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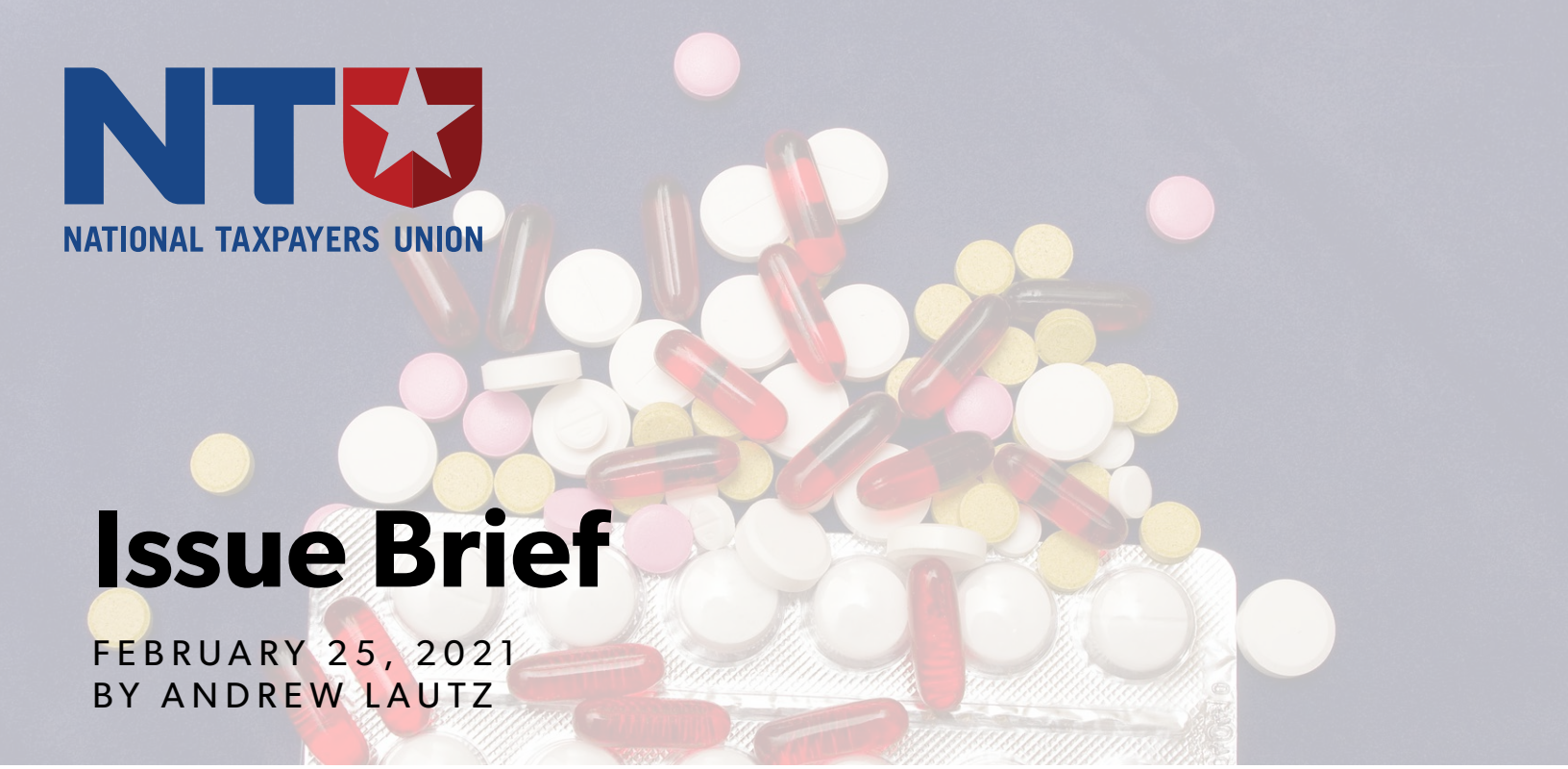

Issue Brief

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A Taxpayer- and Market-Oriented Path Forward for Federal Prescription Drug Policy

Over the past two years, federal policymakers have debated prescription drug policy more often than at perhaps any point since the creation of the Medicare Part D drug benefit in 2003. Several watershed moments have driven the debate thus far, including:

- The introduction of Speaker Nancy Pelosi's prescription drug pricing bill, H.R. 3, which would levy an up to 95-percent excise tax on pharmaceutical manufacturers that refuse to submit to a government-run price negotiation process;
- Former President Donald Trump's aggressive efforts to punish manufacturers with regulations that would allow the importation of prescription drugs from Canada and set the prices Medicare Part B pays for drugs to the prices paid in foreign countries with price controls; and
- The emergence of the novel coronavirus and the efforts of multiple manufacturers (and the federal government) to develop, produce, and distribute vaccines inoculating people against COVID-19, the disease caused by the coronavirus.

All of the above developments remain relevant to this day. Even though H.R. 3 did not receive a vote in the Senate, Speaker Pelosi's party now

Key Facts:

President Biden would be wise to roll back some of the harmful prescription drug policies of his predecessor, such as price controls in Medicare and importation regulations.

Several new policy proposals from lawmakers, such as excise taxes on prescription drugs and inflation caps in Medicare, would further harm patient access and innovation.

A more taxpayer-oriented prescription drug policy would reform Medicare Part D, reward research and development in new drugs, and reduce price controls abroad.

controls the upper chamber of Congress and may bring elements of H.R. 3 (or the entire package) to a vote in both the House and Senate. Though former President Trump is out of office, President Joe Biden actually sees eye-to-eye with the former president on some prescription drug policy matters and may revive them in some form. And while several manufacturers continue to make progress on developing, receiving approval for, and distributing COVID-19 vaccines, future innovations in the biopharmaceutical market may yet be threatened by new proposals from policymakers that would force companies to make tough choices on how to absorb new, government-imposed costs on bringing drugs to market in America.

Below, NTU reviews some of the early actions from President Biden—along with a quick check of his campaign promises on prescription drug policy—and some early prescription drug policy proposals from members of Congress. We then chart out our blueprint for a more taxpayer and market-oriented path forward for prescription drug policy that may, if implemented with care, bend the cost curve for patients *while protecting* incentives for innovation and risk-taking in the biopharmaceutical market.

President Biden's Early Actions Should Steer Clear of Bad Trump Proposals

Several major Trump-era regulations concerning prescription drug policy were either partly or fully in effect when President Biden took office. Here's a brief overview of the current status for several of those initiatives:

A pause in the Trump administration's "Most Favored Nation" proposal for Part B: In November 2020, the Centers for Medicare and Medicaid Services (CMS) under President Trump released a "Most Favored Nation" (MFN) interim final rule that would peg Medicare Part B drug prices to prices paid in a number of foreign countries with government price controls. NTU wrote in December that the regulation would *reduce* private sector price competition that drives down costs for consumers, potentially harm patient access to treatments, and push additional costs for manufacturers onto other payers in the system. We also wrote that a regulation of this scale and scope should not have been issued as an interim final rule in the waning months of the Trump administration, and urged CMS to withdraw the proposal. Fortunately several federal courts have put a halt on the Trump administration's rule, according to the Kaiser Family Foundation (KFF). NTU hopes the Biden administration leaves this proposal in the dust bin; unfortunately the new president has expressed openness to external reference pricing like that proposed in the MFN rule (more on that below).

No current indicators on the Trump administration's importation rule: Earlier in 2020, the Trump administration issued a proposed rule to allow states and certain wholesalers to import prescription drugs from Canada. The administration issued a final rule in October, with the policy going into effect November 30. At the time of the proposed rule, NTU wrote to the Food and Drug Administration (FDA) that the agency failed to define the potential benefits of importation to both patients and taxpayers, and failed to adequately estimate the potential costs of importation. We urged the FDA to withdraw or significantly modify the proposed rule; unfortunately the FDA largely went ahead with their original proposal. According to KFF, the proposal is subject to a lawsuit and the Biden administration has not decided how to proceed. As with MFN, we hope the new president will ditch President Trump's importation proposal (despite Biden's prior support), especially given its lack of clear benefits to taxpayers and the Canadian government's ongoing opposition to the importation proposal.

Use of the Defense Production Act (DPA) for COVID-19 vaccine production: President Biden recently noted on a CNN town hall that he invoked the Defense Production Act (DPA) as part of an agreement with manufacturers Pfizer and Moderna to supply more COVID-19 vaccines to the federal government for distribution. The DPA, which allows presidents to mandate and prioritize manufacturing of certain goods in service of the "national defense," is a 70-year-old law that NTU believes should be used sparingly. NTU and its sister organization NTU Foundation have regularly urged the federal government to exhibit

significant caution when invoking the DPA, because "in areas where [the Trump administration] did use the DPA to intervene in the economy [during COVID], the results were predictably disastrous." We have also seen proposals to use the DPA to protect certain parochial interests and favored industries (unrelated to COVID) and we have seen DPA money wasted at the Pentagon in the past year. Unfortunately, President Biden has already issued two executive orders that could allow for the expansion of DPA rather than its prudent and extremely limited use. We encourage the Biden administration to exercise care and caution with DPA, even in service of combatting the pandemic.

President Biden also made several campaign promises on prescription drug policy that, as of this writing, he has yet to take action on in the White House:

Requiring the government to negotiate the cost of prescription drugs: This is a popular proposal, though recent iterations of allowing the government to "negotiate" prescription drug prices have extended beyond Medicare and to having the government effectively set prices for the *private* sector as well. The nonpartisan Congressional Budget Office (CBO) has long noted that negotiations would not lead to significant price reductions unless the Secretary of Health and Human Services (HHS) has "leverage … to secure larger price concessions from drug manufacturers than competing PDPs [private prescription drug plans in Part D] currently obtain." Unfortunately, recent proposals like H.R. 3 (more below) include "leverage" that would make the negotiation process function more like an extortion of manufacturers, forcing them to accept a government-set price that applies to the public *and* private sectors. This illustrates the catch-22 of requiring the government to negotiate drug prices: government negotiators are ineffective without leverage, and different kinds of leverage (excise taxes, a national formulary for Medicare) threaten patient access to treatments. What's more, as CBO notes, price negotiations are somewhat moot in Medicare Part D because the numerous private plans participating in the program already can and do negotiate drug prices (with leverage like formularies). Negotiations could be more effective if policymakers modernize the Part D benefit (more on that below).

Enacting internal and external reference pricing systems to determine the rates public and private plans pay for drugs: President Biden's campaign prescription drug plan spoke favorably of external reference pricing (setting a drug price based on the price of products in other countries). The new president suggested external reference pricing for "cases where new specialty drugs without competition are being launched," and advocated for that government-set price to apply to public and private payers. Biden also recommended having a U.S. review board establish a price for drugs "entering the U.S. market first, based on an evaluation by the independent board members," which could pave the way for internal reference pricing as well (setting a drug price based on the price of other products in the U.S.). More than 150 economists point out that reference pricing (or, to use another term, price controls) "leads to shortages, squeezes the cost bubble toward some other portion of the economy, and imposes a deadweight cost on society." If manufacturers cannot squeeze the cost bubble to other payers (given reference prices would apply to the private sector as well), one significant concern is that the extremely expensive research and development (R&D) process for new and improved treatments will suffer as a result. And of course, even squeezing the cost bubble for prescription drugs from Medicare to private payers would itself be problematic.

Penalizing manufacturers who raise their prices above inflation: On the campaign trail, President Biden also supported a proposal championed by Democrats and Republicans: penalizing manufacturers with a tax if they raise their drug prices in Medicare above the inflation rate. Manufacturers already pay a penalty in Medicaid for raising their drug prices above inflation, and the Biden/Congressional proposals would apply a similar penalty to the Medicare Parts B and D programs. Many of NTU's critiques of the inflation cap are similar to our critiques of other price controls (particularly, squeezing the cost bubble onto other parts of the economy including private payers). Additionally, the proposed inflation measure (consumer price index, or CPI, for all items) is somewhat of a blunt instrument, given CPI for Medical Care has grown nearly 44 percent faster than general CPI in the past five years.

Generally speaking, all of the above proposals should be avoided given their deleterious impact on consumers and taxpayers. The same goes for several recent Congressional proposals outlined below.

Congressional Proposals Present Many Threats to Patients, Innovation

As mentioned above, H.R. 3 is still the prescription drug bill most frequently championed by House Democrats. The bill would incorporate several of the troublesome policies already mentioned in this paper, including 1) requiring manufacturers to submit to government-run price negotiations, 2) punishing manufacturers with an up-to 95-percent tax on the gross sales of their drugs for failing to reach a price agreement with the government, and 3) establishing inflation cap taxes on prescription drugs in Medicare Parts B and D, among other provisions. NTU strongly criticized the bill in 2019, and pointed out that H.R. 3 could have a negative effect on access to care, jobs, investment, and research and development in America. While H.R. 3 remains the most harmful piece of drug pricing legislation working its way through Congress, several smaller bills would also have a negative impact on patients, consumers, or taxpayers.

Allowing Medicaid to levy penalties on manufacturers exceeding 100 percent of a drug's price (reconciliation legislation): The one drug-pricing measure included in Democrats' reconciliation bill was a long-time policy priority for some: allowing Medicaid to penalize manufacturers with inflation rebates exceeding 100 percent of the manufacturer's average price for the drug. In effect, this means that beyond providing a drug to the Medicaid program for free, some manufacturers may need to *pay* Medicaid for drugs they are providing to patients and medical providers in the program. Besides the general distortionary nature of such a proposal, NTU believes that the provision has no place in a COVID-19 relief bill. Instead, policymakers should debate this proposal through a deliberate and regular legislative process (and not the accelerated reconciliation process).

Prohibiting "price gouging" for any COVID-19 prescription drugs (**H.R. 597**): While legislative text for this bill is not yet available, the outline from sponsor Rep. Jan Schakowsky (D-IL) is concerning. Her bill would prohibit "pharmaceutical monopolies on new, taxpayer-funded COVID-19 drugs," presumably threatening the intellectual property rights that help manufacturers take and underwrite the enormous risks involved in developing new products. It would require the government "to mandate reasonable, affordable pricing of any new, taxpayer-funded COVID-19 drug," though as we pointed out last year with a similar Schakowsky proposal, it is unclear if the lawmakers will bother to define "reasonable" and "affordable" pricing, and whether those definitions will be attached at all to the costs of researching, developing, seeking approval for, manufacturing, distributing, and marketing a new product. The bill also appears to significantly expand the federal government's "march-in rights" to strip intellectual property protections from manufacturers. While any version of this proposal would raise alarm bells for patients and consumers, we note that a lack of specificity from lawmakers—often the case in legislation like this—could invite regulatory interpretations from HHS that further distort the market and adversely impact patient access to drugs.

Allowing Americans to import prescription drugs from Canada (**H.R. 832**; **S. 259**): Bills from Rep. Chellie Pingree (D-ME) and Sen. Amy Klobuchar (D-MN) would help codify the Trump administration's effort to allow prescription drug importation from Canada. All of the above concerns about the Trump rule apply to these bills. Unfortunately, the Senate legislation has the support of 20 percent of the Senate Democratic caucus and two Republican lawmakers.

Restricting certain agreements reached between brand and generic drug manufacturers (**H.R. 153**): This legislation from Rep. Bobby Rush (D-IL)—a long-time priority for the congressman—would "prohibit the practice of 'pay-for-delay,' in which brand name drug companies compensate generics to delay the entry of generic drugs into the market." While at face value this policy may seem well-intentioned, we have warned at NTU that the proposal "would take a sledgehammer to biopharmaceutical innovation around the country in order to treat a 'pay-for-delay' problem that is limited in size and scope." A recent Federal Trade Commission (FTC)

review revealed that nearly 90 percent of agreements between generic and brand-name manufacturer *do not* involve "explicit compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product," but federal and state legislation banning 'pay-for-delay' could ban some of the private-sector agreements that bring benefits to consumers, taxpayers, brand manufacturers, *and* generic manufacturers, especially if the agreements bring other generics to market faster.

A Taxpayer- and Market-Oriented Path Forward for Prescription Drug Policy

Clearly, a better path forward is required—one that protects taxpayers and consumers from harmful policies that raise the cost of prescription drugs in non-governmental sectors, shields patients from harmful policies that reduce access to drugs, and promotes robust competition in the prescription drug market that will bend the cost curve for patients while protecting incentives for innovation and risk-taking in the biopharmaceutical market. What follows is a more taxpayer- and market-oriented path forward for prescription drug policy in the 117th Congress and the Biden administration. All of the below policy planks could garner bipartisan support, and several already have.

Ensure R&D costs do not rise for manufacturers—and all American businesses—starting in 2022: The Tax Cuts and Jobs Act (TCJA), which passed in 2017, made several positive and pro-growth changes to the U.S. tax code. One provision of the law that Congress should repeal, though, is the shift in how the code treats businesses' research and development (R&D) expenditures. Under current law, U.S. companies can immediately write their R&D costs off their tax bill, which provides a major incentive for businesses to invest in innovations that grow the U.S. economy and create jobs. Under TCJA, though, businesses must amortize their R&D costs beginning in 2022—spreading the tax benefit out over five years instead of one. This will crib U.S. efforts, including those in the R&D-intensive biopharmaceutical industry, to dig out of the COVID economic hole and innovate in the years to come. Fortunately, the American Innovation and Competitiveness Act (AICA) from Reps. John Larson (D-CT) and Ron Estes (R-KS) is a popular, bipartisan bill in Congress that would repeal R&D amortization. Congress should pass it in 2021.

Redesign the Medicare Part D prescription drug benefit, including an out-of-pocket cap for seniors: NTU has long held that Part D redesign is the bipartisan prescription drug policy proposal with the potential to most positively impact both patients and taxpayers. Most versions of this proposal would protect seniors in Part D with the first-ever out-of-pocket cap in the benefit (ranging from $2,000 to $3,100 per year). And again, most versions of this proposal would pay for that protection by redesigning the "catastrophic" phase of the benefit, which a slim minority of beneficiaries (around eight percent) reach but where Part D costs are the highest for taxpayers. The current burden—80 percent of which falls on taxpayers and five percent of which falls on patients—would shift to insurance plans, which would cover 80 percent of the new catastrophic phase. The bipartisan Senate proposal would not only protect seniors but taxpayers too, reducing deficits by up to $35 billion over 10 years.

Private Part D insurance plans will likely balk at the proposal to shift their burden in the catastrophic phase from 15 percent of costs to 80 percent. We believe policymakers can and should explore a number of proposals to offer plan sponsors more flexibility in designing Part D plans, including but not limited to:

- Rescinding the CMS subregulatory guidance limiting plan sponsors to no more than three Part D plans (PDPs) per region;
- Repealing provisions or guidance requiring basic and enhanced benefit plan out-of-pocket costs to differ by at least $22 per month;
- Allowing for an additional specialty tier;
- Offering plan sponsors additional flexibility in negotiating with pharmacies;

- Removing two of six protected classes in Part D, as recommended by the Medicare Payment Advisory Commission (MedPAC); and
- Streamlining the process for formulary changes, as also recommended by MedPAC.

Reduce, rather than increase, distortionary rebates in the Medicaid program: In lengthy comments on a harmful proposed Trump administration rule regarding the Medicaid Drug Rebate Program (MDRP), NTU shared some of our objections to the current-law structure of the MDRP:

> The value of additional rebates are not realized by Medicaid patients at the point of sale. Medicaid cost-sharing requirements are already quite low, including for generic, preferred brand name, and non-preferred brand name drugs. This is consistent with the goals of the Medicaid program to provide low-cost health coverage to low-income Americans and vulnerable populations. However, these low cost-sharing requirements mean that every additional dollar of Medicaid rebates benefit state Medicaid agencies and the federal government, not patients or providers.

We also pointed out that in fiscal year (FY) 2017 manufacturer rebates made up more than half of Medicaid's gross spending on outpatient prescription drugs ($34.9 billion out of $64 billion, or 54.5 percent). We added that this significant distortion of market dynamics leads to 1) less capital and lower incentives for manufacturers to pursue the risky and often multibillion-dollar process of developing drugs, 2) the potential for higher launch prices for new drugs that do make it to market, as manufacturers try to recoup the cost of Medicaid rebates that reduce the value of their drugs by more than half, and 3) less private sector negotiation over drug prices between plans and manufacturers.

All of the above leads us to conclude that *reducing*, rather than increasing, rebates in government health programs would lead to fewer price distortions, less 'sticker shock' drug costs for private payers, more research capital for pharmaceutical manufacturers, and more competition in the prescription drug market. A few places where policymakers could reduce rebates:

- The MDRP, where the base rebate amount is typically 23.1 percent of the average manufacturer price (AMP) for a drug;
- MDRP inflationary penalties, which as we note above further distort prices in the market; and
- The Medicare Part D 'donut hole' 70-percent drug rebate.

Unfortunately, many of the proposals outlined above would expand rebates rather than reining them in.

Make the elimination of price controls and the protection of intellectual property two primary goals of U.S. free trade agreements: As NTU President Pete Sepp pointed out in a 2018 issue brief:

> Smart trade policies, in the form of new agreements, enforcing existing agreements, and utilizing dispute forums can be key to ensuring that the intellectual property backing up U.S.-manufactured drugs of all types is protected rather than exploited.

Sepp also noted that bipartisan legislation in Congress called on the executive branch to 1) ensure "that the provisions of any trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law, 2) "achieve the elimination of government measures such as price controls and reference pricing," and 3) "ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for United States products."

NTU is hopeful that the Biden administration takes a more pragmatic and less protectionist approach to U.S. trade agreements over the next four years, which includes unwinding the Trump administration's punitive tariffs (which were largely borne by U.S. businesses and U.S. consumers). President Biden can take the next step forward, though, by pursuing free trade agreements that bolster U.S. IP rights and actually *reduce* some of the foreign price controls that distort the cost of drugs in the U.S.

Reform the 340B Drug Pricing Program to ensure it reaches patients and hospitals truly in need: In October, NTU wrote a letter to the Republican leaders of the Senate Health, Education, Labor, and Pensions (HELP) Committee and the House Energy and Commerce (E&C) Committee after the leaders requested reform proposals for the 340B Drug Pricing Program.

This program, created in 1992, has grown exponentially in recent years and, in NTU's view, beyond its intended purpose. As the HELP and E&C committees noted, the number of active hospitals in the 340B program has grown sixfold in the past 15 years, while the number of "associated sites" participating in the program has grown 45 times in the same period. Some of NTU's recommendations would help Congress assess if the program is properly targeted to at-risk hospitals and at-need populations, as lawmakers originally intended.

Reduce regulatory barriers to competition and patient barriers to accessing biosimilars: Though the NTU team does not weigh in on the intricacies of Food and Drug Administration (FDA) policy, we are concerned by the numerous complaints from governmental and non-governmental stakeholders that the FDA drug approval process is too costly, too time-consuming, and too burdensome. While the agency must always put patient safety and scientific evidence first and foremost, that does not, in our estimation, leave the agency's current processes beyond reproach from health policy experts. Similarly, NTU has written about a variety of ways policymakers could stimulate the development, availability, and use of biosimilars, lower-cost alternatives to expensive biological products.

Conclusion

Threats and opportunities abound for policymakers when it comes to prescription drug policy. Pharmaceutical manufacturers have proven an essential part of the solution to the COVID-19 crisis, working overtime for a year along with frontline health care workers and scientists to beat the virus and the disease. The results are several safe, effective, and viable COVID-19 vaccines that, with significant public and private investment, may reach billions of people in 2021.

Beyond the COVID-19 pandemic, drug costs will remain a challenge for many Americans. Though prescription drug spending makes up less than 10 percent of national health expenditures (NHE), a proportion of Americans struggle to pay out-of-pocket expenses for high-cost prescription drugs. Lawmakers and the Biden administration should focus on narrow, targeted solutions to help those in need, along with broader systemic changes that enhance competition in the biopharmaceutical market and reduce price distortions in the public and private sectors. More punitive measures like an excise tax, inflation caps, or importation plans—though *some* may be well-intentioned—would have disastrous consequences for patients, consumers, and taxpayers alike in the long run.

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