Healthcare's New Frontier

Policy Shifts & Industry Impact of the New Administration

February 2025

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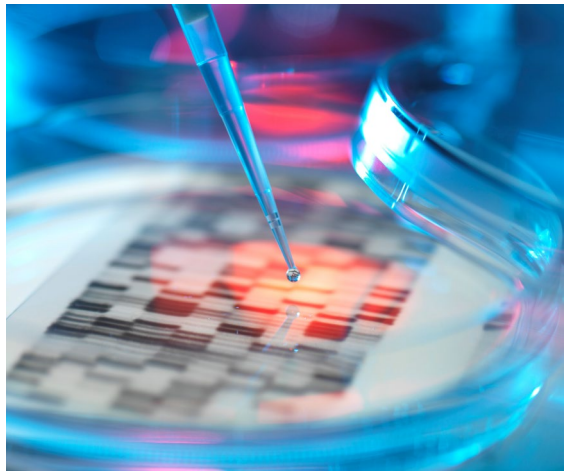

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The New Commercial Calculus

01
The American Healthcare Paradox

The US spends $4.9T on healthcare, primarily on hospitals, physicians and drugs, with growth outpacing GDP

Figure 1: Healthcare spend has outpaced GDP growth since 2000, now making up $4.9T

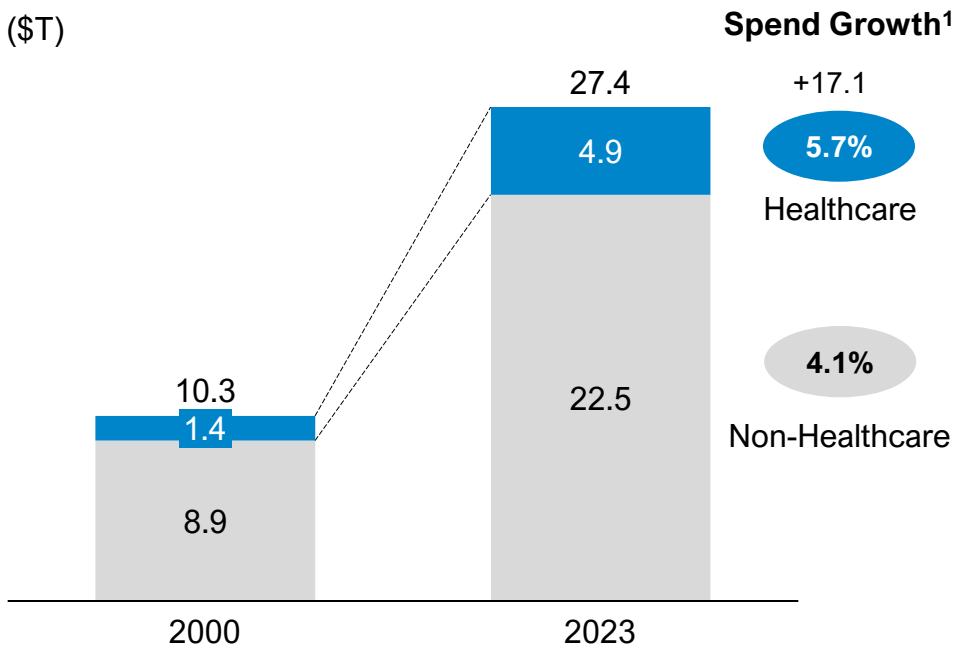
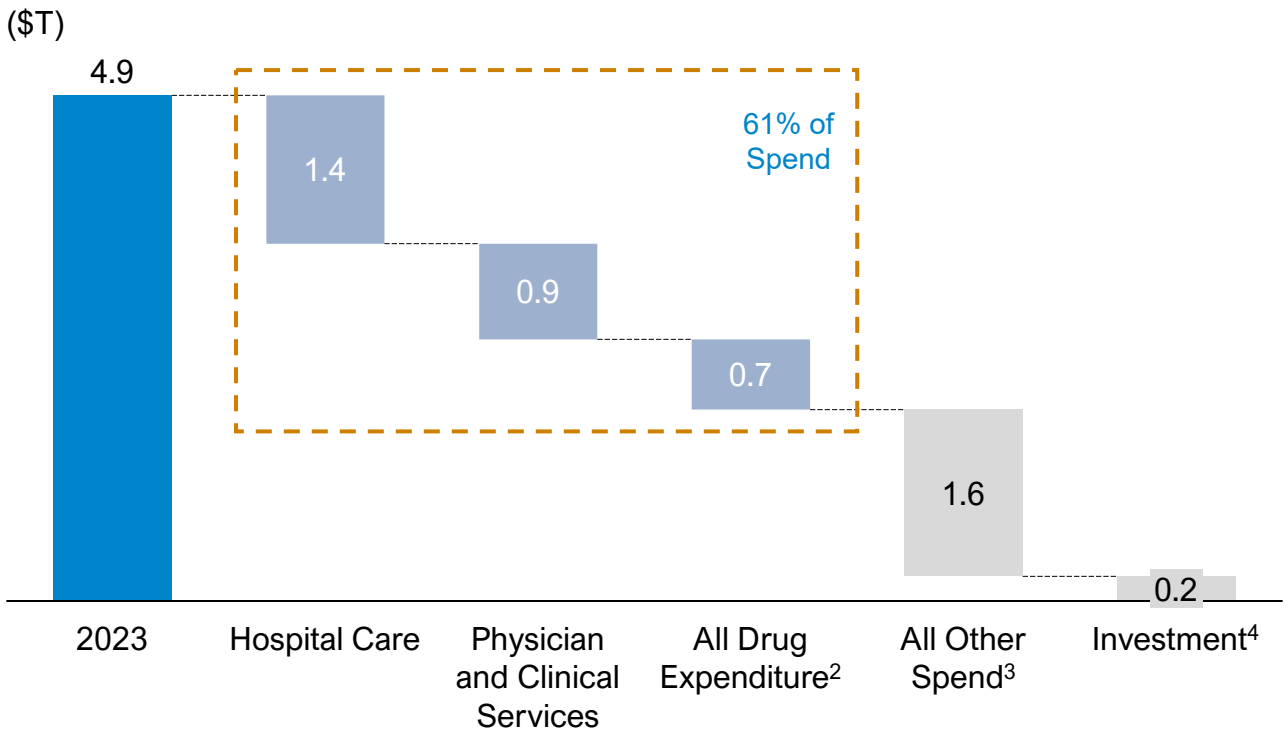


Figure 2: Hospital care, physician and clinical services, and drugs are the three largest spend categories and make up 61% of healthcare spend



Source: KFF, CMS Health Expenditure 2023, AJHP, Alterum, A&M analysis
1. Spend growth is nominal, non-inflation adjusted
All drug expenditure: Includes all specialty and non-specialty drugs, administered across all channels including hospitals and physician clinics, based on manufacturer data
2. All other spend includes ($T): Dental Services (0.17), Home Health (0.15), Nursing Care (0.21), Durable Medical Equipment (0.07), Non-Durable Equipment (0.12), Other Health, Residential, and Personal Care (0.27T), other professional services (0.16T)
3. Investment includes ($T): government research (0.07), Structures and Equipment (0.16)

As spend rises, Americans are increasingly relying on the government to foot the bill

Figure 3: Patient enrollment in government Medicare and Medicaid programs has skyrocketed since 2000

Change in Enrollment by Insurance Type, 2000 - 2023
(Millions of Lives)

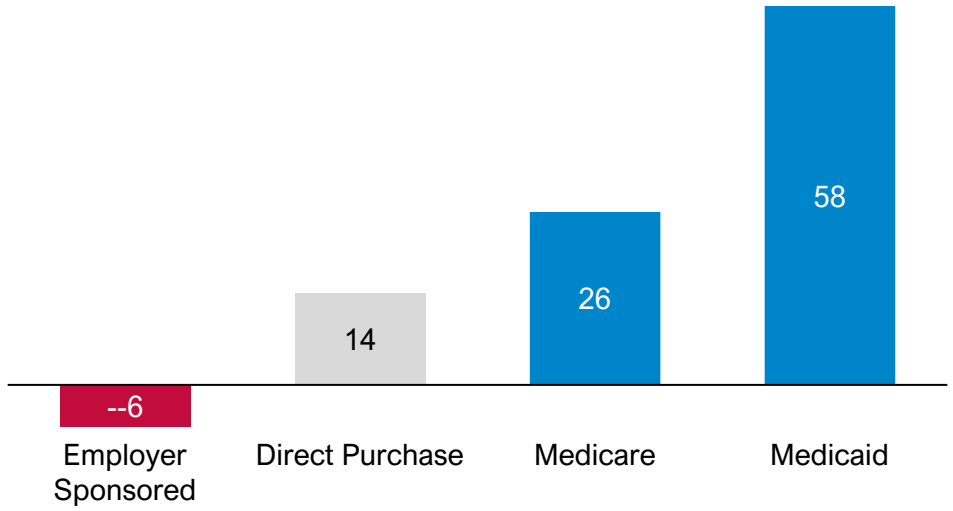
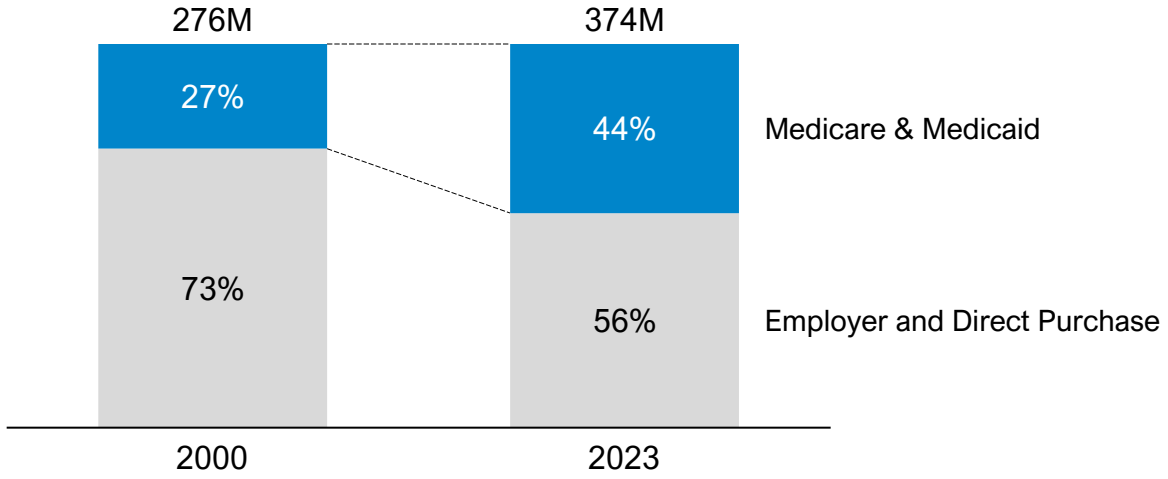


Figure 4: 44% of Americans now rely on the government for health insurance

Enrollment by Insurance Type, 2000 - 2023
(% of US Population)



Source: CMS Health Expenditure 2023, A&M Analysis

While the US leads in pharmaceutical R&D, innovation is increasingly concentrated in narrower indications

Figure 5: The US leads the world in innovative drug discovery, launching over half of the world's novel therapies

FDA New Molecular Entity (NME) Approvals
by Country of Origin, 2024

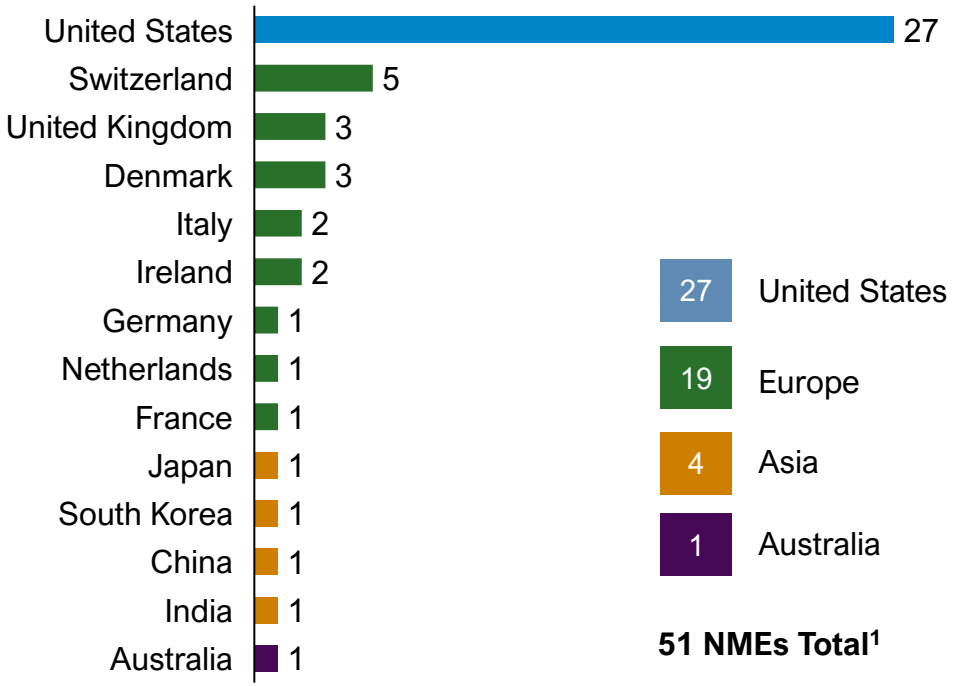
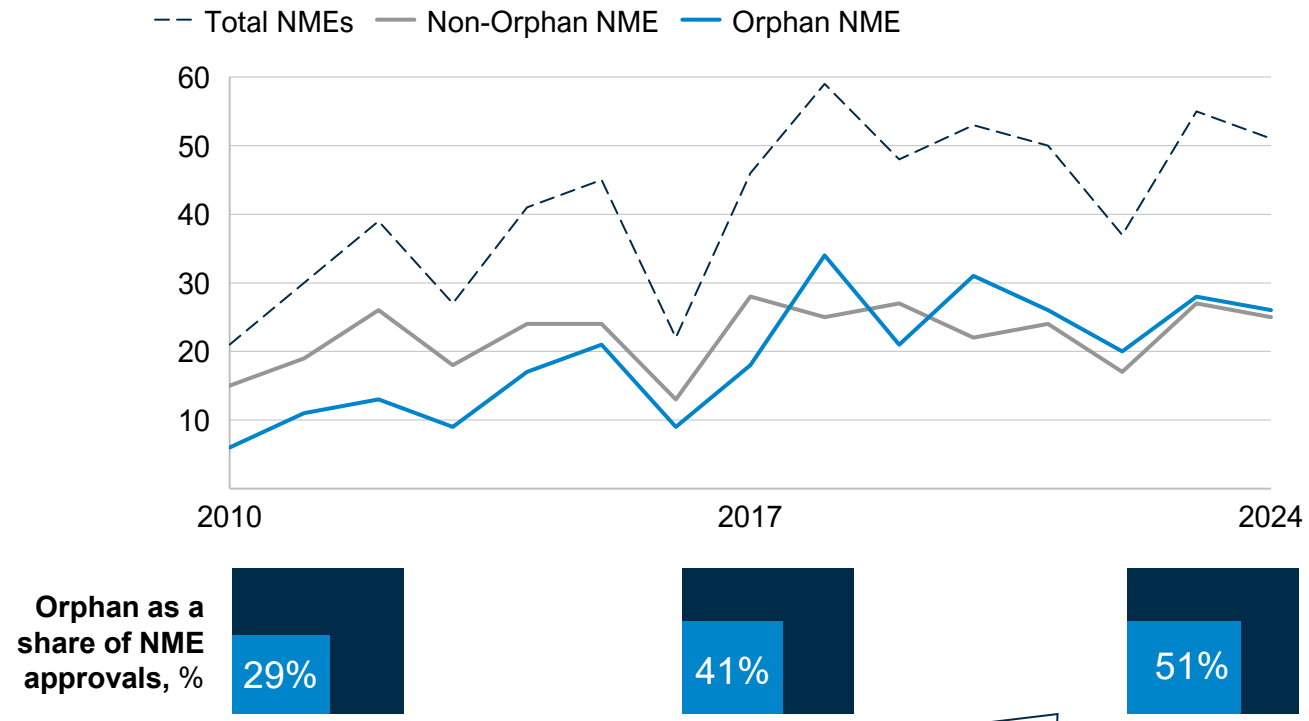


Figure 6: FDA has been approving a larger number of drugs, for increasingly narrower indications

FDA New Molecular Entity (NME) Approvals
Orphan vs. non-Orphan, 2010 - 2024



Source: FDA Novel NMEs 2024, FDA Orphan approvals 2010 - 2024, A&M Analysis
Note: Novel drugs defined as New Molecular Entities (NME)
Orphan NMEs defined as novel drugs approved to treat rare conditions or diseases, with <200,000 patient prevalence
22 of 26 orphan NMEs (85%) in 2024 were for genetic or oncology diseases

And despite outspending and out-innovating peers, Americans generally experience poorer health outcomes

Figure 7: US spends more on healthcare, performs worse across nearly all metrics vs. peers

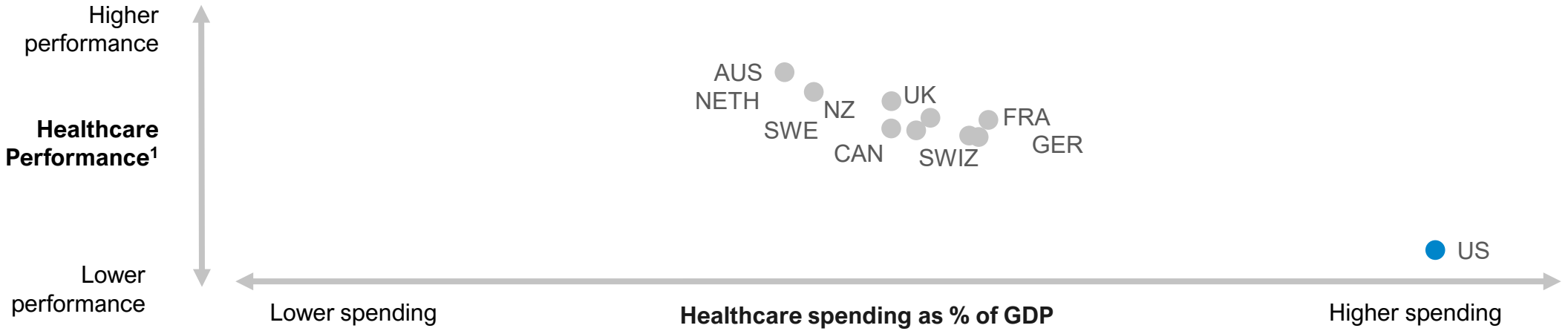


Figure 8: Americans are most likely to live with multiple chronic diseases[2]

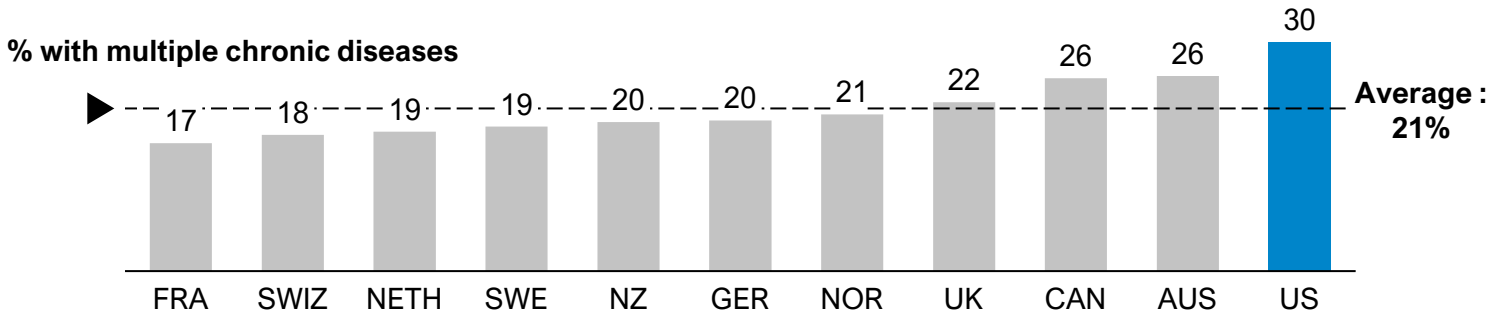
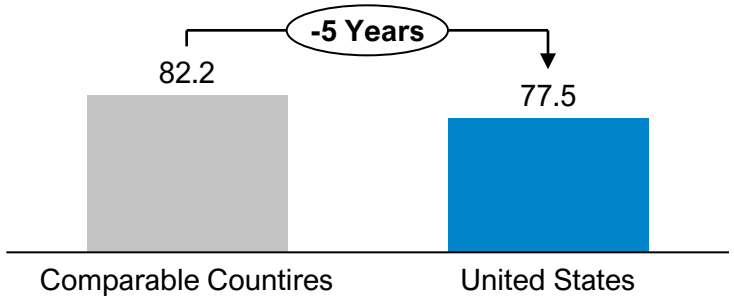


Figure 9: Americans die younger than our peers



Source: OECD, Commonwealth Fund 2023, KFF Health Tracker, Commonwealth Fund 2024, A&M analysis

1. Performance is measured based on access to care, care process, administrative efficiency, equity, and health outcomes rankings. See Commonwealth Survey for more details.
2. Chronic diseases include the following: asthma, cancer, depression, anxiety or other mental health, diabetes, heart disease, hypertension / high blood pressure

These trends are driving the American healthcare system to a tipping point, re-shaping the commercial landscape for stakeholders

Trend	Pharma impact	Payer impact	Provider impact	Key Drivers
Government Coverage Expansion	↑ Outcomes-based contracting	↓ Commercial margins	↑ Risk-sharing demands	Increased scrutiny of costs per enrollee from CMS may accelerate value-based contracts (VBCs) through Medicare advantage and other ACOs
Chronic Disease Epidemic	↑ Combo therapies	↑ Prior authorization	↑ Specialist care	Over half the population lives with chronic disease, attributing to 86% of healthcare costs. Innovative treatments (e.g., GLP-1s) will be managed tightly to control costs
Innovation Concentration	↑ Orphan designations	↓ Cost predictability	↓ Routine procedures	Greater R&D funding towards high-cost rare genetic diseases creates cost uncertainty and reduced need for certain high-volume standardized procedures

The American Healthcare Paradox

Despite significant healthcare spending and groundbreaking R&D, health outcomes remain stagnant, proving innovation alone won't solve the industry's challenges

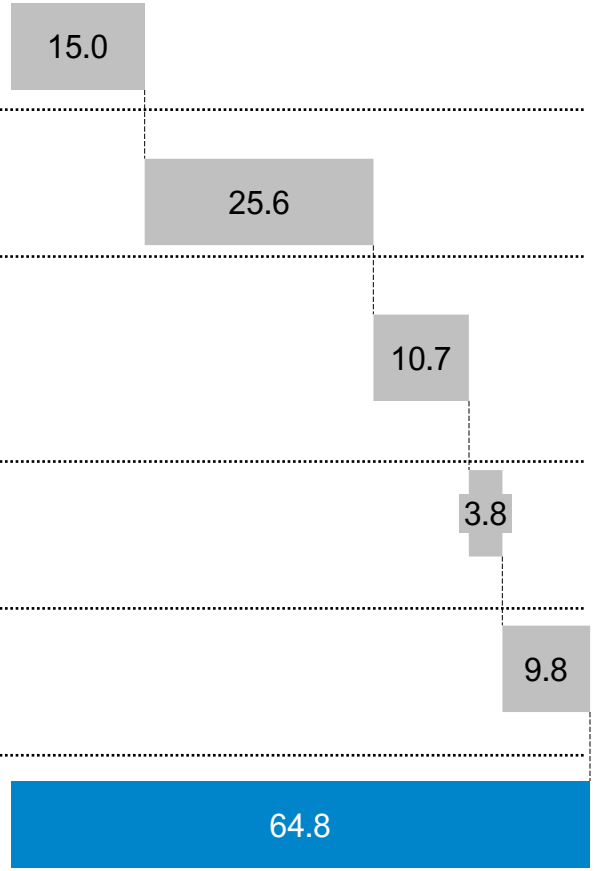
ACOs: Accountable Care Organizations
ODA: Orphan Drug Act

02
Change Agents Reshaping the Market

There are five change agents that will reshape the industry, each with their own operating philosophies

Examples, non-comprehensive

Change Agents	Operational Philosophy	Industry Flashpoint ($B Impacted)
Health & Human Services	Holistic health approaches	Vaccines at risk[1]
Food and Drug Administration	Enhanced evidence thresholds	Orphan drugs at risk[2,3,4]
Centers for Medicare and Medicaid Services	Site-neutral payments	340B rebates at risk[5]
National Institutes of Health	Open scientific discourse	Scientific grants at risk[6]
Department of Government Efficiency	Reduced healthcare waste	Medicaid spend at risk[7]
		Cumulative at Risk



Source: A&M Analysis, 1. Grand View Research 2. Health Affairs 3. Health Affairs 4. NIH 5. Drug Chanels 6. ABC News 7. CMS
Note: Industry impacts reflect modeling assumptions rather than forecasts and should be regarded as directional

Health & Human Services (HHS)

Oversees all public health programs in the US, including CMS, NIH, FDA, and CDC, to protect health and well-being of all Americans

Oversight	**13** Operating Divisions	**$1.6 Trillion** Annual Budget	**83,000** Employees
Operating Philosophy	Critical of pharmaceutical industry influence on public health policies	Cautious stance towards vaccines and a commitment to reevaluating current health practices	Emphasis on prioritizing environmental health as a determinant of public health
Potential Policy Impact	Increase scrutiny on pharmaceutical lobbying, approval fees, and revolving door between industry and FDA	Institute rigorous vaccine safety protocols and create independent committees to examine childhood immunization schedule	Establish a 'food as medicine' arm of the FDA to emphasize role of food in health and address root cause of chronic diseases

Source: U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

Oversees all US drug approvals, medical devices, and food and safety regulations

Oversight	**275** New Drug Applications Annually	**$6.5 Billion** Annual Budget	**18,000** Employees
Operating Philosophy	Scrutiny of drug companies exploiting policies such as the orphan drug act and 340B pricing, beyond original intent	Advocates greater price transparency to improve patient affordability	Critical over prescribing medications and advocates shift towards lifestyle interventions, as first-line treatment
Potential Policy Impact	Reform orphan drug act to prevent designations for Orphan drugs expanding in non-rare disease indications	Mandate pharma companies to disclose R&D costs, pricing strategies, and justifications for price increases	Introduce stringent guidelines on labeling of medications, and increase evidence-based prescribing guidelines

Source: Food and Drug Administration

Centers for Medicare & Medicaid Services (CMS)

Oversee Medicare, Medicaid, and Children's Health and Insurance Program (CHIP), along with private insurance exchanges through the Affordable Care Act

Oversight	**140 Million** Patients on Medicare and Medicaid	**$1.1 Trillion** in Government Spend	**6,700** Employees
Operating Philosophy	Belief in alternative medications and supplements for health and wellness	Expand private sector involvement in public healthcare programs with aim to enhance efficiency and care	Proponent of integrative medicine such as acupuncture, nutrition, and therapy, as a complement to traditional care
Potential Policy Impact	Offer incentives for insurance providers with preventive care programs targeting chronic diseases	Extend Medicare Advantage to all Americans not covered by Medicaid, through increased payroll tax	Increase funding towards CMS innovation center to scale accountable care model through single-payer approach

Source: Centers for Medicare & Medicaid Services

National Institutes of Health (NIH)

Funds biomedical research and advances public health knowledge, while shaping policies on scientific innovation and health research priorities

Oversight	**$48 Billion** in Research Funding	**50,000** Grants Awarded Annually	**18,000** Employees
Operating Philosophy	Interdisciplinary approach with medicine, economics, and health policy, to enhance agency effectiveness and reduce waste	Enhance transparency and public trust to rebuild public confidence following COVID-18 pandemic	Promotes academic freedom and welcomes open scientific discourse across viewpoints
Potential Policy Impact	Establish term limits for NIH leaders, consolidate institutes from 27 to 15, and limit excess funding (e.g., indirect spend)	Allocate funds toward conducting reproducibility studies to detect and prevent scientific fraud	Link NIH grant funding to measures of academic feedback, using assessments such as FIRE freedom of speech rankings

Source: National Institutes of Health
FIRE: Foundation for individual rights and expressions

Department of Government Efficiency

External government advisors tasked with reducing federal spending by $2 trillion

Oversight	**15** Executive Departments	**$6.75 Trillion** Annual Budget	**3,000,000** Employees
Operating Philosophy	Believes government overspends in bureaucratic headcount and non-essential research	Proponent of tech-first approach, pushing for decentralized healthcare systems and blockchain-based patient records	Reduce government fraud and misappropriation of funds
Potential Policy Impact	Mass layoffs across departments, and reduction in clinical investment, and scientific research funding	Pilot programs for crypto-enabled payment systems in large hospital systems	Expanded anomaly detection systems through Medicare, Medicaid, and 340B dispensing

Source: National Archives, U.S. Treasury Fiscal Data, U.S. Bureau of Labor Statistics

03
The New Commercial Calculus

The industry faces four key areas of disruption…

Each with their own considerations

1	Drug Approvals	• Delays in clinical review timelines and fewer novel drug approvals with funding shortages • Modification of PDUFA and MDUFA fee structure • Reform to orphan drug act to limit designation to drugs solely in rare disease indications
2	Reimbursement Models	• Mandated price transparency in drug and provider reimbursement contracts • Expansion of value-based contracts for high-cost specialty drugs and medical devices • Shift in benefits and reimbursement rates for Medicare and Medicaid population
3	Patient Safety	• Scrutiny of DTC advertising for prescription medications • Consumption bans for certain processed ingredients and colorants • Tight enforcement of safety protocols for GmP certification, particularly in India and China
4	M&A	• Reduced bid-ask spread for small and mid-cap biopharma and med-device companies • Pressure to divest retail and specialty pharmacies for healthcare conglomerates • Controls on clinical partnerships with Chinese biopharma, particularly in genomics

Source: A&M Analysis
PDUFA: Prescription Drug User Fee Application
MDUFA: Medical Device User Fee Application
GTN: Gross-to-Net
DTC: Direct-to-consumer

While a backdrop of macroeconomic uncertainty risks further margin compression

Policy changes pose largest risk to biopharma margins

(% Margin Impact) ↓↓↓ -15% to -1% | - Neutral | ↑↑↑ +1% to +15%

Policy Change	Biopharma	Providers	Payers	Key Drivers
Medicare Drug Price Negotiation	↓↓	↓	↑↑	• Medicare negotiations reduce manufacturer net prices for select drugs by 20-30%[1] • Lag time between MFP taking effect and ASP may compress margins for providers • Commercial payers may negotiate higher rebates for select drugs using MFP as a reference price
340B Program Expansion	↓↓↓	↑↑↑	-	• 340B rebates are 5-16% higher than average commercial, reducing net prices[2] • Program expansion further increases the rebates obtained by providers
Orphan Drug Act Reform	↓↓	-	↑	• Orphan drugs approved in rare diseases that expand into common diseases (12-15%) may no longer be eligible for Orphan designations[3] • Orphan drugs that expand in common diseases may offer higher rebates for payers
PBM Transparency Rules	↓	-	↓↓↓	• Forced pass-through of rebates cuts into biopharma's net returns • Provider impact limited unless reimbursement shifts significantly • Payer PBMs risk 10-15% EBIT from reduced markups in specialty generics[4]
Tariff Increases on APIs	↓	-	↓	• Higher import costs raise COGS for 15-20% API-dependent product lines[5] • Providers largely shielded unless drug shortages inflate purchasing expenses • Payers may experience minor cost pressure but pass to employers and consumers

Sources: 1. Brookings IRA Impact, 2024, 2. Drug Channels 340B Analysis, 3. Health Affairs Orphan Label Expansions, 2024 4. FTC PBM second interim report, 2025, 5. Atlantic Council Pharma Imports from China, 2023, A&M Analysis
Notes: MFP = 'Maximum Fair Price', ASP = 'Average Sale Price'

Stakeholders must proactively adapt their commercial models to mitigate the impact on their business

There are a few strategic moves to mitigate disruption ahead

Biopharma

1. **Evaluate orphan pipeline** to assess commercial viability considering more limited post-approval use and stricter adherence to original intent of ODA
2. **Explore alternative pricing models** with direct to patient, value-based, and greater transparency, as PBMs face increased regulatory scrutiny
3. **Shift DTC channels from TV ads to digital platforms**, using data-driven tactics to connect with medical professionals and patient communities where they already engage
4. **Create comprehensive care models** addressing all aspects of a patient's health to differentiate outcomes

Providers

1. **Broaden spectrum of medical care** to include preventative services through nutritionists, mental health, and community / social factors
2. **Accelerate adoption of value-based care models** by leveraging patient data and demonstrating measurable outcomes to position for MA expansion
3. **Seek alternative funding** for clinical and disease state research through private sector investors, and bolster ecosystem of partnerships to mitigate funding cuts to Centers of Excellence
4. **Invest in claims transparency** to mitigate fraud from 340B and Medicaid**,** share insights with pharmacos to maintain access to discounts in dispensing facilities

Payers

1. **Consider divesture of non-specialty pharmacies,** to improve margins and consolidate resources for vertical integration (e.g., specialty providers)
2. **Expand partnerships with ACOs** to scale value-based contracting, and to offload risk to providers
3. **Increase incentives for preventative care measures**, such as fitness memberships, annual check ups, and nutritional care, to align with HHS operating philosophy
4. **Improve price transparency** on drug deductibles, admin fees, and OOP costs, demonstrating good faith to respond to regulator scrutiny

ODA: Orphan Drug Act
DTC: Direct-to-consumer
ACO: Accountable Care Organizations
MA: Medicare Advantage

Can these unconventional change agents disrupt the US healthcare system to the benefit of patients?

Leaders should consider the following:

- **Candidates are new to government** which may take 1-2 years to navigate, at which point congress may flip

- **Most determinants of health outcome are external** to the healthcare system and less influenced by medical care

- **Proposed spending cuts** by DOGE may impact social programs that support vulnerable patient populations under Medicaid

+ **Holistic health approaches** proposed by candidates such as targeting nutrition, physical activity, and mental well-being, may positively impact patient's behavior

+ **Greater transparency** enables patients to make informed decisions about the care they receive

Appendix

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