IMS INSTITUTE
FOR
HEALTHCARE INFORMATICS

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# Medicine use and shifting costs of healthcare

## A review of the use of medicines in the United States in 2013

# Introduction

In 2013, per capita use and cost of medicines increased 0.9% and 1.0% respectively. Nominal spending increased sharply to 3.2% from -1.0% in 2012, prompting questions if medicines were no longer "bending the cost curve" and if a bubble was forming as a result of the Affordable Care Act.

After many years of slowing growth, largely due to patent expiries, a return to growth for medicines is looked at with caution by payers and policy makers alike. Despite this view, little has changed in the dynamics of medicines spending, and in fact, the key elements of long-term savings and restraint in healthcare spending are clear.

In this year's report, we have brought together our review of 2013 from the perspective of the utilization of key healthcare services including physician office visits, hospitalizations and use of the Emergency Room. We have also examined patient costs for medicines and the continued shift in the types of commercial insurance provided by employers. New medicines and breakthroughs in disease areas continued apace, bringing new treatment options to patients with diseases ranging from diabetes to cancer to hepatitis C. Total system spending on medicines, including drug spending outside retail pharmacies, is a key metric many look to as an indicator of healthcare spending levels, and this report provides the first view of this for 2013.

The study was produced independently by the IMS Institute for Healthcare Informatics as a public service, without industry or government funding. The contributions to this report of Lauren Caskey, Jennifer Lyle, Sue Antolik, Mary Ann Cornwall, Kobby Essien, Shiraz Hassan, Thurayyah Jacobs, Jim Letcavage, Bill McClellan, Priya Patel, Carrie Wright, and dozens of others at IMS Health are gratefully acknowledged.

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- Patients are paying higher deductibles, co-pays or co-insurance.
- 78.6% of all prescriptions cost patients $10 or less.
- There are wide variations in the out-of-pocket costs by types of insurance.
- Some patients can use coupons to dramatically reduce their costs.

**TRANSFORMATIONS IN DISEASE TREATMENT** 19

- 36 New Chemical Entities launched in 2013 up from 28 in 2012.
- Seven entirely new treatment mechanisms launched, 17 orphan drugs, and 10 cancer.
- Breakthrough products to treat hepatitis C, multiple sclerosis, cystic fibrosis and a number of cancers launched in 2012/13 and have already reached millions of Americans.

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- Total drug spending was $329.2Bn, up 3.2% nominal or 1.0% real per capita basis.
- Spending increased due to fewer expiries and higher brand price growth.
- Therapy areas can be segmented into groups based on the state of the innovation cycle.

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# Executive Summary

Utilization of all types of healthcare services including medicines rose, and while out-of-pocket costs continue to increase for patients as insurance plan designs change, the vast majority of prescription medicines carry a co-pay of $10 or less. Clusters of innovative medicines were launched bringing new treatment options to patients, especially for cancer. Total drug spending growth rebounded in 2013 from its largest ever decline in 2012. Fewer patent expiries, increased utilization of specialty medicines, and the launch of new medicines contributed to the increase, which remains at historically low levels and less than overall healthcare spending.

- **Changes in the utilization of healthcare and medicines**

  Utilization of healthcare and medicines increased in 2013 whether measured by physician office visits, hospitalizations, or prescriptions filled. For the fourth year in a row, hospitalizations beginning in the ER increased in number - driven by day visits to the ER - but inpatient admissions via the ER declined dramatically. Patient office visits, which have always been relatively evenly split between primary care and specialists, tipped to majority specialist in 2013 for the first time, with greater increases for older patients. Per capita usage of prescriptions increased overall but declined slightly for patients over 65.

- **Patient payment for healthcare and medicines**

  Out-of-pocket costs continue to rise for patients, despite generic medicines now representing 86% of prescriptions, and average out-of-pocket costs falling below $10 overall. Zero co-pays for contraceptives and coupon programs from manufacturers are two of the ways that patient costs are being offset. Patients abandon 3% of prescriptions at the pharmacy, and payers reject another 6% for various reasons linked to formularies and prior authorization required for expensive medicines. The ACA provision ensuring a zero out-of-pocket cost for preventive tests and treatments and for contraceptives has dramatically reduced out-of-pocket costs for women in particular, saving them approximately $483 million in out-of-pocket costs in 2013 for contraceptives alone.

- **Transformations in disease treatment**

  There were 36 New Molecular Entities launched in 2013, including ten new cancer treatments, and 17 orphan drugs, the most in both segments in over a decade. A dramatic rise has occurred in the number of cancer drug launches, with 56 NMEs launched in the last decade, two-thirds of those in the last five years and 27 of them in the last three years.
  In addition, further indications for existing cancer drugs have been launched, bringing proven mechanisms to new tumor populations. Orphan drugs are reaching an increasing number of very small patient populations, and the 17 launched in 2013 is the most in any year since the passage of the Orphan Drug Act in 1983. The next decade promises a much faster approval process for drugs gaining FDA's new Breakthrough Therapy Designation. Clusters of innovation are transforming patient care in hepatitis C, multiple sclerosis, as well as diabetes, stroke and acute coronary syndrome.

- **Spending on medicines**

  Drug spending has been contributing to slower healthcare cost growth since 2007, with real per capita spending growth on medicines below 4% in every year, and only 1% in 2013. Nominal spending rose sharply in 2013 from its decline in 2012. The largest single driver of the increase in spending growth from -1.0% in 2012 to 3.2% in 2013 was the lower impact of patent expiries – $10 billion less than in 2012 – accounting for 3.5% of the 4.2% shift in growth. Spending on medicines overall can be explained by the level of innovative medicines and patent expiries in major therapy areas. The largest clusters of innovation are in specialty therapy areas including oncology, hepatitis C, HIV, and autoimmune diseases, which collectively grew by 11% to $73 billion in 2013. Primary care therapy areas with significant innovation led by diabetes grew by 11% to $37 billion. The largest amount of spending - $128 billion in 2013 – was in therapy areas with limited innovation or patent expiries but still grew at 7%. A significant driver of growth in the market was price increases on protected brands, which contributed $20 billion to growth in 2013, up from $15.6 billion in 2012. All of the higher price growth seen in 2013 was offset by higher levels of off-invoice discounts and rebates, and net price growth was estimated to be nearly unchanged from 2012 at $16.6 billion. The largest driver offsetting positive spending growth was the group of primary care therapy classes affected by significant patent expiries, declining by 10% in 2013 to $80 billion in spending.

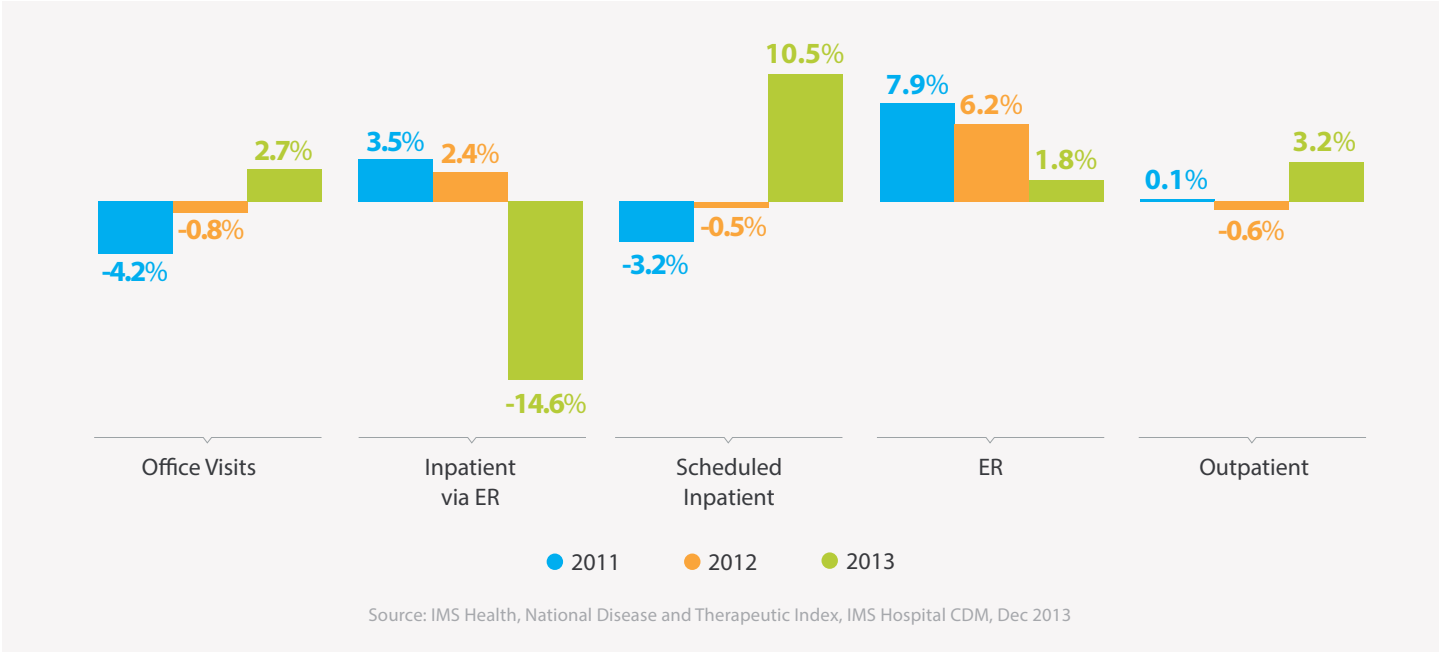
# Changes in the utilization of healthcare and medicines

Overall utilization of healthcare services and medicines grew slightly in 2013 as patients returned to the healthcare system, mostly visiting physician's offices and/or receiving outpatient treatment, but in higher numbers after several years of "self-rationing".

- Patient office visits grew by 2.7% in 2013, a reversal of four years of declines.
- Scheduled inpatient admissions account for only 2.4% of hospitalizations, but grew by 10.5%, which may be the result of some patients having rationed care in years past, and exacerbated their conditions.
- Inpatient hospital admissions via the emergency room represent only 2.5% of all admissions, and declined by 14.6%, perhaps as a response to policies that discourage ER usage.
- Emergency day visits actually increased slightly for all payers, showing that there is potentially more to be done to discourage inappropriate ER usage generally.
- There were 1.6% more prescriptions filled in 2013, an increase in growth of 0.4% over the level in 2012, but reflecting per capita growth of only 0.9%.
- Most therapy areas had small nominal increases, with the largest increases coinciding with some of the most used medicines.
- While cholesterol medicines were notable for their decline, this was more a response to an abnormally high level of prescriptions in the months following the expiry of Lipitor in November 2011, and not linked to recently revised cholesterol management guidelines.
- Pain medicines, particularly narcotics, showed declines largely attributed to the response to the FDA's mandatory phased withdrawal of high-dose acetaminophen-containing opioid combinations, as well as to the removal of crushable forms of oxycodone and their replacement with abuse deterrent forms.

# Patients made more visits to physician offices and hospitals in 2013 with a dramatic drop in inpatient admissions via emergency departments

**Percent change in hospital admissions and office visits**




Source: IMS Health, National Disease and Therapeutic Index, IMS Hospital CDM, Dec 2013

- Visits to physician offices recovered in 2013, but are still 8% lower than in 2008.
- The recovery in office visits was seen among the Medicare and commercially insured populations, while Medicaid visits declined slightly.
- All types of hospital admissions, including inpatient, outpatient and emergency, rose 2.6% in 2013.
- Scheduled inpatient admissions rose 10.5% in 2013, but account for 2.4% of total admissions.
- Hospitals saw an increase of 13 million outpatient visits in 2013.
- Emergency room utilization was flat as in-patient admissions via the ER declined while ER day visits increased for all insurance types.
- The average number of visits per patient decreased slightly in the Medicare and Medicaid populations.

Chart notes:

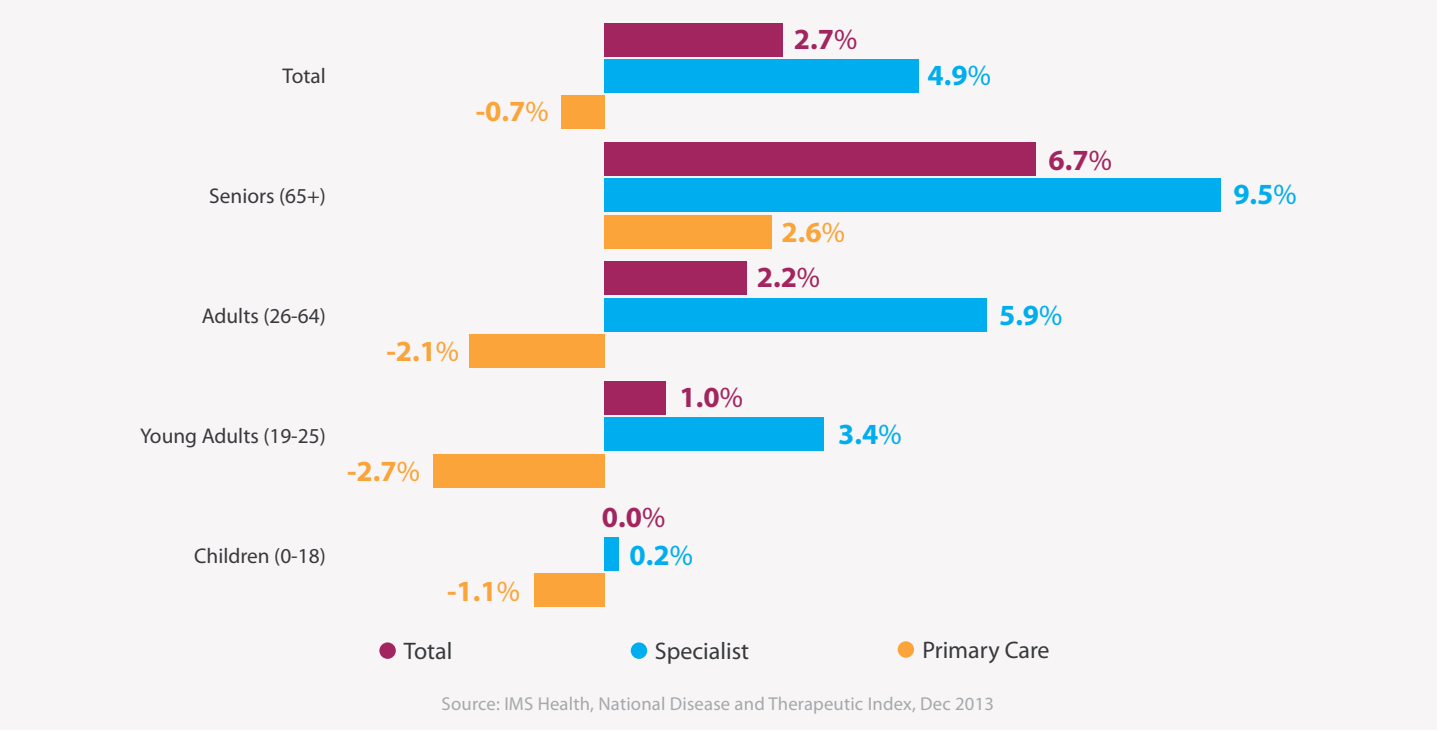
Patient visits projected from a survey of office-based physicians.

ER (emergency room) includes patients who visit the ER and are released without being admitted.

IMS CDM includes hospital-based admissions based on a sample of private hospitals. Outpatient admissions represent outpatient services provided by a wholly-owned hospital facility, and do not include standalone infusion centers or cancer centers.

# Physician office visits increased by 2.7% as patients visited specialists more often and primary care office visits declined slightly

**Percent change in office visits by physician type and patient age in 2013**



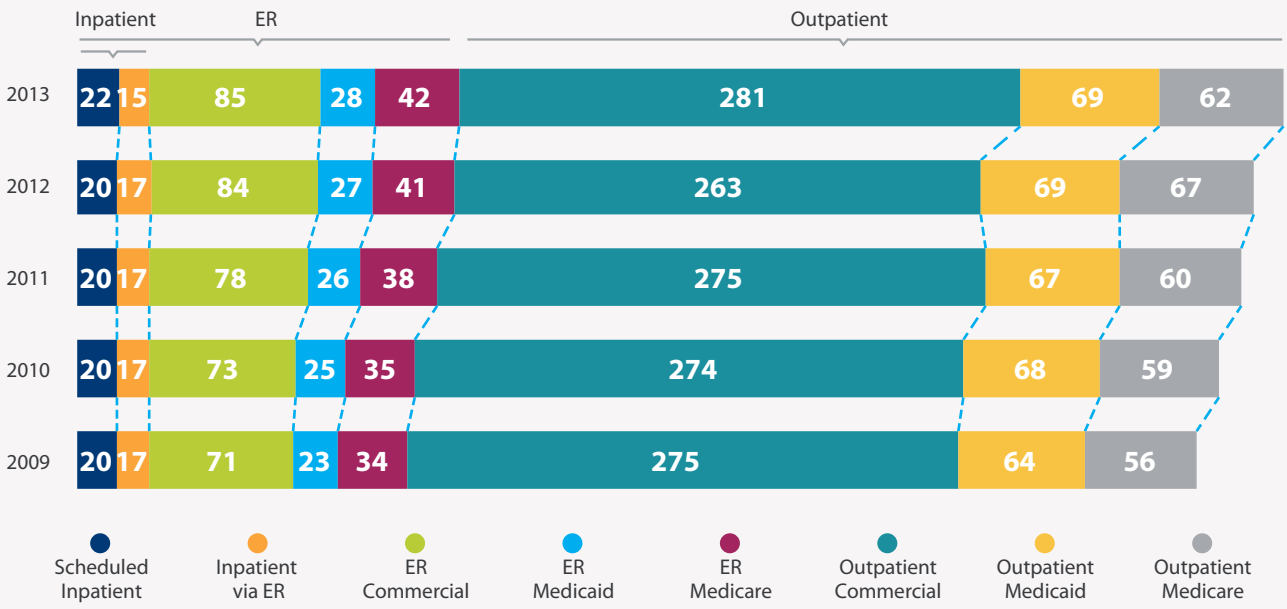

Source: IMS Health, National Disease and Therapeutic Index, Dec 2013

- Visits to physician's offices increased in 2013 after four years of decline, driven by patients visiting specialists, and by the large seniors and adult patient populations.
- Seniors' doctor visits increased 6.7% in 2013 compared to a 1.5% increase in 2012, mostly from seeing specialists more often.
- Adults demonstrated a similar pattern, where specialist visits increased by 5.9% compared to a 0.5% decline in 2012.
- Adults primary care visits continued to decline for the fourth consecutive year, and the rate of decline accelerated from -1.1% in 2012 to -2.1% in 2013.
- Young adults aged 19-25 – those who could stay on their parent's health insurance from late 2010 – had a modest increase in physician visits of 1.0%, compared to a 3.7% increase in 2012.
- Children, including those covered by their parent's insurance and those covered under SCHIP, visited primary care doctors 1.1% less in 2013, a dramatic change compared to the 6.4% decline in 2012.
- Much of the recovery in children's visits was driven by visits to pediatricians paid by Medicaid.
- Among the commercially insured, visits to general and orthopedic surgeons, psychiatrists, and pediatricians had all declined in 2012 and all saw significant increases in 2013.

Chart notes:
Primary Care includes family practice, internal medicine, pediatrics, osteopathic medicine and general practice.

# Patients made more visits to hospitals in 2013, mostly from commercially insured patients' outpatient treatments

## Trends in hospital admissions by pay type (millions)




Source: IMS Health Hospital CDM, Dec 2013

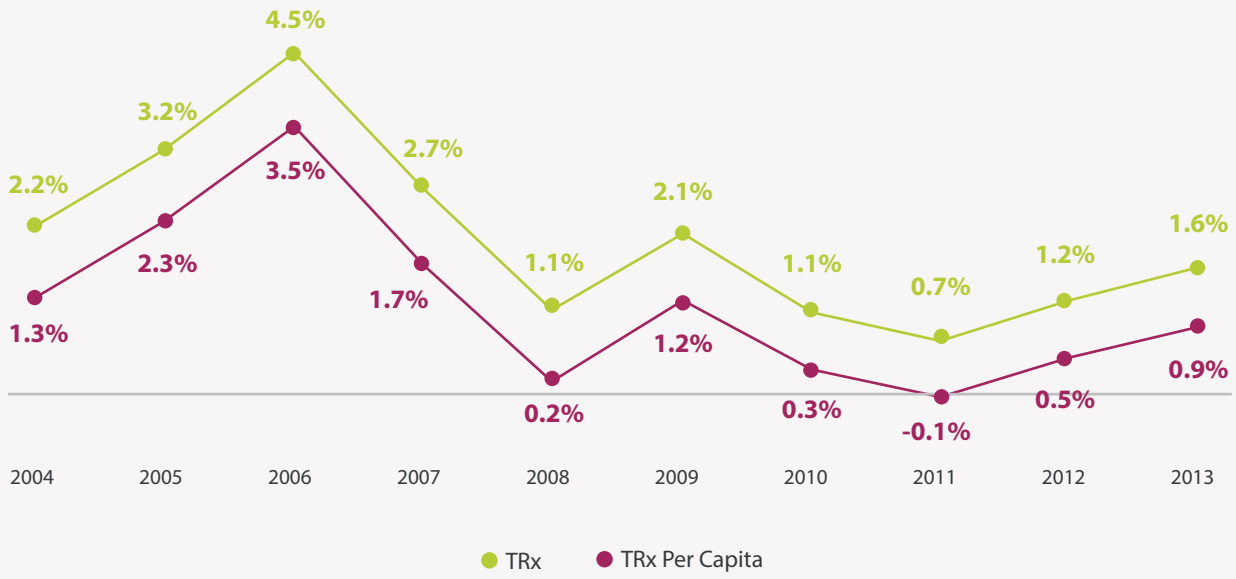
- Hospital admissions of all types rose by 15.1 million admissions in 2013 to a total of 603.4 million admissions.
- Inpatient admissions were flat, with a 10.5% increase in scheduled admissions offset by a 14.6% reduction in admissions via emergency.
- Outpatient care represents 68% of hospital admissions, down two percentage points since 2009, but increasing in the latest year as rates of growth in emergency and inpatient admissions have slowed.
- Outpatient treatment drove the growth in hospital visits, increasing by 13 million in 2013.
- Emergency room day visits slowed with smaller increases by all types of insured patients.

Chart notes:

Chart notes: Scheduled inpatients are those patients who are admitted as inpatients not via the ER. Inpatient via ER are patients who are admitted as inpatients after first visiting the emergency department during the episode of care. Emergency admissions where the episode of care does not result in an inpatient admission can also be called day-patients. Outpatient treatments in hospitals can include patients treated by physicians in clinics or practices owned or operated by hospitals, or day-surgeries. All such determinations are based on the type of reimbursement submitted by the hospital to the relevant insurers.

# Prescriptions increased by 1.6% in 2013, 0.9% on a per capita basis, the second consecutive year reversing flat or declining prescription demand

**Nominal and per capita dispensed prescription growth 2004-13**




Source: IMS Health, NPA, Jan 2014; U.S. Census Bureau

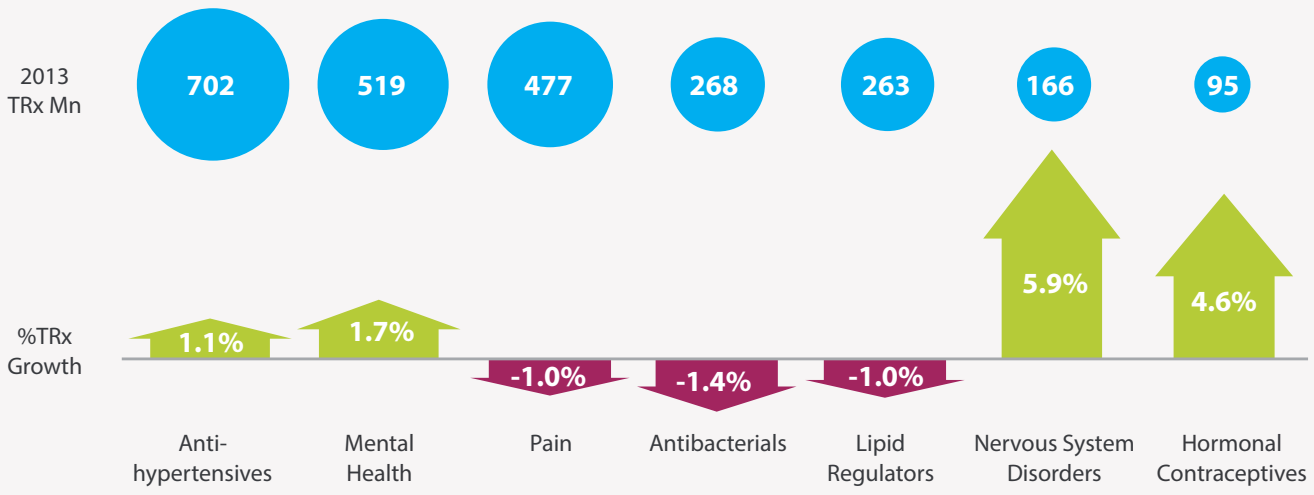
- During the worst years of the economic crisis, from 2009 to 2011, prescription demand was largely insulated from slowing demand.
- Since the official end of the recession in June 2009, prescription demand has recovered relatively weakly.
- There is an important relationship between patients' exposure to healthcare costs and their use of healthcare services and medicines, and while the broader economy recovered, there were forces acting on patients that were making some healthcare progressively less affordable.
- Prescription demand increased the most in the last decade with the implementation of Medicare part D in 2006.
- Of the past five years, only 2009, driven by the H1N1 flu season, had per capita prescription growth above 1%.
- The per capita prescription trend, which shows increasing demand for medicines year by year, provides a useful baseline for understanding the dramatic changes in the insured population and the expected impact on patients' healthcare and prescription utilization in the future.

Chart notes:

Dispensed prescriptions in retail, mail order and long-term care pharmacies. IMS routinely updates its market audits, which may result in changes to previously reported market size and growth rates. This chart adjusts for a trend break in currently reported IMS data and reflects historic growth rate trends.

# Prescription increases were driven by changes in some of the therapy areas with greatest prescription utilization

**Selected therapy areas with largest positive and negative contributions to TRx growth**




Source: IMS Health, National Prescription Audit, Jan 2014

- Therapy areas associated with declining costs, such as hypertension and mental health, saw increasing volume, perhaps related to reductions in patient out-of-pocket costs.
- Prescriptions for pain medicines, including narcotic opioids, declined by 1%, and while most pain medicines had increased usage, the FDA-ordered phasing-out of acetaminophen products with strengths greater than 325mg (started in 2011 and due to complete January 2014) drove reduced usage of combination products that also included opioids. The introduction of abuse-deterrent forms also reduced opioid usage, on a morphine-equivalent unit basis.
- Nervous system disorders grew by 5.9% largely driven by the broad utilization across indications (approved and unapproved) for generic oral gabapentin, originally an epilepsy treatment but now used for a broad range of pain and nervous system disorders.
- Hypertension prescription growth continued below the overall market level despite the availability of low-cost generics of one of the leading medicines, valsartan + hydrochlorothiazide (generic Diovan-HCTZ).
- Lipid regulator prescriptions declined by 1% following a temporary peak in demand following the Lipitor patent expiry in late 2011.
- Prescriptions for contraceptives increased 4.6% as the share of patients with zero co-pay rose from 20% to 50%.

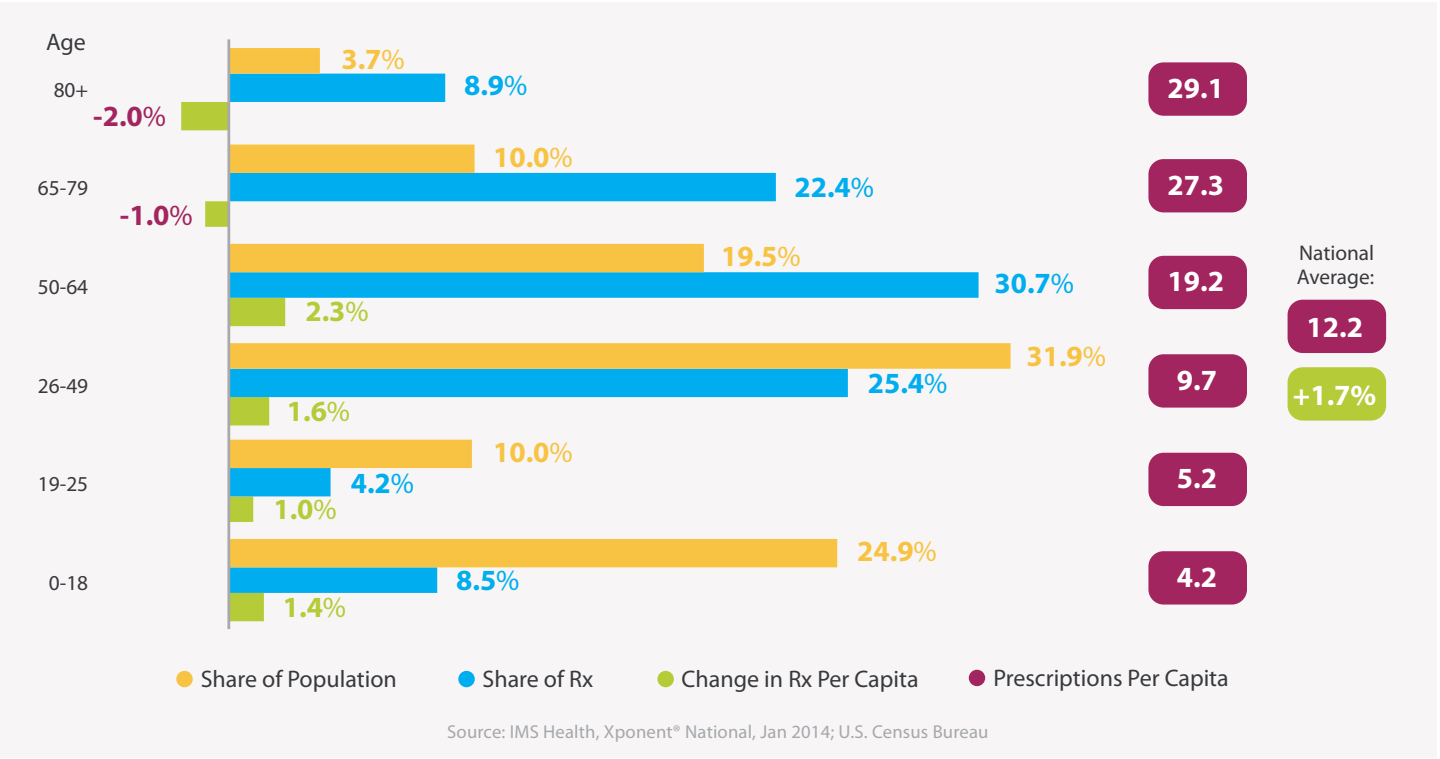
Chart notes:

Therapy areas are based on proprietary IMS Health definitions. Pain includes NSAIDS (Non-steroidal anti-inflammatories), non-narcotic analgesics, and narcotic analgesics.

Mental health includes antipsychotics and antidepressants. Nervous system disorder treatments include therapies for epilepsy and Parkinson's disease.

# Use of medicines by patient groups under 65 years increased, though seniors remain the highest per person consumers of prescription drugs

**Percent population, prescriptions and per capita change in retail prescriptions by age**




Source: IMS Health, Xponent® National, Jan 2014; U.S. Census Bureau

- Americans' use of medicines per person increased, but declined for the largest per capita users, those older than 65.
- Those 80 and over used 2% fewer prescriptions but remain the largest per-person users of medicines.
- All Americans – including the healthy and untreated – on average use 12.2 prescriptions per year.
- Prescription utilization per capita declined slightly among people over 65, from 28.1 to 27.8 prescriptions per year.
- Total prescriptions filled by patients aged 65-79 increased 4.3%, while the 65-79 population increased 5.3%, resulting in a per capita decline of 1.0%.
- Seniors ages 65-79 use five times the amount of drugs as young adults ages 19-25.

Chart notes:
Dispensed prescriptions in retail and mail order pharmacies. Per capita prescription growth shown here does not include long-term care pharmacies, and mail order prescriptions, are unprojected. This may account for the difference between total market per capita prescription growth and the growth shown on this page.

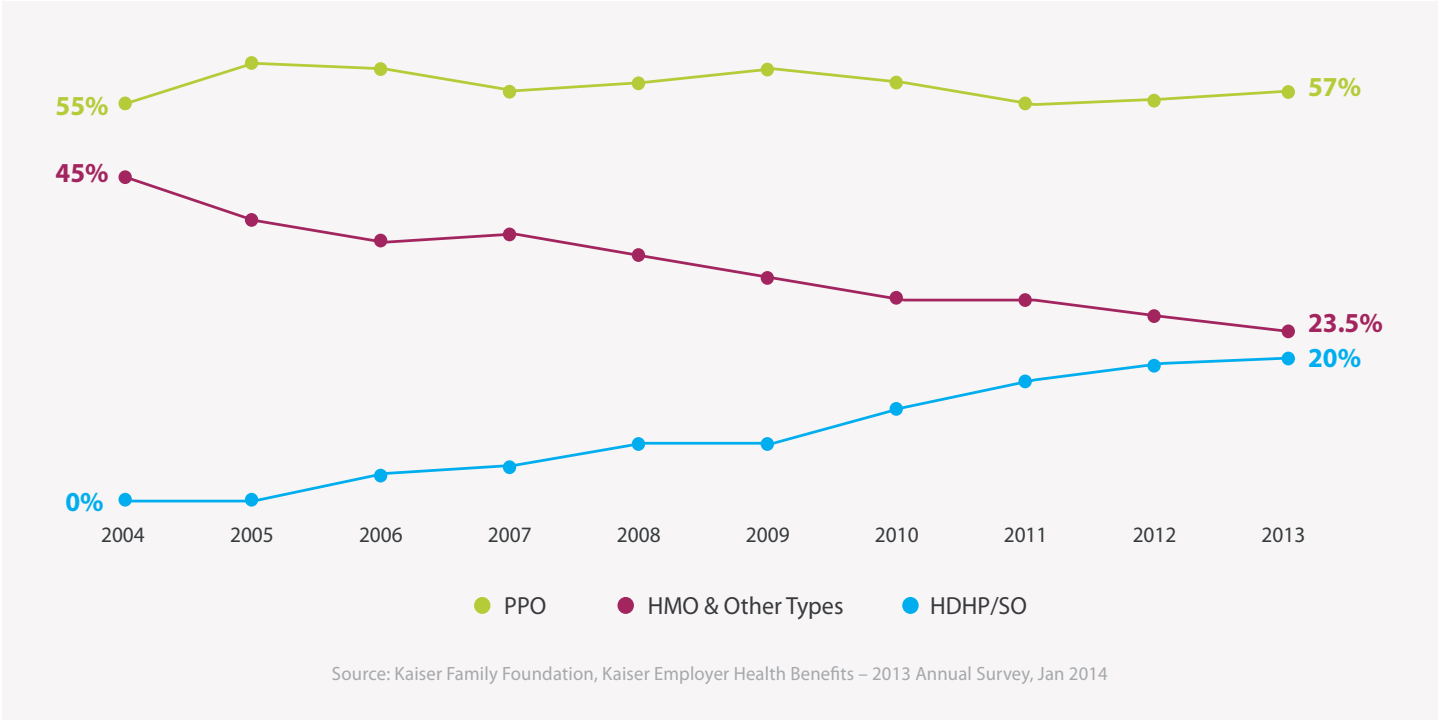
# Patient payment for healthcare and medicines

Patients with insurance are paying higher premiums, deductibles and co-pays or co-insurance for medicines despite cost reductions for many medicines, and offset by the introduction of zero co-pays for preventive medicines.

- Insurance coverage has been shifting to high-deductible plan designs over the past decade, now accounting for 20% of insured patients.
- Average deductibles, where patients see the full cost of their healthcare until they reach an insurance threshold, are up over 150% from five years ago.
- Plans with general deductibles, which can apply to both medical procedures and prescription drugs, now account for 78% of plans, and more than half of those plans have a deductible of $1,000 or more.
- Despite overall increases in out-of-pocket costs, prescription drug costs for most patients are actually declining, with more than half of all prescriptions costing less than $5, and 23% now available with zero out-of-pocket costs.
- 2013 saw a dramatic rise in the number of prescriptions with zero out-of-pocket cost, driven by common preventive medicines and including oral contraceptives for women.
- At the other end of costs, 30% of patient prescription out-of-pocket costs came from just 2.3% of prescriptions, often high-cost specialty medicines or seniors in the donut hole portion of their Medicare part D coverage.
- Prescription drug out-of-pocket costs vary widely by payment type, with Medicare Part D and Medicaid prescriptions costing beneficiaries much less than those with commercial insurance.
- Prescriptions are rejected by insurers or abandoned by patients 9% of the time on average, with the most common insurer reasons being formulary status, or refilling too soon.
- Many newer medicines offer patient savings programs or coupons to mitigate patient costs, often reducing out-of-pocket cost exposure to similar levels for generics in the same classes.

# Insurance coverage has been shifting to high-deductible plan designs over the past decade

**Percentage of workers by employer-based insurance type 2004-2013**




Source: Kaiser Family Foundation, Kaiser Employer Health Benefits – 2013 Annual Survey, Jan 2014

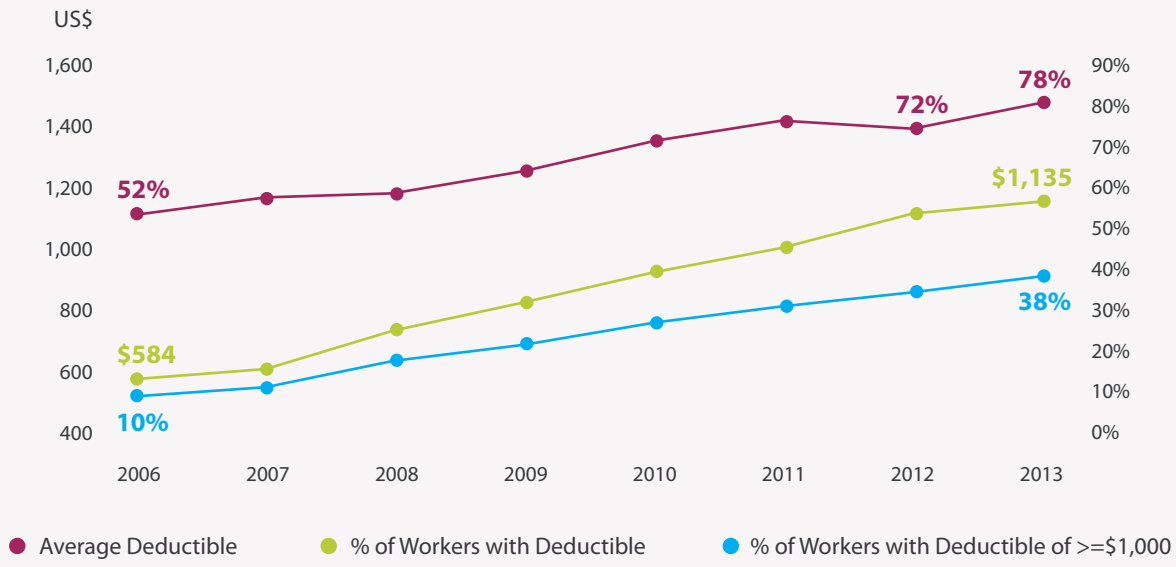
- PPOs remain steady as the largest type of insurance for employer-based coverage, fluctuating through a narrow range of 55 to 58% over the past decade and representing 57% of workers in 2013.
- High-deductible health plans (HDHPs) and those plans with savings options (Health Savings Accounts or HSAs) were introduced for the first time in 2006. They are characterized by lower insurance premiums than PPO plans, and they often have significant deductibles, where the beneficiary pays the full cost of healthcare services until they reach a level of spend where co-insurance begins to apply.
- HDHPs have historically been chosen by younger and healthier individuals. 20% of workers now have this type of plan.
- Employers are actively encouraging employees to choose HDHP plans and 17% of employers only offered high deductible plans in 2013 up 31% from 2012.
- Consumers' out-of-pocket spending tends to be influenced both by their health status and the insurance they choose and is measurably less with high deductible plans, perhaps because of the visible costs during the deductible period.
- HMO and other types have declined in popularity.

Chart notes:

HMO, Other includes HMO plans, which are 60% of the total, POS plans, and traditional plans which were dominant in the1980s but are now less than 1% of plan designs. HDHP/SO refers to high deductible plans and those high deductible plans that include a savings option such as a health savings account.

# Employees are increasingly choosing - or having chosen for them - plans with deductibles whose level is rising

### Employer-based insurance with deductibles 2006-2013

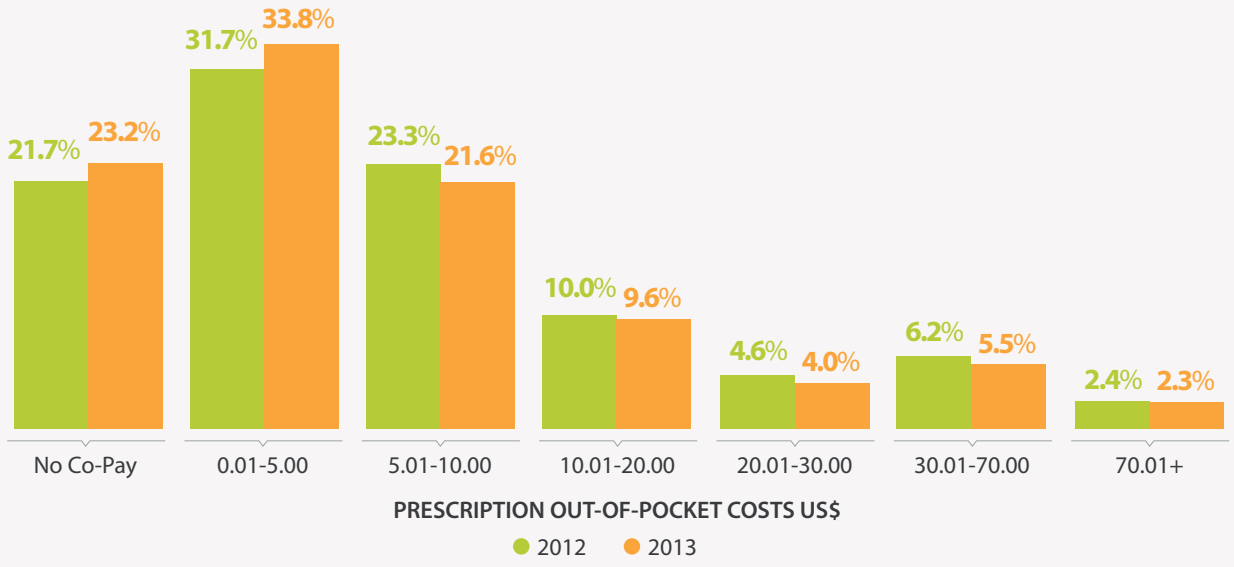



Source: Kaiser Family Foundation, Jan 2014

- Thirty-eight percent of employer-sponsored insured workers have a deductible of more than $1,000.
- Many of these may be in consumer-driven health plans, but traditional insurance is clearly migrating to higher deductibles as well.
- Deductibles rose more slowly in 2013 than in prior years.
- Plans are now increasingly offering in-network vs. out-of-network deductibles to further encourage usage of specific networks with negotiated lower costs and/or demonstrated better outcomes.
- In some cases the in-network deductible is less than half the amount of out-of-network.

# Free prescriptions now represent 23% of all prescriptions filled at the pharmacy, and more than three quarters of all prescriptions cost patients less than ten dollars

**Percent of retail dispensed prescriptions by out-of-pocket costs US$**




Source: IMS Health, Xponent PlanTrak Co-pay Dec 2013

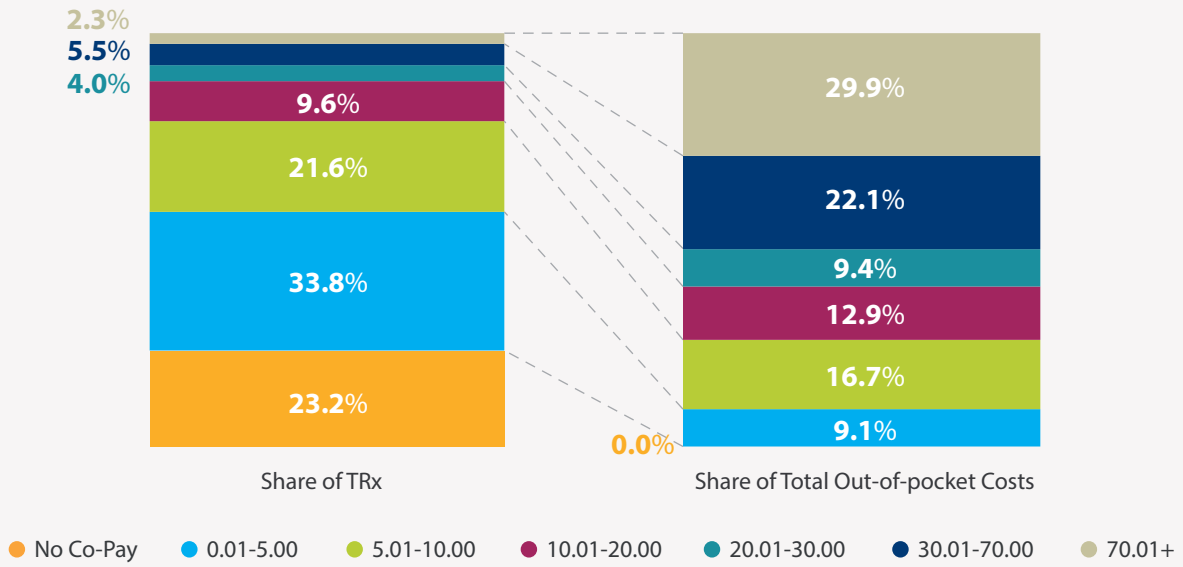
- More than half of all prescriptions cost $5 or less and one in five prescriptions have no co-pay.
- Low cost generics account for nearly all of the growth in prescriptions under $5.
- Patients saved an average of $0.63 on each prescription they filled in 2013 compared to 2012.
- Oral contraceptives account for the largest increases in prescriptions with no co-pay.
- Generics represent most of the prescriptions with out-of-pocket costs below $10, while brands more commonly have out-of-pocket costs above $20.
- For prescriptions with co-pays above $70, while only 2.3% of the total prescription volume, these patients pay a disproportionate amount of overall out-of-pocket costs.

Chart notes:

Out-of-pocket costs cover prescriptions dispensed at retail pharmacies for patients with private insurance, Medicare Part D, Medicaid, and include co-payments and co-insurance as relevant.

# Prescriptions with co-pays over $10 account for three quarters of patient out-of-pocket costs including 30% from the 2.3% of scripts costing more than $70

**Retail dispensed prescriptions by out-of-pocket costs US$**




Source: IMS Health, Xponent PlanTrak Co-pay Dec 2013

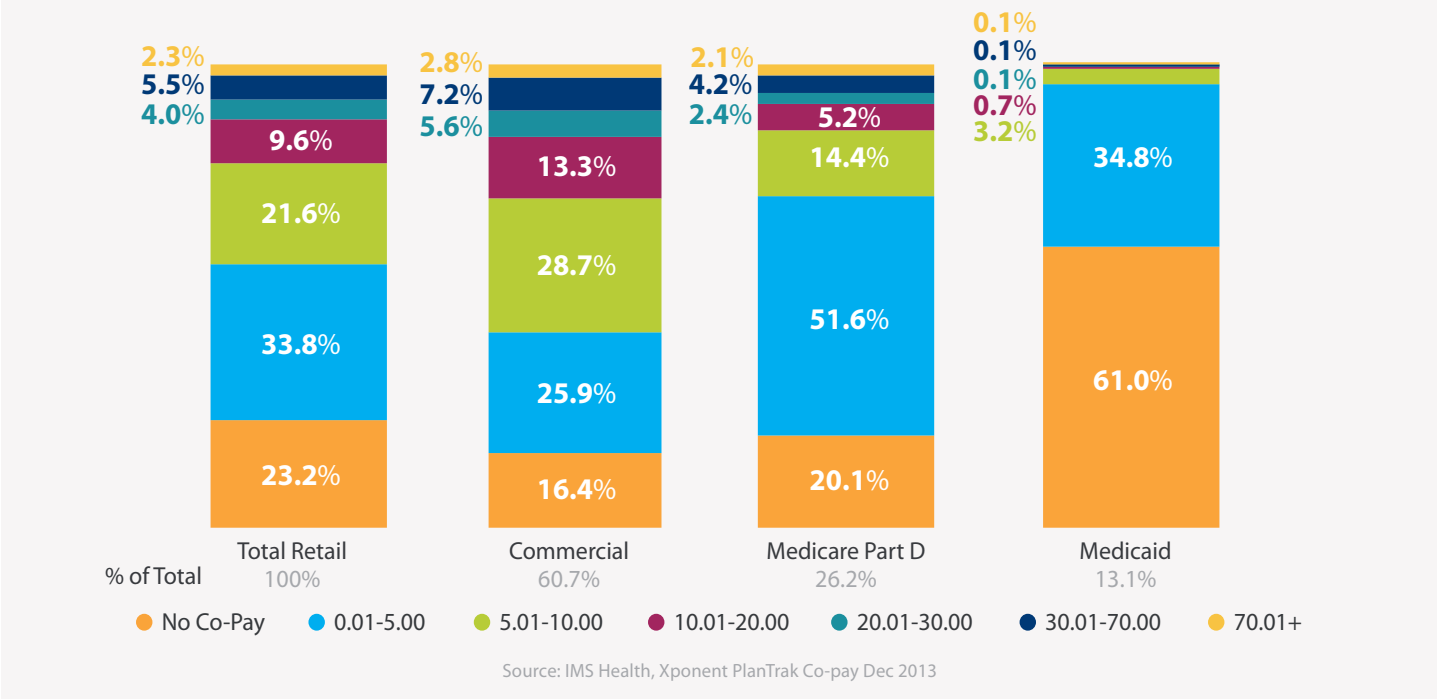
- For co-pays above $70, the average out-of-pocket cost was $145, 15 times higher than the national average.
- These top co-pays were only 2.3% of prescriptions, but accounted for 29.9% of overall out-of-pocket costs paid by patients. They are comprised mostly of co-insurance at set percentages, often 30-40% of high cost specialty medicines, many of which have no generics available in the same therapy area.
- Some plans cap patient out-of-pocket costs annually, or on a single prescription, limiting patients' exposure to higher costs.
- Plans with deductibles, or those who face the donut-hole in Medicare part D can see their costs vary widely during the year for the same medicines.
- Only 7.8% of prescriptions cost more than $30, and in total those patients paid over half of the total out-of-pocket costs.
- The lower cost of generic medicines is a key mechanism used by payers to encourage patients to choose generics over brands, and for the 57% of prescriptions where patients paid less than $5 a month, they only paid 9.1% of overall out-of-pocket costs.

Chart notes:

Out-of-pocket costs at retail pharmacies for patients with private insurance, Medicare Part D, Medicaid, and include co-payments and co-insurance as relevant. Out-of-pocket costs are calculated as the difference between the amount the primary insurer allowed the pharmacy to submit, and the amount left to patient responsibility. Secondary insurance or coupons are not accounted for in these calculations.

# Prescription drug out-of-pocket costs vary widely by payment type

**Percent of retail prescriptions by out-of-pocket costs US$ (2013)**



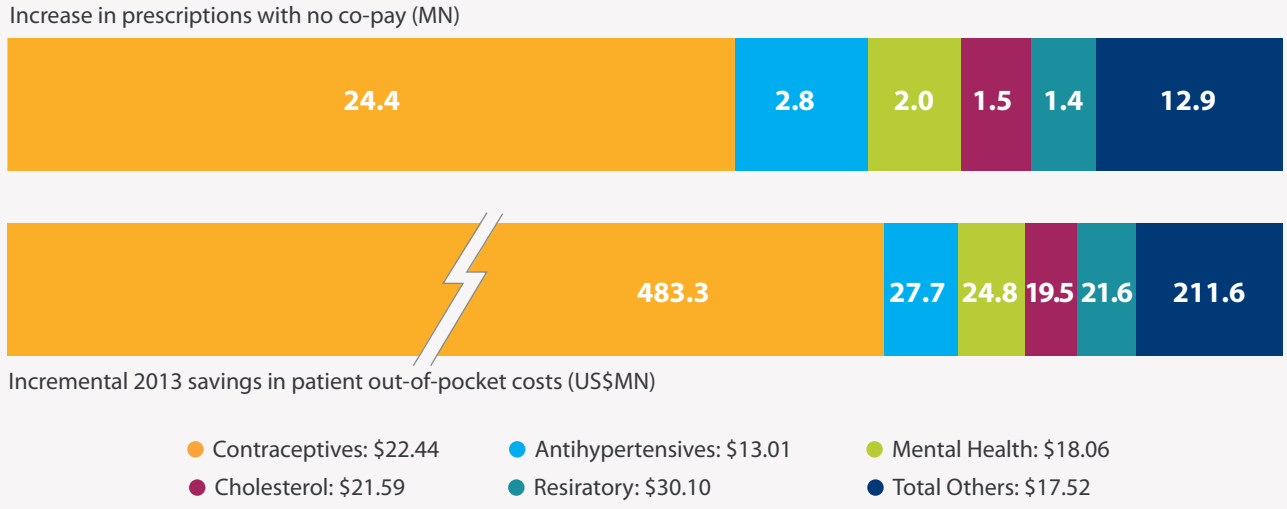

Source: IMS Health, Xponent PlanTrak Co-pay Dec 2013

- The average co-pay for 78.6% of all retail dispensed prescriptions was $10 or less.
- Commercially insured patients filled 60.7% of retail pharmacy prescriptions
- The commercially insured are the most likely to have co-pays over $5.00, partly due to their copayments for branded medicines which are typically $20 or more
- Medicare Part D prescriptions were substantially lower in cost with 86% costing patients less than $10 and only 6% costing more than $30.
- Medicare Part D patients face differing out-of-pocket costs depending on their donut hole status during the year.
- Medicaid prescriptions cost beneficiaries very little, with 95.7% costing less than $5 and 98.9% less than $10.
- Sixty-one percent of prescriptions filled by Medicaid beneficiaries have no co-pay.

Chart notes:
Out-of-pocket costs at retail pharmacies for patients with private insurance, Medicare Part D and Medicaid and include co-payments and co-insurance as relevant.

# Patients saved money on oral contraceptives and preventive drugs as no co-pay prescriptions increased significantly in 2013

## Savings on prescriptions with no co-pay for commercially insured in 2013




Source: IMS Health, Xponent PlanTrak Co-pay Dec 2013

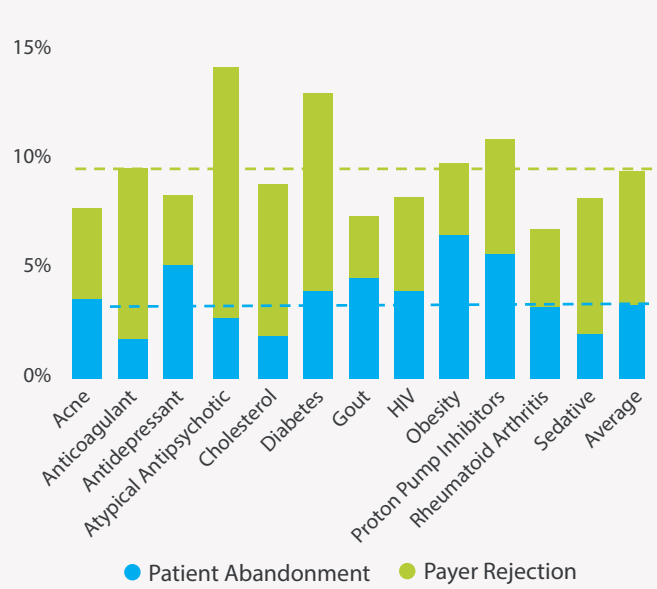
- The commercially insured filled 207 million prescriptions with no co-pay in 2013, an increase of 44.9 million prescriptions.
- Patients saved $789Mn on prescriptions with no co-pay compared to the average co-pay for those medicines in 2012.
- Seventy-three percent of the savings came from medicines for five chronic diseases.
- Patients taking medications in these 5 therapy areas filled 32 million additional no co-pay prescriptions, saving $577Mn in co-pay costs.
- The Affordable Care Act preventive care provisions, including zero co-pays for contraceptives, took effect in August 2012, but for most beneficiaries, they took effect with the new plan year in January 2013.
- Twenty-four million more prescriptions for oral contraceptives were filled with no co-pay than in 2012, saving women $483Mn, or an average of $269.
- The share of women with no out-of-pocket cost for these forms of birth control increased to 56% from 14% one year ago.
- Preventive care typically includes screenings, wellness checks, or anti-smoking treatments without cost sharing. The other therapy areas shown are mainly chronic treatments and while not directly preventive, they may be linked to generous insurance plans or value-based insurance designs which reward patients with lower co-pays for demonstrated adherence and other desirable behaviors associated with expensive chronic diseases.

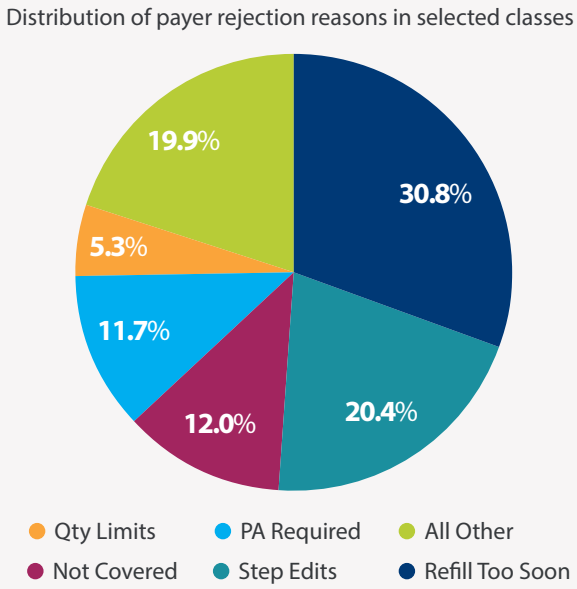
Chart notes:

Out-of-pocket costs at retail pharmacies for patients with private insurance. Savings reflect incremental brand and generic prescriptions with no co-pay. Co-pay amounts reflect average costs for all patients in 2012. Some plans are exempt from providing contraceptive coverage on religious grounds. Zero co-pays for for anti-smoking and contraceptives are covered by the act, other therapies are not directly covered and are shown for context. Chart not to scale.

# Almost 10% of the 3.6 billion retail prescriptions written by physicians are not dispensed to patients

**Percent of retail prescriptions abandoned, rejected and reasons for rejections, 2013**




Source: IMS Health, Formulary Impact Analyzer; Dec 2013

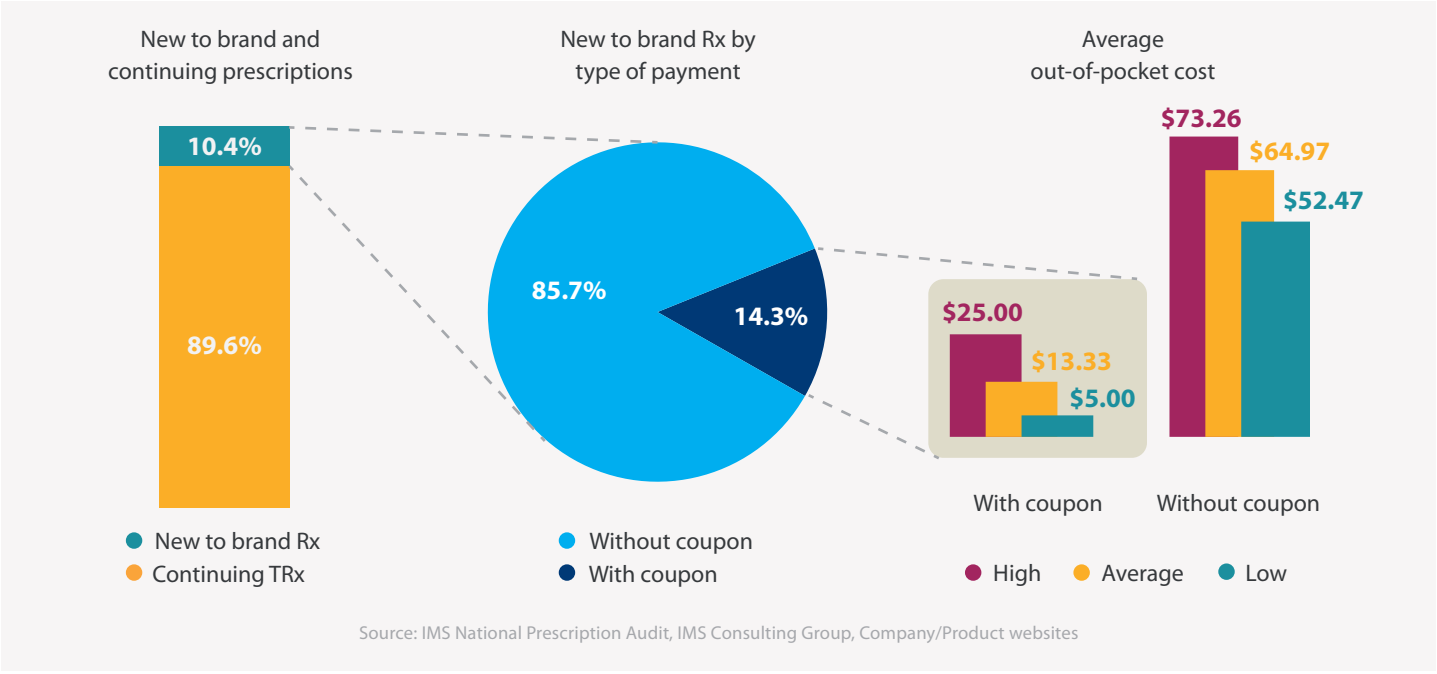
- In some cases, the prescriptions written by physicians are not dispensed in the pharmacy, either they are rejected by payers or abandoned by the patient.
- On average, patients abandon 3% of prescriptions at the pharmacy and insurers reject 6% for a variety of reasons.
- Rejected prescriptions are often replaced with another drug but this is not always the case.
- Among common chronic therapy classes, the rate of abandonment and rejection vary between 6 and 13%, averaging 9%.
- The most common reasons for insurer rejection, are formulary-based rules for a particular patient such as the drug not being covered, a requirement to use a generic prior to trying a branded drug, or requirement for prior authorization.
- These reasons are more commonly applied to prescriptions written for branded medicines and often result in generics being substituted for them.
- Convenience issues such as a patient attempting to refill multiple prescriptions at the same time can result in rejections for "refill too soon". Insurers typically allow a narrow buffer period of 2-3 days, although many allow pharmacists to override those rules directly or via automated phone-lines or internet forms.

Chart notes:

Payer rejections are captured in pharmacy point of sale systems and reported to IMS using standardized NCPDP rejection reasons. Patient abandonment reasons are not categorized in this report but are understood to relate most often to cost, and to convenience.

# In some therapy areas, branded product manufacturers offer patient assistance, coupon or savings programs, which can reduce out-of-pocket costs for eligible patients

## Selected newer generation diabetes brands




Source: IMS National Prescription Audit, IMS Consulting Group, Company/Product websites

- New prescriptions account for 10% and continuing patients make up the other 90% of prescriptions for these newer diabetes medicines, consistent with most therapy areas.
- Coupons are available for all of the newer generation diabetes brands, and are used on average 14% of the time for new patients, though this ranges from 9% to 43% for some of the products in the period analyzed.
- Out-of-pocket costs for branded medicines in diabetes were between $50 and $75, but coupons made that cost as low as $5.
- All of the companies marketing newer medicines in diabetes offer some form of assistance to patients, often limiting cost exposure to a set level per month, linked to eligibility criteria, but often limited to 12 or 24 months.
- These programs are not allowed for patients receiving government assistance but are increasingly common for commercially insured patients in therapy areas with higher out-of-pocket costs.

Chart notes:

"Out-of-pocket costs with card" are based on stated program amounts, not actual patient payments.

Chart based on YTD September 2013.

Brands included: Bydureon, Invokana, Januvia, Onglyza, Tradjenta, Victoza

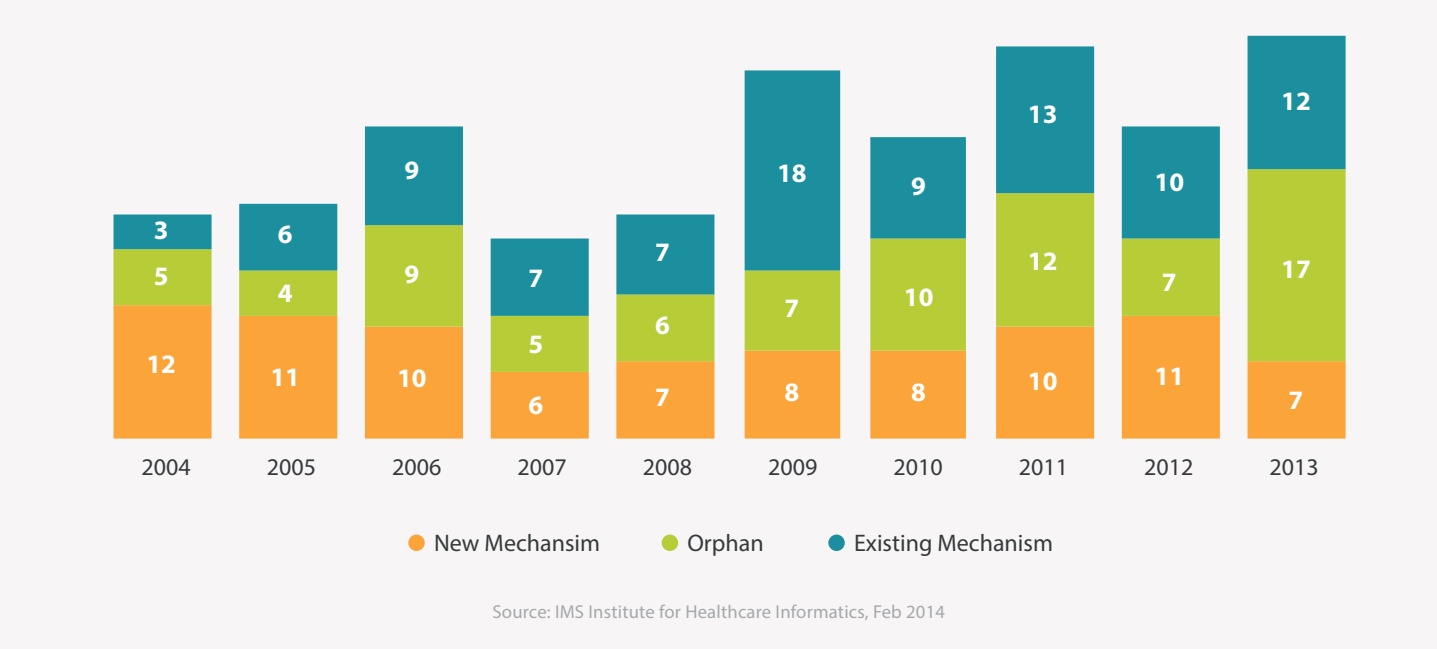
# Transformations in disease treatment

Drugs launched in 2013 demonstrate promise for a sustained volume of innovation, particularly in cancer, a faster pace of development for life-saving drugs, and hope for patients with rare and neglected diseases.

- There were 36 New Molecular Entity (NME) launches in 2013, up from 28 in 2012. Of the 36 launches, 24 were approved in 2013 and 12 were approved in the prior year, some launching 6-12 months after their approval.
- The largest number of orphan drugs – FDA approvals for rare diseases affecting less than 200,000 people in the U.S. – in 10 years were launched for diseases such as cystic fibrosis, pulmonary arterial hypertension, chronic myeloid leukemia, mantle cell lymphoma, and multiple myeloma, making more treatments available to treat those afflicted with rare and neglected diseases.
- In 2013, over 30 Breakthrough Therapy Designations – FDA's newly granted designation which fast-tracks drugs showing preliminary evidence of substantial improvement in patients with life-threatening disease – were granted and three drugs received Breakthrough approval, two for blood cancers and one for hepatitis C. Within those granted, 12 were for oncology, four in hepatitis C, two in both cystic fibrosis and autoimmune disorders, and several single designations for rare diseases.
- There were ten new cancer treatments launched, the most in over a decade, including treatments for blood cancers, melanoma, myeloma, breast and prostate cancers.
- A number of drugs addressing drug resistance in disease areas such as cancer, hepatitis C, and HIV were launched in 2013. This can be illustrated by an increase in progression-free survival by four months for HER2+ metastatic breast cancer patients in patients taking Kadcyla.
- Of the 23 new non-NME 2013 launches, eight were medicines with easier dosing, including an epinephrine auto-injector that talks the user through the process, once-daily formulations of diabetes drugs, an inhalable form of an antipsychotic drug, and a short three-day topical treatment for the prevention of skin cancer.
- Spending overall for new medicines launched within the prior 24 months dipped slightly in 2013 compared to 2012, but reflected an increasingly specialty and oncology group of launches representing over 60% of new medicines spending.

# The number of new molecular entities launched in 2013 is the highest in the last 10 years

**New molecular entities launched in the U.S. 2004-2013**




Source: IMS Institute for Healthcare Informatics, Feb 2014

- Thirty-six NMEs were launched in 2013, 24 of which had novel mechanisms or orphan indications, and eight more than the total in 2012.
- Launches in 2013 were strengthened by a high number of orphan approvals and the increase in applications and approvals for products seeking the new FDA Breakthrough Therapy Designation, signifying a shift towards expediting the availability of drugs to patients in critical need.
- In the last five years, 53 orphan drugs were launched, including 17 in 2013, compared with 29 in the prior five years.
- Of the 12 existing mechanisms, easier dosing for serious diseases was a major thrust of the product launches. This includes dimethyl fumarate (Tecfidera), an oral multiple sclerosis treatment, and the first drug for vitreomacular adhesion (Jetrea) approved as an alternative to surgery.

Chart notes:

New Molecular Entity (NME): A novel molecular or biologic entity or combination where at least one element is novel. NME launches in the U.S. by year of launch, regardless of timing of FDA approval.

New mechanism: First product with a new mechanism of action for its FDA approved indication.

Existing mechanism: Subsequent products with an existing mechanism of action for an indication, including novel biologics that are similar to existing biologics, including Neutroval.

Orphan: Drugs with one or more orphan indications approved by FDA at launch.

# Last year saw the largest number of new orphan drugs in a single year, more than double the number launched in 2012

The record-breaking number of orphan drugs launched last year brought improved quality of life, addressed previously unmet needs, and treatments for so-called "ultra-orphans" which affect a few hundred to a few thousand people.

Among the most notable developments were:

**Quality of life (QoL):** A remarkable improvement over the previous treatment, tobramycin inhalation powder (Tobi Podhaler) introduces the first dry powder inhalable antibacterial for the treatment of pseudomonas aeruginosa (Pa) bacteria in the lungs of cystic fibrosis (CF) patients. Affecting 80% of CF patients, Pa was previously treated through use of a nebulizer, requiring burdensome storage and administration conditions. Another vast QoL advance was introduced with the new short bowel syndrome drug teduglutide (Gattex). Prior treatment included intravenous fluids and parenteral nutrition for up to 12 hours each day, whereas teduglutide is a once-daily subcutaneous injection.

**Unmet need:** The approval and launch of pasireotide diaspartate (Signifor) is a significant step forward in the medical management of Cushing's disease. The first pituitary-directed agent approved for use in Cushing's disease, it is approved to treat benign pituitary tumors resulting in the overproduction of cortisol in the body. Pasireotide diaspartate is a twice-daily injection treatment for those for whom surgery is not an option. The biologic prothrombin complex concentrate (PCC; Kcentra) was approved for use in the urgent reversal of major bleeds that may occur in people taking drugs like warfarin to prevent clotting. The PCC does not have to be typed as plasma currently does and can be administered more quickly in the event of an emergency whereby a clotting factor is needed to prevent major bleeding.

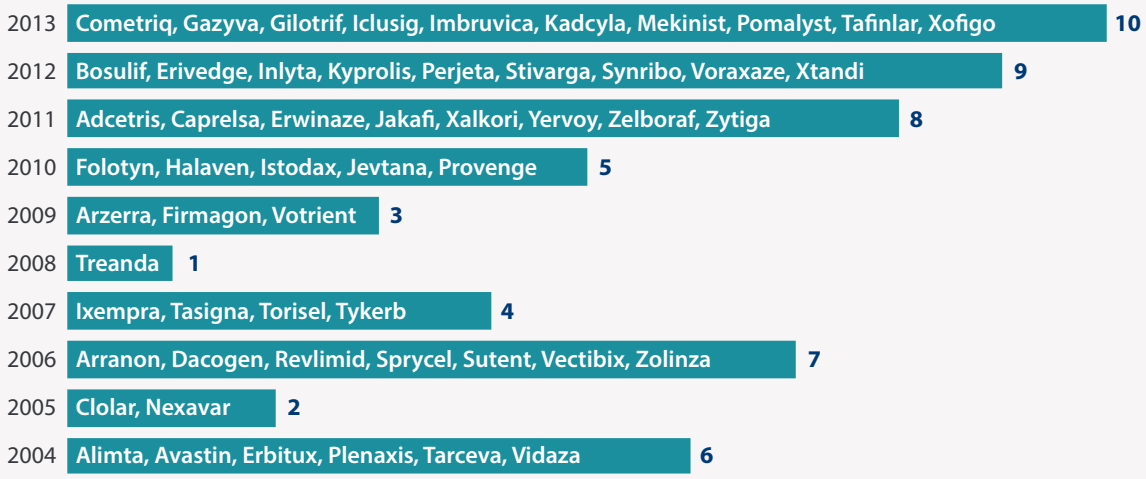
**"Ultra-orphans":** Affecting only a few thousand patients a year, a total of seven ultra-orphan drugs were launched in 2013 targeting high cholesterol, hypertension, hemophila, tuberculosis and cancer. Two drugs (mipomersen sodium and lomitapide mesylate) were approved for homozygous familial hypercholesterolemia (HoFH), a rare genetic condition resulting in near-lethally high levels of cholesterol. Two drugs for pulmonary arterial hypertension (PAH) were approved, a condition of high blood pressure from the arteries to the lungs. For hemophilia B (rixubis), the first new recombinant factor IX drug in more than 15 years launched, and it is the only drug approved for both prophylactic and episodic treatment of hemophilia B. A medicine for multi-drug resistant tuberculosis (bedaquiline) was approved, providing a treatment option where there are few remaining. A cancer drug (ponatinib) was approved for CML or Philadelphia-chromosome positive acute lymphoblastic leukemia (ALL).

Notes:

Ultra-orphan has no standard definition. For this report we assumed <10,000 patients in the U.S

# The number of new oncology medicines continues to increase

## Oncology NMEs launched in the U.S. 2004-2013




Source: IMS Institute for Healthcare Informatics, Feb 2014

- The 10 oncology NMEs launched in 2013 is the most in a decade and a continuing increase over the low point of 2008 which saw only one launch.
- The last 5 years have seen 35 new cancer treatments – of which 30 are targeted therapies – across a range of tumors, bringing significant new treatment options to millions.
- One major headliner in 2013 was obinutuzumab (Gazyva), the first FDA Breakthrough Designated Therapy, for the rare blood cancer, chronic lymphocytic leukemia (CLL).
- New treatments included new medicines and additional uses for existing treatments in acute lymphocytic leukemia (ALL), breast cancer, chronic myeloid leukemia (CML), myeloma, melanoma, non-Hodgkin's lymphoma (NHL), non-small cell lung cancer (NSCLC), and thyroid cancer.

Chart notes:

New Molecular Entity (NME): A novel molecular or biologic entity or combination where at least one element is novel.

NME launches in the U.S. by year of launch, regardless of timing of FDA approval.

Drugs are listed in alphabetical order.

Oncology NME launches include therapeutic oncology treatments, and exclude supportive care and diagnostics.

# There were a number of major oncology advances in 2013

Last year saw a number of major advances in cancer treatment including more targeted individual therapies, greater presence in the immunotherapy space, and approval of companion diagnostics seeking to accurately identify patients who will benefit from approved targeted drugs.

**Chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL):** Receiving the FDA's first Breakthrough Therapy Designation, obinutuzumab (Gazyva) was approved as a first-line treatment for CLL. Offering substantial improvement, when used with chlorambucil the combination aids the immune system in attacking cancer cells. The drug was found to more than double progression-free survival compared to chlorambucil alone.

First approved for MCL with an FDA Breakthrough Therapy Designation late in 2013, ibrutinib (Imbruvica) also received accelerated approved for CLL in February 2014. Imbruvica is highly efficacious in both treatment-experienced (including 3-4 previous therapies) and treatment-naïve patients with B-cell lymphoma. Imbruvica attacks malignant B-cells and leaves healthy immune cells alone, maintaining a healthier immune system throughout the course of treatment. Considered a "patient-friendly drug," Imbruvica has shown high effectiveness, low toxicity, and ease of administration.

**Breast cancer:** In February 2013, the FDA approved the "smart bomb" for metastatic breast cancer, ado-trastuzumab emtansine (Kadcyla). Targeting the aggressive human epidermal growth factor receptor 2 (HER2)-positive breast cancer, the drug was approved for patients with locally advanced or metastatic disease or recurrence, who have previously been treated with trastuzumab (Herceptin) and a taxane. The cytotoxic agent mertansine is delivered by way of the HER2-binding antibody trastuzumab, directly targeting cells expressing HER2 genes and lowering toxicity to surrounding healthy cells. One study demonstrated almost double progression-free survival (6.2 months) for patients taking Kadcyla over other therapies (3.3 months).

**Non-small cell lung cancer (NSCLC):** Targeting metastatic lung cancers that have the gene mutation epidermal growth factor receptor (EGFR), afatinib (Gilotrif) stops cell growth. NSCLC accounts for 85% of lung cancers, which is the leading cause of cancer death in men and women. Gilotrif demonstrates greater progression-free survival in patients with EGFR mutations and was approved with a companion diagnostic test to screen for the EGFR mutation in patients' tumors.

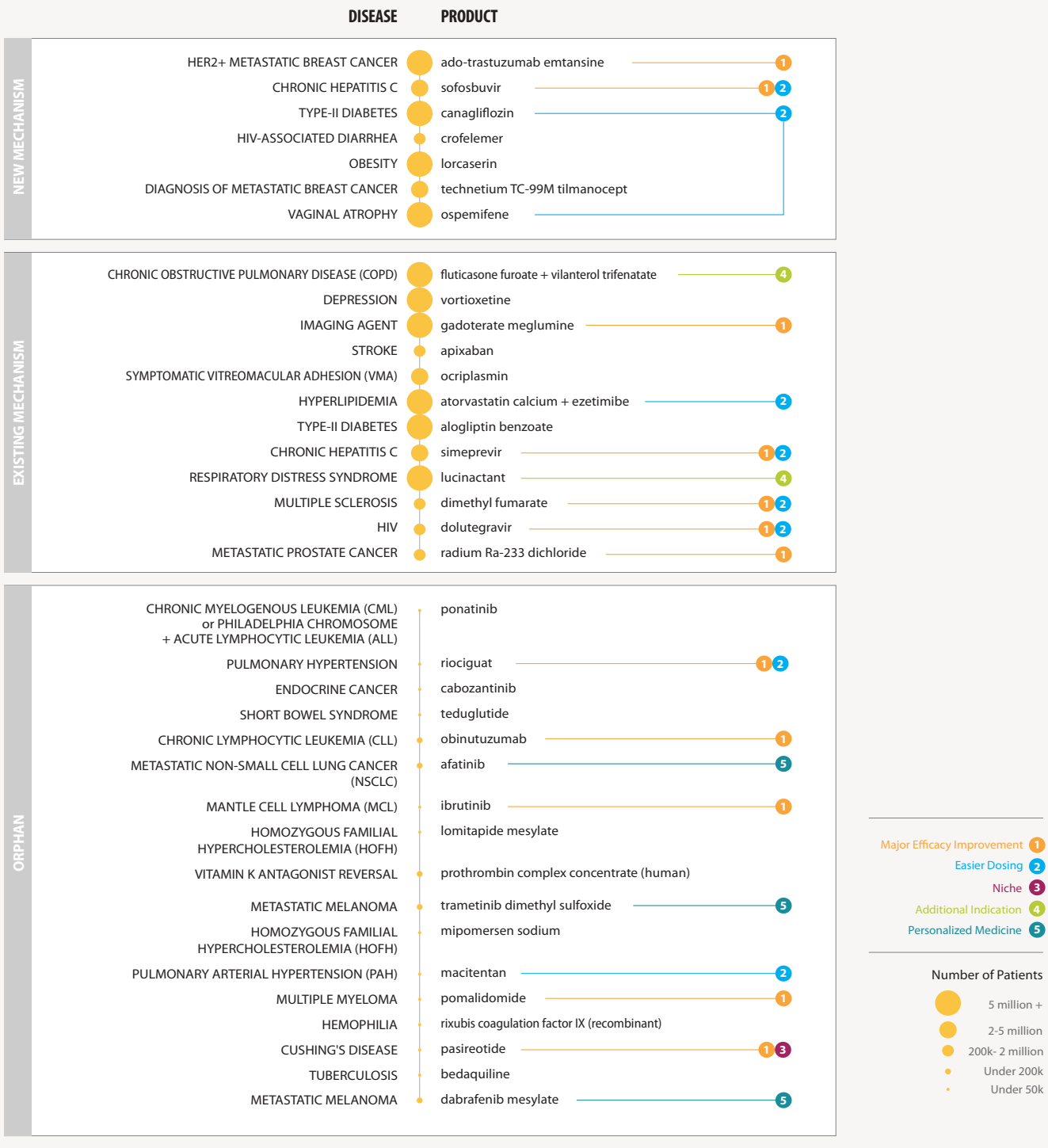
**Melanoma:** Both trametinib and dabrafenib (Mekinist and Tafinlar) were approved for the treatment of metastatic melanoma, the most aggressive form of skin cancer. In January 2014, the two were approved for combination treatment of unresectable or metastatic melanoma. They are indicated for tumors expressing specific BRAF gene mutations (40% of tumors have BRAF mutations). Approval of a companion diagnostic, the second BRAF companion, shows continued therapeutic and diagnostic collaborative efforts.

**Multiple myeloma:** Approval of orphan drug pomalidomide (Pomalyst) for blood cancer offers a new option for patients who have not responded to other drugs. Improved overall survival and increased progression-free survival were seen in patients no longer responding to lenalidomide (Revlimid) or bortezomib (Velcade). The immunomodulatory drug received accelerated approval, giving patients with disease progression earlier access to the third line drug.

Notes:
BRAF is a human gene that makes the protein called B-Raf, which can increase the growth of cancer cells.

# A large number of orphans and drugs with major efficacy improvements were launched

## New molecular entities launched in 2013



# 2013 saw many new formulations and additional uses of existing medicines, especially easier dosing options

## Other new medicine launches in 2013

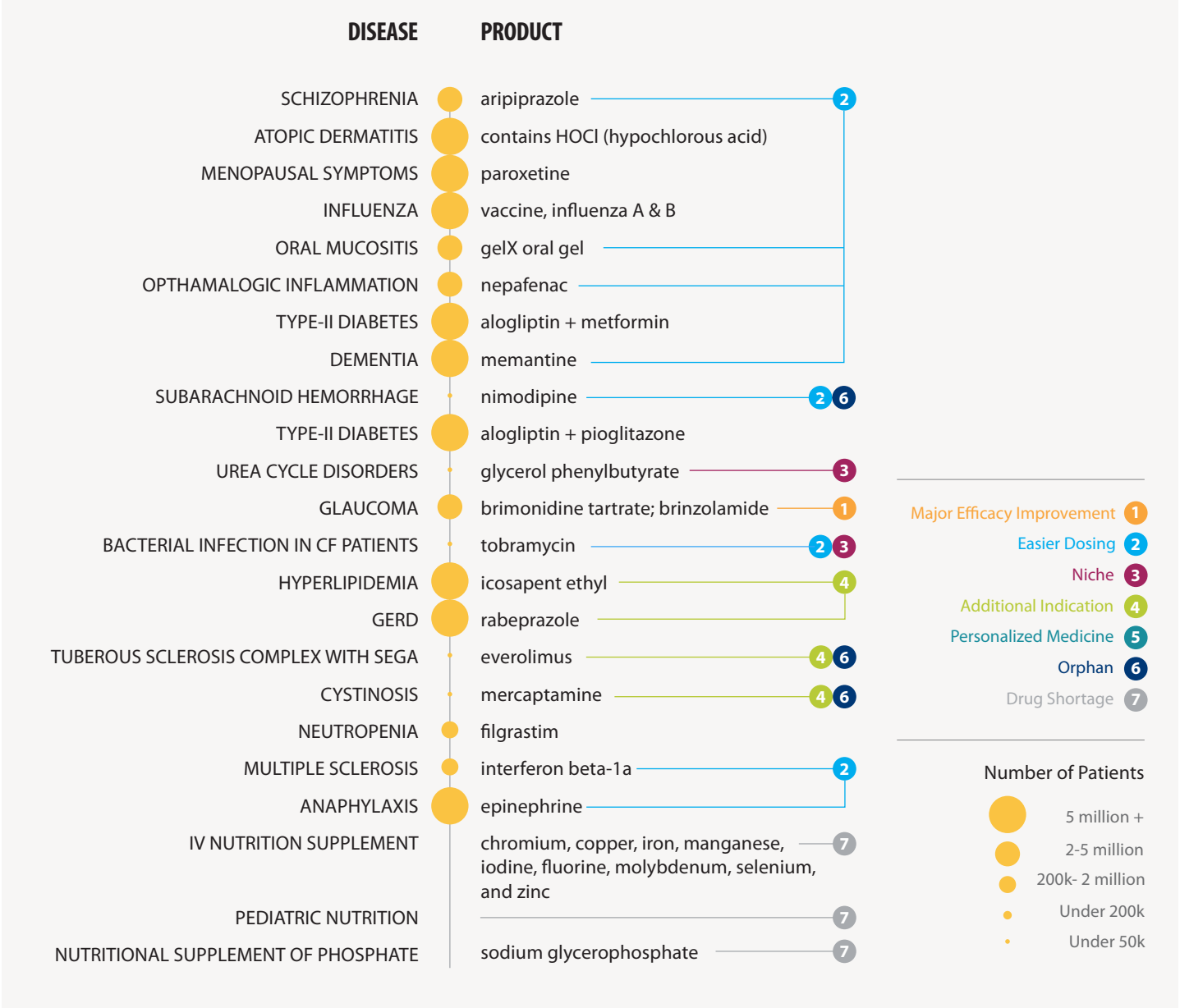



Chart notes:

Patient population estimates based on published literature and intended to represent the total disease population for which the medicine is indicated.

FDA Orphan drugs designations are granted for major improvements for patient populations under 200,000.

Niche indicates smaller patient populations where orphan status was not granted by FDA.

# Some key breakthrough therapies became available for the first time in 2013

New medicines launched last year brought improved efficacy, safety and convenience for diseases affecting patient populations as small as a few hundred with a rare genetic variant of cystic fibrosis to millions battling the most common forms of skin cancer.

Among the most notable developments were:

**Hepatitis C: sofosbuvir and simeprevir (Sovaldi, Olysio).** A new wave of hepatitis C drugs hit the market in 2013, Sovaldi notably eliminating interferons from the treatment regimens of 2 genotypes completely. The drugs shorten treatment time and produce a better response rate than the current drug regimens.

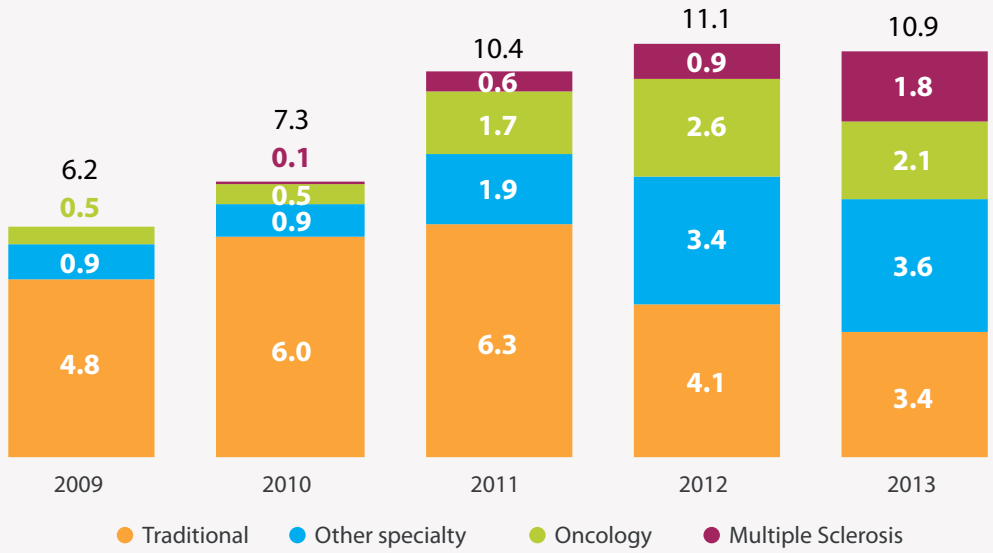
**HIV: dolutegravir (Tivicay).** In August 2013, the FDA approved the use of Tivicay in combination with other antiretroviral agents for adults and children older than 12, treatment-experienced and treatment-naïve, infected with HIV. The once daily drug works to block the virus from entering cells and has a price point comparable to the combinations currently on the market.

**Type 2 diabetes: canagliflozin (Invokana).** Invokana is the first sodium glucose co-transporter 2 (SGLT2) inhibitor to be approved in the U.S. In head-to-head clinical trials, Invokana produced larger reductions in blood glucose levels than sitagliptin (Januvia), the most highly prescribed of the two most novel classes of diabetes therapies. Invokana is the only oral diabetes product that not only improves glycemic control but reduces blood pressure and weight.

**Multiple sclerosis: dimethyl fumarate (Tecfidera).** Tecfidera is the third oral treatment for MS in a market that has been dominated by several injectables, but is expected to become one of the leading therapies for this indication. Being an oral therapy, Tecfidera is more convenient than the injectables that are the mainstay of treatment. Additionally, injectables have MS relapse/flare-up reduction rates of around 30% compared to Tecfidera's 44-53% reduction rate. Tecfidera also has significant relapse reduction advantages over the other two orals on the market.

# Specialty drugs, including new treatments for multiple sclerosis and cancer, drive new brand spending

## New brand spending US$Bn




Source: IMS Health, National Sales Perspectives, Jan 2014

- New brand spending totaled $10.9Bn in 2013, a slight decline (-1.8%) from 2012.
- Spending on new specialty medicines increased 7.7% to $7.5Bn in 2013, and now account for 69% of new brand spending.
- The five largest drivers of new specialty product spending were dimethyl fumarate (Tecfidera) for multiple sclerosis, elvitegravir (Stribild) for HIV-1, interferon beta-1a (Avonex Pen) for multiple sclerosis, ado-trastuzumab emtansine (Kadcyla) for HER2+ metastatic breast cancer and carfilzomib (Kyprolis) for multiple myeloma.
- New treatments for multiple sclerosis accounted for 19% of new brand spending in 2013.
- Spending on new medicines represented 4.1% of total brand spending in 2013.
- There were 36 NMEs launched in 2013 including 20 specialty medicines.
- The December 2013 launch of sofosbuvir (Sovaldi) is the first of several highly anticipated new treatments for hepatitis C.

Chart notes:

New brands defined as brands launched in the prior 24 months including products which are New Molecular Entities (NME) as well as other branded medicines.
Numbers rounded in chart above. New molecular entities include both small-molecules and biologic medicines.
Chart has been adjusted to reflect estimated spending for recently launched products where they are understood to be under-reported by IMS.

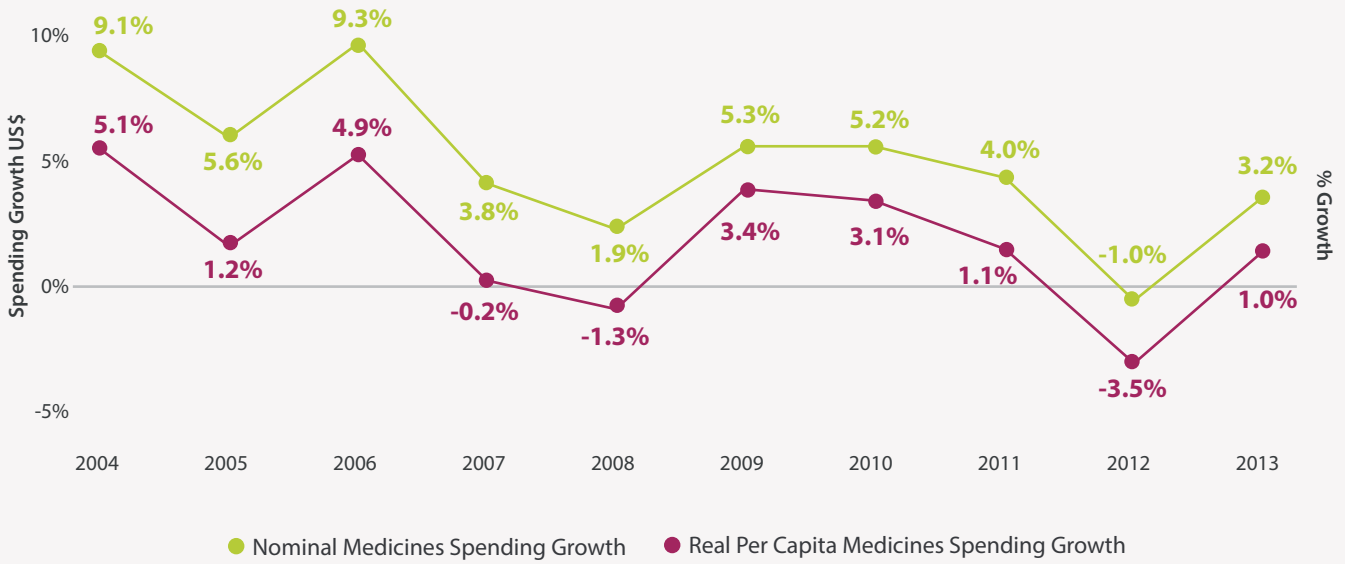
# Spending on medicines

Total spending on medicines on a real per capita basis grew by 1%, as a result of declining use of branded drugs, higher levels of price increases, increased spending on new medicines, and fewer offsetting declines from patent expiries.

- Nominal spending on pharmaceuticals reached $329.2 billion in 2013, an increase of 3.2%, up from a decline of -1.0% in 2012.
- Real per capita spending increased 1.0% in 2013 compared to a decline of 3.5% in 2012.
- Overall spending increased in 2013 largely due to lower patent expiry impact than in 2012, and higher contribution from brand price increases.
- The impact of patent expiries in 2013, $19Bn, was dramatically lower than the $29Bn in 2012 both because of smaller and fewer 2013 expiries, and the roll-off of 2011 and 2012 expiries in the first half of 2013.
- Overall spending increased in 2013 largely due to therapy classes with recent innovation and continued growth from classes not facing significant patent expiries.
- Pricing growth continues at historic levels and is offset by increasing off-invoice discounts and rebates.
- In 2013, generics reached 86% of dispensed prescriptions, and spending in this segment grew by $5.8 billion.
- Overall spending on medicines continued to be concentrated in traditional small-molecule pills dispensed through retail pharmacies, even as higher growth was seen in biologics and specialty drugs – particularly in retail and mail settings.
- The leading ten therapy areas accounted for over 55% of spending on medicines in 2013, led by oncology with $27.9Bn, an increase of 9.2% over the prior year.
- Among the largest therapy classes, diabetes, autoimmune diseases and multiple sclerosis all had spending growth greater than 10%, driven by recent innovations. Mental health, respiratory, lipid regulators and antihypertensives all declined by more than 5% in 2013, mostly due to patent expiries and a lack of newer medicines in these classes.

# Spending on medicines grew by 3.2% in 2013 or 1.0% on a real per capita basis

### Nominal and real per capita spending growth 2004-2013




Source: IMS Health, National Sales Perspectives, Jan 2014; U.S. Census Bureau Jul 2013; Economist Intelligence Unit Nov 2013

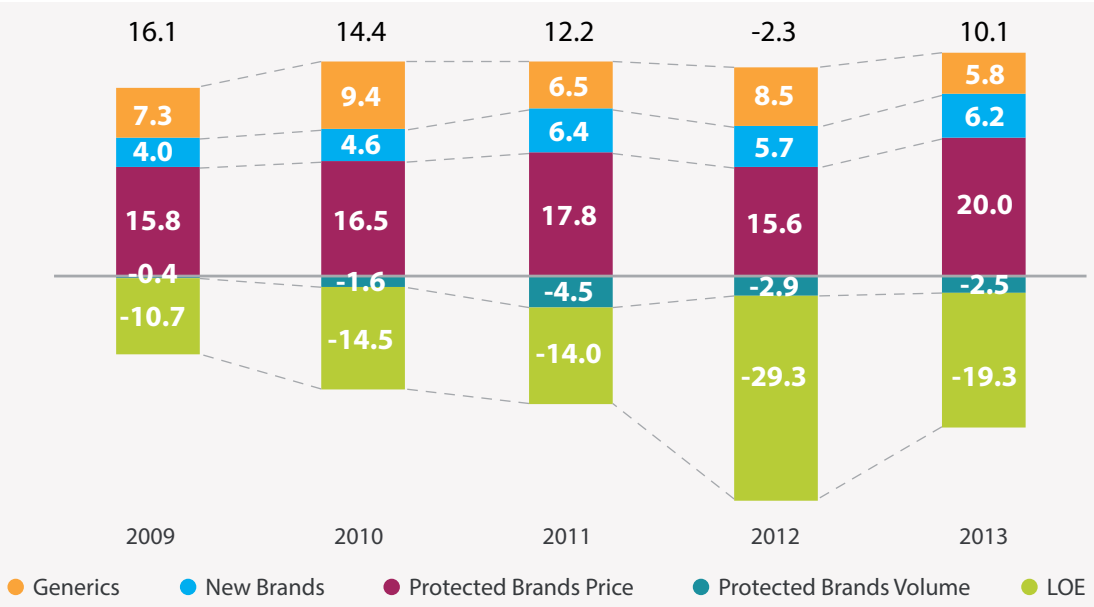
- On a real per capita basis, spending on prescription medicines grew by 1.0% in 2013. The growth was 3.2% on a nominal basis.
- The higher level of nominal spending growth in 2013 reflects the reduced impact of the losses of patent protection in recent years, a modestly higher level of per capita utilization of the healthcare system, and spending on newer medicines.
- When measured in 2005 dollars and adjusted for population growth, medicine spending has been growing at historically low levels, for most of the last decade.
- The return to nominal spending growth in 2013 is not yet a reflection of the access expansions and insurance reforms from the Affordable Care Act, but rather a reflection of cyclical patterns of patent expiries.
- Higher spending growth in 2004 was associated with a period of substantial innovation in medicines, whereas 2006 was linked to the implementation of Medicare Part D drug coverage for seniors.

Notes:

Measures total value of pharmaceutical spending, including generics, branded products, biologics, small-molecules, retail and non-retail channels.
Value measured at Trade Price – the price paid to wholesalers or manufacturers by retail and non-retail channels and excluding off-invoice discounts and rebates that lower net prices received by manufacturers. Real per capita adjustments based on data from U.S. Census Bureau and U.S. Bureau of Economic Analysis.
Statistically significant sample change in IMS National Sales Perspectives in 2013, retrospective to January 2012. Growth rates for 2012 are as first reported in the IMS Institute Report "Declining Use and Costs: For Better or Worse?" published June 2013.

# Overall spending increased in 2013 largely due to lower patent expiry impact than in 2012, and higher contribution from brand price increases

**Components of change in total spending US$Bn**




Source: IMS Health, National Sales Perspectives, Jan 2014

- Total spending on medicines increased from $319.1Bn in 2012 to $329.2Bn in 2013.
- The decline in the volume of protected branded products reduced spending in 2012 by $2.5Bn compared to 2012.
- Increases in the pricing of protected branded products – without consideration to off-invoice discounts or rebates – raised spending by $20Bn.
- Brands losing patent protection or exclusivity, in 2013 or previously, resulted in a reduction in spending of $19.3Bn, $10Bn less than the prior year.
- Spending growth for new brands was $6.2Bn in 2013 compared to $5.7Bn in 2012.
- Spending on generics – including both volume and price effects – increased by $5.8Bn in 2013 compared to the $8.5Bn increase in 2012.

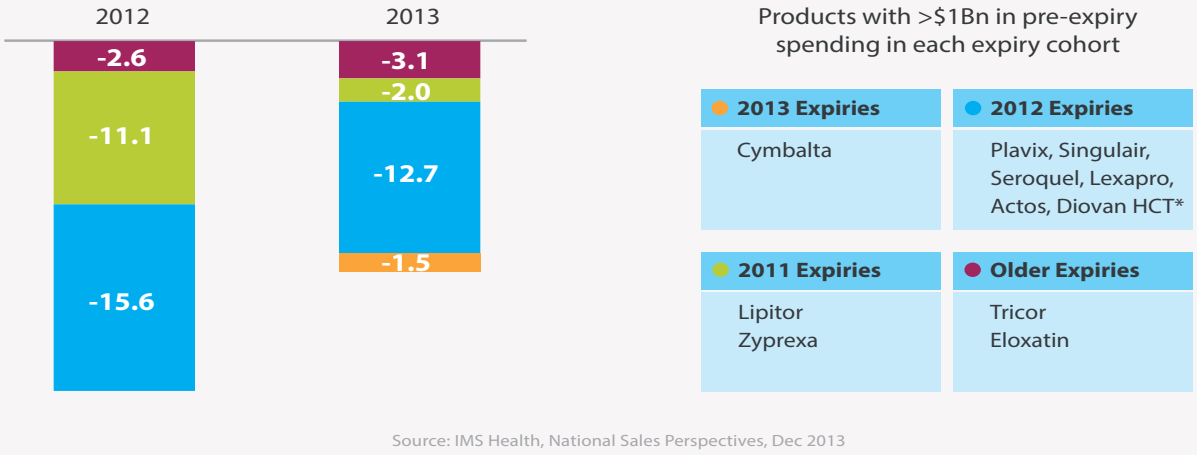
Chart notes:

Segments are mutually exclusive and membership is defined on a monthly basis prior to aggregation into years. Growth is calculated on a monthly basis and aggregated into segments by year.

Protected brands (brands that have not reached patent expiry) have been split based on growth through pricing dynamics and volume (absent pricing dynamics). New Brands segment includes all new products launched in the 24 months prior to the reporting month. Generics segment includes unbranded generics and branded generics. LOE – Loss of Exclusivity – includes branded products that lost patent exclusivity during 2012 or previously.

# The impact of patent expiries in 2013 has been dramatically lower than in 2012 both because of smaller and fewer 2013 expiries, and the roll-off of 2011 and 2012 expiries in the first half of 2013

**Drivers of loss of exclusivity negative brand growth US$Bn**




Source: IMS Health, National Sales Perspectives, Dec 2013

- While patent expiries typically result in dramatic shifts of prescriptions to the generic often within just 6 weeks, many brands are subject to Hatch-Waxman paragraph IV patent challenges which grant the generic challenger(s) 6 months of exclusivity as a reward for their legal challenge.
- Generics typically avoid deep pricing deflation in these circumstances, thus delaying the impact on overall spending.
- For expiries without a paragraph IV exclusivity, the pricing and prescription impact are equally rapid and spending declines much more immediately. In 2011 and 2012 several expiries included generics with 180-day exclusivities which delayed the full impact on spending until the first half of 2013 including Lipitor and Zyprexa.
- 2013 expiries have been much more muted than prior years, with Cymbalta the only $1Bn product expiring in the year, when it did so in December.

Chart notes:

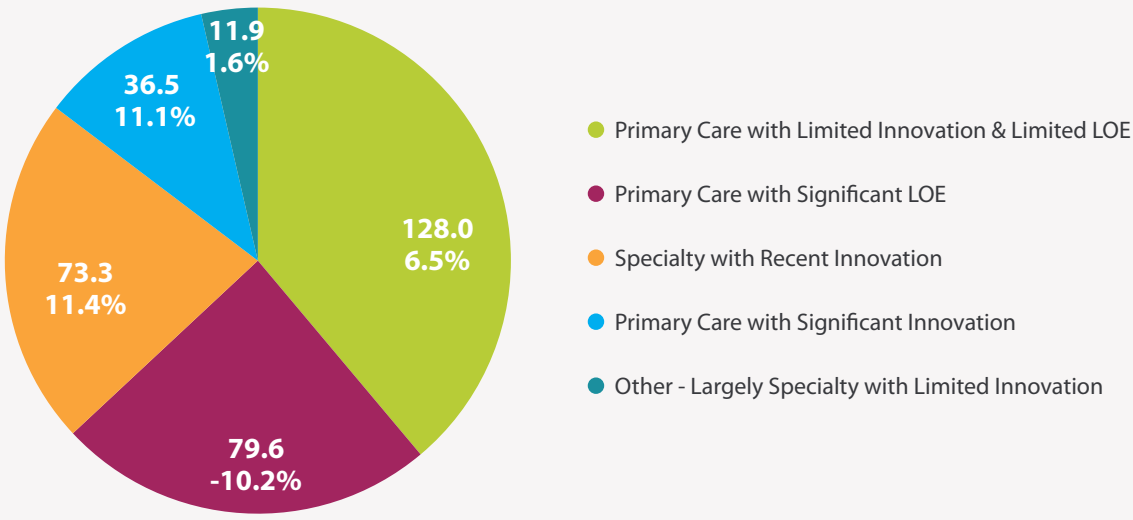
LOE – Loss of Exclusivity – includes branded products that have lost patent exclusivity and faced generic competition to date. Loss of exclusivity year is determined primarily by patent expiry date, but adjusted when expired brands do not face generic competition.

*Diovan lost patent protection in 2012 but has failed to face generic competition, while the fixed-dose combination with hydrochlorothiazide has faced generic competition.

Named products are brands which had pre-expiry spending of >$1Bn.

# Overall spending on medicines can be segmented based on different growth dynamics of therapy classes

**2013 spending by therapy segment US$Bn and % growth over 2012**




Source: IMS Health, National Sales Perspectives, Jan 2014

- Spending on medicines can be segmented by therapy area into classes which demonstrated very different dynamics around innovation and patent expiry.
- The largest group of classes, representing 39% of spending, had very limited levels of new medicines introduced, and very few patent expiries.
- A number of widely used medicines in the primary care setting faced patent expiry over the past 2-3 years and when grouped together these classes represented $79.6Bn in spending in 2013, down 10.2% from 2012.
- The group of specialty classes where many recent innovations have occurred, including oncology, MS, hepatitis C, HIV and treatments for age related macular degeneration collectively contributed $73Bn to spending in 2013, up 11.4% from the prior year.
- Clusters of innovation in primary care treatments including diabetes, gastrointestinal products, obesity, urinary incontinence and novel formulations for Alzheimer's treatments in aggregate generated spending of $36Bn, and these grew by 11.1%.

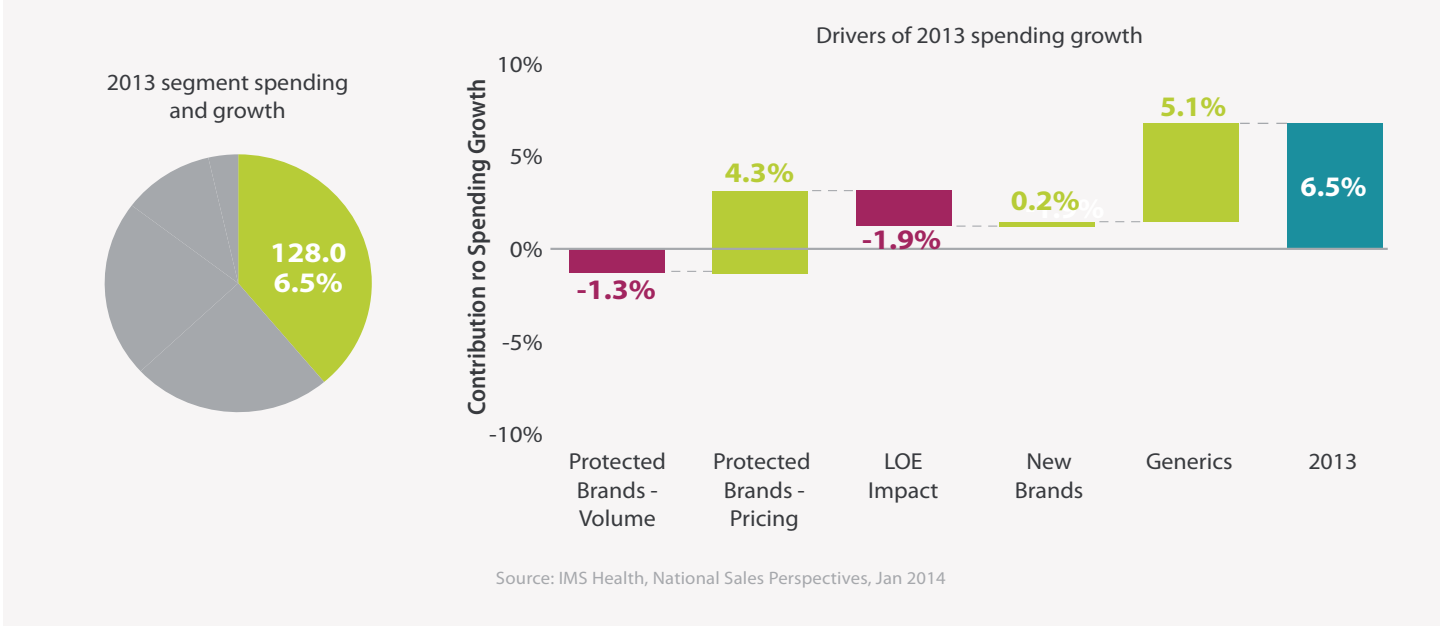
Chart notes:

Segments are mutually exclusive and reflect the spending and change in spending between 2012 and 2013 in billions of dollars.

Segments have been defined by the relative contribution to spending growth from particular product-types. Segments reflecting limited innovation can include new products, though this will be a smaller contribution to class growth. Classes with significant innovations are classed together, regardless of their size in the market.

# In primary care therapy classes with limited innovation and few expiries, growth came from pricing and generics

## Primary care with limited innovation and limited LOE




Source: IMS Health, National Sales Perspectives, Jan 2014

- Nearly 40% of spending on medicines occurs in 45 therapy areas which currently don't have any major patent expiry events or substantial innovation entering the market.
- Spending in these classes in aggregate grew by 6.5%, to $128Bn in 2013 mostly from generics.
- Generic growth contributed 5.1% to overall growth in these classes, nearly half of which was due to generic price increases for single-source generics, which averaged 13.6% price increases, compared to 9.6% average price increases for generics in this segment.
- Protected brand prices increased in this group of classes by an average 11.5%.
- Of the therapy areas included in this segment, only dermatology, nervous system disorders and pain contributed more than $1Bn in growth in 2013.

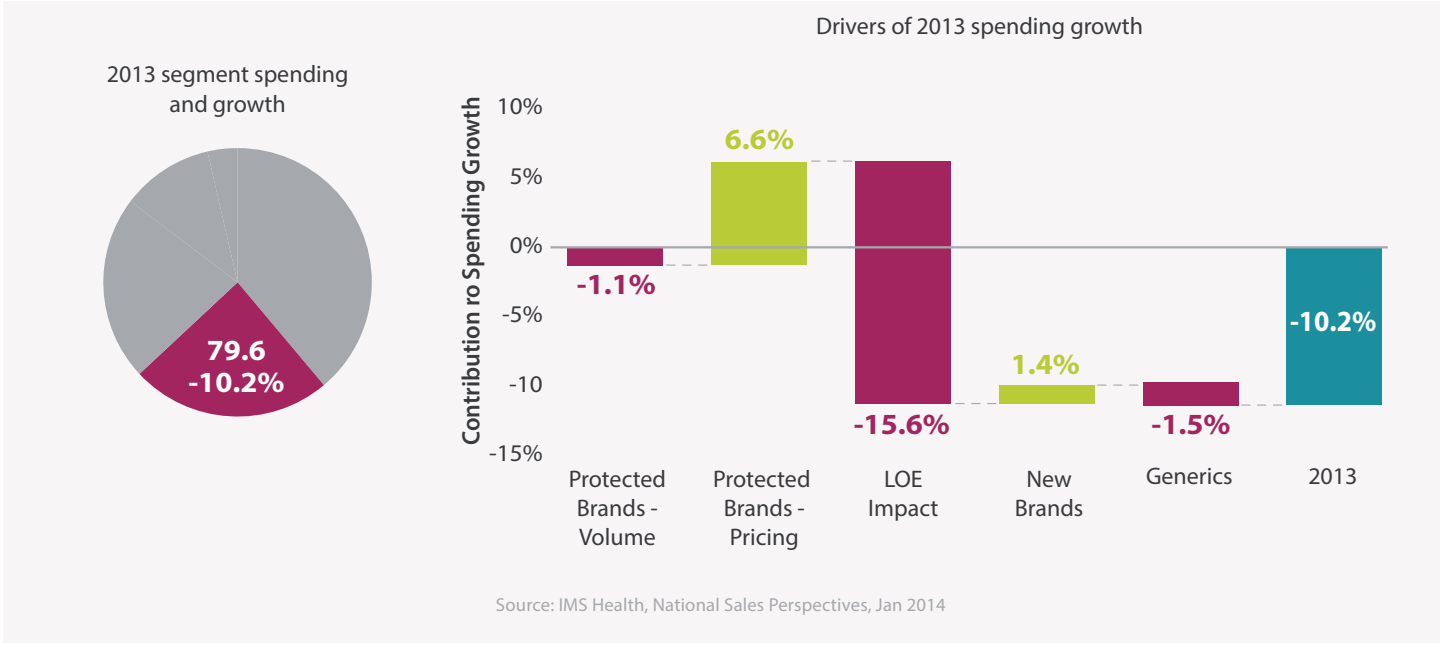
Chart notes:

Segments are mutually exclusive and reflect the change in spending between 2012 and 2013 in billions of dollars. Protected brands (brands that have not reached patent expiry) have been split based on growth through pricing dynamics and volume (absent pricing dynamics). New Brands segment includes all new products launched in 2012 and 2013. Generics segment includes unbranded generics and branded generics. LOE – Loss of Exclusivity – includes branded products that lost patent exclusivity during 2013 or previously.

Dermatology includes all dermatology treatments, but excludes biological autoimmune treatments for psoriasis which are categorized separately by the IMS Institute. Nervous system disorders includes anti-epilespsy and parkinson's treatments, and pain is a broad category including NSAIDS, narcotic analgesics, non-narcotic analgesics, anaesthesia, topical pain treatments and muscle-relaxants.

# In primary care therapy classes affected by significant patent expiries, some new products and pricing partly offset the impact of expiries

## Primary care with significant LOE




Source: IMS Health, National Sales Perspectives, Jan 2014

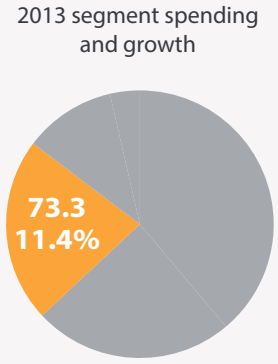
- Therapy areas affected by the so-called "patent cliff" included lipid regulators, anticoagulants, mental health, respiratory treatments for asthma and COPD, hypertension, osteoporosis and allergies.
- In aggregate, this group of classes had $9Bn lower spending in 2013, mostly due to the impact of patent expiries.
- Overall LOE impact in 2013 was -$29.3 billion, and these primary care classes accounted for more than two-thirds of that impact.
- Generics declined in these classes as initial price levels post-expiry were gradually reduced.
- Protected brand volumes declined by 1.1% which is fairly typical of therapy areas with many older branded products. Protected brand prices continued to increase at historic levels.
- Relatively few innovative brands were launched in these therapy areas and new brands contributed only 1.4% to offset the declining growth.

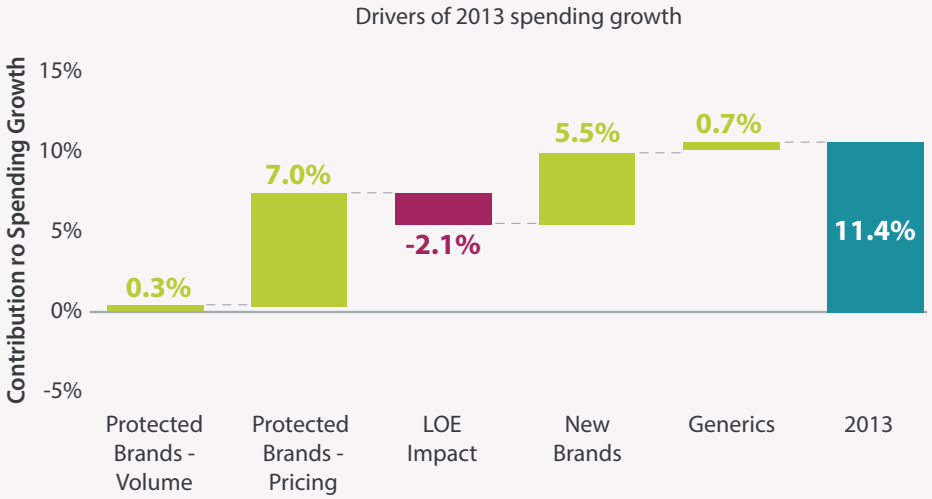
Chart notes:

Segments are mutually exclusive and reflect the change in spending between 2012 and 2013. Protected brands (brands that have not reached patent expiry) have been split based on growth through pricing dynamics and volume (absent pricing dynamics). New Brands segment includes all new products launched in 2012 and 2013. Generics segment includes unbranded generics and branded generics. LOE – Loss of Exclusivity – includes branded products that lost patent exclusivity during 2013 or previously.

# In several specialty therapy areas, where breakthrough therapies have been launched, spending increased above 11%

## Specialty with recent innovation




Source: IMS Health, National Sales Perspectives, Jan 2014

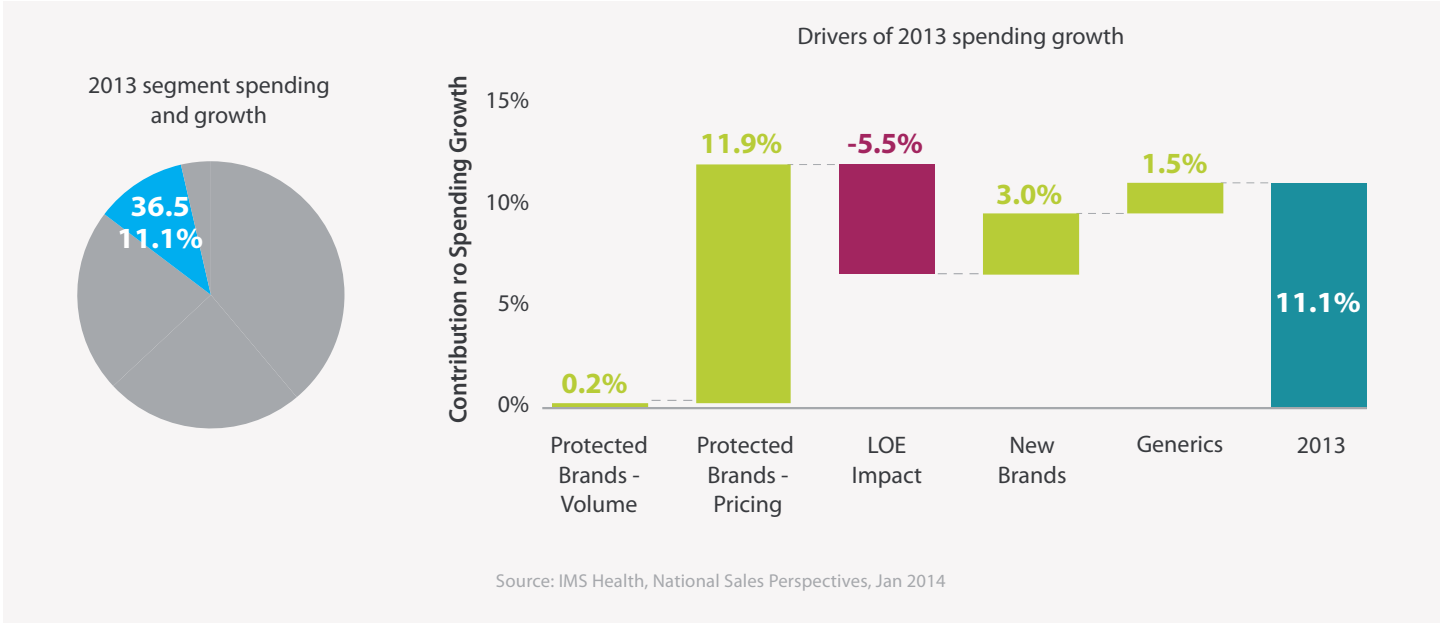
- Therapy areas with new specialty treatments launched in the last 3-4 years all grew above 10% in 2013, with the exception of hepatitis C treatments.
- Hepatitis C showed high spending growth in 2011 and 2012 as new launches showed great promise. Since that time, growth has slowed and actually declined by 33% in 2013 compared to 2012.
- Launches in late 2013, of new treatments in hepatitis C, with significant improvements in tolerability and broad response rates from targeted patients, promise a return to higher spending growth as the millions of chronic hepatitis C patients consider being treated with what some call a "functional cure", and more treatments are in research that may add further treatment options.
- These therapy areas were notable for the lack of substantial volume growth, perhaps as a result of the availability of innovative newer brands which contributed 5.5% to overall growth in these classes.
- Other key therapies in this group include treatments for autoimmune diseases (rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis), where many are biologic medicines, and where there are not yet any biosmilar competitors.
- Oncology, HIV, multiple sclerosis, age-related macular degeneration, and digestive enzyme treatments for generic disorders are included in this group as well and all grew in excess of 10% in 2013.

Chart notes:

Segments are mutually exclusive and reflect the change in spending between 2012 and 2013. Protected brands (brands that have not reached patent expiry) have been split based on growth through pricing dynamics and volume (absent pricing dynamics). New Brands segment includes all new products launched in 2012 and 2013. Generics segment includes unbranded generics and branded generics. LOE – Loss of Exclusivity – includes branded products that lost patent exclusivity during 2013 or previously.

# In primary care therapy classes with significant innovation, growth came from both new brands, pricing and generics and was partly offset by expiries

## Primary care with significant innovation




Source: IMS Health, National Sales Perspectives, Jan 2014

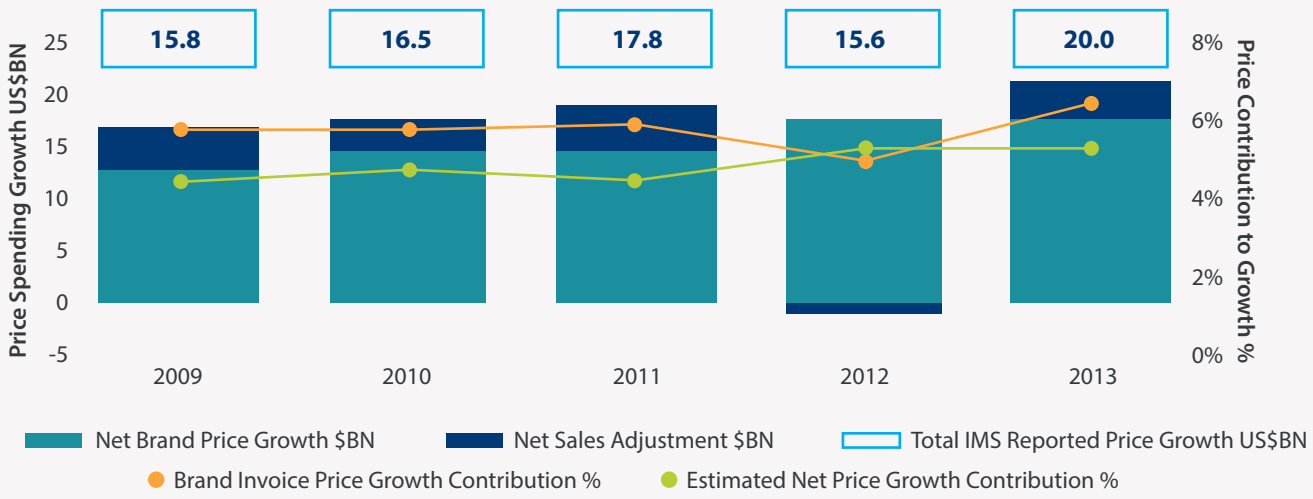
- Diabetes treatments account for $24.3Bn of the $36.5 of spending in these classes, and include several newer mechanisms of treating diabetics including DPP-IV inhibitors, GLP-1 agonists and the newest SGLT2 inhibitors.
- Price increases for insulins, averaging 17% in 2013, drove most of the price growth in diabetes and in this segment overall.
- Protected brand price increases contributed 11.9% to overall growth in these classes, with average increases of 16.7% over 2012, and 80% of the price growth coming from diabetes.
- New treatments for diabetes, GI treatments for genetic disorders, and obesity drugs were important contributors to growth in these therapy classes, though protected brand price growth was the largest contributor.
- Other therapy areas where new medicines were a significant contribution to growth included urinary incontinence, Alzheimer's, nasal allergy treatments, and respiratory treatments not related to asthma and COPD.

Chart notes:

Segments are mutually exclusive and reflect the change in spending between 2011 and 2012 in billions of dollars. Protected brands (brands that have not reached patent expiry) have been split based on growth through pricing dynamics and volume (absent pricing dynamics). New Brands segment includes all new products launched in 2011 and 2012. Generics segment includes unbranded generics and branded generics. LOE – Loss of Exclusivity – includes branded products that lost patent exclusivity during 2012 or previously.

# Net pricing increases for brands contributed an estimated 5.1% to spending growth in 2013 consistent with the prior year

## Protected brand price spending growth




Source: IMS Health, National Sales Perspectives, Jan 2014

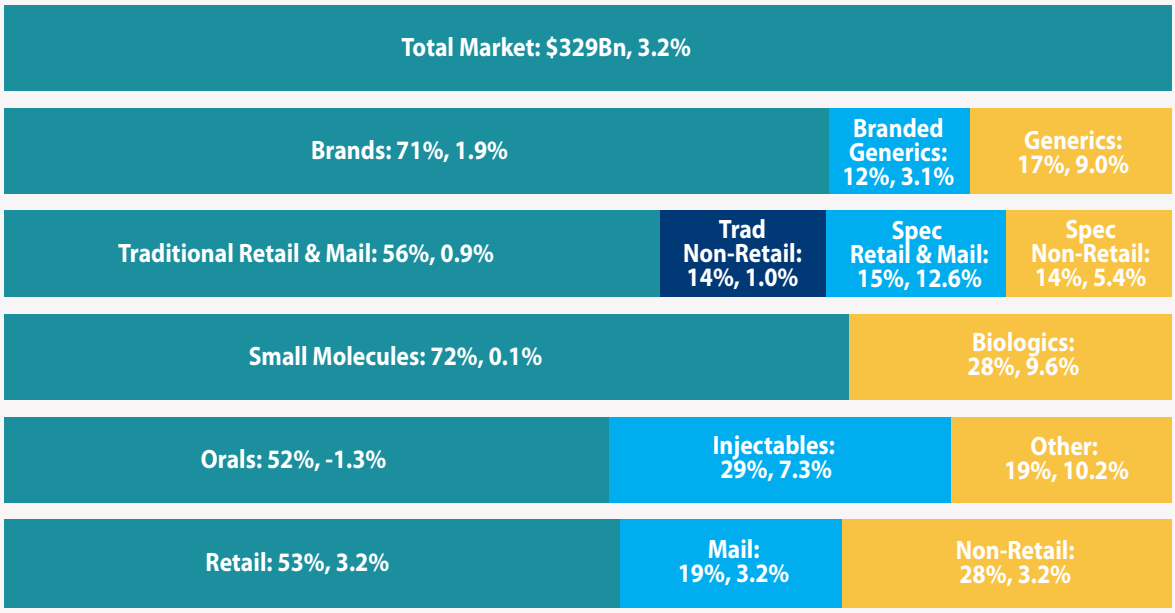
- Protected brand invoice price increases contributed $20.0Bn to growth in 2013, compared to $15.6Bn the prior year.
- Net price growth – after removing discounts and rebates not included in invoice prices – is estimated to be $16.6Bn in 2013 compared to $16.7Bn in the prior year, or 5.1% of brand spending growth.
- The Net Sales Adjustment – measured as the absolute amount of off-invoice discounts and rebates - declined in 2012, associated with the discontinuation of rebates following patent expiries for some of the largest brands.
- For products which remain protected, net prices, after removing discounts and rebates, continue to increase at levels consistent with historic trends.

Chart notes:

Total IMS reported price growth is dollar growth driven by invoice price changes and excludes the impact of rebates and contract pricing agreements. Brand invoice price growth contribution is the contribution to market growth and does not reflect a price growth rate. Estimated net price growth is based on a comparison of company reported net sales and IMS reported sales at invoice prices from wholesaler transactions.

# Specialty medicines and generics outpace growth of traditional, small molecules and brands

### 2013 medicines spending, and growth segmentation comparison




Source: IMS Health, National Sales Perspectives, Jan 2014

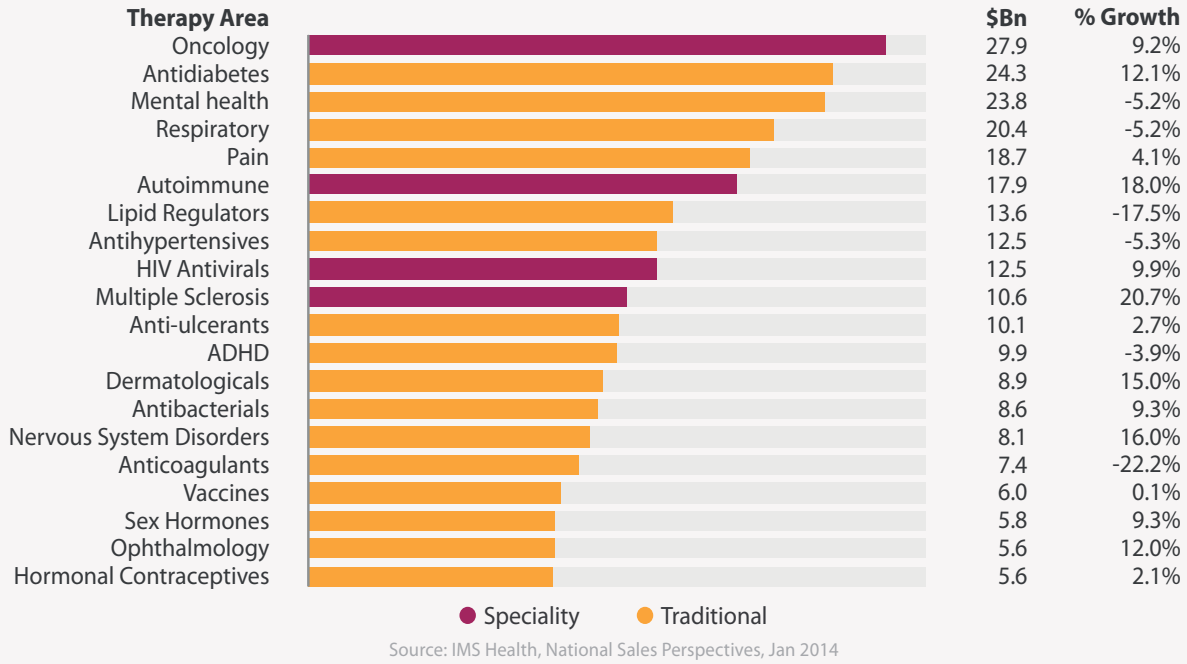
- Spending on branded drugs totaled $232Bn, or 71% of total spending, with branded and unbranded generics accounting for 29%.
- Unbranded generic spending rose 9% in 2013 largely due to the significant volumes of patent expiries in 2011 and 2012.
- Specialty medications now account for 29% of spending up from 23% in 2008, and averaged 10% growth in the last 5 years, and grew by 9% in 2013.
- Specialty medicines in the retail and mail channels were 15% of spending and grew at 12.6% in 2013, slower than the 14.7% in 2012, but still driven by a variety of new medicines for MS, hepatitis C, HIV and autoimmune diseases which can be self-administered by patients.
- Spending on biologic medicines grew by 9.6% to 28% of the total spending 2013, up from 21% in 2008, with most of the growth due to significant innovations in cancer and autoimmune diseases.
- Non-retail settings including hospitals, clinics, long-term care facilities and home health care represent 29% of medicine spending and are often excluded from payer and government measures of medicine spending.

Chart notes:

Each bar represents total spending in nominal dollars using a distinct segmentation of overall spending; the percentage refers to the segments' share of the total. Brands are those products with current or former patent protection or other forms of market exclusivity. Specialty, Traditional, and Biologics segments are based on proprietary IMS Health definitions. Percentages rounded to single percent and do not add to 100%.

# Over one-third of spending is concentrated in the top 5 therapies

## Spending in leading therapy areas




Source: IMS Health, National Sales Perspectives, Jan 2014

- The top 5 classes in 2013 were oncology ($27.9Bn), antidiabetes ($24.3Bn), mental health ($23.8Bn), respiratory agents ($20.4Bn) and pain ($18.7Bn).
- Absolute spending growth gains were highest for autoimmune, antidiabetes, and oncology.
- Spending growth was highest in multiple sclerosis, autoimmune, and nervous system disorders.
- Three specialty classes (MS, autoimmune, and oncology) contributed $6.9Bn, or 68% of total growth.
- Spending in two therapy areas, anticoagulants and lipid regulators, declined more than 15% due to patent expiries.
- Four of the top ten therapy areas had declines in spending in 2013, all declining more than 5%.

Chart notes:

Specialty, Traditional and therapy area definitions based on proprietary IMS Health definitions. Spending measured at the price paid to wholesalers or manufacturers by retail and non-retail channels and excluding off-invoice discounts and rebates that lower net prices received by manufacturers.Vaccines excludes flu vaccines which have been excluded from this edition of the report due to inconsistent data capture across historic periods.

# Notes on sources

This report is based on the IMS services detailed in the panel below. Analyses exclude OTC products and focus on prescription-bound products (including insulins which are available without prescription). Influenza vaccinations have been excluded from this edition due to inconsistent data capture across historic periods. Spending is reported at wholesaler invoice prices and does not reflect off-invoice discounts and rebates.

**IMS National Sales Perspectives (NSP)™** measures spending within the U.S. pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. NSP reports 100% coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices.

**IMS National Prescription Audit (NPA)™** is a suite of services that provides the industry standard source of national prescription activity for all products and markets.

**NPA Market Dynamics (NPA-MD)™** is a national-level prescription offering that links NPA with deidentified patient-level data that tracks patients over time and enables analysis such as whether a patient's prescription was new, switched from another medicine, or added to an existing regimen in the last year. Diagnoses, compliance and persistence, as well as ethnicity analytics are among other analyses that are possible.

**IMS National Disease and Therapeutic Index (NDTI)™** is a database of de-identified patient contacts with office-based physicians projected from a panel of physicians in the U.S. who report on all patient contacts for two consecutive workdays each quarter. Information collected includes patient demographics, diagnosis and treatment information, and physician demographics.

**IMS MIDAS™** is an analytics platform used to assess worldwide healthcare markets. It aggregates IMS's global audits and normalizes to international standards of product naming, company ownership, currency exchange rates, volume metrics and product segmentations, and estimates of price levels at different points in the supply chain. Segmentations include therapy classes, forms, dosages, and those related to brands, generics and patent protection.

**IMS LifeCycle™ R&D Focus™** is a global database for evaluating the market for medicines, covering more than 31,000 drugs in R&D and over 8,900 drugs in active development worldwide. It includes information about the commercial, scientific and clinical features of the products, analyst predictions of future performance, and reference information on their regulatory stage globally.

**IMS Xponent®** offerings provide detailed prescriber and payer/plan level prescription insights for the U.S. and Puerto Rico markets. Considered the industry's premier source of prescription intelligence, only Xponent uses a patented projection methodology to estimate total dispensed prescriptions and units (e.g. pills, mls,etc.), in the outpatient setting, across the retail, mail service, specialty pharmacy,and long term care channels.

**IMS Xponent PlanTrak Co-pay** provides average patient co-pay and co-pay ranges for prescription products based on the allowed amount minus the amount paid by the primary insurer on the transaction. Co-pay metrics are available at various levels to include national, method of payment, payer/plan and prescriber. IMS Health features industry-leading coverage reporting valid co-pay on over 80 percent of all retail prescription transactions.

**IMS Formulary Impact Analyzer (FIA)** provides insight on the lifecycle of activities for paid and unpaid prescription claims as it relates to the retail pharmacy, payer and patient. IMS FIA reports payer rejects along with reason codes, patient reversals and product switching details. Insights are available at national, method of payment, payer/plan, prescriber and desired geographical levels.

**Note on trend-break in sales and prescription reporting:**

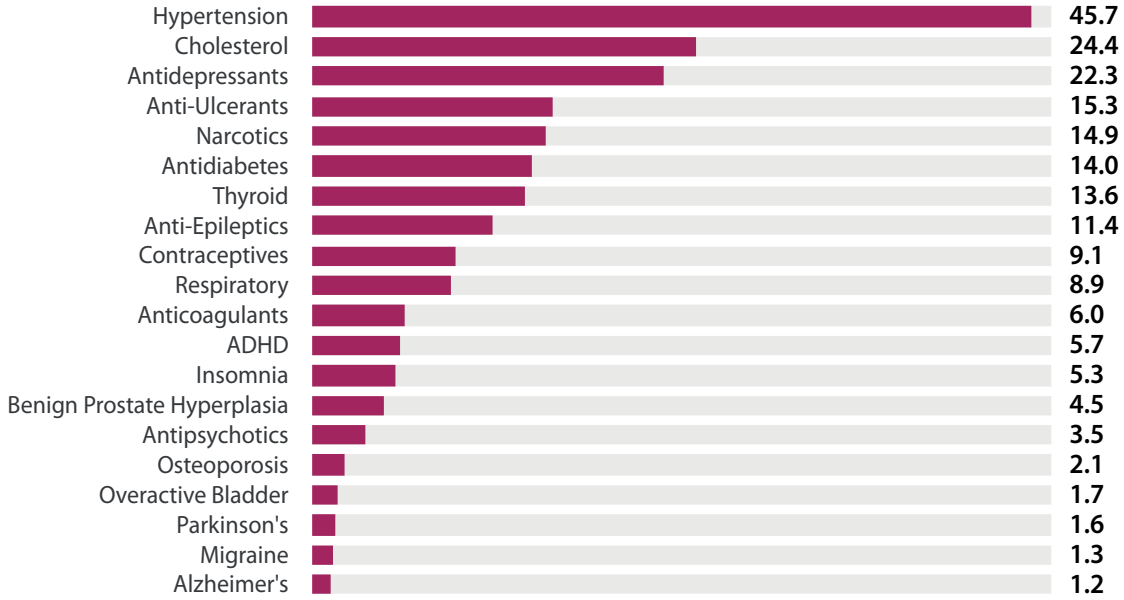
**National Sales Perspectives** reporting – as of January 2012 - no longer includes data from a major wholesaler reflecting sales in several channels associated with Tricare, the health care program serving uniformed service members, retirees, and their families, which prohibits wholesalers from reselling data to third parties like IMS Health. An approximately 2% impact on total sales is seen between 2011 and 2012.

**National Prescription Audit** reporting – as of January 2014 – reflected the addition of Walmart data, with restated periods from January 2012 to January 2014, replacing data which was previously projected. An adjustment has also been applied to the mail channel prescription volumes to account for the Tricare data disruption, which after the adjustments result in a trend break between 2011 and 2012.

For growth analyses of 2012 for either NSP or NPA, rather than calculating based on appendix tables in this report, please refer to last year's report entitled *Declining Use and Cost: For Better or Worse? A Review of 2012.*

# On-therapy patients - 2013

## Treated patients in selected therapies, millions




Source: IMS Health, NPA Market Dynamics, Jan 2014

Appendix notes:

Hypertension includes plain and combo ace inhibitors, angiotensin II inhibitors, renin inhibitors, beta blockers and calcium channel blockers.

Lipid regulators include all cholesterol lowering drugs.

Antidepressants include SSRIs, SNRIs and newer generation products.

Narcotic analgesics include codeine, morphine, propoxyphene and other synthetic narcotics. On-therapy patients reflect those patients on therapy as of December 2012. Narcotics are estimated to be used by as many as 75Mn unique patients per year, though only 15-16Mn are on therapy at any one time.

Anti-ulcerants is limited to the proton pump inhibitors (PPI).

Antidiabetes includes human insulins & analogues, oral antidiabetics and newer generation diabetes treatments including glitazones, GLP-1 analogues and DPP-IV inhibitor classes.

Thyroid includes natural & synthetic thyroid hormonal preparations.

Anti-epileptics include drugs for seizure disorders, some of which are also used for pain indications.

Respiratory agents include maintenance products for asthma & COPD.

Insomnia includes melatonin agonists and other non-barbiturate sleep aids.

Antiplatelets/anticoagulants include oral antiplatelets such as Plavix, and anticoagulants such as warfarin.

ADHD (Attention Deficit Hyperactivity Disorder) includes medications such as Ritalin and newer generation psychotherapeutic agents.

Benign prostate hyperplasia (BPH) includes alpha blockers and other agents.

Antipsychotics includes typical and atypical antipsychotics.

Osteoporosis includes biphosphonates, calcitonins, bone density regulators and bone formation agents, but not hormonal therapies.

Overactive bladder includes antispasmodics for urinary incontinence.

On-therapy patients are defined as those who have received a dispensed prescription in prior months and for which the amount of medicine and dosage prescribed has not been exhausted.

Therapy areas are based on proprietary IMS Health definitions.

Patients treated in these 20 leading chronic therapy areas represented 45% of spending and 60.7% of prescriptions in 2013.

# Top therapeutic classes by prescriptions

| Dispensed prescriptions Mn | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|
| **Total U.S. market** | **3,953** | **3,995** | **4,022** | **4,139** | **4,208** |
| 1 Antihypertensives | 649 | 652 | 649 | 691 | 698 |
| 2 Mental Health | 469 | 481 | 495 | 511 | 519 |
| 3 Pain | 451 | 462 | 470 | 482 | 477 |
| 4 Antibacterials | 275 | 271 | 274 | 272 | 268 |
| 5 Lipid Regulators | 249 | 255 | 255 | 266 | 263 |
| 6 Antidiabetics | 170 | 173 | 174 | 186 | 192 |
| 7 Nervous System Disorders | 135 | 142 | 148 | 157 | 166 |
| 8 Anti-Ulcerants | 146 | 147 | 150 | 159 | 164 |
| 9 Respiratory | 152 | 153 | 153 | 157 | 162 |
| 10 Antithyroid | 109 | 110 | 113 | 122 | 126 |
| 11 Dermatologicals | 101 | 102 | 102 | 103 | 105 |
| 12 Hormonal Contraception | 93 | 91 | 90 | 91 | 95 |
| 13 ADHD | 62 | 67 | 73 | 76 | 80 |
| 14 Anticoagulants | 74 | 74 | 73 | 76 | 76 |
| 15 Vitamins & Minerals | 69 | 74 | 72 | 73 | 74 |
| 16 Corticosteroids | 51 | 53 | 55 | 60 | 61 |
| 17 GI Products | 56 | 55 | 55 | 57 | 58 |
| 18 Nasal Preps, Topical | 41 | 44 | 46 | 48 | 51 |
| 19 Other Cardiovasculars | 52 | 52 | 51 | 51 | 49 |
| 20 Sex Hormones | 46 | 44 | 43 | 45 | 45 |

Source: IMS Health, National Prescription Audit, Jan 2014

Appendix notes:

Therapy areas are based on proprietary IMS Health definitions. Report reflects prescription-bound products including insulins and excluding other products such as OTC products and flu vaccines.

IMS routinely updates its market audits, which may result in changes to Previously reported market size and growth rates.

Includes all prescriptions dispensed through retail pharmacies - including independent and chain drug stores, food store pharmacies and mail order as well as long-term care facilities.

Prescription counts are not adjusted for length of therapy. 90-day and 30-day prescriptions are both counted as one prescription.

# Top medicines by prescriptions

| Dispensed prescriptions Mn | | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|---|
| **Total U.S. market** | | **3,953** | **3,995** | **4,022** | **4,139** | **4,208** |
| 1 | acetaminophen/hydrocodone | 129.4 | 132.1 | 136.7 | 136.4 | 129.2 |
| 2 | levothyroxine | 100.2 | 103.2 | 104.7 | 112.2 | 115.2 |
| 3 | lisinopril | 83.0 | 87.6 | 88.8 | 99.1 | 101.5 |
| 4 | metoprolol | 76.9 | 76.6 | 76.3 | 82.6 | 83.9 |
| 5 | simvastatin | 84.1 | 94.4 | 96.8 | 89.3 | 79.1 |
| 6 | amlodipine | 52.1 | 57.8 | 62.5 | 69.1 | 74.0 |
| 7 | metformin | 53.8 | 57.0 | 59.1 | 67.8 | 72.8 |
| 8 | omeprazole | 45.6 | 53.5 | 59.4 | 66.6 | 70.7 |
| 9 | atorvastatin | 51.7 | 45.3 | 43.3 | 55.5 | 68.4 |
| 10 | albuterol | 54.5 | 55.1 | 56.9 | 61.2 | 63.5 |
| 11 | amoxicillin | 52.8 | 52.4 | 53.8 | 52.8 | 54.2 |
| 12 | hydrochlorothiazide | 47.9 | 47.8 | 48.1 | 51.2 | 50.2 |
| 13 | alprazolam | 45.3 | 47.7 | 49.1 | 49.5 | 49.6 |
| 14 | azithromycin | 54.7 | 53.6 | 56.2 | 54.6 | 48.6 |
| 15 | fluticasone | 30.1 | 34.8 | 38.4 | 42.1 | 45.3 |
| 16 | furosemide | 43.8 | 43.6 | 42.3 | 44.1 | 45.0 |
| 17 | gabapentin | 25.7 | 29.6 | 33.4 | 38.6 | 43.9 |
| 18 | sertraline | 34.8 | 36.2 | 37.6 | 39.7 | 41.7 |
| 19 | zolpidem | 42.7 | 43.7 | 44.6 | 44.0 | 41.5 |
| 20 | tramadol | 25.5 | 28.0 | 33.9 | 39.3 | 41.5 |
| 21 | citalopram | 27.3 | 32.2 | 37.8 | 41.6 | 39.5 |
| 22 | prednisone | 27.8 | 28.7 | 33.7 | 35.2 | 36.5 |
| 23 | acetaminophen/oxycodone | 36.7 | 37.9 | 38.8 | 38.0 | 35.9 |
| 24 | ibuprofen | 30.3 | 31.1 | 32.6 | 34.2 | 35.1 |
| 25 | pravastatin | 17.2 | 20.2 | 23.9 | 33.3 | 34.7 |

Source: IMS Health, National Prescription Audit, Dec 2013

Appendix notes:

Therapy areas are based on proprietary IMS Health definitions. Report reflects prescription-bound products including insulins and excluding other products such as OTC products and flu vaccines.

IMS routinely updates its market audits, which may result in changes to Previously reported market size and growth rates.

Includes all prescriptions dispensed through retail pharmacies - including independent and chain drug stores, food store pharmacies and mail order as well as long-term care facilities.

Prescription counts are not adjusted for length of therapy. 90-day and 30-day prescriptions are both counted as one prescription.

# Top medicines by non-discounted spending

| Non-discounted spending U.S. $Bn | | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|---|
| **Total U.S. market** | | **300.1** | **315.7** | **328.5** | **319.1** | **329.2** |
| 1 | Abilify | 4.0 | 4.6 | 5.3 | 5.7 | 6.5 |
| 2 | Nexium | 6.3 | 6.5 | 6.4 | 5.9 | 6.2 |
| 3 | Humira | 2.5 | 3.1 | 3.7 | 4.5 | 5.6 |
| 4 | Crestor | 3.0 | 4.0 | 4.6 | 5.0 | 5.4 |
| 5 | Cymbalta | 2.8 | 3.2 | 3.8 | 4.6 | 5.3 |
| 6 | Advair Diskus | 4.7 | 4.9 | 4.8 | 4.8 | 5.2 |
| 7 | Enbrel | 3.3 | 3.5 | 3.8 | 4.2 | 4.7 |
| 8 | Remicade | 3.2 | 3.3 | 3.5 | 3.8 | 4.1 |
| 9 | Copaxone | 1.7 | 2.4 | 3.2 | 3.5 | 3.7 |
| 10 | Neulasta | 3.0 | 3.0 | 3.3 | 3.4 | 3.6 |
| 11 | Rituxan | 2.6 | 2.8 | 3.0 | 3.1 | 3.3 |
| 12 | Lantus SoloSTAR | 0.7 | 1.1 | 1.6 | 2.2 | 3.0 |
| 13 | Spiriva Handihaler | 1.7 | 2.1 | 2.5 | 2.7 | 3.0 |
| 14 | Atripla | 1.9 | 2.3 | 2.6 | 2.8 | 2.9 |
| 15 | Januvia | 1.5 | 1.8 | 2.2 | 2.6 | 2.9 |
| 16 | Avastin | 3.0 | 3.1 | 2.7 | 2.6 | 2.7 |
| 17 | Lantus | 1.9 | 2.0 | 2.1 | 2.2 | 2.6 |
| 18 | OxyContin | 2.9 | 3.1 | 2.9 | 2.8 | 2.6 |
| 19 | Lyrica | 1.6 | 1.7 | 1.8 | 2.0 | 2.5 |
| 20 | Epogen | 3.2 | 3.3 | 2.8 | 2.2 | 2.3 |
| 21 | Celebrex | 1.8 | 1.8 | 1.9 | 1.9 | 2.3 |
| 22 | Truvada | 1.4 | 1.7 | 2.0 | 2.2 | 2.3 |
| 23 | Diovan | 1.7 | 2.0 | 2.0 | 2.0 | 2.2 |
| 24 | Herceptin | 1.4 | 1.5 | 1.6 | 1.8 | 1.9 |
| 25 | Gleevec | 1.1 | 1.4 | 1.6 | 1.7 | 1.9 |

Source: IMS Health, National Sales Perspectives, Jan 2014

Appendix notes:

Prescription-bound products including insulins and excluding other products such as OTC products and flu vaccines. Table shows leading products by 2013 spending as reported in IMS's National Sales Perspectives Audit.

IMS routinely updates its market audits, which may result in changes to previously reported data.

Off-invoice discounts and rebates are not reflected and are understood to be significant for some products, resulting in substantial differences between IMS-reported spending and company-reported sales after accounting for off-invoice discounts and rebates.

# Dispensing by payment type

| Dispensed prescriptions Mn | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|
| **Total U.S. market** | **3,953** | **3,995** | **4,022** | **4,139** | **4,208** |
| Commercial Third-Party | 62.9% | 61.6% | 61.3% | 58.6% | 57.0% |
| Medicare Part D | 19.9% | 19.8% | 20.6% | 23.7% | 26.0% |
| Medicaid | 8.3% | 9.6% | 9.5% | 9.4% | 9.0% |
| Cash | 8.9% | 9.0% | 8.6% | 8.3% | 8.0% |

Source: IMS Health, National Prescription Audit, XPonent, PlanTrak Jan 2014

Appendix notes:

Medicare Part D reflects only retail pharmacy prescriptions. Mail order delivery of Medicare Part D prescriptions are not distinguished from other Commercial Third-Party.
Report reflects prescription-bound products including insulins and excluding OTC products and flu vaccines.
Medicaid includes both Fee for Service and Managed Medicaid.

# Dispensing locations

| Non-discounted spending U.S. $Bn | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|
| **Total U.S. market** | **300.1** | **315.7** | **328.5** | **319.1** | **329.2** |
| **Retail Channels** | **214.9** | **226.8** | **236.0** | **228.9** | **236.2** |
| Chain Stores | 105.3 | 108.0 | 112.4 | 110.5 | 115.0 |
| Mail Service | 51.0 | 59.4 | 63.8 | 60.8 | 62.7 |
| Independent | 37.4 | 38.1 | 38.3 | 36.5 | 36.6 |
| Food Stores | 21.1 | 21.3 | 21.5 | 21.2 | 21.8 |
| **Institutional Channels** | **85.3** | **88.9** | **92.4** | **90.2** | **93.1** |
| Clinics | 34.6 | 36.7 | 38.6 | 39.5 | 41.6 |
| Non-Federal Hospitals | 27.5 | 28.0 | 28.2 | 28.0 | 28.3 |
| Long-Term Care | 13.8 | 14.7 | 15.2 | 13.9 | 14.1 |
| HMO | 1.7 | 2.1 | 2.6 | 2.8 | 3.1 |
| Home Health Care | 2.5 | 2.5 | 2.7 | 2.7 | 2.6 |
| Federal Facilities | 4.1 | 3.9 | 4.2 | 2.5 | 2.4 |
| Miscellaneous | 1.0 | 1.0 | 1.0 | 0.9 | 0.9 |

| Dispensed prescriptions Mn | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|
| **Total U.S. market** | **3,953** | **3,995** | **4,022** | **4,139** | **4,208** |
| **Retail Channels** | **3,637** | **3,676** | **3,693** | **3,809** | **3,861** |
| Chain Stores | 2,132 | 2,174 | 2,210 | 2,308 | 2,371 |
| Independent | 756 | 749 | 741 | 739 | 737 |
| Food Stores | 487 | 488 | 482 | 522 | 536 |
| Mail Service | 262 | 264 | 260 | 239 | 217 |
| **Institutional Channels** | **316** | **319** | **329** | **331** | **346** |
| Long-Term Care | 316 | 319 | 329 | 331 | 346 |

Source: IMS Health, National Sales Perspectives, National Prescription Audit, Jan 2014

Appendix notes:

Report reflects prescription-bound products including insulins and excluding OTC products and flu vaccines. IMS routinely updates its market audits, which may result in changes to previously reported market size and growth rates. Prescriptions include all prescriptions dispensed through retail pharmacies - including independent and chain drug stores, food store pharmacies and mail order as well as long-term care facilities.

# Top therapeutic classes by non-discounted spending

| Non-discounted spending U.S. $Bn | | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|---|
| **Total U.S. market** | | **300.1** | **315.7** | **328.5** | **319.1** | **329.2** |
| 1 | Oncologics | 21.6 | 22.6 | 24.1 | 25.5 | 27.9 |
| 2 | Antidiabetics | 15.9 | 18.6 | 20.7 | 21.7 | 24.3 |
| 3 | Mental Health | 29.0 | 31.1 | 32.2 | 25.1 | 23.8 |
| 4 | Respiratory | 18.1 | 19.8 | 21.7 | 21.5 | 20.4 |
| 5 | Pain | 17.3 | 17.6 | 17.9 | 18.0 | 18.7 |
| 6 | Autoimmune | 9.7 | 11.3 | 13.0 | 15.1 | 17.9 |
| 7 | Lipid Regulators | 18.6 | 19.8 | 21.3 | 16.5 | 13.6 |
| 8 | Antihypertensives | 15.4 | 15.6 | 14.0 | 13.2 | 12.5 |
| 9 | HIV Antivirals | 8.2 | 9.4 | 10.4 | 11.4 | 12.5 |
| 10 | Multiple Sclerosis | 5.0 | 6.1 | 7.6 | 8.8 | 10.6 |
| 11 | Anti-Ulcerants | 14.1 | 12.4 | 10.5 | 9.8 | 10.1 |
| 12 | ADHD | 6.7 | 7.9 | 9.2 | 10.3 | 9.9 |
| 13 | Dermatologicals | 5.8 | 6.3 | 6.9 | 7.7 | 8.9 |
| 14 | Antibacterials | 10.4 | 10.2 | 9.3 | 7.9 | 8.6 |
| 15 | Nervous System Disorders | 8.1 | 6.9 | 6.9 | 7.0 | 8.1 |
| 16 | Anticoagulants | 11.2 | 12.4 | 13.6 | 9.5 | 7.4 |
| 17 | Vaccines excl Flu | 4.1 | 4.9 | 5.6 | 6.0 | 6.0 |
| 18 | Sex Hormones | 3.8 | 4.1 | 4.6 | 5.3 | 5.8 |
| 19 | Ophthalmology | 3.6 | 4.3 | 4.9 | 5.0 | 5.6 |
| 20 | Hormonal Contraceptives | 4.7 | 4.9 | 5.2 | 5.5 | 5.6 |

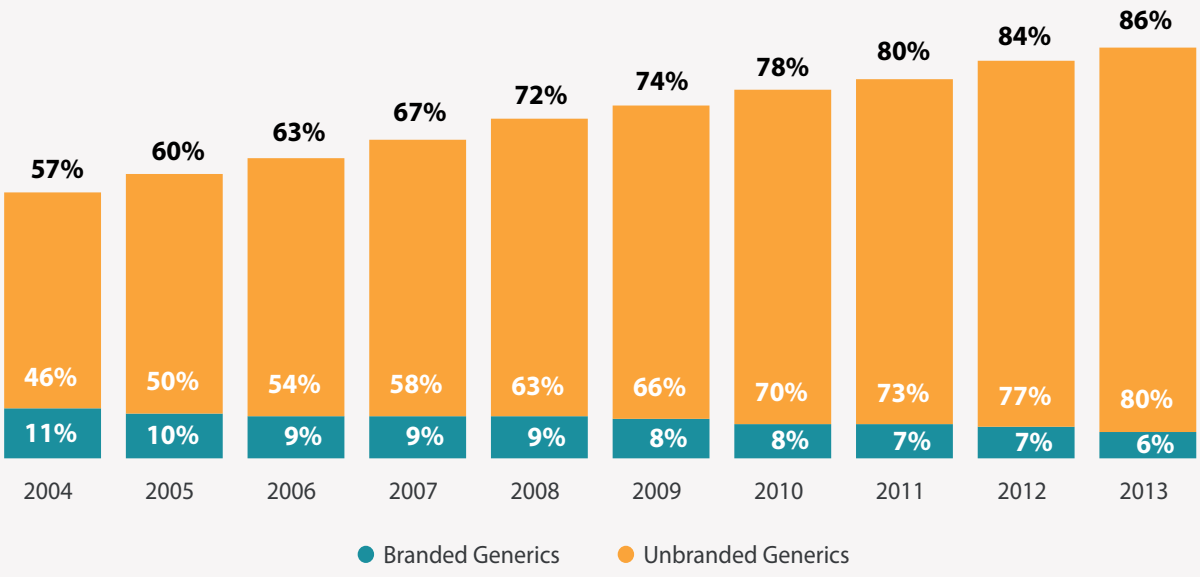
Source: IMS Health, National Sales Perspectives, Jan 2014

Appendix notes:

Therapy areas are based on proprietary IMS Health definitions. Report reflects prescription-bound products including insulins and excluding OTC products and flu vaccines. IMS routinely updates its market audits, which may result in changes to previously reported market size and growth rates.

# Dispensed prescriptions for generics and branded generics

## Percent share of prescriptions




Source: IMS Health, National Prescription Audit, Jan 2014

- Patent expiries for products used by millions of patients have contributed to a nearly 30% rise in the generic share of prescriptions over the last ten years.
- The next five years include patent expiries for an additional 5-6% of prescriptions and further genericization of drug usage is not expected beyond 91-92%.
- Generics are now dispensed 95% of the time when a generic form is available.
- Branded generic medicines have been facing competition in recent years from unbranded generics, and share of prescription volume has steadily declined.

Appendix notes:

Includes all prescriptions dispensed through retail pharmacies, including independent and chain drug stores, food store pharmacies and mail order as well as long term care facilities. Generics total includes branded generic and unbranded generic medicines. Prescription counts are not adjusted for length of therapy.
90-day and 30-day prescriptions are both counted as one prescription.

# Authors

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Murray Aitken is Executive Director, IMS Institute for Healthcare Informatics, which provides policy setters and decision makers in the global health sector with objective insights into healthcare dynamics. He assumed this role in January 2011. Murray previously was Senior Vice President, Healthcare Insight, leading IMS Health's thought leadership initiatives worldwide. Before that, he served as Senior Vice President, Corporate Strategy, from 2004 to 2007. Murray joined IMS Health in 2001 with responsibility for developing the company's consulting and services businesses. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001.

Murray writes and speaks regularly on the challenges facing the healthcare industry. He is editor of Health IQ, a publication focused on the value of information in advancing evidence-based healthcare, and also serves on the editorial advisory board of Pharmaceutical Executive. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.

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Michael serves as Research Director for the IMS Institute, setting the research agenda for the Institute, leading the development of reports and projects focused on the current and future role of biopharmaceuticals in healthcare in the U.S. and globally. Michael writes and speaks regularly on these and other topics and he is sought after for his unique and pragmatic perspectives, backed by rigorous analysis and research, on issues of interest to pharmaceutical companies, financial analysts, trade groups, policy advocates and regulatory agencies. Michael joined IMS Health in 1999 and has held roles in customer service, marketing, product management, and in 2006 joined the Market Insights team which in 2011 became the IMS Institute for Healthcare Informatics. Michael holds a BA in History and Political Science from the University of Essex, Colchester, UK, and an MA in Journalism and Radio Production from Goldsmiths College, University of London, UK.

## Jennifer Lyle

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Jennifer serves as a Research Manager for the IMS Institute, focusing on product pipeline and innovation, and specializing in oncology. Jennifer joined the IMS Institute in 2013 with over 10 years of oncology and other chronic disease research experience. Prior to joining IMS, she worked at the National Comprehensive Cancer Network and Fox Chase Cancer Center where she has held roles in outcomes research and behavioral medicine respectively. Jennifer holds an M.A. in Clinical Psychology from LaSalle University and is currently pursuing a Master's in Public Health with a focus in Epidemiology at Drexel University in Philadelphia, PA.

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# About the Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved patient care.

With access to IMS's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS information and expertise to support the advancement of evidence-based healthcare around the world.

## Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

Demonstrating the effective **use of information** by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the **performance of medical care** through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future **global role for biopharmaceuticals**, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of **innovation in health system products, processes and delivery systems**, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in **developing nations** through information and analysis.

## Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.

# IMS INSTITUTE FOR HEALTHCARE INFORMATICS

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