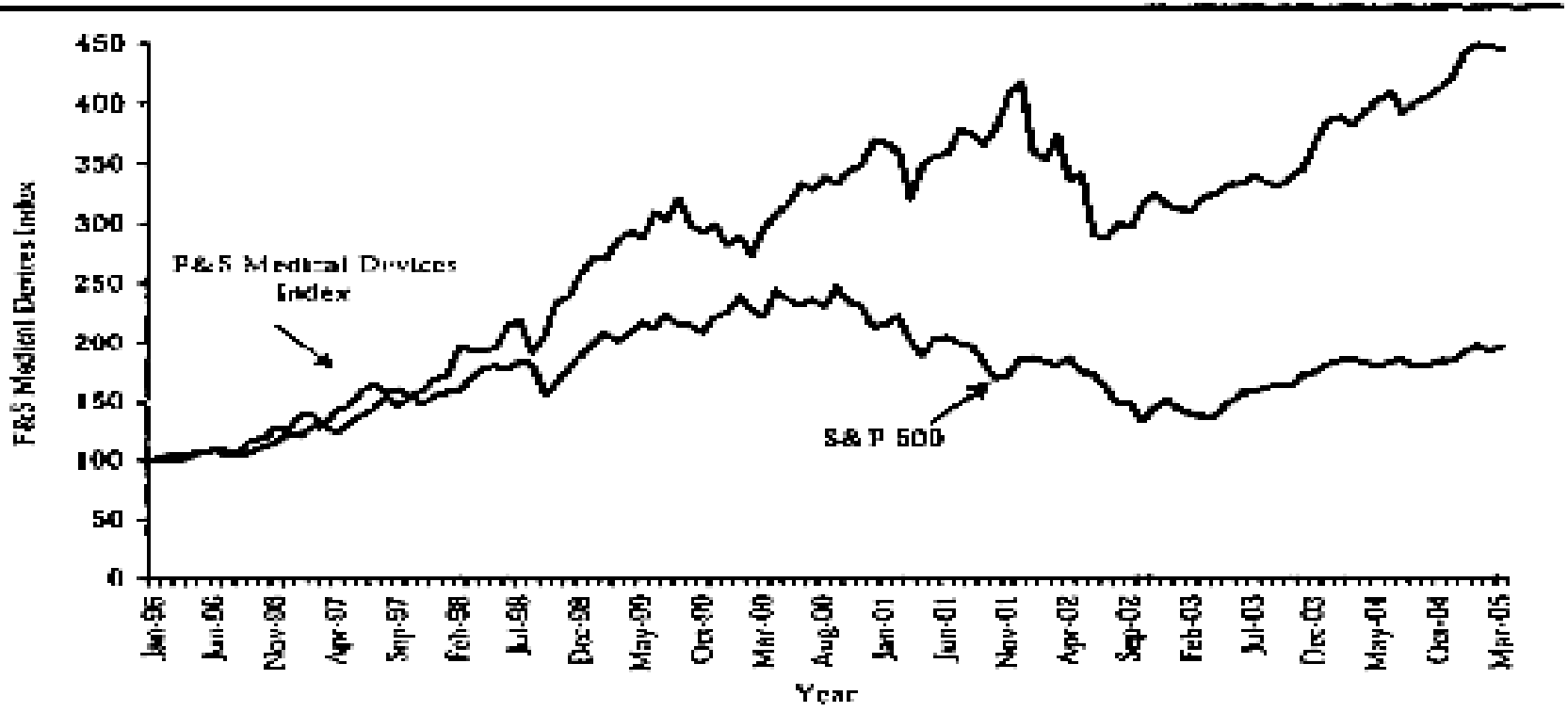
CHART I.1

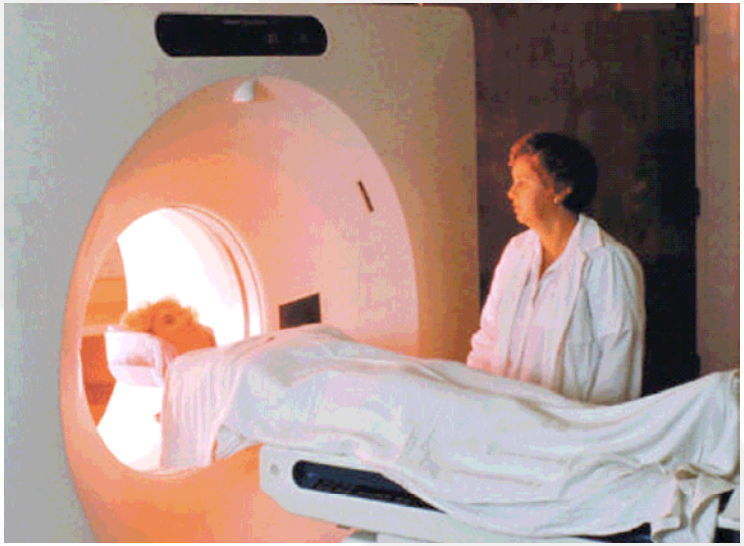
Medical Devices Industry: Performance of Frost & Sullivan Medical Devices Index versus S&P 500 (World), 1996-2005



Note: All figures are rounded. Source: Frost & Sullivan

This depicts the general trend over the past ten years.

Defining AdvaMed's Role



Defining AdvaMed's Role

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FDA

CMS

Design | Clinical | Review

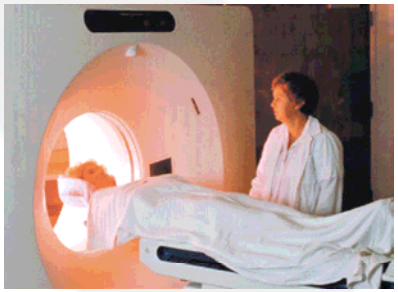
Coverage | Payment

Codin
g

Idea through FDA: 2-6 yrs

Cov & Paymt: 0-6

Japan | Ca | UK | Ko | Germany | Mex | China | Ind | France



Source: Lewin Group, 2000, 2004

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Stakes have never been higher. Today's issues hold significant implications…

For how the medical technology industry is regulated

C·D·R·H Center for Devices and Radiological Health

For how the medical technology industry gets paid

CMS

For how easy or difficult it is to enter new markets

The Public Policy Environment

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- Large deficits
- Rising health care costs
- Medicare in the crosshairs
- Number of the uninsured is large and growing
- Safety/Ethics issues
- Public wants health reform
- Unpredictable election

Deficits are Large—and are Projected to Stay Large

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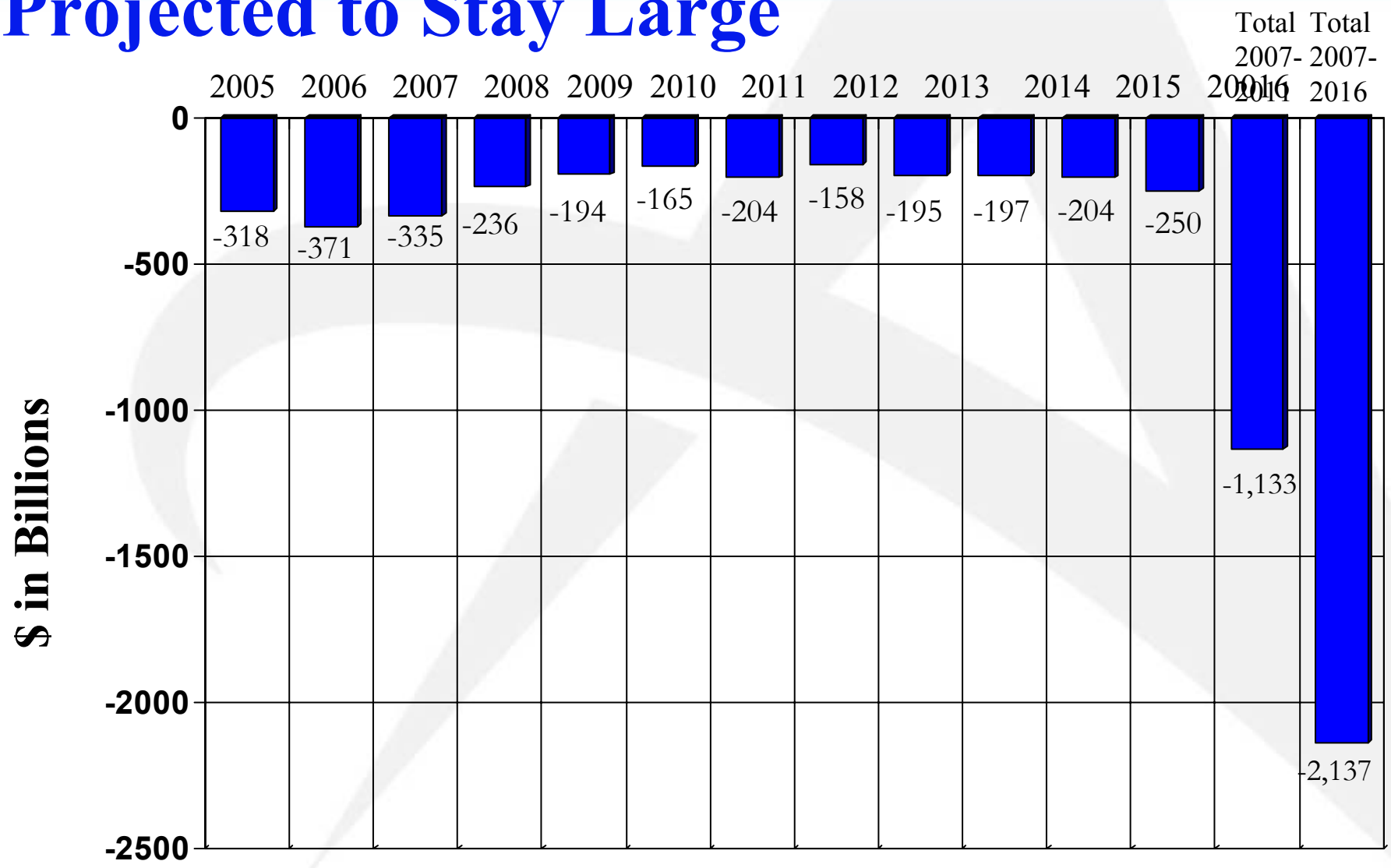

Source: Congressional Budget Office

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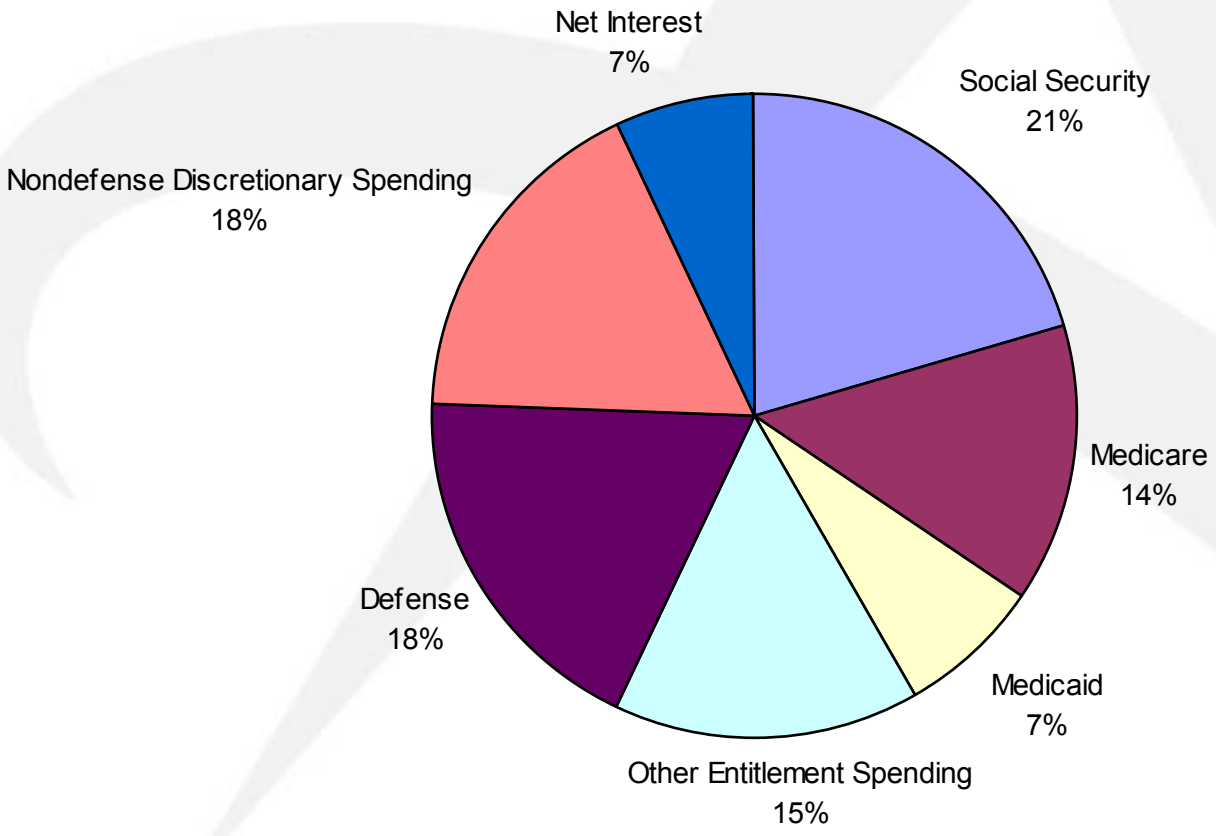
2006 Federal Budget: $2.64 trillion



Source: CBO Budget and Economic Outlook: Fiscal Years 2007-2016, January 26, 2006

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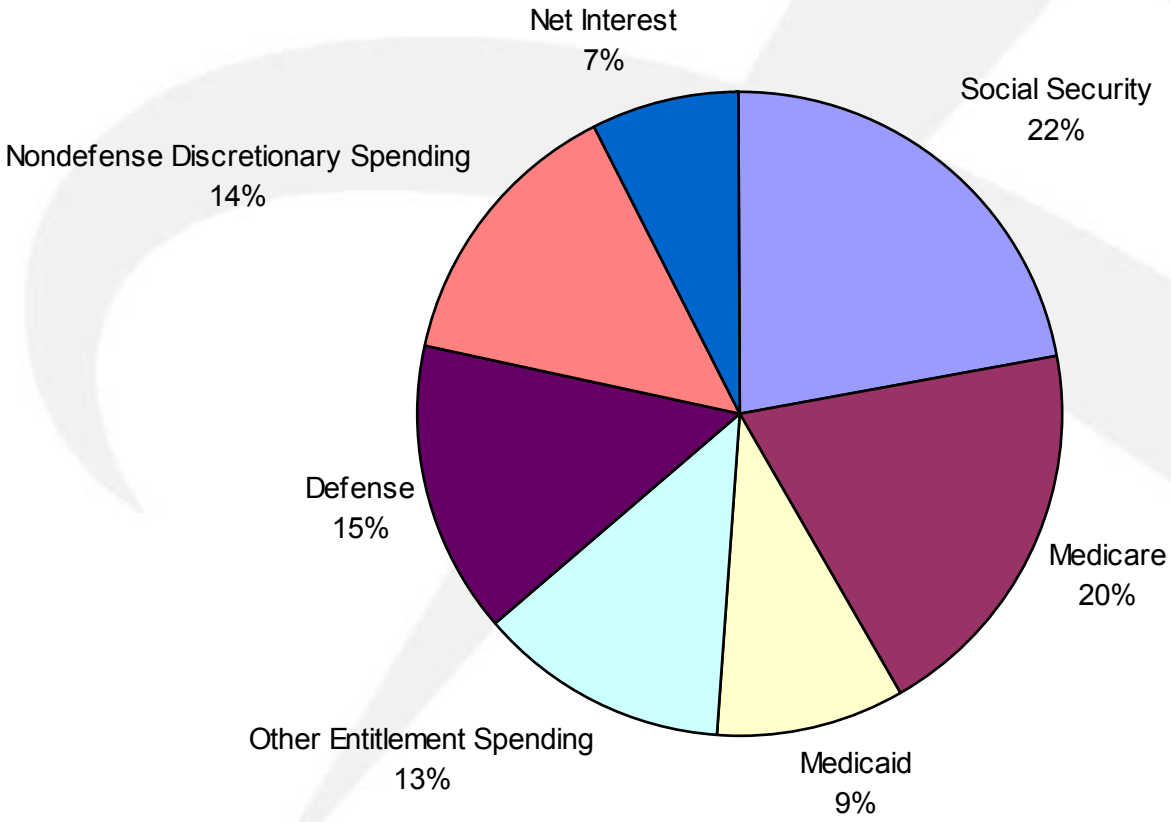
2015 Federal Budget: $3.83 trillion



Source: CBO Budget and Economic Outlook: Fiscal Years 2007-2016, January 26, 2006

Medicare in the Crosshairs

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- Deficit Reduction Act of 2006: $6.4 B in Medicare cuts, including $2.8 B in imaging cuts

- President's 2007 Budget: $36 B in Medicare cuts, including $1.4 B in diagnostic cuts and $6.5 B in oxygen cuts

- President Bush on Medicare: "The cost of these programs [Medicare and Social Security] are growing faster than the economy, …the rate of inflation, and the growth in population. It's unsustainable growth."

Public Wants Reform

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- 82% of voters say that health care is a high priority that will affect their vote in the midterm elections—ahead of every issue but Iraq (CNN/Gallup)

- 76% of voters say that health access and lower costs should be an "absolute priority" for Congress and the President, higher than any other domestic issue (WSJ/NBC News)

The Five Challenges and Opportunities Facing the Medical Device Industry

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- Value-Based Purchasing
- Medicare Payment Reform
- MDUFMA Reauthorization and FDA Reform
- Post-Market Regulation and Industry Reputation
- Foreign Markets

Value versus Cost: A Challenge and an Opportunity

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- **Opportunity**

"Value-Based Purchasing"

-Incentives to use underutilized technology: a vast new market

-Incentives for rapid adoption of value-enhancing new technology

- **Challenge**

"Efficiency" Reimbursement

-Poorly constructed "efficiency" reimbursement could result in incentives to use the cheapest treatment, not the best treatment

- **Gainsharing**

-Commoditization of devices

-Incentives not to adopt new technology

-Cheapest is best approach to in-hospital care

Undertreatment: A Quality Chasm and an Opportunity to Provide Value

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CONDITIONS	FAILURE TO RECEIVE RECOMMENDED CARE (%)
Average 30 conditions	**45%**
Senile Cataract	21.3%
Breast Cancer	24.3%
Low back pain	31.5%
Coronary artery disease	32%
Hypertension	35.3%
Congestive heart failure	36.1%
Cerebrovascular disease	40.9%
Chronic obstructive pulmonary disease	42%
Orthopedic conditions	42.8%
Colorectal cancer	46.1%
Diabetes mellitus	54.6%
Urinary tract infection	59.3%
Dyspepsia/peptic ulcer disease	67.3%
Atrial fibrillation	75.3%
Hip fracture	77.3%

Source: McGlynn et al "The Quality of Health Care Delivered to Adults in the United States" NEJM June 26, 2003

Provider Payment Reforms: Challenges

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- Medicare's payment machinery often can't keep pace with rapid innovation
- Proposed major reforms to DRG system – from "charge" to "cost" based, severity adjusted
  - Cost-reports are often 2-3 years old
- 2006 outpatient rates –failure to maintain payment floors
- ASC reform
- Single price regardless of site of service
- Pricing transparency

Provider Payment Reforms: Opportunities

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Charge compression

- Hospitals mark-up low cost items more than high cost items
- Medicare applies a crude across the board cost-to-charge ratio
- Systematically overpays low-cost items and underpays high cost items

Provider Payment Reforms: Opportunities Cont'd

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Diagnostic Lab Test Payment Reform

- Current system of "cross-walks" and "gap-fills" often underpays for new tests
- AdvaMed backed legislation would enhance stakeholder involvement/transparency:
  - -Create timely process to correct fee-schedule errors
  - -Establish new procedures/criteria for new test payment
  - -Long-term: Develop and test new payment system for molecular diagnostics
  - -Based on value/resource use in patient care management

Provider Payment Reforms: Opportunities Cont'd

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Remote Monitoring Technologies

- Rapid innovation in technologies used to improve management of chronic conditions at home: CHF, Cardio, Diabetes

- Doctors not generally reimbursed for remote interactions that are cheaper and more convenient

MDUFMA Reauthorization

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Key Reauthorization and Reform Topics

- Improved review performance
- Stable, predictable fees
- Third Party Review and Inspection
- Guidance document development
- Appropriate regulation of IVDs
- Critical path analysis

FDA Is Meeting Its MDUFMA Goals—But the Goals Are Not Very Ambitious

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	FY 2007 Goal	FY 2004 Performance
PMA & Panel Track Supplements: % Final Decision Within 320 Days	90%	91.10%
Expedited PMAs: % Final Decision Within 300 Days	90%	100%
510(k)s: % Final Decision Within 90 Days	80%	84%

NOTE: CDRH Goals Only
Source: FDA

MUDFMA Reauthorization: Improved Review Performance

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- Significantly shorten review times
- Establish 180 day goal for expedited PMAs
- Minimize clock stopping behaviors
- Incorporate more interaction in the review process
- Require justification for additional information requests, deficiency letters
- Establish timely appeals mechanisms for negative decisions

FDA Tougher Postmarket Controls

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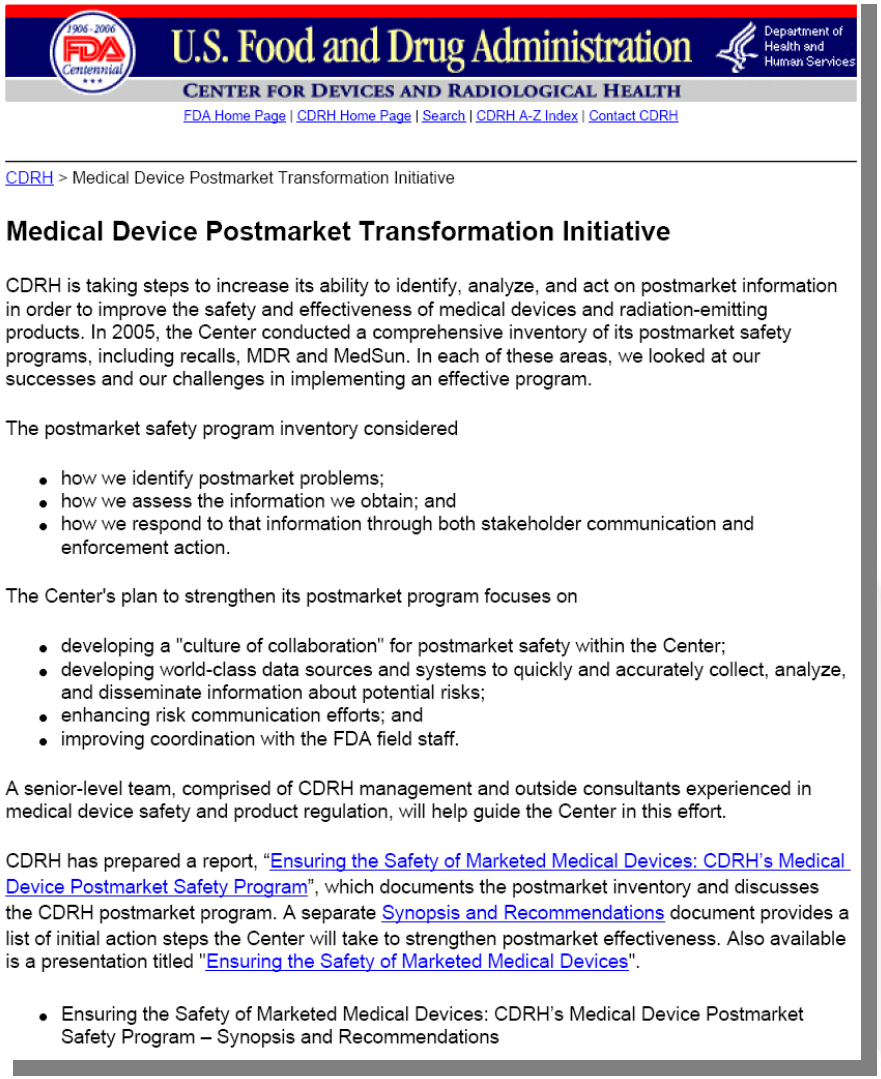
- FDA under pressure from Congress and the media
- CDRH has made post-market safety its top priority



U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | CDRH A-Z Index | Contact CDRH

CDRH > Medical Device Postmarket Transformation Initiative

Medical Device Postmarket Transformation Initiative

CDRH is taking steps to increase its ability to identify, analyze, and act on postmarket information in order to improve the safety and effectiveness of medical devices and radiation-emitting products. In 2005, the Center conducted a comprehensive inventory of its postmarket safety programs, including recalls, MDR and MedSun. In each of these areas, we looked at our successes and our challenges in implementing an effective program.

The postmarket safety program inventory considered

- how we identify postmarket problems;
- how we assess the information we obtain; and
- how we respond to that information through both stakeholder communication and enforcement action.

The Center's plan to strengthen its postmarket program focuses on

- developing a "culture of collaboration" for postmarket safety within the Center;
- developing world-class data sources and systems to quickly and accurately collect, analyze, and disseminate information about potential risks;
- enhancing risk communication efforts; and
- improving coordination with the FDA field staff.

A senior-level team, comprised of CDRH management and outside consultants experienced in medical device safety and product regulation, will help guide the Center in this effort.

CDRH has prepared a report, "Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program", which documents the postmarket inventory and discusses the CDRH postmarket program. A separate Synopsis and Recommendations document provides a list of initial action steps the Center will take to strengthen postmarket effectiveness. Also available is a presentation titled "Ensuring the Safety of Marketed Medical Devices".

- Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program – Synopsis and Recommendations

Key Industry Themes

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- Industry is committed public health partner
  - Two major conferences on post-market issues w/ FDA and HRS
  - Extensive industry/agency collaboration
- FDA has extensive device postmarket authorities
- Focus on effective and timely use of information, rather than collecting more information
- Communication to stakeholders must provide balanced risk/benefit picture

Postmarket Regulation Refinement: Key Issues

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- Recalls
- Unique Indentifiers
- Annual Reports
- Medical Device Reports (MDRs)
- Condition of Approval and Sec. 522 Studies

Legislative Outlook

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2006

- Reconciliation bill unlikely: no major Medicare cuts
- Doctor fee fix a vehicle for "value-based purchasing" and, potentially, for gainsharing expansion
- Hearings on postmarket issues, unethical promotion practices possible

2007

- Budget reconciliation, Medicare cuts likely
- Drug safety bill with device components possible
- MDUFMA reauthorization

International Markets

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U.S. Device Industry Now Receives more than 50% of Revenues from Foreign Sales

- **European Union: $63 billion**
  - Germany: $22.5
  - France: $10.7
  - Italy: $7.3
  - UK: $6.9
- **Japan: $26 billion**
- **China: $8.2 billion**
- **Brazil: $3.1 billion**
- **India: $1.3 billion**

Global Challenges =

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Global Opportunities:

- Rapid growth in overseas-especially emerging markets like China and India
- Japan's healthcare reform and aging population provide opening to help shape reimbursement and regulatory systems
- Nascent regulatory and reimbursement regimes in emerging markets provide opportunity to develop appropriate systems
- Europe's movement to DRGs enables us to leverage our considerable US experience

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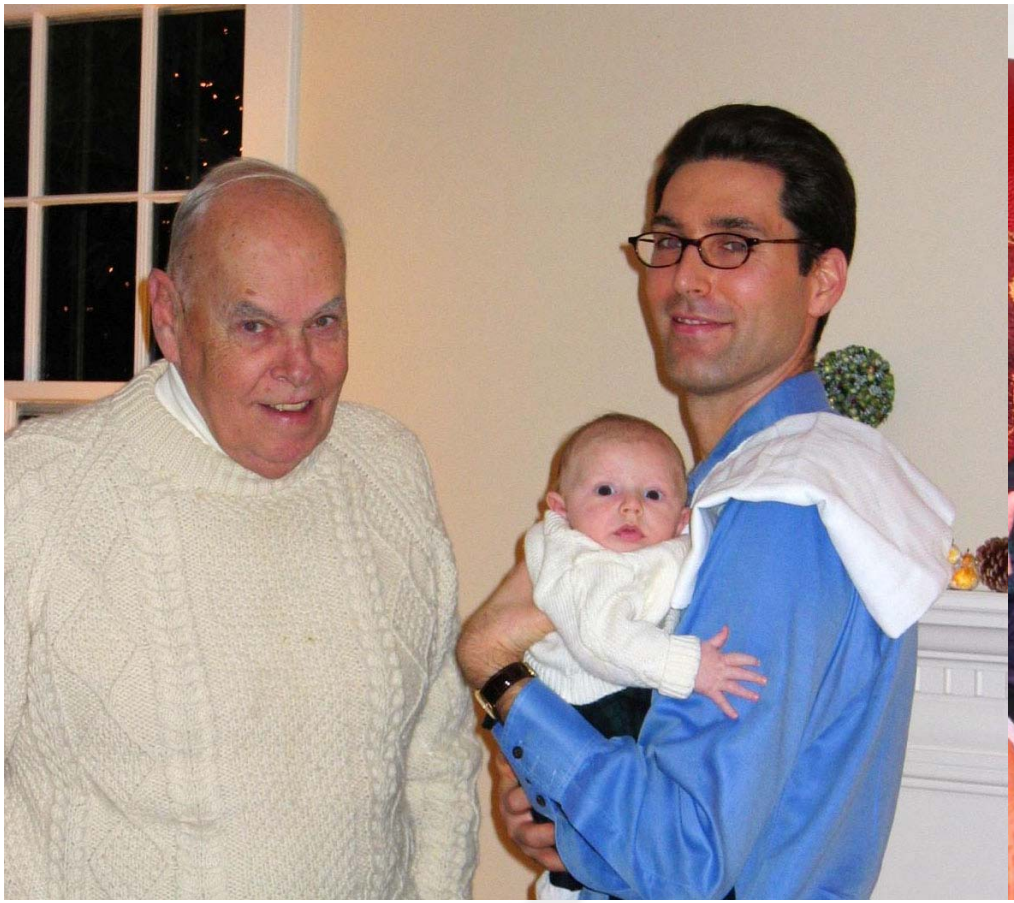

Bringing innovation to patient care worldwide

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