The Response of Pharmaceutical Manufacturers to the Provisions of the ACA

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ABSTRACT

The provisions of the Patient Protection and Affordable Care Act of 2010 (the ACA) engendered a number of effects on pharmaceutical manufacturers, including the annual fee, mandated Medicaid drugs rebates, and Medicare prescription drug coverage “donut hole” relief. The authors conduct theoretical and empirical analyses to assess the consequences of the provisions. Both theoretical and empirical analyses show that the provisions have positive correlations with increased prices for branded prescription drugs. These findings reveal that pharmaceutical manufacturers shift drug costs to patients.

Keywords: Pharmaceutical Manufacturers, Affordable Care Act, Drug costs, Health Care, Donut Hole

I. Introduction

The Patient Protection and Affordable Care Act of 2010 (the ACA), as amended by the Health Care and Education Reconciliation Act of 2010, became law on March 23, 2010 (Patient Protection and Affordable Care Act, 2010). The ACA is divided into 10 titles covering nearly every aspect of health care, from insurance coverage to final delivery of the care. The pharmaceutical industry is one sector that the ACA strongly influences. The provisions of the ACA related to pharmaceutical manufacturers include mandated Medicaid drug rebates, Medicare prescription drug coverage (Part D) “donut hole” relief, and an annual fee imposed on pharmaceutical manufacturers.

A. Section 2501: Mandated Medicaid Drug Rebates

Effective January 1, 2010, most branded prescription drugs minimum rebates increased from 15.1% of the Average Manufacturer Price (AMP)—which is the average price wholesalers pay manufacturers for drugs that are sold to retail pharmacies—to 23.1% of AMP. Similarly, minimum rebates for generic drugs rose from 11% of AMP to 13% of AMP. Furthermore, minimum rebates for clotting factors and pediatric indication drugs augmented from 15.1% of AMP to 17.1% of AMP (Piper, 2010).

Manufacturers are responsible for paying a rebate on such drugs each time they are dispensed to Medicaid patients. Pharmaceutical manufacturers pay these rebates on a quarterly basis. Rebates are shared between the state and federal government so as to offset the overall cost of prescription drugs under the Medicaid Program (Centers for
Medicare & Medicaid Services, 2013).

B. Section 3301: Medicare Prescription Drug Coverage (Part D) “Donut Hole” Relief

Most plans with Medicare prescription drug coverage (Part D) have a coverage gap called a “donut hole.” This means that after a Medicare beneficiary has spent a certain amount of money for covered drugs, he or she has to pay all out-of-pocket costs for prescriptions up to a yearly limit. Once the beneficiary has spent up to the yearly limit, the coverage gap ends, and the drug plan once again covers drugs. The ACA intends to gradually close the gap in drug coverage.

Effective January 1, 2011, if a Medicare beneficiary reaches the coverage gap in his/her Medicare Part D coverage, he or she will automatically get a 50% discount on covered branded prescription drugs. Until that Medicare beneficiary reaches the catastrophic coverage phase, he or she receives a discount when a branded prescription drug is purchased at a pharmacy or ordered through the mail (U.S. Department of Health & Human Services, n.d.). The ACA provides assistance to help Medicare beneficiaries bridge this donut hole. In other words, pharmaceutical manufacturers must provide a 50% discount on branded prescription drugs to Medicare Part D participants for drugs dispensed while a beneficiary is in the donut hole.

C. Section 9008: Annual Fee Imposed on Pharmaceutical Manufacturers

Since January 1, 2011, the ACA imposes an annual fee on “any manufacturer or importer with gross receipts from branded prescription drug sales” (Internal Revenue Service, 2011). According to the provisions of the ACA, the annual fee is applied to only branded prescription drug sales and not sales of generic drugs. “Branded prescription drug sales” is defined to include sales of branded prescription drugs to specified government programs (Medicare, Medicaid, the Department of Veterans Affairs [VA], the Department of Defense [DOD], and the TRICARE retail pharmacy program under 10 U.S.C. § 1074g) or “pursuant to coverage under any of those programs” (Patient Protection and Affordable Care Act, 2010).

The annual fee is based on a calculation of annual sales intended to reflect the market share of the manufacturer. In determining the annual fee, government programs that purchase or provide coverage for the branded prescription drugs (i.e., Medicare, Medicaid, VA, and DOD/TRICARE) provide a yearly report to the Department of the Treasury indicating prior year’s sales (or units of drugs dispensed to beneficiaries and corresponding payment amount) for each branded prescription drug for all manufacturers covered by the program. Dividing the industry into tiers of branded prescription drug sales, the Secretary of the Treasury calculates the annual fee for each pharmaceutical manufacturer or importer based on reports from other specified federal government agencies, as well as a ratio of its branded prescription drug sales to the branded prescription drug sales of all covered entities for the prior year (i.e., market share) (Health Care Education Affordability Reconciliation Act, 2010).

The annual fee imposed on pharmaceutical manufacturers is not tax deductible for U.S. income tax purposes. The branded prescription drug sales do not include sales of any drug or biological product with respect to which a tax credit is allowed for any taxable year under IRC Section 45C (Preserving Access to Orphan Drugs Act, 2013).

In the annual fee program, the ACA specifies the annual revenue collected from pharmaceutical manufacturers. In 2011, a total annual fee of $2.5 billion was imposed on pharmaceutical manufacturers. Beginning in 2012, the annual fee increased to $3 billion each year through 2016, to $3.5 billion in 2017, and to $4.2 billion in 2018. According to the Joint Committee on Taxation, the revenue collected from pharmaceutical manufacturers’ annual fee is projected to raise $30.8 billion over a 10-year period (The Joint Committee on Taxation, 2010). The ACA also states that these additional revenues should be transferred to the Federal Medicare Supplementary Insurance (Part B) Trust Fund.

Admittedly, the ACA is intended to have a salutary impact on its recipients vis-à-vis their prescription drug costs. This intention of the ACA, though, begs the question whether ACA’s provisions truly have an auspicious effect on patient drug costs. To date, answers to this question are vague. Consequently, the purpose of this paper is to analyze the potential impact of the ACA on the pharmaceutical manufacturers and attempts to answer the question whether pharmaceutical manufacturers shift the tax and fee burden to patients via higher branded prescription drug prices.

This paper continues in Section II with a conceptual analysis of cost shifting in the pharmaceutical industry. Section III details the study’s empirical methodology. Section IV discusses the limitations of this research and provides avenues for future research. Section V provides concluding remarks.
II. Conceptual Analysis

The provisions of the ACA are intended to support Medicare/Medicaid by charging pharmaceutical manufacturers and reducing the financial burden for patients. The use of price rebates and discounts in the pharmaceutical industry is not a recent phenomenon in the United States. In fact, the pharmaceutical companies’ utilization of price rebates started in the United States and became commonplace worldwide. The logic behind using price rebates is to achieve financial goals, reduced prices, and budgetary predictability, as well as address concerns about cost effectiveness of new medicines (Morgan, Daw, & Thomson, 2013).

Employment of an annual fee helps offset the cost of expanding coverage in health care reform (Spatz, 2010). According to the Centers for Medicare & Medicaid Services Fact Sheet, in 2011 3.6 million Medicare beneficiaries saved over $2.1 billion on prescription drugs in the donut hole (Centers for Medicare & Medicaid Services, 2012), and millions of uninsured individuals received coverage. The foregoing implies that ostensibly, the provisions of the ACA function as they are proposed. Further analysis, however, reveals the unintentional dark side of the ACA.

Despite the putative benefits that the Act bestows on individuals, an especially critical issue requiring empirical attention pertains to “who bears the burden” of the annual fee, rebates and higher discounts (Brill, 2009). Obviously, pharmaceutical manufacturers are the payers in these three financial arrangements. Indeed, they report a reduction in revenue owing to Medicaid rebates, “donut hole” relief, and expenses from the annual fee. Shown in Table 1 are these two financial metrics for 2010 through 2013 for the seven largest U.S.-based pharmaceutical manufacturers. These firms represent seven of the world’s largest 15 pharmaceutical manufacturers in terms of sales revenues (Pharmaceutical Executive, 2013).

As noted in Table 1, the seven pharmaceutical manufacturers report increased expenses from the annual fee, as well as and reductions to revenue. At the pharmaceutical industry level, a Deloitte Consulting LLP report estimates $52 billion in lost revenue over a 10-year period (Deloitte Consulting LLP, 2011). Policymakers of the ACA expect that increased Medicare drug coverage will generate additional sales for the pharmaceutical industry. However, mandates for additional the annual fee, rebates, and higher discounts that pharmaceutical companies are assessed are likely to offset some of this increase. Reduction to revenue should impel pharmaceutical manufacturers to rethink their business model and embrace a new cost structure in order to remain profitable. Accordingly, the solution to the preceding financial conundrum seems to be obvious; cost shifting (i.e., who bears the burden of the mandates?).

Morrisey (1994) defines two kinds of cost shifting in the hospital market. Static cost shifting entails charging different prices to different groups (i.e., price discrimination). Dynamic cost shifting occurs when providers raise prices to one group of payers because another group of payers is now paying less. There is a plethora of literature on cost shifting in the hospital market. Hay (1983, p. 346) uses the profit maximization model to show that government “reimbursement policy does lead to higher private-sector hospital charges.” Using a similar economic model, Morrisey (1994, p. 12), however, argues that dynamic cost shifting is difficult to execute unless a hospital has “unexploited” market power. “That is, the hospital must have the ability to charge one category of payers a higher price, even though, so far, it has chosen not to do so.” Morrisey (1994) and Frakt (2011) conduct comprehensive reviews of cost shifting in hospitals. Both reviews have mixed results vis-à-vis

|                      | Reductions to Revenue Due to Rebate (in millions) | Expenses for the Annual Fee (in millions) |
|----------------------|---------------------------------------------------|------------------------------------------|
|                      | 2010     | 2011     | 2012     | 2013     | 2011     | 2012     | 2013     |
| **Abbott**           | more than $200 | $400   | $269   | $125   | n/a     | n/a     | n/a     |
| **Amgen**            | $137    | $203    | $150    | $180   | $151    | n/a     | n/a     |
| **Bristol-Myers Squibb** | $283    | $310    | $104    | n/a    | $80     | $90     | $63     |
| **Johnson & Johnson** | about $400 | $425    | $450    | n/a    | $140    | $115    | n/a     |
| **Eli Lilly**        | $229    | $408.80 | n/a     | n/a    | $178    | $170.70 | n/a     |
| **Merck**            | $170    | $150    | $210    | $280   | $162    | $190    | $151    |
| **Pfizer**           | $289    | $648    | $593    | $458   | $248    | $336    | $280    |

(Source: Company Annual Reports and Form 10-Ks via Mergentonline.com)
III. Empirical Methodology

Higher branded prescription drug prices are not solely doctrinaire. Indeed, the accelerated increase of branded prescription drug prices has been reflected in the market—as portrayed in Figure 1.

The dark blue line in Figure 1 is the Brand Prescription Price Index (BPPI) from 2008 to the first quarter of 2014. The slope of the line reflects the increase of prices. As portrayed in Figure 1, the slope of the dark blue line increases at a higher rate after 2010. This means that branded prescription drug prices increased significantly after 2010. A visual assessment, though, can be fraught with subjectivity. Therefore, the authors conduct regression analysis to examine whether the slope of the lines change significantly after the ACA became effective.

The quarterly BPPI from 2008 to the first quarter of 2014 is available at the Express Scripts website. To eliminate the impact of inflation, the authors use the BPPI minus the Consumer Price Index (CPI) to arrive at the adjusted BPPI (i.e., adj. BPPI = BPPI - CPI). Because the ACA became law on March 23, 2010, the authors categorized the adjusted BPPI into two groups: adjusted BPPI prior to March 31, 2010 and adjusted BPPI subsequent to April 1, 2010. The data used in this study are described in Table 2.

The regression model is as follows:

\[
\text{Adjusted BPPI} = \beta_0 + \beta_1 \text{Time} + \epsilon
\]

\(\beta_1\) is the coefficient estimate of Time, which is the slope of the adjusted BPPI line in Figure 1 and the increased rate of the BPPI during the period of time. Two groups of data...
generate two $\beta$s. The outcomes of the regression models are shown in Table 3.

As depicted in Table 3, prior to March 31, 2010, the average adjusted BPPI increases at a rate of 2.456 per quarter. Subsequent to April 1, 2010, the average adjusted BPPI increases at a rate of 4.607 per quarter. Another regression tests the difference between the two increases (i.e., $\beta_{\text{after}}$ and $\beta_{\text{before}}$). We create a dummy variable, after, which is coded 1 for the group after April 1, 2010, and 0 for the group before March 31, 2010; and a variable \textit{afterTime}, which is the product of \textit{after} and \textit{Time}. We then use \textit{after}, \textit{Time}, and \textit{afterTime} as predictors in the regression equation. The regression model (the output of which is shown in Table 4) is as follows:

$$\text{Adjusted BPPI} = \beta_0 + \beta_{\text{after}} + \beta_{\text{Time}} + \beta_{\text{afterTime}} + \epsilon$$

The coefficient estimate of \textit{afterTime} is the BPPI difference between the two time periods: after April 1, 2010 and before March 31, 2010. The difference between the two rates is statistically significant with a $T$-statistic of 5.735 and $p < 0.001$. Therefore, we conclude that after the ACA became law in March 2010, brand prescription drug price increased at a significantly higher rate than prior to the ACA.

### IV. Limitations and Discussion

There are some noteworthy limitations in this research. First, the dataset is small. Only twenty five time-series data are available. We contacted Express Scripts for more data, but did not receive a reply. We also contacted other data sources, but they did not accommodate our request. The Agency for Healthcare Research and Quality’s Medical Expenditure Panel Survey (MEPS) contains a pharmacy component. However, the most recent MEPS pharmacy component survey was conducted in 2009—prior to the ACA; therefore, those data would not have been applicable in this research. We also sought use of the IMS Health dataset but could only find three IMS annual reports, 2010, 2011, and 2012. That dataset was thus more limited than the Express Scripts’ dataset.

Second, employment of the Express Scripts’ BPPI may
have been problematic. Change in a drug price index can have several determinants, including price of new drugs, price changes with existing drugs, and/or increased utilization of existing drugs (if it is market-value weighted). Express Scripts’ BPPI itself is not transparent. We could not ascertain how Express Scripts develops the BPPI (i.e., which drugs are included each year, what the drug prices are, and whether it is a price-weighted index [like the Dow Jones Industrial Average or a market-value weighted index like the Hang Seng Index]). Owing to these concerns with the Express Scripts’ dataset, future researchers should consider reexamining the research question using alternative drug price datasets or undertake efforts to access further information from Express Scripts.

Third, similar to Hadley and Feder’s (1985) study of hospital cost shifting, our analysis may be tenuous because it does not control for other factors, save for inflation. Clearly, multiple factors contribute to the branded prescription drug price increase, such as administrative activities, manufacturing, licensing royalties and fees, and marketing costs (Berndt, 2002); research and development (Rizzo & Zeckhauser, 2009); and moral hazard (Chen, Gertler, & Yang, 2013). To conduct a more definitive test, multivariate regression analysis in which the change of branded prescription drug prices depend on Time and other control variables would be desirable. The challenge in doing so, however, is the difficulty of accessing confidential information from manufacturers.

Although the research possesses some unavoidable limitations, at the very least, we clearly observe that there is a significant positive correlation between the provisions of the ACA and the increase of branded prescription drug prices. According to our conceptual and empirical analyses, we question whether the provisions of the ACA can truly meet their goal of reducing patients’ expenses. Our findings reveal that branded prescription drug prices increased more quickly after the ACA became effective. Moreover, some provisions (e.g., the excise tax on medical devices) came into effect in January 2013. Based on our study’s analysis, the impact of the excise tax on medical devices could be similar to the annual fee imposed on pharmaceutical manufacturers and might, therefore, enhance patients’ financial burden in the health care market.

V. Conclusion

The ACA represents a significant transformation of the American health care system since the advent of Medicare and Medicaid. The provisions of the ACA were planned to benefit patients by providing additional rebates. At the same time, owing to the increased number of patients purchasing discounted prescription drugs, manufacturers may expect the demand for their products to increase (Sanzo, 2010). As a result, both pharmaceutical manufacturers and patients ideally should be better off. However, the ACA reduced pharmaceutical manufacturers’ net revenues through the annual fee, taxes, rebates, and higher discounts. The pharmaceutical manufacturers shift the cost burden to patients, especially branded prescription drug users. Both our conceptual and empirical analyses support that the provisions lead many patients to pay higher prices for the branded prescription drugs.

Furthermore, different patients are affected differently by these price increases. For example, a type-II diabetes patient is likely to be on a generic drug (e.g., metformin) and relatively unaffected by the price hikes. Alternatively, a patient with a severe autoimmune disease (such as rheumatoid arthritis), however, may be taking Humira. If so, the patient may well experience increased financial burden if there is a small change in price per vial, it can lead to dramatic out-of-pocket payments for such medications. Moreover, an elderly patient who is likely to be on five or more medications has a high probability of taking a mix of brand name and generic drugs. Hence, not only do the provisions of the ACA fail to work as intended, they may actually create extremely negative consequences for a set of patients for whom the ACA was intended to be the most helpful. If subsequent investigations bear out our findings, then perhaps policymakers might consider the implications of reducing or repealing the tax, rebate, discounts, and fee of the ACA. A more drastic option—which may raise the hackles of many stakeholders and thus should be pursued with extreme caution—is offered by Roy (2014). He promulgates reforming the entire health care system itself.

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