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February 17, 2023

Senator Joseph Baldacci, Chair
Representative Michele Meyer, Chair
Joint Standing Committee on Health and Human Services
100 State House Station
Augusta, Maine 04333-0100

Senator Baldacci, Representative Meyer, and Honorable Members of the Joint Standing Committee on Health and Human Services,

Please find attached a report on the work of the Commission established by Pursuant to Resolves 2021, Ch. 166, *Resolve, To Assess the Feasibility of the Production of Insulin in Maine*. The Commission was tasked with assessing the feasibility of the independent production of insulin in Maine and providing the insulin produced to low-income residents of the State at low or no cost through hospitals, pharmacies and health care providers in the State, or at a reduced cost on a means-tested basis.

As is noted in the report, the Department has not taken any position on the recommendations made by the commission. DHHS and the Administration will review and react to any proposals related to this work through the Committee process.

Finally, it should be noted that the Legislature did not provide any resources to the Department for the convening of the Commission, research, and writing of this report.

Sincerely,

A handwritten signature in cursive script that reads "Jeanne M. Lambrew".

Jeanne M. Lambrew, Ph. D.
Commissioner

Report: The Feasibility of the Production of Insulin in Maine

Introduction

[Resolve 2021, Ch. 166](#) (introduced as LD 1729, *Resolve, To Assess the Feasibility of the Production of Insulin in Maine*) instructed the Department of Health and Human Services (DHHS) to convene a Commission to assess the feasibility of the independent production of insulin in Maine and providing the insulin produced to low-income residents of the State at low or no cost through hospitals, pharmacies and health care providers in the State, or at a reduced cost on a means-tested basis. This report outlines the work of this commission to answer the questions outlined in the Resolve.

The commission involved participants offering a wide range of viewpoints, as outlined in the Resolve including a designee of the Commissioner of Health and Human Services; a representative of the Department of Health and Human Services (DHHS), Maine Center for Disease Control and Prevention; an individual involved in biomedical research; a representative of the Department of Professional and Financial Regulation, Maine, *Board of Pharmacy*; a representative of the Department of Professional and Financial Regulation, *Bureau of Insurance*; a representative of the University of Maine System; a resident of the State receiving treatment for diabetes or a representative of an organization that represents or advocates for residents of the State receiving treatment for diabetes; two physicians licensed to practice within the State having expertise in the treatment of diabetes and related complications; a research scientist having expertise in the synthesis or production of drugs or biologics; including insulin and insulin analogs; a representative of hospitals and health care providers within the State; and a representative of an organization that advocates for greater access to insulin and insulin analogs and that does not accept funding from an insulin or insulin analogs manufacturer.

The feedback reflected in this report is the product of commission-wide discussion and should not be assumed to be the position of individual members of the commission or the organizations or institutions that they represent.

Finally, while DHHS facilitated this commission, DHHS does not take a position on the recommendations from this group and will review and react to proposed statutory changes as they are developed. We have deep gratitude for the participants who contributed to these conversations.

Commission Participants:

Organization	Representative(s)
The Commissioner of Health and Human Services or the commissioner's designee	Anne-Marie Toderico, PharmD, RPh
A representative of the Department of Health and Human Services, Maine Center for Disease Control and Prevention	Allison Burden, PharmD, RPh
An individual involved in biomedical research	Sri Mohan, Chair of UNE department for Pharmaceutical Sciences

A representative of the Department of Professional and Financial Regulation, Maine Board of Pharmacy	Brad Hamilton, RPh
A representative of the Department of Professional and Financial Regulation, Bureau of Insurance	Violet Hyatt, RN
A representative of the University of Maine System	James Ward IV, VP of Economic Development and Innovation at UMaine
A resident of the State receiving treatment for diabetes or a representative of an organization that represents or advocates for residents of the State receiving treatment for diabetes	Kevin Moates
Two physicians licensed to practice within the State having expertise in the treatment of diabetes and related complications	Dr. Jerrold Olshan Dr. Sarah White
A research scientist having expertise in the synthesis or production of drugs or biologics, including insulin and insulin analogs	Jim Strickland
A representative of hospitals and health care providers within the State	Matt Marston, NLH VP Chief Pharmacy Officer Lisa Harvey McPherson, VP of Government Relations, Northern Light Health
A representative of an organization that advocates for greater access to insulin and insulin analogs and that does not accept funding from an insulin or insulin analogs manufacturer	Allison Hardt, T1 International
Public Members	Dr. Cristobal Alvarado, Parent of a child with Type 1 Diabetes Hilary Koch, Parent of a child with Type 1 Diabetes

Special thanks to Samantha Warren at the University of Maine System for her assistance and support to the commission.

The commission members were invited to three virtual meetings held on the following dates.

- November 17, 2022
- November 28, 2022
- December 6, 2022

Background and Context:

In the United States, 90% of [insulin is produced by three companies](#), Novo Nordisk, Sanofi and Eli Lilly. A [congressional report](#) on insulin pricing released in January 2021 found “multiple instances of companies increasing prices in lockstep with competitors.” Senator Ron Wyden,

Ranking Member on the committee that drafted the report, [stated](#) “[the]consumers are the only ones losing out in America’s broken drug pricing system” Given challenges within the system and increasing prices, one potential strategy to consider is whether a nonprofit or state-led manufacturer could offer alternative, lower pricing or otherwise influence pricing dynamics. In the past, regulations served as a barrier to introducing competition into the insulin market. [Effective March 23, 2020](#), insulins are now regulated as biologics under the Public Health Service (PHS) Act, as amended by the Patient Protection and Affordable Care Act, which makes way for biosimilar applications and competitors. A further regulatory barrier to biosimilar insulin is achieving a designation of interchangeability. A biosimilar insulin with an interchangeable designation could be [treated similarly to generic medications and be automatically substitutable](#) with the reference product. Generics, with automatic substitute status usually result in at least a 50% price decrease from their brand name reference product. Without a designation of interchangeability, biosimilars cannot be automatically substituted at the pharmacy counter which limits their effect on market prices. Non interchangeable biosimilars are associated with limited price decreases in the range of 15 percent. Additionally, the development of a biosimilar is estimated to cost between \$100 million and \$250 million and take approximately 7-8 years of development.¹

While there are many obstacles to the development of insulin and insulin analogs, there have been recent developments that point to increasing competition in the market. As described in detail below, CivicaRx, the Open Insulin Project, and the State of California have all begun to develop strategies to bring insulin products to market. A [report](#) published in BMJ Global Health has estimated the price reductions that could be achieved if numerous biosimilar products entered the market would bring the cost of treatment with insulin products to between \$72 and \$133 per year, as treatment with biosimilar regular human insulin (RHI) and insulin NPH could cost less than or equal to \$72 per year and with insulin analogues less than or equal to \$133 per year.

[Reports](#) estimate that over 30 million Americans have diabetes and more than 7 million of them require insulin. A new [study](#) published in the Lancet, estimates that the number of people with Type 1 Diabetes will more than double by 2040. The demand for insulin will only increase in the coming years, given that new data from [DiabetesJournals.org](#) indicate a large projected increase in young US populations with diabetes in the coming decades (a 65% increase for type 1 and 673% for type 2). According to a [study](#) completed by Yale researchers, 14% of the people who use insulin in the United States spend at least 40% of their post subsistence income (what is available after paying for food and housing) on insulin. This is described as a “catastrophic” level of spending on insulin which can impact people at all income levels. One commission member raised concerns that current market and inflation rates have contributed to increased financial duress among many Maine residents, which may further compromise their ability to afford insulin.²

¹ [Insulin insulated: barriers to competition and affordability in the United States insulin market | Journal of Law and the Biosciences | Oxford Academic \(oup.com\)](#)

² <https://www.hrw.org/report/2022/04/12/if-im-out-insulin-im-going-die/united-states-lack-regulation-fuels-crisis>

For those whom insulin is required to manage their diabetes, there are many potential side-effects and downstream impacts of failing to use their insulin as prescribed. Patients who are [unable to afford their insulin may be rationing their insulin supply](#), which in the short-term results in poor glycemic control. In the long-term uncontrolled (or poorly controlled) diabetes can lead to severe [complications](#) including heart disease, chronic kidney disease, nerve damage, vision problems, potential amputations, etc. Individuals who successfully manage their diabetes reduce their risk of these complications and the costly medical care that accompanies them. <https://www.hrw.org/report/2022/04/12/if-im-out-insulin-im-going-die/united-states-lack-regulation-fuels-crisis>

Commission Meetings

Over the course of three virtual meetings, commission members addressed in detail the questions posed in the LD. Additional feedback was gathered from commission members and other relevant stakeholders through a survey that was disseminated following the three virtual commission Meetings.

Feasibility Assessment:

Commission members developed responses to various questions posed in the Resolve to collectively assess the feasibility of producing insulin in the State through the University of Maine System and other appropriate institutions or through a public-private partnership between the University of Maine System, other appropriate institutions and a licensed drug manufacturer and the feasibility of providing the insulin produced to low-income residents of the State at low or no cost through hospitals, pharmacies and health care providers in the State or at a reduced cost on a means-tested basis.

1. The number of low-income residents of the State who currently require insulin

While the Resolve directed commission members to consider the number of low-income residents of the State who currently require insulin, the commission encourages the inclusion of all Mainers who require insulin to treat their diabetes when completing this assessment. While low-income residents may face significant financial obstacles in accessing insulin, there are other reasons individuals across income statuses could face access risks. Examples include a lapse in insurance, (including the loss of a job which results in loss of insurance, or a child aging off from their parent's insurance coverage), an emergent need for insulin (e.g., if a vial of insulin has been damaged or an unexpected need for insulin arises when away from home), among many other unforeseen situations.

Multiple studies have indicated the extent to which patients ration their insulin, including a study in the [Journal of the American Medical Association](#) which estimated that at one large urban diabetes center, one in four patients were rationing their insulin and [findings from T1 International](#), that indicates among respondents, one in every four people worldwide reported underusing their insulin at least once in the last year due to high cost. This highlights that the need for affordable insulin has a broad impact. A report from the [Annals of Internal Medicine](#) found that 1.3 million Americans with diabetes rationed their insulin which represents 16.5% of

the people to whom insulin is prescribed. Additionally, as described above, 14.1% of those requiring insulin reached “catastrophic” levels of spending on their insulin. This catastrophic level of spending was 61% less likely among Medicaid beneficiaries than among Medicare beneficiaries, suggesting that factors other than income play a role.³

The American Diabetes Association has [estimated](#) that approximately 115,001 people (10.4%) of the adult population in Maine have been diagnosed with diabetes, with an estimated additional 32,000 people who have diabetes, but are not yet aware of it. Further, it is estimated that approximately 373,000 people (35.15% of the adult population) have prediabetes in Maine. While it is difficult to pinpoint the exact number of Mainers who use insulin to manage their diabetes, [research](#) has shown that [approximately 5-10%](#) of those with diabetes have Type 1 Diabetes (previously known as Insulin-Dependent Diabetes) and [estimates](#) that approximately 23% of those with Type 2 Diabetes use insulin to manage their diabetes. For calendar year 2021, 4,650 MaineCare members received insulin through the MaineCare Pharmacy Benefit.

2. The ability of the University of Maine System by itself, in partnership with another appropriate institution or through a public-private partnership with a licensed drug manufacturer to produce insulin and insulin analogs in an amount sufficient to fulfill the needs of low-income residents of the State who require insulin

Commission member James Ward IV, Vice President for Innovation and Economic Development at University of Maine, noted that challenges related to producing insulin and insulin analogs within the State are significant. Within the UMaine system, there are no facilities that could be adapted to manufacture insulin or insulin analogs at this time, and any facility for this purpose would need to be built. Therefore, as there is currently no drug manufacturing occurring in the State of Maine, any manufacturing would involve the development, completion, and FDA approval of a facility in which to do so.

The LD 1729 commission highlighted the need to ensure that budget appropriations are available to cover the cost of both the development of a manufacturing facility, additional costs for the development of insulin products and their regulatory approval, and for the running of the facility. Furthermore, the commission highlighted that it would be prudent to consider that any facility developed to produce insulin or insulin analogs within the State of Maine distribute these products to every resident of Maine requiring insulin, regardless of income status, and potentially expand distribution to residents of other states as a mechanism to recoup development and manufacturing costs.

As highlighted below in Question 5, the State of California, CivicaRx and the Open Insulin Project are three models in development for the production of insulin.

³ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01788>

3. Any long-term cost savings and revenue generation for the State and the University of Maine System

While a full economic analysis to identify the potential for cost-savings and revenue generation is beyond the scope of this report, there are many factors to consider that could potentially drive cost-savings. The development of an insulin manufacturing facility could drive job growth in the State of Maine. These new jobs could potentially bring new residents to the State, driving increases in revenue. As the commission notes above, the distribution of insulin products beyond just low-income residents of Maine, to all Mainers requiring insulin and individuals in other states who require insulin provides the potential for revenue generation and a return on investment.

The commission noted that access to affordable insulin could also impact the possible complications of diabetes in a positive manner and increase savings to the state. One commissioner stated that, “with a stable supply of insulin that is used without fear of it ‘running out,’ many of the secondary conditions can be postponed or even lessened in their severity when they finally do occur. The positive knowledge of knowing that a needed medicine will be there allows the user to put their mind to staying well and other quality of life activities with the health benefits that provides.” The possible cost savings on healthcare (by [assumed decreased occurrences of secondary complications such as retinopathy, nephropathy, neuropathy, etc.](#) due to access to affordable insulin) would positively impact both the individual and the state.

4. Any long-term cost savings and other benefits to low-income residents of the State who would receive insulin and insulin analogs at low or no cost

The commission notes that the cost of insulin can represent a significant burden to individuals, regardless of their income status. While the direct cost of insulin is an important piece of the benefits to individuals, there are added benefits to those who could receive insulin at low or no cost. Members of the commission highlighted that when an individual’s cost for insulin is reduced, the individual may be able to use that savings to access additional tools to manage their diabetes that they could not have otherwise afforded, like continuous glucose monitors, improving their overall health. This improved health could translate into reduced burden on the healthcare system, such as reduced diabetes complications and ER utilization.

Additionally, for some individuals the cost of insulin may force them to choose between their medication and other necessities. By reducing or eliminating the cost of the insulin, individuals can more fully meet their basic needs, improving their quality of life and in many cases their overall health.

Research has estimated that in the United States, the [average cost](#) for Medicare for insulin is approximately \$4,000 per individual, annually as compared to the cost in Canada of \$787 per individual annually. While difficult to assess the actual costs of insulin to patients in the State, the average monthly out of pocket cost for MaineCare members for their insulin is \$4.30. The co-pay for MaineCare members is \$3.00 and MaineCare members average 1.43 insulin prescriptions per person, per month (in calendar year 2021, 4,650 MaineCare members received insulin through the MaineCare Pharmacy Benefit.) This number is reflective of the number of

people receiving MaineCare, not the total population of people with diabetes in the state of Maine.

5. Any costs to the University of Maine System and to the State to produce and distribute insulin and insulin analogs, including additional administrative costs

In order to produce insulin in the State of Maine, a manufacturing facility would need to be developed. In July 2022, [California announced](#) its plans to manufacture and distribute insulin. Initially, California has allotted \$50 million to contract to acquire insulin from a manufacturing partner, with aims to get the product to market by 2024. California has additionally allotted \$50 million for the development of an in-state insulin manufacturing facility. A distribution plan has not yet been announced.

Another model, CivicaRx has indicated they are raising [\\$125 million](#) to cover the cost of developing three insulin products (glargine, lispro and aspart) in both vial and disposable pen form, including necessary clinical trials and other associated costs. CivicaRx reports an additional \$140 million in costs for the creation of a facility to develop this insulin. As stated previously, CivicaRx has contracted with GeneSys, which has made investments in both capital equipment and Research and Development costs, estimated to be \$50-100 million⁴. These costs represent start-up costs and are not ongoing costs. CivicaRx has estimated the release of their insulin products in 2024.

Open Insulin, has [identified potential costs](#) for an ongoing small-scale system to serve an estimated 13,000 (range of 4,000 – 45,000) people with diabetes. The estimated overall cost of equipment is \$949,500, with salaries estimated at \$1 per vial, quality processes estimated at \$2.70 per vial, packaging estimated at \$1 per vial, consumables at \$1 per vial and rent at \$1.30 per vial.

A report published by the [Journal of Law and the Biosciences](#) estimated the development of a biosimilar to cost between \$100 million and \$250 million and approximately 7-8 years of development. [In testimony provided by the Interbiome Foundation](#) on the public production of insulin, estimated launch costs of \$48 million dollars and \$8 million dollars of operating costs for two standardized Insulin-Production-Pilot facilities, with an approximate two-year timeline.

Commission members have highlighted that in addition to the cost of developing a manufacturing facility, there are significant investments to be made in order to bring an insulin or insulin analog product to market, including regulatory and licensing costs.

6. State and federal regulatory or legal obstacles, including requirements for licensure, to the production and distribution of insulin and insulin analogs within the State by the University of Maine System or other appropriate institutions

CivicaRx has highlighted the process they are using to bring their products to market. Allan Coukell, the Senior Vice President of Public Policy of CivicaRx shared that in order to develop biosimilar insulin, they conducted analytical and clinical studies that are consistent with FDA

⁴ Allan Coukell, Senior Vice President of Public Policy for CivicaRx.

guidance. Additionally, there are FDA inspections of the drug substance manufacturing and finished dose facilities that will be carried out during the FDA review of the Biological License Application submissions and/or other FDA filings they may make.

To develop a manufacturing facility there are state licensure requirements that would need to be met. Manufacturers of prescription drugs must be licensed through the [Maine Board of Pharmacy](#). Licenses are renewed on an annual basis for a fee of \$200. According to chapter 117 of the [Maine Pharmacy Act §13800-D](#), manufacturers selling more than 500,000 units of insulin in Maine per year must pay a registered fee of \$75,000.

2009 FDA Guidance for Industry titled “[Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing](#)” notes the 21 CFR part 207 indicates that pharmaceutical manufacturers must register with FDA within 5 days of the time when they start manufacturing.

Current Good Manufacturing Processes (cGMP) that must be followed when producing both drug substances (final active substance) and drug product (final finished product) are covered in 21 CFR Part [210](#) and [211](#) respectively. Compliance with cGMP must be demonstrated in the pre-approval inspection and regular FDA facility audits can be expected, likely every 2-3 years, in order to ensure that the facility is in good standing and in compliance with cGMP and other requirements related to the manufacture of the specific drugs produced in the facility. Failure to comply with regulations can lead to Form 483 observations, warning letters, or a consent decree from the FDA.

7. Available alternative methods for providing insulin and insulin analogs to low-income residents of the State at low or no cost

[CivicaRx](#) announced in [March 2022](#) their plans to manufacture and distribute 3 insulins, in both vial and disposable pen forms, that will be sold at one low and transparent price for all. CivicaRx will manufacture glargine (Lantus), lispro (Humalog) and aspart (Novolog) to be sold at no more than \$30 per vial or \$55 per box of five pre-filled pens. These insulins are expected to become available in 2024. CivicaRx is interested in partnerships with entities, such as state purchasers, who wish to procure low-cost insulin for their stakeholders.

The [Open Insulin Foundation](#) is working to develop a small-scale, community-centered model for insulin production, with the goal of making insulin accessible to all. The Open Insulin Foundation is creating an open-source model for insulin production, developing protocols to produce both short-acting (lispro) and long-acting (glargine) insulin, as well open-hardware equivalents to traditional production equipment. Additionally, they are researching regulatory pathways to bring the insulin to the public.

In California, Santa Clara County created a \$1 million needs-based grant program ([MedAssist](#)) for people who use insulin (as well as asthma inhalers and epinephrine injections (e.g., EpiPen)). The MedAssist program supports individuals who may be enrolled in a health insurance program

but still have high out of pocket costs. Residents of Santa Clara can apply to receive financial assistance.

The [Center for Medicare and Medicaid Services](#) is testing the impact of a model through Medicare Part D to lower the out-of-pocket costs for insulin. This would be a change to the Medicare Coverage Gap Discount Program (the “discount program”) to allow participating Part D sponsors, through eligible enhanced alternative Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug plans (MA-PDs), to offer a Part D benefit design that includes stable, predictable copays for select insulins (no more than \$35 per prescription for the month's supply) in the deductible, initial coverage, and coverage gap phases.

For residents of Maine who receive MaineCare, copays are \$3.00 per prescription. The MaineCare formulary includes the following products available as preferred agents without a prior authorization: Humalog branded lispro, and Novolog branded aspart, rapid acting insulins; Lantus branded glargine and Levemir® branded detemir, long-acting insulins.

[ArrayRx](#) offers a state sponsored drug discount card on behalf of Nevada, Oregon and Washington. All FDA approved drugs are available to citizens of these states at a discount that ranges from 18 – 80%. ArrayRx uses the states combined purchasing power to lower drug costs for uninsured and underinsured individuals, state agencies, labor organizations, and other groups. ArrayRx [offers](#) drug discounts to any resident of Washington and Oregon and was expanded to Nevada residents in September 2022. Their current price for Humalog is \$30.81 for a 30-day supply.

Walmart, with a private label approval and distribution, has had a line of **human insulin** (ReliOn Novolin-N, ReliOn Novolin-R, and ReliOn Novolin 70/30) available at \$24.88 a vial, without insurance or need for a prescription, [since 2000](#) (the ReliOn Novolin 70/30 pens were released in 2018 for \$42.88 a pack). In 2021, [Walmart announced](#) the launch of a first-ever private brand **analog insulin**. Through a partnership with Novo Nordisk, ReliOn NovoLog insulin (insulin aspart) injection was made available, with analog insulin vials at a cost of \$72.88 and Flexpen at \$85.88 (by prescription only).

Prescription Assistance Programs

[Lilly Insulin Value Program](#): Through Lilly’s Insulin Value Program, insulins are available for \$35 per month for those who are commercially insured, or those who have no insurance and cover all Lilly insulins.

[Novo Nordisk](#): Through NovoCare Patient Affordability and Access Support, eligible patients with commercial insurance or those who are uninsured can pay \$99 per month for a monthly supply of combination Novo Nordisk insulin products (up to 3 vials or 2 packs of pens).

[Sanofi](#): Insulin Valyou Savings Program: Patients may pay \$35 per month for one or multiple Sanofi insulins. For this pricing to apply, all Sanofi insulins must be filled at the same time, together each month. The Sanofi insulins included within the program include specified formulations of Admelog, Apidra, Toujeo and Lantus. To be eligible for this program, an individual must have no prescription medication insurance.

While Prescription Assistance Programs (PAPs) offer a potential path to cost-savings for individuals requiring insulin, the commission notes that there are limitations to these programs. PAPs are run by manufacturers and are not established via law. It is at the discretion of manufacturers to change their requirements or discontinue them at any time. PAPs have specific requirements that determine eligibility. One commission member notes that many programs, such as these, are not available to people who receive government insurance (Medicare, Medicaid, VA, TRICARE, etc.), and that some discounts are not applicable or have reduced benefit (higher out of pocket allotments) for the uninsured. As insulin is a life-saving medication, these stringent requirements and complex application processes limit their utility for patients who are in need.

8. Options for capping copayments for insulin and insulin analogs provided through private insurers

On August 16, 2022, the Inflation Reduction Act was signed into law. The bill caps cost-sharing under the Medicare prescription drug benefit for a month's supply of each prescription covered insulin product at \$35 beginning in 2023⁵.

As of 2022, there are approximately 22 states that have capped insulin out-of-pocket (co-pay) charges, ranging from \$25 to \$100 per month. While there are benefits to capping copayments, there are also limitations. These bills may only apply to insurance plans offered by the state, and do not extend to employer-sponsored insurance plans, additionally, these benefits do not extend to those without health insurance.^{6,7} Two states have established limits on the cost of insulin:

- In New Hampshire, a [2020 law](#) set limits on the pricing on insulin products, requiring insurers to limit an individual's insulin costs to \$30 per 30-day supply, after a deductible is applied.
- [Colorado's legislation](#) establishes a \$100 cap on a person's entire 30-day supply of prescription insulin, regardless of the number of prescriptions a person may have. Additionally, Colorado law requires pharmacists to provide eligible individuals with access to one emergency prescription insulin supply within a 12-month period, not to exceed \$35 for a 30-day supply and creates an insulin affordability program through which pharmacists provide eligible individuals with prescription insulin for 12 months, not to exceed \$50 for a 30-day supply.

In Maine, legislation has been enacted to support access to insulin. The [Insulin Safety Net Program](#), among other items, establishes requirements for Manufacturer's Patient Assistance Programs and allows pharmacies to dispense a 30-day supply of insulin to eligible individuals who are in urgent need. Additionally, the Legislature has enacted [An Act to Save Lives by Capping the Out-of-pocket Costs of Certain Medication](#) (Public Law 2019, Ch. 666), which restricts the out-of-pocket costs (deductible, copayment, coinsurance or other cost-sharing requirement) of insulin to not exceed \$35 per 30-day supply, regardless of the amount, type, or

⁵ <https://www.congress.gov/bill/117th-congress/house-bill/5376/text>

⁶ <https://www.ncsl.org/research/health/diabetes-health-coverage-state-laws-and-programs.aspx>

⁷ The Problem with Insulin Copay Caps - [Biologix - Help Us Save Lives with Affordable Insulin](#)

number of insulin drugs needed to fulfill an individual's prescription, up to twice a year, sunseting in 2027. [PL19, Ch. 666](#) and [PL21, Ch. 20](#) allow for emergency refills by pharmacists for a 30-day supply for a \$35 out of pocket cap per insulin prescription. No supplies are covered.

It is important to note that a government entity cannot cap the cost of insulin for the uninsured.

For other cost-savings information, see Prescription Assistance Programs above.

9. The potential for the State to engage in volume purchasing of insulin and insulin analogs at reduced cost

The federal drug importation regulations [exclude biosimilar medications](#) from importation.

It is also unlikely that 340B would provide meaningful direct relief to the citizens of Maine on insulin prices.

The commission could not identify other examples of bulk purchasing relevant to this endeavor. However, please see the response to Question 11 for additional information related to examples of collaborative purchasing.

10. The mechanisms by which the State could establish a program to distribute insulin and insulin analogs to residents of the State

There are many models for distribution that would allow for insulin or insulin analogs to be distributed to residents. The commission has urged that any distribution models focus on direct to home distribution, rather than through health care systems. The commission identified models that were developed through the COVID-19 pandemic utilizing the United States Postal Service, and highlighted a model used by the State of Michigan to distribute vaccines publicly (see question 12). USPS is already contracted to deliver most prescriptions processed by large Pharmacy Benefit Managers (PBMs), such as Express Scripts⁸

The Veterans Health Administration manages pharmaceutical distribution through third party vendors, and previously operated an in-house pharmaceutical distribution model, and could potentially provide expertise on both models. Other potential sources to distribute insulin or insulin analogs include public hospitals and quasi-public institutions (community health centers), working closely with public wholesale distributors.⁹

In Florida, the [Insulin Distribution Program](#) provides a safety-net program that is to be used when residents have no other resources for insulin. Through [Florida's Department of Public Health](#), they maintain a Central Pharmacy and other pharmacies within some of their County Health Departments. The Florida model allows their Central Pharmacy and County Health Departments (with a licensed pharmacy) to fill insulin prescriptions for clients meeting criteria including: those who are uninsured or lack insurance that covers insulin, those whose insurance has a large deductible or copay that the person cannot afford, those who have a net family

⁸ Public Pharmaceuticals State Policy Kit (December 2022), Dana Brown and Tom Latkowski, Democracy Policy Network, Democracy Collaborative and T1International

⁹ Public Pharmaceuticals State Policy Kit (December 2022), Dana Brown and Tom Latkowski, Democracy Policy Network, Democracy Collaborative and T1International

income below 100% of the FPL, those that have no more than \$2,500 in private funds, bank accounts, or assets (other than a homestead) and are not a current Medicaid recipient, etc.

Washington state has a legislative work group working directly with their retail pharmacies to determine if a similar model can be established.¹⁰ Similar to Washington, Maine relies on our current privately owned retail pharmacy system.

11. Opportunities to establish an interstate compact with other New England states to reduce insulin and insulin analog costs in compact states

MaineCare, as a Medicaid agency, participates in an interstate drug purchasing consortium with other Medicaid agencies. The purpose of this consortium is to leverage better supplemental rebates on prescription drugs covered by the program. The state benefits from these proprietary rebates on MaineCare pharmacy claims.

[ArrayRx](#) provides an example of a collaborative which aims to reduce the cost of prescription drug costs. ArrayRx began as a collaboration between two states, Washington and Oregon, and has expanded to include Nevada. The model is a pooled drug cost negotiation model to access the lowest costs for prescription drugs for residents of their states. ArrayRx, a state sponsored prescription drug discount program, highlights that discounts range from 18-80% of prescription drugs. The model used by ArrayRx does not currently offer any centralized storage or distribution.

In March 2022, Blue Cross-Blue Shield announced their intent to partner with CivicaRx to offer low-cost insulin. In Vermont, Blue Cross-Blue Shield Vermont similarly announced the partnership to ensure residents of Vermont will have access to low-cost insulin, estimated at \$30 per vial, in 2024 when Civica begins distributing insulin products. Here is a press release from BCBS VT [Civica Rx Partnership | BlueCross BlueShield of Vermont \(bluecrossvt.org\)](#) Rx Partnership | BlueCross BlueShield of Vermont (bluecrossvt.org)

12. Opportunities to establish a public entity to manage the purchasing and distribution of insulin and insulin analogs with the possibility of eventual transition to a private entity

ArrayRx provides an example of a collaborative which aims to reduce the cost of prescription drug costs. ArrayRx began as a collaboration between two states, Washington and Oregon, and has expanded to include Nevada. The model is a pooled drug cost negotiation model; Nevada, Washington and Oregon combine their covered lives into a stronger negotiating position with the drug manufacturers to acquire steeper discounts for their citizens on these products.

ArrayRx offers two levels of participation to states: member state level and program participant level. To be a Member State, states must enact a statute (legislation) with language that supports cooperation with other states and regional consortia. Member States then appoint one person to participate in the ArrayRx Advisory Council as well as one voting member to the ArrayRx Steering Committee. Alternatively, to be a Participating Program, the state need not enact a statute. Instead, the state is required to create a services contract between itself and ArrayRx.

¹⁰ Democracy Policy Network: Public Medications State Policy Briefing (56:19)

Participating Program states do not get to participate in the advisory council nor the steering committee. The services currently offered by ArrayRx include PBM programs, workers compensation services, prescription drug voucher services, and state-sponsored prescription drug discount cards.

13. Opportunities to establish a model facility to affordably manufacture insulin and insulin analogs and to distribute insulin and insulin analogs to residents of the State

In July 2022, California announced its plans to manufacture and distribute insulin. Initially, California has allotted \$50 million to acquire insulin from a manufacturing partner, with aims to get the product to market by 2024. California has additionally allotted \$50 million for the development of an in-state manufacturing facility. No distribution plan has been announced.

In Massachusetts, [MassBiologics](#) (a public biopharmaceutical research, development, and manufacturing enterprise) is associated with the University of Massachusetts and receives appropriations from the legislature amongst other sources of income. MassBiologics [manufactures](#) Tetanus and Diphtheria Toxoids, Adsorbed (Td) vaccine which is distributed to Massachusetts residents at no charge.

Michigan has a history of public sector biologics with [Michigan Biologics Laboratories](#). The products produced by Michigan Biologics Laboratories included vaccines, which were [distributed free to Michigan residents](#), and some were sold at cost to other states and through contracts with NGOs. Once the demand for the vaccines decreased in 1998, Michigan Biologics Laboratory, a government enterprise, became Michigan Biologics Product Institute, a private entity.

The 2 state-run manufacturing facilities in Massachusetts and Michigan allowed the citizens of their respective states to continue to receive Tdap vaccine during a nationwide shortage in the 1980's.¹¹ As described in Question 7, both CivicaRx and the Open Insulin Foundation are developing models of production that can be reviewed as a model facility examples.

14. Opportunities to procure dedicated funding to support the manufacture of insulin and insulin analogs and the distribution of insulin and insulin analogs to residents of the State

If the state pursues the route of manufacturing insulin and insulin analogs, the commission wishes to highlight the need to have budget appropriations to support the development of a manufacturing facility. California has placed the \$100 million (\$50 million for procurement and \$50 million for production) for their proposal in the state budget. CivicaRx notes that funds required to develop their insulin products are coming from numerous philanthropic sources, including Juvenile Diabetes Research Foundation (JDRF), Helmsley Trust, Kaiser Permanente and many others. The commission would like to emphasize that if insulin were to be distributed more broadly than to Maine state residents that could increase the number of potential donors interested in funding the projects.

¹¹ Public Pharmaceuticals State Policy Kit (December 2022), Dana Brown and Tom Latkowski, Democracy Policy Network, Democracy Collaborative and T1International

Appendix A: Generic Insulin Economic Impact Assessment

The Generic Insulin Economic Impact Assessment was created by commission member, Cristobal G. Alvarado, with Sebastian E. Alvarado and has not been endorsed by the Commission.

Cristobal G. Alvarado

Sebastian E. Alvarado

01.13.23

Economic Impact Assessment of production of generic insulin

CONCLUSION: The State of Maine could save \$330 million at 4 years, \$660 million at 7 years and \$1600 million (\$1.6 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. The most conservative estimate of direct savings alone suggests a possible savings of \$125 million at 4 years, \$200 million at 7 years and \$300 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 estimation of this *Insulin Dividend* based upon variables that can be adjusted along a range of values.

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.¹²

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.¹³ With benefit of hindsight, we can see that his estimation of

¹² <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.

¹³ <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelp.pdf.ashx>

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 (2023 – 2042).¹⁴

Table 1: Projected healthcare dollar costs of diabetes, 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:

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

indirect = expected saving from improvement in productivity, absenteeism and presenteeism + healthcare \$ 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.

The addendum concludes by presenting a dashboard which will allow quick calculation of the “Insulin Dividend” that can be expected based on sliding values for six critical variables:

¹⁴ As listed in Table 1.

1. Proportion of Maine diabetics utilizing MaineInsulin.
2. Price charged per non generic vial
3. Effect of lowered HbA1c on rate of adverse events
4. Effect of lowered HbA1c on productivity/absenteeism/presenteeism
5. Expected rate of inflation
6. Time interval

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.

Using the **least** speculative (most conservative) assumptions, we calculate a cumulative savings of:

- \$ 330M in 4 years,
- \$ 660M in 7 years,
- \$ 1200M (\$1.2 billion) in 10 years.

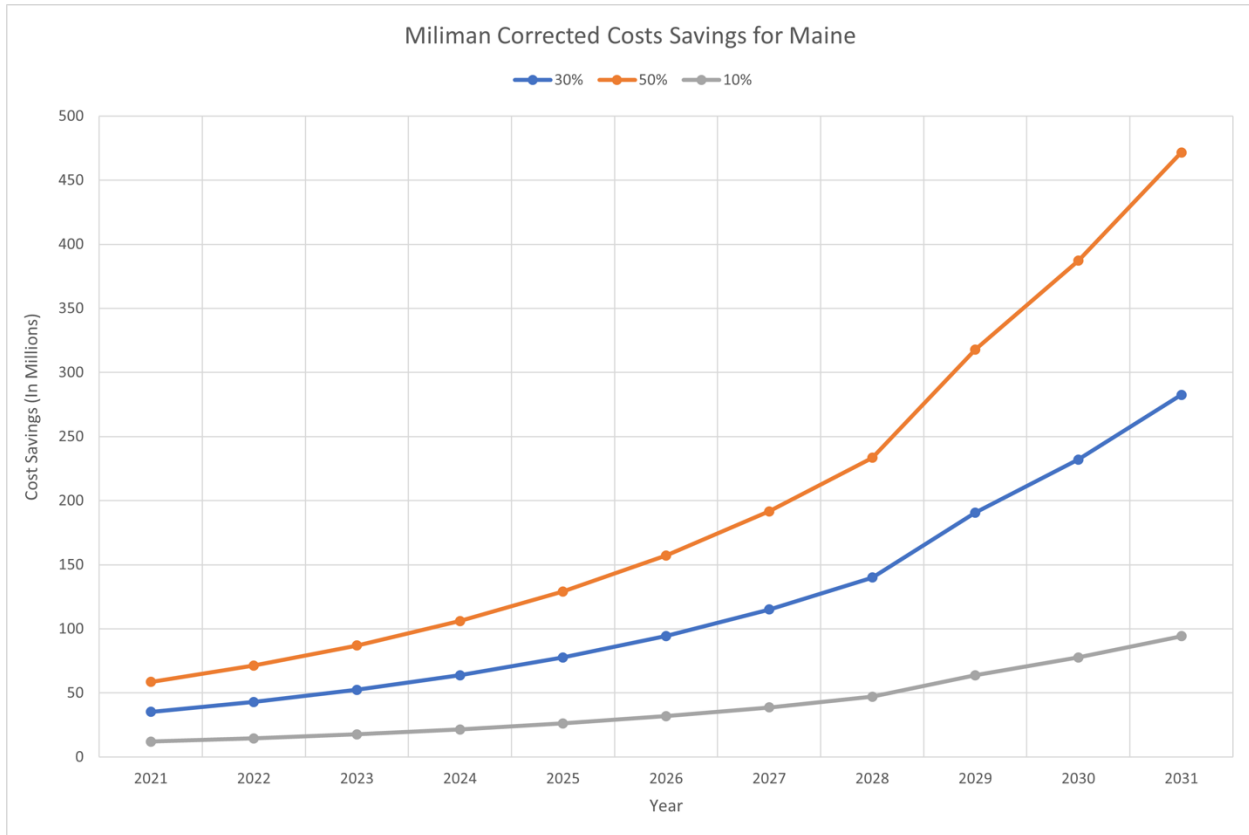
Utilizing the **most** speculative realistic (most liberal) estimations, we calculate a cumulative savings of:

- \$ 1600M (\$1.6 billion) at 4 years,
- \$ 3350M (\$3.35B) at 7 years,
- \$ 5700M (\$5.7B) at 10 years.

Our **“best guess”** scenario calculates a cumulative savings of:

- \$ 743M at 4 years,
- \$ 1600M (\$1.6 billion) at 7 years,
- \$ 2700M (\$2.7 billion) at 10 years.

Figure 1: Yearly savings of transitioning to widely available generic insulin for given decrease in adverse events



DISCUSSION:

President Biden has said several times recently that “Capitalism without competition is exploitation”.¹⁵ 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.”¹⁶ 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.¹⁷ 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.

¹⁵ <https://www.businessinsider.com/biden-slams-capitalism-without-competition-as-exploitation-consumers-workers-corporations-2022-1?op=1>

¹⁶ <https://www.thestudentperspective.org/post/insulin-does-not-belong-to-me-it-belongs-to-the-world>

¹⁷ See Figure 3.

Prevailing consensus is that a vial of insulin can be produced for less than \$10 per vial using modern molecular biological techniques.¹⁸

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.¹⁹ 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.²⁰

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 aggregate estimation of how much money is spent directly on insulin by any entity²¹ and then compare this figure to the amount expected to be spent if generic insulin were substituted.²²

In 2017, total spending on insulin was slightly less than \$15 billion (\$14,981,000,000).²³ Since Maine has 1/242 the population of the US based on recent census data,²⁴ 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,²⁵ as follows.

According to the American Diabetes Association (ADA), approximately 115k Mainers have diabetes.²⁶ For purposes of our calculations, we have noted that 5-10% of diabetics are known to be entirely insulin dependent (also called Type I).²⁷ The ADA estimated 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 150k Mainers who are Type II diabetics.

¹⁸ <https://gh.bmj.com/content/3/5/e000850>.

¹⁹ <https://easydrugcard.com/healthy-living-tips-blog/healthy-living-tips/how-much-does-insulin-cost-in-america-2021-updated/>

²⁰ <https://legislature.maine.gov/statutes/32/title32sec13725.html>

²¹ 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>.

²² <https://gh.bmj.com/content/bmjgh/3/5/e000850.full.pdf>.

²³ <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*.

²⁴ 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.

²⁵ See Figure 2.

²⁶ https://diabetes.org/sites/default/files/2022-01/ADV_2021_State_Fact_sheets_all_rev_1.27_ME.pdf.

²⁷ <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:

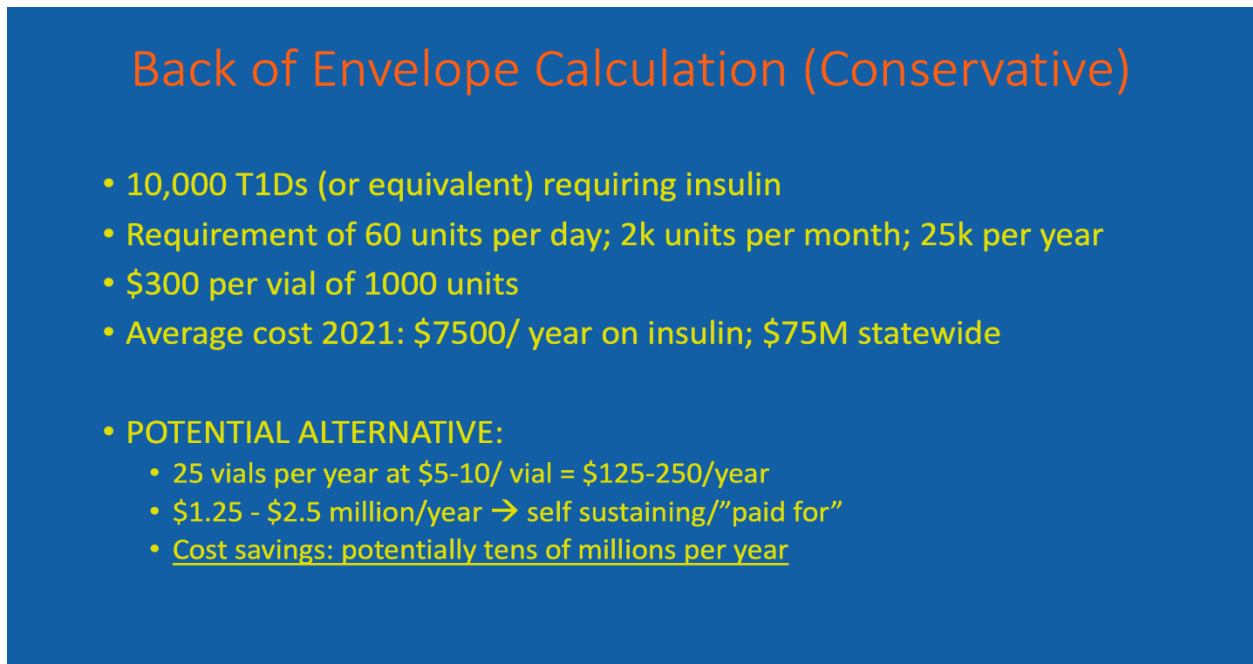
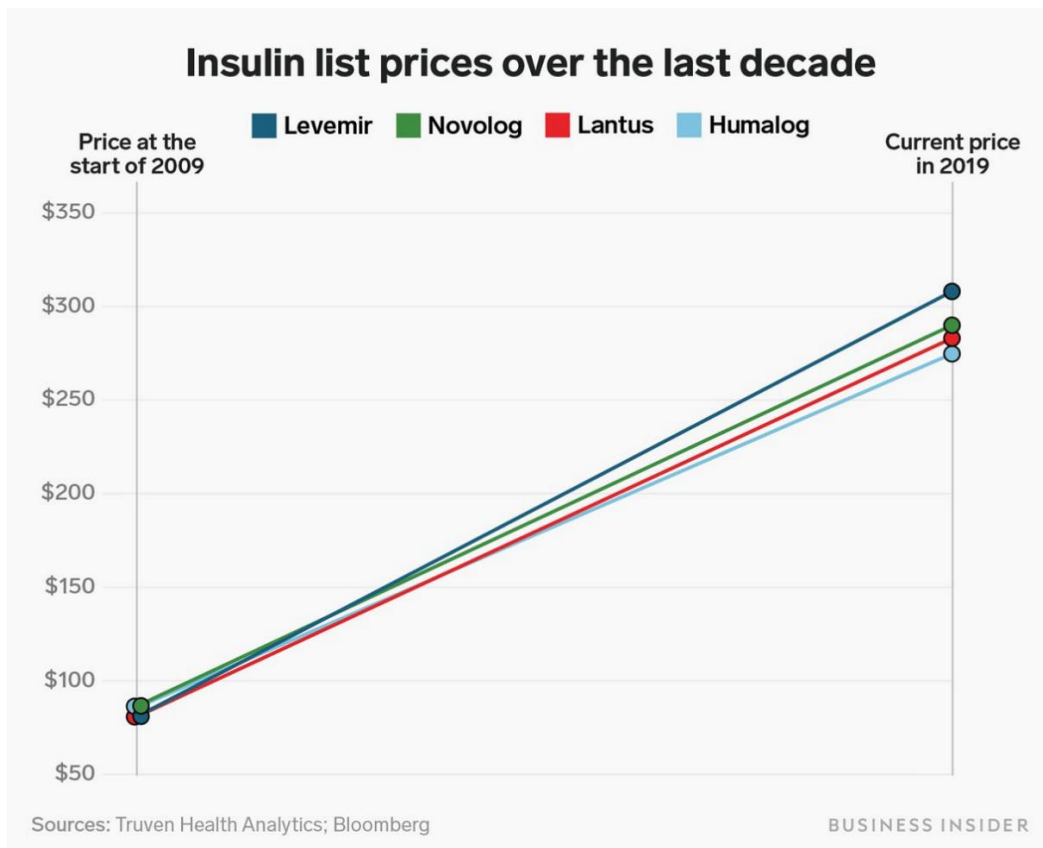


Figure 3:



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,²⁸ 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).²⁹
2. Better glycemic control (lower HbA1c) decreases the number of adverse events in the diabetic population, which consequently lowers healthcare costs.³⁰ See Figure 4.

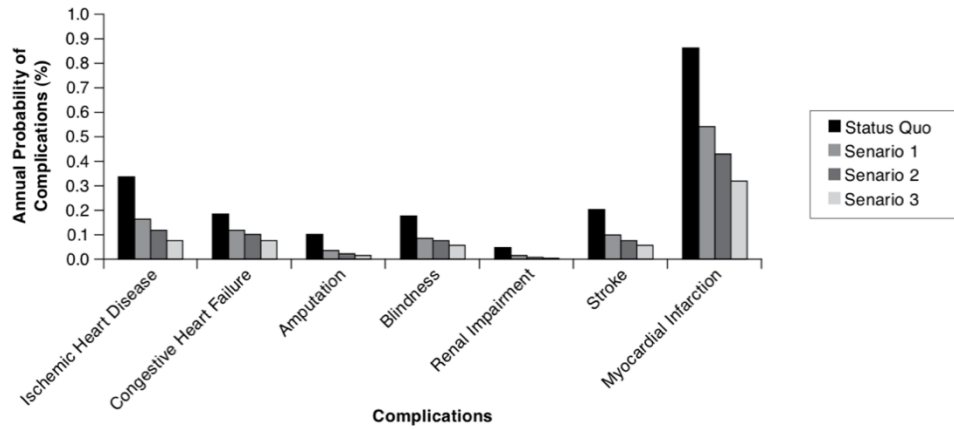
²⁸ See Figure 3.

²⁹ <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.

³⁰ <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelppdf.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>.

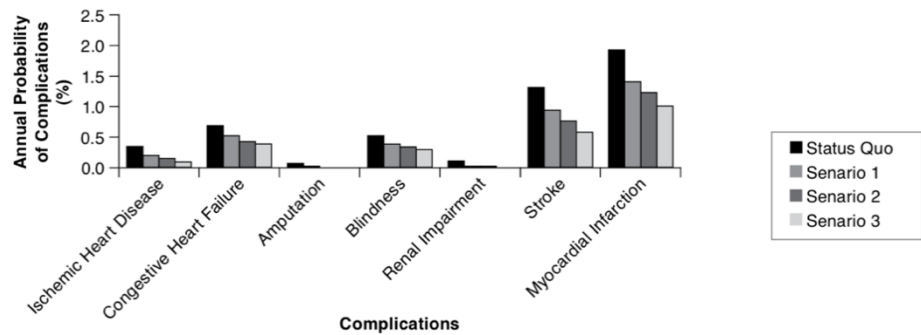
3. Figure 4:

FIGURE 3 Impact of Better Control on Probability of Complications for Commercially Insured Type 2 Diabetes



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

FIGURE 4 Impact of Better Control on Probability of Complications for Medicare Type 2 Diabetes



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

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%

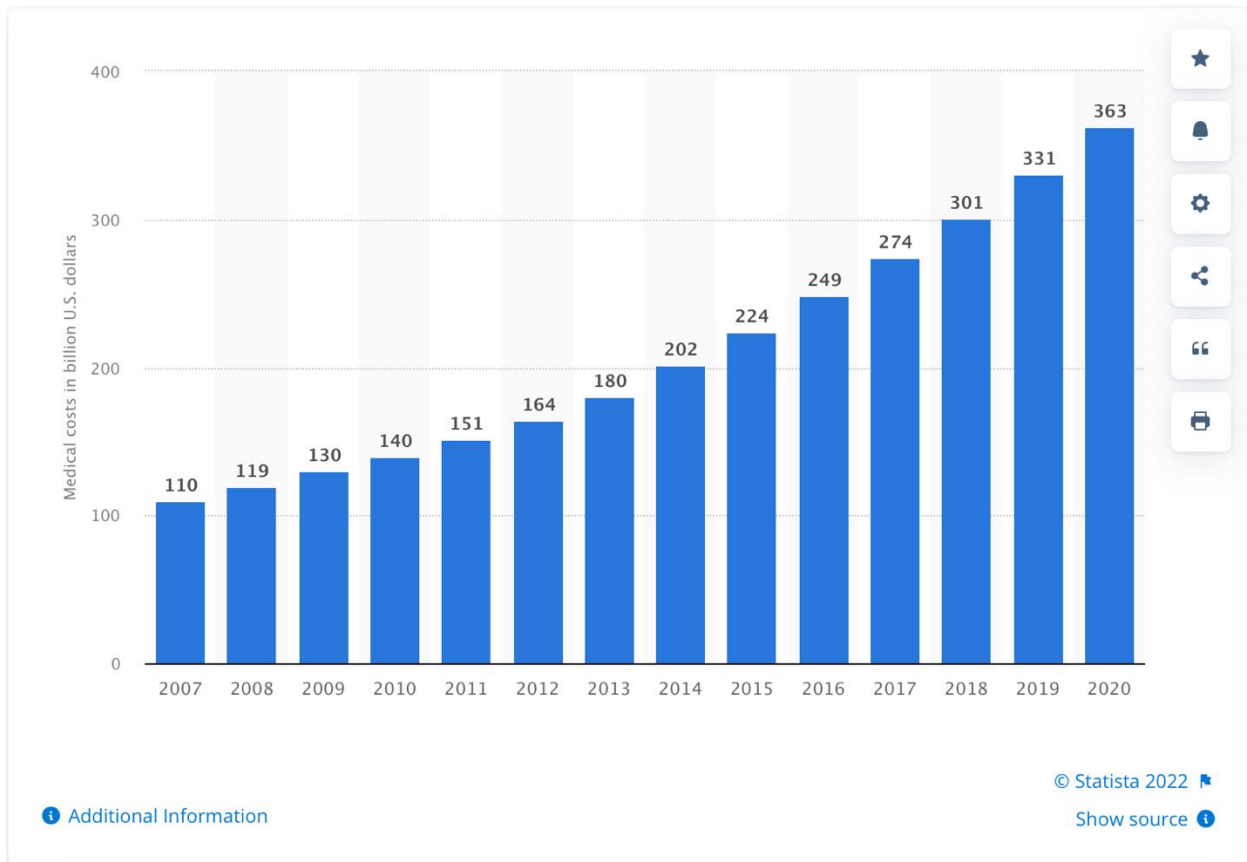
A1c = hemoglobin A1c; ADA = American Diabetes Association; BP = blood pressure; F = female; M = male; mg/dL = milligrams per deciliter; mm Hg = millimeter of mercury.

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 3 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.³¹ Figure 4 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:



³¹ <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.

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 4, 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
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

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 expected costs for diabetes treatments for

2011-2031.³² 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,³³ we have chosen to mirror his models concerning costs³⁴ as well as savings in costs relative to varying improvement in population level glycemic control³⁵ 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 will 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 of realistic estimations (50% decrease in AE), and lastly, a set of assumptions representing a best guess (30% decrease in AE).

³² <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelp.pdf.ashx>

³³ *Id.* at

³⁴ *Id.* at

³⁵ <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/improvedmanagementcanhelp.pdf.ashx>. Table 3 from page 4, *see* Figure 6.

Figure 6: Figures are for the entire U.S – see footnote 8 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 direct medical costs (MC), loss of productivity (P) due to diabetes has been studied extensively for many years. Recovery of this lost productivity is the second component of our calculation of indirect cost savings from transitioning to generic insulin.

As with data and figures regarding medical costs for diabetes, the issue of loss of productivity has been extensively studied.³⁶ When cross-referenced with other datasets, a reliable estimation of dollar costs of lost productivity caused by diabetes can be calculated.³⁷ Loss productivity stems from three primary components: absenteeism, presenteeism and early mortality.³⁸ We constructed an equation describing the amount of productivity loss each year as a percentage of total costs, taking verified data points from 2007 – 2017 to construct the model.³⁹ See Figure 7 for example of the analysis for calendar year 2017.

³⁶ <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.

³⁷ *Id.*

³⁸ <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.

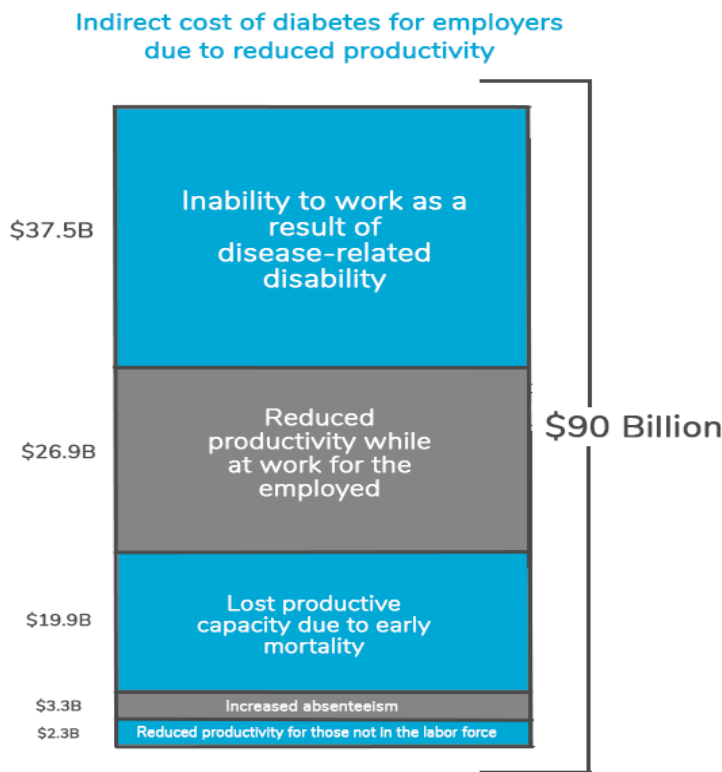
³⁹ *Id.* for 2017 report. See <https://diabetesjournals.org/care/article/26/3/917/29192/Economic-Costs-of-Diabetes-in-the-U-S-in-2002> for 2002 report; see <https://pubmed.ncbi.nlm.nih.gov/18308683/> for 2007 report; see <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3609540/> for 2012 report.

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

Table 6—Indirect burden of diabetes in the U.S., 2017 (in billions of dollars)			
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%

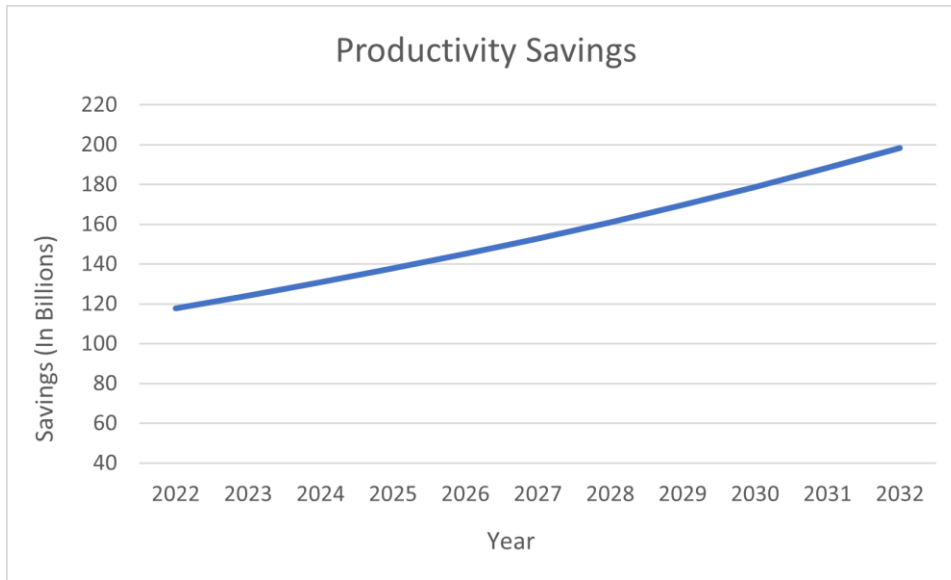
Data source: analysis of the NHIS (2014–2016), CPS (2016), CDC mortality data, and U.S. Census Bureau population estimates for 2016 and 2017. *Numbers do not necessarily sum to totals because of rounding.

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



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 glycemc control.

Figure 9:



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.

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