

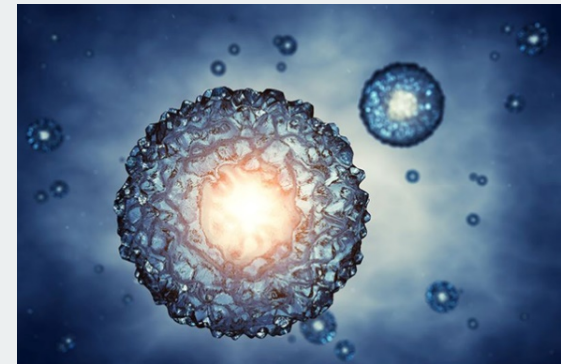
HEALTH ADVANCES

Strategy Consultants for the Healthcare Industry

Biopharma Sales Resilience through Economic Recession

*Analysis of 2008/9's Great Recession on the Sales of
Established, Branded Drug Classes*

Health Advances LLC
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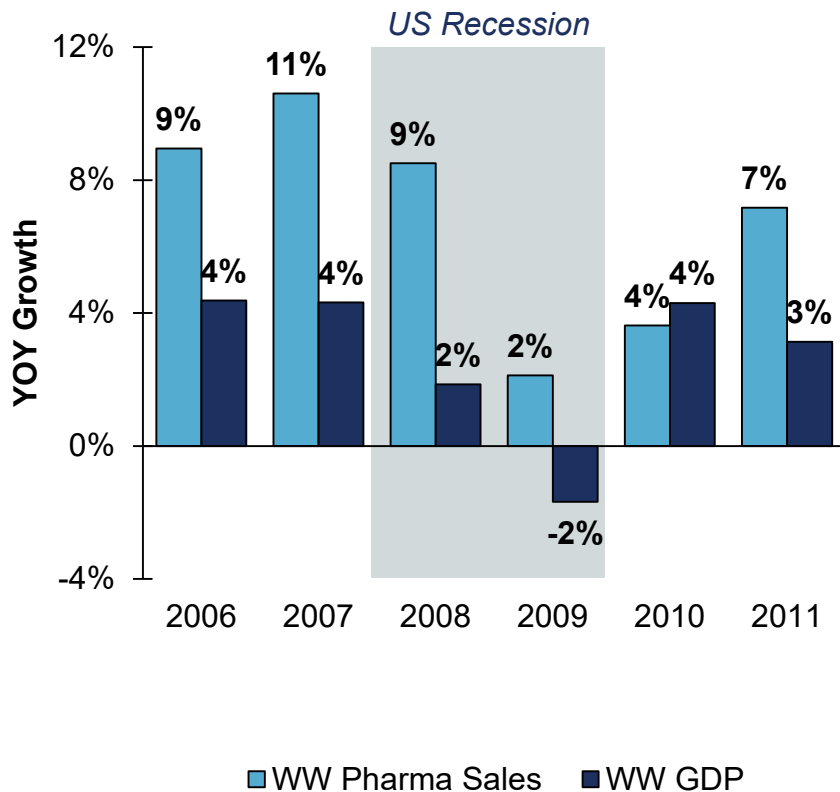
- The biopharma industry is generally more resilient to recessions than the overall healthcare sector, as witnessed through industry sales and biotech market capitalizations
- That said, biopharma sales do face pressures from a recession's economic fallout, as uninsured and Medicaid populations rise and as private payers more aggressively manage drug spend
- We hypothesized that a given drug class' resilience to a recession would be driven by four key criteria: indication severity, indication acuity, drug effectiveness, and the level of competition
 - These criteria would impact the degree to which patients defer drug treatment and payers restrict or manage access to the class
 - Our resilience index correlates well with sales growth pre vs. post recession, based on our analysis of sales of 13 branded drug classes during the 2008/9 Great Recession
- Based on our biopharma sales resilience analysis:
 - Branded drug classes that are highly effective, treat severe and/or acute indications, and face few competitors or alternatives are most resilient to recessions
 - For those drug classes that address less severe indications or face low-cost alternatives, drug manufacturers need to work to ensure continued access and adherence. We provide several recommendations and examples

- ***Recession Effects on the Biopharma Industry***
- Sales Resilience of Specific Branded Drug Markets
- Implications for Industry
- Notes on Methodology
- Contact Information

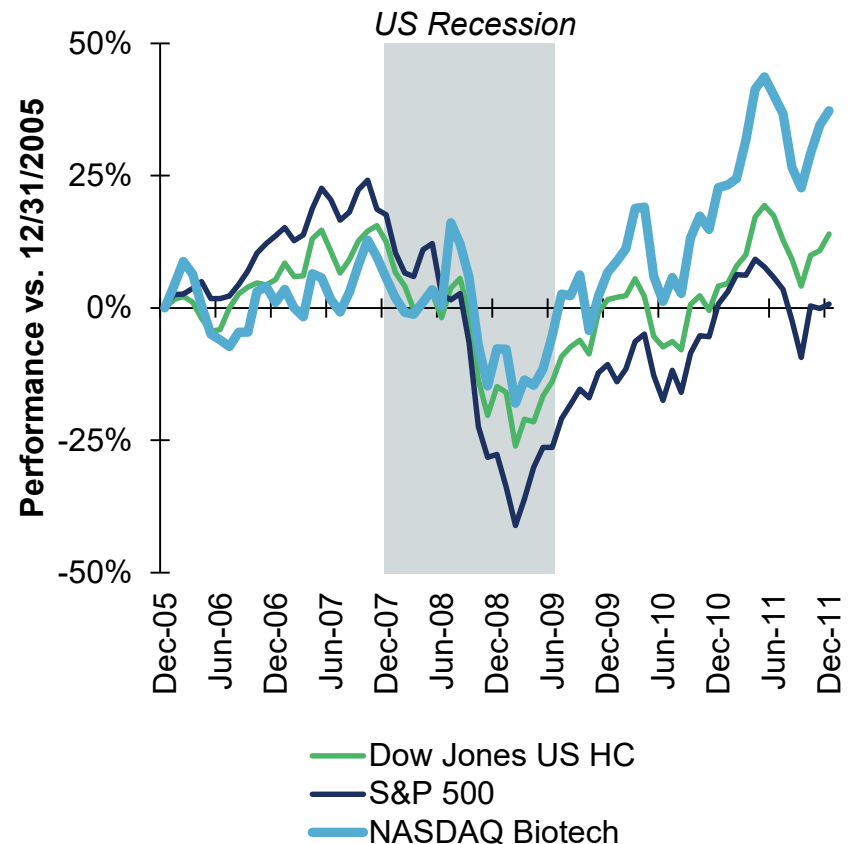
Biopharma Industry Resilience

The biopharma industry is generally more resilient to economic recessions than other sectors, including the healthcare sector at large.

While the global economy contracted in 2009, pharma continued to grow, albeit at a slower pace



Biotech stocks outperformed the overall market as well as broader healthcare stocks

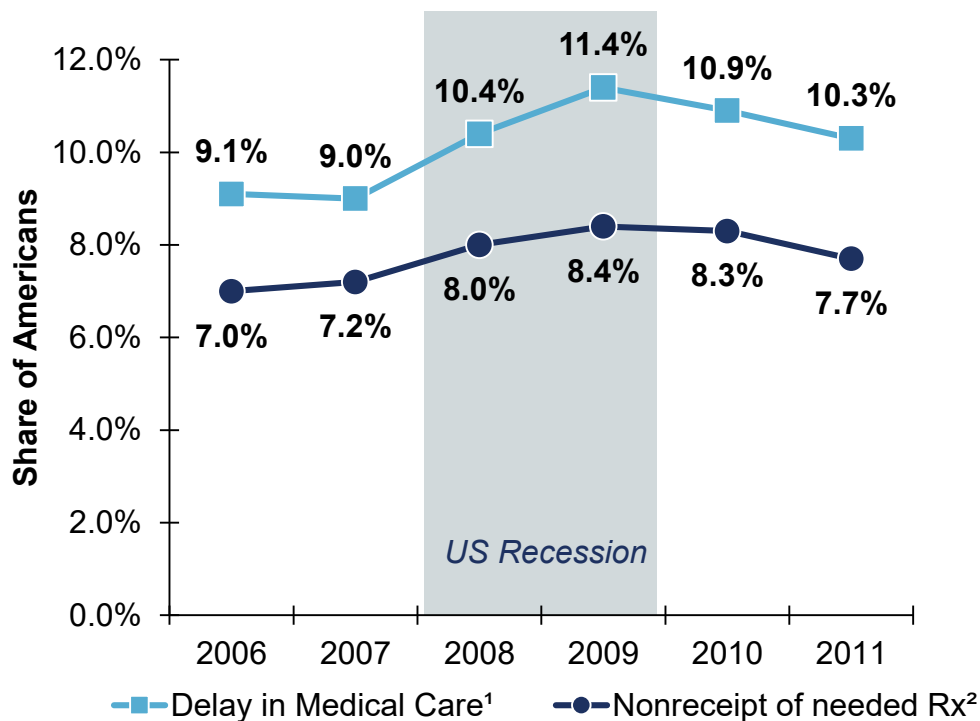


Source: Health Advances analysis, EvaluatePharma, Thomson Eikon.

Lower Deferral Rates of Prescriptions

Partly explaining the resilience, consumer surveys suggest lower deferral rates for prescriptions versus medical services.

Patients deferred medical services more than they deferred prescriptions



Potential Drivers

- Procedures may be viewed as more time-consuming and disruptive than getting prescriptions
- Some prescriptions have a lower out-of-pocket cost to patients than some office visits and procedures

¹ Based on persons responding to the questions, "During the past 12 months was there any time when person needed medical care but did not get it because person couldn't afford it?" and "During the past 12 months has medical care been delayed because of worry about the cost?"

² Based on persons responding to the question, "During the past 12 months was there any time when person needed prescription medicine but didn't get it because person couldn't afford it?"

Source: Health Advances analysis, CDC NCHS, Kaiser Family Foundation.

Recession Factors Impacting Biopharma

Biopharma does face some fallout from recessions, driven by larger uninsured and Medicaid populations and more aggressive access restrictions by payers.

Uninsured and Medicaid populations increase



- Unemployment leaves many patients without insurance or causes them to enroll in Medicaid

Commercial payers more closely manage access to branded drugs



- Payer operating margins decline as they come under pressure from employers to contain premiums

Medicaid

- Medicaid typically pays lower net prices for drugs than commercial or Medicare payers

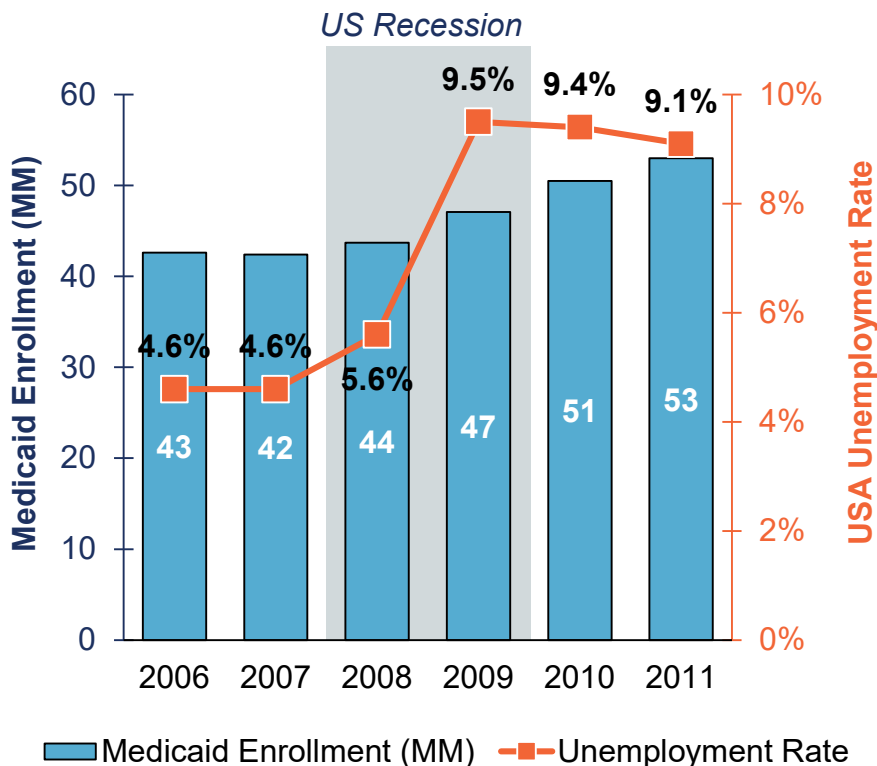


- As a result, payers seek to more aggressively manage utilization of branded drug therapies

Increase in Medicaid Enrollment

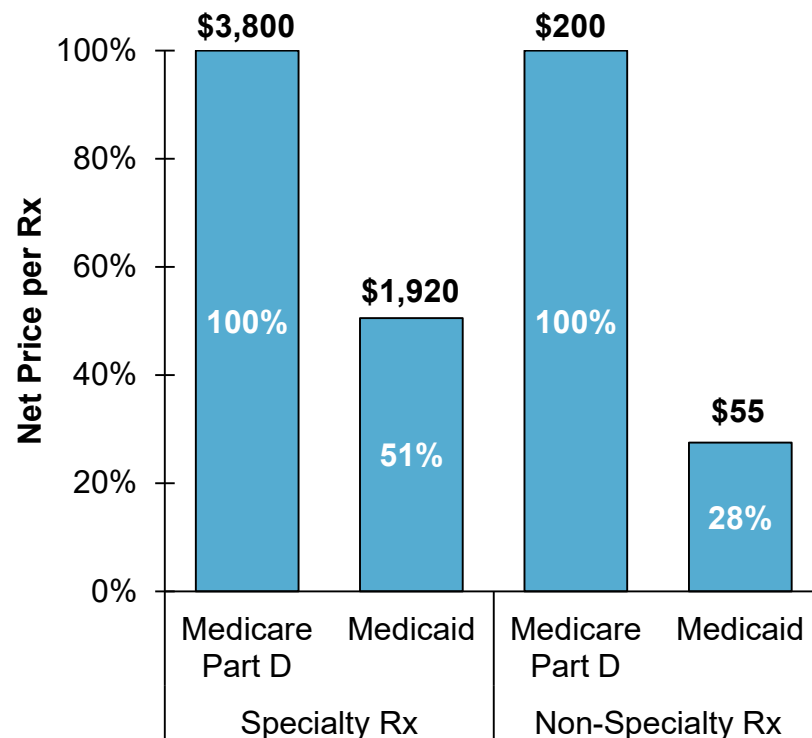
Medicaid enrollment increases with unemployment. Net prices paid for drugs by Medicaid are substantially lower than rates paid by other payers.

As unemployment grows, people lose employer-sponsored coverage and enroll in Medicaid



Medicaid pays substantially lower net prices per prescription than do other payers*

2015



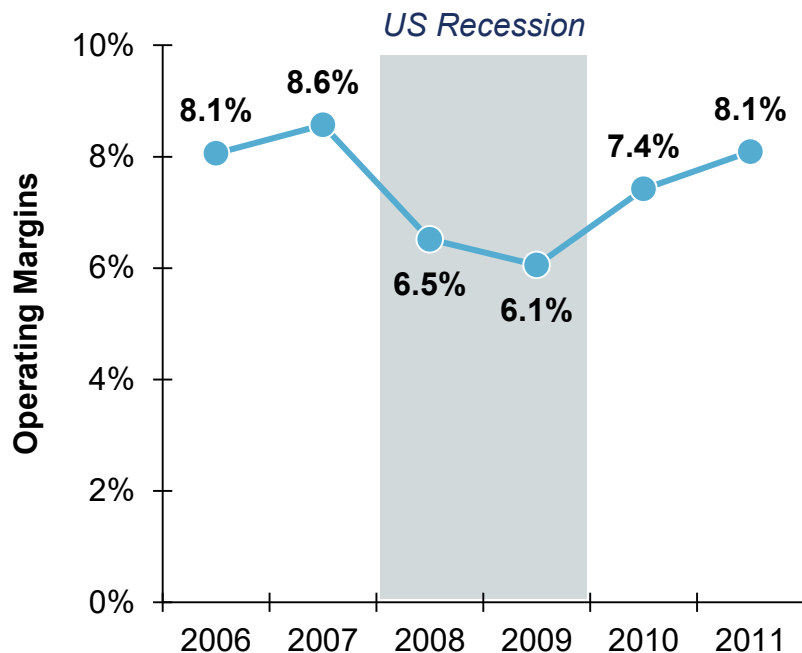
* Weighted average price per prescription for 50 top-selling brand-name specialty and non-specialty drugs. Specialty drugs include four of the following seven characteristics: cost at least \$6,000 per year, be initiated or maintained by a specialist, be administered by a health care professional, require special handling in the supply chain, be associated with a patient payment assistance program, be distributed through nontraditional channels (such as a specialty pharmacy), or require monitoring or counseling either because of significant side effects or because of the type of disease being treated.

Source: Health Advances analysis, Kaiser Family Foundation, US Bureau of Labor Statistics, Congressional Budget Office.

Tightened Access by Commercial Payers

Operating margins of large payer organizations declined in the 2008 recession, leading to more aggressive control of drug utilization and spend.

Payer operating margins¹ declined during the recession



Payers used several strategies to reduce drug costs

Growth of Multi-Tier Plans

- 4- and 5-tier plans enable payers to steer patients toward lower cost alternatives by creating additional copayment tiers
- These plans grew from 6.2% of covered lives to 16.1% of covered lives between 2006-2011²

Increased Use of Closed Formularies

- Closed formularies enable payers to manage their drug costs by limiting members to a subset of therapies
- Closed formularies grew from 38% to 50% of covered lives between 2005-2010²

¹ Weighted average operating margins of Aetna, UnitedHealthcare, Cigna, Humana.

² HMO members only.

Source: Health Advances analysis, Sanofi Aventis Managed Care Digest.

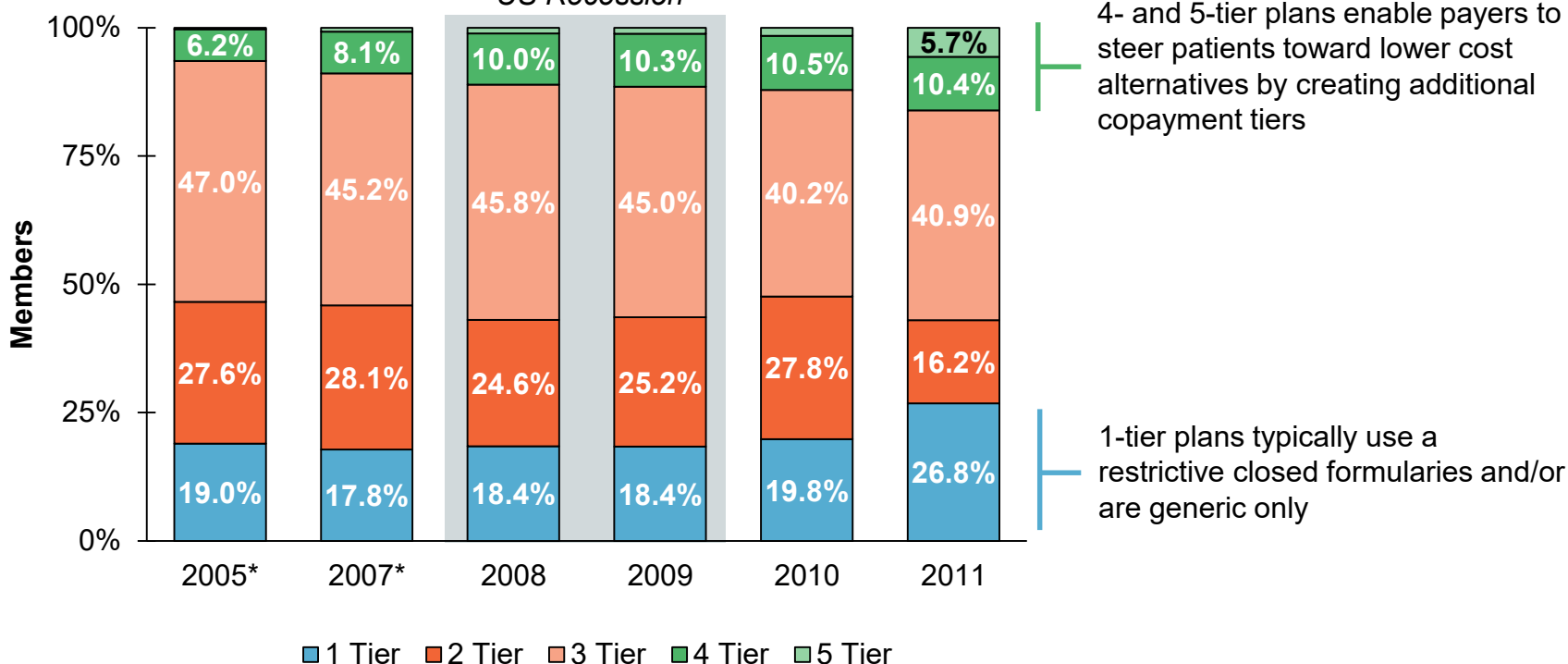
Changes to Formulary Tier Design

The recession prompted payers to leverage formulary tier design in order to manage pharmaceutical utilization and cost.

The recession accelerated a trend towards multi-tier and/or restrictive formulary designs

HMO Plans

US Recession



* 2006 data not available.

Note: About twice as many people are enrolled in PPO plans than HMO plans. However, comparable data is not available for PPO plans.

Source: Health Advances analysis, Sanofi Aventis Managed Care Digest.

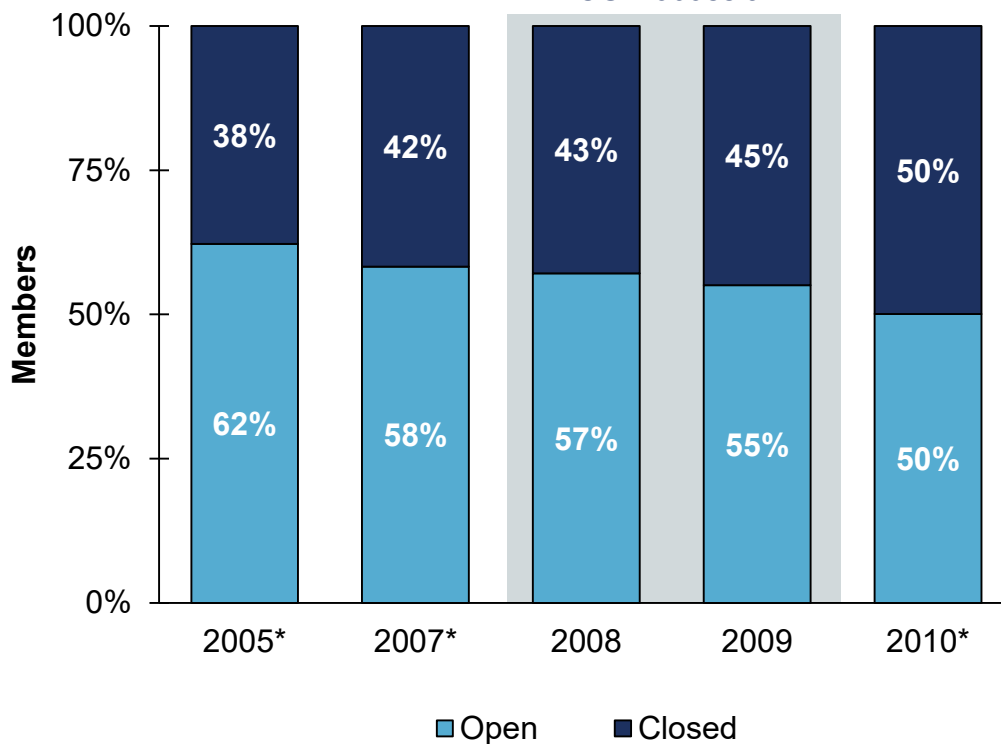
Increased Use of Closed Formularies

Payers increasingly used closed formularies to manage drug utilization following the recession.

The recession accelerated a trend towards closed formularies

HMO Plans

US Recession



- Closed formularies enable payers to manage their drug costs by limiting members to a subset of therapies
 - Drugs not on the formulary are not covered or only covered after a prior authorization process
 - For example, some closed formularies limit members to a single drug within a class
- Some estimates suggest HMOs save 10% to 25% of their drug expenditures through closed formularies

* 2006 and 2011 data not available.

Note: About twice as many people are in enrolled in PPO plans than HMO plans. However, comparable data is not available for PPO plans. We assume the larger trends are similar across the two plan types.

Source: Health Advances analysis, Sanofi Aventis Managed Care Digest.

Hypotheses on Drug Sales Resilience

We hypothesized that in an environment of stricter payer access and higher uninsured and Medicaid populations, sales of drugs that uniquely and effectively treat severe and/or acute diseases are more resilient.

- Payers (and hospitals) need to preserve patient access to needed therapies for severe, life threatening diseases (e.g., stroke or cancer) and patients are less likely to defer these treatments



Drugs indicated for severe and acute diseases are more resilient

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- Payers are unlikely to restrict access to drugs that provide strong, differentiated efficacy (e.g., potentially curative)
 - In some circumstances, these drugs prevent significant downstream costs



Highly effective drugs are more resilient

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- When a drug has few competitors or treatment alternatives, payers have limited ability to restrict access
 - When there are alternatives, payers can use tiering and step edits to encourage lower-cost options
 - When there are multiple me-too competitors, payers can negotiate discounts and reduce costs (and drug class sales)



Drugs with few competitors and alternatives are more resilient

Source: Health Advances analysis.

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Resilience Analysis: Resilience Index Methodology

We assessed a drug class' resilience index according to four criteria, each scored 1 (low) to 3 (high).



	Resilience Index			Examples	
	1	2	3	EGFR TKIs	Parathyroid Hormone
Indication Severity	Quality of life	Morbidity impact; no or little mortality impact	Mortality Impact	3	2
Indication Acuity	Chronic		Acute	2	1
Drug Efficacy	Symptomatic Treatment	Disease-modifying	Potentially Curative	2	2
Drug Competition	>2 Competitors in the same class OR highly attractive low-cost alternatives	1-2 competitors in the same class OR moderately attractive low-cost alternatives	Only drug in the class AND no low-cost alternatives	3	2
			<i>Scaling Factor</i>	-4	-4
			Resilience Index	6	3

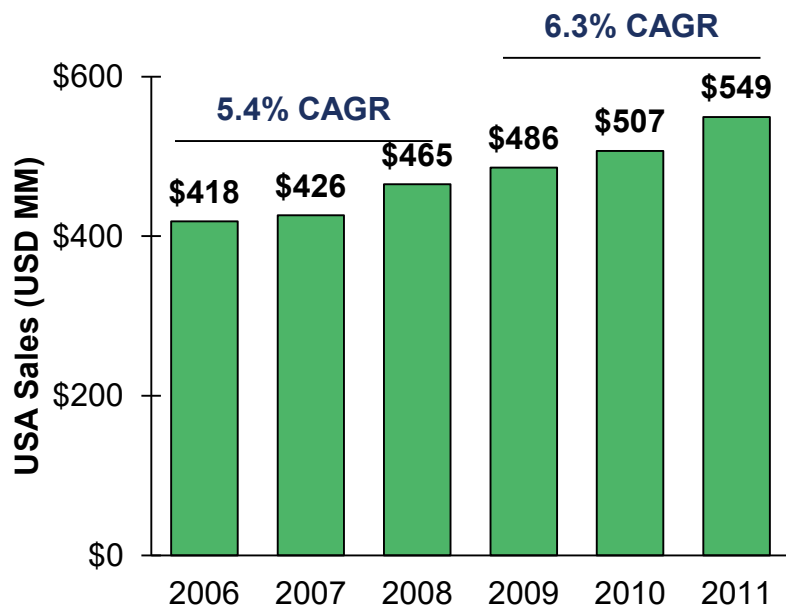
Source: Health Advances analysis.

Resilience Analysis: Growth Score Methodology

We assessed a drug class' growth score based on the change in its compound annual growth rate (CAGR) before and after the recession.

Examples

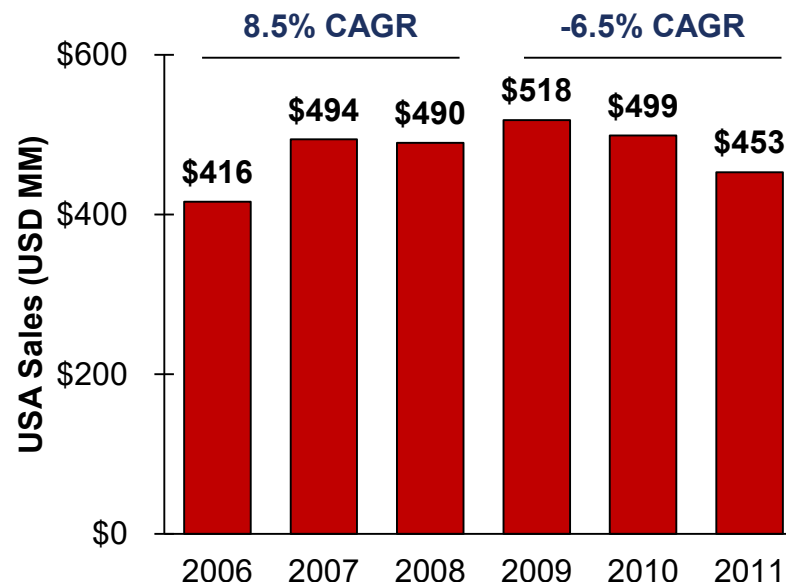
EGFR TKI sales grew unabated after the recession, resulting in a positive growth score



0.9 Growth Score

$$= (6.3\% \text{ '09-'11 CAGR}) - (5.4\% \text{ '06-'08 CAGR})$$

Parathyroid hormone sales declined after the recession, resulting in a negative growth score



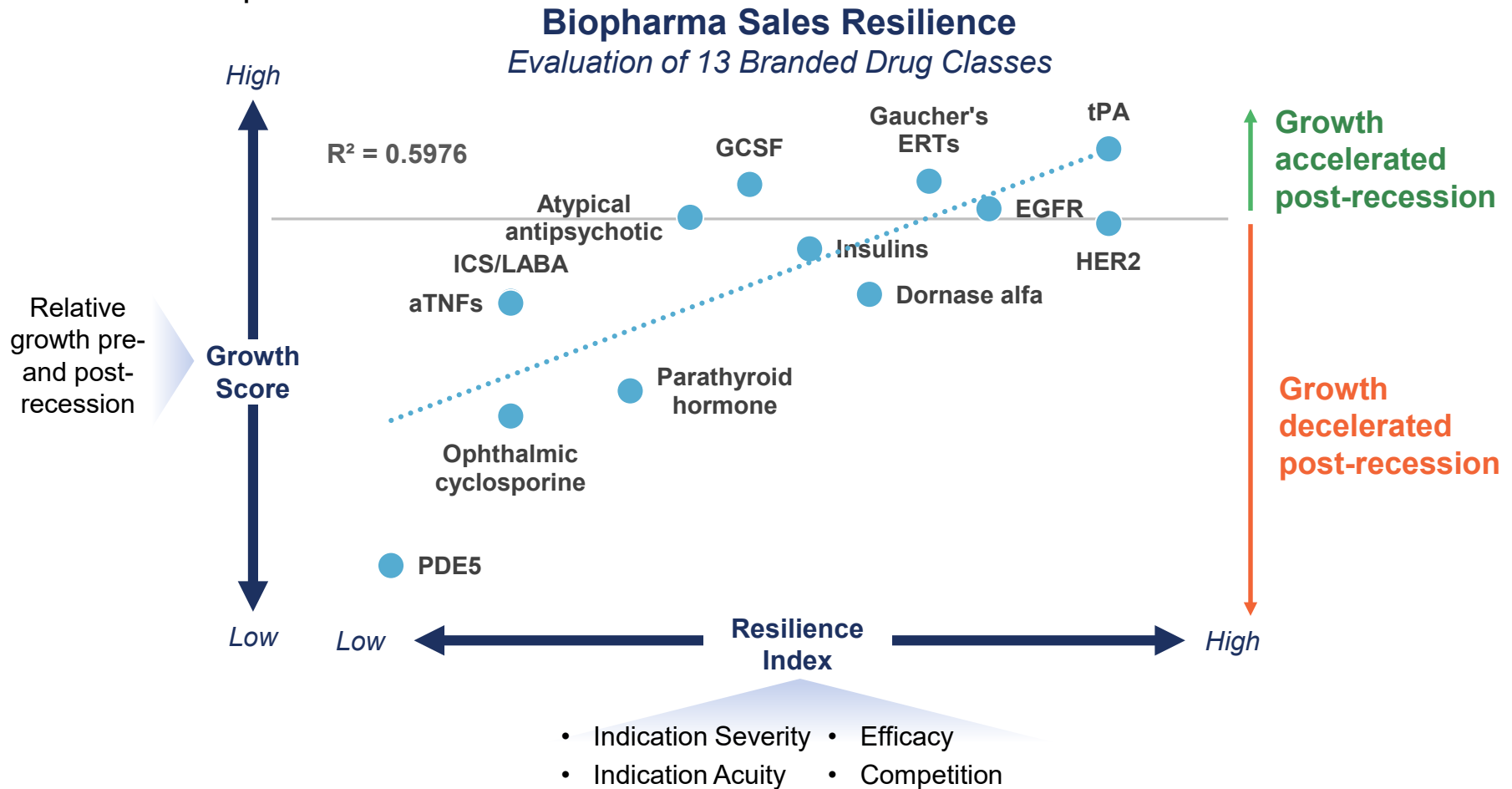
-15.0 Growth Score

$$= (-6.5\% \text{ '09-'11 CAGR}) - (8.5\% \text{ '06-'08 CAGR})$$

Source: Health Advances analysis, EvaluatePharma.

Biopharma Sales Resilience Analysis

Our analysis of biopharma sales through the 2008/9 Great Recession shows that drug classes with high resilience treated severe conditions, offered strong efficacy, and faced limited competition.



Note: GCSF = Granulocyte-colony stimulating factor. ICS/LABA = combination inhaled corticosteroid and a long-acting beta-agonist. ERT = Enzyme replacement therapy. tPA = Tissue plasminogen activator. EGFR = Epidermal growth factor receptor. HER2 = epidermal growth factor receptor 2. aTNF = Anti-Tumor necrosis factor. PDE5 = phosphodiesterase type 5.

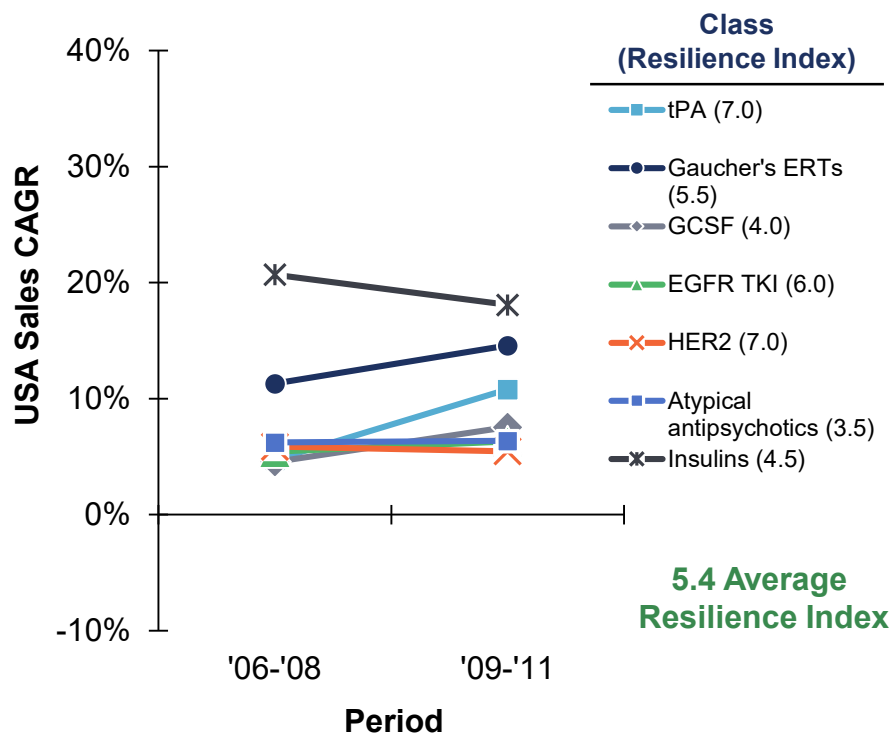
Source: Health Advances analysis.

Most versus Least Resilient Classes

The recession had little impact on the sales growth of more resilient markets (e.g., oncology treatments) but it led to growth deceleration for less resilient markets (e.g., erectile dysfunction).



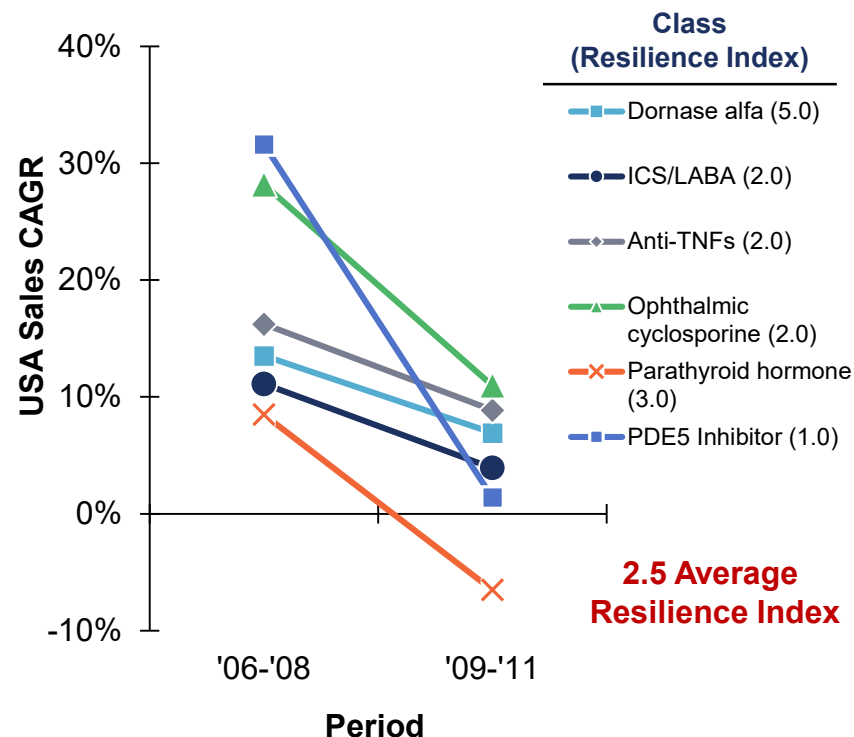
Markets that weathered the recession generally scored high on our resilience index



1.5 Average Growth Score



Markets that struggled in the recession generally scored low on our resilience index



-15.2 Average Growth Score

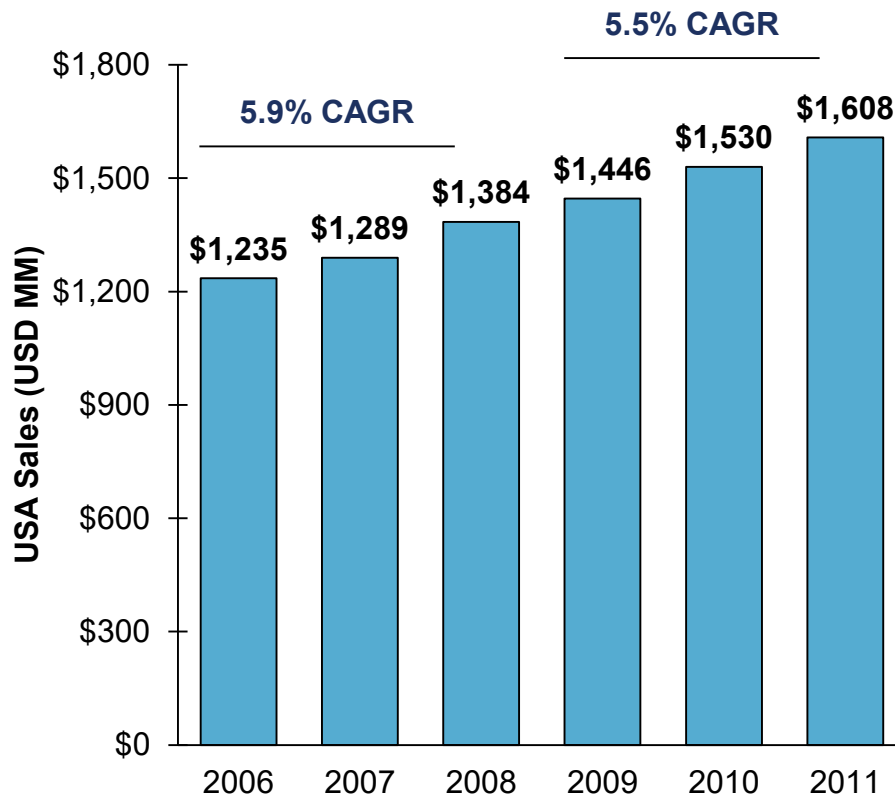
Note: tPA = tissue plasminogen activator. ERT = enzyme replacement therapy. GCSF = granulocyte colony-stimulating factor. EGFR TKI = Epidermal growth factor receptor tyrosine kinase inhibitor. EPO = erythropoietin. HER2 = human epidermal growth factor receptor 2. TNF = Tumor necrosis factor. PDE5 = phosphodiesterase type 5.

Source: Health Advances analysis, EvaluatePharma.

Drug Class Example: Anti-HER2 Antibodies

Herceptin, the only targeted HER-2 antibody, grew steadily through the recession given the severity of the cancer indication and lack of comparably effective alternatives.

Herceptin sales remained stable due to its strong efficacy in a specific tumor type



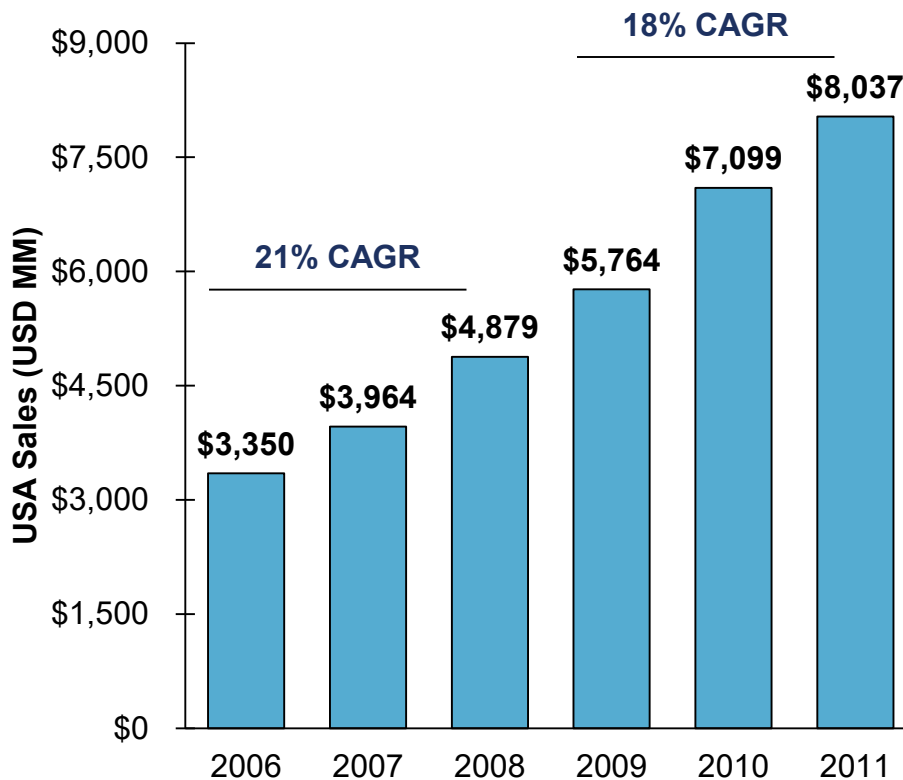
- Herceptin was the first targeted therapy for HER-2 positive breast cancer. It dramatically improved the treatment of this disease
 - Herceptin is indicated for metastatic breast cancer or as an adjuvant treatment for breast cancer
 - One out of five breast cancer cases is HER-2 positive, and this type tends to be more aggressive
 - In combination with surgical resection, treatment with Herceptin may be curative
- Herceptin's annual growth rate pre and post-recession remained stable at 5-6%

Source: Health Advances analysis, EvaluatePharma, Wang 2019 Signal Transduct Target Ther, Nan Jiang 2018 Exp Ther Med, Romond 2005 NEJM.

Drug Class Example: Insulins

As an essential therapy to manage insulin-dependent diabetes, insulin continued its sales growth through the recession.

An essential therapy for many, insulin sales growth continued unabated through the recession



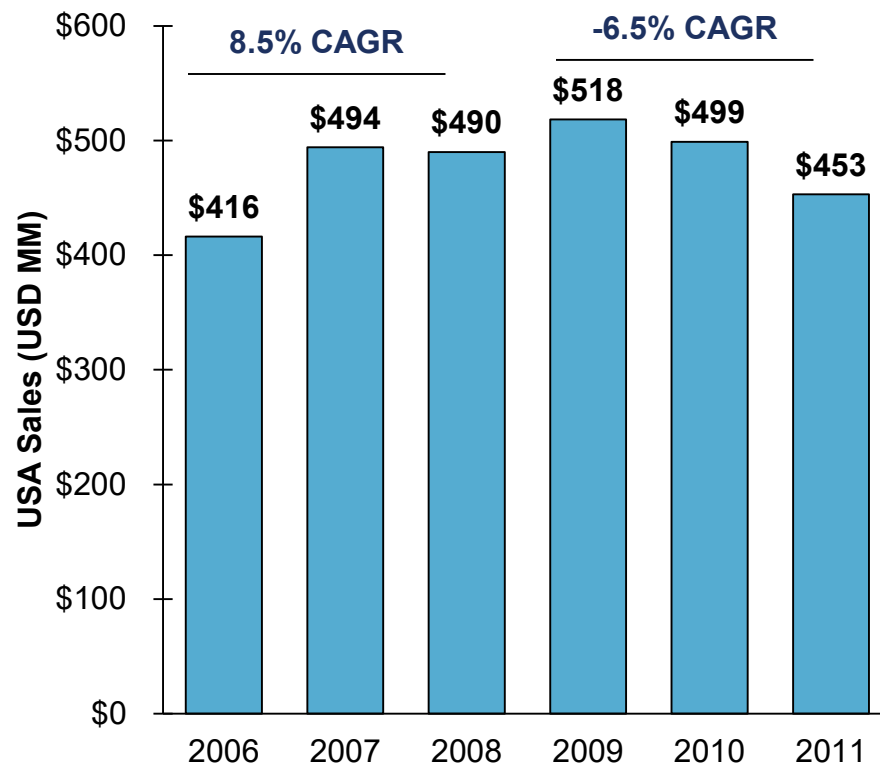
- Many diabetes patients require chronic insulin to manage their disease
 - For people with type 1 diabetes, there is no substitute for insulin therapy
 - People with type 2 diabetes may manage their diseases with oral medications and diet and exercise, but many progress to insulin dependence
- Insulin sales continued to grow rapidly through the recession (~20% CAGR), driven by:
 - Strong adoption of newer analog insulin therapies – Lantus, Novolog and Humalog
 - Patient access supported by payers despite net price increases

Source: Health Advances analysis, EvaluatePharma, UpToDate, DeWitt JAMA 2003.

Drug Class Example: Parathyroid Hormone

Forteo, or parathyroid hormone, struggled to compete against generic bisphosphonates in the wake of the recession.

Parathyroid hormone sales declined post recession as patients increasingly relied on generic bisphosphonates



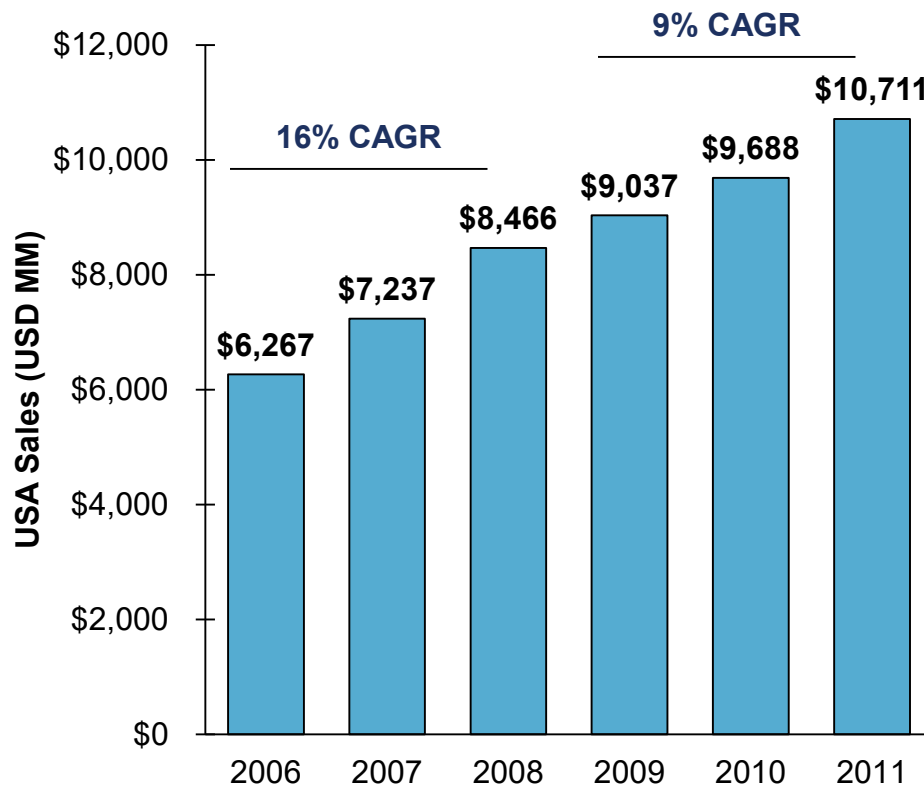
- Forteo is a form of parathyroid hormone used to treat osteoporosis
 - Before 2017, it was the only treatment that catalyzed new bone creation, rather than slowing degradation
 - Forteo is typically reserved for patients more severely affected by osteoporosis
- Forteo sales dropped post recession, as patients remained on generic bisphosphonate therapy
 - In 2008, the patent for a leading bisphosphonate, Fosamax, expired
 - While Forteo is more effective than bisphosphonates, osteoporosis patients don't typically experience acute symptoms and may have chosen to remain on a cheap generic

Source: Health Advances analysis, EvaluatePharma, Mayo Clinic, Smith 2008 CNN Money.

Drug Class Example: Anti-TNFs

Anti-TNF sales growth slowed after the recession, as patients discontinued treatment and remained on generic orals for their inflammatory conditions.

Anti-TNFs sales growth slowed post recession as patients deferred biologic treatment



- Anti-TNFs are premium-priced biologic therapies to treat moderate-severe chronic inflammatory conditions, including rheumatoid arthritis (RA), Crohn's disease, and psoriasis
 - Anti-TNFs are typically prescribed in combination with generic methotrexate or other oral options
- Payer restrictions and patient discontinuations slowed sales growth during the recession
 - Increased co-pays and loss of insurance led to an increased number of discontinued/deferred treatments
 - Payers enacted strict step edits and prior authorization requirements resulting in a reduced number of new patients starting on anti-TNF therapy

Source: Health Advances analysis, EvaluatePharma, Mangoni 2019 BMC Rheumatol, Fortune, AbbVie 10-K, Abbot equity analyst reports.

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- Our resilience index can be used as a heuristic to assess a brand or branded class' sales risk during a recession
 - Generally, indication severity, indication acuity, drug effectiveness, and the level of competition can help gauge a recession's level of impact on sales growth
 - Health Advances can also help with more targeted market evaluations to develop tailored assessments of sales risk and to develop strategies to mitigate risk.
- For drug classes that are less resilient, drug manufacturers need to facilitate drug access and adherence for their patients. This may be achieved by:
 - Enabling faster and simpler enrollment (and re-enrollment) into patient support programs as well as relaxing criteria for enrollment (e.g., immediate access for patients recently unemployed)
 - Enhancing programs to reduce patient costs, including providing temporary free therapy for unemployed patients to ensure continuity of care and reducing barriers to using these benefits
 - Developing solutions to assist patients with prescription fulfillment and adherence
 - Working with payers to alleviate prior authorizations and other utilization management tools, leveraging real-world and health economic evidence

Source: Health Advances analysis.

COVID-19 Industry Examples (Publicly Announced)

Several large pharma companies recently bolstered their patient support programs to ensure continuity of care for their patients and limit the impact of COVID-19.



- Adapted the Merck Patient Assistance Program for patients who lost their job or cannot see their doctor
 - Assessing patients' real-time financial situations
 - Providing assistance with expiring enrollments
 - Offering new options to collect signatures on enrollment forms
- Expanded other access and assistance programs
 - Temporary \$0 co-pay for some products for eligible privately insured patients
 - Relaxed some refill restrictions related to coupon use



- Expanded its patient support programs to help eligible unemployed patients affected by COVID-19
- Expanded program offers free medicine and features include:
 - Immediate access for patients who have lost their employment and health insurance
 - A simple, single point of entry
 - Streamlined enrollment process
 - Vouchers to assist with continuity of care for several self-administered BMS medicines, for eligible patients



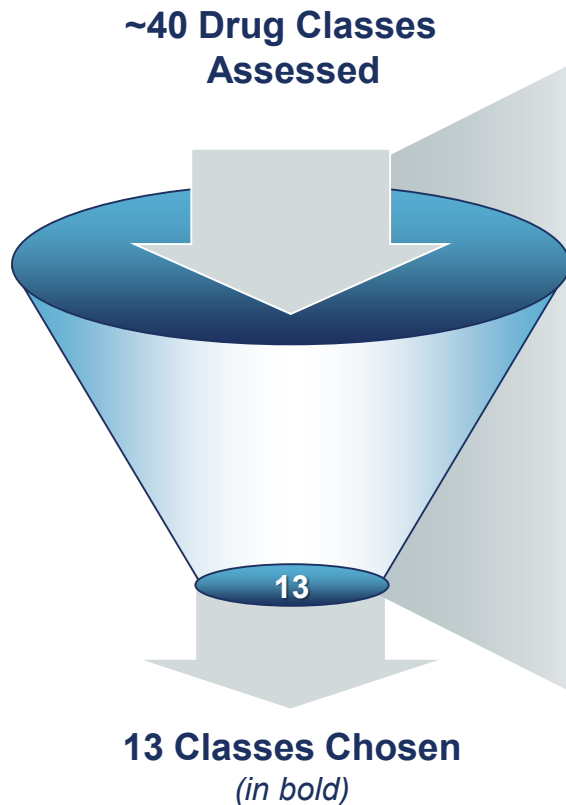
- Enhanced offerings to help patients experiencing difficulties from the COVID-19
 - Simplified access to free medicines for eligible patients
 - Expanded programs to improve affordability and patient support
 - Free temporary supplies of certain medications to avoid treatment gaps
 - Expanded in-home onboarding and administration support
 - Extended fill co-pay card support
 - Where available, extended refills for free-drug programs

Source: Health Advances analysis, company website and press releases.

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Drug Class Selection

Health Advances rapidly evaluated ~40 drug classes to select 13 classes that could best reflect recession impact – e.g. established class, all branded (no generic options).



- 5-HT3 antagonists
- Acetylcholinesterase inhibitors
- **Alteplase/tPA**
- Alpha Blockers
- Aminoketone antidepressants
- Amphetamines
- Antimigraine triptans
- **Anti-TNFs**
- **Atypical Antipsychotics**
- Contraceptive Implants
- DPP-4 inhibitors
- **EGFR**
- EPO
- **Gaucher's ERTs**
- **GCSF**
- **HER2**
- HIV combo therapies
- **ICS/LABA**
- **Insulins**
- Isotretinoin for Acne
- Nasal Corticosteroids
- Non-Barbiturate Hypnotics
- **Parathyroid hormone**
- **PDE5s**
- Clopidogrel
- PPIs
- Pregabalin
- Prostaglandin analogs
- **Dornase alfa**
- **Ophthalmic cyclosporine**
- SNRI
- Statins

Classes were excluded primarily due to generic entry or because they were early in their growth trajectory

Classes Evaluated (1 of 2)

Specialty drug classes received higher resilience scores because these drugs tended to have greater efficacy impact and fewer competitors.

Market/ Drug Class	Example Therapeutic	First Drug Launch/LOE	Resilience Score	CAGR		Description
				'06-'08	'09-'11	
HER2 Therapies	Herceptin	1998 / 2019	7	6%	5%	<ul style="list-style-type: none"> • Effective and highly targeted treatment for metastatic breast cancer patients • Potentially curative in a potentially fatal disease
Tissue Plasminogen Activator	Activase	1987 / 2025 ¹	7	5%	11%	<ul style="list-style-type: none"> • Effective treatment for acute ischemic stroke • High mortality impact, critically acute treatment
EGFRs	Tarceva	2004 / 2019	6	5%	6%	<ul style="list-style-type: none"> • Effective targeted treatment for lung cancer • High mortality impact
Gaucher ERTs ²	Cerezyme	1991 / 2013	5.5	11%	15%	<ul style="list-style-type: none"> • Enzyme replacement therapy for Gaucher Disease • High mortality impact
Cystic Fibrosis Mucolytics	Pulmozyme	1994 / 2015	5	14%	7%	<ul style="list-style-type: none"> • Rare and severe disease • Single drug in the class, however limited efficacy
Insulins	Lantus	2000 / 2015	4.5	21%	18%	<ul style="list-style-type: none"> • Essential treatment for type 1 and some type 2 diabetes patients
GCSFs	Neupogen	1991 / 2013	4	5%	8%	<ul style="list-style-type: none"> • Bone marrow stimulant following chemotherapy • Limited competition

¹ Patents expiring in 2025 are related to manufacturing techniques.

² Note that Genzyme also struggled with manufacturing challenges during this period, but sales growth still persisted.

Note: HER2 = human epidermal growth factor receptor 2; EGFR = epidermal growth factor receptor; GCSF = growth colony stimulating factor; ERT = enzyme replacement therapy.

Source: Health Advances analysis.

Classes Evaluated (2 of 2)

Classes treating less severe, chronic diseases with multiple competitors or alternatives generally scored lower.

Market/ Drug Class	Example Therapeutic	First Drug Launch / LOE	Resilience Score	CAGR		Description
				'06-'08	'09-'11	
Atypical antipsychotics	Abilify	1993/2008 ¹	3.5	6%	6%	<ul style="list-style-type: none"> • Therapy for schizophrenia and other psychological disorders • More than 15 competitors in the drug class
Parathyroid Hormone	Forteo	2002/2019	3	8%	-7%	<ul style="list-style-type: none"> • Treatment for osteoporosis • Single drug in the class, but strong competition from bisphosphonates
Ophthalmic Cyclosporine	Restasis	1994/2019	2	28%	11%	<ul style="list-style-type: none"> • Treatment for dry eye • Strong competition from low-cost alternative treatments
Adrenergic Inhalants	Advair	2001/2010 ²	2	11%	4%	<ul style="list-style-type: none"> • Inhaled therapy for asthma and COPD • Chronic treatment, low disease acuity
Anti-TNFs	Humira	1998/2017	2	16%	9%	<ul style="list-style-type: none"> • Anti-inflammatory immunosuppressant • Multiple low-cost oral classes also used in indications
PDE5 Inhibitors	Viagra	1998/2017 ³	1	32%	1%	<ul style="list-style-type: none"> • Treatment for erectile dysfunction • Low medically necessity

¹ Clorazil was an early atypical psychotic. Generics for it were already available by 1990, but those effects were already established in the market place.

² Inhaled formulations of these drugs have been difficult to replicate and generics did not enter the market in this period.

³ Lower dose generic versions of Viagra (sildenafil) became available in 2012 but were only approved for pulmonary arterial hypertension. This analysis only looks at PDE5 inhibitors that treat erectile dysfunction (ED).

Note: TNF = tumor necrosis factor; PDE5 = phosphodiesterase type 5. Adrenergic inhalants have historically been difficult to replicate into generics.

Source: Health Advances analysis.

While the resilience score provides a framework to rapidly assess the risk to a given market during a recession, it is not a substitute for a comprehensive analysis.

Small Sample Size

- Only evaluated 13 drug classes which were predominantly mature markets in 2006-2011
- Drug classes were selected because they were less affected by confounding factors, like new market approvals or in-class generic entry

Limited Explanatory Variables

- The resilience score is a composite of readily-available explanatory variables (e.g., efficacy, number of competitors)
- However, other data not available on a product-level basis (e.g., net price increases) could also serve as explanatory variables
- This approach also may not account for market-specific nuances, like evolving treatment paradigms and new clinical practices, innovative diagnostic technologies, etc.

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- 20 years of experience in advising senior executive teams on corporate strategy
- Leader in BioPharma Practice, focusing on new product commercialization, lifecycle planning, and M&A strategy
- Strong experience in metabolic, autoimmune, and CNS therapeutic areas; leader of Diabetes/Metabolics and Autoimmune Sub-Practices
- Novartis Pharmaceuticals, Associate, Cardiovascular Business Franchise
- The Advisory Board Company, Senior Research Manager
- Harvard Business School, MBA
- Stanford University, BA with distinction, Human Biology, phi beta kappa



Michael Davitian, Director

- Experience in system economics analyses, facilitating strategic transactions through due diligence, market research analyses, and prioritizing applications and indications for new technologies
- Inverness Advisors, LLC, Healthcare Investment Banking Analyst
- Stanford Financial Group, Healthcare Investment Banking Analyst
- Thomas Weisel Partners, Healthcare Investment Banking Analyst
- Williams College, BA, Biology and Economics



Mansi Shinde, PhD, Engagement Manager

- Experience in market opportunity assessment, early stage commercialization, product and portfolio strategy, revenue forecasting, M&A due diligence, and corporate strategy across the biopharma and diagnostic industries
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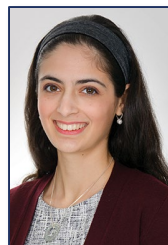
Nishanth Krishnamurthy, PhD, Consultant

- Expertise in medical devices, diagnostics and health IT with a focus on market assessments, competitive analyses and supply chain
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