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ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

ASPE REPORT

Competition in Prescription Drug Markets, 2017-2022

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Executive Summary

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The cornerstone of a well-functioning market is competition. President Biden's Executive Order 14036, "Promoting Competition in the American Economy" identified a lack of competition as a key driver for problems across economic sectors. By incentivizing competition, it is possible to foster innovation and improve the stability of a market, in turn increasing access and affordability of products. The U.S. prescription drug market is the largest drug market in the world; however, drug prices in the U.S. are much higher than in most of the world. High drug prices mean that people often cannot afford prescription drugs, even when those drugs are otherwise available. We used IQVIA data from 2017 through 2022 to identify the level of competition in different prescription drug markets. We focus on competition in the prescription drug market, because the number of competitors for a particular drug is associated with pricing power – drugs with fewer or only one manufacturer, on average, have higher prices than drugs with multiple manufacturers, holding all else constant. Understanding the baseline level of competition in drug markets will allow us an opportunity to further incentivize innovation and competition.

KEY FINDINGS

- In 2022, average cost of a biological product, $174 per prescription, was 3.7 times greater than average cost of a small molecule drug, $48 per prescription.
- Among the 1,838 small molecule drugs in 2022, 43 percent (796 drugs) had only one manufacturer, 16 percent (298 drugs) had 2-3 manufacturers, 9 percent (156 drugs) had 4-5 manufacturers, and 32 percent (588 drugs) had 6+ manufacturers. Drugs with a single manufacturer accounted for a disproportionate share of drug spending; the 43 percent of drugs with one manufacturer accounted for 65 percent of small molecule drug expenditures.
- Among the 268 biological products on the market in 2022, 81 percent (216 products) had only one manufacturer, 13 percent (34 products) had 2-3 manufacturers, 4 percent (12 products) had 4-5 manufacturers, and 2 percent (6 products) had 6+ manufacturers. The 81 percent of biological products with only one manufacturer accounted for 74 percent of total biological product expenditures. The pattern of biological products with one manufacturer accounting for a smaller share of the total spending is different than the pattern seen for small molecule drugs.
- Between 2017 and 2022, for small molecule drugs, the proportion of drugs with 6+ manufacturers rose while those with a single manufacturer declined over time. In contrast, biological products predominantly had one manufacturer, and the proportion of products with one manufacturer continued to increase over time.
- We then focused on high-cost drugs. Among specialty drugs, in 2022, 63 percent of small molecule drugs (273 drugs) and 87 percent of biological products (164 products) had only one manufacturer. Focusing on the top 10 percent of drugs based on price, i.e., the highest priced drugs, 89 percent of small molecule drugs (136 drugs) and 100 percent of biological products (59 products) had only one manufacturer.
- Among the highest priced drugs, the most common therapeutic classes were enzyme inhibitors (68 drugs), immunomodulators (21 drugs), antineoplastic monoclonal antibodies (20 drugs), miscellaneous antineoplastics (9 drugs), and other neurological/ neuromuscular (9 drugs). Ninety-two percent had only a single manufacturer.

Report

Introduction

The cornerstone of a well-functioning market is competition. President Biden's Executive Order 14036, "Promoting Competition in the American Economy" identified a lack of competition as a key driver for problems across economic sectors. By incentivizing competition, it is possible to foster innovation and improve the stability of a market, in turn increasing access and affordability of products. The U.S. prescription drug market is the largest drug market in the world; however, drug prices in the U.S. are much higher than in most of the world. High drug prices mean that people often cannot afford prescription drugs, even when those drugs are otherwise available. Enhancing competition in drug markets is a key priority of this administration. By increasing competition, standard economic theory suggests that the price of drugs will decrease, and more Americans will have access to affordable prescription drugs.

The goal of this report is to examine the level of competition in the U.S. prescription drug market, defined as the number of manufacturers that are currently selling a given active ingredient. We examine different drug characteristics, including small molecule drugs versus biological products, specialty drugs, and the highest priced drugs between 2017 and 2022. We focus on competition in the prescription drug market, because the number of competitors for a particular drug is associated with pricing power – drugs with fewer or only one manufacturer, on average, have higher prices than drugs with multiple manufacturers, holding all else constant. Understanding the baseline level of competition in drug markets helps us identify tailored policy solutions to further incentivize innovation and competition, and it will be important to continue examining competition in prescription drug markets as they evolve over time.

Data and Methods

The primary dataset for this analysis was IQVIA National Sales Perspective (NSP) from 2017 through 2022.[1] IQVIA data are derived from a panel of wholesalers, distributors, and pharmaceutical manufacturers that represent 90 percent of the pharmaceutical market and are weighted to be nationally representative.[1] The IQVIA data include whether a drug was a small molecule drug or a biological product, the setting to which a drug was sold (i.e., retail, mail, or non-retail setting), and the total expenditure associated with the transaction (i.e., sales from manufacturers and wholesalers to pharmacies, hospitals, and other health care settings). While the data do not include payer information, the data include drugs that are eventually used by Americans of all ages and covered by commercial insurance, and public insurance programs, including Medicare, as well as self-pay. Drug spending was measured in inflation adjusted dollars.[2] The IQVIA dataset reports gross drug spending, meaning it does not include rebates.[3] The number of prescriptions was calculated as a measure of the number of units of a drug a manufacturer sold to a wholesaler or pharmacy.[4]

Competition was measured by the number of unique pharmaceutical manufacturers that sold a drug. To assess the level of competition in prescription drug markets, we identified drugs based on their active ingredient. For each drug, we counted the number of unique corporations (i.e., manufacturers) with sales in the data for each

[1] Source of the data: IQVIA. U.S. National Data. <https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data>.

[2] The spending data includes an adjustment for inflation, thereby representing a "real" dollar. The data represent the value of a real dollar as of quarter 1 of 2022. Source: U.S. Bureau of Economic Analysis, Gross Domestic Product: Implicit Price Deflator [GDPDEF], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/GDPDEF, January 30, 2023.

[3] Retail drugs can be subject to rebates while non-retail drugs do not have rebates. As a result, retail drug spending may be overestimated relative to non-retail spending.

[4] The variable in the IQVIA data that is used to measure the number of prescriptions, "eaches", is defined as "the number of single items (such as vials, syringes, bottles, or packet of pills) contained in a unit or shipping package and purchased by pharmacies in a specific time period. In this report, the term "prescription" does not refer to units that are sold directly to patients. Additional information can be found in the appendix.

year and stratified the results into brackets of competitive intensity measured as the count of active manufacturers, regardless of their market share. For example, if a single manufacturer marketed a given molecule[5], then we categorized this as a single manufacturer on the market. These are also known as "single source" drugs. The same process was used to identify whether there were 2-3 manufacturers, 4-5 manufacturers, or 6+ manufacturers.

This report has two primary outcomes of interest: the number of manufacturers for a given molecule and the percent of total revenue that was associated with each level of competition (e.g., what percent of a market had 2-3 manufacturers based on revenue). The goal of assessing the number of manufacturers for a given molecule is to examine how many drugs do not have competition. The goal of assessing the percent of total revenue associated with each level of competition is to understand the monetary value of the prescription drug market that is associated with monopolistic practices. Importantly, we relied on the drugs that appear in the IQVIA database, meaning that a drug had to have been marketed by the manufacturer.[6]

In this analysis, we separately assess small molecule drugs and biological products. In addition, we examine a subset of "specialty" drugs (as opposed to "traditional" or "non-specialty" drugs) and then focus on the top 10 percent of drugs based on price, i.e., "highest priced drugs", most, but not all, of which are specialty drugs. The highest priced drugs were defined on an annual basis, meaning the drugs change for each year of the sample. Table 1 defines the types of drugs examined in this report.

Table 1. Drug Categories and Corresponding Definitions

Drug Category	Definition
Small Molecule Drugs	Small molecule drugs are made using chemical processes with low molecular weight
Biological Products[7]	Biologics are generally large, complex molecules that may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell. Examples include therapeutic proteins (such as filgrastim), monoclonal antibodies (such as adalimumab), and vaccines (such as those for influenza and tetanus)
Specialty Drugs[8]	Typically cost more than $6,000 per year and require administration by a health care provider
Highest Priced Drugs	The top 10 percent of drugs in IQVIA based on price per prescription

[5] We count the unique number of manufacturers that are marketing a drug. In most cases, a single manufacturer would be the brand manufacturer of the originator drug, but in select cases a single manufacturer could be a generic or biosimilar manufacturer if the brand name manufacturer is no longer marketing their product.

[6] There is a subset of drugs that are approved by FDA but not sold by the manufacturer. Examples include: 1) an approved drug in shortage may not have an adequate supply to be utilized in large enough quantities to appear in claims data; 2) in some cases, settlement of patent litigation between brand and generic companies may result in agreements that delay marketing of approved generic drugs; or 3) a drug product has been discontinued from marketing.

[7] U.S. Food and Drug Administration. Biological Product Definitions. https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf

[8] Specialty drugs are defined by IQVIA as products used to treat chronic, rare, or complex diseases that also meet certain additional criteria. More details on the definition of a specialty drug can be found in the appendix. The IQVIA definition of specialty drug is different than the definition of a "specialty tier" in Part D.

Results

Small Molecule Drugs Versus Biological Products

Table 2 shows drug expenditures and the total number of prescriptions from 2017 to 2022 for small molecule drugs and biological products. Total inflation-adjusted expenditures on prescription drugs grew from $522 billion in 2017 to $618 billion in 2022, an 18.4 percent increase. Total prescriptions had a similar percentage point increase, from 8.019 billion in 2017 to 9.315 billion in 2022 (a 16.2 percent increase). The increase in total expenditures was driven by a 54.6 percent increase in expenditures on biological products, from $163 billion in 2017 to $252 billion in 2022. This was despite only a 1.9 percent increase in the *number* of prescriptions, which suggests that spending per prescription, rather than changes in utilization (i.e., a greater number of prescriptions being filled) was the primary driver of increased biological product spending. This pattern is similar to that for the broader prescription drug market.[9] In contrast, spending on small molecule drugs remained almost flat during this period, at approximately $360 billion per year, while the number of prescriptions increased 19.2 percent. This indicates that the price per small molecule drug was dropping during this time period. Overall, the share of total expenditures on small molecule drugs decreased from 69 percent in 2017 to 59 percent in 2022, with a corresponding increase in the share of expenditures on biological products.

Table 2. Drug Expenditures (in Inflation Adjusted Dollars) and Number of Prescriptions for Small Molecule Drugs and Biological Products, 2017-2022

	Small Molecule Drugs		**Biological Products**		**All Drugs**	
	Expenditures Billions, $	Number of Prescriptions Millions	Expenditures Billions, $	Number of Prescriptions Millions	Expenditures Billions, $	Number of Prescriptions Millions
2017	359	6.60	163	1.42	522	8.02
2018	357	6.59	185	1.74	542	8.33
2019	355	6.91	210	1.73	565	8.64
2020	360	6.80	223	1.52	584	8.32
2021	366	7.18	239	1.46	604	8.64
2022	366	7.87	252	1.45	618	9.31
% Change 2017-2022	1.9%	19.2%	55.0%	1.9%	18.5%	16.2%

Source: ASPE analysis of IQVIA National Sales Perspective (NSP) Data. Number of prescriptions refers to the number of units of a drug sold by manufacturers and wholesalers to pharmacies, hospitals and other health care settings. All dollar amounts include an adjustment for inflation meaning they represent a "real dollar" as of quarter 1 of 2022.

Competition Among Small Molecule Drugs and Biological Products

Figure 1 shows the level of competition in small molecule drug and biological product markets. The number of manufacturers can fluctuate from year to year, because it includes both new market entrants, but also market exits. That means that the number of small molecule drugs and biological products reported for each year is the *net* number of drugs on the market, after accounting for both discontinued drugs and new drugs introduced on the market. In total, there were 1,808 unique small molecule drugs in 2017, which increased to 1,838 by 2022. Throughout this six-year period, approximately 800 small molecule drugs (43 percent in 2022) had only one manufacturer, about 300 small molecule drugs (16 percent in 2022) had 2-3 manufacturers, about 150 small

[9] Parasrampuria, S. and Murphy, S. (2022). Trends in Prescription Drug Spending, 2016-2021. https://aspe.hhs.gov/reports/trends-prescription-drug-spending

molecule drugs (8 percent in 2022) had 4-5 manufacturers, and 500-600 small molecule drugs had 6+ manufacturers (32 percent in 2022). The number of drugs with 6+ manufacturers rose while those with a single manufacturer declined over time. Overall, between 2017 and 2022, for small molecule drugs, the number of drugs with 6+ manufacturers rose while those with a single manufacturer declined over time.

The biological product market was smaller than the small molecule market based on the number of products and total spending. There were 209 biological products on the market in 2017, which increased to 268 in 2022 (28 percent increase). On net (after accounting for discontinued products and new products introduced on the market), there were fifty-nine new biological products on the market in this five-year time span, which was approximately twice the number of new small molecule drugs on the market, 30, during the same time period.

The level of competition among biological products was significantly lower than for small molecule drugs. In 2017, there were 166 biological products with only 1 manufacturer (79 percent of biological products), and this increased steadily over time to 216 biological products in 2022 (81 percent of biological products, 30 percent increase). However, the level of competition for 2+ manufacturers remained relatively flat over time (the one caveat is that the level of competition for 4-5 manufacturers doubled during this time period, however there are so few drugs that fall into this category that it is not discernible in the graph). Of the 268 biological products on the market in 2022, 34 biological products (13 percent) had 2-3 manufacturers, 12 biological products (4 percent) had 4-5 manufacturers, and 6 biological products (2 percent) had 6+ manufacturers. The takeaway from this figure is that the percentage of single manufacturers for biological products has seen a slight increase, despite a growth in the number of biological products on the market.

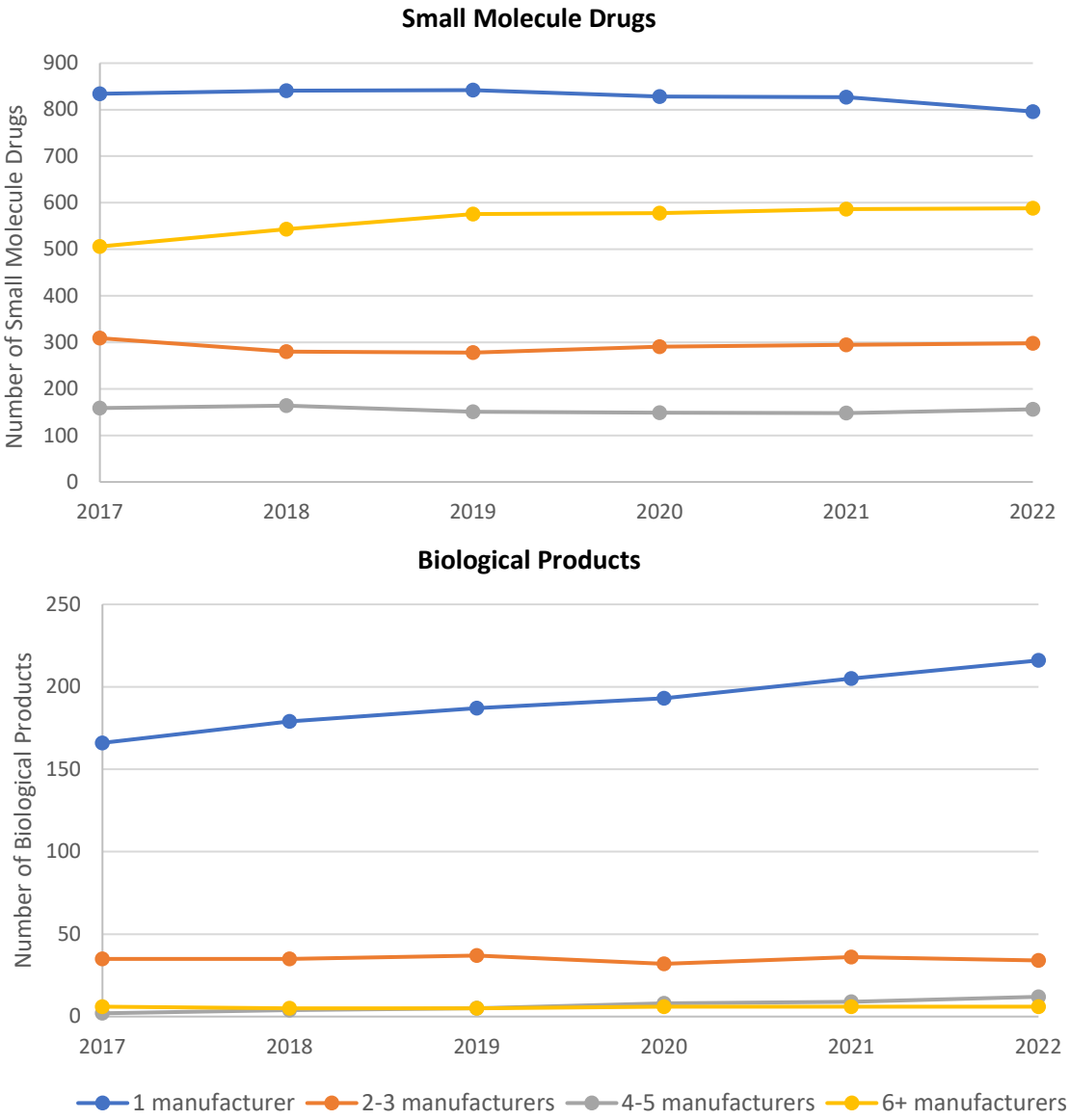
Overall, Figure 1 indicates that there was significantly more competition in the small molecule drug market relative to the biological products market. This is in large part because there are a lot of generics approved by FDA, but only a few biosimilars. There are many reasons that are more generic drugs than there are biosimilar products. Importantly, the generic approval pathway was established in 1984 under the Hatch-Waxman Act, while the biosimilar pathway was established by the Biologics Price Competition and Innovation Act in 2010 as part of the Affordable Care Act.[10] While the biosimilar pathway was modeled off the generic drug approval pathway, the pathways are not the same. For example, while generic drugs are automatically substitutable with the brand name drug by pharmacists, biosimilars require a determination of interchangeability to be considered substitutable by a pharmacist. Another difference is that the first generic drug applicant to submit a substantially complete application and challenge one or more patents listed for the brand drug can receive 180-days of market exclusivity, but there is no such exclusivity for biosimilar products (although the first interchangeable biosimilar receives a period of exclusivity). And a third difference is that Hatch-Waxman links FDA approval of follow-on applications to brand name drugs with the patents listed in the Orange Book covering those products, but there is no equivalent linkage for biologic reference product manufacturers. In addition to the differences in the approval pathways, there are other reasons for differences in competition between generic drugs and biosimilars. For example, generic drugs are significantly easier to manufacture than biological products. Generic drugs are usually synthesized from chemicals meaning each lot of manufactured drugs is the same. In contrast, biological products, including biosimilars, are typically manufactured from living systems (e.g., microorganisms, like yeast and bacteria, and animal cells), resulting in inherent variation (i.e., small changes to the molecule) as a natural part of the manufacturing process.[11] The complexity and variability of these large molecule products usually means that manufacturers conduct significantly more testing, which is both time consuming and costly, to get biosimilar products to market. In addition, reimbursement practices for generics

[10] U.S. Food and Drug Administration. (2016). Implementation of the Biologics Price Competition and Innovation Act of 2009. https://www.fda.gov/drugs/guidance-compliance-regulatory-information/implementation-biologics-price-competition-and-innovation-act-2009

[11] U.S. Food and Drug Administration. Biosimilars Info Sheet. https://www.fda.gov/media/154912/download

and biosimilars tend to be different, especially for public programs, and there are often differences in formulary placement and exclusive contracting for products. Taken together, we see that competition overall has been declining in the more expensive biological product market, while it has been gradually increasing in the small molecule market.

Figure 1. Number of Manufacturers of Small Molecule Drugs and Biological Products, 2017-2022



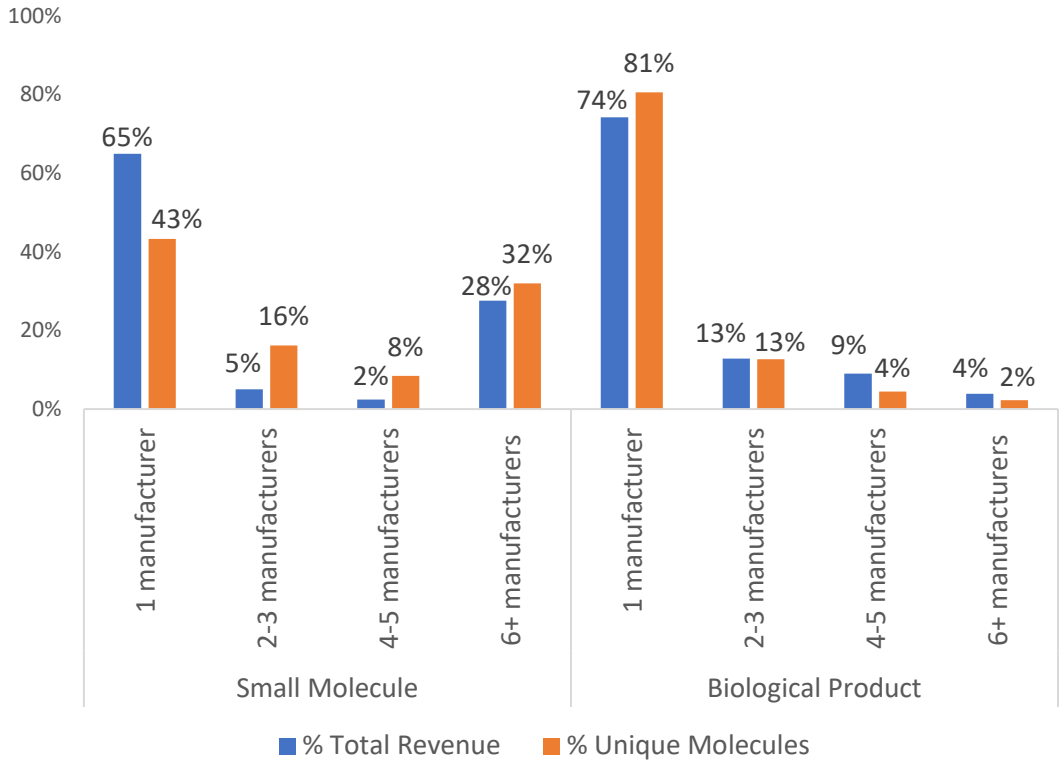
Source: ASPE analysis of IQVIA National Sales Perspective Data

Figure 2 breaks down the number of manufacturers in 2022 among small molecule drugs and biological products based on two criteria 1) the relative percent of total revenues that are attributable to each level of competition (e.g., what percent of market sales are for drugs with only one manufacturer), and 2) the relative percent of unique molecules associated with each level of competition (e.g., what percent of all molecules sold have only one manufacturer). By comparing the respective percentages for each criterion, we can examine whether sales and units sold are equivalent for each level of competition or whether there are systematic differences.

Overall, in the small molecule drug market, in 2022, the 43 percent of small molecule drugs with a single manufacturer accounted for 65 percent of small molecule drug expenditures – indicating that single source drugs are responsible for an outsized share of total spending. Among the other competition categories, the relative percent of total expenditures was lower than the relative percent of drugs represented.

In the biological product market, the vast majority of products, 81 percent, had only one manufacturer and these products accounted for 74 percent of total revenues. In the remainder of the market, 13 percent of products had 2-3 manufacturers, which accounted for 13 percent of total revenues, 4 percent of products had 4-5 manufacturers, which accounted for 9 percent of revenues, and 2 percent of products had 6+ manufacturers, which accounted for 4 percent of revenues. It is important to note that there are a relatively small number of products in these latter categories, so a single biological product can have a large impact on this pattern.

Figure 2. Percent of Total Revenue and Unique Molecules Based on the Level of Competition for Small Molecule Drugs and Biological Products, 2022



Source: ASPE analysis of IQVIA National Sales Perspective Data

Specialty Drugs

Table 3 shows drug expenditures and the total number of prescriptions for specialty drugs from 2017 to 2022 and also breaks out these statistics for small molecule drugs and biological products. Total inflation-adjusted expenditures on specialty drugs grew from $226 billion in 2017 to $316 billion in 2022, a 39.9 percent increase. However, the number of specialty prescriptions *decreased* from 1.16 billion in 2017 to 1.09 billion in 2022, a 6.2 percent decrease. This means that spending per specialty prescription increased 49.2 percent between 2017 and 2022, from $195 in 2017 to $291 in 2022.

The distribution of small molecule drugs versus biological products also changed during this time frame. Between 2017 and 2022, the percentage of specialty drug spending on small molecule drugs *decreased* from 50

percent to 40 percent, while the percentage of specialty drug prescriptions for small molecule drugs *increased* from 19 percent to 23 percent. The inverse translates to the percent of specialty spending on biological products: there was a 10-percentage-point *increase* in spending share, while there was a 4 percentage-point *decrease* in prescription share. Biological products represent a disproportionate and growing share of specialty drug spending over time.

Table 3. Specialty Drug Expenditures (in Inflation Adjusted Dollars), 2017-2022

	Total Specialty Spending Billions, $	Number of Specialty Prescriptions, Billions	Spending Per Specialty Prescription, $	% of Specialty Spending on Biological Products[12]	% of Specialty Prescriptions on Biological Products
2017	226	1.16	195	50	81
2018	246	1.44	171	53	84
2019	270	1.41	191	56	83
2020	288	1.16	248	56	80
2021	302	1.12	271	58	78
2022	316	1.09	291	60	77
% Change 2017-2022	39.9%	-6.2%	49.2%	19.2%	-4.5%

Source: ASPE analysis of IQVIA data. Number of prescriptions refers to the number of units of a drug sold by manufacturers and wholesalers to pharmacies, hospitals, and other health care settings. All dollar amounts include an adjustment for inflation, meaning they represent a "real dollar" as of quarter 1 of 2022.

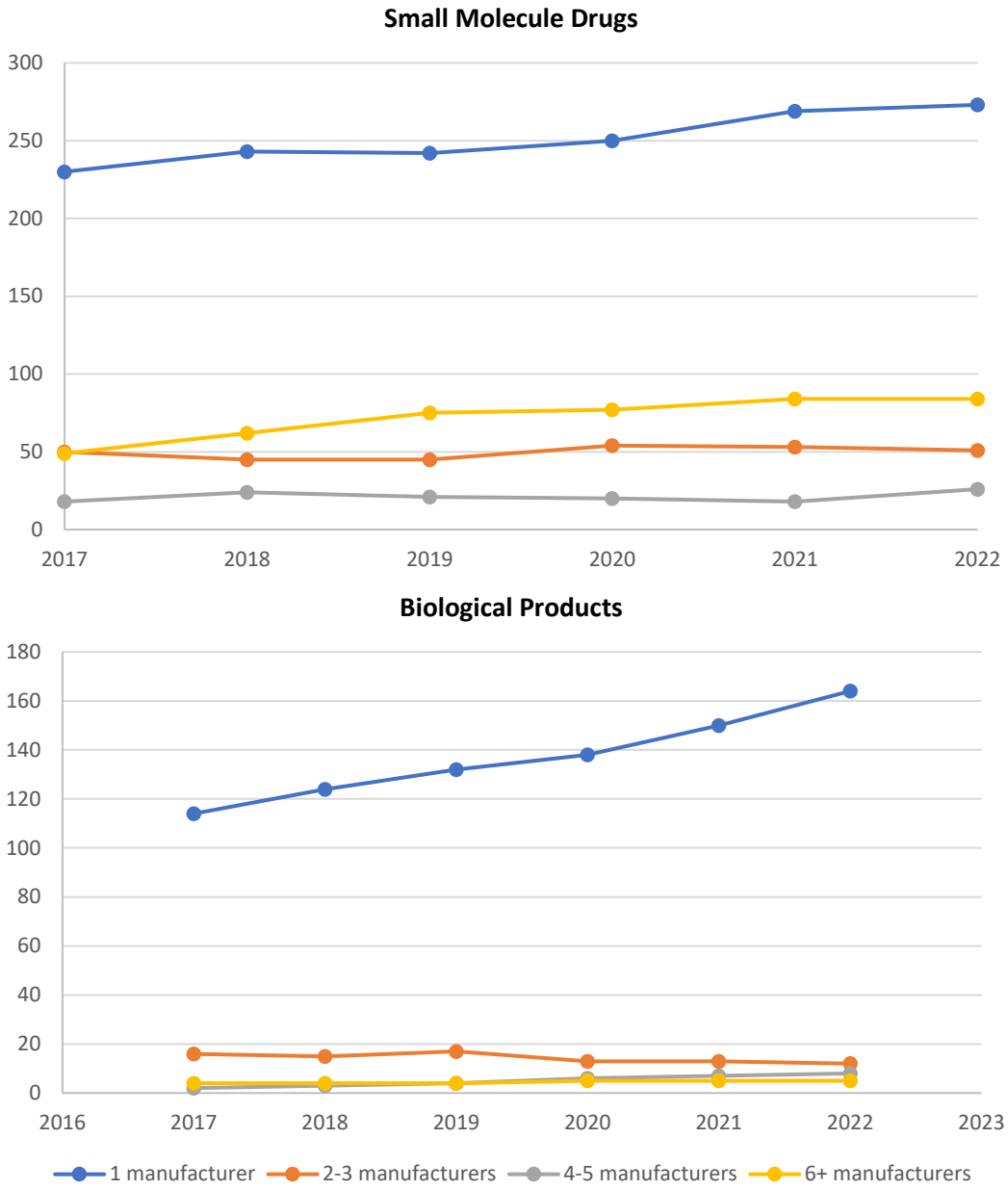
Figure 3 shows the level of competition among specialty drugs in small molecule drug and biological product markets, and both curves show an increase in the share of single-manufacturer products. In total, there were 347 specialty small molecule drugs in 2017 (19 percent of all small molecule drugs), which increased to 434 by 2022 (24 percent of all small molecule drugs). In 2022, 273 specialty small molecule drugs (63 percent) had only one manufacturer, 51 specialty small molecule drugs had 2-3 manufacturers (12 percent), and 26 specialty small molecule drugs (6 percent) had 4-5 manufacturers. The only competition category that changed noticeably, as a percentage share of the total, over the sample period was the number of specialty small molecule drugs with 6+ manufacturers, which increased from 49 drugs in 2017 to 84 drugs in 2022, an increase of 71.4 percent.

In the biological product market, there was an increase in the number of products with only 1 manufacturer from 114 biological products (55 percent of all biological products) in 2017 to 164 biological products (61 percent of all biological products) in 2022. This translates to a 44 percent increase. Among all the other competition categories there were also substantial changes: a 25 percent decrease in manufacturers for drugs with 2-3 manufacturers, a 300 percent increase in manufacturers for drugs with 4-5 manufacturers, and a 25 percent increase in drugs with 6+ manufacturers, but these percent changes were driven by small numbers that likely cannot establish a trend.

Similar to the overall small molecule drug and biological product markets, we saw that in the specialty market, there was more competition among small molecule drugs than among biological products. We also observed a greater percentage increase in biological products with a single manufacturer over time, 44 percent, relative to a 19 percent increase among small molecule drugs. However, the total number of new specialty molecules with only one manufacturer was similar, 50 and 43 for biological products and small molecule drugs, respectively.

[12] The amount of specialty spending on small molecule drugs is the inverse of the numbers presented for biological products (e.g., 81 percent of specialty prescription on biological products translates into 19 percent of specialty prescriptions for small molecule drugs).

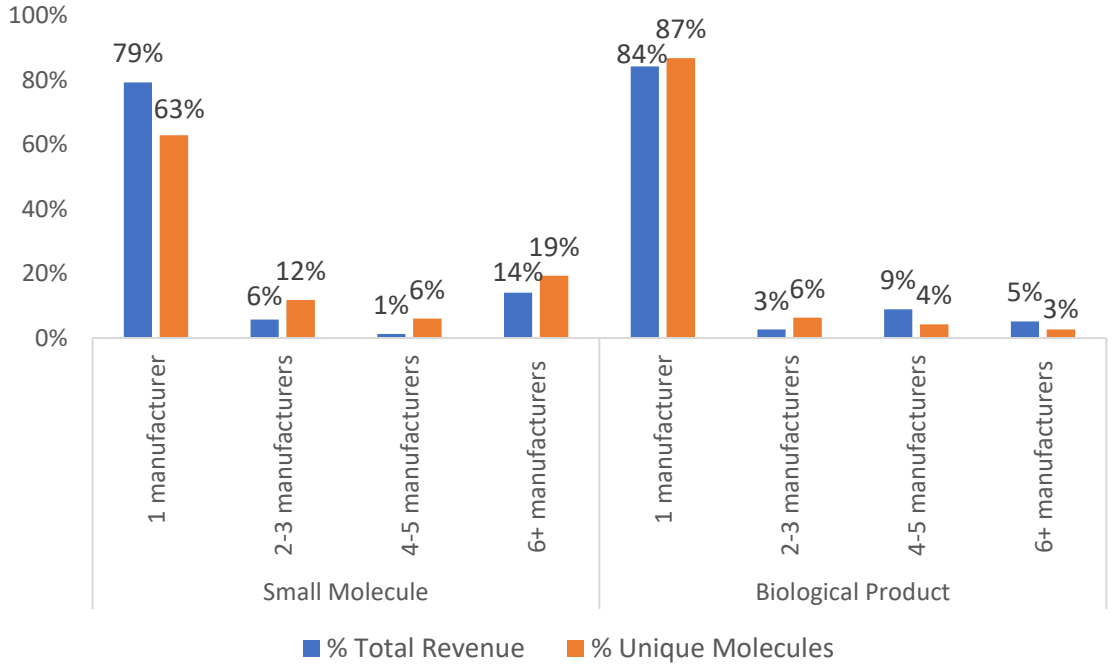
Figure 3. Number of Manufacturers of Specialty Drugs, 2017-2022



Source: ASPE analysis of IQVIA National Sales Perspective Data

Figure 4 breaks down the level of competition by total revenue and total molecules in 2022 among specialty drugs. Overall, in both markets, more than three quarters of total revenue and unique molecules were associated with only 1 manufacturer. However, the directional relationship between the percent of revenue and the percent of molecules was different between small molecule drug and biological product markets. In small molecule drug markets, the 63 percent of molecules with only one manufacturer accounted for 79 percent of total revenue, while for biological products, the 87 percent of molecules with only one manufacturer accounted for 84 percent of total revenue. The remaining categories of competition had a smaller share of the total revenue and molecules, although there was more competition among specialty small molecule drugs than there was competition among specialty biological products.

Figure 4. Percent of Total Revenue and Unique Molecules Based on the Level of Competition for Specialty Drugs, 2022



Source: ASPE analysis of IQVIA National Sales Perspective Data

Highest Priced Drugs

Table 4 shows drug expenditures and total prescriptions for the top 10 percent of drugs based on price per prescription ("highest priced drugs") from 2017 to 2022. It breaks out expenditures and prescriptions separately for small molecule drugs and biologic products. Total inflation-adjusted expenditures on the highest priced drugs grew from $87 billion in 2017 (17 percent of total spending) to $108 billion in 2022 (17 percent of total spending), a 25 percent increase. However, the number of prescriptions for the highest priced drugs *decreased* from 13.2 million in 2017 to 11.4 million in 2022, a 14 percent decrease. This means that spending per prescription among the highest priced drugs increased by 45 percent $6,561 in 2017 to $9,505 in 2022.

From 2017 through 2022, an increasing share of spending and prescriptions on the highest priced drugs were for biological products, with a corresponding decrease for small molecule drugs. In 2017, biological products comprised 30 percent of spending and 34 percent of prescriptions among these highest priced drugs, but by 2022, both of these rates had increased to 49 percent. Accordingly, the share of drug spending and utilization of small molecule drugs among the highest priced drugs dropped from 70 percent to 51 percent and from 66 percent to 51 percent respectively.

Table 4. Highest-Priced Drug Expenditures (in Inflation Adjusted Dollars), 2017-2022

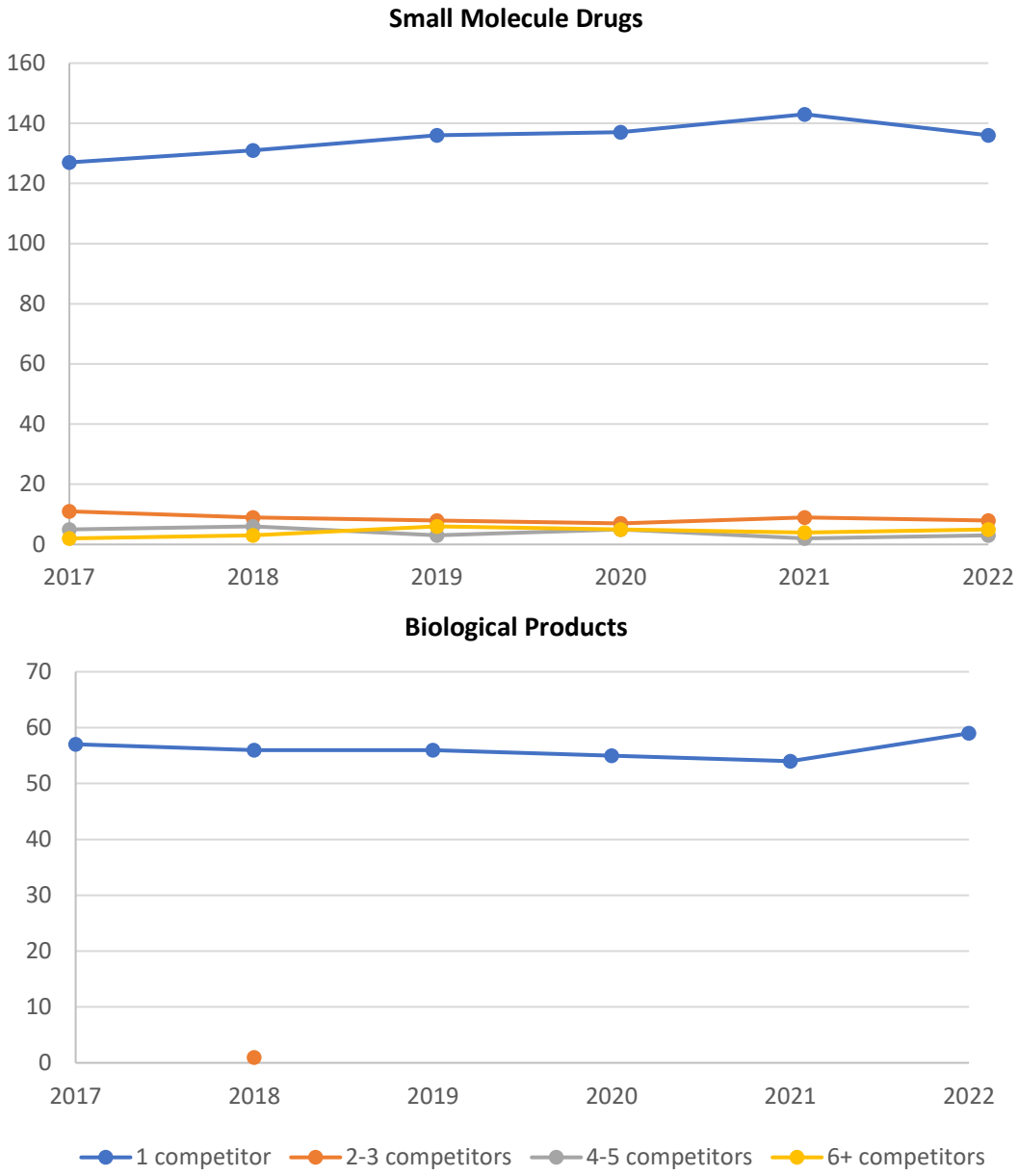
	Total Spending on the Highest Priced Drugs (Billions), $	Prescriptions for the Highest Priced Drugs (Millions)	Spending Per Highest Priced Prescription, $	% of Highest Priced Drug Spending on Biological Products	% of Highest Priced Drug Prescriptions on Biological Products
2017	87	13.2	6,561	30	34
2018	89	12.3	7,224	42	53
2019	95	11.9	7,991	43	49
2020	100	11.9	8,473	50	58
2021	96	10.0	9,618	46	48
2022	108	11.4	9,505	49	49
% Change 2017-2022	24.5%	-14.0%	44.9%	66.9%	43.6%

Source: ASPE analysis of IQVIA data. Number of prescriptions refers to the number of units of a drug by manufacturers and wholesalers to pharmacies, hospitals, and health care settings. All dollar amounts include an adjustment for inflation, meaning they represent a "real dollar" as of quarter 1 of 2022.

Figure 5 shows the level of competition among the highest priced drugs in small molecule drug and biological product markets. We found that the vast majority of the highest priced drugs had only one manufacturer. This may be because the highest priced drugs are also usually those that still have market exclusivity and thus competitors are not yet allowed on the market. In 2022, among the 211 highest priced drugs, 152 (72 percent) were small molecule drugs and the remaining 59 drugs (28 percent) were biological products. In both 2017 and 2022, the vast majority of small molecule, highest priced drugs had only 1 manufacturer: 127 of 145 products in 2017 (88 percent) and 136 of 152 products in 2022 (89 percent). The other categories had so few drugs that trends were not reliable.

We found even less competition in the biological product market – there was no competition at all as each product was manufactured by a single corporation. This striking finding was robust across the sample period with the only exception being one molecule that had 2 manufacturers in 2018, which then disappeared in the subsequent years of analysis. The number of biological products that ranked among the highest priced drugs also remained mostly flat, 57 molecules in 2017 and 59 in 2022.

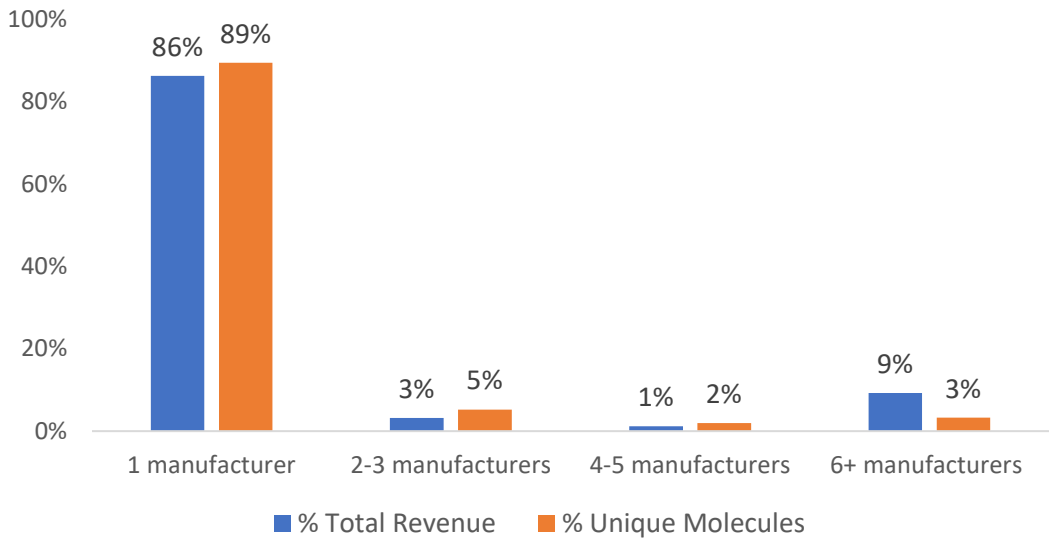
Figure 5. Number of Manufacturers of the Highest Priced Drugs, 2017-2022



Source: ASPE analysis of IQVIA National Sales Perspective Data

Figure 6 breaks down the level of competition by total revenue and total molecules in 2022 among the highest priced, small molecule drugs (we did not examine biological products, since there was no competition). We observed that the 89 percent of small molecule drugs with only one manufacturer accounted for 86 percent of revenues. The other competition categories each accounted for fewer than 9 percent of revenues and molecules.

Figure 6. Percent of Total Revenue and Unique Molecules Based on the Level of Competition for the Highest Priced Drugs, 2022

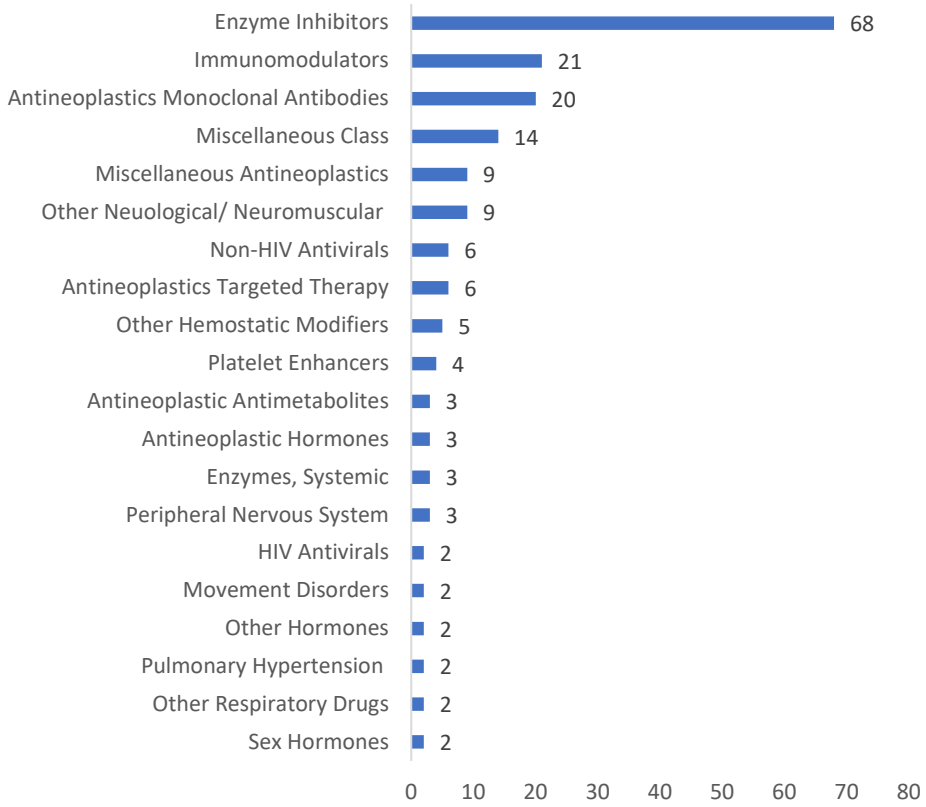


Source: ASPE analysis of IQVIA National Sales Perspective Data

Therapeutic Classes

Our final analysis was to characterize the types of drugs that have the highest spending. Figure 7 shows the therapeutic classes associated with the highest priced drugs. The therapeutic classes that are most common were enzyme inhibitors (68 drugs), immunomodulators (21 drugs), antineoplastic monoclonal antibodies (20 drugs), miscellaneous class (14 drugs), miscellaneous antineoplastics (9 drugs), and other neurological/ neuromuscular (9 drugs). Enzyme inhibitors suppress a chemical reaction from occurring in the body. Common examples include methotrexate (used in chemotherapy and to treat rheumatic arthritis) and protease inhibitors that are used to treat HIV/AIDS. Immunomodulators and antineoplastic monoclonal antibodies are typically used to treat cancer. Immunomodulators are most commonly used to treat multiple myeloma. Some examples are thalidomide (Thalomid), lenalidomide (Revlimid), and pomalidomide (Pomalyst). Antineoplastic monoclonal antibodies treat a variety of cancers, including breast, gastric, kidney, cervical, endometrial, colon, lung, head and neck, and brain cancer, multiple myeloma, acute myeloid leukemia, and melanoma, and osteoporosis. Examples include Bevacizumab (Avastin), daratumumab (Darzalex), trastuzumab (Herceptin), and nivolumab (Opdivo). The “miscellaneous” and “other” categories include a wide swath of drugs used within a general class.

Figure 7. Therapeutic Classes Represented by the Highest Priced Drugs, 2022



Source: ASPE analysis of IQVIA National Sales Perspective Data
Notes: Among the top 10 percent of drugs based on price, the following classes had 1 drug each which are not represented in the figure: Systemic Antiarthritics, Gout Specified Antiarthritic, Anticoagulants, Coagulants, Other Systemic Anti-infectives, Antimalarials, Other Gastrointestinal, Other Genitourinary, Bile Therapy, Other Cardiac Agents, Alkylating Agents, Antimitotic/ Antimicrotubule, Other Vascular Agents, Cholesterol Red, Other Antihyperlipidemic Agent, Antineoplastic Radiopharmaceuticals, Dermatological Prep, Other, Diabetes, Non-Insulin, Therapeutic Enzyme Stabilizers, Hematinics, Hematopoietic Stem Cell Age, Other Ophthalmic Preps, Antidepressants, Tuberculosis Therapy, and Specific Antagonists.

Conclusion

In this report, we examined the level of competition in small molecule drug and biological product markets. We found that, on average, there was much more competition in small molecule markets, compared to biological product markets. When examining small molecule drugs, 57 percent had at least 2 manufacturers, whereas only 19 percent of biological products had at least 2 manufacturers. However, once we narrowed the market to only specialty drugs and the highest priced drugs, then competition in both markets eroded substantially. Among specialty drugs, 63 percent of small molecule drugs and 87 percent of biological products had only a single manufacturer. Finally, when examining only the highest priced drugs (i.e., those in the top 10 percent of spending per prescription), we found that 11 percent of small molecule drugs and 0 percent of biological products had at least 2 manufacturers.

There are several limitations to our analysis. IQVIA is a national, all-payer database. The advantage of this data is that we have the broadest picture of the U.S. prescription drug market to determine levels of competition. However, by not being able to observe payer type, we cannot examine how different plans may use their bargaining power to employ formularies or utilization management tactics. For example, it may be possible for larger insurance companies with greater volumes of prescriptions to negotiate for larger discounts in exchange

for preferred placement on their formulary; however, the downside is that such tactics can restrict access to drugs. This means that patients may experience even more or less competition in the prescription drug market than we observed in our data. Relatedly, we do not know the cost sharing structure of those plans either. As a result, we cannot examine the costs borne by patients via copays or coinsurance for drugs resulting from low competition.

Another limitation relates to how we count the number of competitors - our methodology cannot adjust for the more nuanced effect of how large or aggressive a competitor may be. In our analysis, all competitors are treated equally, so further research is warranted to examine whether different types of market entrants result in a differential effect on the price and volume of drugs sold. Finally, we define competition based on an active ingredient, rather than examining therapeutic competition, which would be a more expansive definition of competition.

Appendix

The variable used to measure the number of prescriptions throughout this report is the "eaches" variable in IQVIA data, which is defined as "the number of single items (such as vials, syringes, bottles, or packet of pills) contained in a unit or shipping package and purchased by pharmacies in a specific time period. An each is not a single pill or dosage of medicine (unless one package consists of a single dose). An each may be the same as a unit if the unit does not subdivide into packages."

The variable used to identify distinct molecules in this report is "combined molecule". This variable treats combination products as distinct, meaning that it will separate combination products from their constituent parts (if those are also sold individually). For example, if there is a product that is just molecule A and a second product that is just molecule B and a third product that is the combination A+B, then there will be 3 separate line items.

We identify competitors based on the "Corporation" variable in IQVIA.

Specialty drugs are defined by IQVIA as products used to treat chronic, rare or complex diseases and that meet 4 or more of the following criteria:

- Initiated and maintained by a specialist
- Generally injectable and/or not self-administered
- Products that require an additional level of care in their chain of custody (i.e., refrigerated, frozen, chemo, biohazard, etc.)
- Expensive (USD $6K annual cost of therapy)
- Unique distribution (e.g., specialty MO, REMS)
- Requires extensive or in-depth monitoring/patient counseling
- Requires reimbursement assistance
- Products that clearly meet the above criteria are defined as Specialty. Products that are borderline (e.g. meet three, rather than four criteria) will be brought before IQVIA's Specialty Governance Board for review and final decision.

Appendix Exhibits

The data that created Figure 1 "Number of Competitors for Small Molecule Drugs and Biological Products, 2017-2022" are:

Small Molecule Drugs

	1 competitor	2-3 competitors	4-5 competitors	6+ competitors	Total
2017	834	309	159	506	1,808
2018	841	280	164	543	1,828
2019	842	278	151	576	1,847
2020	828	291	149	578	1,846
2021	827	295	148	586	1,856
2022	796	298	156	588	1,838
Growth	-4.6%	-3.6%	-1.9%	16.2%	1.7%

Biological Products

	1 competitor	2-3 competitors	4-5 competitors	6+ competitors	Total
2017	166	35	2	6	209
2018	179	35	4	5	223
2019	187	37	5	5	234
2020	193	32	8	6	239
2021	205	36	9	6	256
2022	216	34	12	6	268
Growth	30.1%	-2.9%	500.0%	0.0%	28.2%

The data that created Figure 3 "Number of Competitors for Specialty Drugs, 2017-2022" are:

Small Molecule Drugs

	1 competitor	2-3 competitors	4-5 competitors	6+ competitors	Total
2017	230	50	18	49	347
2018	243	45	24	62	374
2019	242	45	21	75	383
2020	250	54	20	77	401
2021	269	53	18	84	424
2022	273	51	26	84	434
Growth	18.7%	2.0%	44.4%	71.4%	25.1%

Biological Products

	1 competitor	2-3 competitors	4-5 competitors	6+ competitors	Total
2017	114	16	2	4	136
2018	124	15	3	4	146
2019	132	17	4	4	157
2020	138	13	6	5	162
2021	150	13	7	5	175
2022	164	12	8	5	189
Growth	43.9%	-25.0%	300.0%	25.0%	39.0%

The data that created Figure 5 "Number of Competitors for the Highest Priced Drugs, 2017-2022" are:

Small Molecule Drugs

	1 competitor	2-3 competitors	4-5 competitors	6+ competitors	Total
2017	127	11	5	2	145
2018	131	9	6	3	149
2019	136	8	3	6	153
2020	137	7	5	5	154
2021	143	9	2	4	158
2022	136	8	3	5	152
Growth	7.1%	-27.3%	-40.0%	150.0%	4.8%

Biological Products

	1 competitor	2-3 competitors	4-5 competitors	6+ competitors	Total
2017	57	-	-	-	57
2018	56	1	-	-	57
2019	56	-	-	-	56
2020	55	-	-	-	55
2021	54	-	-	-	54
2022	59	-	-	-	59
Growth	3.5%	-	-	-	3.5%

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