ness of options such as signed languages would have allowed his family to make a better-informed decision about his care. Other applications of biotechnology, such as some life-prolonging interventions for aging populations in the United States, may have similarly disabling effects.[5]

*2. Recognize and support multiple normals.* Clinicians can learn to value living with a disability as another equally legitimate way of being in the world. Perspectives from disability-rights movements and disability studies can be incorporated into medical education. Clinicians can respect patients' ability to make informed choices, and they can make their practices welcoming to disabled people by working with signed-language interpreters and ensuring that their exam rooms and equipment are accessible, for example.

*3. Value the expertise of allied health professionals and advocates for people with disabilities.* Physicians can collaborate with audiologists, speech and language therapists, physical therapists, occupational therapists, other rehabilitation workers, and disability advocates. Allied health professionals are often aware of patients' contexts outside the clinic, and disability advocates are untapped sources of expertise on successful inclusion of people with disability in the realms of education, employment, and everyday life. For example, both S.'s family and his surgeon would have benefited from meeting a deaf adult who used signed language and could serve as a role model.

## Case Follow-up

S. is now 12 years old and does not have a working cochlear implant or access to spoken or signed language, although he enjoys gesturing with his family (which does not always result in effective communication). His family is reluctant to consider other options such as Indian Sign Language because they have invested so much in S.'s implant in pursuit of normality and see signed languages as an indication of failure.

*An audio interview with Dr. Friedner is available at NEJM.org*

Disclosure forms provided by the authors are available at NEJM.org.

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# Who Pays in Medicare Part D? Giving Plans More Skin in the Game

Erin E. Trish, Ph.D., Paul B. Ginsburg, Ph.D., Geoffrey F. Joyce, Ph.D., and Dana P. Goldman, Ph.D.

Americans have ranked "taking action to lower prescription drug prices" as their top priority for Congress this year.[1] Policymakers seem to be listening. Proposals have emanated from Senate and House committees, the Trump administration, and several Democratic presidential candidates. Though the specifics vary, many of these proposals share a theme: have the federal government take a more active role in determining drug prices, at least for drugs that are costly and have little competition. There is a sense that the private market is not functioning as it should to constrain prices through competition. It seems worthwhile to assess the role that private plans play in the market today and whether incentives might be better aligned to achieve lower drug prices and other social objectives.

The Medicare Part D program, created by the Medicare Modernization Act of 2003, is ground zero for consideration of new

policies to address prescription-drug prices. Part D was a nationwide experiment in using private health plans to expand coverage with substantial public subsidies — a precursor to the similar experiment with the Affordable Care Act (ACA). Today, Part D covers 45 million beneficiaries and costs the federal government $85 billion per year.[2] In contrast to other parts of the Medicare program, Part D is run and administered entirely by private plans, with regulatory oversight by the federal government. In order to gain legislative approval, the law explicitly prohibited the federal government from directly negotiating or setting drug prices in Part D, and instead relied entirely on competition among private plans in designing formularies and negotiating with manufacturers to enhance choice and lower prices. However, Part D's design also provided only limited incentives to these private firms to manage costs, particularly for high-cost beneficiaries.

Mostly, this limitation reflected lawmakers' concerns about whether the Part D market would even get off the ground. Prior to the 2003 legislation, no market existed for stand-alone prescription-drug plans, and two policy questions were paramount: Would private plans choose to participate in this new market? And would Medicare beneficiaries — especially healthier ones — choose to enroll in a voluntary program? A public–private partnership depends on voluntary participation by plans, and policymakers who engaged in the Part D debate took this concern very seriously.

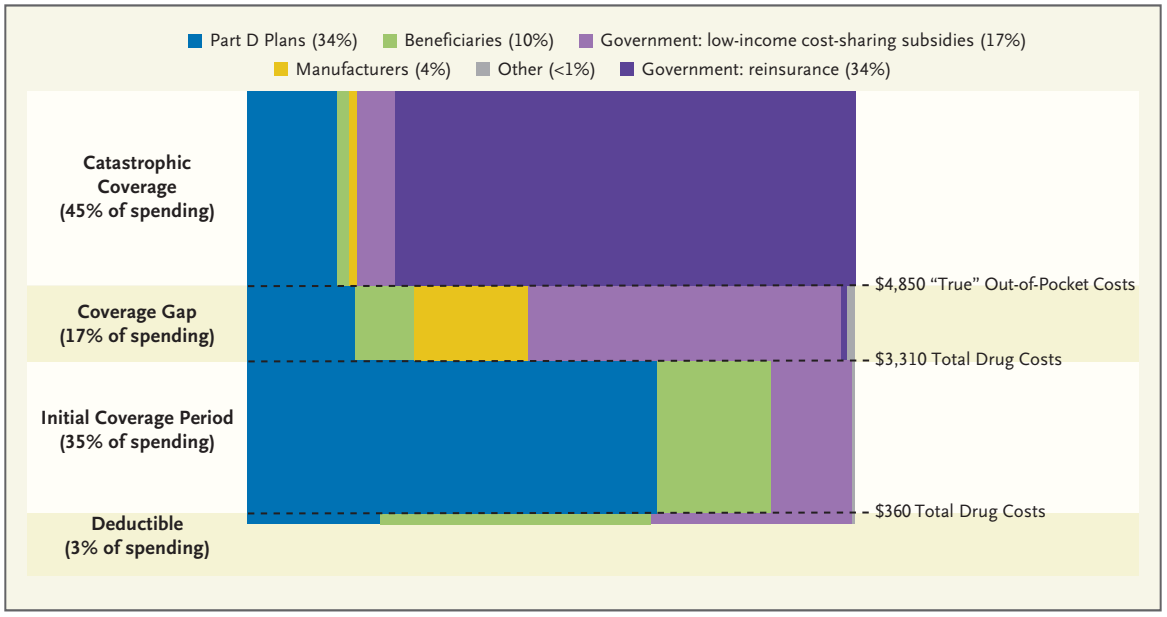
One result was that the enacting law for Part D included several features limiting the financial risk to plans, particularly risks associated with high-cost beneficiaries. Key among these features is the federal reinsurance program: once a beneficiary reaches a "catastrophic limit" — corresponding today to about $8,000 in total drug spending — the federal government steps in to subsidize 80% of the remaining beneficiary spending for the year. The plan's liability falls to just 15%, with patients responsible for the remaining 5%. The net effect is that the government, not the plan, bears most of the burden for those with the highest spending in the program.

In the early years of Part D, government reinsurance seemed reasonable. Less than 20% of total drug spending was for beneficiaries who had exceeded the catastrophic limit, and total federal reinsurance subsidies amounted to less than $10 billion per year. But the Part D standard benefit design has not kept up with the marketplace, particularly the emergence and growth of specialty drugs. Today, nearly half of total Part D spending is for beneficiaries who have exceeded the catastrophic limit, and reinsurance subsidies amount to around $43 billion, representing the largest component of federal spending on the program.[2] As reinsurance spending grows disproportionately, plans bear less and less risk as a share of total spending. This situation calls into question what is being gained through the use of private plans.

In addition to the limited risk in catastrophic coverage, plans also bear very little liability for spending in the so-called coverage gap or "doughnut hole" phase. The ACA and the Bipartisan Budget Act of 2018 addressed the high and problematic cost sharing for beneficiaries by "filling in" this doughnut hole, so beneficiaries no longer face full cost sharing as they did in the early years of Part D. But these changes have relied primarily on contributions from drug manufacturers, rather than on adding to Part D plans' liability.

Other Part D program features also limit plans' ability to effectively manage spending. For example, plans use formularies with varied levels of beneficiary cost sharing as a tool to negotiate drug prices and encourage beneficiaries to use lower-cost options. But Part D plans' ability to do so is limited by federal requirements that they cover all or nearly all drugs in six protected drug classes — which account for about 20% of all Part D spending — although plans can still use utilization-management tools for these drugs.[3] Moreover, these financial incentives are ineffective for low-income beneficiaries (who account for about one third of enrollment and half of total drug spending), since the cost sharing that these patients would face is instead paid almost entirely by the federal government. Although these policies reflect important priorities related to access and affordability, they also undermine plans' ability to effectively negotiate and manage spending.

The net result is that, today, Part D plans are actually responsible for only about 34% of total prescription-drug spending (see graph). In contrast, according to data from the Health Care Cost Institute, health insurers in the commercial market paid an average of 85% of total drug costs in 2016.[4]




**Distribution of Medicare Part D Spending by Benefit Phase and Payer.**

The graph shows the analysis of a 100% sample of 2016 Medicare Part D claims data, accessed through the Centers for Medicare and Medicaid Services Virtual Research Data Center. All spending for claims that "straddle" multiple phases is assigned to the final benefit phase of the claim. For beneficiaries who do not receive low-income subsidies (non-LIS), the distribution of payer liability in the coverage gap is adjusted to reflect 2019 limits (i.e., for branded drugs, liability is adjusted to 70% paid by manufacturers, 25% paid by beneficiaries, and 5% paid by plans; for generic drugs, liability is adjusted to 37% paid by beneficiaries and 63% paid by plans). The figure includes spending for both LIS and non-LIS beneficiaries. "True" out-of-pocket costs include manufacturer-paid discounts.

Thus, despite an intention to rely on private plans to administer the Part D program and design formularies to constrain drug prices, the market has evolved in such a way that the federal government — and not the plans — is directly liable for the majority of Part D spending.

As policymakers debate the pros and cons of various proposals for reforming the prescription-drug marketplace, we believe that they should recognize the need to update the Part D benefit design. Plans now have more than a decade of experience operating in this market, and there is no good economic reason for government to shoulder such a large portion of the risk that plans face. Policymakers can consider reforms that would give plans more insurance risk, such as increasing plan liability in the reinsurance and coverage-gap phases. But it makes sense for these reforms to be coupled with important beneficiary protections — such as a cap on out-of-pocket spending — and changes that allow plans greater flexibility to use formulary and transparency tools, including some that are already used for patients covered by commercial insurance.[5] The federal government could redirect its subsidies to help keep premiums low, but if we want private plans to deliver on value to beneficiaries and taxpayers, it's time to give them more skin in the game.

Private plans have the potential to lead the way toward innovative contracting approaches that emphasize value and, in doing so, deliver on the original vision for the Part D marketplace. But they can be expected to do so only if the right incentives are in place. It took policymakers 40 years to add an outpatient prescription-drug benefit to the Medicare program. Let's hope we don't have to wait 40 more to modernize Part D.

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# Injecting Safety into Supplements — Modernizing the Dietary Supplement Law

Pieter A. Cohen, M.D., and Scott Bass, J.D.

More than 25 years have passed since one of us helped draft the law that redefined the U.S. regulatory landscape for vitamins, minerals, botanicals, live microorganisms, and many other health products. The law, known as the Dietary Supplement Health and Education Act of 1994 (DSHEA), created a new category of products termed "dietary supplements."[1]

Today, this law does not adequately protect the public. Since it was written, the supplement industry has been reshaped by Internet sales and an increasingly complex global supply of new substances. What was a $4 billion market in 1994 with a few thousand products has grown into a more than $40 billion market with tens of thousands of dietary supplements.

We have become particularly concerned about the risks associated with newly discovered, sophisticated, and potentially potent biologic and botanical ingredients that are routinely introduced as new ingredients in supplements. The great majority of these ingredients are never reviewed by the Food and Drug Administration (FDA), even though review is mandated by the New Dietary Ingredients provision in DSHEA.

We believe the time has come to reform this law. For the first time, members of Congress, many manufacturers of dietary supplements, and the scientific community recognize that the law requires changes to enhance public safety.

We recommend reforming DSHEA such that all new ingredients, rather than only a small subset, are reviewed by the FDA and effective systems are implemented to track the safety of all supplements. This approach would provide an enhanced safety net for consumers while limiting the ability of unscrupulous companies to profit from the introduction of dangerous products that have bypassed FDA scrutiny.

The New Dietary Ingredients provision was designed to address the safety of newly introduced ingredients in supplements. For every new ingredient introduced into the market after 1994, manufacturers were expected to provide the FDA with a 75-day advance notice containing safety data establishing that the ingredient "will reasonably be expected to be safe."[1] Instead, a number of loopholes, vague language in the law, and lack of industry compliance have led to the majority of new ingredients being introduced without any safety evaluation by the FDA.

The FDA has also failed to enforce this provision[2] — a failure that has led to even less industry compliance with the law and has contributed to the creation of the current supplement market. An estimated 75,000 new supplement products have been introduced since 1994, while the FDA has received adequate safety data for fewer than 250 new ingredients. The agency has no system for determining how many new ingredients are contained in the tens of thousands of new products on the market.

The safety risks associated with the current system are illustrated by the case of 1,3-dimethylamylamine (DMAA), a pharmaceutical