

10 March 2021

Rebecca Kelly Slaughter, Acting Chairwoman  
Rohit Chopra, Commissioner  
Christine S. Wilson, Commissioner  
Noah Joshua Phillips, Commissioner

Re: Request for Study and Investigation into the Market Structure of the Insulin Industry and Potential Collusion Between Insulin Manufacturers

Dear Acting Chairwoman Slaughter and Commissioners:

The American Economic Liberties Project (Economic Liberties) and signees submit this letter requesting that the Federal Trade Commission (FTC) use its authority to investigate the insulin industry. We suggest two routes for the FTC: 1) open a cartel case into the insulin industry under Section 5, and/or 2) use 6(b) powers to study the insulin industry and its market structure and publish those findings publicly as permitted under 6(f). Specifically, we hope the FTC will focus on widespread allegations of anticompetitive behavior and collusion between insulin manufacturers to maintain monopoly prices and block potential competitors. This request—similar to earlier requests to the FTC from the American Medical Association (AMA) and from Senator Bernie Sanders and the late Representative Elijah Cummings—stems from mounting evidence suggesting that the insulin industry has become cartelized, disproportionately impacting low-income and minority Americans.<sup>1</sup> We have provided a draft order of suggested questions to aid the FTC’s investigation of the insulin industry.

Skyrocketing insulin prices may be largely attributable to a hyper-consolidated industry. Three companies—Eli Lilly, Novo Nordisk, and Sanofi—control 90% of global insulin supply and nearly 100% of US insulin supply.<sup>2</sup> In most cases, the price increases by one company are mirrored by the others within 24 hours; for example, there were at least 13 reported tandem price increases between Sanofi and Novo Nordisk between 2009 and 2016.<sup>3</sup> As Senator Sanders and Representative Cummings noted, “We are concerned that the potential coordination by these drug makers may not simply be a case of ‘shadow pricing’ but may indicate possible collusion.”<sup>4</sup>

Monopoly power, as has been written before, oftentimes amplifies existing societal inequities, and the insulin market is no exception.<sup>5</sup> As many as 1 in 4 people with diabetes cannot afford their insulin – and

---

<sup>1</sup> Nathaniel Weixel, *Physicians group urges FTC to monitor insulin pricing*, THE HILL (Oct. 29<sup>th</sup>, 2018), <https://thehill.com/policy/healthcare/413709-physicians-urge-ftc-to-monitor-anticompetitive-insulin-pricing>; Letter from Senator Bernie Sanders and Representative Elijah Cummings to Loretta Lynch, Attorney General, Department of Justice and Edith Ramirez, Chairwoman, Federal Trade Commission (Nov. 3<sup>rd</sup>, 2016), <https://www.sanders.senate.gov/download/sanders-cummings-letter-to-doj-ftc-on-insulin?inline=file>.

<sup>2</sup> Judith Johnson, *Insulin Products and the Cost of Diabetes Treatment*, CONGRESSIONAL RESEARCH SERVICE (19 Nov. 2018), <https://fas.org/sgp/crs/misc/IF11026.pdf>.

<sup>3</sup> Letter from Senator Bernie Sanders and Representative Elijah Cummings to Loretta Lynch, Attorney General, Department of Justice and Edith Ramirez, Chairwoman, Federal Trade Commission (Nov. 3<sup>rd</sup>, 2016), <https://www.sanders.senate.gov/download/sanders-cummings-letter-to-doj-ftc-on-insulin?inline=file>.

<sup>4</sup> *Ibid.*

<sup>5</sup> See generally, MATT STOLLER, GOLIATH: THE 100-YEAR WAR BETWEEN MONOPOLY POWER AND DEMOCRACY, 2019; Matt Stoller, BIG NEWSLETTER (June 2019-Present), [https://mattstoller.substack.com/archive?utm\\_source=menu-dropdown](https://mattstoller.substack.com/archive?utm_source=menu-dropdown).

have rationed or ceased taking their insulin altogether.<sup>6</sup> At least thirteen Americans have died from rationing insulin in recent years, with many more deaths likely unreported.<sup>7</sup>

The effects are further heightened for Americans of color. Black Americans have a higher prevalence of diabetes compared to white Americans, as well as less and lower quality health care access, resulting in disproportionate rates of diabetes-related complications.<sup>8</sup> Deemed an epidemic for Black Americans by one journalist, amputations for Black Americans are around three times greater than for white Americans.<sup>9</sup> The cost of cartelized insulin for American minorities is literally an arm and a leg.<sup>10</sup>

The exact increases in insulin costs can be difficult to measure because of a lack of transparency in the prescription drug market, but nearly all studies have found dramatic price increases.<sup>11</sup> Consider the case of Humalog (insulin lispro), sold by Eli Lilly. Since 1996, Eli Lilly has increased the list price of a vial of Humalog from \$21 to over \$275.<sup>12</sup> Eli Lilly, like other pharmaceutical corporations, often blames other actors in the supply chain for the exorbitant price of insulin by pointing to the gap between list prices and net prices. But this claim—which is based on limited, confidential data—masks the significant revenue the corporation has derived from price-gouging patients for decades. Even after discounts and rebates, the

---

<sup>6</sup> Shefali Luthra, *Is Insulin's High Cost Keeping Diabetes Patients From Taking their Medicine?*, KAISER HEALTH NEWS (2019), [HTTPS://KHN.ORG/NEWS/IS-INSULINS-HIGH-COST-KEEPING-DIABETES-PATIENTS-FROM-TAKING-THEIR-MEDICINE/](https://khn.org/news/is-insulins-high-cost-keeping-diabetes-patients-from-taking-their-medicine/).

<sup>7</sup> T1International, #insulin4all : In Memory, <https://www.t1international.com/in-memory/>.

<sup>8</sup> CENTERS FOR DISEASE CONTROL AND PREVENTION, UNITED STATES DIABETES SURVEILLANCE SYSTEM (USDSS), <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html#>; For uninsured rates by race and ethnicity, see Samantha Artiga and Kendal Orgera, *Changes in Health Coverage by Race and Ethnicity since the ACA, 2010-2018*, KAISER FAMILY FOUNDATION (MAR. 5 2020), [HTTPS://WWW.KFF.ORG/DISPARITIES-POLICY/ISSUE-BRIEF/CHANGES-IN-HEALTH-COVERAGE-BY-RACE-AND-ETHNICITY-SINCE-THE-ACA-2010-2018/](https://www.kff.org/disparities-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-the-aca-2010-2018/); CENTERS FOR MEDICAID AND MEDICARE SERVICES & OFFICE OF MINORITY HEALTH & NATIONAL OPINION RESEARCH CENTER, RACIAL AND ETHNIC DISPARITIES IN DIABETES PREVALENCE, SELF-MANAGEMENT, AND HEALTH OUTCOMES AMONG MEDICARE BENEFICIARIES, CMS OMH DATA HIGHLIGHT NO. 6. (2017) <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/March-2017-Data-Highlight.pdf>.

<sup>9</sup> Lizzie Presser, *The Black American Amputation Epidemic*, PROPUBLICA (19 May 2020), <https://features.propublica.org/diabetes-amputations/black-american-amputation-epidemic/>; Original study in: Katie Newhall, Emily Spangler, Philip Goodney, Nino Dzebisashvili, David Goodman, and Kristen Bronner, *Amputation Rates for Patients with Diabetes and Peripheral Arterial Disease: The Effects of Race and Region*, 30 ANNALS OF VASCULAR SURGERY (2016), <https://www.sciencedirect.com/science/article/pii/S0890509615007682>.

<sup>10</sup> Note: More extensive figures can be found in an earlier publication from the above citation: Philip Goodney, Nino Dzebisashvili, David Goodman, and Kristen Bronner, *Variation in the Care of Surgical Conditions: Diabetes and Peripheral Arterial Disease*, A DARTMOUTH ATLAS OF HEALTH CARE SERIES, THE DARTMOUTH INSTITUTE FOR HEALTH POLICY AND CLINICAL PRACTICE, [http://www.diabetesincontrol.com/wp-content/uploads/2014/10/www.dartmouthatlas.org\\_downloads\\_reports\\_Diabetes\\_report\\_10\\_14\\_14.pdf](http://www.diabetesincontrol.com/wp-content/uploads/2014/10/www.dartmouthatlas.org_downloads_reports_Diabetes_report_10_14_14.pdf). For example, between 2007 and 2011 there were 1,861,061 Black patients with diabetes, 14,076,702 non-black patients with diabetes, and 15,937,763 total patients with diabetes on Medicare.

<sup>11</sup> For a few examples, see: Jing Luo, Jerry Avorn, Aaron Kesselheim, *Trends in Medicaid Reimbursements for Insulin from 1991-2014*, JAMA INTERNAL MEDICINE (October 2015), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2429536>; Judith Johnson, *Insulin Products and the Cost of Diabetes Treatment*, CONGRESSIONAL RESEARCH SERVICE (19 Nov. 2018), <https://fas.org/sgp/crs/misc/IF11026.pdf>; Benita Lee, *How Much Does Insulin Cost? Here's 23 Brands to Compare*, GOODRX (23 Aug. 2019), <https://www.goodrx.com/blog/how-much-does-insulin-cost-compare-brands/>.

<sup>12</sup> Carolyn Johnson, *Why treating diabetes keeps getting more expensive*, THE WASHINGTON POST (31 Oct. 2016), <https://www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin-prices-have-kept-rising-for-95-years/>.

current net price of Humalog is close to \$150.<sup>13</sup> Since 1996, Eli Lilly has therefore increased the *net* price of insulin by more than 500 percent, even as two other corporations were marketing similar products. This is part of a larger trend. One study, for example, examined reimbursements from 1991 through 2015 under Medicaid and Medicare and found a “near-exponential upward trend in Medicaid payments on a per-unit basis for a wide variety of insulin products regardless of formulation, duration of action, and whether the product was patented.”<sup>14</sup>

Furthermore, international price comparison studies have confirmed that the insulin crisis is a uniquely American phenomenon. American people with diabetes pay far more for most kinds of insulin in average out-of-pocket costs than any other surveyed country, oftentimes several times over.<sup>15</sup> Eli Lilly makes more money from selling insulin in the U.S. than it does in every other country in the world, combined.<sup>16</sup> As the questions below suggest, we believe that the uniquely dysfunctional American health care system facilitates high prices by enabling collusion and anticompetitive behavior in the insulin industry.

These trends have recently attracted significant attention and pushback nationwide. One ongoing class action complaint alleges that the Big Three have violated the federal Racketeer Influenced and Corrupt Organizations (RICO) Act and consumer protection laws in nearly every state in the country.<sup>17</sup> Some states such as Colorado have capped insulin copays, protecting some people with diabetes (although not everyone<sup>18</sup>) but leaving market structure issues unaddressed.<sup>19</sup> As mentioned previously, civil society organizations, Senator Bernie Sanders and Representative Elijah Cummings requested the FTC investigate the market structure for insulin.<sup>20</sup> The Congressional Diabetes Caucus has also investigated the inaccessibility of insulin, concluding that the insulin market is uniquely complex, prone to market failures, and inefficient compared to other prescription drugs.<sup>21</sup> The House Committee on Energy and

---

<sup>13</sup> *Drugmakers Master Rolling Out Their Own Generics To Stifle Competition*, KAISER HEALTH NEWS (August 2019), <https://khn.org/news/drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/>.

<sup>14</sup> Jing Luo, Jerry Avorn, Aaron Kesselheim, *Trends in Medicaid Reimbursements for Insulin from 1991-2014*, JAMA INTERNAL MEDICINE (October 2015), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2429536>.

<sup>15</sup> T1 International, *Access to Insulin and Supplies Survey*, (March 2016), <https://www.t1international.com/access-survey16/>.

<sup>16</sup> Eli Lilly, SEC Filing (Form 10-Q), (September 2020), <https://investor.lilly.com/node/43886/html>.

<sup>17</sup> Katie Thomas, *Drug Makers Accused of Fixing Prices on Insulin*, NEW YORK TIMES (30 Jan. 2017), <https://www.nytimes.com/2017/01/30/health/drugmakers-lawsuit-insulin-drugs.html>; Chaires et al v. Sanofi, U.S. et al, 1:2017cv10158 (D. Mass. 2017), [https://static01.nyt.com/science/01-30-17\\_Insulin\\_Class\\_Action\\_Complaint\\_Hagens\\_Berman.PDF](https://static01.nyt.com/science/01-30-17_Insulin_Class_Action_Complaint_Hagens_Berman.PDF).

<sup>18</sup> Meg Wingerter, *Colorado’s trailblazing insulin price cap isn’t helping everyone, as some discover they aren’t covered*, DENVER POST (17 Feb. 2020), <https://www.denverpost.com/2020/02/17/colorado-insulin-price-cap-loopholes/>.

<sup>19</sup> Jordan Ross, *Colorado passes law capping insulin co-pays at \$100*, JURIST (May 2019), <https://www.jurist.org/news/2019/05/colorado-passes-law-capping-insulin-co-pays-at-100/>.

<sup>20</sup> Nathaniel Weixel, *Physicians group urges FTC to monitor insulin pricing*, THE HILL (Oct. 29<sup>th</sup>, 2018), <https://thehill.com/policy/healthcare/413709-physicians-urge-ftc-to-monitor-anticompetitive-insulin-pricing>; Letter from Senator Bernie Sanders and Representative Elijah Cummings to Loretta Lynch, Attorney General, Department of Justice and Edith Ramirez, Chairwoman, Federal Trade Commission (Nov. 3<sup>rd</sup>, 2016), <https://www.sanders.senate.gov/download/sanders-cummings-letter-to-doj-ftc-on-insulin?inline=file>.

<sup>21</sup> CONGRESSIONAL DIABETES CAUCUS, INSULIN: A LIFESAVING DRUG TOO OFTEN OUT OF REACH (2017).

Commerce's Oversight and Investigations Subcommittee held a number of hearings on insulin price hikes in 2019.<sup>22</sup>

By no means exhaustive, these examples underscore the urgency of the insulin crisis across the United States, where more than 20 million people rely on insulin as a matter of life or death.<sup>23</sup> Unable to afford their insulin, patients report under-dosing their insulin, injecting expired insulin, and starving themselves to control their blood sugars.<sup>24</sup> Stories of patients joining the military for free insulin coverage or allowing themselves to fall into diabetic ketoacidosis to receive emergency room insulin are not uncommon.<sup>25</sup> Bankruptcy, unpayable debt, and economic ruin have become routine for patients dependent on the insulin cartel to remain alive. As one patient despondently noted, "I often cry, and I think, have I done something wrong that I can't afford to take care of myself?"<sup>26</sup>

An FTC study could provide hope for millions of Americans living with diabetes. While the monopoly cost of insulin hurts every person with diabetes in the United States, that pain is not distributed equally. Cartelized insulin amplifies existing inequities as the most vulnerable lose their limbs and livelihoods due to unaffordable insulin. Using its Sections 5, 6(b), and 6(f) authority, the FTC should investigate the heavily evidenced claims of collusion and anticompetitive behavior in the insulin market. Such a study would critically aid Congress and governments in structuring a more affordable and innovative prescription drug market.

Signed:

Action Center on Race and the Economy  
American Economic Liberties Project  
Center for Popular Democracy  
Community Change  
Demand Progress Education Fund  
Health Global Access Project  
I-MAK  
In the Public Interest  
Liberation in a Generation  
Lower Drug Prices Now  
Open Markets Institute  
Patients for Affordable Drugs  
Progressive Doctors  
Public Citizen  
Revolving Door Project  
Social Security Works  
T1International  
The Democracy Collaborative

---

<sup>22</sup> Jacqueline Howard, *On rising insulin prices, lawmakers tell pharma execs: 'Your days are numbered,'* CNN (10 April 2019) <https://www.cnn.com/2019/04/10/health/insulin-prices-congressional-hearing-bn/index.html>.

<sup>23</sup> Kai Bullard, Catherine Cowie, Sarah Lessem, et. al., *Prevalence of Diagnosed Diabetes in Adults by Diabetes Type—United States, 2016*, MMWR MORB MORTAL WKLY REP (CDC Publication), 67:359-361 (2018) <https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a2.htm>.

<sup>24</sup> *Ibid. Chaires v. Sanofi.*

<sup>25</sup> *Ibid. Chaires v. Sanofi.*

<sup>26</sup> *Chaires et al v. Sanofi, U.S. et al*, 1:2017cv10158 (D. Mass. 2017), [https://static01.nyt.com/science/01-30-17\\_Insulin\\_Class\\_Action\\_Complaint\\_Hagens\\_Berman.PDF](https://static01.nyt.com/science/01-30-17_Insulin_Class_Action_Complaint_Hagens_Berman.PDF).

The Insulin Initiative  
Universities Allied for Essential Medicines  
A. Nicole Nichols  
Allie Marotta  
Allison E. Bailey  
Audrey C. Farley, PhD  
Bryan J. Greth  
Clayton McCook, DVM, MS  
Hannah M. Crabtree  
Jeff Dunlop  
John S. Tagliareni  
Kevin E. Wren  
Laura K. Marston, Esq.  
Lauren E. Figg, LMSW  
Lori S. Ruder, DNP  
Madelyn A. Corwin  
Mallory L. Lorge  
Melinda M. Wedding  
Nellie Kassebaum  
Nicole M. Hood  
Nicole M. Smith-Holt  
Sarah J. Stark  
Sarah L. Ferguson  
Sierra A. Sandison  
Ted A. Closson

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION**

**COMMISSIONERS:** **Rebecca Kelly Slaughter, Acting Chairwoman**

**Noah Joshua Phillips**

**Rohit Chopra**

**Christine S. Wilson**

**FTC Matter No.**      **[MATTER NUMBER]**

**ORDER TO FILE A SPECIAL REPORT**

Pursuant to a resolution of the Federal Trade Commission (“FTC” or “the Commission”) dated **[DATE]**, entitled “[**TITLE**],” a copy of which is enclosed, [**COMPANY NAME**], hereinafter referred to as the “Company,” is ordered to file with the Commission, no later than 45 days after date of service, a Special Report containing the information and documents specified herein.

The information provided in the Special Report will assist the Commission in compiling a study of the pricing, manufacturing, and lobbying practices of insulin manufacturers.

The Special Report must restate each item of this Order with which the corresponding answer is identified. Your report is required to be subscribed and sworn by an official of the Company who has prepared or supervised the preparation of the report from books, records, correspondence, and other data and material in your possession. If any question cannot be answered fully, give the information that is available and explain in what respects and why the answer is incomplete. The Special Report and all accompanying documentary responses must be Bates-stamped.

Confidential or privileged commercial or financial information will be reported by the Commission on an aggregate or anonymous basis, consistent with Sections 6(f) and 21(d) of the FTC Act. Individual submissions responsive to this Order that are marked “confidential” will not be disclosed without first giving the Company ten (10) days’ notice of the Commission’s intention to do so, except as provided in Sections 6(f) and 21 of the FTC Act.

## **SPECIFICATIONS**

Please produce the following information, documents, and items:

### **Report Author**

1. Identify the full name, business address, telephone number, and title of the person(s) who has prepared or supervised the preparation of the Company's response to this order and describe in detail the steps taken by the Company to respond to this order.
2. For each specification, identify the individual(s) who assisted in preparation of the response.
3. Produce a list of the persons (identified by name and corporate title or job description) whose files were searched and identify the person who conducted the search.

### **General Company Info**

1. State the Company's complete legal name and all other names under which it has done business, its corporate mailing address, all addresses from which it does or has done business, and the dates and states of its incorporation.
2. Describe the Company's corporate structure, and state the names of all Parents, subsidiaries, divisions, branches, joint ventures, franchises, operations under assumed names, and websites over which it exercises supervision or control.
  - a. For each such entity, describe in detail the nature of its relationship to the Company and the date it was created, acquired, sold, or otherwise changed ownership or control
  - b. Produce organizational charts sufficient to detail the Company's corporate structure.
  - c. Identify each individual or entity having an ownership interest in the Company, as well as their individual ownership stakes and their positions and responsibilities within the Company.
3. Provide a list of all investors with a greater than 2% stake in the Company.
4. How much has the Company spent on shareholder dividends or stock buybacks?
  - a. List all shareholder dividends or stock buybacks quarterly dating back to 1996.

### **Business Practices**

#### **Manufacturing**

1. Where are the Company's insulin and insulin-component manufacturing plants that produce insulin offered for sale and/or use in the United States located?
2. How many insulin and insulin-component manufacturing plants for United States insulin are there?
3. For these insulin manufacturing plants:
  - a. What is the minimum efficient productive scale?
  - b. How many workers are at these plants?
  - c. Do workers have NDAs, noncompetes, mandatory arbitration clauses, or class-action waivers in their arrangements?
  - d. Who are the suppliers to the plants?

List all of their addresses and inventory what the Company purchases from them.

#### Cost estimates

1. How much does it cost the Company to make insulin offered for sale in the United States, excluding all costs claimed as “marketing” and excluding research and development on any non-insulin drugs?
  - a. Per year?
  - b. Per mL?
  - c. Per worker?
2. What percent of the Company’s United States insulin revenue is paid to:
  - a. Workers?
  - b. Managers?
  - c. Executives?
  - d. Shareholders?
3. What percent of the Company’s United States insulin revenue is spent on:
  - a. Maintaining or investing in physical capital for insulin production?
  - b. Overhead for insulin production?  
Please define what constitutes overhead.
  - c. Research & development for insulin?  
Please define what constitutes research & development.

#### Research and development

1. Provide the total expenditures on domestic and foreign drug research & development related to all insulin products, including an itemized, disaggregated description of—
  - a. basic and preclinical research;
  - b. clinical research, reported separately for each clinical trial;
  - c. development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule;
  - d. development of alternative delivery systems, including changes or improvements to previously approved delivery devices;
  - e. other drug development activities, such as nonclinical laboratory studies and record and report maintenance;
  - f. pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act;
  - g. carrying out postmarket requirements, and risk evaluation and mitigation strategies;
  - h. marketing research; and
  - i. the percentage of research & development expenditures described in clauses (a) through (h) of that were derived from federal funding.

#### Marketing

1. Provide the total expenditures on marketing, advertising, and educating for the promotion of a drug, including a breakdown of amounts aimed at consumers, prescribers, managed care organizations, and others, irrespective of whether a particular drug is mentioned in the marketing, advertising, or educating.

#### Sales and Pricing

1. Provide the Company’s gross revenue, net revenue, gross profit, and net profit with respect to insulin products since 1996.
2. Provide the total number of units of each type of insulin product that were sold.

3. Provide pricing information with respect to the sale of insulin products, including—
  - a. wholesale acquisition cost;
  - b. net average price realized by prescription drug benefit managers for drugs provided to individuals in the United States, after accounting for any rebates or other payments from the manufacturer to the pharmacy benefit manager and from the pharmacy benefit manager to the manufacturer; and
  - c. the net price of each drug, after accounting for discounts, rebates, or other financial considerations, charged to purchasers in Japan, Germany, the United Kingdom, France, Italy, Canada, the Republic of Korea, Spain, and Australia.

#### Manufacturer strategy

1. List all correspondence, including but not limited to, written, in-person, telephonic, text messages, emails, voicemails, and social media posts between the Company and all other makers of insulin for sale in the United States between 1996 and today.

#### Contracting

1. Does the Company use exclusive arrangements, loyalty discounts, disloyalty penalties, or other rebates with suppliers or customers?
  - b. List all contractual terms the Company has in its agreements with PBMs, Insurers, Providers, and other customers of insulin.
4. Does the Company use pre-dispute contract arrangements (NDAs, noncompetes, mandatory arbitration, class action waivers) in any contracts?
  1. If so, which?
  2. What percentage of all Company contracts do contracts with pre-dispute terms comprise?
5. Disclose all documents explaining negotiating strategy behind price schedules, especially different price schedules to different purchasers.
6. List all businesses to which the Company sells insulin.
  3. Share copies of the contracts the Company has entered into with all such businesses.
  4. Provide a summary of all insulin products sold by the Company since 1996.
  5. For any and all price increases, please explain with corroborating, contemporaneous documents why the price change occurred on that date and in the amount that it did.
7. List all list prices dating back to 1996.
  - a. For each PBM the Company entered into supply agreements with, estimate and provide an itemized accounting of all rebates the Company gave to PBMs and how those rebates were calculated, from 1996.
  - b. For each insurer the Company entered into supply agreements with, estimate (to the nearest ten-thousand dollar) how much insurers paid the Company for insulin products since 1996.
8. Disclose how the Company sets its insulin prices (list and negotiated) and what factors go into that consideration. Provide all documents that relate to insulin price setting.

## Patents

1. Please disclose all active insulin and diabetes-related patents and patent applications held by the Company or any of its affiliates. For each patent or patent application disclosed, please detail, if applicable:
  - a. Any extension to the patent term and the basis of such extension;
  - b. The type of claims covered by such patent or patent application (for example: base compound, forms of the compound, uses, combinations, formulations, dosages, processes, etc.);
  - c. The filing date;
  - d. Any delays in the patent application process not attributable to the Patent and Trademark Office and/or delays in patent approval (or a patent application advancing toward approval) resulting from awaiting a response from the applicant.
2. Please estimate the effective length of patents for any and all of the Company's insulin-related treatments.

## Data Collection

1. Disclose how the Company handles and collects any and all patient data, including confidential medical records.
2. What purposes does the Company collect this data for?
3. How does the Company handle and store this data?
4. How and when does the Company delete this data?
5. Is this data, whether blinded or unblinded, sold to any outside entities?
  - a. If so, which entities?
  - b. If so, is the sold data blinded or unblinded?
6. Is this data, whether blinded or unblinded, given to any outside entities?
  - a. If so, which entities?
  - b. If so, is the data blinded or unblinded?
7. Does the Company receive patient data or patient information from PBMs?
  - a. If so, what data or information?
  - b. If so, is the data or information blinded or unblinded?

## Governmental Relations

1. Indicate how many people work for the Company on FDA compliance.
2. Indicate how much the Company spends per year on FDA compliance.
3. List how much the Company spends on lobbying or lobbying-related activities related to insulin.
  - a. What percentage of the Company's total lobbying budget is attributable to insulin-related lobbying?
4. How much money did the Company spend on lobbying on insulin-related issues annually since 1996?
  - a. How much of this money was directed to Federal lobbying efforts?
  - b. How much of this money was directed to State lobbying efforts?

## **Patient Relations**

1. Does the Company give or offer financial assistance or in-kind contributions to patient advocacy organizations?
  - c. If so, which organizations?
  - d. For each organization, please list the total amount of financial support and in-kind contributions provided in any form since 1996.
2. Does the Company give information or patient materials to patient advocacy organizations?
  - i. If so, which organizations?
  - ii. For each organization, please list the materials provided since 1996.
3. Does the Company provide financial or in-kind contributions to any patient assistance program or any other programs that provide copay coupons or other patient costsharing assistance?
  - i. If so, which organizations?
  - ii. For each organization, please list the amount and nature of assistance provided since 1996.
  - iii. If so, please detail any benefit accrued to the company resulting from such contributions, including impacts on the Company's tax liability.