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The Life of a Blockbuster

(Source: An article by Jessica Merrill for Scrip Citeline)

Developing blockbuster drugs is a prime goal of biopharmaceutical manufacturers, offering the opportunity to recoup years of investment in drug development and lay a solid financial foundation for the company's long-term future. Building blockbuster brands has never been easy and has become more difficult as competitive dynamics have intensified, as certain therapeutic areas have become saturated, and as market access headwinds have increased. Nonetheless, new drugs reach the market and grow into new blockbuster brands and sometimes even "megablockbuster"-sized sellers.

For decades a blockbuster has been loosely defined as a drug that generates more than US\$1 billion in annual sales. But increasingly, drug makers – and their investors – have set sights on bigger and bigger commercial brands, such as drugs that generate US\$5 billion or more in annual sales and that serve as a solid anchor for their pharmaceutical portfolios.

Of the 487 drugs approved by the US Food and Drug Administration from 2014-2023, 193 are forecasted by Evaluate Pharma to generate peak-year sales over US\$1 billion. This translates to approximately 39% of new drugs being projected to reach blockbuster status.

Among those, the biggest sellers are 17 drugs that are forecasted to reach peak-year sales of more than US\$10 billion, while 42 are expected to post peak-year sales of more than US\$5 billion and 114 are expected to bring in peak-year sales of more than US\$2 billion, according to Evaluate data. (Click <u>HERE</u> to view chart.)

Excluding COVID-related products, the five drugs forecasted by Evaluate Pharma to generate the most revenue in a single year at their peak are Merck & Co., Inc.'s cancer drug *Keytruda* (US\$31.28 billion), Novo Nordisk A/S's obesity treatment *Wegovy* (US\$22.22 billion), Sanofi/Regeneron Pharmaceuticals, Inc.'s immune disease drug *Dupixent* (US\$20.02 billion), Johnson & Johnson's multiple myeloma drug *Darzalex* (US\$16.87 billion) and AbbVie Inc.'s autoimmune therapy *Skyrizi* (US\$16.1 billion).

COVID-19 offered a unique commercial opportunity, and pandemic-related treatments and vaccines are some of the highest-earning products of all time. In the Evaluate dataset, Pfizer Inc./BioNTech's COVID-19 vaccine *Comirnaty* and Pfizer's COVID-19 antiviral *Paxlovid* would both rank in the top five of peak annual revenues. *Comirnaty* and *Paxlovid* have already reached peak year sales, in 2021 for *Comirnaty* at US\$41.21 billion and in 2022 for *Paxlovid* at US\$18.93 billion, which means that while the products generated unprecedented revenue upon their launch in the middle of the COVID-19 pandemic, they have had an atypical launch trajectory and are quickly declining.

Keytruda, on the other hand, continues on its path of being a more traditional pharmaceutical success story. The drug is on *(continued on page 2)*

In Brief...

• Walgreens has inked a partnership with Boehringer Ingelheim to recruit participants for research as it continues to build out its clinical trials business. The company will use its community pharmacies as clinical trial sites for people living with obesity, overweight issues, and type 2 diabetes. Walgreens launched its clinical trials unit in June of 2022. So far, more than 35 clinical trials contracts have been signed with drugmakers.

Pharma manufacturers Sanofi, Pfizer and AstraZeneca will invest a combined €1.87 billion (US\$2.03 billion) in France. Several other pharma giants, including AbbVie, GSK, Novartis, Chiesi and Kenvue have also detailed plans to increase their in-country presence under President Emmanuel Macron's "Choose France" initiative, which was designed to bolster foreign investment by multinationals in France. To date efforts have resulted in a record €15 billion (US\$16.2 billion) and includes companies such as Amazon and Microsoft.

• Following companies such as **Eli Lilly**, **Pfizer** will establish a direct-to-consumer service to market and sell some of its medicines online, avoiding industry middlemen. The company plans to sell products such as its COVID treatment Paxlovid and a migraine nasal spray under the new strategy. Pfizer expects to have the website up before the end of 2024. It will connect patients with consultants to prescribe the drugs, with a supplier filling and shipping the prescriptions.

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IQVIA's "Use of Medicines in the U.S. 2024 Report"

(Source: An article by Sandra Levy for Drug Store News)

New prescriptions for chronic and acute conditions were both above pre-pandemic levels in 2023, reflecting continued growth of chronic prescriptions and a resurgence of seasonal respiratory ailments driving higher acute prescriptions. This finding comes from the IQVIA Institute for Human Data Science's newly released *"Use of Medicines in the U.S. 2024 Report"*.

Several key findings are highlighted in the report, including:

• Flu vaccination rates fell by 17% from the 2022 level and other routine adult and pediatric vaccination rates remain below pre-pandemic levels, although adult vaccination rates have improved since 2021.

• In 2023, total prescription use increased by 3% and reached 210 billion days of therapy. Non-retail medicine use, including a large portion of cancer treatment, was disrupted early in the pandemic but has since seen a sharp rise, particularly in clinics and doctor's office settings.

• Retail prescriptions reached 6.9 billion, a 2.9% increase from 2022, but slower growth year-over-year.

Blockbuster (cont.)...

track to surpass any others in the dataset in generating the most accumulated revenue from its launch in 2014 through 2028, when it will face loss of exclusivity. (LOE)

Keytruda is expected to generate a staggering US\$251.09 billion from 2014-2028. The drug has brought in US\$101.67 billion from 2014-2023, meaning it will more than double the revenue it made in its first nine years on the market in the last five before its LOE.

The other drugs that are expected to accumulate the most revenue in the 14-year period from 2014-2028 are Novo Nordisk's *Ozempic*, Bristol Myers Squibb Company's *Opdivo*, as well as *Dupixent* and *Comirnaty*. Comparisons between the brands in terms of accumulated sales figure are challenging because the drugs all launched at different time periods, between 2014 for *Keytruda* and 2021 for *Comirnaty*, so some of the drugs have had less time on the market than others.

Nonetheless, the data show just how much revenue a mega-blockbuster can contribute to a drug manufacturer's top line over an extended time period, particularly notable given that the cost of making and selling a drug generally declines the longer it is on the market.

Meanwhile, a smaller but still significant blockbuster will generate significantly less over its life. Novartis AG's *Cosentyx* and *Entresto*, for example, are both high-growth mega-blockbuster franchises for the company that are expected to peak at under \$7bn in peak-year revenues. They are expected to generate substantially less over the 14-year time horizon compared to drugs with peak-year sales over US\$10bn.

IQVIA Report (cont.)...

• Shifting enrollment patterns for insurance in 2023 resulted in more patients covered by commercial insurance, while Medicaid enrollees and the uninsured declined. Both Medicare and Medicaid realized rising average numbers of prescriptions per enrollee, while commercially-insured had flat to declining usage per beneficiary.

• Many therapy areas had high growth in days of therapy in 2023, including GLP-1 agonists in obesity and diabetes, immunology treatments, lipid regulators and gastrointestinal medicines, all of which increased more than 9% in 2023. Antibacterial use continued to grow in 2023 and per capita prescription opioid use declined to the lowest levels since 2000.

Additionally, in non-retail drug usage, use of medicines in clinics showed 13% growth since 2019 while retail drug usage of dispensed prescriptions reached 6.9 billion in 2023. Also notable was the fact that nearly 100 million prescriptions were provided to patients through illegal online pharmacies in 2023.

More shortages continue to be reported than resolved, with 58% of the 132 current molecular shortages ongoing for more than two years and 75% of the current shortages ongoing for more than a year. Drug shortages are an ongoing issue in the U.S. healthcare system, although the number and severity of these shortages have changed over time. Over the past five and a half years, 160 new molecule shortages have occurred through June of 2023 while only 51 have been resolved. The most frequently seen shortages tend to be generic and injectables.

With regard to medical spending, spending on medicines at net manufacturer prices reach US\$435 billion in 2023, up US\$10

billion over the prior year. The U.S. market at new prices grew by nearly 10% in 2023, excluding the declining contribution of COVID-19 vaccines and therapeutics. Spending list prices grew at 7.6% over the past five years, while payer's spending grew at 5.2% and patients' costs grew at 2.1%. Spending at list prices increased faster than all-payer net spending.

The outlook to 2028 shows U.S. spending on a continued growth path, driven by innovation and offset by notable expiry events. Also, a factor is the continued increasing gap between list price spending, which will grow at 6.9%, and manufacturer net revenues which will grow at 4-7%. Brand new spending in the U.S. is projected to total US\$122 billion in the next five years, down from the US\$149 billion in the past five years. Net prices for protected brands could see a decline of -1 to -4% while list prices will grow 1% to 4% including impact of price cuts.

The impact of exclusivity losses will increase to US\$93.6 billion over five years, including significant biosimilars. Oncology and obesity will drive growth through 2028, while diabetes, immunology and COVID-19 will contribute to slowing.

To download a copy of the report, visit <u>https://www.iqvia.</u> <u>com/insights/the-iqvia-institute/reports-and-publications/</u> <u>reports/the-use-of-medicines-in-the-us-2024</u>

In Brief (cont.)

• Danish manufacturer **Novo Nordisk** has struck a deal with **Metaphore Biotechnologies** worth US\$600 million. The deal is aimed at the generation of two multi-mechanism compounds for the treatment of obesity. These compounds are long-acting and easily manufactured. This is the 5th early stage deal Novo Nordisk has signed this year.

• Deloitte's Health Equity Institute and the School of Global Health at Meharry Medical College project that mental health inequities in the U.S. will cost nearly US\$500 billion in avoidable costs through 2024 and could escalate to US\$1.3 trillion by 2040 if left unchecked. Most of the expenses can be deemed to be "avoidable and unnecessary" and are associated with premature death and productivity losses.

• Novartis has nominated former Bristol Myers Squibb (BMS) CEO, *Giovanni Caforio*, as its next chairman, a move the company believes will reinforce its goal to become a bigger U.S. market player. Caforio, who stepped down from BMS in November, is set to succeed Novartis's current chairman, *Joerg Reinhardt*, in March of 2025.

• The U.S. Food and Drug Administration (FDA) has approved Amgen's investigational lung cancer immunotherapy *Imdeltra (tarlatamab)*, a first-of-its-kind treatment for small-cell lung cancer. The new therapy, which is endorsed for patients whose disease has worsened after or throughout treatment with platinum-based chemotherapy, has the potential to become a blockbuster for the company, according to analysts. The accelerated approval, which was delivered nearly a month before the FDA's June 12th decision date, is contingent upon verification of clinical benefit in a confirmatory trial.

(Sources: Company Press Releases, Drug Store News, FiercePharma, PharmaVoice, and Reuters)