

Documents Produced by
Eli Lilly



March 8, 2019

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By Hand

Confidential Treatment Requested

The Honorable Charles E. Grassley
The Honorable Ron Wyden
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley and Senator Wyden:

This letter responds to your February 22, 2019 letter regarding the price of insulin.¹ Eli Lilly and Company (“Lilly”) understands the importance of ensuring that our various insulin products are both accessible and affordable to individuals with diabetes, and we continually evaluate how to improve patient access to this important, life-saving medicine. We welcome the opportunity to discuss this issue with you and your staff.

I. Lilly’s Commitment to Affordable Access to Insulin

Affordable access to insulin is an issue that Lilly takes very seriously. We understand that much work is underway among healthcare stakeholders and in Washington to find a long-term solution to address gaps in our current healthcare system that expose some individuals to high prescription drug costs. While that work proceeds, there is a real and pressing need for more immediate solutions, particularly for those patients who take medications for chronic conditions and face high out-of-pocket costs for those medications. Lilly has long provided support for these patients, but in recent years we have recognized that there is an increased need to address patient affordability challenges as more patients bear a greater share of the costs of their medications.

Just this week, Lilly announced the introduction of Insulin Lispro, a lower-priced version of Humalog, our most popular insulin drug.² This new version of Humalog will provide an insulin option with a list price 50% lower than the current Humalog list price. Insulin Lispro is the same molecule as Humalog. The list price of a single vial will be \$137.35, and the list price of a five-pack of KwikPens will be \$265.20. Our efforts to bring this product to market have

¹ The enclosed separate response from counsel provides answers to the specific questions you raised and documents responsive to your requests. In this response, Lilly has used its best efforts to be as accurate and responsive as possible based on our understanding of the terms used in your letter. The representations herein are based on current information and belief.

² We are starting with Humalog U-100, which captures more than 80 percent of people who use our most commonly used insulin.

been underway since 2017, and vials and pens of the lower-priced insulin have already been manufactured. Lilly will now work with supply chain partners to make them available in pharmacies as quickly as possible.

Insulin Lispro will be made available as an authorized generic through a Lilly subsidiary, ImClone Systems. By introducing an authorized generic, we can provide a lower-priced insulin more quickly without disrupting access to branded Humalog, which thousands of insured patients depend on and which will remain available for people who want to continue accessing it through their current insurance plans. Introducing an authorized generic will provide payers time to renegotiate downstream contracts and adjust to new system economics without making patients wait for prices to drop. This lower-price version can help fill important gaps for the uninsured, people on Medicare Part D, and people who may be in the deductible phase of their high-deductible health plan. Importantly, Insulin Lispro does not prevent other generics from entering the market. No patents prohibit competitors from launching products similar to Lilly insulins, and any company willing to incur the expense of producing insulin may seek to bring a product to market in the future. Additionally, both Humalog and Insulin Lispro will be covered drugs available in the Medicaid program and subject to the corresponding federally mandated rebate. Taking into account this rebate, both products will be made available at a net cost to the Medicaid program of approximately \$0. We hope the launch of Insulin Lispro will be a catalyst for positive change across the U.S. healthcare system.

Additionally, in August 2018, Lilly launched new programs including the Lilly Diabetes Solution Center (“LDSC”), a patient-focused hotline staffed by medical professionals, to better connect people living with diabetes to various solutions based on their individual circumstances. Every month, these new solutions help more than 10,000 additional people living with diabetes more easily afford their insulin. For example, the LDSC can connect patients with an immediate need to any one of the nearly 150 clinics across the United States to which Lilly donates free insulin. In 2018 alone, Lilly donated more than 550,000 Humalog U-100 KwikPens. The LDSC also can connect patients to Lilly Cares, a separate charitable organization that provides free insulin to patients who do not have insurance or have Medicare Part D and a household annual adjusted gross income of up to 400% of the federal poverty level.³ For patients whose household income exceeds 400% of the federal poverty level, the LDSC will help them evaluate available options. Such options include Blink Health (www.blinkhealth.com) and Inside Rx (www.INSIDERx.com), which offer savings of up to 40% off the list price of Lilly’s most commonly prescribed insulins.⁴

Our solutions already are helping to lower patients’ out-of-pocket costs. Currently, about 95% of patients filling prescriptions for Humalog, our most commonly prescribed insulin, at a

³ <https://www.lillycares.com/resources.aspx>.

⁴ Although not a Lilly product, the availability of ReliOn—human insulin sold by Walmart at a price to the patient of approximately \$25—provides another option for patients unable to otherwise obtain access to affordable insulin. See https://corporate.walmart.com/_news_/news-archive/2012/07/24/walmart-launches-effort-to-save-diabetes-patients-up-to-60-million-annually.

retail pharmacy pay less than \$100 and 90% of patients pay less than \$50.⁵ That said, we recognize that for some patients the financial burden of affording insulin remains too high. For example, we estimate that each month there are approximately 1,600 likely uninsured patients on Humalog who have not connected to the LDSC and who pay near list price—a group making up approximately 0.27% of the approximately 600,000 total patients who fill a prescription for Humalog each month. We want to reach these patients, make them aware of our LDSC, and help them obtain affordable access. That is why we have publicized the LDSC in multiple ways—using press releases, multiple social media channels, and advertising campaigns that directly target people with diabetes, the general public, and specific communities that have a higher risk of diabetes. Reaching this group of likely uninsured patients, along with those who are shouldering increasingly higher out-of-pocket costs, is also the reason we are launching Insulin Lispro.

Lilly has always sought to make our insulins as affordable as possible for as many people as possible. By providing significant discounts off of the list price, Lilly has been successful in keeping the cost affordable for the vast majority of patients via their insurance programs. In recent years, however, as the insurance market has evolved, Lilly has increasingly realized that not all patients have affordable access to insulin even though they are insured. That is why we have redoubled our efforts to broaden access to affordable insulin by bringing Insulin Lispro to the market at a 50% discount and by creating the LDSC and other measures, as discussed above. Lilly also took an important step toward lowering insulin costs by obtaining approval in 2015 for Basaglar, the first ever follow-on insulin product. Basaglar introduced significant competition in the long-acting insulin market as the lowest-priced basal analog available.⁶ Currently, over 400,000 patients fill a prescription for Basaglar each month, and the product has a list price that is 23% lower than the list price of Lantus®.

But despite the success of these efforts, we recognize that more needs to be done. Ultimately, a more sustainable model that addresses higher costs for the uninsured and people with high deductibles is needed. We look forward to continuing to work with you on this issue.

II. Lilly Provides Price Concessions To Ensure That Patients Have Access to Its Insulins, But More Needs To Be Done To Ensure That All Patients Have Access to Affordable Medicines

As described above, Lilly has been focused on providing affordable solutions within our existing healthcare system. But we are aware that the Committee and others question why the “price” of insulin has been increasing year over year. Any discussion of drug pricing within the current system requires a clarification of terms because the “price” or “cost” of a medication may represent different concepts to different participants in the healthcare system. Manufacturers like Lilly typically set a medication’s “list price,” which is the amount that the manufacturer charges to its wholesale distributor customers. The wholesalers then re-sell the medication to pharmacies

⁵ Almost 9 out of every 10 patients who pay more than \$100 for Humalog are in Medicare Part D plans during the deductible or coverage gap phases of their plan, and current law prohibits manufacturers from providing co-pay assistance to those patients. Based on IQVIA data, FIA data (August 2018 – December 2018).

⁶ <https://investor.lilly.com/news-releases/news-release-details/basaglar-insulin-glargine-injection-100-unitsml-long-acting>.

at a price that those parties separately negotiate. The pharmacies, in turn, dispense the medication to patients and in most cases are paid a price that is individually negotiated by the patient's insurer or by a pharmacy benefit manager ("PBM") retained by the insurer.

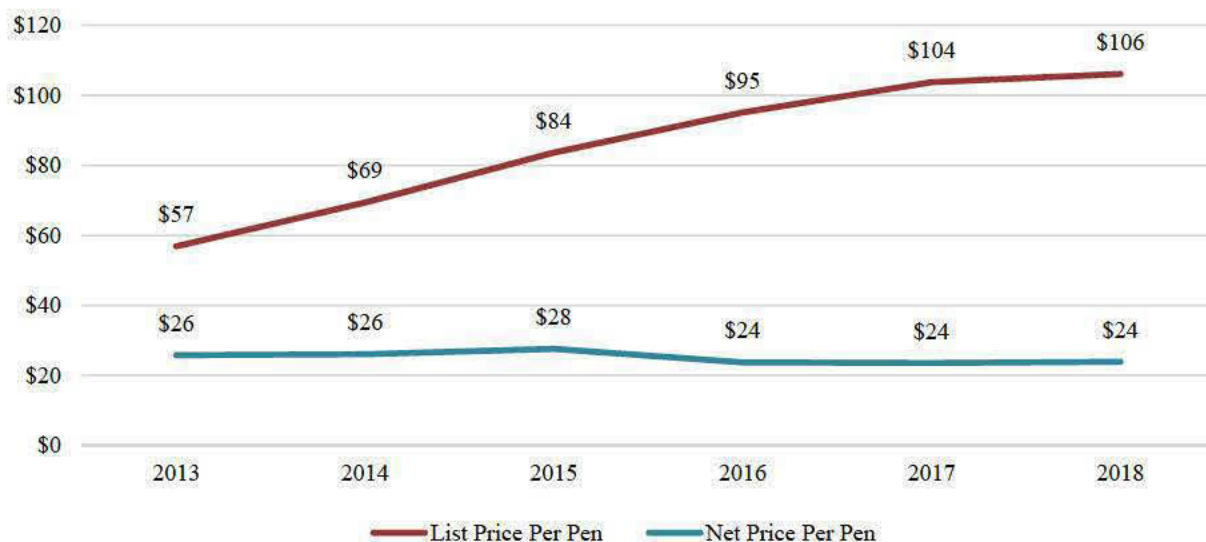
Importantly, manufacturers typically provide rebates and/or fees to insurers or their PBMs, and to federal and state health programs, that reduce the cost of the medication to those entities. Manufacturers also pay other discounts and fees and incur costs related to co-pay assistance to patients and affordability programs.⁷ All of these payments reduce the amount that is ultimately realized by the manufacturer (which is sometimes referred to as a "net price"). In the case of insulins, it has become increasingly common for insurers and PBMs to offer only one insulin manufacturer's line of insulins on their formularies⁸ to achieve the greatest discount (rebate) and thereby the lowest cost. As a result, Lilly and other manufacturers aggressively compete for placement on insurers' formularies and pay rebates to PBMs and insurers to keep medicines available on those formularies in crowded drug classes and, importantly, available to insureds. Overall, average Lilly discounts on U.S. list prices for our products have grown from 41% to 54% in the past five years, with rebates for our insulin products substantially above these rates.

Because of the rebates and fees that Lilly provides to purchasers and insurers (or their PBMs), and other fees and costs Lilly incurs, increases in list prices for Lilly insulins do not reflect corresponding increases in the net price. For example, as illustrated below, between 2013 and 2018, the list price of one of our particular Humalog products—the Humalog U-100 KwikPen—increased by approximately 86%. (Note that the list price of the Humalog U-100 KwikPen has not increased since May 2017.) During that same time period of list price increases, however, the average amount that Lilly received—the net price—declined by approximately 7%.

⁷ Reductions to list price include rebates and discounts paid to commercial insurers, PBMs, and federal and state health programs; discounts mandated under the 340B program to eligible institutions; prompt pay discounts and fee-for-service distribution costs paid to wholesalers; and costs related to patient assistance and affordability programs.

⁸ Drug formularies are ranked lists of drugs that insurers and PBMs use to determine whether certain medicines will be covered by the patient's insurance.

U.S. Humalog U-100 KwikPen List and Net Price by Year, 2013 to 2018



As shown in the data provided in response to Questions 1(c) in your letter,⁹ a similar trend has been observed for Humalog generally (across all product presentations) for the period from 2014 to 2018. During that time, the net price decreased by about 6% despite a list price increase of approximately 55%. For the Humulin family of products, there is also a divergence between list prices and net prices. Net prices increased by about 34% from 2014 to 2018, but did so at a lower rate than list prices, which increased by about 52% during that same time. And in that same time period, the average cost of medical care increased by over 14%.¹⁰ For Basaglar, price data is available only from 2016 through 2018, due to its December 2016 launch date. During that time, the net price declined by about 8%, despite a modest increase in the list price of about 4%.

As noted above, the rebates that Lilly provides help ensure that our insulins are available to most patients. But patients' specific out-of-pocket costs vary significantly depending on numerous factors, most notably the type and terms of their insurance coverage, which Lilly does not control. While Lilly provides rebates in different patient channels for our insulins, in some cases, patients may not directly benefit because of the terms of their insurance coverage. Further, the design of high-deductible commercial insurance and Medicare Part D coverage may lead increasingly to situations where patients must pay near full list price for the drug and the manufacturer still pays a rebate. In such instances, the insurer profits by receiving a rebate even though it has not paid for any portion of the drug's cost. In these situations, even though

⁹ See Letter to the Hon. Charles E. Grassley & the Hon. Ron Wyden from Reginald J. Brown, Mar. 8, 2019, response to requests 1(c) (enclosed).

¹⁰ Data for the average cost of medical care in U.S. cities is available as part of the Bureau of Labor Statistics' Consumer Price Index. The data used here is available at https://data.bls.gov/timeseries/CUUR0000SAM?output_view=data.

manufacturers pay rebates to ensure patients have access to needed medicines via formularies, these savings are often not passed on directly to patients at the point of sale.

Lilly is committed to finding solutions that will ensure that the rebates and discounts it pays actually reach patients at the point of sale. Lilly has advocated for directly passing rebates on to patients, and, thus, we support the policy objective of reducing the patient out-of-pocket burden as advanced by HHS' recently proposed rule.¹¹ We believe the proposal has the potential to lower patients' out-of-pocket costs at the pharmacy counter by enabling manufacturers' price concessions to flow directly to patients. We also support policy solutions for addressing affordability challenges resulting from high-deductible plans, such as caps on patient out-of-pocket costs per transaction and "first dollar" insurance coverage for select chronic medications. We welcome the opportunity to work with you and your staff on these issues.

III. Innovation in Diabetes Treatments

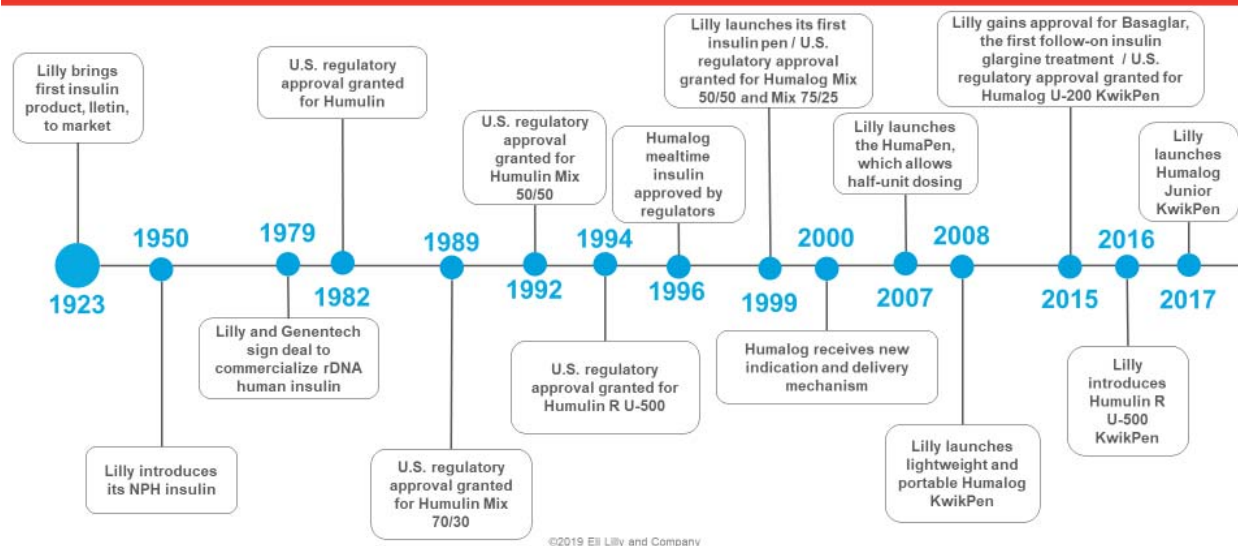
Some have questioned why insulin, a product that was first available nearly a century ago, is not priced lower simply because of its longstanding availability. A significant reason is that today's modern insulins have improved substantially since 1923. That year, Lilly pioneered the manufacturing and distribution of Iletin, the first animal-based insulin. Iletin was the first real hope for treating diabetes, a fatal disease with no effective treatment options. But that insulin was created through processes most would view as crude today—extracting insulin from animal pancreases—leading to purity and quality concerns. Decades later, modern innovation led Lilly to introduce the first recombinant DNA insulin and, eventually, the first human analog insulin. These improvements have been part of a dramatic change in the way diabetes is treated.

Lilly brought the first genetically engineered medicine, Humulin, to market in 1982, ending concerns about whether there would be enough animal-based insulin to serve the growing number of people with diabetes. This product saved lives by allowing the use of a biosynthetic form of human insulin. In 1996, Lilly launched another biotech insulin, Humalog, which mimics the body's own rapid insulin response and has made it easier for people with diabetes to manage their blood glucose. As noted above, in 2015, Lilly obtained approval for the first follow-on insulin biologic, Basaglar. We also have developed a wide range of other diabetes treatments in oral and easy-to-use injectable forms that help people control their glucose levels. The wide range of therapies we offer is essential for physicians and patients to create individualized treatment plans for diabetes.

A timeline showing some of Lilly's significant insulin advancements is set forth below:

¹¹ See HHS, Proposed Rule, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (Feb. 6, 2019).

95 Years of Innovation



Contrary to some widely held assumptions, no patents prohibit competitors from launching products similar to Lilly insulins. In fact, Sanofi launched a follow-on insulin lispro product to compete with Humalog in April 2018, and no patent litigation or other regulatory impediment inhibited Sanofi's launch of its product. While neither patents nor periods of regulatory exclusivity prevent the production and registration of alternative insulin products, insulin production and patient support are expensive and technically difficult. This, coupled with high start-up costs, also may explain why only existing insulin manufacturers have developed insulin alternatives. Additionally, although Lilly has filed or holds patents on certain delivery systems used with some of our insulins (e.g., U.S. Patent Number 7291132 covering "medication dispensing apparatus with triple screw threads for mechanical advantage"), this is not a barrier to insulins delivered in a variety of other ways. Moreover, many of the insulin products Lilly has developed over the years, including lower-priced options, remain available to this day. The main, significant insulin product that Lilly has withdrawn is Iletin, which we stopped manufacturing in 1998 because human insulin alternatives offered greater therapeutic and lifestyle advantages for people with diabetes. Today, patients use newer insulin products because they are more advanced and greatly improve quality of life.

As an innovation-based pharmaceutical company, Lilly continues to push the boundaries of science today to bring better treatments to people with diabetes and other conditions tomorrow. Only about half the people living with diabetes and using insulin are able to fully control their condition. Increased innovation is needed to make diabetes easier to manage, and Lilly is committed to driving new innovative treatments to ease the burden of living with diabetes. For example, later this year, we expect to introduce an easier-to-use nasal glucagon treatment for life-threatening hypoglycemia. And in 2020, if approved, we expect to introduce an even faster-acting version of insulin. Lilly is also active in the space of digital health solutions and is developing a connected diabetes system consisting of devices that we hope will improve adherence, outcomes, and convenience.

Over the last six years, Lilly has invested over \$4 billion in research and development relating to diabetes. This included significant investments in the development of many potentially innovative treatments for diabetes or diabetes complications that were ultimately unsuccessful—an unfortunate part of the development process for new medicines. For example, Lilly made substantial investments seeking to develop new products to manage glucose levels, including a basal insulin with a unique mechanism of action and an inhaled insulin product. We also sought to develop medicines to address complications of diabetes, including a diabetic retinopathy medicine and a medicine to treat diabetic kidney disease. In each case, despite significant investment, the effort to develop the new medicine was unsuccessful.

Lilly has also invested more than \$1.2 billion since 2012 to enhance our insulin manufacturing facilities and in response to the growing diabetes epidemic and increased demand for insulin around the world.¹² More broadly, the company has invested \$5 billion in its U.S. facilities over the last decade. Lilly's facility in Indianapolis—which makes insulin—alone is more than 1 million square feet, the equivalent of about 18 football fields. In addition, the company employs over 11,000 people in Indiana.¹³ Lilly also has a significant manufacturing and research and development presence in New Jersey, California, New York, and Massachusetts. In total, we employ over 16,000 people in the United States.

Moreover, Lilly has invested significant portions of our revenue, including from our diabetes business, to pioneer other life-changing therapies—for cancer, mental health disorders, autoimmune conditions, and, most recently, migraine headaches. From 2013-2017, Lilly spent more than \$25 billion on research and development, always investing at least 20% of its total revenue in R&D. We have spent well over \$3 billion searching—thus far without success—for the first treatment that can slow the progression of Alzheimer's disease. Those resources are essential because pharmaceutical R&D is high-risk. Thousands of molecules are tested and fail for every one that is approved as a new medicine. Even among molecules that make it as far as human testing, only one in eight ends up being approved.

* * *

¹² <https://investor.lilly.com/news-releases/news-release-details/lilly-announces-72-million-investment-diabetes-manufacturing>.

¹³ <https://www.lilly.com/key-facts>.

The Honorable Charles E. Grassley
The Honorable Ron Wyden
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Thank you for the opportunity to provide this response. We are grateful for the Committee's attention to this important issue, and we look forward to continuing a dialogue with you and your staff.

Sincerely,

A handwritten signature in black ink, reading "J. B. Kelley". The signature is written in a cursive, flowing style. The "J" is large and loops around the "B", which is smaller and more compact. The "Kelley" is written in a similar cursive style, with a long, sweeping tail on the "y".

Joseph B. Kelley
Vice President, Global Government Affairs

Enclosures

Reginald J. Brown

March 8, 2019

By Hand

Confidential Treatment Requested

The Honorable Charles E. Grassley
The Honorable Ron Wyden
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden:

We are writing on behalf of Eli Lilly and Company (“Lilly” or the “Company”) in response to your letter dated February 22, 2019. We appreciate the opportunity to address your questions regarding the pricing of Lilly’s insulins. Answers to your questions are set forth below, and documents responsive to your requests are provided on the enclosed password-protected CD at Bates numbers LLY-SFCOM-00000001 – LLY-SFCOM-00000047. The requests you have made are broad and, as discussed with your staff, additional responsive material will be provided on a rolling basis. The password for the CD will be sent under separate cover. We appreciate your staff’s assistance and collaboration. Finally, as you know, Lilly has provided a corporate response under separate cover (the “Lilly Letter”).¹ We would respectfully ask that both responses be included in the Committee’s records.

* * *

- 1. Please provide a list of every insulin product sold in the United States since January 1, 2014, including any variations in formulation, delivery method, or dosing size that would require a product to have a unique National Drug Code (NDC) label. For each product, please provide the following information in an Excel Workbook and in hard copy form:**

¹ See Letter to the Hon. Charles E. Grassley & the Hon. Ron Wyden from Joseph Kelley, Mar. 8, 2019.

- a. A brief description of the product, its dosage size, the volume sold in the United States for each year since January 1, 2014, revenue generated in the United States for each year since January 1, 2014, and gross margin for each year since January 1, 2014.**

A list of Lilly's insulin products sold in the United States since January 1, 2014, including dosage size information, is attached at Bates LLY-SFCOM-00000001.

Sales volume information for these products is attached at Bates LLY-SFCOM-00000002 – LLY-SFCOM-00000004. For each product, Lilly has provided the quantities sold measured in both SKU quantities and equivalent Active Ingredient Units (AIU). As detailed in the methodology tabs, AIU are measured in milliunits ("MU").² Lilly has also provided the gross sales value for each National Drug Code ("NDC")—the product of gross price multiplied by the number of units sold. Note, however, that gross sales is not a measure of the "revenue" realized by Lilly for the reasons set forth in Section II of the Lilly Letter. ~~Lilly does not maintain net revenue data at the NDC level on a consistent and audited basis. We have therefore provided gross revenue at the NDC level and net revenue at the consolidated product family level.~~

Please note that Lilly does not maintain gross margin data at the product or NDC level on a consistent and audited basis. The U.S. Securities and Exchange Commission requires gross margin/net profit data to be compiled only at the enterprise level. As reflected in Lilly's 2018 Form 10-K annual reports, Lilly's global gross margin in 2018 was \$18,125,700,000 for its entire portfolio.

- b. Every list price (i.e., the Wholesale Acquisition Cost or WAC) since January 1, 2014, including the date when each list price was set, changed and went into effect. Please provide these prices on the basis of dosage units, i.e. the form in which they are marketed and sold. Please also specify how you are reporting the price, e.g. per box, per bottle or per milliliter.**

A list of the Wholesale Acquisition Cost ("WAC") price for each of Lilly's insulin products sold in the United States since January 1, 2014 is attached at Bates LLY-SFCOM-00000001.

² MU are not milliliters (mL), nor are they the number of pens or vials. Rather, they reflect the total amount of active ingredient in a given presentation and dosage form. For example, 1,000 MU of insulin is the equivalent of a 10 mL Humalog U-100 vial (10 mL x 100 units per mL = 1,000 MU). Further, Lilly sells insulin products in either 3mL or 10mL presentations. In the Humalog U-100 KwikPen, there are 3 mL of medicine, which means there are 300 MU (3 mL x 100 units per mL = 300 MU). But, in the Humalog U-200 KwikPen, there are also 3 mL but of a more concentrated insulin, so there are 600 MU (3 mL x 200 units per mL = 600 MU).

- c. Every net price that was in effect at any time since January 1, 2014, for Part D plans, and all pharmacy benefit managers (“PBM”) 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 covered lives. 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).**

Information responsive to this request is attached at Bates LLY-SFCOM-00000002 – LLY-SFCOM-00000004. Note that Subsection (c) seeks information regarding the net price that was in effect since January 1, 2014 for all Part D and commercial plans. Because net prices are the function of a number of different variables, as set forth in Section II of the Lilly Letter, there is no single net price per plan. Therefore, we have provided information regarding the average net price Lilly receives for sales in the Medicare Part D and commercial channels. This information was gathered from readily available data kept in the normal course at the Humalog, Humulin, and Basaglar family levels. The response shows net price information per AIU. Using AIUs allows us to aggregate prices for different products within each family (e.g., all of the Humalog products). For context, we have also provided average net price per year and average gross price for each product line across all channels (i.e., “Total Molecule”).

These spreadsheets also provide the top ten commercial and Medicare Part D payer contracts for each product family, covering over 90% of Lilly’s contracted revenues from sales of insulin in these segments.

- 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.**

As noted in Lilly’s response to Question 3(a) below, many PBMs maintain a number of different national formularies, and Lilly’s insulin products may have different status on each formulary. Additionally, many PBMs offer their insurance plan clients “custom” formulary options, which may differ from the PBMs’ national formularies. Thus, for many PBMs and plans, in both the Part D and commercial setting, there is no single “formulary placement” for Lilly’s insulin products.

2. For each product line, please describe all changes to the formulation, delivery method or dosing size that have been made since January 1, 2014. For each product line, please also answer:

Information responsive to this request is attached at Bates LLY-SFCOM-00000005 – LLY-SFCOM-00000008. The attached information is drawn from submissions to the U.S. Food and Drug Administration (“FDA”) relating to modifications to products in Lilly’s Humalog, Humulin, and Basaglar families. The attached tables provide information regarding the new indications, new label information, and significant product improvements for Humalog, Humulin, and Basaglar since January 1, 2014.

In addition to the changes shown in the attached tables, Lilly has embarked on manufacturing modernization initiatives to develop innovative ways to enhance the productivity and efficiency of its insulin manufacturing operations to meet the growing need for insulins while maintaining product quality. ~~Lilly continuously considers possible improvements to its manufacturing process, and Lilly’s technical, manufacturing, and regulatory personnel meet regularly to monitor the progress of ongoing manufacturing initiatives. Manufacturing improvements are undertaken for a variety of reasons, including new regulations, changes in availability of raw materials, safety upgrades, improvements in patient experience and product value, and responding to patient concerns. Lilly’s manufacturing process is never static and requires constant improvement and investment.~~

a. How did the change(s) associated with a new NDC add value to patients?

See the “Rationale for Change” column on the charts attached at Bates LLY-SFCOM-00000005 – LLY-SFCOM-00000008.

b. What were the research and development costs related to the changes described in Question 2(a)? How did the changes described in Question 2(a) affect manufacturing costs?

As noted below in response to Question 5, Lilly reports its research and development expenditures on a company-wide basis in its Form 10-K annual reports filed with the U.S. Securities and Exchange Commission. It has also provided estimates of research and development expenditures at the product family level.

Lilly does not track manufacturing costs at the product modification level.

c. Please explain the relationship between the changes in formulation, delivery method and/or dosing size, and any changes in list (WAC) or net dosage unit prices.

Lilly does not make changes to the list price (WAC) of existing insulin products as a result of changes in formulation, delivery method, or dosing size. Each of Lilly's insulin products, including the various presentations and dosage forms available within each insulin product family, is priced individually. As described in response to Question 7(a) below, changes in list prices reflect consideration of a number of factors, and decisions are made holistically. Thus, while Lilly has continued to develop innovative improvements to the way diabetes is treated, changes in list prices of existing products are not reflective of changes in product presentation and dosage forms.

d. Note any instance in which your company sought and/or received a new patent since January 1, 2014. Please provide all patent applications and approvals. Please also note any NDCs with which the patents are associated.

Lilly has not sought or received patent protection for changes in its insulin product lines sold in the United States since January 1, 2014 that required a unique NDC label.

Patents are not typically associated with NDC labels. The FDA's Orange Book, which is the definitive source for drug patent information, identifies approved drug products and related patent and exclusivity information but typically does not provide NDCs. Nonetheless, where applicable, we have listed the NDCs associated with the respective patents in the table below. All other Lilly insulin NDCs associated with a patent are associated with patents that were sought and received prior to 2014.

Lilly continues to innovate on ways to improve patient adherence and overall treatment options for patients with diabetes. Lilly has filed 17 patent applications from 2015 to 2019 to cover device innovations to improve the patient experience. Most of these patent applications have not published and remain confidential in accordance with 35 U.S.C. § 122. The table below represents the granted patents and patent applications that have published.

| Application Number | Application Date | Patent / Publication Number | Title | NDC |
|--------------------|------------------|-----------------------------|---|---------------------------------|
| 29/495028 | 6/26/2014 | D770038 | Medication Injection Device | 00002-8824-27; 00002-7712-27 |
| 15/505699 | 8/27/2015 | US20170246399 | Sensing System for Detecting a Piston in a Medical Fluid Container | |
| 16/317251 | 7/7/2017 | WO2018/013419 | Dose Detection Module for a Medication Delivery Device | |
| PCT/US2018/019156 | 2/22/2018 | WO2018/160425 | Dose Detection and Drug Identification for a Medication Delivery Device | |
| PCT/US2018/046860 | 8/17/2018 | WO/2019/036576 | Dose Detection Module for a Medication Delivery Device | |
| PCT/US2018/019108 | 2/22/2018 | WO/2019/040117 | Dose Detection Module for a Medication Delivery Device | |
| PCT/US2018/019179 | 2/22/2018 | WO/2019/040118 | Dose Detection Module for a Medication Delivery Device | |
| PCT/US2018/046585 | 8/14/2018 | WO/2019/040313 | Medication Delivery Device with Sensing System | |

e. The gross and per-unit manufacturing costs for each insulin product with an NDC.

Lilly's cost of sales disclosures are included in its Form 10-K annual reports filed with the U.S. Securities and Exchange Commission. Lilly's audited financial data is publicly reported on a consolidated basis for its global aggregate portfolio. Relevant excerpts from Lilly's Form 10-K annual reports, including the Consolidated Statement of Operations for each year, are attached at Bates LLY-SFCOM-00000010 – LLY-SFCOM-00000034 and summarized in the table below.

Eli Lilly and Company and Subsidiaries
Cost of Sales (2014-2018)

| Year | Cost of Sales* |
|-------------|-----------------------|
| 2018 | \$6,430.0 |
| 2017 | \$6,070.2 |
| 2016 | \$5,654.9 |
| 2015 | \$5,037.2 |
| 2014 | \$4,932.5 |

*Dollars in millions

3. 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. The amount of the rebate, discount, or other price concession for coverage of the product and the dates the concession was in effect;

Like other manufacturers, Lilly competes for placement on PBM and payer formularies on the basis of product attributes like efficacy and safety, and by providing rebates to reduce the cost of insulin to PBMs, payers, and patients. Most PBMs maintain multiple formularies and typically solicit bids that require Lilly to provide rebate offers corresponding to a variety of possible formulary statuses. These formularies may include open formularies, closed formularies, and formularies with multiple "tiers" of products available with different levels of restrictions. Bids for all possible formulary statuses are often required so that PBMs can offer a menu of options to a wide variety of insurer clients.

Because Lilly's rebate agreements typically include multiple rebate rates corresponding to different formulary statuses, there is no single rebate rate or "price concession" offered to a PBM for coverage of insulin products. Although PBMs' national formularies are widely adopted by their insurance plan clients, most PBMs maintain multiple national formularies, as well as custom formularies available to specific insurance plans. Thus, the rebate ultimately paid by Lilly depends on the applicable formulary.

Although the rebates, discounts, and other price concessions paid by Lilly may vary significantly even within the same PBM rebate agreement, the chart below provides the total amount of rebates, discounts, and other price concessions paid under Lilly's largest PBM

contracts in 2018 for each insulin product family. The information provided in this response was gathered from readily available data kept in the normal course at the Humalog, Humulin, and Basaglar family level.

| Total Price Concessions Paid to PBMs (2018)³ | | |
|--|------------------------|------------------------|
| | Commercial | Medicare Part D |
| Basaglar | \$349,361,121 | \$194,265,686 |
| CVS Caremark | \$209,686,586 | \$187,061,643 |
| ESI | \$24,841,914 | \$1,050,128 |
| MedImpact | \$3,887,380 | \$12,684 |
| Optum | \$106,060,632 | \$1,875,417 |
| Prime Therapeutics | \$4,884,609 | \$4,265,815 |
| Humalog | \$1,703,889,056 | \$1,201,915,485 |
| CVS Caremark | \$132,321,513 | \$22,725,551 |
| ESI | \$933,642,249 | \$315,234,946 |
| MedImpact | \$4,301,675 | \$4,312,707 |
| Optum | \$594,323,517 | \$770,827,106 |
| Prime Therapeutics | \$39,300,102 | \$88,815,176 |
| Humulin | \$173,735,817 | \$228,298,765 |
| CVS Caremark | \$36,620,294 | \$8,579,347 |
| ESI | \$73,380,416 | \$56,301,472 |
| MedImpact | \$322,397 | \$1,131,520 |
| Optum | \$56,290,092 | \$143,938,343 |
| Prime Therapeutics | \$7,122,617 | \$18,348,083 |
| Total | \$2,226,985,993 | \$1,624,479,936 |

³ This table shows the total price concessions disbursed during calendar year 2018 for Lilly's major PBM customers, which include: rebates for formulary access, value-based agreements, price protection penalties, patient adherence support programs, and incremental rebates associated with product bundling. These figures also include administrative fees, which PBMs require and which are categorized as price concessions for purposes of government price reporting. These figures do not include discounts associated with mail order or cash card programs facilitated by a PBM, since they neither contribute nor are tied to conditions affecting coverage of a product. These figures have been rounded to the nearest dollar.

b. A description of how the rebate or other price concession impacted the product's formulary placement; and

Please see Lilly's response to 3(a) above for a description of how rebates impact formulary placement.

c. 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.

For Lilly's insulin products, Lilly's PBM contracts rarely include prior authorization requirements, step therapy requirements, or other utilization management methods that would affect patient access status. For example, no such conditions apply to any of the formulary statuses for Lilly's insulin products identified in response to Question 1(d) above. Lilly's PBM contracts also do not condition rebates or patient access on volume or revenue targets. Lilly may be in a position to provide more information regarding the terms of its contracts with PBMs in response to Question 4, as explained below. Lilly continues to gather information related to that request and expects to make an additional submission in the near term.

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 at any time on or after January 1, 2014.

Lilly's agreements with PBMs typically contain confidentiality clauses and require notice before Lilly produces the agreement pursuant to a legal requirement. Lilly is in the process of seeking permission from the four largest PBMs to release to the Committee exemplar contracts, potentially redacted as appropriate. Copies of Lilly's notice letters are attached at Bates LLY-SFCOM-00000039 – LLY-SFCOM-00000044. As these letters demonstrate, the company has requested responses from the PBMs no later than March 11. Lilly may be in a position to make a responsive production to the Committee in the near term. As indicated in our teleconference

with Committee staff on March 5, 2019, Lilly intends to keep the Committee apprised of responses by the PBMs and will confer with the Committee regarding appropriate next steps.

5. Please describe the Research and Development program for each of your insulin product lines and what items are included in this cost category. For each fiscal year since January 1, 2014, please provide an itemized accounting of your R&D costs that breaks out costs by activity (e.g., basic research, clinical trials for marketing approval, post-marketing research and surveillance, etc.). Please explain how each activity directly supports R&D for insulin products.

As explained in Section III of Lilly's letter, Lilly engages in significant research and development efforts. Lilly reports its research and development expenditures on a company-wide basis in its Form 10-K annual reports filed with the U.S. Securities and Exchange Commission. As noted in the most recent annual report released on February 19, 2019, at the end of 2018, Lilly employed approximately 8,500 people in human pharmaceutical and animal health research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel. Lilly's research and development expenses were \$5.31 billion in 2018, \$5.36 billion in 2017, and \$5.31 billion in 2016. The relevant section of Lilly's Form 10-K annual report filed pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2018, including Lilly's Consolidated Statement of Operations, is attached at Bates LLY-SFCOM-00000034.

For internal purposes only, Lilly estimates that between 2014 and 2018, it has spent approximately \$244 million on research and development related to Humalog globally, \$66 million on research and development related to Humulin globally, and \$85 million on research and development related to Basaglar globally.⁴ These estimates are likely under-representative because certain costs, such as local medical expenses and billable hours for training and administrative activities are not allocated by product. Accordingly, they are excluded. These estimates include certain data that are neither reproducible nor validated through accepted control mechanisms, and they therefore may be incomplete or inconsistent with Lilly's audited financial reporting, as the Securities and Exchange Commission requires research and development data to be compiled only at the enterprise level. Given the limitations of these estimates, Lilly requests that the Committee give special attention to preserving their confidentiality.

⁴ The estimate for Basaglar includes amounts reimbursed by Lilly's alliance partner Boehringer Ingelheim.

- 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.**

Lilly's marketing and advertising program for its insulin products is designed to provide appropriate information to health care providers, patients, and payers (PBMs and insurers).

Health Care Providers. Lilly employs sales representatives who meet with physicians and other health care providers and provide them with appropriate information regarding its insulin products. Lilly also provides information to health care providers through emails, newsletters, internet advertisements in the form of banner ads, and print ads in journals. Lilly also sponsors and sends representatives to certain conferences attended by health care providers.

Patients. Lilly does not conduct television or radio advertising for its insulin products. Its consumer advertising is over the internet and in print ads in popular press such as *Reader's Digest*. Lilly also engages in consumer-oriented education efforts, including efforts relating to insulin adherence.

Payers. Lilly employs account managers who engage with PBMs and insurers regarding its products, including insulins. Lilly also sponsors and sends representatives to certain conferences attended by payers.

The requested information regarding the itemized cost of Lilly's marketing and advertising efforts related to its insulin products for the years 2016 to 2018 is attached at Bates LLY-SFCOM-00000045. The information provided in this response was gathered from readily available data kept in the normal course at the Humalog, Humulin, and Basaglar family level. Lilly continues to gather information regarding the cost of Lilly's marketing and advertising efforts related to its insulin products for the years 2014 and 2015 and expects to make an additional submission in the near term.

- 7. With respect to your company's process for pricing insulin, please answer the following:**

- a. Please describe your company's process for making pricing and market access decisions related to its insulin products, including how account managers, brand managers, pricing committees, outside consultants and other entities contribute to decisions regarding price, the steps that are involved in determining prices, any internal approval processes, and how prices are communicated to wholesalers, payers and other outside entities.**

Lilly makes pricing decisions for its insulin products in a holistic fashion, taking into account a variety of factors. It does not assign a specific percentage or weight to any individual factor. As a part of Lilly's regular business planning process, the company assesses the insulin pricing environment to identify trends and changes in the market and to establish pricing assumptions for the future. Factors that generally impact those pricing assumptions include:

- the value that the products bring to patients and the health care system;
- current marketplace conditions, including, but not limited to, rebates provided to insurers, pharmacy benefit managers, and other payers and purchasers;
- the need to fund the research and development of the next generation of innovative medicines;
- increasing costs associated with regulatory compliance and state and federal health care program changes;
- selling expenses and other costs associated with bringing products to market; and
- costs to invest in manufacturing capabilities (e.g., technology, quality, and capacity investments) for Lilly's products.

Although Lilly generally seeks to follow the pricing assumptions established as a part of its business planning, the company sometimes deviates from those assumptions as a result of changes in the market. Authority to make pricing decisions for insulin products is vested in the leadership of Lilly's Diabetes Business Unit, in consultation with a steering committee of Lilly stakeholders responsible for assessing pricing decisions. Account managers responsible for contracting with PBMs and insurance plans are not involved in pricing decisions.

Price adjustments on insulin products are communicated directly to Lilly's wholesaler customers by fax and email. Other parties may become aware of price adjustments through publicly available drug pricing databases or other means; Lilly does not provide direct notice of price adjustments on insulin products to PBMs and insurance plans.

- b. Please provide the names and titles of all company officials that have final pricing authority for your company's insulin products.**

Enrique Conterno, Senior Vice President and President, Lilly Diabetes and Lilly USA, LLC, has final pricing authority for Lilly's insulin products.

- 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.**

Lilly continues to gather information related to this request and expects to make an additional submission in the near term.

-
- 8. Please provide a list all internal and external programs that your company has used and funded since January 1, 2014, to financially assist patients purchasing insulin or obtaining free insulin. For each program, please list:**

- a. What type of program it is, for example, a coupon program, an internal patient assistance program, an external patient assistance program, a charity care program, or some other type of program. In each case, please describe how these programs were administered, through an electronic system, debit cards, physical coupons, vouchers, or some other method, and who administered them.**
- b. Eligibility requirements and eligibility exclusions.**
- c. How much money the company has spent on the program for each fiscal year since January 1, 2014. In your answer, please describe how your company calculates its spending on such programs. In other words, when your company accounts for free or discounted products, is it using a product's manufacturing price, retail price, list price, or some other method?**
- d. The number of patients in the United States who were served by the program for each fiscal year since January 1, 2014.**
- e. What percentage of total patients who used your company's insulin products did the program cover each year?**

As explained in Section I of the Lilly Letter, Lilly is committed to ensuring that patients have affordable access to its insulins. In August 2018, Lilly launched new programs including

the Lilly Diabetes Solution Center (“LDSC”), a patient-focused hotline staffed by medical professionals, to better connect people living with diabetes to various solutions based on their individual circumstances. Every month, these new solutions help more than 10,000 additional people living with diabetes more easily afford their insulin. For example, the LDSC can connect patients with an immediate need to any one of the nearly 150 clinics across the United States to which Lilly donates free insulin. The LDSC also can connect patients to Lilly Cares, a separate charitable organization that provides free insulin to patients who do not have insurance or have Medicare Part D and a household annual adjusted gross income of up to 400% of the federal poverty level.⁵ For patients whose household income exceeds 400% of the federal poverty level, the LDSC will help them evaluate available options. Such options include Blink Health (www.blinkhealth.com) and Inside Rx (www.INSIDERx.com), which offer savings of up to 40% off the list price of Lilly’s most commonly prescribed insulins. Information regarding the discounts provided to patients through these programs is attached at Bates LLY-SFCOM-00000046.

Lilly also provides a variety of discounts for its Humalog, Humulin, and Basaglar insulins to patients effectuated through Co-Pay Cards, Cash Savings Cards, and Electronic Coupons.⁶ Information regarding these programs is attached at Bates LLY-SFCOM-00000047.⁷ The first tab lists each of the separate programs and provides information regarding the program’s period of availability, the program type, the third-party vendor administering the program, the eligibility requirements for the program, and the out-of-pocket cost to participants in the programs. The second tab of the attached spreadsheet shows a portion of the cost of these programs—the reduction in price of the product provided to patients.⁸ Lilly is separately gathering information regarding patient utilization and the costs of administering the programs.

Over the years, Lilly has provided free insulin products to a variety of organizations that support patients who live with diabetes. Since January 1, 2014, Lilly has provided free Lilly

⁵ <https://www.lillycares.com/resources.aspx>.

⁶ Co-Pay Card means a physical or virtual card presented at the time a prescription is filled where the patient discount is adjudicated as a secondary payer in addition to the patient’s insurance. Electronic Coupon is a patient discount provided automatically during adjudication process as the prescription is filled at the pharmacy. Cash Savings Cards are physical or virtual saving cards for patients without commercial insurance where Lilly provides a discount to the patient that is adjudicated at the point of sale with Lilly serving as the primary payer. Consistent with HHS OIG guidance on copayment coupons (OIG Special Advisory Bulletin – Manufacturer Copayment Coupons September 2014) the programs are not intended to be utilized where payment may be made, in whole or in part, under a federal health care program. For purposes of this response, Lilly has not included free product samples or vouchers.

⁷ The chart does not include Point of Sales Discount Programs, such as Blink Health and Inside Rx, referenced in the paragraph above. It is limited to Lilly’s Co-Pay Cards, Cash Savings Cards, and Electronic Coupons.

⁸ This information is not readily available prior to 2015.

insulin in the Humalog, Humulin, and Basaglar families through the following organizations or programs:

| Organization | Quantity of Pens ⁹ and Vials |
|---------------------------------|---|
| 2014 | |
| AmeriCares | 380 |
| Catholic Medical Missions Board | 7,200 |
| Diabetes Camps | 34,504 |
| Direct Relief | 12,344 |
| Lilly Cares Foundation | 980,352 |
| Lilly Medicare Answers | 3,488 |
| MAP International | 200 |
| Partners in Health | 6,512 |
| Project HOPE | 43,000 |
| 2015 | |
| Catholic Medical Missions Board | 12,700 |
| Diabetes Camps | 39,807 |
| Direct Relief | 17,696 |
| Lilly Cares Foundation | 748,540 |
| Lilly Medicare Answers | 189,449 |
| 2016 | |
| Catholic Medical Missions Board | 19,050 |
| Diabetes Camps | 40,284 |
| Direct Relief | 23,693 |
| Lilly Cares Foundation | 1,038,710 |
| 2017 | |
| AmeriCares | 23,910 |
| Catholic Medical Missions Board | 4,700 |
| Diabetes Camps | 50,587 |
| Direct Relief | 164,325 |
| Project HOPE | 1,500 |
| Lilly Cares Foundation | 928,664 |
| 2018 | |
| AmeriCares | 24,600 |
| Catholic Medical Missions Board | 14,900 |
| Diabetes Camps | 46,812 |
| Direct Relief | 153,900 |
| Dispensary of Hope | 23,200 |
| Lilly Cares Foundation | 1,233,096 |
| Total (2014-2018) | 5,888,103 |

⁹ This table refers to the number of pens donated—not the number of boxes of pens donated.

The programs described above vary in their qualifications depending on the nature of the program and as determined by the organization, but in all instances, the insulin provided is intended by Lilly to be provided free to qualifying patients. The programs are administered through the provision of physical product to the patient through licensed health care practitioners and/or pharmacists. Lilly does not consistently receive information regarding the number of patients assisted each year, but it has provided the total number of pens and vials donated in the chart above.

f. The amount of revenue and net income each program generated.

Lilly does not track the revenue and net income generated by its patient affordability programs.

g. What was the abandonment rate of patients who were unable to fill their prescriptions at the pharmacy? Did your company or the entities it funded make any effort to follow up with patients who dropped out of these programs?

Lilly is continuing to review its records to determine if it has information responsive to this request.

9. Please describe how the costs of the assistance programs are accounted for within your company's financial statements. Please also describe the types of market information, such as prescribing and use patterns, that your company collects from different types of patient assistance programs and patient hub services.

Lilly is continuing to gather information regarding the accounting treatment of its patient affordability programs. Lilly does not receive prescribing pattern or trend information from the recipients of its donations of free insulin products or from the third parties who administer its co-pay and coupon programs.

10. Please provide a list of all contributions since January 1, 2014, that your company has made to any tax-exempt organizations working on issues related to diabetes, including but not limited to patient groups, disease awareness groups, medical or professional societies, universities or hospitals, industry associations or leagues. For each contribution, please provide the name of the organization that received the

donation, the date the donation was made, the amount of the donation, and a description of the purpose of the contribution (i.e., was the contribution for the general fund, a specific purpose to a specific program, or continuing medical education). Please also note whether the contribution was unrestricted or restricted; if it was restricted, please explain all restrictions. Finally, if your company maintains a foundation or other separate charitable arm, please provide the name of all such entities, and list all diabetes-related donations made from that entity or entities.

Lilly continues to gather information related to this request and expects to make an additional submission in the near term.

- 11. ~~You have previously discussed the ways in which the current rebate system leads to higher costs for consumers, saying in 2018 that, “[w]e are shifting too much of the cost via list pricing directly to consumers. If consumer pricing came down [it] would improve volume and medication adherence for patients.”¹⁰ If the proposed rule from the Department of Health and Human Resources and its Inspector General, *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*,¹¹ is implemented, please describe how it will impact the pricing of your company’s insulin products.~~**

If the proposed rule is finalized for Part D only, the impact on the prices of Lilly insulins is unclear. Part D patients will experience lower out-of-pocket costs for insulin if the significant price concessions that Lilly provides are passed on. If additional actions are taken to extend this approach to commercial payers, then Lilly would anticipate significant list price reductions, as list price rather than rebates would become the basis of competition.

* * *

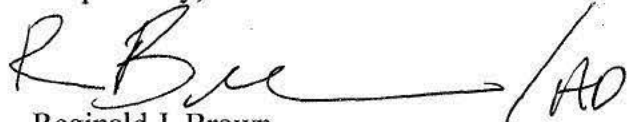
¹⁰ Nathaniel Weixel, *Eli Lilly CEO denounces plan to consider drug imports*, THE HILL (Jul. 24, 2018), <https://thehill.com/policy/healthcare/medical-devices-and-prescription-drug-policy/398599-ceo-of-eli-lilly-denounces>.

¹¹ Proposed Rule, *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 F.R. 2340, (Feb. 6, 2019), <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.

This letter contains proprietary business information and is marked confidential. Lilly respectfully requests that such information be accorded special protection from disclosure and that it be maintained confidential under all applicable Senate and Committee rules. Additionally, this letter and Lilly's productions to the Committee may contain material nonpublic information. Pursuant to the Stop Trading on Congressional Knowledge Act of 2012 ("STOCK Act"), Pub. L. 112-105, 126 Stat. 291, non-public information derived from a person's position as a Member of Congress or employee of Congress or gained from the performance of such person's official responsibilities may not be used as a means for making a private profit. Misuse of such information, including unauthorized disclosures to third parties outside of the Congress, may also give rise to liability under the securities laws, including section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder. *See also* Sen. Select Comm. on Ethics, STOCK Act Requirements for Senate Staff (June 15, 2012). Lilly further requests that Committee staff provide the undersigned with notice and an opportunity to be heard in the event that the Committee determines that it will disclose to a third party any documents from Lilly's production marked as confidential. Such treatment would be consistent with the respect for sensitive and proprietary business information the Committee has shown in the past.

Thank you for the opportunity to provide this response. We are grateful for the Committee's attention to this important issue, and we look forward to continuing a dialogue with you and your staff. The information set forth herein and the documents contained on the enclosed CD are based on initial fact gathering from readily available sources. Should additional or revised data, documents, or information responsive to your requests become available, we respectfully request an opportunity to supplement or amend our response as needed.

Respectfully,

A handwritten signature in dark ink, appearing to read "R. Brown", followed by a long horizontal line and the initials "AD" written to the right.

Reginald J. Brown
Alyssa DaCunha

Message

From: heid_lisa_ [REDACTED]
on behalf of Lisa J Heid [REDACTED]
Sent: 2/6/2014 8:28:55 PM
To: Alex M Azar [REDACTED]
Subject: Re: Urgent - PRASC approval requested for revised offer for Aetna Commercial - Please respond by Noon February 7, 2014

Alex

Yes, you are correct. The feedback we got from the customer was that we were \$40 mil short to win the deal. We believe that is because Novo potentially bundled Levemir and Victoza in their offer. The brand feels they need to be able to offer up to 65% rebate for dual status for those lives remaining dual as a walk away.

Lisa

Sent from my iPhone

On Feb 6, 2014, at 6:58 PM, "Alex M Azar" [REDACTED] > wrote:

Can you give me some context here? Giving permanent 65% rebate for dual? Am I understanding this correctly?

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285
[REDACTED]
[REDACTED]

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On Feb 6, 2014, at 6:37 PM, "Lisa J Heid" [REDACTED] > wrote:


PRASC members,


Sorry for the short turnaround time for this request. Aetna is making their decision on Monday and we need to provide a revised offer to them in order to be competitive for this business. The major changes to the offer that we are requesting approval for are:

- 65% rebate for dual status for Lin and Log for Aetna only –Q2 ,2014 (enhance dual rate prior to Aetna implementation of preferred status in Q3, 2014)

- 65% rebate for dual status for Lin and Log for Aetna only – Q3, 2014- Q4, 2016 (previously 62% enhanced rebate for both Lin and Log for up to 12 months was approved, then dropping back to 45% rebate for dual status for remaining quarters of deal)

- Increase rebate for Humulin u500 from 10% previously approved to 20% rebate



The table below shows what has been previously approved by PRASC compared to the revised offer we are now seeking approval for. The incremental rebate amount for Humulin and Humalog is \$27.7 mil. 

[cid:image002.png@01CF236A.83751E30]


Although these offers appear net sales negative, given Aetna is a strategic account for the DBU and the competitive offers in the marketplace for these products, these rates are required to try to retain this business.

The net sales difference for all of these changes are captured below (this shows the business case impact to both Aetna and Coventry as they will be moving forward with a single formulary decision) :

[cid:image006.png@01CF236A.83751E30]

I have attached the revised pre-read for further details. Feel free to contact me with any questions.

Lisa Heid
Director, Contract Management and Analytics


<Pre-Deal Aetna MHC Humalog Humulin PRASC Revised Offers Feb 6 .pptx>
<image002.png>
<image006.png>

Message

From: azar_alex [REDACTED]
on behalf of Alex M Azar [REDACTED]
Sent: 2/7/2014 1:05:16 PM
To: Michael B Mason [REDACTED]
Subject: RE: Urgent - PRASC approval requested for revised offer for Aetna Commercial - Please respond by Noon February 7, 2014

FOR INTERNAL USE ONLY/NOT FOR USE WITH CUSTOMERS

Just curious. Thanks. No problem.

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285
[REDACTED]

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From: Michael B Mason
Sent: Friday, February 07, 2014 1:02 PM
To: Alex M Azar
Subject: RE: Urgent - PRASC approval requested for revised offer for Aetna Commercial - Please respond by Noon February 7, 2014

Alex:

Thanks for the support. The extra step caused by a wrong assumption on my end. Yesterday afternoon I met with Lisa and Eric's team to review their proposal (65%). I told them I was supportive, but given that we were going over ESI rates that I was going to run it by Enrique. I assumed when I said this that Eric and Lisa were going to hold sending proposal to PRASC members until after I spoke with Enrique. I shouldn't have assumed this. I should have specifically told them not to send it to PRASC until after I had met with Enrique.

Enrique asked me to win this one and was comfortable going over 65% if we needed it.

Sorry about the process misstep on my part.

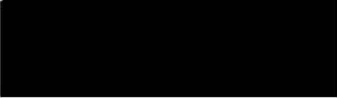
All the best,

Mike

From: Alex M Azar
Sent: Friday, February 07, 2014 12:30 PM
To: Lisa J Heid
Cc: Michael B Mason; Terrence M Lyons; Frank D Cunningham; Wilbur Van Tryon; Eric H Schultz; W Patrick Bruen; Louise Kathleen Bakker; Steven C Benz
Subject: Re: Urgent - PRASC approval requested for revised offer for Aetna Commercial - Please respond by Noon February 7, 2014

Approved. As a process matter, I'm curious why the last minute change from 65 to 66.

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285



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On Feb 7, 2014, at 12:27 PM, "Lisa J Heid" :

Alex, Mike, Terry and Frank,

Please approve Mike's revised request below to move the Dual /exclusive rates to 66% for the 2.5 year term of the contract. The financial impact of this incremental 1 pp is \$3.3 mil for Humalog and \$.3 mil for Humulin. Please let me know if you need any additional information. We are trying to get back with Aetna late this afternoon with their revised offer. Thanks for your help in meeting this customer timeline.

Lisa Heid
Director, Contract Management and Analytics



From: Michael B Mason
Sent: Friday, February 07, 2014 11:19 AM
To: Alex M Azar; Lisa J Heid
Cc: Frank D Cunningham; Terrence M Lyons; Wilbur Van Tryon; Eric H Schultz; W Patrick Bruen; Louise Kathleen Bakker; Steven C Benz
Subject: RE: Urgent - PRASC approval requested for revised offer for Aetna Commercial - Please respond by Noon February 7, 2014

Lisa:

Thanks for your work on this. The teamwork between MHS and Eric's team has been exceptional on this deal. Given the long-term strategic value of this account and the fact that we will likely not be willing to outbid Novo if Prime and Cigna/Catamaran want to move to Preferred this year, Enrique and I are supportive going up to a preferred rate of 66% on this deal. Approve.

Thanks,

Mike

From: Alex M Azar
Sent: Thursday, February 06, 2014 8:47 PM
To: Lisa J Heid
Cc: Michael B Mason; Frank D Cunningham; Terrence M Lyons; Wilbur Van Tryon; Eric H Schultz; W Patrick Bruen; Louise Kathleen Bakker; Steven C Benz
Subject: Re: Urgent - PRASC approval requested for revised offer for Aetna Commercial - Please respond by Noon February 7, 2014

I will defer to DBU leadership on this deal and approve.

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285

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On Feb 6, 2014, at 6:37 PM, "Lisa J Heid" wrote:

PRASC members,

Sorry for the short turnaround time for this request. Aetna is making their decision on Monday and we need to provide a revised offer to them in order to be competitive for this business. The major changes to the offer that we are requesting approval for are:

- 65% rebate for dual status for Lin and Log for Aetna only –Q2 ,2014 (enhance dual rate prior to Aetna implementation of preferred status in Q3, 2014)
- 65% rebate for dual status for Lin and Log for Aetna only – Q3, 2014- Q4, 2016 (previously 62% enhanced rebate for both Lin and Log for up to 12 months was approved, then dropping back to 45% rebate for dual status for remaining quarters of deal)
- Increase rebate for Humulin u500 from 10% previously approved to 20% rebate

The table below shows what has been previously approved by PRASC compared to the revised offer we are now seeking approval for. The incremental rebate amount for Humulin and Humalog is \$27.7 mil. The total rebates requested for

[cid:image002.png@01CF236A.83751E30]

Although these offers appear net sales negative, given Aetna is a strategic account for the DBU and the competitive offers in the marketplace for these products, these rates are required to try to retain this business.

The net sales difference for all of these changes are captured below (this shows the business case impact to both Aetna and Coventry as they will be moving forward with a single formulary decision) :

[cid:image006.png@01CF236A.83751E30]

I have attached the revised pre-read for further details. Feel free to contact me with any questions.

Lisa Heid

Director, Contract Management and Analytics

[REDACTED]

<Pre-Deal Aetna MHC Humalog Humulin PRASC Revised Offers Feb 6 .pptx>

<image002.png>

<image006.png>

Message

From: bott_martin [REDACTED]
on behalf of Martin Bott [REDACTED]
Sent: 5/30/2014 6:13:54 PM
To: Enrique A Conterno [REDACTED]; Michael B Mason [REDACTED]
Subject: RE: Humalog and Humulin - list price

Mike,

I support the recommendation

Martin

Martin Bott
VP Finance, CFO Lilly Diabetes and Global Manufacturing Operations
Eli Lilly and Company
[REDACTED]
[REDACTED]



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From: Michael B Mason
Sent: Friday, May 30, 2014 5:36 PM
To: Enrique A Conterno
Cc: Martin Bott
Subject: Fwd: Humalog and Humulin - list price

Enrique:

As you know we have been discussing a price increase in June. Attached is our proposed price increase.

Let me know if you have any questions.

Mike

P.S. We learned from public sources on Thursday that Novo took a 9.9% price increase across their Insulin portfolio.

Sent from my iPad

Begin forwarded message:

From: W Patrick Bruen [REDACTED]
Date: May 29, 2014 at 2:22:35 PM EDT
To: Michael B Mason [REDACTED]
Cc: Eric H Schultz [REDACTED] Kevin L Cammack [REDACTED] Martin

Bott [REDACTED]

Subject: Humalog and Humulin - list price

Mike,

Per our conversation this morning, I propose +9.9% list price adjustments for all NDCs of Humalog family and Humulin family effective for orders received after 5pm on Wednesday evening June 4.

The resulting list prices:

- Humalog = \$184.30 WAC per 10ml vial versus \$184.85 for Novolog
- Humulin = \$99.80 WAC per 10ml vial versus \$99.65 for Novolin

Of course, the insulin category is among if not the most price competitive class at the contracted price level. Please let me know if you have additional questions or would like to meet to discuss this price adjustment.

Pat

Message

From: wettig_thane_ [REDACTED]
on behalf of Thane E Wettig [REDACTED]
Sent: 10/28/2014 12:07:00 PM
To: Enrique A Conterno [REDACTED]
Subject: Re: FYI

Exactly. And to expect it to grow again in a meaningful way would be a huge planning risk.

Sent from my iPhone

On Oct 28, 2014, at 2:37 PM, Enrique A Conterno <[REDACTED]> wrote:

This is an interesting picture –list prices going way up and so are rebates– after these major changes...our net prices are flat.

From: Thane E Wettig
Sent: Monday, October 27, 2014 12:47 PM
To: Enrique A Conterno
Subject: RE: FYI

Here is the pricing spreadsheet and ppt.

From: Enrique A Conterno
Sent: Monday, October 27, 2014 12:31 PM
To: Thane E Wettig
Subject: RE: FYI

Thank you –send it to me asap (it does not have to be pretty) for our story. Enrique

From: Thane E Wettig
Sent: Monday, October 27, 2014 9:36 AM
To: Enrique A Conterno
Subject: FYI

Enrique,

We're pulling the Humalog performance data that you and I spoke about on Friday. In the US, we have IMS data for Humalog going back to 2000. However, we only have a full year of competitor data going back to 2009. George Antony is checking with IMS to see if we can get the competitive data to match the Humalog data. I will let you know what we find out.


For OUS, we have data internally going back to 1998 on Humalog and competitors. The EMBU data is a bit fragmented – some smaller markets are in some years and out other years. The overall EMBU picture is probably ok, with the caveat that we only capture a subset of larger EMBU markets.

I am also putting together a picture of US pricing history. Given the aggressive assumption in Mike's plan, and the flat to declining net effective price over time, I believe it is important for your exec comm colleagues to understand that the ability to pull the US price lever for Humalog to cover a gap in the overall corporate plan does not exist.

Let me know if any questions.

Rgds,
Thane

Thane Wettig
Vice President, Global Marketing – Lilly Diabetes
Eli Lilly and Company
Lilly Corporate Center, Indianapolis, IN 46285 U.S.A.


<image001.jpg>

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Message

From: conterno_enrique [REDACTED]
on behalf of Enrique A Conterno [REDACTED]
Sent: 11/21/2014 1:23:52 PM
To: John C Lechleiter [REDACTED]
Subject: RE: Novo Price Increase, [REDACTED]

Thanks, John.

From: John C Lechleiter
Sent: Thursday, November 20, 2014 9:21 AM
To: Enrique A Conterno
Subject: Re: Novo Price Increase, [REDACTED]

Thanks for the update.

I think I will spend a half day with one of your reps early in the new year. We can discuss how best to do this.

It's an exciting time for Lilly Diabetes and you're doing a great job leading this important business!

Best Regards -- John

John C. Lechleiter
Chairman, President, and CEO
Eli Lilly and Company

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From: Enrique A Conterno
Sent: Wednesday, November 19, 2014 05:27 PM
To: John C Lechleiter
Subject: Novo Price Increase, [REDACTED]

John,

Today, Novo took a price increase of 9.9% for Novolog and 11.9% for Levemir. As you are aware, we have assumed as part of our business plan a price increase of 9.9% for Humalog before the end of the year.

[REDACTED]

[REDACTED]

[REDACTED]

We can discuss more about any of these topics next time we see each other.

Best regards,

Enrique

Message

From: conterno_enrique [REDACTED]
on behalf of Enrique A Conterno [REDACTED]
Sent: 11/21/2014 1:19:27 PM
To: Christopher W. Ogden [REDACTED]
CC: Martin Bott [REDACTED]; Kevin L Cammack [REDACTED]; Christian Sum [REDACTED]; Steve M Dellinger [REDACTED]; Kimberly Louise Macko [REDACTED]; Michael B Mason [REDACTED]; David R Pugh [REDACTED]
Subject: Re: Unfavorable US G2N Adjustment

Chris,

Thanks - not good news. Given Novo's price increase, let's compensate by taking the price increase earlier. Thoughts?

Best regards,

Enrique

Sent from my iPhone

On Nov 21, 2014, at 1:05 PM, Christopher W. Ogden [REDACTED] wrote:

Mike and Enrique,

We had the Q4 G2N meeting this morning and there is an unfavorable **40M G2N adjustment** that will impact **this quarter**. The variances are spread amongst several segments, but primarily impact Humalog (44M). The segment level drivers are:

- <!--[if !supportLists]--><!--[endif]-->**Managed Care-(18M)**: This is driven by higher ESI utilization (5M) and an accounting error we made regarding Aetna win (10M).
- <!--[if !supportLists]--><!--[endif]-->**Chargebacks-(13M)**: Primarily due to increased utilization trends in PHS, DOD, and VA.
- <!--[if !supportLists]--><!--[endif]-->**Returns-(5M)**: U500 returns were not properly incorporated into Q4 F09 forecast.
- <!--[if !supportLists]--><!--[endif]-->**Medicaid-(3M)**: Medicaid is 15M unfavorable for Humalog offset by [REDACTED] 8M) and Humulin (3M). Humalog Medicaid estimates have a large range (45M) given the growth we are seeing in the TRx data and the fact that Q1 and Q2 payments are not fully complete. Our forecast is aligned to the TRx growth trends which we feel appropriately position the full year Medicaid needs.

This impact will be incorporated into the November accounting. As a reminder, our F09 forecast assumed U.S. Diabetes would beat plan by ~60M (after 20M of stretch), so the size of the adjustment makes it uncertain as to whether we will hit full year plan. Please let me know if you have questions. I understand this is a large impact, so our team can go into detail on any of the assumptions.

Chris

Message

From: fry_stephen_ [REDACTED]
on behalf of Stephen F Fry [REDACTED]
Sent: 11/21/2014 4:21:27 PM
To: Michael B Mason [REDACTED]
CC: W Patrick Bruen [REDACTED] Enrique A Conterno [REDACTED] John C Lechleiter [REDACTED]
[REDACTED]; Derica W Rice [REDACTED] Eric H Schultz [REDACTED]
Subject: Re: December Diabetes Price Increases

Thanks Mike...

Stephen F. Fry
Senior Vice-President, Human Resources and Diversity
Eli Lilly and Company



Sent from my iPhone

On Nov 21, 2014, at 4:17 PM, Michael B Mason [REDACTED] wrote:

John, Derica, Steve:

During your review of price increases this week, LillyUSA communicated a plan to take our price increases on Dec 3rd. On Wednesday Novo unexpectedly took their year-end price increases. This will cause our distributors to expect price increases from Lilly Diabetes, causing them to build inventory. Given this, we have decided to move our diabetes price increases to Monday, November 24. The price increases will be the same rates that were discussed at Executive Committee (Humalog +9.9%; Humulin +9.9%; [REDACTED])

Best regards,

Mike

Message

From: conterno_enrique [REDACTED]
on behalf of Enrique A Conterno [REDACTED]
Sent: 11/21/2014 3:43:41 PM
To: Michael B Mason [REDACTED]
Subject: Re: Approval Requested: LillyUSA List Price Increase Timing

I believe this is our decision - I would just inform them that we are planning to do so.

Sent from my iPhone

On Nov 21, 2014, at 3:41 PM, Michael B Mason [REDACTED] wrote:

Ok. Do you want me to send Steve, Derica and John a message to gain support?

From: Enrique A Conterno
Sent: Friday, November 21, 2014 3:40 PM
To: Michael B Mason
Subject: Re: Approval Requested: LillyUSA List Price Increase Timing

I think we should push for it asap given that Novo has taken a price increase already and thus, distributors will start to inventory.

Enrique

Sent from my iPhone

On Nov 21, 2014, at 3:36 PM, Michael B Mason [REDACTED] wrote:

Enrique:

I asked Pat to make our business plan price increases next week. I received the following reply. The difference in waiting a week is \$1.5M to \$2.0M in 2014. Do you want me to push the price increase through? It looks like I may need to go up to John, Derica and Steve to make it happen.

Mike

From: W Patrick Bruen
Sent: Friday, November 21, 2014 3:10 PM
To: Michael B Mason
Subject: RE: Approval Requested: LillyUSA List Price Increase Timing

Mike,

I have additional background for you regarding the upcoming Humalog list price adjustment timing.

As you recall, the PRA Steering Committee during our meeting on Monday aligned on December 3 as the effective date for year-end adjustments with the exception of [REDACTED] (Humalog +9.9%; Humulin +9.9%; [REDACTED])

reviewed by the Executive Committee). [REDACTED] was the one exception to that timing. As a follow-up to the meeting, Steve Fry, Derica Rice and John Lechleiter authorized December 3rd as the effective date for these year-end adjustments (see the email chain below). This authorization was necessitated by the increases occurring prior to Board approval of the 2015 Business Plan.

To pursue an earlier effective date for Humalog, Steve, Derica and John will need to reauthorize. My recommendation is to proceed with the Humalog adjustment effective December 3 since (1) the financial benefit of an earlier increase is relatively minimal and (2) aligning the LillyUSA adjustments will avoid increases on two days in a short window which may be perceived negatively by payers.

Please let me know your decision. If you decide to pursue the earlier timing for Humalog then I will develop supporting information as requested.

Pat

From: Terrence M Lyons
Sent: Thursday, November 20, 2014 3:26 PM
To: W Patrick Bruen; Theresa Skowron Dunn
Cc: Hormaz M Dubash; John L. Washam; PETER HOOGERHUIS; Jennifer Davison Niemeyer; Wilbur Van Tryon; Steve M Dellinger
Subject: Fwd: Approval Requested: LillyUSA List Price Increase Timing
Importance: High

Pat and Theresa:

Below please find confirmation of approval to implement our planned LillyUSA list price increases effective at 5:00pm on Weds, Dec 3rd, with the exception of [REDACTED]
[REDACTED]
[REDACTED]^h. Please feel welcome to inform other relevant BU leaders of this approval as appropriate.

TML

Terrence M. Lyons
Vice President Finance & Strategic Marketing | CFO, Lilly USA LLC

From: David A Ricks
Sent: Thursday, November 20, 2014 2:21 PM
To: Alex M Azar
Subject: Fwd: Approval Requested: LillyUSA List Price Increase Timing

Alex, I have networked this with Steve John and Derica, please move ahead as you recommend.

Dave Ricks

Begin forwarded message:

From: Alex M Azar [REDACTED]
Date: November 20, 2014 at 7:53:29 AM EST

To: David A Ricks <[REDACTED]>
Subject: Fwd: Approval Requested: LillyUSA List Price Increase Timing

Please let me know if you have concerns with our executing the approved price increases prior to board approval but consistent with what the EC is recommending to the board. I believe this timing is critical to avoid excessive retail stocking in December followed by destocking in January.

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285
[REDACTED]

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Begin forwarded message:

From: Terrence M Lyons [REDACTED]
Date: November 19, 2014 at 5:40:54 PM CST
To: Alex M Azar [REDACTED]
Cc: W Patrick Bruen [REDACTED] Hormaz M Dubash [REDACTED]
Subject: Approval Requested: LillyUSA List Price Increase Timing

Alex:

Per our review at the PRA Steering Cmte on Mon, Nov 17th, we recommend all planned LillyUSA 2014 year-end list price adjustments be implemented effective at 5:00pm on Weds, Dec 3rd, with the exception of [REDACTED] (which would be adjusted the week on Dec 29th).

Implementation in early December mitigates two important exposures to the 2015 Business Plan: From an economic perspective, the December increase timing eliminates penalties under the increasingly prevalent 'price protection' provisions of many Part D and commercial payer contracts. Second, from a channel management perspective, early December implementation provides adequate time for approx 70-100% of excess retail channel inventory build to burn in Q4 (rather than being retained with excess, unplanned burn in Q1 2015.) [Recall that last year insulins increases were executed on Dec 12th, [REDACTED] this timing was too late to effect retail orders through wholesalers given our December order cut-off date, resulting in excessive Q4 2013 build and q1 2014 channel burn.]

Please note that while this recommended timing is in advance of final Board approval of the 2015 Business Plan, ***all increases will be executed at the percentage increases approved by the corporate Executive Cmte.*** The 2015 Business Plan for all Business Units assumed late December execution, thus the December 3rd timing will ***not result in any material price variance versus the Plan proposed for approval to the Lilly Board.***

TML

Terrence M. Lyons
Vice President Finance & Strategic Marketing | CFO, Lilly USA LLC
[REDACTED]

Message

From: rice_derica_ [REDACTED]
on behalf of Derica W Rice [REDACTED]
Sent: 11/23/2014 4:58:44 PM
To: Michael B Mason [REDACTED]
CC: W Patrick Bruen [REDACTED]; Enrique A Conterno [REDACTED]; Stephen F Fry [REDACTED]
[REDACTED]; John C Lechleiter [REDACTED]; Eric H Schultz [REDACTED]
Subject: Re: December Diabetes Price Increases

Hi Mike,

Got it!

Regards,

Derica

Derica W. Rice
Executive Vice President, Global Services and CFO
Eli Lilly and Company
Lilly Corporate Center, Indianapolis, IN 46285, USA

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On Nov 21, 2014, at 4:17 PM, Michael B Mason [REDACTED] wrote:

John, Derica, Steve:

During your review of price increases this week, LillyUSA communicated a plan to take our price increases on Dec 3rd. On Wednesday Novo unexpectedly took their year-end price increases. This will cause our distributors to expect price increases from Lilly Diabetes, causing them to build inventory. Given this, we have decided to move our diabetes price increases to Monday, November 24. The price increases will be the same rates that were discussed at Executive Committee (Humalog +9.9%; Humulin +9.9%; [REDACTED])

Best regards,

Mike

Message

From: cunningham_frank_ [REDACTED]
on behalf of Frank D Cunningham [REDACTED]
Sent: 12/18/2014 3:33:38 PM
To: Alex M Azar [REDACTED] W Patrick Bruen [REDACTED]
CC: Terrence M Lyons [REDACTED]
Subject: RE: ACTION REQUIRED: PRASC Approval Request - CIGNA Commercial Offers

Pat,

I will be in the office tomorrow. I can make 10:00 work if necessary.

Frank

From: W Patrick Bruen
Sent: Thursday, December 18, 2014 3:10 PM
To: Alex M Azar
Cc: Terrence M Lyons; Frank D Cunningham
Subject: RE: ACTION REQUIRED: PRASC Approval Request - CIGNA Commercial Offers

Alex,
I will defer to Frank on your first question.

Since receiving your email, I attempted to understand the rationale for each offer. As you know this is the Russian nested doll situation in which CIGNA had a contract then transitioned to Catamaran without visibility to our ESI rates. [REDACTED] The insulin offers would again result in the same pre-Cat rates to CIGNA however favorable to the current situation thru Cat/ESI since a LPP penalty will be removed.

Regarding convening a call, the committee decision makers, other than Martin Bott, have begun year-end vacations so I will have to throw out a time to discuss. Does a conference call at 10am tomorrow work for the three of you?

Pat

From: Alex M Azar
Sent: Thursday, December 18, 2014 2:29 PM
To: W Patrick Bruen
Cc: Terrence M Lyons; Frank D Cunningham
Subject: RE: ACTION REQUIRED: PRASC Approval Request - CIGNA Commercial Offers

FOR INTERNAL USE ONLY/NOT FOR USE WITH CUSTOMERS

I'm really not wild about doing a deal of this size and complexity electronically. How did we get ourselves in this position? Shouldn't we schedule a call of the committee to consider this?

[REDACTED] No thoughts on DBU deals, as I've not had time to study them and they aren't mine to approve.

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285
[REDACTED]

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From: W Patrick Bruen
Sent: Thursday, December 18, 2014 2:15 PM
To: Alex M Azar; Michael B Mason; Terrence M Lyons; Martin Bott; Frank D Cunningham; John Bamforth
Cc: Wilbur Van Tryon; Lisa J Heid; Theresa Skowron Dunn; Scott W Dell; Eric H Schultz; Alonzo Weems; Christopher Jon Stokes; Timothy Michael Moore; Daniel D. Byrne
Subject: ACTION REQUIRED: PRASC Approval Request - CIGNA Commercial Offers
Importance: High

PRASC Members,

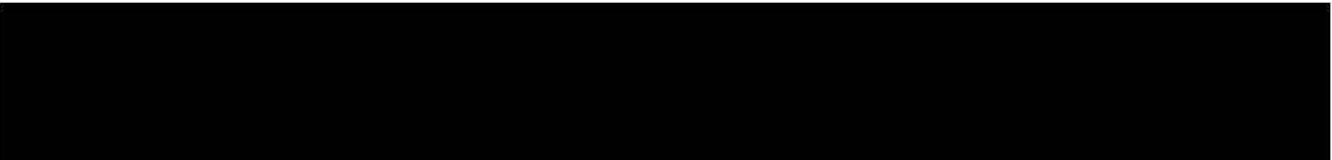
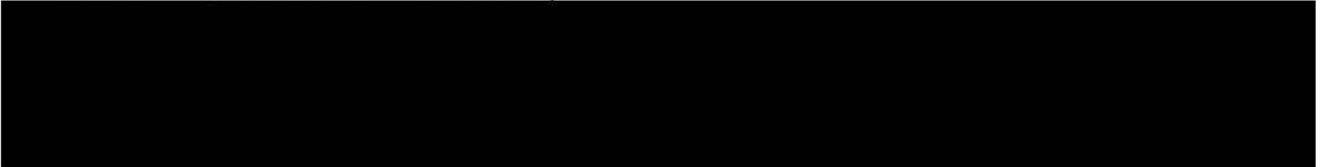
Please review and reply to all with your position on the attached portfolio proposal for CIGNA commercial. I would appreciate your response by close of business on Friday, December 19.

Pat

From: Louise Kathleen Bakker
Sent: Thursday, December 18, 2014 1:30 PM
To: W Patrick Bruen
Cc: Lisa J Heid
Subject: PRASC Approval Request - CIGNA Commercial Offers
Importance: High

Pat,

Please circulate this CIGNA pricing request to PRASC members. This e-mail is being sent to you to request PRASC approval for the CIGNA commercial offers below that are outside guidelines and the total financial commitment >\$50M. These offers are effective 4/1/15 – 12/31/16. As you recall, CIGNA notified manufacturers that they will be taking back contracting responsibility from Catamaran beginning 4/1/15. These offers are in response to their request for a portfolio offer. Sorry for the last minute request, but CIGNA is scrambling in order to complete contract negotiations with all manufacturers by April 1st.


- 
- Humalog - 45% for Unrestricted LBC formulary status (Dual) (same rate that is available to Catamaran clients under ESI agreement)
 - Humalog - 55% for Exclusive LBC formulary status
 - Humulin - 45% for Unrestricted LBC formulary status (Dual)(same rate available to Catamaran clients under ESI)
 - Humulin - 55% for Exclusive LBC formulary status
- 

None of the rates listed above are precedent setting rates.


Deal Essence:

- Insulin: Lilly insulin is currently 'Dual' status on Commercial Tiered and 'Exclusive' on IFP/Exchange formularies. CIGNA has previously evaluated moving to a single insulin line for the Commercial Tiered

book. The decision to remain dual in 2014, and potentially for 2015, was guided on financial modeling done by Catamaran and any guidance provided was the result of Catamaran's assessment of rebates available via "PBM". The strategic intent is to provide a strong dual status rate that is comparable to, but not in excess of, what is otherwise available via the "PBM" and to provide a competitive 'Exclusive' rate for the Value formulary.



Financial Commitment:


The combined financial commitment for these offers is ~ **\$161.7M** for the 1.75 year deal. For the total of the portfolio offers, the **DBU FRAP commitment** is **\$153,026,000** and the .

Please see the attached pre-read for additional details.

Please reply to this email with your decision regarding approval of these deals.

Thanks,
Louise

Louise Bakker
Business Dev. Consultant, Managed Healthcare Services
Lilly USA, LLC



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Message

From: lyons_terrence [REDACTED]
on behalf of Terrence M Lyons [REDACTED]
Sent: 2/25/2015 3:35:18 PM
To: Alex M Azar [REDACTED]
CC: Frank D Cunningham [REDACTED]
Subject: Fwd: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today - Please reconfirm

Alex:

For your reference, below please find the revised insulins OptumRx Part D offer terms approved by Derica Rice and John Lechleiter for FRAP purposes. Key changes from the offer approved by Mike Mason at PRASC seem to be discretionary rebate percentage (from 70% to 68%), revised LPP (10% cap in 2016 versus 8% initially); the 31-Dec-14 LPP anchor date was retained as initially proposed.

Lastly, under separate cover, Josh Smiley has requested LillyUSA implement a more structured process for executive review of material payer deals (requiring CFO and CEO approval). I will engage Web VanTryon in the development of a proposal for PRASC review to ensure it is responsive to payer needs.

TML

Terrence M. Lyons
Vice President Finance | CFO Lilly USA LLC
[REDACTED]

From: Joshua L Smiley
Sent: Wednesday, February 25, 2015 1:35 PM
To: Lisa J Heid
Cc: John C Lechleiter; Derica W Rice; Michael B Mason; Enrique A Conterno; Martin Bott; Christopher W. Ogden; Wilbur Van Tryon; Edward L Runkel; W Patrick Bruen
Subject: Re: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today - Please reconfirm

Lisa,

I know we are working to get this offer to the customer today and many of the business leaders are traveling outside the U.S. Your understanding outlined below is correct for the offer to Optum.

Josh

On Feb 25, 2015, at 1:28 PM, "Lisa J Heid" <[REDACTED]>:

John and Derica,

Given the magnitude of the Optum offer, I just want to confirm exactly what was approved given the details were not outlined in Mike's message included at the bottom of this email. I have confirmed with Mike, below were the walk-in terms referred to in his email.

68% rebate for both Lin and Log
10% LPP price cap for 2016
8% LPP price cap for 2017, 2018
Dec. 31, 2014 anchor date for LPP

At this time we will record that the higher walkaway rates approved by PRASC on February 23rd are not approved for FRAP purposes and that the walk-in rates stated above are

approved. During the negotiation process if any higher FRAP amount is required than the walk-in amounts, we will seek FRAP approval of any modified terms at that point in time. Please confirm by responding to this email that the walk-in terms above is what you have approved for the Optum offer.

I apologize for asking for re-confirmation, but given the size of this deal I want to make sure we are all aligned before anything is discussed with the customer. Thanks

Lisa


From: John C Lechleiter
Sent: Wednesday, February 25, 2015 12:26 PM
To: Derica W Rice
Cc: Michael B Mason; Enrique A Contemo; Martin Bott; Christopher W. Ogden; Joshua L Smiley; Lisa J Heid
Subject: Re: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today

Then I approve. Let's move forward along the lines you recommend. I also look forward to our meeting.

Thanks for huddling on this, guys, across time zones.

Regards -- John

John C. Lechleiter
Chairman, President, and CEO
Eli Lilly and Company



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On Feb 25, 2015, at 9:19 AM, Derica W Rice <[REDACTED]> wrote:

John,

Enrique and I had a chance to talk earlier today. I am supportive of moving forward with the walk-in proposal that was laid out here. As for the walk-away, Enrique and I do not want to put this on the table initially. Enrique will stay close to this negotiation, and vet any movement needed between the proposed walk-in terms and the final walk-away. As for the 2016 impact, he believes that they can manage the majority of the exposure with the ups and downs across the total portfolio of contracting discussions within the diabetes business (at the full walk-away terms).

In terms of key takeaways:

- 1). This deal is consistent with the the contracting strategic review we had earlier
- 2). We are not obligated to move forward if we can not reach acceptable terms. We would allow the existing contract to run its course


3). There are a number of strategic nuances to this proposal that would be shared shared in a live setting. John, I think there would be benefit in having a brief discussion when we are all back in the office, to share the longer term implications of this deal in our overall contracting strategy. Enrique was able to provide some very helpful insights beyond the content of the email.

Enrique, please add to this message if I missed something. I very much appreciate the patience of everyone on this matter. It is complicated, and your allowance for appropriate understanding is valued.

Thanks everyone!

Regards,
Derica

Derica W. Rice
Executive Vice President, Global Services and CFO
Eli Lilly and Company
Lilly Corporate Center, Indianapolis IN 46285 USA1



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On Feb 24, 2015, at 12:32 PM, Michael B Mason  wrote:

John and Derica,

This morning Lisa Heid will be requesting your approval for an offer to secure an exclusive status for Humulin and Humalog on United's Part D formularies. In order to meet United's timeline we need your response by the end of the day today. I apologize for the short turnaround on this one. We will strive to provide you with more time to review these offers as we move forward.

When Enrique, Martin and I recently met with you to review our insulin pricing and contracting strategy, we highlighted five accounts that would likely move from having both Humalog and Novolog on equal formulary status to selecting an exclusive meal time / human insulin partner. The largest and most attractive of these accounts is United's Part D business. In addition, our access in Part D trails Novo, so winning this account would allow us to secure a much stronger position in the important and growing Part D segment. Consistent with our strategy of competing to win when an account decides to make the transition to an

exclusive partner we would like to make an offer that is attractive enough to win the business.

In this case, United is highly motivated to move to single meal time / human insulin brand. They are planning on doing so in either 2016 or 2017. We have a contract with United that goes through the end of 2016. We believe Novo's contract is on a year-to-year basis. Due to this timing, United has the choice of either going to an exclusive arrangement with Lilly in 2016 or waiting until 2017 to go through a bidding process between Lilly and Novo. Novo has a higher share in United's Part D business so it will be difficult for us to win vs. Novo in 2017. We think it is prudent for the long-term to make a 2016 offer.

In the business case sent by Lisa you will see two scenarios. The first business case is one that ties directly to our plan price increase assumptions (9% every 9 months). It generates a 3 year positive business case of \$88M. In order to prevent having to secure additional FRAP approvals if our price increases become more aggressive, our MHS finance team have an additional case assuming very aggressive price increases (9% every 6 months). In this scenario the deal would be \$44M negative over the three year deal. In order to arrive at the business case each deal is compared to a scenario in which we lose the business to Novo and retain 5-10% of United's Part D business at no rebate. The value of this residual business becomes more attractive in the more aggressive price increase scenario. We believe that the plan price increase scenario is the much more likely pricing scenario. In addition, the business case in the lose scenario is highly dependent upon our ending share assumption which is controlled more by United's efforts than our efforts. If United drives to a lower share the value of the residual share quickly erodes. We think it's best to secure this business to gain the strategic advantage of the improved access in Part D.

Our walk-in offer to United would generate a \$200+ million upside for the company over the next three years. Martin and Enrique are in Japan. If you have any questions, feel free to reach out to me. My cell number to [REDACTED]

I appreciate your consideration of this request,

Take care,

Mike

Message

From: lyons_terrence_ [REDACTED]
on behalf of Terrence M Lyons [REDACTED]
Sent: 2/25/2015 5:34:57 PM
To: Alex M Azar [REDACTED]
CC: Frank D Cunningham [REDACTED]
Subject: Fwd: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today - Please reconfirm

For your reference only; thought you might be interested in the nature and degree of corporate oversight in the final approval of the OptumRx insulins deal. This deal seems to represent a departure from the trend toward BU autonomy, and the revision to the final offer terms post PRASC approval are unprecedented in my tenure.

TML

Terrence M. Lyons
Vice President Finance | CFO Lilly USA LLC
[REDACTED]

From: Joshua L Smiley
Sent: Wednesday, February 25, 2015 5:16 PM
To: Wilbur Van Tryon; Lisa J Heid
Cc: Terrence M Lyons
Subject: Fwd: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today - Please reconfirm

Lisa and Web,

This message is to explicitly document Derica's support for the terms outlined below. He and I discussed live yesterday and through email today and Enrique has reconfirmed the terms that he and Derica agreed to. Please use this message as the confirmation of his approval.

Josh

Begin forwarded message:

From: Enrique A Conterno <[REDACTED]>
Date: February 25, 2015 at 4:26:36 PM EST
To: John C Lechleiter [REDACTED], Joshua L Smiley [REDACTED]
Cc: Lisa J Heid [REDACTED], Derica W Rice [REDACTED], Michael B Mason [REDACTED], Martin Bott [REDACTED], "Christopher W. Ogden" [REDACTED], Wilbur Van Tryon [REDACTED], Edward L Runkel [REDACTED], W Patrick Bruen [REDACTED]
Subject: RE: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today - Please reconfirm

Thank you to everyone involved for your engagement on this business opportunity. I want to confirm that the walk-in offer referenced below is correct.

Best regards,


Enrique

From: John C Lechleiter
Sent: Wednesday, February 25, 2015 3:40 PM
To: Joshua L Smiley
Cc: Lisa J Heid; Derica W Rice; Michael B Mason; Enrique A Conterno; Martin Bott; Christopher W. Ogden; Wilbur Van Tryon; Edward L Runkel; W Patrick Bruen
Subject: Re: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today - Please reconfirm


With Josh's OK, let's proceed.

Regards -- John

John C. Lechleiter
Chairman, President, and CEO
Eli Lilly and Company




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On Feb 25, 2015, at 10:34 AM, Joshua L Smiley  wrote:

Lisa,

I know we are working to get this offer to the customer today and many of the business leaders are traveling outside the U.S. Your understanding outlined below is correct for the offer to Optum.

Josh

On Feb 25, 2015, at 1:28 PM, "Lisa J Heid"  wrote:

John and Derica,

Given the magnitude of the Optum offer, I just want to confirm exactly what was approved given the details were not outlined in Mike's message included at the bottom of this email. I have confirmed with Mike, below were the walk-in terms referred to in his email.

68% rebate for both Lin and Log
10% LPP price cap for 2016
8% LPP price cap for 2017, 2018
Dec. 31, 2014 anchor date for LPP

At this time we will record that the higher walkaway rates approved by PRASC on February 23rd are not approved for FRAP purposes and that the walk-in rates stated above are approved. During the negotiation process if any higher FRAP amount is required than the walk-in amounts, we will seek FRAP approval of any modified terms at that point in time. Please confirm by responding to

this email that the walk-in terms above is what you have approved for the Optum offer.

I apologize for asking for re-confirmation, but given the size of this deal I want to make sure we are all aligned before anything is discussed with the customer. Thanks

Lisa

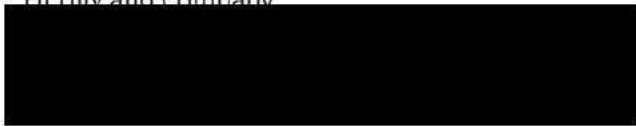
From: John C Lechleiter
Sent: Wednesday, February 25, 2015 12:26 PM
To: Derica W Rice
Cc: Michael B Mason; Enrique A Conterno; Martin Bott; Christopher W. Ogden; Joshua L Smiley; Lisa J Heid
Subject: Re: Preview of Insulin Opportunity with United on their Part D Business Requiring FRAP Approval Today

Then I approve. Let's move forward along the lines you recommend. I also look forward to our meeting.

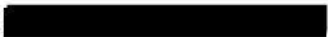
Thanks for huddling on this, guys, across time zones.

Regards -- John

John C. Lechleiter
Chairman, President, and CEO
Eli Lilly and Company



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On Feb 25, 2015, at 9:19 AM, Derica W Rice  wrote:

John,

Enrique and I had a chance to talk earlier today. I am supportive of moving forward with the walk-in proposal that was laid out here. As for the walk-away, Enrique and I do not want to put this on the table initially. Enrique will stay close to this negotiation, and vet any movement needed between the proposed walk-in terms and the final walk-away. As for the 2016 impact, he believes that they can manage the majority of the exposure with the ups and downs across the total

portfolio of contracting discussions within the diabetes business (at the full walk-away terms).

In terms of key takeaways:

- 1). This deal is consistent with the the contracting strategic review we had earlier
- 2). We are not obligated to move forward if we can not reach acceptable terms. We would allow the existing contract to run its course
- 3). There are a number of strategic nuances to this proposal that would be shared in a live setting. John, I think there would be benefit in having a brief discussion when we are all back in the office, to share the longer term implications of this deal in our overall contracting strategy. Enrique was able to provide some very helpful insights beyond the content of the email.

Enrique, please add to this message if I missed something. I very much appreciate the patience of everyone on this matter. It is complicated, and your allowance for appropriate understanding is valued.

Thanks everyone!

Regards,
Derica

Derica W. Rice
Executive Vice President, Global Services and CFO
Eli Lilly and Company

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[REDACTED] wrote:

John and Derica,

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Our walk-in offer to United would generate a \$200+ million upside for the company over the next three years. Martin and Enrique are in Japan. If you have any questions, feel free to reach out to me. My cell number to [REDACTED]

I appreciate your consideration of this request,

Take care,

Mike

Message

From: cunningham_frank_ [REDACTED]
on behalf of Frank D Cunningham [REDACTED]
Sent: 3/20/2015 9:44:16 AM
To: Alex M Azar [REDACTED] Terrence M Lyons [REDACTED]
Subject: FW: United Part D Humulin and Humalog Update

Alex/Terry,

I just wanted to keep you updated on the United Insulins deal. No action required on your part. The DBU has been updated.

Frank

From: Joanne C Sellner
Sent: Thursday, March 19, 2015 5:17 PM
To: Frank D Cunningham
Cc: LouAnn Cash
Subject: United Part D Humulin and Humalog Update

confidential, internal use only

Before I share some good news, let me caveat that I have not heard from the PBM (OptumRx) yet and no amendments are executed. A trusted source at UHC said that MPMC (UHC's approval committee for formulary/finances) approved Lilly for 1 of 1 for all three plans today.

As negotiations progressed, we had two approved options to offer this week:

- A) Lower the year 1 LPP allowable increase from 12% to 10%, OR
- B) In 2016 only, +3.5pp rebate for any 1 of 1 client that converts to Lilly 1 of 1

We chose to offer option B because it saves ~\$18M for Lilly (mostly in 2017-18), and it directly address the challenges in converting Saver Plus.

United's leadership committee made one ask of Lilly - that we are highly engaged in the communication/pull through plan. I of course indicated we fully expect to support this massive patient transition and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation, and DBU executive engagement.

This update puts us 80-90% to the finish line. I recommend no formal communication with results until we have a fully executed amendment. Next steps:

- 1) CMA draw up amendment
- 2) Wait to hear from PBM ~ finalize amendments

Regards,

Joanne Sellner
Managed Healthcare Services, National Accounts
Lilly USA, LLC
[REDACTED]




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Abarca Health

Part D

Annual Price Protection (Insulins)

01/01/2016-12/31/2017 (2 Year Deal)

Lilly

***Approved by VP, Diabetes Business Unit 3/25/2015; No dissent by
President, Lilly USA 3/25/2015***

Leadership Review Date: 03/26/2016

CDC: Steven M. Kidd

Account Manager: Maridel Marti

Abarca Health

Part D, Annual Price Protection (Insulins)

Recommendation to Leadership Review:

Requesting 6% Price Protection to the current 54% Rebate offer

Background:

- Abarca Health is a Puerto Rican PBM that manages the Public Payer System, Commercial and Part D Lives
- They have a history of aggressively pursuing rate enhancements with short turn around demands
- In 2015 the customer moved from Dual access to Exclusive for Lilly Insulins
- The competition is disadvantaged with most segments and customers in the territory, so they are making a competitive threat that is said to include covering the cost of 'transitioning lives away from Lilly products'.
- Insulins are subject to DACO: a 3% WAC reduction imposed by the Puerto Rican Government
- A 52% rebate for Humalog and Humulin was approved and delivered to the customer on 03/13/2015
- 8% APP was approved and delivered to the customer on 03/26/2015
- Intelligence suggests the competition is offering a 54% Rebate + 6% APP

Key Deal Information:

| | | | |
|----------------|---|---------------|-------------|
| Lives | 120,000 Lives (Customer Provided Formulary) | Control Index | N/A |
| Benefit Design | 100% (Closed) | Account Type | Puerto Rico |
| CoPay | \$5/\$10/\$40/33% | Offer Due | 03/26/2015 |

7

Abarca Health

Part D Annual Price Protection (Insulins)

Deal Essence:

- Enhancing Price Protection offer from 8% to 6%
- Enhancing Rebate from 52% to 54% offer for both Humalog and Humulin
- Brand is supportive of both the 6% APP cap and the 54% rebate with the following preference order:
 - 1-Reduce 8% APP cap to 6% APP
 - 2-Increase 52% base rebate to 54%

Request for Leadership Review Approval:

Requesting 6% Price Protection to the current 54% Rebate offer

3

Abarca Health

Part D, Annual Price Protection (Insulins)

Walk-Away Recommendation to DRB/PRASC:

Financial Summary:

| Approval level needed | Product | Current 2 Year Offer | | | | | | | | Proposed 2 Year Deal (in 000's) | | | | | | | |
|-----------------------|---------|----------------------|----------|-------------|---------|------------------|----------------------|------------------------|--------------------------|---------------------------------|----------|-------------|---------|------------------|----------------------|------------------------|--------------------------|
| | | Formulary Status | Rebate % | Admin Fee % | Total % | Price Protection | Expected Gross Sales | Deal Margin Difference | Total Rebate & Admin Fee | Formulary Status | Rebate % | Admin Fee % | Total % | Price Protection | Expected Gross Sales | Deal Margin Difference | Total Rebate & Admin Fee |
| PRASC | Humulin | 1 of 1 | 52 | 1.5 | 53.5 | 8% APP | \$ 25,939 | \$ 2,342 | \$ 13,989 | 1 of 1 | 54 | 1.5 | 55.5 | 6% APP | \$ 25,939 | \$ 1,718 | \$ 14,609 |
| | Humalog | 1 of 1 | 52 | 1.5 | 53.5 | 8% APP | \$ 27,516 | \$ 3,592 | \$ 14,838 | 1 of 1 | 54 | 1.5 | 55.5 | 6% APP | \$ 27,516 | \$ 3,321 | \$ 15,509 |
| | | | | | | | | | | | | | | | | | |
| | | | | | | | \$ 53,455 | \$ 6,333 | \$ 28,827 | | | | Total: | | \$ 53,455 | \$ 5,039 | \$ 30,118.0 |

Price Predictability Impact is 0.9% for Humalog and 0.8% for Humulin

The overall additional walk-away financial impact in comparison to the standing offer is: \$1,294,000

The proposed rebates offered for a particular Lilly product are on a product-by-product, IDIC by IDIC, and benefit design-by-benefit design basis and are not contingent upon with respect to any other Lilly product or the same Lilly product under a different benefit design or IDIC.

Abarca Health

Part D, Annual Price Protection (Insulins)

Supporting Information

Business Case (in 000's) - Effective 01/01/16 - 12/31/17 (2 Year Deal)

| Humalog | | Possible Outcomes | | | | |
|--|--|-------------------|--------------|--------------------|------------------|---------------|
| Deal Period: 01/01/2016 - 12/31/2017 | | Status: Out | Model: Deal | Alternative: End B | Scenario: End B2 | Model: End B2 |
| Abarca Part D | | Customer: Abarca | Volume: 8.8 | AS 90% 4% AP | AS 90% 8% AP | AS 90% 8% AP |
| (in 000's) | | Volume: 8.8 | AS 90% 4% AP | AS 90% 8% AP | AS 90% 8% AP | AS 90% 8% AP |
| Gross Sales | | \$ 26,038 | \$ 27,516 | \$ 27,516 | \$ 27,516 | \$ 27,516 |
| Total Discretionary Rebates & Admin Fee | | \$ 19,408 | \$ 18,829 | \$ 18,829 | \$ 18,829 | \$ 18,829 |
| Total Legitimate Rebates/Discounts | | \$ 3,409 | \$ 3,613 | \$ 3,613 | \$ 3,613 | \$ 3,613 |
| Total Additional Rebates/Discounts | | \$ 1,979 | \$ 2,085 | \$ 2,085 | \$ 2,085 | \$ 2,085 |
| Deal Margin | | \$ 7,246 | \$ 6,989 | \$ 6,989 | \$ 6,989 | \$ 6,989 |
| Average Discretionary Rebates (w/o AP Rebates) | | 20.7% | 14.2% | 14.2% | 14.2% | 14.2% |
| Average Price Paid to Retailer | | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Average Admin Fee | | 1.1% | 1.1% | 1.1% | 1.1% | 1.1% |
| Average Legitimate Rebates | | 13.1% | 13.1% | 13.1% | 13.1% | 13.1% |
| Break-Even Period (Years to Deal) | | 6.7 Yrs | 6.8 Yrs | 6.8 Yrs | 6.8 Yrs | 6.8 Yrs |
| Price to Peak Shift (Years to Break-Even) | | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 |
| Rebate Cost per Box | | \$ 360 | \$ 375 | \$ 375 | \$ 375 | \$ 375 |
| End of Period Share of Market | | 8% | 8% | 8% | 8% | 8% |
| Peak Share Shift | | 0% | 0% | 0% | 0% | 0% |
| Years to Peak Share Shift | | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 |

How were the rates determined?

- AM and Brand agreed based on competitive threat

Business Case Notes:

- Standard share shift assumptions used
- SDH via Customer Claim Utilization: Gross Sales via Claim Audit Reports.
- Assumed Aggressive 9.9 Price Increases every 6 months

| (in 000's) | Market Price | Market Price | Market Price |
|---------------------|--------------|--------------|--------------|
| Likely Deal | \$ (937) | \$ (937) | \$ (937) |
| Alternative Deal #1 | \$ (397) | \$ (397) | \$ (397) |
| Alternative Deal #2 | \$ (265) | \$ (265) | \$ (265) |

Key Deal Driver

For this deal to make sense, you have to believe the offer will close the deal

Alignment

| | | |
|--------------------|-----------|---|
| Brand | | Supportive in light of competitive threat |
| Account Management | | AM believes offer will secure business and limit annual threats |
| CMA | Financial | CMA supportive based on financials |
| | Strategy | Brand aligned with Strategy (Rebates and Price Protection are Outside Guidelines) |

Abarca Health

Part D, Annual Price Protection (Insulins)

Supporting Information

Business Case (in 000's) - Effective 01/01/16 - 12/31/17 (2 Year Deal)

| Hemulin | Status Quo | Possible Outcomes | | | |
|---|------------|-------------------|-----------|-----------|------------|
| | | Worst Case | Base Case | Best Case | Worst Case |
| Deal Period: 01/01/2016 - 12/31/2017 | | | | | |
| Abarca Part D | | | | | |
| (in 000's) | | | | | |
| Gross Sales | \$ 25,900 | \$ 25,900 | \$ 25,900 | \$ 25,919 | \$ 25,900 |
| Total Discountary Rebates & Admin Fee | \$ 19,800 | \$ 14,600 | \$ 14,107 | \$ 13,819 | \$ 13,800 |
| Total Unrelated Rebates/Discounts | \$ 3,351 | \$ 3,351 | \$ 3,351 | \$ 3,351 | \$ 3,351 |
| Total Additional Rebates/Discounts | \$ 1,817 | \$ 1,817 | \$ 1,817 | \$ 1,817 | \$ 1,817 |
| Deal Margin | \$ 7,412 | \$ 6,162 | \$ 6,684 | \$ 6,722 | \$ 6,644 |
| Average Discountary Rebate (m/z/PP Review) | 25.3% | 24.0% | 22.2% | 22.3% | 22.3% |
| Average Price Predictability Rebate | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Average Admin Fee | 1.9% | 1.9% | 1.9% | 1.9% | 1.9% |
| Average Unrelated Rebates | 12.9% | 12.9% | 12.9% | 12.9% | 12.9% |
| Break Even Rebate (versus No Deal) | 62.3% | 62.3% | 62.3% | 62.3% | 62.3% |
| Time to Profitability (Years to Break Even) | 0.30 | 0.15 | 0.30 | 0.30 | 0.30 |
| Business Case per Share | \$ 200 | \$ 200 | \$ 200 | \$ 200 | \$ 200 |
| End of Period Share of Market | 80% | 80% | 80% | 80% | 80% |
| Peak Share Shift | 0% | 0% | 0% | 0% | 0% |
| Years to Peak Share Shift | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

How were the rates determined?

- AM and Brand agreed based on competitive threat

Business Case Notes:

- Standard share shift assumptions used
- SDH via Customer Claim Utilization: Gross Sales via Claim Audit Reports.
- Assumed Aggressive 9.9 Price Increases every 6 months

| Profitability Scenarios - Deal Margin Difference | | | |
|--|------------|-----------|-----------|
| (in 000's) | Worst Case | Base Case | Best Case |
| Likely Deal | | | |
| 1.1 - 50% - 0% APP | \$ (1,250) | \$ 1,718 | |
| Alternate Deal #1 | | | |
| 1.1 - 32% - 0% APP | \$ (748) | \$ 2,220 | |
| Alternate Deal #2 | | | |
| 1.1 - 12% - 0% APP | \$ (631) | \$ 2,338 | |

Key Deal Driver

For this deal to make sense, you have to believe the offer will close the deal

Alignment

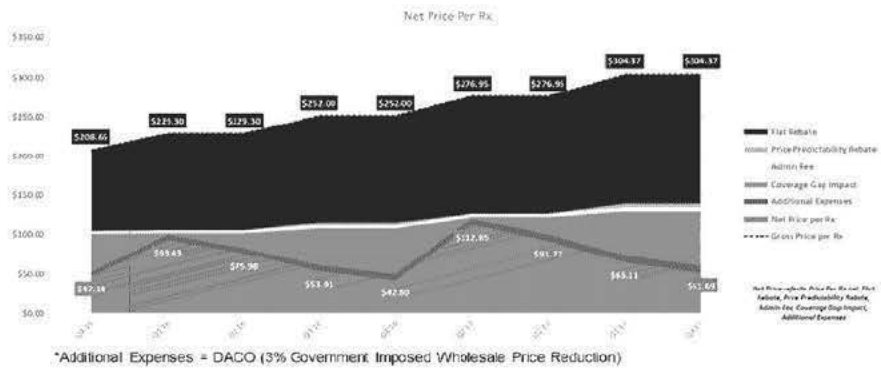
| | | |
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| Brand | | Supportive in light of competitive threat |
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| | Strategy | Brand aligned with Strategy (Rebates and Price Protection are Outside Guidelines) |

Backup

Abarca Health

Part D, Annual Price Protection (Insulins)

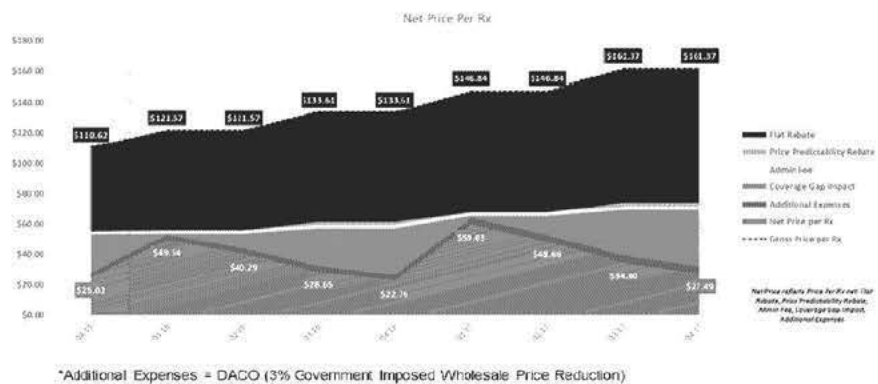
Humalog Net Price



Abarca Health

Part D, Annual Price Protection (Insulins)

Humulin Net Price



Message

From: azar_alex [REDACTED]
on behalf of Alex M Azar [REDACTED]
Sent: 3/30/2015 11:36:30 AM
To: Lisa J Heid [REDACTED]
Subject: Re: Abarca Part D 2016-2017 Enhanced Walk Away-Mike Mason Approval

I don't have a basis to object.

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285
[REDACTED]

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On Mar 30, 2015, at 11:02 AM, Lisa J Heid <[REDACTED]>:

Alex,

As the business owner for PR, I wanted to give you a chance to weigh in on the Abarca Part D offer. Last week both you and Mike approved an 8% APP with a 52% rebate for Abarca for Humulin and Humalog for 2016-2017 Part D. Lilly Insulins are currently preferred. Subsequent to that approval, the field has spoken with the customer and learned that Novo has an aggressive offer to win the business. Field and brand would like to request additional approval for a 54% rebate with 6% APP cap as the final walk away. This deal is net sales positive \$1.7mil on gross sales of \$25.9 Mil for Humulin and \$3.3 Mil on gross sales for \$27.5 Mil for Humalog for the two year deal period.

Mike's approval for the brand is attached below. I have attached the pre-read for your reference.

Lisa

From: Steven Mark Kidd
Sent: Saturday, March 28, 2015 4:30 PM
To: Lisa J Heid
Subject: Fwd: Abarca Part D 2016-2017 Enhanced Walk Away-Mike Mason Approval

Lisa,

Mike has approved. Now we need to connect with Alex.

Steven M. Kidd
Associate Consultant – Business Development – CMA
Managed Healthcare Services
Lilly USA, LLC
[REDACTED]



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Begin forwarded message:

From: "William F. Riesner" [REDACTED]
Date: March 28, 2015 at 12:01:39 PM EDT
To: Steven Mark Kidd [REDACTED]
Subject: Fwd: Abarca Part D 2016-2017 Enhanced Walk Away

Let me know if you need anything else.

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Bill Riesner
Associate Brand Manager – Insulins Payer Strategy
LillyUSA, LLC
[REDACTED]

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Begin forwarded message:

From: Michael B Mason <[REDACTED]>
Date: March 28, 2015 at 10:00:25 AM EDT
To: "William F. Riesner" [REDACTED]
Cc: Martin Bott [REDACTED] John Joseph Peters [REDACTED]
Subject: Re: Abarca Part D 2016-2017 Enhanced Walk Away

I approve.

Sent from my iPad

On Mar 27, 2015, at 5:08 PM, William F. Riesner [REDACTED] wrote:

Mike/Martin

We received feedback from Abarca that the 8% APP offer approved at PRASC on Wednesday was not enough.

The AM is meeting with the account on Tuesday. Along with walking them through the BIM, she would like to have an enhanced offer available if needed.

The attached business case represents the following changes:

- <!--[if !supportLists]--><!--[endif]-->Reduced APP cap from 8% to 6%
- <!--[if !supportLists]--><!--[endif]-->Enhanced rebate from 52% to 54%

We are seeking approval for both enhancements to save on review time, but the AM has been instructed to offer the enhancements (only if needed) in the following order:

1. <!--[if !supportLists]--><!--[endif]-->APP Reduction: -\$250k net sales
2. <!--[if !supportLists]--><!--[endif]-->Rebate Enhancement: -\$1M net sales

All scenarios are still BUC positive vs No Deal.

Given the governance needed for Puerto Rico, we will need your and Alex's approval to make the offer.

If you approve, please reply to this email with the approval.

Let me know if you have any questions. My cell is [REDACTED]

Thanks,
Bill

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Bill Riesner
Associate Brand Manager – Insulins Payer Strategy
LillyUSA, LLC
[REDACTED]

<image001.jpg>

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From: Steven Mark Kidd
Sent: Friday, March 27, 2015 3:23 PM
To: William F. Riesner; R Bruce Christian; Maridel Marti; Lisa J Heid

Subject: Abarca Part D 2016-2017 Enhanced Walk Away
Importance: High

Team,

I have updated the Pre-Read with a Maximum walk away offer of 54% Rebate and 6% APP with the understanding Brand has the following preference in any enhanced offer:

Thanks Steve.

Brand is supportive of both the 6% APP cap and the 54% rebate.

Maridel/Bruce: If an enhancement of the current offer is needed, I would prefer the terms be offered in the following order:

- 1. Reduce 8% APP cap to 6% APP*
- 2. Increase 52% base rebate to 54%*

Let me know what else you need from me.

*Thanks,
Bill*

The next steps that CMA needs are for Bill to ensure Mike Mason is supportive of the enhanced offer and will also be supportive of the FRAP figures. Then Lisa will connect with Alex, who is on vacation, for his Puerto Rico review purposes.

It is understood that Bruce and Maridel have a meeting with the customer Tuesday afternoon.

Regards,

~Steve

Steven M. Kidd
Associate Consultant – Business Development – Managed Healthcare Services
Managed Healthcare Services
Lilly USA, LLC

<image001.jpg>

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<Abarca Part D Insulins 54% Rebate--6% Price Protection Pre-Read.pptx>



<Abarca Part D Insulins 54% Rebate--6% Price Protection Pre-Read.pptx>

Message

From: lyons_terrence_ [REDACTED]
on behalf of Terrence M Lyons [REDACTED]
Sent: 4/10/2015 1:41:58 PM
To: Alex M Azar [REDACTED]; Frank D Cunningham [REDACTED]
CC: W Patrick Bruen [REDACTED] Wilbur Van Tryon [REDACTED]
Subject: Fwd: VA / DOD Insulin Bid Approval - FRAP Approval Requested - Bid response is due to VA by Tuesday, April 14th 2pm

Alex and Frank:

Thought you might find the below dialogue of interest, both as related to the capacity considerations and the direct shipment option posited by the DBU should LLY secure this government bid.

TML

Terrence M. Lyons
Vice President Finance | CFO Lilly USA LLC
[REDACTED]

From: Enrique A Conterno
Sent: Friday, April 10, 2015 1:25 PM
To: Derica W Rice; Lisa J Heid
Cc: John C Lechleiter; Michael B Mason; Anat Ashkenazi; Joshua L Smiley; Terrence M Lyons; Wilbur Van Tryon; MARIA CROWE
Subject: RE: VA / DOD Insulin Bid Approval - FRAP Approval Requested - Bid response is due to VA by Tuesday, April 14th 2pm

Derica,

We have the capacity. Additionally, if we were to win, we would seek to ship directly as much as possible of this bid to eliminate the 3.5% wholesaler fee as a percentage of gross sales -this is a significant amount given the difference between our list prices and net prices.

Best regards,

Enrique

From: Derica W Rice
Sent: Friday, April 10, 2015 1:18 PM
To: Lisa J Heid
Cc: John C Lechleiter; Michael B Mason; Enrique A Conterno; Anat Ashkenazi; Joshua L Smiley; Terrence M Lyons; Wilbur Van Tryon; MARIA CROWE
Subject: Re: VA / DOD Insulin Bid Approval - FRAP Approval Requested - Bid response is due to VA by Tuesday, April 14th 2pm

Lisa,

Thanks for the summary. The incremental income benefits are clear, although the margin on this business is quite low. I have a manufacturing related question: what percent of our current insulin mfg capacity would these volumes occupy? While we could absorb this in our current capacity, how quickly would this push us in the future to consider additional capacity needs? (Do we have enough capacity runway, such that these volumes would not be material). I

have copied Maria to get her perspective. If manufacturing is ok on this basis, I can support this incremental margin gathering opportunity. I just want to make sure it does not come with a significant opportunity cost.

Thanks!

Regards,
Derica

Derica W. Rice
Executive Vice President, Global Services and CFO
Eli Lilly and Company

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On Apr 9, 2015, at 5:49 PM, Lisa J Heid <[REDACTED]> wrote:

John and Derica,

As Mike explained below, VA has requested a response to their Insulin bid. Due to the volume of purchases included in the bid request, length of contract and amount of discretionary discount being proposed, this offer requires both of your approvals for FRAP purposes. Although the total offer in terms of gross sales is extremely large, \$9.4 Bil over the five year period, the estimated net margin is \$246Mil (\$84 Mil for Humulin and Humalog Mix and \$162 Mil for Humalog Vials and pens) for the 5 year period. The total discounts associated with this offer is \$8.75Bil (\$8.2Bil statutory discounts/federal ceiling prices and \$576Mil in discretionary discounts). **This deal has a positive deal margin difference (net sales less variable COPs and wholesaler fees) of \$173.2 Mil over the five year period compared to current status quo since we do not currently have the Insulin business.**

The following pricing offer was approved by PRASC on Thursday, April 9th (prices effective for the 5 year deal period) :

| Short Name | Current Novo Pricing | Lilly Proposed Bid | Lilly PSS Mandated Pricing |
|--------------------|-------------------------|--------------------------|----------------------------------|
| Lin R Vial | 5.29 | 9.80 | 12.56 |
| Lin N Vial | 5.29 | 9.80 | 12.56 |
| Lin 70/30 Mix Vial | 5.29 | 9.80 | 12.56 |
| Log Vial | 21.90 | 24.09 | 47.29 |
| Log Mix Vial | 27.87 | 30.66 | 47.29 |
| Log Kwikpen | 32.84 | 36.12 | 88.63 |
| Log Mix Kwikpen | 41.80 | 45.98 | 88.63 |

I have attached the PRASC pre-read document for further details. Feel free to contact me if you have questions. **Please respond to this email with your FRAP approval. This bid response is due to VA by 2pm on Tuesday, April 14th.**

Lisa Heid
Director, Business Development
Lilly USA
[REDACTED]

From: Michael B Mason
Sent: Thursday, April 09, 2015 3:48 PM
To: John C Lechleiter; Derica W Rice
Cc: Anat Ashkenazi; Enrique A Conterno; Joshua L Smiley; Lisa J Heid; Terrence M Lyons
Subject: VA / DOD Insulin Bid Approval

John, Derica:

You will be receiving an email from Lisa Heid seeking approval required by FRAP guidelines for our VA insulin bid. I wanted to provide you some background on the request.

Every five years the VA conducts a sole source bid / RFP for insulins on behalf of the VA, DOD, Indian Health services and Bureau of Prisons. Novo has the current 5-year contract. Recently, the VA has published the RFP for the next five years and have requested bids to be submitted by April 14th. This business has very high volume, but very low prices. We have crafted a bid that provide us the following return if we were to win the bid:

The figures below represent the deal margins (gross sales less all discounts, variable COPS, wholesaler fees) for both status quo and if Lilly wins the bid

**Bid Group 1 – Humulin and Humalog Mix Vials
Humalog Vials & Pens**

5 year Net Sales

| | <u>Lose Bid*</u> | <u>Win Bid at Proposed Rates</u> |
|-------------|------------------|----------------------------------|
| <u>Bid*</u> | | <u>Win Bid at Proposed Rates</u> |
| | \$15M | \$84M |
| | \$162M | |

Bid Group 2 –

5 year Net Sales

| <u>Lose</u> |
|-------------|
| \$58M |

*We currently have a 30% share in the DOD segment that would likely remain if we lose the bid.

We believe our bid properly balances a competitive offer that would provide a good return to the company. Given that this will be a highly competitive bidding process with Novo and potentially Sanofi, it's difficult to forecast the outcome.

Enrique is supportive of our proposal. Feel free to reach out to me, Anat Ashkenazi or Enrique if you have questions or want to have a live conversation to review our bid.

Take care,

Mike

<04-Humalog Humulin-VA DOD Sole Source Bid Pre-read.pdf>

Message

From: azar_alex [REDACTED]
on behalf of Alex M Azar [REDACTED]
Sent: 5/14/2015 10:45:06 AM
To: Lisa J Heid [REDACTED]
Subject: Re: ACTION: SIS Commercial Insulins Review with APP
Attachments: image001.jpg

Thanks. I don't have a basis to veto.

Alex M. Azar II
President
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, IN 46285
[REDACTED]
[REDACTED]

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On May 14, 2015, at 10:06 AM, Lisa J Heid <[REDACTED]> wrote:

Alex,

I just wanted to make sure you are okay with providing 8% APP to the SIS offer for Insulins. Mike Mason has approved as you can see below. The deal is \$1.3Mil net sales positive compared to no deal. The plan has relatively low dual rates for Insulins (walkaway rates of 22% with 3% admin fee).

Lisa

From: Steven Mark Kidd
Sent: Wednesday, May 13, 2015 8:41 AM
To: Lisa J Heid
Subject: FW: ACTION: SIS Commercial Insulins Review with APP
Importance: High

Lisa,

SIS Commercial has requested LPP, and through the business cases and discussion between Brand and the Account Manager they have agreed upon an APP offer at 8% with the annual reset. Mike Mason is supportive. I haven't received feedback from Anat (although the current protocol doesn't specifically require his or Terry Lyons review for PR).

We need to run this by Alex and ensure he doesn't have a reason to veto. No BioMed products are being offered with price protection. Would you like me to create a write up for his review, or would you prefer to do so?

~SMK

Steven M. Kidd
Associate Consultant – Business Development – Managed Healthcare Services
Managed Healthcare Services
Lilly USA, LLC
[REDACTED]


Lilly

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From: Michael B Mason
Sent: Tuesday, May 12, 2015 4:57 PM
To: William F. Riesner
Cc: Anat Ashkenazi; Steven Mark Kidd; John Joseph Peters
Subject: Re: ACTION: SIS Commercial Insulins Review with APP

Bill

I am supportive.

Mike

Sent from my iPad


On May 12, 2015, at 11:56 AM, William F. Riesner < wrote:

Apologies. Correction to the request (already reflected in the Business Case outputs), just a typo in my explanation.

THE PRASC APPROVAL REQUESTED IS:


- <!--[if !supportLists]--><!--[endif]-->Enhanced Humalog Dual Rate (16% → 25%) Walk in = 19% (+3% Admin Fee)
- <!--[if !supportLists]--><!--[endif]-->Enhanced Humulin Dual Rate (19 → 25%) Walk in = 22% (+3% Admin Fee)
- <!--[if !supportLists]--><!--[endif]-->Addition of 8% APP

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Bill Riesner
Associate Brand Manager – Insulins Payer Strategy
LillyUSA, LLC


<image001.jpg>

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From: William F. Riesner
Sent: Tuesday, May 12, 2015 11:39 AM
To: Michael B Mason;  Anat Ashkenazi
Cc: Steven Mark Kidd; John Joseph Peters
Subject: ACTION: SIS Commercial Insulins Review with APP

Mike/Anat,

SIS is the largest commercial payer in Puerto Rico. Given the account is in Puerto Rico, your and Alex's approvals are required for all offers per our governance.

The account is currently dual. The current SOM/rebates are as follows:

| | Humalog | Humulin |
|-------------|---------|---------|
| Current SOM | 69% | 83% |
| Rebate | 16% | 19% |
| Admin Fee | 3% | 3% |

The contract is set to expire on 6/30/2015 and the customer is requesting enhanced dual rate + price protection for the next 2 years.

The customer tends to require very quick turnaround, so the Account Manager is asking for some flexibility to negotiate, with the full intention of walking in below the walk away rates for Humalog.

THE APPROVAL REQUESTED IS:

- <!--[if !supportLists]--><!--[endif]-->Enhanced Humalog Dual Rate (16% → 22%) Walk in = 19% (+3% Admin Fee)
- <!--[if !supportLists]--><!--[endif]-->Enhanced Humulin Dual Rate (19 → 22%) Walk in = 22% (+3% Admin Fee)
- <!--[if !supportLists]--><!--[endif]-->Addition of 8% APP

Please let me know if you have any questions or concerns.

If you approve, please Reply to All with your approval.

Thanks,
Bill

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Bill Riesner
Associate Brand Manager – Insulins Payer Strategy
LillyUSA, LLC


<image001.jpg>

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From: Steven Mark Kidd
Sent: Friday, May 08, 2015 12:30 PM
To: William F. Riesner
Subject: SIS Commercial Insulins Review with APP

Bill,

Take a look and let me know if you are supportive and I will build the Pre-Reads. This will need Mike's okay and (Alex's lack of a veto) Not PRASC. Also as a reminder the (Additional Expense) represented by a grey line in the Net Price Chart is the 3% DACO.

~SMK

HUMALOG

<image002.png>

<image003.png>

<image004.png>

HUMULIN

<image005.png>

| Profitability Scenarios - Deal Margin Difference | | |
|--|-------------------------------|---|
| In 000's | Status Quo Status Quo-Dual | Likely No Deal Not Covered - Locked Out |
| Likely Deal Dual-25% 8% APP-Walk Away | \$ (453) | \$ 1,334 |

<image006.png>

Steven M. Kidd
Associate Consultant – Business Development – Managed Healthcare Services
Managed Healthcare Services
Lilly USA, LLC



<image007.jpg>

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Message

From: lechleiter_john [REDACTED]
on behalf of John C Lechleiter [REDACTED]
Sent: 6/19/2015 3:21:42 PM
To: Lisa J Heid [REDACTED]
CC: Anat Ashkenazi [REDACTED]; Alex M Azar [REDACTED]; Frank D Cunningham [REDACTED]; Terrence M Lyons [REDACTED]; Michael B Mason [REDACTED]; Derica W Rice [REDACTED]; Joshua L Smiley [REDACTED]; Wilbur Van Tryon [REDACTED]
Subject: Re: Urgent - Request Incremental FRAP approval for ESI Commercial 2016-2017 Bid - Please respond by Noon, Monday, June 22nd

I approve.

Best Regards -- John

John C. Lechleiter, Ph.D.
Chairman, President, and Chief Executive Officer
Eli Lilly and Company
Lilly Corporate Center, Indianapolis, IN 46285 U.S.A.
[REDACTED]

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On Jun 19, 2015, at 8:06 AM, Lisa J Heid <[REDACTED]> wrote:

John and Derica,

On May 15, 2015 you approved \$4.226 Bil of projected rebates on estimated contracted gross sales of \$7.8 Bil for the 2016-2017 ESI bid response. The purpose of this message is to provide an update and request incremental changes based on the contract negotiations and feedback we have received from ESI. Revisions are requested based on a better understanding of the competitive landscape for key therapeutic areas as ESI is completing their formulary modeling. The total incremental FRAP being requested is \$79.4mil for the two year period. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] The remaining incremental FRAP amount of \$24.2 Mil is for enhanced offers for [REDACTED] Humalog and [REDACTED]
Below is a summary of the revisions requested:

[REDACTED]

Humalog National Basic Formulary- Humalog has been preferred in this book of business since January 2014. While the tier-differential benefit design itself has not yielded significant share growth (~3 share points in 2014), increased promotional efforts specific to the plan have increased Humalog share an additional 5 share points in the first four months of 2015. ESI's Value Assessment Committee is evaluating whether to move this book back to dual status equal to Novolog due to financial implications. DBU wants to maintain this book as 1 of 1 preferred to maintain this share growth. We are requesting an incremental 2.5pp rebate to maintain preferred status in this book. **The total incremental FRAP requested is \$5.3 mil over the two year period. This deal is (\$10.8 mil) net sales negative compared to no deal over the two year period. The business case will improve within the deal period by continuing the market share gains we have seen this year. This deal provides strategic value as it allows us to maintain our overall commercial access leadership versus Novolog which has become an important promotional message for Humalog. It also allows us to continue to highlight preferred access across all ESI national formularies. Beyond the deal period, the deal turns positive as share would likely continue to erode from the current point in the No Deal scenario.**

[REDACTED]

The chart below summarizes the key changes

| Product | Previous approval (Rebate + admin fee) | Deal Period/Terms | Revised Rebate Request | Deal Period/Terms | Incremental FRAP required (\$ Mil) |
|---------|--|-------------------|---------------------------|-------------------|---|
|---------|--|-------------------|---------------------------|-------------------|---|

Given the original FRAP request was approved by both of you, any incremental amounts should be approved by both of you. All of these offers were reviewed and approved by PRASC on either June 10th or June 16th. I have attached both PRASC pre-reads for additional detail. Please provide your approval for this incremental FRAP via email. **We request a response by Noon on Monday, June 22nd** so that we can respond back to ESI prior to their next Value Assessment Committee meeting scheduled for next week.

Please feel free to contact me with any questions concerning these offers.

Lisa Heid
Director, Contract Management and Analytics
Managed Healthcare Services
Lilly USA, LLC

[REDACTED]
[REDACTED]
[REDACTED]

<02-[REDACTED]-Express Scripts Inc. (commercial).pdf>

<Express Scripts DRB Slides [REDACTED].pptx>

Message

From: lechleiter_john [REDACTED]
on behalf of John C Lechleiter [REDACTED]
Sent: 9/17/2015 8:55:24 PM
To: Jennifer Graper [REDACTED]
CC: Anat Ashkenazi [REDACTED]; Alex M Azar [REDACTED]; W Patrick Bruen [REDACTED]; Enrique A Conterno [REDACTED]; Frank D Cunningham [REDACTED]; Terrence M Lyons [REDACTED]; Michael B Mason [REDACTED]; Derica W Rice [REDACTED]; Joshua L Smiley [REDACTED]; Wilbur Van Tryon [REDACTED]
Subject: Re: FRAP Approval Requested: Humana Part-D Insulins and [REDACTED] Offer

I approve.

Best Regards -- John

John C. Lechleiter, Ph.D.
Chairman, President, and Chief Executive Officer
Eli Lilly and Company
Lilly Corporate Center, Indianapolis, IN 46285 U.S.A.
[REDACTED]

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On Sep 17, 2015, at 4:20 PM, Jennifer Graper <[REDACTED]> wrote:

John, Derica,

This email is being sent to request your formal FRAP approval for the Humana Part-D Insulins and [REDACTED] deal that was approved by PRASC on September 14, 2015. **The goal is to provide this offer to the customer on Monday, September 21.**

Your reply to this email will serve as your FRAP approval.

Thank you,
Jenny Graper

Maximum Financial Commitment:

- <!--[if !supportLists]--><!--[endif]-->The maximum dollar-commitment (deal cost) of this offer is \$605.609 Million for the two-year deal (on forecasted Gross Sales of \$1.204 Billion).

Deal Term: January 1, 2017 through December 31, 2018

Background:

- <!--[if !supportLists]--><!--[endif]-->The 2017 RFP has just been released and the account team wants to begin the negotiation at a meeting on September 21.

- <!--[if !supportLists]--><!--[endif]-->Lilly's Part D signed contract includes Humalog, Humulin and [REDACTED] with Long-term Price Protection (LPP), and expires December 2016. Contract terms for [REDACTED] and Insulins are as follows:

- <!--[if !supportLists]--><!--[endif]-->**Humalog and Humulin LBC at 25% and 30% Closed rebate, respectively.** Novo's products are also LBC.
- <!--[if !supportLists]--><!--[endif]-->Additional Information: On July 3, 2015 Aetna announced it will acquire Humana. Humana is expected to manage the Part-D business of the combined entity. Insulins and [REDACTED] are not contracted at Aetna: Humalog (Not Covered), Humulin (Not Covered) and [REDACTED] (2LBC).

Deal Essence:

- <!--[if !supportLists]--><!--[endif]-->**Humalog, Humulin-** Humana is the last national dual Part D account. The intent is to renew current rates and LPP terms; however, enhanced LBC walk-away rebate-rates are requested as it is likely Novo will aggressively pursue a preferred deal at this account for 2017

PRASC Approved Offer:

- <!--[if !supportLists]--><!--[endif]-->**Rebate Rates:** Walk-away Closed rebates of **40%** for **Humalog** (for LBC), **Humulin** (for LBC), and [REDACTED] (for LBC/ Appropriate Restrictions) for the period January 2017 through December 2018.
- <!--[if !supportLists]--><!--[endif]-->**Price Predictability Terms:**
 - <!--[if !supportLists]--><!--[endif]-->**Humalog, Humulin:** 6% LPP with WAC Anchor Date of 1/1/2016
 - <!--[if !supportLists]--><!--[endif]-->[REDACTED]
- <!--[if !supportLists]--><!--[endif]-->Likely Deal Margin is Positive vs. No Deal: \$202 Million

Regards,
Jenny

Jenny Graper
Director - Business Development

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Message

From: rotterman_cory_ [REDACTED]
on behalf of Cory Rotterman [REDACTED]
Sent: 11/17/2016 7:27:09 PM
To: John C Lechleiter [REDACTED]; Derica W Rice [REDACTED]
CC: Anat Ashkenazi [REDACTED]; Alex M Azar [REDACTED]; Enrique A Conterno [REDACTED]; Frank D Cunningham [REDACTED]; Lisa J Heid [REDACTED]; Anthony Howard Lawson [REDACTED]; Terrence M Lyons [REDACTED]; Michael B Mason [REDACTED]; Josh Tomas O'Harra [REDACTED]; William F. Riesner [REDACTED]; Eric H Schultz [REDACTED]; Wilbur Van Tryon [REDACTED]; Alonzo Weems [REDACTED]
Subject: Urgent: FRAP Request for ESI Commercial Pass-Through Rebate
Attachments: ESI-Blink Pre-Read 111816.pdf
Importance: High

John and Derica,

Please see below for a pass-through rebate offer to ESI Commercial that **requires your FRAP approval via email response**. Your email response will provide FRAP approval to share a Lilly Legal-approved proposed agreement with ESI.

From a governance perspective, the deal was initially discussed at PRASC on November 7th with a follow-up discussion scheduled for this Friday afternoon as an update on the legal and qualitative diligence that has been performed (summarized below). If additional legal risks or material qualitative concerns arise, we will re-escalate for your consideration. If not, this approval will stand as final FRAP approval to execute the agreement.

Please see the attached slides (certain details pasted below) for a summary of the arrangement.

Transaction overview:

- Lilly transaction with ESI
 - Lilly and ESI will negotiate terms and conditions as a separate exhibit within the current ESI Rebate Agreement
 - A significant portion of the rebate (proposed at 98%) will be passed through to the patient via a third party administrator, in this case Blink Health
 - The patient will see this pass through in the transaction price in the Blink Health application
 - The portion of the rebate that is not passed through to the patient (proposed at 2%) and an administrative fee (proposed at 4.875%) will potentially be shared by ESI and Blink Health through their contractual relationship
- Patient, pharmacy, and reimbursement transaction
 - Patient pays for product through the Blink application (WAC grossed up for pharmacy markup less pass through rebate)
 - Patient shows their receipt from the Blink application and their Rx at the pharmacy
 - Pharmacy processes the Rx with a \$0 copay (patient has already paid Blink Health in the application) and dispenses the product
 - Claims adjudicator reimburses the pharmacy and Blink Health reimburses the claims adjudicator based on their contractual relationships
 - ESI receives Rx data from the claims adjudicator and submits to Lilly for rebate and administrative fee payment per the terms and conditions of the contract between ESI and Lilly

Legal position:

•

Privileged - AC

o
o

Privileged - AC

Deal parameters:

- As a condition of rebate, **98% of the rebate provided must directly benefit the patient** via Blink Health
 - o The objective is to provide a 50% discount to WAC directly to patients for Humalog/Humulin and a 40% discount to WAC directly to patients for Basaglar. The rates below reflect the rate necessary to achieve this objective with the 98% pass-through.
- **Humalog/Humulin U-100:** Provide a rebate of **51% of WAC**
- **Basaglar:** Provide a rebate of **40.9% of WAC**
- Provide a **4.875% admin fee** to ESI to administer the program on behalf of Blink Health

Financial commitment:

- The total estimated **FRAP commitment is \$140.5M** for 2017
 - o This estimate is based on an assumption that 75% of patients with an out-of-pocket cost >\$250 for the listed products utilize the program (data source: IMS)
 - o In addition, this estimate includes a Medicaid Best Price impact of \$15.5M for Basaglar (once verbally agreed upon contracts are signed, the impact is estimated at \$3.5M)

Please do not hesitate to reach out with any questions.

Thanks,

Cory

Cory Rotterman
Director – Business Development
Lilly USA, LLC



Blink – Lilly Partnership

Lilly

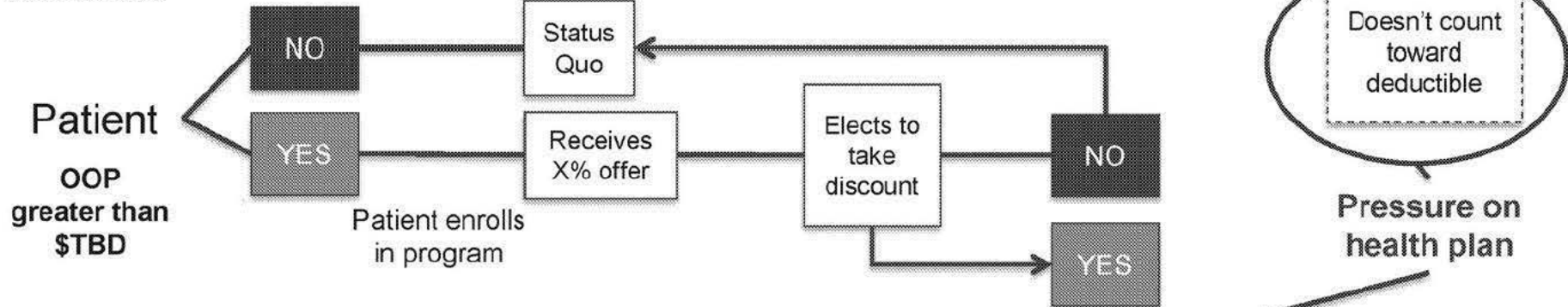
Blink

ESI/Blink - Lilly Contract

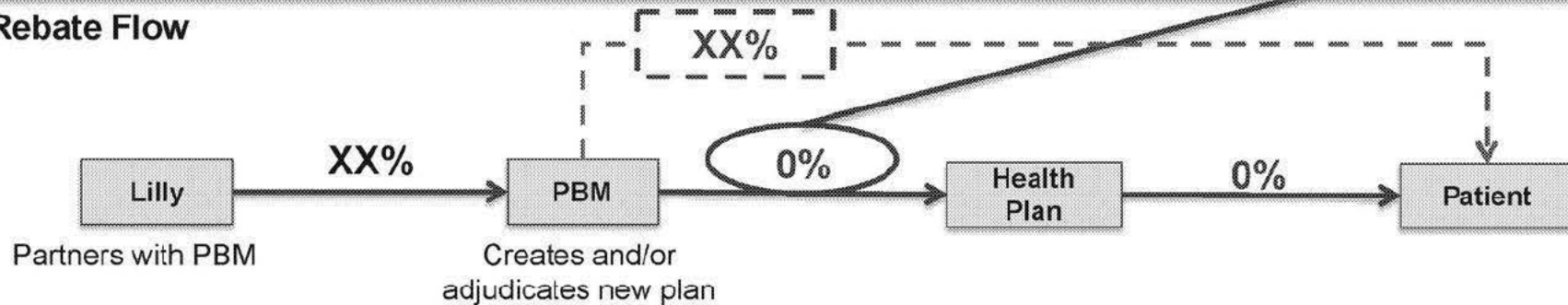
Objective: Provide patients with high out of pocket costs with savings at the point of sale within the current payment system.

Phase 1 Overview & Timeline

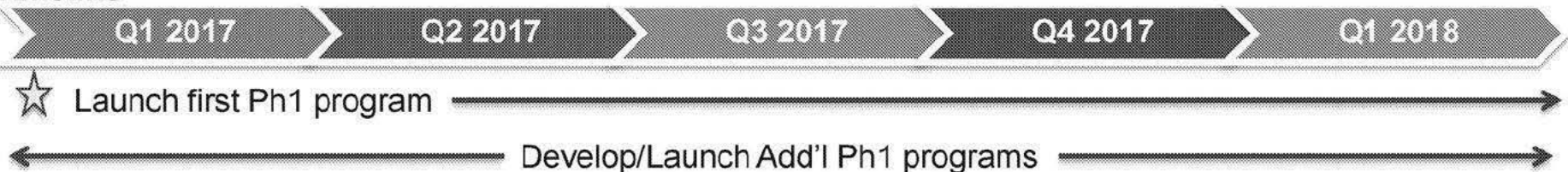
Patient Flow



Rebate Flow



Timeline



Blink Health

Blink Health provides a negotiated point of sale price reduction for patients via smartphone app or website

1. SEARCH

Find the Blink Price for your medication



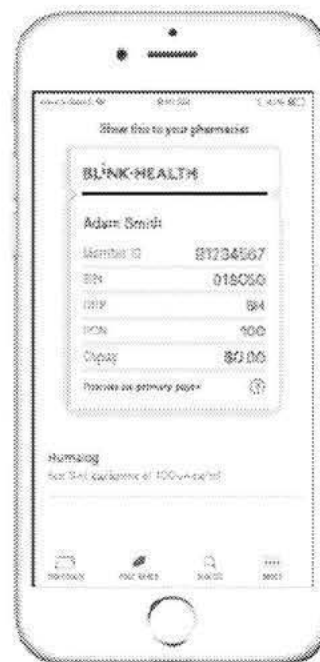
2. PAY

Pay online. Purchases are refundable



3. PICK UP

Show Blink to pharmacist and pay \$0 at pick up



Blink Health is accepted at over 67,000 pharmacies nationwide, including all major chains and most independent pharmacies.

11/17/2016

Walgreens

CVS/pharmacy

Walmart

Walmart

DUANEreade

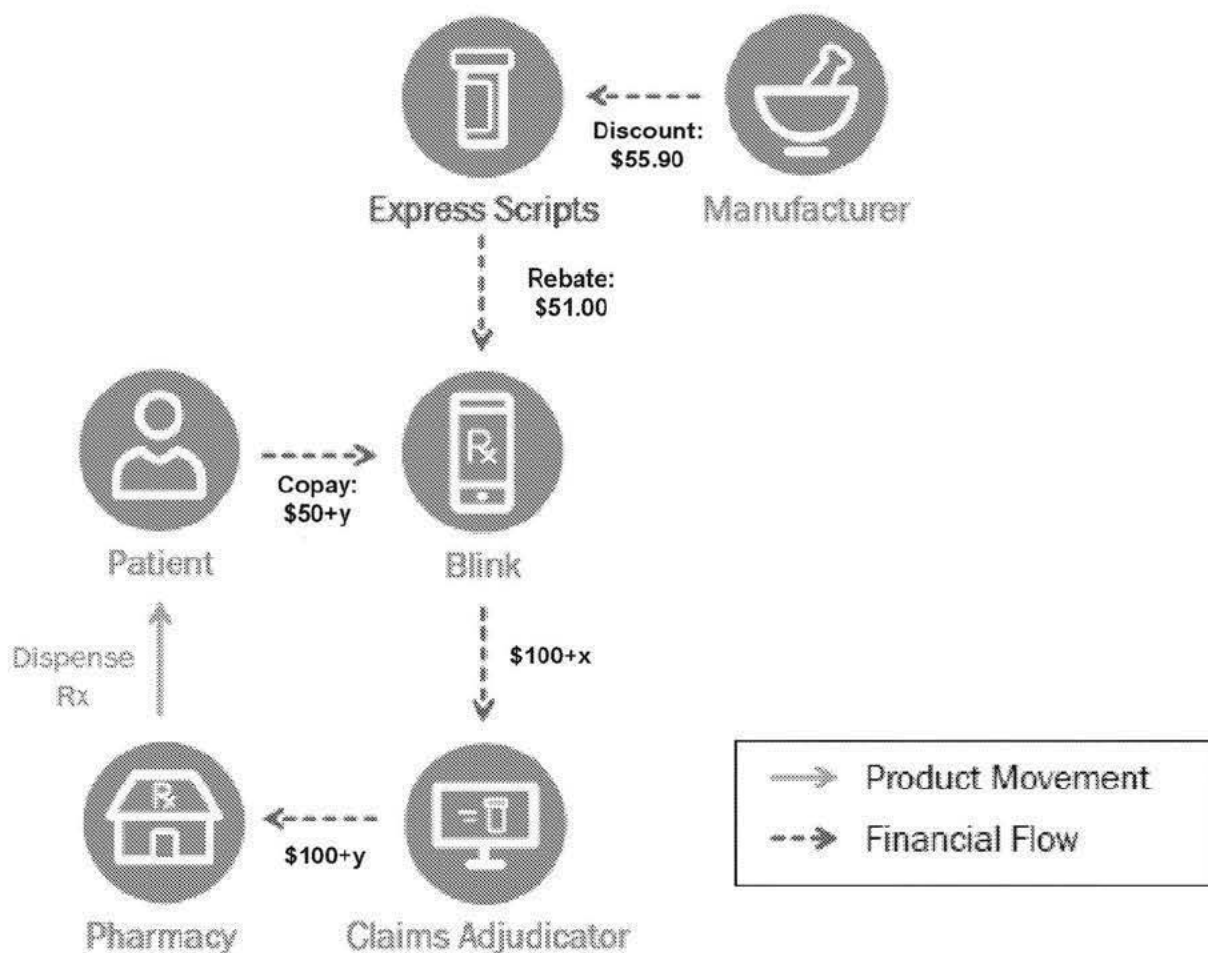
Target

Company Confidential ©2015 Eli Lilly and Company

4

Blink Health Background Logistics

Blink Health – Distribution Flow



11/17/2016

Company Confidential ©2015 Eli Lilly and Company

5

Blink Health Transaction

- Lilly transaction with ESI
 - Lilly and ESI will negotiate terms and conditions as a separate exhibit within the current ESI Rebate Agreement
 - A significant portion of the rebate (proposed at 98%) will be passed through to the patient via a third party administrator, in this case Blink Health
 - The patient will see this pass through in the transaction price in the Blink Health application
 - The portion of the rebate that is not passed through to the patient (proposed at 2%) and an administrative fee (proposed at 4.875%) will potentially be shared by ESI and Blink Health through their contractual relationship
- Patient, pharmacy, and reimbursement transaction
 - Patient pays for product through the Blink application (WAC grossed up for pharmacy markup less pass through rebate)
 - Patient shows their receipt from the Blink application and their Rx at the pharmacy
 - Pharmacy processes the Rx with a \$0 copay (patient has already paid Blink Health in the application) and dispenses the product
 - Claims adjudicator reimburses the pharmacy and Blink Health reimburses the claims adjudicator based on their contractual relationships
 - ESI receives Rx data from the claims adjudicator and submits to Lilly for rebate and administrative fee payment per the terms and conditions of the contract between ESI and Lilly

Legal Assessment

- **Privileged - AC**

Requested Approval

- As a condition of rebate, 98% of the rebate provided must directly benefit the patient via Blink Health
 - The objective is to provide a 50% discount to WAC directly to patients for Humalog/Humulin and a 40% discount to WAC directly to patients for Basaglar. The rates below reflect the rate necessary to achieve this objective with the 98% pass-thru.
- Provide a rebate of 51% of WAC to patients via Blink (via ESI) for the following products:
 - Humalog U-100 (pens & 10mL vials)
 - Humalog U-200 KwikPen
 - Humalog Mixes (pens & 10mL vials)
 - Humulin N, R & 70/30 (pens & 10mL vials)
- Provide a rebate of 40.9% of WAC to patients via Blink (via ESI) for the following products:
 - Basaglar
- Provide a 4.875% admin fee to ESI to administer the program on behalf of Blink Health.

Timeline and Communication Plan

Nov 15

DBU Sales Director Call – Broad Solution Announcement

Nov 16

DBU DSM Call – Broad Solution Announcement

DBU Sales Force Call – Broad Solution Announcement

MHS Market Manager Communication: Broad Solution Announcement

TLAC Communication and Training

Nov 17

Basaglar Price Announcement

Dec 6

Solution Announcement and Press Release

Diabetes Blogger Call – Detailed Solution Announcement

DBU Sales Force Video – Detailed Solution Announcement

MHS Communication – Detailed Solution Announcement

Jan 1/Jan 2

Solution Launch

FRAP Approval (2017)

| | Gross-to-Net Reduction |
|--------------------------------------|------------------------|
| Humalog Vial | \$ 42.5 M |
| Humalog Pen | \$ 47.0 M |
| Humulin Vial | \$ 25.8 M |
| Humulin Pen | \$ 5.2 M |
| Basaglar | \$ 6.5 M |
| <i>Basaglar Medicaid Best Price*</i> | <i>\$ 15.5 M</i> |
| Total | \$ 140.5 M |

*Medicaid Best Price impact assumes the total differential between 45.775% and 23.1% is burdened on this contract. Once verbally agreed upon contracts are signed, the Best Price impact is estimated at \$3.5 M

| | |
|------------------------------|------------|
| Benefit Provided to Patients | \$ 112.6 M |
| Cost to ESI | \$ 12.1 M |
| Cost to Blink Health | \$ 2.3 M |

Phase 1 – Marketing

Launched Jan 1*

- Patient:
 - Pharmacy bag tags
 - Humalog websites
 - Patient email to U200 Customer List
 - Blogger/Diabetes online community dissemination
- Physician:
 - DBU Leadership letter
 - DM, Email
- Pharmacy:
 - PharmAlert email to pharmacists
 - Pharm DM

Q1 2017 Build and launch Q2

Project Advocate Campaign

- Messaging/Tactics/ Market Research

DTC

- Microsite / Banner Ads / Paid Search
- Journal Ad in Diab Publications
- Point of Care Video
- Wall boards for MD office

Physician

- EMR

Tactics Q1 (w/ DTC) – 800K

Execution – 1.4M

DTC (Media) – 4M

Total 6.2M

*2016 Tactic development covered in current scope \$

Message

From: conterno_enrique [REDACTED]
on behalf of Enrique A Conterno [REDACTED]
Sent: 1/20/2017 8:35:26 AM
To: Terrence M Lyons [REDACTED]
Subject: RE: Reply: Urgent Request Today PRASC and FRAP approval for Cigna Part D - Basaglar and Revised Humulin/Humalog Offers - Please respond by Noon, Friday - January 20 th

Well said.

From: Terrence M Lyons
Sent: Friday, January 20, 2017 7:36 AM
To: Theresa Skowron Dunn; Michael B Mason; Frank D Cunningham
Cc: Lisa J Heid; John Joseph Peters; W Patrick Bruen; Dina Belinsky; Alonzo Weems; Wilbur Van Tryon; William F. Riesner; Eduardo A Garcia
Subject: Reply: Urgent Request Today PRASC and FRAP approval for Cigna Part D - Basaglar and Revised Humulin/Humalog Offers - Please respond by Noon, Friday - January 20 th

I approve the Cigna Part D offer for Basaglar as stated below, including the incremental 1% contingent bundle for Humalog as a *walk-away position only*. I echo Mike's concerns that this deal structure continues to erode limited profitability on our core insulins franchise, and would prefer this offer be initially extended without the Humalog bundle unless this becomes absolutely necessary.

From a fiduciary perspective, we also need to do a better job in anticipating these offers, and convening PRASC to discuss. This offer represents yet another example of mgmt reviews being aborted due to time constraints and a process in which all of the deal time is dedicated to account interaction and business case analytics, at the expense of governance review (again no DRB review nor interactive PRASC discussion). It is not acceptable to continue request quarter-billion dollar commitments on complex bundled transactions via virtual means with a six hour lead time. As an advance warning, I do not expect to continue to provide my FRAP approval in the absence of a business review in the future.

TML

Terrence M. Lyons
Vice President Finance | CFO Global Manufacturing & Quality and Lilly Diabetes
[REDACTED]

From: Theresa Skowron Dunn
Sent: Friday, January 20, 2017 5:37 AM
To: Michael B Mason; Terrence M Lyons; Frank D Cunningham
Cc: Lisa J Heid; John Joseph Peters; W Patrick Bruen; Dina Belinsky; Alonzo Weems; Wilbur Van Tryon; William F. Riesner; Eduardo A Garcia
Subject: Urgent Request Today PRASC and FRAP approval for Cigna Part D - Basaglar and Revised Humulin/Humalog Offers - Please respond by Noon, Friday - January 20 th

PRASC,
Please reply with your position by Noon today.

Thanks,
Theresa

Sent from my iPad

Begin forwarded message:

From: "Lisa J Heid" [REDACTED]
To: "W Patrick Bruen" [REDACTED] "Theresa Skowron Dunn" [REDACTED]
Cc: "Wilbur Van Tryon" [REDACTED] "Corey L White" [REDACTED], "John Joseph Peters" [REDACTED] "Edwardo A Garcia" [REDACTED]
"William F. Riesner" [REDACTED]

Subject: Urgent Request PRASC and FRAP approval for Cigna Part D - Basaglar and Revised Humulin/Humalog Offers - Please respond by Noon, Friday - January 20 th

Pat,

Please circulate to appropriate PRASC members. Sorry for the tight timeline but Brand and Account Manager have meeting with CIGNA at 2pm on Friday.

Key elements of the deal:

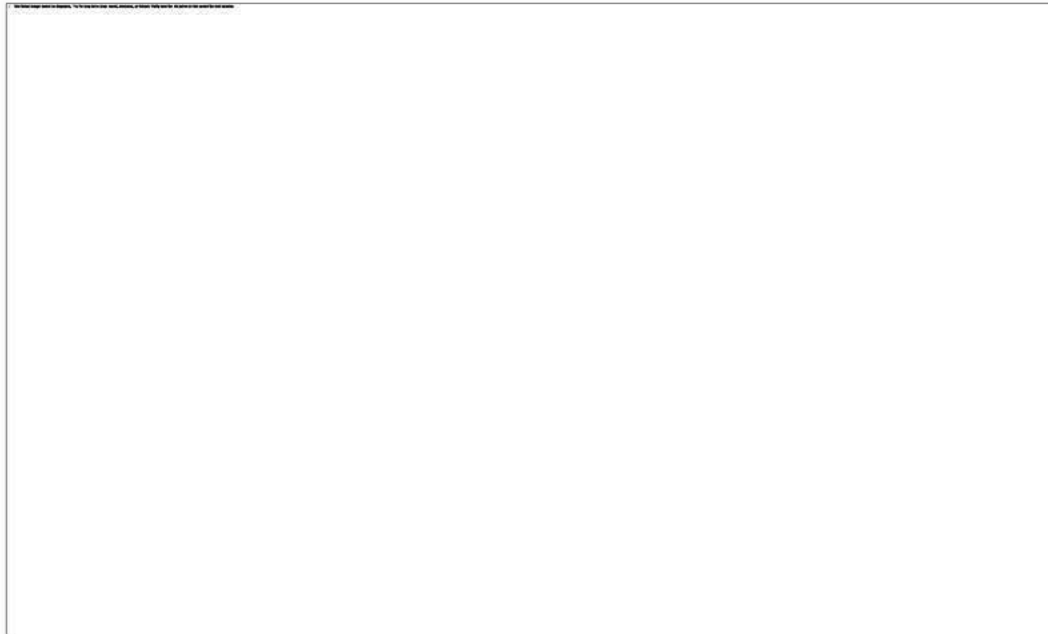
Humulin and Humalog – Cigna is exploring moving Lin and Log to generic tier for MAPD lives. We are requesting an incremental 1% rebate (total of 68% rebate) in the MAPD book of business. As a walk away Brand is requesting the 68% rebate for Generic tier or LBC. Incremental gross sales for Humalog are \$15.2 mil and incremental rebates are \$12.7 Mil over previously approved rate for the life of the deal. Incremental gross sales for Humulin are \$2.7 Mil and incremental rebates are \$1.4 mil over previously approved rates for the life of the deal. This includes 6% LPP with an anchor date of 12/31/16 as Cigna is in the first year of their 3 year Insulin deal.

Basaglar – Brand is requesting 2 offers for Basaglar as well as a contingent bundle with Humalog. This is a two year deal term (1/1/18 through 12/31/19).

Option 1 – Basaglar – 1 of 2 manufacturers, exclusive Insulin Glargine – 58% rebate with 6% LPP, 12/31/17 anchor date.

Option 2 – Basaglar – 1 of 3 manufacturers, exclusive u-100 Glargine – 55% rebate with 6 % LPP, 12/31/17 anchor date.

Contingent bundle with a 1% incremental rebate for Humalog to gain access for Basaglar. This would be applied to either Option 1 or 2 above. This contingency represents an additional \$5.6 mil in rebates. The deal margins shown below do not include the incremental Humalog contingent rebates. The adjusted deal margins would be \$38.5mil for 1 of 2 manufacturer status and \$32.7 Mil for 1 of 3 manufacturer status for the deal period. The business cases for Basaglar are shown below:



The PRASC pre-read is attached for additional details. Sorry for the extremely tight timeline on this offer.

Mike and Terry - the total FRAP commitment for this offer is \$237.8 mil- \$101.9 Mil (Base rebate + contingent rebate for Basaglar), \$11.3 Mil (Humulin) and \$124.6 Mil (Humalog).

Please respond to this email with your approval. If you have questions feel free to contact me.

Lisa Heid
Director, Contract Management and Analytics
Managed Healthcare Services
Lilly USA, LLC



Message

From: conterno_enrique [REDACTED]
on behalf of Enrique A Conterno [REDACTED]
Sent: 3/10/2017 2:36:15 PM
To: Michael B Masor [REDACTED]
Subject: RE: LillyUSA Townhall

Thank you, Mike.

-----Original Message-----

From: Michael B Mason
Sent: Friday, March 10, 2017 2:28 PM
To: Enrique A Conterno
Subject: Re: LillyUSA Townhall

Enrique:

We had productive discussion with all major payers. We continue to receive encouraging signs from CVS Part D with Basaglar which they want us to keep very confidential within and outside Lilly for very good reasons. Basaglar in United Part D is less encouraging. Our only chance is in their basic formularies. They have requested a 1 of 1 rate. All other product discussions were uneventful.

ESI indicated that they will be excluding more products from formularies during their 2018 - 19 bidding cycle. They have been trying to position themselves as having competitive rates with more options than other PBMs, but they have been getting negative feedback from clients. Clients equate more restrictions to lower perceived net cost. They highlighted basal insulin, SGLT-2 and potentially DPP-IV classes as top candidates for more exclusions.

We had a long chat with Everett that I need to update you on next time we are together.

Take care,

Mike

Sent from my iPad

> On Mar 8, 2017, at 7:14 PM, Enrique A Conterno [REDACTED] wrote:

>

> I completely understand. How are the discussions going?

>

> Enrique

>

> -----Original Message-----

> **From:** Michael B Mason

> **Sent:** Wednesday, March 08, 2017 6:44 PM

> **To:** Enrique A Conterno

> **Subject:** LillyUSA Townhall

>

> Enrique:

>

> I won't be able to attend Friday's LillyUSA town hall. I am at PMCA meeting with our most important payer customers. I hope it goes well.

>

> Take care,

>

> Mike

>

> Sent from my iPad

Message

From: Michael B Mason [REDACTED]
Sent: 6/2/2017 10:40:34 AM
To: David A Ricks [REDACTED]; Anat Ashkenazi [REDACTED]; Enrique A Conterno [REDACTED]; Frank D Cunningham [REDACTED]
CC: Susan J Kurkowski [REDACTED]
Subject: RE: Ag Humalog..other insulins

Dave:

We have been evaluating this same idea. While it definitely has cons, it's the best way to effectively lower your list price within the current system. We will schedule time to discuss in the coming weeks.

All the best,

Mike

From: David A Ricks
Sent: Friday, June 02, 2017 10:13 AM
To: Michael B Mason [REDACTED]; Anat Ashkenazi <[REDACTED]>; Enrique A Conterno [REDACTED]; Frank D Cunningham [REDACTED]
Cc: Susan J Kurkowski [REDACTED]
Subject: Ag Humalog..other insulins

Mike,

During SP your group presented a series of options re: biosimilar Humalog. One of these was the idea of launching our own AG to compete in a low list price/no or low rebate strategy market.

Over the last 3 months I have had numerous interactions with policy makers across the country and some of the sharpest and well-read among these often end the discussion we have on high out of pocket costs by asking "Why don't you just launch your products cheaper and do less rebating?" Of course it's not that simple and there are many reasons we don't do this but I keep coming back to the idea you shared and wonder why we just don't set ourselves on that course and launch an alternative pricing form of our Insulins, perhaps beyond Humalog rapid.

I would like your team to work up the economic and operational case for this, what it would take, when we can do it, how broad we should do it and the economic impacts. I would like to review this in the coming weeks, ideally prior to the board meeting. I recognize that is tight but we can operate 80/20 on the assumptions and have a discussion then about advancing this idea or not and at what pace. Please work with Sue in my office to schedule a meeting/call to review your initial assessment. Thanks.

David A. Ricks
Chairman, President, and Chief Executive Officer
Eli Lilly and Company
Lilly Corporate Center, Indianapolis, IN 46285 U.S.A.
[REDACTED]



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Message

From: Terrence M Lyons [REDACTED]
Sent: 6/14/2018 2:56:33 PM
To: Enrique A Conterno [REDACTED]
CC: Frank D Cunningham [REDACTED]; Michael B Mason [REDACTED]; Joshua L Smiley [REDACTED]
Subject: Reply: Tomorrow

Enrique:

I anticipate that the PBMs may raise the following objections and/or considerations in connection with a contemplated list price reset:

- (1) Reduction in the absolute amount of Admin Fees earned upon insulin claims/utilization (since this is expressed as a percentage) while still performing comparable/identical services governed by the Admin Fee;
- (2) Reduction in absolute rebate amounts pressuring the PBMs ability to satisfy contractually obligated rebate guarantees with some clients (employers and insurance plans) in the near/intermediate term;
- (3) Inability to modify/resubmit premiums and associated formularies for Part D plans for the 2018 (and perhaps 2019) plan year(s), or risk that such adjustments may impair market competitiveness (i.e rebate levels on lower gross price levels translating to higher plan premiums).

TML

Terrence M. Lyons
Vice President Finance | CFO Lilly Diabetes
[REDACTED]

-----Original Message-----

From: Enrique A Conterno
Sent: Thursday, June 14, 2018 2:09 PM
To: Frank D Cunningham [REDACTED]; Michael B Mason [REDACTED]
Terrence M Lyons [REDACTED]; Joshua L Smiley [REDACTED]
Subject: Tomorrow

Gentlemen,

We have discussed some of the objections we'll encounter tomorrow -based on our proposal, what do you believe are the top 1-2 objections/requests that we will hear?

Best Regards,

Enrique

Sent from my iPhone

Message

From: Michael B Mason [REDACTED]
Sent: 6/23/2018 12:05:46 PM
To: Enrique A Conterno [REDACTED]
CC: Frank D Cunningham [REDACTED]
Subject: Re: Discussion with John Prince

Enrique,

Thanks for the update and idea. I assumed from the start that we wouldn't be able to lower our list price without impacting our net price.

If you look at our Humalog financials with ESI over the next six quarters our commercial deal margin is \$724M with Part D at \$133M. A 10% net price concession would net ESI and their partners \$86M. Given their concerns about losing \$500M (\$250M from Lilly Insulin) with their downstream customers, I don't think the math would work for them and their downstream customers.

I think we would be better off launching project quilt, working with the PBMs on additional solutions, renegotiating our contracts for 2020 to net price and then taking a price decrease in early 2020. This would allow us to be net price neutral with less impact on the system.

We are working on solutions to a few of the blueprint actions that we can discuss.

Take care,

Mike

Sent from my iPhone

> On Jun 22, 2018, at 3:35 PM, Enrique A Conterno [REDACTED] wrote:
>
> I had a productive discussion today with John Prince. He was complementary of the leadership role Lilly is taking to address the insulin situation, and the excellent collaboration between our organizations.
>
> He re-stated that they would be fully supportive of Lilly pursuing a lower list price option -and understand the challenge for Lilly of not having critical mass to do so right now. He also shared some of the challenges, they would encounter - in particular, the difficulty of persuading many of their customers to update contracts without offering a lower net cost to them. I'll come back to this.
>
> In the meantime, he'd like to work with us to pursue a differentiated solution for patients, e.g. point of sale or other. They have created a team to work on this. I also shared that we could be making an announcement sometime next week to enhance our patient assistance solutions/programs -he offered their capabilities/call center and other to help.
>
> Back to a lower list price. I wonder if we would have more leverage if we framed the discussion as- a 40% list price reduction and 10% net price reduction, instead of 50% list reduction and same net. It would be difficult for them not to take this to their clients. Clearly, more costly to us -but much more compelling.
>
> Best Regards,
>
> Enrique
>
> Sent from my iPhone

Message

From: holtsclaw_stephen_ [REDACTED]
on behalf of Stephen M Holtsclaw [REDACTED]
Sent: 11/8/2016 12:01:12 PM
To: Tammy L Campbell [REDACTED]
CC: Anat Ashkenazi [REDACTED] Enrique A Conterno [REDACTED] Hormaz M Dubash [REDACTED] James Joseph Haney [REDACTED] Chad Hobson [REDACTED] Terrence M Lyons [REDACTED]
Subject: Lilly Diabetes Business Plan EC pre-reads
Attachments: LD 2017-2018 BP Executive Committee Executive Summary-Final.pdf; Lilly Diabetes 2017-2018 BP - Executive Committee-Final.pdf

Hi Tammy,

Please see attached with the Lilly Diabetes Business Plan EC pre-reads. Let me know if you'd instead prefer Word/Pointpoint versions.

Thanks,
Steve

Steve Holtsclaw
Consultant, Lilly Diabetes Finance
Eli Lilly and Company
[REDACTED]

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Executive Committee Executive Summary
2017-2018 Lilly Diabetes Business Plan Review
November 2016

Executive summary

Lilly Diabetes (LD) is achieving its strategic intent of meeting the diverse needs of people with diabetes by offering a wide range of innovative therapies enabled by best-in-class delivery devices with the aim to improve individual outcomes. In doing so, we are progressing towards becoming the leading diabetes company in the US, Europe/Canada, and Japan. The 2017 Plan reaffirms our commitment to delivering top-tier financial performance in the 2017-2018 period and sets the foundation for continued growth in the mid- and long-term with increasing relevance across all diabetes classes.

2017-2018 represents a continuation of the LD strategy

The 2017 LD Business Plan submission represents an on-BAC target submission while delivering \$1.3B revenue growth and \$1.0B BAC growth with significantly expanding profitability margins. The 2017 Plan also reflects continued progress since Strategic Plan with revenue and BAC increasing by \$0.4B and \$0.1B respectively over that plan. The quality of the LD Income Statement continues to improve as launch products grow significantly and investments are increasingly focused on growth engines. Given its tremendous launch success in each region, 2017 LD growth is substantially driven by Trulicity with significant growth offsetting downward pressure on Jardiance and Humalog. 2017 Trulicity is again forecasted to be the largest growth driver for Lilly in 2017.

A few key themes have materialized since the 2016 SP submission. First, the results of the investments in Trulicity have exceeded our expectations, resulting in a \$0.6B revenue increase versus Strategic Plan for 2017. This upside is offsetting the downside from Jardiance, primarily driven by slower U.S. market growth due in part to a 6-month delay to the FDA action date, and insulin pricing. At this time we remain cautiously optimistic on Jardiance and believe that a positive decision on a U.S. label and indication will not only provide an inflection point for Jardiance, but also serve as a catalyst to the overall SGLT-2 market. And lastly, at 29% through Sept YTD, Lilly Diabetes 2016 volume growth has remained strong across products, partially offsetting an 8% YTD price decline (normalized for prior period G2N adjustments) that highlights increasing G2N rate pressure.

The 2017 BP represents an aggressive goal of growing BAC 44% to \$3.1B and expanding margins by nearly 7ppt (prior to recently approved PSC funding). Every region is significantly growing its profitability with 2017 BAC increasing by 29% in the U.S., 25% in EUCAN, and 39% in Japan. Also, each region is expanding margins with 2017 BAC as a percent of revenue increasing to 68% in the U.S. (up 2ppt from 2016), 43% in EUCAN (up 2ppt from 2016), and 33% in Japan (up 6ppt from 2016). The achievement of this plan requires all four areas of risk/uncertainty described later in this document (Trulicity supply, Pricing, G2N, and Jardiance label) to materialize as expected with no significant downsides.

| | 2016 (Perf) | vs. PY Perf % | 2017 | vs. Target Perf | vs. PY Perf % | 2018 | vs. Target Perf | vs. PY Perf % |
|------------------|-------------|------------------|-------|--------------------|------------------|-------|--------------------|------------------|
| Revenue | 5,271 | 20% | 6,584 | 150 | 25% | 7,415 | 61 | 13% |
| Gross Margin | 4,254 | 25% | 5,281 | 121 | 23% | 5,894 | 47 | 12% |
| % of Revenue | 81% | 3.7 ppt | 80% | 0.0 ppt | (0.5) ppt | 79% | (0.0) ppt | (0.7) ppt |
| SG&A | 1,425 | 12% | 1,584 | 110 | 11% | 1,610 | 67 | 2% |
| % of Revenue | 27% | (2.2) ppt | 24% | 1.1 ppt | (3.0) ppt | 22% | 0.7 ppt | (2.3) ppt |
| R&D | 655 | 2% | 542 | 10 | -18% | 522 | 23 | -4% |
| % of Revenue | 12% | (2.3) ppt | 8% | (0.0) ppt | (4.2) ppt | 7% | 0.3 ppt | (1.2) ppt |
| OPEX | 2,080 | 8% | 2,126 | 119 | 2% | 2,132 | 91 | 0% |
| % of Revenue | 39% | (4.5) ppt | 32% | 1.1 ppt | (7.2) ppt | 29% | 1.0 ppt | (3.5) ppt |
| Operating Income | 2,174 | 47% | 3,154 | 1 | 43% | 3,762 | (43) | 0% |
| OID | (6) | -110% | (5) | (1) | -7% | (5) | (1) | 0% |
| BAC | 2,169 | 41% | 3,149 | 0 | 44% | 3,757 | (44) | 19% |
| % of Revenue | 41% | 6.8 ppt | 48% | (1.1) ppt | 6.7 ppt | 51% | (1.0) ppt | 2.8 ppt |

Executive Committee Executive Summary

2017-2018 Lilly Diabetes Business Plan Review

November 2016

The Plan remains aligned with 2020 priorities:

The LD 2017-2018 Plan represents a continuation of the four pillars created with the 2015 Business Plan to guide our journey towards 2020: 1) leverage opportunities and protect the core insulin franchise; 2) accelerate growth of our new products within a narrow window of opportunity; 3) leverage infrastructure and improve manufacturing cost competitiveness; and 4) deliver a steady stream of innovation in our areas of focus. The Humalog and Humulin franchises remain the foundation to our range of therapies with the core insulins expected to deliver \$3.3B in revenue in 2017 (\$4B worldwide), a 1% decline versus 2016. Trulicity has been a key catalyst of the GLP-1 class with U.S. SOM growth driven by investments in DTC, sales force reach, and improved access. By aiming for 3 million TRx in the U.S. in 2017, Trulicity will seek to achieve in year three what it took current GLP-1 class leader, Victoza, five years to accomplish. DTC advertising is included in the base plan in 2017 with heavier investments in the first half of the year to achieve the full-year target and establish stronger positioning ahead of the expected launch of Novo's once-weekly GLP-1, semaglutide, in early 2018. The global Trulicity forecast of nearly \$1.9B requires flawless execution from commercial and manufacturing and importantly, assumes another year of nearly 30% U.S. market growth.

Near-term investments and profitability are focused on new products and highest corporate priorities.

| Priorities | A | B | C |
|------------|---|--|--|
| Product | <ul style="list-style-type: none"> Trulicity Jardiance Humalog <p>Revenue: \$4.4bn SG&A: \$1.0bn % of Revenue: 24%</p> | <ul style="list-style-type: none"> Basaglar <p>Revenue: \$350m SG&A: \$200m % of Revenue: 56%</p> | <ul style="list-style-type: none"> Humulin Trajenta <p>Revenue: \$1.9bn SG&A: \$330m % of Revenue: 18%</p> |

2017-2018 represents a key window of opportunity before competitor entrants:

Significant new product introduction from traditional competitors (Novo, Sanofi, Merck, etc.) and disruption in the connected care space from new competitors will cause the diabetes competitive landscape to look very different by Dec. 2018. Plan assumes the U.S. launch of follow-on/biosimilar competitors: Sanofi's lispro (1Q18), Mylan/Biocon glargine (1H19), and Merck/Samsung glargine (2H19) with Mylan/Biocon and Merck/Samsung assuming application of Hatch-Waxman 30-month stay. Novo's once-weekly GLP-1 semaglutide is expected to launch in early 2018. Novo's FIAsp (ultra-rapid insulin) could launch as early as 1Q18 after a recent delay from the Complete Response Letter. The SGLT-2 class could see considerable change with Merck/Pfizer aiming to join the class in 4Q17 (ertugliflozin) and Sanofi/Lexicon (sotagliflozin) as early as 2018. In addition, Invokana's Cardiovascular Outcomes Trial, CANVAS, is expected to read out in the first half of 2017. While Plan reflects limited impact from these potential competitive launches and events, these potential launches underscore the narrow window of opportunity to significantly improve our competitive position with key brands.

Evolving partnerships and new products in the connected care space will continue to disrupt the traditional diabetes business. In Sept. 2016, Sanofi and Verily (Google) announced a \$500M joint venture aiming to combine devices, software, medicine, and care into a comprehensive diabetes platform. In addition, Medtronic's hybrid closed loop 670G secured FDA approval in Sept., three months after its submission, and will launch in spring 2017. Lastly, Novo and Medtronic continue to expand their respective collaborations with IBM Watson.

Favorable outcomes are assumed in four key areas:

We assume reasonably favorable outcomes in these four key areas 1) pricing pressures, 2) G2N volatility, 3) flawless execution on Trulicity and 4) Jardiance label outcome and uptake.

- 1) Pricing – The Plan assumes realization of nominal list price increases, including for insulins. No material downside has been incorporated into the base plan beyond the known increases in contracted rebates and discounts across key Commercial and Part D payers.

2 of 3

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This document is forward-looking and, therefore, contains predictions and assumptions. Any discussion of currently unapproved products or uses is for planning purposes only. Lilly does not sell products prior to regulatory approval or promote products off-label.

Executive Committee Executive Summary
2017-2018 Lilly Diabetes Business Plan Review
November 2016

- 2) US G2N – Given the high level of rebates in diabetes, and especially in the insulin space, the 2017 U.S. G2N liability for diabetes is estimated at nearly \$9.2B (on US gross sales of \$14B). The Plan incorporates the most contemporary G2N assumption set (including the most current rebate, discount, market share, and segment projections across key Commercial and Part D payers) to estimate this liability, yet even a small percent variance to Plan could result in a material adjustment to reported net sales. The percent contracted and segment mix are assumed to materialize as forecasted as every 1 percent G2N deviation impacts net sales by \$100M.
- 3) Trulicity – Trulicity remains the largest growth driver for the company. [REDACTED]
[REDACTED] In addition, the U.S. Plan assumes the competitive GLP-1 franchises continue to invest to grow the class but simultaneously lose share. Notably, Plan assumes a year of nearly 30% U.S. market growth.
- 4) Jardiance – Our Jardiance forecast assumes we will receive a positive US label outcome this December and assumes an inflection point in revenue uptake. We expect strong SGLT-2 market trends to continue in Japan, Canada, and most European markets.

Given that we are assuming reasonably favorable outcomes on these four key dynamics, limited upside exists.

Key milestones and actions we are taking to mitigate risks:

Two key milestones in late 2016 could have significant bearing on 2017-2018: the Jardiance FDA action date (Dec. 4) and a potential Trulicity REWIND interim readout (DMC review on Dec. 12). On Jardiance, a favorable label outcome in the U.S. is assumed in our submission, and we would reevaluate investment levels in coordination with Boehringer Ingelheim if a different regulatory outcome were to materialize. Additional Jardiance DTC (TV) investment is captured as a triggered buy-up in a positive label scenario and if supported by favorable BASES research in early 2017. While a positive interim read-out for REWIND would represent a significantly positive development for Trulicity, [REDACTED]

[REDACTED] Given the efficiency experienced since the TV launch in late 2015, US Trulicity investment is focused first on TV with \$140M planned in 2017.

Accelerate and strengthen our next wave of innovation:

Key base R&D investments include the Trulicity REWIND CVOT. Two positive CVOTs with GLP-1s have already been demonstrated through LEADER (Novo's Victoza) and SUSTAIN-6 (Novo's semaglutide). The projected FPV for our Jardiance Heart Failure trial is 1Q17. Investments in [REDACTED] support a US submission between 4Q17 and 2Q18. URI Phase 3 Enabling and Open Loop Connected Care investments have been recently approved and represent critical elements to the long-term advancement of the core insulin strategy.

Summary

The Lilly Diabetes 2017 Plan submission represents 44% BAC growth accelerating from a larger 2016 base. In fact, BAC more than doubles from 2015 to \$3.1B. While the core insulin franchises continue to establish the \$3.3B revenue foundation, Trulicity is the keystone of the Plan submission with revenue doubling to \$1.8B. In addition, Plan assumes Jardiance gains a positive label that creates an inflection point for the product. And finally, investments are focused on new products and the highest corporate priorities. The organization is highly capable and fully engaged to effectively compete in a complex, competitive, and dynamic environment. The Plan represents aggressive growth over 2016, a year that is projected to deliver industry-leading revenue growth.

Pre read authors: Anat Ashkenazi, Terrence Lyons, Jim Haney, and Steve Holtsclaw
Executive sponsor: Enrique Conterno

Executive Committee 2017-2018 Business Plan Review

Lilly Diabetes

November 14th-15th, 2016

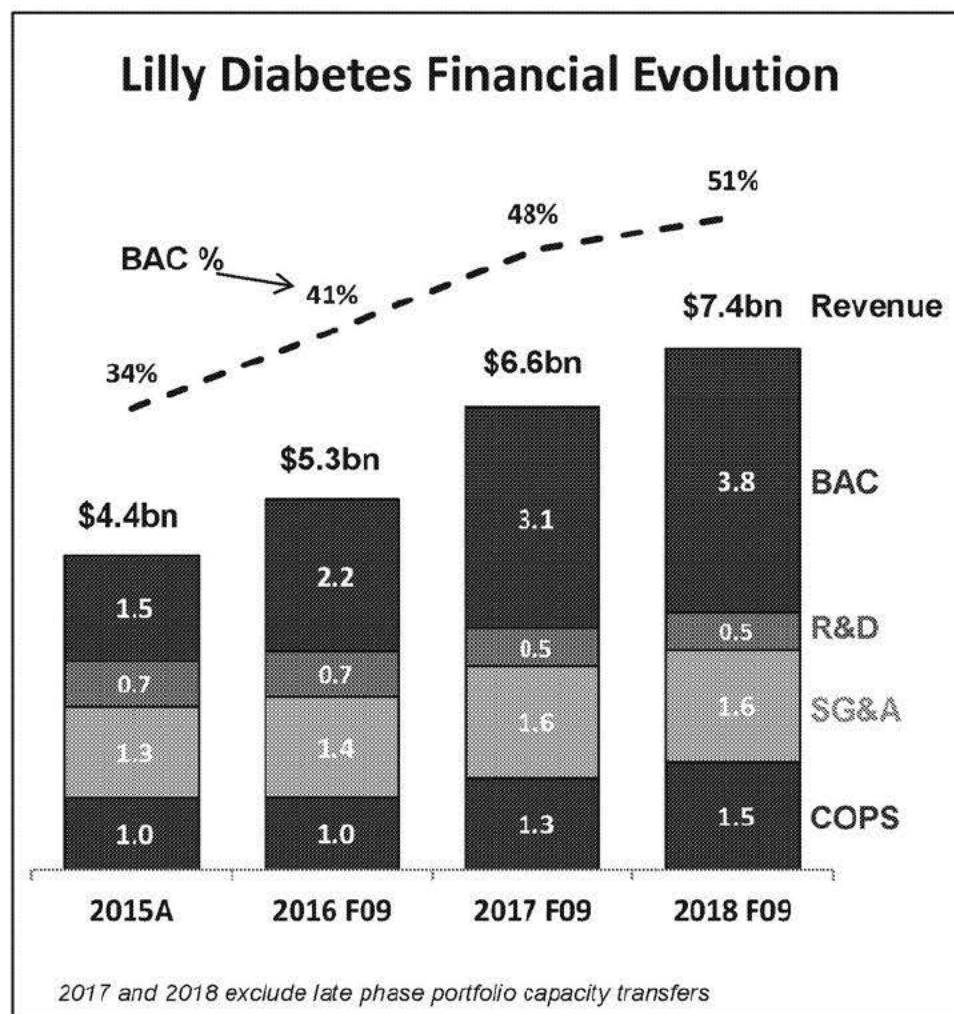
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2017 Lilly Diabetes Plan Executive Summary

1. Significant year over year growth reflected in the 2017 LD Plan submission... **+25% revenue growth** and +44% BAC growth in 2017
2. **Trulicity remains Lilly's largest growth driver** and one of the largest products globally at nearly \$1.9B... 2017 Plan assumes 100% of supply capacity is utilized with no supply disruption
3. **Insulin franchises** remain the foundation to our wide-range of therapy offerings with **\$3.3B in revenue**
4. **Jardiance Plan assumes a positive US label outcome** in December and a subsequent inflection in revenue uptake... 2017 Plan assumes US market growth of 25% coupled with 30% share of market
5. 2017 Plan reflects an **investment prioritization towards sustainable growth engines** while harvesting resources from established brands

2017 Lilly Diabetes Plan is a continuation of our market leadership journey and delivers significant revenue and BAC growth



Plan delivers \$1.3bn of revenue growth and \$1.0bn of BAC growth while expanding profitability margins

- Trulicity becomes Lilly's largest single growth driver with expected revenue growth of nearly \$1B
- Insulin remains Lilly's key franchise projected to generate \$3.3bn in revenue

Aggressive risk profile embedded in the Plan submission

- Trulicity supply - flawless execution required to supply commercial demand
- G2N rates and pricing - % contracted and segment mix are assumed to materialize as forecasted
- Jardiance CV indication – favorable outcome assumed, investment aligned

2016 performance sets the stage for 2017

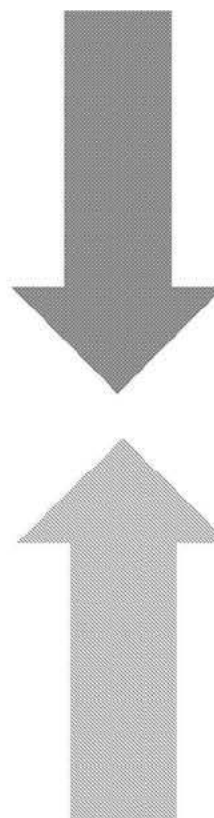
- Trulicity momentum - uptake curves above Victoza
- YOY volume growth across all Diabetes products
- US G2N continues to be source of volatility
- Cautiously optimistic on Jardiance - US indication opportunity balanced against SGLT2 safety profile

2017 Plan priorities are anchored on our consistent long-term strategic goals

2017 Plan Priorities

- ✓ **Leverage opportunities and protect core insulin franchise**
 - Continue to progress connected care and URI
 - Drive concentrated U200 and U500 growth
- ✓ **Accelerate growth of new products within narrow window of opportunity**
 - Position Trulicity investments to maximize growth
 - Capitalize on Jardiance EMPA-REG-OUTCOME
 - Optimize Basaglar investment to deliver an effective launch
- ✓ **Leverage infrastructure and improve cost competitiveness**
 - Deliver 3ppt SG&A improvement
 - Continue manufacturing cost competitiveness agenda while balancing Trulicity supply needs
- ✓ **Deliver steady stream of innovation in areas of focus**
 - Initiate empagliflozin heart failure trial
 - Advance Trulicity REWIND towards interim readout
 - Prepare [REDACTED] for submission between Q4 2017 – Q2 2018

Changes since SP



- ✓ Jardiance EMPA-REG OUTCOME expected launch moved out 6 months to Dec 2016
- ✓ Insulin G2N rate pressure
- ✓ US pricing public policy / media
- ✓ SGLT2 market growth, 31% YTD growth vs. a Plan of 53%
- ✓ Significant volume growth across all products
- ✓ Strong Trulicity uptake across all markets
- ✓ Additional US Trulicity DTC investment
- ✓ US Basaglar contracting wins

2017 Lilly Diabetes Plan Key Assumptions

| US | EUCAN | Japan |
|--|---|--|
| <ul style="list-style-type: none"> ▪ Market performance: GLP-1, mealtime analog and basal markets continue to grow at current growth rates while SGLT-2 market maintains healthy growth ▪ Brand performance: EMPA-REG label launched in early 2017 (pending FDA approval); Humalog share shifts materialize as forecasted (Aetna, Anthem, Humana); Humulin U500 patient-level trends evolve as planned ▪ Competitive landscape: LEADER takes share mainly from Bydureon and Tanzeum; biosimilar lispro does not launch until 2018; Novo is not able to pull through material CVS share (Levemir and Tresiba) prior to Basaglar launch ▪ Payer, Price and G2N: no additional coverage changes and rebate rates hold at forecasted levels; no material changes to key G2N assumptions (% contracted and segment mix) | <ul style="list-style-type: none"> ▪ Environmental: Maintain sufficient access to HCPs despite increased regulations; undefined and evolving biosimilar regulatory landscape – financial incentives for general practitioners to prescribe in France, therapy substitution in Canada, etc.; no uniform pricing and reimbursement structure resulting in parallel imports/exports ▪ Pricing: [REDACTED] France 8.5% decrease; [REDACTED] Italy volume discount (7%); [REDACTED] and Basaglar Canada public access contingent on pricing; UK value based pricing (PPRS) 5% decrease in 2017 ▪ Competitive landscape: biosimilar lispro launch in late 2017 (minimal impact assumed in 2017); 2 biosimilar glargine launches assumed in 2017; Novo FIAsp on the market in 2018 (1-2% Humalog share loss assumed) | <ul style="list-style-type: none"> ▪ Environmental: Diabetes remains a priority disease of the government (9.5M live with Diabetes, 15M with impaired glucose tolerance) ▪ Market performance: oral anti-diabetic (OAD) drugs dominate the market (85% SOM) led by DPP-4s; SGLT-2 and GLP-1 classes continue to accelerate; insulin usage (15% SOM) continues to be disrupted by OADs ▪ Pricing: Increasing government control on NHI price - regular biennial price revision held in 2016 and expected in 2018 ▪ Competitive landscape: Biocon/FUJIFILM biosimilar glargine on the market; biosimilar lispro launch in 2018 |

Lilly has a narrow window of opportunity for market-growth leadership with several best in class products

| | Lilly | novo nordisk | SANOFI | MERCK Be well | AstraZeneca | Johnson & Johnson |
|-----------------------|------------------------|----------------------------------|-----------------------------|---|----------------------|-----------------------------------|
| DPP-4 | Tradjenta | | | Januvia | onglyza | |
| SGLT-2, FDC | Glyxambi Jardiance | | Sotagliflozin (2018) | Ertugliflozin, Ertusita (2017) | forxiga | Invokana canagliflozin tablets |
| GLP-1, GLP-1 Mix | trulicity | VICTOZA liraglutide injection | Lyxumia | Byetta exenatide injection | | |
| | | Xultophy semaglutide | LixiLan (2017) | | Once-weekly BYDUREON | |
| Basal | basaglar | Levemir | LANTUS | Biosimilar glargine (2017) pending 30-month Hatch- Waxman stay | | |
| Concentrated Basal | | TRESIBA | Toujeo | | | |
| Rapid | Humalog | Novo Log | APIDRA | | | |
| | | FIAsp (2018) | Biosimilar lispro (2018) | | | |
| Concentrated Rapid | Humalog 200 KwikPen | | | | | |
| Human | Humulin | Novolin | Insuman | | | |
| Concentrated Human | Humulin R U-500 | | | | | |

Current class leader based on SOM (U.S. + Japan + EUCAN)

Potential entrant during 2017-2018 Plan horizon

★ Best-in-Class based on clinical data and user experience

Lilly Diabetes P&L shows significant growth (+25% revenue and +44% BAC) while profitability margins improve to 48% in 2017

| | 2016 (Perf) | vs. PY Perf % | 2017 | vs. Target Perf | vs. PY Perf % | 2018 | vs. Target Perf | vs. PY Perf % |
|------------------|-------------|---------------|-------|-----------------|---------------|-------|-----------------|---------------|
| Revenue | 5,271 | 20% | 6,584 | 150 | 25% | 7,415 | 61 | 13% |
| Gross Margin | 4,254 | 25% | 5,281 | 121 | 23% | 5,894 | 47 | 12% |
| % of Revenue | 81% | 3.7 ppt | 80% | 0.0 ppt | (0.5) ppt | 79% | (0.0) ppt | (0.7) ppt |
| SG&A | 1,425 | 12% | 1,584 | 110 | 11% | 1,610 | 67 | 2% |
| % of Revenue | 27% | (2.2) ppt | 24% | 1.1 ppt | (3.0) ppt | 22% | 0.7 ppt | (2.3) ppt |
| R&D | 655 | 2% | 542 | 10 | -18% | 522 | 23 | -4% |
| % of Revenue | 12% | (2.3) ppt | 8% | (0.0) ppt | (4.2) ppt | 7% | 0.3 ppt | (1.2) ppt |
| OPEX | 2,080 | 8% | 2,126 | 119 | 2% | 2,132 | 91 | 0% |
| % of Revenue | 39% | (4.5) ppt | 32% | 1.1 ppt | (7.2) ppt | 29% | 1.0 ppt | (3.5) ppt |
| Operating Income | 2,174 | 47% | 3,154 | 1 | 43% | 3,762 | (43) | 0% |
| OID | (6) | -110% | (5) | (1) | -7% | (5) | (1) | 0% |
| BAC | 2,169 | 41% | 3,149 | 0 | 44% | 3,757 | (44) | 19% |
| % of Revenue | 41% | 6.8 ppt | 48% | (1.1) ppt | 6.7 ppt | 51% | (1.0) ppt | 2.8 ppt |

- ✓ Lilly Diabetes revenue is forecasted to grow 25% in 2017 driven by **volume growth across all classes**
- ✓ **Profitability margins** continue to improve as the business grows... BAC moves to 48% of revenue in 2017, a **7ppt improvement versus 2016**
- ✓ **2017 SG&A to revenue** ratio of 24% reflects a year-over-year **improvement of 3ppt**

2017 Plan reflects an investment prioritization towards sustainable growth engines while harvesting resources from established brands

| Priorities | A | B | C |
|------------|---|--|--|
| Product | <ul style="list-style-type: none"> Trulicity Jardiance Humalog <p>Revenue: \$4.4bn SG&A: \$1.0bn % of Revenue: 24%</p> | <ul style="list-style-type: none"> Basaglar <p>Revenue: \$350m SG&A: \$200m % of Revenue: 58%</p> | <ul style="list-style-type: none"> Humulin Traienta <p>Revenue: \$1.8bn SG&A: \$330m % of Revenue: 18%</p> |
| Geography | <ul style="list-style-type: none"> US Japan <p>Revenue: \$5.2bn SG&A: \$1.2bn % of Revenue: 23%</p> | <ul style="list-style-type: none"> EUCAN <p>Revenue: \$1.4bn SG&A: \$290m % of Revenue: 21%</p> | |

- Trulicity, Jardiance, Basaglar, and Humulin U500 account for all of Lilly Diabetes 2017 revenue growth... investment level in these 4 products aligned to deliver aggressive top-line growth
- EUCAN reflected as a Corporate Priority B... viewed as a key region in Lilly Diabetes generating 21% revenue growth against 5% SG&A growth in 2017
- Priority C products include key brands for Lilly Diabetes including Humulin U500 and Trajenta

2017 Plan reflects an investment prioritization towards sustainable growth engines while harvesting resources from established brands

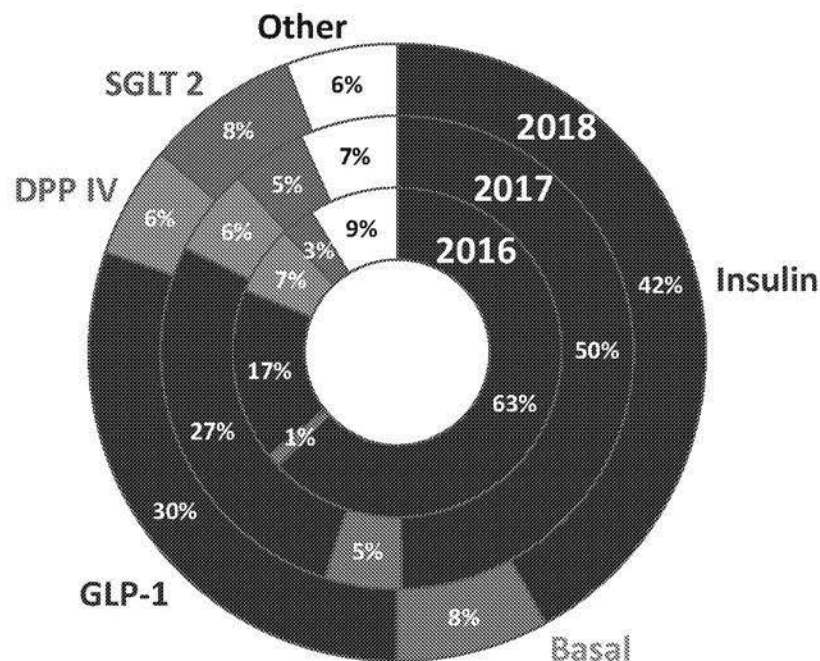
| | ----- Priority A ----- | | Priority B | ----- Priority C ----- | |
|---------------------|------------------------|------------------|-------------|------------------------|------------|
| <i>\$ millions</i> | Total Humalog | Jardiance Family | Basaglar | Total Humulin | Trajenta |
| Sales | 2,291 | 336 | 346 | 980 | 392 |
| <i>YoY Growth</i> | 1% | 94% | 391% | -6% | 7% |
| Gross Margin | 1,921 | 336 | 142 | 866 | 392 |
| <i>% of Sales</i> | 84% | 100% | 41% | 88% | 100% |
| SG&A | 204 | 267 | 199 | 49 | 112 |
| Local Medical | 10 | 8 | 2 | 0 | 3 |
| OPEX | 215 | 274 | 201 | 49 | 116 |
| <i>% of Sales</i> | 9% | 82% | 58% | 5% | 30% |
| Contribution | 1,707 | 62 | (59) | 816 | 276 |
| <i>% of Sales</i> | 75% | 18% | -17% | 83% | 70% |

- Priority A revenue projected to grow 33%, or \$1.1 billion, in 2017 led by Trulicity
- Priority C products expected to deliver \$1.3 billion of contribution margin, 79% of revenue, in 2017

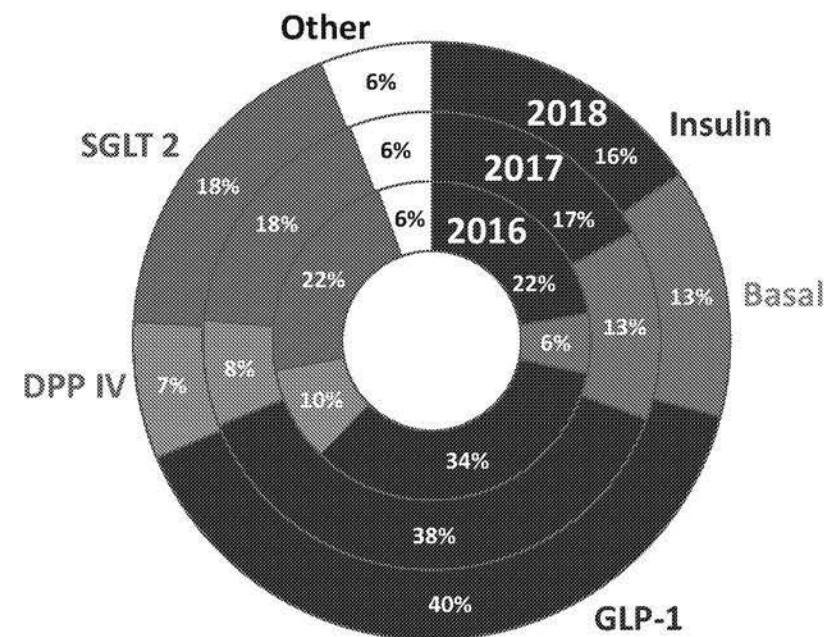
Note: All investments in partnership assets will align with financials as agreed upon in the Alliance governance processes and will comply with all contractual obligations.

Investment prioritization to sustainable growth engines while harvesting resources from less promotionally-impactable products

Lilly Diabetes Revenue Evolution

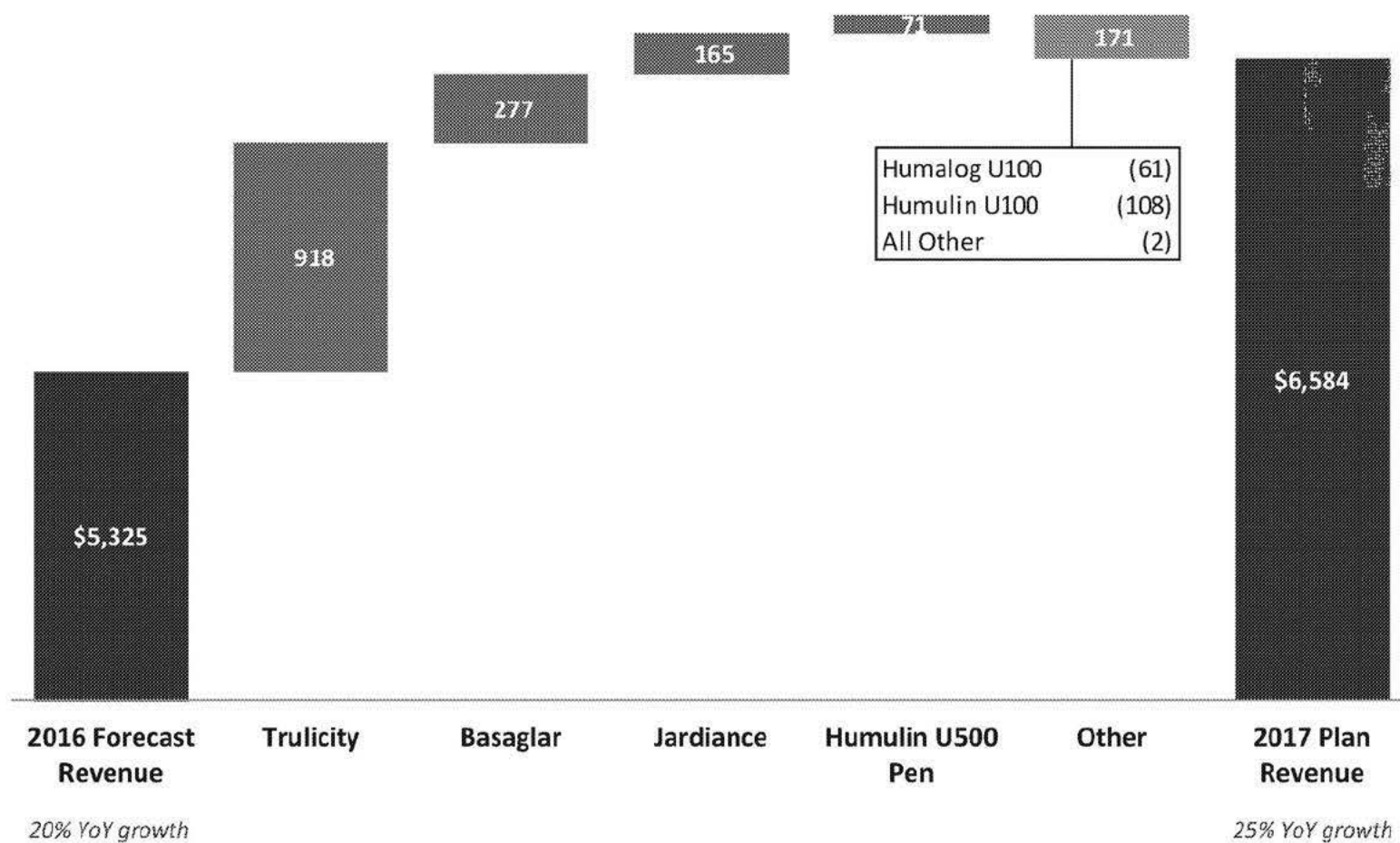


Lilly Diabetes SG&A Evolution

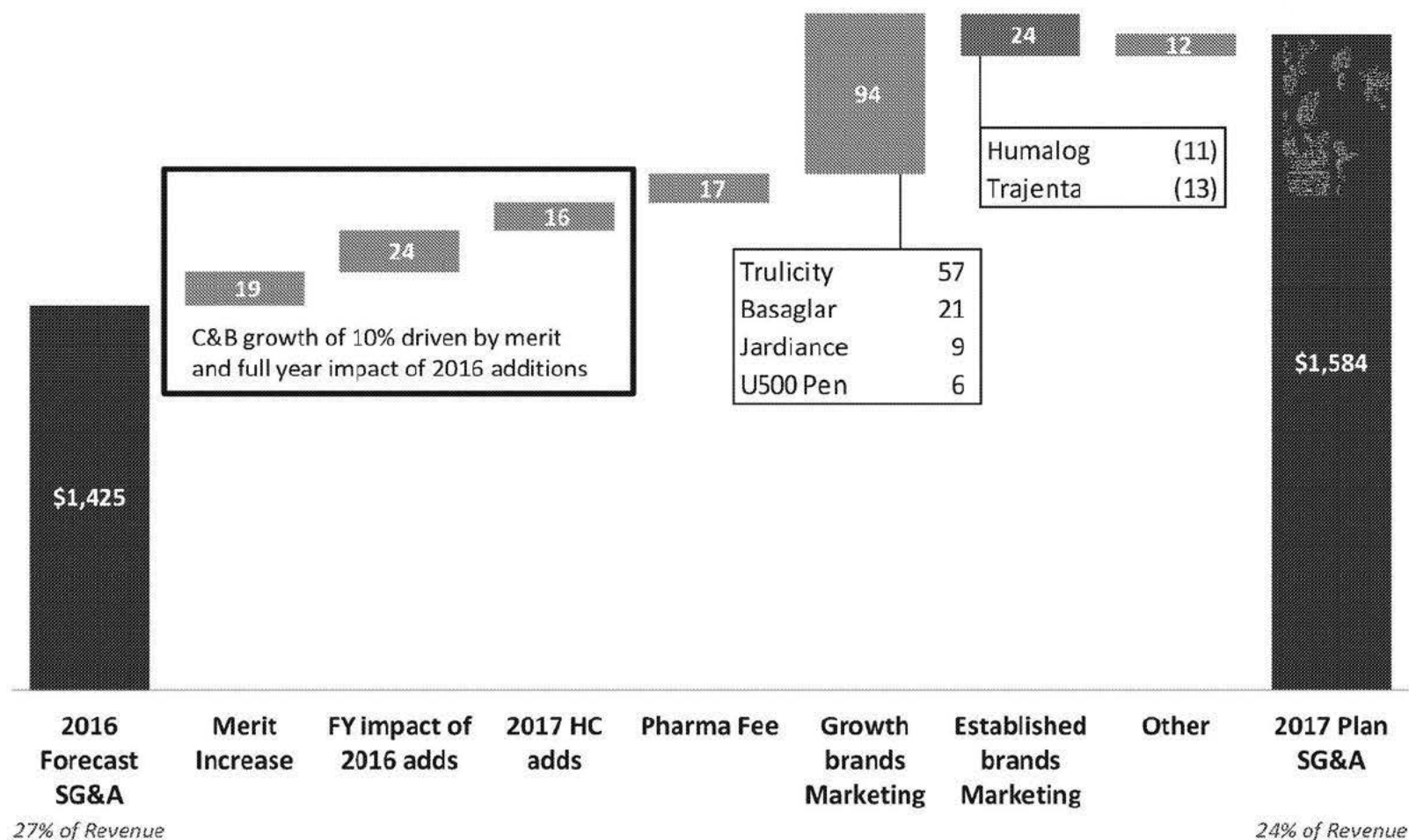


- Trulicity revenue grows to 30% of total Diabetes in 2018, representing 63% of total revenue growth over this period... SG&A investment grows to \$600m or 40% of total SG&A
- Insulin revenue declines 9% through 2018... share of total SG&A investment declines from 22% to 16%
- Orals represent 23% of total revenue growth through 2018, primarily due to Jardiance increasing from \$170M in 2016 to \$595M in 2018... SG&A investment stabilizes at ~25% of total SG&A

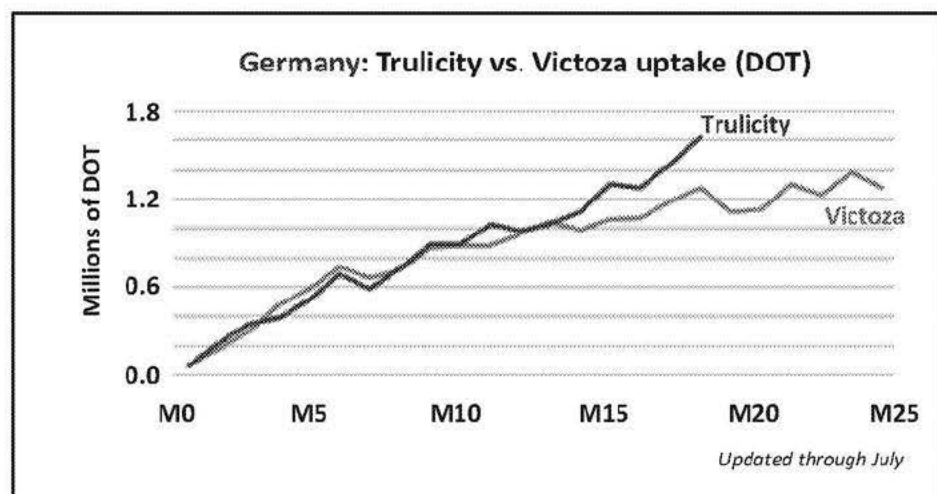
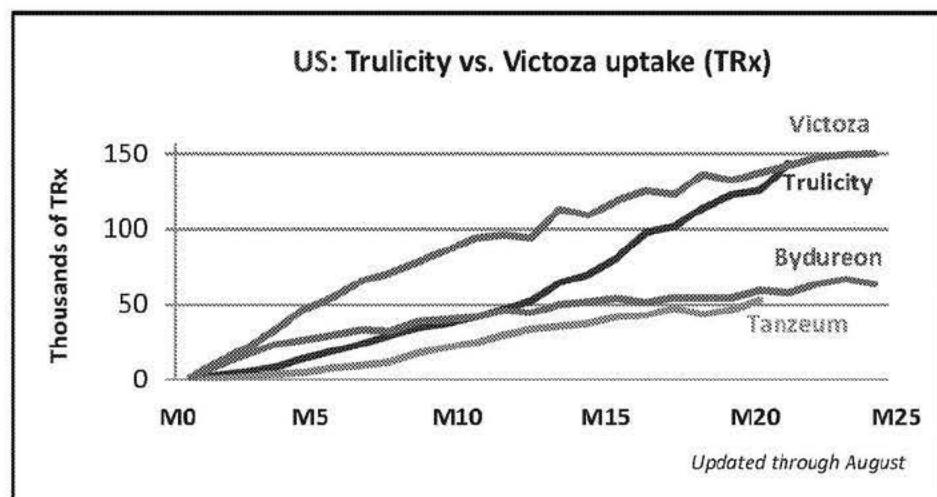
Trulicity contributes more than \$900M of revenue growth from 2016 to 2017



LD delivers 3-point improvement in SG&A ratio while focusing investments in growth brands



Trulicity uptake continues to accelerate across Lilly Diabetes markets and positions Trulicity as Lilly's top growth driver in 2017



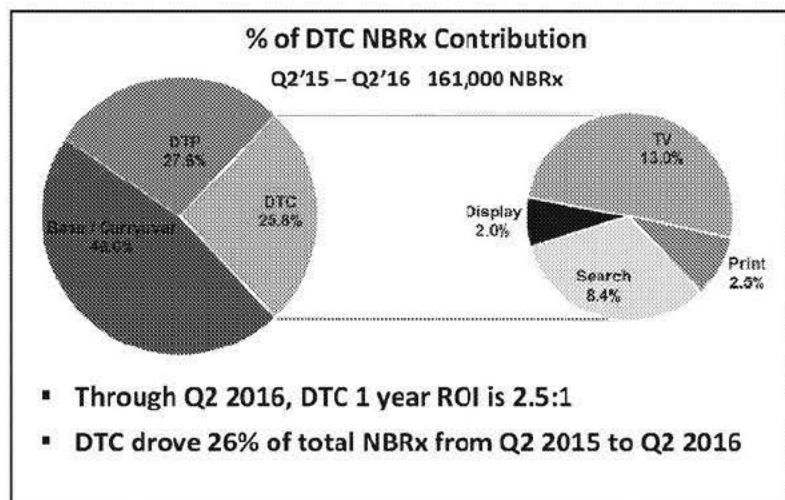
Aggressive SOM and market growth assumptions assumed in Plan

| Trulicity | | 2016 | 2017 |
|-----------|-----------------------|-------|-------|
| US | Market Growth | 30.4% | 28.1% |
| | SOM | 24.8% | 36.3% |
| EU/CAN | France Market Growth | 19.7% | 25.0% |
| | France SOM | 23.2% | 34.1% |
| | Germany Market Growth | 24.8% | 23.0% |
| | Germany SOM | 38.8% | 49.3% |
| | Italy Market Growth | 18.5% | 30.0% |
| | Italy SOM | 21.0% | 32.3% |
| | Spain Market Growth | 18.8% | 19.2% |
| | Spain SOM | 18.5% | 30.3% |
| JP | UK Market Growth | 8.2% | 8.0% |
| | UK SOM | 9.3% | 16.7% |
| JP | Market Growth | 36.0% | 38.2% |
| | SOM | 33.0% | 41.5% |

Flawless commercial and manufacturing execution is required to deliver the 2017 Trulicity Plan

Commercial

Continue to invest in DTC to capitalize on 2016 success - \$140m TV allocated in 2017



2016 US primary care salesforce expansion increased reach by 20,000 targets... new to brand 4 week share of market at 29%

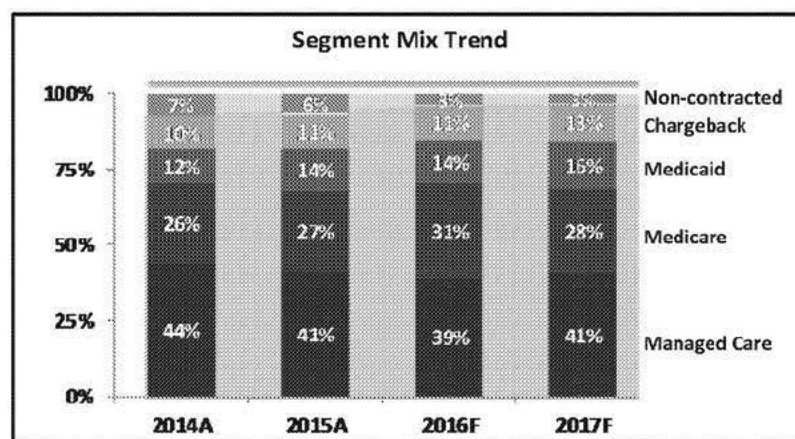
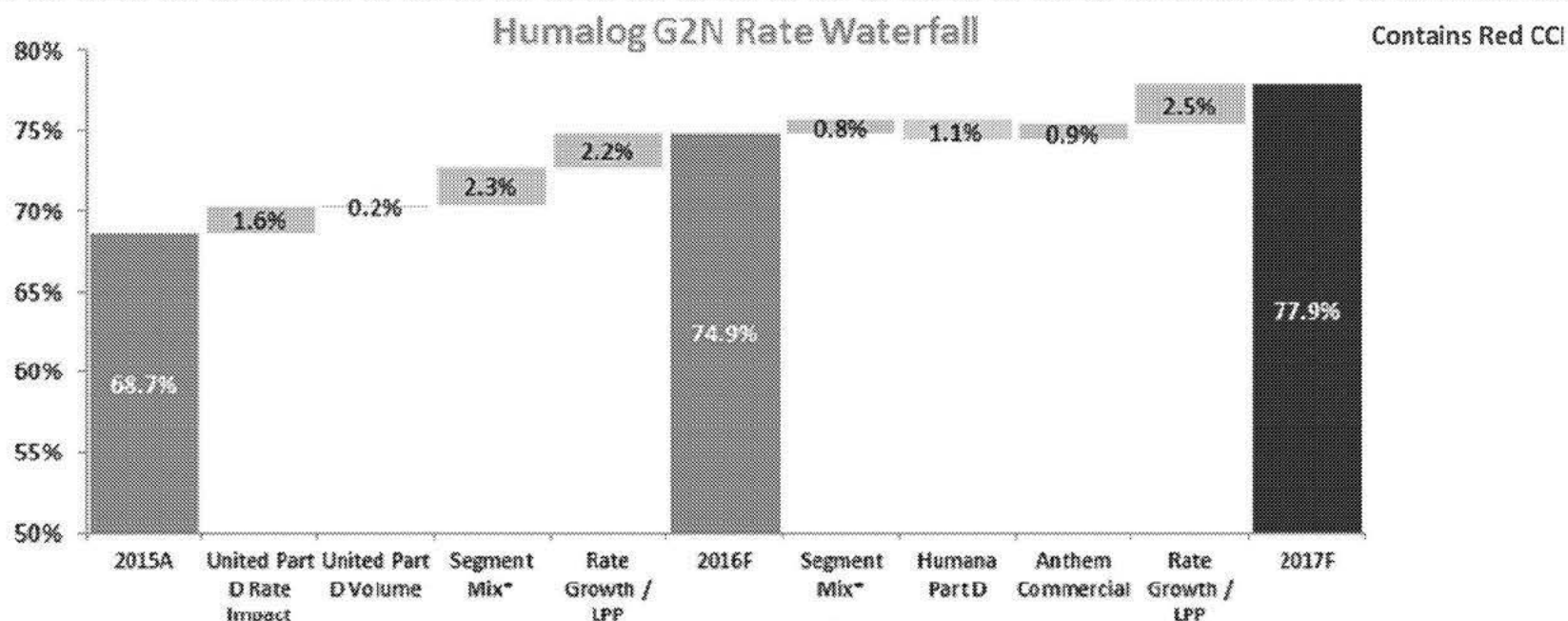
Manufacturing

Supply grows 50% driven by productivity and activation of manual lines in Indy

- US approval of Sesto in late November 2016 is critical to 2017 supply
- Next capacity increment (R3) has been accelerated 6 months into Q4 2017 and is critical for 2018 supply

Significant investments in Trulicity capacity and productivity are underway across the supply chain

Humalog's G2N rate is expected to increase further in 2017 driven by segment mix and rate growth / price protection



Weighted Average Rebate % by Segment

| | 2014A | 2015A | 2016F | 2017F |
|---------------------|-------|-------|-------|-------|
| Managed Care | 50% | 57% | 59% | 61% |
| Medicare | 57% | 60% | 72% | 76% |
| Medicaid | 107% | 107% | 102% | 102% |
| Chargeback | 89% | 90% | 92% | 92% |

Note: rates are normalized for prior period adjustments

US list price assumptions and potential pricing implications

List Price Increase Assumptions

| Product | 2017 F09 | | | | 2018 F09 | | | |
|----------------|----------|-----|------|------|----------|------|-----|------|
| | Jan | Apr | Jun | Jul | Jan | Mar | Apr | Jul |
| Humalog | | | | 8.0% | | | | 8.0% |
| Humulin / U500 | | | | 8.0% | | | | 8.0% |
| Basaglar | | | | | 8.0% | | | |
| Trulicity | | | 8.0% | | | 8.0% | | |
| | | | | | | | | |

Business Plan Implications

- Sales growth to rely on volume growth
- Strategic Plan assumed flat net price - Business Plan assumption includes pricing increases for the diabetes market that may not be realized given current pricing environment
- Mealtime insulin class has largely consolidated to exclusive plans, potentially limiting further price concessions
- Other classes remain partially/fully open allowing further price erosion as products compete for formulary access

Corporate R&D – Lilly Diabetes F09 Forecast

| | 2016 F09 | vs. PY % | 2017 F09 | vs. PY % |
|---------------------------|------------|-----------|------------|-------------|
| BU HL AO | 0 | | (41) | |
| MDU AO | 0 | | (11) | |
| Molecule | 494 | | 376 | |
| Trulicity | 128 | | 140 | |
| Empa | 94 | | 89 | |
| Lina | 80 | | 59 | |
| CC-Reusable Pen | 9 | | - | |
| CC-Prefilled Pen | 0 | | - | |
| CC-MMA | 11 | | - | |
| Project Tango | 35 | | - | |
| Humalog (non-Connected) | 23 | | 29 | |
| Humulin | 17 | | 18 | |
| BIV | 6 | | 10 | |
| [REDACTED] | [REDACTED] | | [REDACTED] | |
| [REDACTED] | [REDACTED] | | [REDACTED] | |
| PCSK9 | 5 | | 3 | |
| URI Vasodilator/Excipient | 14 | | - | |
| URI BioChaperone | 40 | | - | |
| Early Phase/Other | 2 | | 2 | |
| MM/NM/VC | 106 | | 131 | |
| Grand Total | 599 | 3% | 455 | -24% |
| <i>w/Performance Adj</i> | 591 | | | |

Key Priorities

URI & Connected Care: PSC approval for URI Ph 3 enabling and Open Loop Connected Care; represent long-term advancement of core insulin strategy

Trulicity: REWIND CVOT interim analysis expected Dec. 2017. Extension of study fully funded.

Empa: HF study expected FPV 1Q17

Insulins: compound support and investments in partnered pump studies/development

Denotes PSC funding request

CC – Connected Care
MMA – mobile medical app

Trulicity REWIND and BI partnered assets represent the majority of DBU molecule spend. URI Ph 3 enabling and Open Loop Connected Care investments were approved at PSC and represent a critical element to the long-term advancement of the core insulin strategy

2017-2018 Risk Assessment

\$ in millions

| | 2017 | | 2018 | |
|---|--------------------|--------------------|--------------------|--------------------|
| | Revenue | BAC | Revenue | BAC |
| Other Uncertainties: | | | | |
| US Contracting: | -315 to 220 | -315 to 220 | -350 to 250 | -350 to 250 |
| Humalog: % contracted, segment mix, medicaid invoicing | -190 to 140 | -190 to 140 | -225 to 150 | -225 to 150 |
| Humulin / U500: % contracted, segment mix, 5i | -100 to 80 | -100 to 80 | -125 to 100 | -125 to 100 |
| Humalog / Humulin: 2017 ESI NPF closed rate increase | -25 to 0 | -25 to 0 | N/A | N/A |
| Market Growth / Volume | -125 to 45 | -118 to 44 | -220 to 130 | -212 to 128 |
| ██████ GLP-1 market growth uncertainty | -100 to 20 | -93 to 19 | -120 to 30 | -112 to 28 |
| ██████ SGLT-2 market growth and share expansion uncertainty with new indication | -25 to 25 | -25 to 25 | -100 to 100 | -100 to 100 |
| Biosimilar competition | -25 to -15 | -25 to -15 | -160 to 10 | -154 to 4 |
| Biosimilar lispro rate pressure | -25 to -15 | -25 to -15 | -100 to -50 | -100 to -50 |
| Biosimilar lispro volume impact | N/A | N/A | -45 to 45 | -40 to 40 |
| Biosimilar FIAsp volume impact | N/A | N/A | -15 to 15 | -14 to 14 |
| Business Total | -465 to 250 | -458 to 249 | -730 to 390 | -716 to 382 |

2017-2018 Buy-ups & Buy-Downs

\$ in millions

| Buy-Ups | 2017 | | | 2018 | | | Benefit Timing | Commentary (e.g., impact to Revenue, longterm/broader implications, risks, etc.) |
|--|---------|------|-----|---------|------|-----|-------------------|---|
| | Revenue | OPEX | IBT | Revenue | OPEX | IBT | | |
| Additional Jardiance DTC (TV): recommended as triggered buy-up. [\$ values reflect Lilly share] | 33 | 50 | -17 | 30 | | 30 | 2H'17 to 2019 | Trigger timing: April 2017 Trigger pulled if: (1) favorable outcome on EMPA-REG_OUTCOME label update, (2) positive BASES market research and (3) Jardiance achieving revenue plan |

2017 Lilly Diabetes Plan Executive Summary

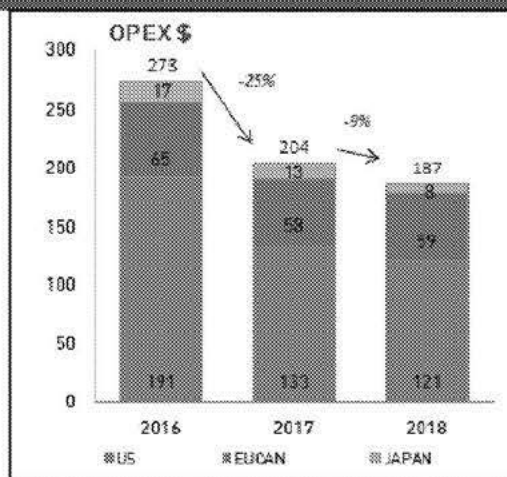
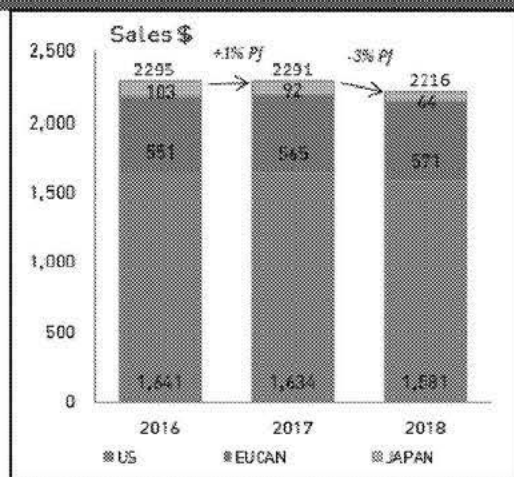
1. Significant year over year growth reflected in the 2017 LD Plan submission... **+25% revenue growth** and +44% BAC growth in 2017
2. **Trulicity remains Lilly's largest growth driver** and one of the largest products globally at nearly \$1.9B... 2017 Plan assumes 100% of supply capacity is utilized with no supply disruption
3. **Insulin franchises** remain the foundation to our wide-range of therapy offerings with **\$3.3B in revenue**
4. **Jardiance Plan assumes a positive US label outcome** in December and a subsequent inflection in revenue uptake... 2017 Plan assumes US market growth of 25% coupled with 30% share of market
5. 2017 Plan reflects an **investment prioritization towards sustainable growth engines** while harvesting resources from established brands

Back Up - CFP Templates

Revenue Growth Drivers (\$ Millions)

| | <u>2016</u> | | | <u>2017</u> | | | <u>2018</u> | | |
|--------------|--------------|----------------|------------|--------------|----------------|------------|--------------|----------------|------------|
| | Revenue | vs. PY Perf \$ | % | Revenue | vs. PY Perf \$ | % | Revenue | vs. PY Perf \$ | % |
| Humalog U100 | 2,212 | (166) | (7%) | 2,136 | (61) | (3%) | 2,016 | (119) | (6%) |
| U200 KwikPen | 83 | 61 | 270% | 155 | 75 | 91% | 199 | 44 | 29% |
| Humalog | 2,295 | (106) | (4%) | 2,291 | 14 | 1% | 2,216 | (75) | (3%) |
| Humulin U100 | 629 | 4 | 1% | 520 | (108) | (17%) | 420 | (100) | (19%) |
| Humulin U500 | 412 | 67 | 19% | 460 | 48 | 12% | 480 | 20 | 4% |
| Humulin | 1,042 | 71 | 7% | 980 | (61) | (6%) | 900 | (80) | (8%) |
| Basaglar | 73 | 62 | 570% | 346 | 277 | 380% | 595 | 249 | 72% |
| | | | | | | | | | |
| Trulicity | 893 | 652 | 268% | 1,800 | 918 | 103% | 2,241 | 441 | 24% |
| | | | | | | | | | |
| Total | 5,325 | 906 | 20% | 6,584 | 1,314 | 25% | 7,415 | 831 | 13% |

Key Brand Summary - Humalog



US

- Humalog volume forecasted to decline in 2017, driven by Humana formulary loss (Commercial and Medicare Part D), partially offset by SOM growth in new preferred Commercial accounts (Anthem and Aetna Premier).
- Net price growth remains very limited due to increasingly higher negotiated rebates and price predictability in most major payer contracts along with other fixed price contracts; gross-to-net materiality will continue to increase, creating meaningful uncertainty around realized net price and reported net sales results
- No impact assumed in base net sales submission for biosimilar lispro (Sanofi) and FIAsp (Novo) in 2017 given current approval and launch assumptions

EUCAN

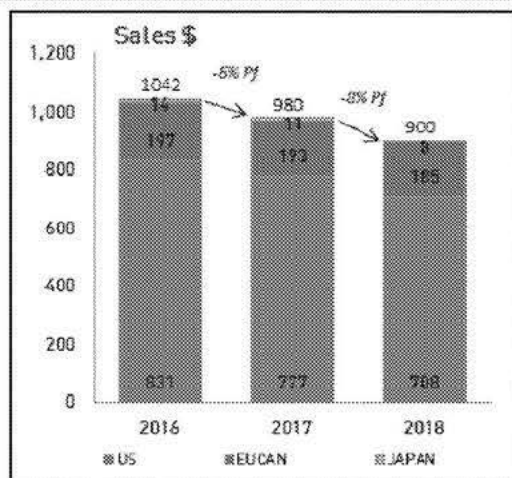
- Potential entry of biosimilar lispro (Sanofi) in 4Q17
- U200 launched in all EUCAN contributing \$54M of growth.
- Humalog U200 promotion and conversion of existing patients are contributing to share gain and protection from biosimilar lispro

Japan

- Revenue decline driven by continued mixture market decline and increased competition by Ryzodeg after 14-day prescribing restriction lifted
- SOM gain in rapid market in 2017 partially offsets SOM decline in mixture market

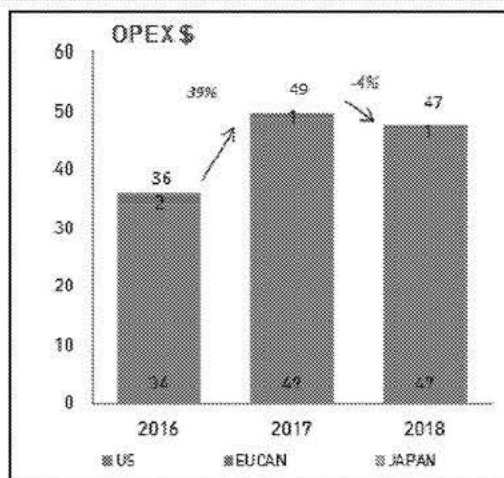
| Humalog | | 2016 | 2017 | 2018 |
|---------|-----------------------|---------|--------|---------|
| US | Market Growth | 3.1% | 2.7% | 2.7% |
| | SOM | 47.9% | 47.1% | 44.3% |
| | Volume Growth | 13.8% | (2.2%) | (1.2%) |
| | Price Growth | (21.2%) | 1.7% | (2.0%) |
| EUCAN | France Market Growth | 3.7% | 3.7% | 3.7% |
| | France SOM | 29.7% | 30.0% | 29.2% |
| | France Volume Growth | 3.7% | 3.7% | (2.6%) |
| | France Price Growth | 0.3% | 1.0% | (0.0%) |
| | Germany Market Growth | 6.1% | 5.6% | 5.6% |
| | Germany SOM | 47.0% | 47.8% | 47.0% |
| | Germany Volume Growth | 10.8% | 5.9% | 2.1% |
| | Germany Price Growth | (2.4%) | 0.1% | 0.0% |
| | Italy Market Growth | (0.6%) | 1.2% | 1.5% |
| | Italy SOM | 43.2% | 45.4% | 43.4% |
| | Italy Volume Growth | 1.7% | 9.6% | (2.8%) |
| | Italy Price Growth | (5.3%) | (5.0%) | 3.3% |
| | Spain Market Growth | (0.1%) | 0.6% | 1.0% |
| | Spain SOM | 31.1% | 31.4% | 30.8% |
| JAPAN | Spain Volume Growth | 0.6% | (1.7%) | 11.8% |
| | Spain Price Growth | (1.4%) | 0.2% | (19.0%) |
| | UK Market Growth | 3.0% | 3.3% | 3.4% |
| | UK SOM | 24.1% | 24.2% | 23.6% |
| BU | UK Volume Growth | 7.9% | 1.7% | 2.0% |
| | UK Price Growth | 4.5% | 1.8% | 0.0% |
| EUCAN | EUCAN Volume Growth | 5.9% | 5.6% | 1.4% |
| | EUCAN Price Growth | (0.8%) | (1.1%) | (0.3%) |
| JAPAN | Market Growth | (2.0%) | (2.6%) | (3.1%) |
| | SOM | 34.9% | 34.4% | 32.6% |
| | Volume Growth | (2.8%) | (3.7%) | (7.4%) |
| | Price Growth | 0.9% | (0.1%) | (22.8%) |
| BU | Volume Growth | 11.4% | (0.4%) | (0.8%) |
| | Price Growth | (15.7%) | 1.0% | (2.4%) |

Key Brand Summary - Humulin



US

- The human insulin market is forecasted to continue its multi-year decline through 2018
- US Humulin sales comprised of U500 (\$458M, 10% growth driven by continued uptake of recently-launched U500 KwikPen) and U100 (\$318M, 24% decline which is more pronounced given favorable prior-year G2N adjustments in 2016)
- All Humulin investment is towards the U500 KwikPen with zero investment on U100.



EU/CAN

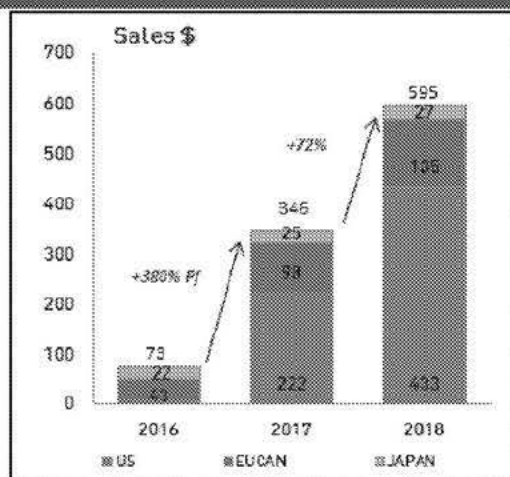
- The Human insulin market continues declining at mid-single digits however with a much higher speed in certain markets

Japan

- No promotional activities on Humulin
- The human insulin market is forecasted to continue its multi-year decline through 2018.

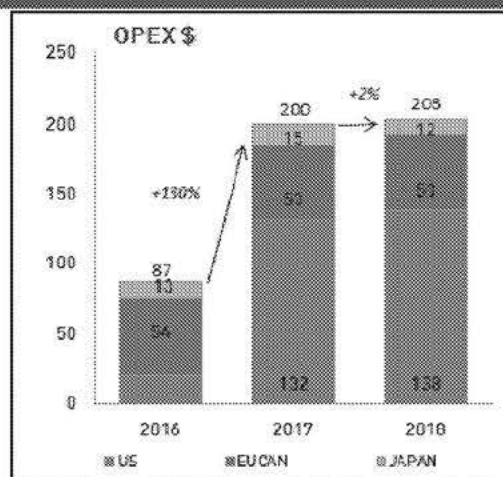
| Humulin | | 2016 | 2017 | 2018 |
|---------|-----------------------|---------|---------|---------|
| US | Market Growth | (6.0%) | (4.6%) | (6.8%) |
| | SOM | 54.5% | 54.6% | 35.4% |
| | Volume Growth | 6.6% | 3.2% | (7.2%) |
| | Price Growth | 2.1% | (9.7%) | (1.7%) |
| EU/CAN | France Market Growth | (9.3%) | (9.5%) | (9.5%) |
| | France SOM | 49.2% | 49.0% | 48.0% |
| | France Volume Growth | (9.8%) | (9.9%) | (15.8%) |
| | France Price Growth | (0.5%) | 0.1% | 0.0% |
| | Germany Market Growth | (11.0%) | (12.0%) | (13.0%) |
| | Germany SOM | 27.2% | 31.2% | 31.0% |
| | Germany Volume Growth | 4.7% | (5.0%) | (5.6%) |
| | Germany Price Growth | (1.0%) | 0.1% | 0.0% |
| | Italy Market Growth | (17.0%) | (18.0%) | (19.0%) |
| | Italy SOM | 49.4% | 50.8% | 53.0% |
| | Italy Volume Growth | (14.9%) | (12.9%) | (33.3%) |
| | Italy Price Growth | (2.2%) | (2.9%) | (0.1%) |
| | Spain Market Growth | (9.7%) | (10.6%) | (12.1%) |
| | Spain SOM | 19.2% | 17.3% | 17.0% |
| | Spain Volume Growth | (3.3%) | (9.1%) | (7.0%) |
| | Spain Price Growth | (3.4%) | 2.4% | 0.0% |
| | UK Market Growth | 6.8% | 5.4% | 6.5% |
| | UK SOM | 71.1% | 72.7% | 72.7% |
| | UK Volume Growth | 7.4% | 4.9% | 2.0% |
| | UK Price Growth | 2.8% | 2.9% | 0.0% |
| | EU/CAN Volume Growth | 3.1% | (3.0%) | (4.2%) |
| | EU/CAN Price Growth | (0.1%) | 0.7% | 0.0% |
| JAPAN | Market Growth | (12.0%) | (12.0%) | (12.0%) |
| | SOM | 34.6% | 34.8% | 35.0% |
| | Volume Growth | (8.1%) | (12.1%) | (17.7%) |
| | Price Growth | (3.8%) | (0.8%) | (6.8%) |
| BU | Volume Growth | 5.7% | 1.8% | (6.8%) |
| | Price Growth | 1.6% | (7.7%) | (1.4%) |

Key Brand Summary - Basaglar



US

- Basaglar will launch in the US on Dec. 15 with solid Commercial access:
- Flawless pull-through against a next generation basal product (Tresiba) and HCP messaging focused on a differentiated patient start experience are required to achieve net sales forecast
- Price expected to be announced in second half of November



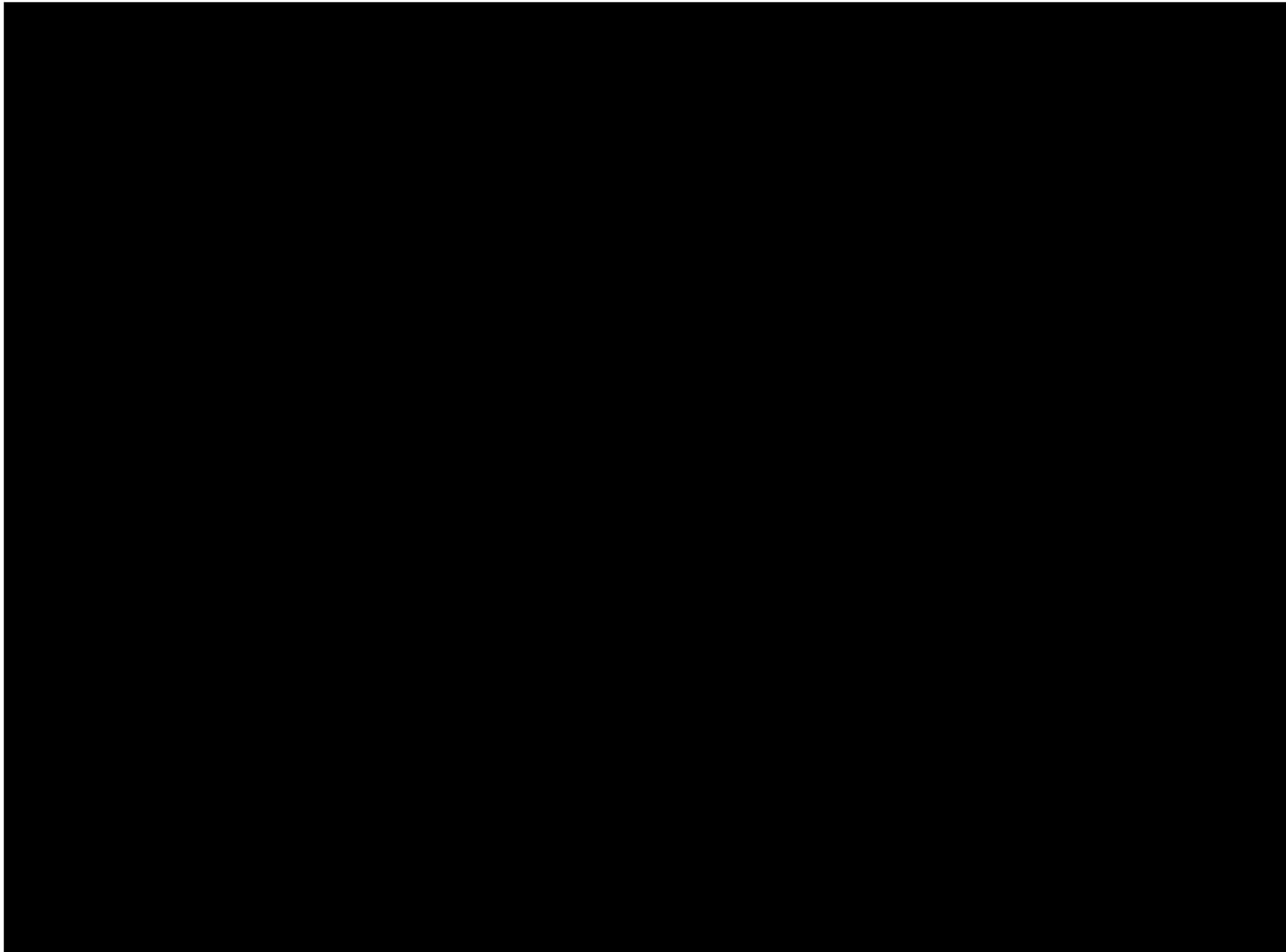
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- Slow uptake in 2016 however sales to more than double in 2017.
- Exit SOM in EUCAN to go from 3.8% to 7.4%.
- 2 competitive biosimilars expected in 2017

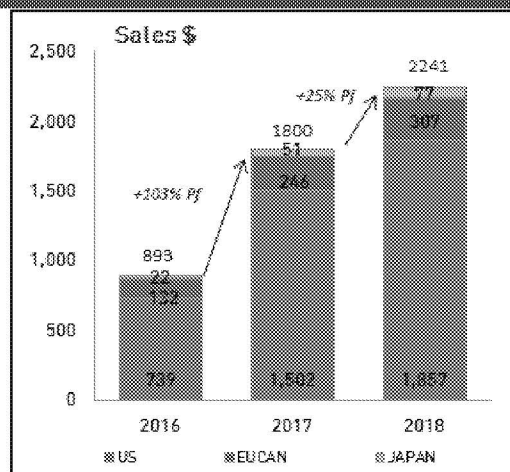
Japan

- Increasing pressure on SOV expected from increased competition from Biocon/Fuji biosimilar and lifting of 14-day prescribing limitation on Lantus XR (Sept. 2016).

| Basaglar | | 2016 | 2017 | 2018 |
|----------|-----------------------|---------|---------|---------|
| US | Market Growth | 3.2% | 2.6% | 2.4% |
| | SOM | 0.0% | 7.1% | 11.1% |
| | Volume Growth | | | 81.8% |
| | Price Growth | 0.0% | (34.1%) | 12.7% |
| EUCAN | France Market Growth | 6.9% | 8.8% | 7.7% |
| | France SOM | 2.1% | 8.4% | 8.5% |
| | France Volume Growth | | 651.1% | 55.6% |
| | France Price Growth | 0.0% | (20.8%) | 0.0% |
| | Germany Market Growth | 10.0% | 9.0% | 8.0% |
| | Germany SOM | 4.2% | 7.3% | 7.3% |
| | Germany Volume Growth | 813.1% | 126.5% | 22.8% |
| | Germany Price Growth | 75.6% | 1.9% | 0.0% |
| | Italy Market Growth | 1.5% | 1.0% | 1.0% |
| | Italy SOM | 7.8% | 10.9% | 10.9% |
| | Italy Volume Growth | | 83.9% | 22.0% |
| | Italy Price Growth | 0.0% | (1.1%) | (0.0%) |
| | Spain Market Growth | 6.8% | 6.2% | 6.0% |
| | Spain SOM | 5.7% | 7.3% | 7.3% |
| | Spain Volume Growth | 981.0% | 84.6% | 24.0% |
| | Spain Price Growth | (16.9%) | 8.7% | 0.0% |
| JAPAN | UK Market Growth | 3.0% | 2.8% | 3.0% |
| | UK SOM | 1.1% | 3.1% | 2.1% |
| | UK Volume Growth | | 238.1% | 92.7% |
| | UK Price Growth | 343.4% | 14.1% | 0.0% |
| BU | EUCAN Volume Growth | 718.1% | 113.1% | 37.4% |
| | EUCAN Price Growth | 2.9% | 18.1% | (0.2%) |
| BU | Market Growth | 6.0% | 5.0% | 4.0% |
| | SOM | 15.2% | 18.5% | 21.3% |
| | Volume Growth | 305.1% | 24.8% | 20.6% |
| | Price Growth | (8.6%) | (4.2%) | (12.7%) |
| BU | Volume Growth | 573.4% | 373.9% | 64.8% |
| | Price Growth | (3.0%) | 6.2% | 7.2% |

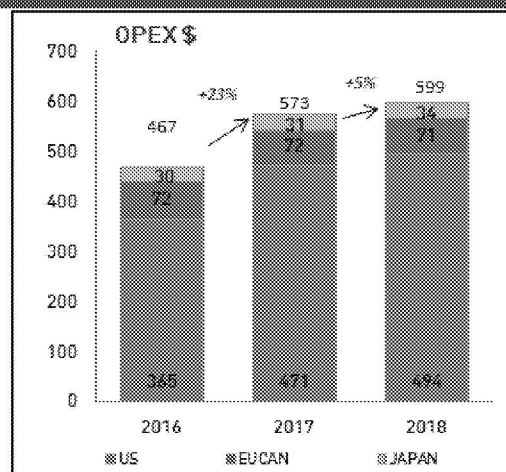


Key Brand Summary - Trulicity



US

- Trulicity net sales forecast requires all key market dynamics to break in Trulicity's favor – continued robust market growth (28% on a meaningfully larger base), LEADER benefit that accrues to the class rather than only to Victoza, minimal competitive impact from novel basal products, new basal / GLP-1 combination products and generic Byetta and no aggressive competitive co-pay card / pricing dynamics
- Higher rebates driven by continued access improvement contain net price growth in 2017 and 2018



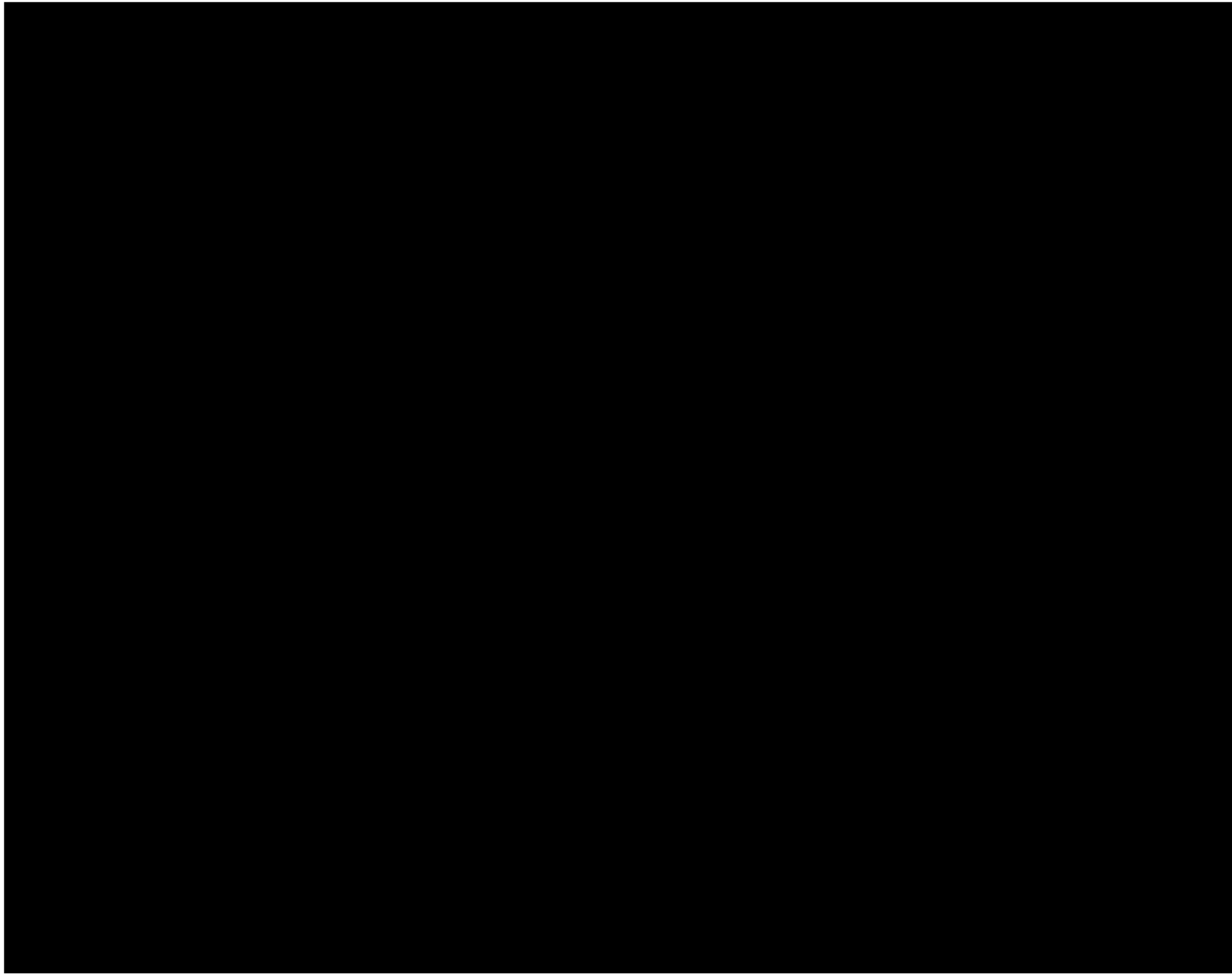
EUCAN

- Currently achieving better uptake than Victoza in 4 key geographies: Germany (8th month), France (16th month), Italy (12th month), Spain (24th month)
- By 2017, Trulicity will represent more than 30% of the segment DOTs in EUCAN. Germany will be the highest share at 49.3%.

Japan

- Alliance with Dainippon Sumitomo helps to achieve high SOV in GP first injectable market
- Trulicity is the 5th to market in the GLP-1 class yet reached 30% DOT SOM upon lifting the 14-day prescribing limitation period
- Accounts for 55% of Japan's 2017 sales growth

| Trulicity | | 2016 | 2017 | 2018 |
|-----------|-----------------------|----------|---------|---------|
| US | Market Growth | 30.4% | 28.1% | 10.1% |
| | SOM | 24.8% | 36.3% | 35.7% |
| | Volume Growth | 301.0% | 94.1% | 22.5% |
| | Price Growth | (45.4%) | 9.3% | 1.1% |
| EUCAN | France Market Growth | 19.7% | 25.0% | 17.0% |
| | France SOM | 23.2% | 34.1% | 39.0% |
| | France Volume Growth | | 143.5% | 28.5% |
| | France Price Growth | 0.0% | (21.5%) | 0.0% |
| | Germany Market Growth | 24.8% | 23.0% | 25.0% |
| | Germany SOM | 38.8% | 49.3% | 49.3% |
| | Germany Volume Growth | 173.1% | 68.5% | 5.0% |
| | Germany Price Growth | (100.9%) | (1.0%) | (0.0%) |
| | Italy Market Growth | 18.5% | 30.0% | 20.0% |
| | Italy SOM | 21.0% | 32.3% | 41.5% |
| | Italy Volume Growth | | 131.1% | 56.8% |
| | Italy Price Growth | 0.0% | (19.5%) | (12.5%) |
| | Spain Market Growth | 18.8% | 19.2% | 16.0% |
| | Spain SOM | 18.5% | 30.3% | 34.0% |
| | Spain Volume Growth | | 118.0% | 25.0% |
| | Spain Price Growth | (99.1%) | 0.3% | 0.0% |
| JAPAN | UK Market Growth | 8.2% | 8.0% | 10.0% |
| | UK SOM | 9.3% | 16.7% | 16.7% |
| | UK Volume Growth | | 139.5% | 34.6% |
| | UK Price Growth | (202.3%) | (0.4%) | (0.0%) |
| EU | EUCAN Volume Growth | 392.7% | 103.5% | 26.0% |
| | EUCAN Price Growth | (97.4%) | (12.4%) | (1.4%) |
| BU | Market Growth | 36.0% | 38.2% | 11.2% |
| | SOM | 33.0% | 41.5% | 49.0% |
| | Volume Growth | | 136.0% | 45.7% |
| | Price Growth | 70.1% | 16.9% | 3.4% |
| BU | Volume Growth | 320.1% | 96.5% | 23.7% |
| | Price Growth | (51.9%) | 6.3% | 0.8% |



Funded Initiatives

| SG&A | | | |
|--|------|----------------|---|
| Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target | | | |
| 2017 | 2018 | Priority Level | |
| 294 | 298 | A | Competitive investment in Trulicity to deliver ~\$1bn in YOY BAC growth; includes DTC [2017: \$140m and 2018: \$142m] |
| 118 | 113 | A | Prepare to capitalize on Jardiance CV label outcome |
| 97 | 100 | A | Retain and protect the \$3.3bn insulin franchise [DBU markets] |
| 22 | 22 | A | Capitalize on Humulin U500 KwikPen launch uptake |
| | | | |
| 116 | 116 | A | Regional / Global initiatives - marketing, communications, strategy, operations, market research, admin, evolution |
| 712 | 738 | A | Diabetes Salesforce [2017 values - US: \$423m; EUCAN: \$180m; Japan: \$109m] |
| 49 | 49 | B | Optimize Basaglar investment |
| 41 | 42 | B | Non-Branded HCP, Consumer and Payer Initiatives |
| 28 | 27 | C | Trajenta SG&A - aligned investment with BI [23% SG&A/Sales delivering ~\$400m in Revenue (LLY share)] |
| | | C | |
| 55 | 41 | | Pharma Fee all products - Fixed |
| 1584 | 1609 | | SG&A Total |

| R&D | | | | | |
|---|-------------|---------------------------------|---|--|--|
| Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target | | | | | |
| 2017 | 2018 | Priority Level A/B/C | | | |
| 140 | 118 | A | Trulicity REWIND extension, high dose Ph2 study, and Pediatric study | | |
| 89 | 61 | A | Jardiance heart failure, Japan safety and efficacy studies, Type 1 DM, post-marketing | | |
| 88 | 87 | A | Global Medical | | |
| 59 | 54 | A | Trajenta CVOT (CAROLINA and CARMELINA), pediatric, add-on to basal | | |
| 43 | 32 | A | Insulins; partnership with Insulet; device updates; Humulin U500 | | |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | | |
| 122 | 152 | B | Corp Development Multi-Molecule/Non-Molecule | | |
| 10 | 8 | B | Easaglar U200 and China | | |
| 4 | 0 | B | DNR-free vial stoppers - Humalog and Humulin | | |
| 3 | 8 | C | Other Development initiatives | | |
| 3 | 0 | C | PCSK9 Phase 3 enabling | | |
| -41 | -40 | C | Admin Objective | | |
| 542 | 522 | | R&D Total | | |

Unfunded Initiatives

\$ Millions

| Deprioritized Investment Opportunities - Amount of Spend not included in Add-up to Achieve Target | | | |
|---|-------------|--|--|
| <u>2017</u> | <u>2018</u> | <u>Priority Level</u> | |
| | | <u>B/C</u> | |
| 50 | 0 | A | Additional Jardiance DTC (TV) * - captured as triggered buy-up |
| 110 | 87 | A | Closed Loop - Connected Care PSC ask |
| 41 | 52 | A | Open Loop - Connected Care PSC ask |
| 79 | 127 | A | URI phase 3 enabling and CD - PSC ask |
| TBD | TBD | A | Trulicity high dose commercial decision |
| 10 | 33 | B | Trulicity AWARD 11 and 12 |
| 75 | 155 | B | PCSK9 commercial decision |
| ■ | ■ | ■ | ■ |
| 376 | 466 | Total Deprioritized Opportunities | |

Development OPEX

\$ in millions

| | | Corporate Development | | | |
|---|------------------------|-----------------------|-------|-------|--|
| | | OPEX | | | |
| Molecule | | 2016 | 2017 | 2018 | Comments |
| Phase 3/New NILEX/ New Portfolio Line Item | Current/ Ongoing | | | | |
| | Dulaglutide | 128 | 140 | 119 | Starting High Dose and Peds study in 2017 |
| | Empa | 94 | 89 | 61 | Lilly Portion Only; HF start in 2017 |
| | Lina | 80 | 59 | 54 | Lilly Portion Only; wind down of Cardiovascular Outcome Trials |
| | Insulins | 38 | 48 | 32 | Insulet partnership on U200 and U500 in Pumps |
| | BIV | 6 | 10 | 8 | BIV U200; BIV China |
| | Subtotal | 346 | 347 | 273 | |
| | New Starts | | | | |
| | URI Phase 3 Enabling | 11 | - | - | Phase 3 enabling for one URI program, PSC request for 2017 |
| | PCSK9 Phase 3 Enabling | 6 | 3 | - | Phase 3 enabling for PCSK9 |
| | Connected Care | 56 | - | - | Open Loop and Tango; 2017 unfunded |
| | URI BioChaperone | 40 | - | - | Partnership with Adocia; |
| | Subtotal | 137 | 25 | 43 | |
| Admin Objectives | | | (41) | (40) | Started the year 2016 with \$124M AO |
| All Other | | 107 | 124 | 160 | |
| Total Corporate Development | | \$591 | \$455 | \$436 | |
| Local R&D | | 75 | 88 | 86 | |
| Total R&D | | \$666 | \$542 | \$522 | |

Note: URI BioChaperone 2017 and beyond funding pending positive commercial decision

Diabetes Headcount

| | Q3 Onboard | YE 2016 Forecast | 2016 Target | YE 2017 Target | YE 2018 Target |
|----------------------|------------|------------------|-------------|----------------|----------------|
| FTE | 4217 | 4233 | 4338 | 4372 | 4365 |
| FDE | 104 | 104 | 103 | 94 | 94 |
| Contractor (D61/D62) | 206 | 206 | 262 | 257 | 257 |
| M path total | 98 | 98 | 96 | 98 | 98 |

Lilly Diabetes headcount (FTE + FDE) projected to increase 145 positions by year-end 2017, which includes 110 current open positions and 35 new positions.

Drivers for FTE Change between Q3 Onboard and 2017 Target:

- **US commercial (75):** salesforce openings (57), marketing openings (11), [REDACTED]
- **EuCan commercial (53):** current openings (19), Germany Jardiance Sales Force expansion (18), France BioMed to Diabetes salesforce conversion (14), Italy FDE to FTE conversion (10), Canada and UK decreases (-8)
- **Medical (12):** current openings (11), 1 FDE to FTE conversion
- **Global Marketing (7):** current openings (2), [REDACTED] (3), Connected Care (2)
- **Other (8):** Strategy & Ops (3), Development (5)
- **M-path adds (2):** Connected Care position, M2 Spain Marketing Leader

Risks/Uncertainties to Achieve Plan:

2017

- Additional adds could be necessary pending approval of URI and PCSK9 programs

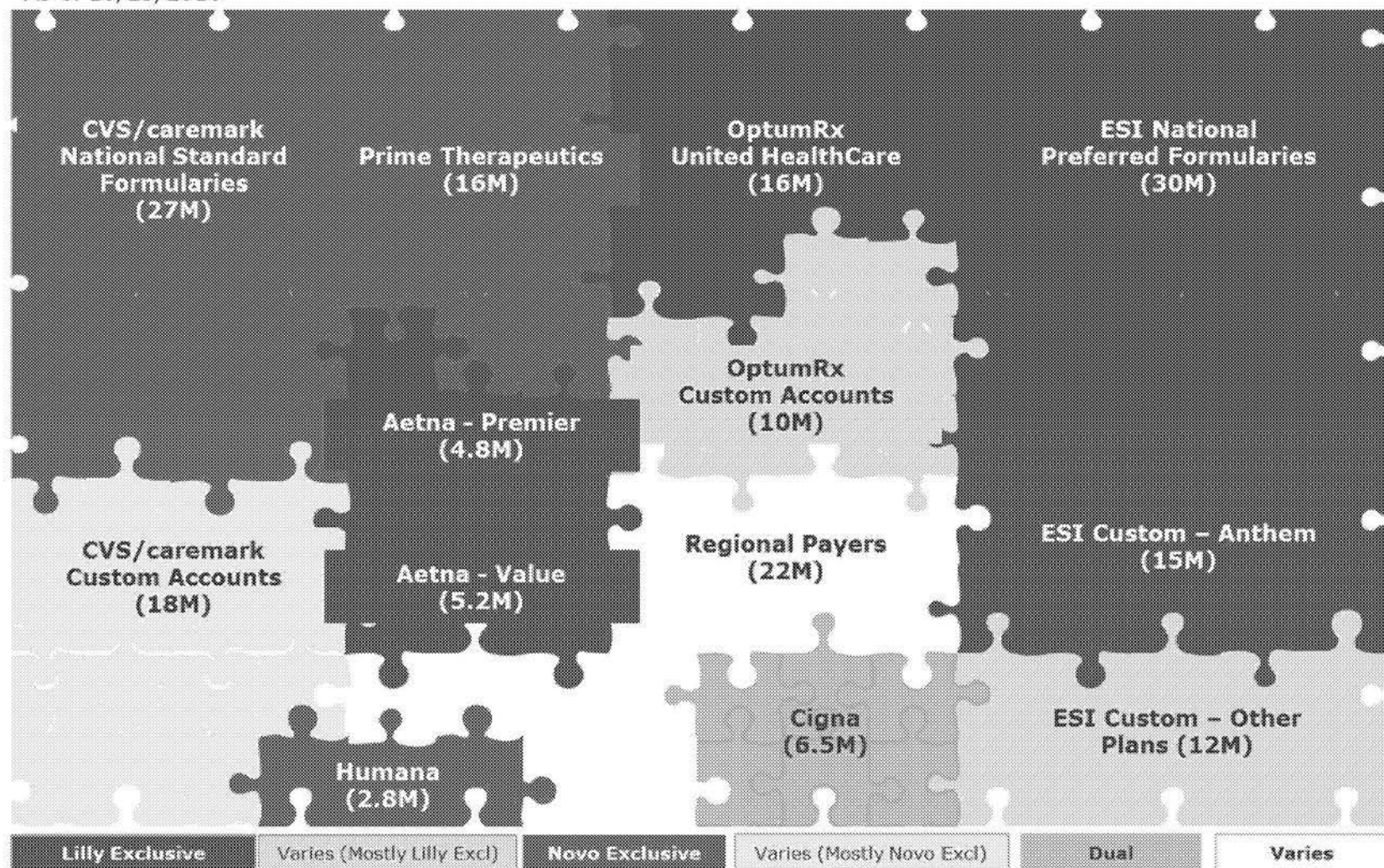
2018

- Assumes delay of Connected Care call center

Humalog 2017 Access Picture*

Commercial Managed Care

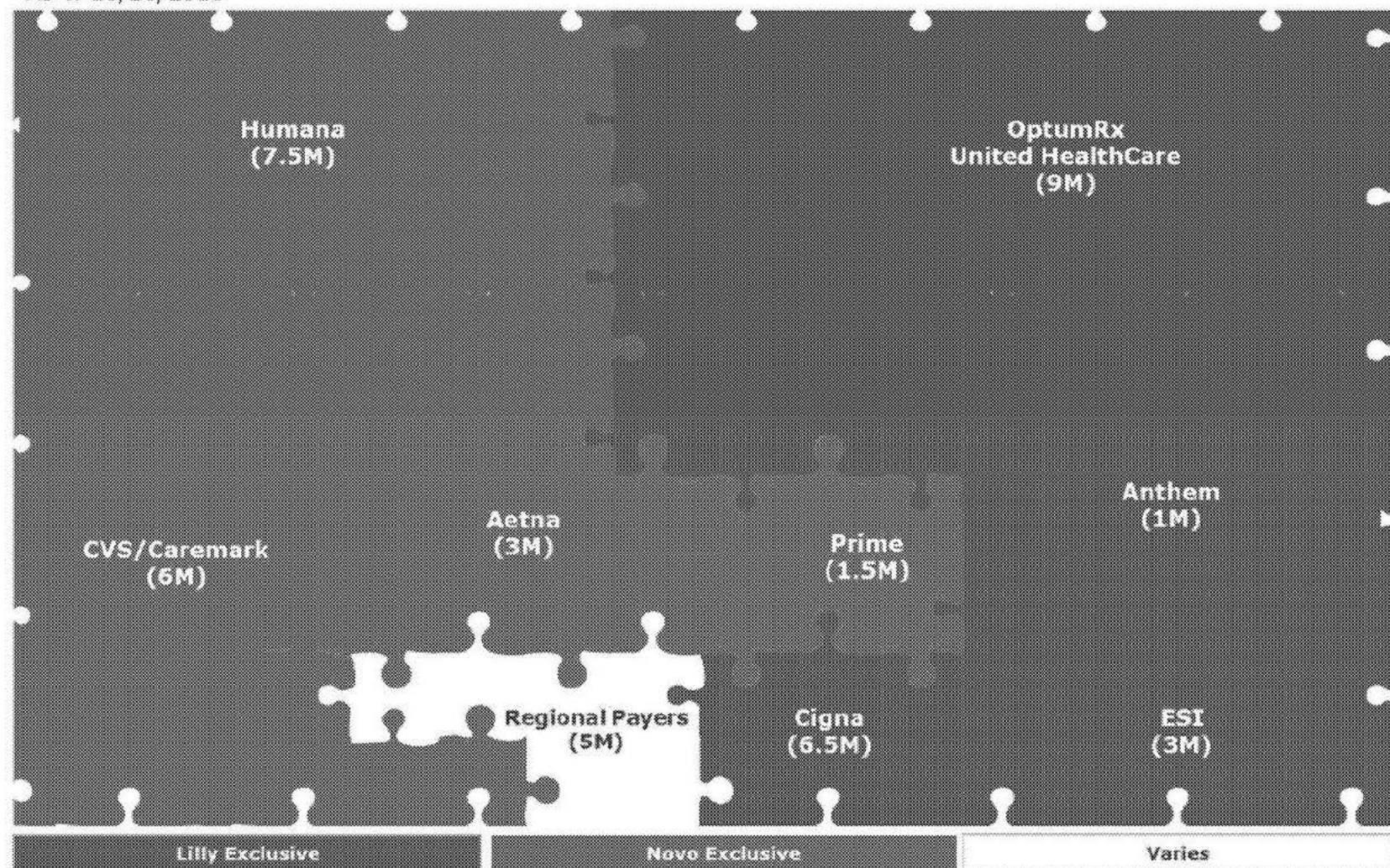
*As of 10/25/2016



Humalog 2017 Access Picture*

Medicare Part D

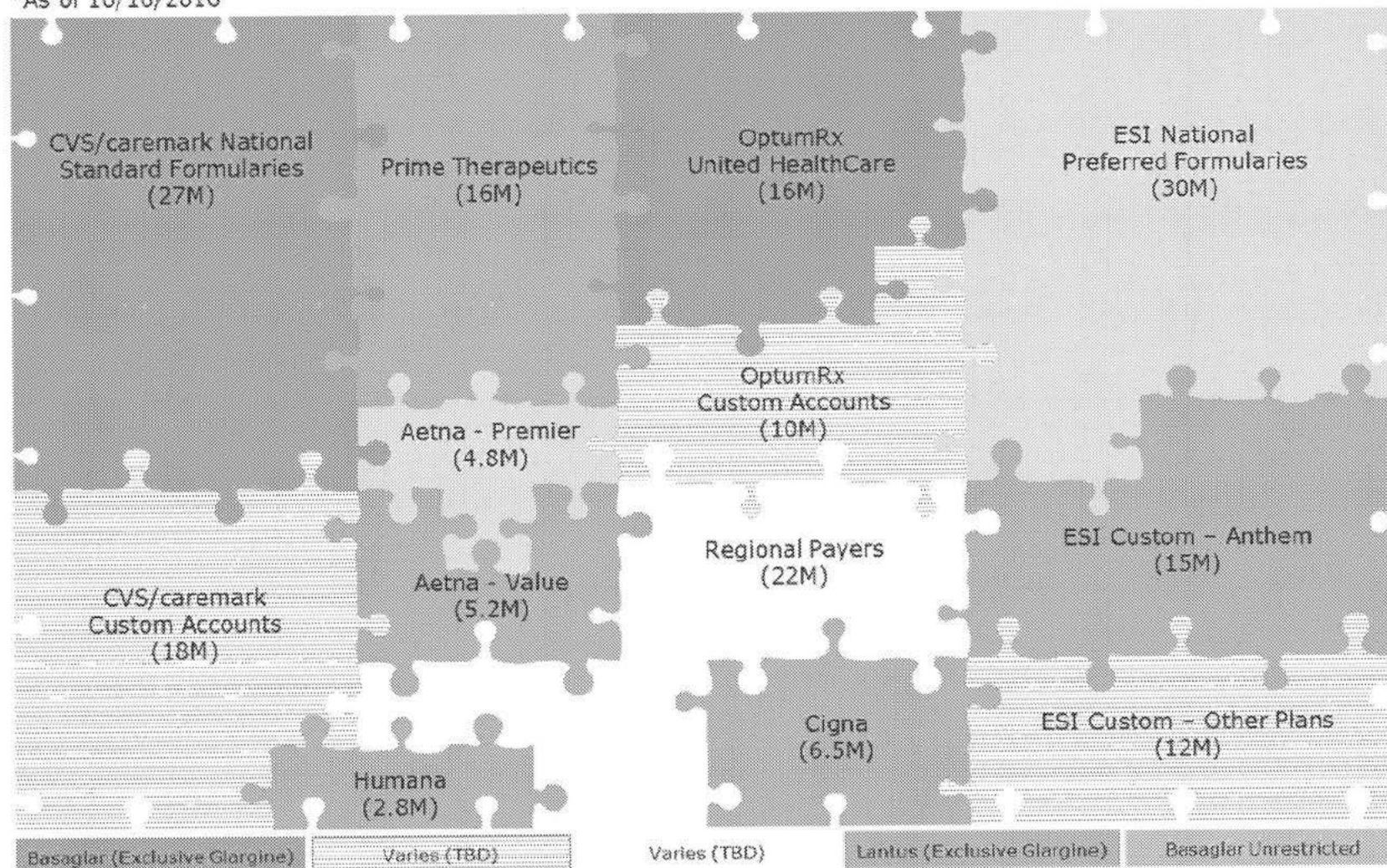
*As of 10/25/2016



Basaglar 2017 Access Picture*

Commercial Managed Care

*As of 10/18/2016



| NDC | Brand Name | Generic Name | Strength | Dosage Form | Package Size | Unit | WAC Effective Date* | WAC Package Price |
|---------------|------------------------|---|---------------------|-----------------------------|--------------|-------------|---------------------|-------------------|
| 00002-7510-01 | HUMALOG | insulin lispro | 100 unit/mL | VIAL (ML) | 10 | milliliters | 05/02/2017 | \$274.70 |
| | | | | | | | 07/13/2016 | \$254.80 |
| | | | | | | | 12/01/2015 | \$237.00 |
| | | | | | | | 05/29/2015 | \$222.70 |
| | | | | | | | 11/25/2014 | \$202.60 |
| | | | | | | | 06/05/2014 | \$184.30 |
| | | | | | | | 12/12/2013 | \$167.70 |
| 00002-7510-17 | HUMALOG | insulin lispro | 100 unit/mL | VIAL (ML) | 3 | milliliters | 05/02/2017 | \$82.41 |
| | | | | | | | 07/13/2016 | \$76.44 |
| | | | | | | | 12/01/2015 | \$71.10 |
| | | | | | | | 05/29/2015 | \$66.81 |
| | | | | | | | 11/25/2014 | \$60.78 |
| | | | | | | | 06/05/2014 | \$55.29 |
| | | | | | | | 12/12/2013 | \$50.31 |
| 00002-7511-01 | HUMALOG MIX 75-25 | insulin lispro protamine and insulin lispro | 100 unit/mL (75-25) | VIAL (ML) | 10 | milliliters | 05/02/2017 | \$284.70 |
| | | | | | | | 07/13/2016 | \$264.10 |
| | | | | | | | 12/01/2015 | \$245.60 |
| | | | | | | | 05/29/2015 | \$230.80 |
| | | | | | | | 11/25/2014 | \$209.99 |
| | | | | | | | 06/05/2014 | \$191.00 |
| | | | | | | | 12/12/2013 | \$173.75 |
| 00002-7512-01 | HUMALOG MIX 50-50 | insulin lispro protamine and insulin lispro | 100 unit/mL (50-50) | VIAL (ML) | 10 | milliliters | 05/02/2017 | \$284.70 |
| | | | | | | | 07/13/2016 | \$264.10 |
| | | | | | | | 12/01/2015 | \$245.60 |
| | | | | | | | 05/29/2015 | \$230.80 |
| | | | | | | | 11/25/2014 | \$209.99 |
| | | | | | | | 06/05/2014 | \$191.00 |
| | | | | | | | 12/12/2013 | \$173.75 |
| 00002-7516-59 | HUMALOG | insulin lispro | 100 unit/mL | CARTRIDGE (ML) | 15 | milliliters | 05/02/2017 | \$510.45 |
| | | | | | | | 07/13/2016 | \$473.50 |
| | | | | | | | 12/01/2015 | \$440.40 |
| | | | | | | | 05/29/2015 | \$414.00 |
| | | | | | | | 11/25/2014 | \$376.65 |
| | | | | | | | 06/05/2014 | \$342.60 |
| | | | | | | | 12/12/2013 | \$311.75 |
| 00002-7712-27 | HUMALOG KWIKPEN U-200 | insulin lispro | 200 unit/mL (3 mL) | INSULIN PEN (ML) | 6 | milliliters | 05/02/2017 | \$424.32 |
| | | | | | | | 07/13/2016 | \$393.60 |
| | | | | | | | 12/01/2015 | \$366.12 |
| | | | | | | | 07/23/2015 | \$344.16 |
| 00002-7714-59 | HUMALOG JUNIOR KWIKPEN | insulin lispro | 100 unit/mL | INSULIN PEN, HALF-UNIT (ML) | 15 | milliliters | 08/14/2017 | \$530.40 |
| 00002-7715-59 | BASAGLAR KWIKPEN U-100 | insulin glargine,human recombinant analog | 100 unit/mL (3 mL) | INSULIN PEN (ML) | 15 | milliliters | 12/15/2017 | \$326.36 |
| | | | | | | | 11/17/2016 | \$316.85 |
| 00002-8215-01 | HUMULIN R | insulin regular, human | 100 unit/mL | VIAL (ML) | 10 | milliliters | 05/02/2017 | \$148.70 |
| | | | | | | | 07/13/2016 | \$137.90 |
| | | | | | | | 12/01/2015 | \$128.30 |
| | | | | | | | 05/29/2015 | \$120.60 |
| | | | | | | | 11/25/2014 | \$109.70 |
| | | | | | | | 06/05/2014 | \$99.80 |
| | | | | | | | 12/12/2013 | \$90.80 |
| 00002-8215-17 | HUMULIN R | insulin regular, human | 100 unit/mL | VIAL (ML) | 3 | milliliters | 05/02/2017 | \$44.61 |
| | | | | | | | 07/13/2016 | \$41.37 |
| | | | | | | | 12/01/2015 | \$38.49 |
| | | | | | | | 05/29/2015 | \$36.18 |
| | | | | | | | 11/25/2014 | \$32.91 |
| | | | | | | | 06/05/2014 | \$29.94 |
| | | | | | | | 12/12/2013 | \$27.24 |
| 00002-8315-01 | HUMULIN N | insulin NPH human isophane | 100 unit/mL | VIAL (ML) | 10 | milliliters | 05/02/2017 | \$148.70 |
| | | | | | | | 07/13/2016 | \$137.90 |
| | | | | | | | 12/01/2015 | \$128.30 |
| | | | | | | | 05/29/2015 | \$120.60 |

| NDC | Brand Name | Generic Name | Strength | Dosage Form | Package Size | Unit | WAC Effective Date* | WAC Package Price |
|---------------|---------------------------|---|----------------------------|------------------|--------------|-------------|---------------------|-------------------|
| 00002-8315-17 | HUMULIN N | insulin NPH human isophane | 100 unit/mL | VIAL (ML) | 3 | milliliters | 11/25/2014 | \$109.70 |
| | | | | | | | 06/05/2014 | \$99.80 |
| | | | | | | | 12/12/2013 | \$90.80 |
| | | | | | | | 05/02/2017 | \$44.61 |
| | | | | | | | 07/13/2016 | \$41.37 |
| | | | | | | | 12/01/2015 | \$38.49 |
| | | | | | | | 05/29/2015 | \$36.18 |
| | | | | | | | 11/25/2014 | \$32.91 |
| | | | | | | | 06/05/2014 | \$29.94 |
| 00002-8501-01 | HUMULIN R U-500 | insulin regular, human | 500 unit/mL (Concentrated) | VIAL (ML) | 20 | milliliters | 12/12/2013 | \$27.24 |
| | | | | | | | 05/02/2017 | \$1,487.00 |
| | | | | | | | 07/13/2016 | \$1,379.00 |
| | | | | | | | 12/01/2015 | \$1,283.00 |
| | | | | | | | 05/29/2015 | \$1,206.00 |
| | | | | | | | 11/25/2014 | \$1,097.00 |
| | | | | | | | 06/05/2014 | \$998.00 |
| | | | | | | | 12/12/2013 | \$908.00 |
| | | | | | | | 05/02/2017 | \$148.70 |
| 00002-8715-01 | HUMULIN 70-30 | insulin NPH human isophane/insulin regular, human | 100 unit/mL (70-30) | VIAL (ML) | 10 | milliliters | 07/13/2016 | \$137.90 |
| | | | | | | | 12/01/2015 | \$128.30 |
| | | | | | | | 05/29/2015 | \$120.60 |
| | | | | | | | 11/25/2014 | \$109.70 |
| | | | | | | | 06/05/2014 | \$99.80 |
| | | | | | | | 12/12/2013 | \$90.80 |
| | | | | | | | 05/02/2017 | \$44.61 |
| | | | | | | | 07/13/2016 | \$41.37 |
| | | | | | | | 12/01/2015 | \$38.49 |
| 00002-8715-17 | HUMULIN 70-30 | insulin NPH human isophane/insulin regular, human | 100 unit/mL (70-30) | VIAL (ML) | 3 | milliliters | 05/29/2015 | \$36.18 |
| | | | | | | | 11/25/2014 | \$32.91 |
| | | | | | | | 06/05/2014 | \$29.94 |
| | | | | | | | 12/12/2013 | \$27.24 |
| | | | | | | | 05/02/2017 | \$530.40 |
| | | | | | | | 07/13/2016 | \$492.00 |
| | | | | | | | 12/01/2015 | \$457.65 |
| | | | | | | | 05/29/2015 | \$430.20 |
| | | | | | | | 11/25/2014 | \$391.50 |
| 00002-8797-59 | HUMALOG MIX 75-25 KWIKPEN | insulin lispro protamine and insulin lispro | 100 unit/mL (75-25) | INSULIN PEN (ML) | 15 | milliliters | 06/05/2014 | \$356.10 |
| | | | | | | | 12/12/2013 | \$323.95 |
| | | | | | | | 05/02/2017 | \$530.40 |
| | | | | | | | 07/13/2016 | \$492.00 |
| | | | | | | | 12/01/2015 | \$457.65 |
| | | | | | | | 05/29/2015 | \$430.20 |
| | | | | | | | 11/25/2014 | \$391.50 |
| | | | | | | | 06/05/2014 | \$356.10 |
| | | | | | | | 12/12/2013 | \$323.95 |
| 00002-8798-59 | HUMALOG MIX 50-50 KWIKPEN | insulin lispro protamine and insulin lispro | 100 unit/mL (50-50) | INSULIN PEN (ML) | 15 | milliliters | 05/02/2017 | \$530.40 |
| | | | | | | | 07/13/2016 | \$492.00 |
| | | | | | | | 12/01/2015 | \$457.65 |
| | | | | | | | 05/29/2015 | \$430.20 |
| | | | | | | | 11/25/2014 | \$391.50 |
| | | | | | | | 06/05/2014 | \$356.10 |
| | | | | | | | 12/12/2013 | \$323.95 |
| | | | | | | | 05/02/2017 | \$530.40 |
| | | | | | | | 07/13/2016 | \$492.00 |
| 00002-8799-59 | HUMALOG KWIKPEN U-100 | insulin lispro | 100 unit/mL | INSULIN PEN (ML) | 15 | milliliters | 12/01/2015 | \$457.65 |
| | | | | | | | 05/29/2015 | \$430.20 |
| | | | | | | | 11/25/2014 | \$391.50 |
| | | | | | | | 06/05/2014 | \$356.10 |
| | | | | | | | 12/12/2013 | \$323.95 |
| | | | | | | | 05/02/2017 | \$530.40 |
| | | | | | | | 07/13/2016 | \$492.00 |
| | | | | | | | 12/01/2015 | \$457.65 |
| | | | | | | | 05/29/2015 | \$430.20 |
| 00002-8803-59 | HUMULIN 70/30 KWIKPEN | insulin NPH human isophane/insulin regular, human | 100 unit/mL (70-30) | INSULIN PEN (ML) | 15 | milliliters | 11/25/2014 | \$347.83 |
| | | | | | | | 06/05/2014 | \$316.50 |
| | | | | | | | 01/13/2014 | \$288.00 |
| | | | | | | | 05/02/2017 | \$471.30 |
| | | | | | | | 07/13/2016 | \$437.25 |
| | | | | | | | 12/01/2015 | \$406.80 |
| | | | | | | | 05/29/2015 | \$382.35 |
| | | | | | | | 11/25/2014 | \$347.83 |
| | | | | | | | 06/05/2014 | \$316.50 |
| | | | | | | | 05/02/2017 | \$471.30 |
| | | | | | | | 07/13/2016 | \$437.25 |
| | | | | | | | 12/01/2015 | \$406.80 |
| | | | | | | | 05/29/2015 | \$382.35 |
| | | | | | | | 11/25/2014 | \$347.83 |
| | | | | | | | 06/05/2014 | \$316.50 |
| | | | | | | | 01/13/2014 | \$288.00 |
| | | | | | | | 05/02/2017 | \$471.30 |
| | | | | | | | 07/13/2016 | \$437.25 |

| NDC | Brand Name | Generic Name | Strength | Dosage Form | Package Size | Unit | WAC Effective Date* | WAC Package Price |
|---------------|-------------------------|----------------------------|-----------------------------------|------------------|--------------|-------------|---------------------|-------------------|
| 00002-8805-59 | HUMULIN N KWIKPEN | insulin NPH human isophane | 100 unit/mL (3 mL) | INSULIN PEN (ML) | 15 | milliliters | 07/13/2016 | \$437.25 |
| | | | | | | | 12/01/2015 | \$406.80 |
| | | | | | | | 05/29/2015 | \$382.35 |
| | | | | | | | 11/25/2014 | \$347.83 |
| | | | | | | | 06/05/2014 | \$316.50 |
| | | | | | | | 01/13/2014 | \$288.00 |
| 00002-8824-27 | HUMULIN R U-500 KWIKPEN | insulin regular, human | 500 unit/mL (3 mL) (concentrated) | INSULIN PEN (ML) | 6 | milliliters | 05/02/2017 | \$574.20 |
| | | | | | | | 07/13/2016 | \$532.58 |
| | | | | | | | 03/28/2016 | \$495.50 |

*The WAC Effective Date represents the price effective date reported by Lilly to the drug information database First Databank.

Lilly USA, LLC
Basaglar Shipment Dollars and Units by NDC
March 2019

| Year | NDC-11 | NDC-11 Description | Gross Sales | SKU Quantity | Active Ingredient Units |
|-------------|-------------------------------------|--------------------------------------|-----------------|--------------|----------------------------|
| 2016 | 00002-7715-59 | BASAGLAR U80 KWIKPEN 100UMLX5PEND AM | \$41,298,402 | 134,472 | 201,708,000 |
| | Total Gross Sales Dollars and Units | | \$41,298,402 | 134,472 | 201,708,000 |
| | Total Net Sales Dollars | | \$15,818,122 | | |
| 2017 | 00002-7715-59 | BASAGLAR U80 KWIKPEN 100UMLX5PEND AM | \$744,066,485 | 2,343,376 | 3,515,064,000 |
| | Total Gross Sales Dollars and Units | | \$744,066,485 | 2,343,376 | 3,515,064,000 |
| | Total Net Sales Dollars | | \$310,495,688 | | |
| 2018 | 00002-7715-59 | BASAGLAR U80 KWIKPEN 100UMLX5PEND AM | \$1,874,621,011 | 5,743,327 | 8,614,990,500 |
| | Total Gross Sales Dollars and Units | | \$1,874,621,011 | 5,743,327 | 8,614,990,500 |
| | Total Net Sales Dollars | | \$622,860,850 | | |
| Grand Total | Total Gross Sales Dollars and Units | | \$2,659,985,898 | 8,221,175 | 12,331,762,500 |
| | Total Net Sales Dollars | | \$949,174,660 | | |