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USA Experiences & Challenges with Medical Devices

Third Supplementary Health Forum
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America's Health Insurance Plans (AHIP)

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Who We Are

America’s Health Insurance Plans (AHIP) is the national association whose members provide coverage and health-related services that improve and protect the health and financial security of consumers, families, businesses, communities and the nation.

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Our Mission

America's Health Insurance Plans and its members create and accelerate positive change and innovation across the health care system for consumers through market-based solutions and public-private partnerships that advance affordability, value, access and well-being.

2017 Priorities

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Health Care Reform
Serve as critical partner for policymakers as they debate and develop how to improve health care, Medicaid, and the individual insurance market

Medicare Advantage
Inform and educate policymakers and the public on the value of MA and advocate for solutions that defend and strengthen the program

Medicaid
Lead industry-wide political, policy, and grassroots advocacy in Washington and the states on the benefits and importance of Medicaid managed care

High-Cost Drugs
Lead the fight to hold pharmaceutical companies accountable and offer market-based solutions to lower drug prices

Consumer and Employer Issues
Engage consumers and employers to improve care and coverage through solutions that lower costs and improve quality

Product Policy
Advocate solutions to improve comprehensive coverage offerings – from disability income, LTC, and Medigap to supplemental, dental and vision

AHIP's Vision

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We will shape and drive market-based solutions and public policy strategies to improve health, affordability and financial security by:

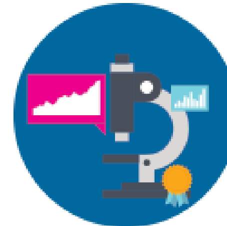
Promoting consumer choice and market competition

Simplifying the health care experience for individuals and families

Supporting constructive partnerships with all levels of government

Partnering with health care providers on the journey from volume to value

Addressing the burden of chronic disease and social factors that impact health

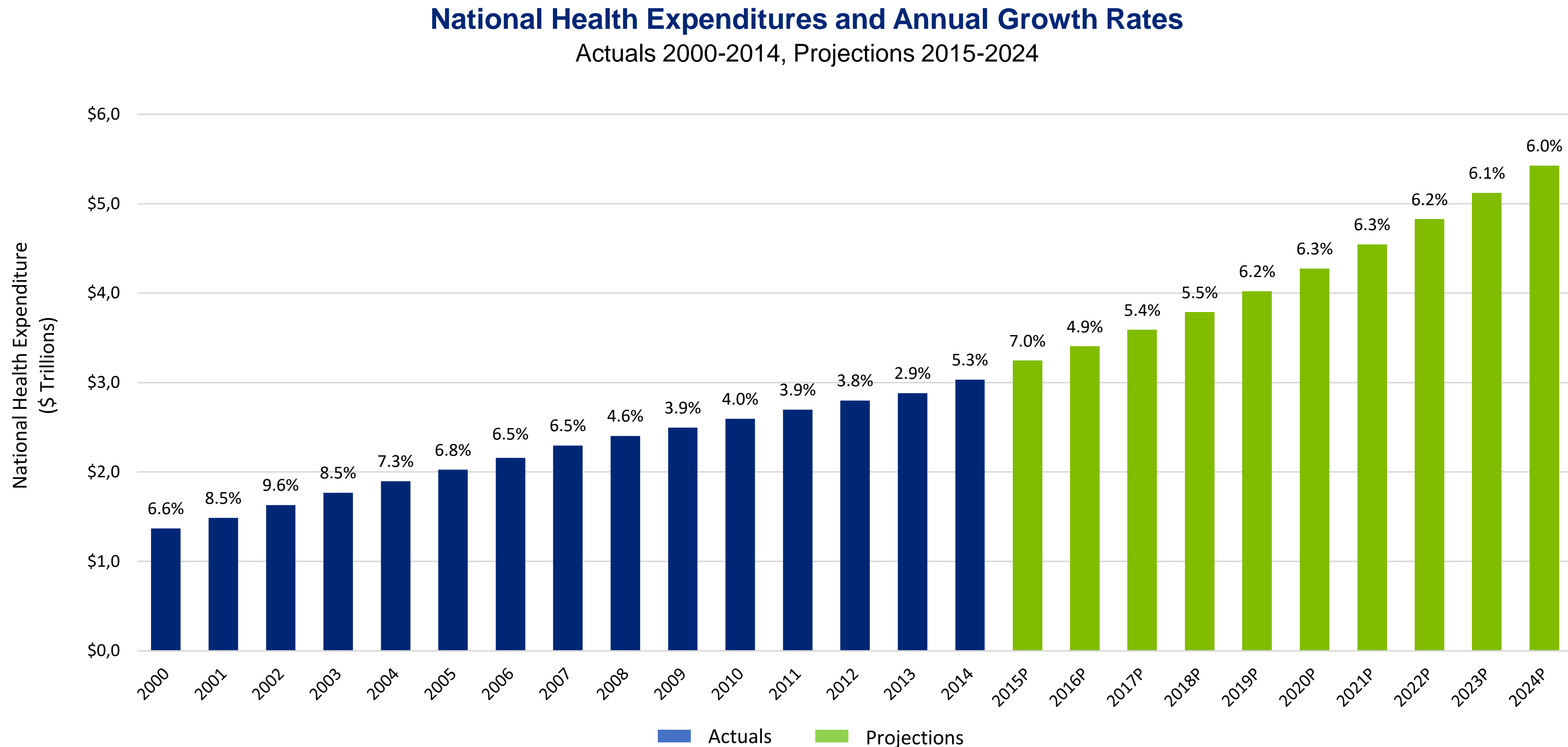


Pursuing the promise of clinical innovations while ensuring value

Harnessing data and technology to drive quality, efficiency and consumer satisfaction

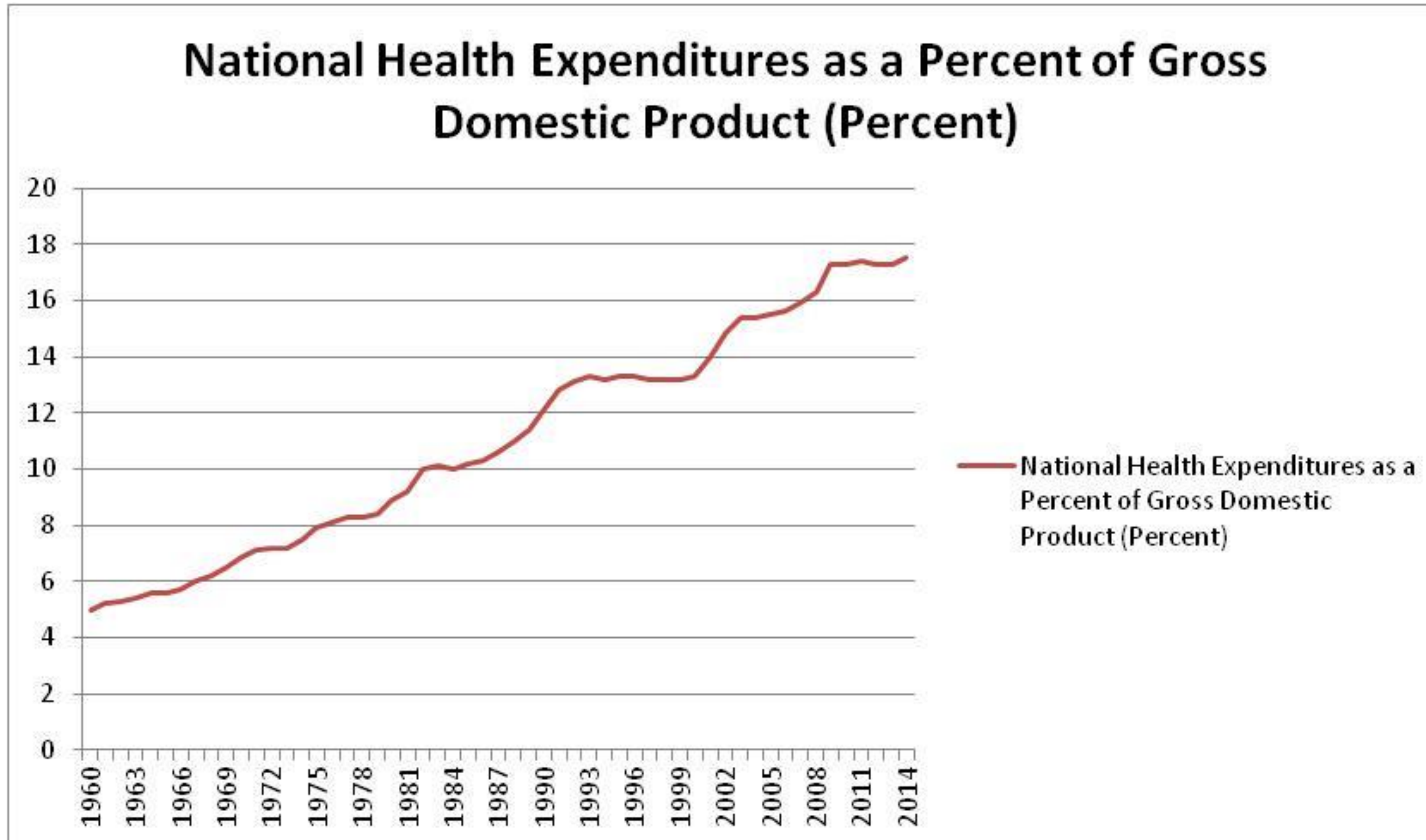
NATIONAL HEALTH EXPENDITURES

U.S. healthcare spending now exceeds $3 trillion per year, with growth rates projected to accelerate through 2024



Source: Centers for Medicare and Medicaid Services (CMS) “NHE Tables” and “Historical and Projections 1960-2024”

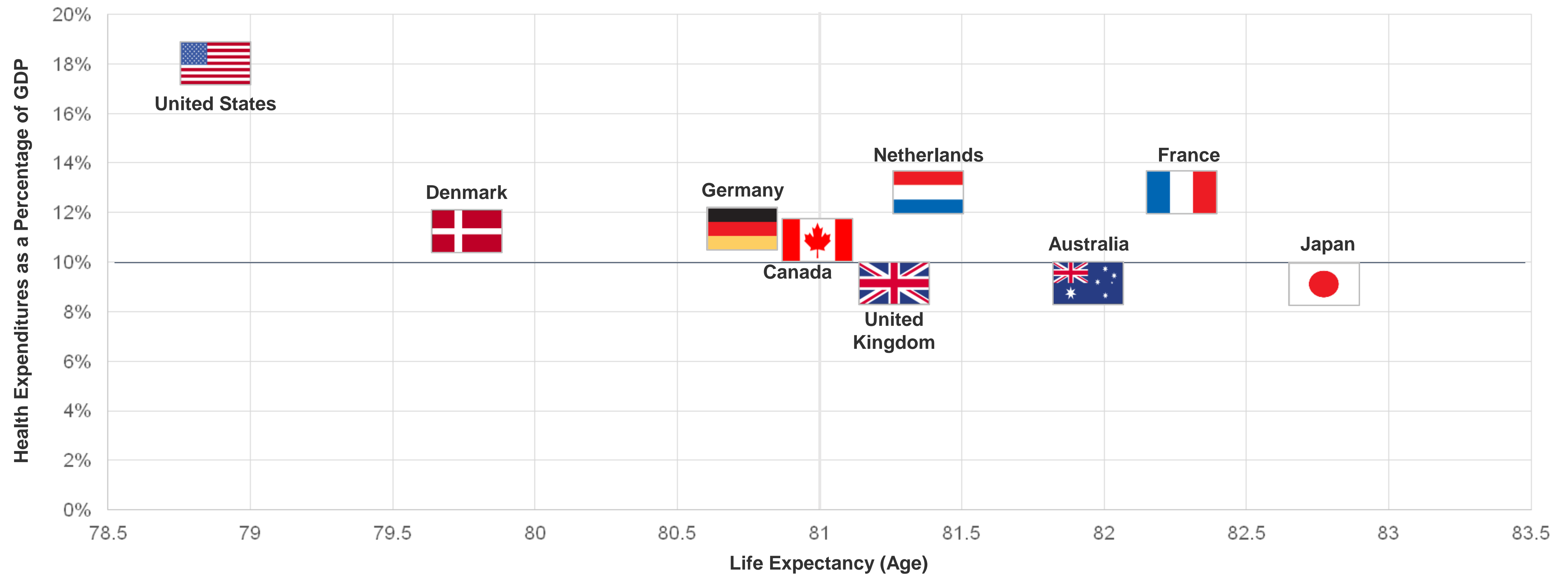
Healthcare Spending in the U.S.



Source: National Health Expenditures: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical.html

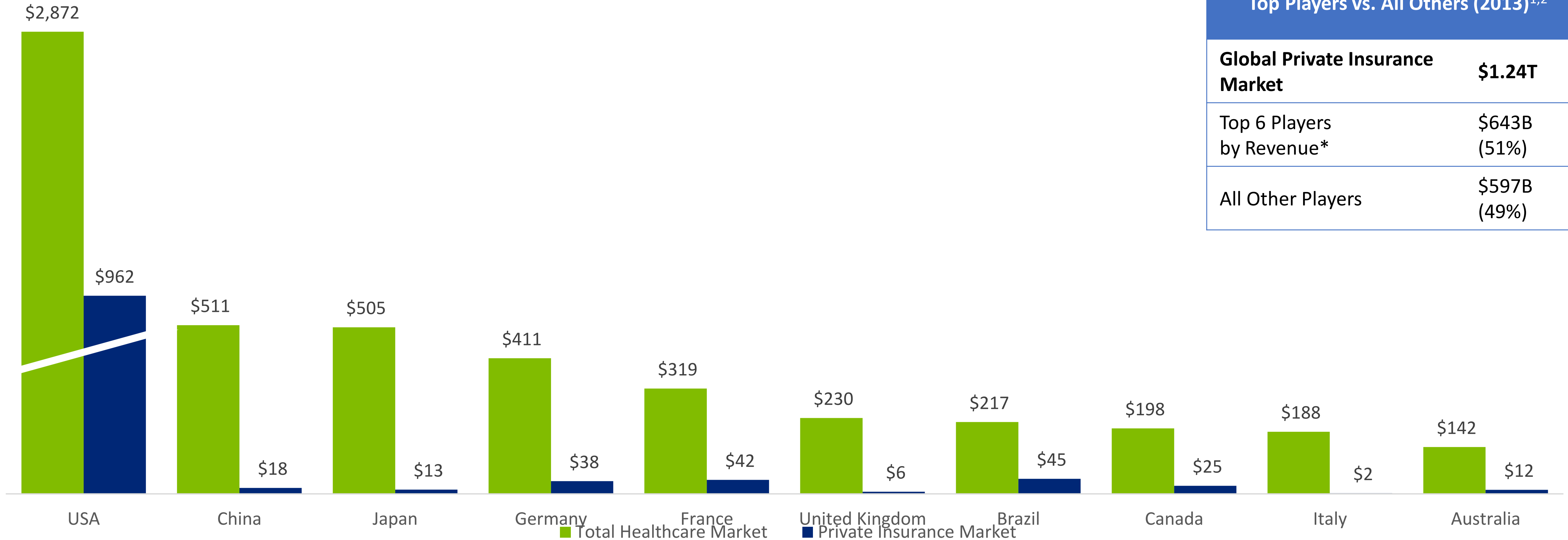
COMPARATIVE VIEW

The U.S. continues to be an outlier in healthcare spending as a percent of GDP, without commensurate returns on key measures of health system performance



Source: Organisation for Economic Co-operation and Development (OECD) iLibrary Health Statistics (2014)

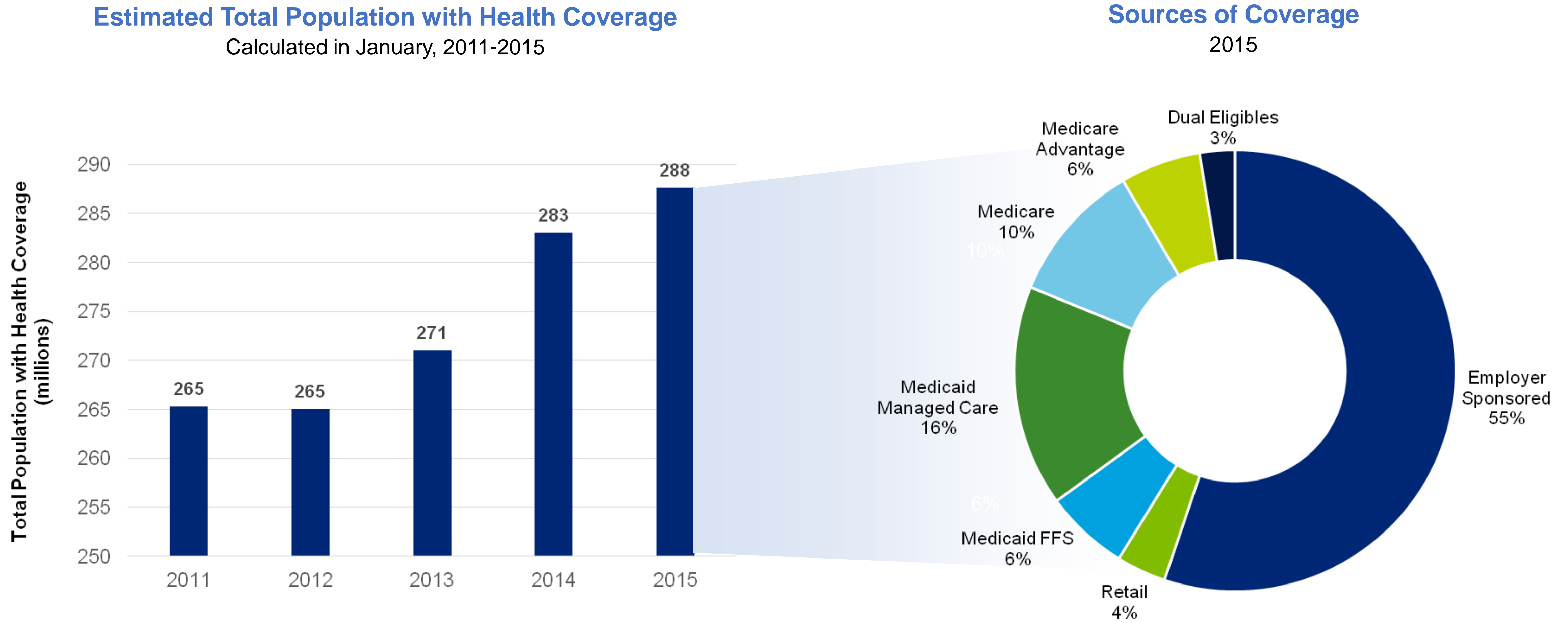
The U.S. is by far the largest commercial health insurance market in the world, but other markets are becoming more attractive as their financing systems and marketplaces evolve



Market Distribution – Top Players vs. All Others (2013)[1,2]	
Global Private Insurance Market	**$1.24T**
Top 6 Players by Revenue*	$643B (51%)
All Other Players	$597B (49%)

Sources: 1. EIU Data Services (2013) 2. Daedal Research Global Health Insurance Market: Trends and Opportunities
*Note: Top player revenue may include some life insurance revenue

288 million Americans had health coverage in 2015, a 6% gain over 2013, with employer-sponsored heath benefits still the largest source of coverage



Source: Health Leaders InterStudy, with U.S. Census "Coverage Rates by Type of Insurance: 2013 and 2014"

Medical Device Industry

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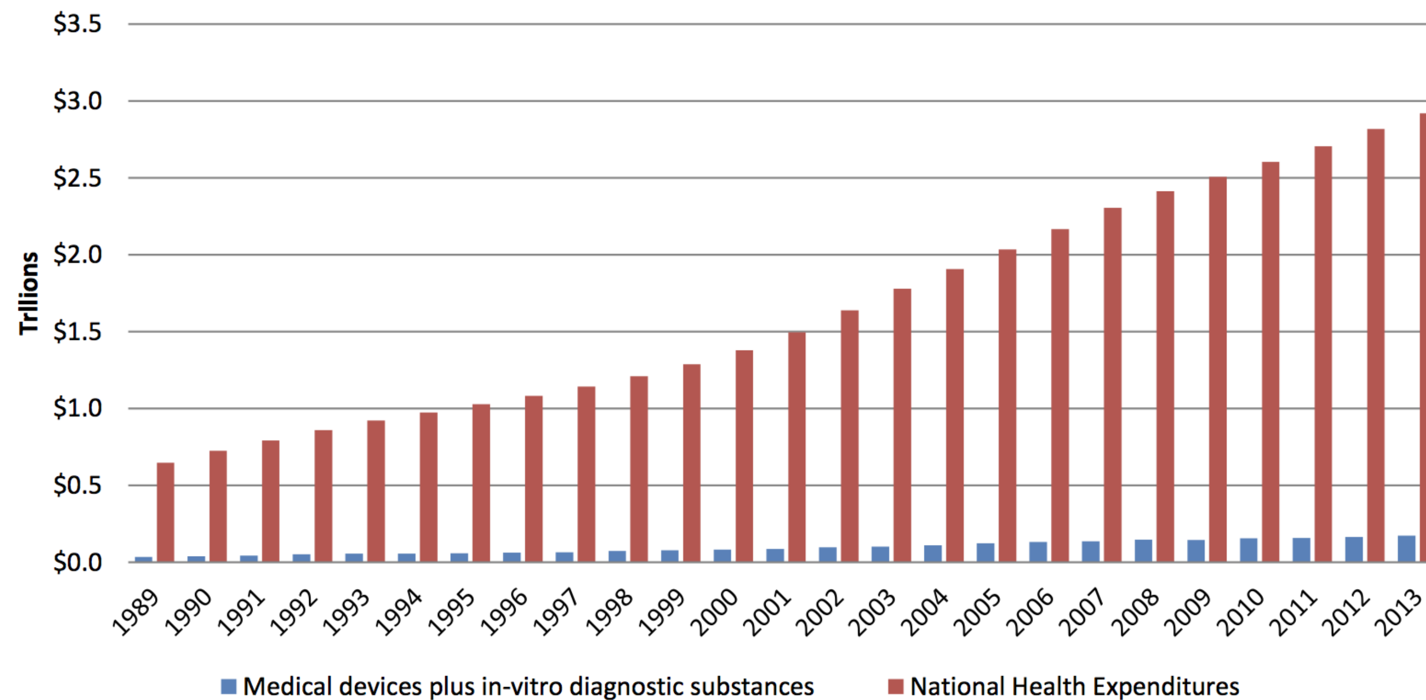
- **The U.S. is the largest medical device market in the world – representing 40% of the global device market in 2015.***
- **In 2013 medical device spending totaled $171.8 billion or 5.9% of total national health expenditures.****
- **The share of NHEs has risen slightly (from 5.3% in 1989 to 5.9% in 2013).****

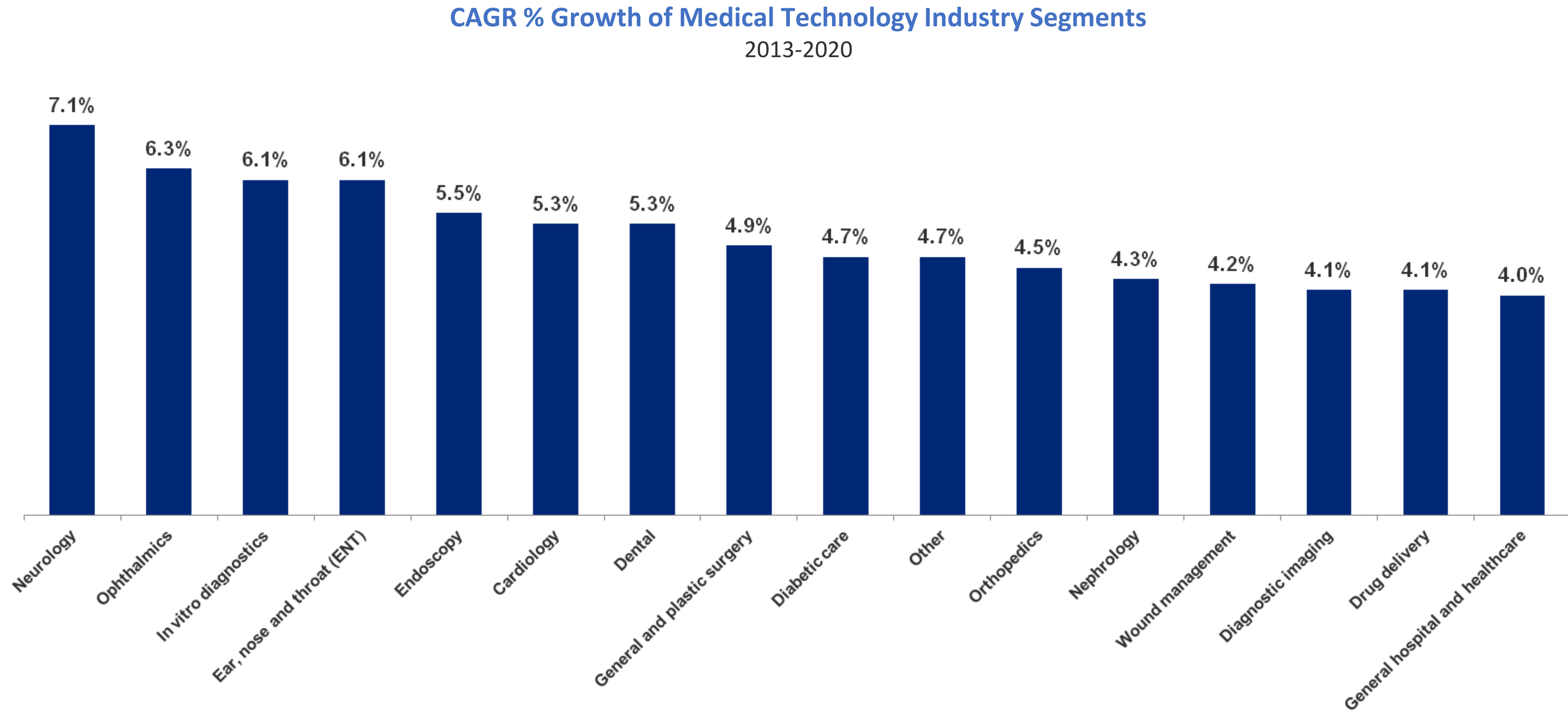
* Select USA.gov. Medical Technology Industry Spotlight
**AdvaMed, June 2015

Medical Device Spending vs. NHE



AdvaMed, June 2015

The Medical Technology (Medtech) industry is projected to grow at a CAGR of 5.0% between 2013 and 2020 on account of increasing adaptability of technologies for medical devices



Source: Evaluate Medtech, World Preview 2014, Outlook to 2020

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TABLE 7–1

The 10 largest medical device companies, 2015

Rank	Company	Country	Global medical device revenue (in billions)
1	Medtronic	United States	$27.7
2	Johnson & Johnson	United States	27.5
3	GE Healthcare	United States	18.3
4	Baxter International	United States	16.7
5	Siemens Healthcare	Germany	15.8
6	Becton Dickinson	United States	12.3
7	Philips Healthcare	Netherlands	11.2
8	Cardinal Health	United States	11.0
9	Abbott Labs	United States	10.1
10	Stryker	United States	9.7

Note: Some companies shown in this table, such as Johnson & Johnson, generate substantial revenues in industries other than medical devices; the figures for these companies are for their medical device divisions only. Figures for Medtronic and Becton Dickinson reflect their acquisitions of Covidien and CareFusion, respectively. Since its acquisition of Covidien, Medtronic has been headquartered in Ireland for tax purposes.

Source: Medical Product Outsourcing 2015; MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2017

FDA oversight: safety and effectiveness

- Premarket Requirements
  - Risk-based approval/oversight process
    - Low risk devices (Class I) – no FDA review before marketing; registration only
    - Moderate risk devices (Class II) – Premarket notification before marketing (510K)
      - Demonstration that "substantially equivalent" to device already on market
    - High risk devices (Class III) – Premarket approval (PMA) before marketing
      - Clinical data providing reasonable assurance of safety and effectiveness

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TABLE 7–2

FDA classification and review of medical devices

Category	Level of risk to patient	Examples	Type of review before device can be marketed
Class I	Low	• Elastic bandages • Examination gloves • Handheld surgical instruments	Most devices required only to register; a small share must submit a 510(k) notification.
Class II	Moderate	• Powered wheelchairs • Infusion pumps • Surgical drapes	Most devices must submit a 510(k) notification; a small share of devices are required only to register.
Class III	High	• Heart valves • Silicone breast implants • Implanted cerebella stimulators	Devices must submit a PMA application; in the past, a significant number of devices were able to submit a 510(k) notification.

Note: FDA (Food and Drug Administration), PMA (premarket approval).

Source: Johnson 2016.
MedPAC Report to the Congress: Medicare and the HealthCare Delivery System June 2017

FDA oversight: safety and effectiveness

- **Postmarket Surveillance**
  - **Adverse Event Reporting**
    - Hospitals and facilities required to report adverse events
  - **Postmarket Surveillance Studies**
    - FDA can require studies as part of monitoring
  - **Unique Device Identifiers**
    - Phased-in adoption to be completed by 2020

Main Drivers for Change

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- Change delivery model from silos to care continuum
- Payment based on value (quality, safety and cost) not volume
- Current health care spending growth not sustainable
- Lackluster quality; improvement slow
- Consumer “skin in the game”
- Provider openness / readiness

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Private Market Trends in Promoting Value

- **Use of medical management review**
- **Demonstrating value -- positive results in quality outcomes and cost savings**
- **Commitment and growth of delivery and payment reform based on value**

Medical Management: Promote Access to Safe, Appropriate and Cost-Effective Care

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- **Significant gaps in evidence-based practice and actual care delivered**
- **Wide variation in provider performance and little/no correlation between spending and health care quality**
- **Safety concerns persist; especially for new therapies without a track record**
- **Therapies prone to overuse**
- **Treatments only effective for specific populations/conditions, often used more generally**
- **Significant amount of “low-value” care – services with little/no clinical benefit; risk of harm outweighs potential benefit**

Medical Management

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improve care, reduce costs

- Adoption of medical management tools, such as medical necessity reviews, formulary and provider tiered network designs, to improve care and reduce costs for patients.

consistent with evidence-based practices

- Medical management tools help ensure care is consistent with evidence-based practices.

- **The value of medical management has been recognized in numerous federal and state government-sponsored programs like Medicare.**

- It is critically important that policy makers recognize the importance of these tools and their effectiveness in addressing long-standing challenges to safe and affordable evidence-based health care.

Demonstrating Value

- How is value defined?

- Value = $\frac{\text{Quality + Delivery + Experience}}{\textbf{Cost}}$

Weaknesses of Fee for Service Payment

Excessive use of low-value services

Insufficient incentives to improve quality of care

Poor coordination of care

Quality and Cost Considerations

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- Clinical Quality:
  - Are results better that local market alternatives, improve annually, approach national best practices?
  - Have improvements in quality and health outcomes been achieved?
- Cost:
  - Is total cost of care producing significant savings; are trend rates likely to preserve or expand savings?
  - Do risk results and contract terms show sustained positive performance?
  - How are PMPM costs and utilization rates changing (such as price, patterns of care, site of care, referrals, provider network)?
- Consumer experience:
  - Has consumer experience improved?

CMS framework that categorizes payments to providers

	Category 1: Fee for Service – No Link to Value	Category 2: Fee for Service – Link to Quality	Category 3: Alternative Payment Models Built on Fee-for-Service Architecture	Category 4: Population-Based Payment
Description	▪ Payments are based on volume of services and not linked to quality or efficiency	▪ At least a portion of payments vary based on the quality or efficiency of health care delivery	▪ Some payment is linked to the effective management of a population or an episode of care ▪ Payments still triggered by delivery of services, but opportunities for shared savings or 2-sided risk	▪ Payment is not directly triggered by service delivery so volume is not linked to payment ▪ Clinicians and organizations are paid and responsible for the care of a beneficiary for a long period (e.g., ≥1 year)
Medicare Fee-for-Service examples	▪ Limited in Medicare fee-for-service ▪ Majority of Medicare payments now are linked to quality	▪ Hospital value-based purchasing ▪ Physician Value Modifier ▪ Readmissions / Hospital Acquired Condition Reduction Program	▪ Accountable Care Organizations ▪ Medical homes ▪ Bundled payments ▪ Comprehensive Primary Care initiative ▪ Comprehensive ESRD ▪ Medicare-Medicaid Financial Alignment Initiative Fee-For-Service Model	▪ Eligible Pioneer Accountable Care Organizations in years 3-5 ▪ Maryland hospitals

Source: Rajkumar R, Conway PH, Tavenner M. CMS – engaging multiple payers in payment reform. JAMA 2014; 311: 1967-8.

Growth of ACOs

Source: Authors' analysis of Leavitt Partners ACO Database

Source: Muhlestein D, Sauders R, and McClellan M. *Health Affairs*. Growth of ACOs and Alternative Payment Models in 2017, June 28, 2017

Payment Reform Is Based on Shared Goals

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- Shared commitment to move away from fee-for-service to shared-risk
- Increased focus on patient outcomes, experience and coordination of care
- Increased focus on reducing the need for, and therefore the impact of, high-cost services
- Value-based approaches are increasingly customized to the provider

Collaboration and Analytics Are Key to Success

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Operational Factors

- Leadership commitment
- Long-term relationship
- Appropriate patient panel size
- Clinical integration/network adequacy
- Clinician acceptance of new payment arrangements

Technical Factors

- Data (e.g., claims history, claims extract, hospital/ER census)
- Analytic reports (predictive, early identification of patients at risk)
- Care management/Care transition
- Consultative support

Source: https://revcycleintelligence.com/news/how-alternative-payment-models-decrease-cancer-care-costs
Source: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-25.html

Bundled Payments/Episodes

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- Combines care delivery, financing and engagement for entire care cycle
- Features:
  - Defined care pathways
  - Dedicated care coordinators and decision support
  - Clear pricing linked to risk
  - Incentives for appropriate use, appropriate site of care and outcomes
- Specialty bundles:
  - Comprehensive care for joint replacement, Bundled Payment for Care Improvement, ACE initiative (orthopedic and cardiac conditions), heart bypass (CABG), and oncology and ESRD bundles

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TABLE 7–3

Prices paid by hospitals for common orthopedic and cardiac devices varied substantially, 2008

IMD	Minimum	25th percentile	Median	75th percentile	Maximum
Artificial knee implants	$3,380	$4,463	$4,925	$6,549	$10,944
Artificial hip implants	$3,828	$5,425	$6,238	$7,262	$10,640
Lumbar spine implants	$3,397	$5,425	$6,238	$7,262	$29,311
Cardiac pacemakers	$4,925	$5,709	$6,197	$7,024	$10,790
Cardiac defibrillators	$19,150	$22,870	$25,066	$28,599	$34,961

Note: IMD (implantable medical device). Prices are for 2008 and were taken from a study that collected data from 61 hospitals in 8 states. Figures are the actual prices paid by the hospital, as opposed to the manufacturer's list price.

Source: Robinson 2015; MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2017

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New Models Deliver Better Outcomes, Satisfaction, Costs

Patient-Centered Medical Home	Accountable Care Models	Episode/Bundled Payment
• Emergency department use reduced 48-68% • Hospital admissions reduced 34-51% • Average hospital length of stay reduced 21-44% • End-of-life care improved as length of time in hospice increased 34%	• Pioneer ACOs generated more than $37M in savings in 2015 • Pioneer ACOs increased mean quality score to 92.26% in 2015; average quality score increased 21% since 2011 • Of the 12 Pioneer ACOs, 9 had overall quality scores above 90% in 2015	• Inpatient days decreased by 17% • Emergency department visits decreased by 30% • Oncology models flatten out Rx spending after a 15-18% increase per year

Source: https://revcycleintelligence.com/news/how-alternative-payment-models-decrease-cancer-care-costs
Source: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-25.html

Estimated Impact of BPCI

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Orthopedic surgery: inpatient hospitalization and 90 days post-discharge (hip and knee)

- cost declined 3% in the first year; 4.2% decline in 21 month
- achieved by less use of institutional post-acute care and inpatient rehab facilities
- no impact on quality of care

Cardiovascular surgery: inpatient hospitalization and 90 days post-discharge

- cost declined 1.9% in first year; exponentially increased in later months

Fraud and Abuse

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- Federal False Claims Act
  - Protects the federal government from being overcharge or sold substandard goods or services (submission of a false or fraudulent claim)
- Anti-Kickback Statute
  - Crime to knowingly, willfully offer, pay, solicit or receive remuneration to induce or reward referrals of items/services reimbursed by the federal government
- Physician Self-Referral law
  - Prohibits referral for certain designated health services payable for Medicare/Medicaid to an entity which the physician has ownership/investment interest
- Physician Payments Sunshine Act & Open Payments Program
  - Increases transparency around financial relationships between physicians/teaching hospitals/drug & device manufacturers via the Open Payments Program, which requires drug/device manufacturers to publicly report payments to physicians & teaching hospitals

What can you do to help our System achieve the goals of Better Care, Smarter Spending, and Healthier People?

- *Eliminate* patient harm
- *Focus* on better care, smarter spending, and better health for the patient population you serve
- *Engage* in accountable care and other alternative contracts that move away from fee-for-service to model based on achieving better outcomes at lower cost
- *Invest* in the quality infrastructure necessary to improve
- *Focus* on data and performance transparency
- Health plans are major ***drivers*** of positive change
- *Test* new innovations and scale successes rapidly
- *Relentlessly pursue* improved health outcomes

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