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Pay for Delay: Historic and Future Costs of Delayed Generic Entry

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April 8, 2025, updated October 16, 2025

Summary

Brand drug manufacturers and their generic competitors sometimes agree to delay generic entry via various mechanisms, including pay-for-delay litigation settlements. This results in higher prices for purchasers and increased federal government spending.

- Historically, between 2014 and 2023, the impact to federal expenditures of delayed generic market entry arising from pay-for-delay was potentially as high as $16.1 billion, or $1.6 billion annually.
    - These costs were borne most heavily, $9.9 billion, within the Medicare program.
    - Federal costs within Medicaid were smaller, at $3.5 billion over that same period.
    - Additional costs for ACA Marketplace subsidies and the tax implications of the wage impacts of higher ESI premiums were $0.5 and $2.2 billion, respectively.
- Over the coming decade (between 2024 and 2033), additional costs to the federal government could exceed $27 billion.
    - Medicare's share would be $18.5 billion.
    - Federal spending within Medicaid would be $4.9 billion.
    - Future costs for ACA Marketplace subsidies and the tax implications of the wage impacts of higher ESI premiums would be $0.9 and $3.1 billion, respectively.
- Generic delays affect individuals as well; the effect on out-of-pocket expenditures between 2014 and 2023 exceeded $4.4 billion. Over the next 10 years, the impact on out-of-pocket expenditures may be as high as $5.3 billion.
- In addition to higher cost-sharing, delays in generic entry led to higher premiums for those with private coverage; over the past 10 years, total premiums for individuals with ESI, ACA Marketplace or other private coverage may have been as much as $12.2 billion higher. For the coming decade, this amount could be as high as $17.9 billion. The bulk of these additional premiums are for employer-sponsored insurance.
- Note that this analysis focuses only on small molecule drugs; the exclusion of similar arrangements for biosimilar products thus understates the impact of generic delays discussed here.

Background

The federal government has made it a priority to identify and challenge anti-competitive patent litigation settlements – agreements between the manufacturers of brand drug products and their generic competitors. In some cases, these brand-generic settlements include financial compensation in the form of a "reverse payment" from the brand to the generic manufacturer in exchange for the generic manufacturer to delay its entry into the market – commonly known as "pay-for-delay." This practice imposes costs on taxpayers, patients and other purchasers of prescription drugs.[1]

The federal government requires reporting these agreements, and in 2004, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) began requiring that generic drug applicants and the manufacturers of brand drugs file with both the Federal Trade Commission (FTC) and the Department of Justice (DOJ) for certain instances of patent litigation settlements. Among the categories identified in the regulatory guidance that necessitates a filing are "Generic-Brand Agreements" between generic drug applicants submitting an FDA Abbreviated New Drug Application (ANDA) and a brand name manufacturer relating to: the marketing, manufacturing or sale of the brand drug in the ANDA; the marketing, manufacturing or sale of the generic drug referred to in the ANDA; or the 180-day generic exclusivity.[2]

These agreements sometimes include reverse payments in the form of a no authorized generic (No-AG) commitment by the brand. No-AG commitments are agreements where a brand drug manufacturer agrees not to launch an authorized generic drug during the 180-day exclusivity period. Because the authorized generic is the ANDA filer's only potential competitor during the 180-day exclusivity period, a no-AG commitment reduces the number of initial generic competitors from two (the ANDA and the AG) to only one – the ANDA. A no-AG commitment transfers profits from the brand firm to the generic firm – a reverse payment – in exchange for the generic firm delaying the market launch of the generic.[3]

Beginning in 2013 and arising from the Supreme Court's decision in *FTC* v. *Actavis* and subsequent related litigation, pay-for-delay agreements have been subject to generally prevailing antitrust principles. As a result, settlement agreements identifying these types of arrangements submitted to the FTC and DOJ have declined precipitously in the intervening years.[4] The FTC has published a series of reports summarizing the contents of agreements filed for fiscal years 2013 through 2017.[5]

While explicit and easily identifiable pay-for-delay agreements are being reported less frequently, other types of agreements used by brand drug manufacturers and accepted by generic manufacturers may achieve the same effect, essentially *implicit* no-AG agreements. These include no-third-party-AG commitments and royalty payment arrangements, among other potential arrangements that reduce the number of competitors similarly to a reverse payment.[6] Because the terms of agreements can be opaque, determining the scope of the continuing problem with such anti-competitive arrangements has been difficult.

The Costs of Pay-for-Delay

For many years, the cost of pay-for-delay has been commonly estimated at $3.5 billion annually for all payers, based on a two-decades old study by the FTC.[7,8] To develop their estimate, the FTC analyzed settlement agreements between brand and generic companies between 2004 and 2009. Generic entry was prohibited for longer if there were explicit compensation, by an average of 17 months. More recently, the Congressional Budget Office (CBO) prepared a federal savings estimate for Senate Bill 142, the "Preserve Access to

Affordable Generics and Biosimilars Act." This bill would develop a framework for the FTC to address many pay-for-delay tactics by making some agreements presumptively illegal and granting the agency the ability to issue cease-and-desist orders. CBO assumed that these changes would lead to shorter entry times for generic drugs and biosimilar products by an average of 17 months (relying on the FTC's analysis). In total, they estimated 10-year federal budget savings of $1.5 billion, or $150 million annually, significantly lower than the other estimates noted herein.[9] It should be noted, however, that most estimates include all payers, whereas CBO's focus was limited to the impact to the federal budget.

The CBO estimate is lower for a number of reasons, but chief among them are two. First, CBO needed to assume that existing settlement agreements would be grandfathered in under the approach outlined in the draft legislation. Over the 10-year budget window, the grandfathering provision precluded a significant volume of drugs from being included in the cost-savings estimate, as the bulk of delayed entries during that period were already in place. As such, the legislation would likely have a larger impact outside of the scoring window. Second, the 17-month delay estimate is based on older data from an earlier reporting regime, as discussed above. The combination of these factors, among others, cause the CBO estimate to likely substantially understate the total economic costs of pay-for-delay.

In addition to the estimates from the FTC and CBO, other studies have estimated higher costs associated with pay-for-delay – between $6.4 billion and $36 billion annually, for all payers. [10]

With such a wide array of estimates of the costs of delay, it is important to keep in mind the challenges inherent in developing such estimates:

- Some estimates review specific policy proposals, which may or may not be able to quickly address a significant share of pay-for-delay while others look at payments on a more global level. The portion of all pay-for-delay that could be quickly eliminated may be relatively small.
- The lack of transparency and complexity of current pay-for-delay arrangements obscures the frequency and magnitude of such arrangements.
- Known agreements vary widely in terms of aggregate amounts. Because total economic impacts are highly determinant on a small number of agreements, any projection is subject to a high degree of uncertainty.
- Since we don't know when the generic would enter the market in the absence of a pay-for-delay agreement, determining the length of delay purchased by a reverse payment is challenging, and even more so when projecting to future arrangements since the timing of successful challenges is unknown.
- As biologic products continue to comprise an ever-larger share of total drug expenditures in the U.S., delays in biosimilar entry may be a growing problem.

A new analysis by Drake and McGuire approaches estimating harms from a different angle, one that does not require constructing a hypothetical counterfactual settlement outcome. In an August 2025 Journal of Health Economics paper titled "Using Stock Price Movements to Estimate the Harm from Collusive Drug Patent Litigation Settlements," Drake and McGuire reviewed settlement agreements reached between 2014 and 2023 for the presence of potential pay-for-delay. By studying the stock price reaction of the impacted brand drug company, they estimate the added profits gained via such agreements. Using this innovative approach, Drake and McGuire estimated that the economic costs of pay-for-delay may have been, conservatively, as much as $3 to $12 billion annually.[11]

This approach has significant advantages over the methods used to develop the estimates discussed earlier. The analysis is based on more recent data, compiled after significant changes to legal and reporting regimes. It also is not reliant on an explicit estimate of average time to delay, as is the case with the FTC and CBO estimates. It instead relies on estimates of generic entry made by investors in the stock market. In addition, the method reveals the scope of the problem, rather than just the portion that can be addressed by a given legislative bill.

Utilizing the results of this analysis, ARC has prepared both historical (2014-2023) and projected (2024-2033) costs of pay-for-delay agreements. The historical period of 2014 to 2023 is consistent with the study period, and the $3 billion annual estimate, approximated from Drake and McGuire's final analysis of settlement agreements, was used as a basis for projections.

Table 1 outlines the federal budgetary costs of pay-for-delay, by program, both federal and private, for both the historical and projection periods.

TABLE 1: FEDERAL ECONOMIC COSTS OF PAY-FOR-DELAY BY INSURANCE PROGRAM

	10-Yr Historical Estimate (2014-2023)		10-Yr Projected Estimate (2024-2033)	
Insurance Program	**Average Annual**	**Total**	**Average Annual**	**Total**
	($ billions)	**($ billions)**	**($ billions)**	**($ billions)**
Total Federal	$1.6	$16.1	$2.7	$27.4
Medicare	$1.0	$9.9	$1.8	$18.5
Medicaid/CHIP	$0.3	$3.5	$0.5	$4.9
ACA Marketplace	$0.1	$0.5	$0.1	$0.9
Employer-Sponsored Insurance	$0.2	$2.2	$0.3	$3.1

These budgetary costs include direct payments, subsidies and changes in federal tax dollars paid. Over the historical period, costs to the federal budget derived from the study are estimated to be in excess of $16 billion, with two-thirds of such costs borne by Medicare. For the projection period, ARC estimates the costs to the federal government to be in excess of $27 billion in total for the next decade.

The costs of delayed generic entry are not only borne by governmental and third-party payers, as individuals bear some of the costs as well. Table 2 outlines the impacts on individuals' out-of-pocket spending, including increased cost-sharing and self-pay. Over the historical and future periods, ARC estimates that out-of-pocket costs have been about half a billion dollars higher, annually, than they would be if generic entry were not delayed.

TABLE 2: OUT-OF-POCKET COSTS OF PAY-FOR-DELAY

	10-Yr Historical Estimate (2014-2023)		10-Yr Projected Estimate (2024-2033)	
	Average Annual	**Total**	**Average Annual**	**Total**
	($ billions)	**($ billions)**	**($ billions)**	**($ billions)**
All Persons, Including Self-Pay	$0.4	$4.4	$0.5	$5.3

Finally, delayed generic entry impacts premiums in the private sector as well, for individuals with ESI, ACA Marketplace or other individually purchased private health insurance coverage. Table 3 outlines the historical and projected impacts of pay-for-delay on these premium payments. Note that these premium burdens are borne by individuals, employers and taxpayers.

TABLE 3: PRIVATE PREMIUM COSTS OF PAY-FOR-DELAY

	10-Yr Historical Estimate (2014-2023)		10-Yr Projected Estimate (2024-2033)	
Insurance Program	**Average Annual ($ billions)**	**Total ($ billions)**	**Average Annual ($ billions)**	**Total ($ billions)**
Total	$1.2	$12.2	$1.8	$17.9
ACA Marketplace	$0.1	$0.7	$0.1	$1.2
Employer-Sponsored Insurance	$1.1	$11.2	$1.6	$16.3
Other Private Coverage	$0.0	$0.3	$0.0	$0.4

The $12.2 billion historic premium effect represents 0.11% of total private insurance premiums for 2014-2023. This percentage is roughly consistent across insurance programs. For the projection period, this estimate is reduced to 0.09%.

Methods

To prepare the above estimates, ARC developed a historical and future baseline of national covered charges for drug expenditures, consistent with the CMS National Health Expenditure Accounts (NHEA).[12] These covered charges include both program and out-of-pocket expenditures but do not include administrative costs or premiums paid for coverage. The baseline includes separate estimates for Medicare, Medicaid (both state and federal shares), other federal programs, other state programs and private health insurance – including employer-sponsored insurance.

To derive the estimates in this brief, ARC converted program spending to premiums to calculate the expected changes in federal payments to the Medicare and Medicaid programs, as well as federal subsidies for Marketplace coverage and the tax effects of changes in costs for ESI coverage. This was done by using administrative loads by program, consistent with those found in the NHEA.

In addition to the above, ARC made a number of simplifying assumptions to derive the estimates, including the share of drug expenditures for branded drugs, a dampened cost assumption for Medicaid due to favorable payment structures, and the proportion of total drug spending for biologics over time. These assumptions were made based on our actuarial judgement and other publicly available data.

Sensitivity Analysis

ARC used Drake and McGuire's annual estimate of total increase in purchaser spending based on the settlements analyzed ($3 billion per year, rounded from the $3.1-$3.2 billion per year estimate). The authors note that "factoring up the harm based on the percentage of reverse-payment settlements not included in our data, we estimate that the industry-wide harm could be about $12 billion per year." A previous, working version of the paper pinned the upper bound at $7 billion per year. The larger value would result in federal historic

economic costs of $64.6 billion with potential 10-year future federal costs of $109.6 billion. The previous upper bound estimate at $7 billion per year results in federal historic economic costs of $37.7 billion with potential 10-year future federal costs of $63.9 billion. Because the larger estimates proposed by Drake and McGuire are not based purely on observed agreements, we consider it a plausible upper bound on the costs associated with delay. We do not use it for our primary estimates due to the lack of empirical support.

As noted by the authors, the estimates in their paper are conservative, due to their event-study methods and their use of the set of sample agreements only. Other sources of conservatism include the lack of study of biosimilar entry delay, discussed below.

Limitations

As noted by others who have prepared similar estimates, there is significant uncertainty over both the frequency and magnitude of pay-for-delay agreements, including the likely prevalence of such agreements in the future. Our analysis eschews some of these considerations by limiting the historical estimate to agreements already analyzed by Drake and McGuire. We have assumed similar levels of aggregate impacts into the projection period.

The other significant limitation relates to biological drugs. Drake and McGuire reviewed only agreements made related to small-molecule drugs and did not consider delays associated with biosimilar entry for biologics. As biologic spending continues to grow as a share of total drug spending, this approach likely underestimates the potential costs of pay-for-delay arrangements.

No specific legislation was analyzed in this analysis. Any potential reform would likely not stop all pay-for-delay. Therefore, the results in this paper represent an upper bound of economic savings that could be achieved with legislative reforms aimed at eliminating anti-competitive agreements for small molecule products. This upper bound would be higher if biosimilars were included.

Disclosures

This work was supported by the Blue Cross Blue Shield Association. Actuarial Research Corporation (ARC) maintains full editorial control over the written policy analysis and savings estimates.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all communications with respect to actuarial services. Ryan Brake, ASA, MAAA, Rodelle Williams, ASA, MAAA, and Cathi Callahan, ASA, MAAA, are actuaries employed by ARC, members in good standing of the American Academy of Actuaries and meet the Qualification Standards for performing the analyses in this brief.

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Notes

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