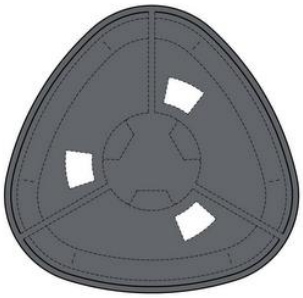
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



**TRADEMARK:**

**SERIAL NO.:** 87/838,079

**FILING DATE:** March 16, 2018

**APPLICANT:** Eli Lilly and Company

**EXAMINING ATTORNEY:** Dominic Ferraiuolo

**LAW OFFICE:** 102

**DECLARATION OF TORI BROWN**
**IN SUPPORT OF RESPONSE TO JUNE 15, 2018, OFFICE ACTION**

I, Tori Brown, pursuant to 28 U.S.C. § 1746, hereby declare the following:

**My Background**

1. I obtained a Bachelor's of Science in Civil Engineering from Purdue University and an MBA from the University of Minnesota. I have worked at Eli Lilly and Company ("Lilly") since 2005 in a wide range of roles. Since November 2012, I have been intimately involved in overseeing the sales, advertising and marketing of a pharmaceutical preparation for the treatment of diabetes that is marketed under the brand name Trulicity (the "Treatment"). Currently, I am the Brand Leader for Trulicity at Lilly. Prior to my current position, from November 2012 to February 2015, I worked as the Brand Manager for Trulicity. In that position, I spearheaded the brand strategy and was closely involved in the launch of the Treatment. As a result, I believe that I am well-qualified to provide information on the sales, advertising, and

marketing of the Treatment and Lilly's use of the above-referenced mark (the "Mark"). I submit this declaration in support of the application to register the Mark that is used in connection with the Treatment.

**Lilly and its History of Innovations in Diabetes Treatments**

2. Since its founding in 1876, Lilly has grown into one of the largest and most successful pharmaceutical companies in the world. Headquartered in Indianapolis, it employs more than 14,000 people in the United States and approximately 33,000 people worldwide. Lilly develops and sells treatments for a wide variety of fields, including diabetes, oncology, immunology, neuroscience and men's health. In 2017, it had global revenues of more than $22.8 billion, more than $12.7 billion of which were from the United States.

3. For almost 100 years, Lilly has been an innovator in the treatment of diabetes. In 1922, Lilly and the University of Toronto began a collaboration to prepare insulin commercially. Lilly research chemist George Walden was instrumental in the development of a pure, stable form of insulin as well as a method for extracting and producing it in large quantities. Thus, Lilly became the first company to manufacture this life-saving medicine on a large scale — making it widely available to people who needed it to control their diabetes.

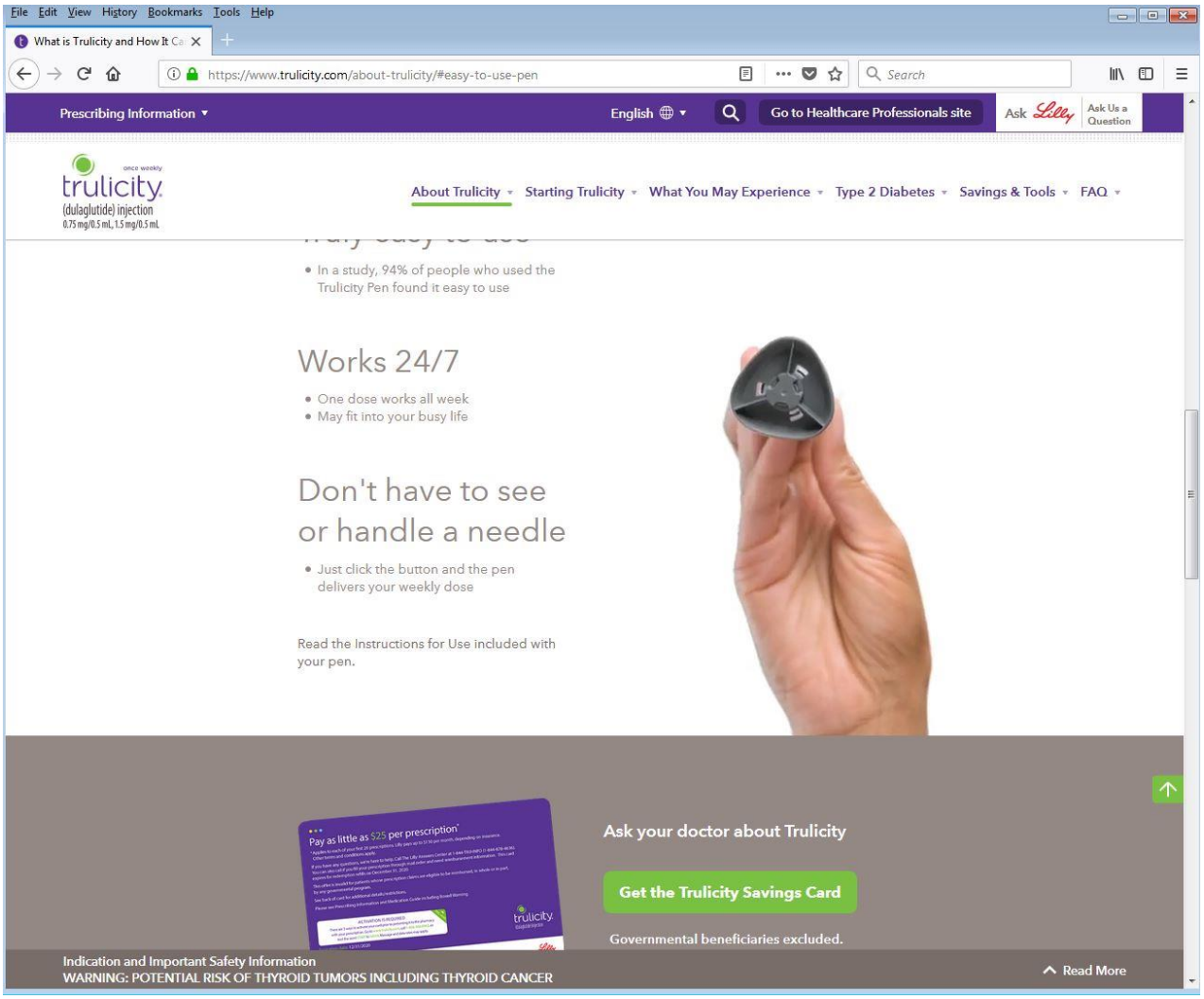
4. Lilly's more recent innovations in this field include the first biosynthetic "human" insulin with recombinant DNA technology in 1982; and the first rapid-acting insulin analog in 1996. In short, Lilly has been a pioneer in treatments for diabetes for nearly a century, and it continues to be an influential leader in the field. In July 2018, for example, the *Indianapolis Business Journal* recognized that diabetes is Lilly's "oldest and perhaps most famous franchise," and that at present, "all eyes in the diabetes community" are on its Treatment. *See* Exhibit 1.

## Background of Lilly's Treatment

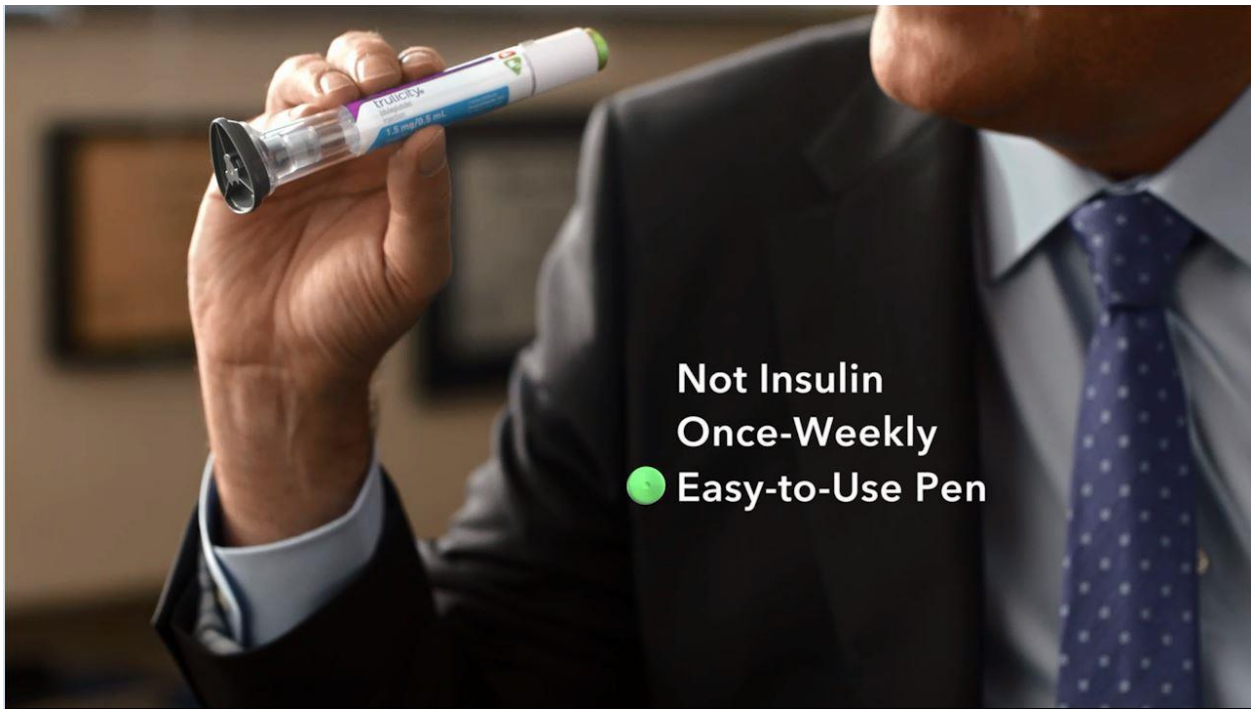
5. Lilly's tradition of innovation in the diabetes field continues to this day and is embodied in the Treatment. The active ingredient in the Treatment, dulaglutide, is a type of medicine called a glucagon-like peptide-1 receptor agonist, or GLP-1 RA for short. Lilly started to use the Mark in clinical trials for the Treatment in the United States in June 2014. Upon obtaining FDA approval, in November 2014, Lilly began to offer the Treatment in the United States in an easy-to-use, once a week, single-dose automatic injector device featuring a trilobular-shaped base cap, the unique appearance of which is the Mark.

## Lilly's Emphasis on the Mark

6. Lilly's advertising and promotion of the Treatment has included significant efforts to focus customer and potential customer attention on the Mark. This implicit look-for advertising has helped to alert the public not only to the existence of the Mark in relation to the Treatment, but also to build an awareness that the Mark's design and color (Pantone 10 C Cool Gray) collectively are distinctive. For example, Lilly has drawn attention to the Mark through an interactive graphic on its website at <trulicity.com/about-trulicity>, which has shown and continues to show, when activated, first the top of the device and then the following image of the Mark:




7. Lilly has also prominently featured images of the Mark in its national television advertisements for its Treatment since the year 2015. Below are screen shots from three separate television advertisements for the Treatment that have aired in the United States in just the years 2017 and 2018 (two in English and one in Spanish). These screen shots show the actors in each ad prominently displaying the Mark:


Not Insulin
Once-Weekly
Easy-to-Use Pen


Not Insulin
Once-Weekly


This type of extensive and focused advertising leads people to notice the Mark and recognize its distinctive design and color.

**Lilly's Sales of the Treatment**

8. Since its introduction in the United States in 2014, the Treatment has become increasingly popular. U.S. sales of the Treatment have increased every year, and have totaled in excess of $4 billion, as shown below:

| Year | Net Sales Revenue in the U.S. |
|---|---|
| 2014 | In excess of $10 million |
| 2015 | In excess of $207 million |
| 2016 | In excess of $737 million |
| 2017 | In excess of $1.6 billion |
| 2018 | Expected to exceed 2017 Net Sales Revenue |

9. Lilly's Treatment is used by millions of Americans, as reflected by the number of prescriptions:

| Year | Prescriptions for the Treatment in the U.S. |
|---|---|
| 2014–2015 | In excess of 380,000 |
| 2016 | In excess of 1,490,000 |
| 2017 | In excess of 3,170,000 |
| 2018 (through Nov. 2018) | In excess of 4,420,000 |

10. Sales of Lilly's Treatment currently comprise approximately 44 percent of the GLP-1 class of products in the United States. Since May 2018 and through today, Lilly's Treatment has been the market leading type 2 diabetes treatment of its kind in the United States.

11. *The Motley Fool* investment service recently reported that the Treatment is projected to be the top-selling diabetes drug in the world by 2024. *See* Exhibit 2.

**Lilly's Marketing and Advertising Efforts for The Treatment**

12. Lilly has invested tens of millions of dollars to market and advertise the Treatment in the United States since 2014. The specific amounts Lilly has spent to advertise and market the Treatment are confidential and, therefore, I cannot reveal them with any more specificity here in this public document.

13. Lilly advertises the Treatment to consumers through four primary means: television commercials, Internet banner advertising, Internet video commercials, and print advertising.

14. Television commercials, which have been featured on all four major networks and cable networks including A&E, AMC, CNBC, CNN, Discovery Channel, Hallmark Channel, Lifetime, TBS, and TNT, and which have aired during popular shows such as CBS Sunday

Morning and NFL football games, have been a significant focus for Lilly in its efforts to advertise and market the Treatment. For example, as cited in a recent article in *The New England Journal of Medicine* (*see* Exhibit 3), in 2017 the Treatment was one of the top 10 most advertised pharmaceutical products as per total expenditures in the United States.

15. Lilly also has an active social media marketing campaign for the Treatment. For example, Lilly maintains an active Facebook page dedicated to the Treatment which features video advertising depicting the Treatment, including images of the Mark. *See* Exhibit 4.

16. Additionally, Lilly's advertising for the Treatment has included a cover wrap for *Good Housekeeping* magazine and other print ads in popular magazines such as *AARP*, *Family Circle*, *Popular Mechanics*, *Reader's Digest* and *Woman's Day*.

17. Lilly also developed a mobile application that promoted the Treatment by showing visual depictions of it, including the Mark. That app eventually was discontinued because growing familiarity with the Treatment among patients and healthcare professionals made it unnecessary.

**Lilly's Direct Sales Team for its Treatment Has Established Goodwill in the Mark**

18. Lilly has a large team of sales representatives working across the United States focused on promoting the Treatment. Since 2014, Lilly has employed approximately 1,300 sales representatives in the United States whose responsibilities include the Treatment. These representatives visit approximately eight physician offices a day and work approximately 48 weeks a year.

19. Since 2014, this sales force has made approximately 9.98 million visits to physician's offices. When a sales representative visits a physician's office, he or she encourages the physicians, physicians' assistants, nurse practitioners, and other members of the medical

office to view and handle a promotional version of the Treatment (shown below) which displays the Mark but does not contain the active ingredient or a needle:


20. Lilly's sales representatives have, in-person, provided more than 600,000 of these promotional devices displaying the Mark to physician's offices, and have explained those devices to physicians and their staffs. This effort has naturally drawn considerable attention to the Mark.

21. Once this promotional device is left at the office, it can thereafter be used by a physician, nurse, or other members of the physician's medical staff to familiarize themselves further with the Treatment, and to in turn inform patients about the Treatment. This type of promotional device is an important means of promoting and explaining the Treatment, especially as access to any prescription pharmaceutical is restricted and the actual medicine must be handled with care. As a consequence, this device directly promotes the Mark in an intimate and stress-free manner. This promotional device does not wear out and can be used repeatedly to highlight its features while building up brand awareness for the Mark.

22. The Lilly sales representatives also leave behind patient education brochures for the Treatment. These can be provided directly to patients by a physician, nurse, or a physician's staff, or they can be placed in a waiting room for a patient to pick up on their own. Lilly has distributed more than two million of these brochures in both English and Spanish.

**Lilly's Attendance at Conferences Promotes the Treatment and Shows the Mark**

23. For several years, Lilly has attended conferences at which it discusses and displays the Treatment. Tens of thousands of physicians and other health care professionals have attended these conferences. For example, Lilly exhibits at the American Diabetes Association Scientific Sessions annual meeting, the American Association of Clinical Endocrinologists' (AACE) national annual meeting, and AACE's regional conferences. At these conferences (which often provide an opportunity for companies such as Lilly to have an exhibit booth), attendees are encouraged by Lilly representatives to interact with the above-referenced promotional version of the Treatment, which shows the Mark. *See* Exhibit 5.

24. Lilly also attends other conferences related to health care, such as the 2016 Barclays Global Healthcare Conference in Miami. At this conference, then Lilly CFO Derica Rice was interviewed about the Treatment and other topics. *See* Exhibit 6.

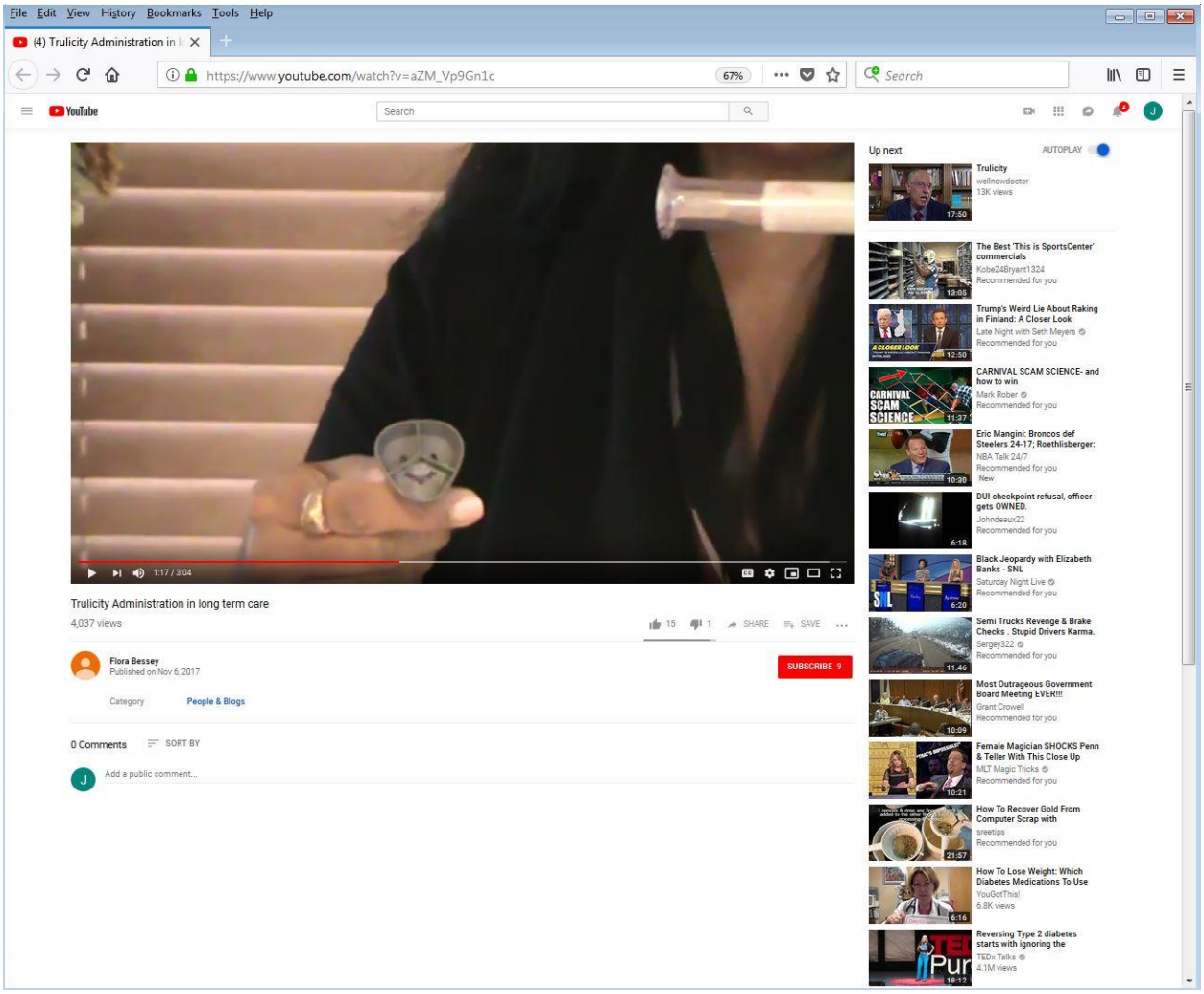
**Unsolicited Media Coverage and Customer Videos**

25. As a market leader in the field of diabetes, Lilly's introduction of the Treatment was immediately the subject of significant customer attention and media coverage. For instance, *The New York Times* reported on FDA approval of the Treatment in September 2014. *See* Exhibit 7.

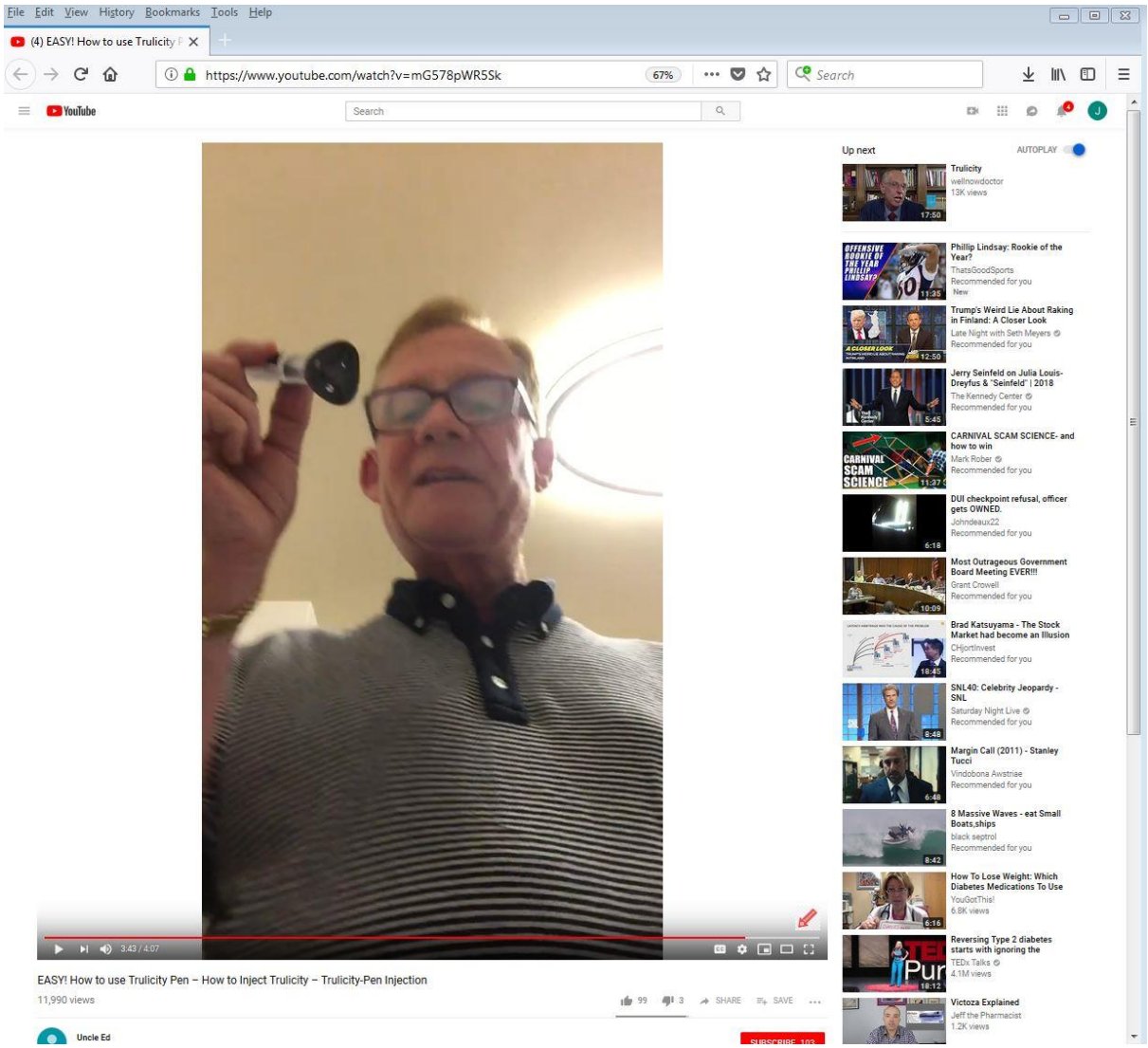
26. The FDA approval and Lilly's launch of the Treatment in the U.S. market was also widely reported in other general news sources across the country, such as the *Boston Globe* and the *Palo Alto Daily Post*, as well as publications focused on diabetes such as *Diabetes Week* and *diaTribe*. *See* Exhibit 8.

27. In addition to traditional news sources, users of the Treatment have posted numerous videos on YouTube describing the device and demonstrating how it works. These videos, which were created and posted without any request or support from Lilly, have

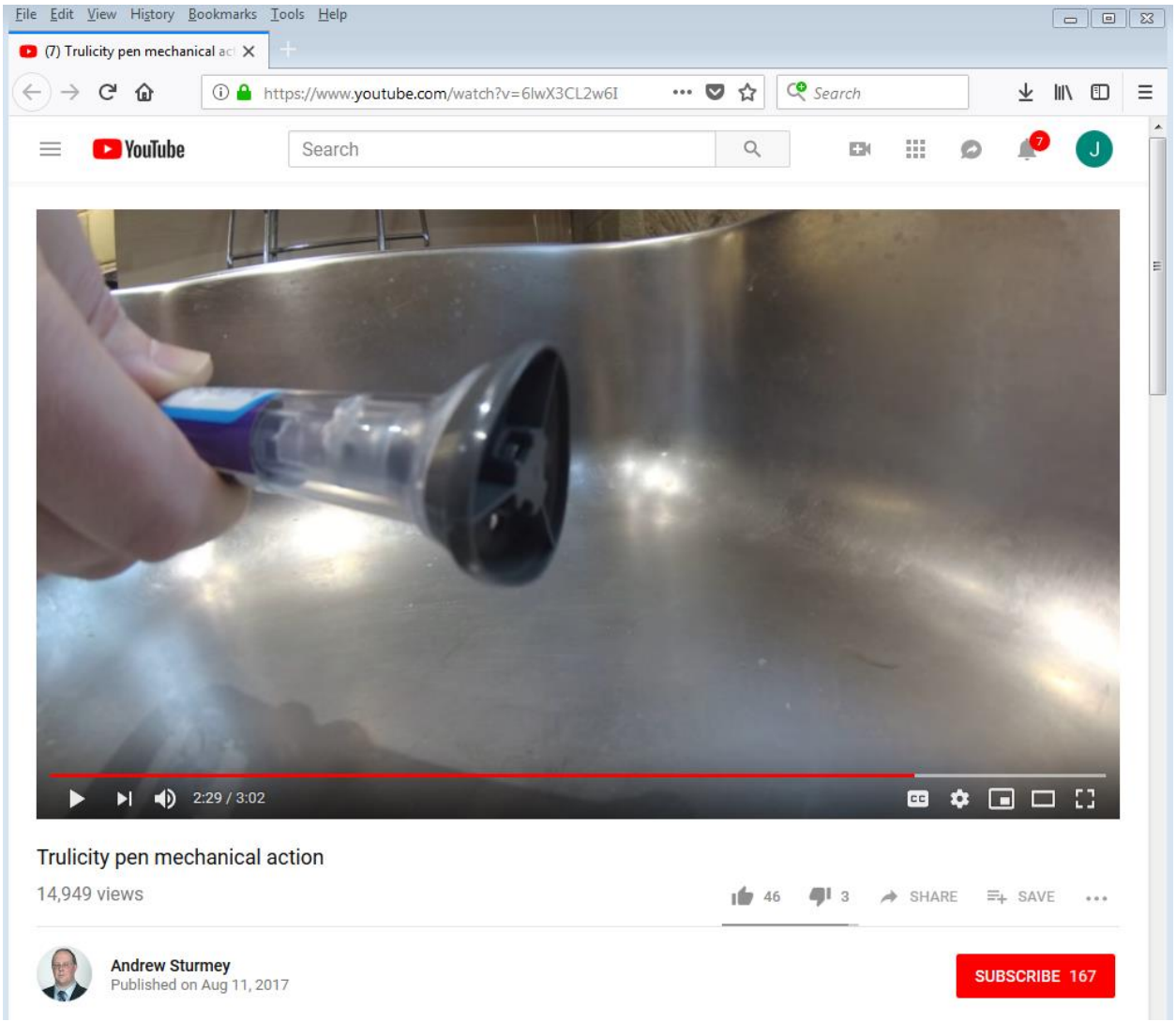
generated nearly 60,000 views and show off the Mark's unique design. Below are screen shots from and links to a sample of three such videos:




https://www.youtube.com/watch?v=aZM_Vp9Gn1c




https://www.youtube.com/watch?v=mG578pWR5Sk




https://www.youtube.com/watch?v=6lwX3CL2w6I&t=2s

## Conclusion

28. Lilly's above-referenced extensive marketing, advertising, and sales efforts have brought significant attention to the Mark and its unique design and color.

29. Lilly's Mark, as used in connection with the Treatment, has become recognizable and distinctive.

30. The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements and the like may jeopardize the validity of Lilly's application and any registration resulting therefrom, declares that all statements made of her own knowledge are true; and all statements made on information and belief are believed to be true.

Executed in Indianapolis, Indiana, on December 17th, 2018.

Tori Brown

# EXHIBIT 1

## BROWN DECLARATION

IBJ.com
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Home

# All eyes on Lilly's fast-growing diabetes drug, Trulicity

John Russell
July 30, 2018

Diabetes is a huge business for Eli Lilly and Co. The company's six major diabetes medicines rang up more than $2 billion in worldwide sales last year and are expected to exceed $4 billion by 2020.

And for the next few months, all eyes in the diabetes community will be on one of those drugs, Trulicity, a popular, once-weekly injectable that is catching on fast with patients and doctors.

Since it was launched in 2014, Trulicity has made a name for itself by causing some patients to lose weight by slowing down how quickly food leaves the stomach and suppressing appetite.

In the first six months of 2018, Trulicity reaped $1.46 billion in sales, up 71 percent from a year ago. The Motley Fool predicts that Trulicity will be the No. 1 top-selling diabetes drug in the world by 2024, with annual sales of $4.6 billion.

Later this year, the Indianapolis-based drugmaker is expected to release data on a late-stage clinical trial designed to study whether Trulicity can reduce heart attacks and other "major cardiovascular events" in patients with type 2 diabetes.

The trial is called REWIND--short for Researching Cardiovascular Events With a Weekly Incretin in Diabetes. The clinical tests are wrapping up this month, and Lilly says it will release summary data in the fourth quarter and detailed data at the American Diabetes Association's conference next summer.

The stakes are high for Lilly. Diabetes is its oldest and perhaps most famous franchise. The company was the first to mass produce insulin in the 1920s. The company is now trying to increase its dominance in the $10 billion diabetes drug market.

Some analysts say the trial results could give a huge boost to Trulicity if successful.

"Trulicity is one of Lilly's largest assets," Louise Chen, an analyst at Cantor Fitzgerald, wrote in a note July 17. She said she has been talking to doctors about likely outcomes of the REWIND trial and feels optimistic the results will be good for patients—and for Lilly.

"Based on our calls, most of the physicians expect a positive outcome for REWIND," she wrote. "This could increase [prescriptions] by 20-30% or by multiples of current sales, which leads us to believe that significant upside remains in the drug, if the doctors are right."

But some analysts are less confident, noting that Danish pharmaceutical company Novo Nordisk is developing a drug in the same class, called semaglutide (or sema, for short) that has shown good early clinical results.

"We would expect sema to be a fairly formidable competitor to Trulicity and slow down the growth of what we see as Lilly's most important product," wrote Vamil Divan, an analyst with Credit Suisse.

And some other analysts are coming down somewhere in the middle.

"We see REWIND as a 50/50 event that could limit Trulicity's long-term prospects" (if unsuccessful), wrote BMO Capital Markets analyst Alex Arfaei.

# EXHIBIT 2

## BROWN DECLARATION

# 5 Biggest Blockbuster Diabetes Drugs of the Future

The diabetes market is growing rapidly. These drugs -- and drugmakers -- should be the biggest winners.

Keith Speights (TMFFishBiz)
Jun 24, 2018 at 6:31AM

Forty-six billion dollars. That's a big number -- and it's how much was made worldwide from selling diabetes drugs in 2017.

You can count on that total growing over the next several years, as more people are being diagnosed with diabetes at alarming rates. And now, more powerful drugs are being developed. All of this makes the diabetes market an intriguing opportunity for investors.

Market research firm EvaluatePharma recently ranked what it projects will be the top diabetes drugs of 2024. **Novo Nordisk**'s (NYSE:NVO) products dominate the list, although **Eli Lilly** (NYSE:LLY) and privately held Boehringer Ingelheim placed highly, as well. Here are the top five biggest blockbuster diabetes drugs of the future, according to EvaluatePharma.


IMAGE SOURCE: GETTY IMAGES.



AUTHOR

Keith Speights (TMFFishBiz)

Keith began writing for the Fool in 2012 and focuses primarily on healthcare investing topics. His background includes serving in management and consulting for the healthcare technology, health insurance, medical device, and pharmacy benefits management industries.

Follow @keithspeights

ARTICLE INFO

Jun 24, 2018 at 6:31AM

Health Care

STOCKS

Eli Lilly and C...
NYSE:LLY

**1. Trulicity**
Eli Lilly's Trulicity is projected to be the No. 1 top-selling diabetes drug in the world by 2024. EvaluatePharma thinks the drug will rake in annual sales of $4.6 billion and claim a market share of 7.8%.

Trulicity is a glucagon-like peptide 1 (GLP-1) receptor agonist that helps the body release insulin more effectively. The drug won Food and Drug Administration (FDA) approval in 2014 for treating type 2 diabetes. Sales for Trulicity totaled more than $2 billion last year, with a global market share of 4.4%.

**2. Ozempic**
Lilly will need to watch out: Novo Nordisk will be breathing down its neck with its own GLP-1 receptor agonist, Ozempic. EvaluatePharma expects Ozempic will make $4.4 billion in sales in 2024, giving Novo's drug a 7.4% market share.

Ozempic also ranked second on another EvaluatePharma list -- the biggest new drug launches of 2018. Novo Nordisk won FDA approval of the drug in treating type 2 diabetes in December 2017, but the full launch of Ozempic began this year. The drug got off to a decent start in Q1, with Novo reporting sales for Ozempic of 69 million Danish krone ($11 million as of May 7, 2018).



**3. Jardiance**
Boehringer Ingelheim and Lilly co-market Jardiance, which is projected to be the No. 3 best-selling diabetes drug in the world in 2024. The drug is expected to generate sales that year of $3.5 billion and capture 5.9% of the worldwide diabetes drug market.

Jardiance is the most successful of several sodium glucose co-transport (SGLT) 2 inhibitors. It won FDA approval in 2014 for treating type 2 diabetes and secured another approval in 2016 for reducing cardiovascular death in adults with type 2 diabetes. The drug made a little over $1.1 billion last year, with Lilly's portion of sales totaling close to $448 million.

**4. Tresiba**
Novo Nordisk's second product in the top five is insulin analog Tresiba. EvaluatePharma thinks

$114.64 $0.30 (0.26%)

**Novo Nordisk**
NYSE:NVO
$46.09 $0.08 (0.17%)

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4 Reasons to Be Wary of This Animal Health IPO

that Tresiba will generate revenue of nearly $3.4 billion in 2024, with a market share of 5.7%.

Tresiba first won FDA approval in 2015 for use by adults with diabetes and gained an additional approval the following year for treatment of children and adolescents with diabetes. Novo Nordisk notched sales of $1.1 billion for the insulin product in 2017 and claimed a market share of 2.4%.



**5. NovoRapid**

Only one of the top five best-selling diabetes drugs of the future is expected to experience a decrease in sales. Novo Nordisk's insulin analog NovoRapid likely will see its market share slip from 6.6% in 2017 to 4.3% in 2024. However, the product should still bring in more than $2.5 billion.

After years on the market, key patents for NovoRapid expired in 2014. Novo Nordisk recorded sales of around $3 billion for the product last year. While sales will slip, the decline will be a relatively mild and gradual one.

**Investing opportunities?**

With these diabetes drugs on track to rack up billions of dollars in sales in the coming years, are Lilly and Novo Nordisk great stocks to buy right now? Maybe.

If you're looking for income, either of these stocks will probably look pretty good. Lilly's dividend yield stands at 2.6%, while Novo's yield is nearly 2.9%.

The growth scenario is murkier. Both companies have promising new drugs and pipelines, but both also are weighed down by headwinds for older drugs. My view is that Novo Nordisk could be in better shape over the long run, especially if clinical studies for an oral version of Ozempic are successful.

splitter

*Keith Speights has no position in any of the stocks mentioned. The Motley Fool recommends Novo Nordisk. The Motley Fool has a disclosure policy.*

# EXHIBIT 3

## BROWN DECLARATION

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

# Disclosing Prescription-Drug Prices in Advertisements — Legal and Public Health Issues

Stacie B. Dusetzina, Ph.D., and Michelle M. Mello, J.D., Ph.D.

On October 15, 2018, the Centers for Medicare and Medicaid Services (CMS) proposed a rule requiring television advertisements for prescription drugs and biologic products to disclose the product's price.[1] The advertisements must state in legible text the wholesale acquisition cost (WAC) for a 30-day supply or a typical course of treatment.

The rulemaking follows an unsuccessful effort in Congress to include a similar measure in the fiscal year 2019 appropriations bill. The idea enjoys broad public support — in a June 2018 poll, 76% of Americans favored requiring drug advertisements to include a statement about how much the drug costs[2] — and it dovetails with moves to improve price transparency in other health care domains. But we think the proposed rule raises substantial public health and legal concerns.

Direct-to-consumer advertising is a natural target for regulation because it stimulates demand for expensive, brand-name drugs when there may be less-expensive generic drugs with similar efficacy and side-effect profiles already available, thus increasing the provision of cost-ineffective care.[3] Yet such advertising could also stimulate undertreated patients to seek medical attention and effective therapies. For example, of the 14% of people in the same poll who reported speaking with their doctor about a specific medication after hearing or seeing an advertisement, the majority (55%) received a prescription for the advertised product, but respondents also said that providers recommended other prescription drugs (54%), over-the-counter drugs (41%), or lifestyle changes (54%).[2]

The CMS proposal reflects a desire to preserve the potential benefits of direct-to-consumer advertising while curbing its ill effects. However, a potential unintended consequence of price disclosure may be to dissuade patients from seeking care because of the perception that they cannot afford treatment. For example, Trulicity (dulaglutide), a widely advertised drug for type 2 diabetes, has a WAC (or list price) of $730 per month. Patients who could benefit from diabetes treatment may assume that they cannot afford it, when in fact insured patients' costs for Trulicity may be much lower, and cheaper treatment options are available (metformin, for instance, costs $4 per month for patients who pay cash). Consequently, the proposal carries a risk of undercutting the main public health benefit of direct-to-consumer advertising: reducing rates of undertreatment.

That CMS chose the WAC as the figure that must be disclosed makes this risk especially acute. The WAC is a good estimate of

what uninsured patients can expect to pay, and deductibles and coinsurance are commonly based on a drug's WAC. However, this price is typically much higher than what insured patients pay. For example, 1 month of treatment with the anticoagulant Eliquis (apixaban) has a list price of $419, but out-of-pocket prices range from $10 for commercially insured patients using the manufacturer's copayment card to $147 for Medicare beneficiaries in the Part D coverage gap (see table). Although CMS will require a statement noting, "If you have health insurance that covers drugs, your cost may be different," this wording doesn't communicate that costs to patients are probably much lower than the WAC.

CMS used the WAC for several reasons. List prices matter for many patients, and having to disclose list prices creates incentives not to raise them. Moreover, it is impracticable to state what patients will actually pay because of variation in insurance design and coverage and the fact that rebates and discounts may not be determined when advertisements are made.

The rule's use of list prices also has important legal implications. Disagreement about whether the WAC accurately represents a drug's price could affect how courts assess the rule when constitutional challenges are inevitably filed.

Compelled disclosures in advertising impinge oncommercial speech rights protected by the First Amendment. However, courts apply a deferential standard of review known as the *Zauderer* standard in challenges to disclosures of "purely factual and uncontroversial" information relating to an advertiser's products or services. Although CMS characterizes its requirement as falling squarely within *Zauderer*, there is a strong argument to the contrary.

Courts applying *Zauderer* have taken a narrow view of what constitutes a factual, uncontroversial disclosure. For example, the Ninth Circuit Court of Appeals, reviewing a required warning that drinking sugary beverages contributes to obesity, diabetes, and tooth decay, held that because the disclosure did not state that overconsumption of beverages was the problem, it was "misleading and, in that sense, untrue."[4] Similarly, the WAC is not a factually accurate representation of what a drug costs for most patients, and the

**Prices for a 30-Day Supply or Typical Course of Treatment for the Top 10 Pharmaceutical Brands According to National Television Advertising Expenditures in 2017.***

| Brand Name | Generic Name | Indication | Quantity and Dose | WAC ($)† | Price for Patients Paying Cash ($)‡ | Out-of-Pocket Prices for Medicare Beneficiaries ($)§ |
|---|---|---|---|---|---|---|
| Humira | Adalimumab | Rheumatoid and psoriatic arthritis | Two 40-mg/0.8 ml pens | 4,872.03 | 4,846.48 | 259.00–1,544.00 |
| Lyrica | Pregabalin | Nerve pain | Ninety 75-mg capsules | 668.84 | 656.54 | 74.00–198.00 |
| Xeljanz | Tofacitinib | Rheumatoid and psoriatic arthritis | Sixty 5-mg tablets | 4,095.64 | 4,075.52 | 220.00–1,350.00 |
| Trulicity | Dulaglutide | Type 2 diabetes | Four 1.5-mg/0.5 ml pens | 730.20 | 632.06 | 74.00–223.00 |
| Eliquis | Apixaban | Anticoagulation | Sixty 5-mg tablets | 419.03 | 424.65 | 74.00–147.00 |
| Keytruda | Pembrolizumab | Cancer | Three 50-mg vials | 4,649.64 | 6,710.52 | 0.00–1,480.53 |
| Xarelto | Rivaroxaban | Anticoagulation | Thirty 20-mg tablets | 419.07 | 424.68 | 74.00–146.00 |
| Taltz | Ixekizumab | Plaque psoriasis and psoriatic arthritis | One 80-mg/ml autoinjector | 5,161.60 | 5,134.02 | 317.00–1,660.00 |
| Breo | Fluticasone and vilanterol | Chronic obstructive pulmonary disease | Sixty 100-μg/25 μg blister strips | 341.04 | 346.95 | 74.00–141.00 |
| Cosentyx | Secukinumab | Psoriatic arthritis | Two 150-mg/ml Sensoready pens | 4,712.38 | 4,687.95 | 260.00–1,500.00 |

* Data were obtained from FiercePharma. The Quantity and Dose column indicates the monthly or typical supply for indications listed.
† Data were obtained from IBM Micromedex. WAC denotes wholesale acquisition cost.
‡ Data were obtained from GoodRx.com.
§ Data were obtained using the Medicare Part D Plan Finder for ZIP code 37205 (Nashville) for patients on traditional Medicare without subsidies. Because Part D requires patients to pay different amounts as they transition across benefit phases, we identified the most and least expensive monthly prescription-fill prices for the patient on the lowest-cost plan. For Keytruda, covered under Medicare Part B, we used the 2018 average sales price for a typical dose. We assumed that patients with supplemental Part B coverage would pay nothing and those without it would pay 20% coinsurance, the standard level for Part B services.

disclosure omits key information. This fact sets it apart from other fee disclosures that have survived legal challenges, such as the basis for calculating attorney fees and the amount of interest charged on loans.

If a compelled disclosure doesn't qualify for *Zauderer* review, courts will apply heightened scrutiny. The most likely standard, *Central Hudson*, asks whether the government has a substantial interest that is directly and materially advanced by the speech restriction and whether the restriction is narrowly tailored to achieving that goal. Although the disclosure rule is narrowly tailored to the government's substantial interest in reducing unreasonable expenditures by CMS programs, it probably doesn't satisfy the material-advancement requirement. Courts have required the government to provide evidence that a required disclosure will effectively address the problem it targets. Graphic warning labels on cigarettes, for example, were struck down because the government's regulatory-impact analysis suggested that they would reduce the U.S. smoking rate by only 0.088%.[5] CMS offered no evidence of the likely effects of the proposed drug advertising price disclosure rule, noting only that it "may" improve consumer decision making but could also create confusion and that CMS could not quantify these effects.[1]

Three aspects of the rule undercut the government's ability to argue that it will materially improve patient decision making and reduce drug spending. First, price information does little to inform consumer decisions if it inaccurately represents actual cost. Second, consumers can already obtain information on cash prices (which usually approximate list prices) online and their own cost from their insurer. CMS could argue that disclosing the WAC may advance the agency's interest in reducing Medicare and Medicaid spending in another way: by shaming companies into lowering list prices. But since Medicare and Medicaid don't pay list prices, this outcome seems implausible.

Third, the rule contains no meaningful enforcement mechanism — CMS plans only to list violators on its website — calling into question whether companies will comply. CMS believes that the main lever for inducing compliance will be private litigation: competitors can sue violators under the Lanham Act, which prohibits false or misleading representations in advertising or promotion. But such suits are not a robust means of enforcement. Omissions don't qualify as falsities under the law unless they create an erroneous belief among consumers. What false belief arises from not stating a product's price? Furthermore, the competitor must show that the falsity caused it to lose sales — a challenging task, since patients and prescribers may prefer one drug over another for various reasons.

Despite the problems associated with requiring disclosure of list prices, the sentiment behind the proposed rule — that patients should know how much drugs will cost before they fill their prescriptions — is sensible. The question is how best to achieve that outcome. Just before the CMS rule was announced, the main trade organization of the pharmaceutical industry, PhRMA, released its own guidelines for voluntary disclosure of the costs of advertised medicines. It proposes that advertisements direct patients to a website where the company provides information about list price as well as "average, estimated, or typical patient out-of-pocket costs." This information is more useful than the WAC alone, but "typical" out-of-pocket costs don't convey the variation in what patients pay.

We think that a better alternative would be making patient-specific cost information accessible at the point of prescribing. Some electronic health records systems now offer this feature, but it is unclear how often prescribers use it. We think that cost should become a routine part of prescribing discussions with patients, although time constraints could make it difficult to have such conversations. Providing salient cost information at the right time could help reduce drug spending while preserving patient choice, but we believe that direct-to-consumer advertising is the wrong vehicle.

Disclosure forms provided by the authors are available at NEJM.org.

From the Department of Health Policy, Vanderbilt University School of Medicine, Nashville (S.B.D.); and Stanford Law School and the Department of Health Research and Policy, Stanford University School of Medicine — both in Stanford, CA (M.M.M.).

This article was published on November 14, 2018, at NEJM.org.

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# EXHIBIT 4

## BROWN DECLARATION

Once-weekly Trulicity® (dulag

https://www.facebook.com/TrulicityUS/

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**Once-weekly Trulicity® (dulaglutide)**
June 5 ·

Welcome to our Facebook page! For a full list of our ground rules, please check out our Community Guidelines at http://elil.ly/2tf5, and check out a few highlights below to best engage with us and the community:

**Community Guidelines:**

- We welcome and encourage your participation in this Trulicity community, which is intended for U.S. audiences over 18 years of age.
- Comments and other material not posted by Lilly don't necessarily reflect our views or opinions; nor do we guarantee their accuracy or reliability.
- While we encourage open conversation, healthcare is a sensitive issue and we may deem some questions inappropriate for response in a public online forum. If that is the case, we'll guide you on how best to get in

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Monday - Friday. Depending on the nature of the question, we may ask to address certain questions via Direct Message.

- Accounts that we may follow or that follow us do not indicate our endorsement of the account or content posted on the account.
- Our posts are informational only and should not be viewed as professional or medical advice. Always consult your physician with any questions you may have regarding your healthcare or treatment.
- We will do our best to respond to your questions as quickly as we can.



once weekly trulicity (dulaglutide) injection 0.75 mg/0.5 mL, 1.5 mg/0.5 mL

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**Once-weekly Trulicity® (dulaglutide)**

December 4 at 11:36 AM ·

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Safety Information
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INDICATION AND LIMITATIONS OF USE
Trulicity is a once-weekly injectable prescription medicine to improve blood sugar (glucose) in adults with type 2 diabetes mellitus. It should be used along with diet and exercise. Trulicity is not recommended as the first medication to treat diabetes. It has not been studied in people who have had inflammation of the pancreas (pancreatitis). Trulicity should not be used by people with type 1 diabetes, people with diabetic ketoacidosis, or people with a history of severe gastrointestinal (GI) disease. It is not a substitute for insulin. It has not been studied in children under 18 years of age.
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3

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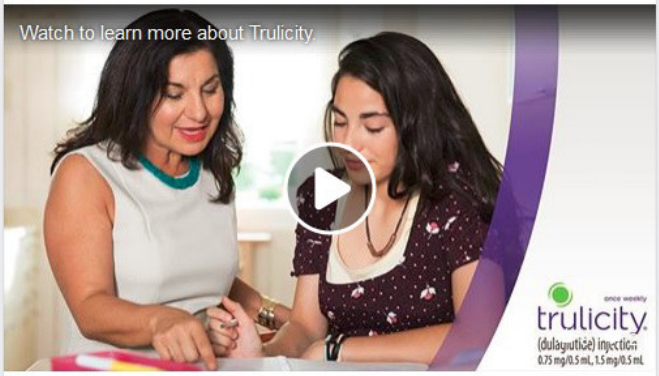


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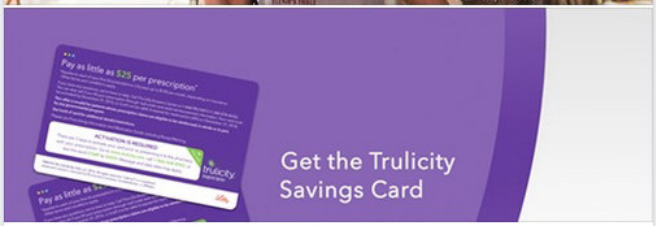


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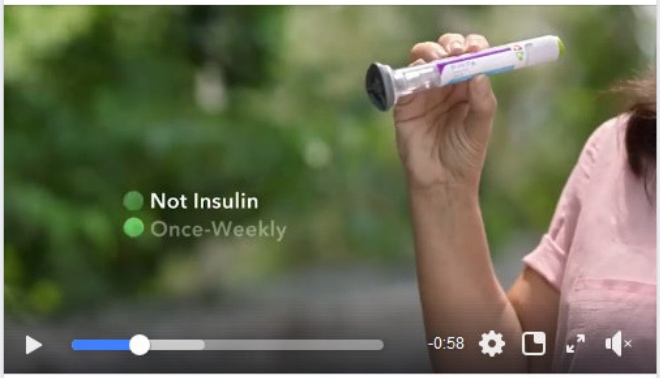


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**Sarah Dillon** I hate Trulicity! I hate the way it makes me feel. I haven't lost any weight and my sugar is so out of whack because even the thought of food sends me running to the bathroom.

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# EXHIBIT 5

## BROWN DECLARATION

# Benzinga: Lilly to Present New Clinical Data at 75th American Diabetes Association Scientific Sessions

**Publication info:** Weblog post. Newstex Finance & Accounting Blogs , Chatham: Newstex. May 27, 2015.



## FULL TEXT

New clinical data demonstrating the range of treatment options represented in Lilly's (NYSE: LLY) diabetes portfolio will be presented in 79 abstracts on June 5-9, at the 75th American Diabetes Association (ADA)(R) Scientific Sessions in Boston. These presentations reflect Lilly's efforts to enhance scientific knowledge and improve current approaches to diabetes management. Thirty-five of the abstracts will be presented as part of the Boehringer Ingelheim-Lilly Diabetes alliance.

"The Scientific Sessions are an important opportunity for researchers and healthcare and industry professionals to come together and share learnings and advances in diabetes care," said David Kendall, M.D., vice president of Medical Affairs, Lilly Diabetes. "We look forward to communicating significant new data that showcase the full range of our diabetes portfolio."

Among the data being presented at this year's Scientific Sessions are:

Basal Insulin Peglispro Lilly will share new efficacy and safety data for its investigational basal insulin peglispro (BIL), including two late-breaking abstracts and the first data presentations from the seven Phase III IMAGINE trials in patients with type 1 and type 2 diabetes. A total of 19 abstracts will be presented, including three oral presentations:

Saturday, June 6, 1:45 to 3:45 p.m., "Basal Insulin Analogs: New Evidence" Oral Session 1:45 p.m.: Basal Insulin Peglispro (BIL) is Superior to Insulin Glargine (GL) in Reducing HbA1c at 52 Weeks in Insulin-Naïve T2D Patients (Pts) Treated with Oral Antihyperglycemic Medications (OAMs): IMAGINE 2 (Lead author: M.J. Davies) [Presentation No. 93-OR] 2 p.m.: Reduced Intra-subject Variability of Basal Insulin Peglispro (BIL) Compared to Insulin Glargine in Patients with Type 1 Diabetes Mellitus (T1DM) (Lead author: T. Heise) [Presentation No. 94-OR] 2:15 p.m.: Greater HbA1c Reduction with Basal Insulin Peglispro (BIL) v Insulin Glargine (GL) in an Open-label, Randomized Study in T1D Patients (pts): IMAGINE 1 (Lead author: S. K. Garg) [Presentation No. 95-OR] Additional data showing BIL's effect on hypoglycemia, liver enzymes and lipids will also be presented.

Trulicity™ (dulaglutide) Lilly will present nine abstracts for Trulicity, a once-weekly, glucagon-like peptide-1 receptor agonist (GLP-1 RA) injectable prescription medication to improve blood sugar in adults with type 2 diabetes along with diet and exercise. Among these presentations are new data comparing the safety and efficacy of Trulicity to other common diabetes medicines in multinational patient populations, and a meta-analysis showing no increased risk of cardiovascular events in patients taking Trulicity. Select presentations are as follows:

Saturday, June 6, 11:30 a.m. to 1:30 p.m., General Poster Session Efficacy and Safety of Once-weekly Dulaglutide versus Once-daily Liraglutide in Japanese Patients with Type 2 Diabetes (Lead author: T. Takamura) [Poster No. 1111-P] Once Weekly Dulaglutide Does Not Increase the Risk for CV Events in Type 2 Diabetes: A Pre-Specified CV Meta-Analysis of Prospectively Adjudicated CV Events (Lead author: K.C. Ferdinand) [Poster No. 1127-P]

Monday, June 8, 8 a.m. to 10 a.m., "Update on GLP-1 Receptor Agonists" Oral Session Efficacy and Safety of Once-Weekly Dulaglutide vs. Insulin Glargine in Combination with Metformin and/or a Sulfonylurea in Predominantly

Asian Patients with Type 2 Diabetes (Lead author: W. Wang) [Presentation No. 280-OR] For more information on presentations, please click here.


Credit: Eddie Staley

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# EXHIBIT 6

## BROWN DECLARATION

# Eli Lilly and Co at Barclays Global Healthcare Conference - Final

**Publication info:** Fair Disclosure Wire ; Linthicum [Linthicum]16 Mar 2016.



## FULL TEXT

Presentation

GEOFFREY MEACHAM, ANALYST, BARCLAYS: It's our pleasure to have a fireside chat with Derica Rice, who's CFO of Lilly, and Ilissa Rassner from the IR team at Lilly. Welcome, guys.

DERICA RICE, CFO, ELI LILLY AND COMPANY: Thank you for having us.

Questions and Answers

GEOFFREY MEACHAM: Let's kick it off with kind of the news of yesterday. I said it earlier, maybe we'll chop the questions at 10 minutes (multiple speakers).

DERICA RICE: You want to get this out of the way.

GEOFFREY MEACHAM: Yes.

DERICA RICE: Okay.

GEOFFREY MEACHAM: Walk us through kind of the decision yesterday on sola with respect to the endpoint regarding what went into the decision. Kind of was there any evaluation of ongoing data, regulatory input, things like that?

DERICA RICE: Let me try to maybe summarize quickly also just what we did, but also many of the questions that we've gotten over the last 24 hours or so.

One, when we made the decision to change the primary endpoint, it really was based upon what we saw as emerging science. And that science was predicated on seeing that cognition truly did proceed and served as a predictor of functional decline.

So this was based upon both us continuing to mine and analyze our EXPEDITION 1 and 2 data, as well as also looking and relying on many of the external publications that were coming to light, many of which emerged in 2015.

That being said, we did discuss this change with the FDA prior to making it. Of course they're not going to comment one way or the other in terms of confirmation that they will absolutely accept the submission, or review

and approval on that basis.

They have been clear that they still expect to see both cognition and functional data, for which we will continue to have both. For us, we know that cognition continues to precede and predict and there is a delay.

It does not represent any change to the way that we are conducting our clinical trial, so that has not changed at all. We still expect and anticipate last patient visits being some time in the October timeframe of this year, for which we have database lock and look to have a top line release. And so for us, it really, is us trying to just keep pace with the emerging science as we see it.

GEOFFREY MEACHAM: And there was no change to the statistical plans of the study, just as aside from the weight of the (multiple speakers).

DERICA RICE: Correct. So there's no hit to the P-value, the required P-value as a result of this change. Mathematically, it does enhance the probability based upon the single endpoint versus a co-primary endpoint.

GEOFFREY MEACHAM: And there was no analysis of blinded ongoing data that went in as an input to this. It's just Lilly's evaluation of the signs that with -- as it's on a continuum.

DERICA RICE: We continue to be completely blinded to the data, so we've had no new data, no new insights to the data itself.

GEOFFREY MEACHAM: When you think about the opportunity from a bigger picture in Alzheimer's, I think one of the companies in this space, ViaGen, has talked about the looking at prodromal or mild patients, the utilization of imaging is obviously going to be helpful, but it's typically pre-symptomatic effective disease.

So how is Lilly thinking about the use of imaging tools to help sort of broaden the population and raise awareness, obviously getting ahead of the sola data.

DERICA RICE: We've done a number of things in this space. We had an opportunity in December of last year at our investor meeting in Boston to really do a deep dive in terms of Lilly's presence in neuro degeneration. And at that meeting, and I think we were able to share that, we have a presence that's far greater and broader than just our play in solanezumab. So it's possible that if solanezumab?is successful, we can have at least seven to eight distinct molecules and clinical stage testing by the end of this year.

Now that breadth spans both us pursuing the amyloid plaque hypothesis, both with a beta in terms of solanezumab. It also includes our imaging agent, Amyvid. But likewise, we also have both a Tau therapeutic in development, as well as a Tau imaging agent.

And in EXPEDITION 3 trial alone, we not only have solanezumab, we're also using our Amyvid diagnostic agent. And at the same time, we're also using our Tau tracer. It is possible, and we'll have to wait to see if the data plays out this way, can you use the Tau tracer as well as a surrogate signal for monitoring or tracking the progression of the disease itself? So there are a number of different angles that we're taking in this space.

GEOFFREY MEACHAM: Derica, from a regulatory standpoint, the FDA and EMEA has placed weight on cognitive endpoints as well as functional endpoints. How has that sort of evolved over time and maybe answer that in the context of your most recent change to the study.

DERICA RICE: Both if you talk to the experts and the clinicians, everyone would agree that cognition precedes and predicts function. And there is that delay. And I think it also has become more widely recognized that in mild Alzheimer's patients, or early stage Alzheimer's disease patients, it's difficult to access functionality. Likewise, the FDA themselves has come here as of late and also has made similar statements.

In their references, in their statements, they're primarily referencing prodromal patients. So earlier than the mild Alzheimer's patients, but nonetheless, drawing the same inferences.

GEOFFREY MEACHAM: Derica, at your Boston Alzheimer's update, you did highlight a number of assets that are also alternative potentially to sola if EXPEDITION 3 ends up not working out. But among those, which, at least at this point, do you or your scientific team think of as potentially most promising among the various non sola assets that you highlighted?

DERICA RICE: Well recall after sola we still have our collaboration with AstraZeneca in terms of the AZD base. We have our own backup base, or what we call base 4. In addition to that, we have our own N3pG compound. And then as I highlighted earlier, we have our own Tau, both diagnostic, but also our Tau therapeutic.

So again, by the end of this year, we could have seven to eight molecules in the clinic alone in the space of Alzheimer's disease. So we believe it's one of the broadest in the industry.

GEOFFREY MEACHAM: Let's switch gears to immunology, first with ixekizumab?and then we'll move on to baricitinib. Maybe help us with kind of the next leg of growth through immunology of franchise. How you view ixe in the context of product differentiation. Maybe also in the context of Novartis having success in first line psoriasis with COSENTYX, what that means for you guys.

DERICA RICE: We're very excited about our opportunity to begin to play in the autoimmune space. If we look at ixekizumab in the area of psoriasis, one, we were very excited about the phase 3 results where we saw a patient, at least 30% to 40% of the patients achieve 100% clearance in terms of their psoriasis plaque.

When we look at how that differentiates versus a COSENTYX, we think we've got greater clearance. We also saw that in the administration of ixekizumab, a patient on ixe may endure about 17 injections per year versus about 32 injections per year for COSENTYX. And based upon our research with both clinicians and with patients, that is viewed as also being quite meaningful. So we think we can separate in that space.

As it pertains to baricitinib, and of course for ixekizumab?we are awaiting FDA action any day. For baricitinib, we submitted the application earlier this year in January. I would estimate that if you take the 2 plus 10, it'll probably be sometime -- we look for FDA action by sometime early 2017.

Again, in this space, we're very excited about the data itself where we were able to achieve superiority versus HUMIRA. We also believe we have a relatively clean side effect profile, definitely versus TOFA or XELJANZ. And then likewise, with the oral administration, we believe we have commercially the opportunity to move all therapeutic administration before TNF use. So we think we can change potentially the treatment algorithm. And therefore, have the opportunity to go after our fair share of new patient starts prior to TNF usage.

Obviously, clearly there is always the opportunity to have the TNF refractory patients or after TNF use. But we think we can go earlier and some could even argue with the fact that we also demonstrated superiority versus

methotrexate, why couldn't baricitinib?be used prior to methotrexate as well?

GEOFFREY MEACHAM: In the context of baricitinib, you have for XELJANZ obviously not as competitive a clinical profile. But how is the marketing strategy going to evolve to sort of get rheumatologists used to prescribing oral therapy and make that a more mainstream or upfront kind of standard right now? When we speak with physician, they're obviously very impressed with the data given superiority over HUMIRA. But there still is kind in the back of their mind, well is this mechanism as potent? Is this another little bit better version of XELJANZ? Like what are the marketing challenges?

DERICA RICE: I think one, in our go-to-market strategy we're not anticipating that there's going to be a massive switching of existing patients off of -- currently reasonably controlled -- off of anti-TNF, onto baricitinib. We know that patients, once they start, they tend to cycle through medications, especially anti-TNF. And once they have been -- they've exhausted that, they can't go back to that same anti-TNF. So if they're properly controlled today, they'll stay on the drug. Again, we think we can go after our fair share of those new patient starts that are still anti-TNF naive.

As it relates to kind of our strategy versus XELJANZ, one, we will have both the structural data at time of launch, which XELJANZ did not. And likewise, I think we'll pursue a different pricing strategy than XELJANZ did. I think they priced at a slight premium because they knew they would only be utilized in the refractory setting.

So we think there is the opportunity for us to, based upon our clinical differentiation, to position commercially baricitinib?differently than XELJANZ was able to.

GEOFFREY MEACHAM: And for both ixe and for baricitinib?, and psoriasis and RA, the paradigm's evolving with regard to biosimilars launch in a few years. It's not clear as to exactly when, but how much of an input is the potential for biosimilars to come in the relatively intermediate to longer term? How much of an input is that when you guys think about your pricing and positioning strategy?

DERICA RICE: We've always anticipated that there will be biosimilars somewhere in the life of an ixe or a bari. And so when we were putting together and assembling our clinical development plan, we based that upon our ability to clinically differentiate. So can we create differential clinical outcomes? And if we can't, then why would someone use our branded drug versus a semi generic or biosimilar that may be much lower priced?

The fact that we were able to achieve that clinical differentiation versus the gold standard in the case of bari versus HUMIRA, even if there was a biosimilar version of HUMIRA, that clinical differentiation still exists. So that is probably the greatest leverage we have with the payers and with the clinicians in that type of biosimilar setting.

GEOFFREY MEACHAM: And then in that context, does it make sense to run another superiority trial to have that a formal claim? Or do you feel like having the BEAM study on the bari label will be enough?

DERICA RICE: You mean versus a biosimilar?

GEOFFREY MEACHAM: Correct.

DERICA RICE: But we do not anticipate running an additional study against a biosimilar once it emerges. We think that the data that we have versus HUMIRA will be sufficient.

GEOFFREY MEACHAM: Beyond psoriasis and RA, there -- TNF and the inflammatory spaces, it's still seen some very rapid growth, particularly in GI diseases. So what is the approach? With these two assets, are there other things in the pipeline that you feel like are particularly attractive?

DERICA RICE: We both have additional indications that we may pursue with both bari and ixe. And then likewise, if you look at our phase 2 portfolio, we have a very interesting asset molecule called IL-23, which has shown some very interesting results in terms of the GI effect. So we think, again, we have a number of opportunities to enter that space as well. And continue to build-out our total presence in the autoimmune area.

GEOFFREY MEACHAM: In the case of bari, I believe ectopic dermatitis was one opportunity. Lupus another. What are some of the data sets that we could expect, say in the next 12 to 24 months, just with regard to a proof of concept?

ILISSA RASSNER, IR, LILLY AND COMPANY: We haven't shared the actual specifics from a data disclosure perspective yet for the phase 3 study. In fact, we actually just announced that we'll be starting those two studies this year. So I would look for those at a later point in time. Certainly when we have more specifics to share, we'll do so.

GEOFFREY MEACHAM: Switching gears to the diabetes space. So obviously with Jardiance expected to have robust growth this year, what would you imagine as the sort of tipping point? Is this sort of a guidelines label change, kind of slow and steady in terms of getting the acceleration and broader use of say the SGLT 2 class?

DERICA RICE: Well a couple of observations. One, when we look at our Jardiance performance, it's been performing very consistent with our internal expectations. Now we realize that our internal expectations may differ a bit from maybe what the investment community was anticipating, given the robustness of the CV data itself.

Recall that we submitted the CV data earlier this year. We wouldn't anticipate the possibility of having that in our label until the latter of Q4 this year, probably late Q4. And then in all likelihood, we wouldn't anticipate that there will be any update to the treatment guidelines until that data also was in the label. So we see that as the most likely next potential for inflection point and the uptake curve of Jardiance.

If you look within the SGLT 2 space, we clearly saw an inflection on the time we announced the data. And Jardiance continues to be on that type of trajectory. Within the SGLT 2 class, today we're capturing about 30% new to brand share within the endo setting. And we're capturing about 20% of the new to brand share in the PCP setting.

GEOFFREY MEACHAM: Staying on the topic of diabetes, so last fall we had EMPA-REG as the first diabetes study with a positive CV outcome. And then just recently in the past few weeks, your competitor, Novo Nordisk, announced positive top line results for the GLP 1 LEADER study. Could you maybe comment on how you think that will affect the GLP-1 class probably over the near-term? And then provide us an update on your development plans with respect to CV outcomes for your GLP-1 in Trulicity.

DERICA RICE: First and foremost, I think it's very encouraging, not only for the class, but really for the type 2 diabetic patient that now you've had two type 2 diabetes medicines that have read out providing a CV benefit, which hadn't been seen before and no one really anticipated.

I think in the case of Victoza and the LEADER trial, we found that to be also particularly very encouraging for

Trulicity. Recall that for Trulicity we have our own CV outcome study that's underway. We will have an interim readout for the Trulicity study in late Q4 this year or very early Q1 of next year. And that our trial is actually powered to demonstrate superiority.

I think for the Victoza LEADER study, one, we haven't seen the data itself yet, just the top line release, but it was powered I think for non inferiority or to do no harm. And I think due to them having more events than anticipated, that they were able to achieve superiority.

So we're quite encouraged, but we can't say that it's a class effect as of yet until we actually see the data of the other specific molecules, including Trulicity, and likewise that's the same thing we've said for Jardiance in terms of it's CV benefit versus other molecules in the SGLT-2 class.

GEOFFREY MEACHAM: And thinking more broadly in diabetes from a pricing perspective, obviously that's been a hot topic in the US at least, and you have the demonstration project that's coming out with regard to comparability in lower ASPs. How would you rank diabetes in the scheme of a lot of the major therapeutic areas that Lilly participates in vis-a-vis oncology or others in terms of sustainability of pricing, the ability to continue to moderately raise prices going forward.

DERICA RICE: When we look at the diabetes space, clearly there were some moments of in our history of intense competition, both if you go back and look at 2012 and 2014 in the mealtime insulin space, where both ESI and CVS came out in their contracting and said we will only carry one mealtime insulin on formulary.

And you probably saw both us and Novo giving much higher level of rebates than we had historically. Subsequent to that, we really haven't seen a lot of aggressive behavior on the part of the payers or the PBMs themselves. I think one, the realizations they've seen is that for those areas of chronic medicines, it's not so easy to switch patients every two to three to four years. That's quite difficult for those patients that rely on chronic therapies. And so I think that's also helped lead to stability subsequent to that.

If you look at our mealtime insulin, Humalog, over the last five years, we've essentially had flat pricing, flat net realized price. I think on a compounded annual growth rate, I think it's increased about 1%. So we've seen stability. Now we haven't seen huge price appreciation, but likewise, we haven't seen significant net price deterioration as well. It's almost been stable.

When I look in the other areas within diabetes, whether it's the SGLT 2 class or now with the GLPs, we have very good formulary access. I can't speak for our competitors, but at least for products like Trulicity or Jardiance, we have vey good formulary access and you've seen how having that formulary access contributes to the significance of the uptake curve.

And that's most well noted if you look at the uptake curve of Trulicity, where in the early month of launch, before we have full formulary access, we entertained a lot of questions from many in the investment community of saying hey, what's happening to the Trulicity launch? It seems we're somewhat muted.

Once we got full formulary access, you really saw that brand begin to take off and we clearly are the leader in terms of share gain in that segment, as well as probably the leader in growth overall within the type 2 diabetes segment. Period.

GEOFFREY MEACHAM: Let's switch gears to oncology. When you look at the Alimta franchise, clearly you guys

have talked about a potential generic in Europe and the US. That's a little bit longer term. And Alimta and both cell genes (inaudible) have really faced competition from IO agents in the past, say 12 months or so. How should we think about the durability of Alimta and the optionality with potentially having maybe more of an upfront combo with IO having, I mean actually kind of a longer term driver?

DERICA RICE: There's no doubt that the IOs have had an impact across the onco franchise. So specifically, with Alimta and maybe cases of first line utilization, was well as the maintenance therapy, we've actually been fairly stable. So in the US we've pretty much held our own. Where we have seen some deterioration in performance is in the later lines of therapy, such as second line and third line. And that clearly has come at the expense of Alimta and those later lines of therapy, but to the benefit of the IO agents.

One of the good news is we do think that going forward, combination of therapies will in all likelihood be probably the say to go. And most recently, Merck announced that they were beginning a phase 3 study, which has in KEYTRUDA in combination with Alimta, which should help to add to its sustainability. And then obviously outside of the US, one of the things we highlighted on our guidance call earlier this year was that we expected the impact of the introduction of generics for Alimta entering the European space, given some of the IP challenges there.

If you recall, there were three elements. One was the EPO, which covered all of Europe. And then there was a challenge in the UK and the challenge in Germany. The EPO challenge was removed, so that was good news. In Germany we initially won and then lost on appeal. And the UK, we initially lost, then won on appeal. If we ultimately lose in the UK, it would not only affect the UK, but also Italy, Spain and France.

Both of those are still -- those appeals are bending in both cases. However, given the win in Germany, they can have an introduction of a generic there, if they so choose to go at risk. In the case of the UK, I think the expectation there is there could be some that will enter the market, but using what they call a different fault form. So they are saying that they're not actually infringing our patent, they're actually going around our patent.

GEOFFREY MEACHAM: That's all the time we have for today, so Derica I think you.

DERICA RICE: Thank you guys. And thank you all.

## DETAILS

| | |
|---|---|
| **Company / organization:** | Name: Eli Lilly &Co; Ticker: LLY; NAICS: 325411; SIC: 2834, 3841, 2833; DUNS: 00-642-1325; Name: Food &Drug Administration; NAICS: 922190; SIC: 9400; DUNS: 13-818-2175; Name: Thomson Financial; NAICS: 551111 |
| **Publication title:** | Fair Disclosure Wire; Linthicum |
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| **Last updated:** | 2018-02-24 |

# EXHIBIT 7

## BROWN DECLARATION

BUSINESS BRIEFING

# *F.D.A. Approves Trulicity, a Drug for Type 2 Diabetes*

**By The Associated Press**

Sept. 18, 2014

The Food and Drug Administration has approved a new injectable diabetes drug from Eli Lilly for adults with Type 2, the most common form of the disease. The agency on Thursday cleared the drug, Trulicity, as a weekly injection to improve blood sugar control in patients with Type 2 diabetes, which affects over 26 million Americans or about 90 percent of the cases in the United States. The drug is part of a new class of medicines called GLP-1 agonists, which spur the pancreas to create extra insulin after meals. The F.D.A. approved Trulicity based on six studies in 3,342 patients that showed improvements in blood sugar control. The drug will bear a boxed warning highlighting that rats tested with Trulicity had cases of thyroid cancer, though it is unclear whether they were caused by the drug. Lilly will be required to conduct follow-up studies.

A version of this article appears in print on Sept. 18, 2014, on Page B2 of the New York edition with the headline: F.D.A. Approves Drug for Type 2 Diabetes. Order Reprints | Today's Paper | Subscribe

# EXHIBIT 8

## BROWN DECLARATION

NewsRoom

9/19/14 Boston Globe B
2014 WLNR 26010559

Boston Globe (MA)


September 19, 2014

Section: Business

# Lilly injectable diabetes drug OK'd

WASHINGTON — The Food and Drug Administration has approved a new injectable diabetes drug from Eli Lilly & Co. for adults with the most common form of the disease.

The agency on Thursday cleared the drug, Trulicity, as a weekly injection to improve blood sugar control in patients with type 2 diabetes, which affects more than 26 million Americans.

The drug is part of a new class of medicines called GLP-1 agonists, which spur the pancreas to create extra insulin after meals.

Type 2 diabetes accounts for 90 percent of US cases of the disease and occurs when the body doesn't properly produce or use the hormone insulin. Drugs to treat the disease represent a large slice of Lilly's product portfolio, which includes the insulins Humalog and Humulin.

Indianapolis-based Lilly is counting on new drugs like Trulicity to replace falling revenue from blockbusters like the antidepressant Cymbalta, which is facing cheaper generic competition after the expiration of its patent.

The FDA approved Trulicity based on six studies in 3,342 patients that showed improvements in blood sugar control.

The drug was studied as a stand-alone therapy and in combination with other commonly used diabetes drugs, such as metformin.

Associated Press

**---- Index References ----**

Company: ELI LILLY AND CO; ELI LILLY AND CO LTD

News Subject: (General Interest Diabetes (1GE92); Health & Family (1HE30); Major Corporations (1MA93))

Industry: (Drug Approval Process (1DR91); Drug Discovery & Development Process (1DR41); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Research & Development (1PH57))

Language: EN

Other Indexing: (Eli Lilly & Co.)

Word Count: 196

End of Document

NewsRoom

9/22/14 Daily Post (Palo Alto, CA) 17
2014 WLNR 26754731

Daily Post (Palo Alto, CA)


September 22, 2014

Section: News

# Weekly shot for diabetes wins OK

## FDA approves Trulicity following six clinical trials

The U.S. Food and Drug Administration has approved a new once-a-week diabetes drug.

Eli Lilly's Trulicity injections are designed to improve blood-sugar levels, along with diet and exercise, in adults with type 2 diabetes, the agency said.

Evaluations

Trulicity's safety and effectiveness were evaluated in six clinical trials in which 3,342 patients with type 2 diabetes received the drug. Patients receiving Trulicity had an improvement in their blood sugar control as observed with reductions in what is called the HbA1c level. Hemoglobin A1c is a measure of blood-sugar control.

Trulicity has been studied as a standalone therapy and in combination with other type 2 diabetes therapies, including metformin, sulfonylurea, thiazolidinedione and prandial insulin.

Type 2 diabetes affects about 26 million people and accounts for more than 90% of diabetes cases diagnosed in the United States. Over time, high blood-sugar levels can increase the risk for serious complications, including heart disease, blindness and nerve and kidney damage.

"Type 2 diabetes is a serious chronic condition that causes blood glucose levels to rise higher than normal," said Dr. Mary Parks, deputy director of the Office of Drug Evaluation II in the FDA's Center for Drug Evaluation and Research. "Trulicity is a new treatment option, which can be used alone or added to existing treatment regimens to control blood-sugar levels in the overall management of type 2 diabetes."

Warning

Trulicity has a boxed warning that tumors of the thyroid gland (thyroid C-cell tumors) have been observed in rodent studies with Trulicity but that it is unknown whether Trulicity causes thyroid C-cell tumors, including a type of thyroid cancer called medullary thyroid carcinoma (MTC), in humans.

**---- Index References ----**

Company: ELI LILLY AND CO

News Subject: (General Interest Diabetes (1GE92); Health & Family (1HE30); Health & Wellness (1HE60))

Industry: (Blood Collection & Blood Products (1BL01); Healthcare (1HE06); Medical Equipment & Supplies (1HE68))

Language: EN

Other Indexing: (Mary Parks)

Word Count: 275

End of Document

NewsRoom

11/24/14 Diabetes Wk. (Pg. Unavail. Online)
2014 WLNR 32696337

Diabetes Week


November 24, 2014

Section: Expanded Reporting

# Lilly's Trulicity™ dulaglutide Now Available in U.S. Pharmacies

Pharmaceutical Companies

2014 NOV 24 (NewsRx) -- By a News Reporter-Staff News Editor at Diabetes Week -- The newest GLP-1 receptor agonist treatment option to help improve glycemic control type 2 diabetes in adults is now available in U.S. pharmacies. Eli Lilly and Company's (NYSE: LLY) Trulicity™ (dulaglutide) is a once-weekly glucagon-like peptide-1 receptor agonist (GLP-1 RA) designed with patients in mind. It comes in a single-dose pen and does not require the patient to mix, measure, or handle the needle.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/players/English/7356751-eli-lilly-and-company-trulicity-dulaglutide-improve-glycemic-control-type-2-diabetes/

"Some adults with type 2 diabetes find that diet, exercise and oral medicines aren't enough to meet their treatment goals," said Dr. Laura Fernandez, senior medical advisor, Lilly Diabetes. "Trulicity may be an option for them as it has demonstrated proven glycemic control, only has to be taken once weekly, and comes in an easy-to-use pen."

Trulicity is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Trulicity is not recommended as first-line therapy for patients inadequately controlled on diet and exercise. It has not been studied in patients with a history of pancreatitis, and other antidiabetic therapies should be considered for patients with a history of pancreatitis. Trulicity is not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Trulicity is not a substitute for insulin and has not been studied in combination with basal insulin. Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is not for patients with pre-existing severe gastrointestinal disease.

Trulicity has a Boxed Warning about potential risk of thyroid c-cell tumors including medullary thyroid carcinoma (MTC). It is contraindicated in patients with a personal history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) and in patients with a prior serious hypersensitivity reaction to dulaglutide or any of its product components.

The U.S. Food and Drug Administration approved Trulicity on Sept. 18, 2014 based on results from a number of studies of Trulicity used alone or in combination with commonly prescribed diabetes medications, including metformin, pioglitazone, glimepiride, and insulin lispro. (Study details are available below.) It is now available to patients in 0.75 mg and 1.5 mg doses, delivered in the single-dose Trulicity pen. In a separate usability study, most patients agreed the Trulicity pen was easy to use.

To help make the cost of therapy more manageable, the Trulicity Savings Card can reduce out-of-pocket costs to $25 for each prescription of Trulicity (up to a value of $150 per month) for a maximum of two years. This is available for commercially insured patients only. Savings cards and eligibility requirements can be found at www.Trulicity.com, in Trulicity sample packages, or in the patient education brochure.



**---- Index References ----**

Company: ELI LILLY AND CO; ELI LILLY AND CO LTD

News Subject: (General Interest Diabetes (1GE92); Health & Family (1HE30); Health & Wellness (1HE60); Major Corporations (1MA93))

Industry: (Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13))

Language: EN

Other Indexing: (Eli Lilly and Company) (Laura Fernandez)

Keywords: Eli Lilly and Company; Gastroenterology; Non-Insulin Dependent Diabetes Mellitus; Peptide Hormones; Pharmaceutical Companies; Proinsulin; Type 2 Diabetes Mellitus

Word Count: 501

# Lilly Launches Trulicity in the US – First Ever Ready-to-Use Once-Weekly GLP-1 Receptor Agonist

**11/24/14 - NEW NOW NEXT**



2 TYPE

*Twitter summary: @LillyDiabetes launches Trulicity in the US – first ready-to-use once-weekly GLP-1, available w/savings program for commercially insured*

On November 10, Eli Lilly and company announced that Trulicity (dulaglutide) is now available in the US, making it the first ready-to-use once weekly GLP-1 receptor agonist to reach the market (no mixing required). Trulicity received FDA approval in September for adults with type 2 diabetes. Lilly is offering a cost-saving program with the Trulicity Savings Card, which will allow commercially insured patients to pay as little as $25 per month out of pocket for up to two years. For more information on Trulicity's clinical trial results or safety information, please see our past new now next in *diaTribe #69* or the drug label here.

Trulicity is available in 0.75 and 1.5 mg doses, both administered via a single-dose "auto-injector" that hides the needle from sight. We had a chance to test out the pen at the recent EASD Conference in Vienna and found it super user-friendly. To take Trulicity, users take the cap off of the pen, twist one end to unlock, and then place the flat end of the pen to their skin. With the push of a single button, the pen inserts a previously hidden needle into the skin, administers the injection in a couple of seconds, and then withdraws the needle back into the device. Very fast and easy! The other currently available once-weekly GLP-1 agonists in the US – Astra Zeneca's Bydureon

## Recommended

Ozempic vs. Standard Care: A Practical Type 2...
11/8/18 · TYPE 2

New Diabetes Care Guidelines From ADA and EASD...
10/10/18 · TYPE 2

Will a Pill for Type 2 Diabetes Help the Heart...
8/15/18 · TYPE 2

## Featured

1 TYPE

**Omnipod First Insulin Pump Partner for Tidepool Loop**

2 TYPE

**Type 2 Diabetes Therapy Invokana Approved to Reduce Risk of Heart Attack, Stroke, and**

(exenatide) and GSK's Tanzeum (albiglutide) – require a "reconstitution" process that takes time to prepare before use. The Trulicity design improves convenience, particularly for anyone with "needle-phobia," and raises the bar for effective GLP-1 agonist delivery – we think many will start taking GLP-1 as a result of the launch. *–MV/AJW*



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