# Documents Produced by

# Sanofi

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[redacted]

**CONFIDENTIAL TREATMENT REQUESTED**

March 8, 2019

Hon. Charles E. Grassley
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Hon. Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Grassley and Senator Wyden:

This letter responds to your February 22, 2019 letter addressed to "Sanofi,"[1] requesting certain information related to Sanofi's insulin products (the "Letter"). Following receipt of your letter, we, on behalf of our client, Sanofi US ("Sanofi"),[2] participated in a productive conversation with your staffs regarding the nature and timing of Sanofi's response to the Letter. During that discussion, we agreed to provide responsive information on a rolling basis over the next two months. Below please find the first submission as part of that rolling production of information responsive to the Committee's requests. Please note that we have prioritized the production of information consistent with our discussion with your staffs, as well as our ongoing discussions regarding the confidentiality concerns we have raised.

As we discussed with your staffs on February 28, 2019, we are committed to working collaboratively with the Committee on its inquiry; however, we are concerned about the potential public disclosure of the competition sensitive information requested, including in particular the information sought in Requests 1(c)-(d), 2(b), (e), 3, 4, 5, 6,

[1] We note that the Committee addressed its letter to "Sanofi." Sanofi is a société anonyme (public limited liability corporation) incorporated under the laws of the Republic of France and headquartered at 54, rue La Boétie 75008, Paris, France. As we understand the Committee's inquiry to involve the pricing of Sanofi's insulin products in the US market, we intend to produce responsive information and documents from the files of our client, Sanofi US, headquartered at 55 Corporate Drive, Bridgewater, NJ 08807, rather than from "Sanofi," its French parent company.

[2] Throughout this Letter, we use "Sanofi" to reference Sanofi US unless otherwise noted.

7(c), and 8(c), which seek net price information, confidential contract terms, internal production costs, and other internal costs (such as product-specific advertising and research and development costs). This information is confidential and proprietary information for competitive reasons and falls within the definition of "trade secret" under the Trade Secrets Act, 18 U.S.C. § 1905, Exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4), and the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836. Moreover, we believe that public disclosure of this information could actually undermine the Committee's policy goal of reducing drug prices for patients and the federal government. From Sanofi's perspective, it is critically important for business, legal, and public policy reasons that its competitors not have access to this information in order to safeguard the competitive process, ensure market competition, and to prevent unintended antitrust risks. We note that Congressional and Executive agencies have historically expressed concern that disclosure of this type of information could inhibit competition.[3]

We remain interested in working with you and your staffs to develop a protocol to address this important issue in a way that preserves the confidential nature of the

[3] *See, e.g.*, CBO, Letter to the Hon. Joe Barton and the Hon. Jim McCrery (March 12, 2007) (concluding that concluding that public disclosure of information regarding price discounts, rebates and other price concessions negotiated between Part D plans and manufacturers could reduce the rebates that PDPs received and thus raise Medicare costs), *available at* https://www.cbo.gov/system/files?file=2018-10/03-12-drug-rebates.pdf; CBO, Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals (June 5, 2008), *available at* https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf; FTC, Office of Policy Planning, *Price Transparency or TMI?* (July 2, 2015) (expressing concern regarding situations in which "information disclosures allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices"), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi; FTC, Office of Policy Planning, Bureau of Competition and Bureau of Economics, Letter to Hon. James L. Seward re: New York Senate Bill 58, at 5 (March 31, 2009) (describing its concerns that a New York state bill that would have required PBMs to disclose their rebate arrangements with drug manufacturers could "facilitate collusion, raise prices, and harm the patients the Bill is supposed to protect"), *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf; FTC, Office of Policy Planning, Bureau of Competition, and Bureau of Economics, to Assemblyman Greg Aghazarian re: California Assembly Bill No. 1960 (September 7, 2004) (concluding that, if manufacturers learn the exact amount of the rebates offered by their competitors through required PBM disclosures, then tacit collusion among manufacturers is more feasible, which may lead to higher prices for PBM services and drugs), *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.

information provided while at the same time enabling the Committee to access information it deems necessary to achieve its investigatory and policy objectives.

*Request 1(a)-(b).*

Information responsive to this request is attached to this letter in an Excel workbook and hardcopy PDF, as requested in your February 22, 2019, letter. Please note that, while pricing data is provided by NDC number, we have provided data regarding gross sales, net sales, and gross units by product line, which is how Sanofi tracks this information.

*Request 2(a) and 5.*

Our response below provides an initial set of information regarding Sanofi's research and development ("R&D") program for the diabetes therapeutic area, which includes insulin, as well as information regarding changes to the formulations, delivery methods, and dosing size of its insulin products and how those changes have added value to patients. Sanofi's R&D activities are global and the information provided below is not limited to activities in the U.S. Please note that Sanofi does not maintain financial accounting information related to its R&D activities in the way requested in Request 5; however, we plan to supplement the information below with additional information responsive to Request 5 in a subsequent submission.

Sanofi reinvests a significant portion of its revenue into the R&D of new or improved medicines and vaccines. Last year, Sanofi globally spent almost $7 billion on R&D, an increase of approximately 7 percent from 2017. Sanofi plans to maintain this level of R&D investment through 2021. For 2018, Sanofi's total R&D investment in diabetes was approximately $800 million; from 2012-2018, Sanofi's total R&D investment in diabetes was approximately $4.5 billion.

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant, and diabetes continues to be a critical area of focus of Sanofi's R&D efforts. Diabetes is a group of metabolic disorders in which patients experience high blood sugar (glucose) levels because the body can no longer use glucose properly. Glucose is the main source of energy for cells in the body. Glucose can only enter cells if insulin, which is produced in the pancreas, is in the bloodstream. Without insulin, the cells of the body cannot use glucose for energy and can starve.

Patients with diabetes do not produce enough insulin, or the cells of their bodies are not responding properly to the insulin produced, and thus glucose cannot enter the

cells to be used as energy. As a result, glucose remains in the blood, causing elevated glucose levels and diabetes. If left untreated, elevated blood glucose levels from diabetes can cause many complications, including cardiovascular disease, stroke, chronic kidney disease, foot ulcers, damage to the eyes and even death. For some patients who make little or no insulin, their bodies turn to alternate forms of energy (ketones), which can lead to diabetic ketoacidosis ("DKA") and death.

Insulin Research and Development

Prior to 2000, insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy over the last century have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

Sanofi's discovery and development of glargine changed all of that. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Our efforts to develop a long-acting insulin were challenging and took many years. Our chemists worked for almost two decades in an effort to discover the needed structural modifications for an effective medicine. It was an arduous task of testing many hundreds of chemical modifications, looking for the desired outcome. Scientists at Hoechst AG (a precursor to Sanofi) made their first discoveries related to insulin glargine in the early 1980s, yet it took until 2000 for insulin glargine to be approved for the treatment of type 1 and type 2 diabetes.

Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The once-daily administration of glargine also proved a significant boon to patient lifestyles. The FDA first approved insulin glargine under the tradename Lantus in 2000. In 2006, Sanofi introduced a reformulation of Lantus, which

offered patients a more stable solution that eliminated the problem of potential cloudiness in prior Lantus vials.

Since its launch, Lantus has been studied in more than 90 million patient lives. Sanofi went above and beyond the regulatory authorities' approval requirements and provided the first large Cardiovascular Outcome Trial ("CVOT") proving the safety and efficacy of an antidiabetic drug. Sanofi sponsored over 200 clinical trials, with more than 200,000 patients treated, resulting in over 2,000 peer reviewed publications.

Since its discovery of insulin glargine, Sanofi has developed a new glargine formulation and a combination product to meet individualized patient needs. While Lantus provided significant improvement for basal insulin requirements, for some patients, Lantus does not provide effective 24-hour basal insulin coverage. In addition, for some patients using higher doses, Lantus had a peak of action that can lead to hypoglycemia. In order to more closely mimic endogenous basal insulin secretion and to help type 2 diabetes patients meet their glycemic goals, Sanofi has developed a next generation basal insulin, Toujeo. Approved by the FDA in 2015, Toujeo provides an improved therapeutic effect at a higher concentration of glargine and exhibits a different and longer-acting profile than Lantus.

Recognizing that approximately half of patients treated with basal (long acting) insulin were still not achieving their blood glucose (HbA1c) targets, Sanofi launched Soliqua 100/33 in 2017. Intended for adults whose Type 2 diabetes is inadequately controlled on basal insulin or an oral antidiabetic medicine, Soliqua is a fixed-ratio combination of Lantus and a non-insulin glucagon-like peptide receptor agonist (GLP-1 RA) that starts working after eating a meal. GLP-1s have been shown to reduce post-mealtime glucose peaks, which have been linked to cardiovascular disease in patients with diabetes; however, their use has been limited by gastrointestinal (GI) side effects. Soliqua® has demonstrated reduction in average and overall glucose levels and reduction in GI side effects, with similar rates of hypoglycemia – thus allowing a balance of lowered glucose levels without more hypoglycemia. Moreover, Soliqua® has been found to have a beneficial effect on body weight, addressing one of the unwanted side effects of insulin.

In addition to its insulin glargine products, which are all basal (long acting) insulins, in 2006, Sanofi launched Apidra (insulin glulisine), a fast-acting, mealtime insulin analog for the control of hyperglycemia in adult patients with type 1 and type 2 diabetes. Apidra is the only mealtime insulin approved for patients to take within 15 minutes before or within 20 minutes after starting a meal. Apidra is typically used in regimens that include a longer-acting insulin or basal insulin analog, such as Lantus.

Sanofi has faced numerous challenges in developing new insulins. For example, to further ease the burden on patients, Sanofi, in partnership with Pfizer, invested in developing Exubera, the first-ever inhaled insulin. Although approved for use and marketed (by Pfizer) in the U.S. in 2006, it was taken off the market after two years when it failed to gain acceptance from patients and providers. Sanofi faced a similar setback in 2014, when Afrezza, another promising inhaled insulin product in which Sanofi had substantially invested, failed to gain acceptance from patients and providers. In addition, from 2004-2016, Sanofi discontinued numerous diabetes projects at various stages of research and development because the company was unable to overcome scientific challenges.

Delivery Device Research and Development

Lantus was initially launched with a vial and syringe. Since that time, Sanofi has developed several more convenient injection devices for administering insulin. Our latest pen delivery system, SoloSTAR, has been a key improvement in easing the daily burden of insulin administration for patients. Sanofi partnered with one of the premier design firms in the world to develop this pre-filled, disposable injection pen for self-administration, which has improved the lifestyle and medication compliance of millions of diabetes patients. The SoloSTAR pen contains numerous features specifically designed to address the needs of diabetics, who often have additional health complications such as impaired vision and reduced dexterity. The pen's features include a clutch that couples and decouples complex internal mechanisms from each other to allow patients to "dial up" a dose for injection; dose dial stops that prevent patients from setting too high of a dose; a rotating dial that can easily correct an over-dialed dose; a specially designed injection button that is easy for diabetics to depress; and, importantly, a highly accurate delivery of the set dose. All of the pen's complex mechanical features and parts were seamlessly incorporated into the SoloSTAR pen's design, while still providing a robust and reliable feel suitable for daily use by patients with a chronic condition. Sanofi launched the Lantus SoloSTAR in 2007; it very quickly became the gold standard for pre-filled, disposable injection pens, and it has won awards for its novel design. Sanofi and its design partners have received patents covering the SoloSTAR device.

Sanofi developed Toujeo SoloStar with several innovative design features and attributes, ranging from the length of time it can be held without overheating the contents, to other ergonomic features designed to make it easier to use. Additionally, Sanofi developed Max SoloStar , which can deliver a more concentrated amount of Toujeo in a single injection, allowing for fewer injections and for some patients fewer refills and related copays.

Current Research and Development Efforts in Diabetes

Today, Sanofi continues to study the safety and efficacy of its current portfolio of insulin products for higher risk patient populations who would benefit from a more stable pharmacokinetic and pharmacodynamic profile, in particular children and geriatric patients with diabetes. Additionally, Sanofi understands that randomized clinical trials do not always provide a full picture of patient outcomes in the clinical setting. Sanofi has launched one of the most comprehensive real world evidence studies for a diabetes medication in the United States, studying Toujeo in numerous ways, ranging from a randomized, pragmatic prospective trial to predictive analytics and machine learning applied to large patient datasets. Sanofi believes that studying its medications in real world settings will continue to help drive needed innovation in diabetes treatment.

Longer term, Sanofi's scientists are working on ways to potentially transform diabetes care by treating not just symptoms but addressing the underlying disease. To this end, Sanofi has initiated a multi-pronged approach aimed at preventing progression to insulin-dependence or restoring insulin-producing cells through stem cell technologies. In addition, Sanofi recognizes that the greatest contributor to the current diabetes epidemic is obesity. Sanofi researchers are exploring the molecular mechanisms by which obesity leads to diabetes, and they are working to design molecules that aim to restore a healthy metabolism and thereby stop diabetes in its tracks. This type of research, and the development of these new technologies, takes many years, and the company continues to invest in these projects with the hope that it can eventually transform the lives of these patients.

*Request 2(d).*

For each Sanofi insulin product, we have listed all patents received since January 1, 2014, for which a certification must be filed pursuant to the Hatch-Waxman Act.[4] These patents are published in the Food and Drug Administration's ("FDA") Orange Book. For each product, we have also identified the drug National Drug Code ("NDC") numbers associated with the product.

[4] New Drug Application ("NDA") applicants must file patent numbers and expiration dates of any patent which "claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b)(1). NDA applicants must amend NDA applications with relevant newly issued patents and NDA holders must file relevant new patents with the FDA no later than 30 days after the patent is issued. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(d)(1), (3).

Please note that patents are not directly associated with NDCs. Patents claim aspects of a technology, such as a drug product, a method of using a drug, a delivery mechanism, a manufacturing process, etc. When patents are listed with FDA in the agency's Orange Book, patents are associated with specific new drug application ("NDA") numbers, and, where applicable, specific presentations of a product under an NDA. Patents are not listed in association with NDC numbers. NDCs are product identification numbers that FDA assigns to new package sizes, new dosage forms, or new strengths of drugs when those products are listed with the FDA. NDC numbers are not static, but rather require updating with certain changes to the characteristics of a drug or its packaging. For this reason, there is no direct association between a patent listed in the Orange Book and an NDC number listed in FDA's NDC database.

For purposes of the Committee's inquiry, we have attempted to align listed patents to NDCs by using the NDA numbers associated with the applicable product, but we advise the Committee that this is not data Sanofi maintains, or analysis that Sanofi conducts in the normal course. Further, we note that, Sanofi files patent applications whenever the inventions are completed and does not time patent filings to NDC assignments or NDA filings.

**Admelog**

Sanofi does not hold any patents issued after January 1, 2014 related to this product that are listed in the Orange Book.

**Admelog SoloSTAR**

| U.S. Patent No.[5] | Title | Issuance Date | New Drug Application (NDA) | Associated NDCs | |
|---|---|---|---|---|---|
| 8679069 | Pen-type injector | 2014-03-25 | N209196 | NDC 0024-5925-00 | 1 SYRINGE in 1 CARTON > 3 mL in 1 SYRINGE |
| | | | | NDCs 0024-5925-05, 0024-5925-01 | 5 SYRINGE in 1 CARTON (0024-5925-05) > 3 mL in 1 SYRINGE (0024-5925-01) |

[5] Note: Many of these patents claim products other than ADMELOG (e.g., APIDRA SOLOSTAR, LANTUS, SOLIQUA, TOUJEO MAX SOLOSTAR, TOUJEO SOLOSTAR). Where applicable, the NDCs for those products are listed in the respective sections of this document.

| U.S. Patent No.[5] | Title | Issuance Date | New Drug Application (NDA) | Associated NDCs |
|---|---|---|---|---|
| | | | | |
| 8992486 | Pen-type injector | 2015-03-31 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9011391 | Pen-type injector | 2015-04-21 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9233211 | Relating to a pen-type injector | 2016-01-12 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9408979 | Pen-type injector | 2016-08-09 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9526844 | Pen-type injector | 2016-12-27 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9533105 | Drive mechanisms suitable for use in drug delivery devices | 2017-01-03 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9561331 | Drive mechanisms suitable for use in drug delivery devices | 2017-02-07 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9604008 | Drive mechanisms suitable for use in drug delivery devices | 2017-03-28 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9604009 | Drive mechanisms suitable for use in drug delivery devices | 2017-03-28 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |

| U.S. Patent No.[5] | Title | Issuance Date | New Drug Application (NDA) | Associated NDCs |
|---|---|---|---|---|
| 9610409 | Drive mechanisms suitable for use in drug delivery devices | 2017-04-04 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9623189 | Relating to drive mechanisms suitable for use in drug delivery devices | 2017-04-18 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9717852 | Cartridge holder and pen-type injector | 2017-08-01 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9775954 | Pen-type injector | 2017-10-03 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |
| 9827379 | Drive mechanisms suitable for use in drug delivery devices | 2017-11-28 | N209196 | Same as above (NDCs 0024-5925-00, 0024-5925-05, 0024-5925-01) |

**Apidra**

Sanofi does not hold any patents issued after January 1, 2014 related to this product that are listed in the Orange Book.

**Apidra SoloSTAR**

| U.S. Patent No. | Title | Issuance Date | NDA | Associated NDCs | |
|---|---|---|---|---|---|
| 8679069 | Pen-type injector | 2014-03-25 | N021629 | NDC 0088-2502-05 | 5 SYRINGE, PLASTIC in 1 CARTON (0088-2502-05) > 3 mL in 1 SYRINGE, PLASTIC |
| 8992486 | Pen-type injector | 2015-03-31 | N021629 | Same as above (NDC 0088-2502-05). | |
| 9011391 | Pen-type injector | 2015-04-21 | N021629 | Same as above (NDC 0088-2502-05). | |
| 9233211 | Relating to a pen-type injector | 2016-01-12 | N021629 | Same as above (NDC 0088-2502-05). | |
| 9408979 | Pen-type injector | 2016-08-09 | N021629 | Same as above (NDC 0088-2502-05). | |
| 9526844 | Pen-type injector | 2016-12-27 | N021629 | Same as above (NDC 0088-2502-05). | |
| 9533105 | Drive mechanisms suitable for use in drug delivery devices | 2017-01-03 | N021629 | Same as above (NDC 0088-2502-05). | |
| 9561331 | Drive mechanisms suitable for use in drug delivery devices | 2017-02-07 | N021629 | Same as above (NDC 0088-2502-05). | |
| 9604008 | Drive mechanisms suitable for use in drug delivery | 2017-03-28 | N021629 | Same as above (NDC 0088-2502-05). | |

| U.S. Patent No. | Title | Issuance Date | NDA | Associated NDCs |
|---|---|---|---|---|
| | devices | | | |
| 9604009 | Drive mechanisms suitable for use in drug delivery devices | 2017-03-28 | N021629 | Same as above (NDC 0088-2502-05). |
| 9610409 | Drive mechanisms suitable for use in drug delivery devices | 2017-04-04 | N021629 | Same as above (NDC 0088-2502-05). |
| 9623189 | Relating to drive mechanisms suitable for use in drug delivery devices | 2017-04-18 | N021629 | Same as above (NDC 0088-2502-05). |
| 9717852 | Cartridge holder and pen-type injector | 2017-08-01 | N021629 | Same as above (NDC 0088-2502-05). |
| 9775954 | Pen-type injector | 2017-10-03 | N021629 | Same as above (NDC 0088-2502-05). |
| 9827379 | Drive mechanisms suitable for use in drug delivery devices | 2017-11-28 | N021629 | Same as above (NDC 0088-2502-05). |

**Lantus**

Sanofi does not hold any patents issued after January 1, 2014 related to this product that are listed in the Orange Book.

**Lantus SoloSTAR**

| U.S. Patent No.[6] | Title | Issuance Date | NDA | Associated NDCs | |
|---|---|---|---|---|---|
| 8679069 | Pen-Type Injector | 2014-03-25 | N021801 | NDC 0088-2219-00 | 1 SYRINGE in 1 CARTON (0088-2219-00) > 3 mL in 1 SYRINGE |
| | | | | NDC 0088-2219-05 | 5 SYRINGE in 1 CARTON (0088-2219-05) > 3 mL in 1 SYRINGE |
| | | | | NDC 0088-5020-01 | 1 SYRINGE in 1 PACKAGE (0088-5020-01) > 3 mL in 1 SYRINGE |
| | | | | NDC 0088-5020-05 | 5 SYRINGE in 1 PACKAGE (0088-5020-05) > 3 mL in 1 SYRINGE |
| 8992486 | Pen-Type Injector | 2015-03-31 | N021801 | Same as above: (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) | |
| 9011391 | Pen-Type Injector | 2015-04-21 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) | |
| 9233211 | Relating to Pen-Type Injector | 2016-01-12 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) | |
| 9408979 | Pen-Type Injector | 2016-08-09 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) | |
| 9526844 | Pen-Type Injector | 2016-12-27 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) | |
| 9533105 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-01-03 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) | |
| 9561331 | Drive Mechanisms | 2017-02-07 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) | |

[6] Note: Many of these patents claim Sanofi insulin products other than LANTUS SOLOSTAR. Where applicable, the NDCs for those products are listed in the respective sections of this document.

| U.S. Patent No.[6] | Title | Issuance Date | NDA | Associated NDCs |
|---|---|---|---|---|
| | Suitable For Use in Drug Delivery Devices | | | |
| 9604008 | Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-03-28 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) |
| 9604009 | Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-03-28 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) |
| 9610409 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-04-04 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) |
| 9623189 | Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-04-18 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) |
| 9717852 | Pen-Type Injector | 2017-08-01 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) |
| 9775954 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-10-03 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) |
| 9827379 | Pen-Type Injector | 2017-11-28 | N021801 | Same as above (0088-2219-00, 0088-2219-05, 0088-5020-01, 0088-5020-05) |

**Soliqua 100/33**[7]

| U.S. Patent No. | Title | Issuance Date | NDA | Associated NDCs | |
|---|---|---|---|---|---|
| 10029011 | Pharmaceutical composition comprising a GLP-1 agonist, an insulin and methionine | 2018-07-24 | N208673 | NDC 0024-5761-05 | 5 SYRINGE in 1 CARTON (0024-5761-05) > 3 mL in 1 SYRINGE |
| 10117909 | Combination of an insulin and a GLP-1 agonist | 2018-11-06 | N208673 | Same as above (NDC 0024-5761-05) | |
| 8679069 | Pen-type injector | 2014-03-25 | N208673 | Same as above (NDC 0024-5761-05) | |
| 8992486 | Pen-type injector | 2015-03-31 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9011391 | Pen-type injector | 2015-04-21 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9233211 | Relating to a pen-type injector | 2016-01-12 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9408979 | Pen-type injector | 2016-08-09 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9526764 | Combination of an insulin and a GLP-1-agonist | 2016-12-27 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9526844 | Pen-type injector | 2016-12-27 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9533105 | Drive mechanisms suitable for use in drug delivery devices | 2017-01-03 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9561331 | Drive mechanisms suitable for use in drug delivery devices | 2017-02-07 | N208673 | Same as above (NDC 0024-5761-05) | |
| 9604008 | Drive mechanisms suitable for use in drug delivery | 2017-03-28 | N208673 | Same as above (NDC 0024-5761-05) | |

[7] Note: Some of these patents claim Sanofi insulin products other than SOLIQUA. Where applicable, the NDCs for those products are listed in the respective sections of this document.

| U.S. Patent No. | Title | Issuance Date | NDA | Associated NDCs |
|---|---|---|---|---|
| | devices | | | |
| 9604009 | Drive mechanisms suitable for use in drug delivery devices | 2017-03-28 | N208673 | Same as above (NDC 0024-5761-05) |
| 9610409 | Drive mechanisms suitable for use in drug delivery devices | 2017-04-04 | N208673 | Same as above (NDC 0024-5761-05) |
| 9623189 | Relating to drive mechanisms suitable for use in drug delivery devices | 2017-04-18 | N208673 | Same as above (NDC 0024-5761-05) |
| 9707176 | Pharmaceutical composition comprising a GLP-1 agonist and methionine | 2017-07-18 | N208673 | Same as above (NDC 0024-5761-05) |
| 9717852 | Cartridge holder and pen-type injector | 2017-08-01 | N208673 | Same as above (NDC 0024-5761-05) |
| 9775954 | Pen-type injector | 2017-10-03 | N208673 | Same as above (NDC 0024-5761-05) |
| 9821032 | Pharmaceutical combination for improving glycemic control as add-on therapy to basal insulin | 2017-11-21 | N208673 | Same as above (NDC 0024-5761-05) |
| 9827379 | Drive mechanisms suitable for use in drug delivery devices | 2017-11-28 | N208673 | Same as above (NDC 0024-5761-05) |
| 9950039 | Insulin glargine/lixisenatide fixed ratio formulation | 2018-04-24 | N208673 | Same as above (NDC 0024-5761-05) |
| RE45313 | Exendin variant peptides | 2014-12-30 | N208673 | Same as above (NDC 0024-5761-05) |

**Toujeo SoloSTAR**

| U.S. Patent No.[8] | Title | Issuance Date | NDA | Associated NDCs | |
|---|---|---|---|---|---|
| 9,345,750 | Long-Acting Formulations of Insulin | 2016-05-24 | N206538 | NDC 0024-5869-03 and 0024-5869-01 | 3 SYRINGE in 1 CARTON (0024-5869-03) > 1.5 mL in 1 SYRINGE (0024-5869-01) |
| | | | | NDC 0024-5869-00 | 1 SYRINGE in 1 CARTON (0024-5869-00) > 1.5 mL in 1 SYRINGE |
| 8,679,069 | Pen-Type Injector | 2014-03-25 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |
| 8,992,486 | Pen-Type Injector | 2015-03-31 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |
| 9,011,391 | Pen-Type Injector | 2015-04-21 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |
| 9,233,211 | Relating to Pen-Type Injector | 2016-01-12 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |
| 9,408,979 | Pen-Type Injector | 2016-08-09 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |
| 9,526,844 | Pen-Type Injector | 2016-12-27 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |
| 9,533,105 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-01-03 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |
| 9,561,331 | Drive Mechanisms | 2017-02-07 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) | |

[8] Please note that some of these patents claim Sanofi insulin products other than TOUJEO SOLOSTAR. Where applicable, the NDCs for those products are listed in the respective sections of this document.

| | | | | |
|---|---|---|---|---|
| | Suitable For Use in Drug Delivery Devices | | | |
| 9,604,008 | Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-03-28 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) |
| 9,604,009 | Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-03-28 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) |
| 9,610,409 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-04-04 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) |
| 9,623,189 | Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-04-18 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) |
| 9,775,954 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-10-03 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) |
| 9,827,379 | Pen-Type Injector | 2017-11-28 | N206538 | Same as above (NDCs 0024-5869-03, 0024-5869-01, 0024-5869-00) |

**Toujeo Max SoloSTAR**[9]

| U.S. Patent No.[10] | Title | Issuance Date | NDA | Associated NDCs | |
|---|---|---|---|---|---|
| 9,345,750 | Long-Acting Formulations of Insulin | 2016-05-24 | N206538 | NDC 0024-5871-01 | 1 SYRINGE in 1 CARTON (0024-5871-01) > 3 mL in 1 SYRINGE |
| | | | | NDCs 0024-5871-02, 0024-5871-00 | 2 SYRINGE in 1 CARTON (0024-5871-02) > 3 mL in 1 SYRINGE (0024-5871-00) |
| 8,679,069 | Pen-Type Injector | 2014-03-25 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |
| 8,992,486 | Pen-Type Injector | 2015-03-31 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |
| 9,011,391 | Pen-Type Injector | 2015-04-21 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |
| 9,233,211 | Relating to Pen-Type Injector | 2016-01-12 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |
| 9,408,979 | Pen-Type Injector | 2016-08-09 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |
| 9,526,844 | Pen-Type Injector | 2016-12-27 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |
| 9,533,105 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-01-03 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |
| 9,561,331 | Drive Mechanisms Suitable For Use in Drug Delivery | 2017-02-07 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) | |

[9] Toujeo SoloSTAR and Toujeo Max SoloSTAR have the same listed patents, but different NDCs.
[10] Please note that some of these patents claim Sanofi insulin products other than TOUJEO MAX SOLOSTAR. Where applicable, the NDCs for those products are listed in the respective sections of this document.

| | | | | |
|---|---|---|---|---|
| | Devices | | | |
| 9,604,008 | Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-03-28 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) |
| 9,604,009 | Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-03-28 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) |
| 9,610,409 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-04-04 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) |
| 9,623,189 | Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices | 2017-04-18 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) |
| 9,775,954 | Drive Mechanisms Suitable For Use in Drug Delivery Devices | 2017-10-03 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) |
| 9,827,379 | Pen-Type Injector | 2017-11-28 | N206538 | Same as above (NDCs 0024-5871-01, 0024-5871-02, 0024-5871-00) |

*Request 7(a)-(b).*

Two years ago, Sanofi announced its progressive and industry-leading pricing principles to help stakeholders understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of our medicines.[11]

Sanofi's Process for Setting U.S. Prices

When Sanofi sets the price of a new medicine, including its insulin medicines, it holds itself to a rigorous and structured process that includes consultation with external stakeholders and considers the following four factors:

1) A holistic assessment of value, including (a) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; (b) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and (c) social value, or how the medicine contributes to patients' quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment ("HTA") approaches and other analyses that help define or quantify value and include patient perspectives and priorities.

2) Similar treatment options available or anticipated at the time of launch to understand the competitive landscape for the therapeutic area(s) in which the medicine may be used.

3) Affordability, including steps Sanofi takes to promote access for patients and contribute to a more sustainable system for patients, payers and health care delivery systems.

4) Unique factors specific to the medicine at the time of launch. For example, Sanofi may be supporting ongoing clinical trials in an effort to learn and provide additional critical information about the product (e.g., longer-term outcomes studies), implementing important regulatory commitments, or developing sophisticated patient support tools that improve care management and help decrease the total cost of care.

Sanofi also carefully considers a number of factors when evaluating whether to change the list price of any of its products, including its insulin products. These factors include the value of the product, the competitive environment, patient access considerations, investment in further product development, and the need to reinvest in

[11] *See* https://mediaroom.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/mediaroom/pdf/2019/Prescription_Medicine_Pricing_2019.pdf.

Sanofi's R&D's efforts more generally. These factors are considered within the context of the company's pricing principles, which includes a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE) growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation. In 2018, all of Sanofi's price increases across its medicines were consistent with those pricing principles, as are all pricing actions taken in 2019.

Sanofi independently sets the list prices for its medicines, including insulin, and we take responsibility for them. But we note that while list prices often receive the most attention, it is important to bear in mind that they reflect the initial price Sanofi sets for its medicines. They are not the amount Sanofi receives nor the prices typically paid by government and commercial insurers, employers, or PBMs. In the current system, manufacturers pay significant rebates off of the list price to government and private payers, as well as other intermediaries, in order to access patient populations. In 2018, 55 percent of Sanofi's gross U.S. sales were given back to payers as rebates, including $4.5 billion in mandatory rebates to government payers and $7.3 billion in discretionary rebates.

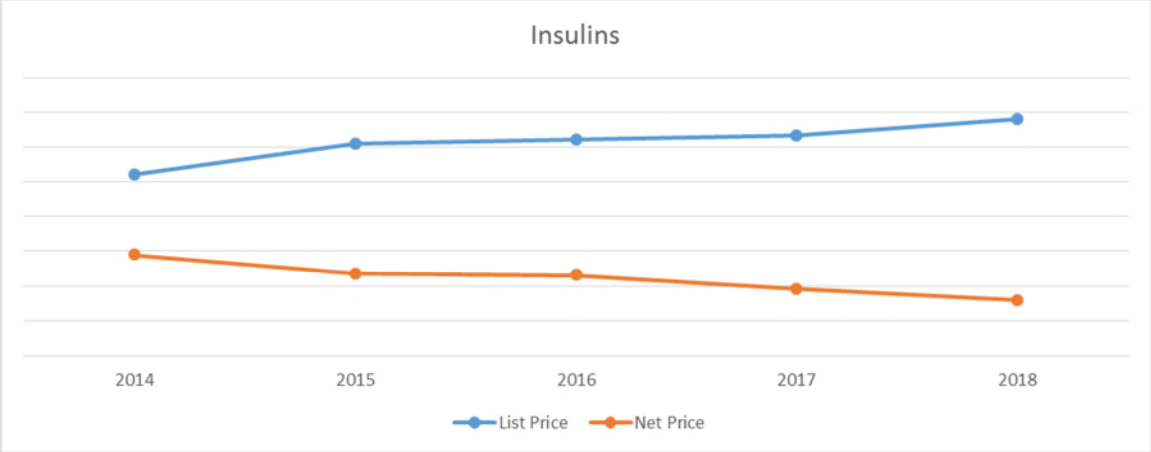
Sanofi's price increases have not kept pace with such requests, resulting in an average net price that has declined for its medications, including insulins. Across Sanofi's entire portfolio of medicines, the average aggregate list price increase was 4.6 percent while the average aggregate net price – that is, the actual price paid to Sanofi – declined by 8.0 percent. The declining aggregate net price in 2018 represents the third consecutive year the amount that health plans and PBMs pay Sanofi for its medicines has declined.

**U.S. Portfolio Annual Aggregate Price Changes***

| Year | Average Aggregate List Price | Average Aggregate Net Price |
|---|---|---|
| 2016 | 4.0% Increase | 2.1% Decrease |
| 2017 | 1.6% Increase | 8.4% Decrease |
| 2018 | 4.6% Increase | 8.0% Decrease |

** Aggregate across Sanofi's prescription product portfolio, including insulins*

Specific to insulin, the aggregate net price across all Sanofi insulin products has declined over the past four years. For Sanofi's entire insulin portfolio, the average net price is 45 percent lower today than it was in 2014.[12]




Sanofi believes that rebates to payers, which result in lower net prices, should benefit patients. Unfortunately, under the current system, savings from rebates are not consistently passed through to patients in the form of lower cost-sharing amounts. For example, the average net price of Lantus, Sanofi's most prescribed insulin, has declined by over 50 percent since 2014, while the average out-of-pocket burden for patients with commercial insurance and Medicare has increased by approximately 16 percent over that same period.

Relevant Personnel Involved in Pricing Process

Several groups within Sanofi are involved in the pricing of Sanofi medicines, including its insulin medicines, in the U.S. market. Key groups with involvement in those activities include Market Access, Strategic Pricing and Contracting (within Market Access) and Marketing, as well as U.S. pricing committees. Below is an overview of the roles of those groups.

- *Market Access*: The Market Access team works across products and assists with pricing and contracting with payers, including health plans and pharmacy benefit managers. Within Market Access, the Strategic Pricing and Contracting team works across products and is involved in pricing and contracting strategy and analytics. Working with Marketing teams and with Finance, the Strategic Pricing and

[12] Based on internal review of pricing actions and payer contracting.

Contracting team researches and analyzes pricing activity and trends, including assessing potential access barriers.

- *Marketing*: The Marketing team (also known as the Brand team) is involved in the development and execution of marketing strategies for Sanofi products, including insulin products. The Brand teams also work with and support teams involved in pricing (including Strategic Pricing and Contracting, and Finance).

- *Pricing Committees*: The U.S. Pricing Committee ("USPC") and Pricing Review Board ("PRB") work together on pricing matters across Sanofi's U.S. product portfolio, including adjustments to the list price (also known as wholesale acquisition cost ("WAC")). The USPC evaluates pricing strategy for products sold in the US. Members of the USPC include the Head of Market Access and the relevant Brand lead. In approximately 2014, Sanofi created the PRB, which includes representatives from the Strategic Pricing and Contracting team, Finance and the relevant Brand, and is involved in analyzing pricing proposals. The PRB may review and approve price proposals before those proposals are presented to the USPC. Pricing actions in the U.S. are also reviewed and approved by Sanofi global executive management.

With respect to the pricing of insulin products in the U.S., Michelle Carnahan, North America Head of Primary Care Business Unit, Gerald Gleeson, Vice President and U.S. Head of Market Access, and Jim Borneman, who is currently serving as interim Brand Lead, US Insulin Products, participate in these U.S. insulin pricing actions.

Communication of Prices to Third Parties

Sanofi announces changes in pricing to all impacted customers -- including PBMs, payers, and GPOs -- by sending pricing notification letters. Sanofi communicates with direct purchasers, including wholesalers and pharmacies, via trade letters that announce newly approved products, changes in pricing, and changes in label indications. These letters provide the information needed by wholesalers and pharmacies to properly load the product information within their business systems. Sanofi also notifies wholesalers of changes in contract pricing via Electronic Data Interchange ("EDI"). Wholesalers load this information into their systems for access by their downstream customers. Sanofi also sends trade letters to drug compendia so that updated pricing information is effectively communicated downstream, including to managed care plans/payers and the government. Sanofi's communications include data such as NDC, selling unit, package size and WAC.

*Request 8(a)-(b).*

The information below describes Sanofi's internal programs that provide financial assistance to eligible patients in purchasing their insulin or obtaining free insulin.

Sanofi is committed to supporting patients in getting the Sanofi insulin products that they are prescribed by healthcare professionals. Sanofi offers three types of programs to help enable appropriate patient access to Sanofi's insulin products: 1) co-pay assistance programs; 2) the Insulins Val*you* Savings Program; and 3) free medicines through Sanofi Patient Connection. Each of these programs, including eligibility criteria, is explained in more detail below.

I. Sanofi Co-pay Assistance Programs for Insulin Products

Commercially-insured, and in some cases cash paying patients, qualify for Sanofi's co-pay assistance programs, which help reduce patients' financial out-of-pocket burden for Sanofi manufactured medicines. For its insulin products, Sanofi offers co-pay support for Lantus, Lantus SoloSTAR, Toujeo SoloSTAR, Toujeo Max SoloSTAR, Apidra, Apidra SoloSTAR, and Soliqua 100/33. These programs are not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical programs.

A. Sanofi Co-pay Cards

To participate in one of Sanofi's co-pay card programs, eligible patients are able to register and download electronic co-pay cards from a Sanofi website, or are able to call a call center to request a physical co-pay card. Patients also may receive physical co-pay cards from their healthcare providers. Physical co-pay cards must be activated prior to use, though an online activation process or by calling a call center. Sanofi's co-pay card programs are administered by a third party vendor.

1. Sanofi Rx Savings Program for Lantus

Eligible Lantus/Lantus SoloSTAR patients with commercial insurance or cash-paying patients may enroll in the Sanofi Rx Savings Card for Lantus. Enrolled patients pay as little as a $0 co-pay, with a maximum savings of up to $600 per package for commercially-insured patients and $100 per package for cash-paying patients. The Sanofi Rx Savings Card for Lantus is valid for up to 3 packages per prescription. The card may not be used for prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or

state programs, including any state pharmaceutical program. For additional information, please see https://www.lantus.com/sign-up/savings-and-support.

2. Sanofi Rx Savings Program for Toujeo

Eligible Toujeo SoloSTAR/Toujeo Max SoloSTAR patients with commercial insurance or cash-paying patients may enroll in the Sanofi Rx Savings Program for Toujeo. Enrolled patients pay as little as a $0 co-pay on the first 3 prescription fills and a $10 co-pay for the next 12 prescription fills, with a maximum savings of $600 per pack for all patients enrolled in a commercial insurance plan and $200 per package for cash-paying patients. The Sanofi Rx Savings Card for Toujeo is valid for up to 3 packs per prescription. The card may not be used for prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical program. For additional information, please see https://www.toujeo.com/toujeo-savings-card-coupon-and-support.

3. Apidra $0 Co-pay Program

Eligible Apidra/Apidra SoloSTAR patients with commercial insurance or cash-paying patients may enroll in the Apidra $0 Co-pay Program. Enrolled patients pay as little as a $0 co-pay, with a maximum savings of $100 per package. The Apidra $0 Co-pay Program is valid for up to 1 package per prescription. The card may not be used for prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical program. For more information, please see https://www.apidra.com/apidra/saving.aspx.

4. Soliqua 100/33 Savings Card

Eligible Soliqua 100/33 Savings Card patients with commercial insurance may enroll in the Soliqua 100/33 Savings Card program. Enrolled patients pay as little as a $0 co-pay, with a maximum savings of $800 per pack. The Soliqua 100/33 Savings Card is valid for up to 1 package per prescription. The card may not be used for prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical program. For more information, please see https://www.soliqua100-33.com/savings-and-support.

B. eVoucherRX Program

Additionally, Sanofi offers the eVoucherRX Program to eligible Apidra/Apidra SoloSTAR, Lantus/Lantus SoloSTAR, Toujeo SoloSTAR/Toujeo Max Solostar, and Soliqua 100/33 patients. Through this program, Sanofi provides commercially-insured patients with financial support automatically through participating pharmacies. Eligible patients receive the benefit of the offer without having to enroll in the program or present a card at the pharmacy counter. Apidra/Apidra SoloSTAR and Soliqua patients receive the same co-pay assistance offered through the corresponding copay card program. The Lantus and Toujeo eVoucherRx programs are available to commercially-insured Lantus/Lantus SoloSTAR and Toujeo SoloSTAR/Toujeo Max SoloSTAR patients during the deductible phase of their benefit. The program reduces these patients' out-of-pocket costs to $0 with a maximum benefit of $1500 per year. The third-party vendor that administers the program screens claim submissions for applicable products in an effort to ensure that the program is not applied to any claim using insurance that has been identified as a federal health care program.

II. Sanofi Insulins Val*you* Savings Program

In early 2018, Sanofi launched the Insulins Val*you* Savings Program, which is a direct purchase discount program that aims to lower out-of-pocket costs for patients who manage their diabetes with Lantus, Lantus SoloSTAR, Admelog, Admelog SoloSTAR, Apidra, Apidra SoloSTAR, and Toujeo, Toujeo SoloSTAR, and Toujeo Max SoloSTAR. The purpose of the Val*you* Savings Program is to provide financial relief to patients currently paying full retail price for Sanofi insulins (including uninsured patients who do not qualify for other patient assistance programs and some commercially insured patients with a high deductible that has not been reached on their plan). Through this program, eligible individuals can access the Sanofi insulin products listed above for $99 per 10 mL vial or $149 for a pack of SoloSTAR pens, which is approximately a 60% discount below the list price and could result in savings of up to $3,000 per year.[13] The Val*you* Savings

[13] Patients with type 1 diabetes require insulin replacement with both background (basal) and mealtime (bolus) insulin. An average adult with type 1 diabetes who weighs 70 kg (155 pounds) should be taking anywhere from 0.5-1 u/kg/ day - depending upon activity levels, and meal choices. If we use the higher daily dose of 1 u/kg/day, the patient would need a total of 70 units/day of insulin, of which ~ half should be mealtime bolus insulin and half should be background basal insulin. That would mean they could possibly get by on one vial of long acting and one vial of short acting or a pen pack for basal and bolus each month. For the average patient with type 1 diabetes, under the Val*you* program, the patient would meet the monthly insulin requirement with two payments of $99.

For patients with type 2 diabetes, many require background (basal) insulin only. Our internal data show that the average daily dose is roughly 45 units per day which results in a monthly requirement of 1350 units

Program is valid for a maximum quantity of ten 10mL vials per fill or ten packs of SoloStar pens per fill, and is valid for one fill per product per month. Under the Val*you* Savings Program, prices are guaranteed for 12 consecutive monthly fills. The program is available at U.S. pharmacies.

The Val*you* Savings Program is administered by a third party vendor. Patients are able to register and download an electronic savings cards from a Sanofi website, or are able to call a call center to request a physical savings card. Patients also may receive physical savings cards from their healthcare providers. Physical savings cards must be activated prior to use, though an online activation process or by calling a call center.

III. Sanofi Patient Connection

Sanofi Patient Connection is a Sanofi-sponsored patient assistance program that provides free Sanofi medicines, including Admelog, Admelog SoloSTAR, Apidra, Apidra SoloSTAR, Lantus, Lantus SoloSTAR, Soliqua 100/33, Toujeo SoloSTAR, and Toujeo Max SoloSTAR, to financially-needy patients who meet certain eligibility criteria. To be eligible for an insulin product through the program, a patient must meet the following criteria:

- The patient must be a U.S. citizen or resident and be under the care of a licensed healthcare provider authorized to prescribe, dispense and administer medicine in the U.S.;

- The patient must also have:

    - No insurance coverage or access to the prescribed product or treatment via their insurance; or

    - Medicare Part D coverage and 1) not have coverage for a generic equivalent product and 2) have spent at least 5% of their annual household income on prescription medications covered through their Part D plan in the current year.

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of basal insulin per month. The Lantus SoloSTAR® pack contains 1500 units of insulin (5 pens x 300 units per pen) and the Toujeo SoloSTAR® pack contains 1350 units of insulin (3 pens x 450 units per pen). For the average patient with type 2 diabetes, under the Val*you* program, the patient would meet the monthly insulin requirement with one payment of $149. Patients on lower doses of Lantus per month could opt for the 10ml vial, which is $99 per vial.

- Patient must have an Annual household income of ≤250% of the current Federal Poverty Level (in 2019, $64,375 for a family of 4).

If a patient appears to be eligible for Medicaid, they are required to provide documentation of a Medicaid denial before they may be eligible for patient assistance. A third party vendor administers Sanofi Patient Connection on behalf of Sanofi. The patient assistance program application is available online[14] and must be sent to the program via fax or mail.

* * *

We remain committed to continuing to work collaboratively with the Committee on its inquiry. As discussed during our February 28, 2019 call with your staffs, we are preparing to continue our production in response to the Letter on a rolling basis. We are also happy to continue our dialogue on protocols for producing confidential information. In the interim, to the extent you have any questions about the information contained above, please do not hesitate to contact me.

Sincerely,

Jeffrey L. Handwerker

Enclosure(s)

[14] *See* http://www.sanofipatientconnection.com/media/pdf/SPC_Application.pdf.

## Response to Request 1(a)-(b)

| NDC | 00088-2220-33 | 00088-2219-05 | 00088-5021-01 | 00088-5020-05 | 00024-5869-03 | 00024-5871-02 | 00088-2500-33 | 00088-2502-05 | 00024-5761-05 | 00024-5924-10 | 00024-5925-05 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Brand** | **Lantus** | **Lantus Solostar** | **Lantus** | **Lantus Solostar** | **Toujeo Solostar** | **Toujeo Max Solostar** | **Apidra** | **Apidra Solostar** | **Soliqua 100/33** | **Admelog** | **Admelog Solostar** |
| **Generic Name** | insulin glargine,human recombinant analog | insulin glargine, human recombinant analog | insulin glargine,human recombinant analog | insulin glargine,human recombinant analog | insulin glargine,human recombinant analog | insulin glargine,human recombinant analog | insulin glulisine | insulin glulisine | insulin glargine,human recombinant analog/lixisenatide | insulin lispro | insulin lispro |
| **Strength** | 100 unit/mL | 100 unit/mL (3 mL) | 100 unit/mL | 100 unit/mL (3 mL) | 300 unit/mL (1.5 mL) | 300 unit/mL (3 mL) | 100 unit/mL | 100 unit/mL | 100 unit-33 mcg/mL (3 mL) | 100 unit/mL | 100 unit/mL |
| **Dosage Form** | VIAL (ML) | INSULIN PEN (ML) | VIAL (ML) | INSULIN PEN (ML) | INSULIN PEN (ML) | INSULIN PEN (ML) | VIAL (ML) | INSULIN PEN (ML) | INSULIN PEN (ML) | VIAL (ML) | INSULIN PEN (ML) |
| **Package Size (mL)** | 10.0 | 3.0 | 10.0 | 3.0 | 1.5 | 3.0 | 10.0 | 3.0 | 3.0 | 10.0 | 3.0 |
| | | | | | | | | | | | |
| | | | | | **WAC per KIU (USD)** | | | | | | |
| **1/1/2014** | 19.128 | 20.208 | N/A | N/A | N/A | N/A | 15.676 | 20.174 | N/A | N/A | N/A |
| **2/1/2014** | 19.128 | 20.208 | N/A | N/A | N/A | N/A | 15.676 | 20.174 | N/A | N/A | N/A |
| **3/1/2014** | 19.128 | 20.208 | N/A | N/A | N/A | N/A | 15.676 | 20.174 | N/A | N/A | N/A |
| **4/1/2014** | 19.128 | 20.208 | N/A | N/A | N/A | N/A | 15.676 | 20.174 | N/A | N/A | N/A |
| **5/1/2014** | 19.128 | 20.208 | N/A | N/A | N/A | N/A | 15.676 | 20.174 | N/A | N/A | N/A |
| **6/1/2014** | 22.208 | 22.208 | N/A | N/A | N/A | N/A | 15.676 | 20.174 | N/A | N/A | N/A |
| **7/1/2014** | 22.208 | 22.208 | N/A | N/A | N/A | N/A | 18.485 | 23.80666 | N/A | N/A | N/A |
| **8/1/2014** | 22.208 | 22.208 | N/A | N/A | N/A | N/A | 18.485 | 23.80666 | N/A | N/A | N/A |
| **9/1/2014** | 22.208 | 22.208 | N/A | N/A | N/A | N/A | 18.485 | 23.80666 | N/A | N/A | N/A |
| **10/1/2014** | 22.208 | 22.208 | N/A | N/A | N/A | N/A | 18.485 | 23.80666 | N/A | N/A | N/A |
| **11/1/2014** | 22.208 | 22.208 | N/A | N/A | N/A | N/A | 18.485 | 23.80666 | N/A | N/A | N/A |
| **12/1/2014** | 24.851 | 24.85066 | N/A | N/A | N/A | N/A | 18.485 | 23.80666 | N/A | N/A | N/A |
| **1/1/2015** | 24.851 | 24.85066 | N/A | N/A | N/A | N/A | 18.485 | 23.80666 | N/A | N/A | N/A |
| **2/1/2015** | 24.851 | 24.85066 | N/A | N/A | N/A | N/A | 20.315 | 26.16333 | N/A | N/A | N/A |
| **3/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 20.315 | 26.16333 | N/A | N/A | N/A |
| **4/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 20.315 | 26.16333 | N/A | N/A | N/A |
| **5/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 20.315 | 26.16333 | N/A | N/A | N/A |
| **6/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 20.315 | 26.16333 | N/A | N/A | N/A |
| **7/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 22.326 | 28.75333 | N/A | N/A | N/A |
| **8/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 22.326 | 28.75333 | N/A | N/A | N/A |
| **9/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 22.326 | 28.75333 | N/A | N/A | N/A |
| **10/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 22.326 | 28.75333 | N/A | N/A | N/A |
| **11/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 22.326 | 28.75333 | N/A | N/A | N/A |
| **12/1/2015** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 22.326 | 28.75333 | N/A | N/A | N/A |
| **1/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 22.326 | 28.75333 | N/A | N/A | N/A |
| **2/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 23.621 | 30.42133 | N/A | N/A | N/A |
| **3/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 23.621 | 30.42133 | N/A | N/A | N/A |
| **4/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 23.621 | 30.42133 | N/A | N/A | N/A |
| **5/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 23.621 | 30.42133 | N/A | N/A | N/A |
| **6/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 23.621 | 30.42133 | N/A | N/A | N/A |
| **7/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 23.621 | 30.42133 | N/A | N/A | N/A |
| **8/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 23.621 | 30.42133 | N/A | N/A | N/A |
| **9/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | N/A | N/A | N/A |
| **10/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | N/A | N/A | N/A |
| **11/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | N/A | N/A | N/A |
| **12/1/2016** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | N/A | N/A | N/A |
| **1/1/2017** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **2/1/2017** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **3/1/2017** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **4/1/2017** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **5/1/2017** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **6/1/2017** | 24.851 | 24.85066 | N/A | N/A | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **7/1/2017** | 24.851 | 24.85066 | 24.851 | 24.85066 | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **8/1/2017** | 24.851 | 24.85066 | 24.851 | 24.85066 | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **9/1/2017** | 24.851 | 24.85066 | 24.851 | 24.85066 | 74.55111 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **10/1/2017** | 25.597 | 25.596 | 25.597 | 25.596 | 78.57777 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **11/1/2017** | 25.597 | 25.596 | 25.597 | 25.596 | 78.57777 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **12/1/2017** | 25.597 | 25.596 | 25.597 | 25.596 | 78.57777 | N/A | 25.511 | 32.85533 | 42.33333 | N/A | N/A |
| **1/1/2018** | 25.597 | 25.596 | 25.597 | 25.596 | 78.57777 | N/A | 25.511 | 32.85533 | 42.33333 | 23.35 | 30.056 |
| **2/1/2018** | 25.597 | 25.596 | 25.597 | 25.596 | 78.57777 | N/A | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **3/1/2018** | 25.597 | 25.596 | 25.597 | 25.596 | 78.57777 | N/A | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **4/1/2018** | 25.597 | 25.596 | 25.597 | 25.596 | 78.57777 | 78.57833 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **5/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **6/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **7/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **8/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **9/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **10/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **11/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **12/1/2018** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |
| **1/1/2019** | 26.954 | 26.95266 | 26.954 | 26.95266 | 82.74222 | 82.74333 | 26.991 | 34.76066 | 44.78866 | 23.35 | 30.056 |

| ($Millions) | Gross Sales ($Ms) | | | | |
|---|---|---|---|---|---|
| **Brand** | **2014** | **2015** | **2016** | **2017** | **2018** |
| Lantus | 10,123 | 11,802 | 10,972 | 10,032 | 8,918 |
| Toujeo | - | 285 | 1,049 | 1,326 | 1,448 |
| Soliqua 100/33 | - | - | - | 77 | 192 |
| Admelog | - | - | - | - | 166 |
| Apidra | 300 | 305 | 289 | 264 | 225 |

| ($Millions) | Net Sales ($Ms)* | | | | |
|---|---|---|---|---|---|
| **Brand** | **2014** | **2015** | **2016** | **2017** | **2018** |
| Lantus | 5,577 | 4,425 | 3,881 | 2,898 | 1,905 |
| Toujeo | - | 151 | 523 | 519 | 406 |
| Soliqua 100/33 | - | - | - | 30 | 73 |
| Admelog | - | - | - | - | 101 |
| Apidra | 173 | 160 | 127 | 116 | 87 |

*This data is derived from public filings which are reported in euros. We have converted the data into U.S. dollars using average annual exchange rates from the applicable year.

| Gross Units (millions) | | | | | |
|---|---|---|---|---|---|
| **Brand** | **2014** | **2015** | **2016** | **2017** | **2018** |
| Lantus | 46,921 | 47,512 | 44,166 | 40,087 | 33,599 |
| Toujeo | - | 1,149 | 4,226 | 5,264 | 5,329 |
| Soliqua 100/33 | - | - | - | 183 | 430 |
| Admelog | - | - | - | - | 612 |
| Apidra | 1,556 | 1,263 | 1,044 | 905 | 723 |

Arnold & Porter

Jeffrey L. Handwerker
[redacted]

**CONFIDENTIAL TREATMENT REQUESTED**

March 29, 2019

Hon. Charles E. Grassley
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Hon. Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Grassley and Ranking Member Wyden:

This letter further responds to your February 22, 2019 letter addressed to "Sanofi,"[1] requesting certain information related to Sanofi's insulin products (the "Letter"). Following receipt of your letter, we, on behalf of our client, Sanofi US ("Sanofi"),[2] participated in a productive conversation with your staffs regarding the nature and timing of Sanofi's response to the Letter. During that discussion, we agreed to provide responsive information on a rolling basis over the next two months. On March 8, 2019, we provided our first submission of information responsive to the Committee's requests. Below and enclosed, please find the second submission as part of our continued rolling production of responsive information. Please note that we have prioritized the production of information consistent with our discussion with your staffs, as well as our ongoing discussions regarding the confidentiality concerns we raised in the conversation with your staffs and in our March 8, 2019 letter. We remain committed in working with you and your staffs to develop a protocol to address this issue in a way that preserves the confidential nature of the information provided while at the same time enables the

[1] We note that the Committee addressed its letter to "Sanofi." Sanofi is a société anonyme (public limited liability corporation) incorporated under the laws of the Republic of France and headquartered at 54, rue La Boétie 75008, Paris, France. As we understand the Committee's inquiry to involve the pricing of Sanofi's insulin products in the US market, we intend to produce responsive information and documents from the files of our client, Sanofi US, headquartered at 55 Corporate Drive, Bridgewater, NJ 08807, rather than from "Sanofi," its French parent company.

[2] Throughout this Letter, we use "Sanofi" to reference Sanofi US unless otherwise noted.

Jeffrey L. Handwerker
[redacted]



Committee to access information it deems necessary to achieve its investigatory and policy objectives.

*Requests 2(b) and 5.*

As noted in our previous letter, Sanofi[3] reinvests a significant portion of its revenue into the research and development ("R&D") of new or improved medicines and vaccines. Last year, Sanofi globally spent almost $7 billion on R&D, an increase of approximately 7 percent from 2017. Sanofi plans to maintain this level of R&D investment through 2021. For 2018, Sanofi's total R&D investment in diabetes was approximately $800 million; from 2012-2018, Sanofi's total R&D investment in diabetes was approximately $4.5 billion.

Below please find a table that describes R&D spending by insulin product each year since 2014. Based on the way Sanofi maintains its financial records, we were not able to break this data out by clinical phase. Thus, the financial data below may cover activities, including pre-clinical, Phase I-IV clinical trial, and other post-market research, e.g., real world evidence studies. This data is maintained in Euros and has been converted to U.S. dollars.

| US$ (millions) | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|
| **Admelog** | 24.45 | 54.53 | 38.25 | 11.26 | 6.15 |
| **Apidra** | 2.31 | 5.47 | 3.64 | 1.36 | 1.04 |
| **Lantus** | 42.79 | 21.95 | 20.76 | 16.44 | 8.24 |
| **Soliqua** | 0 | 1.03 | 40.94 | 70.76 | 68.74 |
| **Toujeo** | 67.53 | 72.45 | 150.25 | 117.84 | 54.43 |

In response to your request to explain how Sanofi's R&D activities support the development of its insulin products, there are several phases to the development of drugs and biological products, including insulin products (collectively "drugs"), and each is important for ensuring that new drug products are safe and effective for the indications

[3] Throughout our response to Requests 2(b) and 5, references to Sanofi describe global activities.

for which they receive approval. The regulatory development of a drug begins with preclinical testing, which can include in vitro testing and animal studies. Preclinical testing provides preliminary information that is used to assess whether it would be reasonable to begin testing a drug in humans.

To support marketing approval, with some exceptions, FDA generally requires that the safety and efficacy of a drug be established through a clinical development program with three phases. The EU and other jurisdictions apply similar requirements. Phase 1 studies involve the initial introduction of a drug in a small group of humans, and provide preliminary dosing and tolerability information that is used to determine whether to initiate pivotal safety and efficacy studies. Phase 2 studies are typically controlled clinical trials conducted to evaluate the effectiveness of a drug for a particular indication in patients with the disease or condition and to determine common side effects and risks. Phase 3 studies are expanded studies performed after preliminary evidence suggests effectiveness of the drug has been obtained and are intended to gather additional safety and efficacy information necessary to evaluate the overall risk-benefit profile of a drug and to provide an adequate basis for physician labeling.

Postmarketing studies, where required or requested by FDA, can help to further refine the safety, efficacy , or optimal use of a product. In some cases, postmarketing studies allow remaining questions about a drug's safety or efficacy to be reviewed in post-approval setting, avoiding delaying approval of a drug that may offer therapeutic benefit. Companies may also voluntarily elect to conduct postmarking studies, including as a means to learn more information about the safety or efficacy of a drug in real world settings.

*Request 2(c).*

As described in our March 8, 2019 letter, Sanofi considers a number of factors when evaluating whether to change the list price of any of its products, including its insulin products. These factors include the value of the product to patients and to society, the competitive environment, patient affordability and access considerations, investment in further product development, and the need to reinvest in Sanofi's R&D's efforts more generally. Changes in formulation, delivery method, or dosing often affect the clinical value of the product and/or contribute to a patient's quality of life by, among other things, simplifying administration and reducing the number of doses required per day. Therefore, such changes would be considered when evaluating whether to adjust the list price of the Company's products. As noted in our prior letter, any changes in list price are made consistent with our pricing principles, which includes a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE)

growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation.

The net price paid by any particular payer for a product reflects an arms-length negotiation between Sanofi and each payer or their pharmacy benefit manager (PBM). There is no direct relationship between changes in formulation, delivery method, and/or dosing size and a negotiated net price.

*Request 2(d)*.

In our prior production, we listed all patents related to Sanofi's insulin products received since January 1, 2014, for which a certification must be filed pursuant to the Hatch-Waxman Act[4] and which are published in the Food and Drug Administration's ("FDA") Orange Book. Below, please find lists of additional patents related to Sanofi's insulin products that Sanofi has received since January 1, 2014.[5] Patents with applicability to multiple products are listed under each applicable product line. We have also provided information on patent applications that are related to Sanofi's insulin products that Sanofi has filed since January 1, 2014 that have not resulted in the issuance of a patent.

Additionally, enclosed with this letter are copies of all patents listed in our March 8, 2019 letter, as well as those listed in this letter. We are in the process of gathering copies of the patent applications, which we will provide in a later production. Please note that some patents are cited multiple times, as they apply to a number of Sanofi's insulin products.

Sanofi has made a good faith attempt to identify all such patents and applications, but please note that this list may not be exhaustive. If we identify any additional patents or applications applicable to this request, we will supplement the production.

[4] New Drug Application ("NDA") applicants must file patent numbers and expiration dates of any patent which "claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b)(1). NDA applicants must amend NDA applications with relevant newly issued patents and NDA holders must file relevant new patents with the FDA no later than 30 days after the patent is issued. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(d)(1), (3).

[5] We have not identified any additional patents for the Apidra, Admelog, or Lantus product lines.

**Toujeo SoloStar and Toujeo Max SoloStar Patents**

| U.S. Patent No. | Title | Issuance Date |
|---|---|---|
| 10,092,513 | Treatment of Diabetes Mellitus by Long-Acting Formulations of Insulins | Oct. 9, 2018 |

**Soliqua 100/33 Patents**

| U.S. Patent No. | Title | Issuance Date |
|---|---|---|
| 8,901,484 | Quantification of impurities for release testing of peptide products | Dec. 2, 2014 |

**Soliqua 100/33 Patent Applications**

| U.S. Application No. | Title | Filing Date |
|---|---|---|
| 14/303,895** | Insulin glargine-lixisenatide fixed ratio formulation | June 13, 2014 |
| 14/446,881** | Quantification of impurities for release testing of peptide products | July 30, 2014 |
| 14/995,910** | Treatment of Pediatric Type 2 Diabetes Mellitus Patients | Jan. 14, 2016 |
| 15/068,286** | Treatment [of] Type 2 Diabetes Mellitus Patients | Mar. 11, 2016 |
| 15/144,270** | Prevention of hypoglycemia in diabetes mellitus type 2 patients | May 2, 2016 |
| 15/186,416** | Pharmaceutical composition comprising ave0010 and insulin glargine | June 17, 2016 |
| 15/197,378** | Pharmaceutical combination for use in glycemic control in diabetes type 2 patients | June 29, 2016 |
| 15/275,867** | Method of treatment of | Sept. 26, 2016 |

** Sanofi later withdrew this application.

| U.S. Application No. | Title | Filing Date |
|---|---|---|
| | diabetes type 2 comprising add-on therapy to insulin glargine and metformin | |
| 15/411,557 | Prevention of hypoglycaemia in diabetes mellitus type 2 patients | Jan. 20, 2017 |
| 16/266,873 | Treatment of Pediatric Type 2 Diabetes Mellitus Patients | July 11, 2017 |
| 15/646,760 | Treatment [of] Type 2 Diabetes Mellitus Patients | July 11, 2017 |
| 15/657,683 | Insulin glargine-lixisenatide fixed ratio formulation | July 24, 2017 |
| 15/730,033** | Pharmaceutical combination for improving glycemic control as add-on therapy to basal insulin | Oct. 11, 2017 |
| 15/803,589 | Pharmaceutical composition comprising a GLP-1 agonist | Nov. 3, 2017 |
| 15/893,577 | Treatment of Type 2 Diabetes Mellitus Patients | Feb. 9, 2018 |
| 15/952,776 | Prevention of hypoglycemia in diabetes mellitus type 2 patients | Apr. 13, 2018 |
| 15/960,488 | Pharmaceutical combination for improving glycemic control as add-on therapy to basal insulin | Apr. 23, 2018 |
| 15/962,770 | Pharmaceutical Composition for Use in the Treatment of a Neurodegenerative Disease | Apr. 25, 2018 |
| 16/013,617 | Pharmaceutical composition comprising a GLP-1 agonist and methionine | June 20, 2018 |
| 15/914,197 | Insulin Glargine/Lixisenatide Fixed Ratio Formulation | Aug. 10, 2018 |
| 16/165,837 | Combination of an insulin | Oct. 19, 2018 |

| U.S. Application No. | Title | Filing Date |
|---|---|---|
| | and a GLP-1-agonist | |
| 16/308,733 | Pharmaceutical combination for use in glycemic control in diabetes type 2 patients | Dec. 10, 2018 |

**SoloStar Patent Applications**

The following two patent applications were filed in relation to the entire SoloStar family of products, and may have applicability to Lantus SoloStar, Apidra SoloStar, Admelog SoloStar, Toujeo SoloStar, Toujeo Max SoloStar, and Soliqua 100/33, depending on the scope of granted claims.

| U.S. Application No. | Title | Filing Date |
|---|---|---|
| 15/681604 | Pen-Type Injector | Aug. 21, 2017 |
| 15/787737 | Improvements in and Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices | Oct. 19, 2017 |

*Request 6.*

In response to Request 6, please find a description of the marketing and advertising activities for Sanofi's insulin products.

Sanofi provides information about its insulin products and related programs to patients through a number of mediums. Product information and information regarding related patient support offerings, such as co-pay cards, are provided online on Sanofi websites and through web ads, online search ads, and social media sites. Additionally, since September 2015, Sanofi has run ads for Lantus and Toujeo in print magazines and on television.[6] Sanofi diabetes sales professionals also provide patient brochures to healthcare professionals' (HCP) offices and pharmacies for HCPs and pharmacists to distribute to patients at their discretion. For patients who opt-in to communications with Sanofi, Sanofi provides product information, diabetes educational information, and

[6] Lantus television ads were limited to a two month run in 2018.

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[redacted]



information regarding patient support offerings through direct mail and email. Sanofi also staffs booths at some patient health fairs, at which product and diabetes educational information are available. Finally, Sanofi communicates information about its co-pay assistance programs to patients through pharmacy programs, in which co-pay savings messages are attached to the pharmacy prescription drug bags of patients who have received a Lantus, Soliqua, or Toujeo prescription and/or such patients are sent letters or emails to remind them of Sanofi's co-pay savings programs.

With respect to HCPs, Sanofi diabetes sales professionals call on relevant HCP offices (endocrinologists and primary care providers) and pharmacies to educate HCPs and pharmacists about Sanofi's insulin products and related programs, provide product samples, and leave patient materials for the HCPs/pharmacists' use with their patients. Sanofi places digital advertising about its products and co-pay assistance programs on websites intended for HCPs, and provides this information to relevant HCPs through email and direct mail. Sanofi also staffs booths at professional congresses and meetings, such as the American Diabetes Association meetings, where it will distribute product information and information about related programs. Finally, Sanofi facilitates speaker programs, through which HCPs educate and inform their peers about the Sanofi insulins they prescribe, including sharing the latest information about the benefits, risks and appropriate uses of the medicines, consistent with the FDA-approved label.

*Request 8(a)-(b)*.

In our March 8, 2019 letter, we provided information regarding Sanofi's internal programs that provide financial assistance to eligible patients in purchasing their insulin or obtaining free insulin.

Subsequent to submitting that letter, we have identified two additional internal financial assistance programs, both of which ended in 2018.

First, the Denial Conversion Program operated nearly identically to the eVoucherRX program and is administered through the same vendor through participating pharmacies. Through this program, Sanofi provided commercially-insured patients with financial support automatically through participating pharmacies. Eligible patients received the benefit of the offer without having to enroll in the program or present a card at the pharmacy counter. Program eligibility was limited to commercially-insured Lantus/Lantus SoloStar, Toujeo SoloStar/Toujeo Max Solostar, and Soliqua 100/33 patients that did not have coverage for the applicable product through their commercial insurance benefit. In contrast, the eVoucherRX program is designed for eligible commercially-insured patients with coverage for the applicable product. Eligible Lantus

Jeffrey L. Handwerker
[redacted]



patients paid as little as a $0 co-pay, with a maximum savings of up to $600 per package. Toujeo patients paid as little as $10 co-pay, with a maximum savings of up to $600 per package. Soliqua patients paid as little as pay as little as a $0 co-pay, with a maximum savings of $800 per package.

Second, Sanofi offered the Voucher on Demand Program to eligible Soliqua 100/33 patients. Through this program, Sanofi provided commercially-insured patients with financial support automatically through participating pharmacies. Eligible patients received the benefit of the offer without having to enroll in the program or present a card at the pharmacy counter. The program reduced these Soliqua patients' out-of-pocket costs to as little as $0 up to a maximum benefit of $800 per package of pens, up to three packages per prescription. The program was operated through a third-party vendor.

We have not identified any Sanofi-funded external programs that financially assist patients purchasing insulin or which provide free insulin to financially-need patients since January 1, 2014.

*Request 8(f).*

Sanofi's point-of-sale programs, including its co-pay cards, the eVoucherRX Program, the Denial Conversion Program, the Voucher on Demand Program, and the Insulins Val*you* Savings Program, do not generate direct revenue for the company. Rather, through a third-party vendor, Sanofi reimburses pharmacies for some portion of the patient's out-of-pocket costs at the pharmacy counter (pursuant to the applicable program's terms and conditions). Such pharmacies have purchased Sanofi insulin products through the normal supply chain. As noted in response to Request 9, below, these programs are recorded as expenses and reductions in sales in Sanofi's financial statements. By reducing patient out-of-pocket costs, these programs do make prescribed medicines more affordable for patients, which in turn may increase adherence and thus reduce the number of instances where patients do not fill prescriptions due to cost. Thus, these programs can help avoid prescription abandonment, which in turn could enable Sanofi to receive more revenues for the product than would be the case if patients had abandoned their prescription. The exact impact of the reduced abandonment rate cannot easily be quantified. However, we believe that such prescriptions are medically appropriate and that abandonment would be harmful to both the patient and the health care system.

Sanofi Patient Connection, which provides free product to eligible financially needy patients, does not generate revenue for the Company.

*Request 9.*

Patient Assistance Program Accounting

Within Sanofi's financial statements, Sanofi includes the administrative costs of the company's co-pay assistance programs, Insulins Val*you* Savings Program, and Sanofi Patient Connection in the "Selling and general expenses" line item. For co-pay assistance programs and the Insulins Val*you* Savings Program, Sanofi records the pharmacy reimbursement amount paid by the company as a reduction in sales. Sanofi records free product provided through Sanofi Patient Connection within "Cost of Sales." Sanofi Care North America, the 501(c)(3) operating foundation that donates free product to Sanofi Patient Connection, records the free goods as a "Contribution" when received from Sanofi, and as a "Donation," when donated to Sanofi Patient Connection.

Market Information Collected from Patient Assistance Programs and Patient Hub Activities

Through Sanofi's point-of-sale patient assistance programs (copay cards, eVoucherRx, Denial Conversion, Voucher on Demand, and Insulins Val*you* Savings Programs, Sanofi receives program anonymized utilization data, including information about patient out-of-pocket costs before application of the program, the average amounts Sanofi reimburses pharmacies through the program, program abandonment rates, the pharmacies patients utilize, and the prescribers writing the prescriptions associated with copay card utilization. This information is used to administer the program. Sanofi may also use this data to develop market and business insights.

Through the Sanofi Patient Connection application,[7] Sanofi collects relevant patient and prescriber information to evaluate patient eligibility and administer the program. Sanofi does not use this information for purposes other than administering Sanofi Patient Connection.

Sanofi does not have a patient support hub for its insulin products.

* * *

We remain committed to continuing to work collaboratively with the Committee on its inquiry. We will continue our production in response to the Letter on a rolling

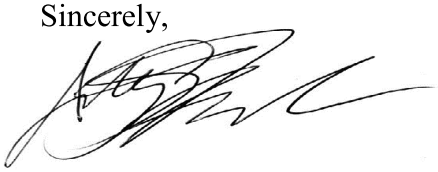
[7] Available at http://www.sanofipatientconnection.com/media/pdf/SPC_Application.pdf.

Jeffrey L. Handwerker
[redacted]



basis. We are also happy to continue our dialogue on protocols for producing confidential information. In the interim, to the extent you have any questions about the information contained above, please do not hesitate to contact me.

Sincerely,



Jeffrey L. Handwerker

Enclosure(s)

Arnold & Porter

Jeffrey L. Handwerker
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**CONFIDENTIAL TREATMENT REQUESTED**

May 24, 2019

Hon. Charles E. Grassley
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Hon. Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden:

This letter further responds to your February 22, 2019 letter addressed to "Sanofi,"[1] requesting certain information related to Sanofi's insulin products (the "Letter"). Following receipt of your letter, we, on behalf of our client, Sanofi US ("Sanofi"),[2] participated in multiple conversations with your staffs regarding the nature and timing of Sanofi's response to the Letter. During those discussions, we agreed to provide responsive information on a rolling basis. On March 8, 2019, March 29, 2019, and April 22, 2019 we provided our first three submissions of information responsive to the Committee's requests. Below and enclosed, please find the fourth submission of responsive information, which includes information responsive to all remaining open requests. We have produced this information consistent with our prior discussions with your staffs, as well as our ongoing discussions regarding the confidentiality concerns we raised in the conversation with your staffs and in our March 8, 2019, March 29, 2019, April 22, 2019, April 29, 2019, and May 17, 2019 letters.

In particular, as described in our letters to the Committee on April 29, 2019 and May 17, 2019, the information provided in this submission is confidential and proprietary information that falls within the definition of "trade secret" under the Trade Secrets Act,

[1] We note that the Committee addressed its letter to "Sanofi." Sanofi is a société anonyme (public limited liability corporation) incorporated under the laws of the Republic of France and headquartered at 54, rue La Boétie 75008, Paris, France. As we understand the Committee's inquiry to involve the pricing of Sanofi's insulin products in the US market, we intend to produce responsive information and documents from the files of our client, Sanofi US, headquartered at 55 Corporate Drive, Bridgewater, NJ 08807, rather than from "Sanofi," its French parent company.

[2] Throughout this Letter, we use "Sanofi" to reference Sanofi US unless otherwise noted.

18 U.S.C. § 1905, Exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4), and the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836. We understand that the Committee and its staff are well-versed in handling such highly sensitive information. Pursuant to Rule XXIX of the Standing Rules of the Senate, we understand that the Committee will provide Sanofi with an opportunity to present any objections prior to any potential public disclosure and will work with us to try to mitigate any competitive harm concerns. We appreciate the Committee's continuing consideration of this important issue.

*Response to Requests:*

> *1(c): Every net price that was in effect at any time since January 1, 2014, for Part D plans, and all pharmacy benefit managers ("PBMs") or other entities that represented or negotiated on behalf of a Part D plan, as well as your company's 10 largest commercial plans, as defined by the number of lives covered. For each net price, please include the date on which the price went into effect. Please provide these prices on the basis of dosage units, i.e. the form in which they are marketed and sold. These prices should be reported on the same basis as the response to Question 1(b).*
>
> *1(d): Every formulary placement since January 1, 2014, for any Part D plan, and all PBMs or other entities that represented or negotiated on behalf of a Part D plan, and your company's 10 largest commercial plans, as defined by the number of covered lives.*
>
> *3(a): For each PBM that has been provided a rebate, discount, or other price concession for one or more of your company's insulin products, please provide the amount of the rebate, discount, or other price concession for coverage of the product and the dates the concession was in effect.*
>
> *3(c): For each PBM that has been provided a rebate, discount, or other price concession for one or more of your company's insulin products, please provide a description of any other terms or contract conditions that were agreed to as part of the rebate or other price concession negotiation that would affect patient access, including but not limited to, elimination of prior authorization, step therapies, volume targets, revenue targets, and other utilization management methods. Please include the dates such concessions remained in effect.*

Information responsive to the above requests is attached to this letter in two Excel workbooks and hardcopy PDFs, the format requested in your February 22, 2019 letter.

The Excel workbooks are titled "Insulin Pricing Information" and "Price Protection Information." Please note that, for purposes of Requests 3(a) and 3(c), we have interpreted the term "each PBM" to be consistent with the scope of information requested in Requests 1(c) and 1(d). For Requests 1(c) and 1(d), we produced the requested information for all "Part D plans, and all PBMs or other entities that represented or negotiated on behalf of a Part D plan, and Sanofi's 10 largest commercial plans, as defined by the number of covered lives." We applied the same construction to Requests 3(a) and 3(c).

Each product line item in the Excel workbook and hardcopy PDF titled "Insulin Pricing Information" represents the rebates, price concessions, and administrative fees offered by Sanofi on the specified insulin product at the specified point in time to a Part D plan or PBM. In the workbook, column B, "Contract Entity," identifies the other party to a Sanofi rebate agreement and the relevant product. Columns H, "Price Start Date," and I, "Price End Date," identify the start and end dates within which the discounts identified on a product line item were, or are, in effect. Column K, "WAC," identifies the Wholesale Acquisition Cost ("WAC"), which is the benchmark price against which price concessions are provided, during the applicable time period.

Requests 1(c) and 3(a)

Most relevant to Requests 1(c) and 3(a), the Excel workbook and hardcopy PDF titled "Insulin Pricing Information" identify the net prices and price concession amounts in effect since January 1, 2014 for Part D plans, PBMs and other entities that negotiated on behalf of a Part D plan, and for Sanofi's top 10 largest commercial plans. Specifically, columns S, "Net Price (Net of Base & Price Protection Rebates)," and V, "Net Price (Net of Base & Price Protection Rebates and Administrative Fee)," identify net prices, and columns P, "Base Rebate Amount," R, "Price Protection Rebate Amount," and U, "Administrative Fee Amount," identify the amount of any base rebate, price protection rebate, and administrative fee applicable to a given product. The net prices identified in column S take into account the base rebate and price protection rebate applicable to an insulin product, and the net prices in column U take into account the base rebate, price protection rebate, and administrative fee applicable to an insulin product. The percentage and amount of the base rebate associated with each insulin product are found in columns L, "Base Rebate Percent," and P, "Base Rebate Amount," respectively. The percentage and amount of the price protection rebate associated with each insulin product are found in columns Q, "Price Protection Rebate Percent," and R, "Price Protection Rebate Amount," respectively. The percentage and amount of the price protection rebate associated with each insulin product are available in the "Insulin Pricing Information" Excel workbook and hardcopy PDF only for the period January 1, 2014

through August 20, 2018. The percentage and amount of the price protection rebate associated with each insulin product for the period starting on August 20, 2018 are available on the "Price Protection Information" Excel workbook and hardcopy PDF.[3] The percentage and amount of the administrative fee associated with each insulin product are found in columns T, "Administrative Fee Percent," and U, "Administrative Fee Amount," respectively.

Requests 1(d) and 3(c)

The Excel workbook and hardcopy PDF titled "Insulin Pricing Information" identify in column W, "Bates Number," the Bates number of the contract or contract amendment where the Committee will find, for the period January 1, 2014 to the present for each relevant insulin product: (1) formulary placement for the product offered to any Part D plan, PBM and other entities that negotiated on behalf of a Part D plan, and Sanofi's top 10 largest commercial plans; and (2) a description of any term or contract condition on the product agreed upon as part of the rebate or other price concession offered to any Part D plan, PBM and other entities that negotiated on behalf of a Part D plan, and Sanofi's top 10 largest commercial plans. By including the information in column W, we intend that the Committee will be able to locate the formulary status and any contract conditions for a specific product by using the Bates number to identify the relevant contract or contract amendment.

[3] On August 20, 2018, Sanofi migrated its internal contracting tracking system from one contracting system (called "CARS") to a new contracting system (called "RMUS"). In the new RMUS system, the system manages price protection rebates. For this reason, Sanofi is not able to integrate the price protection rebates offered by Sanofi for contracts that are active after August 20, 2018 into the product line items, including net prices and price concession amounts, identified in the Excel workbook titled "Insulin Pricing Information." As an alternative, Sanofi is producing a second Excel workbook and hardcopy PDF titled "Price Protection Information" that identify the price protection rebates applicable to insulin products from August 20, 2018 through the present. Specifically, in the Excel workbook and hardcopy PDF titled "Price Protection Information," column B, "Contract Entity," identifies the other party to a Sanofi rebate agreement. Columns H, "Price Protection Start Date," and I, "Price Protection End Date," identify the start and end dates within which the price protection rebate identified on a product line item was, or is, in effect. Column K, "Price Protection Baseline WAC," identifies the baseline WAC upon which the price protection rebate is applicable, and column L, "Price Protection Percent," identifies the maximum percentage by which the baseline WAC can increase before Sanofi would owe a price protection rebate.

*Response to Request 3(b): For each PBM that has been provided a rebate, discount, or other price concession for one or more of your company's insulin products, please provide a description of how the rebate or other price concession impacted the product's formulary placement.*

Sanofi negotiates rebates, discounts, and other price concessions with health plans and their pharmacy benefit managers for the purpose of securing better formulary position for its products. Sanofi's goal when entering into these agreements is to ensure strong access and low cost sharing for patients. Under the current system, this is achieved through offering rebates or other price concessions in exchange for a more preferential formulary placement. As shown in the attached Excel workbooks and hardcopy PDFs provided in response to Requests 1(c), 1(d), 3(a), and 3(c), Sanofi typically offers a plan or PBM multiple different rebate options on a given product, with each offer associated with a specific formulary placement. Although Sanofi's hope in these negotiations is that its rebates will result in the best possible access for patients, it is not Sanofi's ultimate decision whether a product is on formulary, what the product's formulary placement is on a plan formulary, or the way that formulary placement affects patient cost-sharing responsibility for the product. Those decisions are made independently by the health plan or its PBM after a highly competitive negotiation.

*Response to Requests:*

*Second Subpart of Request 2(b): How did the changes described in Question 2(a) affect manufacturing costs? Question 2(a) states: How did the change(s) associated with a new NDC add value to patients?*

*2(e): For each product line, please provide the gross and per-unit manufacturing costs for each insulin product with an NDC.*

Below, please find a chart that provides the gross and per-unit manufacturing costs for each insulin product by NDC number, which is how Sanofi tracks this information internally.

**Gross Manufacturing Costs (US$ (M))**

| Brand | Strength | Dosage | NDC | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|---|---|---|
| Apidra | 100 unit/ML (10ML) | Vial | 0088-2500-33 | 4.01 | 2.45 | 2.12 | 2.05 | 1.75 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Apidra SoloSTAR | 100 unit/ML (5 x 3ML) | Insulin Pen | 0088-2502-05 | 5.45 | 3.87 | 3.64 | 3.77 | 2.88 |
| Lantus | 100 unit/ML (10ML) | Vial | 0088-2220-33 | 76.89 | 63.21 | 61.29 | 60.81 | 46.61 |
| Lantus SoloSTAR | 100 unit/ML (5 x 3ML) | Insulin Pen | 0088-2219-05 | 142.72 | 123.14 | 120.42 | 114.56 | 102.21 |
| Lantus Novaplus | 100 unit/ML (5 x 3ML) | Insulin Pen | 0088-5020-05 | N/A | N/A | N/A | 0.14 | 0.24 |
| LANTUS Novaplus | 100 unit/ML (10ML) | Vial | 0088-5021-01 | N/A | N/A | N/A | 0.14 | 0.29 |
| Soliqua 100/33 | 100 unit-33 mcg/ML (3ML) | Insulin Pen | 0024-5761-05 | N/A | N/A | N/A | 1.96 | 4.37 |
| Toujeo SoloSTAR | 300 unit/ML (3 x 1.5ML) | Insulin Pen | 0024-5869-03 | N/A | 6.44 | 23.49 | 31.18 | 28.30 |
| Toujeo Max SoloSTAR | 300 unit/ML (3ML) | Insulin Pen | 0024-5871-02 | N/A | N/A | N/A | N/A | 1.32 |
| Admelog | 100 unit/ML (10ML) | Vial | 0024-5924-10 | N/A | N/A | N/A | N/A | 2.42 |
| Admelog SoloSTAR | 100 unit/ML (5 x 3ML) | Insulin Pen | 0024-5925-05 | N/A | N/A | N/A | N/A | 3.64 |

**Per-Unit Manufacturing Costs (US$)**

| Product | Strength | Dosage | NDC | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|---|---|---|
| Apidra | 100 unit/ML (10ML) | Vial | 0088-2500-33 | 4.44 | 3.52 | 3.94 | 4.47 | 4.97 |
| Apidra SoloSTAR | 100 unit/ML (5 x 3ML) | Insulin Pen | 0088-2502-05 | 11.78 | 9.59 | 10.36 | 11.27 | 10.10 |
| Lantus | 100 unit/ML (10ML) | Vial | 0088-2220-33 | 3.43 | 2.95 | 3.27 | 3.72 | 3.61 |
| Lantus SoloSTAR | 100 unit/ML (5 x 3ML) | Insulin Pen | 0088-2219-05 | 8.43 | 6.87 | 6.91 | 7.05 | 7.26 |
| Lantus Novaplus | 100 unit/ML (5 x 3ML) | Insulin Pen | 0088-5020-05 | N/A | N/A | N/A | 7.35 | 7.32 |
| LANTUS Novaplus | 100 unit/ML (10ML) | Vial | 0088-5021-01 | N/A | N/A | N/A | 3.96 | 4.12 |
| Soliqua 100/33 | 100 unit-33 mcg/ML (3ML) | Insulin Pen | 0024-5761-05 | N/A | N/A | N/A | 15.74 | 14.99 |
| Toujeo SoloSTAR | 300 unit/ML (3 x 1.5ML) | Insulin Pen | 0024-5869-03 | N/A | 7.48 | 7.37 | 7.77 | 7.33 |
| Toujeo Max SoloSTAR | 300 unit/ML (3ML) | Insulin Pen | 0024-5871-02 | N/A | N/A | N/A | N/A | 9.30 |
| Admelog | 100 unit/ML (10ML) | Vial | 0024-5924-10 | N/A | N/A | N/A | N/A | 9.02 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Admelog SoloSTAR | 100 unit/ML (5 x 3ML) | Insulin Pen | 0024-5925-05 | N/A | N/A | N/A | N/A | 15.182 |

In our March 8, 2019 submission to the Committee, in response to Request 2(a), Sanofi provided information regarding changes to the formulations, delivery methods, and dosing levels for its insulin products and how those changes have benefited patients. Please note that the extensive efforts and financial investments that form the basis of Sanofi's research and development program are not accounted for in Sanofi's calculation of the gross and per-unit manufacturing costs.

*Response to Request 4: Please provide all contracts, including but not limited to, supply agreements, pricing agreements, rebate agreements, and other pricing concession agreements involving insulin products that were agreed to with Part D plans, PBMs or any other entities, such as specialty pharmacies, that represented or negotiated on behalf of a Part D plan, and your company's 10 largest commercial plans, as defined by the number of covered lives, that involved insulin products. Please provide all contracts that were in effect on or after January 1, 2014.*

In response to Request 4, enclosed with this letter are copies of all contracts and contract amendments involving insulin products with Part D plans, PBMs or any other entities that negotiated on behalf of a Part D plan, and the company's 10 largest commercial plans, as defined by the number of covered lives, that were in effect at any time on or after January 1, 2014. These documents are in production folder "SANOFI_SFC_003" on the enclosed disk and are stamped with Bates numbers SANOFI_SFC_00001911 to SANOFI_SFC_00008905 and SANOFI_SFC_00015002 to SANOFI_SFC_0015481. Please note that, for purposes of this response, we have defined "10 largest commercial plans" as commercial plans with nationwide scope, including PBMs or other entities that represented or negotiated on behalf of a commercial plan with nationwide scope. In other words, we have not included statewide insurance plans (e.g., Blue Cross Blue Shield of California) in determining Sanofi's "10 largest" commercial plans.

*Request 6: Please describe your Marketing and Advertising program for each of your insulin product lines. For each fiscal year since January 1, 2014, please provide an itemized accounting of costs, including but not limited to your costs attributable to your sales force, market research, product samples, third party vendors, and medical conference sponsorships. Separately, for the same timeframe, please provide an itemized accounting of the cost of marketing activities targeting prescribers, and direct-to-consumer advertising.*

In our March 29, 2019 submission, we described Sanofi's marketing and advertising activities and provided financial data related to these activities in response to the first part of Request 6. Below, please find additional financial information relating to Sanofi's direct-to-consumer advertising and physician advertising expenditures for its insulin products. We note that, as with other information produced with this letter, Sanofi considers the below information as constituting trade secrets, the disclosure of which would be competition sensitive.

**Approximate Direct-to-Consumer Advertising Expenses (US$ (M))**

| Product | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|
| **Lantus** | 44.44 | 5.59 | 2.99 | 7.68 | 0.07 |
| **Toujeo** | 2.93 | 119.11 | 132.04 | 90.85 | 50.89 |
| **Soliqua** | N/A | 0.94 | 10.09 | 28.47 | 5.47 |
| **Apidra** | 1.07 | 1.31 | 0.75 | 0.67 | 0.27 |
| **Ademelog** | N/A | N/A | N/A | 0.59 | 2.35 |

**Approximate Direct-to-Physician Advertising Expenses (US$ (M))**

| Product | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|
| **Lantus** | 44.53 | 11.53 | 10.43 | 16.32 | 8.32 |
| **Toujeo** | 2.40 | 77.50 | 83.72 | 47.95 | 33.22 |

| | | | | | |
|---|---|---|---|---|---|
| **Soliqua** | N/A | 1.12 | 27.66 | 52.64 | 21.46 |
| **Apidra** | 6.16 | 4.12 | 4.13 | 2.44 | 0.85 |
| **Ademelog** | N/A | N/A | N/A | 0.35 | 2.35 |

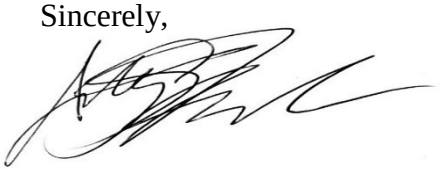
*Request 7(c): Please provide all written and electronic communications records that were sent, received, or otherwise provided to your company's senior leadership related to proposed pricing changes for insulin products since January 1, 2014. Please include any marketing studies that were used in connection with pricing decisions.*

Enclosed with this letter are communications sent, received, or otherwise provided to Sanofi's senior leadership related to proposed pricing changes for insulin products since January 1, 2014. These documents are in production folder "SANOFI_SFC_004" on the enclosed disk and are stamped with Bates numbers SANOFI_SFC_00008906 to SANOFI_SFC_00015001 and SANOFI_SFC_00015482 to SANOFI_SFC_00018515. For purposes of this request, we have defined "senior leadership" to include the members of the Sanofi U.S. Pricing Committee ("USPC") and the Sanofi Pricing Review Board ("PRB"). The communications enclosed with this letter include email communications among USPC members and among PRB members and presentations, summary documents, recommendations, and white papers presented to either the USPC or PRB, that are centrally maintained by Sanofi. As described in our March 8, 2019 submission, the USPC and PRB are responsible for pricing recommendations for Sanofi's US product portfolio, including adjustments to the list price. Please note that, as described in our prior submissions, these documents are from Sanofi's US files.

*  *  *

We remain committed to continuing to work collaboratively with the Committee on its inquiry. To the extent you have any questions about the information contained above or in this production, please do not hesitate to contact me.

Sincerely,



Jeffrey L. Handwerker

Enclosure(s)

[redacted]

# REBATE AND ADMINISTRATIVE FEE AGREEMENT

This Rebate and Administrative Fee Agreement ("Agreement") is entered into by and between Prime Therapeutics LLC, a Delaware limited liability company with its principal place of business located at 1305 Corporate Center Drive, Eagan, Minnesota 55121 ("Prime") and pharmaceutical drug manufacturer, sanofi-aventis U.S. LLC, (hereafter referred to as "SA"), a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807 ("SA"). [redacted] and SA are jointly referred to herein as the Parties and individually as a Party. This Agreement supersedes and replaces any existing agreements between the Parties relating to the same subject matter on or after the Effective Date.

WHEREAS, SA is engaged in the business of developing, manufacturing, and marketing prescription drugs;

WHEREAS, Prime is in the business of managing the pharmacy benefits under arrangements with a variety of Clients (as defined herein);

WHEREAS, Prime's services include, but are not limited to, maintaining Formularies (as defined herein), contracting with pharmaceutical drug manufacturer for Rebates (as defined herein), and allocating such Rebates to Clients in accordance with the arrangements with those Clients;

WHEREAS, in addition to contracting for, and collecting and allocating Rebates to Clients, [redacted] provides additional administrative services to SA for which SA agrees to pay separate Administrative Fees (as defined herein) to [redacted] for its own account; and

WHEREAS, the Parties desire to enter into this Agreement for the purpose of setting forth the terms and conditions under which SA will pay Rebates and Administrative Fees to Prime;

NOW, THEREFORE, in consideration of the foregoing and of the representations, warranties, and promises set forth below and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS. For the purpose of this Agreement, the following terms will have the meanings set forth below:

(a) **"Administrative Fee(s)"** shall mean a fee for services provided by Prime to SA. These services are more fully described in Attachment C.

(b) **Benefit Control/ Highly Managed Formulary Rebate"** shall mean a Formulary design with the highest level of Formulary controls. Clients which have this Formulary control include interventions which require on-line messaging that communicates to the Participating Providers, where applicable, that non-Formulary Pharmaceutical Products will not be reimbursed (Closed Formulary or NDC Lock). In order to qualify for this Formulary control Clients in the aggregate must have 60% of their claims applicable to, or 60% of their Eligible Members covered under, one or more of the following: (A) Closed Formularies in which Eligible Members pay one hundred (100%) of the drug cost of non-formulary Pharmaceutical Products, and/or (B) three tier benefits where (i) the Eligible Members' copayment differentials for Formulary versus non-Formulary Pharmaceutical Products are $\geq$$15.00, or (ii) the Eligible Members' coinsurance differentials for Formulary versus non-Formulary Pharmaceutical Products are $\geq$ 20%.

(c) **"Client"** shall mean an entity that sponsors or administers one or more Plans with which Prime has contracted to provide Formulary Management Services.

(d) **"Eligible Member"** shall mean each member, and eligible dependents of such member, of a Plan (i) who is entitled to receive prescription drug benefits from the Plan and (ii) who pays a co-payment or a coinsurance for the cost of a Pharmaceutical Product and such Plan reimburses Participating Providers in accordance with the Plan's prescription drug benefits. ~~It shall not include individuals using a cash card. Such individuals are specifically excluded from eligibility under this Agreement. In addition,~~ Eligible Members shall not include individuals who are covered by and eligible for benefits under a Medicare Advantage prescription drug plan ("MA-PDP") or a prescription drug plan ("PDP") approved by the Center for Medicare and Medicaid Services ("CMS") pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("Act"), regulations promulgated thereunder, as amended or supplemented, and any other guidance that CMS may issue (the Act, Regulations and CMS guidance collectively referred to hereinafter as "Part D").

(e) **"Formulary"** shall mean a listing in electronic or paper medium which includes various Pharmaceutical Products that is provided or made available to Participating Providers, physicians or other health care providers for purposes of guiding the prescribing and dispensing of Pharmaceutical Products.

(f) **"Formulary Management Services"** shall mean services provided by Prime to Clients. Formulary Management Services shall include some or all of the following: routine communications to Participating Providers or Eligible Members to facilitate awareness of Pharmaceutical Product availability on Formulary; general education and/or consultation to Clients regarding the use of Formularies and Eligible Member co-payment/coinsurance structures which encourage use of Formulary Pharmaceutical Products; clinical and financial consultative services; Rebate administration; on-line claims processing with point-of-sale controls; Pharmaceutical Product utilization evaluation; consultation and/or implementation of Pharmaceutical Product utilization management tools such as Prior Authorization, step therapy, or quantity limits.

(g) **"Guaranteed Rebate"** shall mean a Quarterly Rebate paid to Prime on behalf of a Plan for utilization of an SA Product which has been placed on Formulary, equal to the listed percentage off of WAC and defined in the SA Product Attachments.

(h) **"Market Share Rebate "** shall mean a Quarterly Rebate paid to Prime on behalf of a Plan for each Quarter that the Plan achieves a designated market share for the applicable SA Products, measured in accordance with the SA Product Attachments.

(i) **"Participating Provider"** shall mean those retail pharmacies, licensed and located in the United States, that have a valid NCPDP or NPI number, adjudicate claims on-line in accordance with current NCPDP standards for on-line adjudication, and are under contract with Prime or a Plan to dispense prescriptions for Eligible Members. Internet websites of such licensed retail pharmacies shall be considered acceptable; however, Participating Providers shall not include any other Internet pharmacies. Participating Providers shall include long term care outpatient pharmacies and/or mail order pharmacies which are (i) wholly owned by Prime and dispense only to Eligible Members or, (ii) if not wholly owned by Prime have entered into an agreement with Prime or a Client to provide pharmaceutical services and Pharmaceutical Products to Eligible Members and such agreements include provisions which allow only Prime or a Client (not the mail order pharmacy in its own right) to claim utilization of SA Product(s) for Rebates under this Agreement. Any pharmacy located outside of the United States, an institutional pharmacy or a government-owned pharmacy (both as described in Attachment E) shall not be considered a Participating Provider for purposes of this Agreement.

(j) **"Pharmaceutical Product"** shall mean prescription pharmaceutical products, which are branded drugs or generic drugs.

(k) **"Pharmacy and Therapeutics Committee"** or **"P&T"** shall mean a group of physicians, pharmacists and other health care professionals who function as an advisory panel to Prime and the Plans regarding the safety, efficacy, uniqueness and cost of prescription medications, and the development and maintenance of the Formularies.

(l) **"Plan"** shall mean a health care plan, health maintenance organization, preferred provider organization, self-insured employer and/or union health plan, group or individual plan, or similar funded health benefits program for which Prime has contracted, directly or indirectly to provide Formulary Management Services, which includes the right to receive from manufacturers discounts or Rebates on Pharmaceutical Products utilization by Eligible Members. A Plan shall also have a defined patient population and will not buy Pharmaceutical Products for trade or resale.

Plan shall not include (i) a Part D plan, including an MA-PD plan, a PACE Plan or a cost plan offering qualified prescription drug coverage as it is defined at 42 CFR § 423.4; (ii) programs or entities which maintain no eligibility criteria; (iii) program or entities for which Prime provides only claims processing services, (iv) any cash card program.

(m) **"Plan Formulary"** shall mean any Formulary which is developed by a Plan.

(n) **"Price"** shall mean the wholesale acquisition cost ("WAC") of a Product as established by SA and may be changed by SA at any time. For the purpose of calculating Rebates and Administrative Fees, the WAC in effect on the forty-fifth (45th) day will be used. SA acknowledges that Prime accesses Price information from Medi-Span, First DataBank or such other source of Pharmaceutical Product Price information. In the event of a discrepancy between the WAC as established by SA and the WAC published by Medi-Span, First DataBank or such other source of Pharmaceutical Product Price information, the WAC established by SA shall be used for purposes of this Agreement.

(o) **"Prime National Formulary"** shall mean a Formulary, which is developed by the Prime Therapeutics National Pharmacy and Therapeutics Committee ("National P&T") and is the core Formulary from which Plans with a Formulary process may but shall not be required to base their Plan Formularies.

(p) **"Prior Authorization"** shall mean, with regard to a Pharmaceutical Product, that such Pharmaceutical Product is available to an Eligible Member and a Plan reimburses prescriptions for such Pharmaceutical Product only when appropriate pre-existing criteria applicable for the prescribing of such Pharmaceutical Product have been satisfied.

(q) **"Quarter"** means an entire calendar Quarter during the term of this Agreement.

(r) **"Rebate"** shall mean a retrospective reimbursement of monetary amounts to Prime on behalf of a Plan by SA for SA Product(s) dispensed to an Eligible Member, for which the conditions required to receive a Rebate are satisfied. Rebates do not include Administrative Fees.

(s) **"SA Products"** shall mean those Pharmaceutical Products listed on Attachment A, entitled the "Rebated Product Listing", and described in the Product Attachments, attached hereto and made a part of this Agreement.

(t) **"Therapeutic Class"** shall mean Pharmaceutical Products, which are therapeutically equivalent and included in the same class of SA Products as defined by SA. The Pharmaceutical Products, which are included in a Therapeutic Class under this Agreement, are listed in the applicable Product Attachments. SA agrees to notify Prime in writing prior to the end of a Quarter in which a change to a Therapeutic Class is applicable for the following Quarter. The update will then become effective the first day of the following Quarter. If SA does not notify Prime in writing of such change to the Therapeutic Class, the Therapeutic Class shall remain unchanged. Unless mutually agreed upon by both Parties, line extensions of a SA Product such as new dosage forms or routes of administration, or new strengths, which are available for prescribing and dispensing, shall be considered a single product for the purpose of determining a Plan's Market Share within a Therapeutic Class.

(u) **"Unit"** shall mean, with respect to any SA Product, the smallest unit of measure as set forth in the applicable SA Product Attachments.

(v) "United States" means the United States of America, including all fifty (50) states and the District of Columbia.

2. **INVOICING AND PAYMENT OF REBATES AND ADMINISTRATIVE FEES.**

(a) Rebate Amounts. SA agrees to pay to Prime the amount of Rebates as set forth on SA Product Attachments for each SA Product, provided the terms of the Agreement and SA Product Attachments are met.

(b) Invoicing. As a condition to receiving the Rebate and Administrative Fee payments described herein, [redacted] shall provide to SA, within forty-five (45) calendar days after the end of each Quarter, a Rebate invoice, which will include Usage Data, (as defined in subsection 2.d. below) for SA Products dispensed to Eligible Members by Participating Providers during that Quarter and, if applicable, during the just prior Quarter ("Rebate Invoice"), subject to any regulatory requirements which require both Parties to invoice or pay Rebates within a shorter time frame. For any Quarter and subject to the provisions in Sections 2(g) and 4(b), if it is necessary for [redacted] to submit additional Usage Data not included in the initial submission, it may do so one time only provided such additional Usage Data is submitted within ninety (90) days of the original date of submission, and includes all required data for all Pharmaceutical Products in the Therapeutic Class. Notwithstanding the foregoing, should Prime need to submit Usage Data for a period earlier than ninety (90) days prior to the original date of submission for a Quarter, Prime shall notify SA of such need. SA shall use its best efforts to work with Prime to review and pay Rebates and Administrative Fees on such Usage Data which otherwise satisfies the requirements for payment of Rebates and Administrative Fees.

Any applicable Administrative Fee invoice (the "Administrative Fee Invoice") will be separately transmitted at or near the time the Rebate Invoice is transmitted to SA. Rebate Invoice and Administrative Fee Invoices are hereinafter collectively referred to as the "Invoices". Both Parties agree to support NCPDP billing and payment standards. [redacted] will make every effort to submit Invoices electronically, using the approved format as described in Attachment F. No changes shall be made to the fields, formats or media of data transmission, unless mutually agreed by the Parties.

Usage Data shall be sent to:

sanofi-aventis U.S.
Attn: Contract Administration
55 Corporate Drive 55B-205A
Bridgewater, NJ 08807

(c) National Market Share. If Rebates are calculated on the basis of national market share, such market share information shall be based on IMS NPA Plus Retail Method of Payment Total Prescriptions data ("NMS"). SA shall provide such NMS data to Prime by electronic medium within thirty (30) days after the end of each Quarter. If SA is unable to provide NMS data to Prime by such time, [redacted] shall calculate and submit Invoices for the current Quarter using NMS data from the just prior Quarter. Nonetheless, SA shall calculate and pay Invoices based on the current Quarter's NMS data.

(d) Usage Data. The information set forth in Attachment F will be included in all Usage Data reports with respect to each paid claim for SA Product(s) dispensed and shall include a summary and detailed statement of utilization data by Units and prescriptions. For market share and non-market share based Rebates the Usage Data reports shall also include summary level data of all other Pharmaceutical Products in the applicable Therapeutic Class at the NDC level (as described in the Product Attachments), on an individual Client basis in order to enable SA to validate compliance with the Agreement, and the eligibility for and calculation of Rebates.. If a Plan fails to satisfy the criteria for payment of Rebates for any Quarter, Prime will not be obligated to provide Company with any Usage Data reports applicable to such Quarter for such Plan.

Notwithstanding the foregoing, Prime agrees to use best efforts to provide ad hoc summary data for Plans who fail to meet the Rebate eligibility requirements if Company makes a request for such summary data not more than twice annually. These summary reports shall include summary level utilization data by Units and prescriptions of SA Products and all other Pharmaceutical Products in the applicable Therapeutic Class (as described in the Product Attachments), on an individual Client basis

Usage Data shall not include any utilization for which (i) a Client has less than fifty-one percent (51%) of the total financial risk of all Pharmaceutical Products covered by the Client, or (ii) is otherwise excluded in accordance with Attachment E.

For the purpose of Rebate eligibility, [redacted] shall not (to the best of its knowledge) submit claims on behalf of a Client for SA Products which have been repackaged, imported or reimported into the United States by any person or entity other than SA.

Subject to the following sentence and consistent with Attachment E, Excluded Claims Criteria, final determination of the acceptability of all Usage Data shall be at SA's discretion. Notwithstanding the foregoing, any claims excluded under the terms of this Agreement may be substantiated by [redacted] for Rebate eligibility to the satisfaction of both Parties.

(e) Payments From SA. SA shall pay each Invoice on a Quarterly basis. SA shall use commercially reasonable efforts to make such payment within forty-five (45) calendar days of SA's receipt of such invoices and Usage Data for a Quarter. In any event SA shall pay each Rebate and Administrative Fee invoice within no more than sixty (60) calendar days of SA's receipt of each Rebate and Administrative Fee invoices and Usage Data for a Quarter (the "Grace Period"). Notwithstanding the foregoing, and during the Term of the Agreement, should SA pay more than three (3) Rebate and Administrative Fee Invoices later than forty-five (45) calendar days following receipt of such Invoices and the Usage Data, [redacted] and SA shall renegotiate the payment terms of this Agreement.

SA will transmit its payment to Prime either electronically or by check, the specific means to be agreed upon by the Parties. SA agrees that the time period by which it is to pay any Invoices for any Quarter will not be delayed by: (i) changes made to the Usage Data by SA, unless such changes result from errors in or omission of Usage Data by Prime; (ii) delays by SA in responding to the Usage Data; or (iii) a resubmission of all or any part of the Usage Data by Prime at the request of SA due to, but not limited to, SA's errors, oversights, or omissions, unless the resubmission results from errors in or omission of Usage Data by [redacted]. If SA requests [redacted] to resubmit an Invoice due to [redacted]'s errors in or omissions of Usage Data, the time period by which SA is to pay Rebates and Administrative Fees may be delayed by the amount of time it takes Prime to correct and resubmit such an Invoice.

It is understood that Rebate and Administrative Fee payments will be made only for Units of each SA Product dispensed by Participating Providers to Eligible Members in accordance with the terms of this Agreement. In the event Prime materially breaches the terms of this Agreement, SA shall not be required to make payment of Rebates and Administrative Fees with respect to any Plan or Client which utilizes the Prime National Formulary for the Quarter(s) in which the breach occurs. SA shall not be required to make payment of Rebates and Administrative Fees with respect to a Plan for any Quarter in which it fails to satisfy the requirements for Rebate eligibility. Notwithstanding any other provisions of this Agreement, SA and Prime acknowledge and agree that, with respect to Rebates payable by SA to Prime on behalf of the Plans pursuant to the terms of this Agreement, any single SA Product covered by this Agreement shall not be dependent upon the Formulary status, compliance with Rebate conditions, discount or Rebate payment of any other SA Product.

SA shall not be required to provide any duplicate discounts or duplicate Rebate payments to Prime and/or a Client under another agreement if (i) Prime and/or a Client has previously entered into a Rebate or purchasing agreement with SA and such agreement is still in effect during the term of this Agreement, or (ii) if Prime is a member on another Rebate or purchasing agreement with SA under which duplicate claims are submitted. SA shall notify Prime prior to the Effective Date of this Agreement of any Rebate or purchasing agreements which it has entered into with a Client which are still effective. In

the event duplicate or conflicting agreements exist between the Parties, the Parties will work together to determine which agreement will be honored.

Notwithstanding SA's right to define a Therapeutic Class as set forth in 1(t), if such change materially affects the terms of a Product Schedule, the Parties may renegotiate the terms of such Product Schedule to the mutual satisfaction of both Parties.

(f) Claims Exclusion Criteria. In addition to the general Rebate eligibility requirements under the Agreement, the criteria for determining specific claims exclusions are set forth in Attachment E.

(g) Disputed Invoices. In the event SA disputes any portion of the Invoices, SA shall pay the undisputed portion of each Invoice within the payment period and include a complete statement indicating SA's calculation of Rebates and Administrative Fees and the basis for any disputed amounts. Disputes by SA regarding the data elements of the Invoices shall be limited to the data elements which are defined under Attachments E and F attached hereto and made a part of this Agreement. The Parties will use their best efforts to informally resolve any disputes, including disputes regarding Invoices. If the Parties are unable to reach a mutually acceptable informal resolution, the claiming Party may utilize the dispute resolution procedures set forth in Section 8(m) of this Agreement.

(h) Overpayments and Underpayments. In the event that either Party claims that SA has overpaid or underpaid Rebates and/or Administrative Fees, as a result of an audit or otherwise, the Party claiming to have overpaid or been underpaid shall notify the other Party in writing of the amount of such claim and the specific grounds on which that claim is based. The responding Party shall then have thirty (30) calendar days to submit a written response to the claiming Party. The Parties agree to use their best efforts to informally resolve any such claims. If the Parties are unable to reach a mutually acceptable informal resolution, the claiming Party may utilize the dispute resolution procedures set forth in Section 8(m) of this Agreement. Any claim for overpayment or underpayment of Rebates or Administrative Fees must be asserted in a written document, along with supporting documentation, and received by the Party against whom the claim is made no later than twelve (12) months from the date of the respective Invoice. Unless written notice is made by the claiming Party within twelve (12) months from the date of an Invoice, the Parties expressly waive the right to contest or challenge that invoice.

(i) Sale of Products and Change to Marketing Arrangements. SA shall notify [redacted] in writing within thirty (30) days of any sale of a SA Product or change to a marketing arrangement which impacts payment of Rebates and Administrative Fees by SA under this Agreement. In the event such a sale or change occurs, SA shall pay Rebates and Administrative Fees on any such SA Product through the end of the Quarter in which such sale or change occurs, unless another party agrees to fully assume that obligation, and Prime has consented to such assignment in accordance with Section 8(d) herein.

(j) Costs of Product Recalls and Field Corrections. If SA removes a Product from the market or conducts a field correction on its own initiative, by FDA request or by FDA order, SA shall reimburse Prime any reasonable costs and expenses it or the Plans incur in responding to the recall or field correction; provided, however, that Prime, on behalf of itself and the Plans (i) provides SA with supporting documentation SA reasonably requests and (ii) obtains SA's prior written consent, which shall not be unreasonably withheld to reimburse [redacted] and/or the Plans for such reasonable costs and expenses. Such costs and expenses may include, but are not limited to: (i) costs and expenses incurred by Prime to communicate with Plans and/or Eligible Members about the recall or correction, and (ii) costs and expenses incurred by a Plan to reimburse Eligible Members for a Product which was dispensed to Eligible Members, but which was not completely usable due to the recall or field correction.

3. OBLIGATIONS OF PRIME.

(a) Client List. A list identifying the Clients to be covered by this Agreement is set forth in Attachment D. SA acknowledges that it received and approved such list prior to execution of this Agreement. Thereafter Prime will notify SA of updates to Attachment D. Prime shall be entitled to add Clients at any time upon at least thirty (30) days prior written notice of such addition, unless otherwise mutually agreed by the Parties. Prime shall be entitled to delete Clients at any time, provided, however, that [redacted] shall use commercially reasonable efforts to provide SA with prompt notice of such deletion, unless otherwise mutually agreed by the Parties.

(b) Copy of Formulary. [redacted] shall maintain and provide, or make available, a full copy of the National Formulary and Plan Formularies to SA in either an electronic or paper format. As of the Effective Date of this Agreement, SA acknowledges that it has received such Formulary copies. Prime also shall provide or make available updates regarding Formulary changes, including those made to any of the SA Product(s) or to other Pharmaceutical Products in the applicable Therapeutic Class(es), as described in the SA Product Attachments. In addition, Prime agrees to notify SA sixty (60) days in advance of initiating a review of the Therapeutic Class(es) which contains SA Product(s). If the aforementioned information for Prime is available exclusively on-line and not in written form, than Prime will provide the appropriate website address and access to said Formulary and updates. [redacted] shall also provide or make Formulary updates available to Participating Providers.

(c) Inclusion of SA Products in Formulary. SA Products included on Formulary have been recommended for inclusion by [redacted]'s and/or a Plan's Pharmacy and Therapeutics Committee (or the equivalent thereof) in accordance with their respective processes.

To be eligible for Rebates with respect to a Formulary, the Parties agree that a SA Product must be on such Formulary. In addition, SA Products must be on such Formulary, as applicable, for the entire Quarter, which shall include publication of the applicable SA Products in all written and/or electronic copies of such Formulary provided or made available by Prime and/or a Plan to all Participating Providers. Further, to be eligible for Rebates for an SA Product, Prime and/or a Plan shall not include more than the number of Pharmaceutical Products on Formulary as described in an SA Product Attachment. SA Products shall be available to Eligible Members and be adjudicated accordingly at the lowest co-pay applicable to a Therapeutic Class for branded Pharmaceutical Products, and in the lowest brand tier applicable to a Therapeutic Class for a multiple-tier Formulary structure.

Prime further represents that the offer of Rebates under this Agreement has not affected, and will not affect, clinical decisions made by the applicable P&T Committees concerning the safety or efficacy of any Pharmaceutical Product or the clinical integrity of the Formulary processes.

Subject to the provisions of Section 2 and Section 3(e), in the event Prime or a Plan does not list, or removes or disadvantages one or more of SA Products with respect to the applicable Formulary during any given Quarter, SA shall not be obligated to pay Rebates or Administrative Fees for such SA Product(s) with respect to such Plan for that Quarter. Notwithstanding the foregoing, nothing shall limit SA's obligations with respect to other Plans where such SA Product or any other SA Product was not removed from Formulary. If the Formulary position or status of SA Product(s) changes at any time, [redacted] agrees to notify SA of such change in a timely fashion. If an SA Product(s) is removed from a Formulary, the provisions of this Agreement, insofar as they pertain to such removed SA Product(s) and such Formulary, will terminate as of the effective date of such action.

(d) Disadvantaging Activities. To be eligible for Rebates, SA Products shall not be disadvantaged in comparison to other branded Pharmaceutical Products in the applicable Therapeutic Class and no such corresponding brand Pharmaceutical Products shall have a more favorable Formulary position than that of the SA Products.

Unless imposed for medical reasons and applied consistently to all brand Pharmaceutical Products in the applicable Therapeutic Class, or mutually agreed to by the Parties, Prime shall not engage

in any activity which may discourage the utilization of SA Products. This includes, but is not limited to: (i) NDC blocking, (ii) Prior Authorization requirements, (iii) quantity limits, unless such limits are imposed by the prescribing physician for medical reasons or are consistent with the SA Product's package insert and, if necessary, as more fully described in the Product Attachment; (iv) counter-detailing or counter-promoting, (v) switching or therapeutic substitution and (vi) a higher co-payment or co-insurance than any branded Pharmaceutical Product in a Product's applicable Therapeutic Class and (vii) step edits. This activity list shall not be deemed to be exhaustive. Prime further agrees that it will not promote any branded Pharmaceutical Product in ways that disparage or disadvantage any of the SA Products in the Agreement.

[redacted] shall not provide any communications to Plans, Participating Providers, or others which encourage or require the use of a competitive branded Pharmaceutical Product in lieu of an SA Product(s) in the applicable Therapeutic Class(es).

(e) Exceptions from Disadvantaging. Notwithstanding the foregoing, SA agrees that the following shall not be considered disadvantageous to SA Products: (i) cost sensitive lists or relative dollar signs, which are based on industry standards and actual cost of therapy for cost differentiation between therapeutic agents; (ii) placement of Products on some but not all of a Plan's Formularies; (iii) programs such as mandatory generic programs applicable to Pharmaceutical Products which are therapeutically equivalent to SA's Products (iv) unless otherwise specified in this Agreement, benefit designs which prefer generic Pharmaceutical Products, including, but not limited to, co-payments for generics which are lower than co-payments applicable to SA's Products or placement of generic Pharmaceutical Products on a preferred Formulary tier. Notwithstanding the foregoing, benefit designs which prefer generic Pharmaceutical Products by requiring that a SA Product be Prior Authorized before it is dispensed, shall be considered disadvantageous unless otherwise mutually agreed by the Parties.

(f) Disclosures Required By Law. Prime represents that to the extent required by law (including any requirements under the Employee Retirement Income Security Act of 1974, as amended), it shall disclose the existence or any other aspect of this Agreement to any party with whom its contracts for Formulary Management Services.

(g) Disclosure to Clients. SA acknowledges and agrees that the Rebates paid pursuant to this Agreement have been negotiated by Prime for the benefit of the Clients with which it has a business arrangement. Rebates shall be paid to Prime for distribution and allocation to Prime's Plans or Clients pursuant to the contractual agreement between Prime and such Clients.

(h) Authorization and Disclosure of Administrative Fees. For all Administrative Fees paid hereunder [redacted] represents and warrants that such Administrative Fees have been authorized in advance by the Clients and that with respect to such amounts, Prime represents and warrants that it shall meet all disclosure obligations set forth in 42 C.F.R. 1001.952(j).

(i) Safe Harbor. The Parties each agree that, in performance of this Agreement, each Party will, to the extent applicable, fully comply with the provisions of the Social Security Act, 1128B(b) (42 U.S.C. §1320a-7b(b)), which, inter alia, prohibit the knowing or willful solicitation or receipt of any remuneration, directly or indirectly, in return for purchasing or recommending or arranging purchasing of any goods, services, or items for which payment may be made in whole or in part under a federal or state healthcare program. The Parties acknowledge and agree that the Rebates paid pursuant to this Agreement are intended to constitute discounts (as such term is used at 42 U.S.C. §1320a-7b(b)(3)(A)) and in regulations at 42 C.F.R. §1001.952(h) (the "Discount Safe Harbor"). The Parties further acknowledge and agree that the Administrative Fees paid pursuant to this Agreement are intended to constitute payments covered under the regulations at 42 C.F.R. §1001.952(j) (the "GPO Safe Harbor"). In the event that the Department of Health and Human Services Office of the Inspector General subsequently clarifies or promulgates safe harbor regulations under which the Rebates and Administrative Fees hereunder may be eligible for additional safe harbor protection(s), the Parties shall meet to consider whether modifications of this Agreement are appropriate.

(j) Reporting. Rebates provided in accordance with this Agreement are considered discounts and/or price concessions off the purchase price of Products and will be treated as "direct or indirect remuneration" ("DIR") as such term is described in 42 C.F.R. §423.308. To the extent Administrative Fees provided in accordance with this Agreement do not constitute bona fide service fees as defined in 42 C.F.R §§414.802 and 447.502, such fees will be considered discounts and/or price concessions off the purchase price of Products, and will, to that extent, be treated as DIR. [redacted] represents that it is aware of its obligations to report such Rebates, when applicable, to the appropriate federal and/or state agencies and authorities and will meet any and all requirements for reporting of the Rebates provided hereunder in accordance with federal and state laws and regulations.

(k) Independent Discretion. Nothing in this Agreement shall limit the ability of individual treating physicians, among other activities, to prescribe any Pharmaceutical Product, or Prime or Plans to make available new Pharmaceutical Products, as deemed appropriate in the reasonable professional discretion of any applicable P&T Committee.

(l) Generic/Over the Counter ("OTC") Availability. The date of commercial availability of a generic or OTC equivalent for a particular dosage form of a SA Product shall terminate all Rebate obligations for that dosage form of that SA Product effective as of the date of such commercial availability.

(m) Over-the-Counter. If a Pharmaceutical Product listed in a Therapeutic Class of a SA Product Attachment becomes available for sale as an OTC product, SA shall remove such Pharmaceutical Product from the applicable Therapeutic Class. In the event of such an occurrence, SA and Prime agree to discuss, subject to the provisions of Section 8(n), the Rebate terms applicable to such SA Product affected by the emergence of the OTC Pharmaceutical Product.

(n) Provider Education. [redacted] shall not preclude SA from providing physicians appropriate information and education regarding SA Products. Any information about SA Products shall be fair and balanced.

4. **RECORDS, AUDIT AND CONFIDENTIALITY.**

(a) Records. During the term of this Agreement and for a period of three (3) years thereafter, or such longer period as may be required by law, each of the Parties shall maintain records related to its obligations and responsibilities under this Agreement. SA may have access to the records of Prime relating to Prime's performance of this Agreement during normal business hours and upon reasonable notice, and the execution of appropriate confidentiality agreements. Any inspection or audit shall be subject to any Eligible Member confidentiality limitations, it being expressly understood that [redacted] will not be required to disclose any information contrary to applicable law or in violation of patient confidentiality.

(b) Audit. SA shall have the right, upon reasonable notice, during normal working hours, and subject to applicable laws on patient confidentiality and to the records and confidentiality provisions contained herein, to conduct itself or through a third party, a reasonable audit of the records of Prime necessary to establish that payment amounts have only been paid with respect to SA Products dispensed to Eligible Members in accordance with the terms of this Agreement. In the event SA uses a third party auditor, [redacted] shall have the right to approve or disapprove such independent auditor. Such approval by Prime shall not be unreasonably withheld. SA's right to audit will be limited to the previous four (4) Quarters for which Rebates were paid determined from the date written notice of an audit is given by SA, unless the audit finds, in good faith, that Prime is in material violation of this Agreement, in which case SA shall have the right, at no additional cost, to request up to an additional two (2) previous Quarters' data, measured from the last Quarter for which Rebates were paid.

In the event [redacted] utilizes a third party claims processor, Prime shall identify said third party and obtain on behalf of SA the right to audit such third party's relevant books, records and data as is reasonably necessary to verify information reported by [redacted] as part of its obligations under this

Agreement. Prime represents and warrants that it reviews Participating Providers' compliance by way of its standard desk top audit processes. As part of any audit by SA or a third party auditor, SA or the third party auditor may request a verbal or written summary from Prime of the desk top audit processes.

Prime shall have the right to specify certain confidential, trade secret or proprietary information that should not be disclosed to SA, including any individually identifiable health information, as such term is defined in 45 CFR 160.103. Prime may require SA or its independent auditors to execute a confidentiality and nondisclosure agreement satisfactory to Prime prior to the inception of any audit. SA shall pay all reasonable costs incurred by Prime in complying with any audit or inspection request including, but not limited to, the cost of duplicating any records which it requests from Prime.

SA agrees that audits of Prime shall occur no more than once annually. SA agrees that once an audit applicable to a specific time period under this Agreement is completed, records applicable to such time period shall no longer be subject to any future audits.

(c) Confidentiality. Except as otherwise specifically provided herein, the Parties understand and agree that in the performance of this Agreement, each Party may have access to private or confidential information of the other, including, but not limited to, confidential pricing, marketing or Pharmaceutical Product information, trade secrets, proprietary information, marketing and business plans, Prime's lists, financial information, personnel information, technical information, processes, formulas, procedures, Formulary and associated information, pharmacy lists, information on and relating to invoices and reports provided to SA by Prime, operations, this Agreement and its terms, conditions and contents and any other information or data designated as confidential or proprietary by the disclosing Party (collectively, "Confidential Information"). Each Party agrees that (i) all Confidential Information shall remain the sole and exclusive property of the owner and disclosing Party, and (ii) that it shall maintain and cause its employees and agents to maintain the confidentiality and secrecy of the Confidential Information, and (iii) that it will use the Confidential Information solely in connection with performing its duties and obligations under this Agreement. If SA uses a third party to review or validate claims data and invoices, SA agrees it will notify [redacted] in writing and such third party will sign a confidentiality and nondisclosure agreement with SA, satisfactory to Prime, prior to disclosing the data.

Notwithstanding the foregoing, such Confidential Information shall not include information that: (i) the other Party can establish to have been in its possession prior to receiving the information, (ii) is now or later becomes generally publicly available through no fault of the Party receiving the information, (iii) is received from a third party which had the right to disclose the information, or (iv) is approved by the other Party for disclosure. In addition, the Parties expressly acknowledge and agree that they may disclose their relationship and the SA Products covered by this Agreement for marketing purposes or as required by law. SA also acknowledges that [redacted] may disclose terms of this Agreement to its Clients and/or Plans.

Immediately upon the expiration or other termination of this Agreement, each Party upon written request shall return to the other Party any and all copies of the other Party's Confidential Information, provided that one copy may be kept for archival purposes. The Parties shall comply with any applicable laws related to Eligible Member confidentiality, including those set forth in the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"). The obligations of confidentiality in this Agreement shall survive any termination or expiration of this Agreement for a period of five (5) years thereafter, or such longer period as required by law.

If a Party is compelled by law, regulation, subpoena or government agency to disclose Confidential or proprietary Information, the Party so compelled will use reasonable efforts to provide written notice to the other Party before making such disclosure and will narrowly craft such disclosure to comply with the applicable law, regulation, subpoena or government agency request.

5. TERM AND TERMINATION.

(a) Term. This Agreement shall commence July 1, 2010 ("Effective Date") and shall continue in effect until June 30, 2013.

(b) Termination.

i. Either Party may terminate this Agreement without cause by providing the other Party sixty (60) days advance written notice.

ii. Either Party may terminate this Agreement in the event of a material breach of the terms of this Agreement by the other Party. Such termination shall be effective thirty (30) days after the non-breaching Party gives written notice to the other Party specifying the nature of the breach, unless the other Party cures the breach before the end of the 30-day period.

iii. Either Party may terminate this Agreement upon thirty (30) days advance written notice in the event the other Party: (A) ceases to be actively engaged in business or becomes insolvent, is dissolved or liquidated; (B) files or has filed against it a petition in bankruptcy and such petition is not dismissed within thirty (30) days of the filing; or (C) makes a general assignment for the benefit of its creditors.

iv. In the event of the enactment, promulgation, rescission, modification or interpretation by a court or legislative or regulatory body with jurisdiction over the matter of any law or regulation after the Effective Date of this Agreement which would materially adversely affect the manner in which either Party is obligated to perform under this Agreement, Prime and SA shall each have the right to make a written request of the other to enter into good faith negotiations with the other in order to seek to agree on reasonable terms to maintain the intent of this Agreement without the effect of such enactment, promulgation, rescission, modification or interpretation. If the Parties do not agree within forty-five (45) days of a Party's written request for negotiations, either Party may terminate this Agreement with respect to the affected Product upon written notice to the other Party within five (5) days of the end of such 45-day period. Notwithstanding the foregoing, should any enactment, promulgation, rescission, modification or interpretation by a court or legislative or regulatory body with jurisdiction over the matter of any law or regulation make this Agreement or a material portion of a Party's performance under this Agreement illegal or impossible, either Party may terminate the Agreement immediately.

(c) By Product Termination. SA may, in its sole discretion, delete a SA Product: (i) immediately due to a change in safety profile, (ii) with (30) thirty days written notice if sale or transference of ownership or (iii) with (90) ninety days written notice if discontinued, provided a Best Price is not triggered as described in subsection 8(i). If SA incurs a Best Price in relation to terminating a discontinued Product in accordance with subsection (c) (iii) above, SA shall provide written substantiation to Prime of such occurrence and then may invoke the provisions of subsection 8(i) with respect to such SA Product.

In the event of any such termination, SA shall measure performance and pay Rebates and Administrative Fees based on undisputed Usage Data through and including the date of termination.

Notwithstanding the foregoing, no termination under this Section 5 shall affect the rights and obligations of the Parties which accrue prior to the effective date of such termination.

6. **REPRESENTATIONS AND WARRANTIES.**

Prime represents, warrants, and covenants that:

(a) for the purpose of Rebate eligibility, all Plans shall fit within the definition and criteria of Section 1(l) of this Agreement.

(b) it has entered into written agreements with each Client under which it agrees to disclose the Rebates that [redacted] receives hereunder from SA.

(c) it shall comply, and in accordance with the terms of its agreements with the Clients and as required by law, shall notify Client(s) to comply, with all applicable obligations to properly disclose, distribute, and appropriately reflect all payments provided pursuant to this Agreement in the costs claimed or the charges made under the Medicare/Medicaid programs. Prime shall also comply, and in accordance with the terms of its agreements with the Clients, shall notify the Clients to comply with any other similar Federal or State health care programs in accordance with applicable law, including Section 1128(B) (b) of the Social Security Act and applicable regulations.

(d) any SA Product(s) dispensed to an Eligible Member by an owned mail order Participating Provider will have been dispensed for the Eligible Member's own use under a Plan that has included the SA Product on its Formulary; provided, however, that any SA Product(s) dispensed to an Eligible Member by a non-owned retail or mail Participating Provider will, to the best of [redacted] knowledge, have been dispensed for the Eligible Member's own use under a Plan that has included the SA Product on its Formulary. As used herein, "own use" is defined by the United States Supreme Court ruling in Abbott Laboratories v. Portland Retail Druggists Association, 425 U.S. 1 (1976).

(e) it has entered into lawful agreements with Clients to provide, Formulary Management services, contracted pharmacy network services, and/or other Formulary Management Services and, to the best of its knowledge, Prime has the exclusive right to submit SA Product utilization on behalf of the Clients and Plans for which the Rebates are allocated in accordance with the terms of the agreements with the Clients. With respect to any Rebate or Administrative Fee paid to Prime by SA under this Agreement, the Parties hereby agree that no portion of said Rebate or Administrative Fee is designed to be passed on to any other entity other than a Client, including, but not limited to, any health plan not under this Agreement.

(f) Utilization under this Agreement may be submitted for Rebates for Eligible Members whose SA Product is being paid for, directly or indirectly, by Federal Health Care Program ("Government Program"), as defined in Section 1128B(f) of the Social Security Act ("Act"), provided such Government Program payment is pursuant to or through (i) a risk contract under Section 1876(g) or 1903(m) of the Act or under another state health care program, as defined in Section 1128(h) of the Act, (ii) a Medicare Part C health plan that receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by the Centers for Medicare and Medicaid Services under section 1854 of the Act, or (iii) any other health plan that provides or arranges for items and services for Medicaid enrollees in accordance with a risk base contract with a State agency subject to the upper payment limits in 42 CFR 447.361 or an equivalent payment cap approved by the Secretary of Health and Human Services. If a Government Program Plan ceases to be such a Plan as defined above, Prime shall no longer submit claims for Rebates and Administrative Fees applicable to such Plan starting with the date the Plan ceases to be a Government Program Plan. The term "Government Program" as defined herein does not include the Medicare Part D prescription drug program. In the event utilization is submitted for Rebates under this provision, Prime acknowledges its Plan(s) are required to comply with reporting requirements with respect to the Rebate received hereunder by such contracts, or any other Federal or state requirements.

(g) the execution and delivery of this Agreement and the placement of SA Products on the Prime National or a Client Formulary, in accordance with [redacted] or a Plan's Formulary processes, is not prevented by, and does not and will not conflict with, violate or breach or constitute a default or require

any consent under, any current obligations, contractual or otherwise, that Prime may have to any third party or any other lawful restriction of any kind.

(b) it has entered into lawful agreements with Participating Providers under which such Participating Providers are obligated to comply with all applicable laws relating to the dispensing of the SA Products covered under this Agreement, including, without limitation, any state laws and regulations relating to drug product selection, and consumer protection.

7. INDEMNIFICATION

(a) Prime shall indemnify, defend and hold harmless SA from any and all claims, demands, actions, causes of action, losses, judgments, damages, costs and expenses (including, but to limited to, reasonable attorneys' fees, court costs and costs of settlement) (collectively, "Losses") that SA may suffer as a result of any claim to the extent such claim arises out of the negligence of Prime, gross negligence of Prime, or willful misconduct of Prime, or any breach by [redacted] of any of its representations, warranties and covenants set forth in Section 6 above. [redacted] obligations under this paragraph shall not extend to Losses to or arising from SA's negligence, willful misconduct, or breach of this Agreement.

(b) SA shall indemnify, defend and hold harmless Prime from all Losses that Prime may suffer as a result of (a) bodily injury, death or property damage to an Eligible Member caused by a defect in the SA Product, except to the extent that Prime's negligence or misconduct, or that of its employees or agents, caused such bodily injury or death; (b) the negligence of SA, gross negligence of SA, or willful misconduct of SA, or (c) any breach by SA of any of its obligations, representations, warranties and/or covenants set forth in this Agreement. SA's obligations under this paragraph shall not extend to Losses relating to or arising from Prime's negligence, willful misconduct, or breach of this Agreement.

(c) The indemnifying Party's obligations under this Section 7 are conditioned upon the indemnified Party giving the indemnifying Party (i) written notice of the claim within thirty (30) business days of the date that the indemnified Party first becomes notified of the claim, or earlier if necessary to prevent prejudice to the indemnifying Party, and (ii) assistance in the defense of any claim, including but not limited to the provision of documents, witness testimony, and interviews. The indemnifying Party shall have the sole right to choose counsel to defend any claim, and the indemnifying Party shall have the sole right to settle or otherwise resolve any such claim; provided, however, that the indemnifying Party shall give the indemnified Party an opportunity to comment on any settlement that may directly or indirectly affect the indemnified Party and provided further that in no event shall the indemnifying Party, without the written consent of the indemnified Party, admit any wrongful conduct on the part of the indemnified Party or create any liability for the indemnified Party not covered by this obligation of indemnity. The indemnified Party, at its own expense, may be represented by separate counsel in addition to the counsel selected by the indemnifying Party pursuant to this Section 7(c). In the event that representation of the indemnified Party and the indemnifying Party by the same counsel would be a conflict of interest for such counsel, the indemnified Party may select its own independent counsel without relieving the indemnifying Party of its responsibilities pursuant to this Section 7. Notwithstanding the terms of subsection (i) above, the indemnifying Party's obligations under this Section 7 shall not be relieved if the indemnified Party provides the indemnifying Party with notice of a claim in sufficient time to permit the indemnifying Party to timely answer, plead, or otherwise respond to such claim without prejudice.

8. MISCELLANEOUS.

(a) Compliance with Law. The Parties each agree that they will separately be responsible for securing and maintaining all required licenses, permits and certificates applicable to their respective activities, and each shall comply with any and all federal, state and local laws, regulations and ordinances, including, but not limited to, the applicable requirements of HIPAA and state anti-kickback and state consumer protection and disclosure laws, in performing its respective obligations hereunder.

(b) Severability. The Parties each agree that if any term or provision of this Agreement is declared illegal invalid, is prohibited under applicable law, or unenforceable or in conflict with any law or

regulation such provision shall be ineffective to the extent of any such prohibition without impairing the remaining provisions in any way. If either Party is materially adversely affected, the Parties agree to negotiate in good faith, in an effort to reach a new agreement regarding the subject matter of the severed provision.

(c) Force Majeure. Neither Party shall be liable to the other or any third parties for any delays in the performance of their obligations under this Agreement, or supply of any SA Product(s) if such delays were caused by acts of God, war, riot, insurrection, strike, accident, rebellion, sabotage, labor disputes, storms, floods, fires, explosions, delay of carriers, suppliers or telecommunications providers, failure or shortage of transportation facilities, national defense requirement, ordinance, government acts or regulations or other similar circumstances beyond that Party's control; provided, however, that once the delay is eliminated, the Party shall comply with its obligations as promptly as possible.

(d) Assignment. This Agreement may not be assigned, directly or indirectly, by operation of law or otherwise, by either Party without the prior written consent of the other Party, except: either Party shall be entitled to freely assign, without the written consent of the other Party, this Agreement and its obligations hereunder, to (i) an Affiliate of such Party, or (ii) in conjunction with the sale of all or substantially all of its assets, or a reorganization (including in bankruptcy) or merger with another entity, with notice of the assignment sent to the other Party within thirty (30) days after the assignment. In the event either Party makes such an assignment, each Party will cause the assignee to assume in writing all obligations of such Party under this Agreement.

As used in this Agreement, "Affiliate(s)" means any company that, directly or indirectly, controls or is controlled by or is under common control with a Party by means of ownership of more than fifty (50) percent of the voting stock or similar interest in said company. Affiliates of SA shall include, without limitation, Aventis Inc., Aventis Pharmaceuticals Inc. and Sanofi-Synthelabo Inc, which are all members of the sanofi-aventis Group.

(e) Notice. Any notice and/or other communication required or provided for under this Agreement shall be in writing and shall be deemed given when either personally delivered, sent by certified U.S. Mail, postage prepaid, return receipt requested or delivered by air courier, or transmitted by facsimile or electronic mail and confirmed in writing (sent by air courier or certified U.S. Mail) to the other Party at the address set forth on the first page of this Agreement, or to

[redacted]

If to SA:

sanofi-aventis
Attn: Contract Administration
55 Corporate Drive 55B-205A
Bridgewater, NJ 08807

With a copy to:

sanofi-aventis
Attn: General Counsel
Mail Code 55A-520A
55 Corporate Drive
Bridgewater, NJ 08807

Or to such address as a Party shall give notice to the other in like manner.

(f) Headings. Paragraph and section headings within this Agreement are for reference only and shall not be used in construing this Agreement.

(g) Entire Agreement. This Agreement is the entire agreement between the Parties in regard to its subject matter and supersedes any prior agreements or understandings for SA Products dispensed on dates of service on and after the Effective Date. Nothing in this Agreement shall be linked to or have an effect on any pricing or contractual terms or conditions offered in any other present or future contract between [redacted] and SA.

(h) Amendment. This Agreement may not be amended or modified except by written amendment signed by the Parties.

(i) Best Price. Regardless of any other term of this Agreement, the total discounts, Rebates, and payments to [redacted] for any SA Product shall not in any Quarter result in the establishment of a selling price for the SA Product that either (i) increases SA's statutory-mandated rebates for the SA Product over what they would otherwise be but for this Agreement or (ii) triggers any statutory or regulatory obligation of SA to offer a similar price for the SA Product to any other party ("Best Price"). If necessary to avoid the establishment of any such price, [redacted] agrees that the total Rebates to [redacted] for the SA Product may be reduced to the highest level that avoids the establishment of such price. SA shall provide written substantiation of the incurrence of Best Price prior to any reduction of Rebates.

(j) Exclusive Negotiating Manager for Rebates. Unless otherwise provided in its agreements with its Clients, Prime's agreements with its Clients provide that Prime will serve as each such Client's exclusive negotiating manager for Rebates. SA agrees that it will not, during this term of this Agreement, enter into any agreement with any of Prime's Client to pay Rebates directly to such Client without Prime's express written consent. [redacted] will notify SA in writing of the identity of any of Prime's Clients to which [redacted] has given its consent to directly contract with SA for Rebates on any of the SA Products.

(k) Medicare/Medicaid. It is understood that Rebates hereunder will be made only for SA Products dispensed pursuant to a Plan, in accordance with the terms of this Agreement. No Rebates will be made to [redacted], and no Formulary restrictions or interventions otherwise required under this Agreement may apply, with respect to any SA Products dispensed to any Eligible Members who are eligible to receive reimbursement for prescription Pharmaceutical Products under any federal or state government medical or pharmaceutical assistance program including, without limitation, Medicare and Medicaid. Prime will exclude information on any such Pharmaceutical Products dispensed to such individuals from the Rebate and Administrative Fee invoices provided under this Agreement.

Notwithstanding the foregoing, Rebate payments may be made hereunder and Formulary provisions may apply with respect to SA Products dispensed to Eligible Members enrolled in "eligible managed care organizations" (as defined in 42 C.F.R. § 1001.952(t)(2)(ii)) that have a risk based contract with, or receive capitated payments from, Medicare or a state Medicaid agency; provided that (i) Prime is either an eligible managed care organization or a "first tier contractor" as defined in 42 C.F.R. § 1001.952(t)(2); (ii) SA may not claim payment in any form from a federally funded health care program (including without limitation Medicare or Medicaid) for health care items or services covered under this Agreement; and (iii) neither Party may shift the financial burden of this Agreement to the extent that increased payments are claimed from a federally funded health care program (including without limitation Medicare or Medicaid). [redacted] shall use its best efforts to provide notice to SA prior to execution of this Agreement if it is made aware that a Plan with a risk agreement will need additional information from SA in order to meet any disclosure obligations under such risk agreement.

(l) No Obligation. The Rebates paid under this Agreement impose on Prime no obligation, express or implied, to promote, recommend, or arrange for the purchase, prescribing, or dispensing of any SA Products for which payment may be made under a federally funded health care program (including, without limitation, Medicare or Medicaid) on a fee-for-service basis.

(m) Dispute Resolution and Governing Law. If a dispute should arise with respect to the terms of this Agreement or any right or obligation created by this Agreement, the Parties shall have forty-five (45) calendar days from the date written notice of the dispute is given by one Party to the other to resolve the matter through informal discussion. If the matter is not resolved within those forty-five (45) days, and if any Party wishes to pursue the dispute, such Party may then pursue the legal relief and/or equitable remedies available to said Party under this Agreement; provided, however, that the foregoing shall not affect the right of either Party at any time to seek appropriate equitable relief to enforce Section 4(c). This Agreement will be construed in accordance with the laws of the State of Delaware, and any dispute between the Parties will be resolved in accordance with the laws of the State of Delaware.

(n) Independent Contractors. The Parties hereto are independent contractors engaged in the operation of their own respective businesses. Nothing herein shall be deemed or construed to create any other relationship between the parties.

(o) No Waiver. The failure of either Party to demand strict performance of any term or condition of this Agreement shall not constitute a waiver thereof or in any way limit or prevent subsequent strict enforcement of such term or condition.

(p) No Third Party Beneficiary. Nothing in this Agreement is intended or shall be deemed to confer upon any person, other than the Parties their respective successors and assigns, and the Plans and Clients, any rights, obligations, remedies or liabilities.

(q) Survival The provisions of Article 4 and Sections 2 (d) through 2 (f) and Sections 8(i) and 8(r) shall survive the termination or expiration of this Agreement for any reason. Except as otherwise provided in this Section, all other rights and obligations of the Parties shall terminate upon termination or expiration of this Agreement.

(r) Debarment. Both Prime and SA represent and certify that neither they nor any person or entity employed or engaged by them, including, without limitation, employees, contractors, or agents who will provide services in connection with this Agreement (collectively, "Personnel") are not currently:

(i) excluded, debarred, suspended or otherwise ineligible to participate in federal health care programs as defined in 42 U.S.C. § 1320a–7b or in federal procurement or nonprocurement activities as defined in Executive Order 12689 (collectively, "Ineligible");

(ii) debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), as amended, or any similar state law or regulation ("Debarred");

(iii) excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7, *et seq.* or any state agency from participation in any federal or state health care program as defined in 42 U.S.C. § 1320a-7 and 42 U.S.C. § 1320a-7b ("Excluded"); and/or

(iv) otherwise disqualified or restricted by the FDA pursuant to 21 C.F.R. § 312.70 or any other regulatory authority ("Disqualified").

Prime and SA represent and certify that they will not utilize any Ineligible, Debarred, Excluded or Disqualified Personnel to provide any services hereunder. During the term of this Agreement, if Customer or any Personnel becomes Ineligible, Debarred, Excluded or otherwise Disqualified, Customer shall immediately notify SA in writing within five (5) business days. Upon receipt of such notice of if the other Party becomes aware of any existing or threatened Ineligibility, Debarment, Exclusion or Disqualification, they shall have the right to terminate this Agreement immediately and shall retain all claims, causes of action, defenses, and other rights that they may have at law or in equity. For a period of two (2) years after termination or expiration of the Agreement, should Prime discover that it or any of its Personnel performing services related to this Agreement had become Ineligible, Debarred, Excluded or Disqualified during the term of the Agreement, [redacted] shall immediately notify SA in writing within five (5) business days. Prime represents and warrants that Prime and Personnel performing services related to this Agreement have not been convicted of any crime for which it or its Personnel

could be Ineligible, Debarred, Excluded or Disqualified and that Prime has no knowledge of any conduct for which [redacted] or Personnel could be Ineligible, Debarred, Excluded or Disqualified, and that Prime will notify SA in writing within five (5) business days if such a conviction occurs.

(s) Intellectual Property. Neither Party shall use the other Party's name or any patent, trade name, trademark, service mark or copyrighted material or property of the other Party, other than as expressly permitted by this Agreement or as otherwise agreed to in writing.

(t). Labeling. Prime shall not modify, add to, or delete any content or form of any of the labels, advertising or other written material provided with any Product (collectively, "Materials") in any manner whatsoever. If Prime does so, or if it incorporates all of any portion of the content of the Materials into written, oral, graphic or other material or presentation relating to or mentioning any Product or otherwise, SA hereby specifically disclaims any liability to Prime and to any other party for any damages, claim, penalty or judgment in connection with such material or presentation. Prime shall indemnify and hold SA harmless from any and all costs, expenses, damages, judgments and liabilities (including attorney's fees) incurred by or rendered against SA and arising as a result of such modification, addition, deletion or incorporation of the Materials.

(u) LIMITATION OF LIABILITY. NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY AND THE INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 7, INDEMNIFICATION, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR PAYMENT OF ANY CONSEQUENTIAL, PUNITIVE, INCIDENTAL OR SPECIAL DAMAGES INCURRED BY THE OTHER PARTY.

IN WITNESS WHEREOF, the Parties executed this Agreement as of the last date set forth below.

| PRIME THERAPEUTICS LLC | SANOFI-AVENTIS U.S. LLC |
|---|---|
| By: [signature] | By: [signature] |
| Name: Charles T Roderick | Name: [redacted] Senior Director Contract & Pricing Contract Development |
| Its: CFO | Its: |
| Date: 9/17/10 | Date: 9/20/10 |

## ATTACHMENT A

## REBATED PRODUCT LISTING

[redacted]

Lantus® and Lantus® SoloSTAR®

[redacted]

Line extensions of a SA Product such as new dosage forms or routes of administration, or new strengths, which are newly available for prescribing and dispensing after the Effective Date of this Agreement, will automatically be added to this Attachment A unless either Party notifies the other Party in writing within sixty (60) days after the SA Product is available in the marketplace for prescribing and dispensing that such line extension or strength is not to be added to this Agreement. Notwithstanding the foregoing, SA shall not require that such line extensions or new strengths of a SA Product be added to this Agreement, or the National Formulary or a Plan's Formulary in order for the original NDCs of the Product to be eligible for Rebates and Administrative Fees.

All dosage forms, package sizes and package types of a SA Product shall be eligible for Rebates under this Agreement.

PRODUCT ATTACHMENT (B - 1)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

[redacted]

**PRODUCT ATTACHMENT (B - 3)**
**QUARTERLY REBATE SCHEDULE**
**SANOFI-AVENTIS U.S. LLC**

(insulin glulisine [rDNA origin] injection)

| PRODUCT | PACKAGE SIZE | NDC# | UNIT |
|---|---|---|---|
| Apidra® | 10 mL Vial | 00088-2500-33 | 1mL |
| Apidra® | 5 x 3 mL Cartridge Systems | 00088-2500-52 | 1mL |
| Apidra® SoloSTAR® | 5 x 3 mL Prefilled Pen | 00088-2502-05 | 1mL |

**Apidra® and Apidra® SoloSTAR® Specific Requirements:**

- In each contract Quarter, [redacted] will be eligible for Rebates of up to fifteen percent (15.0%) of the Price for Units of Apidra® and Apidra® SoloSTAR® dispensed by the Participating Providers in the Quarter to Eligible Members based on Usage Data submitted on behalf of each Plan for which Apidra® and Apidra® SoloSTAR® are on Formulary as detailed below.
- Apidra® and Apidra® SoloStar® must be placed on Formulary with unrestricted patient access in the first or second tier of a multi-tier benefit design. Third Tier is considered non-Formulary.
- All package forms of Apidra® and Apidra® SoloStar® must be placed on the same Formulary tier.
- Guaranteed Rebates are equal to the listed percentage off of Price as defined below.
- Market share Rebates will be calculated separately for each Plan as set forth below based on the Plan's market share in a Quarter. The Current NMS ("CNMS") will be carried out to two (2) decimal places (i.e., XX.XX%) as determined by the IMS NPA Plus (Retail/MORX) report data for the applicable period. Market share Rebates will be calculated separately as set forth below based on a Plan's market share total carried out to two (2) decimal places (i.e., XX.XX%) applicable in a Quarter and compared to NMS.

**Rebate:**

| | **Benefit Control / Highly Managed Formulary** |
|---|---|
| **Guaranteed** | **12.0%** |
| > CNMS to 1.00 pts above CNMS | **1.0%** |
| > 1.01 pts above CNMS to 2.00 pts above CNMS | **2.0%** |
| > 2.01 pts above CNMS to 3.00 pts above CNMS | **3.0%** |
| **Total Maximum Reimbursement** | **15.0%** |

"Payment Cap" = The total Rebate paid with respect to any Quarter shall not exceed fifteen percent (15.0%) of the Price applicable in the Quarter.

**APIDRA® AND APIDRA® SOLOSTAR® THERAPEUTIC CLASS**

| THERAPEUTIC CATEGORY | SA PRODUCT | COMPETITIVE PRODUCTS* |
|---|---|---|
| Rapid Acting Insulin | Apidra® | Humalog |
| | Apidra® SoloSTAR® | Novolog |

*Includes all strengths, formulations and NDC numbers associated with the Pharmaceutical Products listed. Any new strengths, formulations and NDC numbers of the listed Pharmaceutical Products will be deemed automatically added.

PRODUCT ATTACHMENT (B - 4)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

[redacted]

PRODUCT ATTACHMENT (B - 4) – (continued)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

**PRODUCT ATTACHMENT (8 - 5)**
**QUARTERLY REBATE SCHEDULE**
**SANOFI-AVENTIS U.S. LLC**

(insulin glargine [rDNA origin] injection)

| PRODUCT | PACKAGE SIZE | NDC# | UNIT |
|---|---|---|---|
| Lantus® | 10 ml Vial | 00088-2220-33 | 1mL |
| Lantus® | 5 x 3ml Cartridge | 00088-2220-52 | 1mL |
| Lantus® SoloSTAR® | 5 x 3ml Pen | 00088-2220-60 | 1mL |

**Lantus® and Lantus® SoloSTAR® Specific Requirements:**

- In each contract Quarter, Prime will be eligible for Rebates of up to seven percent (7.0%) of the Price for Units of Lantus® and Lantus® SoloSTAR dispensed by the Participating Providers in the Quarter to Eligible Members based on Usage Data submitted on behalf of each Plan for which Lantus® and Lantus® SoloSTAR is on Formulary.
- Lantus® and Lantus® SoloSTAR® must be placed on Formulary with unrestricted patient access in the first or second tier of a multi-tier benefit design. Third Tier is considered non-Formulary.
- All package forms of Lantus® and Lantus® SoloSTAR® must be placed on the same Formulary tier.
- Guaranteed Rebates are equal to the listed percentage off of Price as defined below.
- For Performance Rebates, Current National Market Share ("CNMS") is measured as the total number of prescriptions of Lantus® and Lantus® SoloSTAR® dispensed as a percent of the total number of prescriptions dispensed for all Pharmaceutical Products defined in the Lantus® Therapeutic Category. The CNMS is defined as the prescription market share total carried out to two (2) decimal places (i.e., XX.XX%) as determined by the IMS NPA Plus (Retail/MORX) report data for the applicable period.

**Rebate:**

| Formulary Placement | Benefit Control /Highly Managed Formulary |
|---|---|
| **Guaranteed Rebate** | **3.0%** |
| **Performance Rebate** | |
| > CNMS to 0.49 SP* | 0.0% |
| > CNMS +0.50 SP to 0.99 SP | 0.6% |
| > CNMS +1.00 SP to 1.49 SP | 1.2% |
| > CNMS +1.50 SP to 1.99 SP | 1.7% |
| > CNMS +2.00 SP to 2.99 SP | 2.3% |
| > CNMS +3.00 SP to 3.99 SP | 3.3% |
| > CNMS +4.00 SP | 4.0% |
| **Max Rebate** | **7.0%** |

*SP = Share Point

"Payment Cap" = The total Rebate paid with respect to any Quarter shall not exceed seven percent (7.0%) of the Price applicable in a Quarter.

PRODUCT ATTACHMENT (B - 5) (continued)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

## LANTUS® AND LANTUS® SOLOSTAR® THERAPEUTIC CLASS

| SA PRODUCT | COMPETITIVE PRODUCTS* | |
|---|---|---|
| Lantus®<br>Lantus® SoloSTAR® | Insulin<br>Humalog Mix 50/50<br>Humalog Mix 75/25<br>Humulin 50/50<br>Humulin 70/30<br>Humulin N<br>Levemir<br>Novolin 70/30<br>Novolin N<br>Novolog Mix 70/30<br>Relion Mix 70/30<br>Relion N | Non-Insulin<br>Actoplus MET<br>Actos<br>Avandamet<br>Avandaryl<br>Avandia<br>Byetta<br>Janumet<br>Januvia<br>Onglyza<br>Victoza |

*Includes all strengths, formulations and NDC numbers associated with the Pharmaceutical Products listed. Any new strengths, formulations and NDC numbers of the listed Pharmaceutical Products will be deemed automatically added.

PRODUCT ATTACHMENT (B - 6)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

PRODUCT ATTACHMENT (B - 6) (continued)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

PRODUCT ATTACHMENT (B - 7)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

PRODUCT ATTACHMENT (B - 8)
QUARTERLY REBATE SCHEDULE
SANOFI-AVENTIS U.S. LLC

## ATTACHMENT C
## ADMINISTRATIVE FEES

SA agrees to pay [redacted] an Administrative Fee for all SA Products which are included on Formulary. In consideration of Administrative Fees, [redacted] will perform services and reporting related to such Formularies. The Administrative Fee shall equal three percent (3%) of the Price, except for Lantus for which the Administrative Fee shall equal two percent (2%) and shall be calculated as further described below.

SA Products eligible for Administrative Fees are listed in Exhibit A of this Agreement.

The Parties agree that Administrative Fees are completely separate and apart from the Rebates paid on behalf of the Plans. Prime receives Administrative Fees from SA in exchange for administering Rebate agreements. Such administrative activities include administration of the Rebate program, including, but not limited to, contracting with the Clients for disbursement of Rebates hereunder, collecting, processing and reporting the Usage Data hereunder, and the calculation and distribution of applicable Rebates to the Clients on behalf of the Plans in accordance with the applicable terms of the Clients' agreements with [redacted]

The Administrative Fee for each SA Product will be calculated with respect to each Client by multiplying the Eligible Member SA Product utilization by the Administrative Fee rate set forth above.

SA shall pay [redacted] an Administrative Fee as set forth above, but in no event more than three percent (3%) of the WAC of each SA Product multiplied by the number of Rebateable Units utilized during each calendar Quarter. For the purposes of this Agreement, Rebateable Units shall be defined as the utilized units of SA Products that are on contract, are listed on Formulary for the entire calendar Quarter, unless otherwise mutually determined on a SA Product-by-SA Product, Plan-by-Plan, and Quarter-by-Quarter basis, and so long as all of the conditions set forth in section 3(c) and 3(d) are satisfied.

[redacted] shall promptly notify SA if it becomes aware that it no longer complies with the requirements of this Agreement which impact its eligibility for Administrative Fees, and upon such notification, the obligation to pay Administrative Fees shall automatically terminate. Prime acknowledges and agrees that SA is relying upon Prime's due diligence in ensuring that the Rebates hereunder are extended to those Clients who meet the requirements for Rebate eligibility as set forth in this Agreement, and that payment of the Administrative Fees hereunder is, in part, for such due diligence. If SA determines in good faith in its own reasonable discretion that a Client is not eligible for Rebates hereunder, [redacted] agrees that SA shall have no obligation to pay Administrative Fees to Prime applicable to that ineligible Client. Failure to satisfy these conditions shall result in the applicable Client's utilization of specific SA Products not being eligible for Administrative Fees in the Quarter the failure occurs.

**ATTACHMENT D**

**Client List**
**To the Rebate and Administrative Fee Agreement**

## ATTACHMENT E
## Excluded Claims Criteria

In addition to the other sections of the Agreement which set out the terms and conditions for Rebate eligibility, this Attachment E sets out the criteria for determining claims which shall be excluded from Rebate eligibility, unless otherwise mutually agreed by the Parties in writing. In the event the Parties mutually agree upon additional or different criteria than that expressed in this Attachment E, the item agreed upon shall be automatically incorporated into the Agreement effective as of the date set forth in such writing.

If Company excludes claims submitted by [redacted] as ineligible for Rebates on the grounds that the claims fall within one or more of the Categories listed below, Company shall identify the criteria used to make such exclusion and provide a listing to [redacted] of those excluded claims. Upon request from [redacted], Company shall provide additional supporting documentation.

Notwithstanding anything to the contrary here in, if [redacted] substantiates and both Parties agree to include any claims initially excluded under the terms of this Attachment E to the satisfaction of Company, Company shall pay Rebates for said claims.

| Category | Description | Terms for Exclusion |
|---|---|---|
| Duplicate Rxs Same PBM | This category includes "Duplicate Prescriptions" (defined as, same Product, Prescription Number, Pharmacy, Fill Date and Refill Number) within the submitted Invoice Period. | All claims that fit this Category's Description shall be excluded from Rebate eligibility. |
| Duplicate Rxs Multiple Customers | This category includes Duplicate Prescriptions (as defined above) across previous submissions from all of Company's customers. | Claims that fit this Category's Description shall be excluded from Rebate eligibility except as described below with respect to coordination of benefits situations.<br><br>All claims submitted by Prime for which a Plan under this Agreement provides primary coverage in a coordination of benefits scenario, shall be eligible for Rebates regardless of whether another managed care organization providing services to a plan, or a plan submits a Duplicate Prescription on behalf of a secondary payor. Company acknowledges that regardless of its accounting methods, all claims submitted on behalf of a Plan where such Plan is designated as the primary payor for such claims, and are not otherwise excluded under this Agreement, shall be eligible for Rebates. |
| Units Exceeding Maximum Quantity | This category includes claims containing units in excess of the normal amounts needed for the applicable days supply for a Product, as defined by the Plan benefit. | All claims that fit this Category's Description shall be excluded from Rebate eligibility. |

| | | |
|---|---|---|
| Invalid Pharmacy Number | This category indicates the involved pharmacy is not listed as a valid pharmacy with the National Council for Prescription Drug Plans (NCPDP). | All claims containing either missing or invalid NCPDP and/or NPI numbers shall be excluded from Rebate eligibility, unless otherwise agreed to by the Parties. |
| Ineligible Pharmacies | I. **NCPDP Dispenser Class and Type Standard.** Participating Providers shall be classified in accordance with the most current NCPDP Dispenser Class and Type standards. Claims from the following Types and/or Classes of pharmacies shall be ineligible for Rebates: Government Pharmacies, including but not limited to Indian Health Service/Tribal/Urban Health Pharmacies and Military Pharmacies; IV Infusion Hospitals; VA Hospital Pharmacies; and Nuclear Pharmacies.<br><br>For purposes of clarity, all claims from Participating Providers in any other NCPDP Dispenser Class and/or Type, including but not limited to Mail Order Pharmacies and Outpatient Rxs from Long Term Care, Specialty and Institutional Pharmacies; shall be eligible for Rebates, unless otherwise excluded under this Agreement.<br><br>II. **340B "Covered Entities."** All claims from 340B "Covered Entities," as defined by the Public Health Service Act at 42 U.S.C. 256b(a)(4), shall be excluded from Rebate eligibility.<br><br>III. **Outside United States.** All claims from Participating Providers located outside of the United States shall be excluded from Rebate eligibility. | |
| Missing Rx Number | This category indicates prescriptions which do not contain a prescription number. | All claims which do not contain a prescription number shall be excluded from Rebate eligibility. |

## ATTACHMENT F
**Usage Data**

For more information please refer to the NCPDP website www.ncpdp.org
[redacted] shall provide to SA the following information:

Customer shall provide to SA the following information:

**Utilization Data Record (UD)**

| Field Name | Data Type | Field Length | Start Position | End Position |
|---|---|---|---|---|
| RECORD TYPE | A/N | 2 | 1 | 2 |
| LINE NUMBER | N | 11 | 3 | 13 |
| DATA LEVEL | A/N | 2 | 14 | 15 |
| PLAN ID QUALIFIER | A/N | 1 | 16 | 16 |
| PLAN ID CODE | A/N | 17 | 17 | 33 |
| PLAN NAME | A/N | 30 | 34 | 63 |
| SERVICE PROVIDER ID QUALIFIER | A/N | 2 | 64 | 65 |
| SERVICE PROVIDER ID | A/N | 15 | 66 | 80 |
| ENTITY ZIP/POSTAL CODE | A/N | 15 | 81 | 95 |
| SERVICE PROVIDER TYPE | N | 2 | 96 | 97 |
| PRODUCT/SERVICE ID QUALIFIER | A/N | 2 | 98 | 99 |
| PRODUCT SERVICE ID | A/N | 19 | 100 | 118 |
| PRODUCT DESCRIPTION | A/N | 30 | 119 | 148 |
| TOTAL QUANTITY | N | 15 | 150 | 164 |
| UNIT OF MEASURE | A/N | 2 | 165 | 166 |
| REBATE DAYS SUPPLY | N | 4 | 175 | 178 |
| PRESCRIPTION TYPE | N | 2 | 179 | 180 |
| TOTAL NUMBER OF PRESCRIPTIONS | N | 8 | 181 | 188 |
| PRESCRIPTION/SERVICE REFERENCE NUMBER QUALIFIER | A/N | 1 | 189 | 189 |
| PRESCRIPTION/SERVICE REFERENCE NUMBER | N | 12 | 190 | 201 |
| DATE OF SERVICE | N | 8 | 202 | 209 |
| REIMBURSEMENT QUALIFIER | A/N | 2 | 258 | 259 |
| REIMBURSEMENT AMOUNT | N | 12 | 260 | 271 |
| PATIENT LIABILITY AMOUNT | N | 12 | 280 | 291 |
| FILL NUMBER | N | 2 | 292 | 293 |
| RECORD PURPOSE INDICATOR | A/N | 1 | 294 | 294 |
| REBATE PER UNIT AMOUNT | N | 12 | 295 | 306 |

**Express Scripts (ESI)**
**Contracting White Paper 2014 Lantus**
**Medicare Bid Process**

Sanofi is in the process of negotiating with ESI for Medicare Lantus contract offers for 2015. Below outlines an additional request from ESI.

**Summary of Current Offer:**
On 03/25/2014, the following rebate maximums for 2015 were approved by USPC: (See whitepaper attached below as backup)

- 24% for Tier 2, 1 of 2 positioning on formulary
- 30% for Tier 2, 1 of 1 exclusive positioning on formulary with other basal insulins being not covered.
- Plus 10% Price Protection.

- Current Offer: 22% for 1 of 2 and 28% for 1 of 1.

ESI has requested an enhancement to our current 2014 terms due to marketplace changes. This is allowed per our current agreement "At any time during the term of the agreement, ESI may solicit new or enhanced rebate offers with respect to any product based on changes in the marketplace."

ESI's initial request was for 22% Lantus rebate beginning July 1, 2014 ($37M).

**Recommendation:**

- **Effective 10/1/14**:
  - Additional 4% above current terms (14.6% to 18.6%) for Tier 2, 1 of 2 basal insulins ($10M).

| BASELINE | 1Q2014 | 2Q2014 | 3Q2014 | 4Q2014 | FY 2014 |
|---|---|---|---|---|---|
| GROSS SALES | $211 | $217 | $248 | $255 | $931 |
| REBATE % | 14.6% | 14.6% | 14.6% | 14.6% | 14.6% |
| REBATES $s | $31 | $32 | $36 | $37 | $136 |
| **CUSTOMER ASK** | | | | | |
| REBATE % | 14.6% | 14.6% | 22.0% | 22.0% | 18.6% |
| REBATES $s | $31 | $32 | $55 | $56 | $173 |
| VAR TO BASELINE | $0 | $0 | $18 | $19 | $37 |
| **PROPOSED** | | | | | |
| REBATE % | 14.6% | 14.6% | 14.6% | 18.6% | 18.6% |
| REBATES $s | $31 | $32 | $36 | $47 | $146 |
| VAR TO BASELINE | $0 | $0 | $0 | $10 | $10 |

**BACKUP – PREVIOUS WHITEPAPER USED FOR USPC APPROVAL OF 2015 OFFER**

**ESI Medicare 2015**
**Out of Guidelines Rebate Request**
**2015 BUDGET YEAR**

**Recommendation:**

- **Approve ESI Lantus/Lantus SoloStar 2015 Medicare offers of:**

    - **Walk-In Guidance**
        - **18% plus 10% price protection for a co-preferred positioning in the preferred branded tier**
        - **25% plus 10% price protection for exclusive positioning in the preferred branded tier**

    - **Top-Line Guidance**
        - **24% plus 10% price protection for a co-preferred positioning in the preferred branded tier**
        - **30% plus 10% price protection for exclusive positioning in the preferred branded tier**

**Recommendation is based on Core Brand Strategy of Optimizing Value and Patient Retention**
This recommendation supports the organizational goal to retain as many diabetes patients as possible in advance of future pipeline expansion. A weakened position in the Medicare Part D channel, where the population and disease prevalence is growing, would severely compromise our ability to do this. These discount levels do not represent a new best offering within the market place. Despite the increase in rebate relative to 2014 terms (15%), this remains a profitable decision with the ability to move share in this account. For the ESI book of business, the 30% offer for an exclusive formulary position projects to a 2015 positive Net Sales variance of $675M versus a Not Covered Position.

**Negotiation Strategy**
The Top-line Guidance will be offered only if needed. We expect there will be time to counter-offer if our initial offer is not adequate. Our preference is to secure a co-preferred position which there appears to be more potential for with ESI. There is a high probability that we will need to go higher than the walk-in offer for ESI to secure unrestricted access for 2015.

**ESI Background**
The completion of the Medco acquisition resulted in Express Scripts becoming the largest US PBM. Significant steps were executed by Express Scripts during 2013 to fully merge all PBM operations onto a single platform and align formularies effective Jan. 1, 2014.

- 10.2M Medicare lives of which over half are managed senior plans

**ESI Lantus Contracting History and Current**
Lantus maintained a 5% rebate for Medicare through 2012. Rebates were re-negotiated to a 15% rebate for 2013-2014 in the face of the threat of being moved to Not Covered.

We submitted the 2015 Medicare Bid in December at the same rates as 2014. We received feedback stating that our Medicare offer needs to be revised.

- ESI mentioned that Lantus price increases over the past two years have positioned Sanofi as a cost driver that has triggered significant attention.
- ESI shared that Novo has been extremely aggressive recently with their Medicare offer.
- ESI looking for both co-preferred and exclusive offerings. Client plans are requesting an exclusive offer for comparison.
    - ESI confirmed that a competitive bid for 1 of 2 is still a desirable position if the offer is consistent with the competitor.
    - For 2014 they made Humalog exclusive in the RAI category, moving Novolog to Not Covered and made Byetta & Bydureon the only options in the GLP1 category, moving Victoza to Not Covered.

**Express Scripts Formulary Offerings**

ESI offers three formularies in Medicare:

- National Preferred: Main formulary, Multi-Tier with exclusion list categories.
- Basic: Same as National formulary without the exclusion list categories.
- High Performance: Most restrictive and least utilized formulary and continues to decrease as ESI works to promote the cost effectiveness of the National Preferred formulary.

We expect that there will be time to counter-offer if ESI indicates that the offer is not adequate to secure access in 2015 but it will require that we move quickly as timelines for submission to CMS rapidly approach.

**Financials**

The proposed ESI Part D offer of 30% is for exclusive positioning in the Basal Insulin Class. Levemir's offer for similar positioning would have to be ~38% to keep ESI Net Cost to Plan neutral.

**Co-Preferred:**

| ESI Co-Preferred | FY 2015 | | | |
|---|---|---|---|---|
| Scenario | Gross Sales | Rebate $ | Net Sales | Rebate % |
| Current | $980 | $147 | $833 | 15% |
| Walk-In | $980 | $176.38 | $804 | 18% |
| Vartiance to Current | | $29 | ($29) | |
| Top-Line Guidance | $980 | $235 | $745 | 24% |
| Vartiance to Current | | $88 | ($88) | |

**Exclusive: ESI Walk-in offer @ 25% Rebate**

| CALENDAR YEAR SUMMARY | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ESI ONLY | FY 2015 | | | | | | FY 2016 | | | | | |
| Scenario | Gross Sales | Rebate $s | Net Sales | Rebate % | RXs | MS | Gross Sales | Rebate $s | Net Sales | Rebate % | RXs | MS |
| NO CONTRACT | $117 | $0 | $117 | 0.0% | 252,291 | 9.2% | $63 | $0 | $63 | 0.0% | 128,924 | 4.3% |
| *Proposed: 1/1/15 - Lantus Exclusive* | | | | | | | | | | | | |
| Proposed Exclusive | $1,131 | $283 | $849 | 25.0% | 2,435,652 | 88.4% | $1,331 | $333 | $998 | 25.0% | 2,698,636 | 89.8% |
| *Variance to No Contract* | | | *$732* | | *2,183,361* | *79.3%* | | | *$935* | | *2,569,713* | *85.5%* |
| *Cumulative Variance* | | | | | | | | | *$1,666* | | | |

| CONTRACT YEAR 1<br>ESI Net Cost To Plan Analysis<br>Net Cost to Plan = Pharmacy Reimbursement + Pharmacy Dispensing Fee - Rebates | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Scenario | Lantus Rebate % | Lantus Net Cost To Plan | Lantus Copay | Lantus Mkt Sh | Levemir Rebate % | Levemir Net Cost To Plan | Levemir Copay | Levemir Mkt Sh | Total Net Cost To Plan after Copay |
| **Lantus (18%) & Levemir (25%) Tier 2 Co-Preferred** | 18.0% | $909 | $94 | 85% | 25.0% | $159 | $16 | 15% | $958 |
| **Levemir (38%) Tier 2 Excl Lantus NC** | 0.0% | $134 | $26 | 10% | 38.0% | $799 | $99 | 90% | $808 |
| **Lantus (30%) Tier 2 Excl Levemir NC** | 30.0% | $897 | $108 | 98% | 0.0% | $26 | $4 | 2% | $810 |

$s in Millions

Analogue: 88%

**Exclusive: ESI Top-Line Guidance offer @ 30% Rebate**

| CALENDAR YEAR SUMMARY | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ESI ONLY | FY 2015 | | | | | | FY 2016 | | | | | |
| Scenario | Gross Sales | Rebate $s | Net Sales | Rebate % | RXs | MS | Gross Sales | Rebate $s | Net Sales | Rebate % | RXs | MS |
| NO CONTRACT | $117 | $0 | $117 | 0.0% | 252,291 | 9.2% | $63 | $0 | $63 | 0.0% | 128,924 | 4.3% |
| *Proposed: 1/1/15 - Lantus Exclusive* | | | | | | | | | | | | |
| Proposed Exclusive | $1,131 | $339 | $792 | 30.0% | 2,435,652 | 88.4% | $1,331 | $399 | $931 | 30.0% | 2,698,636 | 89.8% |
| *Variance to No Contract* | | | *$675* | | *2,183,361* | *79.3%* | | | *$868* | | *2,569,713* | *85.5%* |
| *Cumulative Variance* | | | | | | | | | *$1,543* | | | |

**Modeling Assumptions:**

1. A single pricing action in June 2014: 14.9% Vial/9.9% Pen
2. No pricing actions to occur in 2015
3. No impact to the basal insulin market from a follow-on basal competitor
4. Offer for preferred, exclusive status
5. Analog: Part D Not Covered

| Analogues | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 |
|---|---|---|---|---|---|---|
| Not Covered | -74.5% | -90.5% | -92.5% | -94.1% | -94.5% | -94.5% |

**From:** Ingram, Garrett PH/US
**Sent:** Tuesday, August 19, 2014 4:12 PM
**To:** Guenter, Peter PH/FR; Purcell, Andrew PH/US; Bartner, Natalie PH/US; Whitaker, Anne PH/US; Kaseta, Michael PH/US
**Cc:** Du, Wei Wei PH/FR; Bray, Scott PH/US; Borneman, James PH/US; Loreaux, Sandy PH/US; McClellan, Mike PH/US
**Subject:** RE: Lantus Weekly Report - Week Ending August 1, 2014

Andrew, Peter & all,

Per Andrew's response the contract is performing to the expectations/forecasts we set when we signed the deal. We will continue to monitor and focus on accelerating pull through. Below is our initial assessment. Additionally, attached are the whitepapers & financials for the OptumRx Commercial & Part D deals. Due to the sequence of events we have completed a post action review that we will be sharing with you in September. Our response to customer feedback resulted in incremental impact. Look forward to reviewing learnings with you. Please let me know if you have any questions or feedback. Best,

Garrett

**UHC Commercial and Part D Response**

Overview: Driven by increasing costs in the basal category, including sanofi price increases on Lantus, UHC approached sanofi with a request for incremental commercial rebate targets. Following a series of sanofi offers in the 15% range, UHC removed Lantus from commercial formulary. Sanofi responded with a last minute bid of 45% for Tier 2 which was rejected by UHC who counteroffered with a 45% rebate for Tier 3 + 7% cumulative PP. Although this offer was deemed to be negative financially vs. a no-contract scenario, the offer was ultimately accepted over access concerns to future products and the need to secure access to patient lives.

In Part D, UHC similarly moved to remove Lantus from formulary in 2015, particularly unhappy about the December 2013 pricing action and suggesting that agreed terms of 35% +7% PP were insufficient. Final terms of 55% + 6% PP were agreed to which also included access to the Saver Plus formulary, a segment of lives of which Lantus had previously been excluded. Lantus Vial added - 7/1/14 and SoloSTAR -10/1/14.

Financials

Budget 14 estimates were locked in late July prior to completion of negotiations, hence, there was a resulting negative financial variance vs. budget estimates.

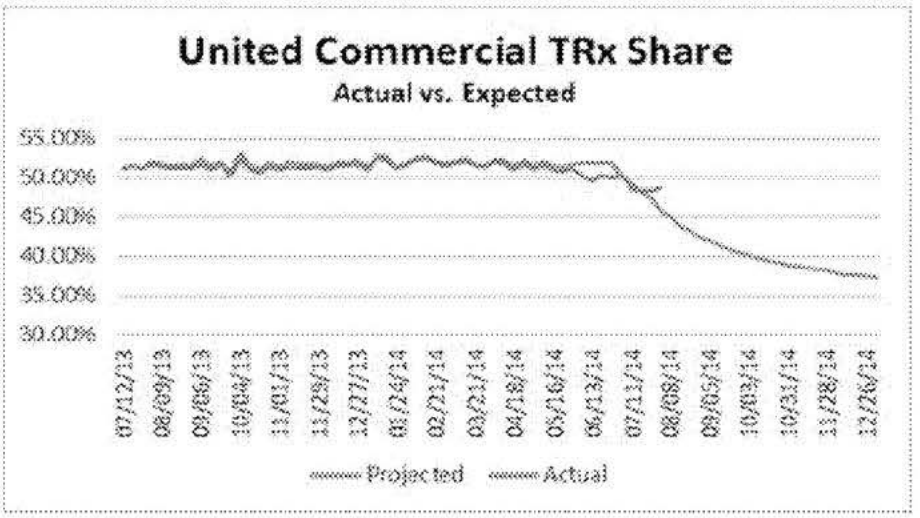
| Variance vs. Budget 14 | | 2014 |
|---|---|---|
| Commercial | $ | (52) |
| Part D | $ | (23) |

Because rebate terms initiate in July 2014, there is an overall negative impact of -$42 M and -$23 M in Commercial and Part D respectively vs. not contracting. For 2015 there is a -$23 M in commercial and an offsetting +$119 M in 2015, driven by the opportunity to access the Saver Plus segment.

| Variance vs. No Contract | 2014 | 2015 |
|---|---|---|
| Commercial | $ (42) | $ (23) |
| Part D | $ (23) | $ 119 |

Current Performance

The commercial tier change occurred on July 1st. Actuals to date are near projections. Erosion appears to have begun in June slightly ahead of expectations.




-----Original Message-----
From: Guenter, Peter PH/FR
Sent: Friday, August 15, 2014 9:01 AM
To: Purcell, Andrew PH/US
Cc: Ingram, Garrett PH/US; Bartner, Natalie PH/US; Du, Wei Wei PH/FR; Bray, Scott PH/US
Subject: Re: Lantus Weekly Report - Week Ending August 1, 2014

agree.

thanks and best regards

peter

Sent from my iPad

> On 15 Aug 2014, at 08:57, "Purcell, Andrew PH/US" <[redacted] wrote:
>
> Hello Peter -
>
> I'll ask Garrett to provide assessment on whether the contract is performing to the expectations/forecasts we set when we signed the deal. I assume the modeling at that time showed we were better to pay those rebates rather than

lose access entirely, but now we need to know if the metrics that were set are being achieved. We will also consider the "go forward" plan to improve profitability at UHC and what options/timing are available to us.
>
> Best regards,
>
> Andrew
>
>
> Andrew Purcell
> VP and Head of Diabetes Patient Centered Unit Sanofi US
>
[redacted]
>
>
>> On Aug 15, 2014, at 8:51 AM, "Guenter, Peter PH/FR" [redacted] wrote:
>>
>> andrew
>>
>>
>> UHC is a terrible bleed. it costs us approx 50 mio rebates this year on top of budget, as well as another 50 mio medicare best price. all this for a tier 3 that apparently does not help us. probably a deal we should not have been doing. we have to get either to a better tiering, either better position our position in UHC.
>>
>> thanks and best regards
>>
>>
>> peter
>>
>> Sent from my iPad
>>
>> Begin forwarded message:
>>
>> From: "Schwarz, Stefan PH/US"
>> [redacted]
>> To: "Adom, Ulric PH/FR"
>> [redacted] "Chancel,
>> Pierre PH/FR"
>> [redacted]
>> "Dousset, Laurent PH/FR"
>> [redacted] 'Du,
>> Wei Wei PH/FR" [redacted]
>> "Durso, Jerome PH/US"
>> [redacted] "Guenter,
>> Peter PH/FR"
>> [redacted] "Jumel,
>> Frederic PH/FR"
>> [redacted]
>> "Malphettes, Stephane PH/DE"
>> [redacted]
>> >>, "Oudet, Ludovic PH/FR"
>> [redacted] "Witz,
>> Pascale PH/FR"

>> [redacted]
>> Cc: "Balzer, Joseph PH/US"
>> [redacted]
>> "Bartner, Natalie PH/US"
>> [redacted]
>> "Borys, Margaret PH/US"
>> [redacted]
>> "Hawthorne, Paul PH/US"
>> [redacted]
>> "Ingram, Garrett PH/US"
>> [redacted]
>> "Kaseta, Michael PH/US"
>> [redacted]"Lata,
>> Denise PH/US"
>> [redacted]'Oehrlein,
>> Scott PH/US"
>> [redacted]
>> "Purcell, Andrew PH/US"
>> [redacted]
>> "Rossilli, Robert PH/US"
>> [redacted]
>> "Whitaker, Anne PH/US"
>> [redacted]
>> Subject: Lantus Weekly Report - Week Ending August 1, 2014
>>
>> Dear all,
>>
>> Please find attached the latest weekly report for Lantus for the week ending August 1, 2014.
>>
>> Key Takeaways:
>> • Lantus NRx share decreased by 0.04%(CW vs. C4W) to reach 53.5%
>> • Levemir NRX share has seen a single largest decrease of -0.22%(vs. PW) in last 8 weeks
>>
>> • Lantus TRx share increased by 0.07%(CW vs. PW) to reach 54.0%
>>
>> • No significant increase in Levemir NRx volume is observed due to Levemir FlexTouch launch at this point of time.
>> o We will continue to monitor impact on a weekly basis
>>
>> • Commercial Plans:
>> o Lantus experienced 3.18% NRx share loss within UHC commercial since Levemir experienced positive formulary change(Tier-2 to Tier-1) beginning May'14 and Lantus experienced negative formulary change(Tier-2 to Tier-3) beginning Jul'14
>> o Lantus experienced 5.01% NRx share loss within [redacted] commercial beginning May'14
>>
>> • Part D Plans:
>> o Caremark and [redacted] show a stable NRx Trend
>> o UHC NRx share stabilized
>>
>> Regards,
>> Joe Balzer
>>
>>

[redacted] **US Recommendation**

Lantus Private Label Strategy

*September 29, 2015*

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| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus* | [redacted] | *Private Label* | *Target July 1, 2015* |
| **Brand Strategy:** | *Reassert Lantus' leadership position to secure and accelerate volume growth in light of the aggressive market challenges, Toujeo launch and biosimilar defense. Differentiate Lantus as 1st basal insulin of choice.* | | |
| **Contracting Strategy:** | *Support Brand strategy by preserving preferred access for Lantus in hospitals through private label programs (i.e.,* [redacted] *with a sole source contracting position in each program that will allow for Lantus to remain in a strong position post-LOE at competitive pricing. Lantus would be the first insulin in these programs, allowing for a significant opportunity to grow share for the glargine franchise.* | | |
| **Recommendation:** | *Enter into private label agreements with key hospital GPOs (*[redacted] *for Lantus SoloStar and Lantus 10ml Vial. Would require that we label branded Lantus in the private label program's label. Maintain current branded contracting strategy (discounts based on market share in the Acute Care COT only); increase admin fee from 1% (current) to 3% (proposed).* | | |
| **Financial Impact:** | *Through participation in the private label programs, we expect an approximate 10% increase in Lantus volume in the inpatient setting The only contracting cost (pre-LOE) is additional admin fee; post-LOE we would have the opportunity to maintain the business at competitive price points (likely across all COTs).* | | |
| **Risk Considerations:** | *Significant long-term risk to Sanofi glargine business at key hospital GPOs if we choose not to participate in the private label programs in the near-term.* | | |
| **Net Sales Analysis** | *Due to the expected 10% increase in volume for Lantus* [redacted] *we expect financial upsides as follows:* [redacted] | | |

**Recommendation:**

- Enter into a private label agreements with key hospital GPOs ([redacted].) for Lantus SoloStar and Lantus 10ml Vial. Would require that we label branded Lantus in the NovaPlus label. Maintain current branded contracting strategy; increase admin fee from 1% (current) to 3% (proposed).
- Our walk-in position with [redacted] would be for Lantus to be the only basal insulin available under the GPO's private label program. The fallback position would be for a sole source glargine award. Branded Lantus and any competitive products currently sold pursuant to agreements with [redacted] will continue to be available to members. The initial focus for the strategy would be to enter into an agreement with [redacted] as they are amenable to retaining the current contracting strategy (with only increased admin fees) until market entry of biosimilar/generic competition.
- Premier would be a secondary target, as they have stated that they would require a single price point across all COTs. If we have an agreement for private label for [redacted] based on the current contracting strategy (with increased admin fees), we can likely move Premier off of their position and enter into a similar agreement as the [redacted] contract.
- These types of agreements will include generic product contracting terms, such as Right of First Refusal, Failure to Supply, etc., which would become effective based on the market entry of biosimilar/generic competition. These terms are standard in the generic market and would be a requirement in a post-LOE environment.

**Winthrop US Recommendation**

Lantus Private Label Strategy

*September 29, 2015*

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**Rationale for Recommendation:**

- Our Sanofi goal is to retain as many diabetes patients on Lantus in advance of future pipeline expansion. A weakened position in the Institutional channel, where the population and disease prevalence is growing, would severely compromise our goal. A weakened presence in the hospital channel would also likely have a negative spillover effect into outpatient, retail and LTC.
- Lantus is losing accounts and share within the institutional channel because of aggressive discounting and bundled contract offerings from Novo Nordisk and Lilly.
- Supports Toujeo launch by maintaining the availability of Lantus for Lantus patients currently on therapy during hospital stays, which allows for the potential transition of appropriate patients to Toujeo upon discharge through transition of care into retail and LTC.
- In conjunction with the recently-approved changes to the Institutional contracting strategy, this agreement would secure a sole source contract for Lantus [redacted] in advance of LOE; including right of first refusal as competitors enter the market, greatly increasing the likelihood of being competitive to help maintain strong Lantus business in the [redacted] post-LOE. This synergistic approach will allow Sanofi to quickly stabilize current business and accelerate volume and market share growth.
- [redacted]l account managers will drive utilization of private label products generally, which will include Lantus private label NDCs, as a key part of their respective portfolios, allowing Sanofi Diabetes field teams to focus efforts on Toujeo and transition of care pull through initiatives. GPO private label representatives do not discuss the clinical merits of any particular products, but rather promote the availability of participating products as part of their respective private label portfolios.
- Financial pressures from Health Care Reform and ACA have forced many hospitals and IDNs to review their formularies including the insulin market. Hospitals and IDN's now employ 60% of physicians and are aligning EMRs and formularies to the clinics. If product is not on formulary at the hospital, the product is non-formulary in the outpatient clinic, significantly disadvantaging the product.
- If we sustain Lantus use in acute setting the patient is more likely to stay on glargine in the post-acute setting. Likewise, a patient admitted to acute setting on glargine will likely stay on glargine. This is particularly key for those [redacted] members that are key academic institutions [redacted]
- Lovenox was the first Sanofi product to be a part of these private label programs, helping to increase market share post-LOE and the ability to maintain and grow volume and share at [redacted] post-LOE in a highly competitive environment. The private label agreements were significant contributors to our ability to retain hospital business at the two (2) largest GPOs in the channel, with the combined volume of [redacted] representing ~62.5% of all enoxaparin sodium used in the hospital channel (at nearly 5 years past LOE). See appendix for additional details regarding Lovenox in the NovaPlus program.

[redacted]

**Winthrop US Recommendation**
Lantus Private Label Strategy
*September 29, 2015*

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[redacted]

**Contracting Assessment**

[redacted]

- Positive financial impact due to expected increase in volume and limited additional contract investment (in the form of increased admin fee):
  - No upside in 2015; ~$3.5MM upside in 2016; ~$3.5MM upside in 2017; net of additional admin fees.
- Having Lantus available to members through the private label programs will allow additional opportunities for the field to engage in pull-through efforts throughout the transition of care continuum for both Lantus and Toujeo. Only contracting cost (pre-LOE) is additional admin fee; post-LOE we would have the opportunity to maintain the business on a long-term basis at competitive price points (likely across all COTs under [redacted]

Assumptions:

- Contract start date of October 2015; 10% volume increase begins in January 2016; incremental volumes based on [redacted] account forecasts
- Incremental 2% Admin Fee for Private Label administrative services
- Includes budgeted average discount rates
- No budgeted price increases on Lantus Vial/SoloStar

- Positive financial impact due to expected increase in volume and limited additional contract investment (in the form of increased admin fee):
  - No upside in 2015; ~$1.5MM upside in 2016; ~$1.5M upside in 2017; net of additional admin fees.

**Manufacturing and Supply Chain Assessment**

- No cost for label development; incremental cost would be due to any variation in COGs between brand and private label.
- COGs for [redacted] estimated to be slightly higher than the branded presentations:
  - Private Label SoloStar Mgmt COGs is ~1.68% higher than branded Lantus SoloStar
  - Private Label 10ml Vial Mgmt COGs is ~4.51% higher than branded Lantus 10ml Vial
  - Legal COGs for private labels are estimated based on the proportion of Mgmt/Legal COGs for branded Lantus.
- Forecast volumes for private labels can be assumed under current manufacturing guidelines
- No Impact on Toujeo manufacturing.

**Winthrop US Recommendation**

Lantus Private Label Strategy

*September 29, 2015*

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| | Branded Lantus | | Private Label | |
|---|---|---|---|---|
| | SoloStar | Vial | SoloStar | Vial |
| WAC | $ 372.76 | $ 248.51 | $ 372.76 | $ 248.51 |
| Net Price (Max Discount) | $ 219.93 | $ 146.62 | $ 212.47 | $ 141.65 |
| Net Price (Avg Discount) | $ 257.20 | $ 171.47 | $ 257.20 | $ 166.50 |
| COGS (Mgmt $) | $ 7.11 | $ 30.55 | $ 7.23 | $ 31.93 |
| COGS (Legal $) - est. | $ 125.16 | $ 66.62 | $ 127.26 | $ 69.63 |
| | *Box of 5* | *10 Vials* | *Box of 5* | *10 Vials* |

| | Branded Lantus | | Private Label | |
|---|---|---|---|---|
| Gross Margin vs. COGs: | SoloStar | Vial | SoloStar | Vial |
| WAC | 98.1% | 87.7% | 98.1% | 87.2% |
| Net Price (Max Discount) | 96.8% | 79.2% | 96.6% | 77.5% |
| Net Price (Avg Discount) | 97.2% | 82.2% | 97.2% | 80.8% |

**Next Steps**

- Confirm final COGs with Supply Chain / Manufacturing / Finance and finalize Sourcing Case (CONFIRMED).
- Finalize negotiations with key GPOs regarding agreements and format of private labels for Lantus.
- Work with Regulatory to create new NDCs and PIs for private label Lantus 10ml Vial and Lantus SoloStar (COMPLETE).
- Work with Supply Chain on sourcing request and artwork / labeling.
- Once labeling is approved, work with Supply Chain to formulate production plan for private label product, based on forecasted volume.

## SITUATIONAL OVERVIEW: US HEALTHCARE COST PRESSURES

As US healthcare costs continue to rise and outpace spending on all other goods and services, stakeholders in the healthcare system are looking for ways to control these costs. The cost of insurance premiums and employee medical claims is at an all-time high. Business leaders are being called upon to make changes at the workplace in order to curb rising costs. This is creating an environment where less choice is becoming an acceptable trade off. Pharmacy Benefits Managers, like Express Scripts, are leveraging their size and positioning their negotiating power as a solution to managing prescription drug spends.

Given these healthcare cost pressures, George Paz, Chairman, CEO, and President of Express Scripts, recently summarized this view which is generally consistent among his PBM and health plan peers:

> "In the near term, we see an opportunity to work with our clients by moving away from open formularies and adding utilization management programs...Both client savings and our profitability improves as clients take advantage of advanced formulary management options that focus on generic and lower-cost brands. Through our advanced formulary and utilization management programs, we can bend the clients' cost curve with little member disruption."[i]

Aggressive pricing actions in high volume categories like diabetes (basal insulins), and specialty categories such as MS have been singled out as trend drivers. Pharmaceutical products within these categories are now becoming susceptible to utilization management tactics that were formerly not employed in those therapeutic areas.

## MARGIN PRESSURES ASSOCIATED WITH ACA IMPLEMENTATION CREATE MORE PRESSURE IN THE SYSTEM

Several factors associated with the ACA place margin pressures on health insurance companies. These pressures can drive payers to extract more rebate dollars and limit formularies. Some of the ACA drivers of margin pressure are:

**Guaranteed Issue/Elimination Pre-existing Condition Denials.** Beginning in 2014, health plans are no longer allowed to no longer deny enrollment or policy renewals to consumers based their costly pre-existing medical conditions. This increases health plan's costs.

**Elimination of lifetime and annual covered benefit spending**. Before the health care law, many health plans set an annual or lifetime limit — a dollar limit on their yearly spending for each enrollee's covered benefits. Enrollee's would need to pay for the medical expenses beyond those limits. ACA no longer allows plans to do this. This increases health plan's costs.

**Medical loss ratio**. Health plans now must meet certain thresholds when it comes to revenue and expenses. The intent of the MLR is to eliminate excess profits and encourage administrative efficiencies. Plans must demonstrate that at least 80% of their revenues (85% in the large group market) must be accounted for with enrollee medical expenses. If they do not, consumers must receive rebate checks to bring the accounting into line with the threshold. The US government has publicized that in 2012, consumers received $500 million in MLR rebate checks and avoided $3.4 billion in upfront premium increases that would have occurred had this and other polices not been in place. This is money that has been taken out of the health plan sector.

**Government premium rate reviews**. Health plans must submit to the government justification for any premium rate increases of 10% or greater. The US government has publicized that in 2012, consumers saved $1.2 billion as a result of this policy. This is money that has been taken out of the health plan sector.

**Fee's to support the exchanges**. In order to manage some of the risk of high cost enrollee's in the exchanges, health fees have been imposed on plans outside of the exchanges. Additionally, for health plans that participate in the exchanges, fees are imposed for participation. This increases plan's costs.
The 10 essential health benefits. The ACA requires plans to cover 10 essential health benefits: 1) ambulatory patient services; 2) emergency services; 3) hospitalization; 4) maternity and newborn care; 5) mental health and substance use disorder services, including behavioral health treatment; 6) prescription drugs; 7) rehabilitative services and devices; 8) laboratory services; 9) preventive and wellness services and chronic disease management; and 10) pediatric services, including oral and vision care. For those plans that did not offer such robust benefits previously, their costs increased with ACA.
**Community rating**. The premise behind a community rating (pure community rating, modified or adjusted community rating) policy is that it sets the standards by which plans may or may not charge certain enrollees higher premiums based on demographic factors. For example, pure community rating would not allow older enrollees to be charged higher premiums than younger enrollees. Prior to ACA, such standards were set at the state level. ACA has set standards at federal level. The overall financial impact to health plans depends upon the overall market presence they have in select states.

- Transparent price competition. Plans that offer benefits in the exchanges now operate in a standardized transparent premium price market. Theoretically, consumers will gravitate to the lowest price when presented with supplier's prices across standardized products (Bronze, Silver, Gold, and Platinum). Such transparency expedites price competition. In the race to offer low prices to attract consumers, health plan revenue can be strained.
- Uncertainty on enrollment and patient mix. Exchange plans are expected to cover the medical expenses of a currently uninsured population. No historical data exists to predict what their costs will be. At the same time, skepticism exists as to whether or not the consumer penalties associated with not buying insurance (the individual mandate) is significant enough to encourage enrollment of healthy individuals. In the event health plans end up covering only the sick, and those expenses exceed the revenue generated from premiums, plans will incur losses. While there are risk protections in place to help compensate for some of these risks and losses, much uncertainly still exists.

Finally, the ACA set a precedent with is formulary coverage policy. While this policy does not place pressure on plan's margins, it does provide an excuse for health plans to assert more exclusivity on drug formularies. ACA regulations allow exchange plans to cover one drug per USP category. (Medicare requires at least two drugs per category). Plans may choose to exploit this precedent setting government policy as they operate in the non-exchange market in order to leverage more rebates and reduce costs.

**PATIENTS & EMPLOYERS DEMONSTRATING A HIGHER TOLERANCE OF RESTRICTION**

Clients are demonstrating a higher level of tolerance for restriction. Evidence of this is the emergence of exclusion lists implemented by Express Scripts and CVS Caremark. Starting in January 2012, CVS Caremark removed 34 brand-name drugs from its standard national formulary. In selecting these products, CVS Caremark cited the following factors: "the plans' ability to obtain the lowest price for formulary products, high product price inflation and the availability of viable lower cost alternatives. [ii]

CVS Caremark claimed great success with this program. According to CVS Caremark:

- More than 100,000 members transitioned from the removed brands to lower cost alternatives
- Plans saved an average $68.35 per transitioned script
- Members saved an average $18.86 per script
- There were virtually no member complaints

Emboldened by its success, CVS Caremark added 17 more brand-name drugs to its exclusion list for the 2014 plan year.

In August 2013, Express Scripts followed CVS Caremark's example. Novo Nordisk lost two contracts with Express Scripts—a contract for its diabetes drug Victoza, won by Bristol-Myers Squibb & Co., and a deal for insulin Novolog, taken by Eli Lilly & Co. Among the medications being dropped in 2014 include a number of major GlaxoSmithKline (NYSE: GSK ) respiratory products being marketed in the US. By far the biggest name to lose coverage from Glaxo's product roster is its blockbuster Advair. This move represented a willingness to move away from a market leading product in a quality driven therapeutic area like asthma. Other recent formulary changes that demonstrate the willingness of a large payer to employ utilization management in a class that had previously been considered "off limits" is characterized by the preferred status and step edit of VPRIV over Cerezyme for Type 1 Gauchers Disease by United Healthcare.

[i] *Express Scripts Holdings, 2013:Q2 Earnings Call, July 30, 2013.*
[ii] *Formulary Innovation Helps Payers Address New Market Challenges,* CVS Caremark, June 2012.

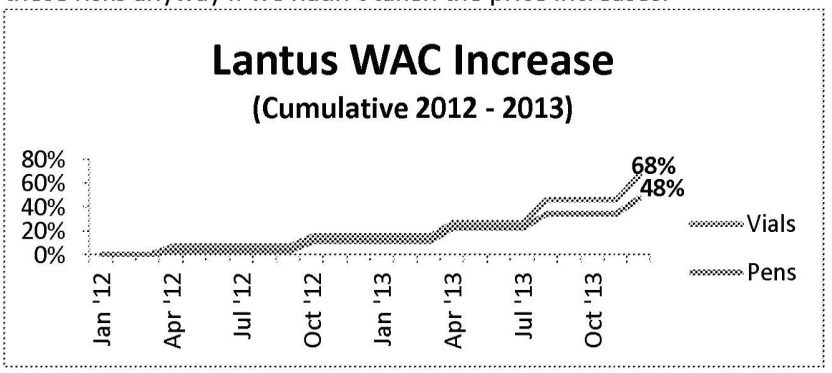
**PAYERS CLAIM PRICE PREDICTABILITY WILL BE "TABLE STAKES" FOR CONTRACTS GOING FORWARD**

One of the pressures driving PBMs and plans to more aggressively manage prescription drug costs with increased predictability is the pressure from clients to secure multi-year premium locks. Customers like Prime Therapeutics, representing many of the Blues Plans throughout the country, have stated that their client RFPs require three year commitments. They have significant challenges managing aggressive pricing actions of high utilization products like Lantus as those changes in price have a measurable impact on their forecasted revenue and profit margins.

This environment has created a tenuous situation for Lantus as payers look to control costs and Novo grows increasingly competitive.

**SANOFI SITUATIONAL OVERVIEW: RISKS HIGHLIGHTED AS PART OF B14 PROCESS ARE MATERIALIZING AT A RAPID PACE**

During the 2014 budget discussion, the NA Pharma Leadership team identified increased rebates and price predictability demands as a high risk for our business. This risk has quickly become a reality. The healthcare market is changing at a rapid pace and payers are reacting strongly to pricing actions in the industry. We went into 2013 with eyes wide open that the significant price increases planned would inflame our customers. However, the strategy to close the price differential between the Lantus vial and pen before the LOE period was believed to be critical to the overall long-term success of the franchise. In addition, the shortfalls with Lantus demand generation and global profit shortfalls put pressure on the US to continue with the price increases to cover gaps. It is difficult to determine whether we would face these risks anyway if we hadn't taken the price increases.




Based on an analysis of 2012 and 2013 volumes, priced at the January 2012 WAC compared to actual sales dollars, we can attribute an incremental $1.3 billion dollars in net sales to the pricing actions that took place in 2012 and 2013.

**IMMEDIATE THREATS OF REMOVAL OF LANTUS FROM FORMULARIES EFFECTIVE JULY 2014**

There are three immediate threats to Lantus: United Healthcare/OptumRx, [redacted] Based on Budget 2014, the books of business at risk in these 3 accounts represent **$456MM in 2014 gross sales and $424MM in 2014 net sales**. The no contract scenario for these accounts differs significantly as the levels of control for each account differ.

**Net Sales Loss Summary**

| FY 2014 | Gross Sales | Rebate $s | Net Sales | Rebate % | Loss Assumption | Net Sales Loss |
|---|---|---|---|---|---|---|
| **OPTUMRX** | $268 | $13 | $254 | 5.0% | 27% | ($17) |
| [redacted] | | | | | | |
| **TOTAL** | $456 | $31 | $424 | 6.8% | 50% | ($76) |

**OPTUM Rx/UNITED HEALTHCARE**

OptumRx/United Healthcare notified Sanofi in early November of their intention to conduct a basal insulin category review. We flagged this notification as part of the budget process. The customer cited pricing actions within the category as the driver for the review. Multiple discussions have occurred with both clinical and financial decision makers at both UHC and Optum Rx.

Currently, Lantus vials are in a tier 2 co-preferred position with Levemir vials. Lantus solostar is in a tier 3 position along with Levemir Flexpen as United has historically positioned pens as a higher tier option.

Multiple offers have been presented with the most recent offer **being 15% rebate with a price protection threshold of 7% using a baseline date of January 1, 2014**. Throughout the negotiation the customer has held their ground on a demand of **33% for a co-preferred position and 43% for an exclusive position**. These financials are challenging to reconcile as they would not allow Sanofi to break even until the **end of 2016**.

**ACTION BEING TAKEN BY THE US TEAM**: We are holding on our offer at 15% rebate. If the account rejects the offer, Lantus would be moved to a tier 3 non-formulary position effective July 1, 2014. Analogs show a 27% loss in volume in 2014 and a 45% loss in 2015. Analogs that would impact Lantus are primarily based on losses seen with Januvia after the same controls were put in place that we would face with Lantus.

**OptumRx/UHC Financials:**

| OPTUMRX | FY 2014 | | | | | | FY 2015 | | | | | | FY 2016 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales | Rebate $s | Net Sales | Rebate % | RXs | MS | Gross Sales | Rebate $s | Net Sales | Rebate % | RXs | MS | Gross Sales | Rebate $s | Net Sales | Rebate % | RXs | MS |
| BUDGET | $268 | $13 | $254 | 5.0% | | | | | | | | | | | | | | |
| NO CONTRACT | $241 | $3 | $237 | 1.3% | 550,975 | 71.6% | $187 | $0 | $187 | 0.0% | 402,273 | 48.4% | $162 | $0 | $162 | 0.0% | 328,608 | 36.8% |
| *Variance to Budget* | | *($10)* | *($17)* | | | | | | | | | | | | | | | |
| 15% + PP | $268 | $29 | $239 | 10.8% | 609,861 | 79.3% | $304 | $50 | $254 | 16.4% | 655,109 | 78.9% | $345 | $55 | $289 | 16.0% | 700,357 | 78.5% |
| *Variance to Budget* | | *$16* | *($16)* | | | | | | | | | | | | | | | |
| *Variance to No Contract* | | *$26* | *$1* | | *58,886* | *7.7%* | | | *$67* | | *252,836* | *30.5%* | | | *$128* | | *371,749* | *41.7%* |

[redacted]

**ACTION BEING TAKEN BY THE US TEAM**: We will make an initial offer of 24% with a fallback position of 27%. We anticipate no more than one opportunity to renegotiate based on the nature of the RFP process being used. The recommendation of 27% is based on customer dialogue and net cost to plan analytics with a competitive Novo bid assumption of 50%. Any decision made by [redacted] will be implemented July 1, 2014.

[redacted]

**ADDITIONAL SIGNIFICANT ANTICIPATED THREATS**

Based on preliminary feedback we have received from ESI, CVS Caremark, and [redacted], there is significant concern that these accounts will initiate RFPs outside of their normal bid cycle as well. ESI had previously communicated, in late 2013, that they anticipate a review of the basal insulin category as part of their Exclusion List offering in the mid-2014 timeframe. At that time we offered an incremental 1.5% to stabilize Lantus through 2015 and remove Auvi-Q from the exclusion list. The offer was rejected due to an unwillingness to remove Auvi-Q from the exclusion list at that time.

| Account | Current Rebate Level | Contract Expiration Date |
|---|---|---|
| ESI | 7.6% | 12/31/15 |
| CVS Caremark | 7.7% | 6/30/16 |
| [redacted] | [redacted] | [redacted] |

Despite general agreement that Lantus represents a clinical advantage over Levemir, the aggressive competitive activity of Novo coupled with the increasing pressure to reduce healthcare spend in the US, has made historically successful pricing and contracting practices unsustainable.

In an effort to mitigate an open negotiation with the big three PBMs that could result in rebate demands north of 20%, the US will use price protection as a means of stabilizing our position for Lantus. We believe with a customer like [redacted] will hold off more aggressive terms being requested. We plan to leverage this tactic since we anticipate minimal benefit from Lantus price increases post July 2014 assuming a bio-similar arrives in mid 2015.

The summary chart below looks at various scenarios to including:

- no contract
- price protection only
- increase in our level of rebates to 15% and 24% with an assumed start date of January 1 2014. (Note: Plan is to start offer at a July 1 2014 baseline in order to minimize exposure)

It is important to understand that any increased rebate level will also come with protection demands as these PBMs are under significant pressure to secure 3 year premium locks with their clients. Therefore, proactively leveraging price protection with no incremental rebates is the approach that creates the greatest chance of stability with the least amount of net sales exposure.

**PBM Multi Scenario Summary**

| FY2014 | No Contract | | | | Budget | | | | PP January 2014 | | | | PP January 2014 + 15% | | | | PP January 2014 + 24% | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales | Rebate $s | Net Sales | Rebate % | Gross Sales | Rebate $s | Net Sales | Rebate % | Gross Sales | Rebate $s | Net Sales | Rebate % | Gross Sales | Rebate $s | Net Sales | Rebate % | Gross Sales | Rebate $s | Net Sales | Rebate % |
| ESI | $1,370 | $58 | $1,312 | 4.2% | $1,531 | $116 | $1,415 | 7.6% | $1,531 | $150 | $1,381 | 9.8% | $1,531 | $210 | $1,321 | 13.7% | $1,531 | $283 | $1,248 | 18.5% |
| CAREMARK | $676 | $29 | $647 | 4.3% | $755 | $58 | $697 | 7.7% | $755 | $74 | $681 | 9.8% | $755 | $103 | $652 | 13.7% | $755 | $139 | $616 | 18.4% |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted]% | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted]% | [redacted] | [redacted] | [redacted] | [redacted] |
| TOTAL | $2,296 | $97 | $2,199 | 4.2% | $2,576 | $195 | $2,381 | 7.6% | $2,576 | $250 | $2,326 | 9.7% | $2,576 | $351 | $2,225 | 13.6% | $2,576 | $473 | $2,103 | 18.4% |
| *Variance to Budget* | | *($98)* | *($182)* | | | | | | | *$55* | *($55)* | | | *$157* | *($157)* | | | *$279* | *($279)* | |
| *Variance to No Contract* | | | | | | *$98* | *$182* | | | *$153* | *$127* | | | *$255* | *$25* | | | *$377* | *($97)* | |

**SUMMARY OF OVERALL RISK AND RECOMMENDATIONS BY ACCOUNT**

In summary, imminent 2014 net sales risks range from **-$76MM (no contract scenario) to -$20MM** (proposed action of $43MM in rebates offset by $23MM in budgeted rebates) as a result of the situations at OptumRx/UHC, Aetna, and Kaiser.

Additional risk ranging from **-$182M (no contract for ESI, Caremark, [redacted] to -$56M (price protection beginning January 2014)** is anticipated, putting our total risk range from **-$76M to -$235M** for 2014. (Total risk range accounts for $23MM in budgeted rebates. See summary chart below.)

In addition to continuing to emphasize the clinical value proposition of Lantus and driving more senior executive engagement in the payer space, the team will look to use price protection as a means of stabilization as we believe we are at a point in time where this is a demand that has come to fruition and waiting for customers to initiate class reviews will lead to further deterioration of our GTN or a loss of position.

**Summary of Proposed Actions by Account**

| | | Proposed Action | | |
|---|---|---|---|---|
| | 2014 Budgeted Rebate | Proposed Rebate Level | Price Protections Threshold | Price Protection Start Date |
| OptumRx/United Healthcare | 5% | 15% | 7% | January 1 2014 |
| [redacted] | | | | |
| Express Scripts | 7.6% | 7.6% | 7% | January 1 2014 |
| CVS Caremark | 7.7% | 7.7% | 7% | January 1 2014 |
| [redacted] | | | | |

**Summary of Net Sales Exposure No Contract Vs. Proposed Action**

| Accounts | No Contract Scenario Net Sales Variance to Budget ($MM) | Proposed Action Net Sales Variance to Budget ($MM) |
|---|---|---|
| OptumRx (UHC) | ($17) | ($16) |
| [redacted] | | |
| ESI | ($102) | ($34) |
| CVS Caremark | ($50) | ($16) |
| [redacted] | | |
| TOTAL | ($258) | ($99) |
| REBATE $ IN BUDGET | $23 | $23 |
| | | |
| VARIANCE TO BUDGET | ($235) | ($76) |

**OVERVIEW OF ANALYTICS TO UNDERSTAND PLAN PERSPECTIVE: NET COST TO PLAN**

As accounts assess the "value" of offers they receive they will look at how total spend within a category shifts based on respective company offers and share change assumptions.

We do not believe portfolio contracting is at play in either [redacted] based on customer dialogue and the formulary position of other Novo brands within those accounts. Rather, it is our understanding that Novo is taking a very aggressive approach with their Levemir discount levels. We also understand from UHC that they are being more aggressive with their price protection terms. Based on customer feedback it appears they are setting their baseline start date in the September 2013

timeframe making their price protection offering more compelling that the January 1 2014 baseline that we offered for Lantus.

In summary, our understanding at this point is that their offer must be greater than 53% rebate on Levemir with a price protection clause that has a baseline start date in the 2013 calendar year. Our intelligence around the [redacted] offer is less developed however it is our understanding that they offered somewhere in the 40% range to secure the legacy [redacted] business therefore, that is our baseline assumption on what they would bid for the now combined, [redacted] business.

**OptumRx/UHC Net Cost To Plan Analysis**

**Net Cost to Plan = Pharmacy Reimbursement + Pharmacy Dispensing Fee – Rebates**

| Scenario | Lantus Avg Rebate % | Lantus Net Cost To Plan | Levemir Rebate % | Levemir Net Cost To Plan | Total Net Cost To Plan |
|---|---|---|---|---|---|
| **Current State** | 2.6% | $264 | 25.0% | $59 | $323 |
| **Sanofi Offer of 15% and PP** | 17.9% | $223 | 35.0% | $51 | $274 |
| **Levemir BreakEven relative to Sanofi 15% Offer** | 0.0% | $198 | 52.5% | $76 | $274 |
| **OptumRx Ask of Sanofi for Exclusivity** | 43.0% | $167 | 0.0% | $57 | $224 |

$s in Millions

Levemir must offer a rebate > 53% to beat Sanofi offer of 15% based on a Year 1 shift assumption of 27%

[redacted]

Despite our belief that portfolio contracting is not at play in these two accounts, we do believe they have leveraged this in accounts where they have a broader foothold. An example of this is CVS/Caremark MMA Part D where Novolog is preferred over Humalog. Previous negotiations that took place in February 2013 implied portfolio offer and internal analytics supported that assumption. The summary below represents the analytics that were done at that time:

**Caremark Part D Net Cost To Plan Portfolio Analysis - Feb 2013**
**Net Cost to Plan = Pharmacy Reimbursement + Pharmacy Dispensing Fee - Rebates**

| Scenario | Lantus Rebate % | Lantus Net Cost To Plan | Levemir Rebate % | Levemir Net Cost To Plan | Degludec Rebate % | Degludec Net Cost To Plan | Portfolio Value | Total Net Cost To Plan |
|---|---|---|---|---|---|---|---|---|
| **Current State** | 25.0% | $448 | 40.0% | $113 | 0.0% | $9 | | $570 |
| **Sanofi Offer of 34% and PP** | 34.0% | $396 | 40.0% | $113 | 0.0% | $9 | | $518 |
| **Novo Break Even: 45% Levemir Rebate + 5% Rebate on other Novo Products** | 0.0% | $166 | 45.0% | $352 | 25.0% | $27 | $26 | $518 |

We are currently not in Lantus negotiations with CVS/Caremark, however we know this account is at risk based on recent exchanges. Our concern is the ability to leverage a broader portfolio and a potential expansion of the exclusion list poses a significant threat. It is our intent to leverage price protection as a means to stabilize the account through 2015 in an effort to thwart an open negotiation that would result in significant incremental rebate exposure or potential loss of the account.

---

North America is working on options to cover this risk range. They include:

Seprafilm promotion X dollars (excluded from budget)
Divestment of Products X dollars
Reduction of Diabetes A&P X dollars

We remain committed to achieve our budget for 2014 and are hopeful that divestments can be used to cover these risks/gaps. If this cannot be leveraged, then it will require difficult choices with investments for Diabetes be included in our actions recognizing this creates risk for us in demand generation.

# OptumRx
# 2015 MMA Part D Bid Proposal

## USPC

November 1, 2013

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# Executive Summary
# Informing USPC of Proposed Deal Terms

- [redacted]
- [redacted]
- [redacted]
- [redacted]

# Proposal Terms and Financial Summary

- [redacted]

($s in millions)

| Product | 2015E Gross Sales | 2014 Rates Net Sales | 2014 Rates Rebate % | 2015 Proposed Net Sales | 2015 Proposed Rebate % | 2015 Proposed Var to 2014 Rates | 2015 Proposed Var to No Deal | No Deal Gross Sales | Channel Target GTN |
|---|---|---|---|---|---|---|---|---|---|
| Lantus | [redacted] | | | | | | | | |
| Renvela/Renagel | | | | | | | | | |
| Apidra | | | | | | | | | |
| Multaq | | | | | | | | | |
| Total | | | | | | | | | |

Key Assumptions: LRP [redacted]

| | 2014 Rates | | | | | | | 2015 Proposed | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Product | LIS | Stds | Blend | PP Threshold | PP Type | Proj PP % | **Proj Ttl %** | LIS | Stds | Blend | PP Threshold | PP Type | Proj PP % | **Proj Ttl %** |
| Lantus Vial | [redacted] | | | | | | | | | | | | | |
| Lantus SS | | | | | | | | | | | | | | |
| Renvela/Renagel | | | | | | | | | | | | | | |
| Apidra | | | | | | | | | | | | | | |
| Multaq | | | | | | | | | | | | | | |

**PP Baseline Date**: December 31, 2011 WAC

**PP Baseline Date**: December 31, 2014 WAC

# Risk\Mitigation Strategy & Monitoring

- Risks
- Mitigation Plan
- Key Performance Management Metrics & Planning
  - Monitor formulary status
  - Compare actuals to forecast
  - Ongoing business updates by Market Access Team

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# Back-up

# BACKGROUND
# OptumRx

- Part D accounts for ~25% of United's total revenue
- #1 Medicare Part D provider
  - Lives are geographically spread throughout all 50 states with Part D market share range of 15-30%
  - HIRC Managed Markets and National Accounts Fall 2013 publication reported OptumRx had 5MM PDP lives and 3MM MA-PD lives
    - Rounding out the top 3 were [redacted] with 5.3MM total lives and Caremark Silverscript with 4.4MM
  - United Medicare and Retirement has a marketing partnership with AARP MedicareRx Plans UnitedHealthcare
  - OptumRx has qualified for all 34 auto-enrollee regions in 2014, up from the 30 regions in 2013 and only 8 in 2012
- Launched new low cost Saver Plus PDP Formulary in 2013 to
  - address CMS Meaningful Difference benchmark;
  - fuel enrollment growth; and
  - reduce plan net costs
- Lantus Opportunity

[redacted]

# MARKET OVERVIEW
# Lantus

- Aggressive Competitors
  - Displace Lantus in High Control Plans and Markets (i.e. Part D) through increased rebates and/or portfolio offers for the sole purpose of removing Lantus from favorable formulary access
  - Attempts to minimize the clinical differentiation between Lantus and Levemir

- Aggressive Payers
  - Price Predictability
    - Accounts requiring more value from price predictability
      - Extension of Timeline/WAC Evaluation periods lengthened, e.g. Caremark Price Protection from June 2013 thru December 2014 for the 2014 Contract, ESI Requesting 2-Year Price Protection
      - Demand for lower threshold percentages
      - Discontinue calculations that exclude prior pricing activity from carrying forward, e.g. no more Reset Calculations
  - Increased Discounts
    - Caremark increase in base rebates was needed to remain on formulary
      - Caremark Base 25% to 32% for 2014
  - Benefit Designs
    - Accounts have shown willingness and ability to remove Lantus from Formulary
    - Cigna 2012, [redacted], OptumRx Saver Plus 2013, [redacted]

# MARKET OVERVIEW
## Lantus

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# Payco Scores – MMA Part D

# ESI/MEDCO PART D LANTUS

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# ESI/ Medco Medicare Part D Lives Estimate

- ESI/Medco
  - **ESI and Medco Combined - 1,689,000 PDP lives**
  - **ESI and Medco alone rank 5th in the channel and represent 5% of the business**

[redacted]

  - **ESI, [redacted] combined represent 4.6 MM lives and 15% of the total business in the channel**
- LIS lives
  - **Medco 65%**
  - **ESI 40%**

[redacted]

**Average: 50%**

**Source: Amundsen**

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# ESI/Medco Medicare Part D Ranking based on contracted gross sales

LANTUS
MEDICARE PART D

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# ESI/Medco Medicare Part D Trend for Lantus (Select Insulin Market Basket)

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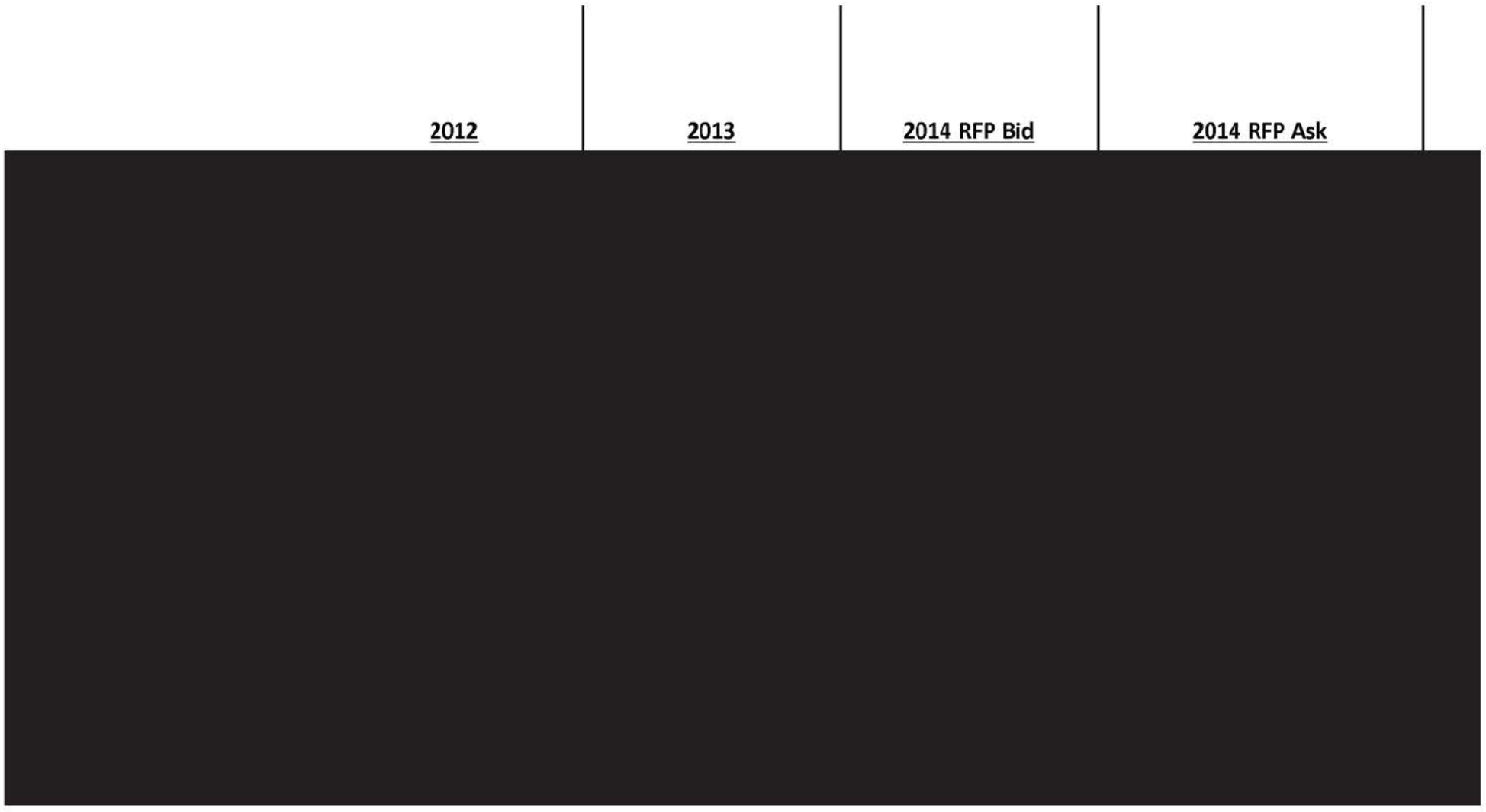
# Situation Analysis: Bid History



# Situation Analysis: Competitive Intelligence/ Customer Feedback

- **Customer has communicated that competitor has enhanced their offer since 2012 discussions**
    - Customer quote " Only need to move 1 in 4 Lantus patients to break even on rebate line"
        - Comment made prior to 2014 bid
    - Suspect offering may be across broader diabetes portfolio (including Novolog, Novolin, and Victoza)
        - Note: Do not have documentation. Based on customer commentary.

# Situation Analysis: Customer Request

- **Financially driven decision by ESI**
  - **15% is the minimum acceptable offer**
- **Why?**
  - **2012 blended rate is 7.45%**
    - Believe customer willing to accept 50% increase in rebate to not deal with disruption despite comment that only need to move 25% of Lantus volume in order to break even on rebate line.
  - **Other discussion points:**
    - Bio-similar timelines are not a consideration
      - Their analysis shows a difference but not a significant as Lantus claims.
      - Lantus vs. Levemir utilization reviews with ESI clinical team have occurred but not provided any tractions
        - ESI analysis shows 15% more utilization of Levemir vs. Lantus
    - Customer sensitive to 2012 price increases
      - Competitor has taken similar increases but they have also enhance rebate offering

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# Level of Control: Payco Scores MMA Part D Overall

# Key Financial Questions

# ESI Net Cost to Plan Analysis (NCTP)

# Financial Summary: Deal vs. No Deal

# Financial Summary: Impact on the GTN in dollars and percentage

# Recommended Course of Action

[redacted]

# Back Up

# ESI Net Cost to Plan Analysis (NCTP) Detail

# Analytics Assumptions

# ADDITIONAL FEEDBACK/ ASSUMPTIONS

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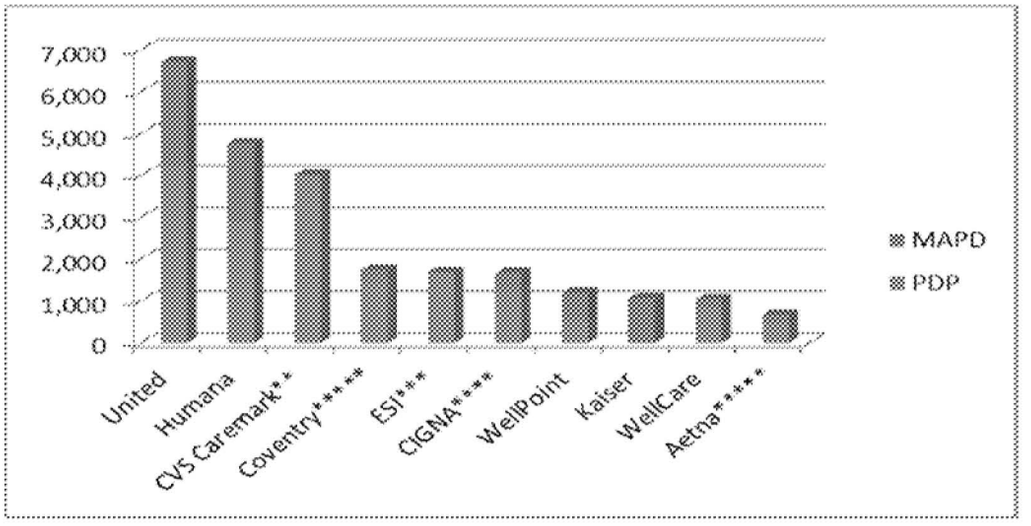
# Current Situation v Degludec Defense Strategy Assumptions

# MAXIMIZING THE ACCESS

# Medicare Market Dominated by Handful of Large Players

| Account | PDP | MAPD | Total | % of Bus. | Abilty to Move Share |
|---|---|---|---|---|---|
| United | 4,234 | 2,474 | 6,707 | 21% | Stellar |
| Humana | 2,906 | 1,859 | 4,765 | 15% | Good |
| CVS Caremark** | 4,018 | 0 | 4,018 | 13% | Good |
| Coventry***** | 1,494 | 251 | 1,745 | 6% | Stellar |
| ESI*** | 1,689 | 0 | 1,689 | 5% | NR |
| CIGNA**** | 1,269 | 396 | 1,665 | 5% | Average |
| WellPoint | 544 | 661 | 1,206 | 4% | Good |
| Kaiser | 0 | 1,067 | 1,067 | 3% | Stellar |
| WellCare | 891 | 156 | 1,047 | 3% | Stellar |
| Aetna***** | 470 | 199 | 670 | 2% | Average |

Source: CMS Monthly Report by Contract, June 2012, HIRC.




- Almost 32 million Medicare beneficiaries
  - 10 million LIS
- About two-thirds of Part D enrollees (63%) are in stand-alone PDP plans; remaining (37%) in Medicare Advantage plans with Part D coverage (MA-PD).
- High level of consolidation
- The top three Part D companies have 49% of enrollees.
- M&A activity continues to increase concentration of business.
  - ** CVS Caremark purchased UAFC/MemberHealth;
  - *** ESI purchased Medco
  - **** CIGNA purchased HealthSpring/Bravo;
  - *****Aetna/Coventry (2014)

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# US Pricing Committee

# Lantus, Toujeo, and Afrezza Pricing and Contracting Guidelines Proposal and Approvals

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# USPC – Recommendations
# WAC Pricing: Toujeo & Afrezza

- **WAC Pricing – Toujeo → parity priced to Lantus at the unit level ($.2485 / IU)**
  - ✓ **$335.48 / Box → 3 pens**

- **WAC Pricing – Afrezza → hybrid pricing structure at $16 / day target**
  - ✓ **360 unit pack = $226**
  - ✓ **480 unit pack = $252**
  - ✓ **600 unit pack = $279**
  - ✓ **840 unit pack = $317**
  - ✓ **960 unit pack = $329**

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## Speaker Notes for Slide 2

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# USPC – Recommendations
# Contracting Guidelines

| | REVISED LANTUS | | | TOUJEO | | AFREZZA | |
|---|---|---|---|---|---|---|---|
| | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | Price Protection | Max Discount / Fixed Price | Price Protection |
| Channel | Vial | SS | | Pen | | | |
| Commercial | 30% | 30% | 6% | 30% | 6% | 23% | NA |
| Medicare - Preferred | 35% | 35% | 6% | 35% | 6% | 23% | NA |
| Medicare - Non-Preferred | NA | NA | NA | 15% | NA | 23% | NA |
| [redacted] | | | | | | | |
| Managed Medicaid | 5% | 5% | NA | 15% | NA | NA | NA |
| Medicaid Supplemental | 85% | 85% | NA | 0% | NA | NA | NA |

[redacted]

* New guidelines and changes are noted in red.

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## Speaker Notes for Slide 3

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# 15B Forecast Review…Toujeo-Lantus parity WAC pricing assumed…Afrezza price assumed at $12 / day

| | Lantus | Toujeo | Glargine | Afrezza |
|---|---|---|---|---|
| Product TRx | 20,171 | 814 | 20,985 | 111 |
| MS% | 68.9% | 2.8% | 71.6% | 0.5% |
| Market TRx | 29,293 | 29,293 | 29,293 | 24,157 |
| Product TRx % Growth vs PY | 1.5% | | 5.6% | |
| Market TRx % Growth vs PY | 5.4% | 5.4% | 5.4% | 6.7% |
| DEMAND Units | | | | |
| Factored Public Demand Units | 48,344,931 | 1,976,641 | 50,321,572 | 124,565 |
| Demand Units - PY | 46,987,925 | | | |
| % Growth vs PY | 2.9% | | 7.1% | |
| Retail Units per TRx | 1,976.4 | 2,418.6 | 1,993.6 | 1,126.0 |
| Net Demand Sales | $ 4,823,882 | $ 318,246 | $ 5,142,128 | $ 38,526 |
| CHANNEL INVENTORIES | | | | |
| Change in Inventory Sales | $ (46,687) | $ 41,488 | $ (5,199) | $ 9,484 |
| Ex-Factory | | | | |
| Factory Shipment Units | 48,068,541 | 2,234,323 | 50,302,864 | 159,530 |
| AGP per Unit | $ 0.2485 | $ 0.2485 | $ 0.2485 | $ 0.3343 |
| Gross Sales | $ 11,945,394 | $ 555,263 | $ 12,500,657 | $ 53,325 |
| Gross-to-Net | 40.2% | 64.8% | 41.2% | 90.0% |
| Net Price per Unit | $ 0.0998 | $ 0.1610 | $ 0.1025 | $ 0.3009 |
| Ex-Factory Net Sales | $ 4,796,304 | $ 359,734 | $ 5,156,038 | $ 48,010 |
| Net Sales - PY | $ 5,630,044 | | $ 5,630,044 | |
| % Growth vs PY | -14.8% | | -8.4% | |

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## Speaker Notes for Slide 4

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Lantus Current Channel Guidelines

| | | Max Discount / Fixed Price | | Price Protection | Contracting Strategy Objective |
|---|---|---|---|---|---|
| Channel | Date | Vial | SS | | |
| Commercial | 02/01/11 | 15% | 20% | NA | Discount range allow for selective responses to invidivual threates and competitive pricing pressures. Secure 1 of 2 products where possible. |
| Medicare | 01/01/14 | 35% | 35% | 6% | Maintain preferred position. Secure 1 of 2 products where possible. |
| [redacted] | | | | | |
| Managed Medicaid | 01/01/14 | 5% | 10% | NA | Maintain and win new preferred positions in his high control segment. Cap discounts less than 100% including costs. |
| Medicaid Supplemental | 10/01/10 | 85% | 85% | NA | Maintain coverage in states requiring supplemental discounts. |
| [redacted] | | | | | |

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## Speaker Notes for Slide 5

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Toujeo Strategy Overview

## Tom Blount

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## Speaker Notes for Slide 6

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Excerpt from US Toujeo strategy

**Vision**
"Aspiration?"

**Toujeo is the leading basal insulin that helps more people living with diabetes reach their goal by providing an optimal insulin experience**

**Goal**
"Broad What?"

**Become the preferred basal insulin**

**Objectives**
"Specific What?"

**Increase awareness of the unmet needs evident with basal insulin therapy and its key drivers**

**Establish Toujeo as the differentiated solution**

**Rapidly achieve patient access that is competitive against alternative basal insulins**

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1 Independently of engagement in our integrated patient solution

# Executing our strategy will allow achieving 2015 targets

**Become the preferred basal insulin**

**Toujeo has 13% of the new patients share for the year**

**Tier 2 access in 75% of commercial lives**

SANOFI DIABETES

SOURCE: Glargine forecast (Oct 8); Team analysis

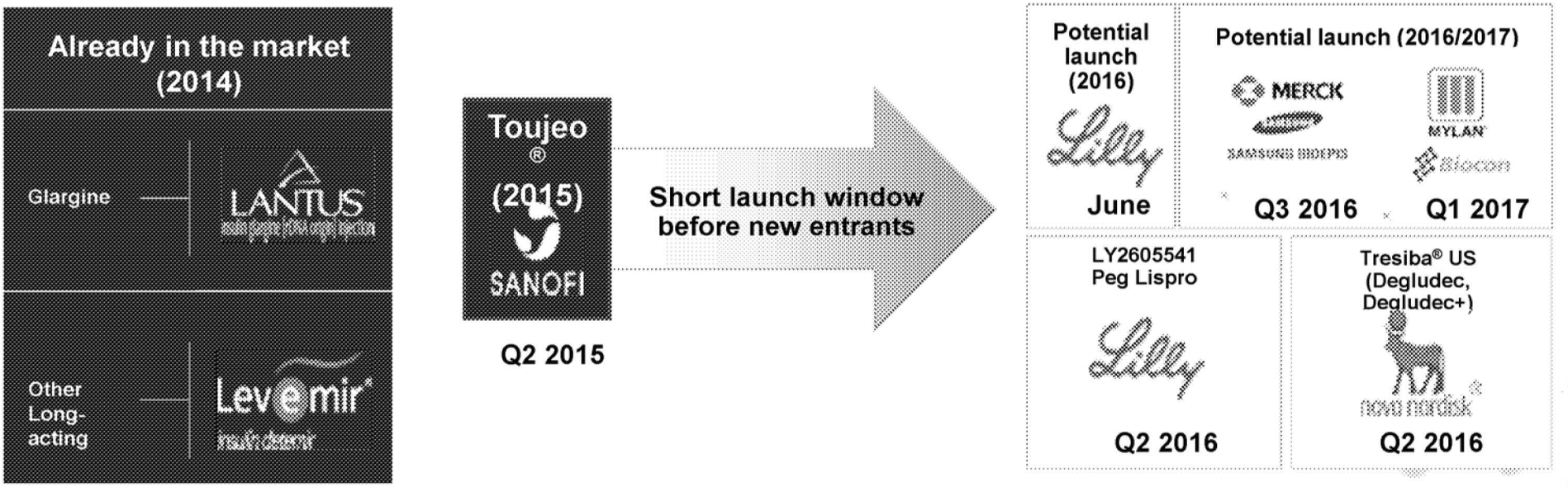
# Toujeo® Launch and Market Assumptions

## Current Toujeo® Launch Assumptions

- PDUFA February 24, 2015
- Stocking and pharmacy promotion in March
- HCP promotion April 1

## Competitive Assumptions

- Lilly/BI in June 2016
- Merck Q3 2016 followed by Biocon/Mylan Q1 2017
- Degludec resubmitted Q2 2015 with launch Q2 2016
- PegLispro launch Q2 2016






SANOFI DIABETES

# Toujeo Forecast & Scenario Overview

## Carlos Soria

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## Speaker Notes for Slide 10

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Toujeo bottoms-up forecast sets the top-down forecast…Commercial channel key focus

| | | Ex: ESI Com. 2015 |
|---|---|---|
| Derive Basal Mkt by Account | • Contracted Lantus data by account<br>• Divided by projected IMS Basal market share | Lantus 7 MIU<br>68.5% Share<br>= Mkt 10.2 M IU |
| Account Level Assumptions | • Account Management Intelligence<br>• Timing and tier status of formulary decision<br>• Rebate level and impact on Lantus | Mar: T3 Open Lives<br>July: Broad T2 at 40% Rebate |
| Select Uptake Analog | • Recently launched diabetes products including Bydureon<br>• Align to patient model peak share (28% 2018) | Apply analog curve with 2015 exit share of 16% = 0.6 M IU |
| Apply WAC and Rebates | • WAC unit parity to Lantus | WAC $0.2485 / IU = **$149 M Gross Sales** |
| Net Sales by Account | | 40% Rebate<br>**$94 M Net Sales** |

# 15B – Key accounts = ESI, CVS-Caremark, [redacted]

[redacted]

| | Account | Covered Lives | Lantus Tier | Toujeo Tier | Rebate | 2015 Toujeo Exit Share |
|---|---|---|---|---|---|---|
| | ESI | 62 | | | | |
| | Open | 21 | T2 | T3/T2 | 40% Jul'15 | 18.0% |
| | Exclusion | 21 | T2 | NC/T2 | 40% Jul'15 | 14.8% |
| [redacted] | | | | | | |
| | Caremark | 36 | | | | |
| | Customs | 18 | T2 | T3 | NA | 13.1% |
| | Opt-Out | 18 | T2 | NC | NA | 4.4% |
| [redacted] | | | | | | |
| | OptumRx | 15.3 | T3 | NC | NA | 4.1% |
| [redacted] | | | | | | |
| | ESI | 5.3 | | | | |
| | Open, Excl, Catamaran | 2.7 | Preferred T2 | NC | NA | 3.2% |
| [redacted] | | | | | | |
| | Caremark | 5.8 | Preferred T2 | NC | NA | 3.2% |
| [redacted] | | | | | | |
| | OptumRx | 8.1 | Preferred T3 | NC | NA | 3.2% |
| [redacted] | | | | | | |



USPC Approved

# Toujeo 15B = $360M…132K patients. Commercial channel key demand = 72% of total demand sales

| Toujeo Bottoms Up Forecast | 2015 | 2016 | 2017 |
|---|---|---|---|
| **Gross Sales** | **$ 555** | **$ 3,544** | **$ 6,143** |
| Demand | $ 486 | $ 3,347 | $ 6,089 |
| Commercial | $ 352 | $ 1,860 | $ 3,032 |
| Medicare | $ 90 | $ 1,187 | $ 2,508 |
| Hospital | $ 5 | $ 33 | $ 61 |
| Medicaid | $ 24 | $ 167 | $ 304 |
| LTC | $ 15 | $ 100 | $ 183 |
| Inventory | $ 69 | $ 196 | $ 55 |
| Avg. WAC/kIU | $ 248.5 | $ 260.9 | $ 274.0 |
| **GTN** | **64.8%** | **52.9%** | **47.5%** |
| **Net Sales** | **$ 360** | **$ 1,876** | **$ 2,920** |
| Demand | $ 392 | $ 2,119 | $ 3,572 |
| Commercial | $ 272 | $ 1,228 | $ 1,971 |
| Medicare | $ 90 | $ 717 | $ 1,310 |
| Hospital | $ 3 | $ 23 | $ 39 |
| Medicaid | $ 15 | $ 65 | $ 104 |
| LTC | $ 13 | $ 86 | $ 148 |
| Other Deductions | $ (88) | $ (367) | $ (683) |
| Inventory | $ 55 | $ 124 | $ 32 |
| **Patients (000)** | **132** | **812** | **1,351** |
| **Exit Patients (000)** | **330** | **1,245** | **1,434** |

**$.2485 / IU assumed for 2015**

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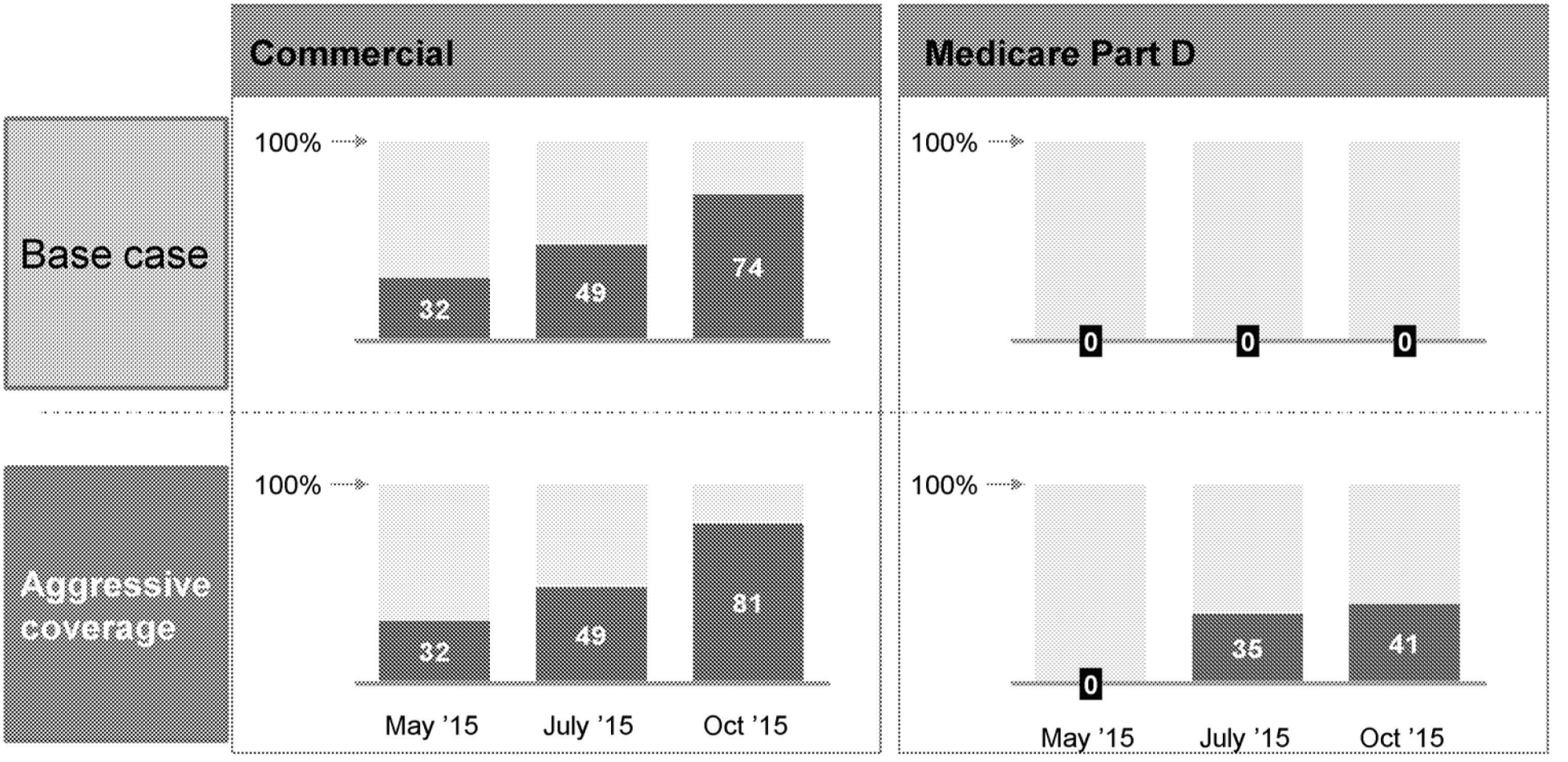
# Aggressive coverage will allow additional access in both commercial and Medicare accounts


**Percent of USA covered lives in 2015**

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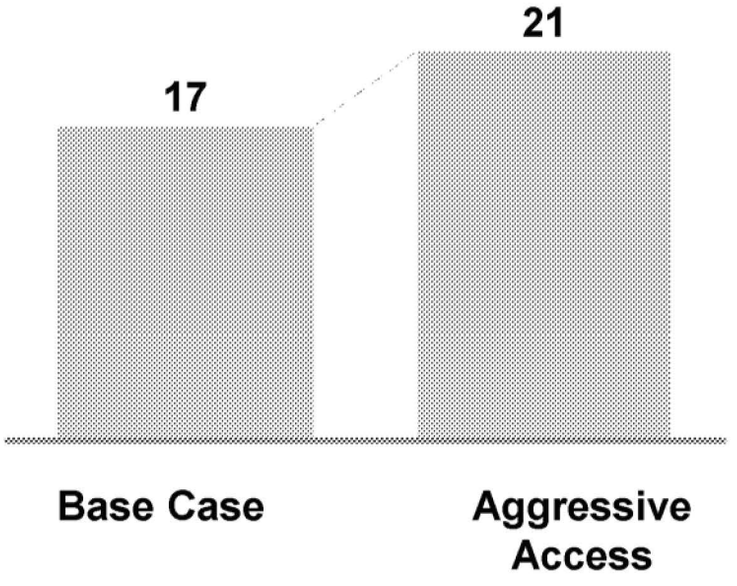
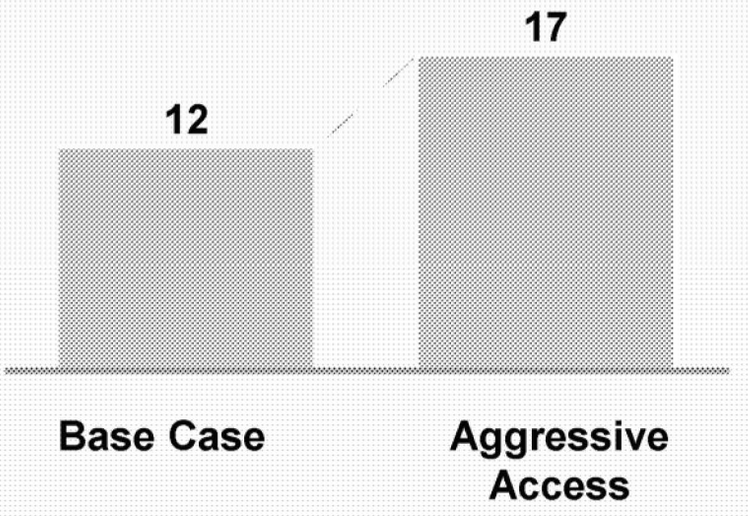
# Aggressive scenario would allow market share of 21% when the biosimilar enters the market

**Exit market share – Commercial volume[1]**
**July 2016 (Biosimilar launch), %**




**Exit market share – Part D volume[1]**
**July 2016 (Biosimilar launch), %**




1 Addressable volume; analysis using bottom up account model
SOURCE: Glargine forecast; Account model; team analysis

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# Aggressive Scenario → incremental coverage in Medicare with Wellpoint, CVS-CM, [redacted] Optum, & [redacted]

| | Account | Covered Lives | Lantus Tier | Toujeo Tier | Toujeo Rebate | 2015 Toujeo Exit Share |
|---|---|---|---|---|---|---|
| | ESI | 62 | | | | |
| | Open | 21 | T2 | T3/T2 | 40% Jul'15 | 18.0% |
| | Exclusion | 21 | T2 | NC/T2 | 40% Jul'15 | 14.8% |
| [redacted] | | | | | | |
| mmercial | Caremark | 36 | | | | |
| | Customs | 18 | T2 | T2 | 45% Oct'15 | 15.6% |
| | Opt-Out | 18 | T2 | T2 | 45% Oct'15 | 9.8% |
| [redacted] | | | | | | |
| | OptumRx | 15.3 | T3 | NC | NA | 4.1% |
| [redacted] | | | | | | |
| | ESI | 5.3 | | | | |
| | Open, Excl, Catamaran | 2.7 | Preferred T2 | NC | NA | 3.2% |
| [redacted] | | | | | | |
| Me care | Caremark | 5.8 | Preferred T2 | T2 | 50% Jul'15 | 9.8% |
| [redacted] | | | | | | |
| | OptumRx | 8.1 | Preferred T3 | T3 | 61% Sep'15 | 9.5% |
| [redacted] | | | | | | |

Changes to Base Scenario in Red

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# Aggressive scenario → incremental patients (132K to 185K)…-$107M impact to Lantus (-$84M Glargine impact)

| Toujeo Bottoms Up Forecast | Base Forecast 2015 | 2016 | 2017 | Aggressive Scenario 2015 | 2016 | 2017 | Variance 2015 | 2016 | 2017 |
|---|---|---|---|---|---|---|---|---|---|
| **Gross Sales** | $ 555 | $ 3,544 | $ 6,143 | $ 660 | $ 4,658 | $ 7,321 | $ 106 | $ 1,114 | $ 1,178 |
| Commercial | $ 352 | $ 1,860 | $ 3,032 | $ 362 | $ 1,949 | $ 3,094 | $ 10 | $ 89 | $ 62 |
| Medicare | $ 90 | $ 1,187 | $ 2,508 | $ 175 | $ 2,154 | $ 3,611 | $ 85 | $ 967 | $ 1,102 |
| Hospital | $ 5 | $ 33 | $ 61 | $ 5 | $ 33 | $ 61 | $ - | $ - | $ - |
| Medicaid | $ 24 | $ 167 | $ 304 | $ 24 | $ 167 | $ 304 | $ - | $ - | $ - |
| LTC | $ 15 | $ 100 | $ 183 | $ 15 | $ 100 | $ 183 | $ - | $ - | $ - |
| Inventory | $ 69 | $ 196 | $ 55 | $ 79 | $ 254 | $ 68 | $ 11 | $ 57 | $ 14 |
| Avg. WAC/kIU | $ 249 | $ 261 | $ 274 | $ 249 | $ 261 | $ 274 | $ - | $ - | $ - |
| **GTN** | **64.8%** | **52.9%** | **47.5%** | **58.0%** | **52.5%** | **46.6%** | -6.9% | -0.5% | -0.9% |
| **Net Sales** | $ 360 | $ 1,876 | $ 2,920 | $ 383 | $ 2,443 | $ 3,415 | $ 23 | $ 567 | $ 495 |
| Commercial | $ 272 | $ 1,228 | $ 1,971 | $ 267 | $ 1,282 | $ 2,008 | $ (5) | $ 54 | $ 37 |
| Medicare | $ 90 | $ 717 | $ 1,310 | $ 131 | $ 1,310 | $ 1,893 | $ 41 | $ 593 | $ 582 |
| Hospital | $ 3 | $ 23 | $ 39 | $ 3 | $ 23 | $ 39 | $ - | $ - | $ - |
| Medicaid | $ 15 | $ 65 | $ 104 | $ 15 | $ 65 | $ 104 | $ - | $ - | $ - |
| LTC | $ 13 | $ 86 | $ 148 | $ 13 | $ 86 | $ 148 | $ - | $ - | $ - |
| Inventory | $ 55 | $ 124 | $ 32 | $ 58 | $ 159 | $ 40 | $ 3 | $ 35 | $ 7 |
| Other Deductions | $ (88) | $ (367) | $ (683) | $ (104) | $ (483) | $ (815) | $ (17) | $ (115) | $ (132) |
| **Patients (000)** | **132** | **812** | **1,351** | **185** | **1,019** | **1,537** | **53** | **206** | **187** |
| **Exit Patients (000)** | **330** | **1,245** | **1,434** | **462** | **1,487** | **1,632** | **132** | **242** | **198** |
| ***Lantus Net Sales Variance*** | | | | | | | ***$ (107)*** | ***$ (416)*** | ***$ (295)*** |
| ***Glargine Net Sales Variance*** | | | | | | | ***$ (84)*** | ***$ 151*** | ***$ 200*** |

# GTN Risks & Opportunities

| GTN Risks/Opportunities | Budgeted | Utilized | Remaining |
|---|---|---|---|
| Medicaid | $120 | $120 | $0 |
| At Risk Contracts | $69 | $13 | $56 |
| Toujeo Access | $12 | $9 | $3 |
| [redacted] | | | |
| Other Incremental Positive | | | $2 |
| Other Incremental Negative | | | ($1) |
| **Total** | **$286** | **$142** | **$145** |

- **Limited pull-through with price increases…Lantus price increase of +6% in July 2015 = +$37M in Net Sales ($6M plus $31M in clawback)**

SANOFI DIABETES

# Aggressive scenario impact to Lantus Rebates = +$67M…+$33M in Commercial & +$34M in Medicare

| Payer | Channel | Initial Date | Lantus Incr Rebate | Lantus Gross $ Full Yr | Lantus Gross $ Impacted | Incr Rebate $ |
|---|---|---|---|---|---|---|
| [redacted] | | | | | | |
| ESI | Part D | | | $1,162 | | |
| [redacted] | | | | | | |
| CVS | Part D | 7/1/2015 | 2% | $729 | $364 | $7 |
| CVS | Commercial | 7/1/2015 | 5% | $838 | $419 | $21 |
| Optum | Part D | 9/1/2015 | 2% | $922 | $307 | $6 |
| Optum | Commercial | | | $180 | | |
| Comprehensive | Part D | | | $135 | | |
| [redacted] | | | | | | |
| **Total** | | | | | | **$67** |

[redacted]

**Base $12 M**

**Incr. Aggressive +$55 M**

**($67M Total Aggressive)**

SANOFI DIABETES

# Lantus and Toujeo budget forecast rebate comparison by account…Glargine rebate at 32 & 36% (Com & Medicare)

| | Lantus | | | | Toujeo | | | | Sanofi Glargine Total | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *$M* | Gross Sales | Rebate | % Rebate | Net Sales | Gross Sales | Rebate | % Rebate* | Net Sales | Gross Sales | Rebate | % Rebate | Net Sales |
| ESI | 1,668 | 591 | 35.5% | 1,076 | 149 | 55 | 37% | 94 | 1,817 | 646 | 36% | 1,170 |
| Caremark | 875 | 353 | 40.3% | 522 | 50 | - | 0% | 50 | 925 | 353 | 38% | 572 |
| [redacted] | | | | | | | | | | | | |
| OptumRx | 188 | 99 | 52.6% | 89 | 6 | - | 0% | 6 | 194 | 99 | 51% | 96 |
| [redacted] | | | | | | | | | | | | |
| Other | 403 | 64 | 16.0% | 338 | 94 | 15 | 16% | 79 | 497 | 79 | 16% | 417 |
| **Total Commercial** | **3,704** | **1,222** | **33.0%** | **2,482** | **352** | **81** | **23%** | **272** | **4,056** | **1,303** | **32%** | **2,754** |
| ESI Part D | 1,162 | 256 | 22.0% | 907 | 19 | - | | 19 | 1,181 | 256 | 22% | 925 |
| Caremark Part D | 761 | 387 | 50.8% | 374 | 12 | - | | 12 | 773 | 387 | 50% | 386 |
| [redacted] | | | | | | | | | | | | |
| OptumRx Part D | 922 | 572 | 62.0% | 350 | 16 | - | | 16 | 938 | 572 | 61% | 366 |
| [redacted] | | | | | | | | | | | | |
| Other | 798 | 204 | 25.6% | 594 | 24 | - | | 24 | 822 | 204 | 25% | 618 |
| **Total Medicare** | **4,675** | **1,737** | **37.1%** | **2,938** | **90** | **-** | | **90** | **4,765** | **1,737** | **36%** | **3,028** |

- **Toujeo % Rebate is average rebate against total 2015 gross sales which includes non-contracted sales prior to access being secured**
- **Once access is secured Toujeo rebates are as follows: ESI 40%, [redacted] (note Lantus rebate includes risk adjustment for potential pharmacy program sale to ESI, [redacted]**

SANOFI DIABETES

# Total Glargine rebate risk comparison…10% incremental Toujeo rebate drives 0.9% incremental on Glargine

| $M | Toujeo Gross Sales | Toujeo % Rebate* | Sanofi Glargine Total Gross Sales | Sanofi Glargine Total % Rebate | Sanofi Glargine Total 10% Incremental Toujeo Rebate | Sanofi Glargine Total Glargine Incremental % Rebate |
|---|---|---|---|---|---|---|
| ESI | 149 | 37% | 1,817 | 36% | 15 | 0.8% |
| Caremark | 50 | 0% | 925 | 38% | 5 | 0.5% |
| [redacted] | | | | | | |
| OptumRx | 6 | 0% | 194 | 51% | 1 | 0.3% |
| [redacted] | | | | | | |
| Other | 94 | 16% | 497 | 16% | 9 | 1.9% |
| **Total Commercial** | **352** | **23%** | **4,056** | **32%** | **35** | **0.9%** |

Adding an incremental 10% rebate to all Commercial Toujeo business leads to an incremental 0.9% rebate to the total glargine 2015 sales

SANOFI DIABETES

# Toujeo WAC Pricing Recommendation

## Tom Blount

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## Speaker Notes for Slide 22

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Toujeo WAC Pricing Recommendation…$.2485 / IU at parity to Lantus & Levemir (IU-basis)

## Toujeo recommendation is priced at parity to Lantus & Levemir on a unit basis

**WAC Price**

- **$335.49 Per Box**
  - **$0.2485 per IU**

| Units | Lantus | Toujeo |
|---|---|---|
| IUs per mL | 100 | 300 |
| IUs per pen | 300 | 450 |
| mLs per pen | 3.0 | 1.5 |
| Pens per box | 5 | 3 |
| IUs per box | 1500 | 1350 |

| Price | Lantus | Toujeo |
|---|---|---|
| Price per IU | $0.2485 | $0.2485 |
| Price per pen | $ 74.55 | $111.83 |
| Price per mL | $ 24.85 | $ 74.55 |
| Pens per box | 5 | 3 |
| Price per box | $372.76 | $335.48 |

## Rationale

- **Supports Toujeo strategic objectives to gain rapid patient access that is competitive to alternative basal insulins and to remove cost as a barrier for switch patients**
  - **Neutralizes objections to cost since Toujeo has only a small window in which to gain access**
  - [redacted]
  - **Keeps Toujeo WAC in proximity to Levemir, defusing competitive threats**
  - **Reduces cost arguments when biosimilar glargine products launch since not aggressive**
- **Payors overwhelmingly preferred a low WAC, low discount for a new basal insulin, noting a high WAC only hurts patients with coinsurance on their pharmacy benefit**
  - ***"In reality, net is net, but the WAC changes what the consumer pays out-of-pocket. I would rather have low WAC, low discount every time" – Pharmacy Director***
- **A WAC premium would require deeper discounts to achieve net parity to Lantus**

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# Toujeo Pricing & Contracting Research
# Key take-aways → premium price will impede access

## Toujeo access will depend on net cost of glargine

- Premium pricing generally results in non-preferred or restricted status for Toujeo, especially since payers believe there are few unmet needs with current basal therapy
- Majority of HCPs indicate a high willingness to prescribe Toujeo; however, the willingness to prescribe was negatively impacted by an increased copay
- Almost all current basal patients would accept their doctor's recommendation to switch to Toujeo if there were no additional cost—acceptance drops if copay is increased

| Dimension | Findings |
|---|---|
| Managed Care Payors | Toujeo is seen as a parity product to Lantus; Toujeo access will depend on net cost of the glargine franchise<br>• Discounts on Lantus for Toujeo preferred access can increase Toujeo preferred access but effect diminishes when Toujeo is priced at premium<br>• Toujeo is acknowledged for its effect on hypoglycemia for Medicare patients but that differentiation may not be meaningful enough to warrant preferred access |
| Healthcare Providers | HCPs responded favorably to blinded profiles of Toujeo but access barriers and increased co-pay appear to offset clinical advantages of Toujeo |
| Patients | Patients responded favorably to blinded profiles of Toujeo but would ultimately choose a lower cost agent over Toujeo |

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Source: Compass P&C Research July 2014

# Commercial Channel Contracting Guidelines
# Lantus & Toujeo

## Shawn Jacot

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## Speaker Notes for Slide 25

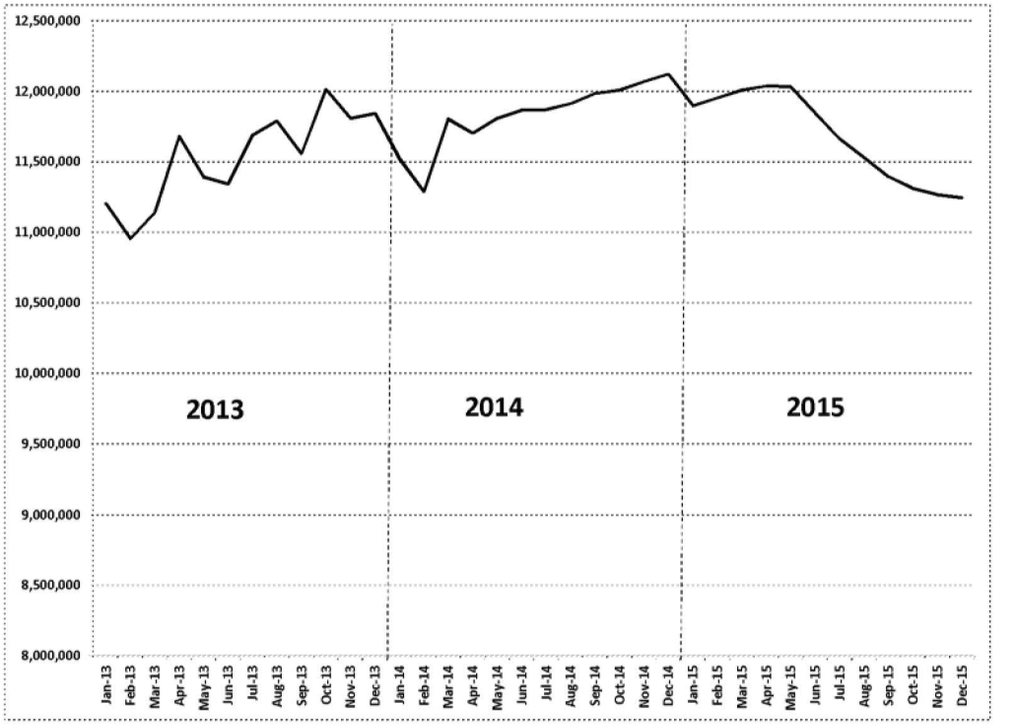
The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Commercial Channel – 15B Lantus: $2.3B…33% of total business…top 5 accounts = 89% of Lantus Net Sales

| GROSS SALES (MUSD) | 2013 | 2014 | 2015 |
|---|---|---|---|
| All Channel | 7,434 | 10,142 | 11,326 |
| Managed Care | $ 2,218 | $ 3,100 | $ 3,704 |
| % of Business | 29.8% | 30.6% | 32.7% |
| YTD Growth | 16.5% | 39.8% | 19.5% |
| YTD % of Business | 29.8% | 30.6% | 32.7% |
| YTD Discount % | 5.3% | 12.8% | 33.0% |

| DEMAND UNITS | 2013 | 2014 | 2015 | 15B Net Sales |
|---|---|---|---|---|
| Managed Care | 139 | 142 | 149 | $ 2,312 |
| YTD Growth | -5.4% | 2.5% | 4.8% | |
| YTD % of Business | 32.7% | 32.7% | 32.7% | |
| ESI | 22 | 65 | 67 | $ 1,076 |
| YTD Growth | -5.5% | 194.1% | 3.0% | |
| YTD % of Business | 16.0% | 45.8% | 45.0% | |
| YTD Discount % | 5.1% | 9.1% | 35.5% | |
| CVS-Caremark | 37 | 36 | 35 | $ 522 |
| YTD Growth | -4.8% | -1.3% | -3.2% | |
| YTD % of Business | 26.6% | 25.6% | 23.6% | |
| YTD Discount % | 5.0% | 8.8% | 40.3% | |
| PRIME | 13 | 13 | 13 | $ 281 |
| YTD Growth | 11.6% | -0.3% | -0.5% | |
| YTD % of Business | 9.2% | 9.0% | 8.5% | |
| YTD Discount % | 6.1% | 10.9% | 11.1% | |
| UHG-Optum | 6 | 8 | 8 | $ 89 |
| YTD Growth | 80.4% | 36.3% | -1.3% | |
| YTD % of Business | 4.1% | 5.4% | 5.1% | |
| YTD Discount % | 5.0% | 29.6% | 52.6% | |
| CIGNA | 5 | 5 | 5 | $ 86 |
| YTD Growth | 2.7% | 7.7% | 2.4% | |
| YTD % of Business | 3.4% | 3.6% | 3.5% | |
| YTD Discount % | 6.4% | 9.1% | 33.7% | |

## Commercial Channel Demand Unit Trend




- Channel average discount grows from 13% to 33% (2014-2015)
- Demand growth falls by 2% due to Toujeo conversion

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## Speaker Notes for Slide 26

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Commercial Key Accounts - Lantus

| Lantus Vial | REBATE% (excl PP) | | Price Protection | | | | | Total Rebate% | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 2014 | | | 2015 | | | |
| Commercial | 2014 | 2015 | PP% | Baseline Date | PP | PP% | Baseline Date | 2014 | 2015 |
| ESI | 6% Q1-Q3, 10% Q4 | 26% | NA | NA | Cumulative Net | 10% | 05/14/14 | 9.1% | 35.5% |
| CVS CAREMARK | 6.7% | 30% | NA | NA | Cumulative Net | 7.5% | 05/29/14 | 8.8% | 40.3% |
| [redacted] | | | | | | | | | |
| OPTUM Rx | 5% Q1-Q2, 45% Q3-Q4 | 45% | 7.0% | 12/31/13 | Cumulative Net | 7.0% | 12/31/13 | 29.6% | 52.6% |
| [redacted] | | | | | | | | | |

| Lantus Pen | REBATE% (excl PP) | | Price Protection | | | | | Total Rebate% | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 2014 | | | 2015 | | | |
| Commercial | 2014 | 2015 | PP% | Baseline Date | PP | PP% | Baseline Date | 2014 | 2015 |
| ESI | 8.8% Q1-Q3, 12.8% Q4 | 26.0% | 10% | NA | Cumulative Net | 10.0% | 05/14/14 | 9.1% | 35.5% |
| CVS CAREMARK | 8.3% | 30.0% | NA | NA | Cumulative Net | 7.5% | 05/29/14 | 8.8% | 40.3% |
| [redacted] | | | | | | | | | |
| OPTUM Rx | 5% Q1-Q2, 45% Q3-Q4 | 45.0% | 7.0% | 12/31/13 | Cumulative Net | 7.0% | 12/31/13 | 29.6% | 52.6% |
| [redacted] | | | | | | | | | |

## Speaker Notes for Slide 27

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Commercial Guidelines – Recommendation (Lantus)

**Channel Strategy Objective: To maintain preferred unrestricted access – 1 of 2 manufacturers.**

| | Lantus Current Guidelines | | | Lantus Recommended Guidelines | | |
|---|---|---|---|---|---|---|
| | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | | Price Protection |
| Channel | Vial | SS | | Vial | SS | |
| Commercial | 15% | 20% | NA | 30% | 30% | 6% |

- Current contracts exceeding maximum discount: 3
- Key contracts with price protection exceeding revised price protection guidelines: 0
- Risk associated with regional contracts going to maximum discount = ~$155M
- [redacted]

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## Speaker Notes for Slide 28

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Toujeo Commercial Key Accounts…71% of total Net Sales…ESI, [redacted] contracted

| Channel/Account | Rebate | 2015 Gross Demand Sales | % of Total Gross Sales | 2015 Rebate $ | 2015 Net Demand Sales |
|---|---|---|---|---|---|
| ESI | 40% Jul'15 | $ 149.0 | 30.6% | $ 55.1 | $ 93.8 |
| Caremark | NA | $ 50.0 | 10.3% | $ - | $ 50.0 |
| [redacted] | | | | | |
| OptumRx | NA | $ 6.5 | 1.3% | $ - | $ 6.5 |
| [redacted] | | | | | |
| Other | 18% Jul'15 | $ 94.1 | 19.4% | $ 15.2 | $ 78.9 |
| **TOTAL Commercial** | | **$ 352.5** | **72.5%** | **$ 81.0** | **$ 271.5** |

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## Speaker Notes for Slide 29

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Recommended approach to negotiate glargine contracts

## Strategy: Leverage glargine family discounts and price protection on Lantus & Toujeo to achieve Tier 2 unrestricted access

| Level of Control | Incremental Lantus rebate ranges | Toujeo and Lantus price predictability (annual cap) |
|---|---|---|
| High | 0 – 8% | 6% |
| Medium | 0 – 6% | 7% |
| Low | 0 – 4% | 8% |

Level of Control based on regulation of basal and rapid acting category

- Ability to affect market share through the use of formulary controls:
  - Step edit/ Prior Authorization
  - Exclusion Lists
  - Number of preferred brands

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# Incremental 2% discount on Lantus offsets an 18% dosage increase on Toujeo

## Demonstrate to a plan the equivalent change in rebate percentages

| | Baseline | | | Scenario 1 | | | Scenario 2 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Lantus | Toujeo | Total | Lantus | Toujeo | Total | Lantus | Toujeo | Total |
| TRx (units) | 900 | 100 | 1,000 | 900 | 100 | 1,000 | 900 | 100 | 1,000 |
| Market Share (%) | 90% | 10% | 100.0% | 90% | 10% | 100.0% | 90% | 10% | 100% |
| WAC / Rx ($) | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 |
| WAC ($) | 223,650 | 24,850 | 248,500 | 223,650 | 24,850 | 248,500 | 223,650 | 24,850 | 248,500 |
| Rebate (%) | 10.0% | 10.0% | 10.0% | 10.0% | 28.0% | 11.8% | 12.0% | 10.0% | 11.8% |
| Rebate ($) | 22,365 | 2,485 | 24,850 | 22,365 | 6,958 | 29,323 | 26,838 | 2,485 | 29,323 |
| Net Cost to Plan | 204,649 | 22,739 | 227,388 | 204,649 | 18,266 | 222,915 | 200,176 | 22,739 | 222,915 |
| NCTP After Copay | 182,149 | 20,239 | 202,388 | 182,149 | 15,766 | 197,915 | 177,676 | 20,239 | 197,915 |

**Assumes payors evaluate the differentiated Toujeo label**

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# Commercial Guidelines – Recommendation (Toujeo)

**Channel Strategy Objective: To achieve preferred unrestricted access – 1 of 2 manufacturers.**

| | REVISED LANTUS | | | TOUJEO | |
|---|---|---|---|---|---|
| | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | Price Protection |
| Channel | Vial | SS | | Pen | |
| Commercial | 30% | 30% | 6% | 30% | 6% |

- Current contracts exceeding maximum discount: 2
- Key contracts with price protection exceeding current guidelines: 3
- Risk associated with all contracts going to maximum discount = NA

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## Speaker Notes for Slide 32

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicare Channel Contracting Guidelines
# Lantus & Toujeo

## Shawn Jacot

SANOFI | US Market Access

## Speaker Notes for Slide 33

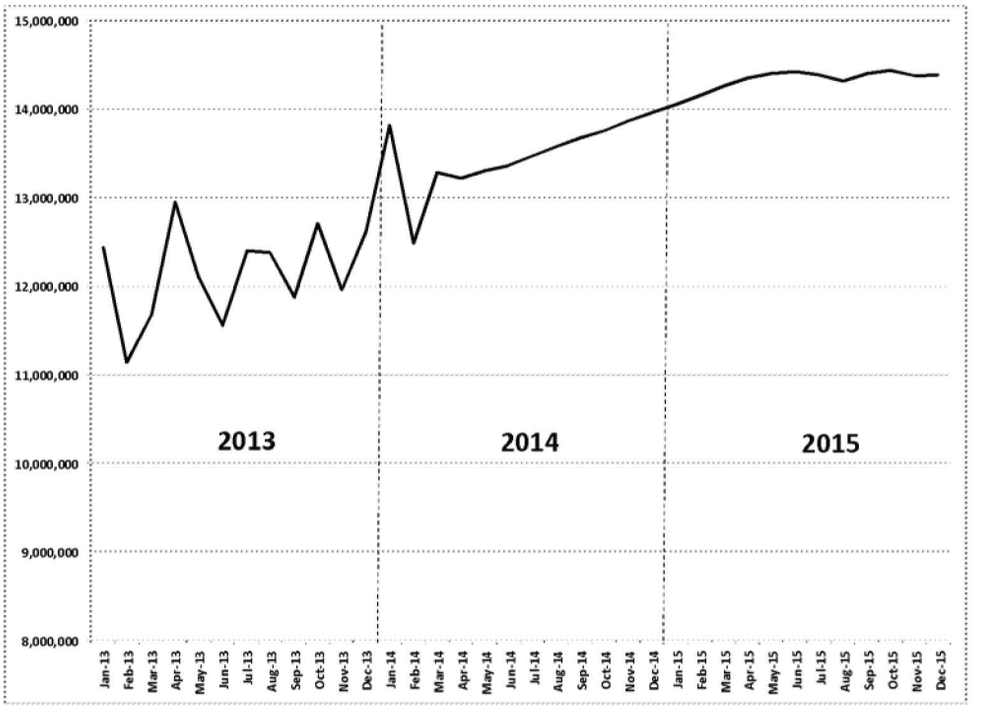
The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicare Channel – 15B Lantus: $2.7B…41% of total business…top 5 accounts = 87% of Lantus Net Sales

| GROSS SALES | 2013 | 2014 | 2015 |
|---|---|---|---|
| Medicare | $ 2,334 | $ 3,534 | $ 4,675 |
| YTD Growth | 62.9% | 51.4% | 32.3% |
| YTD % of Business | 31.4% | 34.8% | 41.3% |
| YTD Discount % | 11.2% | 29.4% | 37.1% |

| DEMAND UNITS | 2013 | 2014 | 2015 | 15B Net Sales |
|---|---|---|---|---|
| Medicare | 146 | 164 | 188 | $ 2,655 |
| YTD Growth | 32.4% | 12.1% | 15.0% | |
| YTD % of Business | 41.3% | 41.3% | 41.3% | |
| ESI | 10 | 43 | 47 | $ 907 |
| YTD Growth | -7.0% | 352.0% | 8.8% | |
| YTD % of Business | 6.5% | 26.3% | 24.9% | |
| YTD Discount % | 5.3% | 19.2% | 22.0% | |
| Humana | 25 | 29 | 30 | $ 536 |
| YTD Growth | 22.2% | 15.1% | 4.1% | |
| YTD % of Business | 17.3% | 17.7% | 16.1% | |
| YTD Discount % | 6.5% | 16.5% | 28.5% | |
| CVS-Caremark | 33 | 32 | 31 | $ 374 |
| YTD Growth | 127.1% | -2.1% | -5.8% | |
| YTD % of Business | 22.7% | 19.9% | 16.3% | |
| YTD Discount % | 16.9% | 46.7% | 50.8% | |
| Optum Rx | 31 | 36 | 37 | $ 350 |
| YTD Growth | 7.7% | 14.0% | 4.5% | |
| YTD % of Business | 21.3% | 21.7% | 19.7% | |
| YTD Discount % | 5.3% | 41.7% | 62.0% | |
| CIGNA | 2 | 5 | 7 | $ 139 |
| YTD Growth | 237.8% | 202.8% | 61.9% | |
| YTD % of Business | 1.0% | 2.8% | 3.9% | |
| YTD Discount % | 14.3% | 26.8% | 24.5% | |

## Medicare Channel Demand Unit Trend




- Channel average discount grows from 29% to 37% (2014-2015)

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## Speaker Notes for Slide 34

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicare Key Accounts - Lantus

| Lantus Vial | REBATE% (excl PP) | | Price Protection | | | | | Total Rebate% | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 2014 | | | 2015 | | | |
| Medicare Part D | 2014 | 2015 | PP% | Baseline Date | PP | PP% | Baseline Date | 2014 | 2015 |
| ESI | 15% Q1-Q3, 19% Q4 | 22.0% | 10% | 12/31/13 | Reset Net | 10.0% | 12/31/14 | 19.2% | 22.0% |
| CVS CAREMARK | 32.0% | 42.0% | 9% | 06/03/13 | Cumulative Net | 7.5% | 05/29/14 | 46.7% | 50.8% |
| [redacted] | | | | | | | | | |
| OPTUM Rx | 11.3% Q1-Q2, 55% Q3-Q4 | 55.0% | 7% | No PP H2 | Reset Net | 6.0% | 12/31/13 | 41.7% | 62.0% |
| [redacted] | | | | | | | | | |

| Lantus Pen | REBATE% (excl PP) | | Price Protection | | | | | Total Rebate% | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 2014 | | | 2015 | | | |
| Medicare Part D | 2014 | 2015 | PP% | Baseline Date | PP | PP% | Baseline Date | 2014 | 2015 |
| ESI | 15% Q1-Q3, 19% Q4 | 22.0% | 10% | 12/31/13 | Reset Net | 10.0% | 12/31/14 | 19.2% | 22.0% |
| CVS CAREMARK | 32.0% | 42.0% | 9% | 06/03/13 | Cumulative Net | 7.5% | 05/29/14 | 46.7% | 50.8% |
| [redacted] | | | | | | | | | |
| OPTUM Rx | 13.9% Q1-Q3, 55% Q4 | 55.0% | 7% | No PP H2 | Reset Net | 6.0% | 12/31/13 | 41.7% | 62.0% |
| [redacted] | | | | | | | | | |

## Speaker Notes for Slide 35

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicare Guidelines – No change (Lantus)

**Channel Strategy Objective: To maintain preferred unrestricted access – 1 of 2 manufacturers.**

| | Lantus Current Guidelines | | | REVISED LANTUS | | |
|---|---|---|---|---|---|---|
| | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | | Price Protection |
| Channel | Vial | SS | | Vial | SS | |
| Medicare - Preferred | 35% | 35% | 6% | 35% | 35% | 6% |
| Medicare - Non-Preferred | NA | NA | NA | NA | NA | NA |

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## Speaker Notes for Slide 36

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicare Key Accounts - Toujeo

| Channel/Account | Rebate | 2015 Gross Demand Sales | % of Total Gross Sales | 2015 Rebate $ | 2015 Net Demand Sales |
|---|---|---|---|---|---|
| ESI Part D | NA | $ 18.8 | 3.9% | $ - | $ 18.8 |
| Caremark Part D | NA | $ 12.2 | 2.5% | $ - | $ 12.2 |
| [redacted] | | | | | |
| OptumRx Part D | NA | $ 15.9 | 3.3% | $ - | $ 15.9 |
| [redacted] | | | | | |
| **TOTAL Medicare** | | **$ 90.1** | **18.5%** | **$ -** | **$ 90.1** |

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## Speaker Notes for Slide 37

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Recommended approach to negotiate glargine contracts

## Strategy: Leverage glargine family discounts and price protection on Lantus & Toujeo to achieve Tier 2 unrestricted access

| Level of Control | Incremental Lantus rebate ranges | Toujeo and Lantus price predictability (annual cap) |
|---|---|---|
| High | 0 – 8% | 6% |
| Medium | 0 – 6% | 7% |
| Low | 0 – 4% | 8% |

Level of Control based on regulation of basal and rapid acting category

- Ability to affect market share through the use of formulary controls:
  - Step edit/ Prior Authorization
  - Exclusion Lists
  - Number of preferred brands

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# Value of a rebate percentage point change on a Plan's Net Cost

## Demonstrate to a plan the equivalent change in rebate percentages

| | Baseline | | | Scenario 1 | | | Scenario 2 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Lantus | Toujeo | Total | Lantus | Toujeo | Total | Lantus | Toujeo | Total |
| TRx (units) | 900 | 100 | 1,000 | 900 | 100 | 1,000 | 900 | 100 | 1,000 |
| Market Share (%) | 90% | 10% | 100.0% | 90% | 10% | 100.0% | 90% | 10% | 100% |
| WAC / Rx ($) | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 | 248.50 |
| WAC ($) | 223,650 | 24,850 | 248,500 | 223,650 | 24,850 | 248,500 | 223,650 | 24,850 | 248,500 |
| Rebate (%) | 10.0% | 10.0% | 10.0% | 10.0% | 28.0% | 11.8% | 12.0% | 10.0% | 11.8% |
| Rebate ($) | 22,365 | 2,485 | 24,850 | 22,365 | 6,958 | 29,323 | 26,838 | 2,485 | 29,323 |
| Net Cost to Plan | 204,649 | 22,739 | 227,388 | 204,649 | 18,266 | 222,915 | 200,176 | 22,739 | 222,915 |
| NCTP After Copay | 182,149 | 20,239 | 202,388 | 182,149 | 15,766 | 197,915 | 177,676 | 20,239 | 197,915 |

**Assumes payors evaluate the differentiated Toujeo label**

# Medicare Guidelines – Recommendation (Toujeo)

**Channel Strategy Objective: To achieve preferred unrestricted access – 1 of 2 manufacturers (primary). To achieve non-preferred access (secondary).**

| | Lantus Current Guidelines | | | TOUJEO | |
|---|---|---|---|---|---|
| | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | Price Protection |
| Channel | Vial | SS | | | |
| Medicare - Preferred | 35% | 35% | 6% | 35% | 6% |
| Medicare - Non-Preferred | NA | NA | NA | 15% | NA |

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## Speaker Notes for Slide 40

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicaid Channel Contracting Guidelines
# Lantus & Toujeo

## Shawn Jacot

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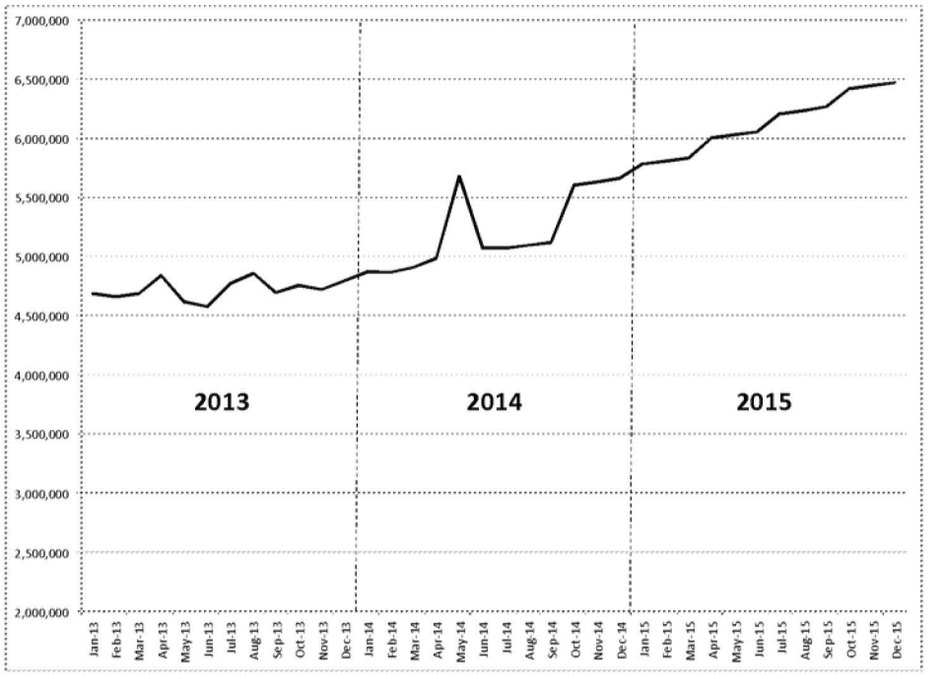
## Speaker Notes for Slide 41

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicaid Channel – Lantus: $20M projected Net Sales in 15B…98.4% average rebate

| DEMAND UNITS | 2013 | 2014 | 2015 | 15B Net Sales |
|---|---|---|---|---|
| Managed Medicaid | 21,549,959 | 24,510,414 | 36,382,844 | $ 13 |
| YTD Growth | 16.2% | 13.7% | 48.4% | |
| YTD % of Business | 4.6% | 5.2% | 8.0% | |
| YTD Discount % | -4.7% | -4.9% | -4.9% | |
| Mandated Medicaid | 20,096,797 | 20,084,945 | 16,673,024 | $ 7 |
| YTD Growth | -8.3% | -0.1% | -17.0% | |
| YTD % of Business | 4.3% | 4.3% | 3.7% | |
| YTD Discount % | -72.0% | -91.0% | -98.4% | |
| | | | | |
| Total Medicaid | 41,646,755 | 44,595,360 | 53,055,868 | $ 20 |
| % of Business | 9.0% | 9.5% | 11.6% | |
| YTD Growth | 2.9% | 7.1% | 19.0% | |
| YTD % of Business | 9.0% | 9.5% | 11.6% | |

## Medicaid Channel Demand Unit Trend




- **Toujeo – 15B Medicaid Net Sales = $15M (Mandated Medicaid only – no Managed Medicaid assumed)**

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## Speaker Notes for Slide 42

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Medicaid Guidelines – Recommendation (Lantus)

**Channel Strategy Objective: Patient preservation maintaining access within targeted states and plans.**

| | Lantus Current Guidelines | | | REVISED LANTUS | | |
|---|---|---|---|---|---|---|
| | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | | Price Protection |
| Channel | Vial | SS | | Vial | SS | |
| Managed Medicaid | 5% | 10% | NA | 5% | 5% | NA |
| Medicaid Supplemental | 85% | 85% | NA | 85% | 85% | NA |

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## Speaker Notes for Slide 43

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Managed Medicaid Strategy…15% discretionary rebate to secure access for early adoption

- **Strategic Imperative**
  - Leverage select targeted Plans in the Managed Medicaid Channel for early adoption of Toujeo; Convert Lantus to Toujeo to offset net loss in channel
- **Seek Approval for…**
  - Commercial Managed Medicaid discounts on Toujeo up to 15% (reevaluate strategy as URA + Rebate approaches 75%)
- **Risks**
  - Pricing Actions and Best Price offered to Commercial/Institutional/LTC account will determine the URA
  - Limited uptake in 5 states that require capitated lives to follow state PDL
  - Offer 1 year agreements to minimize risk

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# Managed Medicaid BE Analysis…20% conversion to Toujeo = breakeven point at 40% URA

| | | WAC | Rebate | URA | PP | DPA | COGs | Net | Rebate +URA | plus other |
|---|---|---|---|---|---|---|---|---|---|---|
| URA and Profitability | Lantus | $268.49 | 5% | 99% | 2.0% | 1.6% | 1.9% | $ (25.5) | 104.0% | 109.5% |
| | Toujeo 1 | $268.49 | 15% | 40% | 2.0% | 1.6% | 3.8% | $ 100.4 | 55.0% | 62.6% |
| | Toujeo 2 | $268.49 | 15% | 60% | 2.0% | 1.6% | 3.8% | $ 47.3 | 75.0% | 82.4% |
| | Toujeo 3 | $268.49 | 15% | 75% | 2.0% | 1.6% | 3.8% | $ 7.0 | 90.0% | 97.4% |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Gross Sales | Lantus Sales | $ 535.0 | $ 481.5 | $ 428.0 | $ 374.5 | $ 321.0 | $ 267.5 | $ 214.0 | $ 160.5 | $ 107.0 | $ 53.5 | $ - |
| | Toujeo Sales | $ - | $ 53.5 | $ 107.0 | $ 160.5 | $ 214.0 | $ 267.5 | $ 321.0 | $ 374.5 | $ 428.0 | $ 481.5 | $ 535.0 |

| | | | | | | | | | | | | Breakeven |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Toujeo Scenario 1 URA 40% | Lantus Share | 100% | 90% | 80% | 70% | 60% | 50% | 40% | 30% | 20% | 10% | 0% | 79.83% |
| | Toujeo Share | 0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100% | 20.17% |
| | Lantus Net | $ (50.8) | $ (45.7) | $ (40.7) | $ (35.6) | $ (30.5) | $ (25.4) | $ (20.3) | $ (15.2) | $ (10.2) | $ (5.1) | $ - | $ (40.6) |
| | Toujeo Net | $ - | $ 20.1 | $ 40.2 | $ 60.3 | $ 80.5 | $ 100.6 | $ 120.7 | $ 140.8 | $ 160.9 | $ 181.0 | $ 201.2 | $ 40.6 |
| | Total Net | $ (50.8) | $ (25.6) | $ (0.4) | $ 24.8 | $ 50.0 | $ 75.2 | $ 100.4 | $ 125.6 | $ 150.8 | $ 176.0 | $ 201.2 | $ - |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Toujeo Scenario 2 URA 60% | Lantus Share | 100% | 90% | 80% | 70% | 60% | 50% | 40% | 30% | 20% | 10% | 0% | 64.94% |
| | Toujeo Share | 0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100% | 35.06% |
| | Lantus Net | $ (50.8) | $ (45.7) | $ (40.7) | $ (35.6) | $ (30.5) | $ (25.4) | $ (20.3) | $ (15.2) | $ (10.2) | $ (5.1) | $ - | $ (33.0) |
| | Toujeo Net | $ - | $ 9.4 | $ 18.8 | $ 28.2 | $ 37.7 | $ 47.1 | $ 56.5 | $ 65.9 | $ 75.3 | $ 84.7 | $ 94.2 | $ 33.0 |
| | Total Net | $ (50.8) | $ (36.3) | $ (21.8) | $ (7.3) | $ 7.2 | $ 21.7 | $ 36.2 | $ 50.7 | $ 65.2 | $ 79.7 | $ 94.2 | $ - |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Toujeo Scenario 3 URA 70% | Lantus Share | 100% | 90% | 80% | 70% | 60% | 50% | 40% | 30% | 20% | 10% | 0% | 21.49% |
| | Toujeo Share | 0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100% | 78.51% |
| | Lantus Net | $ (50.8) | $ (45.7) | $ (40.7) | $ (35.6) | $ (30.5) | $ (25.4) | $ (20.3) | $ (15.2) | $ (10.2) | $ (5.1) | $ - | $ (10.9) |
| | Toujeo Net | $ - | $ 1.4 | $ 2.8 | $ 4.2 | $ 5.6 | $ 7.0 | $ 8.3 | $ 9.7 | $ 11.1 | $ 12.5 | $ 13.9 | $ 10.9 |
| | Total Net | $ (50.8) | $ (44.4) | $ (37.9) | $ (31.4) | $ (24.9) | $ (18.5) | $ (12.0) | $ (5.5) | $ 1.0 | $ 7.4 | $ 13.9 | $ - |

Lantus Gross Sales $535 = Budgeted Gross Sales of Lantus $511M + budget Toujeo $24M

Net Sales Caluculations include rebate, URA, PP, DPA, COGs

**Scenario 1-Toujeo requires 5% conversion to achieve B15; Franchise BE at 20%**

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# Projected government prices…Toujeo best price at 45% off WAC – Lantus Medicaid price = 99% off WAC

| | Lantus 2014 | Lantus 2015 | Toujeo 2015 |
|---|---|---|---|
| WAC | $220.98 | $248.50 | $248.50 |
| AMP | $211.33 | $245.24 | $244.78 |
| Best Price | $111.25 | $111.25 | $136.68 |
| Non-FAMP | 190.85 | $211.23 | $241.05 |

**Assumptions/Comments:**

- **Lantus WAC: annual average; assume no price increases in 2015**
- **Toujeo WAC: assumed to be equal to Lantus Vial Package Price in 2015**
- **Lantus & Toujeo AMP: estimated annual average**
- **Lantus Best Price: based on the lowest price for the year**
- **Toujeo Best Price: estimated to be equal to 45% rebate off WAC**
- **Lantus & Toujeo Non-FAMP: estimated annual average (based on the VA's fiscal year, for example Lantus 2014 = Oct 2013 through Sept 2014 sales)**

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# Medicaid Guidelines – Recommendation (Toujeo)

**Channel Strategy Objective: To achieve access rapid access in targeted managed medicaid plans and states.**

| | REVISED LANTUS | | | TOUJEO | |
|---|---|---|---|---|---|
| | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | Price Protection |
| Channel | Vial | SS | | Pen | |
| Managed Medicaid | 5% | 5% | NA | 15% | NA |
| Medicaid Supplemental | 85% | 85% | NA | 0% | NA |

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## Speaker Notes for Slide 47

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Hospital Channel Contracting Guidelines
# Lantus & Toujeo

## Shawn Jacot

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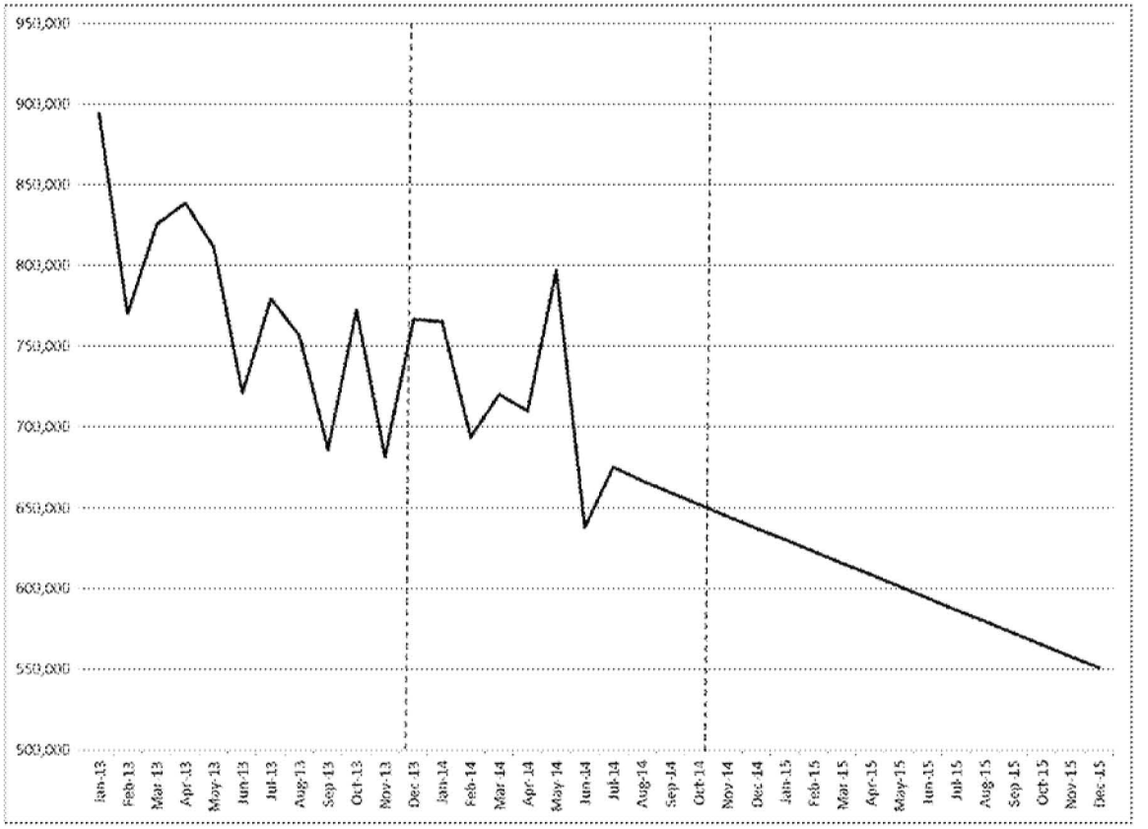
## Speaker Notes for Slide 48

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Hospital Channel Review – Lantus…15B Net Sales = $125M…unit and share growth showing steady decline

## Hospital Demand Unit Trend




- 15B Net Sales = $125M
- Demand unit growth…
  - 13A = -11.8%
  - 14F2 = -11.2%
  - 15B = -13.8%
- Percent of business…
  - 13A = 2.0%
  - 14F2 – 1.8%
  - 15B = 1.6%
- Average Discount…
  - 13A = 11.8%
  - 14F2 = 24.5%
  - 15B = 29.2%

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## Speaker Notes for Slide 49

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Institution Market Access Landscape

- Institutions in this panel are moving towards carrying only one product per diabetes class
- Indicates existing contracts are typically portfolio deals with one manufacturer
- Institutional payers were more satisfied with Levemir than Lantus because of net cost
- Respondents estimate that 8.5% of their total drug spend is for diabetes medication, of which over half is spent on basal insulin products
- Patients admitted to the hospital are switched to the basal insulin on formulary, and when discharged are prescribed the original home insulin

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Source: Toujeo Market Access Landscape and Pricing Strategy Long Term Care and Institutional Payor Report July 21, 2014 Compass Strategic Consulting

# Institution Strategy → maintain Lantus business in top tier accounts…follow-up to 11/21 USPC

- **Strategic Imperative**
  - Maintain Lantus Base Business in top tier accounts; Toujeo strategy is focused on discharge and transitions of care
- **Seek Approval for**
  - Revision to Current Lantus Program – Enhance Tier 3 from 25% to 30% and Tier 4 from 30% to 35%; Reduce Price predictability on Lantus from 10% to 5% with July reset, Market Share Calculation includes Toujeo
  - Toujeo – set at maximum commercial rebate
  - 9-month Lantus 40% Ramp-up Program approval
- **Risks**
  - Pricing Actions and Best Price offered to Commercial/Institutional/LTC account will determine the URA.

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# Hospital Market Composition…Tier 5 institutions comprise 69% of Lantus business…

| Program Tier | Lantus | | Tier Structure | Basal Basket* | Select Insulin Basket** | | | |
|---|---|---|---|---|---|---|---|---|
| | Count | % of Total | | Lantus MS% | Lantus MS% | Levemir MS% | NPH MS% | Premix MS% |
| LANTUS SYS TIER 2 | 64 | 0.86% | 38.00% to 51.99% | 62.08% | 46.15% | 28.19% | 12.75% | 12.91% |
| LANTUS SYS TIER 3 | 168 | 4.15% | 52.00% to 67.99% | 74.90% | 58.74% | 19.68% | 13.69% | 7.90% |
| LANTUS SYS TIER 4 | 166 | 5.22% | 68.00% to 74.99% | 82.10% | 70.00% | 15.27% | 9.43% | 5.30% |
| LANTUS SYS TIER 5 | 403 | 16.77% | 75.00% to 100.00% | 88.60% | 79.95% | 10.28% | 6.11% | 3.66% |
| LANTUS TIER 1 | 4,955 | 24.83% | 0.00% to 49.99% | 19.20% | 13.79% | 58.06% | 17.51% | 10.64% |
| LANTUS TIER 2 | 409 | 5.53% | 50.00% to 59.99% | 70.70% | 54.80% | 22.71% | 14.87% | 7.62% |
| LANTUS TIER 3 | 482 | 11.39% | 60.00% to 69.99% | 78.52% | 62.94% | 17.22% | 12.51% | 7.33% |
| LANTUS TIER 4 | 402 | 11.03% | 70.00% to 79.99% | 85.64% | 74.90% | 12.56% | 7.88% | 4.66% |
| LANTUS TIER 5 | 1,039 | 20.23% | 80.00% to 100.00% | 95.61% | 90.22% | 4.14% | 4.03% | 1.60% |
| Grand Total | 8,089 | 100.00% | | 63.17% | 51.10% | 29.80% | 12.03% | 7.08% |

* Basal = Lantus and Levemir

** Select represents Lantus Program Market Basket

Source SPM Lantus Hospital Cube DDD 2Q2014

No Tier 1 Systems enrolled in Lantus Program

- **18% of total hospitals at Tier 5 represent 37% Lantus Volume**
  - **Tier 3 – 5 represent 69% of Total Lantus Volume**
- **Lantus Basal insulin share is>70% in majority of Tiers; total Basal share 63.2% (Overall MS% Select Insulin is 51%)**
- **Tier 5 Hospitals Require conversion from NPH and Premix**

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# Proposed Lantus Tier Strategy…revision to current agreement → inclusion of 5% price predictability

| | | | Current | | Proposed | |
|---|---|---|---|---|---|---|
| Row Labels | Tier | % Business | Discount | GTN % | Discount | GTN % |
| LANTUS SYS TIER 1 | 0.00% to 37.99% | 0.0% | 1% | 0.0% | 1% | 0.0% |
| LANTUS SYS TIER 2 | 38.00% to 51.99% | 0.9% | 9% | 0.1% | 9% | 0.1% |
| LANTUS SYS TIER 3 | 52.00% to 67.99% | 4.1% | ***25%*** | 1.0% | ***30%*** | 1.2% |
| LANTUS SYS TIER 4 | 68.00% to 74.99% | 5.2% | ***30%*** | 1.6% | ***35%*** | 1.8% |
| LANTUS SYS TIER 5 | 75.00% to 100.00% | 16.8% | 40% | 6.7% | 40% | 6.7% |
| LANTUS TIER 1 | 0.00% to 49.99% | 24.8% | 1% | 0.2% | 1% | 0.2% |
| LANTUS TIER 2 | 50.00% to 59.99% | 5.5% | 9% | 0.5% | 9% | 0.5% |
| LANTUS TIER 3 | 60.00% to 69.99% | 11.4% | ***25%*** | 2.8% | ***30%*** | 3.4% |
| LANTUS TIER 4 | 70.00% to 79.99% | 11.0% | ***30%*** | 3.3% | ***35%*** | 3.9% |
| LANTUS TIER 5 | 80.00% to 100.00% | 20.2% | 40% | 8.1% | 40% | 8.1% |
| Grand Total | | 100.0% | | 24.4% | | 26.0% |

***Projected 4Q Tier based on 2Q Data***

- **Increase Tier 3&4 Discounts by 5%; 30% of Hospital volume to receive an incremental 5% (-1.6% GTN impact)**
- **Offer 5% price predictability on Lantus**
- **Market Share calculation based on eaches (1pen = 1 vial)…(Lantus + Toujeo) / (Total Select Insulin Basket)**

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# Financial analyses…3 scenarios: Tier 3-4 enhancement + PP, 40% flat, & 60% flat (meet competition)…15B already at risk

- **Enhanced Tier Option with 5% PP Provides incremental Net Sales vs. Baseline of $2.3M Y1with 2% increase in Discount**
- **Guaranteed 40% requires 2-Year payback period; however risk that customers could actually lose volume**
- **60% Discount is an extremely competitive rate however even with aggressive growth assumptions unlikely to see Return on Investment**
- **All three scenarios are negative if assume no growth**

**Recommendation**

| 2015 | Budget | Lantus Enhance Tiers and - 5% PP | Lantus Guaranteed 40% | Lantus Guaranteed 60% |
|---|---|---|---|---|
| Gross Sales | $ 176,147,405 | $ 184,616,874 | $ 193,086,343 | $ 202,443,954 |
| Rebate $ | $ 51,507,695 | $ 57,675,726 | $ 77,234,537 | $ 121,466,373 |
| Rebate % | 29.2% | 31.2% | 40.0% | 60.0% |
| Net Sales w/ growth | $ 124,639,710 | $ 126,941,148 | $ 115,851,806 | $ 80,977,582 |
| Common Units | 708,821 | 742,903 | 776,984 | 814,639 |
| Difference v Baseline w/ growth | | 2,301,438 | (8,787,904) | (43,662,128) |
| Net Sales w/o growth | $ 124,639,710 | $ 121,116,762 | $ 105,688,443 | $ 70,458,962 |
| Difference v Baseline w/o growth | | (3,522,948) | (18,951,267) | (54,180,748) |

| 2016 | Budget | Lantus Enhance Tiers and - 5% PP | Lantus Guaranteed 40% | Lantus Guaranteed 60% |
|---|---|---|---|---|
| Gross Sales | $ 173,328,026 | $ 195,613,082 | $ 217,898,139 | $ 242,676,993 |
| Rebate $ | $ 51,998,408 | $ 62,596,186 | $ 87,159,256 | $ 145,606,196 |
| Rebate % | 30.0% | 32.0% | 40.0% | 60.0% |
| Net Sales w/ growth | $ 121,329,618 | $ 133,016,896 | $ 130,738,883 | $ 97,070,797 |
| Common Units | 697,476 | 787,152 | 876,827 | 976,538 |
| Difference v Baseline w/ growth | | 11,687,278 | 9,409,265 | (24,258,821) |
| Net Sales w/o growth | $ 121,329,618 | $ 117,863,057 | $ 103,996,815 | $ 69,331,210 |
| Difference v Baseline w/o growth | | (3,466,561) | (17,332,803) | (51,998,408) |
| 2-Year Net Sales w/ growth | $ 245,969,328 | $ 259,958,044 | $ 246,590,689 | $ 178,048,379 |
| Difference v Baseline w/ growth | | $ 13,988,716 | $ 621,361 | $ (67,920,948) |
| 2-Year Net Sales w/o growth | $ 245,969,328 | $ 238,979,819 | $ 209,685,258 | $ 139,790,172 |
| Difference v Baseline w/0 growth | | $ (6,989,509) | $ (36,284,069) | $ (106,179,155) |

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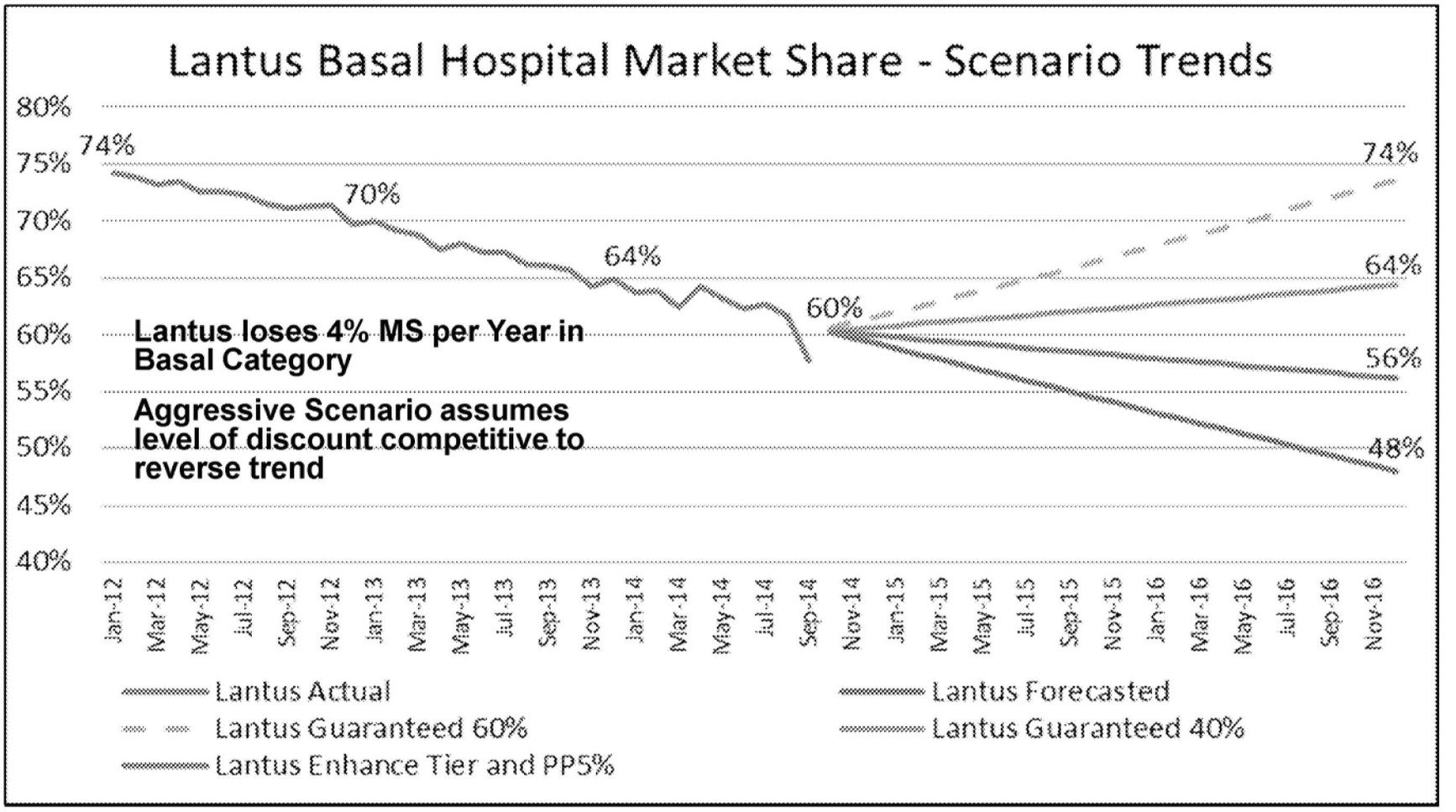
# Scenario market share trends…share loss offset with 40% flat and 60% rebate options

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# Toujeo net parity in hospital is not viable…significant discounts necessary to match cost to plan → drives best price implications

| | Lantus | | Toujeo | |
|---|---|---|---|---|
| | Discounts | Net | Discounts | Net |
| TIER 1 | 1% | $ 73.80 | 34% | $ 73.80 |
| TIER 2 | 9% | $ 67.84 | 39% | $ 67.84 |
| TIER 3 | 30% | $ 52.19 | 53% | $ 52.19 |
| TIER 4 | 35% | $ 48.46 | 57% | $ 48.46 |
| TIER 5 | 40% | $ 44.73 | 60% | $ 44.73 |

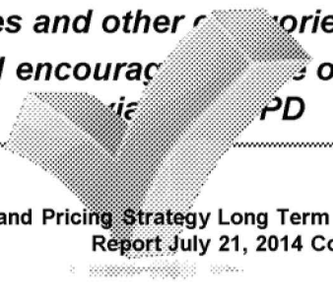
| | Lantus | Toujeo |
|---|---|---|
| Units/pen | 300 | 450 |
| Units | $0.249 | $ 0.249 |
| Pen | $74.55 | $111.83 |

- **Pen wastage in hospital setting due to (*one pen, one patient*) safety requirements**
- **Toujeo requires up to a 60% discount to achieve Net parity price per pen (450 unit Toujeo pen vs 300 unit Lantus pen)**
- **60% Best Price Implications negates Managed Medicaid Play; may also spillover to commercial Managed Care in Integrated Delivery Networks**

# Hospital and LTC pen preference…vial is the desired presentation in the institutional setting…

- **Institutional respondents saw a pen as a barrier for utilization whereas long term care respondents expressed additional interest in the product if it was available in a pen**

| Institutional payors (n=5) | Long term care payors (n=5) |
|---|---|
| • Institutional respondents believe that a pen only offering will deter uptake and utilization<br>• *A vial is very important with insulin. We may not use it at all if it was pen only – INST*<br>• *We do not use pens in the hospital – plain and simple. Unless it was really significantly superior product, but regardless the pen would still be an issue – INST*<br>• Payors noted an institutional sized pen would reduce waste, which was expressed as a major concern for payors<br>• *If there was an institutional pen size that would be positive. We could incorporate that into our formulary. The 30 day pen is very prohibitive considering [illegible] aver[illegible]length of stay is 4 [illegible] INST* | • Long term care payors welcomed the idea of a pen only basal insulin product<br>• *Pen only is a positive for a more concentrated insulin. Based on my past experiences with U500, my biggest concern is how it is dosed. The pen increases safety and eliminates dosage concerns – LTC PD*<br>• *It will go over great as a pen. I think vials will be out of date in a few years – LTC PD*<br>• Respondents noted that they are promoting the use of pens wherever applicable<br>• *We are a company looking to promote pens based on the success we have using them in diabetes and other [illegible]ories – LTC PD*<br>• *We would encourag[illegible]e of a pen over a [illegible] PD* |



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Source: Toujeo Market Access Landscape and Pricing Strategy Long Term Care and Institutional Payor Report July 21, 2014 Compass Strategic Consulting

# Hospital Guidelines – Recommendation (Lantus)

## Channel Strategy Objective: To maintain Lantus Base Business in top tier accounts; Toujeo strategy is focused on discharge and transitions of care

| | | Lantus Current Guidelines | | | REVISED LANTUS | | |
|---|---|---|---|---|---|---|---|
| | | Max Discount / Fixed Price | | Price Protection | Max Discount / Fixed Price | | Price Protection |
| Channel | Date | Vial | SS | | Vial | SS | |
| Hospital | 06/01/14 | 40% | 40% | NA | 40% | 40% | 5% |

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## Speaker Notes for Slide 58

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Hospital Guidelines – Recommendation (Toujeo)

## Channel Strategy Objective: To focus on discharge and transitions of care

[redacted]

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## Speaker Notes for Slide 59

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Other Channels Contracting Guidelines
# Lantus & Toujeo

## Shawn Jacot

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## Speaker Notes for Slide 60

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Other Channels Review – Lantus…LTC channel = $573M in projected 15B Net Sales…rebate double counts erode sales

| DEMAND UNITS | 2013 | 2014 | 2015 | 15B Net Sales (MUSD) |
|---|---|---|---|---|
| DOD | 12,938,256 | 14,973,559 | 16,548,291 | $ 55 |
| YTD Growth | 11.5% | 15.7% | 10.5% | |
| YTD % of Business | 2.8% | 3.2% | 3.4% | |
| YTD Discount % | -75.5% | -81.7% | -86.1% | |
| VA | 39,784,159 | 37,263,217 | 39,890,117 | $ 107 |
| YTD Growth | -0.7% | -6.3% | 7.0% | |
| YTD % of Business | 8.6% | 7.9% | 8.3% | |
| YTD Discount % | -82.0% | -89.7% | -89.5% | |
| Tricare | 3,056,189 | 2,950,141 | 2,881,071 | $ 52 |
| YTD Growth | -13.2% | -3.5% | -2.3% | |
| YTD % of Business | 0.7% | 0.6% | 0.6% | |
| YTD Discount % | -41.8% | -37.0% | -27.8% | |
| Long Term Care | 22,365,589 | 23,710,319 | 26,596,963 | $ 573 |
| YTD Growth | -0.5% | 6.0% | 12.2% | |
| YTD % of Business | 4.8% | 5.0% | 5.5% | |
| YTD Discount % | -5.5% | -9.4% | -13.3% | |
| PHS Statutory | 18,348,091 | 18,866,366 | 18,720,073 | $ 3 |
| YTD Growth | 29.0% | 2.8% | -0.8% | |
| YTD % of Business | 3.9% | 4.0% | 3.9% | |
| YTD Discount % | -86.3% | -92.9% | -99.3% | |
| Staff Model | 5,552,119 | 5,506,113 | 5,108,249 | $ 90 |
| YTD Growth | 3.4% | -0.8% | -7.2% | |
| YTD % of Business | 1.2% | 1.2% | 1.1% | |
| YTD Discount % | -9.8% | -27.7% | -28.9% | |

**Other Channels Net Sales = $881M**

**LTC demand exposed to rebates across other channels – Medicare & Medicaid**

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## Speaker Notes for Slide 61

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# LTC Market Access Landscape

- LTC facilities align patients' insulin to a product covered by their Part D plan
- Most LTC respondents do not make a preference for basal insulins, but do restrict products in the other diabetes classes
- Most LTC respondents were equally satisfied with Lantus and Levemir, and did not highlight any major differentiating factors
- Estimated the overall diabetes drug spend among LTC institutions is nearly 20% of the total drug spend —basal insulin is about 7% of total drug spend

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# Long Term Care Strategy…Toujeo focus following Medicare access…discounts recommended at Lantus levels

- **Strategic Imperative**
  - **Maintain Lantus Market Share and Access as Sanofi secures Part D access for Toujeo; New Patient Starts on Toujeo**
- **Seek Approval for**
  - **Toujeo – Discounts at same level of Lantus**
  - **Market share based on (Toujeo + Lantus / Select Insulin Basket)**
  - **Provide price predictability for LTC channel at 7% with annual reset on January 1**
- **Risks**
  - **Toujeo Part D access is critical to success in channel**
  - **Conversion may require incremental discounts on Toujeo to offset (additional units of Toujeo required to get to goal)**

# Pressure for Price Predictability…recent price increases have triggered requests…

- **Provide price predictability for LTC channel at 7% with annual reset on January 1**

- **Many LTC providers have complained that the contract revision implemented in October has lost value with the recent 11.9% price increase – Offering price predictability enables customers to regain some value, and efficiently manage their budgets**

# Current Lantus LTC Pricing Structure…max rebate = 15%...no price predictability…GPO's max = 12%

- **Pharmerica / Omnicare:**
  - Upfront discount of 1%
  - Rebated based upon market share achieved

| | Long Term Care Pharmacy Providers | | |
|---|---|---|---|
| | Market Share | | Discount |
| | Mkt Share LL | Mkt Share UL | Lantus % |
| Tier 1 | 53.00% | 59.99% | 9% |
| Tier 2 | 60.00% | 64.99% | 10% |
| Tier 3 | 65.00% | 69.99% | 11% |
| Tier 4 | 70.00% | 74.99% | 12% |
| Tier 5 | 75.00% | 99.99% | 14% |

| LANTUS THERAPEUTIC CATEGORY | |
|---|---|
| SA Product | Competitor Products |
| Lantus | **Insulin** |
| | Humalog Mix 50/50 |
| | Humalog Mix 75/25 |
| | Humulin 50/50 |
| | Humulin 70/30 |
| | Humulin N |
| | Levemir |
| | Novolin 70/30 |
| | Novolin N |
| | Novolog Mix 70/30 |

- **All GPO's:**
  - Upfront discount of 10%
  - Administrative Fee of up to 2%

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# Financial Model Results for LTC…6% conversion of Lantus to Toujeo needed to hit Toujeo 15B

| ($M) | 2015 Budget Lantus | 2015 Budget Toujeo | 2015 Budget Glargine | 2015 LTC Model Toujeo | 2016 LTC Model Toujeo |
|---|---|---|---|---|---|
| Total Gross Sales | $ 11,945 | $ 555 | $ 12,501 | $ 555 | |
| LTC Gross Sales | $ 661 | $ 15 | $ 676 | $ 15 | $ 83 |
| LTC % of Total Gross | 6% | 3% | 5.4% | 3% | |
| Rebate % | 13.3% | 13.8% | 13.3% | 13.2% | 13.4% |
| Rebate | $ 88 | $ 2 | $ 90 | $ 2 | $ 11 |
| Net Sales | $ 573 | $ 13 | $ 585 | $ 13 | $ 72 |
| Budget Exit Share | | | | 6% | |

**In order to achieve 2015 Budget, Sanofi will need to convert 6% of Lantus utilization (both SoloStar & Vial) to Toujeo in Q4 2015**

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# Other Channel Guidelines – Recommendation (Lantus)

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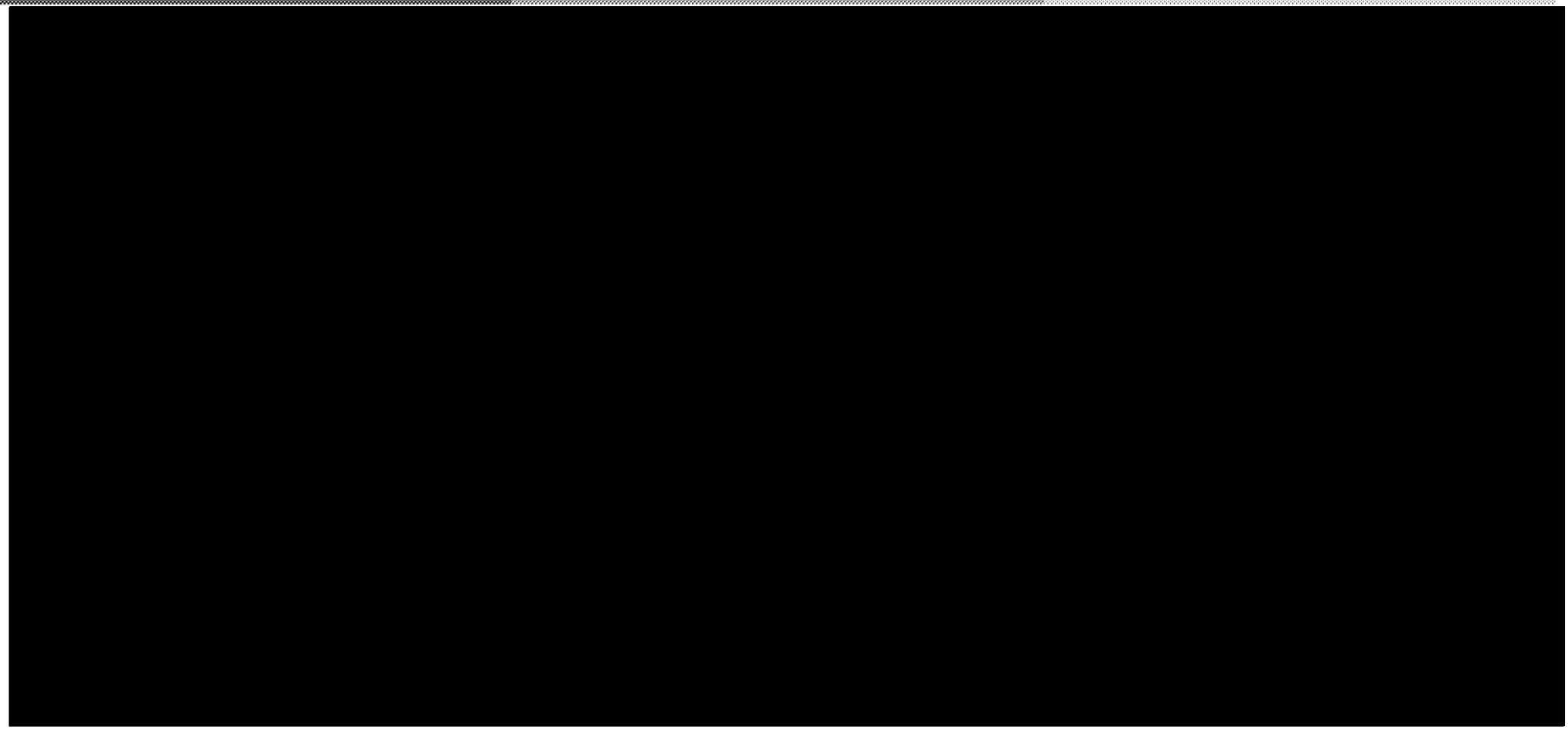
## Speaker Notes for Slide 67

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Other Channel Guidelines – Recommendation (Toujeo)



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## Speaker Notes for Slide 68

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Afrezza WAC and Contracting Guideline Recommendations

## Chris Christensen

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## Speaker Notes for Slide 69

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

# Pricing Recommendation Overview

## WAC Price Recommendation

| Units/SKU Pack<br>Units/Day | 360<br>12 | 480<br>16 | 600<br>20 | 840<br>28 | 960<br>32 |
|---|---|---|---|---|---|
| **WAC** | **$226.06** | **$252.33** | **$278.59** | **$316.76** | **$328.65** |
| WAC/ Insulin Unit | $0.63 | $0.52 | $0.43 | $0.38 | $0.34 |
| WAC/Day | $7.54 | $8.41 | $9.29 | $10.56 | $10.96 |

**Note: Forecasted average daily dose >32 units/day**

## Contracting Guidelines

| Channel | Discount ranges | Rationale |
|---|---|---|
| **Commercial** | **Up to 23%** | **Strategic/Selective contracting to achieve broad T3 unrestricted access.** |
| **Medicare** | **Up to 23%** | **Targeted contracting to high LIS plans only** |

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# Bottom-up Account View

| National Account | Formulary Status at Launch | | RAI Market Volume | RAI Gross Sales | OAD2+ and Basal+ Market Volume | OAD2+ and Basal+ Gross Sales |
|---|---|---|---|---|---|---|
| [redacted] | | | | | | |
| CVS Caremark Rx | 50% T3 | 50% NC | 12,720 | $4.8 | 6,553 | $2.5 |
| Express Scripts PBM | 70% T3 | 30% NC | 19,999 | $7.5 | 10,303 | $3.9 |
| [redacted] | | | | | | |
| Optum Rx | 10% T3 | 90% NC | 4,123 | $1.6 | 2,124 | $0.8 |
| [redacted] | | | | | | |
| Total | - | | 70,525 | $26.5 | 36,331 | $13.7 |

**Total Demand Sales: $40.3**

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# Bottom-Up Summary

| Afrezza Bottom-Up Sales Forecast | Align to forecast |
|---|---|
| Top Account RAI Gross Sales | $22.8 |
| Additional RAI Gross Sales | $3.7 |
| OAD 2+ and Basal+ Gross Sales | $13.7 |
| Total Demand Gross Sales | $40.2 |
| Total Inventory Sales | $13.1 |
| Total Ex-Factory Gross Sales | $53.3 |
| Gross to Net | 90.0% |
| Total Ex-Factory Net Sales | $48.0 |

**Potential upside depending on changes to price and tier status**

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*Price/day: $12*

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# Payer Research on Diabetes Category and Price/Access Management

| Payer Topic | Findings |
|---|---|
| Current diabetes management | • Top 3 disease categories<br>• High priority due to prevalence, costs, and healthcare utilization |
| Management of the rapid-acting class | • **Tier 2 status is driven by heavy contracting (1/1 and 1/2 contracts with deep discounting)**<br>• Some contracts may leave room for Afrezza® on tier 3 without impacting current contracts (competitors would be likely to react)<br>• Use of Exclusion lists, PAs and SEs is growing |
| Review of new inhaled insulin | • A unique mechanism of action is the criteria for creating a new class<br>  ○ Afrezza will not likely be placed in its own class<br>• **A majority of plans will place the new product on tier 3 initially (at launch)**<br>• PA is possible for more restrictive plans (failure of injectable insulin) |
| Unmet need | • Get more patients to goal<br>• Better safety and efficacy<br>• Improved compliance |

**Total lives managed by payer sample: 197 MM**

30 Pharmacy/Medical Directors from National/Regional/Medicare payers were targeted to gain insight on category management and reaction to the clinical profile and pricing considerations. An additional 15 pharmacy and medical directors were included from IDNs, PBMs, and Medicaid/Managed Medicaid payers to gain channel insights.

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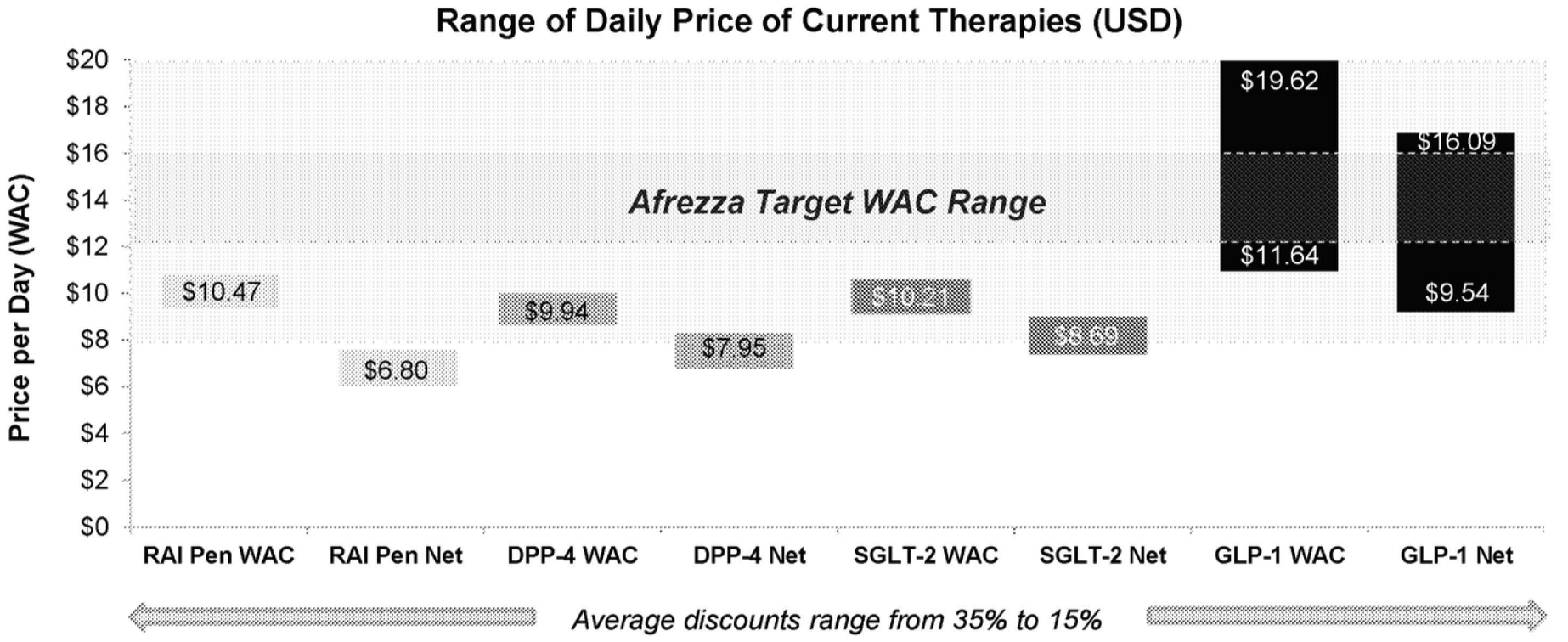
# The team assessed a broad range of target WAC price points from $8-$20 per day




| RAI Pen | DPP-4 | SGLT-2 | GLP-1 |
|---|---|---|---|
| Humalog KwikPen<br>Novolog FlexPen<br>Apidra SoloStar | Januvia<br>Onglyza<br>Tradjenta | Farxiga<br>Invokana<br>Jardiance | Byetta<br>Bydureon<br>Victoza<br>Tanzeum |

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*Analysource, Accessed 11/19/2014, insulin assumes 40 units/day*

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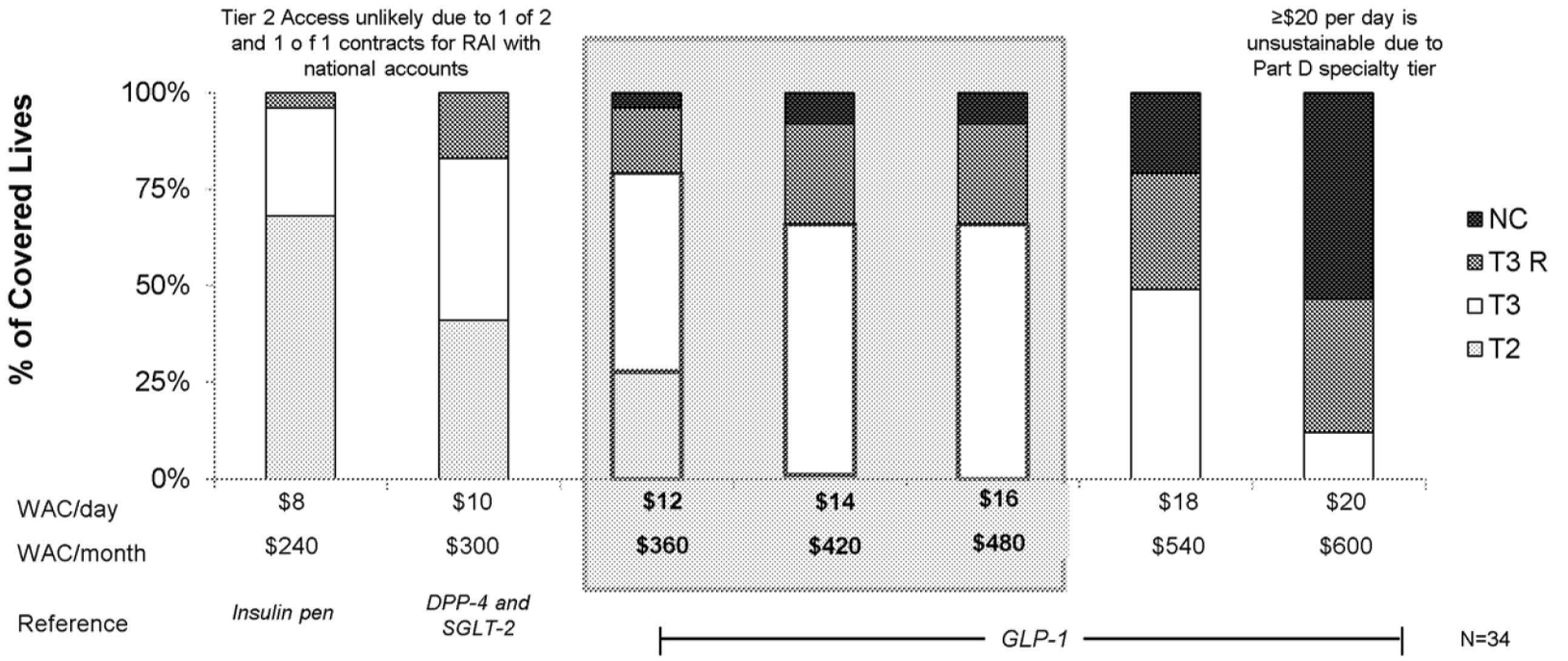
# The optimal WAC pricing corridor is $12-$16 per day to get broad unrestricted Tier 3 strategy

## Afrezza Commercial Access by Price Point




- **Some discounts will be required for tier 3 access**
- **Additional discounts will be required to remove restrictions**
- **Broad tier 2 access unlikely due to 1/2 and 1/1 contracts in RAI class for large accounts**

***Due to concerns of releasing proprietary discount information, payers respond to prices considering a range of net to WAC cost. Most payers did not have an accurate understanding of what diabetes patients/therapies cost***

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# Optimal SKU Pricing Considered All Findings To Date

- **Price Target**
  - **The primary and secondary research support an average target WAC price of $16 per day cost for Afrezza**
  - **Little difference in T3 access between $12/day and $16/day**
    - **Not Covered (NC) increases significantly at $18/day**
    - **Most recent GLP-1 entry (Trulicity) has a WAC of $16.27/Day**
    - **It will be difficult to compete in the T2 space even if rebated net prices were only a few dollars/day**
- **Price structures => Flat, Linear and Hybrid**
- **Price challenges**
  - **Fixed SKUs vs. per unit/dial-up dosing & titration to multiple packs fulfillment**
  - **High COGS**
  - **Actual uptake/utilization vs. est. dosing distribution data (especially in year 1)**
  - **Price actions could hit specialty threshold in Medicare**

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# Several pricing structures were considered, but the hybrid pricing model is the most flexible

- **Mitigates the risk of each methodology by allowing for higher prices at lower SKU packs while safeguarding the margin at higher SKU packs**
  - **Ensures appropriate WAC/COGS ratio**
  - **De-risks pack utilization uncertainty**

| | Flat Pricing | Linear Pricing | Hybrid Pricing |
|---|---|---|---|
| | Variable price per unit cost<br>Fixed price per SKU cost<br>(e.g., all packages have the same WAC) | Fixed price per unit cost<br>Variable price per SKU cost<br>(e.g., package WAC reflects a standard cost per unit) | Variable pricing across SKUs with less differential than linear<br>(e.g., packages with 4s and 8s fixed pricing, regardless of mix) |
| Risks | • High insulin unit price<br>• Higher doses require 2 packs/double price<br>• Stakeholder response | • Lower margins at lower doses<br>• Higher doses could reach specialty price threshold | • Lower margins at high dose vs. linear<br>• Higher insulin unit price at lower doses |
| Opportunities | • Revenue maximizing price at the lower doses<br>• Reduced risk at lower doses<br>• Predictable pricing across SKUs | • Easy to understand<br>• Higher margins at higher doses | • Secures margin across dose range (low and high)<br>• Reduces risk related to unknown actual utilization (low/high doses)<br>• More palatable than flat pricing, as payer cost at higher doses is tempered |

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# Process to establish SKU pricing based on average daily target price of $16

**Dosing** — Daily dosing data

**SKU Optimization** — Dose ranges 12 to 64 units/ day

**Utilization** — Annualized utilization (230 DOT)

| SKU Packages Configuration | | | | | |
|---|---|---|---|---|---|
| Units perDay | 12 | 16 | 20 | 28 | 32 |
| ***SKU Configuration*** | ***4Ux90*** | ***4Ux60 8Ux30*** | ***4Ux30 8Ux60*** | ***8Ux60 12Ux30*** | ***8Ux30 12Ux60*** |
| Units per SKU pack | 360 | 480 | 600 | 840 | 960 |
| **Estimated utilization by SKU** | | | | | |
| **Pack Utilization** | **10%** | **12%** | **29%** | **34%** | **15%** |
| 1/Month Utilization | 67% | 67% | 33% | 20% | 33% |
| 2/Month Utilization | 33% | 33% | 67% | 80% | 67% |

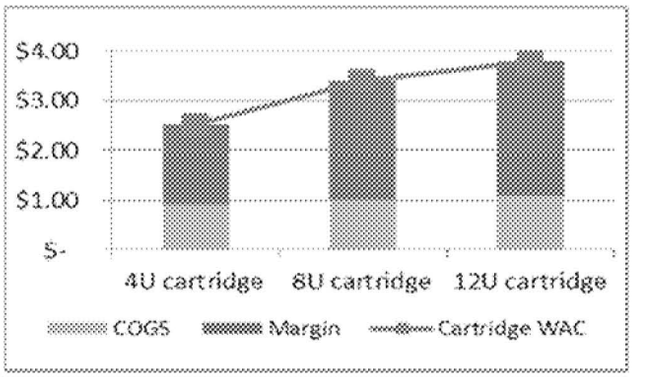
**Cartridge Price**

4U Cartridge COGS is baseline. High, relatively flat COGS allow larger multiplier and a 'flatter' curve.

| COGS (per cartridge) | | |
|---|---|---|
| 4U | 8U | 12U |
| **$0.92** | **$1.02** | **$1.10** |
| *Increase %* | *11%* | *7%* |
| *Increase from 4 units* | | *20%* |

| WAC (per cartridge) | | |
|---|---|---|
| 4U | 8U | 12U |
| **$2.51** | **$3.39** | **$3.78** |
| *Increase %* | *35%* | *12%* |
| *Increase from 4 units* | | *51%* |

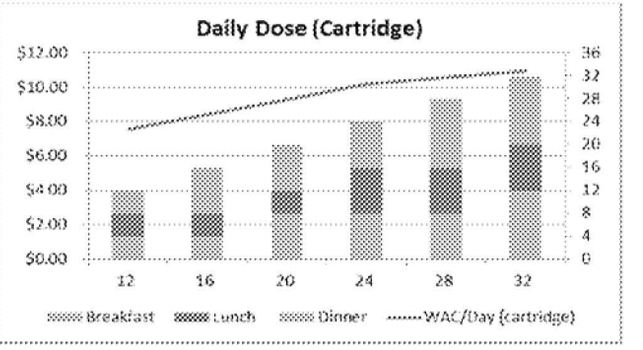
**Cartridge titration inform SKU configuration.**




**SKU Price**

| SKU Pack | 360 units | 480 units | 600 units | 840 units | 960 units |
|---|---|---|---|---|---|
| Daily | 12 | 16 | 20 | 28 | 32 |
| **WAC** | **$226** | **$252** | **$279** | **$317** | **$329** |

**Unit cartridge prices fixed in each SKU**

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# The price per day is based off of the utilization forecast and results in a WAC comparable to RAI pens

- **WAC SKU pack pricing ranges from $226 for the 360 unit pack to $329 for the 960 unit pack, representing an increase of 45% from the lowest to the highest pack.**

| COGS per SKU | | | | | |
|---|---|---|---|---|---|
| **Units/SKU pack** | **360** | **480** | **600** | **840** | **960** |
| *SKU Configuration* | *4Ux90* | *4Ux60 8Ux30* | *4Ux30 8Ux60* | *8Ux60 12Ux30* | *8Ux30 12Ux60* |
| Units/Day | 12 | 16 | 20 | 28 | 32 |
| COGS | $83 | $86 | $89 | $94 | $96 |
| COGS x2 | $165 | $171 | $178 | $188 | $193 |
| **Utilization by SKU** | | | | | |
| **Pack Utilization** | **10%** | **12%** | **29%** | **34%** | **15%** |
| 1/Month Utilization | 67% | 67% | 33% | 20% | 33% |
| 2/Month Utilization | 33% | 33% | 67% | 80% | 67% |

| Hybrid Pricing per SKU | | | | | |
|---|---|---|---|---|---|
| *WAC/Day* | *$7.54* | *$8.41* | *$9.29* | *$10.56* | *$10.96* |
| Hybrid WAC | $226 | $252 | $279 | $317 | $329 |
| Hybrid WAC x2 | $452 | $505 | $557 | $634 | $657 |
| Avg. Daily WAC (Util.) | $10.05 | $11.21 | $15.48 | $19.01 | $18.26 |
| Hybrid WAC/COGS | 174% | 195% | 214% | 236% | 241% |
| Weighted Avg. WAC | $1.02 | $1.30 | $4.53 | $6.42 | $2.76 |
| | **$16** | | | | |
| **WAC per Unit** | **$0.63** | **$0.53** | **$0.46** | **$0.38** | **$0.34** |
| Premium vs. Novolog | 140% | 101% | 77% | 44% | 31% |

Premium to Novolog FlexPen: Based on $0.26/insulin unit

**COGS ranges from $83/360pk to $96/960pk, an increase of only 17% from lowest to highest pack**

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*Source: Dosing utilization from IMS claims data; assumes all SKUs available over a 230 day Rx*

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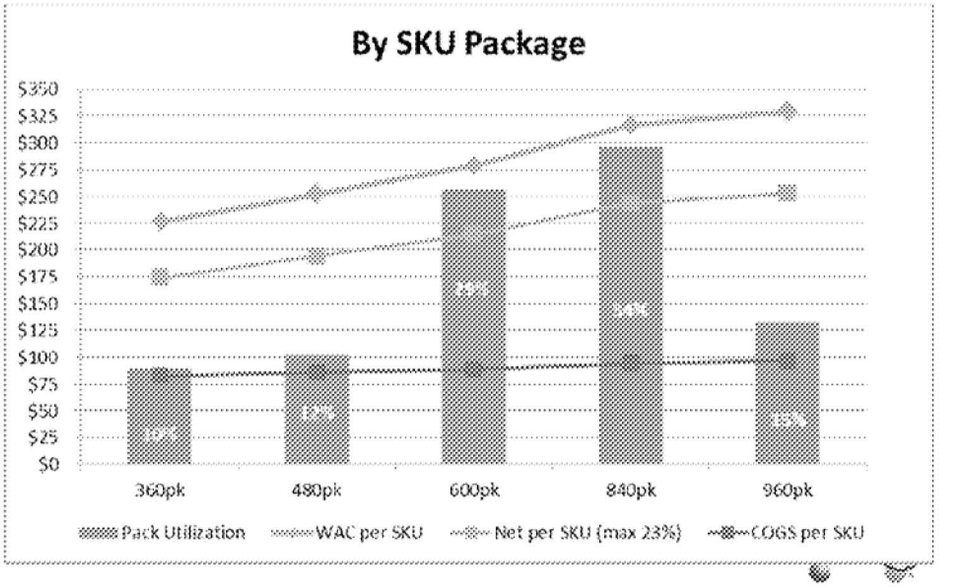
# Sensitivity corridors for WAC and net price targets

- **Developed three scenarios to evaluate price sensitivity impact of the dosing distribution claims data for the patient segments**
  - **Narrow price sensitivity corridor when using 40 units/day as the threshold separating OAD 2+ and Basal+ patients from RAI maintenance**

| Low Case | Base Case | High Case | |
|---|---|---|---|
| 100% | 61% | 32% | % of dosing ≤ 40 units/day |
| $13 | $16 | $17 | Avg. daily price |

- **The max commercial rebate of 23% yields an avg. net price of $12.3/day or $174/360pk to $253/960pk.**
  - **When the full GTN impact is applied, the avg. net price goes to $11/day**

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# WAC by SKU Pack

## WAC Price Recommendation

| Units/SKU Pack<br>Units/Day | 360<br>12 | 480<br>16 | 600<br>20 | 840<br>28 | 960<br>32 |
|---|---|---|---|---|---|
| WAC | $226.06 | $252.33 | $278.59 | $316.76 | $328.65 |
| WAC/ Insulin Unit | $0.63 | $0.52 | $0.43 | $0.38 | $0.34 |
| WAC/Day | $7.54 | $8.41 | $9.29 | $10.56 | $10.96 |

Three SKU at launch (360pk, 480pk and 600pk), two SKU by July 2015 (840pk and 960pk)

- Rationale:
  - Payer research support higher price point (avg. WAC $16/day)
    - no significant access difference between $12-$16/day
  - Hybrid pricing structure de-risks dosing uncertainty and ensures acceptable Price/COGS ratio
    - The value proposition around unmet need focuses on OAD2+ and Basal+ patient population which will titrate to goal
    - High but relatively flat COGS

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# Suggested Contract Guidelines and estimated GTN impact

| Payer Segment* | Discount Ranges** | Examples | |
|---|---|---|---|
| **High** | Up to 23% | NC to T3 | 23% |
| | | PA to T3 | 20% |
| | | PA to T3SE | 15% |
| **Medium** | Up to 9% | NC to T3 | 9% |
| | | PA to T3 | 7% |
| | | PA to T3SE | 5% |
| **Low** | Up to 7% | NC to T3 | 7% |
| | | PA to T3 | 5% |
| | | PA to T3SE | 2-3% |

* Size of payer and degree of control / ** Severity of restriction(s)

| GTN with commercial contracting | |
|---|---|
| **2015** | ~87% |
| ***2016 Est.*** | *~82-83%* |

## Speaker Notes for Slide 82

Most plans will place Afrezza within T3 at launch
Upon review, the tier placement may worsen and / or restrictions may be added. In these cases, the resources to remove barriers may be applied.
We don't anticipate high levels of discounts will be required to achieve the desired coverage. The discounts shown here reflect what was shown in the contracting model as breakeven.

# Contract Guidelines

## Commercial contract guideline recommendation

| Payer segment | Discount ranges | Rationale |
|---|---|---|
| **High** | Up to 23% | Remove restrictions to T3U (restrictive steps / PA) |
| **Medium** | Up to 9% | Remove restrictions to T3U (restrictive steps / PA) |
| **Low** | Up to 7% | Likely T3U |

- **Medicare: Up to 23% for high LIS plans (ex: Silverscript)**
  - Targeted approach; only pro-actively contract with high LIS plans
- **Medicaid: Only mandated discounts**
- **Other Government Channels: Only mandated discounts**
- **Institutional: GPO admin fee up to 3%**

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**USPC Approved** afrezza

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## Speaker Notes for Slide 84

The US pharmaceutical market is forecast to grow at a CAGR of 6.4% (±1.5%) during the period 2013-2018, reaching $464.0 billion by 2018.

**From:** Paternoster, Dominick /US
**Sent:** Thursday, December 14, 2017 4:02 PM
**To:** Halenar, Lori /US
**Cc:** Jacot-Guillarmod, Shawn /US
**Subject:** FW: URGENT FOR APPROVAL - 2018 CVS Med D Tier 3 offer - (Part 3) Revised Financials

Documentation for CVS Med D T3 2018-2019 offer…part 2

---

**From:** Paternoster, Dominick /US
**Sent:** Wednesday, December 13, 2017 8:52 PM
**To:** Steelman, Mike /US; Borys, Margaret /US; Jacot-Guillarmod, Shawn /US; Oelrich, Stefan /DE; Gleeson, Gerald /US; Zhang, Quan /US; Gilhodes, Laurent /FR; Geremia, Joseph /US; Perkins, Andrew /US
**Cc:** Albano, James /US; Forman, Brian /US
**Subject:** RE: URGENT FOR APPROVAL - 2018 CVS Med D Tier 3 offer - (Part 3) Revised Financials

Please disregard footnote ***Financials above do not include net of all costs in the summary below. Financials incorporate net sales after other costs.

---

**From:** Paternoster, Dominick /US
**Sent:** Wednesday, December 13, 2017 8:44 PM
**To:** Steelman, Mike /US; Borys, Margaret /US; Jacot-Guillarmod, Shawn /US; Oelrich, Stefan /DE; Gleeson, Gerald /US; Zhang, Quan /US; Gilhodes, Laurent /FR; Geremia, Joseph /US; Perkins, Andrew /US
**Cc:** Albano, James /US; Forman, Brian /US
**Subject:** URGENT FOR APPROVAL - 2018 CVS Med D Tier 3 offer - (Part 3) Revised Financials

<< File: CVS Caremark Tier 3 Assessment High Level Summary 12.13.17.xlsx >>
US BUPC and GPC Members:

Contracting and Finance have reconciled the variances vs 3YFF for 2018-2019 for the Caremark Part D recommendation. Financials have been revised to incorporate [redacted] and are restated in the recommendation below. A detailed summary is provided for all years in the attached.

Note: all scenarios are positive vs 3YFF with the exception of Scenario 1 (-7M). Alll scenarios are positive over the 2 year period. The team is aligned to Scenario 3 as the recommendation (eff 2/1/18 T3 67% Choice/Template, enhanced Plus/Custom as noted below). Thank you for your time and attention to this matter. Any questions please do not hesitate to contact me.

Upon full BUPC/GPC approval the team will immediately proceed with offer development for customer presentation and discussions.

Thank you,
Dominick

***

**CVS Caremark Medicare 2018 – Lantus/Toujeo**

**Background:**

- CVS/Caremark total 13M Lives... Affiliated SilverScript PDP ~5.5M Total Lives (of which ~78% LIS)... non-Affiliated 7.3M Lives where Caremark is the PBM... inclusive of [redacted] (3.1M lives)
- 2018 Coverage: CVS/Caremark Plus Formulary LAN/TOU (1-2).... Choice Formulary LAN/TOU - Not Covered... [redacted] LAN/TOU (1-2)
- Plus Formulary (~1-2M lives) will have Lantus/Toujeo in a preferred position with Novo

**2018 and 2019 Recommendation:**

- Choice/Template Formularies → (Non-Preferred Tier) Walk In = 67% LAN/TOU... PP 0% (Lantus), 3% (Toujeo) → 67% Blend Rate
- Plus/Custom Formularies → Provide an enhanced 2018 offer → 74% Blend Rate (Lantus Standard eligible 74%/ LIS 80%, Toujeo Standard 69% / LIS 75%)... PP 0% (Lantus), 3% (Toujeo)

**Rationale:**

- Provides alternative formulary option vs NC for Choice/Template formularies

**Additional Considerations:**

- Government Pricing: Financial impact to Sanofi: N – Part D excluded from gov't pricing Best Price calculations; Operational/system impact: N

**Financials F2 2017 3YFF (Net Sales after other costs):**

- Baseline F2 17 3Y FF 2018 Caremark [redacted] $201 (contracted + non-contracted sales less other costs)... overall blended rebate 45.9%
- Variance vs. 3Y FF
  - Sc 1: Effective 1/1/18 T3 67%, blended rate 69.5%... -$7M
  - Sc 2: Effective 2/1/18 T3 67%, blended rate 65.9%... +$18M
  - Sc 3: Effective 2/1/18 T3 67%, blended rate 65.7%... +$33M - RECOMMENDATION
  - Sc 4: Effective 4/1/18 T3 67%, blended rate 58.7%... +$81M

Note: Sc 2-4 appear more financially feasible for Sanofi however note that delay in access makes deal less attractive for Customer (See Caremark perspective in table below)

2018 Detail Financial Analysis Below...2019 and 2 year cumulative provided in the attached:

---

**From:** Steelman, Mike /US
**Sent:** Wednesday, December 13, 2017 4:27 PM
**To:** Borys, Margaret /US; Jacot-Guillarmod, Shawn /US; Oelrich, Stefan /DE; Gleeson, Gerald /US; Zhang, Quan /US; Gilhodes, Laurent /FR; Geremia, Joseph /US; Paternoster, Dominick /US; Perkins, Andrew /US
**Cc:** Albano, James /US; Forman, Brian /US
**Subject:** RE: URGENT FOR APPROVAL - 2018 CVS Med D Tier 3 offer - (Part 2)

Hi Shawn,

I concur with Margaret and from the GPC side (on behalf of Dominika/Kathleen), if the financials bear out in comparison to 3YFF once verified by Finance/Laurent, then ok to move ahead.

**Mike Steelman**
Head of Global Pricing
[redacted]

[redacted]

**From:** Borys, Margaret /US
**Sent:** Wednesday, December 13, 2017 9:02 AM
**To:** Jacot-Guillarmod, Shawn /US; Oelrich, Stefan /DE; Gleeson, Gerald /US; Zhang, Quan /US; Gilhodes, Laurent /FR; Steelman, Mike /US; Geremia, Joseph /US; Paternoster, Dominick /US; Perkins, Andrew /US
**Cc:** Albano, James /US; Forman, Brian /US
**Subject:** RE: URGENT FOR APPROVAL - 2018 CVS Med D Tier 3 offer - (Part 2)

All,

I approve Scenario 3 bid, pending confirmation of comparison to 3YFF as discussed.

Margaret

**Margaret Borys**
Head of US Diabetes Insulins
Sanofi NA
55 Corporate Drive
Bridgewater, NJ
[redacted]

-----Original Appointment-----
**From:** Jacot-Guillarmod, Shawn /US
**Sent:** Tuesday, December 12, 2017 6:18 AM
**To:** Jacot-Guillarmod, Shawn /US; Oelrich, Stefan /DE; Gleeson, Gerald /US; Zhang, Quan /US; Borys, Margaret /US; Gilhodes, Laurent /FR; Steelman, Mike /US; Geremia, Joseph /US; Paternoster, Dominick /US; Perkins, Andrew /US
**Cc:** Albano, James /US; Forman, Brian /US
**Subject:** URGENT FOR APPROVAL - 2018 CVS Med D Tier 3 offer - (Part 2)
**When:** Wednesday, December 13, 2017 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).

[redacted]

<< OLE Object: Picture (Device Independent Bitmap) >>

Laurent and Margaret,

Thank you for your time this morning to review our Lantus and Toujeo T3 proposal for CVS Caremark Part D for 2018. The team has reviewed your requests below and addressed the issues discussed during the call in the narrative provided below. We discussed with Quan Zhang and Jim Albano this afternoon and overall the team believes that the most likely scenario to be considered by the customer is scenario 3.

We will set up an ad hoc meeting tomorrow morning to discuss in greater detail.

**Summary:**

**Q. The variance in the financials vs. 3YFF must be presented on the net sales after Coverage gap, DPA fee and cash discounts: on that basis, Sc.1 is negative -12M$ vs. budget 2018.**

2018 Net Sales after all other costs (CG, DPA, Cash) for SC1 still represent a negative variance vs Not Covered (3YFF Contracted and Non Contracted sales). Assessment also displayed Sc1 Gross Sales $ < Sc2 and Sc3. Team identified incorrect erosion rate for a Standard Eligible in a Choice/Template formulary covered in a T3 position which were not aligned. By correcting link → Sc1 Gross Sales $ > Sc2 and remain lower vs Sc3 (which is expected). Please note: difference between Sc2 and Sc3 is the transition rx fill accounted for in Sc3, which provides 1 month of rx coverage for a brand moving from covered to not covered. CMS regulations require 1 month coverage for a brand moving from a covered to not covered position. Sc2 was not modeled with this transition and is likely not a viable option for comparison.

Reviewing net sales after other costs, we identified a improper link for the Not Covered Gross sales which deflated gross sales . We have since corrected, unfortunately the increase in Not Covered gross sales created a larger variance to -$29M (2018). Revised variances → Sc1 -$29M, Sc2 -$4 for 2018 but turn positive in 2019 assuming the scenario maintains over 2 years. Sc3 and Sc4 remain positive +$11m and +$58M in 2018 and continue to remain positive in 2019. Revised 2018, 2019 and 2 year cumulative is attached.

**Q. Do the scenarios include the enhanced rebates on the Plus/Custom formularies? Up to what level of enhanced rebate in Plus/Custom could you go in order to keep scenario 1 neutral vs. budget 18 (net net, 0 instead of -12M$)?**

Yes, rebates are enhanced for both Choice/Template and Plus/Custom formularies. The current 2018 (1-2) total payment → Lantus 70% Toujeo 65%, blend 69%. The revised proposal increases the Plus/Custom blended to 74% (+5%). The Choice/Template T3 offer Lantus and Toujeo at 67%.

In order to make Sc 1 net neutral (-$29M) to budget 18 (3YFF contracted and non contracted sales) the offer for Choice/Template T3 would need to be 61% (L/T), this assumes the enhancement to Plus remains as noted above. ***This is not likely a viable solution since financials will not be favorably reviewed by customer.***

**Q. Can you provide in the each scenario the breakdown between Plus/Custom, Choice, [redacted], Non-contracted?**

Historical gross sales distribution by formulary (2017) is as followed:

- SilverScript Choice Formulary 47% of sales
- SilverScript Plus Formulary 12% of sales
- CVS Caremark PBM Template Formulary (follows Choice) 26% of sales
- CVS Caremark PBM Custom Formularies [redacted] 13%
- [redacted]

Assessment was performed utilizing actual CVS customer data for a running 12 months. The team supplemented the data for [redacted] using existing contracted sales. Erosion analogs were applied to the Standard and LIS eligible by formulary (Choice/Template, Plus/Custom and [redacted] based on coverage and patient OOP exposure to result in adjusted Gross Sales, blended erosion and rebate rates at the enterprise account level, which were then applied to the forecasted gross sales (F1 2017).

**Q. Is Tresiba on formulary?**

For 2018, Levemir, Tresiba and Basaglar are preferred in the Choice/Template formularies and Lantus and Toujeo are Not Covered. For Plus Formularies and [redacted] Lantus and Toujeo are preferred with Levemir and Tresiba with Basaglar as not covered.

**Q. Please confirm the co-pay amount per TRx in a non-preferred position vs. preferred, in the part-D space?**

**LIS eligible copays**: do not vary between preferred and non-preferred is ~$8.25.
**Standard Eligible Copay:** for non-preferred products are co-insurance %s ranging from 40%-50% for Plus and 34%-50%. For example, based on a Lantus SS Rx at $696 (2018) the copay range can be from $236 (34% co-ins) to as high as $348 (50% co-ins).

<< OLE Object: Picture (Device Independent Bitmap) >> << File: CVS Caremark Tier 3 Assessment High Level Summary 12.12.17.xlsx >>

# BU Pricing Review Board

## November 30, 2017

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PENDING SA LEGAL REVIEW

USMarket Access

# Business Unit Pricing Review Board

***DCV BU***

[redacted]

[redacted] **Soliqua 100/33, Apidra, Lantus, Toujeo – Topic: CVS/Caremark Medicare Part D 2019 Bid**

PENDING SA LEGAL REVIEW

**CVS/Caremark Medicare Part D – Apidra, [redacted] Soliqua 100/33**

FOR APPROVAL

**Apidra (1-Many) offer: Max Payment 15%…Base rebate 12%... Admin Fee 3%... PP 5%**

[redacted]

**Soliqua 100/33 (1-1) or (1-2) offer: Max Payment 56%…Base rebate 53%... Admin Fee 3%... PP 6%**

**Term: 1/1/2019 – 12/31/2019**

Background:

- CVS/Caremark total 13M Lives… Affiliated SilverScript PDP ~5.5M total Lives… ~78% LIS… non-Affiliated 7.3M lives where Caremark is the PBM… inclusive of Aetna
- Effective 1/1/2018 Aetna's Part D business is moving under Caremark…. 3.1M Lives
- For 2019, [redacted] Med D may fall under SilverScript and is included in this offer/financials and separately, [redacted] is soliciting a 2019 bid directly from Sanofi
- RFP due 12/8/2017

Current Contract:

- Apidra... Preferred Tier…(1-many) Max Payment 15%... Base Rebate 12%… Admin Fee 3%... Price Protection 5%
- [redacted]
- Soliqua… Preferred or Specialty Tier…(1-1) or (1-2) Max Payment 56%... Base Rebate 53%… Admin Fee 3%... Price Protection 6%
- Term: 1/1/2018 – 12/31/2018

Initial Proposal:

- Maintain same rebates and PP terms
- Term: 1/1/2019– 12/31/2019

Rationale:

- Customer has not provided reason or concern for SA to revise offer
- Maintain current level of access

Additional Considerations:

- Government Pricing: Financial impact to Sanofi: N - Part D excluded from Government Pricing; Operational/system impact: N

Financials:

- Rates within 2019 3YFF

FOR APPROVAL

# CVS/Caremark Medicare Part D – Lantus/Toujeo
# Max Payment 72% Lantus / 67% Toujeo…PP 0% Lantus, 3% Toujeo
# Term: 1/1/2019 – 12/31/2019

**Background:**

- CVS/Caremark total 13M Lives… Affiliated SilverScript PDP ~5.5M total Lives… ~78% LIS… non-Affiliated 7.3M lives where Caremark is the PBM… inclusive of [redacted]
- Effective 1/1/2018 Aetna's Part D business is moving under Caremark…. 3.1M Lives
- For 2019, [redacted] Med D may fall under SilverScript and is included in this offer/financials and [redacted] Med D is soliciting a 2019 bid directly from Sanofi
- 2018 Coverage: Choice Formulary (7.4M) Not Covered… Plus Formulary (5.35M) Covered 1-2
- CVS rejected Sanofi's offer of a blended total payment of 78% for 2018 T2 formulary placement
- RFP Due 12/8/2017

**2019 Current/Initial Offer (maintain same terms as current contract):**

- If CVS maintained L/T on formulary through '20 an incremental deferred payment offer of 2%
- Total Payment = Lantus 67% (base) +3% (admin) +2% (deferred) = 72%…Toujeo 62% (base) +3% (admin) +2% (deferred) = 67%
- Total Blend inclusions of admin fee and deferred payment = 71%
- Lantus PP 0%... Toujeo PP 3%

**Rationale:**

- Responding to CVS's Request to bid for 2019 formulary position with the largest Part D sponsor

**Additional Considerations:**

- Government Pricing: Financial impact to Sanofi: N - Part D excluded from Government Pricing; Operational/system impact: N

**Financials:**

- Next Slide

FOR APPROVAL

## CVS/Caremark Medicare Part D – Lantus/Toujeo
## Max Payment 72% Lantus / 67% Toujeo…PP 0% Lantus, 3% Toujeo
## Term: 1/1/2019 – 12/31/2019

*CVS &[redacted]

| in Millions | 3YFF F2 2017 71% | Rejected - T2 2018 Offer 78% | T2 Max Approved 79% | Non-Preferred Tier Choice, Maintain Plus 69% | Not Covered (81% Erosion) |
|---|---|---|---|---|---|
| Gross Sales | $315 | $606 | $606 | $374 | $138 |
| Rx Erosion | 0% | 221% | 221% | 22% | -81% |
| Rebate % | 71.0% | 77.7% | 79.3% | 69.1% | 0.0% |
| Rebate $ | $155 | $471 | $481 | $258 | $0 |
| **Net Sales** | **$160** | **$135** | **$126** | **$115** | **$138** |
| less | | | | | |
| 2% Prompt Pay | $6 | $12 | $12 | $7 | $3 |
| 1.6% DPA | $5 | $10 | $10 | $6 | $2 |
| Other Cost | $16 | $30 | $30 | $19 | $7 |
| **Net Sales after other costs** | **$133** | **$83** | **$74** | **$83** | **$126** |
| less | | | | | |
| 2% COGS | $6 | $12 | $12 | $7 | $3 |
| **Final Net** | **$127** | **$71** | **$62** | **$76** | **$123** |
| Breakeven Rebate to Baseline | | | 73.61% | 57.20% | |
| Breakeven Rebate to NC | | | 77.24% | 63.09% | |

**CVS/Caremark Medicare Part D – Lantus/Toujeo**
**Max Payment 72% Lantus / 67% Toujeo…PP 0% Lantus, 3% Toujeo**
**Term: 1/1/2019 – 12/31/2019**

# BACK UP

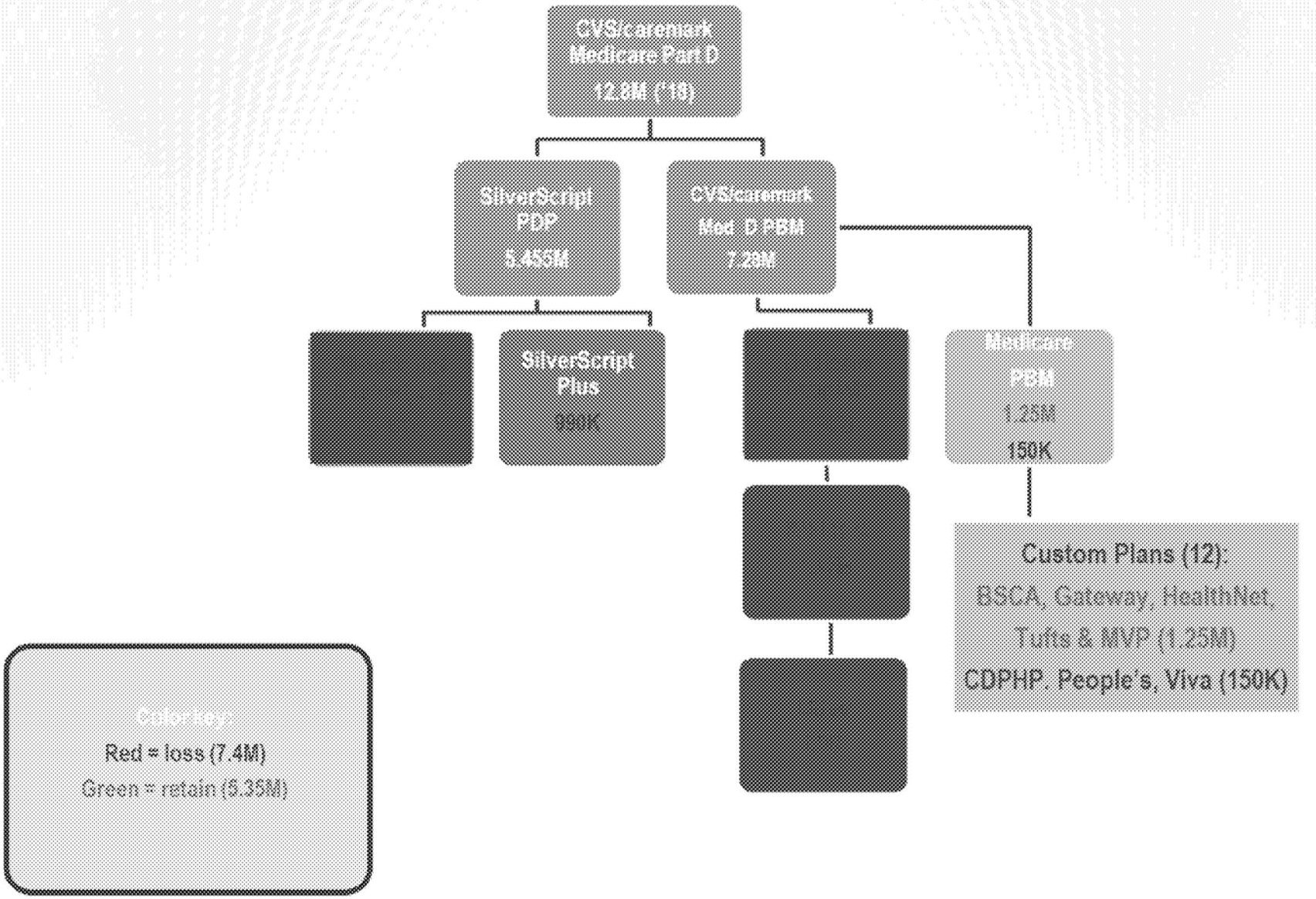
FOR APPROVAL

# CVS/Caremark Medicare Part D – Lantus/Toujeo
## Max Payment 72% Lantus / 67% Toujeo…PP 0% Lantus, 3% Toujeo
## Term: 1/1/2019 – 12/31/2019

| | | 2018 | | | | 2019 | | | | 2020 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1Q | 2Q | 3Q | 4Q | 1Q* | 2Q | 3Q | 4Q | 1Q** | 2Q | 3Q | 4Q*** |
| 2018 Base | Lantus | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% | 68.00% |
| | Toujeo | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% | 63.00% |
| 2018 Revised EY | Lantus | 70.00% | 70.00% | 70.00% | 70.00% | | | | | | | | |
| | Toujeo | 65.00% | 65.00% | 65.00% | 65.00% | | | | | | | | |
| 2019 Base | Lantus | | | | | 70% | 70% | 70% | 70% | | | | |
| | Toujeo | | | | | 65% | 65% | 65% | 65% | | | | |
| 2019 Revised EY | Lantus | | | | | 72.00% | 72.00% | 72.00% | 72.00% | | | | |
| | Toujeo | | | | | 67.00% | 67.00% | 67.00% | 67.00% | | | | |
| 2020 Base | Lantus | | | | | | | | | 72.00% | 72.00% | 72.00% | 72.00% |
| | Toujeo | | | | | | | | | 67.00% | 67.00% | 67.00% | 67.00% |
| 2020 revised EY | Lantus | | | | | | | | | 75.00% | 75.00% | 75.00% | 75.00% |
| | Toujeo | | | | | | | | | 70.00% | 70.00% | 70.00% | 70.00% |

FOR APPROVAL

# CVS/Caremark Medicare Part D – Lantus/Toujeo
## Max Payment 72% Lantus / 67% Toujeo…PP 0% Lantus, 3% Toujeo
## Term: 1/1/2019 – 12/31/2019




SANOFI





USMarket Access

**Sanofi Pricing Committee Recommendation 10/5/2017**

WellDyneRx, LLC.

Prepared By: Gary T White

| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus and Toujeo* | *WellDyneRx, LLC. Commercial* | *New Direct Contract Customer* | *1/1/2018 – 12/31/2019* |

**Recommendation:**

*This Lantus and Toujeo offer will be for a Tier 2 preferred position on WellDyneRx's Clinical Focus formulary (one of two manufacturers) and for a Tier 2 exclusive position on their more closed Clinical Outcomes Formulary) and within their "Closed Diabetes Carve out" which uses the Clinical Outcomes formulary. This carve out which uses the Clinical Outcomes formulary allows clients to move the management of Diabetes from their Clinical Focus Formulary to WellDyneRx's more closed Clinical Outcomes formulary.*

*WellDyneRx has indicated we need to be competitive with Basaglar to retain our current formulary position. Our recommendation is to offer three rebate tiers to match Sanofi contract risk to WellDyneRx's formulary control within their two Commercial formularies.*

| *Formulary / Controls* | *Lantus Rebate Offer* | *Toujeo Rebate Offer* | *Price Protection* |
|---|---|---|---|
| *Clinical Focus (Tier 2 to Tier 3 copay differential)* | *42%* | *40%* | *7% [Reset-Net]* |
| *Clinical Focus (Tier 2 to Tier 3 copay differential plus PA and / or SE)* | *46%* | *44%* | |
| *Clinical Outcomes (including Closed Diabetes Carve out Program)* | *50%* | *48%* | |

**Rates in the table above represent Walk-Away rates; intent is to walk-in with initial proposals 4% less than rates referenced above*

**Financial Impact:**

- Sanofi has the opportunity to retain glargine business at WellDyneRx at a lower rebate rate than the national PBM rates, downside risk is a move to a Not Covered position and accompanying volume loss.

**Risk Considerations:**

***Risk of Contract:*** [redacted]

***Risk of No Contract:*** [redacted]

**Customer Background:**

**WellDyneRx is a Regional PBM with 945,000 Commercial lives. Their typical clients are employers, unions, and public / government entities (e.g. Suffolk County Employee Medical Health Plan (EMPH)) in the 1K to 5K group size. In 2018, WellDyneRx is consolidating three formularies used in 2017 down to two Commercial formularies:**

Their *Clinical Focus Formulary* and a more closed *Clinical Outcomes Formulary*. These differ largely through the utilization management techniques used.

- Within the *Clinical Focus Formulary*, Prior Authorizations and / or Step Edits requiring failure of preferred product(s) are used with clients coming to this formulary from their 2017 National Preferred Formulary. Clients coming to the *Clinical Focus Formulary* from the 2017 Basic Formulary will simply face a Tier 2 to Tier 3 copay differential to access non-preferred products.
- Within their narrower *Clinical Outcomes Formulary*, utilization management techniques include Exclusion Lists identifying non-preferred, NDC Blocked products and "preferred" formulary alternatives. A Medical Exception process will allow patient access to these "Blocked" non-preferred products based on preferred product failure and medical necessity. Once an exception is granted, the patient pays a Tier 3 copay.

| Clinical Focus and Clinical Outcomes Formulary Tiers | Clinical Focus Formulary | Clinical Outcomes Formulary |
|---|---|---|
| Co-Pay Generic Tier | $5 - $10 | $ 5- $10 |
| Co-Pay Preferred Branded Tier | $35 | $35 |
| Co-Pay Non Preferred | $50 | $50 |

- One way WellDyneRx plans to create a differentiated market position is by emphasizing formulary products with low Average Wholesale Price (AWP) compared to competitors, which is a key reason Basaglar has gotten their attention given its lower WAC. Another is by creating Closed Category options; these Closed Category options will allow employers using the Clinical Focus Formulary to move select high cost therapeutic categories to the more managed Clinical Outcomes Formulary.

**Current Situation and Contract Terms:** [redacted]

| Lantus and Toujeo | Clinical Focus Formulary using Tier 3 Differential | Clinical Focus Formulary using Tier 3 Step-Edit | Closed Diabetes Carve-out (NA in 2017) | Clinical Outcomes Formulary |
|---|---|---|---|---|
| Formulary Lives<br>945,000 Lives Total | 452.5K | 452.5K | 0 | 40K |
| Current Formulary Position for both | Tier 2 | Tier 2 | NA | Tier 2 |
| Current Market Share | [redacted] | | | |
| Current Contract Rebate | | | | |
| Price Protection Threshold | | | | |
| Admin Fee | | | | |
| **Current Average Rate** *(is the avg for the account, accounting for mix of business, price protection, admin fee for the customer)* | | | | |

**Proposed:** [redacted]

| **Lantus and Toujeo** | | [redacted] |
|---|---|---|
| Anticipated Formulary Lives Distribution (12/31/2018) 945,000 Lives Total | | |
| Proposed Formulary Position | | |
| Current Market Share | | |
| Proposed Rebate – Lantus | LAN | |
| Proposed Rebate - Toujeo | TOU | |
| Price Protection Threshold | | |
| Admin Fee | | |
| **Current Average Rate** *(is the avg for the account, accounting for mix of business, price protection, admin fee for the customer)* | | |

**Rationale**

[redacted]

**Risk Assessment:**

[redacted]

**Summary Financial Assessment:**

[redacted]

**Assumptions:**

[redacted]

**From:** Fondaco, Michael /US
**Sent:** Wednesday, September 27, 2017 9:32 PM
**To:** Borys, Margaret /US; Halenar, Lori /US
**Subject:** RE: Preliminary PRB Agenda 9/28/17

Margaret,

In a nutshell, WellDyneRx is a PBM with ~1M lives. They currently use Gateway as their claims aggregator under ESI. WellDyne believes they can better negotiate rebates on their own instead of getting their rates nipped by both Gateway and ESI. Much more information to be presented tomorrow but the bottom line is the proposed rates are less than the ESI rate so it's a savings to the brand.

Feel free to call me if you have any questions.

Thanks.

Mike
[redacted]

**From:** Borys, Margaret /US
**Sent:** Wednesday, September 27, 2017 5:10 PM
**To:** Halenar, Lori /US; Fondaco, Michael /US
**Subject:** FW: Preliminary PRB Agenda 9/28/17

Lori/Mike,

I've not heard of the Lantus/Toujeo new customer that is on the agenda for today. Can you guys give me background? Also, I'm in San Fran and can't participate today.

Margaret

Margaret Borys
[redacted]

-----Original Message-----
**From:** Halenar, Lori /US
**Sent:** Wednesday, September 27, 2017 05:01 PM Eastern Standard Time
**To:** Wentworth, Jim /US; Burke, Mary /US; Siragusa, Carrie /US; Bass, Cynthia /US; Spencer-Pike, Kathy /US; Marchessault, Ron /US; Burke, Maureen /US; Cann, Chris /US; Youngquist, Kristin /US; Koenig, Sheldon /US; Gleeson, Gerald /US; Borys, Margaret /US; Gilhodes, Laurent /FR; Geremia, Joseph /US; Yonce, Cary /US
**Cc:** Lydon-Fersch, Karen /US; Jacot-Guillarmod, Shawn /US; Ridolfi, Phillip R. /US; Paternoster, Dominick /US; Seasock, Roger /US; Perry, Kara /US; Hansson, Petur /US; Cirri, Liz /US; Fondaco, Michael /US; Adams, Patricia /US; Haley, Alfred /US; Goldate, Kelly /US; Forman, Brian /US; Baisley, Tricia /US; Vetti, Rick /US; Downing, Max /US; Clay, Chris /US; Bray, Scott /US; Biddlecom, Michael /US; Krammer, Ron /US; Mueller, Matthew /US; Rozzelle, Jennifer /US; Demmerle, Alicia /US; Barnes, Stephen /US; Renzo, William /US;

Sullivan, Gerard /US; Bruce, Jonathan /US; McDaniell, Craig /US; Haley, Alfred /US; Christofilakes, Rachel /US; Buckelew, Daniel /US; Kensicki, Ronald /US; Pearlstein, Cindy /US; Steuart, Scott /US; Faught, Shannon /US; Gamel, Laura /US; Perkins, Andrew /US; Sullivan, Gerard /US; Lui, Leeann /US; Borneman, James /US; Albano, James /US; Sakae, Asako /US; Harris, William /US; Halenar, Lori /US
**Subject:** Preliminary PRB Agenda 9/28/17

**PRB Members, below is the preliminary agenda for Thursday's PRB meeting. If your business area is not included in the agenda, it is not necessary for you to attend the meeting.**

****Please be advised that due to limited space in the conference room, we are asking that only voting members, presenters, contract strategy leads, legal and compliance attend the meeting in person.****

**Sanofi PRB**
**Please utilize the Sanofi Conf. Call Number Toll Free [redacted] Conference Code: [redacted]**
**WebEx Link:** https://sanofi-americas.acms.com/r5x1brm9i90/

***DCV BU***

**Product:** Lantus/Toujeo
**Topic:** WellDyneRx, LLC Commercial (New Customer)
**Presenter:** A. Haley

***GM BU***

**Product:** Sevelamer
**Topic:** Sevelamer AG WAC and contract pricing
**Presenter:** P. Adams

**Thanks,**
**Lori**

**Lori Halenar**
**Strategic Pricing and Contracting**
[redacted]

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# Soliqua 2017/2018 Tracker

## SOLIQUA 2017 BIDS

| | | Lives (M) | Latest / Expected Offer Date | Latest / Expected Offer Blended Rate*** | Offer Details | Status | Expected Date of Notification | Term | Net Sales | 2017 F1 Gross Sales | 2017 F1 Rate | 2017 F1 Net Sales | 2017 F1 Access Start Date | 2017 F1 Formulary Position | Variance vs 17-F1 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Commercial | ESI | 50.2 | 09/18/17 | 30% | EA 15% no PP thru 12/31, T2 1-1 35%, 1-2 30%, NP 10% eff 1/1/18 (no UM), PP 6% Custom Form T2 1-2 15% w/ UM eff 10/1/17- 12/31/18, PP 6% (not yet accepted) | ACCEPTED | 3/13/17 EA 7/31/17 PBT 7/31/17 NP 9/19/17 CF | 1/1/15-12/31/17 EA 9/1-12/31/18 PBT 1/1-12/31/18 NP 10/1-12/31/18 Custom Formularies | 22 | 32 | 59% | 19 | 3/15 NP 7/1 Pref | Preferred | 2.8 |
| | CVS | 41.7 | 05/02/17 | 27% | NP 25% 6/1-9/30/17, T2 1-2, 42% PP 7.5% | ACCEPTED | 5/23/17 NP 4/3/17 PBT | 4/1-9/30/17 NP 10/1-12/31/18 PBT | 11 | 15 | 50% | 8 | 7/1/2017 | Preferred | 3.5 |
| | UHC OptumRx | 26.4 | 1/12/2017 5/30/2017 | 46.75% 39% | One of many Preferred | ACCEPTED | 01/29/2017 05/1/2017 | 7/1/17- 6/30/21* | 12 | 22 | 47% | 12 | 7/1/2017 | Preferred | - |
| | Humana | 2.5 | 09/18/17 | 30% | 1-1 30% w/UM, 1-2 30% w/UM PP 6% | In progress | 10/31/17 | 12/1/17- 12/31/18 | 1 | 1 | 35% | 1 | 7/1/2017 | Preferred | 0.1 |
| | Aetna | 9.8 | 5/15/2017 8/21/2017 | 25% | 1-1 30% w/UM, 1-2 25% w/UM From 1-2 30% w/UM Val PP 6% | From ACCEPTED 1-2 Value (In prog) | 8/10/2017 9/30/2017 | 10/1/17- 12/31/18 | 3 | 4 | 19% | 3 | 7/1/2017 | Pref Prem Cov Val | (0.3) |
| | CIGNA | 6.4 | 05/31/17 | 25% | T2 1-1, 1-2 25% Unrestricted, VBC 3% (start date TBD), PP 6% | ACCEPTED | 08/19/17 | 7/1/17- 12/31/19 | 3 | 4 | 30% | 3 | 7/1/2017 | Preferred | 0.2 |
| | Prime | 12.5 | 08/15/17 | 32% | 1-2 w/UM 27.25% 1-2 Unrest 32.25% 1-2 NP w/UM 5% PP 6% | In progress | 09/30/17 | 10/1/17- 12/31/18 | 7 | 11 | 30% | 8 | 7/1/2017 | Preferred | (0.2) |
| Medicare | ESI | 4.5 | 02/10/17 | 25% | EA 15%, PP 0% until 7/1, T2 1-2, 25%, PP 6% | Accepted EA thru 6/30/17 In Progress for PBT | 10/31/17 | Acceptance - 12/31/18 | - | 0 | 0% | - | 1/1/2018 | Preferred | - |
| | CVS | 8.9 | 03/24/17 | 42% | Pref 42% 1:2 Fixed Unit 6% PP No Restriction | In progress | 10/01/17 | 6/1/17- 12/31/18 | 1 | 2 | 50% | 1 | 10/1/2017 | Preferred | 0.1 |
| | Optum Rx* | 7.8 | 03/28/17 | 53% | 1-1 53% 1-2 50% PP 6% '19- 21 | ACCEPTED | 04/07/17 | 5/1/17- 12/31/21 | 4 | 8 | 54% | 2 | 7/1/2017 | Preferred | 1.2 |
| | Humana | 7.5 | 09/18/17 | 50% | 1-2 50% w/UM PP 6% | In progress | 10/31/17 | 12/1/17- 12/31/18 | 2 | 4 | 37% | 2 | 7/1/2017 | Preferred | (0.2) |
| | Aetna | 2.7 | 02/08/17 | 20% | 1-1 25%, 1-2 20% PP 6% | In progress | 10/01/17 | 7/1/17- 12/31/17 | - | 0 | 0% | - | 1/1/2018 | NC | - |
| | CIGNA | 1.4 | 08/24/17 | 30% | 1-2 30% w/UM, PP 6% | ACCEPTED | 08/29/17 | 10/1/17- 12/31/18 | 0 | 1 | 30% | 1 | 7/1/2017 | Preferred | (0.1) |
| | Prime | 1.1 | | | | | | | - | 0 | 0% | - | 1/1/2018 | Preferred | - |
| | Kaiser | 8.1 | 06/21/17 | 28% | Pref Contracted FBC 28%, PP 6% Endo/Endo Consult | ACCEPTED | 08/01/17 | 8/1/17- 12/31/20 | 1 | 1 | 0% | 1 | 1/1/2018 | | (0.1) |

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# Glargine 2018 Tracker

## Glargine 2018 Bids

| | | Lives (M) | Latest Offer Date | Latest Offer Blended Rate | Offer Details | Status | Expected Date of Notification | Term | Offer Gross Sales | Offer Net Sales | Approved Rates Blend | Approved Rates LAN | Approved Rates TOU | 2018 LRP Gross Sales | 2018 LRP Rate | 2018 LRP Net Sales | 2018 LRP Access Start Date | 2018 LRP Form Position | Δ vs LRP |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Commercial | ESI | 50.2 | 06/16/17 | 69% | 1-1 70/70%, 1-2 68/68%, 1-3 63/63% [L/T] | In progress | 9/30/2017 | 1/1/18-12/31/19 | 1,162 | 359 | 63% | 65% | 60% | 1,147 | 69% | 351 | 1/1/2018 | Pref 1of3 | 8 |
| | CVS^ | 41.7 | 06/16/17 | 63% | Limits 1-1 70%, 1-2 68%, 1-3 63% Troupe 1-1 64%, 1-2 63%, 1-3 61% | Lost | 8/3/2017 | 1/1/18-12/31/19 | 101 | 48 | 70% | 70% | 70% | 101 | 66% | 34 | 1/1/2018 | NC | 3 |
| | UHC Optum Rx | 15.9 10.5 | 07/15/16 | 51% | No Opportunity (UHG) Tier 2 = 51% (OPT) | No update from 2017 | | 1/1/17-12/30/20 | 224 | 110 | 65% | 65% | 65% | 224 | 65% | 78 | 1/1/2018 | Pref 1of2 | 31 |
| | Humana | 2.5 | 03/20/17 | 52% | 1-1 63% L, 61% T 1-2 53% L, 51% T | In progress | 9/30/2017 | 1/1/18-12/31/19 | 35 | 17 | 55% | 55% | 53% | 35 | 55% | 16 | 1/1/2018 | Pref 1of2 | 1 |
| | Aetna | 9.8 | 5/15/17 P 5/16/17 V | 54% | Prem 1-2 55% L, 52% T Value 1-2 56% ('18), 62% ('19) | Prem ACCEPTED Value Lost | 8/10/2017 | 1/1/18-12/31/19 | 81 | 37 | 58% | 60% | 58% | 81 | 58% | 34 | 1/1/2018 | Pref 1of2 Val NC | 3 |
| | CIGNA | 6.4 | 08/23/17 | 0% | 1-1 55%, 1-2 51%, 1-3 [illegible] | Lost | 8/15/2017 | 1/1/18-12/31/19 | 25 | 25 | 51% | 55% | 55% | 123 | 55% | 55 | 1/1/2018 | Pref 1of2 | (14) |
| | Prime | 12.5 | 10/06/16 | 50% | 1-2 50% | No update from 2017 | N/A | 1/1/17-12/31/18 | 224 | 112 | 54% | 57% | 52% | 224 | 60% | 90 | 1/1/2018 | Pref 1of2 | 22 |
| Medicare | ESI | 4.5 | 06/01/17 | 56% | 1-1 ESI PDP 63%, 1-1 56%, 1-2 54%, 1-3 53%, 6% PP | In progress | 10/1/2017 | 1/1/18-12/31/19 | 619 | 276 | 55% | 56% | 54% | 619 | 54% | 287 | 1/1/2018 | Pref 1of2 | (11) |
| | CVS | 8.9 | 08/03/17 | 78% | Plus/Custom (1-2) LAN 80% LIS/74% STD TOU 75% LIS/69% STD Choice/Template (1-3) LAN 80% LIS/72% STD TOU 75% LIS/67% STD 0% PP LAN, 3% PP TOU | In progress | 10/1/2017 | 1/1/18-12/31/19 | 1,071 | 239 | 64% | 65% | 60% | 1,157 | 69% | 356 | 1/1/2018 | Pref 1of2 | (117) |
| | Optum Rx | 7.8 | 11/06/16 | 60% | 1-1 66%, 1-2 60% | In progress | 8/23/2017 (UHC) 10/1/2017 (Optum) | 1/1/18-12/31/19 | 1,087 | 430 | 65% | 65% | 65% | 1,087 | 64% | 391 | 1/1/2018 | Pref 1of2 | 39 |
| | Humana | 7.5 | 03/20/17 | 52% | 1-1 63% L, 61% T 1-2 53% L, 51% T | In progress | 9/1/2017 | 1/1/18-12/31/19 | 720 | 346 | 55% | 55% | 53% | 720 | 52% | 346 | 1/1/2018 | Pref 1of2 | - |
| | Aetna | 2.7 | 12/12/16 | 69% | Currently NC, 1-2 70% L, 65% T | In progress | 10/1/2017 | 1/1/18-12/31/19 | 12 | 4 | 55% | 55% | 53% | 12 | 52% | 6 | 1/1/2018 | NC | (2) |
| | CIGNA | 1.4 | 12/16/16 | 36% | 1-2 36% | In progress | 10/1/2017 | 1/1/18-12/31/19 | 180 | 116 | 39% | 39% | 39% | 180 | 40% | 108 | 1/1/2018 | Pref 1of2 | 7 |
| | Prime | 1.1 | 02/14/17 | 54% | 1-1 56%, 1-2 53% | In progress | 10/1/2017 | 1/1/18-12/31/19 | 125 | 58 | 52% | 53% | 51% | 125 | 54% | 58 | 1/1/2018 | Pref 1of2 | (0) |
| | Kaiser | 8.1 | 08/12/16 | 66% | LAN = 65% TOU NP = 15%, Fixed Price | Status Quo | 8/12/2016 | 1/1/17-12/31/20 | 139 | 47 | 66% | | | 139 | 66% | 48 | 1/1/2018 | Pref 1of1 | (0) |

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**From:** Fondaco, Michael /US
**Sent:** Friday, July 28, 2017 9:24 PM
**To:** Gleeson, Gerald /US; Geremia, Joseph /US
**Cc:** Halenar, Lori /US; Paternoster, Dominick /US; Jacot-Guillarmod, Shawn /US; Perkins, Andrew /US
**Subject:** RE: CVS Part D Glargine Proposal

Team,

Attached is a supplemental deck to be used in our meeting on 7/31 with the Global team. Additional slides answer Laurent's questions and also include a 2019 summary in response to Margaret's request for a 2-yr view. Summary of deck:

Slide 1 – Original 2018 BUPC Financial Summary

Slide 2 – 2019 Financial Summary

Slide 3 – Per Laurent's request for 1) side-by-side comparison, 2) erosion rates,

- After inclusion of additional fees, we are still profitable up to an 89% rebate
- After all other fees have been included, the No Contract scenario is more profitable. This was discussed at length during PRB. There are other mitigating factors to consider beyond pure dollars...
    - How would it look to be removed from the largest Medicare plan?
    - Top line sales volume would significantly erode

Slide 4 – and, 3) tipping point analysis

- CVS would need to shift 68.9% of glargine volume to Novo to break even (at an assumed 81% Novo rebate offer)

If you have any questions about the contents of this message before Monday morning, please respond to Andrew or me via e-mail.

Best regards,

Mike

**From:** Gleeson, Gerald /US
**Sent:** Friday, July 28, 2017 11:43 AM
**To:** Perkins, Andrew /US
**Cc:** Geremia, Joseph /US; Halenar, Lori /US; Paternoster, Dominick /US; Fondaco, Michael /US; Jacot-Guillarmod, Shawn /US
**Subject:** Re: CVS Part D Glargine Proposal

Andrew, please send to me when ready.

Sent from my iPad

On Jul 28, 2017, at 7:22 AM, Perkins, Andrew /US <[redacted]> wrote:

> No problem – I should have all of this but need to combined into one easy file.

I will get working on this today

Andrew

---

**From:** Geremia, Joseph /US
**Sent:** Friday, July 28, 2017 7:01 AM
**To:** Perkins, Andrew /US; Halenar, Lori /US; Paternoster, Dominick /US; Fondaco, Michael /US; Jacot-Guillarmod, Shawn /US
**Cc:** Gleeson, Gerald /US
**Subject:** Fwd: CVS Part D Glargine Proposal

Team
Andrew I believe you may have some of this information available. Can you take a look and model as outlined below

Lori we probably need a BUPC early next. Preferably Tuesday am.

All any questions please let me know.

Thanks
Joe

Sent from my iPhone

Begin forwarded message:

> **From:** "Gleeson, Gerald /US" <[redacted]
> **Date:** July 28, 2017 at 6:46:23 AM EDT
> **To:** "Gilhodes, Laurent /FR" <[redacted]
> **Cc:** "Borys, Margaret /US" <[redacted]>, "Oelrich, Stefan /DE" <[redacted]>
> **Subject: Re: CVS Part D Glargine Proposal**
>
> Laurent - good feedback and we will refine the additional inputs you outlined. We are also pushing for a 2 year approach as well.
>
> In addition, we'll prepare for a BUPC early next week.
>
> Regards,
>
> Gerry
>
> On Jul 28, 2017, at 6:02 AM, Gilhodes, Laurent /FR <[redacted]> wrote:
>
> > ...but it is still useful to compare with baseline to understand the erosion assumptions.
> > Thanks.

**De :** Borys, Margaret /US
**Envoyé :** vendredi 28 juillet 2017 11:44
**À :** Gilhodes, Laurent /FR; Gleeson, Gerald /US; Oelrich, Stefan /DE
**Objet :** RE: CVS Part D Glargine Proposal

Laurent,

I would also recommend looking at this with a multi-year scenario in mind and potential impact to other plans. And, as you know, because we've already been informed that we lost the business, the only true comparison for decision-making purposes now is new contract terms vs no contract. Comparison to LRP would be for expectation setting only.

Margaret

Margaret Borys
[redacted]

-----Original Message-----
**From:** Gilhodes, Laurent /FR
**Sent:** Friday, July 28, 2017 03:37 AM Eastern Standard Time
**To:** Gleeson, Gerald /US; Oelrich, Stefan /DE
**Cc:** Borys, Margaret /US
**Subject:** RE: CVS Part D Glargine Proposal

Gerry,

I would need the following additional information before making a recommendation:

- Financials:
  - side by side comparison from gross sales to net (including Rebates, Coverage Gap, prompt pay and DPA fees) of the various scenarios: a) LRP Baseline b) No Contract c) New proposal
  - Details of the No Contract scenario for sales evolution compared with baseline by books of business (Choice, Plus, [redacted])
- Tipping point:
  - What percentage of current Glargine volumes do they need to switch Novo basals to break even vs. our current offer (69% blend)

From a governance standpoint, will you plan for a formal BUPC call next week? The proposal will have to be discussed with Peter early next week.

Thanks.
Laurent

**De :** Gleeson, Gerald /US
**Envoyé :** vendredi 28 juillet 2017 00:38
**À :** Oelrich, Stefan /DE; Gilhodes, Laurent /FR
**Cc :** Borys, Margaret /US
**Objet :** CVS Part D Glargine Proposal

Stefan/Laurent - as per our discussion last week, the following reflects our Glargine proposal for CVS Silverscript Medicare Part D.

As you are aware, CVS/Caremark submitted their 2018 formulary to CMS with Lantus and Toujeo excluded from their Choice formulary representing approx. 10M lives. Our proposal as outlined below refelcts an aggressive counter offer to remain on formulary. My team is meeting next Thursday with CVS/Caremark, and we are seeking your approval to present the offer below.

The offer was reviewed and approved at today's PRB meeting.

If you have questions or need additional information please let me know.

Regards,

Gerry

**

**CVS/Caremark Medicare Part D – Lantus & Toujeo 2018 Bid Response**

**Background:**

- **CVS/Caremark total 13M Lives… Affiliated SilverScript PDP 5.5M Lives (of which ~78% LIS)… non-Affiliated 7.3M Lives where Caremark is the PBM…includes A[redacted] 3.1M**

**lives moving to CVS/Caremark effective 1/1/18**

- **Current Coverage: CVS/Caremark L/T 1 of 2… MS 71.5% and [redacted] L/T NC…MS 19%...overall blended L/T… MS 60%**
- **Lantus/Toujeo will remain preferred access on the Plus Formulary (2.4M lives) with Novo**
- **CMS allows Part D sponsors to add products but not remove once formularies are submitted**

**Prior Offer 1-2:**

- **If L/T on formulary through '19 an incremental deferred payment offer of 2%**
- **Total Payment = Lantus 65 (base) +3 (admin) +2 (deferred) = 70%, Toujeo 60 (base) +3 (admin) +2 (deferred) = 65%**
- **Total Blend 69%**

**Revised Proposal 1-2 and 1-3:**

- **Increase Base Rate: +12 points (Lantus 77%)…+12 points (Toujeo 72%); Remove deferred payment offer**
- **Total Payment = Lantus 77 (base) +3 (admin) = 80%, Toujeo 72 (base) +3 (admin) = 75%**
- **Total Blend = 79%**

**Rationale/Assumptions:**

- **Assumption – based on our Net Cost To Plan (NCTP), we assume an 85% erosion rate with competitor rate of 81% and 2% portfolio rebate. This equates to $119M additional rebates to Caremark**

- **In order for SA to equal NCTP, SA to offer 80% blended rebate (+10 points) to cover the $119M**

- **Protects Sanofi Net Sales = $243M**

**Financials LRP (Net Sales):**

- **Baseline LRP → Caremark $356M (blended rebate 69%), [redacted] $6M (blended rebate 52%) = Total Net Sales $362M (overall blended rebate 69%)**

- **Revised bid → Variance vs. LRP…Total Net Sales -$104M… Assume blended rate 79.2% and 30% incremental of [redacted] non contracted volume**

- **No Contract → Variance vs LRP….Total Net Sales -$103M…Assume loss of coverage ~60% volume downside for glargine as SA will retain Plus ~ 2.4M lives**

**

# BU Pricing Review Board

# CVS Medicare Part D Supplemental Analysis

## July 31, 2017

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7/27/2017

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PENDING FINAL SA LEGAL REVIEW

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FOR APPROVAL

# CVS/Caremark Medicare Part D / [redacted] – Lantus/Toujeo 2018 Re-Bid
# CVS - Pref 1-3…Total Blended Payment 79.2%

**Background:**
- CVS/Caremark total 13M Lives… Affiliated SilverScript PDP ~5.5M Total Lives (of which ~78% LIS)… non-Affiliated 7.3M Lives where Caremark is the PBM… inclusive of [redacted]
- Effective 1/1/18 Aetna's Medicare Part D business is moving under Caremark…. 3.1M Lives
- Current Coverage: CVS/Caremark L/T 1 of 2… MS 71.5% and [redacted] L/T NC…MS 19%...overall blended L/T… MS 60%
- SilverScript submitted two formularies for 2018 (Choice & Plus) to CMS excluding L/T from Choice ~ 10M Lives
- Plus Formulary will have Lantus/Toujeo preferred with Novo ~2.4M lives
- CMS allows Part D sponsors to add products but not remove once formularies are submitted

**Latest Offer:**
- If CVS maintained L/T on formulary through '19 an incremental deferred payment offer of 2%
- Total payment = Lantus 65 (base) +3 (admin) +2 (deferred) = 70%…Toujeo 60 (base) +3 (admin) +2 (deferred) = 65%
- Total Blend inclusions of admin fee and deferred payment = 69%

**Revised Proposal 1-3 and 1-2:**
- Increase Base Rate: +12 points (Lantus 77%)…+12 points (Toujeo 72%)
  - Total Payment = Lantus 77 (base) +3 (admin) = 80%…Toujeo 72 (base) +3 (admin) = 75%
  - Total Blend inclusions of admin fee = 79%

**Rationale:**
- Responding to CVS's Request to re-bid for 2018 to maintain formulary position with the largest Part D sponsor
- Net Cost to Plan (NCTP) assumes 85% erosion rate. Assume 81% competitor rebate and 2% portfolio rebate. In order for SA to equal NCTP, SA to offer 80% blended rebate to make up $119M additional rebates to Caremark.
- Invest incremental 10 points = $119M to protect Sanofi Net Sales = $243M

**Additional Considerations:**
- Government Pricing: Financial impact to Sanofi: N - Part D excluded from Gov't Pricing; Operational/system impact: N

**Financials LRP (Net Sales):**
- Baseline LRP Caremark $356M... blended rebate 69%… [redacted] $6M…blended rebate 52%… Total Net sales 362M… overall blended rebate 69%
- Variance vs. Baseline…Proposed offer blended rate 79.2%...Total net sales -$104M… assume 30% incremental of [redacted] non contracted volume
- Variance vs. No Contract….Total Net Sales -$103M

FOR APPROVAL

# CVS/Caremark Medicare Part D / [redacted] Part D – Lantus/Toujeo 2018 Re-Bid
# CVS - Pref 1-3…Total Blended Payment 79.2%

**Background:**

- CVS/Caremark total 13M Lives… Affiliated SilverScript PDP ~5.5M total Lives… ~78% LIS… non-Affiliated 7.3M lives where Caremark is the PBM… inclusive of [redacted]
- Effective 1/1/18 Aetna's Part D business is moving under Caremark…. 3.1M Lives
- Current Coverage: CVS/Caremark L/T 1 of 2… MS 71.5% and [redacted] L/T NC…MS 19%...overall blended L/T… MS 60%
- SilverScript submitted two formularies for 2018 (Choice & Plus) to CMS excluding L/T from Choice ~ 10M Lives
- Plus Formulary with have Lantus/Toujeo preferred with Novo ~2.4M lives
- CMS allows Part D sponsors to add products but not remove once formularies are submitted

**Latest Offer:**

- If CVS maintained L/T on formulary through '19 an incremental deferred payment offer of 2%
- Total payment = Lantus 65 (base) +3 (admin) +2 (deferred) = 70%…Toujeo 60 (base) +3 (admin) +2 (deferred) = 65%
- Total Blend inclusions of admin fee and deferred payment = 69%

**Revised Proposal 1-3 and 1-2:**

- Increase Base Rate: +12 points (Lantus 77%)…+12 points (Toujeo 72%)
  - Total payment = Lantus 77 (base) +3 (admin) = 80%…Toujeo 72 (base) +3 (admin) = 75%
  - Total Blend inclusions of admin fee = 79%

**Rationale:**

- Responding to CVS's Request to re-bid for 2018 to maintain formulary position with the largest Part D sponsor.
- Net Cost to Plan (NCTP) assume 85% erosion rate. Assume 81% competitor rebate and 2% portfolio rebate. In order to SA to equal NCTP SA to offer 80% blended rebate to make up $119M additional rebates to Caremark.
- Invest incremental 10 points = $119M to protect Sanofi Net Sales = $243M

**Financials LRP 2019 (Net Sales):**

- Baseline LRP Caremark $331M... blended rebate 71%... [redacted] $6.6M…blended rebate 57%… Total Net sales 336M… overall blended rebate 71%
- Variance vs. baseline…Proposed offer blended rate 79.2%...Total net sales -78.5M… assume 30% incremental of [redacted] non contracted volume
- Variance vs. no contract….Total net sales -$81M

# CVS Side-by-Side Comparison (Total GTN View) and Erosion Rates by Book of Business

| | Baseline LRP Glargine 2018 | Glargine 80% Rebate | No Contract Glargine |
|---|---|---|---|
| Gross Sales $ | $ 1,169,490,233 | $ 1,247,609,257 | $ 473,836,156 |
| Rebates $ | $ 807,473,889 | $ 989,409,507 | $ 215,272,542 |
| Rebate % | 69% | 79% | 45% |
| Net Sales $ | **$ 362,016,344** | **$ 258,199,750** | **$ 258,563,614** |
| 2% Prompt Pay | $ 23,389,805 | $ 24,952,185 | $ 9,476,723 |
| 1.6% DPA | $ 18,711,844 | $ 19,961,748 | $ 7,581,378 |
| COG 2% | $ 23,389,805 | $ 24,952,185 | $ 9,476,723 |
| Other Costs | $ 58,474,512 | $ 62,380,463 | $ 23,691,808 |
| Net Sales $ after Other Cost | **$ 238,050,380** | **$ 125,953,169** | **$ 208,336,981** |
| | *Variance to LRP* | **$ (112,097,211)** | **$ (29,713,399)** |

## Assumptions:

- **30% shift of Novo's Aenta volume to Lantus and a 3% decrease in Lantus volume to Basaglar.**
- **Includes [redacted] non-contracted volume**
- **No Contract Rebate Blend assumes paying 69% for the Plus Formulary**

## Erosion Rate

- **Overall erosion of gross sales would be 60%**
- **Choice Formulary – 81% Lantus/Toujeo volume erosion**
- **Plus Formulary – No erosion. Sanofi is bound to the current 69% blend rebate offer**
  - **CVS would retain 26% of the overall lives with the Plus Formulary**
- **Includes the $119M increase in rebates from Novo increasing their offer**

# Tipping Point
## Break Even Assumptions

| 2018 CVS Breakeven v. SA 69% Blended Rebate | |
|---|---|
| Rebate $ Needed to BE | $ 468,245,300 |
| CVS BE Conversion Rate | **68.86%** |
| Gross Sales Avail for conversion | $ 578,080,617 |
| Novo Rebate % | 81% |
| Novo Rebate $ | $ 468,245,300 |

- **If CVS rejects sanofi 2018 blended rate of 69%, it would require Novo to capture 68.9% of current Glargine volume to break even**
- **This assumes a Novo rebate of 81% (This would require an 86.4% volume capture for Novo to break even)**

Note: [redacted] was able to shift 81% of Lantus/Toujeo volume when excluded from formulary.

# US DCV
# Glargine Pricing Review

April 6, 2017

SANOFI

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# 2017 Glargine Pricing
# Toujeo price action…17B assumes +3% effective 01/01/17

- Focus on differentiation of pricing → Toujeo vs Lantus…gross and net
- 20% of upside derived from non-contracted business (~$4M)…targeted for cash card and copay card programs
- Cancellation of price action to 2018 = -$19M (vs 17B)
- Ramifications of price action
  - Impact to ongoing 2018 negotiations ([redacted] [redacted] requiring equivalent net pricing to retain coverage…
  - Public relations → focus on insulin pricing…
  - Group pricing policy and pricing evolution disclosures…
- Full glargine price action? → no impact to negotiations but similar public ramifications

# 2017 Glargine Pricing
# Toujeo price action…17B assumes +3% effective 01/01/17

- **Postponement of the Toujeo price action = -$19M (vs 17B)**

| | Toujeo B17 Downside ($Millions) | | | | |
|---|---|---|---|---|---|
| Channel | 01/01/17 | 03/01/17 | 04/01/17 | 07/01/17 | 10/01/17 |
| Commercial | | (1.2) | (1.8) | (3.9) | (6.2) |
| Medicare w/ Coverage Gap | | (1.2) | (1.9) | (3.9) | (6.3) |
| Medicaid* | | (0.1) | (0.2) | (0.3) | (0.5) |
| [redacted] | | | | | |
| Total | - | (2.6) | (3.9) | (8.2) | (13.1) |

**Focus for cash-card and copay programs…cash paying and HDHP patients**

- **Price action effective 05/01/17 = -$5M…**
- **Lost coverage in 2018 (vs 2018 3YFF)… -$95M**
  - [redacted]
  - [redacted]

# 2017 Glargine Pricing
# Lantus price action…alignment with Toujeo pricing…

- **Postponement of the Toujeo price action = -$19M (vs 17B)**

| | Lantus B17 Upside ($Millions) | | | | |
|---|---|---|---|---|---|
| Channel | 01/01/17 | 03/01/17 | 04/01/17 | 07/01/17 | 10/01/17 |
| Commercial | 28.7 | 23.9 | 21.5 | 14.3 | 7.2 |
| Medicare w/ Coverage Gap | 22.4 | 18.7 | 16.8 | 11.2 | 5.6 |
| Medicaid* | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) |
| [redacted] | | | | | |
| Total | 48.6 | 40.5 | 36.4 | 24.3 | 12.1 |

- **Impact of 05/01/17 price action (+3%) = +$32M…**

# US DCV
# 2018 Glargine Approval Requests

SANOFI

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FOR APPROVAL

[redacted] – Lantus / Toujeo
**Preferred Brand Tier: 38-50% Rebate… 6% PP [Cumm-Net]…Total Payment Rate: ~47.5%**
**Term: 01/01/2018 – 12/31/2019**

Background:
- Lives: ~7M Lives
- Response due date: 04/14/2017
- Other information: Preferred brand Tier co-pay : $25, non-preferred brand tier co-pay: $55. Predominately 3T design with some 4T. Non-formulary drugs are listed as NC requiring documented failure on preferred brands and a medical exception.

Current Contract:
- (1 of 2) Manufacturer position at 35% (85% of sales) … (1 of 1) Manufacturer position at 40% (15% of sales)
- Price Protection = 6% [Cumulative-Net ]

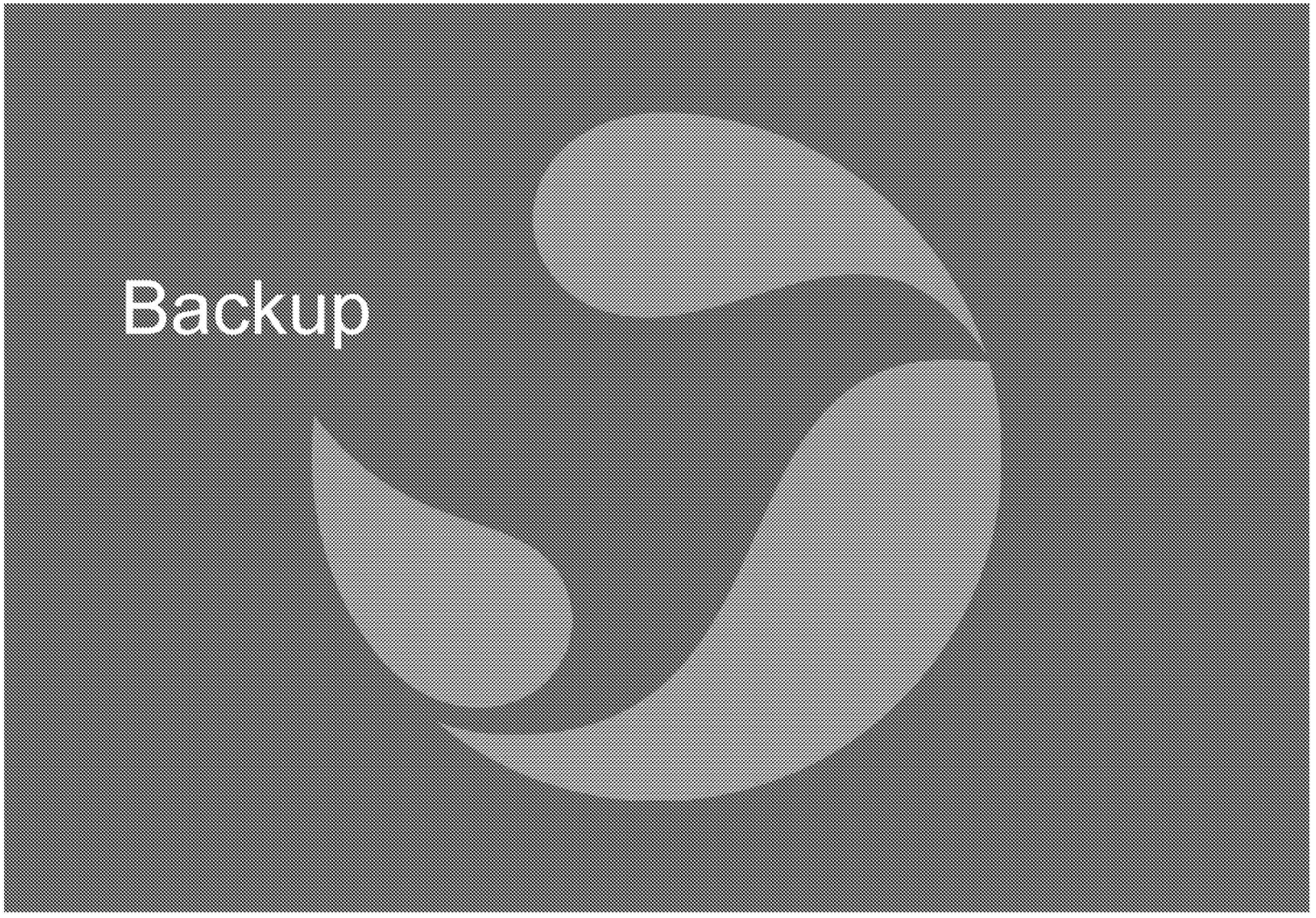
Proposal:
- Term: 01/01/2018 to 12/31/2019
- Preferred Brand Tier: (1 of 3 MFR's) 38% ... (1 of 2 MFR's) 47% ... (1 of 1 MFR's) 50% ... Toujeo Exclusive Basal 50%
- Price Protection = 6% [Cumulative-Net ] … Year 1 & 2
- UM Criteria: None

Rationale:
- [redacted] has asked for offers for the basal insulin category. [redacted] is reviewing the category in the late May timeframe to make access decisions that will be implemented on 01/01/2018.

Additional Considerations:
- Government Pricing: Financial impact to Sanofi: N; Operational/System impact: N
- Other: [redacted] removed Victoza from formulary 01/01/2017 and refers to Trulicity as its "workhorse" GLP1. [redacted] has referenced Lilly's deep frustration with current NC position for Basaglar.

Financials (Net Sales):
- 3YFF Net Sales → 2018 = $69.8M (45% rebate rate)
- Variance to Net Sales → 2018 = -$3.0M (47.5% blended rate)
- No contract (variance vs 17B) → 2018 = -$30.0M... Health Partners MN Lantus Analog (Based on 2017 YTD TPS Data)

# Backup



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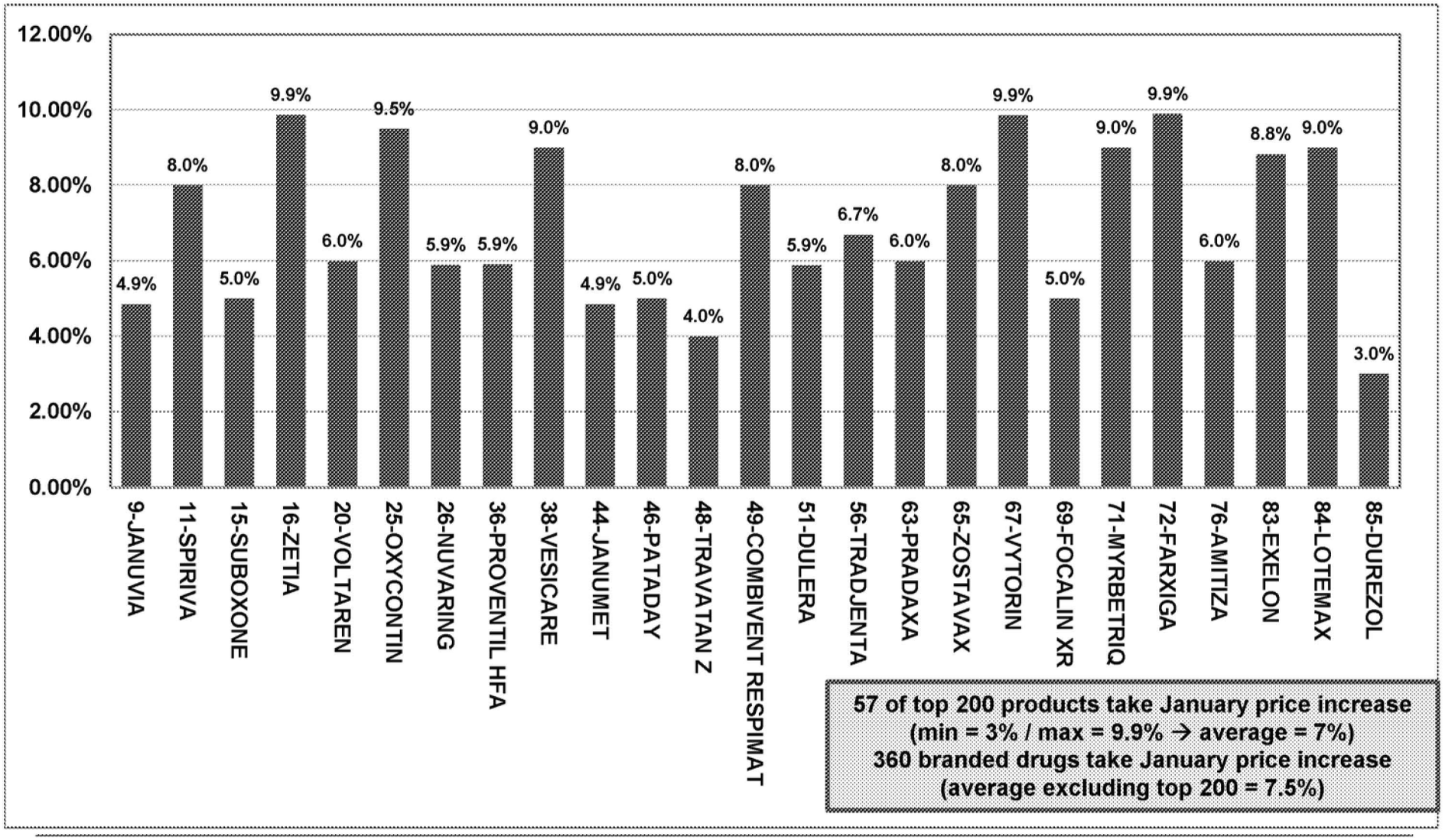
# Lantus Price Evolution

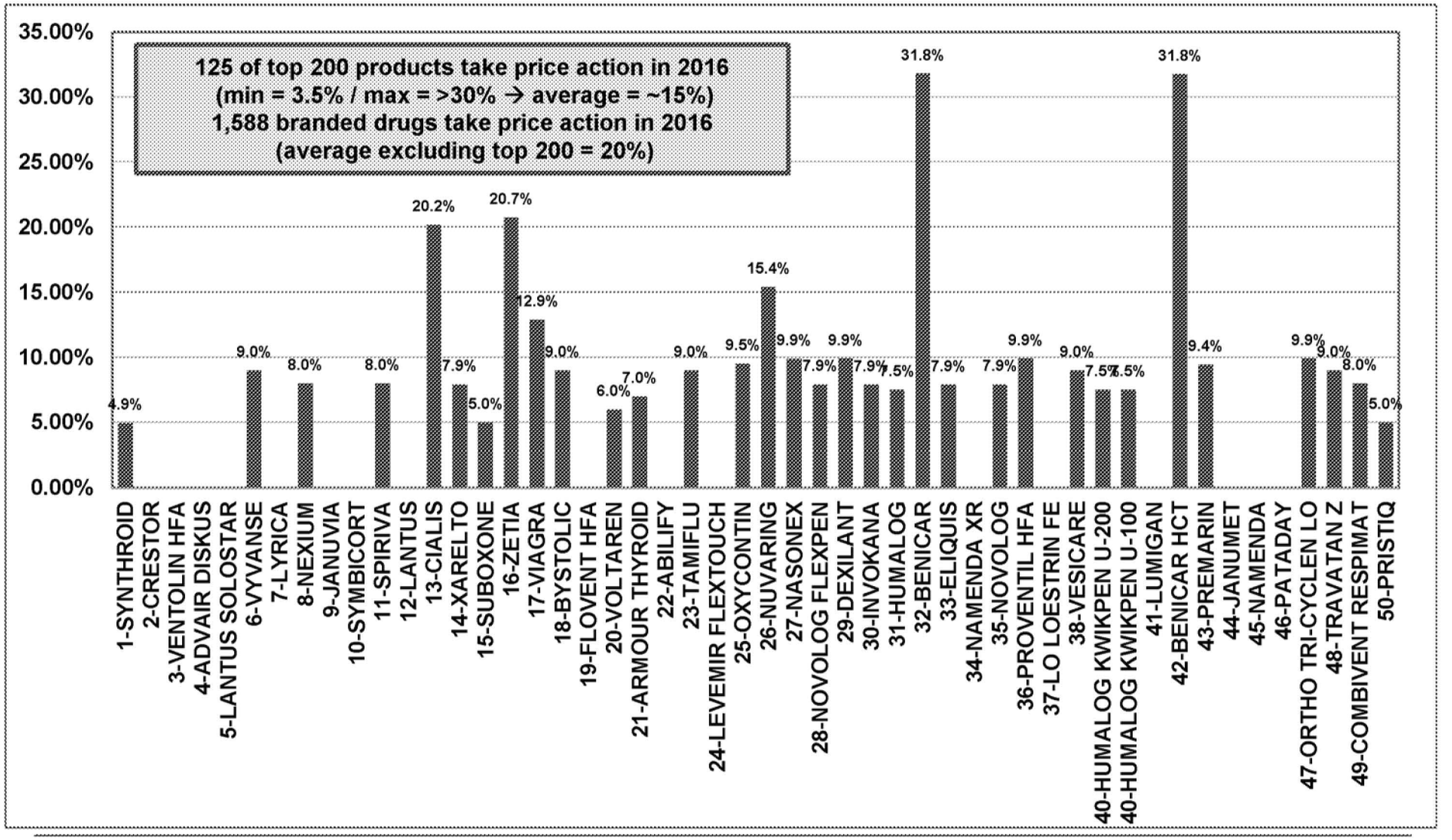
| | NS | VOL | Price | WAC | GTN | CPI | CPI Growth | Act Growth | Δ | WAC | Net | Growth vs 2007 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2005 | | | | | | 3% | | | | 57.35 | 46.92 | | |
| 2006 | 40% | 19% | 20% | 15% | 5% | 3% | 29 | 184 | 155 | 64.67 | 54.97 | | |
| 2007 | 30% | 17% | 13% | 13% | 0% | 3% | 35 | 167 | 132 | 71.96 | 61.22 | WAC | NET |
| 2008 | 31% | 16% | 14% | 18% | -3% | 4% | 62 | 236 | 174 | 83.04 | 68.81 | 15.4% | 12.4% |
| 2009 | 24% | 14% | 10% | 12% | -3% | 0% | (9) | 207 | 215 | 91.95 | 74.66 | 27.8% | 22.0% |
| 2010 | 7% | 4% | 3% | 10% | -7% | 2% | 42 | 76 | 34 | 100.64 | 76.72 | 39.9% | 25.3% |
| 2011 | 15% | 11% | 4% | 10% | -6% | 3% | 91 | 109 | 18 | 109.98 | 79.37 | 52.8% | 29.7% |
| 2012 | 22% | 6% | 16% | 19% | -4% | 2% | 68 | 508 | 439 | 130.05 | 91.03 | 80.7% | 48.7% |
| 2013 | 26% | 7% | 19% | 25% | -6% | 2% | 59 | 754 | 694 | 160.16 | 107.27 | 122.6% | 75.2% |
| 2014 | 12% | 1% | 11% | 35% | -24% | 2% | 80 | 563 | 484 | 215.74 | 119.28 | 199.8% | 94.8% |
| 2015 | -20% | 1% | -21% | 15% | -37% | 0% | 6 | (1,202) | (1,208) | 248.41 | 93.97 | 245.2% | 53.5% |
| 2016 | -13% | -6% | -6% | 0% | -7% | 1% | 45 | (290) | (334) | 248.45 | 87.48 | 245.2% | 42.9% |
| | | | | | | | $ 304 | $ 731 | $ 428 | | | | |

# Industry Price Actions

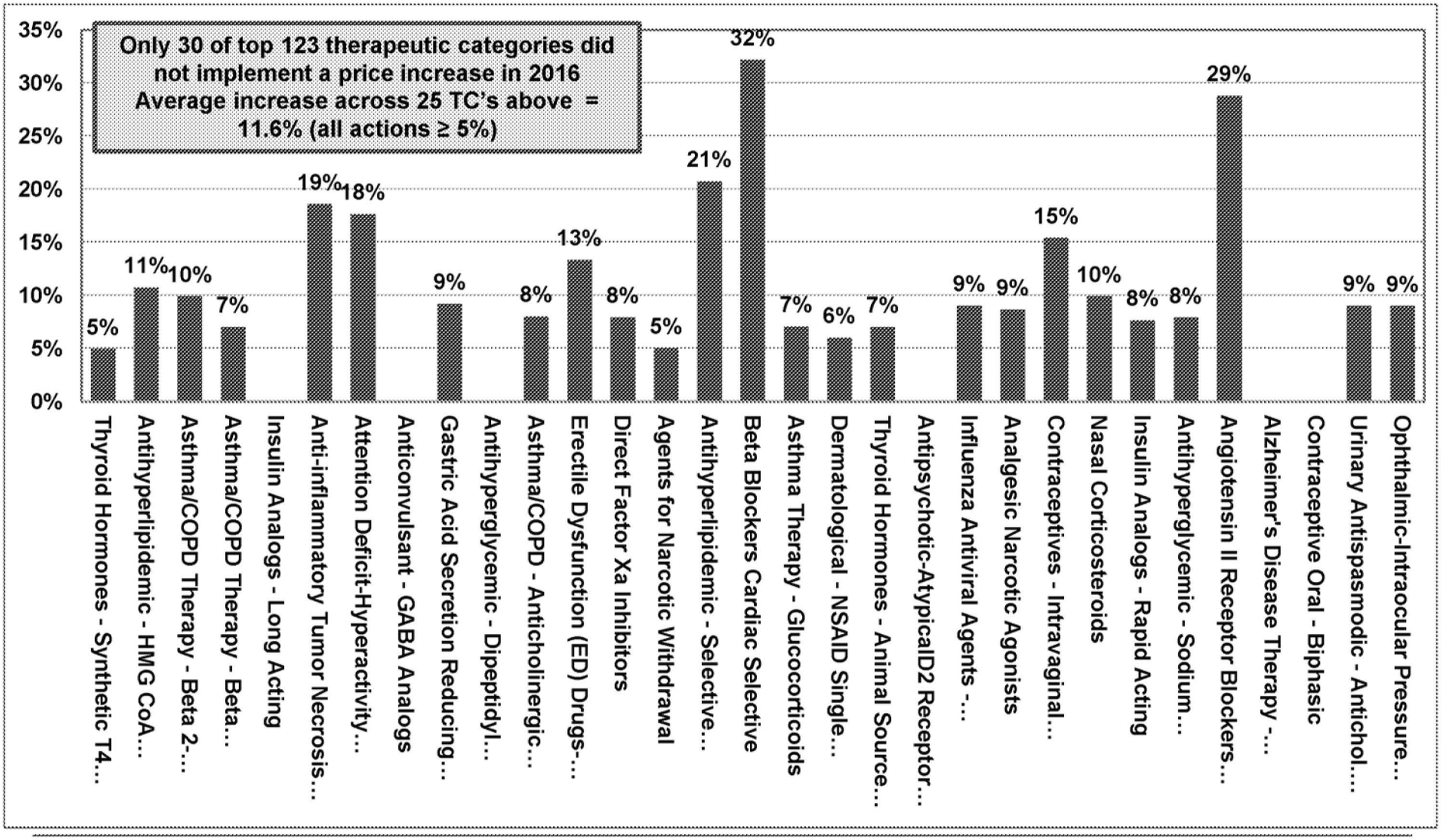
# Pharma Industry price actions…57 of top 200 products took a price increase in January 2017…range from +3.0% to +9.9%...

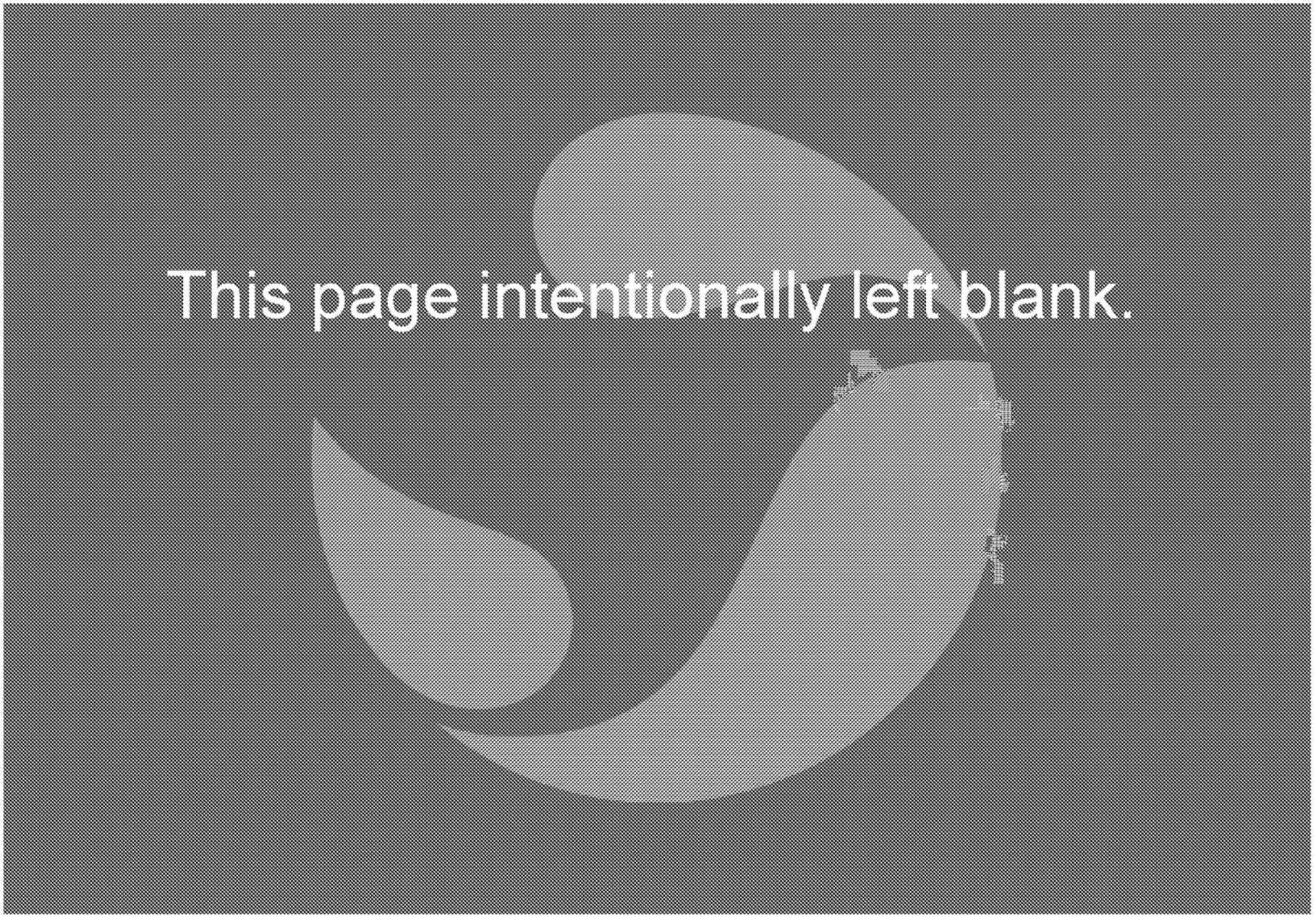


# Top 50 products → price action impacts over 2016…33 products took at least one action…



# 2016 price action impact by therapeutic area…



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Sanofi USPC Recommendation

ESI/[redacted]2017 Glargine Part D Revision
November 16, 2016

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| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus/Toujeo* | *Part D – PST Exclusive* | *Contract Offer Proposal* | *1/1/17 through 12/31/17* |
| **Contracting Strategy:** | *Secure 2017 access for Lantus & Toujeo in Tier 3 Exclusive for [redacted]. Improve ESI's PST Exclusive (1 of 1 Manufacturer) offer* | | |
| **Recommendation:** | **Formulary Status**: Part D – PST Exclusive Portfolio Option (LAN & TJO Bundle) | **Preferred Tier 2. Exclusive Formulary Position.**: Walk IN: 47%* MAX: 48%* *total payment inclusive of 4.875% Admin Fee | **Price Protection (cumulative net)**: 6% |
| **Financial Impact:** | **Baseline Net Sales (3YFF) ESI $331M (43%)**<br><br>**Net Sales Variance to Baseline:**<br>**Scenario 1a:** Increase ESI PST Exclusive - Walk In 47% → -$0.9M<br>**Scenario 1b:** Increase ESI PST Exclusive - Max 48% →-$1.2M<br>**Scenario 2:** Increase [redacted] (SCO) +2% (45%) → -$1.7M | | |

**Customer Background:**

- [redacted] encompasses 39 million medical lives; 1 million of which are enrolled in Part D business.
- Currently this account covers Lantus & Toujeo Exclusive for PDP business. Levemir & Tresiba are non-preferred
- [redacted] will review Sanofi Glargine proposal in late November and may make decision prior to 4Q16. [redacted] sales are ~15% of total ESI in the channel (SEP2016 YTD rebate claims). Anthems PDP sales are approx. 35% of Anthem's Part D sales.

**Current Contract Terms:**

- Lantus & Toujeo – PST Exclusive (1of1 Manufacturer) 44%, 6% PP Cum'l Net (full detailed ESI offer below)

**Proposal Recommendation:**

- Lantus & Toujeo – PST Exclusive (1of1 Manufacturer) 48%, 6% PP Cum'l Net, inclusive of AF (4.875%)

**Rationale for Recommendation:**

- The Part D business accounts for 22% of total [redacted] volume.
- [redacted] recently stated that Basaglar is being considered for 2017 Part D addition to formulary. Account is requesting an increase to the 2017 offer to keep Lantus & Toujeo Exclusive for PDP business and parity with Levemir for MAPD business.
- 35% of [redacted] Part D sales are currently in the PST Exclusive rebate payout cell and represents 100% of the ESI Part D sales for that particular payout cell.
- An offer to increase ESI's PST Exclusive rebate offer only for [redacted] offer would not increase exposure to ESI its remaining clients as no other plans is currently in that payout cell. The PST Exclusive option by Agreement definition requires Lantus/Toujeo exclusivity and all other CPC competitors to be NDC Blocked and/or SE through Preferred Brands (see PST definition below)
- This recommendation is in lieu of offering an increased rebate for all of [redacted], which will have rebates > ESI base business. This approach creates a greater financial risk to SA if such rebates would spills over to the rest of ESI's Part D business.
- Clinically Lantus & Basaglar are very similar so primary differentiation will be cost. [redacted] will choose product with lowest net cost for 2018 Part D.

ESI/[redacted] 2017 Glargine Part D Revision
November 16, 2016

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**Competitive/Market Landscape:**

- Of the Part D business, PDP & MAPD lives are evenly divided 50/50. Lantus and Toujeo are Exclusive on PDP book and Preferred with Levemir on MAPD.
- According to October TPS data, Levemir TRx = apprx 15.6% share and Tresiba = 1.0% share.
- Assumption is that Lilly [redacted] offer will be 57%-60% rebate.

**Financial Assessment:**

| | | ESI [redacted] | | |
|---|---|---|---|---|
| | | YR2017 | YR2017 | YR2017 |
| **GLARGINE** | **Gross Sales** | **$581** | **$87** | **$31** |
| **Baseline** | Rebate % | 43% | 43% | 44% |
| | Net Sales | $331 | $50 | $17 |
| **Scenario 1a: Increase PST Exclusive WALK In - 47%** | | | | variance |
| | Rebate % | | | 47% |
| | Net Sales | | | $16 ($0.92) |
| **Scenario 1b: Increase PST Exclusive MAX - 48%** | | | | |
| | Rebate % | | | 48% |
| | Net Sales | | | $16 ($1.22) |
| **Scenario 2: [redacted] SCO increase +2% pts** | | | | |
| | Rebate % | | 45% | |
| | Net Sales | | $48 | ($1.74) |

**Financial Model Assumptions:**

- Sales calculation based on F216/B17 3YFF ESI for Lantus, Lantus SoloStar and Toujeo 2017
- Assumes [redacted] Formulary access effective 1/1/17 PST Exclusive for its PDP Business.
- Price Predictability at 6% PP cumulative net basis– no pricing actions in forecast (no impact)
- Assume [redacted] is 15% of total ESI Part D and [redacted] PDP PST Exclusive sales are 35% of Anthem's Part D business
- Scenario 1 Walk In & Max - increase only to the PST Exclusive offer from 44% to 47-48% respectively
- Scenario 2 Assumes increasing [redacted] rebates 2% pts across all sales. [redacted] current avg rebate 43%

**Risk Assessment:**

- Market Access Risk: No action may jeopardize 2018 access for LAN/TJO
- Operational Risk: None
- Transparency risk? Risk is low, recommendation integrated as part of the several options under ESI's PSG
- Other: n/a
- Government Financial Risk? None

**ESI 2017 current PSG offer**

Lantus and Toujeo Rebate Table Effective **1/1/2017 through 12/31/2017**

| Rebate Table | Lantus Rebates (Stated as % of WAC) | Toujeo Rebates (Stated as % of WAC) |
|---|---|---|
| PST Exclusive –Portfolio Option | 44.00% | 44.00% |
| Preferred Exclusive – Portfolio Option | 44.00% | 44.00% |
| Preferred 1 of 2 – Portfolio Option | 42.00% | 42.00% |
| Preferred 1 of 3 – Portfolio Option | 39.00% | 39.00% |

*The above rebates include Customer's Administrative Fee.

*Customer's Administrative Fee effective January 1, 2017 shall be 4.875%.

**ESI Defined terms**

**PST** - shall mean a program, developed and administered by ESSC or a Covered Plan, in which the Product must be tried by the Part D Eligible Individual or, as a consequence of not trying the Product: (i) the Part D Eligible Individual is required to pay 100% of the cost of the non-Preferred branded product regardless of whether the applicable deductible has been satisfied, or (ii) the Covered Plan imposes an NDC block against coverage benefits for non-covered products. Provided, however, in each case Part D Eligible Individual may obtain the non-Preferred or non-covered product when medically necessary. Existing users of a non-Preferred or non-covered branded product will not be grandfathered beyond statutory requirements, unless mutually agreed otherwise.

**Preferred** - refers to a Product that adjudicates at the lowest co-pay or coinsurance tier for branded products within its designated CPC.

**Sanofi USPC White Paper**
**Express Scripts Commercial**
Lantus/Toujeo Contract Offer
April 21, 2016

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**EXECUTIVE SUMMARY**

| Brand(s) | Customer / Channel | Type of Request | Time Period |
|---|---|---|---|
| Lantus/Toujeo | Express Scripts/Commercial | 2017 Bid Proposal | 1/1/17 to 12/31/18 |

**Glargine Brand Objective:**
Protect glargine family access from increasing payer control and disrupt competitive access to maintain the broadest Tier 2 coverage

**Commercial Channel Strategy:**
Leverage market leader position of the glargine franchise to maintain current preferred access and manage profitability. Ensure patients continue to have unrestricted access to Lantus & Toujeo at the lowest branded copay to minimize treatment disruption

**Pivotal Question:**
ESI has submitted its 2017 basal bid solicitation and has indicated its desire to add only one insulin glargine product to its basal insulin category (Lantus or Basaglar). What is the appropriate level of rebate for Sanofi to offer ESI to maintain its current glargine family formulary status?

**Customer Insight**

- ESI has stated that a 42% rate would be insufficient
- ESI has utilized an exclusion list on market leaders (e.g., Victoza)
- ESI has informed Sanofi they intend to include only one insulin glargine on formulary

**Recommendation:**

Respond to ESI Commercial 2 Year Bid Cycle (2017-2018).

**Current Contract *: (across Open, Controlled and Closed). Blended rate = 35.2%**

| Product | Rate Type | 1 of Many | 1 of 3 Mfgs | 1 of 2 Mfgs | 1 of 1 Mfgs |
|---|---|---|---|---|---|
| Lantus | Base Rate | No Bid | No Bid | 36.0% | 42.0% |
| Toujeo | Base Rate | No Bid | No Bid | 34.0% | 40.0% |

*all rates inclusive of an ESI Administrative Fee of 4.875%
6% Cumulative Net price protection

**Proposed*: (ESI portfolio rate† across Open, Controlled and Closed)**
Average total ESI blended for walk-in = 42%
Average total ESI blended for fall back = 46%

Differentiate rates based on plans active exclusion of products in the injectable anti-diabetic category

| Product | Rate Type | 1 of Many | 1 of 3 Mfgs | 1 of 2 Mfgs | 1 of 1 Mfgs |
|---|---|---|---|---|---|
| Lantus | Base Rate | No Bid | Walk-In: 36% (avg), 38% (max)** | Walk-In: 41% (avg), 44% (max)** | Walk-In: 45%,(avg), 48%(max)** |
| | | | Fall Back: 38% (avg), 40% (max)** | Fall back: 45% (avg) 48% (max)** | Fallback: 49% (avg), 52% (max)** |
| Toujeo | Base Rate | No Bid | Walk-In: 36% (avg), 38% (max)** | Walk-In: 41% (avg), 44% (max)** | Walk-In: 45%,(avg), 48%(max)** |
| | | | Fall Back: 38% (avg), 40% (max)** | Fall back: 45% (avg) 48% (max)** | Fallback: 49% (avg), 52% (max)** |

*all rates inclusive of an ESI Administrative Fee of 4.875%
† all offers contingent upon all forms of Lantus, Lantus SoloStar and Toujeo being on preferred brand formulary tier
6% Cumulative Net price protection
** Maximum rate is for qualified plans only (plans that utilize exclusions in injectable anti-diabetics) Average numbers represent a weighting across all plans per manufacturer status

**Financial Impact:**

***Baseline F215/B16 3YFF → 48.4% 2017 and 52.3% 2018 blended average rate – Preferred Savings Grid***
***Net$: 2017 3YFF $530M, 2018 3YFF $420 → 2017-18 cumulative: $950M***

***Variance to Baseline (Net Sales):***
***Scenario 1 (Walk-In)*** *(Analog used: 74% downside – plans utilizing exclusions assumed to cover 55% of volume)*
*(1of2) 41%,(1of1) 45%, (1of3) 36%,* ***42% blended avg****:*

| | |
|---|---|
| | *2017: +$70M, 2018: +$93M → 2017-18 cumulative: +$163M*<br><br>***Scenario 2 (Fall Back)*** *(Assumptions: 80% downside, Novo rebate increase +10% -plans utilizing exclusions assumed to cover 69% of volume)*<br>*(1of2) 45%, (1of1) 49%, (1of3) 38%,* ***46% blended avg***<br>*2017: +$29M, 2018: +$58M → 2017-18 cumulative: +$87M*<br><br>***No Contract, 74% downside*** *(Assumptions: plans utilizing exclusions assumed to cover 55% of volume)*<br>*2017: -$19M, 2018: -$63M → 2017-18 cumulative: -$82M*<br><br>***No Contract, 80% downside*** *(Assumptions: Novo rebate increase +10%, plans utilizing exclusions assumed to cover 69% of volume)*<br>*2017: -$114M, 2018: -$151M → 2017-18 cumulative: -$265M* |

**Account Background and Insights:**

- ESI is a national PBM that manages ~80.8 Million Lives
- ESI has three types of national formularies (Basic, Preferred and High Performance)
    - Basic (10.9M lives)– similar to Preferred formulary without exclusion capabilities
    - Preferred (20.1M)- majority of ESI managed lives with exclusion capabilities - most custom clients will align to this formulary
    - High Performance (1.1M) - generic first formulary (Note: Lantus covered - single source status)
- ESI custom clients (Anthem, BCBSMA, etc...) represent 60% of total (49M Lives). Anthem accounts for 12M Lives or 15% of total ESI
- Most of ESI utilization (~82%) is in the controlled benefit design with a co-pay variance from Preferred Branded tier to Non Preferred Branded tier of > $20. The average tier 2 brand Co-Pay is ~$23
- FY15 Sanofi basal insulin share = 78%; 76% Lantus and 2% Toujeo (Source - ESI portal data)
- Toujeo and Lantus are currently on the ESI commercial formularies and covered in a preferred tier 2 position for the majority of the ESI commercial lives. Toujeo was added to Commercial formulary in June 2015.
- Express Scripts appears to favor Lilly brands over Novo's across diabetes categories. For example in the rapid acting insulin market ESI has excluded Novolog and in the GLP-1 market they excluded Novo's market leader Victoza despite positive CV outcomes data. Lilly is well positioned to provide a portfolio manufacturer opportunity once Basaglar is commercially available.

**Likely Competitive Approach and Response:**

- Lilly is actively engaged with ESI for 2017 commercial business. Pricing has not been confirmed however ESI has informed that the following assumptions pose a threat to Sanofi's glargine franchise:
    - Discounts for Basaglar in the mid 60's have been communicated by ESI to Sanofi. This is likely a starter for ESI to consider excluding Lantus and Toujeo. Modeling assumed 70%.
    - Basaglar WAC will be 15% to 25% less than the WAC price of Lantus. Sanofi modeling assumed 15%.
- ESI has signaled, with the right competitive price, they would not have significant challenges moving to Basaglar in 2017 despite a follow-on biologic (Basaglar) approval.
- In addition ESI has indicated that Novo must also enhance its current rate to maintain current access for their basal insulin(s). Novo is likely to enhance its current rebates given recent Tresiba addition to part D formulary.

**Current Formulary Coverage for Basal Insulins:**

| 2016 | ESI National Formularies | 85% of Rxs | 15% of Rxs |
|---|---|---|---|
| | | 1 of 2 MFG (FY15 Mkt Shr) | 1 of 1 MFG (FY15 Mkt Shr) |
| Lantus Vials | Preferred Brand Tier | 72% | 85% |
| Lantus Solostar | Preferred Brand Tier | | |
| Toujeo | Preferred Brand Tier | 3% | 2% |
| Levemir | Preferred Brand Tier | 25% | 13% |
| Tresiba | Non-Preferred Brand Tier | 0% | 0% |

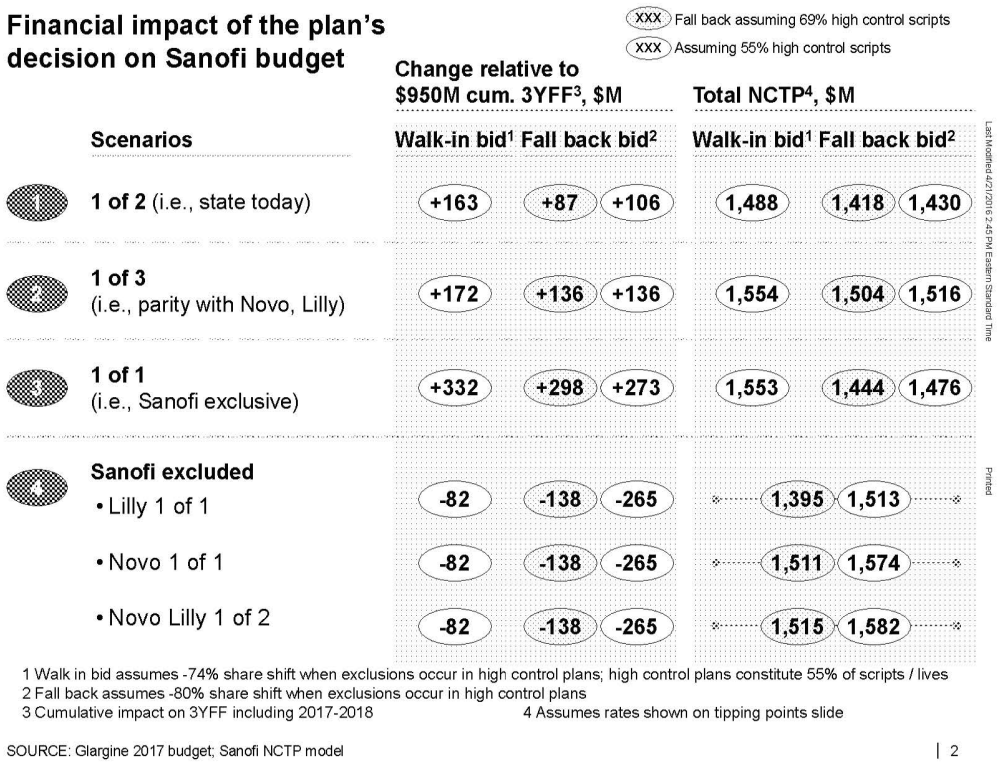
**Rationale for Recommendation:**

- Based on differentiated level of control exercised by different plans, and to add granularity to the bid negotiation, a differentiated bid is proposed that gives higher rates to plans that have demonstrated the willingness and ability to control injectable anti-diabetics through use of exclusions (i.e., NDC block, 100% patient OOP)
- ESI must show its clients significant savings in the basal market and therefore they seek to leverage the follow-on biologic entry in negotiations. ESI has made public comments (see appendix below) to support follow-on-biologics and has stated that they can manage the basal insulin class.
- With the pending commercial availability of Basaglar (2017), ESI has indicated that the basal insulin category is being considered as an exclusion therapeutic category for 2017 and confirmed that their clients are demanding cost relief thus pressuring ESI to secure lower costs for this category.
- ESI stated they are currently planning to adopt only one glargine product for their 2017 commercial formulary. They stated it will be either Sanofi or Lilly. ESI stated clients will accept the change from Lantus/Toujeo due to the potential saving they will get with Basaglar as Lantus is currently the number one drug spend for ESI (Source: 2015 ESI Drug Trend Report).
- We (Sanofi) intend to make the case to ESI that they can keep Lantus/Toujeo for their clients by providing competitive pricing, which will allow them to achieve their goals for clients without disrupting the market. **In discussions, ESI has stated that a 42% rate would be insufficient.**
- ESI stated Lilly will be very aggressive to acquire an exclusive glargine formulary status. They also shared that Lilly recognizes that they will have limited opportunity to drive share with parity status. ESI insinuated that Lilly recognizes they have to win in some markets or with some key payers.
- ESI is likely to be a primary access target for Lilly due to their strong business relationship. There is speculation that Lilly may be willing to discount deeper for Basaglar with this PBM. Toujeo formulary access is at risk post follow-on biologic. Additional clinical meetings to support Toujeo's current position are being scheduled.
- When asked, ESI stated conversion from vial to pen is not an issue for clients. They stated they could switch vials to pens with no problem based on co-pay incentives. Current vial utilization is 31% of total vs. national distribution of 45%. Levemir vial utilization is 18% at ESI. The hypothesis has been raised that patients currently using Lantus vials may not be willing to convert to an alternative pen device form, thus making the vial utilization 'sticky.' However, no evidence has been able to support this hypothesis.

**Risk Assessment:**

- In addition to a possible loss of access at ESI, there will be increased pressure to maintain access at all other national PBMs (i.e. Caremark and OptumRx).
- A loss of Lantus/Toujeo access will impact future product launches (i.e. Lixi, iGlarLixi, etc.).
- Basaglar availability introduces exclusion possibilities for the basal insulin category in 2017.
- The majority of lives are highly managed (i.e. copay differentials and NDC block). Client plans can choose between exclusion list formularies or a basic formulary with non-formulary products covered at higher co-pay tiers. Products which are excluded are NDC blocked with 100% OOP to patients.

**Net Cost to Plan Assessment:**
**(Note: figures based on IMS Plantrak data)**




**NCTP Assumptions** (supporting documentation is listed below)**:**

- Rebates**:** Rebate values for Sanofi's modeling can be found in the tables below. In most cases, these values correspond to the midpoint of the ranges McKinsey have used in their modeling (as seen below).

- Plans' ability to exclude (NDC block): Based on analysis of the ESI portal data, we have found that between **55%** (based on historical performance in injectable diabetic category) and **69%** (based on understanding of the account and levels of control) of TRx volume passes through plans that can **exclude** across ESI.

- Downside analogs (for walk-in scenarios): The assumed downside analogs that McKinsey have used in their analysis assume:
  - Tier 2 to not covered (NDC block) leads to a share shift of -74% after 4 months
  - Tier 2 to Tier 3 leads to a share shift of -30% after 4 months.

- Downside analogs (for fall back scenarios): The assumed downside analogs assume:
  - Tier 2 to not covered (NDC block) leads to a share shift of -80% after 4 months, based on ESI control seen in rapid-acting insulin exclusion scenarios
  - Tier 2 to Tier 3 leads to a share shift of -30% after 4 months.

**Competitive Rebate Assumptions:**

## A blended rate of 41% will satisfy plan economics to place Sanofi at 1 of 2 parity

Plan minimum rebate relative to bids to exclude Sanofi; sticky vials[1]
Plan minimum rebate relative to bids to exclude Sanofi; non-sticky vials
Sanofi break-even rebate relative to today

**Summary: Sanofi bid tipping points vs. competitive threat scenarios**

| | Threat scenarios: Threat description | Lilly bid in scenario[4] | Novo bid in scenario[4] | Novo bid 1 of 2 parity with SNY[4] | Plan tipping point[5], % |
|---|---|---|---|---|---|
| Plans with high level of control[3] | Lilly 1 of 1 threat (Lilly T2, SNY Novo NC)[1] | 70% | 0% | 0% | 35, 47, 53 |
| | Novo 1 of 1 threat (Novo T2, SNY Novo NC) | 0% | 68% | 68% | 35, 43 |
| | Novo + Lilly 1 of 2 threat (Novo Lilly T2, SNY NC) | 65% | 63% | 63% | 35, 45 |
| Plans with low level of control[3] | Lilly 1 of 1 threat (Lilly T2, SNY Novo T3)[2] | 65% | 0% | 0% | 18, 35 |
| | Novo 1 of 1 threat (Novo T2, SNY Lilly T3) | 0% | 48% | 48% | 24, 35 |
| | Novo + Lilly 1 of 2 threat (Novo Lilly T2, SNY T3) | 55% | 43% | 43% | 19, 35 |

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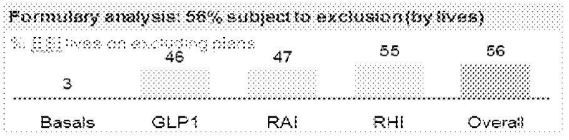
1 Sticky vial bar assumes 50% of vials are retained by Novo and Sanofi 2 Assumes a consistent 30% drop in vials and pens (i.e., no additional "stickiness")
3 High level of control plans = plans that have NDC blocks in injectable antidiabetics (i.e., credible threat of implementing basal exclusion list); exclusion results in -74% share drop; low level of control plans have ability to deliver a -30% share drop only
4 Average of likely bid range used for modeling shown
5 Compared to Novo likely 1 of 2 bid of 48% for high control plans and 38% for low control plans; average of range of tipping points

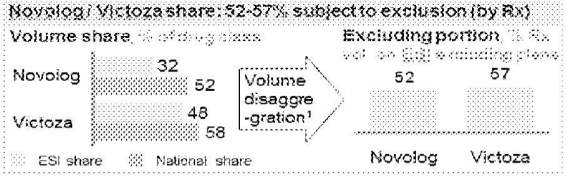
SOURCE: Payor 360 analysis

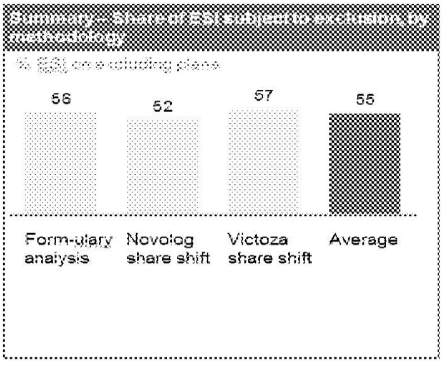
**Plan's Ability to Exclude Assumptions:**

**Historical ESI Performance**

## The share of ESI volume subject to exclusion is ~55%, based on current access of injectable anti-diabetics drugs




1 Excluding select public and EGWP plans where data is unavailable
2 Assuming 75% share drop when fast-acting insulins are excluded
3 Assuming 30% share drop when GLP1's are excluded

SOURCE: MMIT; IMS Plantrak

SA Internal assessment of ESI Bid request, rebate data submission and formulary design

*Source: ESI Portal Data and SA Rebate Claims Data (Jan 2015 – Feb 2016)*

**Potential Plan Volume That Can Exclude**

## Utilization and distribution of lives across ESI.

*How Sanofi contracts*

*How ESI markets to clients*

| | | | | |
|---|---|---|---|---|
| [illegible] | 1% | 7% | 0% | 8% |
| [illegible] | [illegible] | [illegible] | [illegible] | 35% |
| [illegible] | [illegible] | [illegible] | [illegible] | 2% |
| [illegible] | 9% | 11% | [illegible] | 18% |
| [illegible] | 0% | 38% | [illegible] | 47% |
| | 1% | 83% | 17% | 100% |

| | | |
|---|---|---|
| [illegible] | 10.9 | 13% |
| [illegible] | 20.1 | 25% |
| [illegible] | 1.1 | 1% |
| [illegible] | 12 | 15% |
| [illegible] | 36.7 | 45% |
| [illegible] | 80.8 | 100% |

| [illegible] | [illegible] |
|---|---|
| No Exclusions | 0% |
| 50% Excluding | 23% |
| 100% Excluding | 46% |

Custom plans, which represent the majority of the utilization, represents an uncertainty in our assumptions. We estimate 69% of the business has the capability to NDC block.

SANOFI [illegible] USMarket Access

**Downside Analog Assumptions:**

## Past exclusions in basals indicate an average share loss of ~74% across both part D and Commercial plans, with up to ~80% in aggressive cases

**Part D exclusion examples – excluded before March 2014[1]**

| | Plan name | Market share 11/15, % | Share drop relative to national share[2,3], % |
|---|---|---|---|
| Levemir | • Anthem Blue Cross MedicareRx Standard | 9 | 71 |
| | • SummaCare Medicare Ruby | 6 | 79 |
| | • Medica Dual Solution | 6 | 79 |
| Lantus | • Coventry Medicare Advantage | 22 | 68 |
| | • Aetna Medicare Select Plan - Standard 2 | 20 | 72 |
| | • Aetna Medicare (Rx Saver, Value, Standard) | 19 | 73 |
| | • Aetna Medicare Essential Plan | 17 | 76 |

**Commercial exclusion examples**

| | Plan | Date of shift | Share before shift, % | Share after 12 months, % | Share drop after 12 months, % |
|---|---|---|---|---|---|
| Levemir | BCBS (MA) | May 14 | 16% | 5% | 72 |
| | Priority health (MI) | Jan 15 | 11% | 2% | 77 |
| Lantus | Health first | Oct 14 | 19% | 7% | 65 |

**ESI exclusion examples – outside basals – based on % of lives which excluded**

| | Plan | Share before shift, % | Share post shift, % | Share drop % |
|---|---|---|---|---|
| Victoza | ESI | 44% | 24% | 45 |
| Novolog | ESI | 52%[1] | 9% | 83 |

**~74% drop in share assumed** for ESI high control commercial plans

The maximum observed share shift, assuming very aggressive behavior from the plan, is up to ~80% (avg of top 4 analogues)

1 Data not available before March 2014; change in share is assumed to be difference in current share from current national average
2 Calculated as plan 1 -(plan market share 11/15 / national market share) 3 Assumes national share is 71% for Lantus, 29% for Levemir McKinsey & Company | 9
SOURCE: IMS; Plantrak; MMIT

**Financial Assessment:**

**Recommended bids for ESI Commercial**

| | | Recommended bids[1] | | | |
|---|---|---|---|---|---|
| | | Walk-in bid, % | | Fall back bid, % | |
| 1 of 3 | High control plans | 38 | Blend 36 | 40 | Blend 38 |
| | Low control plans | 33 | | 35 | |
| 1 of 2 | High control plans | 44 | Blend 41 | 48 | Blend 45 |
| | Low control plans | 37 | | 39 | |
| 1 of 1 | High control plans | 48 | Blend 45 | 52 | Blend 49 |
| | Low control plans | 41 | | 43 | |
| Share shift assumption | | -74 | | -80 | |
| Total ESI blended rate[2] | | 42 | | 46 | |
| Impact on 3YFF[3], $M | | 55% high control lives: +163<br>69% high control lives: +145 | | 55% high control lives: +106<br>69% high control lives: +87 | |

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1 Walk-in recommended bid blends assume 55% volume and lives in high control plans (i.e., plans that have exclusions for antidiabetics) and 69% for fall back bids
2 Assumes 15% of current ESI scripts are on plans taking 1 of 1 rates; remaining 85% are on plans taking 1 of 2 rates
3 Cumulative impact on 3YFF including 2017-2018

SOURCE: Payor 360; Glargine 2017 budget

**Financial Assumptions:**

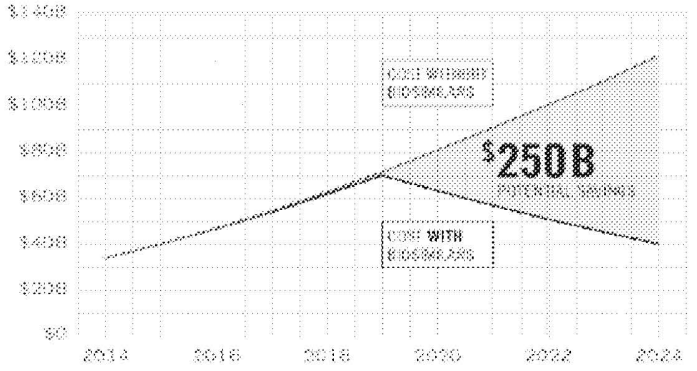
- **General Assumptions**:
  - Walk In bid assumes 55% of ESI lives have ability to exclude control and a downside analog of 74% for those exclusion capable plans. For the remaining 45% of lives, a loss of access would result in copays shifting from Preferred Tier to Non Preferred Tier at a copay differential of $20 with a downside analog of 30%.
  - Fall back bid assumes 69% of ESI lives have ability to exclude control and a downside analog of 80% for those exclusion capable plans. For the remaining 31% of lives, a loss of access would result in copays shifting from Preferred Tier to Non Preferred Tier at a copay differential of $20 with a downside analog of 30%.
  - No price increases assumed for Lantus and Toujeo (4/14/16 through Dec 31 2018). Price protection of 6% Cumulative Net is provided on all offers.
  - ESI Lantus utilization distribution between 1of2 and 1of1 is 85/15% for Lantus and Toujeo. Distribution is held constant for 2017 and 2018
  - Rebate %s represents the aggregated total payment for ESI. Total payments includes an Admin Fee % of 4.875% and Price Protection rebates (where applicable).

**Appendix**

JP Morgan HealthCare Conference 01.11.16 – ESI

## Core PBM opportunity : Biosimilar adoption

### Biosimilars Represent the Next "Generic Wave"




Source: Express Scripts research

- >4X increase in U.S. specialty prescription spend since 2006
- 30% average discount for biosimilars in countries where they are available
- $250 billion could be saved in the next decade if just 11 biosimilars are approved
- $45 million in wasted spend for each day Zarxio, America's first biosimilar, was delayed approval
- 160 biosimilars in development for six top-selling biologics

**We are best-in-class at leveraging drug competition**

**Sanofi BU PRB Whitepaper**

Commercial Contract 2017

| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| All Contract Products | Commercial | Admin Fee | 1/1/2017 – 12/31/2017*<br>*Contract Term Date |
| **Contracting Strategy:** | 2017 Commercial Bid | | |
| **Recommendation:** | Increase administrative fee from 3.00% to 4.75% effective January 1, 2017<br>Alignment for all Sanofi Business Units | | |
| **Financial Impact:** | Estimated 2017 Gross Sales of $495.4M → Incremental impact of **~$8.7M**<br>• Apidra $1.7M Gross $ →Admin Fee impact **~$0.1M**<br>• Lantus $291.5M Gross $ →Admin Fee impact **~$5.1M**<br>• [redacted]<br>• Toujeo $69.6M Gross $ →Admin Fee impact **~$1.2M** | | |

**Customer Background:**

- OptumRx provides pharmacy benefit management (PBM) services for more than 41 million people nationwide. This business processes more than 600 million adjusted retail, mail and specialty drug prescriptions annually through a network of more than 67,000 retail pharmacies, and operates two state-of-the-art mail service facilities.

**Lives:**

- As of January 1, 2016, OptumRx total external and United Commercial lives are 28.1M
  - 1.5M (5.3%) Premium
  - 19.5M (69.4%) Highly Managed
  - 1.8M (6.4%) Focused UM
  - 4.1M (14.6%) Managed
  - 1.2 M (4.3%) Covered

**Formulary Management Capability:**

- Utilization Management capabilities include but not limited to: Step Edits, Quantity Limits, Prior Authorizations, NDC Blocks and Exclusion.

**Rationale for Recommendation:**

- The recommendation is in response to the customer's request to increase Admin Fees from 3.00% to 4.75%.
- Factors leading to the reassessment and increase include:
  - Alignment with market competitive rates
    - [redacted] Caremark →4% ESI →4.875% *note that ESI rate increased in 2016 by .5points*
  - Request of manufacturers to provide increased transparency to client-level compliance with rebate eligibility from prior levels
  - Increased number of manufacturer requested audits
  - Increased complexity of manufacturer required conditions for rebate eligibility
- The incremental 1.75% is <u>not</u> negotiable. If we do not agree to the 1.75% it will be captured from product(s) base rebate.

**Risks:**

- Admin Fee Increase will be expected for new products.
- Risk of setting PBM administrative fee precedent for current/future business [redacted]
  - Estimate additional annual exposure if Caremark requests a similar rate: ~$7.2M (Appendix)
  - [redacted]
- **Legal Issues:**
  - [redacted]
  - [redacted]

Privileged

**Potential Negotiation Strategy:**

- Lower rate (Walk in) of 4% to align w/ Caremark
- Fixed Admin Fee Rate: Clause in Contract that locks rate at 4.75% for term of agreement

**Financial Assessment:**

- Cost of incremental 1.75% Administrative Fee for OptumRx

| | 2017 Incremental Cost |
|---|---|
| Apidra | 0.1M |
| Lantus | 5.1M |
| [redacted] | |
| Toujeo | 1.2M |
| [redacted] | |

**Financial Model Assumptions:**

- Assume incremental 1.75% Admin Fee across entire Managed Care and State Exchange business.
- 2017 and 2018 Gross Sales taken from 3YFF (F2'15/B'16)

## Appendix

**Risk if Administrative Fees increase to 4.75% for other PBM's**

| Caremark | 2017 Gross Sales | Current Admin Fee | Admin Fee Increase | Impact |
|---|---|---|---|---|
| Apidra | 20.4M | 4.00% | 0.75% | 0.2M |
| Lantus | 579.9M | 4.00% | 0.75% | 4.3M |
| [redacted] | | | | |
| Toujeo | 164.7M | 4.00% | 0.75% | 1.2M |

| OptumRx | 2017 Gross Sales | Current Admin Fee | Admin Fee Increase | Impact |
|---|---|---|---|---|
| Apidra | 3.3M | 3.00% | 1.75% | 0.1M |
| Lantus | 291.5M | 3.00% | 1.75% | 5.1M |
| [redacted] | | | | |
| Toujeo | 69.6M | 3.00% | 1.75% | 1.2M |

| Prime | 2017 Gross Sales | Current Admin Fee | Admin Fee Increase | Impact |
|---|---|---|---|---|
| Apidra | 2.5M | 3.00% | 1.75% | 0.0M |
| Lantus | 267.3M | 3.00% | 1.75% | 4.7M |
| [redacted] | | | | |
| Toujeo | 131.1M | 3.00% | 1.75% | 2.3M |

**Data Source: F2/B'16 3YFF**

**Sanofi USPC Recommendation**

Cigna-HealthSpring 2017-2019 Lantus/Toujeo & [redacted] Contract Offer

January 25th, 2016

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| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus/Toujeo* [redacted] | *Cigna–HealthSpring – Medicare* | *Contract Offer Proposal* | *1/01/2017 – 12/31/2019* |
| **Contracting Strategy:** | *Lantus and Toujeo – Maintain Access in transforming marketplace by offering a portfolio deal*<br>*Renvela – Maintain Access in transforming marketplace.* | | |

**Recommendation:**

| Rebate Offer | Lantus/Toujeo Preferred Brand - 1 of 1 Manf. | Lantus/Toujeo Preferred Brand 1 of 2 Manf. | Cumulative Price Protection (w/ relief) |
|---|---|---|---|
| **INITIAL BID** | | 28%<br>Already submitted | 8% |
| **REVISED OFFER** | 40% | 32% | 4% (outside of guidelines) |

[redacted]

***RISK:*** *Cigna is threatening to move forward with their 2017 formulary submission to CMS without including Lantus/Toujeo,* [redacted]

**Financial Impact:**

*Lantus/Toujeo:*

*Baseline Net: 2017…$169.6M; 2018…$152.5M; Cumulative…$322.1M*

*Opt 1 variance vs. Baseline (1 of 2, increased rebate to 32%): 2017…-$9.4M; 2018…-$8.5M; Cumulative…-$17.9M*

*Opt 2 (1 of 2 to Exclusive @ 40%): 2017…-$23.3M; 2018…-$21.3M; Cumulative…-$44.6M*

*NC: 2017…-$103.6M; 2018…-$64.5M; Cumulative…-$168.1M*

[redacted]

**Sanofi USPC Recommendation**

Cigna-HealthSpring 2017-2019 Lantus/Toujeo & [redacted] Contract Offer

January 25th, 2016

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**Customer Background:**

- Cigna-HealthSpring, (Cigna's Medicare division), is the nation's 5th largest Medicare Provider
- Over 1 million, (56%) of their lives are covered as Low Income Subsidy, ranked 2nd with regards to the % of Low Income Subsidy lives
- Cigna-HealthSpring's internal PBM provides pharmacy coverage through their in-house PBM for 2 million Pharmacy lives.
- PDP and MA-PD – Majority of plans are 5-Tier benefit designs with Tier-3 as Preferred Brand tier, the lowest cost branded tier
    - Average Co-Pay for Preferred Brand Tier is $45 for ~ 500,000 MAPD Lives
    - Average Co-Insurance is 20% for ~ 1.45 Million PDP Lives
        - 65% of PDP lives are Low Income Subsidy with a maximum "Out of Pocket" Co-Pay for Brand is $6.60
            - Exceptions:
                - Cigna-HealthSpring Leon Cares Formulary for ~44,000 lives in Miami (Tier-2 = Preferred Brand) - $10
                - Achieve Plan Formulary for ~ 5,500 lives in Pennsylvania and ~3,000 in MD/DC/DE (Tier-6 = Diabetes Tier) - $10
- Top states and their top MSAs for Cigna-HealthSpring MAPD
    - Geographic Influence
        - MAPD

| State | Enrollment | Largest Markets (MSAs) | MSA Rank |
|---|---|---|---|
| TX | 107,157 | Houston-Sugar Land-Baytown, TX - 43,927 | #2 |
| TN | 89,857 | Nashville-Davidson- Murfreesboro, TN – 52,225 | #1 |
| PA | 56,481 | Philadelphia, MSA PA, DE, MD – 59,484 | #2 |
| AL | 52,572 | Mobile-Fairhope, AL – 13,555 | #1 |
| | | Birmingham-Hoover, AL – 12,188 | #4 |
| FL | 50,233 | Miami-Miami Beach-Kendall, FL – 44,570 | #3 |
| IL | 26,312 | Chicago-Naperville-Joliet, IL – 25,384 | #3 |
| MD | 14,444 | Baltimore-Towson, MD – 11,433 | #2 |

    - Largest Stand-Alone PDP Enrollment for Cigna

| State | Enrollment | State | Enrollment |
|---|---|---|---|
| New York | 154,613 | North Carolina | 63,415 |
| Texas | 143,035 | Pennsylvania | 56,549 |
| Illinois | 106,131 | Mississippi | 46,357 |
| Tennessee | 72,847 | Alabama44,542 | |
| Michigan | 72,338 | Virginia | 41,127 |

    - Formulary Management Capability:
        - Cigna-HealthSpring utilization management tools include Medical/Lab criteria, Step Edits, Quantity Limits, Prior Authorizations, NDC Blocks, and Exclusion to control their formularies.
        - Cigna-HealthSpring will be able to effectively lock down the formulary if they decide to go to exclusivity.

**Current Contract Terms:**

- **Lantus/Toujeo**
    - **28% - Preferred Brand Manufacturers, 1 of 2**
- [redacted]

**Sanofi USPC Recommendation**

Cigna-HealthSpring 2017-2019 Lantus/Toujeo & [redacted] Contract Offer

January 25th, 2016

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**Competitive/Market Landscape:**

[redacted]

**Rationale for Recommendation:**

- Customer stated that this needs to be our best and final offer.
- Cigna stated that they have allowed quite a few years of price increases; new entrants to the phosphate binder class and with competitive offers from Novo for their long acting forms of insulin, as well as bio-similar agents on the horizon, they feel they will have enough to offer providers and members to justify moving Renvela and Lantus/Toujeo off of formulary.

**Lantus/Toujeo Financial Assessment:**

| | 2016 | | | | 2017 | | | | 2018 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales ($M) | Total Payments ($M) | Total Payments (%) | Net Sales ($M) | Gross Sales ($M) | Total Payments ($M) | Total Payments (%) | Net Sales ($M) | Gross Sales ($M) | Total Payments ($M) | Total Payments (%) | Net Sales ($M) |
| Baseline (1of 2 Manf. @ 28%) | 259.5 | 72.7 | 28.0% | 186.8 | 235.6 | 66.0 | 28.0% | 169.6 | 211.8 | 59.3 | 28.0% | 152.5 |
| No Contract (NC) | 259.5 | 0.0 | 0.0% | 259.5 | 66.0 | 0.0 | 0.0% | 66.0 | 61.4 | 0.0 | 0.0% | 61.4 |
| Variance to Baseline | 0.0 | -72.7 | -28.0% | 72.7 | -169.6 | -66.0 | -28.0% | -103.6 | -150.4 | -59.3 | -28.0% | -91.1 |
| Option 1 (1of 2 Manf @ 32%) | 259.5 | 72.7 | 28.0% | 186.8 | 235.6 | 75.4 | 32.0% | 160.2 | 211.8 | 67.8 | 32.0% | 144.0 |
| Variance to Baseline | 0.0 | 0.0 | 0.0% | 0.0 | 0.0 | 9.4 | 4.0% | -9.4 | 0.0 | 8.5 | 4.0% | -8.5 |
| Variance to No Contract | 0.0 | 72.7 | 28.0% | -72.7 | 169.6 | 75.4 | 32.0% | 94.2 | 150.4 | 67.8 | 32.0% | 82.6 |
| Option 2 (1 of 1 Manf. @ 40%) | 259.5 | 72.7 | 28.0% | 186.8 | 243.9 | 97.6 | 40.0% | 146.4 | 218.7 | 87.5 | 40.0% | 131.2 |
| Variance to Baseline | 0.0 | 0.0 | 0.0% | 0.0 | 8.3 | 31.6 | 12.0% | -23.3 | 6.9 | 28.2 | 12.0% | -21.3 |
| Variance to No Contract | 0.0 | 72.7 | 28.0% | -72.7 | 177.9 | 97.6 | 40.0% | 80.3 | 157.2 | 87.5 | 40.0% | 69.8 |

**Lantus/ Toujeo Financial Model Assumptions:**

- Baseline represents Final Bottoms-up F2'15 forecast (2015-2018) for Lantus & Toujeo co-preferred with Levemir
- Baseline incorporates FOB market events for 2017 & 2018
- No pricing actions on either brand (2015-2018)
- Lantus/Toujeo NC Scenario - X-Factor – HealthSpring Levemir Family T2 to NC analog (2010-2011)
- Option 1: Same as baseline; increased rebate to 32%; Lantus and Toujeo, 1 of 2 manufacturers
- Option 2: Lantus/Toujeo 1 of 2 to Exclusive; Levemir & basaglar NC – X-Factor analog above applied in reverse to Lantus and Toujeo. Upside applied 2/3rd to Lantus and 1/3rd to Toujeo.

[redacted]

**Sanofi USPC Whitepaper**

Anthem.

Medicare Part D Contract Offer

January 21, 2016

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| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Toujeo & Lantus* | *ESI SCO Anthem Medicare Part D* | *Contract Offer Proposal* | *1/1/17 to 12/31/17* |
| **Contracting Strategy:** | *Maintain preferred brand tier access for insulin glargine Franchise (Lantus and Toujeo)* | | |
| **Recommendation:** | [redacted] | | |
| **Financial Impact:** | | | |

**Customer Background:**

- Anthem is currently a top 10 Part D plan with approximately 1M lives. <15 % are LIS.
- Anthem lives are evenly split between MA-PD and PDP lives though trending year to year towards increasing MA-PD and declining PDP business.
- Anthem has made an offer to acquire Cigna. There are significant regulatory hurdles that would have to be overcome but if successful would more than double Anthem's Medicare business (from 1m to 2.5m).
    - The deal is expected to close in late 2016.

[redacted]

**Formulary Management Capability**

- All lives are highly managed with all non-contracted products not listed on formulary. Exceptions are much less likely to get through Part D than commercial.
- Anthem Medicare uses a 5 tier formulary 1st: Preferred Generic $5, 2nd: non-preferred Generic $16, 3rd: Preferred brand $40, 4th: non-preferred brand $90, 5th: Specialty tier 33% coinsurance. On the PDP formulary cost sharing starts for 4th tier non preferred brand at 38%.

- [redacted]

**Rationale for Recommendation:**

- Anthem has told us that Toujeo and Lantus access is up for bid for their 2017 formulary. They are adamant that there is strong internal pressure to secure better financials for the basal insulin category. Anthem believes they can do this with the follow-on biologic from Lilly. They have also indicated that they could get where they need to be through much higher discounts from Sanofi or higher discounts from Sanofi coupled with discounting from Novo.
- As an Express Scripts Select Client, Anthem is able to negotiate directly with manufacturers but the contracts are managed by Express Scripts.
- The relationship between Anthem and Express Scripts has been strained throughout the first 6 years of their 10 year deal. The contention spilled into the public forum from comments that Anthem CEO made regarding ESI's failure to meet its obligations to Anthem. Anthem CEO, Swedish described a $3B annual shortfall which ESI says is not accurate.
- Communication between the two organizations is not good, which has created serious negotiating challenges for us.

**Competitive/Market Landscape:**

- In recent meetings Anthem has confirmed that they are in active negotiations with Novo and Lilly regarding contracts for 2017 Medicare business. Novo is actively working to secure Tresiba access. Anthem has heretofore been reluctant to go exclusive across all Medicare (currently we are exclusive for PDP but not MA-PD) because of the significant discounts they are receiving from for Levemir.
- Lilly is actively engaged with Anthem for 2017 Medicare and commercial business. Anthem believes they would not have significant challenges moving to Basaglar in 2017 if the WAC price and discounts are in line with what they are thinking (20% lower WAC and discounts >40% )
- The insulin glargine franchise is at risk of being displaced by the FOB

**Financial Assessment:**

| | 2016 | | | | | 2017 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales ($M) | Total Payments ($M) | Total Payments (%) | Net Sales ($M) | Market Share (%) | Gross Sales ($M) | Total Payments ($M) | Total Payments (%) | Net Sales ($M) | Market Share (%) |
| [redacted] | | | | | | | | | | |

**Financial Model Assumptions:**

[redacted]

[redacted]

**Risk Assessment:**

[redacted]

**Detailed Financial Analysis (Custom View)**

- n/a

# USPC
# 2-27-2015

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US Market Access

# Lantus Auvi-Q Bundle Discussion

Background

- Express Scripts and Envision have Contracts that increase Lantus rebates if Auvi-Q is added to formulary thus creating a bundled arrangement
- Current Terms: Ex. ESI Lantus 1 of 2 26%, 1 of 1 32% Auvi-Q 1 of 2 – 30%, 1 of 1 – 65%

Situation/Risk

- The potential of adding Toujeo will create a "triple" product bundle
- Discounts are allocated based sales of product with the potential of the 65% dicount impacting the reported Governemnt best price on Toujeo and potential for increasing the Medicaid mandated rate
- Government Pricing Compliance/Operation Risk in calculating bundle

Discussion

- Amend Contract to remove Auvi-Q from bundled arrangement

Rationalle: Reduces Risk of Government impact and Compliance

Risk: Exposes Auvi-Q at ESI and Envision. ESI ~$55M Net, ~$1M Net

# USPC
# 1-5-2015

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# US Pricing Committee
## Meeting Agenda – 1/5/15

**Offer Decisions:**

**Pricing Actions:**

**Other:**

1. **Distribution Performance Agreements**

**Follow-up Items:**

**On Deck:**

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# Wholesaler Distribution Performance Agreements (DPA) Negotiations

January 5, 2015

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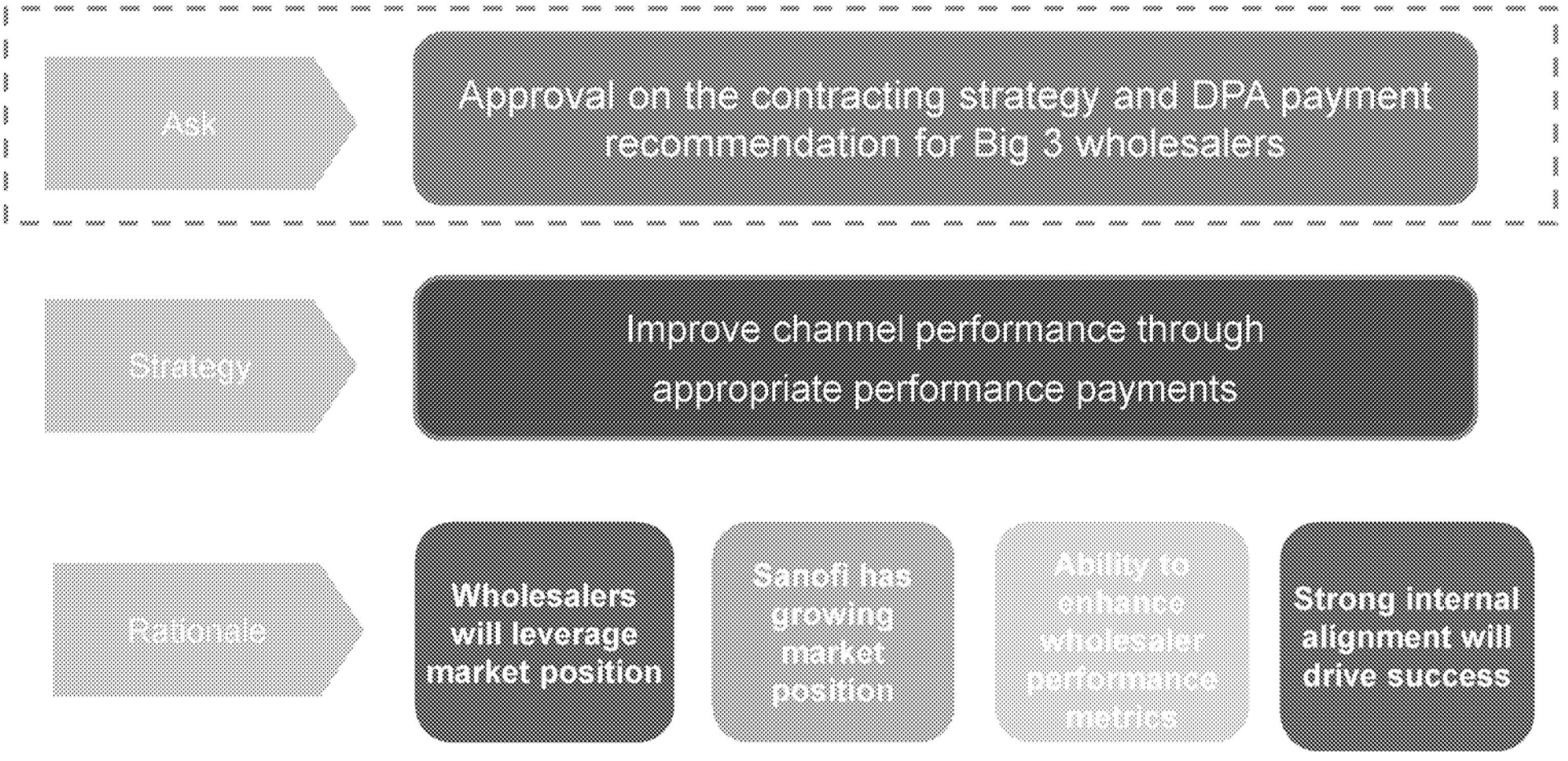
# Enhancing wholesaler performance requires a targeted negotiation strategy

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# Speaker Notes for Slide 4

- Presenting to you today obtain approval on strategy and DPA payment recommendation
    - Whse agreements expire Jun 2015
- Strategy – improve channel performance through appropriate payments
- Realized favorable benefits from current DPA. Last neg, we were able to obtain perf metrics to drive whse performance
- It will be a challenging negotiation with wholesalers
    - Whse are powerful – distribute 85% pharma business and Sanofi's business
    - Further strengthened their market position
    - Challenges will be negotiating during new product launches
- Sanofi has many things going for us: Projecting sales growth with several new product launches – Market Position will be key in will determine ability to improve channel performance and enhance wholesaler performance
    - Wholesalers belief in our forecast will be critical improving whse performance
    - Ask for your support if having any interactions with customers

# Recommendation: Maintain current DPA payments at 1.6% and RDC/NLC fees at 0.12 - 0.15% (fully aligned to budget & LRP)

| Big 3 Whse ($M) | 2014 Est | 2015 | 2016 | 2017 |
|---|---|---|---|---|
| **Gross Sales** | 14,138.6 | 14,905.3 | 17,090.0 | 17,362.1 |
| Cash Discounts | 282.8 | 298.1 | 341.8 | 347.2 |
| DPA Payments | 216.3 | 233.7 | 268.0 | 272.2 |
| RDC/NLC Fees | 13.3 | 18.5 | 21.2 | 21.5 |
| **DPA Subtotal** | 512.4 | 550.3 | 631.0 | 641.0 |
| Inventory Clawback | (140.1) | (56.6) | (54.4) | (17.6) |
| **Net DPA Payment** | 372.3 | 493.7 | 576.6 | 623.4 |
| | 2.6% | 3.3% | 3.4% | 3.6% |

2.0%
1.5 - 1.6%
0.12 - 0.15%
3.6 - 3.7%

3 – 5 year agreement eff 7/1/15

- 0.01% change in DPA payments = $1.46M in 2015
- Ability to seek improvements in DPA payments exist using inventory reduction; Potential risk to 2015 budget, savings will be realized over 3 years.
- Seeking approval to negotiate up to 1.75% on DPA payments - incremental 0.15% has been flagged as a risk to 2015 budget

| Big 3 Whse ($M) | 2015 | 2016 | 2017 |
|---|---|---|---|
| **Incremental Risk (.15%)** | 10.96 | 25.12 | 25.52 |

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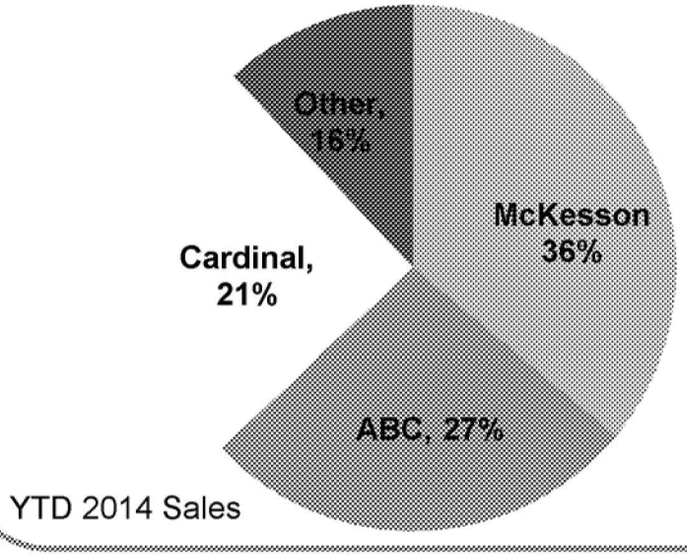
## Speaker Notes for Slide 5

Exposure is significant – DPA fees represented approx. $512M ($127) 2014 & 550M 2015 - Wholesaler play a critical role in our success.  Cannot bypass

# We must be strategic with wholesalers who have further solidified their market position

**Wholesalers will leverage market position**

## ~85% of Sanofi Sales




## Hard to displace

- New alliances with largest retail chains
  - Walgreens – ABC
  - Walmart – McKesson
  - Rite Aid – McKesson
- Essential channel for products requiring mass distribution
- Expert negotiators who will leverage their position

# Speaker Notes for Slide 6

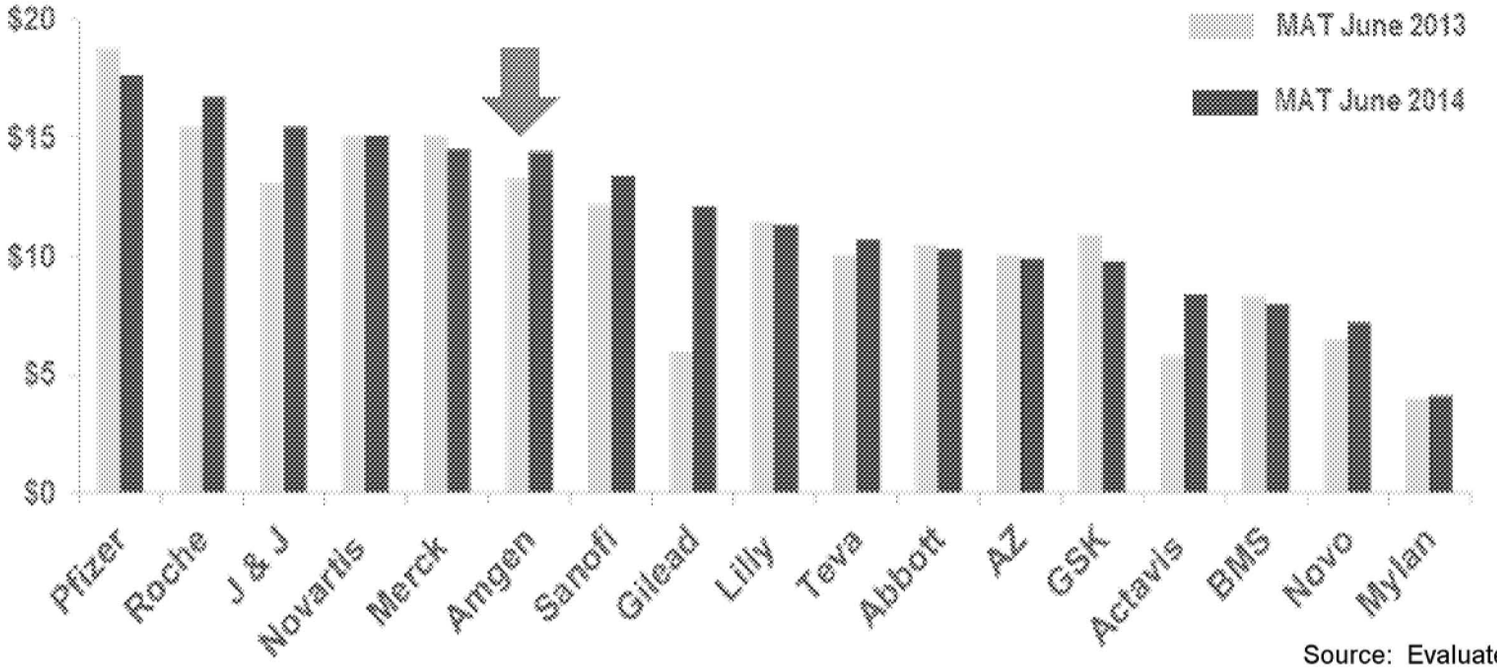
- It will be a challenging negotiation
  - we currently have a favorable agreement
  - Wholesalers play a major role in pharm distribution, they connect dispensing outlets to manufacturers – cannot do without whse
  - Distribute
  - Wholesalers are large and are building strong alliances with retailers

- We have developed a customer specific approach based on customer insights
- Customer approach:
  - Treat each customers separately
  - Analyzing approach for each – obtaining additional insights
  - Leverage 1 against the other during negotiations

- Take a closer look at each customer

# Negotiations will depend largely on wholesaler's confidence in Sanofi's position

Sanofi has growing market position




Source: Evaluate Pharma

- Wholesalers evaluate manufacturers based on sales and growth potential, faith in long range forecast will be a key factor
- Several other manufacturers are negotiating DPAs around the same time period and may impact wholesaler's approach and requirements

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## Speaker Notes for Slide 7

Sanofi ranked #7 based on sales
1 of 4 companies with double digit growth in 2014
Several new product launches – 3 in 2015

# Our strategy will leverage each wholesaler's objectives to enhance our commercial conditions

Ability to enhance wholesaler performance metrics

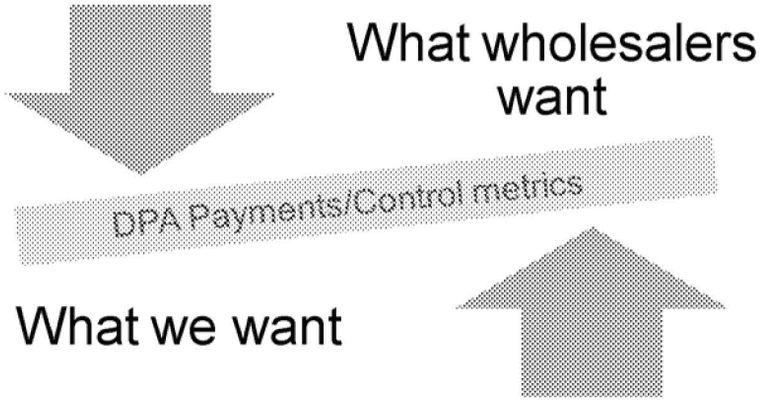
## Our Viewpoint

- Align orders to demand to enable accurate forecasting
- Add new performance based channel control metrics
- Retain favorable aspects of current agreement

## Wholesaler Viewpoint

- Higher payments
- Hold lower inventory
- Reduce accountability for performance

## Balancing Act

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## Speaker Notes for Slide 8

What we want:

- Stable orders to allow accurate forecasting - Align wholesalers' orders with underlying demand
- Add new performance-based channel control metrics
- Retain favorable aspects of current agreement (Inventory clawback metric)
- Support of upcoming new product launches

From customer's perspective:

- We have analyzed each customer, and have identified the areas that each wholesaler will be looking to improve to meet their corporate objectives – leverage to enhance what we're looking for
- Customers looking to get back what they gave up in previous negotiations (value of pricing - inventory appreciation)

# Effective performance metrics are crucial in achieving optimal channel performance

Ability to enhance wholesaler performance metrics

| Type | Companies | Central Distribution Center | Proposed DPA Payment | Clawback | Proposed Performance Requirements | | |
|---|---|---|---|---|---|---|---|
| | | | | | Data Completeness | Customer Service Level | Inventory Level* |
| PROPOSED Big 3 Wholesalers | ABC/Bellco | **TBD** | **1.60%** | 100% Clawback | 867 Data = 852 Data | Service level >98.5% | Inventory range 16 - 20 days |
| | Cardinal | **0.12%** | **1.60%** | 100% Clawback | 867 Data = 852 Data | Service level >98.5% | Inventory range 16 - 20 days |
| | McKesson | **0.15%** | **1.60%** | 100% Clawback | 867 Data = 852 Data | Service level >98.5% | Inventory range 16 - 20 days (Lantus 14 - 20 days) |

* Inventory Metric for Group A Strategic Products

Proposed Performance Metric Improvements:

- Customer Service Level : Addition of new performance metric to drive effective inventory management
- Inventory Level: Tighten metrics to achieve consistent ordering and align orders to demand (1) More frequent measurement (monthly) (2) Payment weighting to quarter end (3) Addition of new product category with varied metrics
- Enhance current EDI 867 sales out reporting to allow better data visibility

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# Speaker Notes for Slide 9

What we want:

- Stable orders to allow accurate forecasting - Align wholesalers' orders with underlying demand
- Add new performance-based channel control metrics
- Retain favorable aspects of current agreement (Inventory clawback metric)

From customer's perspective:

- We have analyzed each customer, and have identified the areas that each wholesaler will be looking to improve to meet their corporate objectives – leverage to enhance what we're looking for
- Customers looking to get back what they gave up in previous negotiations (value of pricing - inventory appreciation)

    - Streamlined demand variability – order consistency for accurate forecasting
    - Efficient channel performance – adding/enhancing metrics
    - Retain favorable aspects of current agreement
    - Product availability for new product launches
    - All achieved through appropriate incentives

# Organizational readiness and commitment is required for a successful negotiation

Strong internal alignment will drive success

- Wholesalers are expert negotiators and may use aggressive disruption factors to secure a favorable agreement
  - Refuse to stock new product
  - Unilateral termination of central distribution center agreements
  - Reduce service levels on Lantus and other products
  - Ordering slowdown in non-US countries
  - Escalate negotiations to senior leadership

## Speaker Notes for Slide 10

What we want:

- Stable orders to allow accurate forecasting - Align wholesalers' orders with underlying demand
- Add new performance-based channel control metrics
- Retain favorable aspects of current agreement (Inventory clawback metric)

From customer's perspective:

- We have analyzed each customer, and have identified the areas that each wholesaler will be looking to improve to meet their corporate objectives – leverage to enhance what we're looking for
- Customers looking to get back what they gave up in previous negotiations (value of pricing - inventory appreciation)

# Next Steps

- Finalize draft agreements with Contracting & Legal — Jan 2015
- Account Manager Training & Preparation — Jan - Feb 2015
- Customer Presentations & Negotiations — Start Mar 2015

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## Speaker Notes for Slide 11

What we want:

- Stable orders to allow accurate forecasting - Align wholesalers' orders with underlying demand
- Add new performance-based channel control metrics
- Retain favorable aspects of current agreement (Inventory clawback metric)

From customer's perspective:

- We have analyzed each customer, and have identified the areas that each wholesaler will be looking to improve to meet their corporate objectives – leverage to enhance what we're looking for
- Customers looking to get back what they gave up in previous negotiations (value of pricing - inventory appreciation)

# On-Deck
## Next USPC = 1/15/15…tentative topics

**01/15/15 →** **Optum Commercial [redacted] + Auvi-Q)**

**01/22/15 →** **TBD**

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# Back up Slides

AmerisourceBergen

**Wholesalers will leverage market position**

| Wholesaler | Retail Customer | Other Channels |
|---|---|---|
| ABC – 27% | Walgreens | Express Scripts<br>Kaiser<br>DaVita |

| Company | Customer Assessment | Likely Requests to Sanofi |
|---|---|---|
| AmerisourceBergen | • Leading position in specialty distribution (with biggest exposure to weak community oncology market)<br>• Profitability struggles with large, low margin customers<br>• Launching new logistics center in Q4<br>• Alignment with Walgreens (equity ownership; board seats; WBAD generic GPO)<br>• EU and Latin American expansion<br>• Recent re-organization in personnel - may be dealing with a less experienced team | 1. Slower payment terms, e.g., 2%/45 vs. current 2%/34<br>2. Carve-out specialty products<br>3. Remove Inventory Appreciation clawback<br>4. Alter performance and inventory metrics for large customers (ESI, WAG)<br>5. Asking for higher payments – getting more aggressive |

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## Speaker Notes for Slide 14

Attracted to specialty portfolio – channel strategy on [redacted] will be key
Gained Walgreens & ESI in 2013
Profitability struggles (cashflow key topic)

CardinalHealth

**Wholesalers will leverage market position**

| Wholesaler | Retail Customer |
|---|---|
| Cardinal – 21% | CVS<br>Kmart<br>Kroger<br>Safeway |

| Company | Customer Assessment | Likely Requests to Sanofi |
|---|---|---|
| CardinalHealth | • Cost-cutting after major customer losses (ESI, WAG)<br>• Business focus on med-surg hospital market<br>• Weak position in non-hospital specialty drug distribution<br>• New generics JV with CVS Caremark<br>• Smaller share than ABC and MCK<br>• Major presence in China<br>• Challenging to negotiate with – can be unreasonable | 1. Higher payments ("Next Best Alternative")<br>2. Access to specialty products |

## Speaker Notes for Slide 15

- Share of market decreasing
- Looking for ways to grow business (Med- surg) as result of recent customer losses (ESI & Walgreens)
- Want to grow specialty business
- Difficult to negotiate with

# McKESSON

**Wholesalers will leverage market position**

| Wholesaler | Retail Customer | Other Channels |
|---|---|---|
| McKesson – 36% | Rite Aid<br>Wal-Mart<br>Target<br>Publix<br>Giant Eagle | VA<br>Optum RX<br>Omnicare |

| Company | Customer Assessment | Likely Requests to Sanofi |
|---|---|---|
| McKESSON | • Largest full-line wholesaler<br>• Very strong #2 in specialty, esp. oncology<br>• Strong position in med-surg physician market<br>• Building new chain partnerships (RAD, WMT)<br>• Expensive EU expansion (Celesio) | 1. Reduce inventory levels<br>2. Twice-weekly deliveries (with adjusted payment timing)<br>3. Likely to ask for more frequent payments of DPA (monthly)<br>4. Global relationship and terms |

## Speaker Notes for Slide 16

- Largest full line wholesaler
- Looking for more efficiencies – asking for more frequent deliveries
- Wanto to do less

# Primary Elements of Executive Compensation

| Wholesaler Financial Metric | AmerisourceBergen | Cardinal Health | McKesson |
|---|---|---|---|
| **Earnings per Share** | ✓ | ✓ | ✓ |
| **EBIT/EBITDA** | | ✓ | ✓ |
| **ROIC** | ✓ | | |
| **Cash Flow** | | | ✓ |
| **Dividend Yield** | | ✓ | |
| **Tangible Capital** | | ✓ | |

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# Key DPA Negotiating Items for Wholesalers

| Wholesaler Financial Metric | Fee Basis Points | Pricing Expectations | Payment Terms | Inventory Levels |
|---|---|---|---|---|
| **Earnings per Share** | ✓ | ✓ | | |
| **EBIT/EBITDA** | ✓ | ✓ | | |
| **ROIC** | ✓ | ✓ | ✓ | ✓ |
| **Cash Flow** | | | ✓ | ✓ |
| **Dividend Yield** | | | | |
| **Tangible Capital** | | | | ✓ |

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**Sanofi USPC Recommendation**

Aetna Inc.

2016 Medicare Part D RFP

December 16, 2014

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| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus, Auvi-Q* | *Medicare* | *Contract Offer Revision* | *1/1/2016 – 12/31/2016* |
| **Contracting Strategy:** | • *Obtain unrestricted access for Lantus and Auvi-Q* | | |
| **Recommendation:** | [redacted] | | |
| **Financial Impact:** | ***Lantus***<br>• *Status Quo – No Contract, 2016 Net Sales $115.5M*<br>• *Scenario 1: Contract w/ 35% Rebate + 10% Price Protection, 2016 Net Sales impact $3.0M*<br>• *Scenario 2: Contract w/ 30% Rebate + 10% Price Protection, 2016 Net Sales impact $12.2M*<br>[redacted] | | |

**Background:**

- As of 3Q14, Aetna has approximately 2.3 Million Medicare Part D lives (~6% of MMA channel) in the U.S.
- Aetna acquired Coventry in May 2013 and enhanced Medicare footprint by adding > 1.0 Million Part D members with largest enrollment in Texas, Michigan, California and Pennsylvania.
- Lantus is in a Not Covered position for 60% of the business and Non-Preferred for 40% of the business.
- Lantus Family market share share fell from 66.3% (1/13) to 47.3% (1/14) and is currently 33.7% (9/14). Lantus was moved to Not Covered on Aetna's MMA formulary on 1/1/13.
- Auvi-Q is in a Not Covered position for 100% of the business and market share is 0.6% (9/14).

**Recommendation:**

- [redacted]

**Rationale for Recommendation:**

- Aetna will be reviewing all therapeutic classes in 1Q15 and will be consolidating their 2016 bid submission with Coventry into ONE filing for all Medicare products under the Aetna entity.
- Aetna's RFP due 12/19/14 provides an opportunity to improve access for Lantus & Auvi-Q across all PDP/MA-PD formularies.
- Novo has secured an agreement with Aetna to position Levemir as the exclusive basal insulin on the 2015 Aetna Medicare Part-D formulary.
- [redacted]

**Customer Benefit Design and Formulary Strategy:**

Aetna Inc. usually submits their RFP submission in the November time-frame in advance for the Medicare Part D bid cycle. Aetna's Medicare Clinical Assessment Committee will meet in the January-February 2015 time-frame to conduct clinical reviews and value assessments. A Blackout Period due to Medicare P&T meetings is mid-March through early-April 2015. The Formulary Status will be completed and communicated to manufacturers by August 1, 2015.

**Sanofi USPC Recommendation**
Aetna Inc.
2016 Medicare Part D RFP
December 16, 2014

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The 2016 PDP/MA-PD product categories will be similar to the 2015 filing:

- Low Premium Product Category (Saver): Aetna Medicare Rx Saver (PDP)
- Enhanced Product Category: [redacted]
- Basic Product Category: [redacted]
- MA-PD: Health Plans will utilize a formulary variation of the PDP option

| TIERS | CO-PAY RANGES |
|---|---|
| Tier-1 Preferred Generics | $2-7 |
| Tier-2 Non-Preferred Generics | $5-12 |
| Tier-3 Preferred Brands | $35-45 |
| Tier-4 Non-Preferred Brands | 37-50% |
| Tier-5 Specialty | 25-33% |

**Return on Investment in MUSD (Lantus):**

| | 2015 | | | | | | 2016 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | TRx (units) | Market Share (%) | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | TRx (units) | Market Share (%) |
| Baseline / No Contract | 115.1 | 0.0 | 0.0% | 115.1 | 361,134 | 32.9% | 115.6 | 0.0 | 0.0% | 115.6 | 364,305 | 32.0% |
| 35% GTD + 10% PP [Reset-Net] | 115.1 | 0.0 | 0.0% | 115.1 | 361,134 | 32.9% | 182.3 | 63.8 | 35.0% | 118.5 | 575,360 | 50.5% |
| Variance to Baseline | 0.0 | 0.0 | 0.0% | 0.0 | 0 | 0.0% | 66.9 | 63.8 | 35.0% | 3.0 | 211,055 | 18.5% |
| 30% GTD + 10% PP [Reset-Net] | 115.1 | 0.0 | 0.0% | 115.1 | 361,134 | 32.9% | 182.3 | 54.7 | 30.0% | 127.6 | 575,360 | 50.5% |
| Variance to Baseline | 0.0 | 0.0 | 0.0% | 0.0 | 0 | 0.0% | 66.9 | 54.7 | 30.0% | 12.2 | 211,055 | 18.5% |

*Key Assumptions ROI (Recommendation):*

- *Baseline and No Contract Scenario are the same, Lantus is currently Not Covered in 60% of business and Non-Preferred / ST in 40% of business*
- *Share shift calculated using [redacted] (Lantus Not Covered → Tier 2)*
- *No planned Lantus Pricing Actions in 2015 / 2016*
- *Factored up TPS data following receipt of 3Q14 customer data in order to align data sets*
  - *No contract data available for Lantus due to Not Covered position*
  - *See Appendix for conversion factors applied to TPS data set*

**Net Cost to Plan in MUSD (Lantus):**

| | 2016 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Scenario | Lantus Rebate % | Lantus Net Cost To Plan | Lantus Copay | Lantus Mkt Sh | Levemir Rebate % | Levemir Net Cost To Plan | Levemir Copay | Levemir Mkt Sh | Total Net Cost To Plan after Copay |
| Baseline - Status Quo | 0.0% | $118 | $50 | 32.0% | 40.0% | $169 | $31 | 68.0% | $206 |
| Scenario 1 | 35.0% | $123 | $23 | 50.5% | 20.0% | $162 | $23 | 49.5% | $240 |

Note: Baseline scenario is the same as No Contract scenario

*Key Assumptions Net Cost to Plan (Recommendation):*

- *Co-Pays were derived by taking an average of the co-pay range*
  - *T3: $40 / T4: 42.5%*
- *Other assumptions: 20% mark up for plan cost, 15% network discount and $1.75 pharmacy dispensing fee/unit*
- *Levemir 40% rebate for sole preferred LAI, 20% rebate for co-preferred LAI*

## ROI Model Description

| | | | |
|---|---|---|---|
| **Model Product Line:** | LANTUS | **Model Creation Date:** | 12/12/2014 |
| **Model Plans / PBMs:** | [redacted] | **Model Author:** | Alfred Haley |
| **Model Units (e.g., ml, Rx)** | Rx | | |

**Model Purpose:**

Aetna 2016 MMA RFP for Lantus.

### Overview of Scenarios

**Baseline**

**Description:** Lantus:
MAPD- NF/ST
PDP- varies
No Rebates

**Analog:** N/A
**Data Sources:** [redacted]

**Scenario 1**

**Description:** [redacted]

**Analog:**
**Data Sources:**

**Scenario 2**

**Description:** [redacted]

**Analog:**
**Data Sources:**

**No Contract**

**Description:**

**Analog:**
**Data Sources:**

### Detail Detail

[redacted]

# APPENDIX

## Conversion Factors

### Prescription Volume

| Lantus Vials | | Levemir | |
|---|---|---|---|
| 3Q14 TPS | 20,082 | 3Q14 TPS | 85,011 |
| 3Q14 Customer | 38,732 | 3Q14 Customer | 176,218 |
| Variance | 92.87% | Variance | 107.29% |

| Lantus Solostar | |
|---|---|
| 3Q14 TPS | 25,605 |
| 3Q14 Customer | 51,407 |
| Variance | 100.77% |

### Unit Volume

| Lantus Vials | | Levemir | |
|---|---|---|---|
| 3Q14 TPS | 404,333 | 3Q14 TPS | 1,776,343 |
| 3Q14 Customer | 539,725 | 3Q14 Customer | 2,274,200 |
| Variance | 33.49% | Variance | 28.03% |

| Lantus Solostar | |
|---|---|
| 3Q14 TPS | 526,294 |
| 3Q14 Customer | 619,670 |
| Variance | 17.74% |

[redacted]

**Sanofi USPC Recommendation**
Apidra Price Increase
November, 2014

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| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Apidra* | *All* | *Contract Offer Revision* | *December 5, 2014* |
| **Recommendation:** | • *Approve a WAC increase of 9.9%* | | |
| **Financial Impact:** | • *Additional $2.5 Million in Sales in 2014 and a risk of $300,000 in 2015due to a lower claw back realization* | | |
| **Risk Considerations:** | • All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. | | |

**Recommendation:**

- Implement a 9.9% price increase on Apidra effective December 5, 2014:

| NDC | Brand Name | Generic Name | Strength | Current WAC | Proposed WAC | Increase |
|---|---|---|---|---|---|---|
| 00088-2500-33 | APIDRA (10ml Vial) | INSULIN GLULISINE | 100 unit/mL | $ 184.85 | $ 203.15 | 9.90% |
| 00088-2502-05 | APIDRA SOLOSTAR (Box of 5 Pens) | INSULIN GLULISINE | 100 unit/mL | $ 357.10 | $ 392.45 | 9.90% |

**Rational for Recommendation:**

- Increased Gross and Net Sales.
- Apidra has employed a fast follower strategy to Novolog/Humalog price increases – Novolog just implemented their increase effective November 18th.
- 2015 Budget has 8.0% increase effective January 2015 – by bringing the increase forward to December, an additional $2.5 Million in Sales will be realized in 2014- $1.4 Million due to the claw back , and $1.1 Million by the pricing action
- 2015 Net sales will be lower by $300,000 as there is a lower claw back at the beginning of the year compared to budget, and we do not realize additional net sales from Medicare contracts since they are price protected.

**Financial Assessment:**

| 2014 Net Sales (M.USD) | | | 2015 Net Sales (M.USD) | | |
|---|---|---|---|---|---|
| 14F2 | Scenario 1 | Change | 15B | Scenario 1 | Change |
| $ 171.3 | $ 173.8 | $ 2.5 | $ 175.5 | $ 175.2 | $ (0.3) |

**Risk Assessment:**

- All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients.

**Sanofi USPC Recommendation**
<Prime Therapeutics Commercial>
<November 7, 2014>

| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus* | *PRIME Commercial* | *Rebate change* | *2015 and 2016* |

[redacted]

**Rationale for Recommendation:**

- We are currently at risk with PRIME due to recent public comments around increases in Lantus rebates impacting the U.S. market for diabetes. PRIME is questioning their current rebate status with Lantus. They are requesting/requiring an increase in 2015. If we need to increase rebates to stay preferred, we can ask for coverage of any future glargine at the same price per day. PRIME also says they no longer want performance as a part of the contract, but all rebates to be guaranteed. Prime's current Lantus product rebate has basically remained unchanged since the contract inception in July 2010. In 2014, the admin fee was increased 1 point and price predictability was implemented.
    - Without a 2015 increase, they can and have threatened to exclude any new glargine products. PRIME has a new exclusions list for 2015, which currently includes Apidra.
    - Low risk of Lantus being blocked in 2015, high risk of other glargine being blocked without a new deal. Higher risk of negative changes in 2016.
- This change in 2015 could set us up well for a single manufacturer/exclusive 2016 year. Any 2016 commercial offer will need to be completed by the end of November for a January business committee review.

**Financial Assessment:**

| | 2015 | | | | | | 2016 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | TRx (units) | Market Share (%) | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | TRx (units) | Market Share (%) |
| Baseline | 334.6 | 36.9 | 11.0% | 297.7 | 628,762 | 78.9% | 369.6 | 33.0 | 8.9% | 336.6 | 654,595 | 78.8% |
| [redacted] | | | | | | | | | | | | |

**Market Overview:**

- Exclusion list in 2015

[redacted]

**Competitive Landscape:**

[redacted]

**Risk Assessment:**

- **Environmental Impact Statement:**

[redacted]

- **Legal Risk:**
- **Compliance Risk:**
- **Operational Risk:**

**Performance Measurement:**

[redacted]

**Detailed Financial Analysis:**

**Yearly Summary**

| Baseline |
|---|
| Item |
| Sanofi TRx (units) |
| Competitor TRx (units) |
| Sanofi TRx Share (%) |
| Gross Sales ($) |
| Guaranteed Rebate (%) |
| Performance Rebate (%) |
| Administration Rebate (%) |
| PP Penalty Rebate (%) |
| Total Rebate (%) |
| Guaranteed Rebate ($) |
| Performance Rebate ($) |
| Administration Rebate ($) |
| PP Penalty Rebate ($) |
| Total Rebate ($) |
| Net Sales ($) |

| Scenario 1 |
|---|
| Item |
| Sanofi TRx (units) |
| Competitor TRx (units) |
| Sanofi TRx Share (%) |
| Gross Sales ($) |
| Guaranteed Rebate (%) |
| Performance Rebate (%) |
| Administration Rebate (%) |
| PP Penalty Rebate (%) |
| Total Rebate (%) |
| Guaranteed Rebate ($) |
| Performance Rebate ($) |
| Administration Rebate ($) |
| PP Penalty Rebate ($) |
| Total Rebate ($) |
| Net Sales ($) |

| Scenario 2 |
|---|
| Item |
| Sanofi TRx (units) |
| Competitor TRx (units) |
| Sanofi TRx Share (%) |
| Gross Sales ($) |
| Guaranteed Rebate (%) |
| Performance Rebate (%) |
| Administration Rebate (%) |
| PP Penalty Rebate (%) |
| Total Rebate (%) |
| Guaranteed Rebate ($) |
| Performance Rebate ($) |
| Administration Rebate ($) |
| PP Penalty Rebate ($) |
| Total Rebate ($) |
| Net Sales ($) |

| No Contract |
|---|
| Item |
| Sanofi TRx (units) |
| Competitor TRx (units) |
| Sanofi TRx Share (%) |
| Gross Sales ($) |
| Guaranteed Rebate (%) |
| Performance Rebate (%) |
| Administration Rebate (%) |
| PP Penalty Rebate (%) |
| Total Rebate (%) |
| Guaranteed Rebate ($) |
| Performance Rebate ($) |
| Administration Rebate ($) |
| PP Penalty Rebate ($) |
| Total Rebate ($) |
| Net Sales ($) |

**Modeling Assumptions:**

- Budgeted pricing actions are assumed in the model.
- [redacted]
- Assumes no change to formulary status in 2015, so although a no contract scenario was not prepared.

## ROI Model Description

| | | | |
|---|---|---|---|
| **Model Product Line:** | Lantus | **Model Creation Date:** | |
| **Model Plans / PBMs:** | PBM | **Model Author:** | R. Seasock |
| **Model Units (e.g., ml, Rx)** | TRx's | | |

[redacted]

Assessment of Scenarios

**Baseline** **Scenario 1**

[redacted]

Model Results

**Model Results, Output or Recommendations:**

**Approved Scenario:** [redacted]

# OptumRx Medicare Part D Lantus 2016 Offer

October 2014

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# Summary OptumRx/UHC Part D 2016

| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus* | *OptumRx/UHC Medicare* | *Contract Offer Revision* | *1/1/2016 – 12/31/2020* |
| **Contracting Strategy:** | *Ensure unrestricted Lantus access – 1 of 1 Manufacturer - Exclusive PDP positioning* | | |
| **Recommendation:** | • ***Approve a 5-year offer of 61% rebate for Lantus in their PDP plans (Saver Plus and Preferred) only with 6% Cumulative Price Protection with a 12/31/2013 baseline.***<br>• *MAPD remains status quo at 55% with 6% Cumulative Price Protection with 12/31/2013 baseline.*<br>• *Current Offer: 55% rebate for 1 of 2 Manufacturers with 6% cumulative price protection and baseline WAC date of 12/31/13.* | | |
| **Financial Impact:** | • *PDP Exclusive Offer vs Current Contract – Excluding other costs, net sales increase by **+8.9 M** in 2016 and **+30.2M** in 2017. Including other costs, net sales variances are **(8.2) M and +2.8 M** respectively.*<br>• *PDP Exclusive Offer vs. No Contract – Excluding other costs, net sales variance of **(114.8) M** in 2016 and **+124.7 M** net sales in 2017. Including other costs, net sales variances are **(201.2) M** and **(13.4) M** respectively.* | | |
| **Risk Considerations:** | • *Loss of Lantus patient base during critical Diabetes Franchise years of 2016 and 2017.*<br>• *Failure to respond could potentially position Lantus as not covered in the PDP segment should the account turn to the competition.*<br>• *Risk of spillover to other customers and business segments.* | | |
| **Probability of Success:** | *Probability of Success – 50%* | | |

# Financial Summary

| Scenario | 2016 Gross Sales ($M) | 2016 Rebates ($M) | 2016 Other Costs | 2016 Net Sales ($M) | 2017 Gross Sales ($M) | 2017 Rebates ($M) | 2017 Other Costs | 2017 Net Sales ($M) |
|---|---|---|---|---|---|---|---|---|
| **Baseline - Current 1 of 2 55%** | 1060.7 | 632.7 | 144.6 | 283.4 | 1205.5 | 718.1 | 164.3 | 323.1 |
| **No Contract** | 551.6 | 0.0 | 75.2 | 476.4 | 392.9 | 0.0 | 53.6 | 339.3 |
| Variance to Baseline | -509.1 | -632.7 | -69.4 | 123.6 | -812.7 | -718.1 | -110.8 | 16.3 |
| **Scenario 1 - Proposed Exclusive 61%** | 1186.0 | 749.1 | 161.7 | 275.2 | 1406.5 | 888.9 | 191.7 | 325.9 |
| Variance to Baseline | 125.3 | 116.5 | 17.1 | -8.2 | 201.0 | 170.8 | 27.4 | 2.8 |
| Variance to No Contract | 634.4 | 749.1 | 86.5 | -201.2 | 1013.6 | 888.9 | 138.2 | -13.4 |

# Toujeo – Contract Language Update

**The following language has been added to some Lantus Agreements in the GPO, LTC and Managed Care Space**

"*Any new FDA approved SA insulin glargine product in the Long-acting insulin Sub-Therapeutic Category shall be automatically added to this Agreement* ***and the Formulary(ies)*** *on the same terms and conditions, including Rebate terms, as Lantus; provided, that the Rebate percentage(s) shall be adjusted as may be necessary to achieve net parity pricing with Lantus*."

Adding this Language has spurred some questions/considerations that require further discussion:

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# Questions/Considerations

**Strategy –**

- Toujeo strategy not yet finalized.
- The language sets Net Pricing before the strategic price & strategy have been decided.
- Established a bundle with this language. If bundled in commercial, it will set a high BP, thus a high Medicaid rebate (traditional & Mgd Med) from day one and for the lifecycle of Toujeo.
  - If higher Lantus rebates are offered for the placement of Tujeo on Form, it is a bundle.
  - If product rebate levels are negotiated together and Lantus rebate increases, it is a bundle.
  - If higher Lantus rebates are offered regardless of Tujeo Form decision, no bundle.
  - If Lantus rebates remain status quo, no bundle.
  - (JIM, KEEP THESE BULLET PTS OR NOT AS YOU SEE FIT)

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# Questions/Considerations

**Questions–**

- Does this apply to all business sectors? (Comm, PtD, Mgd Med, GPO, LTC)
- If language is currently not in the contract do we proactively add via an amendment. (Risk: can open Lantus negotiations).
- Is language negotiable?
- If contract language states "*added to the Agrmt*", but not "*and the Form*", customer has no obligation to add Tujeo to Form. Customer would get rebate only once they add Toujeo to Form.
- If Customer accepts the language, then decides not to add Toujeo to Form, will Sanofi withhold Lantus rebates?
- Customer Formulary decisions must be made for clinical reasons. From 2003 OIG guidance*: *"the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs."*

http://www.ehcca.com/presentations/pharmaaudio20030521/HHSOIGGuidanceRaisesConcerns.pdf

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# Tuojeo – Contracts

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# Agenda

| Time | Item | Presenter |
|---|---|---|
| 4:30 - 4:45 | Lantus Co-Pay Offer | Lori Halenar |
| 4:45 - 5:00 | [redacted] | Sandip Mehta |
| 5:00 – 5:15 | Auvi-Q Price Increase | Emily Ahrens<br>Herve Hubert |
| 5:15 - 5:30 | [redacted] | Chris Christensen |

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# Lantus Co-Pay Offer Request

## *Summary*

| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brands(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus* | *Commercial / Cash* | *Co-Pay Offer* | *Oct 2014 – June 2016* |
| **Strategy:** | Retain existing Lantus patients refilling and encourage new Rx; create a base for future co-pay offers that will covers multiple Sanofi diabetes products; increase CRM Lantus user database as a consideration for future portfolio growth | | |
| **Recommendation:** | Approve expansion of 12 month benefit offer nationally | | |
| **Financial Impact:** | GTN and A&P Impact – $15.9M:<br>• 2014 - $1.07M (incremental)<br>• 2015 - $10.9M (included in latest LRP)<br>• 2016 - $3.9M (included in latest LRP)<br>Incremental Revenue – $11M | | |

**Rationale for Recommendation**

- Address cost barriers making it easier for patients to be compliant with Lantus therapy
- Benefits not only Lantus performance in 2014 and 2015 but also an important consideration for the future diabetes portfolio growth
- Continue to reinforce positive competitive perceptions about Lantus access for commercial patients to motivate physicians to prescribe Lantus
- Use new Lantus co-pay offer as an initial step for franchise co-pay offer during Toujeo launch and other launches (e.g. "Pay No More Than $25 for Lantus; Pay No More Than $20 for Toujeo")
- Increase CRM Lantus user database as a consideration for future diabetes portfolio growth (Lantus Expanded co-pay program will bring 45K+ patients into the database)

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# Lantus Co-Pay Offer Request

## *Financial Summary*

- Estimated impact ~ $15M GTN and $800K A&P
- Assumes:
  - **Keep $100 cap per script**
  - **October 2014-June 2015 – Registration Period**
  - **October 2014-June 2016 – Claims Period**
  - **Print 150K cards – distribute ~ 50K in 2014 and 100K in 2015**

| Lantus Co-Pay Financials | |
|---|---|
| Estimated patients redeeming cards | 45,000 |
| Average claims per pateint | 5 |
| Average reimbursement per claim | $67 |
| Estimated Reimbursements | $15,075,000 |
| GTN Impact | 0.05% |
| Incremental Revenue | 11M * |

| Lantus Co-Pay Costs Per Year 2014-2016 | | | |
|---|---|---|---|
| | 2014 | 2015 | 2016 |
| Estimated patients utilizing cards | 9,600 | 45,000 | 35,400 |
| Average claims per pateint | 1.5 | 3.5 | 1.5 |
| Average reimbursement per claim | $67 | $67 | $67 |
| Estimated Reimbursements | $964,800 | $10,552,500 | $3,557,700 |
| GTN Impact | 0.01% | 0.10% | 0.04% |
| A&P Fees | $100,000 | $402,000 | $300,000 |

* Based on patient persistency and compliance improvement only; No spill over impact from improved access perceptions is incorporated; No incremental Toujeo revenue is included; Assumes Net SoloStar Price of $203 (per Finance)

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# Auvi-Q Price Increase Request

*Summary*

| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brands(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Auvi-Q* | | *Price Increase* | *October/November 2014* |
| **Recommendation:** | Implement an Auvi-Q price increase to match Epipen potential Q4 PI and maintain the current 10% price premium. Base scenario modeled below aligned with the F2 assumption of +14.9% in October. | | |
| **Financial Impact:** | The impact of not taking this price increase will be $1.6M versus the preliminary 2014F2 projection. | | |

## Recommendation

- Implement a price increase on Auvi-Q as a fast follower to a potential Mylan EpiPen price increase expected to be taken in October/November with a goal of maintaining the current 10% premium.

## Rational for Recommendation

- Budget 2014 has a 14.9% price increases built in October
- Maintain fast follower strategy to Epipen price increase

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# Auvi-Q Price Increase Request

*Financial Summary*

- The impact of not taking this 14.9% price increase will be $1.6M in 2014 and $10.9m in 2015 versus the preliminary 2014F2 15B projection.

| MUSD | 2014 NO PI | % GTN | PI IMACT | 2014 W/ PI | % GTN | 2015 NO PI | % GTN | PI IMACT | 2015 W/ PI | % GTN |
|---|---|---|---|---|---|---|---|---|---|---|
| **GROSS FACTORY** | **$128.9** | **100.0%** | **$4.5** | **$133.4** | **100.0%** | **$327.6** | **100.0%** | **$48.8** | **$376.4** | **100.0%** |
| **MANDATED** | **$9.0** | **7.0%** | **$.6** | **$9.6** | **7.2%** | **$28.3** | **8.6%** | **$4.4** | **$32.7** | **8.7%** |
| **GVT DISCRETIONARY** | **$.7** | **0.6%** | **$.0** | **$.7** | **0.5%** | **$.7** | **0.2%** | **$1.3** | **$2.0** | **0.5%** |
| MEDICARE | $.6 | 0.5% | $.0 | $.7 | 0.5% | $1.6 | 0.5% | $.2 | $1.8 | 0.5% |
| MANAGED MEDICAID | $.1 | 0.1% | $.0 | $.1 | 0.1% | $.2 | 0.1% | $.0 | $.2 | 0.1% |
| **COMMERCIAL** | **$15.0** | **11.7%** | **$1.9** | **$16.9** | **12.7%** | **$78.9** | **24.1%** | **$25.4** | **$104.3** | **27.7%** |
| MANAGED CARE | $14.9 | 11.6% | $1.9 | $16.8 | 12.6% | $77.9 | 23.8% | $25.3 | $103.2 | 27.4% |
| HOSPITAL | $.0 | 0.0% | $.0 | $.0 | 0.0% | $.9 | 0.3% | $.1 | $1.0 | 0.3% |
| LTC | $.0 | 0.0% | $.0 | $.0 | 0.0% | $.0 | 0.0% | $.0 | $.0 | 0.0% |
| STAFF MODEL | $.0 | 0.0% | $.0 | $.0 | 0.0% | $.0 | 0.0% | $.0 | $.0 | 0.0% |
| **OTHER INCENTIVES** | **$14.9** | **11.6%** | **$.4** | **$15.4** | **11.5%** | **$46.0** | **14.1%** | **$6.9** | **$52.9** | **14.1%** |
| CASH DISCOUNTS | $2.6 | 2.0% | $.1 | $2.7 | 2.0% | $6.6 | 2.0% | $1.0 | $7.5 | 2.0% |
| DPA FEES | $2.1 | 1.6% | $7.3 | $9.4 | 7.0% | $19.6 | 6.0% | $2.9 | $22.5 | 6.0% |
| SALES RETURNS | $3.3 | 2.6% | $.1 | $3.5 | 2.6% | $15.2 | 4.7% | $2.3 | $17.5 | 4.7% |
| **NET SALES** | **$89.3** | **69.3%** | **$1.6** | **$90.8** | **68.1%** | **$173.6** | **53.0%** | **$10.9** | **$184.5** | **49.0%** |

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**Sanofi USPC Recommendation**

Lantus [redacted] Contracting Strategy Revision

June 4, 2014

| EXECUTIVE SUMMARY | | | |
|---|---|---|---|
| **Brand(s)** | **Customer / Channel** | **Type of Request** | **Time Period** |
| *Lantus* | [redacted] | *Contract Strategy Revision* | *Effective July 1, 2014* |
| **Brand Strategy:** | *Reassert Lantus' Leadership position to secure and accelerate volume growth in light of the aggressive market challenges & U300 launch; Differentiate Lantus as 1st Injectable of choice.* | | |
| **Contracting Strategy:** | *Support Brand Strategy by preserving preferred access for Lantus at key [redacted]s & Systems* | | |
| **Recommendation:** | • *Increase discounts available for Tier 3, 4, and 5, with a maximum available discount of 40%.*<br>• *Create a Tier 5 opportunity for Individual [redacted] at 80% market share*<br>• *Include price predictability of 10% annually, based on net pricing.*<br>• *Increase the Re-evaluation discount (Comeback Agreement) to 25%.* | | |
| **Financial Impact:** | *Recommended changes are neutral to F1 2014.*<br>*Average discount within the 30% accounted for in F1 2014; recommendation average discount of 29% (+1% admin fee) is in-line with F1 2014.* | | |
| **Risk Considerations:** | *Considerable risk for lost [redacted] access and business, particularly with the latest price increase for Lantus. Loss of access in [redacted] segment will likely have a negative impact on LTC and retail segments.* | | |

**Recommendation:**

- Increase discounts available to Acute Care Class of Trade (COT) through Institutional GPOs. Changes only apply to Tiers 3, 4 and 5 to incentivize accounts to strive for higher market share performance; no change in discounts for Tiers 1 and 2. Increases the maximum available discount to 40% (from 20%).
- Include price predictability of 10% annually, based on net pricing.
- Make Tier 5 available to individual [redacted], with a minimum market share threshold of 80%.
- Increase the Re-evaluation discount (Comeback Agreement) to 25% (Tier 3 level discount); current Re-evaluation discount is 14%.

CURRENT CONTRACT TERMS

EFFECTIVE JANUARY 1, 2014

| | Individual Hospitals | | | | Integrated Systems | | | |
|---|---|---|---|---|---|---|---|---|
| | Market Share | | Discount | | Market Share | | Discount | |
| | Mkt Shr LL | Mkt Shr UL | Vial % | Pen % | Mkt Shr LL | Mkt Shr UL | Vial % | Pen % |
| Tier 1 | 0.00% | 49.99% | 1% | 1% | 0.00% | 37.99% | 0% | 0% |
| Tier 2 | 50.00% | 59.99% | 9% | 9% | 38.00% | 51.99% | 9% | 9% |
| Tier 3 | 60.00% | 69.99% | 14% | 14% | 52.00% | 67.99% | 14% | 14% |
| Tier 4 | 70.00% | 100.00% | 17% | 17% | 68.00% | 74.99% | 17% | 17% |
| Tier 5 | | | | | 75.00% | 100.00% | 20% | 20% |

PROPOSED CONTRACT TERMS

EFFECTIVE JULY 1, 2014

| | Individual Hospitals | | | | Integrated Systems | | | |
|---|---|---|---|---|---|---|---|---|
| | Market Share | | Discount | | Market Share | | Discount | |
| | Mkt Shr LL | Mkt Shr UL | Vial % | Pen % | Mkt Shr LL | Mkt Shr UL | Vial % | Pen % |
| Tier 1 | 0.00% | 49.99% | 1% | 1% | 0.00% | 37.99% | 1% | 1% |
| Tier 2 | 50.00% | 59.99% | 9% | 9% | 38.00% | 51.99% | 9% | 9% |
| Tier 3 | 60.00% | 69.99% | 25% | 25% | 52.00% | 67.99% | 25% | 25% |
| Tier 4 | 70.00% | 79.99% | 30% | 30% | 68.00% | 74.99% | 30% | 30% |
| Tier 5 | 80.00% | 100.00% | 40% | 40% | 75.00% | 100.00% | 40% | 40% |

**Rationale for Recommendation:**

- Lantus is losing accounts and share within the institutional segment because of aggressive discounting and bundled contract offering from Novo Nordisk.

- Current WAC prices for Lantus and Levemir are at parity. We understand that Novo Nordisk is offering Levemir discounts up to ~55%, and the current maximum Lantus discount available is 20%. On a net pricing basis, Lantus Vial is at ~43% premium to Levemir Vial (based on current maximum available discounts). Based on the recommendation, the Lantus Vial premium to Levemir Vial would be reduced to ~24% on a net pricing basis, but not closed completely (assuming Novo Nordisk matches our May 30, 2014 WAC increase – *Novo Nordisk matched the WAC increase effective May 31, 2014*).
- Increased discounts focused on Tiers 3, 4, and 5 place additional discount investment to protect our position with those [redacted] that are performing to higher market share levels, while also providing incentives for accounts to increase their share and corresponding discount opportunity. Approximately 67% [redacted] is at Tier 4 or Tier 5. With the introduction of Tier 5 for Individual [redacted], 48% of Lantus volume would be at Tier 5.

**Estimated Lantus Volume Allocation (Current)**

| Tier 1 | Tier 2 | Tier 3 | Tier 4 | Tier 5 |
|---|---|---|---|---|
| 11% | 10% | 13% | 43% | 24% |

**Estimated Lantus Volume Allocation (Post-Tier 5 for Individual Hopsitals)**

| Tier 1 | Tier 2 | Tier 3 | Tier 4 | Tier 5 |
|---|---|---|---|---|
| 11% | 10% | 13% | 19% | 48% |

- The table below details the change in net pricing, by tier, from the current discount levels (pre-May 30 WAC increase) to the recommended discount levels (post-May 30 WAC increase). We expect the incremental discounts for Tiers 3-5 to both address the increasingly competitive contracting, as well as neutralize the negative impact of the May 30 WAC increase for higher market share accounts.

| SoloStar | CURRENT | | Post Price Increase / Change in Discounts | | |
|---|---|---|---|---|---|
| | WAC | $ 303.12 | Inc %: | 9.9% | |
| | | | New WAC: | $ 333.13 | |
| | Discount | Net Price | Discount | Net Price | % Change vs. Current |
| Tier 5 | 20% | $ 242.50 | 40% | $ 199.88 | -17.6% |
| Tier 4 | 17% | $ 251.59 | 30% | $ 233.19 | -7.3% |
| Tier 3 | 14% | $ 260.68 | 25% | $ 249.85 | -4.2% |
| Tier 2 | 9% | $ 275.84 | 9% | $ 303.15 | 9.9% |
| Tier 1 | 1% | $ 300.09 | 1% | $ 329.80 | 9.9% |

| Vial | CURRENT | | Post Price Increase | | |
|---|---|---|---|---|---|
| | WAC | $ 191.28 | Inc %: | 16.1% | |
| | | | New WAC: | $ 222.08 | |
| | Discount | Net Price | Discount | Net Price | % Change vs. Current |
| Tier 5 | 20% | $ 153.02 | 40% | $ 133.25 | -12.9% |
| Tier 4 | 17% | $ 158.76 | 30% | $ 155.45 | -2.1% |
| Tier 3 | 14% | $ 164.50 | 25% | $ 166.56 | 1.3% |
| Tier 2 | 9% | $ 174.06 | 9% | $ 202.09 | 16.1% |
| Tier 1 | 1% | $ 189.37 | 1% | $ 219.86 | 16.1% |

- The organizational goal is to retain as many diabetes patients as possible in advance of future pipeline expansion. A weakened position in the Acute Care channel, where the population and disease prevalence is growing, would severely compromise our ability to do this. Every Lantus script lost in this space is a lost opportunity for a U300 script.
- Despite a significant increase in discount relative to where we are today, this remains a profitable decision as the ability exists in these accounts to move significant share and potentially gain business from accounts that we have already lost.

- In order for Sanofi to be positioned to expand the future diabetes portfolio, Lantus must maintain high levels of access in this [redacted] segment, particularly since [redacted] are a key point influence with potential impact on both the LTC and retail segments.
- There is urgency around the timing of this recommendation, particularly in light of the May 30 Lantus WAC increase and Novo Nordisk's recent push to have [redacted] and systems sign letters of commitment prior to July 1. The availability and execution of this recommendation will provide Sanofi with an ability to mitigate the impact on the Institutional business.

**Financial Assessment:**

- No negative financial impact expected; F1 2014 accounted for an increase in [redacted] discounts to an average of 30%, effective July 1.
- The average discount for the recommendation is expected to be 29% (+1% admin fee = 30% total), versus a pre-F1 2014 average discount of 16% (+1% admin fee).
- Price predictability of 10% (net with annual reset) is not expected to create any financial exposure, based on current WAC increase plan of 7% in January 2015.

| | 2013 | | | | | 2014 | | | | | 2015 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | TRx (units) | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | TRx (units) | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | TRx (units) |
| Baseline | 152.3 | 18.3 | 12.0% | 134.0 | 968,762 | 183.5 | 29.4 | 16.0% | 154.1 | 882,956 | 208.4 | 33.3 | 16.0% | 175.1 | 882,956 |
| Budget (F1 2014) | 152.3 | 18.3 | 12.0% | 134.0 | 968,762 | 188.1 | 43.8 | 23.3% | 144.3 | 882,956 | 209.8 | 62.9 | 30.0% | 146.9 | 882,956 |
| Variance to Baseline | 0.0 | 0.0 | 0.0% | 0.0 | 0 | 4.6 | 14.5 | 7.3% | -9.8 | 0 | 1.4 | 29.6 | 14.0% | -28.2 | 0 |
| Variance to Baseline (Σ) | 0.0 | 0.0 | | 0.0 | 0 | 4.6 | 14.5 | | -9.8 | 0 | 6.0 | 44.1 | | -38.0 | 0 |
| Recommendation | 152.3 | 18.3 | 12.0% | 134.0 | 968,762 | 188.1 | 43.8 | 23.3% | 144.3 | 882,956 | 209.8 | 62.9 | 30.0% | 146.9 | 882,956 |
| Variance to Baseline | 0.0 | 0.0 | 0.0% | 0.0 | 0 | 4.6 | 14.5 | 7.3% | -9.8 | 0 | 1.4 | 29.6 | 14.0% | -28.2 | 0 |
| Variance to Baseline (Σ) | 0.0 | 0.0 | | 0.0 | 0 | 4.6 | 14.5 | | -9.8 | 0 | 6.0 | 44.1 | | -38.0 | 0 |
| Variance to Budget | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0% | 0.0 | 0.0 | 0.0 | 0.0 | 0.0% | 0.0 | 0.0 |
| Variance to Budget (Σ) | 0.0 | 0.0 | | 0.0 | 0 | 0.0 | 0.0 | | 0.0 | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |

*Note: Σ symbol indicates cumulative variance*

*<u>Key Assumptions (Recommendation):</u>*

- *F1 2014 includes increased average discount of 30%, effective July 1, 2014.*
- *Recommendation includes maximum discount of 40% (+1% administrative fee); average discount of 29% (based on proposed tiers and <u>Q4 2013</u> tier performance volume distribution).*
- *Recommendation assumes 10% price predictability on net pricing with annual reset, effective July 1.*
- *WAC increase of 16.1% on the Vial and 9.9% on SoloStar on May 30, 2014 (Budget / F1 2014 scenario assumes increase on May 30, 2014).*
- *Volume kept static to demonstrate the pure impact of offering incremental discounts and price predictability.*

**Market Overview:**

- [redacted] continue to be under increasing pressure to cut costs across all classes of spend, and the insulin class is now a target.
- Outside pressures such as the ISMP safety letter have made many facilities change treatment protocols from use of pens back to vials for safety concerns. This has contributed to increased costs to [redacted] because of product waste to the systems and individual facilities.
- [redacted] reimbursement is being cut by Medicare, which further reduces their margins.

**Competitive Landscape:**

- Lantus is currently at a disadvantage when pricing is looked at unit to unit in the [redacted] While our teams continue to reinforce the clinical differentiation for Lantus, [redacted] are placing more weight on acquisition cost as a key variable while making formulary decisions.

- For some key institutions, Novo Nordisk has changed the market basket to include just Lantus and Levemir, making it significantly easier for [redacted] to achieve higher discounts under their portfolio offer.
- Novo Nordisk is aggressively pursuing Lantus [redacted] by offering a ramp up to their Gold Level discount (understood to be ~52%) for a period of six (6) months to facilities that sign a letter of commitment by July 1st.
- Some [redacted] are stating that Novo Nordisk is claiming that they expect to have label changes in their PI that say that Levemir are unit to unit equivalent to Lantus.
- The current PHS pricing for Levemir ($0.10 per vial) is much less than Lantus (Q2 2014 = $7.00 per vial, Q3 2014 = $1.54 per vial; Q4 2014 = $0.10 per vial – assuming WAC increase during Q2 2014); the PHS price for Lantus is expected to be reduced to penny pricing ($0.10 per vial) later in 2014 due to statutory calculations.
- Novo Nordisk has a much more liberal application of their systems definition, including offering inpatient pricing to affiliated facilities and some closed door pharmacies. Sanofi's definition includes Owned, Leased, and Managed inpatient facilities only.
- Novo has positioned Levemir as a "loss leader" to better position their full diabetes portfolio (i.e. Victoza, Novolog and other insulins).

**Risk Assessment:**

- **Environmental Impact Statement:** Continued WAC increases will create further pressure in the [redacted] community. Without a corresponding increase in available discounts, we are at considerable risk of negative actions against Lantus and potentially other Sanofi brands.
- **Financial Risk:** Recommendation is neutral versus F1 2014. We are at significant risk of lost business without a more competitive contract offering. Based on the most recent [redacted] (attached), approximately $36 million of annual gross sales is at risk, including inpatient volume and other volume associated with facilities under the influence of each [redacted]. Based on a review of fifteen (15) [redacted] lost over the past two (2) years, Lantus market share dropped from an average of 70% to 40% after those systems moved against Lantus.
- **Legal Risk:** Privilege
- **Compliance Risk:** No anticipated compliance risk.
- **Operational Risk:** Operational risk is limited to timing of the execution of the contract roll-out in relation to the timing of the WAC increase. Given that the mid-year 2014 WAC increase will occur on May 30 (prior to rollout of the revised contract), we will likely experience a negative reaction from accounts during the month of June, prior to the effective date of the increased discounts. We feel that this risk can be mitigated to some extent with swift execution of the recommended increased discounts into the marketplace.
- **Risk for Spill-Over Risk**: We do believe that there will be an impact on the Commercial and part D business if we lose the business within the acute care facilities that are currently under threat, based on the populations within the service areas that they cover as well as others that could decide to move based on our future pricing strategies. Due to the fact that we do not have a complete breakdown of the exact lives and demographics from each plan that are touched by these facilities we do not have an exact dollar impact. However, Sanofi internal research indicates that of Lantus patients switched to Levemir in the inpatient setting, approximately 40% of those patients do not resume their Lantus-based therapy post-discharge.

**Detailed Financial Analysis (Custom View)**

| Baseline | | | |
|---|---|---|---|
| **Item** | **Jul-13 : Jun-14** | **Jul-14 : Jun-15** | **Jul-15 : Dec-15** |
| Sanofi TRx (units) | 904,380 | 882,956 | 441,478 |
| Competitor TRx (units) | 0 | 0 | 0 |
| Sanofi TRx Share (%) | 100% | 100% | 100% |
| Gross Sales ($) | 165,425,847 | 201,587,187 | 104,202,073 |
| Guaranteed Rebate (%) | 0% | 0% | 0% |
| Performance Rebate (%) | 13% | 15% | 15% |
| Administration Rebate (%) | 1% | 1% | 1% |
| PP Penalty Rebate (%) | 0% | 0% | 0% |
| Total Rebate (%) | 14% | 16% | 16% |
| Guaranteed Rebate ($) | 0 | 0 | 0 |
| Performance Rebate ($) | 21,589,186 | 30,238,078 | 15,630,311 |
| Administration Rebate ($) | 1,654,258 | 2,015,872 | 1,042,021 |
| PP Penalty Rebate ($) | 0 | 0 | 0 |
| Total Rebate ($) | 23,243,444 | 32,253,950 | 16,672,332 |
| Net Sales ($) | 142,182,403 | 169,333,237 | 87,529,741 |

| Budget (F1 2014) | | | |
|---|---|---|---|
| **Item** | **Jul-13 : Jun-14** | **Jul-14 : Jun-15** | **Jul-15 : Dec-15** |
| Sanofi TRx (units) | 904,380 | 882,956 | 441,478 |
| Competitor TRx (units) | 0 | 0 | 0 |
| Sanofi TRx Share (%) | 100% | 100% | 100% |
| Gross Sales ($) | 169,401,135 | 202,949,479 | 104,906,252 |
| Guaranteed Rebate (%) | 0% | 0% | 0% |
| Performance Rebate (%) | 13% | 29% | 29% |
| Administration Rebate (%) | 1% | 1% | 1% |
| PP Penalty Rebate (%) | 0% | 0% | 0% |
| Total Rebate (%) | 14% | 30% | 30% |
| Guaranteed Rebate ($) | 0 | 0 | 0 |
| Performance Rebate ($) | 22,185,479 | 58,855,349 | 30,422,813 |
| Administration Rebate ($) | 1,694,011 | 2,029,495 | 1,049,063 |
| PP Penalty Rebate ($) | 0 | 0 | 0 |
| Total Rebate ($) | 23,879,490 | 60,884,844 | 31,471,876 |
| Net Sales ($) | 145,521,645 | 142,064,635 | 73,434,377 |

| Recommendation | | | |
|---|---|---|---|
| **Item** | **Jul-13 : Jun-14** | **Jul-14 : Jun-15** | **Jul-15 : Dec-15** |
| Sanofi TRx (units) | 904,380 | 882,956 | 441,478 |
| Competitor TRx (units) | 0 | 0 | 0 |
| Sanofi TRx Share (%) | 100% | 100% | 100% |
| Gross Sales ($) | 169,401,135 | 202,949,479 | 104,906,252 |
| Guaranteed Rebate (%) | 0% | 0% | 0% |
| Performance Rebate (%) | 13% | 29% | 29% |
| Administration Rebate (%) | 1% | 1% | 1% |
| PP Penalty Rebate (%) | 0% | 0% | 0% |
| Total Rebate (%) | 14% | 30% | 30% |
| Guaranteed Rebate ($) | 0 | 0 | 0 |
| Performance Rebate ($) | 22,185,479 | 58,855,349 | 30,422,813 |
| Administration Rebate ($) | 1,694,011 | 2,029,495 | 1,049,063 |
| PP Penalty Rebate ($) | 0 | 0 | 0 |
| Total Rebate ($) | 23,879,490 | 60,884,844 | 31,471,876 |
| Net Sales ($) | 145,521,645 | 142,064,635 | 73,434,377 |

**Financial Model Assumptions:**

## ROI Model Description

| | | | |
|---|---|---|---|
| **Model Product Line:** | Lantus | **Model Creation Date:** | 22-May-2014 |
| **Model Plans / PBMs:** | [redacted] | **Model Author:** | M. Siemers |

**Model Purpose:**

This model is to evaluate potential contracting changes to the Lantus [redacted] contracting strategy. The model will look at increased discounts and price protection at various levels.

**Baseline**

| | |
|---|---|
| **Description:** | Market share based performance agreement with a current maximum discount of 20% at Tier 5. Average weighted discount of 15% (based on Q1 2014 actual performance). Projections based on straight-line forcast of Q3 2013 - Q1 2014 actuals. |
| **Analog:** | |
| **Data Sources:** | SPM / Bottoms-Up Forecast |

**Budget**

| | |
|---|---|
| **Description:** | Increased discounts to an average of 30%, based on increased average discounts in the 2014 F1. Projections based on bottoms-up forecast for [redacted]. WAC Increase effective May 30, 2014. |
| **Analog:** | |
| **Data Sources:** | SPM / Bottoms-Up Forecast |

**Recommendation**

| | |
|---|---|
| **Description:** | Increased discounts to a maximum of 40% (Tier 5 market share attainment). Average weighted discount of 29%. Includes price predictaility of 10% (net with annual reset. Projections based on bottoms-up forecast for [redacted]. WAC Increase effective May 30, 2014. |
| **Analog:** | |
| **Data Sources:** | SPM / Bottoms-Up Forecast |

**No Contract**

| | |
|---|---|
| **Description:** | |
| **Analog:** | |
| **Data Sources:** | |

[redacted]:

| At Risk [redacted] Accounts | | | |
|---|---|---|---|
| Account Name | # of Total Accounts | Annual Gross Dollars at Risk | 1 YR Lantus TML Volume |
| [redacted] | 3 | $ 5,149,194 | 263,980 |
| | 122 | $ 5,130,468 | 263,020 |
| | 61 | $ 3,703,117 | 189,845 |
| | 19 | $ 2,421,865 | 124,160 |
| | 77 | $ 1,893,057 | 97,050 |
| | 29 | $ 1,821,860 | 93,400 |
| | 16 | $ 1,781,093 | 91,310 |
| | 14 | $ 1,722,087 | 88,285 |
| | 47 | $ 1,679,467 | 86,100 |
| | 10 | $ 1,408,236 | 72,195 |
| | 27 | $ 1,203,618 | 61,705 |
| | 9 | $ 1,075,756 | 55,150 |
| | 4 | $ 1,057,615 | 54,220 |
| | 12 | $ 836,222 | 42,870 |
| | 2 | $ 816,502 | 41,859 |
| | 15 | $ 727,379 | 37,290 |
| | 9 | $ 724,843 | 37,160 |
| | 18 | $ 703,776 | 36,080 |
| | 10 | $ 580,596 | 29,765 |
| | 12 | $ 539,829 | 27,675 |
| | 36 | $ 501,889 | 25,730 |
| | 3 | $ 446,882 | 22,910 |
| | 11 | $ 421,934 | 21,631 |
| | 3 | $ 343,696 | 17,620 |
| | 15 | $ 331,407 | 16,990 |
| | 6 | $ 289,567 | 14,845 |
| | 2 | $ 198,766 | 10,190 |
| | 2 | $ 192,524 | 9,870 |
| | 2 | $ 118,109 | 6,055 |
| | 2 | $ 59,025 | 3,026 |
| Total | 582 | $ 37,880,379 | 1,941,986 |

# Lantus Price Increase

May 2014

Reviewed by Legal May 20, 2014

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# EXECUTIVE SUMMARY
# Lantus Price Increase

| VOTE | FINANCIAL IMPACT |
|---|---|
| • May 30th: 16.1% vial, 9.9% pen (vs F1 14.9% vial, 9.9% pen) | • -$387 mill net sales if no increase taken<br>• 16.1% vs 14.9% vial increase:<br>  ◦ + $8 mill net sales<br>  ◦ 0.25% GTN erosion |
| **ISSUE SUMMARY & RATIONALE** | **RISK ASSESSMENT** |
| • Current WAC parity with Levemir<br>• Modifying vial increase to 16.1% vs F1 14.9% provides financial upside and brings vial and pen to parity | • Risk associated with any price increases<br>• Selective proactive management may be needed to maintain product access<br>  ◦ Caremark commercial & part D, hospital, wholesaler<br>• PR Risk: ADA conference June 13 – 17 |

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All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.

# VOTE
# Lantus Price Increase

- Recommendation / Vote:
  - **May 30th: 16.1% vial, 9.9% pen (vs. F1 14.9% vial, 9.9% pen)**

- Situational Overview
  - **Last Price Increases**
    - December '13: 14.9% vial, 9.9% pen
    - August '13: 14.9% vial, 9.9% pen
    - April '13: 9.9% vial, 9.9% pen

  - **Lantus & Levemir at WAC parity, pen currently at a 5.6% premium to vial**

| | WAC per ml | | |
|---|---|---|---|
| | Levemir WAC (current) | Lantus WAC (current) | Lantus WAC (proposed) |
| **Vials** | $19.13 | $19.13 | $22.21 |
| **Pens** | $20.21 | $20.21 | $22.21 |



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# ISSUE SUMMARY & RATIONALE
# Lantus Price Increase

- **Issue**: Modification of F1 price increase

- **Rationale for Change**:
  - **Positive financial impact**
  - **Vial to pen price parity**
    - Simplify messaging
    - Set single price point in advance of Toujeo launch

- **Anticipated Impact if Approved**: Positive net sales impact, WAC parity of vial & pen leading to a more favorable pricing foundation for Toujeo

- **Anticipated Impact if NOT Approved**: If no pricing action, considerable negative financial impact, potential pricing challenges for Toujeo

- **Monitoring Plan**: Ongoing monitoring of account access & media outlets



All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.

# FINANCIAL IMPACT
# Lantus Price Increase (2014 Family)

| MUSD | F1 - 14.9% Vial, 9.9% Pen | | | F1 - 16.1% Vial, 9.9% Pen | | | Impact of 1.2% Increase | | |
|---|---|---|---|---|---|---|---|---|---|
| Channel | Gross Sales $ | Disc $ | Net Sales $ | Gross Sales $ | Disc $ | Net Sales $ | Gross Sales $ | Disc $ | Net Sales $ |
| **Total** | **10,044** | **4,474** | **5,570** | **10,074** | **4,495** | **5,579** | **30** | **22** | **8** |
| **Mandated** | **3,322** | **2,605** | **716** | **3,334** | **2,616** | **718** | **13** | **11** | **2** |
| Managed Medicaid | 518 | 444 | 74 | 520 | 446 | 74 | 2 | 2 | 0 |
| Mandated Medicaid | 452 | 388 | 64 | 454 | 390 | 64 | 2 | 2 | 0 |
| Medicare Part D Coverage Gap | 615 | 298 | 317 | 617 | 299 | 318 | 2 | 1 | 1 |
| [redacted] | | | | | | | | | |
| **Discretionary** | **8,079** | **1,482** | **6,597** | **8,103** | **1,494** | **6,609** | **23** | **11** | **12** |
| Managed Care | 3,869 | 515 | 3,354 | 3,879 | 520 | 3,359 | 10 | 4 | 5 |
| State Supplemental Medicaid | 58 | 12 | 45 | 58 | 12 | 45 | 0 | 0 | 0 |
| Discretionary Managed Medicaid | 146 | 22 | 124 | 146 | 22 | 124 | 0 | 0 | 0 |
| Medicare | 3,115 | 819 | 2,296 | 3,124 | 824 | 2,300 | 9 | 6 | 3 |
| State Exchange | 46 | 6 | 40 | 46 | 6 | 40 | 0 | 0 | 0 |
| Long Term Care | 486 | 38 | 448 | 489 | 39 | 450 | 3 | 1 | 1 |
| Outpatient Care | 14 | 0 | 13 | 14 | 1 | 13 | 0 | 0 | 0 |
| Hospital | 248 | 48 | 200 | 248 | 48 | 200 | 1 | 0 | 1 |
| Staff Model | 99 | 22 | 76 | 99 | 23 | 77 | 0 | 0 | 0 |
| **Additional Incentives** | **-** | **386** | **(386)** | **-** | **386** | **(386)** | **-** | **(0)** | **0** |
| Cash Discount | - | 201 | (201) | - | 201 | (201) | - | 1 | (1) |
| Coupons/Other | - | 17 | (17) | - | 17 | (17) | - | - | - |
| DPA | - | 161 | (161) | - | 161 | (161) | - | 1 | (1) |
| DPA - WAC Clawback | - | (40) | 40 | - | (42) | 42 | - | (2) | 2 |
| GPO Fees | - | 6 | (6) | - | 6 | (6) | - | - | - |
| Sales Returns | - | 42 | (42) | - | 42 | (42) | - | 0 | (0) |
| **Other (1)** | **(1,357)** | **-** | **(1,357)** | **(1,363)** | **-** | **(1,363)** | **(6)** | **-** | **(6)** |

(1) Other includes double-counted and non-contracted gross sales.

- -$387 mill net sales impact to F1 if no price increase taken
- Impact of moving from 14.9% vial increase to 16.1%
  - **Positive net sales impact of $8 mill***
  - **Additional GTN erosion of 0.25%**

*includes net effect of extending price protection baseline to price prior to increase for Caremark commercial

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All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.

# RISK ASSESSMENT
# Lantus Price Increase

- **General**: All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.
- **Customer**: Need for selective proactive management to maintain access
  - **Accounts with June or July price protection baseline dates to move to price protect the May 30th action**
    - Caremark commercial & part D
  - **Planned changes to [redacted] for 7/1 to account for price increase change**
  - **Potential challenges if wholesaler contracts renegotiated in the June timeframe**
- **Financial**:
  - **Access risk which may lead to financial risk**
  - **If no pricing action taken, then -$387 net sales hit**
- **Privilege**
- **Compliance**: No specific compliance issues identified at this time
- **Public Relations**: All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Work with Communications department to prepare statements as needed.
  - **ADA conference June 13 - 17**
- **Operational**: N/A



All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.

# Backup

# FINANCIAL IMPACT
# Lantus Price Increase (2014 Vial)

| MUSD | 2014 F1 | | | | | | Increase from 14.9% to 16.1% | | |
|---|---|---|---|---|---|---|---|---|---|
| Channel | % of Bus | Disc % | GTN Ded % | Gross Sales $ | Disc $ | Net Sales $ | Gross Sales $ | Disc $ | Net Sales $ |
| **Total** | **100%** | **54%** | **54%** | **4,608** | **2,489** | **2,119** | **30** | **22** | **8** |
| **Mandated** | **42%** | **84%** | **40%** | **1,950** | **1,644** | **306** | **13** | **11** | **2** |
| Managed Medicaid | 6% | 93% | 5.6% | 279 | 259 | 20 | 2 | 2 | 0 |
| Mandated Medicaid | 5% | 93% | 5.0% | 251 | 232 | 19 | 2 | 2 | 0 |
| Medicare Part D Coverage Gap | 6% | 47% | 2.7% | 267 | 126 | 141 | 2 | 1 | 1 |
| [redacted] | | | | | | | | | |
| **Discretionary** | **78%** | **19%** | **16%** | **3,576** | **676** | **2,900** | **23** | **11** | **12** |
| Managed Care | 32% | 13% | 4% | 1,490 | 201 | 1,290 | 10 | 4 | 5 |
| State Supplemental Medicaid | 1% | 9% | 0% | 46 | 4 | 42 | 0 | 0 | 0 |
| Discretionary Managed Medicaid | 1% | 14% | 0% | 46 | 7 | 40 | 0 | 0 | 0 |
| Medicare | 30% | 28% | 8% | 1,379 | 389 | 989 | 9 | 6 | 3 |
| State Exchange | 0% | 12% | 0% | 18 | 2 | 16 | 0 | 0 | 0 |
| Long Term Care | 9% | 8% | 1% | 396 | 30 | 365 | 3 | 1 | 1 |
| Outpatient Care | 0% | 4% | 0% | 14 | 0 | 13 | 0 | 0 | 0 |
| Hospital | 2% | 22% | 1% | 111 | 24 | 87 | 1 | 0 | 1 |
| Staff Model | 2% | 24% | 0% | 75 | 18 | 57 | 0 | 0 | 0 |
| **Additional Incentives** | | | **4%** | **-** | **169** | **(169)** | | **(0)** | **0** |
| Cash Discount | | | 2% | - | 92 | (92) | - | 1 | (1) |
| Coupons/Other | | | 0% | - | 0 | (0) | - | - | - |
| DPA | | | 2% | - | 74 | (74) | - | 1 | (1) |
| DPA - WAC Clawback | | | 0% | - | (22) | 22 | - | (2) | 2 |
| GPO Fees | | | 0% | - | 4 | (4) | - | - | - |
| Sales Returns | | | 0% | - | 21 | (21) | - | 0 | (0) |
| **Other (1)** | **-20%** | **0%** | **0%** | **(918)** | **-** | **(918)** | **(6)** | **-** | **(6)** |

(1) Other includes double-counted

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**Express Scripts (ESI)**
**Contracting White Paper Lantus / AUVI-Q**
**2015/2016 Commercial Bid**

This proposal is in response to the 2015 ESI Commercial RFP which is due to the customer on May 1st.

**Summary of Current Position:**

**Lantus** - Kelly Rhodus, SR. Director Contracting at ESI, has advised that Sanofi will need to be far more aggressive with commercial than we have been in years past and that price protection for Lantus is an absolute minimum. She stated that Novo, specifically Levemir, has changed the game with regard to rebates and that we will need to rebate aggressively. ESI has stated that they want an exclusive basal insulin offer along with a 1 of 2 basal insulin offer to be submitted for consideration. They have advised repeatedly that the competitive responses by the pharmaceutical manufacturers will dictate the direction of negotiations going forward for 2015. We have received confirmation from ESI that Novo is providing enhanced rebates effective July 1, 2014. We have not included an enhanced stand-alone 2014 rebate in our Walk-in offer. However, we do feel there is a high probability that this will be brought into the negotiations at a later date.

**Auvi-Q** - [redacted] and additional Lantus rebates of 1.5% for the first six months of 2014 and added an additional 1.5% for the second six months of 2014. This offer was heavily debated by ESI. Ultimately, the offer was rejected due to the announcement of the exclusion list formularies and an unwillingness of ESI to make any changes after the announcement. Feedback from ESI is that it was highly unlikely that any change will occur until January 1, 2015 unless the offer is attractive enough.

**Recommendation:**

- **Portfolio offer of Lantus and Auvi-Q to get Auvi-Q removed from Exclusions List as soon as possible**
- **Enhancement of Lantus terms to keep Lantus off Exclusions List for 2015+**

**ESI 2014-2015 Commercial Bid Proposal**

| Walk In | | | | | |
|---|---|---|---|---|---|
| Product | | Current | July-September 2014 | October-December 2014 | January-December 2015 |
| Lantus | Exclusions List | 8% for 1 of 2 | NA | +2% Auvi Q* | 25% for 1 of 1 + 10% PP / +2% Auvi-Q* |
| | Other | 8% for 1 of 2 | NA | +2% Auvi Q* | 18% for 1 of 2 + 10% PP/+2% Auvi-Q* |
| | Tier 3 | NA | NA | NA | NA |

[redacted]

| Max Guidance | | | | | |
|---|---|---|---|---|---|
| Product | | Current | July-September 2014 | October-December 2014 | January-December 2015 |
| Lantus | Exclusions List | 8% for 1 of 2 | NA | 12% for 1 of 2 / +3% Auvi Q* | 47% for 1 of 1 + 10% PP / +3% Auvi-Q* |
| | Other | 8% for 1 of 2 | NA | 12% for 1 of 2 / +3% Auvi Q* | 27% for 1 of 2 + 10% PP/+3% Auvi-Q* |
| | Tier 3 | NA | NA | NA | NA |

[redacted]

## ESI Offer LANTUS Commercial Financial Impact

LANTUS

| | 2014 | | | | | | | | 2015 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | Lantus Rebate for AuviQ ($M) | Net Net Sales ($M) | TRx (units) | Market Share (%) | Gross Sales ($M) | Rebates ($M) | Rebate (%) | Net Sales ($M) | Lantus Rebate for AuviQ ($M) | Net Net Sales ($M) | TRx (units) | Market Share (%) |
| BASELINE | 1,531 | 116 | 7.6% | 1,415 | | 1,415 | 3,392,882 | 80% | 1,672 | 127 | 7.6% | 1,545 | | 1,545 | 3,508,296 | 80% |
| NO CONTRACT | 1,531 | 116 | 7.6% | 1,415 | | 1,415 | 3,392,882 | 80% | 783 | 0 | 0.0% | 783 | | 783 | 1,642,971 | 37% |
| WALK-IN | 1,531 | 116 | 7.6% | 1,415 | 8 | 1,407 | 3,392,882 | 80% | 1,813 | 381 | 21.0% | 1,432 | 33 | 1,398 | 3,803,455 | 87% |
| MAX GUIDANCE | 1,531 | 133 | 8.7% | 1,398 | 12 | 1,386 | 3,392,882 | 80% | 1,813 | 646 | 35.6% | 1,167 | 50 | 1,117 | 3,803,455 | 87% |
| Variance to Baseline | | 16 | | | 12 | -28 | | | | | | | | | | |

2014 Budget Impact: Walk-In -$8M /Max Guidance -$28M

## ESI Net Cost to Plan Financials

### 2015 ESI Lantus Net Cost To Plan Summary - WALK-IN OFFER

ESI Net Cost To Plan Analysis
Net Cost to Plan after Copay = Pharmacy Reimbursement + Pharmacy Dispensing Fee - Rebates - Copay

| Scenario | Lantus Rebate % | Lantus Net Cost To Plan | Lantus Copay | Lantus Mkt Sh | Levemir Rebate % | Levemir Net Cost To Plan | Levemir Copay | Levemir Mkt Sh | Total Net Cost To Plan after Copay | | | Lantus Net Sales | Levemir Net Sales |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lantus\Levemir Co-Preferred | 20% | $1,357 | $88 | 80% | 45.0% | $258 | $22 | 20% | $1,506 | Variance to Co-Preferred | | $1,338 | $253 |
| Levemir Preferred on Exclusions List @ 65% | 18% | $865 | $59 | 50% | 60.4% | $468 | $55 | 50% | $1,219 | ($286) | Variance to Levemir Preferred | $853 | $455 |
| PROPOSAL: Lantus Preferred on Exclusions List @ 27% | 23% | $1,423 | $96 | 88% | 41.3% | $172 | $15 | 12% | $1,485 | ($21) | $265 | $1,402 | $169 |

$s in Millions

Exclusion List Analog: 88%

### 2015 ESI Lantus Net Cost To Plan Summary - MAX GUIDANCE

ESI Net Cost To Plan Analysis
Net Cost to Plan after Copay = Pharmacy Reimbursement + Pharmacy Dispensing Fee - Rebates - Copay

| Scenario | Lantus Rebate % | Lantus Net Cost To Plan | Lantus Copay | Lantus Mkt Sh | Levemir Rebate % | Levemir Net Cost To Plan | Levemir Copay | Levemir Mkt Sh | Total Net Cost To Plan after Copay | | | Lantus Net Sales | Levemir Net Sales |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lantus\Levemir Co-Preferred | 30% | $1,190 | $88 | 80% | 45.0% | $258 | $22 | 20% | $1,338 | Variance to Co-Preferred | | $1,170 | $253 |
| Levemir Preferred on Exclusions List @ 65% | 28% | $770 | $59 | 50% | 60.4% | $468 | $55 | 50% | $1,124 | ($215) | Variance to Levemir Preferred | $757 | $455 |
| Lantus Preferred on Exclusions List @ 57% (Levemir NCTP Break Even) | 43% | $1,067 | $96 | 88% | 41.3% | $172 | $15 | 12% | $1,128 | ($211) | $4 | $1,045 | $169 |
| PROPOSAL: Lantus Preferred on Exclusions List @ 50% | 40% | $1,127 | $96 | 88% | 41.3% | $172 | $15 | 12% | $1,189 | ($150) | $65 | $1,106 | $169 |

$s in Millions

Exclusion List Analog: 88%

If Levemir was to offer a 65% rebate, to keep the Net Cost To Plan unchanged, Lantus would need to offer a 57% rebate for Exclusions List Business.

## Lantus Assumptions

**2015 ESI Lantus Net Cost To Plan Assumptions - WALK-IN OFFER**

| | | | | | CO-PREFERRED | | Levemir Preferred on Exclusions List | | Proposed Lantus Preferred on Exclusions List | |
|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Lives (Millions) | % of Business | Market TRxs | Analog | Lantus Rebate % | Levemir Rebate % | Lantus Rebate % | Levemir Rebate % | Lantus Rebate % | Levemir Rebate % |
| **EXCLUSIONS LIST** | **32** | 43% | 1,871,091 | **88%** | **20.0%** | **45.0%** | **0.0%** | **65.0%** | **27.0%** | **0.0%** |
| **CUSTOM HPs** | **30** | 40% | 1,754,148 | **0%** | **20.0%** | **45.0%** | **20.0%** | **45.0%** | **20.0%** | **45.0%** |
| **OTHER EMPLOYERS** | **13** | 17% | 760,131 | **0%** | **20.0%** | **45.0%** | **20.0%** | **45.0%** | **20.0%** | **45.0%** |
| **AGGREGATE** | **75** | 100% | 4,385,370 | 38% | 20.0% | 45.0% | 18.3% | 60.4% | 23.3% | 41.3% |

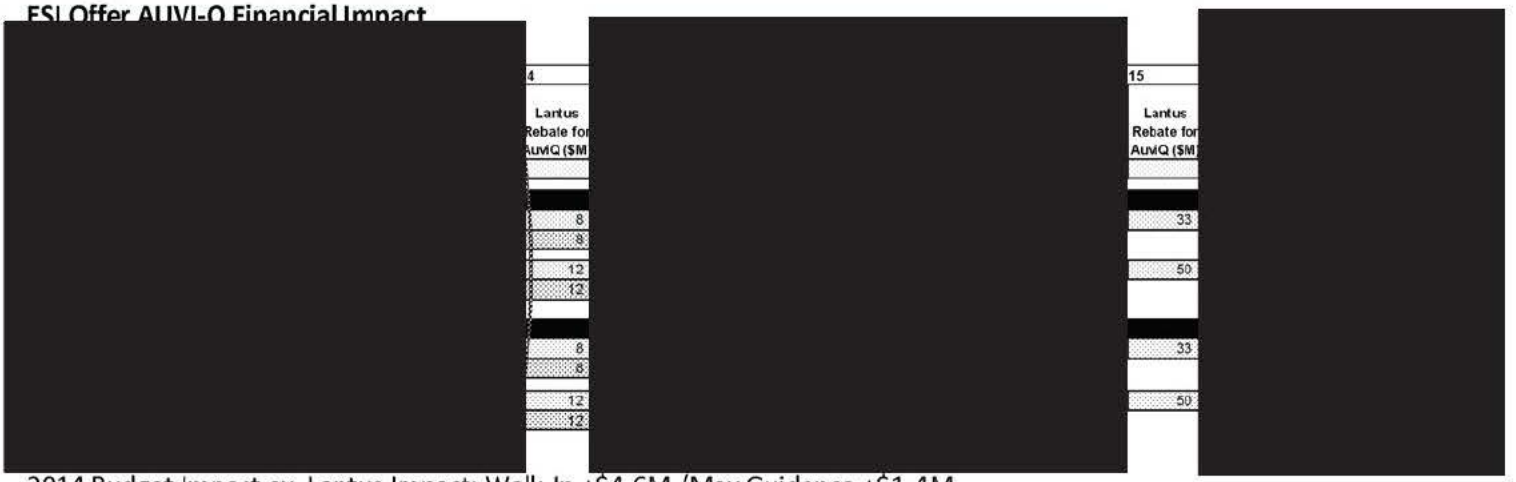
**2015 ESI Lantus Net Cost To Plan Assumptions - MAX GUIDANCE**

| | | | | | CO-PREFERRED | | Levemir Preferred on Exclusions List | | Lantus Preferred on Exclusions List (Levemir NCTP Break Even) | | Proposed Lantus Preferred on Exclusions List | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Lives (Millions) | % of Business | Market TRxs | Analog | Lantus Rebate % | Levemir Rebate % | Lantus Rebate % | Levemir Rebate % | Lantus Rebate % | Levemir Rebate % | Lantus Rebate % | Levemir Rebate % |
| **EXCLUSIONS LIST** | **32** | 43% | 1,871,091 | **88%** | **30.0%** | **45.0%** | **0.0%** | **65.0%** | **57.0%** | **0.0%** | **50.0%** | **0.0%** |
| **CUSTOM HPs** | **30** | 40% | 1,754,148 | **0%** | **30.0%** | **45.0%** | **30.0%** | **45.0%** | **30.0%** | **45.0%** | **30.0%** | **45.0%** |
| **OTHER EMPLOYERS** | **13** | 17% | 760,131 | **0%** | **30.0%** | **45.0%** | **30.0%** | **45.0%** | **30.0%** | **45.0%** | **30.0%** | **45.0%** |
| **AGGREGATE** | **75** | 100% | 4,385,370 | 38% | 30.0% | 45.0% | 27.5% | 60.4% | 42.8% | 41.3% | 39.5% | 41.3% |

| | |
|---|---|
| Market TRxs | 4,385,370 |
| Lantus Baseline Mkt % | 80% |
| LantusWAC/RX | $477 |
| LevemirWAC/RX | $524 |
| Network Disc% | 16% |
| Dispensing Fee/RX | $1.75 |
| Copay Tier 2 | $25 |
| Copay Tier 3 | $50 |

Based on Budgeted Pricing Actions: Vial 14.9% / Pen 9.9% July 2014, 2015: No Pricing Actions

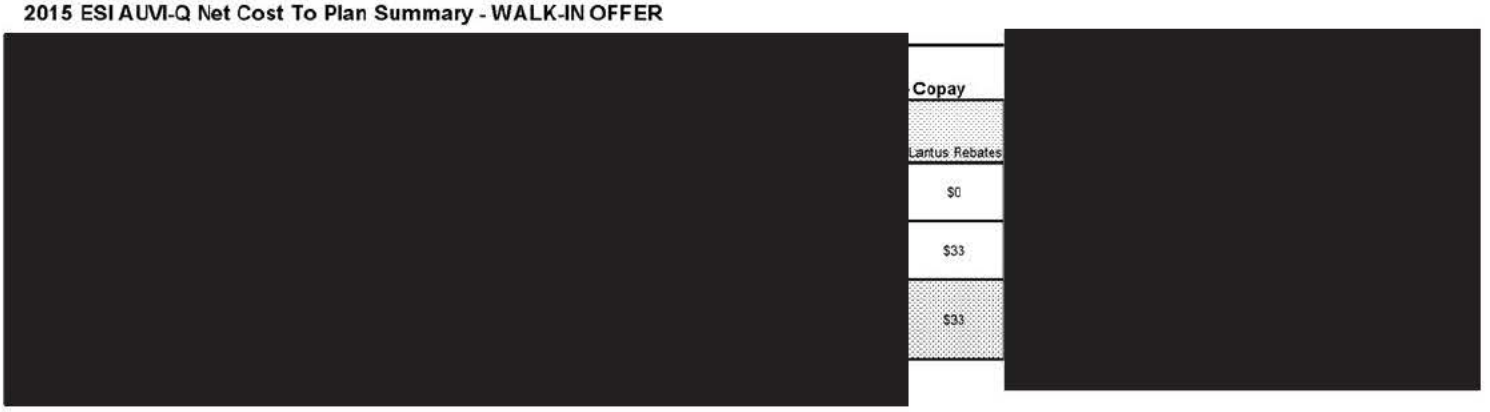
**ESI Offer AUVI-Q Financial Impact**



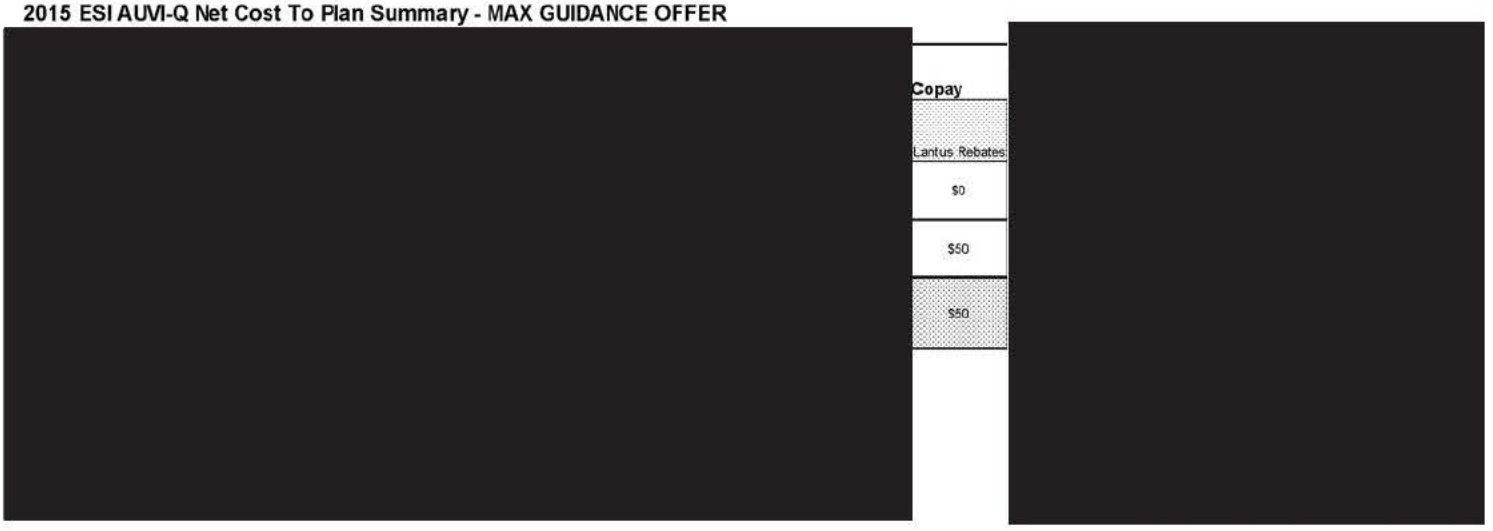

2014 Budget Impact ex. Lantus Impact: Walk-In +$4-6M /Max Guidance +$1-4M

**ESI Net Cost to Plan Financials**

**2015 ESI AUVI-Q Net Cost To Plan Summary - WALK-IN OFFER**




**2015 ESI AUVI-Q Net Cost To Plan Summary - MAX GUIDANCE OFFER**



**Auvi-Q Assumptions**

[redacted]

| | |
|---|---|
| Lantus Rebates | $50M |

[redacted]

## BACKUP

**ESI Background**

The completion of the Medco acquisition by Medco resulted in ESI becoming the largest US PBM. Significant steps were executed by ESI during 2013 to fully merge all PBM operations onto a single platform and align 2014 formularies.

| | 2014 Lives (Millions) | 2015 Lives (Millions) | Change (Millions) |
|---|---|---|---|
| EXCLUSIONS LIST | 22.5 | 32.0 | 9.5 |
| CUSTOM HPs | 30.0 | 30.0 | 0.0 |
| OTHER EMPLOYERS | 22.5 | 13.0 | (9.5) |
| AGGREGATE | 75.0 | 75.0 | 0.0 |

- [redacted] 2014 as a result of being placed on the exclusions list on January 1, 2014.

**Lantus Contracting History with ESI**

Account Management and Contracting have worked closely together to maintain a 5% rebate for Commercial contracts through 2012. Sanofi was notified by ESI that Lantus was positioned to be removed from formulary effective 2013. Rebates were re-negotiated resulting in a 6% Lantus Vial & 9% Lantus SoloStar rebate (no price protection).

**Lantus Overall Threat**

The Commercial business is at additional threat due to competitive rebate pressures and changing formulary design as well as Lantus pricing actions.

- ESI has shared that Novo has been extremely aggressive the last few months and this has triggered the need to revise our offer.
    - For 2014 ESI made Humalog exclusive in the RAI category, moving Novolog to Not Covered and made Byetta & Bydureon the only options in the GLP1 category, moving Victoza to Not Covered.
- Comments during discussion with ESI confirmed that modeling has occurred and that the current contracted offer will result in a Not Covered position for 2015. This is based on competitive offers by Novo and client plans requesting exclusive offers for comparison.
- They have shared that the basal category is under consideration for exclusion list status for 2015. This interest in an exclusive offer is consistent with recent actions they have taken to reduce the number of branded options available to patients.
- Lantus price increases over the past two years have positioned Sanofi as a cost driver that has triggered significant attention from ESI.

**Auvi-Q Contracting History with ESI**

[redacted] The ESI contract offers were enhanced multiple times. The latest offer which included a Lantus bundle has been removed from consideration. [redacted]

**Background Summary**

Benefit Designs are becoming more restrictive with tighter controls

- PBMs are looking to "not covered" products as an answer to co-pay cards
- Migration to exclusion type formularies is increasing at an increasing rate
- Where patients previously wanted choice, they are now more accustomed to switching products to reduce costs
- Patients are looking for tighter formularies if it means out of pocket costs decrease.
- PBMs are utilizing internal capabilities to drive formulary compliance

- PBMs have demonstrated ability to dramatically impact market share with exclusion type formularies

**ESI Formulary Offerings**

ESI offers three similar formularies. The National Preferred, Basic, and High Performance formularies are all available for commercial books of business. The National Preferred is the core formulary for ESI. It is a multi-tiered formulary except for those categories that have been identified as exclusion categories. Non-formulary products that fall in the exclusion therapeutic categories are not covered under the national preferred formulary. The Basic formulary is the same as the National Preferred formulary without the exclusion categories. Products in categories that are exclusion categories in the National Preferred formulary are covered at a 3rd tier co-pay level under the Basic formulary. The High Performance formulary is most restrictive and least utilized formulary.

**Changing Formulary Design – Added Threat**

Formulary offerings by ESI continue to evolve as a result of cost pressures and changing patient expectations. Patient choice has historically been considered necessary for the PBM to be competitive. This thinking has dramatically changed over the last year. ESI previously worked to provide a formulary design that would lower cost while providing the greatest amount of patient choice. This allowed ESI to recommend low cost alternatives while giving the patient the option of paying a greater percentage of cost if they chose non-formulary options. This resulted in patients paying a higher co-pay for non-preferred products primarily through multi-tier benefit designs. Pharma manufacturers responded to non-preferred access with the use of co-pay cards and coupons to help patient's off-set higher cost non-formulary products in commercial markets where patient choice resulted in a higher co-pay. The PBMs identified the use of exclusion list formularies with non-formulary products being not covered as an option to address the challenges with patient co-pay cards and coupons. ESI was concerned with how patients and physicians would react to such a change and elected to monitor steps taken by Caremark as they implemented an exclusion list formulary in 2012. Not only was there acceptance of these more restrictive steps, patients and employers welcomed the more restrictive formularies. Patients and payers were willing to give up choice in return for having lower costs. ESI responded to their client requests to reduce costs by bringing forward their own formulary with exclusion categories effective January 2014. ESI changed their National Preferred formulary effective January 1, 2014 to include 19 therapeutic categories as exclusion categories resulting in 44 drugs immediately becoming not covered on formulary.

**Formulary Compliance Controls and Cost**

Non-formulary products are at an even greater risk as ESI has attempted to separate itself from other PBMs by applying principles of behavioral science to implement programs that motivate patients to comply with formulary agents. ESI claims to improve clinical outcomes, save money for clients, and also optimize its own revenues, as these programs drive patients to generics and formulary agents and increase utilization of mail. ESI has conducted extensive research to better understand where consumers get their drugs, which drugs they take, and whether they take them as prescribed. The ESI approach—branded as Consumerology—operates from the premise that members' behavior does not always match their intention. Patients want to do the right thing (which the PBM defines as using lower-cost generics, home delivery, or other lower-cost pharmacies), but human nature makes them prone to inattention and inertia. ESI then uses advanced risk-prediction tool to identify members who are likely to be non-adherent to medications and target them for interventions that support compliance with formulary agents.

The demonstrated impact on market share by changing to the exclusion formularies is dramatic for products with not covered status. ESI shared this week that Victoza has dropped over 60%. [redacted] ESI has commented that they are not concerned about including a market leader as an excluded product. They shared that the precedent has already been set by [redacted] and United and that Lantus is no longer protected.

**LANTUS NET COST TO PLAN DETAILS**

**WALK-IN**

**2015 ESI Lantus Net Cost To Plan Summary - Detail by each Book of Business**

**MAX GUIDANCE**

**2015 ESI Lantus Net Cost To Plan Summary - Detail by each Book of Business**

**AUVI-Q NET COST TO PLAN DETAILS**

**WALK-IN**

**2015 ESI Auvi-Q Net Cost To Plan Summary - Detail by each Book of Business**

**MAX GUIDANCE**

**2015 ESI Auvi-Q Net Cost To Plan Summary - Detail by each Book of Business**