

ELI LILLY

ORGANIZATIONAL PROFILE

Eli Lilly was founded as a small lab in 1876 by Colonel Eli Lilly in Indianapolis, Indiana. Eli Lilly, with its headquarters still in Indianapolis, now employs more than 43,000 people worldwide (approximately half in the U.S. and half outside the U.S.) and markets its drugs in 146 countries.

Eli Lilly is well-positioned within the health care, mass media, political and academic sectors through its Board of Directors. Lilly's board members serve on the boards of health care corporations like Clarian Health partners, American International Group, and the Healthcare Co. (HCA), and media conglomerates McGraw-Hill and the New York Times. Others are professors at universities. Sidney Taurel, chairman and chief executive officer, sits on the President's Homeland Security Advisory Council and the President's Export Council. Taurel is also on the executive committee of the board of directors of the Pharmaceutical Research and Manufacturers Association (PhRMA), the most influential pharmaceutical industry lobbying group in North America.

Eli Lilly is particularly committed to biotechnology. The following is a quote from the Lilly Research Laboratories webpage:

We also have made investments in technologies such as genomics, combinatorial chemistry, high-throughput screening and gene regulation. These tools of biotechnology are enriching our understanding of hundreds of potential drug targets and helping us accelerate the development of promising new therapies.¹

It has a relatively large number of collaborations with biotech companies and universities in the area of genomics, recombinant protein development, monoclonal antibodies, combinatorial chemistry, and at least one partnership in nanobiotechnology.

Key Facilities and Divisions

Research and development facilities are located in Australia, Belgium, Canada, England, Germany, Japan, Singapore, Spain and the United States. Clinical research is conducted in more than 60 countries. Manufacturing facilities are located in Brazil, China, Egypt, France, Germany, Ireland, Italy, Japan, Korea, Mexico, Pakistan, Puerto Rico, Spain, the United Kingdom and the United States.

Some of its key administrative, manufacturing and research and development plants include:

US

- **Lilly Corporate Center in Indianapolis, Indiana:** administrative headquarters, research laboratories
- **Lilly Laboratory for Clinical Research at Indiana University Medical Center in Indianapolis:** early-stage clinical trials
- **Lilly Technology Center, Indianapolis:** development, manufacturing, U.S. affiliate
- **Clinton (Ind.) Laboratories:** manufacturing
- **Greenfield (Ind.) Laboratories:** toxicology, animal health research, manufacturing
- **Tippecanoe Laboratories, Lafayette, Indiana:** development, manufacturing
- **Research Triangle Park Laboratories (RTP Labs), Durham, North Carolina:** research laboratories
- **Prince William County, Virginia:** manufacturing

¹ Eli Lilly website, "Lilly Research Laboratories," at <http://www.lilly.com/research/>, last accessed January 15, 2004.

Puerto Rico

- **Mayaguez:** bulk chemical synthesis plant in for active ingredients for Prozac, Darvocet, and Axid, in addition to some parts of the supply chain for Evista
- **Puerto Rico Industrial Park in Carolina:** two plants. One plant manufactures dry products such as tablets. The second is a bulk plant that ferments antibiotics.

India

- **40 hospitals:** 17 large and small clinical projects running in India as of May, 2003, at over 40 hospitals in the country, including government and private hospitals

New biotech facilities planned:

- **Prince William County, Virginia:** planned insulin manufacturing facility, in partnership with Flad & Associates, in Prince William County, Virginia. The facility will produce Humalog and Humulin. Construction began in 2003 and is expected to be completed in 2007. Eli Lilly says it will invest \$425 million in the facility.
- **Puerto Rico:** New biotech facility for the manufacturing of Humalog. In 2001, Eli Lilly announced that it would invest \$250 million in the facility, which is planned to open in 2005.²
- **Liverpool, UK:** From 2003 to 2007, Eli Lilly plans to invest £ 220 million (\$ 360 million) to expand its manufacturing and R&D capacity in the UK operations. It will use \$45 million of that to expand its Liverpool biotech facility, which manufactures the recombinant growth hormone Humatrope (somatropin).

Headquarters

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285 USA

Board of Directors

Sidney Taurel: Chairman of the Board, President and Chief Executive Officer, Eli Lilly. Became CEO in July 1998 and chairman of the board of directors on January 1, 1999. Was president and chief operating officer from February 1996 and member of the board since July 1991. Chairs Eli's policy committee and senior management forum. Key affiliations:

- Member of the executive committee of the board of directors of **Pharmaceutical Research and Manufacturers of America (PhRMA)**.
- Member of **The Business Roundtable** and **The Business Council** Board member of IBM Corporation and McGraw-Hill Companies, Inc.;
- Member of the Board of overseers of the Columbia Business School
- In June 2002 was appointed to the President's **Homeland Security Advisory Council**, a select group whose members provide George W. Bush with advice on homeland security matters.
- In 2003 was named to the **President's Export Council**, the U.S.' chief advisory committee on international trade issues.

Steven C. Beering, M.D.: President Emeritus, Purdue University. Held chairmanships of the Association of American Medical Colleges, and the Association of American Universities. Past regent of the National

² Marialba Martinex, "Eli Lilly Decision To Invest \$250 Million Is Based On Quality Of Workforce & Business Environment," in *Puerto Rico Herald*, April 26, 2001.

Library of Medicine. Director of NiSource, Inc., the American United Life Insurance Company, the Indiana Business Modernization and Technical Corporation, the CID Equity Partners, and the Indiana State Chamber of Commerce.

Sir Winfried F. W. Bischoff: Chairman, Citigroup Europe. Non-executive director of The McGraw-Hill Companies and of Land Securities since 1999.

Martin S. Feldstein, Ph.D.: President and CEO, National Bureau of Economic Research, and George F. Baker Professor of Economics, Harvard University. Member of the executive committee of the Trilateral Commission and a director of the Council on Foreign Relations. Director of American International Group and The Healthcare Co. (HCA), and an economic advisor to several businesses in the United States and abroad. Regular contributor to *The Wall Street Journal* and has authored more than 300 research articles in economics.

George M. C. Fisher: Retired Chairman of the Board and CEO, Eastman Kodak Company. Member of the boards of directors of Delta Air Lines, Inc., and General Motors Corporation. Served on the President's Advisory Council for Trade Policy and Negotiations. Former chairman of the Industry Policy Advisory Committee. Past member and former chairman of the US-China Business Council.

Alfred G. Gilman, M.D., Ph.D.: Regental Professor and Chairman, Department of Pharmacology, The University of Texas Southwestern Medical Center. Member of the board of directors of Regeneron Pharmaceuticals, Inc., and chairman of the Steering Committee of the Alliance for Cellular Signaling. Was the editor of Goodman and Gilman's *The Pharmacological Basis of Therapeutics* from 1980-1990 and is currently the consulting editor.

Charles E. Golden: Executive Vice President and Chief Financial Officer, Eli Lilly. Also member of the National Advisory Board of J.P. Morgan Chase & Co., and board of director of Hillenbrand Industries, Inc. and Clarian Health Partners and the Indiana Chamber of Commerce.

Karen N. Horn, Ph.D.: President, Global Private Client Services, and Managing Director, Marsh, Inc. Director of The U.S.-Russia Investment Fund (Presidential-appointed).

Ellen R. Marram: Managing Director, North Castle Partners. Member of the Board of Directors of Ford Motor Company and The New York Times Company as well as several private companies.

Franklyn G. Prendergast, M.D., Ph.D.: Edmond and Marion Guggenheim Professor of Biochemistry and Molecular Biology, Professor of Molecular Pharmacology and Experimental Therapeutics and Director, Mayo Clinic Cancer Center. Member of the board of directors of St. Mary's and Methodist Hospitals in Rochester. Member of the American Chemical Society, American Society for Photobiology, American Association for the Advancement of Science, Biophysical Society, Sigma Xi, and the American Society for Biochemistry and Molecular Biology.

Kathi P. Seifert: Executive Vice President, Kimberly-Clark Corporation. Member the board of directors of the Theda Care Health Group and the U.S. Fund for UNICEF (United Nations Children's Fund).

ECONOMIC PROFILE

Eli Lilly's \$2 billion research and development (R&D) budget is concentrated on a few diseases such as diabetes, osteoporosis, cancer and depression. Eli Lilly is one of the few large pharma companies with an in-house expertise in biotech drugs (i.e. protein-based pharmaceuticals) that matches its strengths in more conventional drug discovery. Lilly has approximately 140 alliances with outside firms for R&D purposes, and licensing out patents. Eli Lilly experienced a significant downturn in sales in 2000 when one of its key patents on Prozac – once the corporation's top selling drug – was overturned in court. Lilly lost close to one-third of its share value and within a month, the corporation lost 70% of sales to generic rivals. Prozac has also generated much controversy as it has been linked to thousands of suicides

amongst patients taking the drug. Currently, Eli Lilly's top-selling drugs are Zyprexa (generic name olanzapine) and Humulin. Humulin is a recombinant insulin for diabetes, which has caused severe side effects and deaths in diabetics.

In response to dropped sales because of Prozac, in October 2001 Eli Lilly announced plans to hire 5,000 more sales representatives over a period of three years. This was in addition to the 4,000 sales representatives that the corporation had hired between 1999 and 2001. With a total of 9,000 new sales reps, Eli Lilly's global sales force has doubled from 2000 to 2004, and its spending on sales and marketing doubled from 1999 to 2003.³

Financials, 2002 (dollars in USD, millions, except per-share data)

	2002	2001	2000
Net sales	\$11,077.5	\$11,542.5	\$10,862.2
Net income	\$2,707.9	\$2,780	\$3,057.8
Earnings per share - basic	\$2.50	\$2.58	\$2.83
Capital expenditures	\$1,130.9	\$884	\$677.9
R&D expenditures	\$2,149.0	\$2,235.1	\$2,018.5
Federal lobbying expenditures	\$6.8	\$6.5	\$5.3

Major Shareholders

Lilly Endowment, Inc. - 13.73%
 Capital Research and Management Company - 6.16%
 Barclays Bank Plc - 3.22%
 Wellington Management Company, Llp - 3.17%
 State Street Corporation - 2.64%
 The Vanguard Group, Inc. - 1.94%
 Washington Mutual Investors Fund - 1.92%
 State Farm Mutual Automobile Insurance Co. - 1.79%
 National City Corporation - 1.66%
 Northern Trust Corporation - 1.35%
 JP Morgan Chase & Company - 1.2%

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Eli Lilly's Top Selling Drugs (figures in USD)

Drug	Treatment area	Year of FDA approval	Sales 2002	Sales 2001	Sales 2000
Zyprexa (Olanzapine)	Schizophrenia and acute bipolar mania	1996	\$3.7 billion	\$3.1 billion	\$2.3 billion
Humulin (human insulin lispro)	Diabetes	1982	\$1.0 billion	\$1.1 billion	\$1.1 billion
Gemzar (gemcitabine HCl)	Pancreatic and non-small-cell lung cancer	1996	\$875 million	\$723 million	\$559 million
Humalog (insulin lispro)	Diabetes	1996	\$834 million	\$628 million	\$350 million
Evista (raloxifene hydrochloride)	Prevention and treatment of osteoporosis in postmenopausal women	1997	\$822 million	\$665 million	\$521 million

³ Jewell, Mark, "Lilly to expand sales staff by 5,000," Associated Press, October 24, 2001.

⁴ "Eli Lilly and Co.," *Yahoo! Finance*, December 18, 2003, <http://finance.yahoo.com/q/mh?s=LLY>

Prozac/Sarafem/ Prozac Weekly (Fluoxetine)	Depression, obsessive- compulsive disorder (OCD), bulimia (including long-term treatment), panic disorder, premenstrual dysphoric disorder (PMDD)	1987	\$734 million	\$2.0 billion	\$2.6 billion
Actos (pioglitazone)	Oral medication for Type 2 Diabetes	1999	\$392 million	\$361 million	\$223 million
ReoPro (abciximab)	Prevention of complications of coronary antioplasty	1994	\$384 million	\$431 million	\$418 million
	Prevention of cardiac ischemic complications	1997			
Humatrope somatropin)	Growth hormone deficiency (pediatric and adult) and Turner syndrome	1985	\$329 million	\$313 million	\$301 million

Other drugs on the market

Cialis (tadalafil): marketed through Lilly ICOS joint venture. Treatment for erectile dysfunction. Approved in the U.S. in 2003. For the full year of 2003, total global Cialis sales were \$203.3 million, of which \$73.5 million is reported in Lilly's revenue and \$129.8 million is reported in the joint venture's income statement.

Xigris (drotrecogin alfa): Treatment of adult severe sepsis patients at high risk of death. Received FDA approval in November 2001. Generated \$160.4 million in sales in 2003, an increase of 60 percent compared with 2002.

Strattera (atomoxetine HCl): Treatment of attention-deficit hyperactivity disorder. Approved by FDA in November 2002 for use in children, adolescents and adults. Generated \$370.3 million in sales in 2003.

Forteo (teriparatide [rDNA origin] injection): Treatment for severe osteoporosis. Approved by FDA in November 2002. Generated \$65.3 million in sales in 2003.

Biotech Drugs

Humalog: recombinant 'human' insulin

Humulin: recombinant 'human' insulin

Humatrope: recombinant 'human' growth hormone Somatropin

ReoPro: monoclonal antibody ('antibody' created from a clone of fused tumor cells, which replicate endlessly, and mammalian cells. Mass produced in a lab).

Forteo: recombinant 'human' parathyroid hormone

Xigris: recombinant 'Human' Activated Protein C

Drugs in the pipeline

Under regulatory review

Duloxetine: Treatment for stress urinary incontinence (SUI) – accidental loss of leakage of urine as pressure on the bladder increases, such as from a cough, sneeze or laugh or from exercise.

OFC (olanzapine-fluoxetine combination): Treatment for Bipolar depression.

Alimata: Treatment for Mesothelioma, which is a tumor on the lining of the lung associated most frequently with asbestos exposure

Planned submissions for regulatory review pending outcome of ongoing studies

Protein Kinase C beta inhibitor: Treatment for Microvascular complications of diabetes

Affinitak: Treatment for non-small-cell lung cancer, most common type of lung cancer.

Exenatide: Treatment for Type 2 Diabetes

LY544344: Treatment for generalized anxiety disorder, most common anxiety disorder.

Top Competitors

Abbott Labs

Amgen

AstraZeneca

Baxter

Bayer AG

Boehringer Ingelheim

Bristol-Myers Squibb

Genentech

GlaxoSmithKline

Johnson & Johnson

Merck

Novartis

Novo Nordisk

Pfizer

Roche

Schering-Plough

Wyeth

(Hoover's Company Profiles, 2003)

Recent Biotech Transactions

November 2003 – Eli Lilly reached an agreement to acquire California-based Applied Molecular Evolution (AME) for an estimated \$ 400 million. Lilly said in a statement that it hopes the deal will "enhance its stature as a world leader" in biotechnology. AME has been experiencing financial difficulties, having reported a loss of around \$ 17.5 million in 2002. AME will keep its name and be a wholly-owned subsidiary of Lilly. The merger gives Lilly access to the AMEsystem platform technology – a protein discovery process that will be used across all of Lilly's therapeutic areas to accelerate drug discovery. The acquisition is based on a collaborative agreement established in 2001 between AME and Lilly, involving the use of the AMEsystem platform technology.

November 2003 – Eli Lilly bought UK biotech company Amersham's cellular screening technology for an undisclosed amount. The technology will help Lilly with drug discovery. Lilly has also purchased a high-throughput sub-cellular imaging system and signed a deal that gives it rights to a fluorescent protein. The merged company will be called GE Healthcare Technologies.⁵ Amersham was created (as a private company) when it was spun-off from the UK Atomic Energy Authority in 1982. Amersham was acquired by General Electric in October 2003 for \$9.7 billion. Amersham is a nanobiotechnology company. Nanobiotech refers to the development of nanoscale materials – smaller than a virus or bacterium and larger than a single molecule – with biomedical applications such as drug delivery or cancer detection. Nanobiotech can also be used to create tiny machines that roam the body to seek and destroy cancer cells and viruses, as well as develop more sensitive biosensors.

September 2003: Genomics company Perlegen Sciences, Inc. expanded its research collaboration with Eli Lilly, initiated in December 2002. As part of the deal, Perlegen will use its proprietary technology to individually genotype Perlegen-identified single nucleotide polymorphisms (SNPs) in clinical samples to identify genetic markers for Lilly. Lilly plans to increase its research funding support to Perlegen, in addition to the undisclosed milestone payments and royalties that were part of the original collaboration.

⁵ "Amersham sells screening technology to Eli Lilly," in *Pharma Marketletter*, November 10, 2003

Perelegen was formed in late 2000 as a spin-off from Affymetrix, Inc. Perlegen has ongoing research collaborations with several large pharmaceutical corporations such as AstraZeneca, Bristol-Myers Squibb and Glaxo SmithKline. SNPs are the DNA sequence variations amongst individuals. Pharmacogenomics, which is the study of how SNPs affect the ways people respond to drugs. While the pharmaceuticals industry is promoting pharmacogenomics as a way to predict adverse drug reactions in specific populations, in reality, it wants to use pharmacogenomics as a way to revive failed drug candidates, abandoned because of lack of efficacy or adverse reactions. There are also hopes that pharmacogenomics will lead to cheaper drug development by targeting specific populations, with similar genetic profiles, thereby making clinical trials less complicated and time consuming. Health maintenance organizations (HMOs) are interested in pharmacogenomics because they say it will help them reduce their costs by prescribing drugs that would cut down on the number of patient visits to hospitals or shorten patients' length of hospital stay. But pharmacogenomics will give HMOs access to information pertaining to peoples' genetic profiles.

July 2003: Signed a three-year lease for 10,000 square feet of biotechnology research space in the Torrey Sorrento Science Center at 10575 Roselle Street, San Diego, CA, 92121. Total consideration was \$306,000. Earlier in the year, Eli Lilly signed a collaboration agreement with Structural Genomix, a private San Diego biotechnology company, under which Structural Genomix will build a copy of its gene-to-structure platform for Eli Lilly's drug research. The project will be housed in the leased space, which is located next to Structural Genomix's corporate headquarters.⁶

February 2003: Entered a three-year research collaboration with Albany Molecular Research Inc. (AMRI). The goal of the collaboration is to discover and develop potential therapeutic agents for diseases of interest to both companies. Lilly will transfer to AMRI its extensive and broad natural products collection, advanced technology natural product library, and related databases. This collection includes microorganisms, plant samples, and marine invertebrates and a library of over 100,000 samples that was designed to accelerate drug discovery. AMRI will take full ownership and possess exclusive worldwide rights to the collection and test drug libraries. AMRI will screen samples from the Lilly collection, as well as those from its own natural product libraries, for activity against disease targets identified and provided by Lilly. AMRI will take on the costs of building an expanded screening group and seek to discover drug lead candidates against several Lilly targets. AMRI would receive milestone and royalty payments on compounds that meet specific research and development benchmarks agreed to by both parties and also retain the right to further develop any compounds that Lilly chooses not to further develop. In addition, Lilly will have the option to contract with AMRI for further lead optimization, medicinal chemistry or scale-up of any active compounds.⁷

January 2003: Eli Lilly Canada Inc. and MDS Proteomics, Inc. (MDSP), a subsidiary of MDS Inc., signed an initial pilot study agreement to explore the use of MDSP's proprietary technology PhosMap™. PhosMap™ enables researchers to identify and characterize changes in the chemical modification of proteins that may arise in response to drug treatment. PhosMap™ can be used to identify novel targets in disease, to compare the effects of different drug candidates, and to develop assays that can be used throughout pre-clinical and clinical development. The study between NDSP and Eli Lilly will focus on Eli Lilly's drug candidates. MDS Inc. is an international health and life sciences company. Its products and services include: laboratory testing, imaging agents for nuclear medicine testing, sterilization systems for medical and consumer products, research and clinical development services for planning and delivery of cancer treatment, analytical instruments to assist in the development of new drugs, and medical/surgical supplies.⁸

January 2003: Galen Holdings acquired the U.S. sales and marketing rights to biotech drug Sarafem from Eli Lilly for \$295 million. Sarafem, under patent protection until 2007, is actually the same drug as

⁶ *PR Newswire*, "Eli Lilly Signs Three-Year Lease With The Shidler Group to Carry Out Structural Genomics Research," July 24, 2003.

⁷ *Business Wire*, "AMRI Announces Natural Products Research Collaboration with Eli Lilly and Company; Closes on Organichem Acquisition," February 12, 2003.

⁸ *Canada NewsWire*, "MDS Proteomics and Eli Lilly Canada announce new collaborative research initiative in proteomics," January 14, 2003.

Prozac, which lost its patent protection in 2003. Sarafem, a prescription drug, is being marketed as a treatment for premenstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome. Launched by Lilly in 2000, Sarafem generated sales of approximately \$85 million in the U.S. in the year ended December 31, 2001. As part of the transaction, Galen and Lilly entered into a separate supply agreement, in which Lilly will manufacture Sarafem for Galen until 2006.⁹

December 2002: Announced expansion of collaboration with Alkermes for the development of inhaled formulations of insulin. This expansion followed the achievement of development milestones relating to clinical progress, and scale-up and manufacturing activities for Alkermes' insulin dry powder aerosols and inhalers. Pursuant to the agreement announced, Lilly agreed to purchase \$30 million of newly issued convertible preferred stock of Alkermes. Alkermes agreed to fund the joint development program for inhaled insulin during 2003 and 2004. The collaboration cannot terminate without cause until January 2005.¹⁰ According to Kiran Mazumdar Shaw, Chairman and Managing Director of Biocon India Group (another company trying to develop a non-injectable form of insulin) "oral insulin is a daunting challenge and the chances of commercial success are really slim."¹¹ A news article in The Hindu Business Line reports that inhalable insulin will be much more costly than an injectable version, since it will need at least five times or more of the drug. Also, there are concerns that inhalable insulin could cause lung fibrosis as insulin is a growth factor, and the drug would reach the lungs directly.¹²

Subsidiaries (for full list of subsidiaries see Appendix I)

Elanco Animal Health: Develops, manufactures and markets drugs and feed ingredients (e.g. antibacterials, parasiticides, anticoccidials and productivity enhancers) for livestock. Products are marketed primarily to cattle, poultry, and swine producers. Key operations in North America, Europe, the Middle East, Africa, the Asia-Pacific area and Latin America. Employs approximately 2,000 people and markets its products in more than 100 countries.

Sales

2002 - \$693.1 million

2001 - \$686.1 million

2000 - \$668.5 million

Leading products

Tylan®: first antibiotic developed exclusively for agricultural use

Coban®: widely used in chickens to prevent coccidiosis, a common poultry disease

Rumensin®: hormone widely used for more efficient beef production

Micotil® and **Pulmotil®:** antibiotics used to control respiratory disease in cattle and swine, respectively

Paylean®: swine lean-meat enhancer that improves the amount of quality meat in high-value cuts.

InnoCentive: Online forum for scientists and companies to collaborate. InnoCentive is an e-business company of Eli Lilly. Includes over 20,000 scientists and researchers from 125 countries, and member companies. 'Seeker' companies submit an InnoCentive Challenge™, which includes a detailed description and requirements, a deadline and an award amount for the best solution. InnoCentive publishes the Challenges on its Website, www.innocentive.com, and works with scientists around the world to generate high-quality solutions. The Seeker company reviews all submissions, and awards are issued by InnoCentive for only the best solutions that meet the Seeker's requirements. Award amounts typically range from USD \$5,000 to \$100,000. The name of the Seeker company remains confidential and secure for any scientific challenge posted on innocentive.com.

Distia: created in 1972 to act as a sales division for Eli Lilly. Consisted of approximately 150 sales representatives and was formed to market products directed to primary care physicians (i.e. general

⁹ "PRODUCT RIGHTS: Sarafem rights acquired from Lilly for \$295M," in *Women's Health Weekly*, January 16, 2003

¹⁰ "Alkermes and Lilly Announce Expansion of Collaboration for Inhaled Insulin for the Treatment of Diabetes," *Business Wire*, Dec. 13, 2002

¹¹ Madhumathi D.S. "Pharma majors in race for painless insulin," *The Hindu Business Line*, October 14, 2003.

¹² Ibid

practitioners, family practitioners, and other physicians working in office-based, nonhospital environments). Today it markets Prozac and Keflex. Has produced and distributed pamphlets on depression in collaboration with the National Institute of Mental Health. Approximately half of Eli Lilly and Dista's sales representatives are registered pharmacists, who advertise to physicians, wholesalers, hospitals, HMOs, retail pharmacists and other health care professionals. Their efforts are supported by Eli Lilly through advertisements in medical and drug journals, distribution of literature and samples of certain products to physicians and exhibits for use at medical meetings. In the past few years, large buyers of drugs, such as health maintenance organizations (HMOs), governments and long-term care institutions, have begun to account for an increasing portion of total drug purchases in the U.S.

Control Diabetes Center: disease management company founded in Dallas, Texas in 1992. Disease management was a concept initiated by pharmaceutical corporations during the mid-1990s amidst the movement to further privatize the American healthcare system. Colleen Fuller, in her book *Caring for Profit*, refers to disease management as 'disease state management' (DSM) and points out that the main goal is to increase corporate profits by reducing patients' use of health-care services and shift behaviours towards non-institutional alternatives, such as drugs. DSM uses information collected by physicians who treat chronic patients.¹³ Drug corporations use databases containing this information to identify patients with chronic disease, who are then solicited and offered 'educational services' by the disease management group. The services are often paid for by employers and HMOs, while drug corporations use them to promote their drugs. From 1992 to 1999, CDC had entered into contracts with HMOs and other health insurers, giving it access to 5 million patients, including 300,000 diabetics. CDC has provided services to over 15,000 diabetics.¹⁴ Eli Lilly has the largest market share worldwide of insulin, through its recombinant insulin products Humulin and Humalog. The company acquired CDC in 1994. While Eli Lilly expanded the operation into 11 additional geographic areas: Boston, Albany, Long Island, Atlanta, Philadelphia, Miami, Cincinnati, Ft. Worth, Phoenix, Houston, and Tyler, Texas it was eventually determined that expansion was too costly. The centers were sold (except the Dallas and Fort Worth centers which are used as research and development sites) and the company began subcontracting out its services across the country.

Integrated Medical Systems: operates medical communications networks that link physicians to hospitals and pharmacies throughout the U.S. These networks enable Lilly to create closer ties with health care providers and payers, as well as let the corporation get the information it wants to healthcare professionals, patients and HMOs. Specifically, clinical, administrative and financial information is delivered to hospitals, payers/managed-care plans, labs and physicians. Lilly acquired IMS Inc. in 1995 when the company was at the height of its success and considered a national leader in communication networks and services linking health care professionals, HMOs and the pharmaceuticals industry. As of 1995, more than 200 hospitals, HMOs, clinical reference labs, pharmaceutical companies and professional organizations were linked through IMS' Medacom™ networks, with over 30,000 physicians, conducting more than 30 million transactions annually. Major clients include health benefits and health insurance companies, including Humana and Blue Cross/Blue Shield Plans. Kinetra, a joint-venture company created by Electronic Data Systems and Eli Lilly in 1997, into which IMS Inc. was integrated, was acquired by Healthon/WebMD in 2000 for \$300 million. At the time of the acquisition, Kinetra's networks served 50,000 physicians. IMS, Inc. continued to be a subsidiary of Eli Lilly.

Funding Bodies

Lilly Endowment, Inc.: financed by Eli Lilly and Company, but separate from the operations of the company. Was established in 1937 by members of the Lilly family as a way to pursue their personal philanthropic interests. *Forbes* estimates the Lilly family fortune at \$1.3 billion. Has given millions to the American Enterprise Institute (AEI) Center for the study of Government Regulation. Also a big supporter of the Hudson Institute. (Mitchell E. Daniels, Jr., former President of Eli Lilly's North American

¹³ Fuller, Colleen, *Caring for Profit*, New Star Books (Vancouver) and Canadian Centre for Policy Alternatives (Ottawa), 1998. Pg. 199.

¹⁴ Bodenheimer, Thomas, "Disease management in the American market," in the *British Medical Journal*, BMJ 2000;320:563-6 (February 26).

Pharmaceutical Operations, was a member of the Hudson's Board of Trustees at the time he worked for Eli Lilly).

Eli Lilly and Company Foundation: provides product donations to patient groups, for disaster relief and 'medical missions'; matches employee and retiree gifts to cultural, educational, and selected health care organizations; funds public policy research; provides support to groups working on therapeutic areas of most interest to the company; funds partnerships with academic institutions; and funds community projects.

Tax Breaks

October 2003: Eli Lilly was part of a coalition of corporations (including Merck, Intel, Sun Microsystems, Dell Computer and Hewlett-Packard) and trade groups that lobbied for a tax holiday on foreign profits. In October 2003 the Senate Finance Committee approved a bill that would give a one-time tax holiday to corporations that have accumulated as much as \$400 billion in foreign profits on which they have yet to pay American taxes. Proponents of the bill claim that the tax holiday could bring in as much as \$300 billion into the U.S., and would increase investment and create jobs. The coalition's main lobbyists included Bill Archer (former Republican congressman and chair of the House Ways and Means Committee) and his former chief of staff Donald Carlson. Eli Lilly said that it had \$8 billion in untaxed overseas profits. The main purpose of the bill was to replace a tax break for American exporters that has been declared an illegal subsidy by the World Trade Organization. The bill reduces the corporate tax rate of U.S. manufacturers by as much as 10 percent and offers some new permanent tax breaks for U.S. companies with operations overseas.¹⁵

September 2003: Eli Lilly announced that it would spend at least \$41 million to move its drug distribution center. The new 200,000-square-foot building in the suburb of Plainfield will replace Lilly's current warehouse in Indianapolis, where its manufacturing operations are based. The building will include large spaces for Eli Lilly's insulins and other products requiring refrigeration. The center, on a 34-acre site near the interchange of Interstate 70 and Indiana 267, will ship Eli Lilly drugs nationwide. A potential second phase, which would double the size of the building, would cost about \$30 million. Eli Lilly will benefit from a 10-year property tax abatement, voted on by the Plainfield Town Council.¹⁶

August 2003: Eli Lilly announced that it will spend \$322 million on improvements at its drug manufacturing complex near downtown Indianapolis. The work will add 456,000 square feet in manufacturing, office and laboratory space. Construction was scheduled to start in 2003 and be completed in two to three years. The plan includes four new projects. Three of the projects, totaling \$237 million, are related to Lilly's insulin operations. They include renovation of an insulin finishing facility, and two new administrative buildings. The other project is an \$85 million building to support manufacturing of a longer-lasting form of Lilly's top-selling drug, the anti-psychotic Zyprexa. The Development Commission granted Eli Lilly preliminary approval for a \$314 million property tax abatement over 10 years.¹⁷

POLITICAL PROFILE

In 2002, Eli Lilly spent \$6.8 million in federal lobbying expenditures and employed 64 lobbyists, making it the third largest spender of all leading pharmaceutical and biotech companies in the U.S. (Noteworthy, Eli Lilly is the 11th largest pharmaceutical corporation worldwide). That same year, the pharmaceutical industry as a whole gave \$19.1 million to candidates in the mid-term elections, with 73 percent of that money going to the Republicans. Within the industry, Lilly gave the most: \$1.6 million, according to the Center for Responsive Politics. In the end, a number of bills were passed that favoured the interests of the pharmaceuticals industry. Measures that Congress approved were:

¹⁵ Andrews, Edmund L., "Senate Panel Bill to Give Tax Windfall to U.S. Companies," in *The New York Times*, October 2nd, 2003.

¹⁶ Associated Press, "Eli Lilly to move distribution center to Plainfield," September 10, 2003.

¹⁷ Associated Press Eli Lilly plans \$322 million expansion at Indianapolis August 21, 2003

- A provision in the Homeland Security Bill that prevents lawsuits against makers of vaccine preservatives, including thimerosal, a mercury-based preservative that has been linked with the neurological disorder autism. An estimated 150 individual autism lawsuits and thousands more under preparation target Lilly.¹⁸
- Extension of manufacturers' patents in exchange for testing a drug's safety for use by children under the pediatric incentive bill. The extension was worth \$900 million in additional Prozac revenues for Lilly, according to the consumer group Public Citizen.
- Renewal of a program to speed FDA approval of drugs by raising money for government review from user fees. Drug companies complain it takes too long to get drugs through the FDA system.

Blocked were:

- Reimportation of cheaper drugs sold in Canada
- Quicker process for generic drugs to get to market to compete with pricier, brand-name versions.¹⁹

Some present and past In-house lobbyists

Desiree Filippone – Executive Director, Global Government Affairs. Was a speaker at a workshop at the 2003 BIO Annual Convention. Workshop was called “China and the WTO’s TRIPS Agreement.” It focused on China’s efforts to comply with the World Trade Organization’s Trade Related Aspects of Intellectual Property Rights agreement as they relate to biotech. Other speakers of the workshop were Joseph M. Damond, Associate Vice President, Japan and Asia-Pacific, Pharmaceutical Research and Manufacturers Association (PhRMA) and Mark Cohen, Attorney-Advisor, Office of Enforcement, U.S. Patent and Trademark Office.

Anne Urban – former legislative director in the office of Senator Robert Kerrey (D-NE) and top economic aide to Senator Joseph Lieberman (D-CT). Also a Principal at lobbying firm Venn Strategies, which focuses on health care policy. Urban has had more than 20 years of legislative, public policy and government relations experience both on Capitol Hill and in the private sector. In November of 2003 Urban was named one of Washington's Top 10 Tax Lobbyists by *Tax Analysts*.

Deborah Steelman – Past Vice President, Corporate Affairs. Founder of lobby firm ‘Steelman Health Strategies.’ Also held a White House staff position under President Reagan and served on a number of federal advisory commissions, including the National Bipartisan Commission on the Future of Medicare. Steelman was also chairman of the Quadrennial Advisory Council on Social Security and Medicare as a presidential appointee by then-President George Bush Sr. Has resigned from Eli Lilly, but continues to “consult” with the corporation on governmental affairs and health policy issues.

Lobbying firms used by Eli Lilly:

Albers & Company – some of its other clients include Merck and CVS/pharmacy. Lobbied on behalf of a pharmaceutical corporation to increase the pharmacy budget in the Commonwealth of Virginia in order to market a newly approved drug. It created a coalition of mental health consumer organizations to lobby key legislative leaders “on the value of [the] new drug for sufferers of mental illness.” In the end, the General Assembly increased funding from \$500,000 to nearly \$14 million.²⁰

PodestaMatton – firm’s leading clients in 2000 were PhRMA, Genentech and Novartis. Eli Lilly is an indirect client through PhRMA. Provided two early biotech companies with access to key policy-makers

¹⁸ Thomas Frank, “A Loss For Parents Of Autistic Kids Suits vs. drug makers blocked,” *Newsday*, November 24, 2002.

¹⁹ Maureen Groppe, “Lilly, other drug firms find friends in Congress,” *Vaccination News*, November 29, 2002.

²⁰ http://www.alberscom.com/our_results.html

and legislative intelligence, while lobbying White House, Congress and FDA officials about the companies' potential. Helped persuade the White House to reform U.S. patent law for Genentech, and helps the company resolve intellectual property disputes in Europe and Japan. Was sought by PhRMA to lobby the FDA for a shorter drug development process (under the drug user fee act).

The Legislative Strategies Group – founded by Martin Gold, a former aide to Senators Howard Baker (R-Tenn.) and Mark Hatfield (R-Ore.). Earned a total of \$600,000 from Hoffman-La Roche, Amgen and Biogen in 2000²¹. Staff members have included Steven Hilton, a former staff member for the Clinton White House and Senate Judiciary Committee, and Larry Smith, a former Senate Sergeant at Arms and staff director for the Senate Rules Committee.

Ricchetti Inc. – founded by Steve Ricchetti, former deputy chief of staff for President Clinton and former executive director of the Democratic Senatorial Campaign Committee. Lobbied for the pediatric incentive bill on behalf of Eli Lilly and Pharmacia in 2001 and was paid \$390,000 from the two drug companies in that period. The bill, which was passed, grants an extra six months of patent protection if a corporation tests the safety of its drugs in children. In January 2001, the FDA estimated that the bill would cost consumers \$14 billion in delayed access to cheaper generics over 20 years.²²

Washington Council Ernst & Young -- clients also include Baxter Healthcare, Pfizer, Aventis and the Coalition for Consumer Choice in Healthcare. In 2002, earned approximately \$1 million from the drug industry. A key lobbyist with the Council is Doug Badger, the primary White House health policy advisor. Badger also served on Bush's Human Services Transition Team in early 2001, and was Chief of Staff to former Assistant Senate Majority Leader Don Nickles (R-OK).

HC Associates – other clients include PhRMA, Merck, Wyeth, Genzyme, Baxter Healthcare and Amgen. In 2002 received a total of approximately \$1.1 million from these clients, as well as Eli Lilly. Founded by Howard Cohen, its current President. Cohen is former Chief Health Counsel for the Committee on Commerce, U.S. House of Representatives; his primary responsibilities included Medicare and Medicaid policy developments, as well as federal regulation of drugs. Cohen also worked at the Greenberg Traurig lobbying firm, where he was part of Bush's Health and Human Services Transition Team. Cohen was also hired by PhRMA, a client of Greenberg Traurig, to lobby for the pediatric incentive bill. Cohen sits on the board of directors of the Coalition for Health Services Research, a research and lobbying group.

Clark & Weinstock – Other clients include PhRMA and Schering-Plough. In 1994 established an office in Washington, D.C. headed by Vin Weber, U.S. House of Representatives (R-Minn.) from 1981 to 1993. Vic Fazio joined Clark & Weinstock in 1999. Fazio was U.S. House of Representatives (D-Calif.) from 1979 to 1998 and Chairman, Democratic Caucus from 1995 to 1999. In 1999, Weber and Fazio represented PhRMA for its lobbying efforts on Medicare and blocking bills for the reimportation of cheaper generic drugs. Mitch Bainwol, former lobbyist with Clark & Weinstock and past chief of staff to Senate Majority Leader Bill Frist (R-Tenn.), went on to hold the executive director position with the National Republican Senatorial Committee from 2001-2002.

Business and Lobby Groups

(Eli Lilly is a member to the following groups)

USCIB (US Council For International Business) – purpose is to facilitate international free trade by providing “premier access to international policy makers and foreign regulators.” It is the U.S. affiliate of the: International Chamber of Commerce (ICC); Business and Industry Advisory Committee to the Organization for Economic Co-operation and Development (OECD); and International Organisation of Employers. Its members include 300 multinational corporations, law firms and business associations. It has a Biotechnology Committee, which is chaired by DuPont's Vice President Global Regulatory Affairs

²¹ The Other Drug War, Public Citizen's Congress Watch, based on Lobby Disclosure reports filed with the Secretary of the Senate and Clerk of the House pursuant to the Lobby Disclosures Act of 1995.

²² Public Citizen's Congress Watch, *The Other Drug War II; Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up*, June 12, 2002.

Terry Medley, and sets out to enhance confidence in biotech and stop “non science-based” barriers to trade in biotech products. Its official role is to work directly with the OECD’s Biotechnology Committee, with the ICC (which has consultative status at the United Nations) and with major international organizations to promote and pursue industry objectives. Sidney Taurel, Eli Lilly’s chairman, president and CEO sits on the Board of Trustees of USCIB.

Business Roundtable (BRT) – association of CEOs of leading corporations with a combined workforce of over 10 million employees in the U.S. and \$3.7 trillion in revenues. One of the most influential business lobbies in the U.S. Advocates for public policies that foster vigorous economic growth. Its Task Forces are directed by member CEOs who direct research and preparation of position papers, make policy recommendations, and lobby Congress and the Administration on select issues. BRT co-chair is Henry A. McKinnell, CEO of pharmaceutical giant Pfizer. In January 1998 the Education & the Workforce Task Force ran a print ad encouraging its audience to help “raise standards in America’s schools,” which called for increasing programs and enrollment in expensive market-driven fields like laser technology, advanced computing and molecular genetics. In July 2000, BRT founded The Leapfrog Group (see below), which is a consortium of more than 145 corporations (e.g. Eli Lilly, Aventis, AstraZeneca, GlaxoSmithKline) and other large private and public health care purchasers that provide healthcare benefits. Eli Lilly has contributed financially to BRT.

The Leapfrog Group – works with medical professionals throughout the U.S. to determine purchasing principles of health care services and products at hospitals. The Leapfrog Board of Directors, which includes leaders from Leapfrog members and representatives from other industry organizations and consumer groups, establish these principles. Encouraged under Leapfrog principles are Computer Physician Order Entry (CPOE) systems. CPOE systems are electronic prescribing systems that intercept errors when drugs are ordered. They create a record of prescriptions per patient, and integrate orders with patient information, including laboratory and prescription data. The upfront costs of CPOE systems are also expensive. According to Leapfrog, at Brigham and Women’s Hospital, the cost of developing and implementing CPOE was approximately \$1.9 million, as well as \$500,000 in maintenance costs per year.²³

Pharmaceutical Research and Manufacturers Association (PhRMA) -- represents the U.S.’s top pharmaceutical and biotech corporations. The most influential pharmaceutical lobby group in the U.S. In 2001, PhRMA paid for all of the advertising in a special issue of *Newsweek* magazine, which contained articles solely on health-related topics, including one article promoting stem cell research at a biotech firm in India called Reliance Life Sciences. The issue hit newsstands September 10, 2001. Copies were also distributed to congressional aides dealing with health-related legislation, with a letter from Alan Holmer, President of PhRMA promoting the issue.²⁴ Most recently, the PhRMA made enormous gains from its lobbying efforts. New U.S. Medicare legislation, that extends prescription drug benefits to Medicare recipients, will enable more older people to afford expensive prescription drugs while pharmaceutical corporations will gain billions of dollars in sales. The legislation will forbid the federal government from negotiating lower drug prices, and will not lift prohibitions on large-scale re-importation of cheaper drugs from Canada. Over the past 10 years, PhRMA and its members have invested more than \$558 million into political contributions, lobbying and advertising campaigns. Eli Lilly is the 4th largest spender amongst PhRMA members on lobbying, having contributed more than \$36 million between January 1996 and December 2002. Steven M. Paul, M.D., Executive Vice President of Science and Technology and President of Lilly Research Laboratories is on the Board of Directors of the PhRMA Foundation, which provides competitive research fellowships and grants to students in disciplines significant to the pharmaceutical industry. Current CEO of Eli Lilly, Sidney Taurel, is a member of the executive committee of the board of directors of PhRMA, and was previously chairman of its board.

European Federation of Pharmaceutical Industry Associations (EFPIA) – represents many of the largest pharmaceutical corporations with operations in Europe, European trade associations and smaller

²³ The Leapfrog Group, “Computer Physician Order Entry,” factsheet, last revised April 18, 2003. Found at http://www.leapfroggroup.org/FactSheets/CPOE_FactSheet.pdf

²⁴ “Drugmakers’ Lobby Sponsors Newsweek Health Issue,” Bloomberg, September 17, 2001.

biotech companies. Is part of the Forum for European Bio-industry Coordination (FEBC), which heavily lobbied the European Parliament and national representatives to the Council of Ministers between 1988 to 1995 for proposed legislation that would give intellectual property (IP) protection for biotechnology inventions. Industry argued that IP was critical for innovation in scientific research within the EU, and that the lack of such legislation was forcing European companies to move their biotech research to the U.S. There was significant opposition to the legislation, from groups like Genetic Resources Action International and the ETC group (then RAFI). The opposition was enough to cause a majority vote against the proposed legislation. But from 1995 to 1998, pro-biotech groups continued to lobby. EFPIA launched an ad campaign, using the slogan 'No patent, No cure.' Advertisements using the slogan and signed by pharmaceutical corporation CEOs ran in the *European Voice*, which is a weekly magazine that strictly covers EU issues²⁵. By July 1998, the EP had voted in favour of the legislation, which had very minor amendments to the proposal that had been rejected in 1995. In 2000, EFPIA established the Emerging Biopharmaceutical Enterprises group, a medium through which pharmaceutical and biotech companies can pool expertise and lobby for favourable regulation specifically on biotech.

Transatlantic Business Dialogue – established in 1995 to harmonize standards, certification and regulatory policies globally. Allows industry leaders to work with governments to increase transatlantic trade and investment opportunities by removing barriers “caused by duplication and differences in the EU and US regulatory systems”. Based on the principle of transatlantic Mutual Recognition Agreements (MRAs), which apply an “Approved Once, Accepted Everywhere” standard. At the 1996 TABD Annual Meeting in Chicago, a working group on the MRA covering pharmaceuticals was created. The group consisted of FDA officials, officials from both Directorates General I (Trade) and III (Industry) of the European Commission, and six executives from pharmaceutical corporations – Boehringer Ingelheim, Glaxo Wellcome (now Glaxo SmithKline), SmtihKline Beecham (now Glaxo SmithKline), Eli Lilly, Monsanto (no longer has a pharmaceuticals operation), and Warner Lambert (now Pfizer). The working group created a new framework for the MRA, which consisted of significant input from the drug corporation executives. At the 1998 EU-US Summit in Birmingham, UK, the MRA package was signed by EU Foreign Trade Commissioner and Commission Vice President Sir Leon Brittan, US Secretary of Commerce William Daley and US Trade Representative Charlene Barshefsky. Many MRA agreements can be implemented without ratification by the US Congress, the European Parliament or EU Member State parliaments.²⁶

Biotechnology Industry Organization (BIO) – Largest industry association for the biotech industry. Has been met with opposition over the past several years with protests at its annual conventions. Lobbied Senate Majority Leader Tom Daschle, for extending protection to corporations involved in making all components of children’s vaccines. In a letter addressed to Daschle on November 18th, 2002, Carl Feldbaum, president of BIO, wrote that U.S. drug corporations are “well positioned” to develop new vaccines to fight bioterrorism attacks and “Without adequate liability protection, it will be infeasible for many of our companies to be a source of anti-terrorism technology.”²⁷ This is in Eli Lilly’s interests, since the corporation was facing 150 lawsuits related to thimerosal – a preservative, used until recently, developed by Lilly for use in children’s vaccines. It is suspected that thimerosal causes autism. In turn, Lilly has been using fears of bioterrorism to get out of these lawsuits. In November 2002, the Homeland Security Bill was passed with a provision that protects Eli Lilly and other makers of thimerosal. The provision forces lawsuits over thimerosal into a special “vaccine court,” which may result in the dismissal of thousands of cases filed by parents who argue that mercury in the preservative has poisoned their children, causing autism and other neurological ailments.

Healthcare Leadership Council – a coalition of nearly 50 drug companies, health care providers and hospitals. Membership includes CEOs from corporations like CIGNA Corporation, Amgen, Abbott Laboratories, Glaxo SmithKline, Johnson & Johnson, Merck and Pfizer. Deborah Steelman, past vice president of Corporate Affairs at Eli Lilly is the founder of HLC. HLC is a major donor to the Republicans.

²⁵ Thaker, Shail, “The Criticality of Non-Market Strategies: The European Biotechnology Patents Directive,” Kellogg School of Management, 2003. Found at <http://www.kellogg.northwestern.edu/academic/biotech/articles/shail.pdf>

²⁶ “Transatlantic Business Dialogue (TABD); Putting the Business Horse Before the Government Cart,” by Corporate Europe Observatory, Briefing Paper, October 25, 1999, <http://attac.org.uk/attac/document/ceo-tabd.pdf?documentID=24>

²⁷ Durbin, Kathie, “Young Victims Wounded by Legislation,” in *The Columbian*, November 23, 2002.

During the 2000 election cycle, HLC gave \$22,500 in soft money donations, all of which went to the Republicans. In 1998, the Council reported lobbying expenditures of \$740,000 and \$1,020,000 in 1999. HLC is also a member of the industry-sponsored front group Citizens for Better Medicare.²⁸

Citizens for Better Medicare – founded by members of PhRMA and HLC. Citizens for Better Medicare's members made more than \$9.9 million in soft money, political action committee (PAC) and individual contributions to federal parties and candidates in the 2000 U.S. election cycle. Three-quarters of that money went to the Republicans, who were spearheading a drug proposal that would give private insurance companies subsidies to cover drug benefits for senior citizens. Under the Republican plan, the government would subsidize private insurance companies to cover drug benefits for senior citizens. This plan was rejected by the Health Insurance Association of America (HIAA), the largest health insurance business group in the U.S. HIAA argued subsidies would not be enough to provide an affordable drug benefit because of increasing drug prices. The Republicans' proposal was easily passed by the House Ways and Means Committee (which holds closed-door meetings to make decisions to contribute to the legislative process). The 23 members who voted in favour of the bill received an average of \$16,500 in contributions from members of Citizens for Better Medicare, while the 14 members who voted against the plan took in an average of \$6,000.

Revolving Doors

Sidney Taurel – in June 2002 was appointed to the President's Homeland Security Advisory Council (PHSAC), a select group whose members were chosen to provide Bush with advice on homeland security matters. In particular, they will provide input to the President on developing and coordinating the implementation of a comprehensive national strategy to increase America's security. PHSAC consists of leaders in state and local government, the private sector, academia, as well as individuals like William H. Webster, former Director of the Federal Bureau of Investigation and James T. Moore, Commissioner of the Florida Department of Law Enforcement. In May 2002, Taurel spoke at a Capitol Hill forum on bioterrorism and community preparedness. In his speech, Taurel stated that bioterrorism countermeasures cannot be a task of government alone. Taurel outlined the need to engage the pharmaceuticals industry.²⁹

Dr. Gail Cassell – vice president of scientific affairs, and distinguished Lilly research scholar, infectious diseases. In June 2002 Cassell was appointed to serve on the Advisory Council on Public Health Preparedness. The Council, which reports directly to Health and Human Services Secretary Tommy Thompson, is responsible for advising the Secretary on actions to respond to public health and bioterrorism emergencies. Cassell has served as Lilly's vice president of infection diseases since October 1997. Cassell was also appointed with PhRMA to provide scientific leadership for the development of the industry's bioterrorism strategy.

Mitch Daniels – former Eli Lilly senior executive and currently preparing to run for Indiana governor in 2004. Prior to joining Lilly, Daniels served as chief of staff to Senator Richard Lugar, was appointed executive director of the National Republican Senatorial Committee when Lugar was elected chairman. In 1984, Daniels was appointed as President Reagan's deputy assistant for intergovernmental affairs, served as Reagan's chief political adviser and liaison to state and local officials from 1985 to 1987. Daniels then became executive vice president and chief operating officer of right-wing think tank, the Hudson Institute in Indianapolis. After leaving that position, he continued to serve on the Institute's Board of Trustees. In 1990, Daniels became the vice president of corporate affairs at Eli Lilly, and was promoted to president of the corporation's North American operations in 1993, and then went on to serve as senior vice president of corporate strategy and policy in 1997. After leaving Lilly, Daniels went on to work as director of the Office of Management and Budget (OMB) under the Bush Administration. As director, Daniels was responsible for overseeing the preparation of the federal budget and supervising the spending of executive-branch agencies, including for medicare/health-related spending. In a Wall Street Journal profile published in August 2001, Daniels stated, "To the extent I bring anything ... to this

²⁸ www.Opensecrets.org

²⁹ "Lilly Commits Two Senior Officials To War On Terrorism," Business Wire, June 11, 2002.

job...maybe it's an ability to think about how a product, whether it's Prozac or a president's proposal, is marketed."³⁰ Daniels also had stock holdings of between \$50,000 and \$100,000 in Citigroup, General Electric and another drug company, Merck.³¹ Daniels held this position until 2003.

Randall Tobias – In July 2003, President Bush named Randall Tobias, former chairman and CEO of Eli Lilly, to coordinate the \$15 billion U.S. Emergency Plan for AIDS Relief program to help prevent and treat AIDS in Africa and the Caribbean. The money will be directed to 14 countries, mostly in Africa, and is meant to expand efforts to curb the spread of the disease, pay for medicine and training of health workers, build clinics, expand testing for HIV, and help orphans whose parents have died in the epidemic. Tobias has had little direct experience working on HIV/AIDS issues. During Senate hearings in October 2003, Tobias provided incorrect information about the capacity of poor countries to absorb U.S. funding for AIDS treatment and prevention. Tobias also claimed that declines in the rate of HIV infections in Uganda are the result of campaigns focused primarily on abstinence. Jodi Jacobson, executive director of the Center for Health and Gender Equity points out that promotion of abstinence has only been one aspect of the broader strategy in Uganda, and criticized Tobias for portraying work in the country as a "one-dimensional strategy." Tobias worked at Eli Lilly from 1982 to 1998. He and Lilly have been major donors to the Republican Party. Between 1999 and 2001, Tobias donated \$4,000 to Bush's campaign, and he and his wife donated a total of \$37,000 to the GOP and its state elections committee. Lilly donated \$23,000 to Bush's campaign in 2000 and spent \$234,000 on direct mail to its stockholders on Bush's behalf, according to the Center for Responsive Politics.³² Eli Lilly is a member of PhRMA, which is lobbying the U.S. Government to seek greater intellectual property rights to protect monopolies on expensive medicines in the developing world.

SOCIAL PROFILE

Bioterrorism as a platform

Eli Lilly is using bioterrorism as a platform for a number of reasons. Lilly is looking to boost its public image following controversy on the safety of Prozac, avoid dealing with lawsuits on thimerosal, create broader markets for its drugs and attract investments for the development of new drugs. On overall public image, Lilly donated more than \$1.5 million to the American Red Cross and other agencies for relief efforts in New York City post-September 11th, and has used this donation to promote its efforts against terrorism. Defenders of the provision said it's needed to make sure fear of lawsuits doesn't cause pharmaceutical companies to stop making vaccines, particularly those needed to fight bioterrorism.

In November 2002, the Homeland Security Bill was passed. This included a provision that protects Eli Lilly and other makers of thimerosal – invented by Lilly, and until recently, used as a preservative in many common children's vaccines. The provision forces lawsuits over thimerosal into a special "vaccine court," which may result in the dismissal of thousands of cases filed by parents who argue that mercury in the preservative has poisoned their children, causing autism and other neurological ailments. An estimated 150 individual autism lawsuits and thousands more under preparation target Lilly.³³ The provision was mysteriously slipped into the Bill by Republicans, to which Lilly is a major donor. During the 2002 election cycle, Eli Lilly gave \$1.6 million to political candidates – more money than any other pharmaceutical company – with 79 percent of it going to Republicans, according to the Center for Responsive Politics (a nonprofit research group that monitors campaign finances). In addition, Eli Lilly chairman, president and CEO Sidney Taurel is on the White House Advisory Council on Homeland Security.³⁴

³⁰ Pellegrini, Frank, "Person of the Week: Mitch Daniels," Time.com, Friday, Aug. 17, 2001.

³¹ <http://www.opensecrets.org/bush/cabinet/cabinet.daniels.asp>.

³² Goldstein, Amy and David Brown, "Bush to Name Ex-Lilly CEO to Run AIDS Fund Praise and Skepticism for Major GOP Donor," *Washington Post*, Wednesday, July 2, 2003; Page A02.

³³ Thomas Frank, "A Loss For Parents Of Autistic Kids Suits vs. drug makers blocked," *Newsday*, November 24, 2002.

³⁴ Sheryl Gay Stolberg, "A Capitol Hill Mystery: Who Aided Drug Maker?," in *New York Times*, November 29, 2002.

Other activities:

- Lilly contributed \$2 million to the Centers for Disease Control (CDC) to help scientists from “developed and developing countries” for surveillance of emerging infectious diseases and biological threats to “fight bioterrorism.” Lilly is also making some of its research facilities accessible to researchers from CDC, National Institutes of Health and Department of Defense for government and/or industry driven development of antibiotics and new antivirals. Lilly has already begun testing its cancer drug Gemzar to determine if it could be used to treat smallpox. Lilly states that any of its antibiotics shown to be effective in fighting anthrax or other bioterrorism agents, if approved for that use, will be provided at no profit for victims of bioterrorism. While none of Lilly’s current products are indicated for the treatment of anthrax, Lilly claims that there is scientific evidence that the disease may be susceptible to a number of the corporation’s existing antibiotics.
- Eli Lilly and three other leading pharmaceutical corporations – Bayer, GlaxoSmithKline and Pharmacia are involved in a public-private partnership that is described as a “national educational program for health care providers to help them better identify and treat bioterrorism threats such as anthrax.”³⁵ The program was launched in April 2002 at the U.S. Department of Health and Human Services. As part of the program company sales representatives will distribute 20,000 ‘education guides’ – on anthrax diagnosis and treatment – to doctors’ offices, hospitals, health care clinics and pharmacies in 13 cities. The literature was produced by PhRMA in conjunction with the CDC.³⁶ It contains full-colour photographs of types of anthrax in its various stages and explanations of what to look for and how to treat victims. According to a PhRMA announcement a few days prior to the announcement by Thommy Thompson on the program, there are over 100 companies developing 256 medicines and vaccines for infectious diseases. Some of these companies are working with the Department of Defense.

The four companies involved in the pilot project are coordinating distribution by city as follows:

Bayer Corporation – Albany, Boston, Hartford
GlaxoSmithKline – Chicago, Miami, Philadelphia
Eli Lilly and Company – Detroit, D.C., Indianapolis, Nashville, Tampa
Pharmacia Corporation – Los Angeles, Phoenix³⁷

Recombinant insulin – in October 1982, the FDA approved the marketing of recombinant insulin for diabetics. This was the first product of genetic engineering approved for human use. Its trademark name is Humulin and is manufactured by Eli Lilly. Despite the fact that it was the first recombinant drug approved for human use, its approval by the FDA came only five months after Eli Lilly submitted an application. This was in contrast to 20 to 30 months, which was the usual time period given for approval at the time. Since then, Humulin, as well as Novo Nordisk’s recombinant insulin products have been approved and marketed internationally. As of February 2002, The Society for Diabetic Rights, a group representing Canadian diabetics, announced that they had uncovered reports of eight deaths and 465 adverse drug reactions linked to recombinant insulin. In the U.S., there had been 92 reported deaths and 4,000 adverse reactions reported by diabetics as of February 2002.³⁸

Dr. Henry Miller, the medical officer in charge of Humulin at the FDA at the time, was instrumental in the rapid licensing of Humulin and recombinant growth hormone. Miller was also a major biotech proponent, and went on to serve as the founding director of the FDA’s Office of Biotechnology from 1989 to 1994. He has written extensively on FDA reform, calling for less “burdensome” drug regulation procedures that would take less time and less money. In an article published in *Nature* in October 1998 he writes, “Although biotechnology applied to pharmaceuticals has made signal contributions to medical

³⁵ PhRMA, “America’s Pharmaceutical Companies Partner With Federal Government to Launch Education Program on Bioterrorist Threats,” press release, April 11, 2002

³⁶ Homeland Health, “America’s Pharmaceutical Companies Partner with Federal Government to Launch Education Program on Bioterrorist Threats,” press release, April 11, 2002.

³⁷ <http://www.homelandhealth.com/news/media/newsreleases//2002-04-11.141.phtml>

³⁸ Prithi Yelaja, “Safety of synthetic product called into question,” in *Toronto Star*, February 7, 2002.

therapeutics, it languishes far behind its potential. Life-saving products will continue to emerge, albeit at a trickle of what is possible.”³⁹

When Humulin was approved, Miller stated that the drug showed no clinical advantage over animal insulin, except in the rare cases in which diabetics develop insulin resistance due to formation of antibodies. FDA officials said Humulin was approved so quickly because it resembled animal insulins so closely. Meanwhile, the FDA also announced that “any change in insulin should be made cautiously and only under medical supervision” at the time of approval. Even an Eli Lilly spokesperson stressed that animal insulins would continue to be produced and warned patients against switching to the new insulin without first consulting their physicians.⁴⁰

Over the years, Eli Lilly switched its tune. Since approval, Eli Lilly and Novo Nordisk’s recombinant insulins have gradually replaced animal-based insulins. From 1995 on, Novo Nordisk stopped selling all its animal insulins in the U.S. and Eli Lilly dropped its beef-pork mix, which was once the country’s most-used insulin. By April 2000, the only animal insulin left on the U.S. market was a purse pork product sold by Eli Lilly. In April 2000, a class action lawsuit was filed on behalf of diabetic Suzan Kawulok, who reported “unbearable pain and loss of most use” of her arms caused by Lilly’s recombinant insulin. The 18-page lawsuit stated that Eli Lilly and Novo Nordisk “discontinued or significantly reduced the manufacture of animal-based insulins knowing that diabetics had serious adverse symptoms” from the GE products. The lawsuit also alleged that the two corporations failed to warn patients that GE insulin could cause injurious, life-threatening symptoms, including arthritic syndromes and a lack of awareness of low blood sugar. It also accused Lilly and Novo Nordisk of trying to prevent other companies from making animal-based insulins.⁴¹ Eventually the lawsuit was withdrawn.

In Canada, in February 2002, a group called the Society for Diabetic Rights (http://members.tripod.com/diabetics_world/canadian_society_for_diabetic_ri.htm) called for a public inquiry into the safety of recombinant insulin, stating that the drug is causing harm and death in Canadians. The group, consisting of diabetics and their physicians, also demanded that Health Canada ensure that animal insulins be made more widely available. So far, Health Canada has made slight modifications in its language on recombinant insulin. The following is what Canada’s drug safety regulatory body says about recombinant insulin:

Although the vast majority of people with diabetes use human biosynthetic insulins successfully without any problems, in the past few years, a small number of individuals have reported difficulties. Some individuals reported experiencing hypoglycemia (low blood sugar) without clearly recognizable symptoms, and wide and sudden swings in blood sugar levels, which lead to increased difficulty controlling their diabetes. The reasons for these difficulties are still unclear.

In comparison, the following is the warning in Eli Lilly’s package insert for its recombinant insulin drug:

A few patients who have experienced hypoglycemic reactions after transfer from animal-source insulin to human insulin have reported that the early warning symptoms of hypoglycemia were less pronounced or different from those experienced with their previous insulin.

Other Violations

Prozac

Prozac, once Eli Lilly’s top-selling drug, has had a controversial history. Prozac was approved for release by the FDA in late 1987, despite the 27 deaths that occurred during controlled clinical trials of the drug. Fifteen of the deaths were from suicides, six by overdose, four by gunshot and two by drowning. Eli Lilly and FDA officials were aware of these deaths, and that they were linked to the use of Prozac. Eli Lilly also

³⁹ Henry Miller, “Rising costs hold up drug discovery,” in *Nature*, 395, 835, 1998.

⁴⁰ Lawrence K. Altman, “A new insulin given approval for use in U.S.,” in *The New York Times*, October 30, 1982, section 1, page 1.

⁴¹ Associated Press, “N.M diabetic sues over insulin,” Saturday April 8, 2000.

possessed data confirming very high rates of agitation amongst people on Prozac, and that it caused psychotic mania in patients who had never experienced mania. Eli Lilly hid this information from the public, doctors and some of it from the FDA.⁴²

As of September 1993, there had been close to 30,000 adverse reaction reports associated with Prozac filed to the FDA, including side effects such as delirium, hallucinations, convulsions, violent hostility and psychosis, plus 1,885 suicide attempts and 1,734 deaths – 1,089 by suicide. FDA continues to allow Prozac to stay on the market.⁴³ Prozac, as well as Zoloft and Paxil, are included in a group of anti-depressant drugs known as SSRIs – “selective serotonin reuptake inhibitors” – which are increasingly linked to suicidal behaviour. In January 2003, the FDA approved Prozac for treating children and adolescents. Dr. David Healy, Reader in Psychological Medicine at the University of Wales College of Medicine and Visiting Professor of Medicine at the University of Toronto (U of T), figures that at least 250,000 people worldwide have attempted suicide because of Prozac alone, and 25,000 have succeeded.⁴⁴ Healy has also written more than a dozen books, including his most recent, *Let Them Eat Prozac*.

Healy was also in the news when he was fired by U of T after a presentation he gave at the university, as part of a symposium organized by the Centre for Addiction and Mental health in November 2000. Healy spoke of the possible links between anti-depressant drugs like Prozac, to suicidal behaviour, and stressed the need for research in this area. Healy had accepted a professorship at U of T and the position of clinical director of the mood and anxiety disorder program at the CAMH in September 2000. Shortly after his presentation at the symposium, U of T ended the contract. Eli Lilly is one of the biggest private contributors to CAMH.⁴⁵ Eli Lilly had given more than \$1.5 million to the CAMH in February 1999. The U of T Faculty Association reacted by filing a grievance about the matter⁴⁶. Healy himself launched a \$9.4 million lawsuit against U of T for breach of contract. In the settlement, Healy was offered a visiting professorship in which he spends a week a year at U of T for three years.⁴⁷

David Dunner, professor of Psychiatry and Behavioral Sciences at the University of Washington, was paid by Eli Lilly to conduct an early clinical trial on 100 people of Prozac. Results from the trial were submitted by Lilly with its New Drug Application in seeking FDA approval. Meanwhile, since 1982, Dunner has received more than \$1.4 million from Lilly for his research and seminars. In 1991, Dunner served on an FDA advisory committee that evaluated whether or not anti-depressants such as Prozac contributed to suicides. The committee unanimously agreed there was insufficient evidence to conclude the drugs played a role. Meanwhile, five of the 10 members of the Committee, including Dunner, earned money from drug companies, including Eli Lilly. Dunner had also advised the company on marketing the drug to physicians.⁴⁸

More than 200 lawsuits against Eli Lilly have been filed as a result of adverse reactions from Prozac⁴⁹. In 1994 alone, 160 cases were pending against Prozac. That year, sales from Prozac reached \$1.7 billion – almost one-third of Eli Lilly’s sales. The first case that went to trial occurred in the Fall of 1994, and was filed by victims of a shooting by Joseph Wesbecker, who, in September 1989, shot and killed eight people and wounded twelve or more at his former workplace, and then killed himself. Wesbecker had a ten-year history with mental illness, and at least two suicide attempts. One month before the shootings, Wesbecker had begun taking Prozac. The plaintiff lawyers focused on Prozac as the cause of

⁴² Breggin, Peter, *The Anti-Depressant Fact Book: What Your Doctor Won't Tell You About Prozac, Zoloft, Paxil, Celexa, and Luvox*, Perseus Books Group, Cambridge, Massachusetts, 2001.

⁴³ Kelly Patricia O'Meara, “Regulating Vitamins; Under proposed legislation dressed up as a public-safety concern, the standard for natural dietary supplements would be set far above that for highly profitable drugs being pushed by pharmaceutical giants,” in *Insight*, September 16, 2003.

⁴⁴ Ric Giombetti, “Suicide Science; Dr. David Dunner: Paxil's Friendly Ghostwriter?” in *CounterPunch*, April 8, 2002.

⁴⁵ Ruderman, Larissa, “Prominent Professor Loses Teaching Position,” *The Varsity*, June 28, 2001.

⁴⁶ Nelson, Jeremy, “David vs. Goliath,” *The Varsity*, September 27, 2001.

⁴⁷ Canada NewsWire, “Joint statement of Dr. David Healy, the Centre for Addiction and Mental Health and the University of Toronto,” April 26, 2002.

⁴⁸ David Wickert, “Can UW faculty members serve two masters fairly?,” *The News Tribune*, October 14th, 2002

⁴⁹ Jeff Swiatek, “Lilly faces another Prozac lawsuit; Tennessee widow says husband hanged himself 13 days after drug was prescribed,” in *The Indianapolis Star*, June 25, 2002.

Wesbecker's actions. The *Fentress* case was considered a relatively weak one, partially because of the difficulty in proving that Prozac caused Wesbecker to act as he did. The jury decided in favour of Eli Lilly, by a 9-3 vote – the smallest possible margin. However, soon after the trial, the judge for the trial, John W. Potter, stated that Eli Lilly had fixed the trial. Lilly had secretly given a huge sum of money to Paul Smith, the lead plaintiff lawyer, and his clients, in return for a weaker case to the jury. The amount of money has never been publicly disclosed, but was described the judge who replaced Potter (following pressure from Eli Lilly) as so large that disclosure would harm Eli Lilly.⁵⁰

It turned out that Judge Potter took Lilly to the Kentucky Supreme court over the undisclosed settlement of the *Fentress* case. In May 1996, the Court decided unanimously in favour of Potter. In 1997, Lilly launched a major ad campaign for Prozac, and ran ads in more than 20 major magazines. According to Victoria Murphy, a spokesperson for Eli Lilly “the goal is very simple: to encourage people suffering from depression to get into treatment..there are a variety of drugs available, but naturally, Eli Lilly intends to remain in a leadership role.” Prozac remained the leading anti-depressant drug until it lost patent protection in 2001.

Eli Lilly has made numerous attempts to extend patent protection of Prozac. The corporation allegedly authorized a marketing program in which a free one-month trial of Prozac Weekly was mailed to existing Prozac users to boost sales of the drug. Prozac Weekly is protected by a formulation patent that expires in 2017. Another version of Prozac, called Sarafem, is being marketed for the treatment of premenstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome. It is under patent protection until 2007.

Cymbalta, anti-depressant: A 19-year-old woman who volunteered to take part in a clinical trial of Cymbalta (duloxetine), a new Eli Lilly drug, committed suicide during her participation in the trial in February 2004. The trial was taking place at the Indiana University Medical School campus. The board that oversees all of Eli Lilly's trials on the campus in Indianapolis has ordered the corporation to stop accepting new participants for the local trial of duloxetine. Duloxetine is not only the main ingredient for Cymbalta, but also being used in another Lilly drug to treat stress urinary incontinence. City police said that the patient hung herself in the bathroom of her room at Eli Lilly's hotel-like research lab at the Medical School. The patient had been receiving \$150 a day plus meals, and was among 25 local volunteers and 100 nationally who agreed to take part in the clinical trial. Investigators hope results expected in March 2004 from a toxicology test will determine whether duloxetine played a role in Johnson's death.⁵¹

HIV/AIDS drugs – Eli Lilly was one of 39 pharmaceutical corporations that launched a lawsuit against the government of South Africa. The corporations took South Africa to court over its Medicines and Related Substances Act, a law that would allow the country to import cheaper HIV/AIDS drugs allegedly in violation of patent rights. The lawsuit was launched in February 1998. On April 19, 2001, the pharmaceuticals corporations, under extremely significant international pressure, dropped their case.

Drug testing – in 1996, a *Wall Street Journal* story revealed that for over 20 years Eli Lilly recruited homeless men, mostly alcoholic, in Indianapolis to test experimental drugs. Lilly paid these individuals a relatively low price to participate in these trials. When the story was released, directors of Indianapolis church-run inner-city missions, frequented by homeless men, admitted that they were reluctant to speak up about their doubts on the clinical testing because they were receiving funding from the Lilly Foundation. The Lilly Foundation is an independent entity from Eli Lilly, but is built on Lilly stock and is a major Eli Lilly shareholder, with a 15% ownership.

Diethylstilbestrol (DES) – From 1947 to 1971 Eli Lilly marketed DES despite of inadequate testing. DES was prescribed for the prevention of miscarriage. DES is a synthetic female hormone (estrogen). Between 1941 and 1971, many women who had a history of miscarriage, slight bleeding or diabetes, were given

⁵⁰ Breggin, Peter, *The Anti-Depressant Fact Book: What Your Doctor Won't Tell You About Prozac, Zoloft, Paxil, Celexa, and Luvox*, Perseus Books Group, Cambridge, Massachusetts, 2001.

⁵¹ Death prompts changes in Lilly drug trial, *Fort Wayne News Sentinel*, February 11, 2004.

DES in the form of pills, injections or suppositories. Studies suggest a possible increase in breast cancer in mothers who took the drug DES. In daughters whose mothers took DES during their pregnancy, DES appears to interfere with proper growth and development of the uterus, cervix, vagina, and fallopian tubes. DES was finally banned in 1971 after millions of women were exposed. DES was used in as many as 30 countries, and was manufactured by over 200 pharmaceutical companies under more than 300 names. It was prescribed for hundreds of treatments beyond miscarriage, including: for prostate cancer; breast cancer; acne; menopause symptoms; breast milk suppressant after pregnancy; morning-after-pill on college campuses; to stunt height growth in teenage girls; to prepare transsexuals for sex change; and to stimulate livestock growth.⁵²

Oraflex – Lilly sought FDA approval for release of Oraflex in the U.S. despite reports of the drug causing deaths in England. In 1983, during one Oraflex suit, Dr. W. Ian H. Shedden, vice president of the Lilly Research Labs, testified under oath that he withheld from FDA information concerning 29 European deaths linked to the use of Oraflex. While Lilly lost the case, and was ordered to pay \$6 million to the plaintiff (later settled for an undisclosed amount), many victims remain uncompensated in the U.S. and the UK. In a criminal case in 1985, Lilly was found guilty on 25 counts of withholding information, but paid only a \$1,000 fine for each count.⁵³

Cancer – Like many large pharmaceutical corporations, Eli Lilly profits off of cancer. It manufactures drugs to treat cancer and drugs that cause cancer and produces carcinogenic by-products from its operations. At Eli Lilly's Clinton, Indiana plant alone, Lilly releases 175 tons of recognized carcinogens into the environment every year. Lilly's drug Evista, for the treatment of osteoporosis, has been found to induce ovarian cancer at one-third the recommended human dose in test animals. Recombinant Bovine Growth Hormone (rBGH) was developed in partnership between Eli Lilly and Monsanto and is a synthetic hormone developed from genetic engineering that increases milk production in cows. Studies indicate a possible link between rBGH and breast and gastrointestinal cancer. Eli Lilly's Elanco also sells the cattle hormone Rumensin. Eating hormone-treated meat is suspected to affect estrogen levels, which may increase the risk of cancer.

STAKEHOLDER PROFILE

Patient and health professionals groups

American Cancer Society (ACS): Eli Lilly is one of many corporate donors that provides more than \$100,000 per year to ACS. Many drug, chemical and cosmetic companies are also amongst \$100,000 plus donors. Eli Lilly staff sit on two of ACS's peer review committees – Marcio Chedid is on the Peer Review Committee for Cancer Drug Development and Jeremy R. Graff is on the Peer Review Committee for Molecular Genetics and Oncogenes.

American Diabetes Association (ADA): Largest association for diabetics in the U.S. Eli Lilly is a "Banting Circle Elite Sponsor," which means donates more than \$750,000 per year. ADA promotes Eli Lilly's products. Eli Lilly is also a corporate partner in "Make the Link! Diabetes, Heart Disease and Stroke" an initiative of ADA and the American College of Cardiology. "Make the Link" is meant to increase awareness of the link between diabetes and heart disease. This program provides Eli Lilly and other drug companies to promote drugs for heart conditions.

American Heart Association (AHA): In 2002/2003, Eli Lilly contributed between \$50,000 – 99,000 to the AHA. Eli Lilly is one of the main sponsors of AHA's "Heart of Diabetes" campaign, whose spokesperson is actress/singer Rita Moreno, who played Anita in the 1962 movie "West Side Story." Takeda

⁵² <http://www.desstories.com/desinfo.html>

⁵³ Summa, John, "Eli Lilly," *Multinational Monitor*, Vol. 9, No. 6, June 1998.

Pharmaceuticals, the other main sponsor of the campaign, and Eli Lilly have more than one partnership to co-develop and co-market diabetes drugs. The “Heart of Diabetes” campaign is meant to educate and raise awareness across the U.S., targeting people with type 2 diabetes, insulin resistance and related cardiovascular risks.

American Medical Writers Association (AMWA): the leading professional association for writers, editors, and other communicators of biomedical information. Eli Lilly was a sponsor of the AMWA 2003 Annual Conference, and is also one of two benefactors of AMWA. The other is Takeda Pharmaceuticals. AMWA offers: continuing education, including distance learning; networking opportunities through an annual conference and chapter activities; website services, including job listings and a members’ freelance directory; and the AMWA Journal. Members are mainly freelance writers who work for pharmaceutical companies, universities and medical schools, hospitals, nonprofit organizations, government agencies, journals, and other businesses and organizations.

American Psychiatric Association (APA): World’s largest psychiatric organization. Eli Lilly funds a number of APA projects, including: the Lilly Psychiatric Research Fellowship, which is awarded to a post-graduate medical trainee, and provides an honorarium of \$35,000; Adolf Meyer Lectureship, which provides an honorarium of \$3,000 to a winning lecturer for a presentation at the APA Annual Meeting; and APA/Lilly Products Resident Research Award, which recognizes five psychiatric residents for original scientific research, who each receive \$1,500 each while \$1,000 is given to the residency program. Lilly was also part of a group of drug corporations that paid the APA about \$50,000 per session to control which scientists and papers were presented and to help shape presentations during the weeklong APA annual meeting in 2002.⁵⁴

American Psychiatric Foundation (APF): receives \$20,000 from Eli Lilly under general donations. APF is a charitable and educational affiliate of the 38,000 member American Psychiatric Association (APA). APF provides grants for educational programs on issues related to mental illness, including treatment. The Foundation also administers fellowships for psychiatry residents about development of public policy related to patient care.

Council of Science Editors (CSE): formerly the Council of Biology Editors, CSE’s purpose is to encourage networking, education and discussion amongst members in the scientific, scientific publishing and information science communities, as well as to be an authoritative resource on current and emerging issues in the communication of scientific information. Eli Lilly is a regular sponsor of CSE Annual Meetings.

International Diabetes Federation (IDF): receives funding from Eli Lilly of \$100,000 or more each year. Eli Lilly is a long-term contributor to IDF. In August 2003, it was announced that Eli Lilly would provide \$180,000 over a three-year period to IDF’s Child Sponsorship Program - Life for a Child with Diabetes. Rotary International is the other collaborator on the Program. The Child Sponsorship Program was established in November 2000, and aims to provide more children and adolescents with diabetes in “developing countries” with the means to acquire insulin, equipment and information. The funds from Eli Lilly have been placed in trust with the Rotary Foundation to be used for matching grants.

National Alliance for the Mentally Ill (NAMI): calls itself a “nonprofit, grassroots, self-help, support and advocacy organization of consumers, families, and friends of people with severe mental illnesses.” Eli Lilly is amongst many leading pharmaceutical corporations that provides donations to NAMI on an annual basis. Eli Lilly’s money goes towards various programs, publications and campaigns. Eli Lilly was also the only sponsor for a key NAMI publication called “Access to Effective Medications: A Critical Link to Mental Illness Recovery.” Eli Lilly has also exclusively funded “In Our Own Voice: Living with Mental Illness,” which is a 1.5 hour interactive, multi-media presentation “by consumers for consumers and others” about mental illness. Eli Lilly is the only corporate sponsor for the “Hearts and Mind” educational

⁵⁴ Vedantam, Shankar, “Symposiums Sponsored by Pharmaceutical Companies Trouble Some Psychiatrists,” *Washington Post*, May 26, 2002; Page A10.

program, which aims to increase awareness on the increased risk of heart disease and related conditions, including diabetes, to severe psychiatric conditions. The program includes a 13 minute video and a 26 page booklet.

National Mental Health Association (NMHA): receives more than \$700,000 from Eli Lilly on an annual basis. Eli Lilly contributes the most to NMHA than any other pharmaceutical corporation. NMHA is an advocacy, education and research, and service group. NMHA's main campaign is called the Campaign for America's Mental Health. Eli Lilly was a founding sponsor of the Campaign, and continues to be a main sponsor. The Campaign was established in 1994. Each year millions of people are 'educated' on and screened for mental illnesses through the Campaign, while hundreds of millions of media impressions are generated yearly. Some activities of the Campaign include 'Childhood Depression Awareness Day', 'College Student Outreach Initiative', 'May Is Mental Health Month', and 'National Depression Screening Day'.

Society for Women's Health Research (SWHR): Aims to integrate inclusion of women in major medical research studies. The Society "works to increase public and private funding for research on women's health, promote the inclusion of women in medical research studies, and encourage the scientific examination of the basic biological and physiological differences between men and women." The Society works with policy makers, researchers, and the public. The Society's Corporate Advisory Council includes a number of pharmaceutical corporations, including Eli Lilly. Eli Lilly, through The Lilly Center for Women's Health, provides money to SWHR for annual grants from \$5,000-\$30,000 for pilot projects in both basic gender-based research and clinical studies in women's health. Eli Lilly also funds SWHR's campaign *Some Things Only a Woman Can Do™*, which provides women with information on volunteering for medical research, including clinical drug trials. Eli Lilly was also one of three pharmaceutical corporations (others being Aventis and Wyeth) to fund a town hall meeting on menopause in March 2002, co-organized by SWHR and the U.S. Department of Health and Human Services.⁵⁵

Universities and Public Institutions

Indiana Genomics Initiative (INGEN): Launched in December 2000 with a \$105 million grant from Lilly Endowment. In April 2003 Lilly Endowment announced another \$50 million towards INGEN.⁵⁶ INGEN is a key component of BioCrossroads (originally called the Indian Central Life Sciences Initiative). BioCrossroads was established in 2002 by the city of Indianapolis, the Central Indiana Corporate Partnership, the Indiana Health Industry Forum, Indiana University (IU) and Purdue University. Partners announced investments of \$1.5 billion for BioCrossroads over five years, largely for construction, workforce, collaborations and marketing the area as a "world-class health and life sciences hub." A key collaborator of BioCrossroads is Inproteo (previously called the Indiana Proteomics Consortium). Eli Lilly and Company was a key force in BioCrossroads, having contributed \$900 million during the 3 years leading up to its establishment. Inproteo was founded by Lilly Endowment, IU Advanced Research Technology Institute and the Purdue Research Foundation. Also part of the BioCrossroads network is the Purdue Discovery Park. Lilly Endowment also donated \$26 million to a new research complex at the Discovery Park, which included the development of the Birck Nanotechnology Center.⁵⁷

Indiana University: in May 2003, Richard D. DiMarchi, Group Vice President for Lilly Research Laboratories left the corporation, and accepted a tenured professorship as the Jack and Linda Gill distinguished chair in biomolecular science at IU. DiMarchi maintains a relationship with Lilly as a Visiting Lilly Scholar consulting in the areas of gene-based pharmacology, diabetes, and obesity. DiMarchi's most recent responsibilities were associated with Lilly's investments in research technologies and product development. DiMarchi has played a key role in advancing the field of biopharmaceutics. He has had direct involvement in the discovery and/or development of several Lilly drugs and drug candidates,

⁵⁵ Mundy, Alicia, "Hot Flash, Cold Cash; How a once-respected women's group went through The Change--with the help of drug industry money," in *Washington Monthly*, January/February 2003.

⁵⁶ IU press release, "\$50 Million Grant From Lilly Endowment Boosts Genomics Initiative," April 6, 2003.

⁵⁷ Indiana University press release, "IU School of Medicine has key role in Central Indiana Life Sciences Initiative," February 13, 2002.

including Humulin®, Humalog®, Evista®, Forteo®, Xigris® and PKC beta inhibitor. DiMarchi joined Lilly in 1981. He is the author of more than 150 scientific publications and patents, and is a founding member of the American Peptide Society.⁵⁸

World Health Organization, the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention, Brigham and Women's Hospital (an affiliate of Harvard Medical School), Purdue University, and several companies: working with Eli Lilly to increase the number of trained personnel and drugs available to meet the treatment needs resulting from the expanding crisis of Multi-Drug Resistant Tuberculosis. Lilly's total financial contribution to this effort will be approximately \$70 million through 2006.

Howard University: received \$1.4 million from Eli Lilly for a long-term partnership to increase the representation of blacks and other minorities in medical and pharmaceutical research and to provide students and faculty members with expanded opportunities for research, internships, and employment.

University of Michigan Depression Center: received \$750,000 from the Eli Lilly Foundation in July 2002. The unrestricted, three-year gift from the Lilly Foundation is the largest ever given to a U-M program by the foundation. The money is meant to help accelerate new programs in which people with depression get treatment, and initiate a potential future network of depression centers across the U.S.⁵⁹

McMaster University: Created the Eli Lilly Canada-May Cohen Chair in Women's Health in 2000. Eli Lilly Canada agreed to support the chair with a \$1 million contribution over five years to support research activities. The Eli Lilly Canada-May Cohen Chair will conduct epidemiological research and clinical trials related to determinants and prevalence of women's health problems. The chair holder is also responsible for developing policy recommendations from research findings and educate the public and health care professionals on women's health.⁶⁰

Mount Sinai Hospital (Toronto): entered into a five-year partnership with Eli Lilly in 2001 for diabetes research. Eli Lilly Canada agreed to contribute \$1 million over that time to the Samuel Lunenfeld Research Institute at Mount Sinai. The 'Eli Lilly Research Program in Diabetes' is meant to evaluate the incidence and localized outbreaks of diabetes in First Nations' peoples and "other minorities."

University of Montreal, Teaching Hospital of the University of Montreal: received \$1 million from Eli Lilly Canada in March 2001 to create the Lilly Research Fund on Breast Cancer. ScotiaBank also contributed \$1 million to create the Scotiabank Chair in Diagnosis and Treatment of Breast Cancer. The Hospital also invested \$500,000 in the creation of the Chair. The breast cancer research centre, created with the \$2.5 million investment, is developing new methods for the detection and treatment of the disease.⁶¹

University of Toronto, Centre for Addiction and Mental Health (CAMH): Eli Lilly Canada is one of the principal donors to CAMH, having given over \$1.5 million in February 1999 in support of CAMH's Centred on Hope Campaign. In September 2000, Eli Lilly Canada announced the development of two fellowships at CAMH called The Eli Lilly Canada Fellowships in Women's Mental Health. Eli Lilly Canada has also helped establish the Eli Lilly Education Centre at CAMH.

University of Toronto, Faculty of Pharmacy: Industrial Pharmacy Residency Program is administered jointly with Eli Lilly Canada. Provides pharmacists with specific experience and training in the field of pharmacoconomics in the context of the pharmaceutical industry. The program also provides residents with the opportunity to explore all other major areas of the pharmaceutical industry such as marketing, research and development and medical information. It is a one-year program. The discipline of

⁵⁸ IU Chemistry Department, march 3, 2003

⁵⁹ "U-M Depression Center receives \$750K gift from Eli Lilly Foundation," July 12, 2002.

⁶⁰ "McMaster University and Eli Lilly Canada Create \$1 Million Chair In Women's Health," Eli Lilly press release, 06/02/2000.

⁶¹ Université de Montréal, "\$2.5 Million in funding for breast cancer research at UdeM and the CHUM; Launch of the Scotiabank Chair in Diagnosis and Treatment of Breast Cancer," press release, March 8, 2001.

pharmacoeconomics involves the comparison of the costs and consequences of adopting one pharmaceutical alternative over another drug or non-drug alternative.

University of Toronto, University Health Network: received a \$400,000 donation from Eli Lilly Canada to assist in the creation of the Scott Taylor Chair in Lung Cancer Research.

University of Melbourne, the Mental Health Research Institute of Victoria, and the Alfred Psychiatric Research Centre: involved in a \$ AUD 5 million partnership with Eli Lilly. Projects include a five-year study to determine effective ways of promoting recovery from a first psychotic episode and preventing it from recurring; research into depression in post-menopausal women that will help identify those most at risk and determine the impact of the illness on other aspects of their health; analysing changes in brain receptors in people with schizophrenia and how medication interacts with specific receptors to prevent the decline in brain function associated with the condition; one of the world's largest and most comprehensive studies of people with bipolar disorder. The study will follow 240 people over a two-year period, and help determine the most effective type of treatment.⁶²

National University of Singapore (NUS), and the Agency for Science, Technology & Research (A*STAR): have a joint venture with Eli Lilly called the Lilly-NUS Centre for Clinical Pharmacology Pte Ltd. At the time of its establishment it was the only Lilly Clinical Pharmacological unit outside U.S. with its own clinical research unit for conducting clinical trials with new pharmaceutical agents. The Company was formed in late 1996 and became operational in 1997 in temporary facilities at the National University Hospital. From August 1998, it has occupied facilities in the Clinical Research Centre of the NUS.

Cancer Care Ontario (CCO) and the Canadian Institutes of Health Research (CIHR): have a partnership worth \$3.75 million with Eli Lilly Canada to support "translational" cancer research. \$1.275 million of the money comes from CCO, \$1.275 million from Eli Lilly Canada, and \$1.2 million from CIHR. Translational scientists are trained to convert basic discoveries in the lab into clinical patient care.⁶³

National Cancer Institute (NCI), the Foundation for the National Institutes of Health (FNIH), and five pharmaceutical companies, including Eli Lilly: partnership proposed by the American Association of Cancer Institutes (AACI) and coordinated by the Friends of Cancer Research. Pharmaceutical corporations include Aventis, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, and Novartis. The partnership provides a total of \$5.7 million to the six cancer centers to increase accessibility of early phase clinical trials to geriatric and 'minority' patients.

Princeton University: Eli Lilly has endowed a graduate student fellowship in chemistry in honor of emeritus professor Edward C. Taylor at Princeton. The \$500,000 gift, which was augmented with a \$250,000 matching contribution from a fund established by alumnus Gordon Wu, creates a permanent fund whose income will pay for the education of an exceptional graduate student with interests in organic chemistry. The fellowship builds on the department's relationship with Lilly, which is developing Alimta, a potentially major cancer drug that Taylor discovered.

University of North Carolina at Chapel Hill: received \$5 million from alumni Vaughn and Nancy Bryson to establish a clinical genetics research center on the university's medical campus. Vaughn Bryson, who is retired, is a former chief executive officer at Eli Lilly. In February 2001, UNC Chancellor James Moeser announced a campus-wide genomics initiative representing a public-private investment of at least \$245 million over the next 10 years. Four new buildings affiliated with genomics research are supported by a combination of funds from the statewide higher education bond referendum, prior state appropriations and campus sources including private gifts.⁶⁴

Patent Disputes

⁶² Major, Jason, "\$5m to mental health alliance," November 26, 2003

⁶³ New \$3.75 Million Cancer Research Program Delivers Cancer Care from "Bench to Bedside", June 2002.

⁶⁴ Former Eli Lilly CEO gives \$5M to UNC, *Triangle Business Journal*, July 2, 2003

Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, Harvard University and Ariad Pharmaceuticals (Cambridge, Mass): filed a suit against Eli Lilly in 2002 claiming that two of Lilly's drugs – Evista (used against osteoporosis) and Xigris (used to treat sepsis) – infringed on a patent (No. 6,410,516). The patent had been issued to researchers from MIT, Whitehead and Harvard and then licensed to Ariad in 1991. The suit, filed in federal court in Boston, seeks damages commensurate with the amount of a "reasonable royalty" but did not give a figure. A spokesman for Lilly said the company had begun work on the two drugs before the patent application was filed, in 1986, and considers this an "after-the-fact" patent.⁶⁵

Inproteo: recently obtained a license from Lilly for the rights to the so-called His-tag technique. While the patent will not expire until December 4, 2004, the company is mounting a major campaign to collect royalties from those users that it believes are infringing the patent. Inproteo has identified about 600 companies and institutions using the technique, according to an article in *The Scientist*. The company has written letters to about 200 of the companies and institutions, including universities like Stanford and Harvard. Max J. Kenemore, patent counsel for Inproteo says, "We are going after everyone we can find who is using this lab tool." The His-tag technique, which was patented by Lilly in 1986, involves separating and purifying proteins by attaching peptides, which are amino-acid compounds. Mr. Kenemore says Inproteo is looking through patents and publications to identify parties that describe their use of the technique as part of their research. "The publications are an admission of infringement," he says. Inproteo has not disclosed how much it expects to collect from the effort, but Mr. Kenemore says it hopes to use the proceeds to cover operating expenses once its initial three years of financing runs out. Founded in April 2002 with an initial investment of \$12-million, Inproteo was called the Indiana Proteomics Consortium. Its goal is to commercialize inventions developed by Lilly and the two universities.⁶⁶

City of Hope Medical Center in Duarte, California: The development of Humulin occurred as a result of a partnership between Genentech and the City of Hope Medical Center, initiated in 1976. During the partnership, in 1978, City of Hope scientists synthesized the gene for human insulin and then produced insulin by putting that gene in bacteria. The work was funded by Genentech in exchange for a 2 percent royalty on resulting patents to the Medical Center. Over 100 patents resulted from the research.⁶⁷ But in 1999, the Medical Center filed a lawsuit in the California state court, claiming that Genentech did not pay all of the royalties it owed from the 20 deals in which Genentech licensed the patents to other companies, like Eli Lilly.⁶⁸ The Medical Center won the case, and in June 2002, Genentech was ordered by the court to pay more than \$500 million in punitive and compensatory damages. Genentech tried to appeal the ruling, but without success.

⁶⁵ Blumenstyk, Goldie, "Possible Legal Battle Over Drug Patent," *The Chronicle of Higher Education*, July 19, 2002.

⁶⁶ 2 Universities Team With Pharmaceutical Giant to Seek Back Royalties on a Patented Technique, *The Chronicle of Higher Education*, September 19, 2003.

⁶⁷ City of Hope National Medical Center, "City of Hope National Medical Center awarded \$200 million in punitive damages in lawsuit against Genentech, Inc.," press release, June 24, 2002.

⁶⁸ Andrew Pollack, "Medical Center Seeks More Payments From Genentech," in *The New York Times*, August 29, 2001.

APPENDICES

Appendix 1 – Eli Lilly Subsidiaries

Andean Technical Operations Center (Peru)	Beimirco SA, Uruguay	BountyLab Corporation (Indiana)
Chugai Lilly Clinical Research Co, LTD. (Japan)	Control Diabetes Services, Inc. (Indiana)	Creative Packaging Limited (UK)
Damsen Trading Ltd, Malta	Damsen Trading Limited, Switzerland	Darilor SA, Uruguay
Del Sol Financial Services, Inc. (British Virgin Islands)	Dista Ilac Ticaret Ltd Sti (Turkey)	Dista, Inc. (Indiana)
Dista Italia S.r.l.	Dista Mexicana, S.A. de C.V. (Mexico)	Dista Products & Compana Venezuela S.A.
Dista Products Limited (UK)	Dista, S.A. (Spain)	Dista-Produtos Quimicos & Farmacuticos, LDA (Portugal)
E L Management Incorporated (Delaware)	Elanco Animal Health, Korea, Ltd.	Elanco Products Limited (UK)
Elanco Quimica Limitada (Brazil)	Elanco Trustees Limited (Ireland)	Elanco-Valqumica, S.A. (Spain)
ELCO Dominicana, S.A. (Dominican Republic)	ELCO Insurance Company, Ltd. (Bermuda)	ELCO International Sales Corporation, United States and Virgin Islands
Elco Participation, sarl (France)	ELCO SAE (Egypt)	Eli Lilly & Co. (Ireland) Limited
Eli Lilly & Co. LTD. (UK)	Eli Lilly and Company (India) Pvt. Ltd.	Eli Lilly and Company (N.Z.) Limited (New Zealand)
Eli Lilly and Company (Taiwan), Inc.	Eli Lilly Asia, Inc. (Delaware)	Eli Lilly Asian Operations, Limited (Hong Kong, PRC)
Eli Lilly Australia Pty. Limited	Eli Lilly (Basingstoke) Limited (UK)	Eli Lilly Benelux, S.A.
Eli Lilly Canada Inc. (Canada)	Eli Lilly CR s.r.o. (Czech Republic)	Eli Lilly Danmark A/S
Eli Lilly de Centro America, S.A. (Guatemala)	Eli Lilly de Centro America, Sociedad Anonima (Costa Rica)	Eli Lilly de Mexico, S.A. de C.V.
Eli Lilly do Brasil Limitada (Brazil)	Eli Lilly Egypt	Eli Lilly Export S.A. (Switzerland)
Eli Lilly Finance S.A. (Switzerland)	Eli Lilly Funding Ltd. (Hong Kong)	Eli Lilly Ges.m.b.H. (Austria)
Eli Lilly Group Limited (UK)	Eli Lilly Holding Company Ltd. (UK)	Eli Lilly Holding GmbH (Germany)
Eli Lilly Holdings Ltd (UK)	Eli Lilly Industries, Inc. (Delaware)	Eli Lilly Interamerica Inc. y Compana Limitada (Chile)
Eli Lilly International Corporation (Indiana)	Eli Lilly Iran, S.A. (Iran)	Eli Lilly Israel Ltd.
Eli Lilly Italia S.p.A.	Eli Lilly Japan K.K.	Eli Lilly Leasing Limited (UK)
Eli Lilly Malaysia Sdn Bhd.	Eli Lilly Maroc S.a.r.l. (Morocco)	Eli Lilly Nederland B.V.
Eli Lilly Nederland Holding B.V.	Eli Lilly Nigeria Ltd.	Eli Lilly Norge A.S. (Norway)
Eli Lilly Pakistan (Pvt.) Ltd.	Eli Lilly (Philippines), Incorporated	Eli Lilly Polska Sp. z.o.o. (Ltd.)
Eli Lilly Property Limited (UK)	Eli Lilly Regional Operations GmbH (Austria)	Eli Lilly Resources Limited (UK)
Eli Lilly S.A. (Switzerland)	Eli Lilly (S.A.) (Proprietary) Limited (South Africa)	Eli Lilly Singapore Pte. Ltd.
Eli Lilly Spain Holding ETVE, S.L.	Eli Lilly Suzhou Pharmaceutical Company Limited (China)	Eli Lilly Sweden AB
Eli Lilly Vostok SA, Geneva (Switzerland)	Eli Lilly y Compana de Mexico, S.A. de C.V. (Mexico)	Eli Lilly y Compana de Venezuela, S.A.
Elsa France, S.A.	GEMS Services, S.A. (Belgium)	Greenfield Pharmaceuticals Limited (UK)
InnoCentive, Inc (Delaware)	Integrated Disease Management (NZ) Limited	Integrated Medical Systems, Inc. (Colorado)
Irisfarma S.A. (Spain)	Kinsale Financial Services, Ltd. (Ireland)	LE Heston Energy, LLC (Delaware)
LICO sarl (France)	Lilly Clinical Operations S.A. (Belgium)	Lilly del Caribe, Inc. (Cayman Islands)
Lilly Del Mar, Inc. (British Virgin Islands)	Lilly Deutschland GmbH (Germany)	Lilly Development Centre S.A. (Belgium)
Lilly Forschung GmbH (Germany)	Lilly France S.A.S	Lilly Global Services, Inc. (Indiana)
Lilly GmbH (Germany)	Lilly Grodzisk Sp. z.o.o. (Poland)	Lilly HK Finance I, LLC (Hong Kong)
Lilly Hungaria KFT	Lilly ICOS (Delaware)	Lilly Industries Limited (UK)
Lilly Korea LTD.	Lilly Pharma Fertigung & Distribution GmbH (Germany)	Lilly Pharma Holding GmbH (Germany)
Lilly Pharma Ltd. (Russia)	Lilly Pharma Produktion GmbH & Co. KG (Germany)	Lilly Property Limited (UK)
Lilly Research Centre Limited (UK)	Lilly Resources Limited (UK)	Lilly Services S.A. (Belgium)
Lilly Systems Biology PTE LTD (Singapore)	Lilly Turkey A.S.	Lilly, S.A. (Spain)

Lilly-Farma, Produtos Farmaceuticos, Lda. (Portugal)	Lilly-NUS Centre for Clinical Pharmacology Pte. Ltd. (Singapore)	Oldfields Financial Management S.A. (Switzerland)
OY Eli Lilly Finland Ab	PaRxner B.V. (The Netherlands)	Pharmabrand, S.A.C.I. (Greece)
Pharmaserve - Lilly S.A.C.I. (Greece)	PRAXICO Ltd. (Hungary)	Spaly Bioquimica, S.A. (Spain)
STC Pharmaceuticals, Inc.	TDM BV (The Netherlands)	Vital Farma Produtos Farmaceuticos (Portugal)
Vitalia Pharma Sp. Z.o.o. (Poland)		

Appendix 2 – Eli Lilly Trademarks

Actos [®] *(pioglitazone hydrochloride, Takeda), Takeda	Affinitak [™] (LY900003 and formerly ISIS 3521, ISIS Pharmaceuticals), Lilly
Alimta [®] (pemetrexed disodium, Lilly)	Axid [®] *(nizatidine, Lilly), Reliant Pharmaceuticals, LLC
Ceclor [®] (cefaclor, Lilly)	Cialis [™] *(tadalafil, ICOS), Lilly ICOS LLC
Coban [®] (monensin sodium, Elanco)	Cymbalta [™] (duloxetine hydrochloride)
Darvon [®] *(propoxyphene hydrochloride, Lilly), NeoSan Pharmaceuticals, Inc.	Dobutrex [®] (dobutamine hydrochloride, Lilly)
Evista [®] (raloxifene hydrochloride, Lilly)	Forteo [®] (teriparatide of recombinant DNA origin, Lilly)
Forsteo [®] (teriparatide of recombinant DNA origin, Lilly)	Gemzar [®] (gemcitabine hydrochloride, Lilly)
Humalog [®] (insulin lispro of recombinant DNA origin, Lilly)	Humatrope [®] (somatropin of recombinant DNA origin, Lilly)
Humulin [®] (human insulin of recombinant DNA origin, Lilly)	Keflex [®] (cephalexin, Dista)
Micotil [®] (tilmicosin, Elanco)	Permax [®] (pergolide mesylate, Lilly)
Prozac [®] (fluoxetine hydrochloride, Dista)	Prozac [®] Weekly [™] (fluoxetine hydrochloride, Lilly)
ReoPro [®] (abciximab, Centocor), Lilly	Rumensin [®] (monensin sodium, Elanco)
Sarafem [™] *(fluoxetine hydrochloride, Lilly), Galen Holdings PLC	Strattera [™] (atomoxetine hydrochloride, Lilly)
Surmax [®] (avilamycin, Elanco)	Tylan [®] (tylosin, Elanco)
Vancocin [®] (vancomycin hydrochloride, Lilly)	Xigris [®] (drotrecogin alfa (activated), Lilly)
Zyprexa [®] (olanzapine, Lilly)	

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Actos[®] is a trademark of Takeda Chemical Industries, Ltd.

Axid[®] is a trademark of Reliant Pharmaceuticals, LLC.

Cialis[™] is a trademark of Lilly ICOS LLC.

Darvon[®] is a trademark of NeoSan Pharmaceuticals, Inc.

Sarafem[®] is a trademark of Galen Holdings PLC.