

**Biosimilars and Follow-on Products in the United States:  
Adoption, Prices, and Users**

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## **Abstract**

Biologic drugs account for a disproportionate share of the increase in pharmaceutical spending in the US and worldwide. Against this backdrop, many look to the expanding market for biosimilars - follow-on products to biologic drugs - as a vehicle for controlling pharmaceutical spending. This study explores the early years of entry of biosimilar and related follow-on products (jointly, "biosimilars/FOPs") in the US. Using monthly sales data from 2005-2019 on ten drug classes, we examine how quickly biosimilars/FOPs gained market share and the subsequent trajectory of prevailing (net invoice) prices. Our analysis suggests that although uptake has been slower than what is typically seen in generic drug markets, the most recent entrants have captured market share more rapidly than comparable earlier biosimilars/FOPs. We also document that from their time of entry, lower biosimilar/FOP prices help to offset the overall trend in average annual price increases of reference products. Our findings can provide insight into future policy reforms aimed at increasing competition and utilization of biosimilars, leading to expanded patient access and significant cost savings.

Lowering drug prices is a frequent topic of discussion in the United States (US) and lawmakers have recently proposed several pieces of related legislation.<sup>1</sup> In the months before leaving office, the Trump Administration issued multiple executive orders and proposed rules related to drug pricing.<sup>2,3</sup> The vast majority of Americans consider lowering prescription drug pricing and broader health care spending among the top policy issues.<sup>4</sup>

One cost savings opportunity involves encouraging competition in biopharmaceutical markets following exclusivity expiration (i.e., after patent terms and regulatory exclusivities have ended). For generic drugs, the 1984 Drug Price Competition and Patent Term Restoration Act (commonly called the "Hatch-Waxman Act") is estimated to have saved over \$1.8 trillion over a recent decade by creating a mechanism for rapid and extensive post-exclusivity competition for branded small molecule drugs in the US.<sup>5</sup> However, the provisions of the Hatch-Waxman Act do not apply to a key class of drugs called biological products, also known as "biologics."

Biologics are complex large molecules and are typically difficult to characterize completely.<sup>6</sup> Unlike common small molecule drugs such as antihistamines or statins that are chemically synthesized, biologics are products such as vaccines, monoclonal antibodies, gene therapies, and allergenics that are composed of biological material (typically nucleic acids, amino acids, proteins, and cells).

As of 2015, biologics represented 38% of US drug spending and 70% of drug spending *growth*, although they were used by less than 2% of the population.<sup>7</sup> Given biologics' disproportionate contribution to drug

spending, successful policy efforts to stimulate competition in these product markets are likely to have a meaningful impact on overall US drug spending growth.

Because the Hatch-Waxman Act did not apply to biologics regulated under the Public Health Service Act, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) as part of the 2010 Patient Protection and Affordable Care Act. This legislation established “an abbreviated licensure pathway” for biosimilars and interchangeable products – the biologic analogue to generics – to compete with branded reference biologics.<sup>8</sup> Five years later in 2015, the first BPCIA biosimilar product received a US Food and Drug Administration (FDA) license. Some complex, biosimilar-like products were previously approved via the traditional biological product approval pathway (351(a)) or via new drug (505(b)(2)) or abbreviated new drug applications (ANDA/505(j)).<sup>9</sup>

The BPCIA defines a biosimilar as “a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product”<sup>6</sup> (i.e., it possesses essentially the same molecular composition as the reference product and produces comparable clinical effects). Unlike generics, biosimilars are not necessarily designated as fully interchangeable, meaning only the prescriber, not pharmacists, can substitute a biosimilar for the reference product, which presents a competitive barrier. Providers may be unfamiliar with biosimilars, adding to the challenge of substituting biosimilars for reference products. An *interchangeable* biosimilar has further demonstrated low immunological or other switching risk with the reference product; for example, this can be done through additional

clinical trials. As of January 2021, no US interchangeable biosimilars had been licensed.

To date, the pace and extent of US biosimilar adoption, the impact of biosimilar competition on prices and quantities of products used, and differences across distinct payers with differing incentive structures have not been well documented. (One recent study, however, has documented overall price reductions of 5.4 to 7 percentage points associated with each additional competitor in seven biosimilar markets.<sup>10</sup>) We present data on these topics and discuss how the emerging US biosimilar market compares with US generic drug markets. The results reported here provide novel insights into the early years of biosimilar and related follow-on competition in the US, and early evidence to inform policy discussions and actions to enhance the achievement of the BPCIA's goals.

## **Data and Methods**

Our data include the US biologic drug classes (and one complex molecule) that experienced follow-on entry in the years 2005-2019. For simplicity, we collectively refer to these "follow-on products" (FOPs) as biosimilars/FOPs and differentiate between the subset of these products entering the market through the 351(k) process established by the BPCIA versus those approved via other FDA regulatory pathways. The products not approved through the 351(k) pathway were selected for inclusion because they are considered biologics/biosimilars by non-US regulators and/or were a so-called section 505 drug "deemed to be a license" under section 351.<sup>11</sup> For example, enoxaparin sodium is defined as a complex molecule

rather than a biologic in the US. However, because it is considered a biosimilar in the European Union (EU), we include it in our sample.<sup>12,13</sup> Because enoxaparin sodium was approved in the US as a generic drug and is sold primarily through retail pharmacies, it provides unique insights into potential interchangeable biologic drug competition.

#### Sample selection

We focused on the set of biosimilars/FOPs launched in the US from 2005 through 2019 (Appendix C).<sup>14</sup> We collected monthly (US dollar) sales and quantity data for biosimilars/FOPs and their reference products over this period.

#### Data sources and preparation

We obtained FDA and European Medicines Agency (EMA) approval dates for each product.<sup>15,16</sup> Monthly quantity, sales, and price data were provided by IQVIA for each product National Drug Code (NDC) at the sales channel level (e.g., clinics, non-federal hospitals, long-term care facilities, etc.) from IQVIA's National Sales Perspective (NSP) dataset from January 2005 through December 2019. Monthly quantity, Wholesale Acquisition Cost list price, and sales NDC data were obtained from IQVIA's DDD dataset beginning in January 2011. IQVIA also provided US launch dates for each biosimilar/FOP. Appendix A provides definitions of the disaggregated levels at which data were collected and detail on quality assurance tests performed.<sup>14</sup>

Several data transformations were required for analysis. To enable unit comparability, we calculated product units (in milligrams or units) based on the active pharmaceutical ingredient for each NDC by multiplying the NDC strength by the number of units. We calculated biosimilar/FOP

volume market share for each product class and average price per unit (total dollar sales divided by units). To understand competition over time, we calculated time since initial biosimilar/FOP launch. To explore possible biosimilar/FOP usage differences among drug purchasers facing different reimbursement incentives, we used the disaggregated data to create groups that reflect nine payer incentive types (PITs): 340B facilities, non-340B hospitals, those engaging in bundling and/or treating end stage renal disease, chain pharmacies, non-chain pharmacies, federal facilities, integrated health systems (such as Kaiser Permanente), nursing homes, and fee-for-service and/or outpatient facilities. Detailed definitions of each PIT are provided in Appendix B.<sup>14</sup>

#### Analytic Implementation

We calculated unit sales and the market share of reference product units in each product class for all sample products at the total US, channel, and PIT levels. Additionally, we calculated a price ratio defined as the ratio of average market price to the pre-biosimilar/FOP entry price in each drug class in each month following biosimilar/FOP entry. This price ratio was calculated as the weighted average of the unit prices of all reference product and biosimilar/FOP product sold divided by average reference product price in the month preceding initial biosimilar/FOP entry.

In regression analyses including data from all products, we explored predictors of differences in FOP take-up, where the key dependent variables are the reference product volume share of the product class market and price ratio. The key explanatory variables are linear measures of elapsed months since initial biosimilar/FOP entry, "later" biosimilar/FOP entry

(i.e., in 2018 or 2019 versus prior to 2018), use of the BPCIA regulatory pathway (i.e., 351(k)/BPCIA versus other pathways), and indicator variables for sales channels or PITs.

In robustness analysis, we also controlled for binary indicators for oncology products, for chronic disease drugs, and a cubic measure of elapsed months since biosimilar/FOP entry. Additionally, we explored predictors of the price ratio using the same set of independent variables and robustness tests. To ensure the robustness of our results and explore product heterogeneity, we limited the sample to specific time horizons beyond the entry of the first biosimilar/FOP, with the main models including data from all products and supplementary analyses considering individual product classes (Appendix G).<sup>14</sup> We grouped channels and PITs that were less than 5% of volume and not one of the top three channels or PITs for a product class into an "other" category (See Appendix A).<sup>14</sup>

Finally, we calculated daily volumes of reference product in each class by sales channel and PIT and present these disaggregated utilization data graphically.

### Limitations

The relatively short US biosimilar/FOP marketing period is the largest limitation of this study; half of our sample products were launched in 2018 or later. The EU's biosimilar history is nearly twice as long as that of the US and has been studied in more detail.<sup>17,18</sup> Given the relatively short time horizon, our results may not be representative of future market dynamics that may evolve as patients, health care providers, regulators, and insurers gain experience with biosimilars, and as interchangeable products enter the market.



The availability and completeness of price data further limit this study. The NSP dataset provides net invoice prices but does not include rebates or other "off-invoice" payments. Nor does it include data on downstream channel price mark-ups or patient payments from co-pays or co-insurance. The DDD dataset provides list prices (Wholesale Average Cost), which are different from manufacturers' ultimate net price. Thus, the impact of biosimilar/FOP competition on prices reported here may misstate the true impact of biosimilar/FOP competition on manufacturers or primary payers.

Reporting restrictions are also a known limitation of the DDD dataset. Notably, Kaiser Permanente, a significant early biosimilar adopter,<sup>19</sup> requests their primary suppliers to restrict reporting of sales to their outlets. This likely means that the DDD-based analyses underestimate the speed and size of biosimilar uptake in the integrated health system PIT and overall.

Additionally, most current biosimilars/FOPs and their reference products are physician-administered and therefore circumvent retail pharmacies, limiting comparison to generics. Differences in supply chains, discounting, and rebate practices for physician versus patient-administered drugs may result in uptake and pricing differences. Interchangeable products entering the market may further alter competitive dynamics.

## **Results**

Our analysis sample contained ten reference product classes with 23 biosimilar/FOPs (for a detailed summary, see Appendix C).<sup>14</sup> As of the end of 2019, 26 biosimilars and 14 other FOPs had been approved in the US,

with 12 of each having been launched. Because rituximab experienced its first biosimilar/FOP in November 2019, this drug class was excluded for lack of meaningful data availability. The remaining 11 biosimilars approved via the BPCIA pathway and 12 FOPs approved via alternative pathways were included in the analysis sample. Of the alternative pathway FOPs, three used the 505(b)(2) pathway, eight were approved through ANDAs, and one used the 351(a) pathway.<sup>20</sup> For all biosimilars/FOPs, the FDA-approved indications were the same as those of their respective reference products. Up to 180 months of data were available for some product classes, with an NSP average of 92 months (median: 66 months) of biosimilar/FOP experience per class.

#### Individual Products: Market share and Prices

Exhibit 1 displays reference product market share changes by product class from one year before to up to four years after initial biosimilar/FOP entry. (Additional months of data are available for some products; however market shares tend to level out over time.) The six product classes with biosimilars approved via the BPCIA pathway are identified with triangles and the five product classes experiencing biosimilar/FOP competition prior to 2018 are identified with hollow shapes as early entrants. By the end of 2019, reference product market shares in our sample ranged from 6% to 89% (median: 80%).

Product classes that faced earlier biosimilar/FOP entrants display steady monotonic declines in reference product market shares. The two product classes with the longest competitive history, somatropin (example

indications: growth hormone deficiency, Prader-Willi syndrome) and enoxaparin sodium (example indications: Prophylaxis of deep vein thrombosis, Acute deep vein thrombosis), eventually experienced relatively stable reference product market share, albeit at vastly different levels. Product classes facing later (2018 or beyond) biosimilar/FOP entry experienced more rapid reference product market share declines than product classes with earlier entrants. This pattern is especially notable for the two most recent product classes with biosimilars: bevacizumab (example indications: glioblastoma, colorectal/lung/kidney/cervical/ovarian cancer) and trastuzumab (example indications: breast/stomach/esophageal cancer).

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Exhibit 1: Biosimilars/FOPs approved in the US with summary statistics

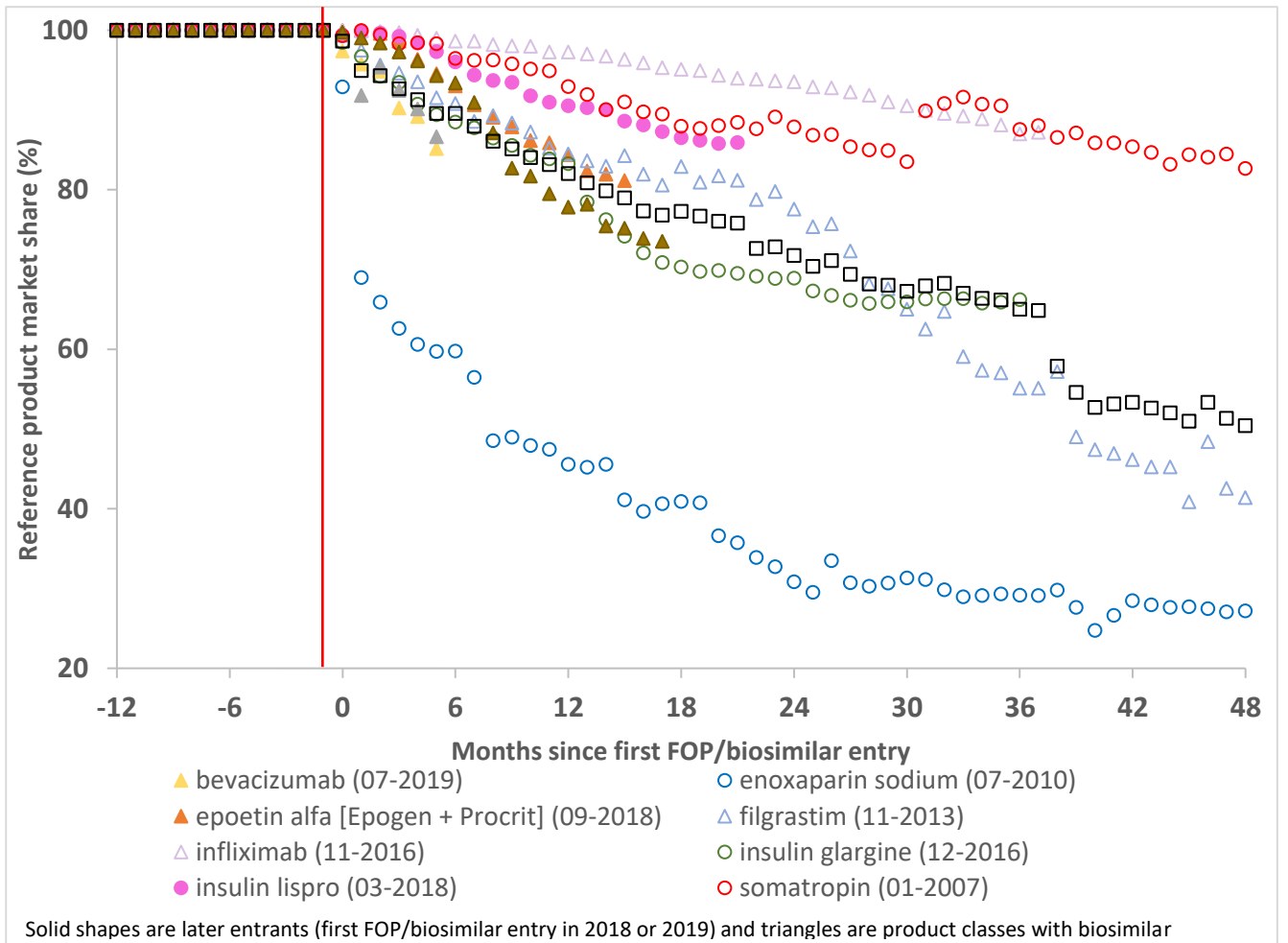


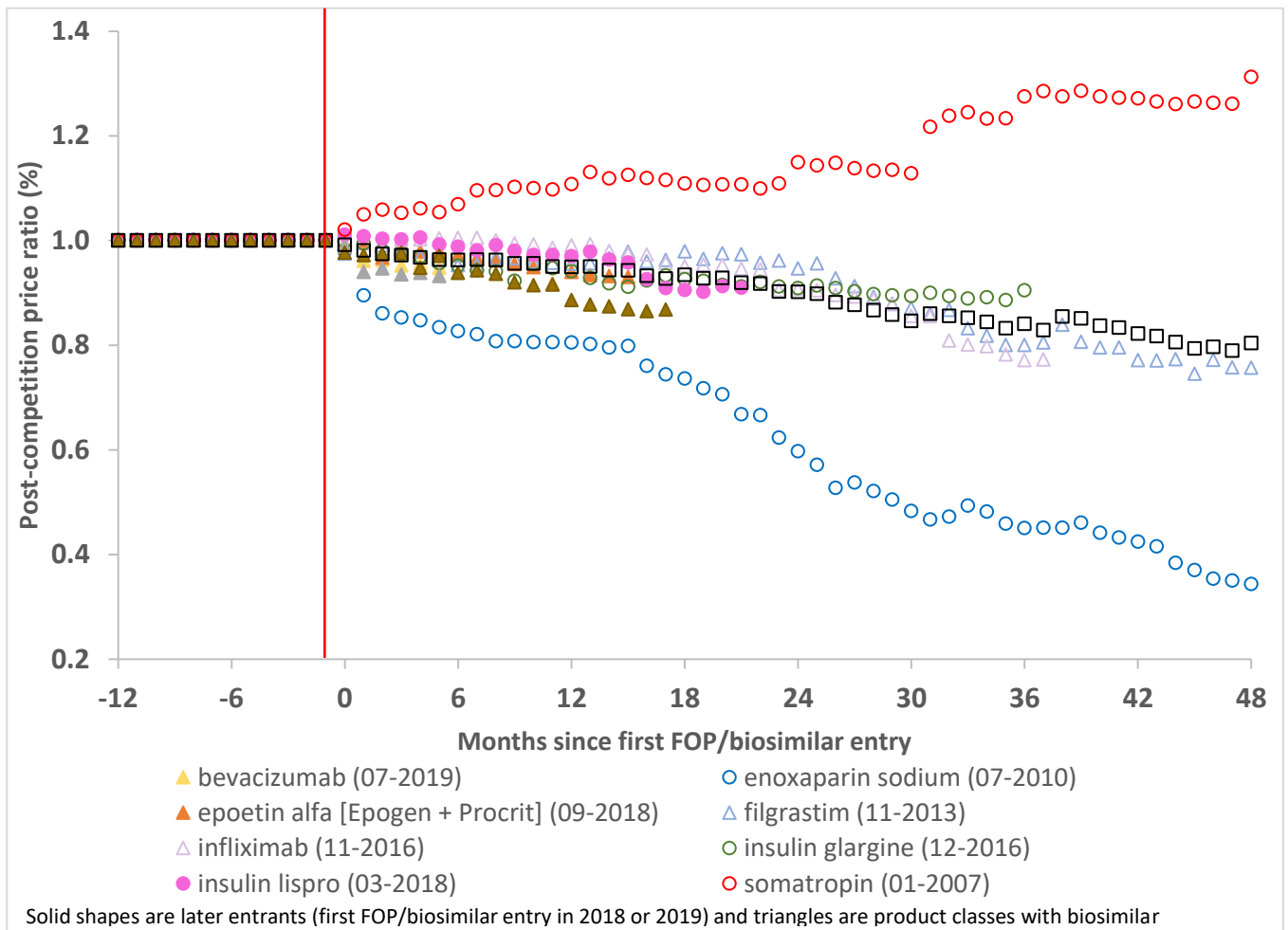
Exhibit 2 presents price ratios by product class from one year before to four years after initial biosimilar/FOP entry. As in Exhibit 1, the price ratios observed in most later entrant classes have steeper declines than those of classes with earlier biosimilar/FOP entry. For example, the price ratios for trastuzumab, bevacizumab, and pegfilgrastim tend to be lower than most of the other products; these products all saw their first biosimilar launch in the final two years of our period of observation. Meanwhile, somatropin (the product class with the earliest biosimilar/FOP) experienced increases in its price ratio over time, although unit prices

of the FOP remained significantly lower than those of the reference product throughout all years (results not presented).

The enoxaparin sodium class with its early entrants, presents a notable exception to the finding that later entrants experienced steeper declines in market share and prices on average. Enoxaparin sodium experienced the largest decline in both reference product market share and its price ratio. Notably, this product was approved under an ANDA and sold as a substitutable generic drug in the US, but is considered a biosimilar in the EU. As the only product in our sample that was interchangeable by pharmacists it is thus a potential benchmark for the competitive dynamics one might expect from a fully interchangeable biosimilar. Appendix E presents further detail on market share and utilization for individual biosimilar/FOPs.<sup>14</sup>

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Exhibit 2: Decline in market share and price of reference products subsequent to biosimilar/FOP entry



Overall Market Share and Prices Ratios: Regression Analysis

Exhibit 3 presents ordinary least squares regression results. All models are estimated using data from post-biosimilar/FOP entry months. Models 1-3 show the decline in reference product volume market share upon competitor entry using the NSP dataset: Model 1 indicates that on average, each additional month of biosimilar/FOP competition was associated with a 0.462 percentage point (pp) decline in reference product market share ( $p < 0.01$ ), an average increase in biosimilar/FOP market share of 5.54pp per

year. Model 2 considers differences among product classes with earlier versus later entrants. The coefficient on the "later entrant" variable indicates that on average, classes with later biosimilars/FOPs had higher reference product market shares, though this result is mechanical: by definition, these products have had fewer months of biosimilar/FOP competition at every point in time. The estimated coefficient of interest in model 2 is on the interaction term, which indicates that in later entrant product classes, each month of biosimilar/FOP competition was associated with an *additional* 0.287pp decline in reference product market share ( $p < 0.01$ ). In other words, markets with more recent biosimilar/FOP competition experienced more rapid declines in reference product share – on average, an additional 3.44pp per year – mirroring the graphical trends seen in Exhibit 1.

Model 3 considers differences between classes with competitors approved via the BPCIA versus other regulatory pathways. Here, the BPCIA indicator shows that, on average, product classes with biosimilars approved via BPCIA have greater reference product market share, but that result is also mechanical: in nearly all cases, non-BPCIA product classes experienced FOPs entry several years before the first BPCIA products were approved. Thus, in our sample (and at every point in time), BPCIA-affected product classes had fewer months of observed biosimilar/FOP competition than non-BPCIA classes. As in model 2, the key coefficient of interest is therefore the interaction term, which indicates that following the launch of the first biosimilar/FOP, product classes with BPCIA-approved biosimilars saw an additional 0.665pp decline in reference product market share per month ( $p < 0.01$ ), or an additional 7.98pp per year on average. This highlights

that competition facilitated via the BPCIA led to more rapid declines in reference products' market shares as compared to other pathways.

Models 4-6 of Exhibit 3 illustrate the evolution of the price ratio following biosimilar/FOP entry. Model 4 shows that on average, each additional month of biosimilar/FOP competition was associated with an *increase* in the price ratio; however, this overall time trend was driven entirely by somatropin, as seen visually in Exhibit 2. Following the same logic as in model 2, we report the differences for product classes with later versus earlier entrants in model 5; the coefficient on the interaction term indicates that being a late entrant product class was associated with a 0.810pp average monthly *decline* in the price ratio ( $p < 0.01$ ), offsetting the impact of the positive coefficient on the overall price time trend. For additional detail on average price increases seen in all markets leading up to biosimilar/FOP entry and subsequent price changes in reference product and biosimilar/FOP prices see Appendix E.<sup>14</sup>

Model 6 reports differences among biosimilars/FOPs approved via different regulatory pathways. In this model, the interaction term is again the coefficient of interest and shows that having reference products with BPCIA-approved competitors was associated with an additional 1.02pp monthly decline in the price ratio following biosimilar/FOP entry ( $p < 0.01$ ). Thus, product classes with BPCIA-approved competitors saw steeper price declines. The negative coefficients on both interaction terms are twice the magnitude and opposite in direction to the coefficient on the overall time trend, such that on average in a product class with one or more later entrants, BPCIA-approved biosimilar(s) would be expected to see declining price ratios over time.



All regression models are qualitatively robust to controlling for binary indicators for oncology products, for chronic disease drugs, and a cubic measure of elapsed months since biosimilar/FOP entry (Appendix H).<sup>14</sup>

Appendix G presents results from Exhibit 3 by individual product class.<sup>14</sup> These indicate that the average time trend in the decline of reference product share varied by market, ranging from 0.34pp per month for infliximab (example indications: rheumatoid arthritis, psoriatic arthritis) to 2.4pp for bevacizumab. The monthly time trend for price ratios varied from *positive* 0.69pp for somatropin to *negative* 1.1pp for trastuzumab.

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Exhibit 3: Association between biosimilar/FOP entry and reference product market shares and price

Variable	Monthly NSP Market Share, 2005-2019			Monthly NSP Price Ratio, 2005-2019		
	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Months since first biosimilar/FOP entry	-0.00462***	-0.00424***	-0.00383***	0.00414***	0.00462***	0.00497***
Later entrant (first biosimilar/FOP entry in 2018 or 2019)		0.16974***			0.24461***	
Interaction of Later entrant and Months since first biosimilar/FOP entry		-0.00287***			-0.00810***	
Biosimilar/FOP approved via BPCIA			0.24274***			0.27144***
Interaction of Biosimilar/FOP approved via BPCIA and Months since first biosimilar/FOP entry			-0.00665***			-0.01016***
Constant	0.84306***	0.80934***	0.78442***	0.78784***	0.74583***	0.74506***
R-squared	0.431	0.454	0.501	0.133	0.147	0.190

Source: Authors' analyses.

Notes: OLS regressions analyses were performed using reference products. Every model included 496 observations. The dependent variable for models 1-3 is the monthly market share of the reference product and takes a value from 0-1; for models 4-6 it is the monthly price ratio of the product class in its current month versus the month before biosimilar

entry. Cells are blank when variables were not included in that model. Months since first biosimilar/FOP entry is equal to the number of months since (and including) the entry of the first biosimilar. \*\*\* p<0.01, \*\* p<0.05, \* p<0.1

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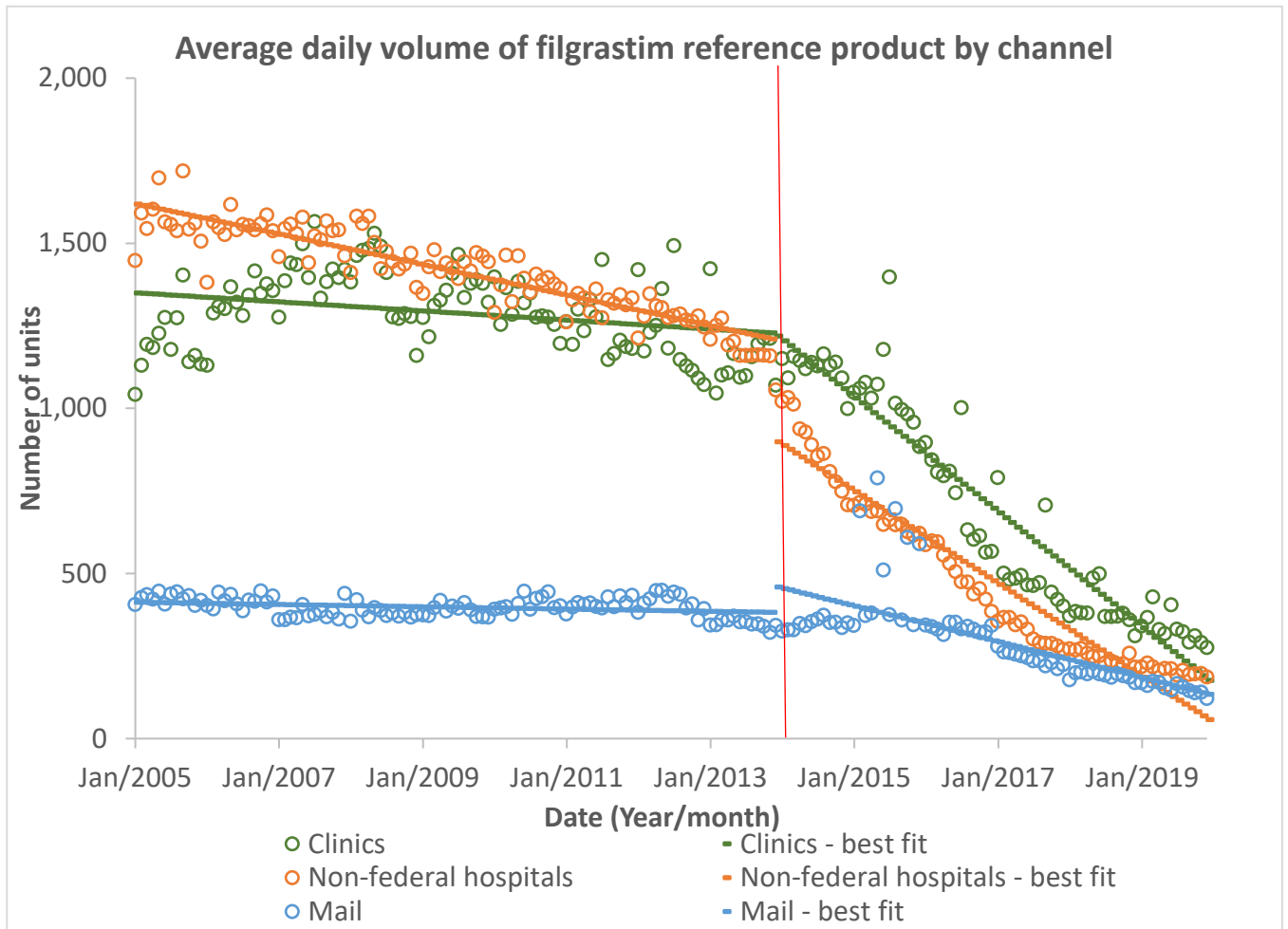
Channel and Payer Incentive Type: Utilization

Exhibits 4 and 5 provide an illustrative example of the average daily volume in standardized units of reference product sold through different channels and PITs for a sample product: filgrastim. Similar graphs for the remaining products are presented in Appendix E.<sup>14</sup> The top three channels and PITs by product class volume and any additional channels/payer types with at least 5% of the volume for each of the product classes were included in these figures.

Exhibit 4 shows that the most common channels in which filgrastim were sold included clinics, non-federal hospitals, and mail. In this market, there were clear declines in reference product use in all three major channels after the biosimilar/FOP entered the market.

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Exhibit 4: Average daily volume of filgrastim reference product by channel before and after biosimilar/FOP entry.

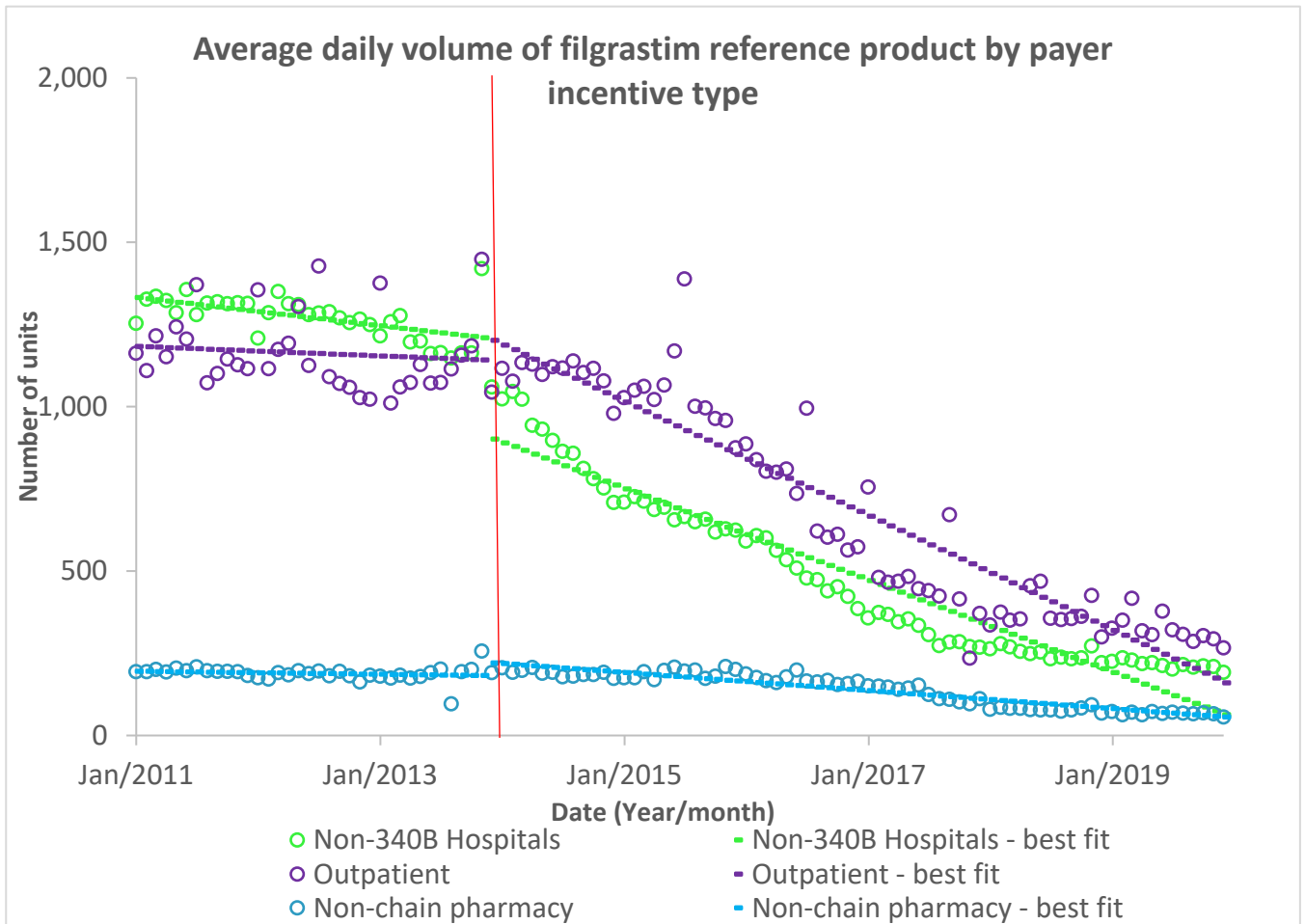


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Exhibit 5 illustrates the payer incentive types with the greatest shares of volume for filgrastim (non-340B hospitals, outpatient, and non-chain pharmacy). In the filgrastim market, there were declines in reference product volume for all three of the largest PITs with the most dramatic declines in reference product volume for outpatient and non-340B hospitals.

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Exhibit 5: Average daily volume of filgrastim reference product by PIT before and after biosimilar/FOP entry.



Although filgrastim reveals declines in reference product use across multiple channels and PITs, there was significant heterogeneity in post-biosimilar/FOP market dynamics across other product classes, channels, and PITs. Some channels and PITs appear to be more aggressive adopters of biosimilars/FOPs while others are less so. In addition, the channels and PITs in which most reference product volume is sold vary greatly across product classes. Additional information about channel/PIT reference

product market share and total product class volume expansion/contraction is presented in Appendix I.<sup>14</sup>

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## **Discussion**

To-date US market experience with biosimilars/FOPs has been brief, with half of the ten key product classes seeing biosimilars/FOPs market entry in 2018 or later. Nevertheless, early data are informative for guiding future policy; in all product classes, the market share of reference product declined on average with time since biosimilar/FOP launch. Despite this apparent increase in competition, some reference products maintained existing market share. Indeed in the fourth quarter of 2019, the market share of reference products in our sample ranged from 6% to 90%. While biosimilar/FOP take-up was gradual (especially for earlier entrants) and not as large as what is typically seen in small molecule generic drug markets, it follows a similar trend to that observed among generic drugs in the years that immediately followed the passage of the Hatch-Waxman Act.<sup>21</sup> Notably, the decline in reference product market share occurred even though biosimilars/FOPs – unlike their small molecule generic counterparts – are not designated by the FDA as interchangeable. Due to this distinction, only one of the products studied here (enoxaparin sodium) was eligible for automatic pharmacy substitution for the reference product.

Moreover, Exhibits 1 and 2 indicate that product market shares and price ratios for reference products facing later entrants and BPCIA biosimilars/FOPs declined more steeply as compared to other products

approved earlier or through other pathways. Given the limited number of observations for the more recent market entrants, future research will provide important insights as biosimilar/FOP adoption evolves. Nevertheless, our results provide some early data that recent biosimilar/FOP entrants have experienced more rapid take-up, suggesting potential learning about these products' perceived safety and value by physicians, payers, and patients. Future research should explore the potential strategies (e.g., extended patent litigation or increased bundling) of reference product manufacturers, who may respond differently to biosimilar/FOP entry depending on the make-up of their overall product portfolio and other factors.

Notably, biosimilars/FOPs are not always available in all reference product package sizes, modalities, or strengths. These limitations may inhibit physician and patient adoption in some circumstances. For example, when the biosimilar drug Retacrit entered the market in 2018, it shipped in just nine NDCs, compared to the 26 offered by the reference product, Procrit. Similar patterns (more NDCs among reference products) exist across all other product classes except for infliximab, in which both reference product and biosimilars/FOPs each ship only one NDC (data not shown).

The coming years will inform whether the steep reference product market share decline observed in later entrant product classes (Exhibit 1) represents a new normal for a maturing biosimilar marketplace as well as how far reference product market shares may ultimately decline. It will also be crucial to analyze whether future biosimilars/FOPs continue to have greater price declines as the number of competitors increases and as additional product classes experience biosimilar/FOP entry, as many

have noted that to-date, early list price discounts for biosimilars/FOPs have been meaningfully smaller than what is seen in generic markets.<sup>22,23</sup> In addition, “biobetter” (i.e., differentiated biologics in the same product class that allegedly embody some improvement(s) over the original biologic and its biosimilars) reformulations of both reference products and biosimilars/FOPs may play a role. For example, in mid-2020, Amgen highlighted growth in use of a reformulation of its pegfilgrastim product that facilitated fewer clinic visits during early months of the COVID-19 pandemic.<sup>24</sup>

To the extent that the enoxaparin sodium product class can be considered a proxy for competition among interchangeable biologic products, the gap between the price reductions seen in that product class versus all other biosimilar/FOP product classes suggests that substantial price declines may occur with interchangeability and longer periods of competition. Over long periods of time, other factors that impact prices are also likely to come into play. These include additional competitors entering, the desire/need for manufacturers to recoup development costs, and the maturation of the biosimilar landscape and public knowledge thereof. (Notably, after nearly a decade of FOP competition, the 2019 price of enoxaparin sodium had declined to only 20% of the price of the reference product prior to FOP competition, relative to a median of 92% among the remaining nine newer, non-interchangeable product classes.)

## **Conclusions**

Data from the early years of US biosimilar/FOP competition provide insight into how much, and by which types of buyers, these products were

used. Concerns have been voiced that biosimilar competition has not reduced prices rapidly or deeply.<sup>25</sup> Biosimilar market optimists have counseled patience to allow competition to develop and markets to mature.<sup>26</sup> The results of this study suggest that the introduction of biosimilars is associated with declines in both reference product market share and prevailing prices in drug classes with biosimilar/FOP competition. Further, product classes that experienced more recent biosimilar/FOP entry saw more rapid declines in reference product market shares and prices. As with small molecule generic drugs, price declines are likely to continue as additional competitors arrive. Further policies to encourage more robust, broad competition may be warranted to achieve maximum biosimilar competition and thus savings. It will be useful for future research to identify and quantify factors affecting the differential rates of biosimilar/FOP diffusion across product classes, sales channels, and PITs.

Additional topics meriting further study include factors affecting the number of biosimilar/FOP competitor entrants in each class, whether manufacturers choose to come to market as biosimilars or as "biobetters," determinants of delays between FDA approval and product launch (including litigation), and characteristics of product classes in which overall volume increases or decreases following biosimilar/FOP entry.

While open questions remain, early data on biosimilar/FOP competition in the US reveal both growing adoption as well as heterogeneity among buyers, indicating that more targeted policies, incentives, and information campaigns may be helpful in stimulating future use. Future researcher should explore these dynamics over longer



periods of time and as additional biosimilars/FOPs enter the US market in order to facilitate evidence-based public policies in the future.

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#### **List of exhibits**

**Exhibit 1 (Figure): Biosimilars/FOPs approved in the US with summary statistics**

Source: Authors' analyses of IQVIA dataset.

**Exhibit 2 (Figure): Decline in market share and price of reference products subsequent to biosimilar/FOP entry**

Source: Authors' analyses of IQVIA dataset.

**Exhibit 3 (Table): Association between biosimilar/FOP entry and reference product market shares and prices**

Source: Authors' analyses of IQVIA dataset.

**Exhibit 4 (Figure): Average daily volume of filgratim reference product by channel before and after biosimilar/FOP entry.**

Source: Authors' analyses of IQVIA dataset.

**Exhibit 5 (Figure): Average daily volume of filgrasim reference product by PIT before and after biosimilar/FOP entry.**

Source: Authors' analyses of IQVIA dataset.