

MEDICARE PART D'S EFFECT ON EVERGREENING, GENERICS, & DRUG PRICES

BY GEOFFREY T. SANZENBACHER AND GAL WETTSTEIN*

Introduction

The launch of Medicare Part D in 2006 expanded prescription drug coverage to all seniors. Its obvious effect has been to improve the well-being of those who gained coverage by reducing their exposure to drug costs. But the law has also boosted demand for drugs and given insurers who provide Part D coverage more leverage over drug manufacturers. Both of these changes could give manufacturers of brand-name drugs an extra incentive to protect their monopoly status, with unforeseen impacts on the generic drug market and, ultimately, on prices. This *brief*, based on a new study, explores these impacts by first looking at whether Part D made manufacturers more likely to make small changes to their drugs to maintain monopoly power – a practice known as “evergreening.”¹ The analysis then assesses any impacts of Part D on generic entry and, ultimately, drug prices.

The *brief* proceeds as follows. The first section provides background on Part D and evergreening, and discusses how they could affect generic entry and drug prices. The second section describes the data. The third section looks at trends in the drug market before and after Medicare Part D was enacted. The fourth section presents the main results on the effect of Part D on evergreening, generic entry, and prices. The final section concludes that, while Part D

increased evergreening and decreased generic entry, drug prices overall were lower than they would have been without Part D, likely as a result of the increased insurer bargaining power. Still, since the results also show that evergreened drugs saw price increases relative to other drugs, policymakers may want to consider the costs and benefits of regulating this behavior.

Background

To date, evidence on the effect of Part D on drug prices has been mostly good news.² However, these studies used data from the first few years after Part D passed, which may have been too early to capture the response of drug manufacturers to these changes – responses that could potentially affect prices.

For branded drug manufacturers – which develop new drugs – one such response would be to try to hold onto the monopoly power given to their products for longer.³ This monopoly power is designed to reward manufacturers for innovating by protecting their products from generic versions for a substantial period of time.⁴ One strategy to extend this power is to seek additional approvals from the Food and Drug Administration (FDA) that cover a narrower

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concept than the original product.⁵ For example, the anti-depressant Paxil received approval for an extended-release version of the original.⁶ Even though a generic manufacturer could produce a version of the original Paxil, it could not produce an extended release version right away. This “evergreening” of a product – so-called because it keeps monopoly power going – would allow Paxil’s manufacturer to continue to be the only seller of at least one version of the product, market it as superior to the original version, and therefore maintain higher prices.

Branded companies are not the only ones that could change their behavior. Research suggests that generic manufacturers were especially hurt by the power gained by insurers after Part D’s passage. Each generic manufacturer is often competing with many other manufactur-

ers, meaning insurers can play one off of the other.⁷ This fact, combined with any increase

in evergreening, could discourage generic manufacturers from entering the market. Like an increase in evergreening, any decrease in generic entry would likely increase prices by reducing the amount of competition that producers face.

Data

To explore potential changes in drug company behavior and their impact on prices, the analysis uses data from the FDA and the *Medical Expenditure Panel Survey* (MEPS).

To identify whether branded drug companies evergreened a product in a given year, and whether a generic product gained approval, the analysis relies on the Drugs@FDA online database. This resource includes data on over 16,000 approvals for original products, changes to those products, and generic entrants going back to 1984. Since the goal of the analysis is to identify changes caused by Part D, only drugs approved prior to 2003 – the year the legislation was passed – are included in the sample.

The analysis defines an approval as evergreening if it is listed as being for a “New Dosage Form;” “New Dosage Form and New Combination;” or “New Combination.”⁸ The label of these approvals as evergreening is not meant to imply that the new approval has no clinical value, a topic which is often debated, but simply that a brand new drug was not created by the approval.⁹ Generic entry is simply defined as having a generic manufacturer gain approval for a drug in a given year.

When analyzing branded and generic companies’ decisions, an important consideration is the expiration of any existing protections for the branded drug.¹⁰ Branded companies are more likely to evergreen a product as its protections expire, and generic companies are more likely to enter at that time. The protections take two forms. The first is a patent, which protects specific aspects of a drug (e.g., the main ingredient, the coating of the drug, etc.), typically for 20 years after the patent is granted.¹¹ The second is an FDA-granted exclusivity, which forbids any generic product from launching, typically for three to five years.¹² For any approved drug, this study has data on the expiration date for any patents or exclusivities.

The drug products most affected by Medicare Part D are those that are used frequently by people ages 65

and over. To identify these products, the analysis turns to the MEPS, an annual survey conducted by

the U.S. Agency for Healthcare Research and Quality. The MEPS contains information on drugs prescribed, the reimbursements for these drugs from various payers, and the drugs’ therapeutic class. These data can be merged onto the basic demographic portion of the MEPS to determine whether or not a given prescription was for someone over age 65 – and thus likely affected by Medicare Part D. Once the FDA and MEPS data are merged, the final sample contains 299 unique drugs with information on their approvals and protections and on the share of people over age 65 who use them.

Drug Market Trends Before and After Medicare Part D

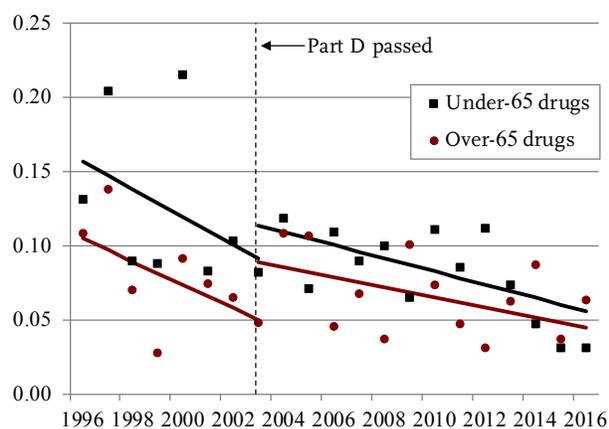
An initial way to assess the potential impact of Part D on evergreening, generic entry, and drug prices is to simply compare trends over time for two groups of drugs: those that are and are not frequently used by older people. For the purposes of this analysis, drugs that are more often prescribed to individuals ages 65 and over (i.e., drugs above the median share of prescriptions to older people) are called “over-65 drugs” and those under the median share are “under-65 drugs.” Under-65 drugs were less affected by Part D, so any change in evergreening, generic entry, or pricing for these drugs would likely reflect general trends in pharmaceutical markets. Conversely, over-65 drugs would see more impact of the policy change. Thus,

Evergreening can deter competitors from
introducing generic alternatives.

any difference between over-65 drugs and under-65 drugs in the period after 2003 would likely be caused by Part D.

Figure 1a shows that, for both groups of drugs, evergreening was on a downward trend prior to Part D but then experienced a bump when Part D was passed; this increase was over twice as large for the “over-65 drugs.”¹³ This result is suggestive of changed behavior by branded drug firms whose products had a high exposure to Part D.

FIGURE 1A. SHARE OF DRUGS WITH EVERGREENING APPROVALS, BY LEVEL OF EXPOSURE TO PART D, 1996-2016

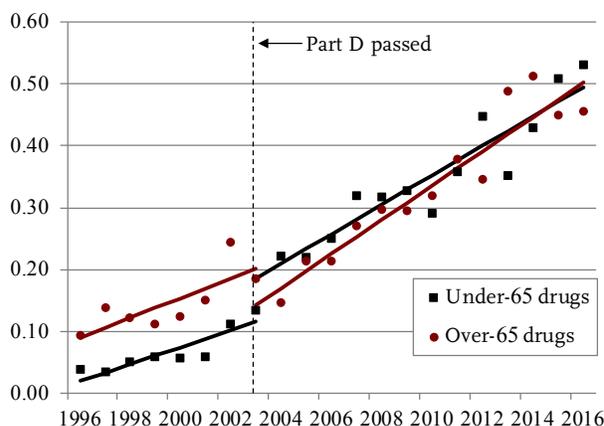


Sources: Authors’ calculations using data from the *Medical Expenditure Panel Survey* (MEPS) (1996-2016); and the Food and Drug Administration (FDA) (1996-2016).

Figure 1b shows the same kind of picture for generic entry. This time, the number of generic approvals was trending upwards, but over-65 drugs saw a bump down, whereas under-65 drugs saw a bump up. Indeed, over-65 drugs used to have higher rates of generic entry, while now they are similar. This pattern suggests that Part D did discourage generic entry, likely due to a combination of increased evergreening and insurer power.

Given more evergreening and less generic entry, one might expect Part D to have increased drug prices. And, in fact, both of these trends *were* associated with upward pressure on prices. However, Figure 1c suggests that Part D actually decreased prices over-

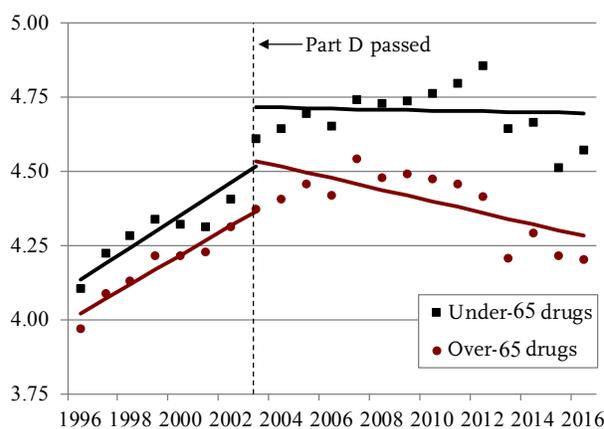
FIGURE 1B. SHARE OF DRUGS WITH GENERIC APPROVALS, BY LEVEL OF EXPOSURE TO PART D, 1996-2016



Sources: Authors’ calculations using MEPS and FDA data for 1996-2016.

all for the drugs in the sample. Although drugs for both younger and older people saw an uptick around the time Part D passed, the increase was smaller for over-65 drugs and, after Part D, these drugs began to get cheaper, whereas under-65 drugs maintained their prices.¹⁴

FIGURE 1C. LOG OF TOTAL SPENDING PER PRESCRIPTION, BY LEVEL OF EXPOSURE TO PART D, 1996-2016



Sources: Authors’ calculations using MEPS and FDA data for 1996-2016.

While the results of this simple exercise provide an indication of the impacts of Part D on the drug market, such an analysis may miss some factors that could confound the findings. For example, if many drugs used disproportionately by older individuals happened to have patents expiring in 2004, then it might look like Part D caused an increase in evergreening or generic entry that had nothing to do with the law.¹⁵ Therefore, the analysis runs three separate regressions – one for each outcome of interest – using the same basic equation:¹⁶

Outcomes (evergreening approvals,
generic approvals, drug prices) =

f (% of users over 65, % of users over 65 x Post 2003,
expirations, year, therapeutic class,
sales, manufacturer ID)

In this equation, the most important variable is the percentage of people over age 65 using the drug multiplied by whether Part D had been passed (“Post 2003”). The idea is that drugs with the largest values for this interaction variable will see larger changes in evergreening, generic entry, and drug prices. In the drug price regression, the controls include measures for evergreening and generic entry, which will enable the analysis to link any changes in these outcomes to price.

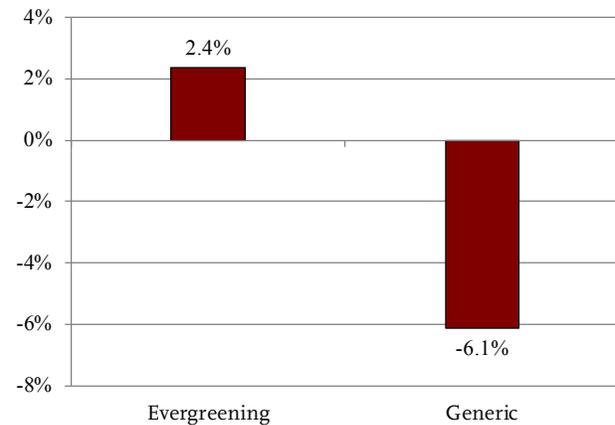
Regression Results

The regression results confirm the findings of the preliminary analysis presented above. Figure 2 shows that branded companies were more likely to evergreen following Part D – by 2.4 percentage points relative to a baseline rate of 10 percent. And generic companies were 6.1 percentage points less likely to launch for an average drug relative to a baseline rate of 14 percent.¹⁷

Figure 3 indicates that, overall, Part D decreased drug prices by 19 percent relative to a scenario in which the program had never existed. The figure also shows the results from the regression on evergreening and generic entry, indicating that drugs with an evergreening exclusivity are 9.5 percent more expensive than drugs without one, and drugs with one fewer generic version are 9 percent more expensive.

However, because Part D encouraged only a fraction – albeit a statistically significant one – of drug manufacturers to evergreen or not enter with a

FIGURE 2. EFFECT OF PART D ON EVERGREENING AND GENERIC ENTRY FOR A DRUG WITH AVERAGE EXPOSURE

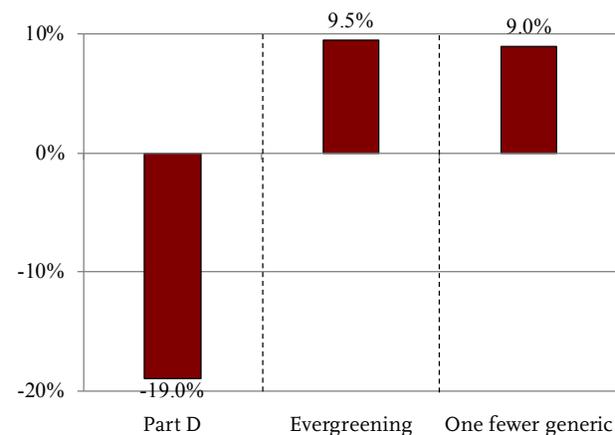


Note: Both estimates are statistically significant at least at the 5-percent level.

Sources: Authors' calculations using MEPS and FDA data for 1996-2016.

generic, the price increases induced by these behavioral responses to Part D are small. These results simply involve multiplying the coefficients in Figure 2 (which show the effect of Part D on the volume of evergreening and generic entry) by the coefficients in Figure 3 (which show the correlation of evergreen-

FIGURE 3. RELATIONSHIP OF PART D, EVERGREENING, AND GENERIC ENTRY TO DRUG PRICES

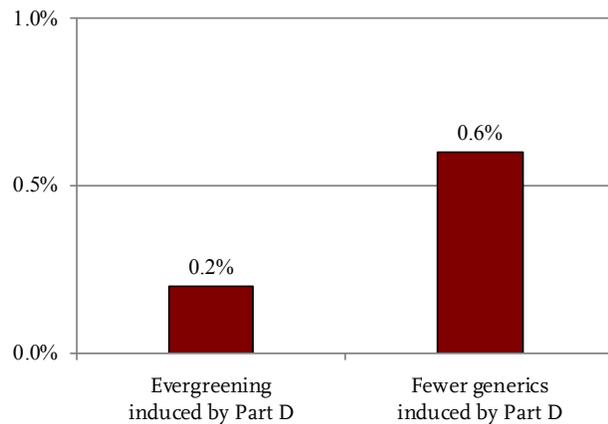


Note: These data show the effect on the prescription price.

Sources: Authors' calculations using MEPS and FDA data for 1996-2016.

ing and generic entry with prices). So, the estimated relationship between evergreening and prices that was induced by Part D is 0.2 percent ($2.4 * 9.5$); and the comparable relationship for generic entry is 0.6 percent ($6.1 * 9.0$)(see Figure 4).

FIGURE 4. RELATIONSHIP OF EVERGREENING AND GENERIC ENTRY TO DRUG PRICES THAT WAS INDUCED BY PART D



Sources: Authors' calculations using MEPS and FDA data for 1996-2016.

Conclusion

While Part D seems to have encouraged branded companies to evergreen their products and discouraged generic companies from launching them, its overall effect was still to lower prices for drugs used by those 65 and over. It is worth emphasizing that this finding does not mean drug prices are *falling* due to Part D, but rather that prices are lower than they would have been without it. While the fact that Part D likely has helped to keep prices down is good news, the regression results do suggest that evergreening, itself, is associated with higher prices. Policymakers may want to consider the value of approvals for these kinds of changes to drugs, weighing any clinical advantage against increased cost. In any case, while drug prices are on the rise, it seems likely that Part D has partially ameliorated the problem.

Endnotes

- 1 Sanzenbacher and Wettstein (2019).
- 2 See Duggan and Morton (2010, 2011) for studies on prices and Lakdawalla and Yin (2015) for information on insurance market power and pricing. Part D has also increased drug insurance coverage and utilization (Engelhardt and Gruber 2011), as well as overall well-being (Wettstein 2019 forthcoming).
- 3 This power is due to patents and to the granting of “exclusivities” from the Food and Drug Administration.
- 4 The cost of innovating can be steep. For example, DiMasi, Grabowski, and Hansen (2016) report development costs ranging from \$800 million to \$2.6 billion; and Van Norman (2016) reports a long lag between pre-clinical testing and approval. See Kesselheim, Sinha, and Avorn (2017) for information on how long the monopoly period generally lasts.
- 5 For an excellent discussion, see Gaudry (2011).
- 6 See Huskamp et al. (2008). Fowler (2017) provides a discussion of different types of “line extensions” that a branded drug manufacturer may pursue.
- 7 See Hemphill and Sampat (2012) and Lakdawalla and Yin (2015).
- 8 This approach is similar to Fowler (2017).
- 9 For a study comparing efficacy in an original version of a product to an evergreened version, see Alkhafaji et al. (2012), which found limited evidence that the evergreened version of citalopram was an improvement. For a paper suggesting that this practice does little to advance patient care and instead represents gaming by pharmaceutical companies, see Feldman (2017).
- 10 These data were acquired through a Freedom of Information Act application.
- 11 Patents are usually granted before a drug gains approval – hence, the pre-generic period is usually less than 20 years.
- 12 So-called “orphan” drugs for rare conditions often receive seven years of exclusivity, and drugs for pediatric populations often receive six years.
- 13 In general, researchers believe evergreening is increasing over time. For example, see Gaudry (2011). However, the drugs included in this sample were approved prior to 2003, and evergreening eventually becomes less likely as drugs age and generics successfully enter.
- 14 It may seem counterintuitive that prices are not going up in this figure given all the focus on rising drug prices today, but these drugs were all approved prior to 2003, and thus many have generic versions serving to drive their prices down. In the full sample of the MEPS, drug prices do indeed rise over time at an average rate of 4.4 percent per year over the 1996-2016 period.
- 15 Other relevant controls include a drug’s total sales – top-sellers are more likely to be evergreened – and the number of generic competitors already in existence, which obviously affects both the price and the value of new generics entering.
- 16 One difference between the equations is that in the evergreening equation, patents or exclusivities expiring the next year are controlled for, since companies may act strategically in advance of the expirations. In the generic regression, whether these protections ran out in the current year are included. In the price regressions, expirations are replaced by the number of existing generic approvals and by current coverage of an evergreening exclusivity.
- 17 Full results are available in Sanzenbacher and Wettstein (2019).

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