FOREST LABORATORIES INC
Form DEFA14A
August 08, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934
(Amendment No.)

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Check the appropriate box:

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FOREST LABORATORIES, INC.
(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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INTRODUCTORY NOTE

The following materials are included in this Forest Laboratories, Inc. (Forest or FRX) Schedule 14A / DEFA14A filing and have also been posted, along with information about Forest s 2011 Annual Meeting of Shareholders, at: www.FRX2011annualmeeting.com.

Carl Icahn has sought to use the potential HHS-OIG exclusion action to suggest that Forest s Board acted inappropriately in supporting Mr. Solomon. Forest believes that these documents demonstrate what the Company has always stated: that Mr. Solomon has never been accused of wrongdoing, and that the potential exclusion was simply based on his position at Forest. The recent letter, dated August 5, 2011, from the HHS-OIG dropping the case is a strong validation of the Board s decision to support Mr. Solomon.

1. August 5, 2011 Case Closure Letter from the Office of Inspector General U.S. Department of Health & Human Services ("HHS-OIG") to Howard Solomon
2. June 13, 2011 Submission On Behalf of Howard Solomon to HHS-OIG from Davis Polk & Wardwell LLP
3. April 5, 2011 FRX Board Meeting Minutes
4. March 30, 2011 FRX Letter to HHS-OIG from Debevoise & Plimpton LLP
5. March 29, 2011 FRX Presentation to HHS-OIG from Debevoise & Plimpton LLP

Important Information

The materials contained on the www.FRX2011annualmeeting.com website contain certain previously published third-party material. Unless otherwise indicated, consent of the author and publication has not been obtained to use the material as proxy soliciting material.

Forest Laboratories, its directors, director nominees and certain of its executive officers may be deemed to be participants in the solicitation of proxies from Forest shareholders in connection with the matters to be considered at Forest Laboratories 2011 Annual Meeting. On July 18, 2011, Forest Laboratories filed its definitive proxy statement (as it may be amended, the Proxy Statement) with the U.S. Securities and Exchange Commission (the SEC) in connection with such solicitation of proxies from Forest shareholders. FOREST SHAREHOLDERS ARE STRONGLY ENCOURAGED TO READ THE PROXY STATEMENT AND ACCOMPANYING PROXY CARD AS THEY CONTAIN IMPORTANT INFORMATION. Detailed information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, is set forth in the Proxy Statement, including Appendix B thereto. Shareholders can obtain the Proxy Statement, any amendments or supplements to the Proxy Statement and other documents filed by Forest Laboratories with the SEC for no charge at the SEC s website at www.sec.gov. Copies are also available at no charge at Forest Laboratories website at www.frx.com or by writing to Forest Laboratories at 909 Third Avenue, New York, New York 10022.

Forward Looking Information

Except for the historical information contained herein, this document may contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, changes in laws and regulations affecting the healthcare industry, and the risk factors listed from time to time in Forest Laboratories Annual Reports on Form 10-K (including the Annual Report on form 10-K for the fiscal year ended March 31, 2011), Quarterly Reports on Form 10-Q, and any subsequent SEC filings.

Howard Solomon
c/o Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022
Dear Mr. Solomon:
Re: OI File Number H-l1-40460-9
You were previously advised that an exclusion action was being proposed under section 1128(b)(15) of the Social Security Act based on your relationship to Forest Pharmaceuticals, Inc.
Based on a review of the information in our file and consideration of the information that your attorneys provided to us, both in writing and during an in-person meeting, we have decided to close this case. We anticipate no further action related to this matter.

cc: Robert B. Fiske, Jr.
Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017

SUBMISSION ON BEHALF OF HOWARD SOLOMON TO THE OFFICE OF INSPECTOR GENERAL U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES davis polk & ward well llp 450 Lexington Avenue New York, New York 10017 (212)450-4000 by: Robert B Fiske, Jr. Martine M. Beam on Ross Galin Karen Luftglass June 13,2011

TABLE OF CONTENTS page

On behalf of Howard Solomon, the President, Chairman and Chief Executive Officer of Forest Laboratories, Inc. (Forest or the Company), we respectfully submit this memorandum in response to the notice of intent to exclude, dated April 8, 2011, from the United. States Department of Health & Human Services (HHS), Office of Inspector General (OIG or the Office). **INTRODUCTION** While we recognize that, under certain circumstances, it might make sense to exclude an individual from participation in federal health care programs even absent a personal criminal conviction, such circumstances are not present here. Over the past thirty years, Mr. Solomon has built Forest from a small vitamin and generics manufacturer into a company that brings life-saving drugs to the U.S. market to satisfy unmet patient needs, and has done so in an entirely ethical and responsible manner. Under Mr. Solomon s leadership, Forest has never before had any issues with the OTG or the Department of Justice (DOJ). Nor has it ever been alleged that Mr. Solomon participated in the conduct at issue in the recent resolution, or that he bears personal responsibility for that conduct simply by virtue of his role as CEO. Under the OIG s own Guidance for Implementing Permissive Exclusion Authority, the exclusion of Mr. Solomon under Section 1128(b)(15)(A)(ii) of the Social Security Act would be unjust and would be inconsistent with the stated purpose of exclusion to protect the federal health care program and its beneficiaries from untrustworthy participants without putting patient access to care at risk. *First,* while we do not dispute that the Company conduct at issue was serious, the nature and scope of the misconduct do not support the exclusion of Mr. Solomon. The

Levothroid conduct resulted from a misunderstanding of the unique regulatory landscape associated with the FDA s reclassification of Levothroid a grandfathered drug that had been on the market for decades as an unapproved new drug, and the FDA s related Guidance for Industry. Likewise, the off-label promotion of Celexa was limited, and. accounted for a tiny percentage of sales (well-below the off-label use of other drugs within the SSRI class). Moreover, the timing of the conduct militates against exclusion. The OIG s new policy of using the Secretary s permissive exclusion authority against executives was not in place at the time the conduct occurred over eight years ago. And, even at the time the Company s plea was agreed to, the OIG had not yet issued guidance regarding how it intended to exercise its permissive exclusion authority. The retroactive application of the OIG s new policy would be highly unjust, particularly given that executives whose companies engaged in even more grievous and allegedly recidivist conduct during this same time period, and even more recently, have not been excluded. *Second,* Mr. Solomon played no role in the misconduct and we are not aware of any allegation that Mr. Solomon knew, or should have known, that Forest or its employees were violating any law, FDA regulation or federal health care program requirement.[1] Nor does Mr. Solomon bear personal responsibility for the conduct simply by virtue of his role as CEO. To the contrary, for the past thirty years, Mr. Solomon has led the Company with unflagging integrity and at all times engaged in the type of oversight that the OIG would expect of a diligent and responsible CEO. Since being ! Mr. Solomon has not been afforded notice of (let alone opportunity to contest) any particular factual allegations that might underlie the OIG s consideration of his proposed exclusion. Mr. Solomon has requested the opportunity to review any such allegations and any materials purportedly supporting them, and to respond to them in advance of the OIG s final determination.

chosen as CEO in 1977, in large measure because of his integrity, Mr. Solomon has implemented a strategic vision for Forest focused on co-developing and acquiring licenses for drugs that, in many cases, otherwise would not have become available to patients in the United. States. Mr. Solomon s personal integrity has been critical to the partnerships required to bring these important drugs to the U.S. market. Exclusion of Mr. Solomon would harm ongoing similar efforts and unfairly tarnish an otherwise spotless career. *Third,* Mr. Solomon has long set the highest standard for ethical conduct at the Company and has always insisted on compliant behavior. His response to the misconduct uncovered in the investigation full cooperation and a re-doubled commitment to compliance so as to guard against future issues was the exact response the OIG would desire from a pharmaceutical executive. Indeed, Mr. Solomon has substantially enhanced Forest s compliance program and eliminated certain activities that were related to the conduct at issue in the DOJ investigation. In addition, under the OIG s supervision, and with Mr. Solomon s active support and participation, the Company is fully and successfully implementing a demanding Corporate Integrity Agreement (CIA). *Fourth,* thanks in no small part to Mr. Solomon s leadership, Forest had an exemplary record before these recent issues. As noted above, prior to the Levothroid and Celexa investigation, Forest had never been the subject of either OIG or DOJ enforcement inquiries. As such, neither Forest nor Mr. Solomon has engaged in the type of recidivist conduct that the OIG has identified as a primary reason for its new policy of executive exclusion. Exclusion of Mr. Solomon would also cause significant collateral consequences to Forest s shareholders and the patients who depend on its drugs. Mr.

Solomon s anticipated successor unexpectedly retired last year to attend to health and family matters. Although he remains a member of Forest s Board of Directors, he is no longer is a position to discharge executive duties. As a result, the Company undertook a management reorganization with the goal of identifying a new successor. Pursuant to that reorganization, certain executives were promoted and Mr. Solomon temporarily took on additional responsibilities, including the role of President. The management reorganization contemplates Mr. Solomon s continued service because he is critical to Forest s relationships with its current business partners and is integral to ongoing discussions about licensing new products for distribution in the United States. Because both of these responsibilities are central to Forest s business model, Mr. Solomon s exclusion likely would have a negative impact on Forest s shareholders. Moreover, based on Mr. Solomon s long track record of bringing products to United States patients, his exclusion also likely would have an adverse impact on federal health care program beneficiaries, namely the patients who depend on Forest s drugs. Moreover, as a precedential matter, if Mr. Solomon is excluded on these facts, then the bar for executive exclusions will be set so low that, if the OIG intends to apply exclusion on an even-handed basis in the future, then every CEO of every company that enters a guilty plea will likewise face a substantial threat of exclusion, even in the complete absence of personal fault. Such a policy would seriously hamper law enforcement efforts to reach negotiated resolutions that would permit pharmaceutical companies to continue to distribute their drugs to federal health care program beneficiaries, because every company will have to assume that, if it settles with the government, its CEO may be excluded.

Finally, exclusion here would undermine not advance the OIG s efforts to use the Secretary s exclusion authority to eliminate untrustworthy participants from the federal health care system and to foster responsible corporate cultures. Excluding Mr. Solomon a corporate leader of great character and. integrity who has led. Forest in an ethical manner and has never been alleged to have engaged in, or known of, misconduct -based solely on the misconduct of others in which he was not involved and for which he bore no personal responsibility will be viewed by the industry as an arbitrary exercise of authority. As a result, his exclusion would neither deter misconduct nor encourage greater vigilance. To accomplish its goal, the OIG should send the message that it will exercise its exclusion authority fairly and in accordance with its prescribed factors. The OIG can only do this by deciding not to exclude Mr. Solomon. **I. THE EXCLUSION OF MR. SOLOMON WOULD BE INCONSISTENT WITH THE PURPOSE AND INTENT OF THE EXCLUSION STATUTE A. The Purpose of the Exclusion Statute Would Not be Served by Excluding Mr. Solomon** Section 1128(b)(15)(A)(ii) provides for the permissive exclusion of an owner, officer or managing employee of a sanctioned entity based on the individual s role or interest in the sanctioned entity/ The statute and permissive nature of the exclusion authority grant the Secretary significant power,[3] which the OIG has stated it will wield with care: [2] 42 U.S.C. § 1320a-7(b)(15) (2011); Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act, Office of the Inspector General (Oct. 19, 2010). Copies of the statute and the guidance are attached to the Affirmation of Marline M. Beamon, dated June 13, 2011 (the Beamon Aff.) as Exhibits (Exs.) 1 and 2. [3] In fact, we question the constitutionality of the statute and its grant of power, at least as it would have to be construed and applied to permit exclusion in this case. We do not, however, seek to debate that question in the confines of this submission. In addition, we question the constitutionality of Section

We are mindful of our obligation to exercise this authority judiciously, and we do not propose to exclude all officers and managing employees of a company that is convicted of a healthcare-related offense.^ Federal courts, the HHS Departmental Appeals Board and the OIG itself consistently have explained that the statutory purpose of permissive exclusion is not punitive; rather, the primary purpose of permissive exclusion is to protect federal health care programs and their beneficiaries from untrustworthy participants.[5] Consistent with (b)(15)(A)(ii), both on its face and as applied to Mr. Solomon on these facts. In particular, excluding Mr. Solomon without meaningful pre-deprivation administrative or judicial review and without a rational relationship to the legitimate state interests the statute was designed to protect, runs afoul of the Equal Protection and Due Process Clauses of the Constitution, among others. The OIG should use its discretion carefully to chart a course that avoids these and other constitutional infirmities, including by properly construing the statute not to permit exclusion of individual officers or managers where there is no demonstration of personal fault, or at a minimum making clear that the OIG does not intend to abuse the Secretary s statutory discretion by seeking to exclude individuals without such a demonstration. [4] *Improving Efforts to Combat Health Care Fraud,* Subcomm. on Oversight of the H. Comm. on Ways & Means (March 2, 2011) (testimony of Lewis Morris, Chief Counsel to the Inspector General, U.S. Dep t of Health and Human Servs.) (3/2/11 Morris Testimony); *New Tools for Curbing Waste and Fraud in Medicare andMedicaid,* Subcomm. on Fed. Fin. Mgmt, Gov tlnfo., Fed. Servs. andlnt l Sec. of the S. Comm. on Homeland Sec. and Governmental Affairs (March 9, 2011) (testimony of Daniel R. Levinson, Inspector General, U.S. Dep t of Health and Human Servs.) (3/9/11 Levinson Testimony). opies of the transcripts from this testimony are attached to the Beamon Aff. as Exs. 3 and 4. [5] For example, in an interview last year discussing the OIG s exclusion authority under Section 1128(b)(15), Mr. Morris reportedly explained: [Ultimately the Inspector General s Office is not here to mete out punishment. We are here to protect the integrity of the Medicare and Medicaid programs, to promote their efficiency and their effectiveness, and Congress has given us a mandate to remove from the program those who have abused our patients and demonstrated that they are not trustworthy. Walter Armstrong, *Crackdown on C-Suite,* pharm. executive, June 2010, at 64. A copy of this article is attached to the Beamon Aff. as Ex. 5. *See also Manocchio v. Kusserow,* 961 F.2d 1539, 1542 (11th Cir. 1992) (While the desire to provide a deterrent is a punitive goal, we find that the legislative history... demonstrates that the primary goal... is to protect present and future Medicare beneficiaries... Therefore, since the legislative intent of the exclusionary period is to protect the public, the sanction is remedial, not punitive.); *In re Sukumar Roy,* DAB CR 205 (1992) (The purpose of exclusions, as evidenced by Congress, is remedial.); *In re Charles J. Burks,* DAB CR 54 (1989) (Congress enacted section 1128 of the Act to protect the Medicare and Medicaid programs from fraud and abuse and to protect the beneficiaries and recipients of those programs from incompetent practitioners and inappropriate or inadequate care...The key term to keep in mind is protection, the prevention of harm.); 3/2/11 Morris

this purpose, in seeking passage of Section 1128(b)(15), the OIG declared that the provision was intended to rid the industry of so-called mobile owners *i.e.,* repeat offenders who move on from an excluded company and continue to engage in misconduct at other companies.[6] More recently, the OIG has stated, that permissive exclusion under Section 1128(b)(15) also is intended to address situations in which the owners or officers of a sanctioned company view monetary fines and penalties as a cost of doing business.[7] The OIG has stated that it believes that it can influence such views [b]y excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud.[8] None of these rationales supports the exclusion of Mr. Solomon. There is no basis whatsoever to conclude that Mr. Solomon is untrustworthy or poses a threat to health care program participants. Mr. Solomon has dedicated his career to bringing drags to the market that he believes will help patients and satisfy unmet medical needs, and he has done so in an entirely responsible and ethical manner. Mr. Solomon was not directly involved in any misconduct t Forest; nor could he Testimony ([Tjhe OIG is using its exclusion authorities to bar from the federal health care programs those individuals who lack integrity and pose a threat to our beneficiaries.). Copies of these cases and the transcript from this testimony are attached to the Beamon Aff. as Exs. 6, 7, 8 and 9. [6] *See, e.g.. Medicare and Medicaid Fraud: Administrative Sanctions and Repeat Offenders in HHS Health Care,* Subcomm. on Human Res. and Intergov t Relations of the H. Gov t Reform and Oversight Comm. (Sept. 28, 1995) (testimony by June Gibbs Brown, Inspector General, U.S. Dep t of Health and Human Servs.). A copy of the transcript from this testimony is attached to the Beamon Aff. as Ex. 10. [7] *See* 3/2/11 Morris Testimony; 3/9/11 Levinson Testimony (Section 1128(b)(15) can be used to alter the cost benefit calculus of the corporate executives who run companies that view paying civil penalties and criminal fines if caught, as a cost of doing business.). Copies of the transcripts from this testimony are attached to the Beamon Aff. as Exs. 3 and 4. [8] 3/2/11 Morris Testimony; 3/9/11 Levinson Testimony. Copies of the transcripts from this testimony are attached to the Beamon Aff. as . 3 and 4.

reasonably be held personally responsible for that conduct by virtue of his position. To the contrary, at all times Mr. Solomon acted as a diligent and responsible CEO. For decades, Mr. Solomon has worked hard to establish the correct, firm ethical tone at the top and. has left no doubt among those who work at Forest that he expects 100% compliance with all laws, FDA requirements and federal health care program requirements. Indeed, under Mr. Solomon s direction, the Company has never before been the subject of any DOJ or OIG inquiry. As a result, it cannot be said that Mr. Solomon views the monetary sanctions arising from the DOJ investigation simply as a cost of doing business.

Nor, having led Forest for over thirty years, can it possibly be suggested that Mr. Solomon is mobile or poses a threat of continued wrongdoing. At 83 years old, his interest is not in leaving Forest so that he can use some other company to engage in renewed misconduct, but rather his interest is in staying with the company he so ably built to ensure its continuity and a smooth transition to the next generation of leadership. Under these circumstances, it is difficult to see how the exclusion of Mr. Solomon could possibly be justified in the name of protecting the patients who use Forest s products or other beneficiaries of the federal health care programs.

B. The Exclusion Statute Was Not Intended to Prevent Someone of Mr. Solomon s Character from Leading a Pharmaceuticai Company

Over the course of his nearly 60 years in the legal and business communities, Mr. Solomon has justifiably earned a reputation as a person of tremendous character. He is widely regarded as a devoted husband and father, and a businessman of the highest integrity. Indeed, it is his integrity on which so much of his and Forest s success has

been built. The exclusion statute was not intended to prevent a person like Mr. Solomon from leading a pharmaceutical company.

1. Personal Background

Born in the Bronx, New York in 1927, Mr. Solomon grew up in very modest circumstances. His father supported the family by collecting remnants from women s dresses and sewing them on a borrowed machine into neck-ties, which his mother would press and his father would sell. Mr. Solomon was an excellent public school student who attended P.S. 75 and later graduated from the prestigious Bronx High School of Science. Following high school, he attended the City College of New York, which was then tuition-free. Following service in the military at the end of World War II, Mr. Solomon capitalized on the opportunity afforded by the G.I. Bill to study law at Yale Law School, graduating in 1952.

Mr. Solomon married his first wife in 1961. The couple had two sons together and were happily married for thirty years. In 1991, Mrs. Solomon passed away after a long battle with ovarian cancer. Mr. Solomon cared for his wife when she fell ill, accompanying her to every doctor s appointment, and he was at her side at every treatment and at the time of her death. The Solomon family was deeply affected by this loss, and Mr. Solomon s elder son, Andrew, later fell into a deep depression, partly as a result of his mother s passing.

When Andrew fell ill, Mr. Solomon moved him into his home and became his constant companion and caregiver, assuring his son that together they would fight his disease and that his condition would improve. They ate dinner together ever} night, with Andrew at times relying on his father to cut his food when the debilitating effects of his

disease were at their worst. When Andrew, a writer, expressed concern that he would not be able to make it through a book tour for his first novel on his own, Mr. Solomon joined him to provide the support he needed. Andrew, who fortunately was able to emerge from the worst of his depression after a few months, later wrote a book detailing his experience, *The Noonday Demon: An Atlas of Depression,* which was awarded the National Book Award. The book s dedication reads: For my father, who gave me life not once, but twice.

In addition to his devotion to his family, Mr. Solomon also strongly believes in the importance of contributing to his community and has generously donated his time and service to several organizations. For example, Mr. Solomon is a member of the Board of Trustees at New York Presbyterian Hospital, where he endowed the Carolyn B. Solomon Neurological Surgery Suite, named after his first wife.[9] He has also been a member of the Board of Trustees of Cold Spring Harbor Laboratories, a not-for-profit research institution focused on genetics and molecular biology. Additionally, Mr. Solomon is involved with several institutions devoted to the arts, including as a member of the Board of Directors of the Metropolitan Opera (where he also serves as the chairman of the finance committee and is actively involved on the executive committee), as a member of the Board of Trustees of the New York City Ballet and as a member emeritus of the Board of Directors of the Lincoln Center for Performing Arts.

Similarly, Forest, through Mr. Solomon s leadership, has demonstrated a corporate commitment to giving back to the community. In 1991, Forest created the

[9] Despite having donated millions of dollars to many worthy causes, the surgical suite named for his late wife is the only donation that bears the Solomon name.

Patient Assistance Program, which provides Forest products to approximately 60,000 low-and no-income patients each quarter. In 2010, Forest provided approximately $93 million of products to needy patients. The Company also engages in several forms of corporate giving, including providing grants and. contributions to professional associations and not-for-profit organizations. In fiscal year 2010, for example, the Company donated $9.4 million to support health care education and non-profit entities such as the National Alliance for the Mentally 111, the Alzheimer s Association and the Jed Foundation.[10] In recognition of the Company s support, Mr. Solomon was an honoree at the Jed Foundation s recent 10th annual fundraiser. 2. **The CEO of Forest**

Mr. Solomon spent the first 25 years of his professional career as a practicing attorney, first at Moses and Singer, then at the firm now known as Kaye Scholer LLP, and eventually at Tenzer Greenblatt, where he was assigned to represent Forest and later was appointed to Forest s Board of Directors. After leaving Tenzer Greenblatt, Mr. Solomon continued serving on the Board, and practiced in a small law office while also pursuing various entrepreneurial opportunities.

In the 1970s, the Forest Board asked Mr. Solomon, in his capacity as outside counsel, to investigate allegations of accounting fraud that had been made against Forest s then-Chairman. Mr. Solomon s scrupulous investigation concluded that the Chairman should resign. Following that investigation, in 1977, the Company was saddled with both legal and reputational issues, and the Board needed a new chief

[10] The Jed Foundation works nationally to reduce the rate of suicide and the prevalence of emotional distress among college and university students.

executive officer who could guide Forest out of this precarious situation. The Board asked Mr. Solomon to take the position, in no small part because of his demonstrated integrity and commitment to ethics and because of the Board s belief that it could trust Mr. Solomon to lead, the Company through the difficult period, following the revelation of the former Chairman s misconduct. Their trust was well placed: within months of assuming the CEO role, at least one of Forest s partners explicitly stated that it was continuing its relationship with Forest because of Mr. Solomon s personal integrity and candor regarding the conduct of Forest s former chairman.

Mr. Solomon has since worked to build Forest from a small vitamin and generics manufacturer into a mid-sized pharmaceutical company, and he has done so in an ethical and responsible manner. Under his leadership, Forest has licensed, developed and marketed products for the treatment of disorders affecting the central nervous and cardiovascular systems, as well as anti-infective and respirator} therapies. A principal focus of Mr. Solomon has been to bring new medications to the United States to help address important, unmet patient needs. Under Mr. Solomon s leadership, Forest has been able to bring such products to the market by partnering with biotechnology companies and mid-size foreign research companies. These companies often have chosen to work with Forest because of the personal commitment from Mr. Solomon to nurture their relationships and products and because of their continuing access to him whenever issues arise.

Celexa, a selective serotonin reuptake inhibitor (SSRI) approved by the FDA for the treatment of depression, is an archetypal example of Mr. Solomon s dedication to patient care and Forest s successful use of partnerships to effectuate this goal.

Mr. Solomon s focus on patients, and his interest in Celexa in particular, stemmed in part from his son s battle with depression and his personal understanding of the need for effective antidepressant therapies. It was around the time that Mr. Solomon was caring for his son that he first learned, of Celexa, which had. been developed, by H. Lu.nd.beck, a Danish company, and at the time was available only in Europe (where it was known as Cipramil). Over the course of several months, Mr. Solomon met with the head of Lundbeck, Erik Sprunk-Jansen, in an effort to convince him to enter into a licensing agreement with Forest, so that Forest could develop and market Celexa in the United States. Mr. Sprunk-Jansen was initially hesitant to partner with Forest because he had previously participated in failed negotiations and/or partnerships with three other, larger U.S. pharmaceutical companies. In fact, one of those companies had abandoned the product mid-way through development. Following extensive discussions, however, Mr. Sprank-Jansen ultimately decided that Mr. Solomon was someone who could be trusted and was committed to bringing his product to United States patients, and he agreed to enter into a licensing agreement with Forest.

In 1998, the Company received FDA approval to market Celexa (citalopram), which today, combined with its successor Lexapro, accounts for approximately one-third of the antidepressant prescriptions written by U.S. doctors. But for Mr. Solomon s perseverance and the strength of his character, this franchise, the treatment choice of so many physicians, would not be available to U.S. patients because Mr. Sprunk-Jansen had determined not to pursue the U.S. market.

Mr. Solomon s dedication to patient care has led Forest to make many other important products available to United States patients, including:

Lexapro: In addition to Celexa, Forest s partnership with Lundbeck led to the introduction of Lexapro, which is FDA-approved for the treatment of depression and generalized anxiety disorder in adults and is one of only two drugs approved for the treatment of adolescent depression. Lexapro, together with citalopram, is also the most prescribed antidepressant in the United States.

Namenda: Forest has partnered with Merz, a family-controlled German company, which developed Namenda, Forest s second largest product. Namenda was introduced in 2003 and is the only drug in its class that is FDA-approved for the treatment of moderate to severe Alzheimer s disease.

Systolic: Forest licensed Bystolic after a large U.S. pharmaceutical company had decided not to market the drug. Bystolic is FDA approved for the treatment of hypertension.

Savella: Forest partnered with Cypress Bioscience, a small biotechnology company, to bring Savella to the market and, in 2009, obtained FDA approval for Savella for the management of fibromyalgia. Savella is one of only three drugs approved for this condition, and is the only drug developed exclusively for this purpose.

Daliresp: Forest partnered with Nycorned to bring Daliresp to the market. Like Celexa, Daliresp previously had been licensed by another, larger pharmaceutical company, which ultimately decided not to pursue an NDA for the product. Daliresp, a novel medication, was recently FDA- approved as the only oral treatment for chronic obstructive pulmonary disease (COPD). Were it not for Mr. Solomon s efforts, this product would not be available to the affected patient population.

In fact, in the last 38 months, Forest has had five products approved by five different divisions of the FDA, of which four were first-cycle reviews. Mr. Solomon remains critical to the maintenance of existing relationships with the companies from which those drugs are licensed, particularly because in many instances he has spent decades developing relationships of trust with their founders and CEOs.

Compliance has always been paramount to Mr. Solomon, and he consistently has set a strong ethical tone at the top. He has continuously stressed to employees that [i]t is

the goal and expectation of Forest.. .that all [of its] employees maintain the highest standards of business ethics and conduct.[11] In fact, for decades, all new employees have been required to sign Standards of Business Conduct & Ethics, which begin with a strongly worded, message about compliance authored, by Mr. Solomon. He has repeatedly communicated that Forest s products must be marketed in a responsible manner that fully complies with all applicable laws and regulations, and in a manner that ensures they are used appropriately to improve patient care. He has done so by reinforcing that Forest s greatest responsibility is to the patients whose lives [it] want[s] to continue to improve...[12], and by consistently emphasizing to the sales force during sales meetings and in written communications that Forest s products have a profound effect on [patients] lives and confer miraculous benefits, and that in marketing these products, the pharmaceutical industry has rigorous guidelines and ethical standards that must be observed.[13] Mr. Solomon demands responsible behavior not only from Forest s sales force, but also from the sales forces of the companies with which Forest partners. At his insistence, Forest s co-promotion agreements explicitly require partners to meet Forest s high compliance standards. In several cases, that requirement has forced companies to enhance their compliance programs.

Mr. Solomon s deep belief in focusing on patients and science has led Forest to refrain from mass media direct-to-consumer advertising. In Mr. Solomon s words, Forest

[11] *See* Beamon Aff. Exs. 11 (1993 Standards of Business Ethics & Conduct), 12 (1999 Standards of Business Ethics & Conduct) and 13 (2004 Legal & Ethical Conduct Program).

[12] Beamon Aff. Ex. 14.

[13] Beamon Aff. Ex. 15.

believe[s].. .that attempting to influence physicians through their patients, like utilizing direct-to-consumer advertising, is often inappropriate and [Forest] ha[s] refrained from that type of promotion.[14] Consistent with this mindset, Forest has not joined the Pharmaceutical Research and. Manufacturers Association (PhRMA) because the Company prefers to chart its own course. Forest does, however, abide by PhRMA s Code regarding promotional practices. The Company also voluntarily adopted compliance measures recommended by the OIG for implementing an effective corporate compliance program.

Having spent decades building Forest into the Company that it is today, Mr. Solomon has long been focused on building a management team that will ensure Forest s future success. Until recently, Dr. Lawrence Olanoff, the Company s former-President and Chief Operating Officer, was Mr. Solomon s anticipated successor. In December 2010, Dr. Olanoff unexpectedly retired to devote more time and attention to family, health matters and academic pursuits. As a result of Dr. Olanoff s retirement, the Company reorganized its executive team and adopted a plan intended to identify new senior executives. As part of this reorganization, Mr. Solomon has temporarily assumed the role of President and he now directly supervises the heads of the medical, marketing, business development and compliance groups as well as the CFO. The Company expects that one of these individuals will emerge as Mr. Solomon s successor, and another as President and COO, but Mr. Solomon s continued leadership and mentoring of these potential candidates is critical to the carefully constructed succession plan.

[14]BeamonAff.Ex. 16.

As described above, however, Mr. Solomon s importance to Forest goes well beyond ensuring an orderly transition to new management. Mr. Solomon offers the wisdom of an 83-year old who has more than 30 years of experience in the pharmaceutical industry and. the vitality and. energy of a much younger man. Currently, he is personally engaged in ongoing negotiations regarding the licensing of several new products. His continued role at the Company, particularly in the wake of Dr. Olanoff s departure, is critical to the Company s ability to license these products. His exclusion would prematurely deprive Forest and its shareholders of a uniquely qualified leader.

II. EXCLUSION OF MR. SOLOMON WOULD BE INCONSISTENT WITH THE OIG S PUBLISHED GUIDANCE REGARDING THE EXERCISE OF ITS DISCRETION

A. Under the Factors Set Forth in the OIG s Published Guidance, Mr. Solomon Should Not be Excluded

The OIG has identified four factors that it will consider in determining whether an individual should be excluded under Section 1128(b)(15)(A)(ii). They are: (1) the circumstances of the misconduct and the seriousness of the offense; (2) the individual s role in the sanctioned entity; (3) the individual s actions in response to the misconduct; and (4) information about the sanctioned entity. Each of these factors weighs heavily against excluding Mr. Solomon. We respectfully submit that, in a situation such as this, where the Company is not a recidivist - indeed, where it has enjoyed a spotless record -the factors that should be given the greatest consideration are those that relate specifically to the individual being considered for exclusion. The two factors that relate specifically to Mr. Solomon personally his role at Forest and his response to the misconduct -counsel strongly against his exclusion.

1. The Circumstances of the Misconduct and Seriousness of the Offense Do Not Support Exclusion

In the fall of 2010, Forest Pharmaceuticals, Inc. (FPI), a wholly owned subsidiary of Forest, pled guilty to two strict liability misdemeanor violations of the Food, Drug and Cosmetic Act,[15] entered into a civil settlement agreement, committed to pay $313 million and agreed to enter into a five-year CIA.[16] The core conduct at issue in the investigation involved allegations of off-label promotion of Celexa (and to a more limited extent, Lexapro), distribution of Levothroid above levels prescribed in an FDA Guidance, and improper payments to health care providers.

Although we do not dispute that the conduct at issue was serious, the nature and limited scope of the misconduct, particularly in relation to the conduct of other pharmaceutical companies whose officers have not been excluded, weighs against the exclusion of Mr. Solomon. This is especially true in light of the fact that in neither its criminal Information nor its offer of proof at the plea allocution did the government so

[13] Forest also pled guilty to one felony charge of obstruction of an agency proceeding in connection with conduct that took place at Forest s Cincinnati facility concerning Levothroid. It is our understanding that the OIG does not consider the obstruction charge the only of the three charges that is intent-based to be a basis for excluding Mr. Solomon. In any event, the government did not suggest that Mr. Solomon had any involvement in, or knowledge of, the conduct underlying this charge. Rather, the government s offer of proof related solely to employees and plant management personnel based in the Cincinnati facility.

[16] As explained in our May 23, 2011 letter to the OIG, we question whether there are facts supporting a determination that FPI is a sanctioned entity within the meaning of the Social Security Act (the Act). The statute defines the term sanctioned entity as an entity that has been convicted of one of seven offenses described in the Act and further specified in sections 1001.101 through 1001.401 of the Secretary s regulations, or that has been excluded from participation in a program under title XVIII or under a State health care program. 42U.S.C. § 1320a-7(b)(15)(B) (2011); 42 C.F.R. § 1001.1051(b). We do not believe FPI meets the definition of a sanctioned entity. Excluding Mr. Solomon would, therefore, be inappropriate not simply as a matter of discretion, but as a matter of law. Despite our request for additional information, the OIG s May 26, 2011 response to our letter provided no insight into why the OIG believes FPI qualifies as a sanctioned entity, but promised to consider our arguments that it is not a sanctioned entity in reaching its decision regarding Mr. Solomon s possible exclusion. We, therefore, incorporate by reference herein the arguments set forth in our May 23rd letter, a copy of which is attached to the Beamon Aff. as Ex. 17.

much as suggest that Mr. Solomon participated directly or indirectly in the misconduct underlying the violations, or that he knew or should have known that Company employees were engaging in conduct that violated any law, FDA regulation or federal health care program requirement.

(a) The Conduct Underlying the Levothroid Charge Was Unique

Unlike most unapproved drug cases, the Levothroid investigation and plea did not involve any allegation of tampering with a product or the making of false or misleading statements regarding efficacy or safety. Rather, the conduct that provided a basis for the criminal plea involved Forest s failure to comply with an FDA Guidance regarding the distribution levels of Levothroid a levothyroxine sodium product (levothyroxine drug) that had been on the market for decades as a grandfathered product.

By way of background, on August 14, 1997, the FDA issued a public notice (the 1997 Notice) reclassifying all levothyroxine drugs as new drugs, and requiring manufacturers to submit and obtain approval of new drug applications (NDAs). The 1997 Notice recognized the medical importance of levothyroxine drugs to millions of patients afflicted with hypothyroidism, and, therefore, allowed manufacturers to continue marketing these drugs while pursuing their NDAs. Shortly thereafter Forest began the process of seeking an NDA for Levothroid. Forest made this decision even though Levothroid represented only 3% of Forest s sales and was not a product that Forest s sales force detailed or otherwise promoted to physicians. Forest decided to expend the resources to seek the in large measure because it believed the drug was critical to

the patients who relied upon it, and the Company made progress toward the NDA over the course of the next several years.

In 2001, several manufacturers, including Forest, had not yet received their NDAs. At that time, the FDA issued, a Guidance for Industry, which indicated, that the FDA would extend the deadline for approval of an NDA and would exercise its enforcement discretion not to bring an enforcement action against those manufacturers that continued to actively pursue their NDAs and abided by a prescribed phase-down distribution schedule (the Phase Down Guidance or the Guidance).

Although Forest actively pursued an NDA for Levothroid, it did not abide by the distribution schedule set forth in the Guidance. The decision not to follow the phase-down schedule was made by those Company employees responsible for the manufacturing and distribution of Levothroid and by those with regulatory expertise, including the then-President and COO and the head of Regulatory Affairs, who had previously been employed at Knoll Pharmaceuticals, the manufacturer of the market leader in this category of drugs, Synthroid. Those individuals made the decision not to follow the phase down schedule based on what appears to be a misunderstanding of the regulatory status of Levothroid during the pendency of the Guidance.

Significantly and again in contrast to other unapproved drug cases Forest did not market a drug for a use for which it did not have substantial scientific evidence of efficacy or safety. The FDA has never questioned Levothroid s efficacy as a hypothyroidism treatment over the several decades that the product has been available. In fact, Levothroid s established efficacy is precisely why the FDA allowed it to remain

on the market throughout the six years of the NDA application process. 17 Although the FDA reclassified levothyroxine drugs as new drugs because of concerns about the formulations stability and potency, it did not believe the drugs posed any safety risk that would, justify immediate market withdrawal. 18 (b) The Scope of the Misconduct Related to Celexa Was Narrow The government alleged that, between 1998 and 2002, Forest promoted Celexa off-label for the treatment of children and adolescents suffering from depression. The vast majority of Celexa s use almost 96% was on-label. However, it was determined that there were limited instances of off-label promotion by certain of Forest s sales representatives and field managers. There is no allegation that this misconduct was headquarters-directed. More specifically, there is no indication that senior management in any way encouraged, participated in, or condoned the limited instances of field-level violations by certain sales representatives and field managers. To the contrary, the sales force was consistently trained to promote products only for on-label use and to refer any off-label questions from physicians to the Company s Professional Affairs department. 17 The 1997 Notice recognized the medical importance of levothyroxine drugs to millions of patients afflicted with hypothyroidism, as well as the lack of medical alternatives and, therefore, provided manufacturers three years to gain approval of their NDAs and allowed them to continue marketing their levothyroxine drugs during the three-year approval period. The deadline for obtaining an approved NDA was extended in July 2000 and again in July 2001 by another two years to August 14, 2003 or six years from the date of the 1997 Notice. 18 This confidence in Levothroid s safety profile is supported by the fact that Forest received only a very small number of serious adverse event reports for Levothroid during the time the Phase Down Guidance was in effect.

Indeed, the scope of the misconduct was so narrow that it would be unreasonable to believe that it could have been detected by senior officials. Because the rate of off-label use of Celexa was always well below that of the other SSRIs that were on the market when Celexa was introduced, and. because physicians are permitted, to prescribe drugs for off-label uses, there was no objective indication that Celexa was being promoted improperly. Moreover, even a searching review of call notes by counsel in the course of the investigation revealed only an extremely small amount of off-label promotion. Specifically, of the 4.66 million call notes reviewed by Forest s counsel for the time period between 1998 and 2002, only 0.6% were arguably suggestive of pediatric promotion. 19 Similarly, of the 6,885 physician recall reports (known as verbatims) that were reviewed by counsel for the same period of time, only 0.3% were arguably suggestive of pediatric promotion. In other words, as depicted in the charts below, the data indicates that 99.4% of call notes and 99.7% of verbatims reflected potential on label promotion. 19 This is not surprising because pediatric specialists were not intentionally included on call panels; rather, physicians were included based solely on their history of prescribing SSRIs. Indeed, the government did not allege that Forest intentionally included pediatric specialists on its call panels.; rather, it stated that Forest obtained data to identify practitioners who prescribed SSRIs, and created call panels using that data.

No compliance system, even one using today s more sophisticated technology let alone any system in existence at the time of the conduct at issue could have detected a pattern of off-label promotion based on such scant evidence. While not a defense to off-label promotion, in the context of considering whether exclusion is appropriate, it should be noted that the pediatric use of Celexa did not raise significant safety concerns. In fact, in March 2009, the FDA approved Lexapro as a safe and effective treatment for adolescent depression. The approval was supported by two studies, one positive study involving adolescents taking Lexapro and one positive study involving adolescents taking Celexa. It also bears noting that the off-label promotion by other companies whose CEOs have not been excluded was far more egregious than the conduct at Forest. Such cases have involved companies alleged to be recidivists, corporate-driven campaigns to promote products for off-label uses, significantly larger percentages of off-label use, and patient safety concerns. 20 20 See, e.g., Eli Lilly (Zyprexa): alleged to be a recidivist company, Sentencing Memorandum stated that senior executives and managers of the company knew and approved of the [off-label

Aside from the limited off-label promotion by the sales force, two other issues relating to Celexa were cited by the DOJ. First, the criminal Information references an issue relating to two pediatric studies, one of which was conducted by Lundbeck and was not widely disseminated. No decision was made by Forest senior management to intentionally conceal or purposefully not disseminate the Lundbeck study. The Lundbeck study was a negative study (meaning that it was inconclusive for efficacy) and demonstrated no statistically significant health issues. Because over 50% of all antidepressant studies are negative including for anti-depressants that have been approved by the FDA and are known to be effective for the treatment of depression the fact that the Lundbeck study was negative was not considered to be meaningful to prescribers. Evidence also demonstrates that Forest scientific personnel viewed the study as flawed and poorly conducted because, inter alia, unlike most depression studies, severely ill and hospitalized patients and patients with multiple diseases were allowed to promotion]. Government s Memorandum for Entry of Plea & Sentencing at 11, United States v. Eli Lilly & Co. (E.D. Pa. Jan. 15, 2009). Eli Lilly (Evista): criminal Information stated that marketing team developed off-label marketing and promotional messages. See Press Release, U.S. Dep t of Justice, Eli Lilly and Company to Pay U.S. $36 Million Relating to Off-Label Promotion (Dec. 21, 2005), available at http: ww-w.justice.gov/ opa/pr/2005/Decernber/05_civ685. Cephalon (Gabitril, Provigil, Actiq): Sentencing Memorandum stated that off-label marketing was no accident, and that there was a highly organized and deliberate effort to maximize revenue despite legal restrictions. approximately 80-90% of prescriptions for off-label uses. Government s Memorandum for Entry of Plea & Sentencing, United States v. Cephalon, No. 08-598 (E.D. Pa. Sept. 29, 2008). See also Chris Adams & Alison Young, Marketing Plays Big Role in Rising Off-Label Sales, CHARLOTTE observer, Nov. 3, 2003, at 1A; John Carreyrou, Potent Product: Narcotic Lollipop Becomes Big Seller Despite FDA Curbs, wall st. J., Nov. 3, 2006, at Al; Anahad O Connor, Wakefulness Finds a Powerful Ally, N.Y. times, June 29, 2004, at Fl. Pfizer (Bextra): alleged to be a recidivist company; Sentencing Memorandum contended that illegal conduct was pervasive throughout company and stemmed from messages created at high levels within the national marketing team; approximately 57% of sales for off-label use. United States Sentencing Memorandum at 28, United States v. Pharmacia & Upjohn Co., No. 09 CR 10258 (D. Mass. Oct. 9, 2009).

participate in the study, patients were permitted to initiate and undergo psychotherapy during the study (and as many as two-thirds of patients did so), patients were given multiple therapies in addition to Celexa, and the study was conducted over a period of more than four years and. in multiple European countries. 21 As such, the dissemination of the Lundbeck study was handled in a manner consistent with scientific community and industry practices at the time. 22 Importantly, even though it was never authorized for use in promotion, the study was shared with the FDA. Finally, the qui tarn complaint discusses Forest s Regional Advisory Boards relating to Celexa. The boards were used by Forest to collect local market data and better understand doctors concerns and opinions regarding Forest s marketing efforts. A modest fee of no more than $500 was paid to advisors in order to compensate them for the four hours they spent attending a meeting (held most often on Saturday mornings at modest venues) and providing such feedback. 23 Although the government was concerned that such advisory boards could implicate the anti-kickback law, nothing indicates that anyone in the Marketing department or senior management viewed the payments to physicians in connection with these meetings, which were a common practice in the industry, as a quid-pro-quo in exchange for prescriptions. 21 See Anne-Liis von Knorring, et al.,^4 Randomized, Double-blind, Placebo-controlled Study of Citalopram in Adolescents With Major Depressive Disorder, 26 J. clinical PsYCHOPHARMACOLOGY 311 (2006). A copy of this article is attached to the Beamon Aff. as Ex. 18. /z See Erick H. Turner, et al., Selective Publication ofAntidepressant Trials and Its Influence on Apparent Efficacy, 358 new eng. J. med. 252 (2008) (1/3 of adult antidepressant studies registered with the FDA between 1987 and 2004 were not published; only 38% of negative studies were published). A copy of this article is attached to the Beamon Aff. as Ex. 19. 23 The payment of a modest fee to compensate participants for their time is consistent with industry practice and contemplated by the PhRMA Code.

Under these circumstances, the nature and limited scope of the misconduct -which involved the uncommon application of an FDA Guidance for Industry to a drug that had. been on the market for decades, and. a limited, amount of off-label promotion by field-level employees, without any significant safety issues do not warrant the unprecedented exclusion of a corporate officer who played no role in the conduct at issue. 2. Mr. Solomon s Role At Forest Does Not Support Exclusion (a) Mr. Solomon Has Used His Position as CEO to Establish an Expectation of Ethical and Compliant Behavior Mr, Solomon has always set an impeccable tone at the top. He has frequently and consistently emphasized the importance of ethical behavior, the necessity of conducting business in compliance with the law, and the importance of serving patient needs. Indeed, this message is delivered to all employees at the outset of their employment through Forest s Standards of Business Conduct and Ethics (the Standards). In the Standards, Mr. Solomon states: It is the goal and expectation of Forest Laboratories, Inc. and all of its subsidiaries that all our employees maintain the highest standards of business ethics and conduct. It is the honesty and moral integrity of the company s employees and of the company s activities and decisions which enable all of us to hold our heads high and speak with pride about our efforts. As a pharmaceutical company in a regulated industry, we seek faithfully to obey the laws and regulations applicable to us. We will honor in fact and spirit the regulations governing the testing, approval, manufacture and distribution of our products because we are both morally and legally obligated to do so.

All employees are required to read the Standards and sign an acknowledgement that they will comply with the policies contained therein. 24 Mr. Solomon reinforces these expectations in his remarks at sales meetings and product launches. For example, during a speech in June 2002 in connection with the launch of Lexapro, Mr. Solomon stated: [Y]ou should know that at Forest we stay comfortably within the boundaries...We don t communicate to the government or to our employees, or to physicians or to investors, or to our partners, or to anyone, information that we know is wrong or that could mislead them. We believe you can develop a successful business and stay safely within the boundaries of law and ethical behavior. And indeed, that is precisely why we are successful. 25 Similarly, at a speech in 2005 to launch Campral (a drug approved for the treatment of alcohol dependence), Mr. Solomon stated: And we should acknowledge that pharmaceutical companies have a greater responsibility than other industries, precisely because our products are so valuable and therefore indispensable for so many people. Our products are beneficial but also dangerous. They must be promoted and marketed with care and accuracy, and with all the proper precautions that are necessary to assure patient safety. And physicians must administer them with knowledge and care. At Forest, we try very hard to be consistently correct in dealing with physicians and with patients. 26 Mr. Solomon s commitment to ethics and patient care is a consistent point of emphasis in his Letters to Shareholders: 24 See Beamon Aff. Exs. 11, 12 and 13. 25 Beamon Aff. Ex. 20. 26 Beamon Aff. Ex. 21.

Marketing our products requires us to scrupulously inform physicians about [our] products. We are constantly communicating with physicians, but it must always be accurate and in ways that ultimately serve their patients interests. Above all, it is incumbent on us not to abuse our access to physicians in ways that compromise their responsibility to their patients. 27 (b) Mr. Solomon Was Responsible and Diligent in His Role as CEO Forest does not conduct basic research. Rather, Forest s business model is based on the development of partnerships with small, and often non-U.S., research and biotechnology companies that have begun to develop new products but lack the capital, expertise, or platform to bring those products to the U.S. market. Those partnerships are where Mr. Solomon focuses his time. He has always devoted the vast majority of his time to charting corporate strategy and identifying business opportunities, including making decisions about whether to license new products, participating in negotiations with potential partners, nurturing relationships with existing partners, and making decisions concerning whether to enter into co-marketing arrangements. Forest reviews at least 200 product opportunities each year and not a single new product is licensed, or new transaction selected, without Mr. Solomon s involvement and approval. Consistent with widely accepted best management practices, Mr. Solomon hired experienced, qualified individuals for management positions. In fact, Forest has employed a remarkably stable group of senior managers on whom Mr. Solomon has relied. It was to those individuals that Mr. Solomon reasonably delegated responsibility for, and oversight of, various operational aspects of Forest s business. For example, Dr. 27 Beamon Aff. Ex. 16.

Olanoff, the former President and COO, oversaw the review of the NDAs that were submitted during his tenure as Chief Scientific Officer, as well as presentations to the FDA Advisory Committees. Likewise, Forest employed other experienced individuals to head. Sales, Marketing and. Regulatory Affairs, among other areas. Those individuals provided periodic updates on their respective areas of responsibility to Mr. Solomon, and would often bring specific issues to Mr. Solomon s attention for his input and consideration, but otherwise operated with considerable and appropriate autonomy within their respective domains. With respect to the Compliance group, Mr. Solomon afforded it reasonable autonomy, but maintained the type of higher-level oversight and presence that is expected of a CEO of a company of Forest s size. Mr. Solomon communicated frequently with the President and COO, who oversaw the Chief Compliance Officer (CCO) and the compliance program, and with the CCO himself. These communications were focused on making clear Mr. Solomon s expectation that all Forest employees are required to conduct themselves in an ethical and compliant manner, and on ensuring that the COO and CCO were implementing an effective compliance program. Day-to-day administration of compliance was left to the COO, however. Moreover, although not officially a member of the Company s Compliance Committee, Mr. Solomon has attended its meetings. He has been involved in major policy decisions, including those related to revisions of the Company s Code of Conduct, and enhancements to the compliance program, including a substantial addition of resources over time. In addition, as a member of the Board of Directors, Mr. Solomon receives quarterly compliance reports.

(c) Mr. Solomon Was Neither Directly Nor Indirectly Responsible for the Misconduct Mr. Solomon was neither directly nor indirectly responsible for the misconduct at issue by virtue of his role as CEO. Mr. Solomon at all times engaged in the type of oversight that the OIG would expect of a diligent and responsible CEO. (i) Mr. Solomon Reasonably Believed Forest s Conduct With Respect to Levothroid Was Appropriate As discussed, throughout the relevant period, Mr. Solomon s primary focus was on the development of new products and business partnerships. At the time that the FDA s Phase Down Guidance was in effect, this was a particularly critical responsibility because Celexa which represented almost 70% of Forest s sales was facing an impending loss of exclusivity. Mr. Solomon, therefore, was deeply involved with at least fifteen products that were being tested, reviewed or considered for licensing by Forest. 28 By contrast, Levothroid, which had relatively stable sales, was not promoted by Forest s sales force, and, in any particular quarter during the Guidance period, accounted for no more than approximately 3% of Forest s total revenues. It was not one of Mr. Solomon s significant areas of focus. Consistent with his role as CEO and the division of labor among Forest s senior management, Mr. Solomon was aware that Levothroid, a product that had been on the market for decades, had been reclassified by the FDA as a new drug and, importantly from his perspective, that Forest was required to submit an NDA. He understood that a 28 Six of these products became actively promoted products (including Lexapro, Namenda, Benicar, Campral, Combunox and Savella) and others went into Phase III testing (including ML 3000, Lercanidipine, Dexloxiglumide and Desmoteplase).

deadline had been set by which manufacturers were either required to have obtained an NDA or to stop distributing levothyroxine drugs entirely. Mr. Solomon was aware that Forest was actively working toward obtaining approval and that it expected to receive approval prior to the deadline set by the FDA. While he was aware that Forest was required to seek and obtain NDA approval to continue distributing Levothroid in the future, Mr. Solomon who is not an FDA regulatory expert reasonably and in good faith relied on the expertise of individuals on his executive leadership team who possessed the regulatory and operational expertise to manage the application process, interpret the FDA s Guidance, and determine how the Company should comply with it. In that regard, the head of the Regulatory Affairs Department who, as mentioned, in addition to being a regulatory expert, previously had been employed by Knoll Pharmaceuticals, the manufacturer of Synthroid, the leading levothyroxine drag was responsible for providing regulator} expertise and for having familiarity with FDA guidance and requirements. In addition, the former President and COO and then-Chief Scientific Officer shared responsibility for the manufacture and distribution of Levothroid. Each of these individuals, and those reporting to them, had extensive experience with Levothroid and in interpreting and following regulatory requirements. By following their collective guidance over the years, Forest had established an excellent regulatory track record and enjoyed a positive working relationship with the FDA. As such, Mr. Solomon had every reason to trust his team s advice and believed them to be fully capable of complying with any and all FDA requirements, including the Guidance.

As a result, Mr. Solomon did not personally review the FDA s Guidance nor would a CEO be expected to do so and was not consulted in connection with its interpretation. Others with regulatory expertise made the determination that the Company need, not follow the prescribed, phase-down schedule. At some point prior to receipt of the August 7, 2003 Warning Letter, Mr. Solomon learned that Forest was not phasing down its distribution of Levothroid. He was assured at that time that the head of Regulatory Affairs believed that the Guidance was voluntary and that it was appropriate for Forest to continue making Levothroid available to the patients who depended on it. Based upon that assurance, Mr. Solomon had no reason to believe that Forest was acting improperly, and, with respect to Levothroid, he continued to believe the Company was seeking an NDA, which he understood to be the primary objective of the FDA Guidance. Mr. Solomon was surprised to receive a Warning Letter in August 2003 because he had understood, based on what he was told by his experts, that the phase-down was voluntary. Upon learning that the FDA believed that Forest was no longer entitled to the benefit of the agency s enforcement discretion under the Guidance, Mr. Solomon directed those responsible to comply with the Warning Letter and expected that the Company would halt distribution of Levothroid in compliance with the letter.
(ii) Mr. Solomon Had No Reason to be Aware of Marketing Improprieties Although Mr. Solomon s primary focus as CEO was new product development and maintenance of Forest s partnerships, Mr. Solomon maintained a high-level understanding of the Company s strategic plans and market performance for all of its promoted drugs, including Celexa. None of the information he received regarding Celexa

suggested, nor should have suggested, that certain members of Forest s sales force were engaged in off-label promotion. During the time that Forest actively promoted Celexa (1998-2002), the level of off-label usage by pediatric patients was quite low. The average rate of pediatric use for other SSRI antidepressants when Celexa entered the market was 6.23% of total prescriptions (at a time when none of them was approved for the treatment of pediatric depression). Celexa s average pediatric rate of use over the course of its promotion was 4.06% which was 35% lower than the baseline for other SSRIs. Celexa never exceeded that baseline, despite the drug s huge growth for the treatment of depression in adults over that same time period. As a result, the rate of Celexa s pediatric use certainly did not raise any red flags that would have alerted the head of the sales force or the Chief Marketing Officer let alone Mr. Solomon to potential improprieties. It is also important to consider that it would have been impossible for Mr. Solomon or anyone else in his position, for that matter - to prevent the limited amount of off-label promotion that took place with respect to Celexa. All companies face some irreducible risk of field-level misconduct that cannot be prevented, no matter what level of compliance and oversight is imposed. Mr. Solomon attempted to minimize this risk through the best mechanisms available to CEOs: the establishment of the proper tone at the top and the implementation of a compliance program that became increasingly robust over time in parallel with changing industry norms and OIG actions. Having done so, it cannot fairly be said that Mr. Solomon had responsibility for rogue employees conduct that he had done everything he reasonably could have to prevent.

Although he was not involved in decision-making concerning the details of marketing strategies or how they would be executed, Mr. Solomon did periodically receive high-level marketing and performance overviews. A slide deck referenced in the qui tarn complaint is an example of the type of material that Mr. Solomon occasionally received. On the 40th page of this 50-page presentation, there was a single notation that Regional Advisory Boards might lead hesitant physicians to prescribe Celexa. As an initial matter, Mr. Solomon is provided with thousands of pages of slides each year, and there is no evidence that Mr. Solomon reviewed or focused on this statement. Moreover, on its face the statement at issue does not indicate that the Company was engaged in wrongdoing; rather it merely notes that there might be an incidental benefit from the information physicians would be exposed to at Regional Advisory Boards. In any event, given his other responsibilities, Mr. Solomon was not involved in the design, structure, or details of any such program. Finally, while Mr. Solomon was generally aware of study results and participated in the determination of whether such results were material for purposes of financial disclosure, he left to qualified personnel decisions concerning the proper means and timing of the publication of studies and determinations about how studies should be disseminated to physicians. Consistent with this process, Mr. Solomon was not involved in determinations regarding the use and dissemination of the Lundbeck study.

3. Mr. Solomon s Responsible and Prompt Response to the Misconduct Does Not Support Exclusion (a) The Company, Under Mr. Solomon s Leadership, Took Action to Address the Misconduct Under Mr. Solomon s leadership, the Company has built a strong compliance program and has repeatedly taken a proactive approach to compliance issues. Even before the conduct at issue in the government s investigation came to light, the Company took a number of measures in response to increasing concerns in the industry and by the government that certain activities carried risks of abuse. When the conduct underlying the government s investigation became known, again at Mr. Solomon s direction, the Company took substantial steps to mitigate the impact of the conduct and to ensure that similar misconduct will not occur in the future. All of these activities establish clearly that Mr. Solomon took extraordinary care, both before the conduct came to light, based on the information available to him, and afterward to prevent misconduct in the first instance and to promptly and thoroughly remediate any misconduct that did occur. Mr. Solomon s actions establish that he has been and remains an extremely ethical, trustworthy, and reputable leader, and that there is no basis for excluding him from federal health care programs and no legitimate purpose to be served by such an exclusion. (i) Mr. Solomon Has Overseen the Establishment of a Robust Compliance Program Mr. Solomon has overseen the establishment of a compliance program that features each of the seven elements of an effective compliance program as outlined by the OIG. This program is supported by a compliance group headed by a seasoned CCO and boasts positions for 57 full-time employees. The core of the program was implemented

well before the Company knew it was being investigated, and has evolved over time as the Company has grown from a small vitamin and generics manufacturer into a mid-sized manufacturer of branded products. The Company s compliance program has consistently kept pace with industry developments. Indeed, Mr. Solomon instructed his Compliance group to carefully review DOJ resolutions for insights into the types of conduct that Forest should be monitoring, and to review CIAs for ideas that could be incorporated into Forest s program. To ensure that the program is as strong as it can be, Mr. Solomon has supported the effective use of benchmarking. In 2007, the Company undertook a comprehensive review of the compliance program and, as a result of that review, implemented several enhancements to the program. In addition, the CCO is a member of the Pharmaceutical Compliance Forum, which includes CCOs of other leading pharmaceutical companies, and he regularly takes advantage of the benchmarking opportunities offered by that organization. As with any good compliance program, the foundation of Forest s program is clear policies. The core principles of Forest s compliance program, which takes its name and symbol from the compass because of the compass s role in providing guidance, are set forth in the Legal and Ethical Conduct Program. This book, which is provided to all Forest employees, begins with a message from Mr. Solomon that unambiguously establishes the expectation of Forest Laboratories, Inc. and all of its subsidiaries that all our employees maintain the highest standards of business ethics and conduct. 29 In 29 See Beamon Aff. Ex. 13.

addition to this overarching policy guidance, Forest employees receive compliance manuals specific to their job responsibilities. For instance, the Company s policy manuals address product promotion, sampling and non-promotional scientific exchange. All new employees are trained, on Forest s policies. Training not only reinforces the substance of the policies, but also reinforces the expectation that those policies will be strictly followed. At the completion of orientation, new hires are asked to sign an Acknowledgment and Agreement that they have read and will abide by Forest s policies as conditions of employment. This includes abiding by Forest s commit[ment] to following the highest ethical standards, as well as legal requirements, in relationships with healthcare professionals. 30 Training for new sales employees involves significant classroom instruction, including by a member of the Compliance group. Following orientation, sales colleagues are required to take an on-line compliance course. This obligation is successfully completed only when the colleague passes a post-course exam. Thereafter, sales colleagues receive annual training that takes the form of live training and workshops, as well as on-line courses. In addition, sales employees receive dedicated compliance training at national and regional sales meetings, which are held 2-4 times each year. Commercial employees receive a similar steady diet of compliance training. Notably, Forest has always prohibited off-label promotion and sales representatives have always been trained accordingly. Nonetheless, in late 2002 and 2003, the Company began to strengthen its training to more specifically address off-label 30 See Beamon Aff. Ex. 13.

promotion. Prior to the licensing of Celexa, Forest did not sell products that had significant off-label markets. By the time of Lexapro s launch in late 2002, the Company had come to recognize the need for improved training on those issues, and accordingly bolstered, its training regimen. In addition, Forest policy has always required, that sales representatives refer all questions about off-label uses to the Professional Affairs department (now the Medic al Information and Communication department). To ensure that compliance training is understood and policies are followed, during Mr. Solomon s time as CEO, Forest has made significant investments in compliance monitoring. These efforts include reviewing sales representatives call notes. Notably, whereas many companies in the pharmaceutical industry have abolished the use of free-text call notes, Forest has continued their use in large part because of the ability to monitor discussions in the field. Similarly, Forest reviews physician recall statements (or verbatims) for indications of improper sales messaging. The Company also monitors requests for off-label information that are submitted to Forest s Medical Information and Communication Department in order to detect signs that requests might have been prompted by a sales colleague. In recent years, Forest has adopted the practice of having Compliance group members participate in field rides with sales colleagues. This process, which supp lements the field rides performed by sales managers, allows Compliance personnel to observe sales representatives in action and better gauge their understanding of the rules and guidelines. Compliance also works with other departments to perform 38

audits of speaker programs,31 sales representatives expense reports and product sample records. Although until recently Mr. Solomon did not have primary oversight of the Compliance program or the CCO, Mr. Solomon played, an important role in the establishment and evolution of this robust program. He consistently has made clear to his senior leadership including the President/COO and CCO who are responsible for the program s upkeep &# 151; that he expects Forest to be an industry leader with respect to compliance. Mr. Solomon has done everything in his power to see that the expectation of Forest Laboratories, Inc. and all of its subsidiaries that all our employees maintain the highest standards of business ethics and conduct is not just words in a book, but, in fact, how Forest operates. (ii) Prompt Remediation of Conduct Involved in the Government s Investigation (1) Call Panels and Speaker Bureaus Prior to 2005, Forest s call panels were generated based solely on physicians prescribing histories, without regard to their specialties. In January 2005, Forest removed from its call panels physicians whose specialties suggested they may prescribe a product predominantly outside of its approved label. The decision to remove these specialists was made by Mr. Solomon and Forest s Compliance Committee as a result of the industry s growing recognition of risks created by calling on phy sicians with specialties that are not aligned with a drug s approved indications. Since then, Forest has used 31 This practice began before the adoption of the CIA, and was augmented by the CIA requirement of 175 audits per year. Sales representatives are also now required to complete post-program certifications that the program was conducted in a compliant manner. 39

objective data to analyze the specialists on its call panels prior to a product s launch and in connection with substantive modifications to the panels. Call panels also undergo review by the Compliance Department on a quarterly basis. Similarly, in April 2005, before the conduct in the investigation surfaced, the Company removed all child specialists from its speakers bureaus for the same reasons. Notably, speakers have always been contractuall y required to give on-label presentations and both speakers and the sales force were consistently trained on this requirement. Speakers were also provided with approved slide decks containing appropriate promotional claims and product information. Speakers were never encouraged by the corporate office or Marketing department to promote for pediatric use, and were never provided with any approved materials relating to pediatric use. When the government s investigation revealed that some non-compliant pr ograms had been conducted in the field during the period of Celexa s promotion, the Company further strengthened speakers contractual obligation to comply with Company policies and enhanced speaker training. The Company also strengthened its policy against speakers using their own slides, and instituted a monitoring program. (2) Study Disclosure When study dissemination became an issue in the industry and for Forest, the Company quickly implemented procedures to ensure that all study results are properly disseminated. For example, in 2005, Forest established an online Clinical Trial Registry, which provides disclosure of ongoing and completed studies. Further, in 2004, the Company suspended the distribution of all Professional Affairs letters (on all topics) after an internal review determined that the Lundbeck study 40

had been omitted from the standardized letters. Although Professional Affairs letters assist the Company in answering important product questions from healthcare providers and consumers, the embargo remained in place for several years. This was a direct result of the conservative direction from senior management, who would, not authorize use of the letters until they felt the Company understood how the omission had occurred and had implemented policies and proc edures to ensure that a similar omission would never recur. It was not until 2008 that Forest returned to the limited use of these letters to respond to questions from the public regarding Bystolic, which at the time was a newly launched hypertension product. Comprehensive standard operating procedures governing every aspect of the Medical Information and Communication department are now in place. Letters are authorized for use only after a team that includes legal, regulatory and medical personnel has revi ewed and approved them. (3) Other Compliance Measures In early 2006, the Company eliminated local-level advisory board meetings in recognition of concerns in the industry and in government that local-level consulting programs could be subject to abuse or misperception. Even prior to their elimination, Forest Regulatory Affairs personnel reviewed all planned advisory board programs since their inception, including the number of proposed programs, to ensure they complied with applicable regulations. Sinc e local-level meetings were eliminated, all advisory boards have been centrally conducted and are very limited in number. Employees are also required to complete a needs assessment prior to obtaining budgetary approval. In June 2003, prior to any issues in the investigation coming to light, the Company terminated its preceptorship program. Again, this action was taken in 41

connection with a growing recognition in the industry, propelled by issuance of the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, that the practice could carry risks of abuse and misperception. Because the Company believes that these programs provide valuable training opportunities, Forest reinstated, its preceptorship program in 2004, only after a careful analysis ordered by Mr. Solomon had been performed, but with the important change that physicians are no longer compensated for their time spent training a sales representative. Instead, a charitable donation is made by Forest in the physician s name to one of several approved charities. In addition, substantial paperwork requirements were implemented to document the legitimate purpose of, and learnings from, the program, and the number of preceptorships which sales representatives are permitted to conduct was strictly limited. Finally, the Lexapro ExCEED study, conducted in 2003, was the last large-scale naturalistic post-marketing study that Forest conducted. Forest has not conducted such a study in eight years.
(4) Discipline After the Company learned of the off-label misconduct in the investigation, 28 employees were disciplined. Some of the employees at issue in the investigation -including the two who had engaged in the most serious off-label conduct were no longer with the Company. Of those who remained, calls notes and/or field documents suggested they may have en gaged in off-label promotion or expense report impropriety in the late 1990s or early 2000s. As a result, each of those employees was placed on probation or given a formal warning.

(iii) Other Examples of Prompt Remediation of Compliance Concerns Mr. Solomon s prompt response to the misconduct underlying the criminal plea is squarely in line with how Mr. Solomon has always acted when confronted with allegations of misconduct. When he has become aware of specific instances of potential improper conduct, he has acted swiftly to ensure that proper steps were taken to investigate the conduct and disciplined employees as ap propriate. For example, in August 2003, when Mr. Solomon received a letter from Novartis concerning allegations of improper sales practices by a Forest sales representative, he deemed it a matter of utmost importance, ordered a full investigation of the alleged conduct and instructed that appropriate disciplinary action be taken.32 Similarly, in October 2004, Mr. Solomon became aware of a letter from Eli Lilly alleging that a speaker made an inappropriate statement comparing the safety and efficacy of an Eli Lilly product to a Forest product during an office visit with a Forest sales representative.33 Mr. Solomon again ordered an investigation, this time of the practice of physician ride-alongs.34 His instructions to the Compliance group are memorialized in an email from a marketing executive to other senior executives: I spoke with Howard about this matter on Friday and he asked that we get together as a group and study this issue. 32 See Beamon Aff. Ex. 22. The investiga tion of the conduct described in the letter from Novartis, led by the compliance manager, concluded that the majority of the alleged conduct either could not be substantiated or was related to activities that Forest had since ended in order to comply with the new PhRMA guidelines. In the one instance where conduct was substantiated and contrary to Forest s existing policy, the sales representative was put on probation. See Beamon Aff. Ex. 23. 33 See Beamon Aff. Ex. 24. 34 Physician ride-along&#14 8; refers to a physician accompanying a sales representative on a pre planned visit to another physician s office. 43

He asked that we put clear guidelines, direction and training in place to define how this activity should be conducted and how it should not be conducted. Once we have such a plan defined, he wants us to be sure that we believe that such direction, training, etc provides adequate controls. If we do not feel that this activity can be adequately controlled, he would, like us to end. the practice. If we do feel it can be adequately controlled he wants us to make s ure that the representatives and physician speakers understand exactly how they should engage in this type of programming.35 The sales force was subsequently instructed that all in-office programs with speakers must be pre-scheduled, organized through the speakers bureau vendor as a speaker program, and attended by multiple doctors.

(b) Mr. Solomon Cooperated Fully Throughout the Six-Year Investigation The plea agreement resolved a six-year civil and criminal investigation conducted jointly by the United States Attorney s Office for the District of Massachusetts, the Office of Consumer Litigation and the Commercial Litigation Branch of the DO J. There is, and can be, no doubt that both the Company, led by Mr. Solomon, and Mr. Solomon personally cooperated fully throughout the government s investigation. In connection with the investigation, millions of documents were collected from hundreds of custodians, over six million individual call notes were analyzed, and hundreds of produ ctions were made. Additionally, numerous factual presentations were made by Company counsel on issues of interest to the USAO.36

35&eBeamonAff. Ex. 25. 36 This includes a report on findings concerning misconduct by sales representatives in New England. The Company also voluntarily traveled around the country to interview sales representatives and managers to gauge the scope of the misconduct that the investigation was focused on, and reported the results of that investigation to the government. 44

Mr. Solomon himself cooperated fully and testified before a grand jury. The DOJ has never suggested to Forest or Mr. Solomon personally that his conduct could merit criminal charges, under the Park doctrine or otherwise.37 4, Relevant Information About Forest Weighs Against Exclusion Forest is not a recidivist it has had no prior issues with the OIG or the DOJ, and has never before been the subject of any criminal or enforcement action. With Mr .. Solomon s support, even prior to the government s investigation, Forest had taken a number of steps to enhance its compliance and training program. After the government s investigation began, at Mr. Solomon s direction, Forest re-doubled its compliance efforts to prevent misconduct from occurring in the future. Moreover, the CIA Forest s first such agreement is extremely comprehensive and includes several enhanced compliance measures, such as Board and Offi cer certifications, the establishment of a Board Compliance Committee, and the retention of a Board Compliance Expert, as well as extensive monitoring provisions. The CIA provides additional assurance against future misconduct, and will ensure that any misconduct that does occur will be reported to the OIG and properly addressed. The exclusion of Mr. Solomon would have significant collateral consequences for the Company, its shareholders and patients who rely on Forest s current products and will benefit from those that are under development. Forest is somewhat unique in that it is a public company built on sustained, long-term growth by a small group of long-serving senior managers who are not fungible. Primary among them is Mr. Solomon, who has served as the CEO for over thirty years and as President and COO since December 2010. 37 &e Beamon Aff. If 3. 45

Mr. Solomon indisputably provides significant value to Forest s shareholders. Over the course of the last twenty years, under Mr. Solomon s ethical leadership and without ever before having an issue with the OIG or the DOJ, Forest s annualized total return to shareholders is 23%. This is only a single percentage point below the return Warren Buffet has delivered for Berkshire Hathaway shareholders, and among the highest of all CEOs who have served for at least 20 years and are still serving.38 Further, as noted, because Mr. Solomon s presumed successor unexpectedly retired to focus on his family s health, Mr. Solomon has assumed the additional roles of President and COO while new candidates for those roles are developed. It is crucial that Forest s future leaders can develop and maintain effective relationships with Forest s business partners, which will need to be carefully and diplomatically transition ed over time. Excluding Mr. Solomon would interfere significantly and unjustifiably with the Company s ability to continue with its plan for an orderly transition to new senior management. Further, as discussed above, Forest has a unique business model in that its pipeline is built by licensed products. Mr. Solomon continues to play an essential role in that partnership-based business model. All of Forest s major promoted products and its products in development are the result of Mr.&nbs p;Solomon s initiative and involvement. He continues to foster these relationships in a way that no one else at Forest is able to at this point in time because of his unique experience and tenure at the Company. In addition, Mr. Solomon is critical to developing new partnerships with research and biotechnology companies that seek to partner with Forest in large measure because of Mr. Solomon s 38 See Scott DeCario, The CEO 20-20 Club, FORBES, Apr. 28, 2011, available at http://blogs.forb es.com/scottdecarlo/201 l/04/28/the-ceo-20-20-club/. A copy of this article is attached to the Beamon Aff. as Ex. 26. 46

reputation and experience. If Mr. Solomon is excluded, these existing relationships and Forest s opportunities to develop new relationships could be jeopardized. Indeed, for many of Forest s partners, the personal relationship with Mr. Solomon is a driving force in the partnership. These companies rely on the fact that they can pick up the phone and. reach Mr. Solomon personally to discuss business issues when the need arises. By way of example, Forest is actively involved in negotiations with a European company to partner with Forest in developing an important new treatment option for lupus. The European company is also working with a biotechnology company on the product. Forest learned of a dispute between the two companies regarding the funding of clinical studies that threatened the continued development of the product. The companies turned to Mr. Solomon, whom each trusted based on his experience and reputation, to mediate the d ispute. Mr. Solomon is actively working to bring the two companies together, so that the drag may continue to be developed and ultimately distributed in the United States. It bears noting, however, that the parties cooperation remains tenuous and is predicated on Mr. Solomon s continued mediation. Mr. Solomon also meets regularly with the CEOs and other senior executives of Forest s partners. For example, he meets often with the CEO of Almirall, a Spanish company from which Fo rest has licensed two products for which it is preparing to submit NDAs aclidinium for the treatment of COPD, and a long-acting beta agonist for the treatment of COPD and asthma. Because Almirall has come to trust Mr. Solomon and believe in his abilities, it has approached him about developing yet another product. In recent months, Mr. Solomon also has personally forged a relationship for Forest with executives from an Austrian company that has developed a product that Forest hopes to 47

license. He also has worked to develop the trust of the CEO of Grunenthal, a German company with which Forest has conducted two transactions. This is a particularly critical time for Forest s future. Lexapro, Forest s largest product, will lose exclusivity next year, and. Namenda, Forest s second, largest product, will lose exclusivity in 2015. It is, therefore, more important than ever that Mr. Solomon remain CEO so that he can lead the Com pany in licensing new products, developing new partnerships that will sustain Forest in the future and successfully transitioning these critical personal relationships to a successor. Indeed, Mr. Solomon currently is actively involved in discussions with multiple companies regarding new products. These discussions would be jeopardized were he to be excluded. III. COLLATERAL CONSEQUENCES ON OTHER INVESTIGATIONS We believe serious negative collateral consequences would flow from any decision to exclude M r. Solomon. These negative consequences should be of paramount importance to the OIG as it looks for a fair and meaningful way to effectuate its policy of executive exclusion. Specifically, the exclusion of Mr. Solomon would have a chilling effect on the government s ability to negotiate settlements. If Mr. Solomon a man of great character and integrity who has led a company for over 30 years without prior incident, who did not participate in the misconduct, and who worked to establish a strong compliance program and to remediate the wrongdoing is excluded, then the CEO of every company that pleads guilty will be perceived as vulnerable to exclusion. Such a precedent will negatively impact the ability of the government to reach negotiated resolutions that 48

require an acknowledgment of wrongdoing, as companies will consider a settlement with the government to be a potential prelude to the exclusion of their CEOs. As a matter of policy, Mr. Solomon s exclusion would send the message to corporate executives that even when they did. not personally engage in wrongdoing, have for years run an ethical company, and have implemented state-of-the-art compliance measures, they can nevertheless be excluded. Mr. Solomon s exclusion, therefore, would be viewed by the industry as an arbitrary exercise of authority. As a result, it would neither deter misconduct nor encourage greater vigilance. Moreover, by excluding Mr. Solomon, not only would the OIG fail to accomplish its mandate to protect federal health care programs from untrustworthy participants, but it also may deter qualified, ethical individuals from serving as corporate managers and officers in the pharmaceutical industry. CONCLUSION The Inspec tor General has stated that [w]e are mindful of our obligation to exercise this [permissive exclusion] authority judiciously, and we do not propose to exclude all officers and managing employees of a company that is convicted of a healthcare-related offense. 39 If the OIG is to be true to these words, as well as to its own published guidance regarding the exercise of its discretion, the OIG should not exclude Mr. Solomon. While we recognize that, under certain circumstanc es, it might make sense to exclude an individual from participation in federal health care programs even absent a 39 3/9/11 Levinson Testimony. A copy of the transcript of this testimony is attached to the Beamon Aff. as Ex. 4. 49

personal criminal conviction, such circumstances are not present here. As discussed in detail above, not only do each of the four factors support the exercise of the OIG s discretion not to exclude, but in particular, the two factors that focus on Mr. Solomon personally weigh strongly against his exclusion. In a situation such as this one, where an individual is being considered for exclusion, the factors relating to the individual s role and res ponse to the misconduct should be afforded the greatest weight. As CEO, Mr. Solomon has led Forest in an ethical and responsible manner for more than thirty years, requiring that all Forest employees maintain the highest standards of business ethics and conduct. 40 He was not responsible for the day-to-day oversight of the business units involved in the misconduct and was not alleged to have engaged, either directly or indirectly, in the misconduct. Mr. Solomon did, however, react promp tly and forcefully to address and remediate the misconduct when it was brought to his attention. In light of these facts, and the narrow scope of the misconduct by a company that has never previously been the subject of government scrutiny, excluding Mr. Solomon would be unjust, unfair and would fail to further the purposes of the exclusion statute. While we understand the OIG s desire to send a clear message to corporate leaders in this industry that the culture must change, excluding a man of Mr .. Solomon s character and integrity is not the appropriate way to deliver this message. Having served notice that the OIG is serious about its intention to use its exclusion authority, the message it should now send is that it will follow its prescribed factors and exercise the Secretary s authority fairly. 40 See Beamon Aff. Exs. 11, 12 and 13. 50

In light of the devastating impact the Secretary s exclusion of Mr. Solomon would have on his career and reputation, as well as the severe consequences for the Company, its shareholders and patients, Mr. Solomon should not be excluded. We respectfully request an opportunity to meet with the OIG before any final decision with respect to Mr. Solomon is made. To ensure a fair process it is critical that if the OIG has questions or disagrees wit h any of the points in this submission, we be afforded, on Mr. Solomon s behalf, an opportunity to address those issues directly. 51

MINUTES OF A
SPECIAL MEETING
OF THE
BOARD OF DIRECTORS
OF
FOREST LABORATORIES, INC.
APRIL 5, 2011

A Special Meeting of the Board of Directors of Forest Laboratories, Inc. (the Corporation) was held at 10:00 a.m. at the offices of the Corporation. Present in person or by telephone were the following members of the Board of Directors:

Howard Solomon
Lawrence Olanoff
Dan L. Goldwasser
William J. Candee III
Dr. Lester Salans
Dr. Peter Zimetbaum
Kenneth E. Goodman

constituting a quorum of the Board. Also present were Frank Perier, Executive Vice President, Administration and Chief Financial Officer, Herschel S. Weinstein, Vice President General Counsel and Andrew Ceresney, a partner in the law firm of Debevoise & Plimpton LLP.

Mr. Weinstein informed the members of the Board that on March 14, 2011, the Office of Inspector General of the United States Department of Health and Human Services had informed the Corporation by a telephone call to the Debevoise firm that it was considering an order excluding Mr. Solomon, the Corporation s CEO, from participating in Federal health care programs. Mr. Weinstein indicated that the purpose of the meeting was to describe the implications of this development in order to allow the Board to consider appropriate responses on the part of the Corporation. Mr. Weinstein then introduced Mr. Ceresney, a partner at the Debevoise firm that was counsel to the Corporation in connection with OIG matters, to provide the relevant background and to describe the legal consequences of such an exclusion order.

Mr. Ceresney reviewed with the Board the history of settlement discussions with the Department of Justice that led to the September 2010 settlement of a United States civil and criminal investigation of certain marketing practices of the Corporation and a meeting attended by Debevoise with the Chief Counsel to the OIG following OIG s recent phone call. Mr. Ceresney also reviewed the consequences of an exclusion order with respect to Mr. Solomon,

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Mr. Ceresney further summarized the administrative procedures relating to exclusion proceedings and the judicial procedures which would be available if an exclusion order was entered (
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Mr. Weinstein then described senior management s recommendations in light of the possibility of OIG issuing an exclusion order. Such recommendations included continuing efforts to seek to dissuade OIG from proceeding with the exclusion order, assistance to, and cooperation with, Mr. Solomon s counsel in supporting Mr. Solomon s litigation strategy and development of an appropriate investor relations strategy. Mr. Weinstein also recommended

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Mr. Weinstein further reported that senior management believes that Mr. Solomon s continued service as the CEO and director is in the best interest of the Corporation and recommends that the Corporation take all reasonable steps to avoid the issuance of an exclusion order and, if one is issued, to enjoin its enforcement. Summarizing the views of management, Mr. Weinstein noted the following reasons in support of management s position:

Mr. Solomon continues to make a major contribution to the success of the Corporation. The Corporation s business model is the development and marketing of novel pharmaceuticals through partnerships; accordingly, the ability to attract new partners as well as to maintain strong relationships with its existing partners is essential to the Corporation s business model. Mr. Solomon has had, and continues to have, a key role in the development and maintenance of those relationships.

The management reorganization implemented and announced in December 2010 included promotions of key members of management with a view to developing a succession plan to ultimately filling the COO and CEO positions. This reorganization was premised upon the continued leadership of Mr. Solomon.

If OIG successfully implements an exclusion of Mr. Solomon, absent an injunction or temporary restraining order, Mr. Solomon would be required to resign as an officer and director within 20 days in order to preserve the eligibility of the Corporation s products for coverage under government funded medical reimbursement programs.

FOREST000051

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Implementing a transition in that short time frame could be disruptive and detrimental to the Corporation.

The failure of the Corporation to actively resist an exclusion action may be seen (both by employees and investors) as a tacit acknowledgment of morally culpable acts on the part of management, potentially undermining both employee morale and investor confidence.

The Corporation should not be made to suffer these harms given that the proposed exclusion order does not reflect any wrongdoing or even any suggestion of wrongdoing by Mr. Solomon but instead reflects, in management s view, an unprecedented and punitive use of the Department of Health and Human Service s regulatory authority as to the Corporation.

In response to questions from Board members, Messrs. Weinstein and Ceresney reviewed the procedural aspects of an exclusion order. In addition, in response to such questions, Mr. Weinstein

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Mr. Weinstein indicated that for the reasons enumerated, the Corporation s senior management recommends that the Corporation retain its own counsel and otherwise cooperate with counsel retained by Mr. Solomon in connection with this matter, as well as discharge its Bylaw indemnification obligations to Mr. Solomon. Accordingly, Mr. Weinstein presented specific resolutions to be considered for adoption by the Board (and noted that Mr. Solomon had recused himself from participation in the voting as to such resolutions).

Upon motion duly made and seconded, the following resolutions were unanimously adopted by the Board of Directors:

WHEREAS, the Office of the Inspector General (OIG) of the Department of Human Health and Services has notified Forest Laboratories, Inc. (the

FOREST000052

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Company) that it is considering an order excluding Howard Solomon, the Company s CEO.

WHEREAS, the Board is advised that the OIG s action is based upon the fact that a subsidiary of the Company has pleaded guilty to the commission of two strict liability no intent misdemeanors and an interpretation by the OIG of its governing legal mandate to the effect that OIG may order such exclusion without being required to allege or prove that Mr. Solomon has any personal knowledge or awareness for the acts of that subsidiary.

WHEREAS, the exclusion of Mr. Solomon could materially damage the business of the Company if Mr. Solomon were to continue to serve as an officer or director of the Company by jeopardizing the eligibility of the Company s products for reimbursement under government medical reimbursement programs, including Medicare and Medicaid, and accordingly if such an order were to be issued and become effective it is anticipated that Mr. Solomon would be required to sever his director and officer relationship with the Company.

WHEREAS, in December 2010 the Board approved a management reorganization designed to increase the responsibilities and further the development of certain key executive officers as part of a management succession plan intended to ensure the continued availability to the Company of a pool of highly trained and effective candidates to lead the Company in the future.

WHEREAS, such reorganization contemplated the continued leadership of the Company by Mr. Solomon.

WHEREAS, the loss of Mr. Solomon s executive leadership as a result of an exclusion would force the Company to implement a truncated succession plan, and could negatively impact the management reorganization approved by this Board of Directors in December 2010 and could negatively impact the Company s operations and create uncertainty among the Company s employees, investors, and business partners, including potential business partners with whom the Company is seeking to build alliances.

WHEREAS, the Company s Bylaws provide for mandatory indemnification of any officer or director involved in any action or proceeding by reason of the fact that he is an officer or director to the fullest extent permitted by Delaware corporate law.

FOREST000053

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NOW THEREFORE BE IT

RESOLVED, that the Board of Directors of the Company approve the Company s indemnification of Mr. Solomon for all costs incurred by him in connection with the OIG s consideration of an order of exclusion against him, and in connection with any challenge to the validity of such order or effort to otherwise prevent the enforcement of any such order, in each case, to the fullest extent authorized by, and subject to the applicable provisions of, the Company s Bylaws and applicable law; and

RESOLVED, that the Company retain its own counsel and other experts as appropriate to support Mr. Solomon in connection with these matters, and that the Company s executive officers and such counsel are hereby authorized and directed to take all actions necessary and appropriate to avoid the issuance of any such order of exclusion against Mr. Solomon and if issued to avoid or mitigate the adverse impact on the Company of any exclusion action against Mr. Solomon if so taken by the OIG.

RESOLVED, that the proper officers of this Corporation and its counsel be, and they hereby are, authorized to take all such further action, to do all such acts and things and to execute and deliver all such agreements, instruments and documents in the name and on behalf of this Corporation and under its corporate seal or otherwise and to pay all such fees and expenses as in their judgment shall be necessary, proper or advisable in order to fully carry out the intent and to accomplish the purposes of the foregoing resolutions.

FOREST000054

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March 30, 2011
By FEDERAL EXPRESS

CONFIDENTIAL / FOIA EXEMPT

The Honorable Daniel R. Levinson, Esq.
Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5250
330 Independence Ave., S.W.
Washington, D.C. 20201

Forest Laboratories, Inc.

Dear Mr. Levinson:

We represent Forest Laboratories, Inc. (FLI) and its subsidiary Forest Pharmaceuticals, Inc. (FPI) (together Forest or the Company), a public company whose shares trade on the NYSE, in connection with a civil and criminal investigation conducted by the Department of Justice that was concluded in September 2010, and as part of which FPI pled guilty to two no-intent misdemeanors in November 2010. Judgment was entered in accordance with that plea agreement on March 2, 2011.

During the negotiations relating to the resolution of the criminal investigation, your Office informed us that it was considering conditioning a waiver of permissive exclusion for the corporate entity on Forest s disaffiliation from eight of its top executives. Subsequently, we were informed that your Office was limiting its disaffiliation condition to Howard Solomon, currently Forest s Chief Executive Officer, President, and Chairman of its Board of Directors. After some dialogue, your Office agreed to withdraw its request for disaffiliation, and Forest was granted a waiver of exclusion and entered into an extensive Corporate Integrity Agreement. The Company recently reported to your office on its successful implementation of the CIA. Then, two weeks ago, days after FPI s judgment of conviction was final, we were informed by your Chief Counsel, Lew Morris, that your Office is considering whether to seek to permissively exclude Mr. Solomon under 42 U.S.C. § 1320a-7(b)(15) based, in our view, solely on his position as an officer or managing employee of FPI, even though he had no involvement in, awareness of, or reason to know of any criminal misconduct. Yesterday, we met with Mr. Morris and others in your Office to discuss this matter and to explain why exclusion of Mr. Solomon in these circumstances would be unjustified and a misapplication of the factors listed in your Office s October 19, 2010 Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15). We write to ask for the opportunity to meet with you personally if your Office is inclined to move ahead with a Notice of Intent to Exclude Mr. Solomon.

A decision to exclude Howard Solomon would have a devastating impact on Forest and its public shareholders. Mr. Solomon has been CEO of Forest for over 30 years, and continues to play a critical role in Forest s business specialty, which is identifying and bringing to the United States market novel and important therapies, often initially invented by relatively small U.S. and ex-U.S. pharmaceutical companies who are looking for a partner with whom to complete the development of these products and bring them successfully to the U.S. market. These products include Celexa and Lexapro, originally developed in Denmark and now the leading antidepressants in the U.S. (but originally turned down for development by much larger U.S. pharmaceutical companies), and Namenda, the only NMD A antagonist approved for the treatment of Alzheimer s Disease in the U.S., which was developed by Forest in close collaboration with its German inventor. Forest s recently launched novel antibiotic Teflaro, which has been widely heralded as an important development in the ongoing battle against antibiotic resistant infections in hospital settings, was also a direct result of Forest s collaborative activities. Mr. Solomon was crucial in achieving these collaborations and remains crucial to their ongoing success.

Mr. Solomon s role only increased in importance a few months ago, when Forest s President and COO, Lawrence Olanoff, M.D., unexpectedly retired. Following Dr. Olanoff s retirement, Mr. Solomon took on additional responsibilities, including the role of President, and the Board announced a plan for identifying a number of senior managers to lead Forest in the future. The plan relies upon Mr. Solomon s continued leadership for a period of time until one or more of those employees are ready to assume senior leadership positions. Those leadership changes following Dr. Olanoff s decision to retire were announced publicly in November 2010 to the market by press release and within Forest by means of a memorandum from Mr. Solomon to all employees. As a result, confidence in the continued strength and stability of Forest s leadership was established. The Company is functioning well with this plan. Removal of Mr. Solomon at this stage would upend that plan and harm innocent shareholders and employees.

Beyond the harm to the Company, exclusion under the facts of this case would be terribly unjust and unfair. This would be the first time that your Office would use Section (b)(15) to exclude a pharmaceutical company executive where the Company has pled guilty to criminal offenses, and where the executive has not himself been convicted of a crime or even charged with a crime. It also would represent the broadest possible reach of that provision to an executive who had no awareness of the conduct and who had no reason to know of the conduct. And it would do so in a case involving aged conduct indeed, much of the conduct is over a decade old that is much less egregious than other cases in which pharmaceutical companies have pled guilty but where no executive was excluded. We understand that your Office has announced a change in policy intended to hold individuals more accountable for corporate misconduct. But this case which involves conduct that occurred well before you announced that policy, and which involves minimal conduct (none of which Mr. Solomon had knowledge of) that pales in

comparison to other cases in which there was no exclusion is not the case in which to apply it for the first time. We are concerned that perhaps Forest is being singled out because it is a relatively small company compared to other pharmaceutical companies, and because Mr. Solomon is 83 years old and may be considered expendable, which is simply not the case. You and Mr. Morris assured Congress earlier this month that your Office will exercise its (b)(15) exclusion powers judiciously. Doing so here compels a decision not to exclude Mr. Solomon.

Howard Solomon has had a long and distinguished career in which he has never been accused of misconduct. He has led Forest s extensive compliance enhancements over the last decade since the conduct at issue, and it is undisputed that he has always set a strong ethical tone at the top of the Company. In light of these compelling circumstances, and the severe impact that even a Notice of Intent to Exclude would have on Forest once it is disclosed, we respectfully request an opportunity to meet with you before any final decision is made on issuing such a Notice of Intent to Exclude.

We would be happy to discuss this matter and provide any additional information that would be helpful. Thank you for your consideration.

* * * * *

As you will see, we have stamped this letter with the legend CONFIDENTIAL / FOIA EXEMPT. On behalf of Forest, we hereby request, pursuant to 5 U.S.C. § 552(b)(4), that confidential treatment be accorded to all copies of this letter and any transcriptions, notes, memoranda or other records created by or at the direction of the U.S. Department of Health and Human Services (including your Office), or officers or staff members thereof, that reflect, refer, or relate to this letter. The letter contains customarily non-public, confidential commercial and financial information, which, if disclosed, would cause substantial competitive harm to Forest, and which is exempt from disclosure under applicable law, including the Freedom of Information Act (FOIA) Exemption 4. Please inform Andrew Ceresney of any request under FOIA seeking access to any of the foregoing records, including this letter, to enable us to substantiate the grounds for confidential treatment, unless the U.S. Department of Health and Human Services intends to deny such request for access on other grounds. Forest requests that you telephone Mr. Ceresney at (212) 909-6947 rather than rely on the United States mail for such notice.

cc: Lewis Morris, Esq.

FOREST000046

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Forest Laboratories, Inc. March 29, 2011 Meeting Office of Inspector General U.S. Department of Health & Human Services Confidential / FOIA Exempt CONFIDENTIAL FOREST000001

Exclusion Would be Unjustified and Unfair Drastic departure from past practice and application of new policy in this case not warranted Underlying conduct does not justify exclusion under OIG s stated criteria Conduct 8 13 years old Underlying conduct much less serious than conduct of other firms that did not result in exclusion of individuals No safety issues or public health risk Minimal field-level off-label promotion Levothroid unique and sui generis Entire class of drugs had been on market for decades FDA permitted drug to remain on market to meet patient need until 8/14/03; Forest ceased to distribute on 8/9/03 Guidance non-binding on its face FDA knew Forest was continuing to distribute 2 Confidential / FOIA Exempt CONFIDENTIAL FOREST000002

Exclusion Unjustified and Unfair, cont. Underlying conduct does not justify exclusion, cont. Two no-intent misdemeanors No charge of wrongful intent or attempt to deceive or mislead regulators or consumers Forest not a recidivist Unlike other companies where there were no individual exclusions, Forest has never had a prior issue This is Forest s first CIA CIA contains many enhanced provisions, including Board/Officer certifications, Board Compliance Committee, and Board Compliance Expert, as well as extensive monitoring provisions 3 Confidential / FOIA Exempt CONFIDENTIAL FOREST000003

Exclusion Unjustified and Unfair, cont. Mr. Solomon was not aware of nor should he have been aware of any criminal misconduct No basis for presumption of exclusion Off-label promotion No awareness of any off-label promotion Very low rate of off-label usage and off-label promotion, in face of very significant growth in on-label usage Raised no red flags 4 Confidential / FOIA Exempt CONFIDENTIAL FOREST000004

Exclusion Unjustified and Unfair, cont. Mr. Solomon was not aware of nor should he have been aware of any criminal misconduct, cont. Levothroid Had been on market since 1950s and FDA allowed continued distribution while companies sought NDAs Mr. Solomon understood Forest was pursuing NDA, which was FDA s goal Mr. Solomon not involved in decision not to phase down Told by Company experts that guidance was non-binding and not mandatory, which made sense in light of title and history Mr. Solomon believed FDA was fully aware of distribution and company was being transparent with FDA 5 Confidential / FOIA Exempt CONFIDENTIAL FOREST000005

Exclusion Unjustified and Unfair, cont. Other OIG factors weigh strongly against exclusion Mr. Solomon does not present any risk to federal health care programs Not involved in or aware of any misconduct Has always set strong tone at the top and emphasized ethical business practices E.g., June 2003 speech to sales managers: Nevertheless it is very important that we stay well within the letter and intent of the law, not at the periphery of the law, but at the core of its requirements. Even when we think those requirements are an unnecessary nuisance, we have to observe them. It is not clever to play at the boundaries, it is foolish and dangerous. Committed resources to support substantial enhancements to compliance program well before CIA imposed 6 Confidential / FOIA Exempt CONFIDENTIAL FOREST000006

Exclusion Unjustified and Unfair, cont. Exclusion would have a disproportionate impact on Forest, a public company, and its shareholders Mr. Solomon plays central role in forging and fostering relationships with licensing and co-development partners, which is the foundation of Forest s business Particularly critical time for Company President & COO unexpectedly retired in December; Mr. Solomon now has additional senior managers reporting to him Succession plan in place (recently approved by the Board) that will result in new senior management (CEO, President and COO) in coming years Serious legal and constitutional challenges to exclusion under these circumstances Mr. Solomon is a highly ethical, fully in charge, and active 83-year-old CEO and there is no basis to exclude him 7 Confidential / FOIA Exempt CONFIDENTIAL FOREST000007

Nature of the Conduct and Mr. Solomon s Lack of Knowledge or Reason to Know Confidential / FOIA Exempt CONFIDENTIAL FOREST000008

Limited Field-Level Off-Label Promotion Limited field-level violations of Company policy Bulk of conduct occurred more than a decade ago No corporate-directed effort to promote off-label Unlike in other cases, sales force not trained, directed, or encouraged by corporate management to promote for pediatric use, and were trained to promote on-label Unlike in other cases, Marketing Department did not provide sales force with pediatric reprints or other pediatric marketing materials Call notes and verbatims also reflect very low levels of off-label promotion in field Absence of corporate involvement reflected in very low percentage of pediatric prescriptions Patient safety not jeopardized SSRIs are standard of care in treating pediatric depression Lexapro now FDA-approved for adolescent depression 9 Confidential / FOIA Exempt CONFIDENTIAL FOREST000009

Minimal Amount of Possible Off-Label Promotion Celexa Call Notes Possible Pediatric Promotion: Only approximately 0.6% of all Celexa call notes reviewed* 4.66 million call notes (1998-2002) *Under broad reading of call notes that could even arguably be suggestive of possible pediatric promotion by sales rep 10 Confidential / FOIA Exempt CONFIDENTIAL FOREST000010

Minimal Amount of Possible Off-Label Promotion Celexa Physician Verbatims Possible Pediatric Promotion: Only approximately 0.3% of all physician verbatims* 6,885 physician verbatims (1998-2002) *Under broad reading of verbatims that could even arguably be suggestive of possible pediatric promotion by sales rep 11 Confidential / FOIA Exempt CONFIDENTIAL FOREST000011

Percentage of Pediatric Prescriptions in SSRI Market Percentage of Celexa pediatric Pediatric Share of Uses for SSRIs1,2 prescriptions as percentage of total 1997 2004 25% prescriptions lower than for all other SSRIs during promotion period No SSRI approved for pediatric depression 20% Prozac only SSRI approved for pediatric depression 15% PediatricSharebyDrug 10% 5% Celexa promotion ends 0% 1997 1998 1999 2000 2001 2002 2003 2004 Celexa Luvox Paxil Prozac Zoloft Negative Paxil Notes: publicity grows 1. Pediatric Share equals the number of pediatric uses (uses for patients under 18) divided by the number of all uses. with UK, US warnings 2. SSRIs include Celexa, Prozac, Luvox, Paxil, and Zoloft. Sarafem is excluded because it is only indicated for PMDD. Source: IMS NDTI Data 12 Confidential / FOIA Exempt CONFIDENTIAL FOREST000012

Mr. Solomon Had No Reason to Know of Off-Label Conduct No instances of off-label promotion brought to his attention No corporate direction to promote off-label Instances of off-label promotion extremely minimal Pediatric usage of Celexa did not raise any red flags Background rate of pediatric usage before Forest entered SSRI market Celexa pediatric usage was below pediatric usage of other SSRIs during entire Celexa promotion period despite growth in Celexa usage for adult depression When Celexa entered the market, average rate of pediatric use of SSRIs was 6.23% Celexa averaged 4.06% during promotion 13 Confidential / FOIA Exempt CONFIDENTIAL FOREST000013

No Intent to Conceal Lundbeck Study Results No decision made by Forest senior management not to disseminate study Study handled consistently with scientific community and industry practice at the time for negative studies generally not actively disseminated unless clinically meaningful in some way Study was negative, inconclusive on efficacy Study did not demonstrate safety issues Columbia reanalysis further reinforced absence of safety issue Contemporaneous evidence reflects that Forest scientific personnel viewed study as flawed and poorly conducted As was documented by study investigator in article that published study results in 2006 Mr. Solomon not involved in decisions on dissemination of studies 14 Confidential / FOIA Exempt CONFIDENTIAL FOREST000014

Levothroid Circumstances sui generis very unusual situation Drug had been on market since 1950s, with no safety issues FDA kept drugs on market to meet patient need, declared they posed no health threat, while companies pursued NDAs Senior management believed phase-down was voluntary and non-binding based on plain language of FDA guidance Understood that distribution must cease altogether by August 14, 2003 if no approved NDA had been obtained, and always intended to and did follow that deadline Forest actively pursued NDA for Levothroid throughout phase-down period, and anticipated approval before deadline No evidence any member of Forest s senior management intended to violate the law or mislead FDA 15 Confidential / FOIA Exempt CONFIDENTIAL FOREST000015

Levothroid, cont. Levothroid did not present any safety issues Sold for decades before 1997 new drug announcement Hypothyroidism affects millions of Americans; if untreated, can lead to serious consequences Condition can be managed with daily levothyroxine tablet FDA declared all levothyroxine products new drugs to address concerns about stability and potency of formulations FDA determined levothyroxine drugs were medically necessary, should remain on market, and presented no public health threat No evidence any patient was harmed by taking Levothroid 16 Confidential / FOIA Exempt CONFIDENTIAL FOREST000016

Levothroid, cont. FDA was not misled about Levothroid s distribution FDA aware of distribution and aware Forest was not following phase-down schedule Forest NDA was pending during entire period FDA addressed distribution through Warning Letter at end of guidance period, and Forest ceased distribution within hours Mr. Solomon Levothroid a very small product for Forest Mr. Solomon not involved in decision not to phase down When became aware, was told guidance non-binding according to Head of Regulatory Made sense in light of regulatory history and fact that it was a guidance Understood Forest being transparent with FDA No red flags alerted Mr. Solomon that continued distribution in excess of guidance violated the law 17 Confidential / FOIA Exempt CONFIDENTIAL FOREST000017

Regional Advisory Boards Designed and executed by Forest as bona fide program intended to gather specific local feedback as to how to market its products more effectively Feedback collected and distributed to Marketing and Sales employees Purpose of fee paid to advisors was to compensate them for their time in attending meeting and providing feedback Advisors signed consulting agreements, which explained issues on which advisor insights were solicited Advisors paid at most $500 for four hours Meetings generally held on Saturday mornings in hotel conference rooms typically within driving distance Fees standard and commensurate with services provided 18 Confidential / FOIA Exempt CONFIDENTIAL FOREST000018

Regional Advisory Boards, cont. No one in Marketing or senior management viewed modest RAB compensatory fees as a quid-pro-quo in exchange for prescriptions At the time, RABs were common industry programs that were not viewed as being problematic As to Mr. Solomon, reference in civil complaint to Slide No. 40 in 50-slide marketing deck from January 2002 notes simply that RABs could have effect of leading hesitant physicians to prescribe Celexa Reference does not raise any possible inference that RABs intended as quid-pro-quo exchange Instead, reflects recognition that information learned at RABs may potentially lead to future prescriptions by providing physicians with additional information from other physicians, not that advisor fees were intended as a quid pro quo No evidence programs were designed to induce prescriptions in exchange for the advisory fees 19 Confidential / FOIA Exempt CONFIDENTIAL FOREST000019

Forest s Conduct Compared to Prior Cases Involving No Exclusion Confidential / FOIA Exempt
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No Exclusion of Officers in Recent Cases Other recent investigations featuring far more egregious conduct, including safety issues, did not result in exclusion of any officers CORPORATE COMPANY DATE CONDUCT CHARGE Pfizer Sept. 2009 1 Felony Recidivist company (Bextra) misbranding Corporate-driven campaign to promote off-label ([M]arketing team positioned Bextra for unapproved uses [particularly acute pain] and Intent to dosages, commissioned market research to test its sales materials, defraud or and confirmed these unapproved messages ; illegal conduct was mislead pervasive throughout the company and stemmed from messages created at high levels within the national marketing team)* Approx. 57% of drug sales for off-label uses Patient safety jeopardized (Bextra not approved for acute pain due to increased risk of serious cardiovascular thromboembolic events; withdrawn from market in 2005 at request of FDA for safety reasons) Sales compensation specifically rewarded off-label promotion of Bextra *U.S. Sent. Mem. 21 Confidential / FOIA Exempt CONFIDENTIAL FOREST000021

Exclusion Unprecedented, cont. CORPORATE COMPANY DATE CONDUCT CHARGE Lilly Jan. 2009 1 Misdemeanor Recidivist company (see below) (Zyprexa) misbranding Corporate-driven campaign to promote off-label ([S]enior executives and managers of the company knew and approved of the [off-label promotion] *; management created marketing materials promoting Zyprexa for off-label uses, ... and directed its sales personnel to promote Zyprexa for off-label uses) Approx. 42% of the drug s sales for off-label uses Patient safety jeopardized (adverse side effects included diabetes and other serious health problems; Lilly reportedly marketed adverse effects as benefits) *U.S. Sent. Mem.; DOJ Press Release Lilly Dec. 2005 1 Misdemeanor Corporate-driven campaign to promote Evista off-label (Evista) misbranding (marketing team developed off-label marketing and promotional messages)* *Information 22 Confidential / FOIA Exempt CONFIDENTIAL FOREST000022

Exclusion Unprecedented, cont. CORPORATE COMPANY DATE CONDUCT CHARGE Cephalon Sept. 2008 1 Misdemeanor Corporate-driven campaign to promote three drugs off-label (Gabitril, misbranding (...the very top levels of the company knew and approved of [the off-label promotion]. This was a highly organized and Provigil, deliberate effort...)* Actiq) Continued after FDA twice warned company to cease activity Roughly 80-90% of prescriptions off-label Patient safety jeopardized (Actiq highly addictive Schedule II substance 80 100 times more powerful than morphine; Gabitril caused seizures) Deliberate attempt to bilk Medicaid (sales reps allegedly coached doctors to falsify diagnosis codes) Sales compensation structured to require off-label promotion to meet targets * U.S. Sent. Mem. 23 Confidential / FOIA Exempt CONFIDENTIAL FOREST000023

Factors Present in Other Cases Not Present Here Factors in other cases Corporate-driven campaign Patient safety issues Significant percentage of off-label prescriptions Recidivist companies None of these factors present in this case Celexa had very low rate of off-label prescribing when compared to off-label prescribing in other cases Celexa percentage of off-label prescriptions lowest among other off-label investigations Provides additional objective evidence there was no corporate push Except in cases involving guilty pleas from individuals, no company executives excluded in other off-label cases 24 Confidential / FOIA Exempt CONFIDENTIAL FOREST000024

Estimated Rate of Off-Label Prescriptions as Percentage of Total Prescriptions 100% 94% 90% 90% 88% 86% 85% 80% 79% 80% 78% 70% 60% 60% 57% 50% 42% 40% 20-30% 30% 25% FOREST 20% 10% 4.06% 0% Neurontin(1) Provigil(2) Gabitril(3) Actimmune(4) Temodar(5) Actiq(6) Topamax(7) Seroquel(8) Genotropin Bextra(10) Zyprexa(11) Abilify(12) Genotropin Celexa (14) (adult)(9) (ped)(13) Notes 1. Warner Lambert. USAO Sentencing Mem. at 14. 2. Cephalon. New York Times, Wakefulness Finds a Powerful Ally, June 29, 2004. 3. Cephalon. Knight-Ridder, Marketing Plays Big Role in Rising Off-Label Sales, Nov. 3, 2003. 4. Intermune. New York Times, Suit by Former Employee Charges Promotion of Drug s Off-Label Use, May 12, 2004. 5. Schering-Plough. Complaint filed in In re Schering Plough Intron/Temodar Consumer Class Action, No. 06-5774 (D.N.J.) (complaint alleges 85- 95%). 6. Cephlalon. Wall Street Journal, Potent Product: Narcotic Lollipop Becomes Big Seller Despite FDA Curbs, Nov. 3, 2006. 7. Ortho-McNeil (Johnson & Johnson). Knight-Ridder, Marketing Plays Big Role in Rising Off-Label Sales, Nov. 3, 2003. 8. AstraZeneca. Knight-Ridder, Marketing Plays Big Role in Rising Off-Label Sales, Nov. 3, 2003. 9 and 13. Pharmacia. Complaint filed in US ex rel Rost v. Pfizer, 03-CV-11084 (D. Mass. 2003). 10. Pfizer. USAO Sentencing Mem. at 25. 11. Eli Lilly. Knight-Ridder, Marketing Plays Big Role in Rising Off-Label Sales, Nov. 3, 2003. 12. BMS. On information and belief. 14. Forest. Average Celexa rate between 3Q1998-3Q2002. Confidential / F.O.I.A. Exempt CONFIDENTIAL 25 FOREST000025

Howard Solomon Confidential / FOIA Exempt CONFIDENTIAL FOREST000026

Mr. Solomon Mr. Solomon does not pose any threat to federal health care programs Statutory purpose of exclusion is not punitive, but to protect federal health care programs and beneficiaries from untrustworthy participants Consistently has fostered a strong ethical business culture and tone at the top Did not turn a blind eye to field misconduct, but instead took strong actions to prevent it Dedicated resources to building compliance program Repeatedly reinforced importance of compliance Ensured Company s compliance policies and systems kept pace with evolving industry norms On occasions when misconduct came to Mr. Solomon s attention, he responded in the clearest and strongest terms that the Company needed to get to the bottom of the misconduct and take appropriate action 27 Confidential / FOIA Exempt CONFIDENTIAL FOREST000027

Demonstrated Commitment to Compliance Prior to 2003 Company proactively developed promotional compliance policies consistent with industry standards Senior executives, including Mr. Solomon, took leading role in communicating policies As industry standards evolved, Forest enhanced and clarified its policies For example, Company quickly reviewed and revamped promotional policies in response to issuance of PhRMA Code (even though Forest is not a member of PhRMA) Policies repeatedly reinforced during training, at sales meetings, and in communications to field OIG Guidance issued April 2003 Within one month of issuance: Compliance Manager appointed Compliance Committee formed Charged with implementing full adherence to OIG Guidance Chaired by President and COO 28 Confidential / FOIA Exempt CONFIDENTIAL FOREST000028

Commitment to Compliance, cont. Mr. Solomon issues strong Oct. 2004 email from directive to investigate practice Marketing Executive to of physician ride-alongs and senior executives terminate if they cannot be adequately monitored Physician ride-alongs subsequently ended 29 Confidential / FOIA Exempt CONFIDENTIAL FOREST000029

Commitment to Compliance, cont. Continued strides in Compliance Program over past 8 years under Mr. Solomon s direction Significant strengthening of off-label training for sales reps (and marketing personnel) Heavy focus on monitoring enhancements, even before CIA Growth of Compliance Department and personnel Regular audits of sales reps call notes Sales rep monitoring by Compliance personnel Unannounced audits of speaker programs Regular review of requests for off-label information Regular review of physician verbatims New expense system Company continues to build compliance infrastructure as it implements CIA 30 Confidential / FOIA Exempt CONFIDENTIAL FOREST000030

Mr. Solomon, cont. Born in the Bronx to very modest means Attended local public schools, then eventually attended Yale Law School Built Forest from a small generic manufacturer to a thriving mid-sized pharmaceutical company that brings life-saving drugs to market Mr. Solomon s interest in Celexa stemmed from his son Andrew s illness from depression Andrew is the noted author of Noonday Demon, winner of the National Book Award, about his struggles with depression Dedicated book to his father: For my father, who gave me life not once, but twice. 31 Confidential / FOIA Exempt CONFIDENTIAL FOREST000031

Mr. Solomon s Critical Importance to Forest Forest is a public company Exclusion of Mr. Solomon would have devastating collateral consequences to Forest and its shareholders Forest business model based on development and licensing partnerships Small or foreign research and biotech companies depend on partners like Forest to provide resources to develop new drugs for U.S. market Mr. Solomon is critical in developing and maintaining these partnerships 32 Confidential / FOIA Exempt CONFIDENTIAL FOREST000032

Mr. Solomon s Critical Importance, cont. Current partners include: Lundbeck Danish company Forest partnered with to bring Celexa and Lexapro to U.S. market Merz family-controlled German company that developed Namenda, Forest s Alzheimer s drug Almirall SA Spanish company partnering with Forest to develop Aclidinium, a COPD (chronic obstructive pulmonary disorder) drug Ironwood company based in Cambridge, MA working with Forest to develop irritable bowel syndrome drug Nycomed privately held company worked with Forest to develop Daliresp, a recently approved COPD drug Merck KGaA German company that partnered with Forest to develop Campral, an alcohol addiction drug Gruenenthal (pain product), AstraZeneca (Teflaro), Pierre Fabre (antidepressant) 33 Confidential / FOIA Exempt CONFIDENTIAL FOREST000033

Mr. Solomon s Critical Importance, cont. Departure now would be especially damaging President & COO retired in December 2010 Five executives reporting to Howard, some of whom are potential future candidates for senior management positions such as CEO, President and COO but are not yet ready Careful succession plan recently formulated by Board Particularly precarious time in Company s leadership which will have enormous impact on future of the business 34 Confidential / FOIA Exempt CONFIDENTIAL FOREST000034

Summary The OIG s (b)(15) Factors Weigh Heavily Against Exclusion of Mr. Solomon Confidential / FOIA Exempt CONFIDENTIAL FOREST000035

OIG Factors Weigh Strongly Against Exclusion The Circumstances of the Misconduct and Seriousness of the Offense Conduct now 8-13 years old No safety dangers posed to patients Federal program beneficiaries received safe and effective drugs No corporate involvement in minimal field-based off-label promotion Pediatric sales always a very small percentage of overall sales No affirmative decision by senior management to conceal Lundbeck study Conduct consistent with industry and scientific community practice Levothroid issues involved failure to follow voluntary guidance in unique and unprecedented situation Two no-intent misdemeanors No charge of wrongful intent or attempt to deceive or mislead regulators or consumers Forest not a recidivist 36 Confidential / FOIA Exempt CONFIDENTIAL FOREST000036

OIG Factors Weigh Against Exclusion, cont. Individual s Role in Sanctioned Entity As CEO, Mr. Solomon holds high-level role in the company Direct responsibility for promotion fell under the authority of his chief marketing officer and the heads of the sale force, not under Mr. Solomon Direct responsibility for the manufacture and distribution of Levothroid was shared by the President & COO and the chief medical officer, not under Mr. Solomon Howard relied on his direct reports who were trusted professionals with whom he had worked for years to flag important issues He had no knowledge or reason to know of the minimal off-label conduct at issue that was in violation of Company policy and no knowledge or reason to know that the distribution of Levothroid would be regarded as a violation of the law or that the Guidance could be considered binding 37 Confidential / FOIA Exempt CONFIDENTIAL FOREST000037

OIG Factors Weigh Against Exclusion, cont. Individual s Actions with Respect to Misconduct Would have been impossible for Howard to prevent the limited field-level misconduct Exercised strong and ethical leadership and set exemplary tone at the top Under his leadership, Company trained sales force to promote within label Marketing Department never instructed or directed sales force to promote off-label Lack of any corporate direction reflected in low rate of pediatric sales Inevitable that rogue employees will exist at every company Reliance on senior managers and Head of Regulatory with regard to impact of guidance was appropriate 38 Confidential / FOIA Exempt CONFIDENTIAL FOREST000038

OIG Factors Weigh Against Exclusion, cont. Individual s Actions, cont. Actions were taken to address any issues once Mr. Solomon became aware of them. Examples: Significantly expanded compliance program Professional Affairs letters embargoed upon discovery that Lundbeck study had been inadvertently omitted Fully cooperated throughout burdensome six-year DOJ investigation Company spent tens of millions on this effort 39 Confidential / FOIA Exempt CONFIDENTIAL FOREST000039

OIG Factors Weigh Against Exclusion, cont. Information About the Entity Forest has had no prior issues with DOJ or OIG Good corporate actor with demonstrated desire and commitment to prevent misconduct Corporate Integrity Agreement will address any concerns going forward Forest is a public company with a comparatively small group of senior managers who are not fungible Exclusion of Mr. Solomon will have devastating impact on the Company 40 Confidential / FOIA Exempt CONFIDENTIAL FOREST000040

Exclusion Would Present Serious Legal and Constitutional Issues Confidential / FOIA Exempt
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Wrong Case for Legal Testing Serious legal and policy issues with OIG action Elements of (b)(15) are not met Forest not a sanctioned entity because the no-intent misdemeanors do not relate to fraud or financial misconduct Due Process challenge (b)(15) exclusion process for officer or managing employee fails to comply with requirements of Due Process Clause because allows Secretary unconstrained discretion without any meaningful judicial review 42 Confidential / FOIA Exempt CONFIDENTIAL FOREST000042

Wrong Case, cont. Legal and policy issues, cont. Exclusion would contravene legislative purpose behind (b)(15) Provision intended to address serial wrongdoers who start new business after being sentenced In 1995, then-Inspector General Brown testified before Congress that (b)(15) was necessary to exclude culpable individuals who reincorporate or start another business with no fear of exclusion. If we were empowered to act against the culpable individuals in such a situation, then we would be able to close the door on mobile owners. (b)(15) not intended to apply to senior-level executives at legitimate pharmaceutical corporations who were not personally involved in or aware of wrongdoing To exclude Mr. Solomon would be unwarranted, unfair, and would stigmatize the distinguished, ethical reputation Mr. Solomon has earned in the community 43 Confidential / FOIA Exempt CONFIDENTIAL FOREST000043