

# **The Role of Coding in the Development of the Biosimilar Market:**

**Considerations for  
Policymakers**

**July 2015**

## **The Role of Coding in the Development of the Biosimilar Market: Considerations for Policymakers**

As the first biosimilars make their way to market in the United States based on the Food and Drug Administration's (FDA) implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA),<sup>1</sup> the Centers for Medicare & Medicaid Services (CMS) also has an important role to play in the development of the biosimilar marketplace. CMS has recently proposed a policy under which all biosimilars with a common reference biologic would be placed into a single code for billing and payment.<sup>2</sup>

The Moran Company was asked by our client, Hospira, to consider the potential economic impact of such a decision on the biosimilar marketplace. In order to reach a conclusion on this question, we reviewed relevant literature, focusing particularly on competition among generic drugs, since biosimilar competition is relatively new. We also conducted an analysis of the impact on pricing of analogous coding situations to shed light on the potential impact of the CMS policy.

### **Statement of the Policy Question**

With its recent Proposed Rule and other discussion,<sup>3</sup> CMS has begun the process of determining how biosimilars will be reimbursed in the Medicare program, which we expect will influence the formation of the market. The agency characterizes its decision to put all biosimilars for a common reference biologic into a single HCPCS code as “similar to the ASP calculation for multiple source drugs.”<sup>4</sup> This characterization ignores a fundamental difference between the proposed CMS policy for biosimilars and the current system for small molecule generic drugs. The BPCIA requires that innovator biologics will continue to be coded separately from biosimilars. Small molecule generics, by contrast, are typically in the same HCPCS code as their branded counterparts. The CMS proposal for biosimilar coding creates a two tier system for reference biologics and their corresponding biosimilars which could result in a less stable market for biosimilars over time. As CMS and other policymakers contemplate policy options for biosimilar coding, they will need to consider which coding policy will result in a robust, sustainable biosimilars market over the long term.

### **Highlights of Our Findings**

- In the small molecule market, assigning generics and their branded counterparts to the same HCPCS code when they are deemed equivalent by the FDA was intended to

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<sup>1</sup> The BPCIA was enacted in Title VII of the Affordable Care Act.

<sup>2</sup> Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; 80 Fed. Reg. 135 at 41801 (July 15, 2015) (hereafter, “Proposed Rule”).

<sup>3</sup> Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/May-7-2015-DrugAgenda.pdf>

<sup>4</sup> Proposed Rule at 41801.

encourage greater price competition. BPCIA prevents this policy from being applied to the biosimilars market; reference biologics will require a HCPCS code distinct from biosimilars.

- CMS has proposed “joint” or “lump” coding of all biosimilars for each reference product, further adding to the complexity of the market, which will potentially include several layers of approved biologics: interchangeable or non-interchangeable biosimilars, their reference biologics and potentially competing biologics that are not approved as biosimilars and have not been used as reference products.
- Given the significant investment required to bring a biosimilar to market, these products are inherently more risky for manufacturers to bring to market than small molecule generic drugs. A decision to put all biosimilars for a reference biologic into one HCPCS code, while the reference biologic enjoys its own code, would create considerable additional risk for biosimilar manufacturers, potentially discouraging investment in biosimilar development.
- Policymakers evaluating alternative coding policies need to consider the differing market dynamics that will be created depending on how biosimilar products will be coded for reimbursement purposes. Under a lump coding policy, the reimbursement rate will advantage customers of the lowest-priced biosimilars, while penalizing customers of biosimilars whose sales prices are above the blended ASP. Each additional entrant to the market will drive the Medicare reimbursement rate lower.
- Under this scenario, manufacturers of Medicare-sensitive products may find it uneconomic to remain in the market even if they are priced at a substantial discount to the reference biologic. Moreover, potential biosimilar manufacturers evaluating the potential risk of this sort of market outcome may be deterred from entry. In either case, the number of biosimilar suppliers would be limited, reducing competition in the marketplace overtime, causing prices to rise.
- The pricing structure in a lumpcoded biosimilar market is highly likely to equilibrate into duopolistic competition between the reference product and the least-cost biosimilar. As both microeconomic theory and this analysis suggest, prices in such markets can be expected to be substantially higher than would prevail if additional biosimilar competition was encouraged to enter.
- Policymakers need to decide what objective they are trying to achieve. If the focus of policy is on minimizing Medicare reimbursement for individual biosimilars, then lump coding is the shortest route to that objective. But, if the objective is to lower the total social cost of biologics, while maintaining a robust supply, there is a strong case to be made that lump coding will prove counter-productive, by restricting long-term competition against reference biologics.

The balance of this paper presents an overview of the literature we reviewed, and more details on the theories underlying our analysis.

## State of the Literature on the Economics of Generic Entry

Classic drugs, such as aspirin, are chemically synthesized; their active ingredients are “small molecules.” The FDA describes generic small molecule drugs at the highest level as identical to their branded counterparts in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.<sup>5</sup> Most sources estimate that small molecule generics cost between \$1 million and \$5 million to develop, far less than the cost to develop a new branded drug.<sup>6</sup> Generic development is fairly straightforward and less costly because producers are not starting from scratch, and they can rely on the safety and efficacy trials of the branded drug by demonstrating bioequivalence.<sup>7</sup> In the decades following the passage of the Hatch-Waxman Act, which created an abbreviated FDA approval process for generic drugs, generic drugs have become an important part of the pharmaceutical landscape.<sup>8</sup> More than 80% of all prescriptions are for generics.<sup>9</sup>

### *Market size a predictor of generic entry*

Numerous researchers have explored generic entry. Most agree that market size is a key determinant for entry. Generally, revenue serves as an indicator of market size. A study examining generic entry for 98 drugs that lost patent protection between 1986 and 1992, found that brand revenue the year before patent expiration is the largest predictor of generic entry, with higher revenues attracting more entrants.<sup>10</sup> In a later analysis of 40 drugs that first encountered generic competition between 1992 and 1998, researchers found that generic entry was greatest for “blockbuster” drugs, those with pre-generic sales of \$500 million or greater.<sup>11</sup>

### *Generic prices decrease as entrants increase*

In addition, researchers generally find that as the number of generic entrants increase, generic prices decrease. Researchers looking at drug prices for thirty drugs that lost patent protection between 1976 and 1987 found that with a single generic entrant, generic price is approximately 60 percent of the branded drug price. Generic price drops further to 46% and 34% of the branded

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<sup>5</sup>US Food and Drug Administration (FDA), “Generic Drugs Questions and Answers,”

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>

<sup>6</sup>For example, David Harding, “Gaining Market Share in the Generic Drug Industry Through Acquisitions and Partnerships,” Thomson Reuters, December 2010, p. 6

<sup>7</sup>FDA, “Generic Drugs Questions and Answers”

<sup>8</sup>Garth Boehm, Lixin Yao, Liang Han, Qiang Zheng, “Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984,” *Acta Pharmaceutica Sinica B*, 3(5), 2013, p. 298

<sup>9</sup>FDA, “Office of Generic Drugs Reorganization”,

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm378126.htm>

<sup>10</sup>Fiona Scott Morton, “Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry,” 1998, p. 15

<sup>11</sup>Atanu Saha, Henry Grabowski, Howard Birnbaum, Paul Greenberg, Oded Bizan, “Generic Competition in the US Pharmaceutical Industry,” *International Journal of the Economics of Business*, 13(1) February 2006, p. 18

drug price with 5 and 10 generic entrants, respectively.<sup>12</sup> In analyzing their 1994 retail pharmacy data set, comprised of 112 branded drugs with generic entrants, the Congressional Budget Office (CBO) found that with one to ten generic manufacturers, generic prices were on average 61% of the branded price; with 11 to 24 generic manufacturers, the percentage fell to less than 50%.<sup>13</sup>

### ***The Intersection of Biosimilars with this literature***

A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.<sup>14</sup> While there is some disagreement in definition, biologics are generally thought of as large molecules, derived from proteins in living cells.<sup>15</sup> For this reason, biosimilars are not copies of their reference products as chemically derived generics are to branded drugs.<sup>16</sup> In the US there will be a multi-tiered system of biologics: reference biologics, biosimilars, interchangeable biosimilars, and biologics within the same therapeutic class. How CMS will code each of these to ensure a level playing field, attractiveness of the new market to manufacturers, and long-term sustainability over short-term savings has yet to be clarified.

### ***Fewer biosimilar entrants***

Given the relative newness of biosimilar competition, empirical evidence regarding the effects of biosimilar entry is thin. However, there has been a great deal of discussion about the expected impact of biosimilar entry in the literature. Biologics present an enormous market. In recent years, biologics have been among the top selling drugs.<sup>17</sup> Yet, despite this large market, most experts predict that the number of entrants into the biosimilars market will be far smaller compared to what was observed in the small molecule market. CBO anticipates between one and three biosimilar entrants per typical innovator biologic.<sup>18</sup> After modeling a break-even analysis, one author questions whether there will be entry for any biologics besides blockbusters.<sup>19</sup>

### ***Cost and capacity hurdles***

Experts cite numerous reasons for the smaller number of entrants, one being cost and capability. According to the CBO, the development and production of a biosimilar is more complex and costly than for the typical generic drug. Other researchers note that capital investment in property, plant, and equipment, specifically cell culture facilities, are higher for biosimilars than

<sup>12</sup>Richard Caves, Michael Whinston, Mark Hurwitz, Ariel Pakes, Peter Temin, "Patent Expiration, Entry, and Competition in the US Pharmaceutical Industry," Brookings, 1991, p. 36

<sup>13</sup>US Congressional Budget Office (CBO), "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," Government Printing Office, 1998, p. 32

<sup>14</sup>FDA, "Information for Consumers (Biosimilars),"

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm>

<sup>15</sup>Thomas Morrow, Linda Hull Felcone, "Defining the Difference: What Makes Biologics Unique." *Biotechnology Healthcare*, 1(4), 2004, p. 25

<sup>16</sup>FDA, "Information for Consumers (Biosimilars)"

<sup>17</sup>Peter Ubel, "The Best-Selling Biologic Drugs," *Forbes*, December 16, 2014,

<http://www.forbes.com/sites/peterubel/2014/10/16/the-best-selling-biologic-drugs/>

<sup>18</sup>CBO, "Congressional Budget Office Cost Estimate: S. 1695 Biologics Price Competition and Innovation Act of 2007," June 25, 2008, p. 6

<sup>19</sup>Alex Brill, "The Economic Viability of a U.S. Biosimilars Industry," Matrix Global Advisors, February 2015, p. 2

for small molecule generics; manufacturing and material costs will be greater, as well.<sup>20</sup> Some estimates of biosimilar development range from \$100 million to \$250 million.<sup>21</sup> The complexity also means that firms looking at entry may face very different costs.

### ***Entry a function of risk***

Market entry is also a function of risk.<sup>22</sup> While the higher costs noted above may serve as a practical impediment to entry, higher costs also represent greater financial risk. The costs to develop a biosimilar and get through the approval process are sunk costs that pharmaceutical producers are betting on being able to recoup over the life of the product. Issues with development, approval, competition, and pricing erosions serve as threats to this upfront investment.

Biosimilars will continue to face competition from the reference biologic (as well as biologics in the same therapeutic class). While this is also true of generic drugs, experts anticipate competition from the reference biologic to be greater than that posed by branded drugs. The Federal Trade Commission (FTC) characterized the level of competition between the biosimilar and its reference drug to be more like brand-to-brand competition than brand-to-generic competition. Further, the FTC suggests that originators could retain as much as 70 to 90 percent of their market share after biosimilar entry.<sup>23</sup>

One reason for potentially greater competition with the reference biologic relates to interchangeability. In the small molecule drug market, the majority of states have policies in place that encourage generic substitution. To aid states in creating their policies, the FDA puts out an “Orange Book” which includes ratings based on therapeutic equivalent evaluations. According to the FDA, “a therapeutically equivalent drug can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.”<sup>24</sup> To be deemed therapeutically equivalent, a generic must, among other criteria be bioequivalent. As part of the FDA approval process for generics, generic applicants must demonstrate bioequivalence, with the most common method being through a single dose, two-treatment, crossover-designed study in 24-36 normal adult volunteers.<sup>25</sup>

For biosimilars to meet the standard of interchangeability, an applicant must demonstrate that the biosimilar can be expected to produce the same clinical result as the reference product and, if administered more than once, the risk of switching between the biosimilar and reference product is not greater than if the patient only used the reference product. According to the draft guidance the FDA put out in May 2015, “it would be difficult as a scientific matter for a prospective

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<sup>20</sup>Henry Grabowski, Iain Cockburn, Genia Long. “The Market For Follow-On Biologics: How Will It Evolve?” *Health Affairs*, 25(5), September 1, 2006, p. 1294

<sup>21</sup>For example, Henry Grabowski, Rahul Guha, Maria Salgado, “Regulatory and Cost Barriers Are Likely To Limit Biosimilar Development and Expected Savings in the Near Future,” *Health Affairs*, 33(6) June 1, 2014, p. 1050

<sup>22</sup>Grabowski et al., 2006, p. 1297

<sup>23</sup>Federal Trade Commission (FTC), “Emerging Health Care Issues: Follow-on Biologic Drug Competition,” June 2009, pp. iii-v

<sup>24</sup>FDA, “Orange Book Preface,” <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>

<sup>25</sup>Ibid

biosimilar applicant to establish interchangeability in an original 351(k) application<sup>26</sup> given the statutory standards for interchangeability.” Further, the FDA notes that it is still considering the type of information that would be needed to determine a biosimilar is interchangeable with a reference product.<sup>27</sup> The FDA will publish a “Purple Book” of interchangeable and non-interchangeable biosimilars. CMS is currently silent on how they will code these multiple layers of biologics.

Interchangeability ratings and subsequent substitution aided in the growth of the generic drug market.<sup>28</sup> Without interchangeability, physicians may be less willing to prescribe biosimilars. In particular, they may be disinclined to switch patients who are already on and responding well to a reference biologic.<sup>29</sup> Therefore, biosimilars may be primarily competing for new patient starts rather than those already on the reference biologic.<sup>30</sup> These biosimilars—both interchangeable and non-interchangeable—will be competing against each other as well in a coding system that creates an unequal playing field relative to their reference products.

Another risk biosimilar manufacturers will face is the development of “biobetters.” Biobetters are biologics that offer improvements over the originator biologic through modifications to the originator molecule and manufacturing process.<sup>31</sup> Unlike small-molecules, large molecules, by virtue of being large, lend themselves to greater manipulation. Biobetter products are already underway for several originators experiencing the introduction of biosimilars in the EU.<sup>32</sup> CBO noted that in the long run, “the potential for innovator companies to modify existing product lines could become an increasingly significant constraint on the ability of FOBs [follow-on biologics] to compete.”<sup>33</sup>

## Market Dynamics under Alternative Coding Policies

Policymakers evaluating alternative coding policies need to consider the differing market dynamics that will be created depending on how biosimilar products will be coded for reimbursement purposes.

Prior to the entry of a biosimilar competitor, pricing for the reference biological of that biosimilar will presumably reflect a pricing premium over the manufacturer’s production costs due to the value of the intellectual property embedded in the product patent. When the first

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<sup>26</sup>Meaning an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. 351(k) refers to a section of the Public Health Service Act added by the BPCIA.

<sup>27</sup>FDA, “Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,” 2015, pp. 4-7, <http://www.fda.gov/downloads/Drugs/Guidances/UCM273001.pdf>

<sup>28</sup>Boehm et al., 2013, p. 298

<sup>29</sup>Henry Grabowski, Genia Long, Richard Mortimer, “Implementation of the Biosimilar Pathway: Economic and Policy Issues,” *Seton Hall Law Review*, 41(2), 2011, p. 528

<sup>30</sup>Ibid

<sup>31</sup>Grabowski et al., June 2014, p. 1048

<sup>32</sup>Henry Grabowski, Rahul Guha, Maria Salgado, “Biosimilar Competition: Lessons from Europe.” *Nature Reviews Drug Discovery*, 13(2), 2014, p. 100.

<sup>33</sup>CBO, 2008, p. 8

biosimilar enters the market, the reference biologic will continue to be reimbursed at its own Average Sales Price (ASP) plus 6%. Under the statute, the first biosimilar entrant will be reimbursed under a separate code, with reimbursement set to equal the biosimilar's own ASP, plus an amount equal to 6% of the reference product ASP. Assuming that the biosimilar entrant prices its product at some amount of discount to the full price of the reference biological, providers being reimbursed under Medicare may be indifferent to the choice between the reference biological and the biosimilar in economic terms, but some amount of volume can be expected to move from the reference product to the biosimilar, as private payers create financial incentives for using the biosimilar, and beneficiaries are motivated by lower cost sharing to accept the biosimilar in lieu of the branded product. At first entry, the reference biologic may or may not lower prices to combat market share shifts to the biosimilar.

At this point, Medicare coding policy doesn't matter, because each of the products in the market is being reimbursed at its own ASP plus an amount equal to 6% of the reference biologic ASP. Were a second competitor to enter, however, market dynamics would change.

When a second biosimilar enters, the choice of Medicare coding policy will have an important influence on product pricing dynamics. If each product is awarded and allowed to bill under its own code, both products will compete against the reference biologic – and each other – on price. The experience with generic entry in the small molecule market predicts that, holding reimbursement policy constant, a second (and each subsequent) competing biosimilar entrant will increase pricing pressure on all products in the market, resulting in lower prices from all market participants

If all biosimilars are required to be reimbursed under the same code, the Medicare segment of the market for the reference biologic and its biosimilar competitors may follow a different dynamic. Under such a “lump coding<sup>34</sup>” policy, the ASP component of the reimbursement rate will advantage customers of the lowest-priced biosimilars, while penalizing customers whose sales prices are above the blended ASP. Each additional entrant to the market will drive the Medicare reimbursement rate lower.

The major constraint against a pricing “race to the bottom” in this scenario is that each biosimilar manufacturer will face its own costs, which may differ from manufacturer to manufacturer. Under a lump-coding policy, biosimilars that are at the upper end of the cost distribution of biosimilar products viewed in isolation may face reimbursement rates that put purchasers “under water” if cost differentials—and thus ASP differentials—approach or exceed the “6% of reference biologic ASP” payment add-on amount. Under this scenario, manufacturers of Medicare-sensitive products may find it uneconomic to remain in the market even if they are priced at a substantial discount to the reference biological. If this happens, the number of biosimilar product options is reduced, and pressure on the manufacturer of the reference biologic to cut prices is diminished. Potential biosimilar manufacturers evaluating the potential risk of this sort of market outcome may in fact be deterred from entry, since it is impossible to know, ex ante, how the manufacturer's own cost structure would compare to that of other biosimilar candidates that have not yet entered.

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<sup>34</sup> We borrow this term from the days of commercial “Major Medical” policies, when all drugs covered by the policy were reimbursed at a single “per drug” rate.

Given that we lack evidence of the effects of biosimilar market entry in the U.S., it is impossible to predict what market equilibrium will be reached under a lump-coding policy. But the choice policymakers face is fairly clear. The only advantage of a lump coding policy is that it will minimize the Medicare reimbursement rate for individual biosimilars in the short-term. Yet it is quite possible that it will result in higher-than-achievable reimbursement rates over time for biosimilars and their reference biologics if competition is restricted to only the lowest-cost biosimilar manufacturers.

In deciding this question, policymakers need to decide what objective they are trying to achieve. If the focus of policy is on minimizing Medicare reimbursement for new market entrants, then lump coding is the shortest route to that objective. But if the objective is to lower the total social cost of biologics over time, there is a strong case to be made that lump coding will prove counter-productive, by restricting competition against reference biologics.

## **Evidence from Medicare Part B Experience**

While microeconomic theory supports the concern that lump coding biosimilars could deter competition against the reference biologic, none of the countries currently reimbursing biosimilars uses that mechanism to set reimbursement rates, and hence there is no direct evidence against which to test this prediction from theory.

Current reimbursement policy under Medicare Part B in the United States does, however, provide useful evidence of the potential effects market entry and exit on market pricing.

In that program, a single reimbursement rate for a drug or biologic is set based on the ASP of all of the products assigned to a single billing code. While the purpose of that policy is to expose branded products to direct price competition with generics, it also has the effect of causing price competition among multiple brands when more than one brand is assigned to a billing code. That situation arises with some frequency since a number of products reimbursed under this framework are in fact biologics, many of which are separately branded by manufacturers even though they are assigned to a single billing code. We used this evidence to test the sensitivity pricing in this sort of market to the entry and exit of branded products within the same billing code.

We identified entry and exit “events” employing the annual coding cross-walk that maps individual product National Drug Codes (NDCs) to the HCPCS coding system employed by the CMS to reimburse drugs under Medicare part B. We assumed that a first appearance of a new branded NDC in a HCPCS code reflects the market entry of that product, while the first disappearance of the product reflected market exit. For products on the market between 2006 and 2013, for which data on ASP are available, we were able to determine the path of blended pricing across all products surrounding an entry or exit “event” within a HCPCS code.

Overall, we found 180 events occurring between 2007 and 2012 for which we could find ASP prices in the year prior to and subsequent to an event. Of these, 58 observations reflected entry events, while 122 exit events occurred in the same period.<sup>35</sup>

Analysis of the pricing action around entry events reflects a pattern fully consistent with the microeconomics of generic competition.

#### Pricing Effect of Product Entry

Brands Pre-Event	Brands Post-Event	Number Observations	Mean Change ASP
1	2	34	-11.30%
2	3	12	-12.60%
2	4	1	-93.90%
3	4	8	-5.50%
4	5	3	-8.30%
		58	

Each row in this table shows the change in unweighted mean price (ASP + 6%) associated with events that increased the number of competitors in the event year. In the first row, for example, we found 34 events that resulted in the number of branded products increasing from 1 to 2, reflecting first entry of a brand in competition to an existing sole source brand. As predicted by theory, each additional branded entrant causes the mean ASP values to decline, on average. While the relatively small number of observations of entry by 4 or 5 brands makes the reported averages somewhat turbulent, these data strongly suggest that brands placed in price competition with multiple manufacturers will face considerably greater pricing pressure than brands facing a single branded competitor.

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<sup>35</sup> Due to the way we constructed our analysis, some products sold under brand names in our sample were likely brought to market under Abbreviated New Drug Applications. As a result, our analysis is not exactly parallel to what will occur in the nascent biosimilar marketplace, but we believe that it fairly demonstrates the potential effects of the proposed CMS coding policy.

## Pricing Effects of Product Exit

Brands Pre-Event	Brands Post-Event	Number Observations	Mean Change ASP
2	1	70	2.40%
3	1	17	8.90%
3	2	17	5.40%
4	1	1	112.90%
4	2	6	58.30%
4	3	6	-2.90%
5	3	1	6.10%
5	4	4	-14.10%

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The second table shows the effect of product exit on ASP pricing. While the small number of observations of 4 and 5 brand markets makes the data for these markets somewhat murky, these findings are consistent with the prospect that exit from a market of three or more competitors will have a significant upward effect on average prices.

We undertook this analysis because we believe that inter-brand competition under the lumpcoded Part B reimbursement regime is the closest observable proxy for what will happen if CMS finalizes its proposal to lumpcode biosimilars. We believe that the results of this analysis reinforce the discussion of economic theory the prior sections of the report.

## Conclusion

In advancing its proposal to lumpcode biosimilar products for each reference biologic into a single code, CMS represents that this policy would be similar to the current system that applies to small molecule generic drugs. However, this characterization ignores a key distinction. The major difference between these two regimes is that CMS is currently prohibited by statute from requiring the reference biologic to be blended into the same code as biosimilars. In that environment, the standard CMS rationale for lumpcoding brands and generics—to intensify pricing pressure on the branded drug—is totally irrelevant. In this context, lumpcoding the biosimilars separately will have the effect of either deterring entry, or accelerating the exit of biosimilar products that are price-competitive against the reference biologic, but not against the single biosimilar that is the least costly to produce at relevant levels of output. Thus, this pricing structure is highly likely to equilibrate into duopolistic competition between the reference product and the least-cost biosimilar. As both microeconomic theory and this analysis suggest, prices in such markets can be expected to be substantially higher than would prevail if additional biosimilar competition was encouraged to enter.

CMS and other policymakers, therefore, may wish to consider the long-term impact of the decision to lumpcode biosimilars on the stability of the biosimilar market over time.