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Concerns Around Budget Impact Thresholds: Not All Drugs Are the Same

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ABSTRACT

Background: The use of budget thresholds is a recent development in the United States (e.g., the Institute for Clinical and Economic Review drug assessments). Budget thresholds establish limits that require some type of budgetary action if exceeded. This research focused on the advisability of using product-level budget thresholds as fixed spending caps by examining whether they are likely to improve or worsen market efficiency over status quo. **Objective:** The aim of this study was to determine whether fixed product-level spending caps are advisable for biopharmaceuticals. **Methods:** We systematically examined 5-year, postlaunch revenue for drugs that launched in the United States between 2003 and 2014 using the IMS MIDAS database. For products launched between 2011 and 2014, we used historical revenue as the baseline and trended out 60 months postlaunch based on exponential smoothing. Forecasted fifth-year revenue was compared to analyst reports. Fifth-year revenue was compared against a hypothetical \$904 million spending cap to determine the amount of annual

spending that might require reallocation. Descriptive statistics of 5-year, postlaunch revenue and annual spending requiring reallocation were calculated. **Results:** Adhering to a \$904 million product-level spending cap requires that approximately one-third of new drug spending be reallocated to other goods and services that have the potential to be less cost-effective due to significant barriers. **Conclusion:** Fixed product-level spending caps have the potential to reduce market efficiency due to their independence from value and the presence of important operational challenges. **Keywords:** budget impact analysis, budget thresholds, budget triggers, spending caps.

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Introduction

In recent years, there has been growing concern about the amount of US health care dollars spent on biopharmaceuticals and on the cost of individual therapies. Part of the response to these concerns has been the development of value frameworks in the United States. Although most of these frameworks are limited to value assessment at the individual patient level using techniques such as cost-effectiveness, some, such as the Institute for Clinical and Economic Review (ICER), include population-level budget impact [1].

Budget impact is an objective measure of expected changes in expenditure resulting from a medical service or biopharmaceutical [2] and by definition does not evaluate the value of said service or biopharmaceutical or its societal affordability [3]. Budget thresholds are used in conjunction with budget impact to establish limits that require some type of budgetary action if

exceeded. Budget thresholds may be characterized by the following three elements: 1) level of aggregation of the budget (i.e., the total spending at the individual product level, total spending on all biopharmaceuticals, or total health spending—drug as well as nondrug); 2) threshold amount; and 3) action required (reduce spending below the cap, trigger for alternative solutions). Spending caps are used when there is a decision rule that spending should not exceed a predetermined threshold; caps may be either fixed or variable (e.g., the spending cap amount depends on number of factors, potentially including value). In the event that spending exceeds the threshold, either the price of the product or service must be lowered or utilization of the service or biopharmaceutical must be reduced to satisfy the spending cap. In comparison, triggers for alternative solutions result in efforts aimed at reducing spending elsewhere in the budget or identifying alternative ways to pay for the unanticipated expense (e.g., long-term financing, accepting spending above the cap).

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Prior research has shown that price controls, such as lowering a price to meet a spending cap, negatively affect innovation [4]. Therefore, this research focused on the question of whether reallocation of spending based on individual, fixed, drug-level spending caps is advisable in the US market.

The US payer market is diverse, with both public and private payers. Reallocation possibilities for private payers are limited to health care services, whereas public payer reallocation opportunities include both health care and public services (e.g., education, public safety, transportation). In efficient markets, spending for a product or service would be determined by the point at which marginal benefit (e.g., health gained) is equal to marginal costs [5]. The US health care market, however, is not perfectly efficient due to the presence of patents on the supply side (e.g., drug manufacturers) and consolidated buying power on the demand side (e.g., payers and preference-based measures).

Thus, the relevant policy consideration is whether spending caps move marginal benefits and marginal costs closer together or further apart (e.g., does the use of product-level thresholds make the market more efficient). To explore this issue, we analyzed the potential impact of fixed spending caps at the individual product level on historical new product revenue patterns.

Methods

To better understand the impact of a fixed product-level budget cap, we analyzed all new molecular entities (NMEs) that launched between 2003 and 2014. For each NME included in the analysis, we examined revenue from the fifth year postlaunch because this provides enough time on the market for a biopharmaceutical to fully realize its budget impact. In addition, this is the time frame currently used by ICER in their budget impact calculations. Use of the fifth year of revenue required us to break our analysis into two analytic sets. The first set, 2003 to 2010, was limited to those products that had a full 5 years of revenue data. The second analytic set, 2011 to 2014, focused on those products that required forecasting the fifth year of revenue. The fifth-year revenue of each product was compared to a hypothetical spending cap based on the \$904 million ICER budget threshold.

2003 to 2010 Analysis

For those biopharmaceuticals with 5 years of revenue data, we used FDA approvals, IMS MIDAS data (QuintilesIMS MIDAS™), and secondary research to determine all NMEs that launched between 2003 and 2010. We removed products that met the following criteria from the list of NMEs:

- incomplete or unavailable IMS MIDAS data;
- generic or branded generic products;
- combined molecules with one previously launched molecule;
- discontinued products.

We gathered product-level gross revenue data at the molecule level by consolidating revenue across the various product forms and doses. As a final step, we inflated product-level gross revenue to 2016 dollars by incorporating an inflation adjustment for products that reached fifth-year revenue prior to 2016. NME fifth-year revenue was summed by launch year. Both product level and total annual gross revenue based on IMS MIDAS sales were analyzed using descriptive statistical techniques, including analysis of mean, median, interquartile range, and plotting of the distribution.

2011 to 2014 Analysis

Because products that launched after 2010 did not have 5 full years of observation, we examined the data for the available years and extrapolated out to 5 years. To do so, NMEs were identified between 2011 and 2014 using the same methods described in the 2003 to 2010 analysis. We used a forecasting tool (IMS Therapy Forecaster, QuintilesIMS Incorporated, Danbury, CT, USA) that produces estimates by combining quantitative data, key opinion leader research, and internal expertise to trend the baselines using exponential smoothing until 60 months since launch. Gross revenue forecasts were compared to the top 25 products using 2015 and 2016 Cowen & Co. equity research reports. The comparative results of the 25 products are as follows:

- 18 products were in line with analyst forecasts;
- 6 products exceeded analyst forecasts;
- 1 product was below the analyst forecast.

Based on these results, the forecasted revenues were not adjusted. Next, 2011 to 2014 NME product and total annual gross revenue were combined with 2003 to 2010 data for a total of 296 NMEs that were analyzed using descriptive statistical techniques, including analysis of mean, median, interquartile range, and plotting of the distribution. Results did not change significantly between the 2003 to 2010 and 2003 to 2014; therefore, the results presented below are for the 2003 to 2014 analysis.

Analysis of Historical Revenue Above Spending Cap

In the final phase, revenue above a hypothetical spending cap of \$904 million was calculated using a two-step process. In the first step, products that exceeded the spending cap were identified by comparing fifth-year revenue against the \$904 million threshold. For each product that exceeded the threshold, revenue above the spending cap was calculated by subtracting \$904 million from the product revenue. This excess revenue was then summed on an annual basis. Mean, median, and interquartile ranges were calculated for the revenue above the spending cap.

Results

The distribution of 2003 to 2014 fifth-year, postlaunch, product-level NME revenue, which is shown in Figure 1, is a right-skewed distribution with a median revenue of \$150 million, mean revenue of \$394 million, and an interquartile range from \$36 to \$467 million. The total number of products exceeding \$904 million, which is the budget threshold used by ICER, was 13%, while the number of products exceeding this threshold in any given year ranged between zero and nine. Looking at the distribution of cumulative revenue, we found that blockbusters (\$904 million or more) account for 59% of total NME revenue.

Year-to-year variability of fifth-year, product-level revenue between 2003 and 2014 was significant, with median revenue ranging between \$90 and \$194 million and mean revenue ranging between \$233 and \$604 million. Figure 1 illustrates how each year's interquartile range compares against the 2003 to 2014 average with a significant number of years being narrower or wider than the average. This finding is consistent with the coefficient of variation at the product level being equal to 1.75, which indicates significant dispersion across the results.

The total annual fifth-year revenue between 2003 and 2014 above the hypothetical spending cap of \$904 million was significant, with a median value of \$2133 million (27% of NME revenue), mean value of \$3181 million (31%), and interquartile range from \$671 (14%) to \$3767 million (34%). Figure 1 illustrates how each year's revenue above the spending cap compares with the 2003 to

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