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Economic Impact Assessment of production of generic insulin

ABSTRACT: Estimating the possible dollar savings which can be realized by transitioning to state produced generic insulin has three parts:

1. How much money is saved directly in terms of spending less money on insulin?
2. How many heart attacks, strokes and other morbid conditions which disproportionately affect diabetics could be prevented with an easily available, inexpensive supply of insulin made by the State, and how much money would be saved as a result?
3. How much productivity would be gained by diabetics as a group having markedly fewer events causing absenteeism and inability to work?

We have used an outstanding actuarial work by Pyenson written in 2010 as the basis for generating various predictive models. We observe that no matter how constrained the set of assumptions used, significant savings can be realized, suggesting that investment costs could be recovered in a short timeframe.

We hope this is of assistance to legislators and we are always available for questions or criticisms.

CONCLUSION: The State of Maine could cumulatively save approximately \$2 billion at 4 years, \$4 billion at 7 years and \$8 billion at ten years by transitioning to an insulin market in which Maine-produced generic insulin is widely available for its citizens, if not more.

Estimating direct cost savings **alone** using conservative assumptions for price of a vial and number of insulin vials required suggests a possible savings of \$200 million at 4 years, \$350 million at 7 years and \$500 million at 10 years. Using more liberal “best guess” assumptions, estimated direct cost savings could approach \$320 million at 4 years, \$590 million at 7 years and \$990 million at 10 years.

GOAL: The purpose of this addendum is twofold:

1. Utilizing varying assumptions to estimate potential future insulin markets, to calculate the amount of dollar savings that can be expected by transitioning from the current status quo insulin market to a market where Maine-produced generic insulin is widely available.
2. To provide legislators with a dashboard that will allow quick graphic visualization of this *Insulin Dividend* based upon the various models.

<https://www.canva.com/design/DAFXyEvGcGg/dha5-dpAwkziSDLZP5kHSA/view#4>

METHODOLOGY: Total dollar savings can be calculated by adding together the expected direct savings and the expected indirect savings. Direct savings accrues from a lowered cost for purchased insulin. Indirect savings are the savings expected from more effective glycemic control at a population level.¹

The indirect costs savings has two components:

1. healthcare dollars saved due to lower adverse event rate (decreased numbers of heart attacks, strokes, amputations, blindness, early mortality, and other events which disproportionately occur in diabetic population)
2. the consequent increase in societal productivity of citizens from lower absenteeism, lowered presenteeism and lowered mortality.

Predicting how much a decreased adverse event rate will translate into a real dollar savings requires construction of an extremely complex nonlinear function. Each 1% reduction in adverse event rate does not equate to a specified amount of savings in healthcare dollars.

Here, we depend heavily on the outstanding work by Pyenson et al, who, in 2010, endeavored to forecast costs of diabetes over the next twenty years.² With benefit of hindsight, we can see that his estimation of the rate of change for total costs has been uncannily accurate for ten years (2011 - 2021) after comparison to actual values, and so we adapt his equations over an even broader confirmed data sets for costs (2007-2020) and apply them to projected costs over the coming years (2022 – 2042).³

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6583414/>. Herkert D, Vijayakumar P, Luo J, Schwartz JI, Rabin TL, DeFilippo E, Lipska KJ. Cost-Related Insulin Underuse Among Patients with Diabetes. JAMA Intern Med. 2019 Jan 1;179(1):112-114. doi: 10.1001/jamainternmed.2018.5008. PMID: 30508012; PMCID: PMC6583414. Insulin rationing due to price disproportionately affects communities of color.

² <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelppdf.ashx>

³ As listed in Table 1.

Table 1: Projected healthcare dollar costs of diabetes per year, using Pyenson’s methodology

YEAR			Healthcare cost (for U.S.)	Healthcare Cost (FOR MAINE)
2022	16		433.078	1.790
2023	17		475.572	1.965
2024	18		522.235	2.158
2025	19		573.477	2.370
2026	20		629.747	2.602
2027	21		691.538	2.858
2028	22		759.392	3.138
2029	23		833.904	3.446
2030	24		915.727	3.784
2031	25		1005.578	4.155
2032	26		1104.246	4.563
2033	27		1212.595	5.011
2034	28		1331.576	5.502
2035	29		1462.230	6.042
2036	30		1605.705	6.635
2037	31		1763.258	7.286
2038	32		1936.269	8.001
2039	33		2126.257	8.786
2040	34		2334.886	9.648
2041	35		2563.986	10.595
2042	36		2815.565	11.635
	NET TOTAL (in billions)		\$ 27,096.82	\$ 111.97

After first generating reasonable estimates for total expenditure going forward, we then apply Pyenson’s analysis to derive, as he did, a single number for what healthcare dollar savings can be expected at a given level of AE reduction. Now that his forecasts have been verified, relying on Pyenson’s work allows the most realistic estimate for determining cost savings from decreases in adverse rate event achievable without conducting entirely new original research.

Accordingly, we designate the expected decrease in adverse rate event as one of the sliding variables in our dashboard. Theoretically, setting the decrease to zero will limit an estimate calculated by the dashboard to only direct costs.

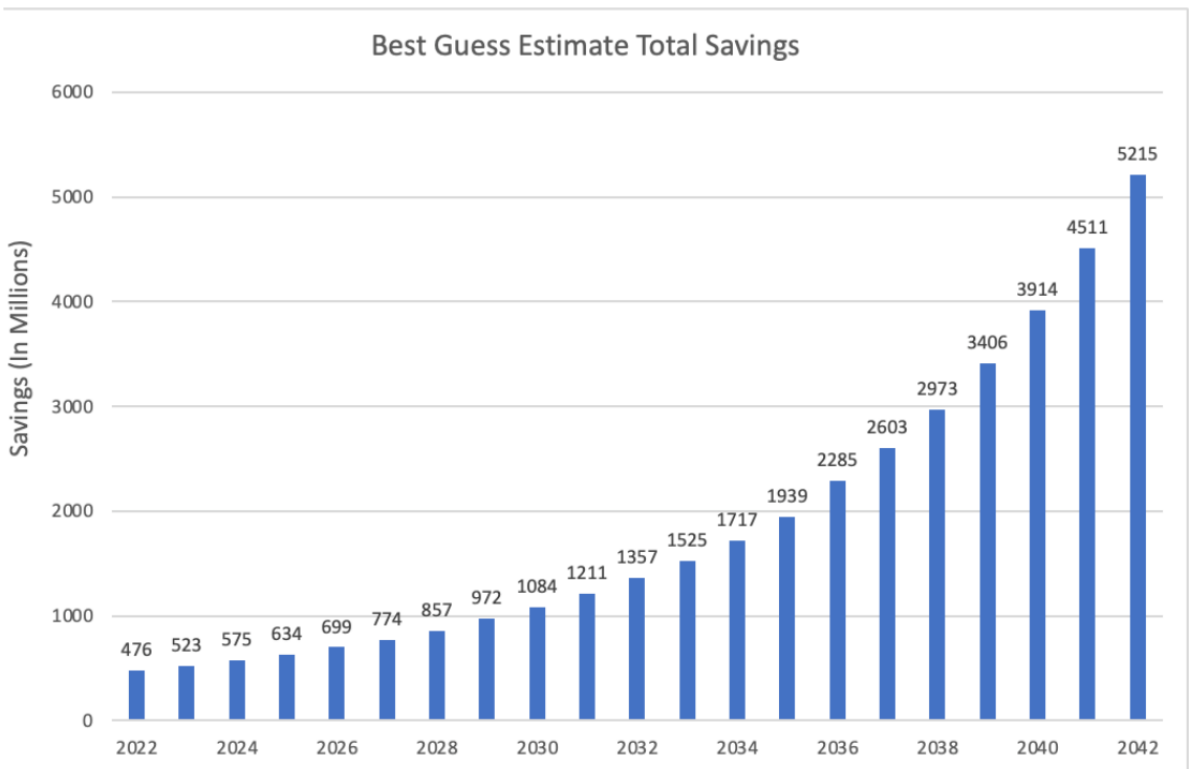
In equation form: Savings = direct + indirect, where:

$$\text{direct} = \$ \text{ spent on insulin now} - \$ \text{ spent in proposed regime}$$

$$\text{indirect} = \text{expected saving from improvement in productivity, absenteeism and presenteeism} + \text{healthcare } \$ \text{ saved by lowering rate of AE.}$$

This preliminary sum is then adjusted by an assigned rate of inflation over a selected time interval, since expected savings will compound with time to a certain extent and will always be subject to inflation.

Figure 1: Yearly savings of transitioning to widely available generic insulin using best realistic assumptions.



RESULTS: According to these calculations, the State of Maine can expect significant savings from transitioning to generic insulin, no matter the set of assumptions we choose. See Figure 1.

Our **“best guess”** scenario calculates a cumulative savings of:
\$ 2.2 Billion at 4 years,
\$ 4.5 Billion at 7 years,
\$ 9.1 Billion at 10 years.

Using the **least** speculative (most conservative) assumptions, we calculate a cumulative savings of:
\$ 2 Billion in 4 years,
\$ 4.1 Billion in 7 years,
\$ 8 Billion in 10 years.

Utilizing the **most** speculative realistic (most liberal) estimations, we calculate a cumulative savings of:
\$ 2.4 Billion at 4 years,
\$ 4.9 Billion at 7 years,
\$ 10.2 Billion at 10 years.

DISCUSSION:

President Biden has said several times recently that “Capitalism without competition is exploitation”.⁴ There is no better way to describe the situation that currently exists with insulin manufacture and pricing.

Dr. Frederick Banting became the youngest ever recipient of the Nobel Prize in Medicine in 1923 (age 32) following his discovery in 1921 of a method to produce insulin. Following his classic set of experiments, Dr. Banting sought and received a patent for production of the insulin molecule. Rather than pursue the tremendous financial gain possible from his discovery, Dr. Banting altruistically sold his patent for \$1 to the University of Toronto, famously exclaiming “Insulin does not belong to me, it belongs to the world.”⁵ In doing so, Dr. Banting stated that he wanted to make sure that no patient would ever be in a situation where they couldn't afford this lifesaving medication.

Fast forward a century in time, and we have a current environment in which three major pharmaceutical companies dominate over 95% of the production of insulin. The price of a vial of insulin has risen in lockstep over the last almost three decades, with price exceeding on average \$300 a vial today.⁶ The insulin used during the 1990s is currently off patent and generic. These forms of insulin that are available as off patent formulations are safe and effective and have years of use documenting this safety profile. Prevailing consensus is that a vial of insulin can be produced for less than \$10 per vial using modern molecular biological techniques.⁷

A. Direct costs savings

The biggest challenge in calculating how much money would be directly saved by transitioning to generic insulin is the difficulty understanding exactly what price is currently being charged. Because of the byzantine complexity of healthcare spending, different entities are faced with different pricing.⁸ Because of the recent legislation passed in Maine to create a cap on out-of-pocket expenses, some fortunate individuals are not exposed to the actual price or charge.⁹

It is critical to understand that despite out of pocket caps or other cost saving devices aimed at individuals, ultimately, some entity is still exposed to the “list price”, be it an insurance company or the government itself. Accordingly, for this calculation, we have chosen to use the best

⁴ <https://www.businessinsider.com/biden-slams-capitalism-without-competition-as-exploitation-consumers-workers-corporations-2022-1?op=1>

⁵ <https://www.thestudentperspective.org/post/insulin-does-not-belong-to-me-it-belongs-to-the-world>

⁶ See Figure 3.

⁷ <https://gh.bmj.com/content/3/5/e000850>.

⁸ <https://easydrugcard.com/healthy-living-tips-blog/healthy-living-tips/how-much-does-insulin-cost-in-america-2021-updated/>

⁹ <https://legislature.maine.gov/statutes/32/title32sec13725.html>

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aggregate estimation of how much money is spent directly on insulin by any entity¹⁰ and then compare this figure to the amount expected to be spent if generic insulin were substituted.¹¹

In 2017, total spending on insulin was slightly less than \$15 billion (\$14,981,000,000).¹² Since Maine has 1/242 the population of the US based on recent census data,¹³ a reasonable calculation of the amount spent on insulin in Maine is \$70 million/year. Alternatively, we arrive at a similar figure with a “ground up” model, by estimating how many vials of insulin are required each year for a state the size of Maine and multiplying by the commonly quoted price per vial of \$300/vial,¹⁴ as follows.

According to the American Diabetes Association (ADA), approximately 150k Mainers have some form of diabetes.¹⁵ For purposes of our calculations, we have noted that 5-10% of diabetics are known to be entirely insulin dependent (also called Type I).¹⁶ This agrees with the ADA estimate that some 1.9 million Americans, which translates to about 8000 Mainers, are dependent on insulin as a life-saving medication.

Non-insulin dependent diabetics (Type II) are patients who do not require as much insulin as Type I diabetics; typically, these patients retain some capacity to produce insulin but are increasingly resistant to its effects. According to the ADA, there are around 140k Mainers who are Type II diabetics. In this group, some use insulin consistently, some rarely and some never.

¹⁰ https://diabetes.org/sites/default/files/2022-04/ADV_2022_State_Fact_sheets_all_rev_ME-4-4-22.pdf. This fact sheet summarized the comprehensive report by the ADA entitled *Economic Costs of Diabetes in the U.S. in 2017*. See <https://diabetesjournals.org/care/article/41/5/917/36518/Economic-Costs-of-Diabetes-in-the-U-S-in-2017>.

¹¹ <https://gh.bmj.com/content/bmjgh/3/5/e000850.full.pdf>.

¹² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5911784/pdf/dci180007.pdf>. See page 922, Table 3 in this excellent comprehensive report entitled *Economic Costs of Diabetes in the U.S. in 2017*.

¹³ Census data population shows the US to have a total population of 330 - 335 million and the State of Maine to have a population of 1.372 million. We have chosen to disregard the minor corrective factor needed to consider the slightly older population of Maine, because such a corrective factor would only serve to increase any expected Insulin Dividend. Since this will be a systematic factor throughout our calculation, we have chosen to use the more conservative figure.

¹⁴ See Figure 2.

¹⁵ https://diabetes.org/sites/default/files/2022-01/ADV_2021_State_Fact_sheets_all_rev_1.27_ME.pdf.

¹⁶ <https://timesulin.com/what-is-insulin-dependent-diabetes/#:~:text=But%205%20to%2010%20percent%20of%20people%20living,the%20onset%20of%20insulin%20dependent%20diabetes%20is%20sudden.>

Figure 2:

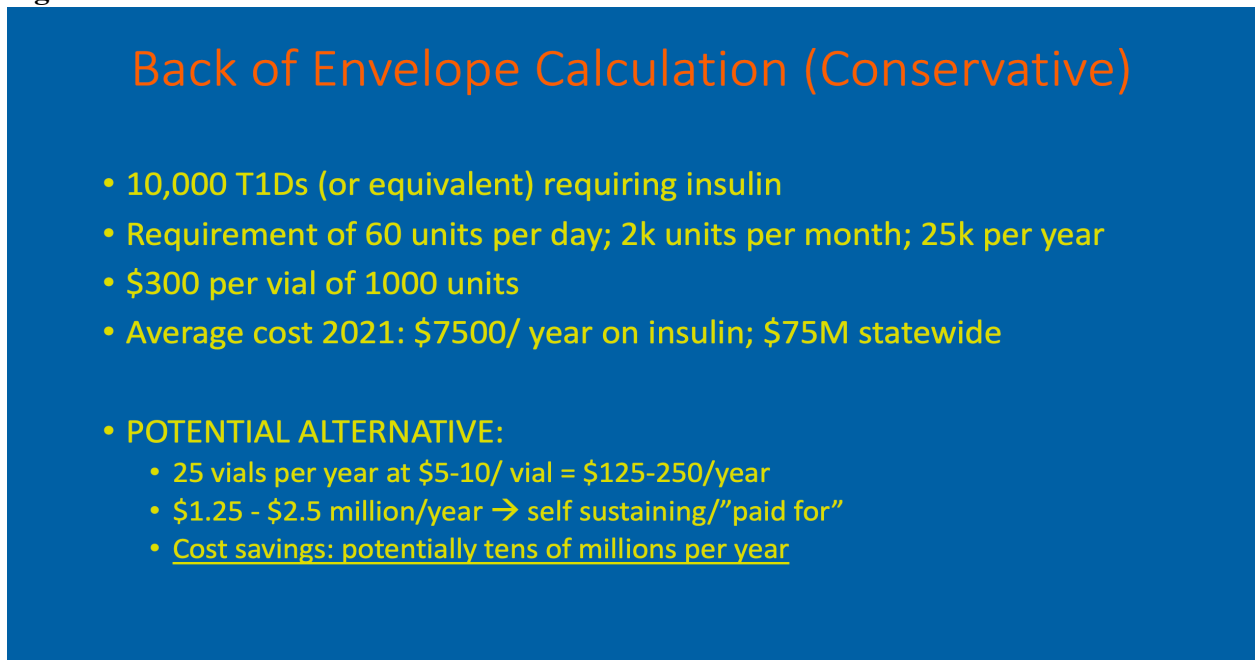
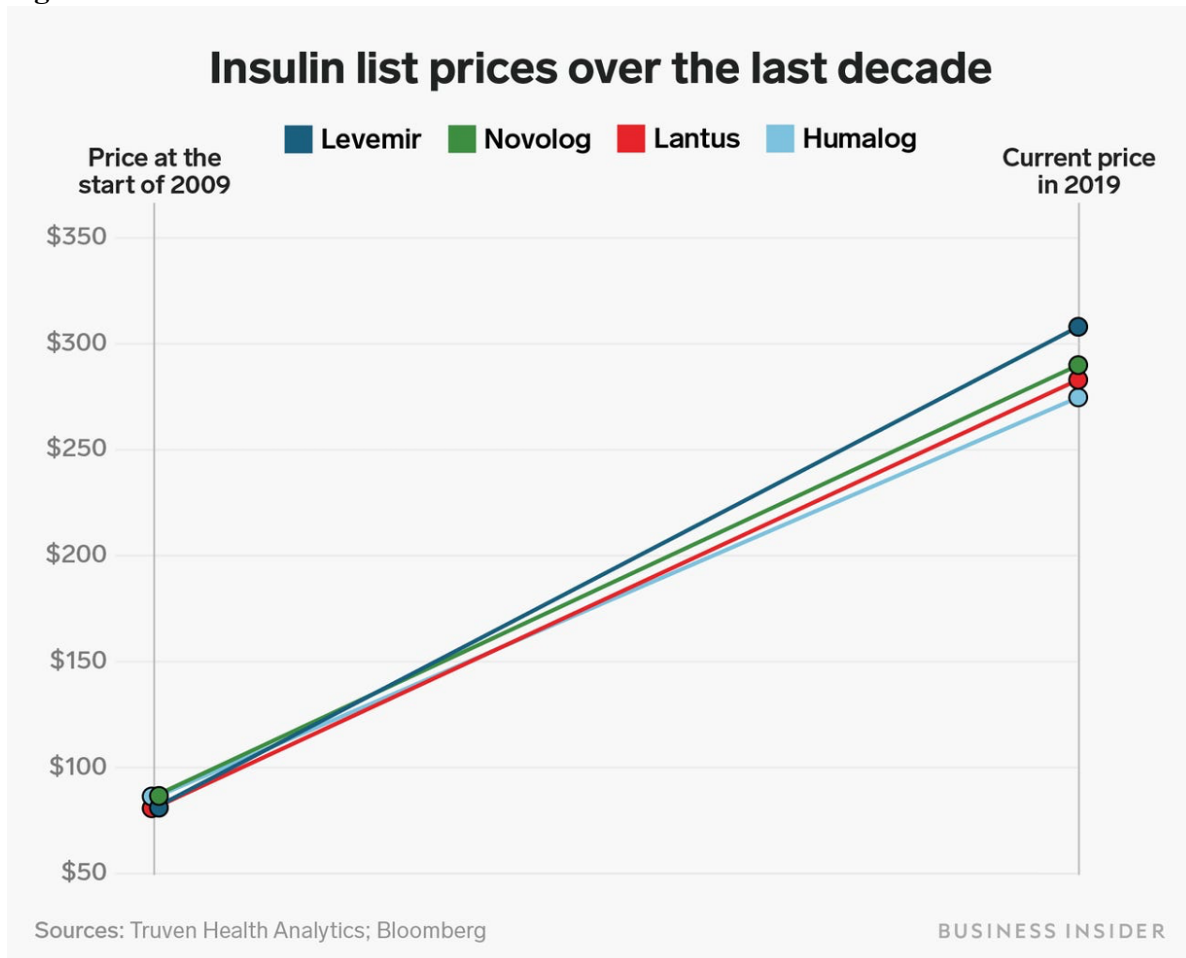


Figure 3:



Since it is difficult to ascertain the insulin requirements of non-insulin dependent diabetics, for the purposes of this calculation, we have again chosen to assign the 150k Mainers who are Type II as being equal in insulin requirements to 2500 Type I Mainers. Once again, we choose to use a likely significant underestimate of “Type I equivalents” in the total Type II populations to ensure any potential error results in an underestimate of savings. The average Type I will use about 2 vials of insulin a month if they are using an insulin pump, more if the patient uses a shot regimen. This amounts to 25 vials a year, or 250,000 vials for the entire state with 10,000 Type I “equivalents”. At a current price of \$300/vial,¹⁷ this amounts to \$75 million per year.

Reassuringly, we have arrived at very similar figures via two completely different approaches.

B. Indirect Cost Savings

Estimation of indirect cost savings are always fraught with potential error, since by the very nature of the calculations, various assumptions must be made. We base the model for our calculations on two widely accepted principles:

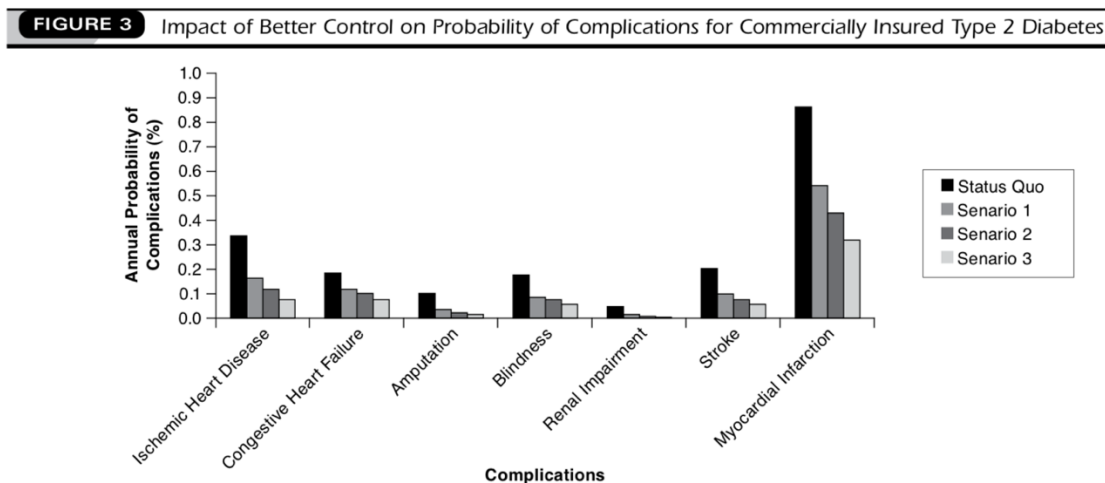
1. Easy access to affordable insulin will allow better glycemic control as measured by Hemoglobin A1c (HbA1c).¹⁸
2. Better glycemic control (lower HbA1c) decreases the number of adverse events in the diabetic population, which consequently lowers healthcare costs.¹⁹ See Figure 4.

¹⁷ See Figure 3.

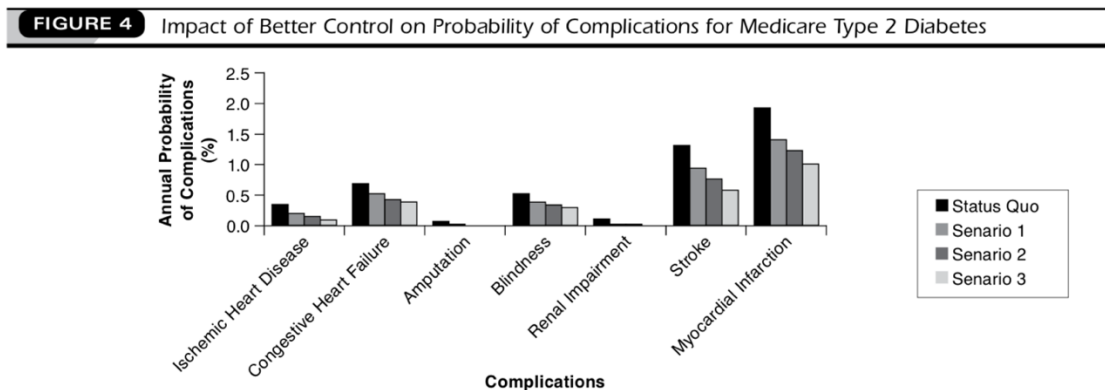
¹⁸ <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/191184>. See also <https://www.tandfonline.com/doi/epdf/10.1080/03007995.2020.1787971?needAccess=true&role=button>, providing an objective analysis of relationship between decreased HbA1c and decreased healthcare costs.

¹⁹ <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelp.pdf.ashx>. See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6583414/>. See also Figure 4, from page 615 of <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2013.19.8.609>.

Figure 4:



Source: Authors' analysis of NHANES 2005-2008 and UKPDS modeling.
 NHANES=National Health and Nutrition Examination Survey; UKPDS=United Kingdom Prospective Diabetes Study.



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Where Scenarios 1, 2 and 3 are defined:

TABLE 2 Clinical Targets and Improvement Scenarios

	ADA Clinical Targets	Improvement Amount		
		Scenario 1	Scenario 2	Scenario 3
A1c (%)	< 7%	↓1% A1c	↓1.25% A1c	↓1.5% A1c
Systolic BP/diastolic BP (mm Hg)	< 130/80 mm Hg	↓10 mm Hg	↓20 mm Hg	↓30 mm Hg
High-density lipoprotein (mg/dL)	> 40 mg/dL (M) > 50 mg/dL (F)	↑20%	↑35%	↑50%
Total cholesterol (mg/dL)	< 200 mg/dL	↓20%	↓35%	↓50%

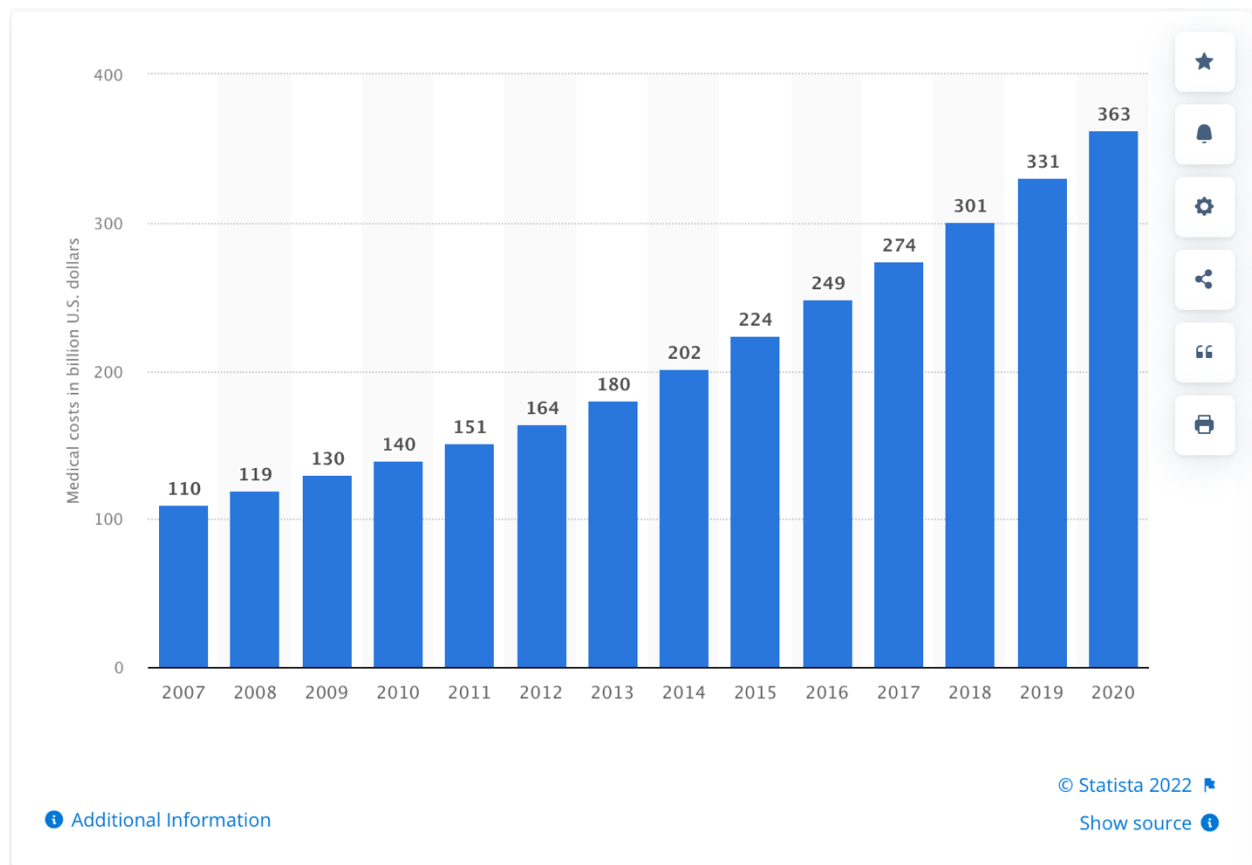
A1c=hemoglobin A1c; ADA=American Diabetes Association; BP=blood pressure; F=female; M=maie; mg/dL= milligrams per deciliter; mm Hg= millimeter of mercury.

To calculate indirect costs, we then consider two distinct categories of potential savings – decreases in medical costs (dollars spent on healthcare) and recovery of lost productivity.

1. Decrease in healthcare costs attributable to decreased rate of adverse events

As Figure 4 demonstrates, total medical costs are decreased with better glycemic control, as a natural consequence of decreasing the rates of all major adverse events commonly seen in the diabetic population. The dollar costs of healthcare necessary for the care of complications of diabetes is well studied and characterized, yielding a wealth of reliable fundamental data generated over the course of decades of rigorous study.²⁰ Figure 5 is an amalgamation of the last 14 years of verified, reliable data regarding the amount of money spent on the medical costs of diabetes each year (MC).

Figure 5:



²⁰ <https://www.statista.com/statistics/242157/us-diabetes-type-2--medical-costs-from-2007-to-2020/>. See also <https://diabetes.org/about-us/statistics/cost-diabetes>, for most recent verified data. For full report see <https://diabetesjournals.org/care/article/41/5/917/36518/Economic-Costs-of-Diabetes-in-the-U-S-in-2017>. See also *supra* footnote 4 and Figure 5.

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We will use these figures as the base figures from which we derive any calculation of possible savings from transitioning to generic insulin. **In order to accurately forecast savings, we must first accurately forecast expenditures,** and the data from figure 4 represent the most authoritative estimates of expenditures available from which to build a predictive model.

To build our model, we first calculated an equation to describe the growth of medical costs attributed to diabetes (MC) from 2007 – 2020 as represented in Figure 5, as this period is marked by consistent low inflation and further, is not confounded by effects of the pandemic.

Once the best fit equation was developed, we then applied the equation to generate figures for expected MC yearly to 2042, as seen in Table 1. Here, we make a critical assumption that the next 20 years will grow at a rate approximately equal to the rate of growth over the last 14 years.

These calculated yearly figure for MC became the basis for calculating indirect cost savings from its two components: savings from decreases in adverse event rate as discussed in section 1, and from consequent in productivity secondary to better long term glycemic control as discussed in section 2.

Table 1: Projected healthcare costs due to diabetes (in 2022 dollars)

YEAR		Healthcare cost (for U.S.)	Healthcare Cost (FOR MAINE)
2022	16	433.078	1.790
2023	17	475.572	1.965
2024	18	522.235	2.158
2025	19	573.477	2.370
2026	20	629.747	2.602
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2035	29	1462.230	6.042
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2039	33	2126.257	8.786
2040	34	2334.886	9.648
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2042	36	2815.565	11.635
	NET TOTAL (in billions)	\$ 27,096.82	\$ 111.97

In order to calculate how decreases in adverse event (AE) rate would translate to healthcare dollars saved, we relied heavily on the outstanding actuarial analysis by Pyenson in his 2010 work. In 2010, Pyenson et al created an elaborate and comprehensive actuarial analysis of

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expected costs for diabetes treatments for 2011-2031.²¹ With benefit of retrospective review in 2022, this actuarial analysis from 2010 has been uncannily accurate thus far with respect to predicting changes in the demographics of diabetics as well as the costs attributed to care.

Given the strength and sophistication of Pyenson's actuarial analysis,²² we have chosen to mirror his models concerning costs²³ as well as savings in costs relative to varying improvement in population level glycemic control²⁴ in constructing our calculations. Using Pyenson's now verified estimates, we take advantage of the incredibly sophisticated analysis Pyenson used to calculate a single number for each year and derive an equation describing how those savings increased over time.

It is critical to understand that it is not a straightforward calculation to estimate healthcare savings secondary to any intervention. There are many variables which must be considered. Pyenson's model predicting how costs of diabetes would rise for the next twenty years has been uncannily accurate for the first ten years, with benefit of hindsight analysis in 2022. We therefore apply this derived equation to our baseline calculated figures for MC and generate a figure for estimated savings in MC for each year until 2042, applying various corrective factors as appropriate. As an example, while the function Pyenson derived to calculate healthcare savings has proven accurate over the past decade, Pyenson applied this equation to estimations of total healthcare expenditures on diabetes which were somewhat frameshifted upwards, as we can see with the benefit of hindsight. Since the estimates were shifted upward by a constant factor, we applied this constant factor to correct downward the estimate of total medical costs we used to then apply Pyenson's equation to derive an estimate for healthcare dollar savings. Since our derived equation for amount of savings is calculated from Pyenson's accurate, reliable, and well populated data set, we feel this is the best realistic predictive model for calculating savings that might be expected in the future.

We are essentially carrying Pyenson's 2010 analysis forward on the best possible estimates we have for MC for the period 2022 - 2042, acknowledging Pyenson's analysis has proven uncannily accurate for 2011- 2020.

Applying the derived equation for savings to the data set of predicted MC for 2022 - 2042 already discussed, we can then determine a total dollar figure for savings expected in a generic insulin market as compared to a status quo insulin market going out yearly to 2042. Mirroring Pyenson, we calculate decreased costs for three scenarios: an estimate for the low range of realistic values (10% decrease in AE), an estimate utilizing assumptions that are at the high end

²¹ <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelppdf.ashx>

²² *Id.* at

²³ *Id.* at

²⁴ <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelppdf.ashx>. Table 3 from page 4, *see* Figure 6.

of realistic estimations (50% decrease in AE), and lastly, a set of assumptions representing a best guess (30% decrease in AE).

Figure 6: Figures are for the entire U.S – see footnote 13 (p.6) for method to calculate figure for Maine

Table 3: Reduction in Diabetes Related Complications, Associated Costs and Associated Mortality with 10% to 50 percent Improvement in Diabetes Control

	Reduction of Uncontrolled by 30%						Reduction of Uncontrolled by 50%	Reduction of Uncontrolled by 10%
	Commercial	Medicare	Medicaid	Other	Uninsured	Total	Total	Total
2011								
Number of reduced diabetes related complications	35,000	44,000	4,000	2,000	9,000	94,000	155,000	31,000
Savings from reduced diabetes related complications (million)	\$1,100	\$1,000	\$100	< \$50	\$100	\$2,300	\$3,800	\$800
Avoided deaths from reduced diabetes related complications	2,200	4,800	200	100	600	7,900	13,300	2,700
2031								
Number of reduced diabetes related complications	48,000	79,000	8,000	2,000	7,000	144,000	239,000	48,000
Savings from reduced diabetes related complications (million)	\$60,800	\$47,200	\$4,800	\$2,100	\$3,000	\$117,900	\$196,500	\$39,300
Avoided deaths from reduced diabetes related complications	10,900	14,700	1,600	500	1,500	29,200	48,700	9,700

Source: Milliman actuarial projection. Dollars are trended estimates for years. Diabetes related complications include stroke, myocardial infarction, amputation, ischemic heart disease, congestive heart failure, renal failure and blindness

2. Increase in productivity attributable to decreased rates of absenteeism and presenteeism and less early mortality

As with data and figures regarding medical costs for diabetes, the issue of loss of productivity has been extensively studied.²⁵ When cross-referenced with other datasets, a reliable estimation of dollar costs of lost productivity caused by diabetes can be calculated.²⁶ Loss productivity stems from three primary components: absenteeism, presenteeism and early mortality.²⁷

Recovery of this lost productivity is the second component of our calculation of indirect cost savings from transitioning to generic insulin. We constructed an equation describing the amount

²⁵ <https://diabetesjournals.org/care/article/41/5/917/36518/Economic-Costs-of-Diabetes-in-the-U-S-in-2017>. See Figure 7 which reproduces Table 6 from this piece.

²⁶ *Id.*

²⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5911784/>. Provides analysis of both direct and indirect health care expenditures secondary to diabetes in the U.S. in 2017.

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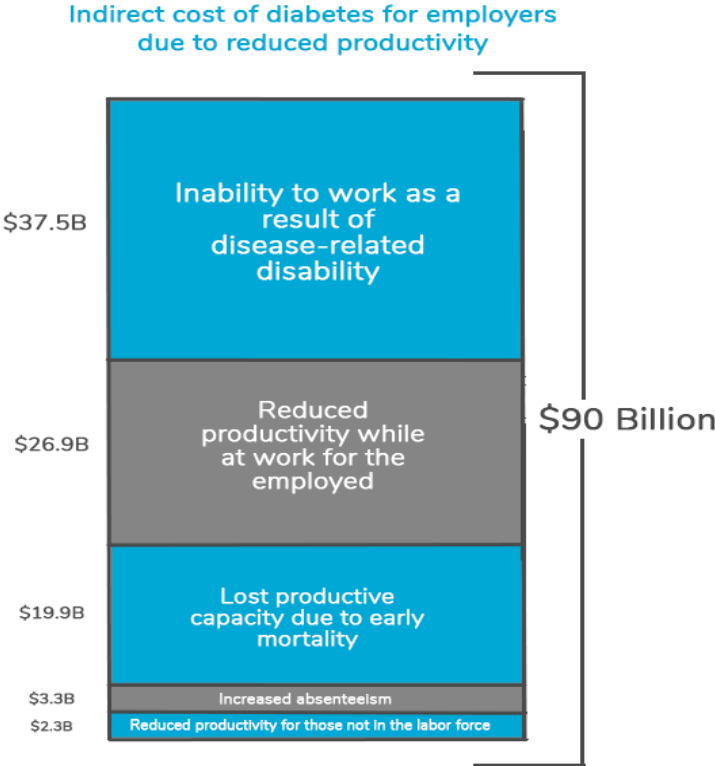
of productivity loss each year as a percentage of total costs, taking verified data points from 2007 – 2017 to construct the model.²⁸ See Figure 7 for example of the analysis for calendar year 2017.

Figure 7: Total productivity loss in U.S in 2017 = \$90B

Cost component	Productivity loss	Total cost attributable to diabetes (\$)	Proportion of indirect costs*
Work days absent	14 million days	3.3	3.7%
Reduced performance at work	114 million days	26.9	29.7%
Reduced productivity days for those not in labor force	14 million days	2.3	2.6%
Reduced labor force participation due to disability	182 million days	37.5	41.7%
Mortality	277,000 deaths	19.9	22.1%
Total		89.9	100%

Data source: analysis of the NHIS (2014–2016), CPS (2016), CDC mortality data, and U.S. Census Bureau population estimates for 2016 and 2017. *Numbers do not necessarily sum to totals because of rounding.

Figure 8: Applying column 3 in Figure 6 to estimate of \$90B lost productivity in U.S in 2017



²⁸ *Id.* for 2017 report. See <https://diabetesjournals.org/care/article/26/3/917/29192/Economic-Costs-of-Diabetes-in-the-U-S-in-2002> for 2002 report; see <https://pubmed.ncbi.nlm.nih.gov/18308683/> for 2007 report; see <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3609540/> for 2012 report.

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Using the equation generated to describe the function of increasing productivity loss costs with time, our model calculates losses secondary to lost productivity going forward, which are potentially recovered (losses “saved”) with better population-level glycemic control. These “productivity savings” are simply a percentage of total costs associated with diabetes, as reflected in Table 1. Calculating this figure from known data in 2017 and previously suggests these “productivity losses” are about 33% of total costs associated with diabetes. For our model, we have chosen to set this percentage at 20% to estimate a reliable floor for savings.

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1. How much money is saved directly in terms of spending less money on insulin?
2. How many heart attacks, strokes and other morbid conditions which disproportionately affect diabetics could be prevented with an easily available, inexpensive supply of insulin made by the State, and how much money would be saved as a result?
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Again, we hope this is of assistance to legislators and we are always available for questions or criticisms.