

# Patients Struggle With High Drug Prices

*Out-of-pocket costs for pricey new drugs leave even some insured and relatively affluent patients with hard choices on how to afford them*



LEXEY SWALL FOR THE WALL STREET JOURNAL

**BY JOSEPH WALKER**

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BELLEVILLE, Ill.— Jacqueline Racener’s doctor prescribed a new leukemia drug for her last winter that promised to roll back the cancer in her blood with only moderate side effects.

Then she found out how much it would cost her: nearly \$8,000 for a full year, even after Medicare picked up most of the tab.

“There’s no way I could do that,” Ms. Racener says. “It was just

prohibitive.” Worried about depleting her limited savings, Ms. Racener, a 76-year-old legal secretary, decided to take the risk and not fill her prescription.

The pharmaceutical industry, after a long drought, has begun to produce more innovative treatments for serious diseases that can extend life and often have fewer side effects than older treatments. Last year, the Food and Drug Administration approved 41 new drugs, the most in nearly two decades.

The catch is their cost. Recent treatments for hepatitis C, cancer and multiple sclerosis that cost from \$50,000 annually to well over \$100,000 helped drive up total U.S. prescription-drug spending 12.2% in 2014, five times the prior year’s growth rate, according to the Centers for Medicare and Medicaid Services. High drug prices can translate to patient costs of thousands of dollars a year. Out-of-pocket prescription-drug costs rose 2.7% in 2014, according to CMS.

For many of the poorest Americans, medicines are covered by government programs or financial-assistance funds paid for by drug companies.

For those in the middle class, it is a different story. Though many patients can get their out-of-pocket costs paid by drug companies or drug-company-funded foundations, some patients make too much money to qualify for assistance. Others are unaware the programs exist. Medicare patients, who represent nearly a third of U.S. retail drug spending, can’t receive direct aid from drug companies.

The upshot is even patients with insurance and comfortable incomes are sometimes forced to make hard choices—tapping savings, taking on new debt or even forgoing treatment.

“Drugs are so expensive that once they flow through our rag-tag insurance system, we have patients who can’t afford them, or they can barely afford them, so they’re not getting therapies,” said Peter Bach, a physician and health-policy researcher at Memorial Sloan Kettering Cancer Center in New York.

A quarter of U.S. prescription-drug users said it was difficult to afford them, in an August survey by the Kaiser Family Foun-

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Jacqueline Racener's doctor recommended a drug called Imbruvica to treat her leukemia. The catch: Her annual income at the time disqualified her for copay-assistance programs for the costly treatment.

dation. In another survey, published in the journal *Lancet Haematology* in September, 10% of insured U.S. patients with the blood cancer multiple myeloma said they had stopped taking a cancer drug because of its cost.

A look at how patients are coping with the cost of the medicine prescribed for Ms. Racener, called Imbruvica, illustrates the issues.

The drug blocks proteins that cause malignant cells to multiply and stay alive. Approved in 2013 for a rare illness called mantle-cell lymphoma, the medication, which is known generically as ibrutinib, was later approved to treat some patients with chronic lymphocytic leukemia, the condition Ms. Racener has.

"People who had one foot in the grave after failing multiple prior chemotherapies, when given ibrutinib, had dramatic responses," said Kanti R. Rai, a leukemia expert at North Shore-LIJ Cancer Institute in Lake Success, N.Y.

The drug's wholesale list price is \$116,600 a year for leukemia

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patients. For the higher dose needed for lymphoma, it is about \$155,400. Producers gave insurers discounts averaging 11% in 2014, financial statements show.

For patients on Medicare—more than half of Imbruvica users—the federal insurance picks up the bulk of the cost under the Part D prescription-drug plan. But most Medicare patients still faced out-of-pocket costs of \$7,000 or more a year.

For patients with insurance purchased privately or provided by an employer, out-of-pocket costs vary widely, from a small copay to thousands of dollars. The Affordable Care Act capped commercially insured patients' out-of-pocket costs for all care, including drugs. The 2016 cap is \$6,850.

Drug companies, aware that costs borne by insured patients can limit sales, have stepped up their spending on programs to defray them, such as copay coupons.

The aid programs can come with income limits and other restrictions. In the case of Ms. Racener in Belleville, a suburb of St. Louis, a hospital social worker looked into help from nonprofit foundations funded by drug companies. Her income was too high to qualify.

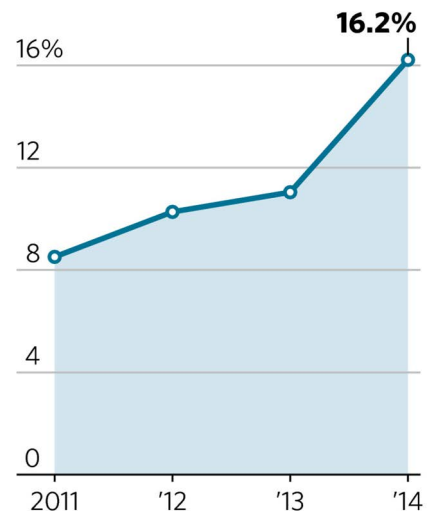
She earned about \$80,000 between her job and Social Security. Her car payments, credit-card debt and a \$600 monthly mortgage on her ranch house made the drug prescribed for her leukemia in February unaffordable.

Ms. Racener's adult children offered to take out loans to help. "We're middle-class, we don't have that type of money in the bank," said her oldest daughter, Rebecca Brawley.

Ms. Racener didn't want to burden them. She decided to skip the drug and, if her symptoms got worse, to try chemotherapy, a therapy that would be covered by her insurance with minimal personal expense, but one she dreaded.

Then some good news came along—riding on bad news. In

**Expensive specialty medications consume a rising share of Medicare's spending for drugs\***



\*Medicare Part D program for prescription drugs taken outside doctors' offices

Source: Centers for Medicare and Medicaid Services

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WHITNEY CURTIS FOR THE WALL STREET JOURNAL

John DiPersio, chief of oncology at Washington University School of Medicine in St. Louis, says, 'The financial destitution that modern therapies bring on patients and their families is enormous.'

August, Ms. Racener's work hours were cut back, and her pay fell by 40%. She applied for aid to a drug-maker-funded nonprofit called the Patient Access Network Foundation, and, with her much-reduced income, she qualified.

In October, eight months after Imbruvica was prescribed for Ms. Racener, she filled the prescription and began taking it. Her disease causes a proliferation of white blood cells. Their number has come down significantly, her doctor says.

"Thank you, Lord," Ms. Racener remembers thinking. "Thank you that I'm going to be able to get this, and it's not going to cost my family beaucoup bucks."

Ms. Racener's doctor, John DiPersio, chief of oncology at Washington University School of Medicine, says the expense of new cancer drugs is burdensome for growing numbers of patients whose insurance entails substantial copays. "The financial destitution that modern therapies bring on patients and their families is enormous," he says.

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Imbruvica was developed by Johnson & Johnson and Pharmacyclics LLC, a company AbbVie Inc. acquired in May. AbbVie has pegged global sales of the drug at \$1 billion this year and \$5 billion in 2020.

AbbVie declined to comment on the drug's price. Pharmacyclics' former CEO, Robert Duggan, said in a June interview the price represents its value in the marketplace. After patents expire in about 15 years, a generic version will be much cheaper, he said, adding: "That's where society wins. People look at it in the very short term."

The other producer of Imbruvica, Johnson & Johnson, says new drugs are helping turn some cancers from life-threatening to manageable, but "more costs are being shifted to patients, making it hard for some to get the medicines they need."

Health insurers say patients pay more for their care because costs continue to climb. Drug prices are one of the main drivers of insurance-premium increases, says Clare Krusing, a spokeswoman for America's Health Insurance Plans, an industry group. Lowering patients' share of expensive drugs' cost would mean even higher premiums, she says.

Drug companies point to aid they provide. J&J says it helps patients manage costs both through its own programs and by donating to charities.

Pharmaceutical companies can't provide copay aid directly to Medicare recipients. Doing so could be construed as a violation of the U.S. anti-kickback statute, which prohibits companies from using financial incentives to encourage the sale of their products to federal health-care programs. Companies can, however, point the patients to nonprofit organizations they finance, which cover copays for patients who meet income tests.

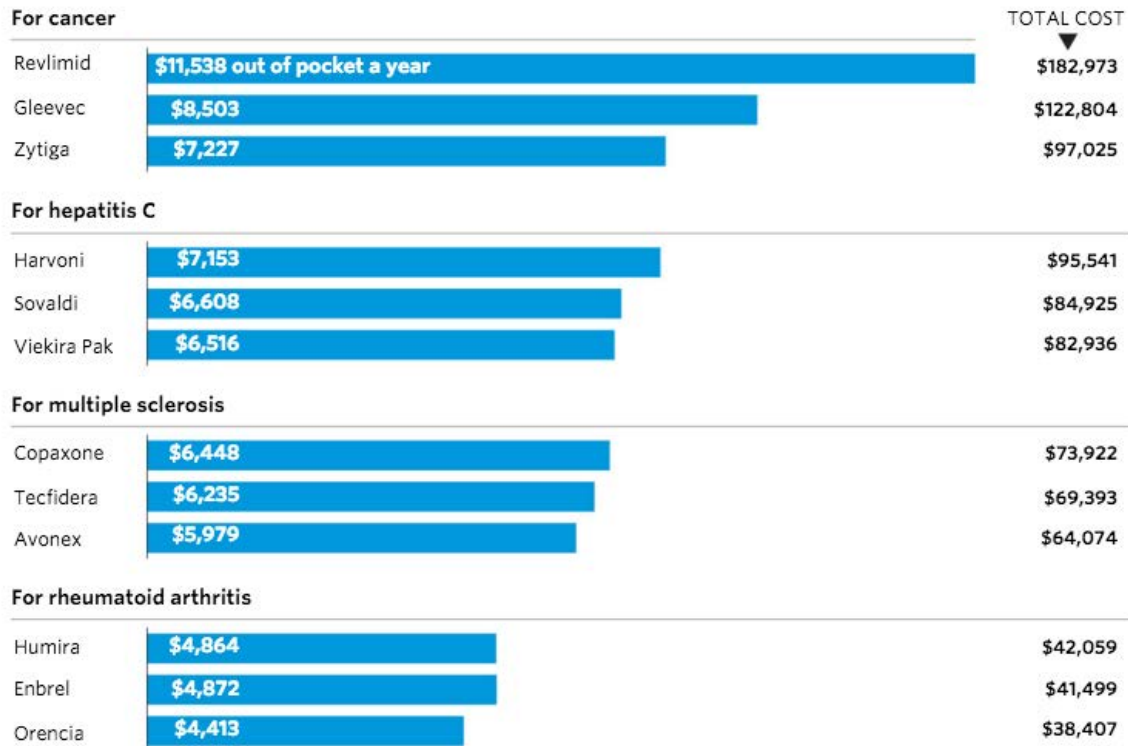
For commercially insured patients, drugmakers can directly provide copay aid, and frequently do. The makers of Imbruvica will cover all but \$10 of such patients' monthly copays, regardless of income.

More broadly, about 44% of commercially insured patients'

# THE DYSFUNCTION IN DRUG PRICES

## Patient's Share

Medicare patients who take expensive drugs can be on the hook for thousands of dollars in out-of-pocket spending each year, even after their insurance pays the bulk of the drug's cost. Below are projected 2016 costs for a dozen commonly used specialty medications.



Note: Total cost is based on drugs' retail pharmacy prices. Prices are based on default dose and quantity. Analysis includes 20 national and near-national prescription-drug plans.

Source: Georgetown/Kaiser Family Foundation analysis of data from Centers for Medicare and Medicaid Services

prescriptions for so-called specialty drugs—costly medicines for serious diseases that sometimes need special handling or storage—involved copay coupons in 2013, said a study in the journal *Health Affairs*.

Copay assistance is only relevant, of course, if insurance is covering the bulk of the drug's cost. That isn't the case for Brien Johnson of Sterling, Va.

Mr. Johnson never expected to be unable to afford medicine he needed. He and his wife own a legal-advertising company that has provided a good living.

A few years ago, after his doctor noticed swollen lymph nodes, Mr. Johnson was diagnosed with mantle-cell lymphoma. Treatment with chemotherapy was ineffective. He began

taking Imbruvica around December 2013. In about a month, he says, his disease went into remission.

His health insurance paid for it for about a year. Early in 2015, according to Mr. Johnson, the insurer said it wouldn't continue paying for the drug under the medical portion of his policy, which covers services provided in doctors' offices. Instead, Imbruvica—an oral drug taken at home—would fall under the policy's prescription-drug benefit, and that has a maximum yearly payment of \$5,000, or only about 4% of Imbruvica's annual price at the time. The Affordable Care Act banned such limits except for existing health plans for individuals.

Though the Johnsons earned nearly \$200,000 a year, the cost would be too much. "If the drug was a couple thousand a month, I could've worked it out," Mr. Johnson says. "But at \$12,000 a month, it would have wiped us out in a year."

His insurance is a Blue Cross Blue Shield policy from Anthem Inc. A spokeswoman for Anthem said the insurer notified Mr. Johnson he could change policies to one that included full prescription-drug coverage, but he chose not to. Anthem agreed to pay for his Imbruvica in 2014 but "clearly communicated that these additional benefits" wouldn't extend into 2015, said the spokeswoman, Jill Becher.

She said Anthem recognizes the cost of cancer drugs has risen substantially and is "committed to working with our members to ensure that they are able to access the most effective therapy."

Mr. Johnson says he considered switching his coverage but decided not to because other plans had higher deductibles and he feared his current doctors wouldn't be available in them.

He got one free month's supply of Imbruvica from its manufacturers, he says, but was ineligible for continued aid because of his income.

When the drug ran out, his "cancer kicked into a more aggressive level," he says. He has lost 80 pounds, and his lymph nodes have swollen again.

He made plans for a stem-cell transplant, which his insur-



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Mr. Johnson is undergoing intense chemotherapy aimed at putting his disease in remission so that he can have a stem-cell transplant.

ance covers, but which carries risks of serious side effects. In mid-December Mr. Johnson, 56, began intensive chemotherapy aimed at putting his disease in remission so he can have the transplant.

“I don’t know how much longer I have to live, and I don’t want to spend my last days fighting Blue Cross Blue Shield over Imbruvica,” Mr. Johnson says.

Patients on Medicare are starting to feel some relief from out-of-pocket expenses through a provision in the Affordable Care Act that requires a gradual lowering of patient contributions. When the reduction is complete in 2020, the median out-of-pocket cost for Medicare patients taking oral cancer drugs will be \$5,660 a year, according to a study in the *Journal of Clinical Oncology*. Even that is more than the average beneficiary’s household spends on food in a year, the study said.

Leukemia patient Michele Steele’s doctor prescribed Imbruvica last year after she finished her fourth round of chemo-

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therapy. Though shocked at the nearly \$8,000 out-of-pocket expense for the year, she and her husband, Bill, who are retired and live in Laguna Niguel, Calif., decided to put the cost on their credit card and find a way to sort it out later.

“How are we going to do this?” Ms. Steele, 68, remembers thinking. “I was just really scared.”

They cut back on nonessentials such as movies and restaurants. “There’s nothing else to cut back on,” Ms. Steele says. “We’ve always lived very frugally.”

In August, they found a way out. They read in an online newsletter for leukemia patients about the Patient Access Network Foundation’s copay grants. After striking out on aid requests in the past, Mr. Steele says, “I just didn’t want to get my hopes up.” But it turned out the couple’s combined income of around \$82,000 was just below the cutoff point.

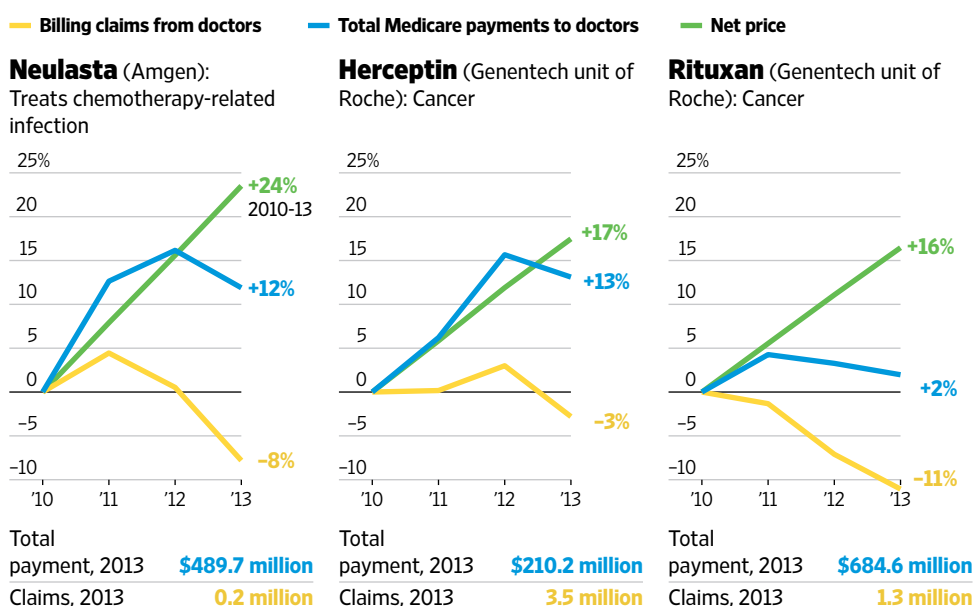
Ms. Steele’s reaction? “Relief, huge relief,” she says.

# Price Increases Drive Drug Firms' Revenue

*Boosts outpace inflation and often are imposed even when demand falls*

## Revenue Infusions

Medicare payments for 10 big drugs administered in doctors' offices rose an average of 8% over four years despite an average 4% drop in unit volume. Below are the three with the biggest price increases from 2010 through 2013.



Note: Prices reflect the average net price companies reported receiving from their customers, excluding rebates given to certain government health programs.

Source: Centers for Medicare and Medicaid Services

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BY JOSEPH WALKER

OCTOBER 6, 2015, PAGE A1

Demand for a drug called Avonex has declined every year for the past 10.

Not a problem for its manufacturer. U.S. revenue from the drug has more than doubled in that time, to \$2 billion last year.

The key: repeated price increases. The multiple sclerosis drug's maker, Biogen Inc., raised its price an average of 16% a year throughout the decade — 21 times in all.

It is an example of drug companies' unusual ability to boost

prices beyond the inflation rate to drive their revenue, even when demand for the drugs doesn't cooperate.

A result of this pricing power is that across 30 top-selling drugs sold by pharmacies, U.S. revenue growth has far outpaced demand in the past five years, according to a Wall Street Journal analysis of corporate filings and industry data. Revenue growth averaged 61%, three times the increase in prescriptions.

Attention has focused lately on new drugs with eye-popping prices and on a few whose price a new owner abruptly raised several-fold. But what many drug companies rely on for sales growth is a pattern of steady increases, year in and year out, on older medicines. Wholesale-price increases for the 30 drugs analyzed by the Journal averaged 76% over the five-year stretch from 2010 through 2014. That was more than eight times general inflation.

For 20 leading global drug companies last year, 80% of growth in net profits stemmed from price increases in the U.S., according to a May report by Credit Suisse.

Pricing power helps some in the pharmaceutical industry to compensate for sluggish demand, new competition or weak product pipelines. "Pricing has covered up a multitude of other disappointments over the past 15 years" in the sector, said Geoffrey Porges, a biotech analyst at AllianceBernstein LP.

This is no cause for cheer, of course, to certain other market participants, notably the many large companies that pick up the tab for their employees' prescriptions. Drug pricing has helped drive up spending on benefits at Lowe's Cos., said Bob Ihrie, a senior vice president at the home-improvement retailer.

"It's one thing when you read about a new drug in the newspaper, and all the costs of launching it. But when it's drugs that have been on the market and you see these price increases, you go, 'Why would this be?'" Mr. Ihrie said. "I feel like we're really being taken advantage of."

Pharmaceutical companies defend their pricing as helping to finance development of innovative medicines, an expensive and risky enterprise they say wouldn't attract investment without

the potential for large returns when a new drug succeeds.

Many in the industry also say a focus on drug prices is short-sighted because it overlooks drugs' role in helping to contain overall health-care costs by preventing disease complications.

Robert Zirkelbach, a spokesman for Pharmaceutical Research and Manufacturers of America, a trade group, said that eventually, prices for all drugs will decline sharply when they lose patent protection and go generic.

Avonex maker Biogen has noted the central role of price boosts in the drug's success. "For 2014 compared to 2013, the increase in U.S. Avonex revenues was primarily due to price increases, partially offset by a decrease in unit sales volume of 10%," Biogen said in its 2014 financial report. A similar note has appeared in its annual reports since 2005.

But Biogen points to the way this revenue funds its quest for new medicines. The company spent an average of \$1.19 billion annually on R&D from 2005 through 2014, or 24% of total revenue. Besides Avonex, the company has brought out two other multiple sclerosis drugs and is studying a treatment to repair nerve damage from the disease.

"Over the past two decades, which is the life of Avonex, we've done more than any other company to improve the treatment of multiple sclerosis," said Daniel McIntyre, a Biogen senior vice president. "The reality is that revenues from therapies available today make this possible."

### **Users and payers**

What gives the pharmaceutical industry so much pricing power? Part of the reason is the patent protection drug makers have on new products, which keeps competitors from offering copies for up to two decades.

Another part of the answer is the insurance-based health system, in which consumers rarely feel the full brunt of price increases.

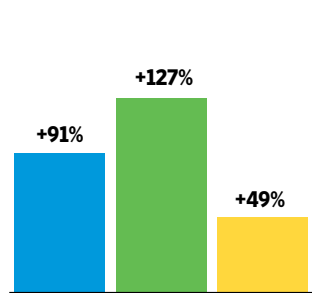
In most markets, products are ordered, paid for and consumed

**Prescription for Sales**

Price increases help drug makers boost revenue at a rate outpacing consumer demand. For six big-selling drugs, here are 2010–14 percent changes in wholesale price, U.S. revenue and dispensed prescriptions.

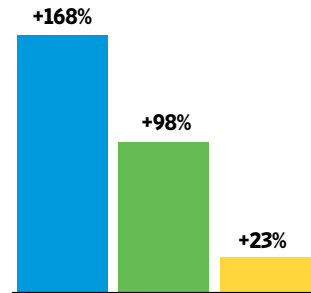
■ Price ■ Revenue ■ Prescriptions

**Humira** (AbbVie):  
Treats arthritis



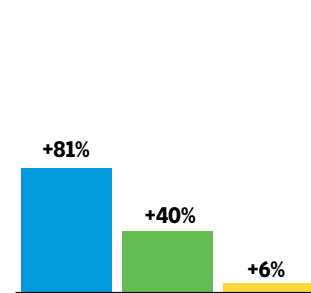
Revenue, 2014 **\$6.52 billion**  
Prescriptions, 2014 **2.1 million**

**Lantus** (Sanofi):  
Diabetes



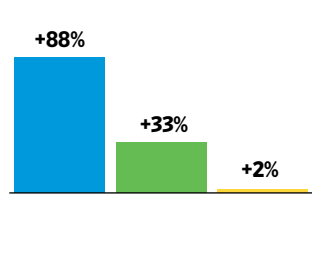
Revenue, 2014 **\$5.61 billion**  
Prescriptions, 2014 **20.0 million**

**Abilify** (Otsuka):  
Schizophrenia



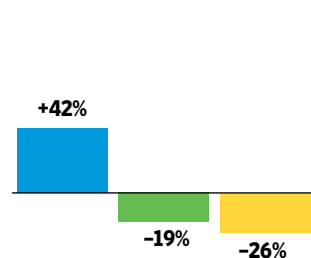
Revenue, 2014 **\$4.93 billion**  
Prescriptions, 2014 **9.1 million**

**Enbrel** (Amgen):  
Arthritis



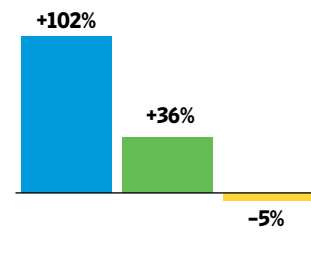
Revenue, 2014 **\$4.40 billion**  
Prescriptions, 2014 **1.7 million**

**Advair** (GlaxoSmithKline):  
Asthma



Revenue, 2014 **\$3.25 billion**  
Prescriptions, 2014 **15.3 million**

**Copaxone** (Teva):  
Multiple sclerosis



Revenue, 2014 **\$3.10 billion**  
Prescriptions, 2014 **0.7 million**

Note: Prices reflect wholesale list prices set by companies and don't take into account rebates and discounts given by drug makers. Price changes are from the start of 2010 to the end of 2014.  
Sources: Truven Health Analytics; IMSHealth Inc.; EvaluatePharma; SEC filings

THE WALL STREET JOURNAL.

by the same party, notes Sara Fisher Ellison, a Massachusetts Institute of Technology economist. But prescription drugs are ordered by a physician, used by a patient and usually paid for by a third party, either an insurer or a large employer.

Neither doctors nor patients typically have much of a sense of drugs' prices. That blunts what economists call price sensitivity, the tendency of higher prices to curb demand.

"It confuses incentives and dampens the normal economic dynamics," Ms. Ellison said.

In addition, some drugs long on the market develop customer loyalty that provides a price umbrella. If patients who started

on a drug such as Avonex a decade ago are happy with it, they or their doctors may see no reason to switch to a new one that comes along.

At an investment conference in 2009, Biogen's then-CEO James Mullen was asked whether the company could keep raising Avonex's price. He said he was surprised at "how unresistant the market has been to price increases."

Mr. Mullen declined to comment.

Until about a year ago, price increases were garnering little public attention because spending on drugs had moderated. U.S. expenditures for most prescription drugs grew by an average of 2.7% from 2007 through 2013, according to data from the Centers for Medicare and Medicaid Services. That was a slower growth rate than in several previous years, due largely to greater use of generics as some big-selling drugs lost patent protection.

The moderating price effect from generics now is tapering off. Pharmacy-benefits manager CVS Health Corp. said drug spending by its customers jumped 12.7% last year, more than triple the prior year's rise.

Price boosts represented more than 80% of this increase, CVS said.

Similarly, Medicare's spending on its prescription-drug benefit rose 8% last year on a per capita basis, after several years of averaging less than 1%. A leading reason for the surge was "price increases for both brand-name and generic drugs," Medicare's board of trustees said in a recent report.

The Journal examined 30 of last year's top drugs by revenue that are sold by U.S. pharmacies, looking at data from the start of 2010 through the end of 2014. The analysis used corporate financial statements, prescription figures from IMS Health Holdings Inc. and wholesale-pricing data provided by Truven Health Analytics. It excluded drugs that weren't yet on the market in 2010 or for which full data weren't available.

For 18 of these 30 drugs, both revenue and the number of dispensed prescriptions for them rose. But revenue rose twice as

fast as prescriptions.

For the cancer drug Gleevec, from Novartis AG, prescriptions rose 2% over the five years, but the wholesale price doubled, to \$102,000 for a year's supply at the end of 2014. The price increases helped to drive Novartis's U.S. revenue from the drug up 69% over the period, to \$2.17 billion in 2014.

Gleevec is a strikingly effective drug that has been approved for more cancers since its 2001 launch for chronic myeloid leukemia, or CML. Asked about the price increases on Gleevec, Novartis said it is "a life-changing medicine" whose "success is funding the next generation CML innovations."

Drug makers often give rebates from the wholesale prices — also called list prices — to large purchasers such as insurers and pharmacy-benefit managers. Even so, the wholesale prices are a meaningful measure because they are the starting point from which rebates are given.

In competitive markets such as asthma and diabetes therapy, which have multiple drugs that can be substituted for one another, manufacturers often give especially large rebates as they seek better positioning on insurers' "formularies" of covered drugs.

Take insulin, of which there are several brands, among them Humalog from Eli Lilly & Co. The company gave rebates averaging 56% of its list price last year, Credit Suisse estimates.

A spokeswoman for Eli Lilly said that although it doubled Humalog's price over five years, steep rebates meant that its net price rose only 3%.

### **Shallower discounts**

With a drug that is harder to substitute for, such as Amgen Inc.'s arthritis treatment Enbrel, discounts are shallower. Amgen raised Enbrel's wholesale price 88% over the five years. The rebates it provided averaged 21% last year, Credit Suisse estimates.

Over the five years from 2010 through 2014, U.S. prescriptions for Enbrel rose 2% while Amgen's revenue from it went up



by a third.

Some rebates are locked in. Medicaid and the Veterans Health Administration are legally entitled to rebates of at least 23.1% and 24%, respectively, on purchases of patent-protected drugs. Drug companies must also pay additional rebates to the two health programs if their drug prices exceed inflation.

Among the 30 retail drugs the Journal examined, 10 produced revenue increases for their makers last year despite lower demand.

Prescriptions for these drugs declined an average of 17%. But their wholesale prices went up an average of 80%. After discounts, revenue from the drugs rose 22%.

For two drugs in the 30, both revenue and demand fell. But revenue fell less.

For a different category of drugs — those usually administered in doctors' offices, such as intravenous cancer drugs — prescription volumes aren't reliably tracked by commercial databases. To assess these, the Journal identified last year's 10 top-selling such drugs and analyzed 2010-2013 data on how much Medicare reimbursed doctors for them.

Medicare bases these reimbursements on the average price that drug makers report receiving from customers, excluding certain government buyers such as the Veterans Health Administration and Medicaid.

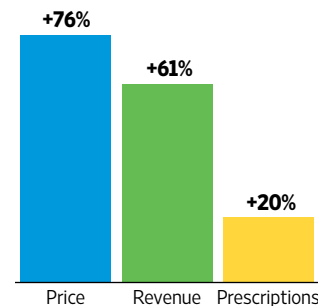
For four of the doctor-administered drugs, the number of billing claims from doctors fell, yet Medicare's outlays to doctors rose because prices went up.

For example, Medicare payments for Neulasta, an infection-fighting drug sold by Amgen, rose 12% over the four years, while claims from doctors who used it fell 8%.

The manufacturer reported that the average net price it received for this 13-year-old drug rose 24% over the four years, undergirding Medicare's higher payouts.

### Upping the Bill

U.S. prices for 30 top-selling drugs rose nearly four times as fast as prescription volume, on average, from 2010 through 2014.



Note: Wholesale list prices, not reflecting rebates and discounts given by drug makers.

Sources: Truven Health Analytics; IMS Health Inc.; EvaluatePharma; SEC Filings

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An Amgen spokeswoman said the company prices its products to “reflect the economic value that is delivered to patients, providers and payers.”

Avonex, the drug with 21 price increases during a decade of falling demand, reached the U.S. market in 1996. It was just the second drug shown to delay symptoms of the most common form of multiple sclerosis.

The maker of Avonex, Biogen, initially set its wholesale price at about \$9,200 for a year of treatment. The strategy at that time focused on expanding the market, said a former Biogen vice president of sales, Michael Bonney. “We probably had pricing power, but we decided not to exercise it,” he said.

As more MS drugs appeared, including some taken orally, (Avonex is injected), Avonex’s share of the market steadily fell. Each year from 2005 through 2014, the company sold fewer units of Avonex, company financial statements show.

But Biogen’s U.S. revenue from the drug kept growing as it raised the price up to three times a year. In the decade through 2014, the wholesale price, before discounts or rebates, more than quadrupled to an annual \$62,000 per patient.

When former CEO Mr. Mullen was asked about the price increases at the 2009 investment conference, he said, according to a transcript: “If there’s price increases that can be taken and delivered to shareholders, we’ll go get it, but I do think we got to make sure we take a long enough view and you don’t start to put this thing in a box, where you get the backlash.”

Today, Avonex is among the least-popular MS drugs, said Clyde Markowitz, a specialist in the disease at the Hospital of the University of Pennsylvania, but it is still used by patients who have had good results. While costs for all MS drugs have skyrocketed in the past decade, Dr. Markowitz said, Avonex’s price growth has been extraordinary.

“It’s absolute insanity, what’s happened,” he said. “For a drug that’s 20 years old, and they just keep jacking up the price.”

# \$1,000 Hepatitis C Pill Is Hard for States to Swallow



MAX WHITTAKER/PRIME FOR THE WALL STREET JOURNAL

Harvoni patient Randall Murphy and his physician, Catherine Moizeau.

**BY JOSEPH WALKER**

APRIL 9, 2015, PAGE B1

A pricey pill made by Gilead Sciences Inc. caused Medicaid spending on hepatitis C treatments to soar last year, even as most states restricted access to the drug, leaving many low-income patients untreated.

State Medicaid programs spent \$1.33 billion on hepatitis C therapies through the third quarter of 2014, or nearly as much as the states spent in the previous three years combined, a Wall

Street Journal analysis of federal data shows. The growth was primarily driven by Gilead’s Sovaldi, a highly effective therapy that has a wholesale cost of \$84,000 per person over the course of treatment, or \$1,000 per pill. The price has sparked an outcry from insurers, members of Congress and others worried about the cost of treating an estimated three million Americans with hepatitis C, which can lead to cirrhosis or cancer of the liver.

The data show patient access to Sovaldi varied widely state by state, reflecting different coverage of the drug and also long-standing disparities in how states deliver health benefits to the poor. Many states limited Sovaldi’s availability to the very sickest patients, primarily those with severe liver scarring.

These barriers to treatment have sparked local disputes about coverage, with officials pleading budgetary constraints and doctors complaining that economic considerations are trumping medical judgment. The soaring costs and tension are likely to continue as other expensive drugs reach the market.

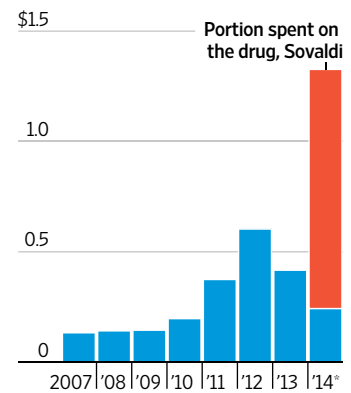
“Now we have a wonder drug for hepatitis C; in fact, we have several, but as soon as the drugs appeared they’ve been snatched from our grasp,” Brian R. Edlin, associate professor of medicine at Weill Cornell Medical College, said. “We could literally end the hepatitis C epidemic if we put these tools to use.”

In total, states spent \$1.08 billion on Sovaldi in the first nine months of 2014, representing 82% of all hepatitis C drug spending, according to the Journal’s analysis of the data, which provide the most comprehensive picture yet of Sovaldi’s financial impact on Medicaid programs. The second-largest expenditure, at \$136.3 million, was for Olysio, a pill made by Johnson & Johnson that was often used in combination with Sovaldi.

States are entitled to get a portion of their money back

**Rising Cost**

Medicaid spending on hepatitis C medications, in billions



\*Through 3Q  
Source: Centers for Medicare & Medicaid Services  
THE WALL STREET JOURNAL.

through legally mandated rebates of at least 23.1%. Rebates are expected to be higher this year after the launch of a competing hepatitis C drug made by AbbVie Inc. The data analyzed by the Journal doesn't include rebates.

Sovaldi was Medicaid's third-largest drug expenditure after Abilify, an antipsychotic medication that cost \$1.73 billion, and a generic version of the cholesterol-lowering treatment Lipitor, which totaled \$1.12 billion in spending.

Texas, which has the nation's third-largest Medicaid population after California and New York, spent nothing on Sovaldi in the first nine months of the year, according to the data, making it the only state in the U.S. to not pay for the drug.

Although federal data for the full year isn't yet available, a state spokeswoman confirmed Texas didn't pay for the drug in the fourth quarter, either. A Texas state spokeswoman said "price was the biggest issue" affecting coverage of Sovaldi in 2014. Beginning this month, Texas has made AbbVie's drug Viekira Pak available to patients with advanced disease, the spokeswoman said.

Gilead has provided free hepatitis C drugs to several hundred Texas Medicaid patients and more than 10,000 people with all insurance types across the U.S., Cara Miller, a Gilead spokeswoman, said. "Most states have covered Sovaldi with varying degrees of access and many are in the process of" reviewing their policies after the launch of newer drugs, she said.

New York, known for offering relatively generous Medicaid coverage, was the biggest spender on Sovaldi during the first nine months of 2014, at just over \$297 million, or 7.6% of the state's total drug spending. New York spent \$47.50 on Sovaldi per Medicaid enrollee. California, the most populous state in the U.S., spent \$86.94 million on the drug, or \$7.29 per enrollee.

California uses private and nonprofit insurers to administer Medicaid benefits to most enrollees. Doctors in California say some insurers are denying hepatitis C drugs even to patients with advanced disease.



MAX WHITTAKER/PRIME FOR THE WALL STREET JOURNAL

Randall Murphy, a Medicaid recipient with late-stage liver disease, was approved in early April for Gilead's Harvoni after being denied last fall.

Catherine Moizeau, a Davis, Calif.-based primary-care physician, said Medicaid insurers denied hepatitis C treatment to about 30 of her Medicaid patients last year, including some who are “on the edge” of decompensated cirrhosis, the point at which most patients die unless they receive a liver transplant. Under California’s statewide policy, such patients should be eligible for treatment.

Randall Murphy, a Medicaid recipient with late-stage liver disease, said his insurer rejected his applications for Gilead’s Sovaldi at least twice after Dr. Moizeau first prescribed it last summer.

This fall, she prescribed for Mr. Murphy a new Gilead drug, Harvoni, which was also denied by California Health & Wellness, a subsidiary of Centene Corp. In a February denial letter, the insurer said Dr. Moizeau hadn’t provided enough informa-

tion about Mr. Murphy's condition and test results.

In early April, Mr. Murphy was approved to receive Harvoni.

"They're picking and choosing who gets to live and who gets to die and they're not even being honest about it," Mr. Murphy, of Coloma, Calif., said in an interview prior to receiving the treatment.

Centene Corp. declined to comment on Mr. Murphy specifically, citing privacy rules. "We consistently ensure members, who meet the state's evidence-based guidelines submitted by their providers, have access to hepatitis C medication regardless of cost," a spokeswoman said in an email.

The state has received reports about "inappropriate denials," but has found "the majority of the denials were appropriately made," said Anthony Cava, a spokesman for the California Department of Health Care Services, which oversees the state's Medicaid program.

Mr. Cava said the drug's cost didn't play a role in the state's policy.

Medicaid spending on hepatitis C is likely to keep climbing. Competition between Gilead and AbbVie has allowed states to negotiate discounts totaling 40% or greater for the drugs, which should help states widen coverage.

Still, most states aren't planning to open access to all medically eligible patients, and will continue to limit access to those with advanced liver damage, Matt Salo, executive director of the National Association of Medicaid Directors, said.

"Total costs will go up," Mr. Salo said. "While we're fortunate that the price per pill has come down from \$1,000, it's still too high to provide complete access for the millions of infected patients in this country."