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SOCIAL SECURITY WORKS.

ENDING THE INSULIN CRISIS WITH THE AFFORDABLE DRUG MANUFACTURING ACT

Executive Summary

- When Republican and Democratic messages are presented, voters support the government manufacturing insulin, 58 percent to 32 percent.
- Even without a Democratic message, voters support the government manufacture of insulin, 48 percent to 33 percent.
- In both scenarios tested, independents, on net, support generic manufacture of insulin.
- Voters support executive action to generically produce insulin.
- Voters don't like pharmaceutical companies. Polling consistently indicates that the electorate is heavily in favor of creative government action to stop the hoarding of public goods and make lifesaving drugs affordable.

Seven million Americans need insulin every day to control their blood sugar and avoid life-threatening medical events.[1] This includes everyone with type 1 diabetes as well as many who have developed type 2 diabetes. The World Health Organization has designated insulin an "essential medicine," which means that governments have a duty to make it affordable.[2] In America, however, the cost of a vial of insulin has tripled over the past two decades,[3] and clinician-researchers at Yale University found that a quarter of their diabetes-center patients (people who were covered and in care) were rationing their insulin.[4] Put simply, because insulin is no longer affordable here, America is failing its duty.

Three Fortune 500 companies (Sanofi, Novo Nordisk, and Eli Lilly) manufacture over 97 percent of the American insulin supply. No real pipeline for generic alternatives to insulin produced by these companies has emerged, even though the patents for the most-common drugs have expired. Americans pay for over $100 billion each year on diabetes treatment, more than any other disease. Likewise, spending on care—which mostly consists of drug costs—increased at a rate over two decades that was only comparable to the opioid-associated increase in pain care.[5]

The insulin crisis is an urgent problem with severe costs, both financial and human. That's why the late Representative Elijah Cummings made Antionette Worsham his first witness for his first hearing as Chair of the House Oversight Committee this past January. Worsham is an Ohio mother whose daughter Antavia had type 1 diabetes and had started rationing her insulin due to its increasing cost in 2016. One year after she began rationing, Antavia died of diabetic ketoacidosis at the age of twenty-two.[6] Her needs had not been covered by Kevin's Law, named after another type 1 diabetic who died while rationing his medicine; Ohio and Florida passed Kevin's Law in 2016, to extend supplies to emergency insulin in certain circumstances.[7] And yet, currently, Antoinette is worried that her other daughter, who is in college, will also have to start rationing soon.

Companies have responded to hearings and state-level attempts at regulation with public-facing moves that do not change the underlying market dynamic. The pharmacy-benefits manager Express Scripts has offered to cap monthly insulin payments at $25 (the average list price is $450, a month).[8] Similarly, the pharmaceutical company Eli Lilly recently announced that it would make a so-called "authorized generic"—not a true generic, rather a cheaper version of the same medicine marketed by the same manufacturer—of its rapid-acting insulin (insulin lispro) available to American consumers at a reduced price of $137 per vial.[9] This is a reduction only when compared to today's prices; for instance, when insulin lispro (known then as "Humalog") was new to the market in 2001, a vial was priced at $35.[1011] However, Senators Elizabeth Warren and Richard Blumenthal conducted a survey of 190 chain and 196 independent pharmacies across the country, which revealed that insulin lispro was not in stock or made available to patients in

83 percent of surveyed pharmacies. Furthermore, only 15 percent of surveyed pharmacies offered insulin lispro to patients without being prompted to dispense the authorized generic.

The private market has failed to deliver insulin to patients that need it. Rep. Cummings knew the importance of making essential drugs affordable, which is why he chose insulin as his first focus when he was made Chair of the House Oversight Committee. The broken marketplace makes reintroducing the Affordable Drug Manufacturing Act (ADMA) imperative. It would reduce artificial barriers to competition, and would allow the government to manufacture essential, generic medications, with a mandate to produce insulin within the year.[12]

This memo will lay out the case for supporting this bill. It will first detail the insulin-pricing crisis, then it will outline how the ADMA would work. Finally, it will demonstrate that government-produced drugs—which might seem like a drastic break from the political norm—is popular with both swing voters and partisans.

The History of Insulin

Insulin is a hormone that regulates the production and storage of sugar in the human body. In people without diabetes, the pancreas produces a sufficient amount at a sufficient rate. People with type 1 diabetes do not produce enough insulin to effectively regulate blood sugar, while people with type 2 diabetes need more insulin to achieve normal levels of blood sugar. The goal of insulin is to mimic the process of a nondiabetic body and prevent both immediate health events and long-term risks of diabetes, such as blindness, kidney failure, and heart disease. In general, patients take short-acting doses before meals, and long-acting (basal) doses to regulate their levels for the rest of the day.

Insulin was first extracted from animals and patented for medical use in 1923. The original patent was sold for one dollar to University of Toronto because, as one of the scientists who won the Nobel Prize for developing it, said, "Insulin belongs to the world."[13] In the US, however, Eli Lilly held the patent and was able to patent aspects of insulin's manufacturing process. Beef- and pork-insulin extracts were used in the US until the 1980s, when scientists figured out how to manufacture insulin from human DNA ("human insulin").[14]

Human insulin was effective, but scientists continued tweaking the molecule. These modified molecules were known as "insulin analogs," and they reshaped the market in the early 2000s.[11,14] Most prominent were long-acting Lantus (insulin glargine) from Sanofi, rapid-acting Humalog (insulin lispro) from Eli Lilly, and rapid-acting Novolog (insulin aspart) from Novo Nordisk. (These companies compose what is known as "the big three.") And in 2010, more than 95 percent of insulin-using adults with type 2 diabetes were prescribed the analogs.[11]

With a new lock on the market, costs skyrocketed. Between 2008 and 2014, Medicaid's reimbursement price of Lantus increased 13 percent each year, while healthcare costs were generally declining across the country.[15] This increase was the result of an ability to control prices. Because insulin is a "biologic" drug (it comes from a living organism), this meant that exclusive control over the production process would last for twelve years before new manufacturers could step in and make a generic, or "biosimilar" insulin, and the price increase of insulin partially stagnated when Eli Lilly released a glargine-like product.[15]

It is unclear whether the analogs are an actual improvement over the earlier human insulin for people with type 2 diabetes, even as the price tripled.[3] A 2018 review of randomized trials could not find any improvement in adults with type 2,[16] while a 2019 trial of more than 14,000 older adults with type 2 found that switching to the

older insulin did not result in clinically significant changes.[17]

But generic competition is not coming from outside these three companies. By the end of 2015, eleven major insulin products had no exclusivity protection.[18] Despite this, the only generic insulins currently available in the US are manufactured by Eli Lilly and Novo Nordisk, and no "biosimilars" have come to market. In recent years, Walmart has started to offer $25 vials of human insulin—which was also produced by the same company that makes the more-expensive medications.[8]

In October 2018, Merck had to withdraw its approved generic version of insulin glargine from the market because it would not be able to reap the gains of a lower price. The big three had effectively negotiated rebates with insurance plans, while keeping list prices high so people on high-deductible plans and people without insurance would pay enormous sums.[11] Because it is biologic, insulin is relatively expensive to make and slightly tougher to regulate, but the big three have swaddled their products in a variety of extra patents and have held back on making generic versions easily available.[18]

The Affordable Drug Manufacturing Act

In December 2019, Sen. Elizabeth Warren and Rep. Jan Schakowsky reintroduced their Affordable Drug Manufacturing Act which would "amend the Public Health Service Act to establish an Office of Drug Manufacturing" (ODM) in the Department of Health and Human Services.[12] The director of the ODM would be appointed by the president, confirmed by the Senate, and could not be either a former drug-company lobbyist or an executive at a company that had recently been implicated in law-breaking.

The ODM would function as a steward of public property—i.e., generic medications—and have a threefold mandate: (1) increase competition and address shortages of prescription drugs, (2) reduce the cost of drugs for taxpayers and consumers, and (3) increase patient access to drugs.

The ODM would be able to step in, apply for FDA approval, and manufacture medications—or contract with pharmaceutical manufacturers—if no companies were making the medication or if it determined one or two companies were making an essential drug and there had been a spike in cost and there was not an equivalent generic alternative. Then medications would be sold at a "fair price" that covers production costs. The ODM could also produce pharmaceutical ingredients to help accelerate and buttress the pharmaceutical supply chain. Production of insulin--along with Naloxone, which reverses opioid overdose, and essential antibiotics--would be statutorily required within a year. The insulin requirement is intended to act as a spur to biosimilar production, and inject competition into the marketplace.

Therefore, the ODM would not simply foster competition among private producers, but it would also directly compete with them if they hoarded public goods. Pharmaceutical companies have been able to charge giant mark-ups on generic products like insulin because of they've patented new delivery devices; they would still be able to charge for the device, but the ODM's ability to step in would reduce their ability to charge exorbitant prices for marginal (or non-existent) improvements. This kind of approach has been advocated by several progressive economists as a way to prevent price gouging by private actors while effectively provisioning essential goods and services. These "public options" can also be used to meet goals that markets are have failed to meet on their own, such as guaranteed provision of a good or service to those unable to pay for it and to marginalized groups who have been systematically excluded from participation in markets

This is not as costly as it may seem. A recent study estimated that an insulin analog biosimilars using imported active pharmaceutical ingredients (which is common for other drugs) would cost, at most, $133/year per patient to produce—well below currently existing prices.[19] Even if one assumes that markups in the supply chain doubles the price, this means that if the government produced enough insulin for every person in America who needed it—which is an unlikely outcome—it could do so for $2 billion/year, which is roughly a third of the net income) Eli Lilly earned in the first nine months of 2019.[20]

The Public Supports the Generic Manufacture of Insulin

In a recent survey, we tested support for the generic manufacture of insulin. To ensure the policy would remain popular even if the pharmaceutical industry spends heavily against it, we tested a version of the question in which voters saw no positive Democratic message. In the split with both messages, we asked voters:[1]

> *Some Democrats have proposed allowing the government to manufacture a generic version of insulin and sell it at a price that covers the manufacturing costs and ensures patients have access to the drugs.*
>
> ***Democrats say that this would lower the cost of insulin and guarantee that everyone with diabetes gets the insulin that they need. They say that pharmaceutical companies should not be allowed to exploit people who need medicine just to boost profits.***
>
> *Republicans say that this proposal a government takeover of healthcare which would waste taxpayer money, lead to insulin shortages, and result in lower-quality insulin. They argue that this will reduce investments in new prescription drugs, destroying high-paying jobs and preventing better drugs from coming to market.*
>
> *Would you support or oppose this proposal?*

Whereas in the other split, we asked a similar item but without a Democratic statement.[2]
Fifty percent of the sample received statement one, and fifty percent received statement two. In the condition that included the Democratic message, we rotated the Democratic and Republican messages so voters would randomly see one or the other first.

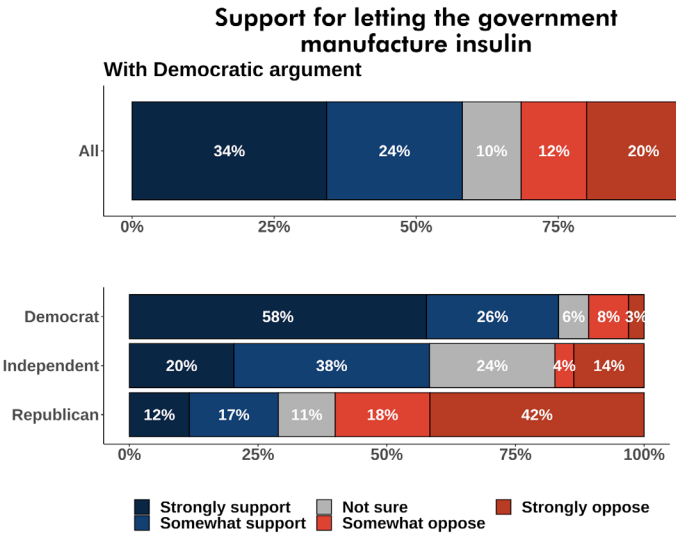
In both conditions voters support the policy. In an environment where voters see both messages, support for the policy is overwhelming (58 percent to 32 percent), with a net-positive support of 40 points. As before strong support (34 percent) was greater than strong opposition (20 percent).

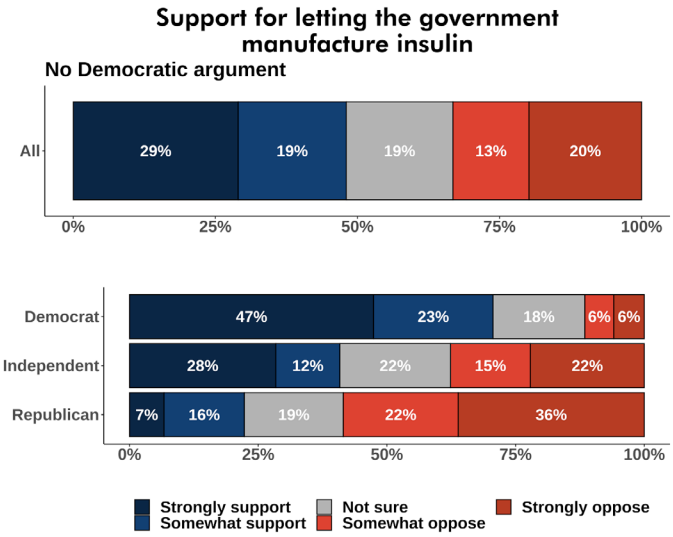
1 In the survey itself, the Democratic message was not bolded, but is highlighted here for ease of comparison with the control condition statement.

2 Some Democrats have proposed allowing the government to manufacture a generic version of insulin and sell it at a price that covers the manufacturing costs and ensures patients have access to the drugs.

Republicans say that this proposal a government takeover of healthcare which would waste taxpayer money, lead to insulin shortages, and result in lower-quality insulin. They argue that this will reduce investments in new prescription drugs, destroying high-paying jobs and preventing better drugs from coming to market.

Would you support or oppose this proposal?





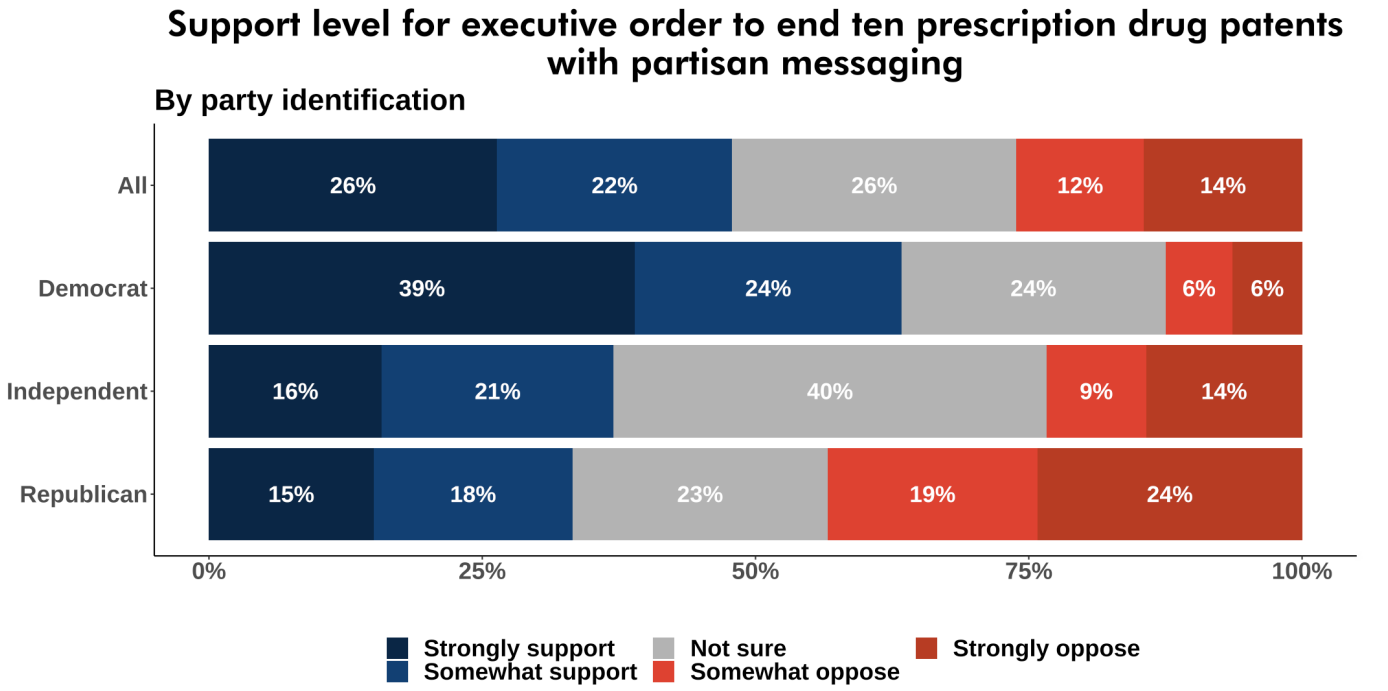
Even when no positive Democratic message is provided, voters overall support the policy, 48 percent to 33 percent, with independents supporting it, 40 percent to 37 percent. Even with no positive message, strong support (29 percent) was greater than strong opposition (20 percent). Even if the legislation faces a strong media deficit, it will have net support among voters.

In addition, voters clearly recognize the urgency of the insulin crisis, and they support the use of executive action to strip drug companies of their patents and open the market to producers of generic drugs. In a poll from October through November, on behalf of Data for Progress, registered voters were asked to consider the following:

> *Some Democrats have argued that the next President should use their executive authority to end the patents on ten drugs, including insulin. They argue that ending the patents will allow other companies to create generic versions of drugs, adding competition to the market and reducing the cost of drugs.*
>
> *Republicans argue that this would reduce the incentives for drug manufacturers to invest in new drugs and destroy jobs in the pharmaceutical sector.*
>
> *Would you [support or oppose] the next President using their executive authority to end the patents of ten drugs?*

We found that almost half of voters supported this proposition, with 26 percent of voters reporting they were unsure how they felt, and another 26 percent of voters opposing the policy. Net support for an executive order to end the patents on a few common and lifesaving drugs was overwhelmingly positive, with voters supporting such a move by 22 points.

Broken out by party identification, 63 percent of Democrats supported such an executive order, with just 12 percent opposing it. Republicans indicated greater opposition, with 43 percent saying they opposed executive action to end the ten drug patents, and 33 percent in support of the executive action. Thirty-seven percent of independents supported this use of executive authority, 23 percent opposed it, and 40 percent were unsure. This item continued to portray the trends we observed in previous questions, where independents are more unsure than their partisan counterparts on issues of executive action in pharmaceutical reform.



Some Democrats have argued that the next President should use their executive authority to end the patents on ten drugs, including insulin. They argue that ending the patents will allow other companies to create generic versions of drugs, adding competition to the market and reducing the cost of drugs.Republicans argue that this would reduce the incentives for drug manufacturers to invest in new drugs and destroy jobs in the pharmaceutical sector. Would you [support or oppose] the next President using their executive authority to end the patents of ten drugs?

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Conclusion

Many lifesaving drugs exist because of taxpayer-funded innovation and regulation, but our current system encourages corporations to take as much credit as possible and hold the public hostage. Voters are paying too much, and their family members are suffering for no good reason. That's why they prefer access to public goods instead of mealy-mouthed promises by the corporate hoarders who got us into this mess. Our polling indicates that voters want the government to act creatively, and leaders who want to win elections—and secure a healthy and innovative future for everyone—should get behind government-produced insulin as quickly as possible.

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Polling Information

Executive Order Polling:

The survey was conducted by YouGov Blue as part of its registered voter omnibus and fielded on YouGov's panel from November 16, 2019 - November 18, 2019 and included 962 voters. The results were weighted to be representative of the population of US voters by age,

race/ethnicity, sex, education, US Census region, and 2016 US Presidential vote choice.

Insulin Test:
On behalf of Data for Progress, YouGov Blue fielded a survey of US registered voter as part of its Registered Voter Omnibus. The sample included 1,062 US voters and was weighted to be representative of the population of voters by age, race/ethnicity, sex, education, US Census region, and 2016 Presidential vote choice. Here, we focus on the results of a message test centered around letting the government manufacture generic pharmaceuticals.

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