year. With efforts to identify persons with hepatitis C and connect them with treatment, a major decline in the morbidity and mortality of this disease is possible.

Meanwhile, HCV vaccine research continues, but multiple virologic and immunologic factors have made vaccine development an elusive goal. Nevertheless, the consequences of the discovery of HCV three decades ago have provided the knowledge and tools to achieve global control and elimination of this disease within the next three decades.

An audio interview with Dr. Hoofnagle is available at NEJM.org

The Nobel committee has rightly acknowledged the importance of the discoveries made by these three outstanding and generous scientists.

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

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Broken Promises — How Medicare Part D Has Failed to Deliver Savings to Older Adults

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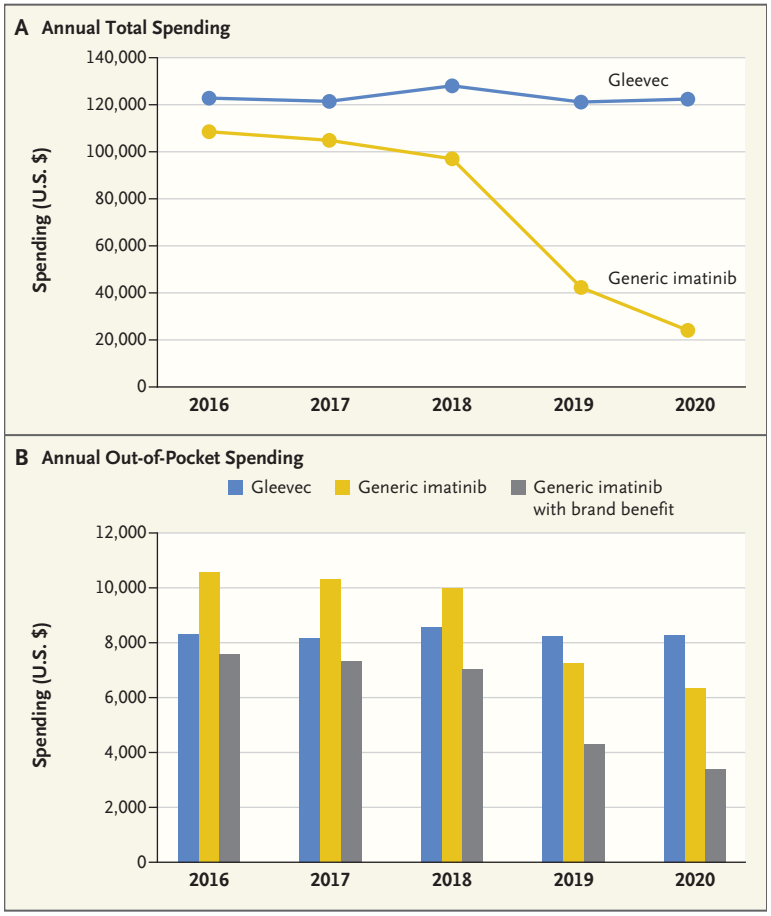
Drug prices in the United States are high, particularly for innovative drugs used to treat rare and life-threatening conditions. In some cases, a reasonable defense of high prices for brand-name drugs is that they are temporary — historically, the prices paid by plans and patients for most small-molecule drugs have decreased substantially soon after patents expired. Rapid price reductions rely on competition among generics manufacturers, with large reductions typically achieved after multiple generic products become available.[1] For the growing number of expensive specialty drugs, including those for rare diseases, it's unclear whether and how quickly this level of price competition can be achieved.[1] Furthermore, even if generic specialty drugs have far lower list prices than their brand-name counterparts, savings that accrue to Medicare beneficiaries are limited by the design of the Medicare Part D benefit.

Nearly two thirds of new medicines approved between 2011 and 2015 and covered by Medicare Part D were specialty drugs.[2] Although most of these products are still under patent protection, market entry of generic versions is anticipated for many specialty drugs during the next decade. The introduction of generic competitors for Gleevec (imatinib) highlights critical policy failures that should be addressed to ensure rapid adoption of generic products and savings for Medicare beneficiaries who use generic specialty drugs.

As one of the first targeted cancer therapies, imatinib has revolutionized the treatment of chronic myeloid leukemia (CML) and other hematologic and solid tumors. By targeting the *BCR-ABL* mutation, imatinib has transformed diseases with universally fatal outcomes into chronic diseases that have a limited effect on people's life expectancies. List prices were high when Gleevec was approved in 2001 ($30,000 per year) and tripled within 10 years. At the time of generic entry in 2016, point-of-sale spending on Gleevec (excluding rebates obtained by health plans and pharmacy benefits managers after the point of sale) for people covered by Medicare Part D exceeded $120,000 per patient per year (see figure). For people with CML, high cost remains an important barrier to medication access and adherence as well as to clinical outcomes, since high levels of adherence (above 90%) are needed to achieve optimal outcomes.

Given the high price of Gleevec and its long-term use by people with CML, generic entry was eagerly anticipated in the United States. Prices for generic imatinib were



Changes in Annual Total and Out-of-Pocket Spending for Imatinib and Gleevec after Generic Entry, 2016 to 2020.

Data are from authors' analysis of Medicare formulary files for the first quarter of 2016 to the first quarter of 2020. Estimates of annual total plan spending are based on median per-fill, point-of-sale prices for all Part D plans in the first quarter of the year indicated for a 30-day supply of 400 mg of the drug. Estimates of out-of-pocket spending are based on the 2020 benefit design ($435 deductible, 25% coinsurance for drug spending between $435 and $4,020 [initial-coverage phase], 25% coinsurance on brand-name or generic products until total out-of-pocket spending reaches $6,350 [coverage gap], and 5% coinsurance thereafter [catastrophic-coverage phase]). A 70% manufacturer discount on brand-name drugs is credited toward patient out-of-pocket spending on brand-name drugs in the gap. We estimate spending on brand-name and generic products under the current benefit design and expected spending on generics if the coverage-gap discount applied to these products.

initially also high, however, and decreased substantially only beginning in 2018 after the fourth manufacturer of a generic product entered the market. Median list prices for generic imatinib eventually fell to approximately $2,000 per fill in mid-2020 for Part D plans (approximately $24,000 per year; see the Supplementary Appendix, available at NEJM.org). This average is 80% lower than Gleevec's list price at the time of approval of the first generic competitor.

Medicare beneficiaries have not benefited from these price reductions in the same way that plans have, however. For the first 3 years after generic products became available, Medicare beneficiaries needing imatinib saw their out-of-pocket spending rise if they transitioned from Gleevec to generic imatinib. In 2016, for example, estimated annual out-of-pocket spending on Gleevec was $8,322, as compared with $10,570 for generic imatinib. This phenomenon is a function of Part D's current benefit design, which requires that manufacturers offer a 70% discount for brand-name (but not generic) products dispensed in the so-called coverage gap. Research has shown that this design feature can result in higher out-of-pocket spending on generic drugs than on their brand-name counterparts, even if the generic drug has a lower list price.[3,4] Specifically, this policy allows discounts offered by manufacturers on brand-name drugs filled in the coverage gap to count as out-of-pocket spending for patients. In 2020, patients who use generic drugs must spend $5,019 out of pocket to exit the Part D coverage gap and qualify for catastrophic coverage, whereas users of brand-name drugs must pay only $1,321 out of pocket. Ultimately, the coverage-gap discount helps patients reach the more generous catastrophic-coverage phase faster and with lower out-of-pocket spending when they use brand-name drugs than when they use generic drugs.

Using the 2020 Part D benefit design and the median point-of-sale price for the brand-name drug and generic products in each year from 2016 to 2020, we found that annual out-of-pocket spending on generic imatinib in 2020 was only 24% lower than estimated spending on Gleevec just

before generic entry ($6,352 vs. $8,322), despite the roughly 80% difference in list price. If generic products were covered in the same way as brand-name products are, annual out-of-pocket spending for imatinib would have been approximately half the amount expected under the current benefit design ($3,394 vs. $6,352 in 2020).

Beneficiaries also often lost the opportunity to choose the brand-name drug when it was the less-expensive option for them, as plans rapidly shifted away from brand-name drug coverage. By late 2017, only 20% of Part D plans covered Gleevec; by mid-2020, only 5% of plans did so. The lack of brand-name drug coverage on Part D formularies creates an important dilemma. Rapid replacement of brand-name drugs with generics on formularies is generally desirable, since it typically increases use of lower-priced generic drugs and could encourage new generic entrants by limiting the brand-name product's market share. This rapid adoption of generics, however, also places a financial burden on Medicare Part D beneficiaries under the current benefit design when out-of-pocket spending for generics is higher than for a brand-name drug, as was the case for imatinib for the first 3 years after the entry of generic products. In addition, manufacturer copayment-support programs for high-priced, brand-name drugs may be less available after the entry of generic alternatives, since these funds are typically provided by manufacturers with the goal of increasing use of brand-name products. Generic specialty drugs like imatinib are less likely to be covered by patient-assistance programs that Medicare beneficiaries might have used to reduce their out-of-pocket costs for the brand-name version,[5] which would further exacerbate financial challenges for patients needing ongoing treatment.

Numerous high-priced specialty drugs, including treatments for cancer, rheumatoid arthritis, multiple sclerosis, and other complex conditions, will face generic competition in coming years. It is illogical that Medicare beneficiaries will potentially face higher out-of-pocket prices for these treatments once generics are available.

Members of both the U.S. Senate and the House of Representatives have introduced Medicare Part D reform bills that address these issues along with making other modifications to the Part D benefit design that would reduce patient and Medicare spending on prescription drugs. Specifically, these proposals would eliminate the coverage gap and the corresponding discount on brand-name drugs and require beneficiaries to pay 25% coinsurance on all fills — for both brand-name and generic drugs — until an out-of-pocket limit is reached (either $2,000 or $3,100, depending on the proposal). Both proposals would create parity under the Part D benefit for brand-name and generic products, thereby simplifying the benefit design for patients. Their key differences are related to the amount required to reach the out-of-pocket spending limit. Either option would represent a substantial improvement over the status quo. Although drug-pricing bills have stalled because of other legislative priorities, it is critical that policymakers take action on sensible reforms to the Part D program that will promote use of less-expensive generic drugs and reduce out-of-pocket spending for patients.

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