Data Exclusivity Period Length and Federal Government Savings from Enactment of the Biologics Price Competition and Innovation Act of 2007

Joseph Golec
Finance Department
School of Business
University of Connecticut
2100 Hillside Road, Unit-1041F
Storrs, CT 06269-1041
Phone: 860-486-6327
Fax: 860-486-0349
Email: jgolec@business.uconn.edu

John A. Vernon
Department of Health Policy and Administration
University of North Carolina-Chapel Hill
and
National Bureau of Economic Research

Ted Buckley
Director of Economic Policy
Biotechnology Industry Organization
1201 Maryland Avenue SW, Suite 900
Washington, DC 20024

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Abstract

Senate Bill S.1695, the Biologics Price Competition and Innovation Act of 2007 would establish an abbreviated regulatory procedure for the Food and Drug Administration (FDA) to license follow-on biological (FOB) drugs. The motivation for the bill is to save money for the Federal government and other purchasers of biologics. The Congressional Budget Office estimates Federal savings of $5.8 billion over the ten year scoring window covering 2009-2018. The length of data exclusivity to be awarded to innovator biologics upon FDA approval also is under debate. We show that by setting the data exclusivity period below 14 years, the government saves at most an additional $1.4 billion over ten years which represents only 0.11 percent of expected Federal drug spending, and 0.012 percent of Federal healthcare spending over the scoring window. Furthermore, we show that adopting a data exclusivity period of less than 14 years will have significant impacts on research and development (R&D) spending and thus, fewer, innovative biologics used to treat patients will be brought to market. This is because innovative biotechnology firms will lose a significant portion of their sales to copycat FOB firms. The average biologic does not cover its costs until 17 years after it starts selling the product. Because firms rely heavily on cash flow from sales to fund their R&D, fewer sales imply less R&D spending. We show that biotechnology R&D is likely to fall by at least $41 billion. The long-run effect is likely to be much larger due in part because the high-cost, high-sales breakthrough biologics will face greater FOB competition. Innovator firms may fund more lower-cost, less-innovative biologics because they will face fewer FOBs, allowing them to retain a greater proportion of sales.

I. Introduction

On June 27, 2007 the Senate Committee on Health, Education, Labor, and Pensions reported Senate Bill S.1695, the Biologics Price Competition and Innovation Act of 2007. If enacted, the bill would establish an abbreviated regulatory procedure for the Food and Drug Administration (FDA) to approve follow-on biologic (FOB) drugs. These "biosimilar" drugs presumably would be sold at lower prices than the original innovator biologic drugs, providing the Federal government and other purchasers of biologics some savings. An important question is: how much will the Federal government save? The answer is partly determined by the length of data exclusivity awarded to innovator biologics. However, an equally important question is: how much FOBs will cost innovative biotechnology firms and the public in terms of future new biologics?

On June 25, 2008, the Congressional Budget Office (CBO) issued a report that estimated that S.1695 would save the Federal government about $5.8 billion over the ten-year scoring window covering 2009-2018[1]. Our paper shows that the Federal government does not save much more over the scoring window whether it offers innovator biologics five years of data exclusivity or 14 years.

However, the potential impact of offering less than 14 years of data exclusivity on biotechnology research and development (R&D) spending is substantial. A paper by Vernon, Bennet and Golec based on a more accurate cost of capital shows that the breakeven point is at least 17 years.[2,3] With a data exclusivity period of less than 14

[1] Congressional Budget Office Cost Estimate, S.1695 Biologics Price Competition and Innovation Act of 2007, June 25, 2008, www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf, (accessed on August 1, 2008).
[2] John Vernon, Bennett, Alan and Joseph Golec, , 2008, "Exploration of Potential Economics of Follow-on Biologics and Implications for Data Exclusivity Periods for Innovators." (May 5, 2009). Available at SSRN: http://ssrn.com/abstract=1399784.

years, copycat firms could be on the market before innovator firms have earned enough in sales from their new biologics to cover their R&D costs. The loss in market share before the breakeven point would sharply cut their revenues. Because biotech firms heavily rely on sales revenues to fund R&D, they will substantially cut their R&D resulting in fewer innovative biologics for patients reaching the market. Essentially, a data exclusivity period shorter than 14 years will shift financial resources too quickly from innovative biotechnology firms who spend heavily on R&D, to copycat FOB firms, who spend little or nothing on R&D. Indeed, copycats are allowed to free-ride on the research data that the innovator paid to generate in order to win FDA approval to compete with the innovator. The net result is that one can expect fewer new, innovative biologics used to treat patients in the future.

The next section of this paper illustrates why the Federal government will not save much more by adopting a short data exclusivity period rather than a 14 year data exclusivity period. Section III discusses how shorter data exclusivity periods will reduce R&D spending by innovator biologic firms and reduce the number of new biologics. Section IV summarizes and concludes the paper.

II. The Length of Data Exclusivity and Federal Government FOB Savings

Most biologics sold in the U.S. are approved by the FDA under the Public Health Service Act (PHSA), although a few have been approved under the Food, Drug, and

[3] Grabowski (2008), which uses a cost of capital figure based only on larger biotech firms, shows that the break-even lifetime for new innovator biologics is between 12.9 years and 16.2 years. Grabowski, Henry, "Follow-on Biologics: Data Exclusivity and the Balance between Innovation and Competition." Nature Reviews, Vol. 7, June 2008, 479-488.

Cosmetic Act (FDCA). Currently, there is no act setting forth a pathway for FDA approval of FOBs whose reference drug was approved under the PHSA. The Senate Bill S.1695, the Biologics Price Competition and Innovation Act of 2007, sets forth a new pathway under PHSA[4].

Currently, innovator drugs that are approved under FDCA are effectively given protection before a generic competitor enters for up to 14 years This time period allows the innovator to recoup its R&D and other costs before generic competitors enter the market and partly or wholly capture the innovator drug's sales. Congress recognized that innovator firms needed enough exclusivity to encourage them to continue to invest in R&D; otherwise, firms would see little prospect of covering their costs and would cut back on R&D, leading to fewer new breakthrough drugs.[5]

The Senate realized that a certain period of data exclusivity is required if innovator biologic firms are to continue developing new lifesaving medicines. Accordingly, S.1695 contains a provision that establishes 12 years of data exclusivity. However, others have proposed adopting a bill that would provide as little as zero years of data exclusivity. The underlying notion is that the Federal government would save even more if low-priced FOBs entered the market even earlier than 12 or 14 years. To see why there would be very little additional savings over the CBO's ten-year scoring window covering 2009-2018, consider Table 1.

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[4] Congressional Budget Office Cost Estimate, S.1695 Biologics Price Competition and Innovation Act of 2007, June 25, 2008, www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf, (accessed on August 1, 2008).

[5] For innovator drugs and biologics approved under the FDCA, the Drug Price Competition and Patent Term Restoration Act of 1984 (referred to as the Hatch-Waxman Act) provides an abbreviated pathway. This act amends FDCA and is mostly used for approval of the more common, chemical-based generic drugs. Simply adopting the Hatch-Waxman for FOBs is not appropriate for a number of reasons that go beyond the scope of this paper. However, a significant impediment to just adopting Hatch-Waxman is the fact that it requires the generic to be substantially the same as the innovator drug, while the approval standard for FOBs is not that they are the same but rather that they are similar to the innovator biologic.

Table 1. Federal Spending on the Top 11 PHSA-Approved Biologics in 2005

Name	Total Federal Spending in 2005[6]	FDA Approval Date	5 Year Data Exclusivity Ends	12 Year Data Exclusivity Ends	14 Year Data Exclusivity Ends
Epogen/Procrit	$ 2,599,151,054	June 1, 1989	1994	2001	2003
Aranesp	$ 996,422,423	September 17, 2001	2006	2013	2015
Rituxan	$ 776,592,754	November 26, 1997	2002	2009	2011
Neulasta	$ 567,305,102	January 31, 2002	2007	2014	2016
Remicade	$ 558,887,755	August 24, 1998	2003	2010	2012
Avastin	$ 294,152,307	February 26, 2004	2009	2016	2018
Advate	$ 272,863,250	July 25, 2003	2008	2015	2017
Neupogen	$ 188,169,906	February 20, 1991	1996	2003	2005
Herceptin	$ 135,016,424	September 25, 1998	2003	2010	2012
Erbitux	$ 124,640,198	February 12, 2004	2009	2016	2018
NovoSeven	$ 115,326,492	March 25, 1999	2004	2011	2013
Total	$ 6,628,527,665				

First, note that the table includes only the top PHSA-approved biologics. Top selling biologics such as Insulin are excluded because they were approved under FDCA and already have the Hatch-Waxman pathway for generics, hence; S.1695 does not apply to them. Also, note that the top two biologics represent over half of the total sales. This illustrates the substantially skewed nature of the sales distributions for all drugs, including biologics. High sales and profits for a few blockbusters are necessary for firms to adequately fund their total R&D budgets because the R&D costs of many other

[6] Moran and company.

biologics never get covered because either they never reach the market or they provide too little profit.[7]

The timing of when FOBs would enter the market involves much uncertainty. CBO assumes that S. 1695 will be enacted near the beginning of 2009, but they also assume that there would be significant delays before FOBs would appear. First, after passage, the FDA must establish regulatory and review procedures. Second, copycat firms would need to produce the appropriate clinical data to build strong FOB applications for the FDA to review. Third, the FDA would have to review and approve specific applications for FOBs. In addition, copycat firms may need to construct production facilities, which are typically much more complex and expensive than traditional pharmaceutical facilities.

All of these steps take time, even if some could proceed simultaneously. We agree with the CBO that there would be little or no FOB entry in the first five years of the budget window (2009-2013); hence, there will be little or no Federal savings in those years. This leaves us to consider the savings that are expected between 2014 and 2018.

The Federal savings one can expect over 2014 to 2018 for the top 11 PHSA-approved biologics is little affected by the length of data exclusivity because most would already have lost data exclusivity protection by 2014. To illustrate this, Table 1 lists the dates of FDA approval for each biologic. If five years (or less) of data exclusivity were offered in a new FOB pathway, all of the top 11 biologics would be subject to FOB competition in 2014. Note that 5 years of data exclusivity simply means that the FDA cannot approve an FOB that relies on the innovator's safety and effectiveness data until

[7] Grabowski, Henry. "Follow-On Biologics: Data Exclusivity and the Balance between Innovation and Competition." Nature Reviews: Drug Discovery. Vol 7. June 2008.

five years have elapsed following the approval date. This means that the Federal government could begin saving on all 11 biologics starting in 2014.[8]

Now consider how lengthening data exclusivity to 12 years would affect Federal savings. Only three biologics would have data exclusivity for part of the 2014 to 2018 period: Avastin and Erbitux for two years and two months and Advate for one year and seven months. These three represent only one tenth of total Federal spending on biologics, and the Federal government would only forego savings for less than half of the scoring period. Hence, the difference in Federal savings between awarding five years of exclusivity compared to 12 years of exclusivity is very small. If 14 years of data exclusivity are awarded, Aranesp and Neulasta would also have some exclusivity during the scoring window, but again, the foregone savings will still be quite small. The differences in savings are computed below.

A. Reproducing the CBO Federal FOB Savings Estimates

In order to determine the different amounts of savings that would accrue with different numbers of years of data exclusivity, it is necessary to reproduce the CBO score. Given the paucity of insight that CBO gives when presenting their score, an exact reproduction is not possible. However, we provide a reasonable approximation.

The CBO did not release many of the details regarding their computation of Federal FOB savings during the 2009-2018 scoring window. Therefore, we piece together their figures from the information that CBO reveals about the significant

[8] Throughout the paper we assume that the FOB is able to design around the patent of the innovator biologic. For more information on this issue, please reference the following URL: http://bio.org/healthcare/followonbkg/FOBSMarket_exclusivity_20070926.pdf We also assume a follow-on product is available for each biologic on the day that the data exclusivity ends. Both of these are liberal assumptions – that is assumptions that bias our results in terms of more savings.

assumptions used in their June 25, 2008 scoring report to the Senate Committee on Health, Education, Labor, and Pensions. They provide little detail on their less significant assumptions, however, so that we cannot account for them in our reproduction of their figures. These small differences could account for the small discrepancies between their savings figures and ours.

We start with total federal spending on the top 11 PHSA biologics for 2005, which Table 1 shows is about $6.63 billion. We estimate that the top 11 represent 75 percent of total Federal spending on biologics, implying a total of $8.8 billion in 2005. The CBO also used 75 percent. Following the CBO, we assume that biologic sales and government spending will grow at seven percent throughout the period.[9]

Next, we need the share of biologic spending on FOBs. The CBO reports their assumed beginning and end-year FOB market shares but not the shares for the intervening years. They assume that FOBs capture 10 percent of the market in the entry year and 35 percent in the fourth year. In Table 2, we adopt these beginning and end shares, and also assume that FOB market share rises by five percent increments each year except for the last year when it rises by ten percentage points to 35 percent.

The CBO assumes that FOBs would be sold at a 20 percent price discount to the innovator biologic in the first year that they reach the market (2014) and at a 40 percent discount in the last year of the budget window (2018). They do not specify price discounts in the intervening years. Again we adopt their endpoints and assume that price discounts increase by five percentage points in each intervening year. These price

[9] Please note, we do not necessarily agree or disagree with the assumptions that the CBO used. Rather, we are trying to reproduce their score in order to inform the debate as to how different number of years of data exclusivity could impact the score of the legislation.

discounts are uncertain because many believe that the costs of FOB development and production might not be much lower than the costs of innovator biologics.

The CBO's bottom line estimates of Federal savings are $0.2, $0.6, $1.1, $1.7, and $2.3 billion for the years 2014, 2015, 2016, 2017, and 2018, respectively, for a total of $5.9 billion over the ten year scoring window. Our reproduction of their estimates is very close; $0.3, $0.7, $1.1, $1.6, and $2.7 billion for the years 2014, 2015, 2016, 2017, and 2018, respectively. Our estimate of $6.4 billion is quite close to the CBO score. The only year where there is a significant discrepancy between the CBO figures and ours is in 2018, and this could be due to the effects of a combination of minor assumptions not revealed in their report, and which are not part of our estimates.[10] However, neither estimate is particularly large when one considers that the federal government is projected to spend $1,237 billion on drugs and $12,158 billion on overall healthcare expenditures over 2009 – 2018.[11]

Our estimate – like the CBO estimate – assumes that there is a 12 year data exclusivity period. We consider the effects of different data exclusivity periods in the next section.

[10] There are several reasons that could account for the difference. The CBO may assume that there is a certain expectation that some of the patents cannot be designed around. The CBO may assume that the growth rate for some products would drop below 7% towards the end of the scoring window due to a maturing market. Further, the CBO could have assumed that certain FOBs would enter the market later due to the technological challenges in producing a highly similar FOB.

[11] Projected figures on federal spending are from the National Health Expenditure Projections 2007 – 2017, www.cms.hhs.gov/NationalHealthExpendData/Downloads/proj2007.pdf, (accessed August 1, 2008). The Centers for Medicare and Medicaid Services (CMS) projected that federal drug (total federal healthcare) spending would grow at 10% (7.5%) from 2007 – 2017. We use the same growth rates to compute 2018 spending figures ($186 billion for drugs and $1,651 billion for total healthcare). To calculate the total we sum the CMS figures over 2007 – 2017 and add the calculated 2018 figures.

Table 2. A Reproduction of the CBO's Estimates of the Federal Government Saving from Enactment of the Biologics Price Competition Act of 2007 (S. 1695)

		Scoring Window (2008-2018)												
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Federal Spending on Biologics ($Billions)	8.8	9.5	10.1	10.8	11.6	12.4	13.3	14.2	15.2	16.3	17.4	18.6	19.9	21.3
Assumed Sales Growth (%)		7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%
Federal FOB Savings ($Billions)					0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.1	1.6	2.7

B. The Effects of Different Data Exclusivity Periods on Federal Savings

Table 1 shows if data exclusivity is set at 12 years all but 3 of the top 11 biologics will potentially face FOB competition in 2014. However, when one assumes five years of data exclusivity, all of the biologics could be immediately subject to FOB competition in 2014 because their data exclusivity would already have expired by then. In fact, if one sets data exclusivity to be ten years or less, there is no change in the Federal savings. All of the biologics have the potential to face FOB competition in 2014.

Setting the data exclusivity at 5 or 10 years increases the Federal savings by $0.4 billion over the budget window – that is about a 5 percent increase in savings over the 10 year scoring window.[12]

If data exclusivity is set at 14 years rather than 12 years as specified in the Senate bill, there could be some additional loss in savings because FOB competition for Avastin, Erbitux, and Advate will be delayed by another two years, and Aranesp and Neulasta would also not face FOBs immediately. Federal savings would decline by $1.0 billion over the budget window. Therefore, total Federal savings would fall from $6.4 billion to $5.4 billion.[13]

[12] Please note: There are liberal assumptions in the increase in savings. That is that every biologic would have FOB competition immediately starting in 2014. It is unclear that the technology will exist to produce FOBs for more complicated biologics (e.g., monoclonal antibodies) in 2014. Thus, the increase savings figure should be viewed as an upper bound.

[13] Once again this figure should be viewed as an upper bound. As noted previously the savings figure calculated in this study is higher than the CBO figure. If the CBO figure of $5.9 billion in savings were utilized the additional savings from extending the data exclusivity from 12 years to 14 years would amount to only $0.5 billion.

Table 3 summarizes the savings that the Federal government can expect from FOBs under different assumed data exclusivity periods. It illustrates that the amount of savings over the scoring period is relatively insensitive to the length of the data exclusivity period. Further, it shows the change in savings that is associated with the different data exclusivity periods as a percentage of the overall drug spending and healthcare spending from 2009 – 2018.

Table 3. The Effects of Different Data Exclusivity Periods on Federal Savings on FOBs Over the 2009-2018 Budget Window

	Data Exclusivity Period		
	5 years instead of 12 years	10 years instead of 12 years	14 years instead of 12 years
Change in Federal savings	Additional $0.5 billion in savings	Additional $0.5 billion in savings	Loss of $1.0 billion of savings
Savings change as a percent of overall federal drug spending[14]	0.04% increase	0.04% increase	0.08% decrease
Savings change as a percent of overall federal healthcare spending[15]	0.004% increase	0.004% increase	0.008% decrease

[14] For clarification: The figures in this row are the change in savings divided by the total federal drug spending over the 10 year period. For instance the 5 year instead of 12 year figure is calculated by dividing $0.5 billion by $1,237 billion.

[15] For clarification: The figures in this row are the change in savings divided by the total federal healthcare spending over the 10 year period. For instance the 5 year instead of 12 year figure is calculated by dividing $0.5 billion by $12,158 billion.

III. The Effects of Various Data Exclusivity Periods on Biologic R&D Spending

The previous sections imply that the Federal government does not save much more if it restricts the data exclusivity period to less than 14 years, especially when compared to total Federal spending on drugs and healthcare. At most, the increase in savings over the budget window equals 0.11 percent of projected Federal drug spending over the scoring window, and only 0.012 percent of Federal healthcare spending.

Nevertheless, selecting a data exclusivity period shorter than 14 years would have a large impact on biotech firms' R&D spending. With less R&D spending, fewer new, innovative biologics would come to market and lessen treatment options for patients. The reasons for this are two-fold. First, because FOBs will take substantial dollar amounts of sales from innovator biotech firms and because biotech firms heavily rely on sales revenues to fund R&D, they will substantially cut their R&D. Too short a data exclusivity period will shift financial resources from innovative biotech firms who spend heavily on R&D, to copycat FOB firms, who spend little or nothing on R&D. The net result is that one can expect fewer new, innovative biologics in the future. Second, reason is the uncertainty of how the FOB marketplace will evolve.

Biotech firms' R&D spending has grown sharply in lock step with their sales. Table 4 illustrates how both pharmaceutical and biotech firms have grown their sales and R&D spending from 1990 to 2006. The total sales and R&D figures understate the true figures because they are compiled from the Compustat data base (pharmaceutical firm

SIC = 2834, and biotech firm SIC = 2836), which includes only publicly-traded firms.[16] Biotech firms are more likely to be privately held and excluded from the Compustat data.

Over 1990 to 2006, Table 4 shows that the number of pharmaceutical firms has about doubled (143 to 243), their combined sales have about quadrupled ($120 to $449 billion), and their combined R&D spending has grown about seven fold ($11 to $76 billion); all outstanding accomplishments. The biotech industry has grown even faster. The number of biotech firms has about tripled (73 to 226), their combined sales have grown about 24 fold ($2 to $48 billion), and their combined R&D spending has grown about seven fold ($0.6 to $18 billion).

Table 4. Sales and R&D Spending for Pharmaceutical and Biotech Firms ($millions)

	Pharmaceutical Firms					Biotech Firms			
Year	# Firms	Sales	R&D	R&D/Sales		# Firms	Sales	R&D	R&D/Sales
1990	143	120432	11258	0.09		73	2191	647	0.30
1991	152	130957	12757	0.10		94	2847	972	0.34
1992	168	145780	15429	0.11		109	3765	1487	0.40
1993	182	165061	18774	0.11		127	4526	2331	0.51
1994	188	179253	19985	0.11		139	5549	2273	0.41
1995	202	204036	23165	0.11		163	7164	2803	0.39
1996	213	249748	27995	0.11		176	8798	3458	0.39
1997	234	249946	33310	0.13		195	9947	3826	0.38
1998	252	274882	34828	0.13		206	12337	4584	0.37
1999	268	298350	36390	0.12		218	14582	5152	0.35
2000	272	327112	42967	0.13		225	16840	7270	0.43
2001	281	344278	48715	0.14		245	20182	7734	0.38
2002	276	379160	50290	0.13		247	22978	12598	0.55
2003	282	380559	61822	0.16		248	27421	10487	0.38
2004	278	399341	67888	0.17		255	34834	12097	0.35
2005	261	418317	65821	0.16		254	41681	12729	0.31
2006	243	448868	75628	0.17		226	47711	18345	0.38

[16] Although SIC codes are reasonably accurate identifiers for industry, there is some misclassification in the Compustat database. We switched 29 firms listed as pharmaceutical firms (SIC 2834) by Compustat to the biotech group. This has little effect on the results because most of the firms are small except for Genentech, Chiron, Celephon, and Celgene

For our purposes, the most important statistic is in Table 4 is the ratio of firms' R&D spending to their sales. Both pharmaceutical and biotech firms reinvest a portion of their sales revenues into R&D on new drugs. But compared to pharmaceutical firms, biologics firms reinvest about twice as much of per dollar of sales revenue into R&D. Pharmaceutical firms reinvested about 15 percent of sales on average, and biotech firms reinvested about 38 percent on average. The average for all U.S. firms in all industries is only three percent.

The primary problem that we see with selecting a data exclusivity period shorter than 14 years is that it will shift revenues from innovative biotech firms to copycat FOB firms before innovator firms can break even in order to adequately fund R&D for future innovative therapies. As Vernon, Bennett and Golec (2009) find the break-even point for biotech firms is 17 years,[17] offering less than 14 years of data exclusivity on innovator biologics could have devastating effects on R&D spending because it would allow FOB competition before most innovator biologics reach breakeven, particularly for small firms. With a data exclusivity period less than 14 year, copycat firms are expected to offer FOBs at reduced prices before innovator firms have earned enough in sales of their new biologics to cover their R&D costs. Data exclusivity of 14 years is the bare minimum required, and for some firms, it may still be too short.

Indeed, shorter exclusivity could lead to the worst of both worlds – fewer new biologics to treat patients and little savings. To see this, consider the CBO's assertion

[17] John Vernon, Bennett, Alan and Joseph Golec, , 2008, "Exploration of Potential Economics of Follow-on Biologics and Implications for Data Exclusivity Periods for Innovators." (May 5, 2009). Available at SSRN: http://ssrn.com/abstract=1399784.

that four years after introduction of a FOB, the FOB would capture 35% of market entry and the price reduction would be 40%. That means, that the savings would be 14%; however, the revenue lost to innovator company would be 35%. Thus, the savings would be modest at best, but the effect on R&D would be significant and larger. *Ceteris paribus* the negative effect on R&D would result in fewer innovative biologics coming the market.

The expected loss in R&D spending by innovative biotech firms can be computed from their expected loss in sales and biotech firms' ratio of R&D to sales. Based on Table 4 figures, we conservatively estimate that for each dollar in sales transferred from the original innovator biologic to its copycat FOB, biotech firms will spend about 35 cents less in R&D.

If data exclusivity is set at 12 years, as proposed in S. 1695, according to our modeling all of the biologics except Avastin, Erbitux, and Advate would face immediate FOB competition in 2014, and by 2016, all of the biologics would face FOB competition. Consequently, according to our model, innovator biologic firms would lose $27.7 billion in sales to copycat firms during the scoring window, leading them to spend $9.7 billion less on R&D.[18] If instead, data exclusivity is set at 14 years, the situation is somewhat improved because FOB competition for Avastin, Erbitux, and Advate will be delayed by another two years, and Aranesp and Neulasta will also not face immediate FOBs competition. Assuming 14 years of data exclusivity, innovator biologic firms will lose

[18] It should be noted that while the revenue loss can be large, at the same time the savings can be much more limited. For example consider the following hypothetical example. If an FOB captures 50% of the market and prices 20% below the innovator product, then the overall savings to the healthcare system are 10%. However, the loss of revenue to the innovator company is 50%. Thus, in this example 10% savings are traded for 50% revenue loss.

$25.8 billion in sales to copycat firms during the scoring window, leading them to spend $9 billion less on R&D.

Until now, we have only focused on the federal level. However, as the CBO points out, the FOB pathway will reduce not only federal spending on biologics, but also overall spending in the U.S. on biologics. CBO estimates that overall spending will be reduced by $25 billion. Using this information and the information presented above, it follows that if data exclusivity is set at 12 years, as proposed in S. 1695, innovator biologic firms would lose $117.4 billion in sales to copycat firms during the scoring window, leading them to spend $41.1 billion less on R&D. With less R&D spending, fewer new innovative biologics will come to market, which will result in fewer treatment options for patients.

While initially the CBO has predicted a slow uptake of FOB products, it is likely – however, not certain – that in the long run there will be more significant savings from a FOB pathway. The savings associated with Hatch-Waxman were lower in the first 10 years of enactment due to a number of factors including physician's lack of experience with generic products and lack of incentives on the part of health insurance companies for patients to take generics rather than brand name drugs. In the same way FOB savings may increase for reasons such as physicians becoming more familiar with the products and insurance companies designing benefits to encourage the utilization of FOBs. Thus, in the long run the effects of a data exclusivity period less than 14 years on innovator firms R&D could be more extreme. Further, the ability of innovator firms that do not have a product revenue stream to raise capital could be extremely limited as the level of

uncertainty surrounding the ability of innovator biologics to recoup the R&D costs would be greatly increased.

Investment decisions are being made presently for biologics that will not reach the market for a decade or more. There is great uncertainty as to how the FOB marketplace will evolve. There are reasons, cited above, to believe that as time passes FOBs will gain market share more quickly than during the next 10 years. Further, there is great uncertainty as to whether FOBs will be able to avail themselves of an abbreviated FDA approval pathway while at the same time avoid patent infringement suits by designing around the innovator biologic. If the data exclusivity is set below 14 years, the uncertainty surrounding the ability of patents to protect the innovator biologic from FOB competition early in the product lifecycle coupled with the possibility of a FOB quickly gaining market share could cause a precipitous drop in investment. As our present economic circumstances demonstrate uncertainty can play havoc in an economic sector.

A. Long Run Effects Adopting Data Exclusivity Shorter than 14 years

We expect the long-run loss in R&D spending and the reduction in future new biologics to be substantially larger than we estimated strictly based upon the sales that innovator firms will lose to FOBs during the scoring window. The reason that we expect a much larger negative effect is that the distribution of sales across biologics is highly skewed towards breakthrough biologics that generate unusually large sales. Breakthrough biologics will attract more FOBs because they offer greater profit potential. The innovator firm essentially establishes a large market which FOBs get to partly exploit.

Shorter data exclusivity will shift financial resources too quickly from innovative biotechnology firms who spend heavily on R&D, to copycat FOB firms, who spend little or nothing on R&D. Because new breakthrough products typically represent new costly science, the most costly to develop medicines are more likely to face FOB competition.[19] Therefore, firms are likely to shift their R&D spending from high risk, high cost, long breakeven biologics to more certain, quicker breakeven biologics.

To see this, realize that biotech firms make R&D spending decisions ex ante, while FOBs get to select the products that they will compete with ex post. FOBs will enter the high revenue, high profit markets. Now consider the ex ante incentives when innovative biotech firms could face FOB competition earlier in the biologic's market lifetime. Assume two types of projects: a high-cost, high-risk, high-return, project H, and a low-cost, low-risk, low-return, project L. Risk here refers to the probability that the project yields a marketable medicine. Firms allocate R&D spending between them so that the ex ante risk adjusted return of the last dollar spent on H equals that of L. FOBs reduce the risk-adjusted return of H compared to L, hence, firms will cut back on projects like H, and R&D will fall by more than if all projects faced the same probability of FOB competition. Breakthroughs will face much greater FOB competition.

Overall, a short data exclusivity period provides poor ex ante incentives for innovative biotech firms. High-cost, high-risk breakthrough projects are discouraged and relatively low-risk medicines are encouraged. A recent Government Accounting Office

[19] Richard G. Frank, 2003, "New Estimates of Drug Development Costs." Journal of Health Economics 22, 325-330.

(GAO) study considered pressing issues in new drug development.[20] In particular, it sought ways to encourage more R&D investment into high-risk innovative medicines. One of the proposals in the GAO study suggested that risky breakthrough medicines could receive 30-year patents, instead of the normal 20-year patents. Such a policy would essentially confer much longer exclusivity than the 12 years proposed in S.1695. If we want innovative medicines, a longer exclusivity period is required. This clearly illustrates the tension between generating Federal savings from FOBs and the costs in terms of the level and types of R&D that will be foregone if data exclusivity is set too short.

IV. Conclusions

We have shown that adopting a data exclusivity period shorter than 14 years provides the Federal government with relatively small savings but produces relatively large costs in terms of foregone R&D spending and fewer new innovative biologics. A shorter data exclusivity period is counterproductive with respect to encouraging innovative, new breakthrough biologics.

The costs in terms of forgone R&D and new biologics could be larger than our estimates. New breakthrough medicines typically represent risky new costly science. Those blockbuster products also generate the lion's share of the industry sales and profits. It is likely that FOB's will enter blockbuster markets first, taking proportionately more of the revenue and profit that innovative biotech firms rely on to fund their R&D. Therefore, a larger portion of biotech R&D spending could be affected than we assume.

[20] United States Government Accounting Office, New Drug Development, GAO-07-49, Washington, D.C., November 2006.

In this paper, we have highlighted the importance of considering both the economic costs and benefits associated with FOBs. The costs – fewer, needed treatment options for patients – are often less tangible than the benefits because they are somewhat obscured by industry growth and scientific advances, and the pipeline time between an R&D reduction and fewer new medicines. Sound public policy should weigh the substantial costs against the benefits.