

FOREST LABORATORIES INC
Form DEFA14A
July 28, 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.)**

Filed by the Registrant
Filed by a party other than the Registrant

Check the appropriate box:

- Preliminary Proxy Statement
- Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
- Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material Pursuant to § 240.14a-12

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

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

Payment of Filing Fee (Check the appropriate box):

- No fee required.
- Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

- Fee paid previously with preliminary materials.

Edgar Filing: FOREST LABORATORIES INC - Form DEFA14A

o Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

Note:

The materials contained in this Forest Laboratories, Inc. Schedule 14A / DEFA14A filing are also available, along with information about Forest's 2011 Annual Meeting of Shareholders, at: www.FRX2011annualmeeting.com.

Presentations:

07.28.2011 Forest Laboratories, Inc. Presentation, Forest Labs: A Leading Pharma Company, dated July 2011

Letters:

07.25.2011 Letter from Dr. Jorge Gallardo, Chairman of the Board, Almirall

07.18.2011 Letter from Peter M. Hecht, CEO, Ironwood Pharmaceuticals

06.23.2011 Letter from Lisa A. Rickard, President, U.S. Chamber Institute for Legal Reform

06.15.2011 Letter from John J. Castellani, President and CEO, PhRMA

04.18.2011 Letter from Dr. Jochen Hückmann, Shareholders Council, Merz

04.08.2011 Letter from the Department of Health & Human Services

News Reports:

05.05.2011 Forest Firing The government seeks to sack an innocent boss The Economist

05.02.2011 Kathleen Spitzer The Wall Street Journal

04.29.2011 The Government's Power to Oust a C.E.O. DealBook, The New York Times

04.26.2011 U.S. Effort to Remove Drug CEO Jolts Firms The Wall Street Journal

Important Information

The materials contained herein and 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 contain 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.

,ilo Ed il Viow , vo r~.. Tool, Holp 6 Prosontot & Matorials I Forosl 2011 A nn u ~ 1 Mooling - Windows
Intomot hpklrOf prcwKlod by SARD VERBINNEN & CO 00 ~ http.IIwww.ln0:2011. nnu. lmoool in9.(
om. pro. onl.lion. -m.t ori.ls! :6 Pr..onl olion, & Molori,l< I Foro i IOll Annu, 1M.,D Ib.~ Forest La bo r a t
o r ies, Inc , V i s ~ f r x .com p Home Press Releases ShareJoldllflette rs Presentatloos Our Nommees
Proxy Matena ls SEC Filings Contact Presentations Date 07282011 Letters Date 07.25.2011 07.182011
06232011 06.152011 04.18.2011 04.082011 Title f oresf Labs A Leading Pharma Comoony Title
Lrtter!rom Dr,Joroe Galklrdo.Chairman of the Boord AlminU litter frQ!!! Peter M. Illtcht CEQ.
Ironwood Pharmawutjcal litter from lisa A. R!ckard. president U.S.Chamoor Inst rtute for Looal Reform
Letter from John J .Castelklni. President and CEQ. PhRMA litter !rom Dr.Jochen Hlickmann.
Shareholders Council. Mell Lett er from the Department of He.a~h & Human SeMers News Reports Date
05052011 05022011 04.292011 Title f orest Firing The Economist KatMoon S!!iIm
TheW.11streetJoom.1 The Government s ! 9w<>r to Oust a C.E.o, DealBook. The New YorlITimes

il. Edit View F, vor ~.. Tool, Help 6 Pr. sentot & Mate,i.I, I Fore sl 2011 A n n u ~ 1 Mooting - Windows
Intomrl h pklr , prcwKled by SARD VERBINNEN & CO 00 ~ http.IIwww.loo:2011. nnu. lmeeling.(
om..p.ooenl.tion! -m.teri.ls! p forest labs A leadina Ph.lm. Company Date Title 07.2 8.2011 Letters :6
Pr... nlol on , & Mirteri,f< I 0, ,12011 Annu, 1M Date Title 07252011 l ett er from Dr.Jorge
Galklrdo,Chairman 01the Boord.Almirall 07,18201 1 Lrtterlrom Pfirr M. IWchtCEQ. Ironwood
ph.rmareutlcal 06,232011 litter IrQ!!! liM A. ROck,rd, PresKlent U.S.Chamber I smut . for
le<l.l.Reform 06,15.201 1 letter from John J .Castel , presKlen! 4 CEO,PhRMA 04,182 011 Lene, from
Dr. Joc hen Hlickmann. Shareholders Council. M rz 04,08,2011 !.fUlir Irom the Deoortment 01H ,~h &
Hu m~n SIrvice News Reports ~ I Date Title 0505201 1 forest f irina The Economist 05022011 Kat h
~n Spitler TheWa11Street Joorn~ 1 04.292011 The Government s I 2vrer to OUst ~ C.E.Q, DealBook,The
trew York Times 04.262011 II .S. Effort to Remove DrugCEQJolt s firms TheWall Str t Jou rnal PRESg
RELEASES S~ E~DERL ET T ERS PR ES E ~T ATI O ~g OUR >fOMINEES PROXY MA TERIALS
SEC FILINGS CON TACT ~ 2011 Forest LiOOOroto es, ~ c Ir4>ortll nt ~ f o r , n

Forest Labs A Leading Pharma Company July 2011

This presentation, entitled, Forest Labs: A Leading Pharma Company, dated July 2011, has been separately filed with the SEC by Forest Laboratories, Inc. under Schedule 14A on a Form DEFA14A filed with the SEC on July 28, 2011.

Dr. Jorge Gallardo
Chairman of the Board

Almirall, S.A.
General Mitre, 151
08022 Barcelona
Spain
Tel. (34) 93 291 30 10
Fax (34) 93 291 32 05
jorge.gallardo@almirall.com

July 25th, 2011
Mr. Howard Solomon
Chairman & Chief Executive Officer
Forest Laboratories, Inc.
909 Third Avenue
New York, N.Y. 10022-4731

Via e.mail: Mindy.Pollack@frx.com

Dear Howard,

Almost six years have gone by since the strong relationship between Forest and Almirall was initiated with collaboration on the development of Acridinium Bromide, an innovative molecule for the treatment of COPD. Over these years strong bonds have been established at all levels between the two companies. I have very much enjoyed the working meetings with you and the way you have tackled difficult issues. The same can be said about everyone involved from both sides in research activities through the Steering Committees established. We have had to face difficult situations but we have always come out with solutions in favor of the project and to the benefit of patients. Filing for the monotherapy has now been completed and we all expect a positive response from regulatory authorities. Also, the combo project is moving forward and meeting anticipated time lines. Additionally, both companies also agreed on 2009 to jointly develop our once-a- day LABA LAS 10077. The profile of this molecule is very positive in terms of activity and safety and teams in both companies are very enthusiastic about the project. Certainly, we were happy to establish this new collaboration with Forest in view of the excellent experience we have enjoyed and, as I said before, the very close relationship at all levels between the two companies. Additionally, besides the fact that we share a common interest in Linaclotide and Roflumilast, both companies being licensees for these products, we continue to explore new areas of collaboration for new products and territories.

Howard, I have been in the industry for 46 years now, and I have had a number of agreements and relationships with all kind of companies and CEOs. I can tell you very sincerely that I place our relation with Forest very high on the list and from a personal view, my relationship with you. I have admired and learned a lot from the way you run the company to the benefit of patients and in defense of shareholder interest. I have been meaning to tell you this for a long time.

I look forward to a continuity and enhancing of this collaboration and I wish you all the best in the difficult times that lie ahead.

With my best personal regards,

/s/ Jorge Gallardo
Jorge Gallardo

IRONWOOD PHARMACEUTICALS 301 BINNEY STREET, CAMBRIDGE, MA 02142 USA

July 18, 2011

Mr. Howard Solomon
Chairman, Chief Executive Officer & President
Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022
Howard,

I would like to offer some perspective on why Ironwood chose Forest to be our 50/50 linaclotide U.S. development and commercialization partner in 2007 and provide my view on how the collaboration is performing so far. First, a bit of context.

As you know, Ironwood is a young company but one with enormous passion for creating and commercializing differentiated medicines that offer meaningful benefit to patients. We are focused on two simple but ambitious goals to serve patients as well as we are able, and to deliver outstanding returns to our shareholders. Our hope is to excel with both goals and earn the right to reinvest a portion of the subsequent profits to create additional drugs, on our journey to build a special pharmaceutical company that grows, thrives and endures for many generations. We have been building expertise and functional capabilities from the ground up since 1998 to accomplish those two goals, and we try to access needed capabilities just ahead of the requirements called for by our most advanced drug candidate, linaclotide. We believe in our team's ability to thoughtfully evaluate data and invest our scarce capital prudently, so on balance we tend to retain risk and reward rather than handing off responsibility to someone else. When we choose to partner it is to avoid building redundant or underutilized capacity ourselves, which we believe is a more efficient use of shareholder capital at this stage of our development.

Linaclotide is a very unusual opportunity, a completely new approach demonstrating exciting potential to treat a very large number of patients suffering from chronic intestinal pain, bloating and constipation. We believe that there are more than 30 million Americans who suffer frequently from these highly bothersome symptoms, and at least 10 million of those are currently seeking medical help and are dissatisfied with current treatment options. Given the size of the patient pool, we recognized early in linaclotide's development that a large primary care sales force would be required to reach the full range of potential prescribing physicians, and that it made strategic sense to access that capability from a partner who could supplement the launch and growth of linaclotide with an already established and effective primary care presence rather than building our own full primary care capabilities from scratch. However, we sought much more from a partner than just primary care capabilities. We expect Ironwood to be
IRONWOODPHARMA.COM

growing and thriving well beyond the patent life of linaclotide, and the history of long term collaborations in the biotech and pharmaceutical industry is sordid and full of cautionary tales. Therefore, we were looking for a highly collaborative team that would work alongside us for the life of our drug, would care as passionately as we do about the patients we are here to serve, and would work intimately with us to integrate our own growing capabilities with theirs.

There are a dozen or so pharmaceutical companies with U.S. primary care forces sufficient to provide the capabilities we sought, and, when we initiated partnership discussions in 2007, we received strong expressions of interest from virtually all of them. What distinguished Forest from the crowded field was your culture of partnership and collaboration. Building collaborations and working with partners is a core competency for Forest and is deeply embedded into your culture and successful history. It is my strong belief that this is unique in our industry and not easily replicated or substituted. When it came time to choose among the potential partners, we put our money where our mouth is. There were offers with bigger up-front payments and/or bigger collective milestone payments, but we chose to work with Forest because we believed strongly that together we would forge the best partnership and that, by integrating and drawing on the best of each company's capabilities, we would be able to benefit the most patients and maximize long term profits for both companies. We structured the deal as a true partnership of equals and both companies committed themselves to the hard work of making that structure successful.

So how is it going, four years in? Quite simply, we believe that the collaboration has exceeded the industry norms and my own (somewhat higher) expectations. Neither company is perfect, but as in any good marriage we both work on it, talk about it, focus on it, refine and improve it. We find our Forest colleagues—from you to your leadership team to the front lines of each function—smart, ethical, thoughtful, data-driven, good listeners, and strong problem-solvers open to the best solution wherever its source. We are proud to be collaborating with Forest and hope to continue to work side-by-side to improve and enhance our 50/50 partnership for many years to come.

Vey truly yours,

Peter M. Hecht
Chief Executive Officer

Lisa A. Rickard
President

June 23, 2011

Daniel R. Levinson
Office of Inspector General
United States Department of Health and Human Services
330 Independence Ave., S.W.
Washington, D.C. 20201

Dear Inspector General Levinson:

On behalf of the U.S. Chamber of Commerce, and U.S. Chamber Institute for Legal Reform, I write to express our serious concerns regarding the U.S. Department of Health and Human Services Office of Inspector General's (OIG's) exercise of its permissive exclusion authority to exclude officers and managing employees of sanctioned health care entities without a finding of either wrongdoing or knowledge of wrongdoing on the part of the officer or managing employee. The OIG's current use of exclusionary authority in this manner is seriously troubling because it undermines fundamental fairness and due process. As such, we urge the OIG immediately to begin to exercise its permissive exclusion authority against officers and managing employees of sanctioned entities based only on specific findings of such individuals' wrongdoing or knowledge of wrongdoing, and to make corresponding revisions in the OIG Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act (the OIG Guidance).

At the outset, we wholeheartedly support the government's efforts to curb health care fraud and abuse, but we believe that the OIG Guidance creates draconian and patently unfair penalties for health care industry professionals without corresponding deterrence or enforcement benefits to the government.

First, the OIG's proposal to exclude officers and managing employees of sanctioned entities without a finding of wrongdoing or knowledge of wrongdoing, and without the possibility of administrative or judicial review, is fundamentally unfair to the sanctioned individuals. Our judicial system imposes severe sanctions on individuals, such as exclusion from one's livelihood, only upon an independent finding by a neutral arbiter that the individual has acted in a manner that justifies the sanction imposed. It does not countenance draconian penalties for guilt by association - which is the approach effectively adopted in the OIG Guidance. Courts have repeatedly discredited this approach, holding that [t]he concept of guilt by

ph (202) 463-3107 fax (202) 463-5302 lrickard@uschamber.com 1615 H Street, NW Washington, DC 20062-2000

Daniel R. Levinson

June 23, 2011

Page 2

association is repugnant to our notion of elemental justice and fair play, *United States v. Swayne*, 700 F.2d 467, 469-70 (8th Cir. 1983); *see also, e.g., NAACP v. Overstreet*, 384 U.S. 118 (1966) (Warren, C.J., and Douglas, and Brennan JJ., dissenting from dismissal of certiorari) (stating that the concept of guilt by association is a philosophy alien to the traditions of a free society).

Second, the OIG's approach may violate such individuals' due process rights under the Fourteenth Amendment of the U.S. Constitution. Courts have consistently recognized that depriving an individual of his or her livelihood especially when it impacts the individual's ability to take advantage of other employment opportunities triggers due process rights. *See, e.g., Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564 (1972); *Wisconsin v. Constantineau*, 400 U.S. 433 (1971). When the OIG excludes an individual from a federal health care program, that individual is effectively barred from working in the health care industry, as any health care entity that employs such an individual could be subject to penalties and potential exclusion.

Under the OIG's stated approach to permissive exclusion, the government would essentially destroy a health care executive's ability to obtain employment in the health care industry with no finding that the executive engaged in, or had knowledge of, any wrongdoing. Compounding the problem, the OIG Guidance asserts that the OIG's exercise of discretion is not subject to administrative or judicial review. As the Supreme Court has held, [w]here a person's good name, reputation, honor, or integrity is at stake because of what the government is doing to him, notice and an opportunity to be heard are essential. *Constantineau*, 400 U.S. at 437. The OIG offers no such meaningful notice or opportunity if it exercises its authority to exclude based solely on [individuals'] position within the entity.

Third, the OIG's proposed treatment of officers and managing employees does nothing to further the goals of exclusion—namely, protection of federal health care programs from individuals and entities who have in the past, and may in the future, seek to fraudulently obtain unlawful funds from such programs. In targeting for exclusion any officer or managing employee of a sanctioned entity, where there is no showing whatsoever of his or her participation in, or knowledge of, fraud or other wrongful conduct, the OIG would punish innocent individuals without any benefit to the federal fisc. Put simply, the OIG will not be protecting Medicare from waste, fraud, or abuse if it excludes individuals who have no knowledge of wrongdoing, let alone have actually participated in wrongdoing. Nor will exclusion of such individuals have the effect of deterring undesirable behavior in the future. Instead, it may deter

Daniel R. Levinson

June 23, 2011

Page 3

other qualified individuals from assuming positions of responsibility in the health care industry for fear of unjust and unjustified sanctions.

In sum, we urge the OIG to revise its Guidance on permissive exclusion to reflect a policy of using exclusion only after specific findings of such individuals wrongdoing or knowledge of wrongdoing. We also call for the OIG to immediately begin to use its discretion and again exercise its permissive exclusion authority against officers and managing employees of sanctioned entities based only on specific findings of such individuals wrongdoing or knowledge of wrongdoing.

Sincerely,

/s/ Lisa A. Rickard

Lisa A. Rickard

cc: The Honorable Kathleen Sebelius, Secretary of the Department of Health and Human Services
The Honorable William Corr, Deputy Secretary, Department of Health and Human Services
William B. Schultz, Acting General Counsel, Department of Health and Human Services

John J. Castellani
PRESIDENT AND CHIEF EXECUTIVE OFFICER

June 15, 2011

Daniel R. Levinson

Office of Inspector General

United States Department of Health & Human Services

330 Independence Avenue, S.W.

Washington, D.C. 20201

Dear Inspector General Levinson:

Pharmaceutical Research and Manufacturers of America (PhRMA) submits this letter to express our concerns regarding the Office of Inspector General s (OIG) stated intent to exercise its authority pursuant to 42 U.S.C. § 1320a-7(b)(15)(ii) to exclude health care executives of sanctioned entities without a showing of knowledge, and to urge OIG instead to invoke its exclusion authority only on the basis of an appropriate and reviewable finding of wrongdoing on the part of the excluded person.

PhRMA s member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. Our membership includes small companies and large multi-national corporations that employ hundreds of thousands of Americans. These companies develop and supply critical medications to the American people through federal health care programs and otherwise, and in doing so strive to ensure compliance with the law. To that end, our members invest significant resources in maintaining robust compliance programs that focus on setting appropriate standards of conduct, training their employees and other representatives on those standards, and taking steps to monitor and enforce those standards throughout all aspects of their business activities. PhRMA s members also believe that government enforcement policies can play an important role in complementing internal compliance efforts and in providing strong incentives for compliance, but that *unsound* policies can profoundly harm the public interest.

No-fault exclusion is unsound as a policy matter for several reasons: it conflicts with principles of fundamental fairness; it will inevitably result in arbitrary application; and it could interfere with efforts to reach appropriate negotiated resolutions of the government s allegations against corporate defendants, without providing a corresponding public benefit.

Pharmaceutical Research and Manufacturers of America

950 F Street, NW, Washington, DC 20004 Tel: 202-835-3420 FAX: 202-715-7055 Jcastellanl@phrma.org

Daniel R. Levinson

June 15, 2011

Page Two

Exclusion of Individuals Without a Showing of Fault Is Inconsistent with Principles of Fundamental Fairness

Exclusion from participation in federal health care programs is an extraordinary sanction that should not be imposed unless the individual at issue has engaged in wrongdoing. In virtually all cases, excluding a corporate executive from the federal health care system will cause that person to be fired or forced to resign, because otherwise the employer itself will be subject to exclusion under 42 U.S.C. § 1320a-7(b)(8) as a company controlled by a sanctioned individual. The excluded individual will lose not only his job but also his career and his livelihood, because no company doing business in the health care industry could employ that individual without risking the same fate. Depriving a person of a job, career, and livelihood, without any finding of fault, is contrary to basic notions of justice. See Holmes, *The Common Law* 50 (1909) ([C]riminal liability, as well as civil, is founded on blameworthiness. ... [A] law which punished conduct which would not be blameworthy in the average member of the community would be too severe for that community to bear.); *Staples v. United States*, 511 U.S. 600, 617 (1994) (imposing severe punishments for offenses that require no *mens rea* would seem incongruous). These penalties are simply too severe to be imposed on an individual without a reviewable finding of wrongdoing.¹

The unfairness of imposing so severe a penalty on a person who has not been shown to be culpable is compounded by the fact that OIG s no-fault exclusions of individuals may be premised entirely on convictions of the *company*. Such convictions typically result not from contested proceedings where facts and legal theories can be tested, but rather from negotiated settlements between the government and the company. In these situations, unlike where exclusion is predicated on an individual s own conviction, the excluded person is not a party to the settlement agreements that gave rise to the predicate offense, and OIG s rules would seem to preclude him from contesting the legal and factual basis for the offense. See 42 C.F.R. § 1001.2007(a)(1) (review limited to whether [t]he basis for the imposition of the sanction exists and whether [t]he length of exclusion is unreasonable). To impose an extreme penalty without a finding of personal fault and, in the typical case, on the basis of an unadjudicated violation allegedly committed by others is patently unfair. It is also contrary to the deep-rooted historic tradition that everyone should have his own day in court. *Richards v. Jefferson County*, 517 U.S. 793, 798 (1996) (internal quotation marks omitted).

¹ The Supreme Court has recognized that, as a general matter, strict liability for individuals is legally tolerable only where the penalties are relatively small, and conviction does no grave damage to an offender s reputation. *Morissette v. United States*, 342 U.S. 246, 256 (1952); see *Staples*, 511 U.S. at 617-618. The penalty of exclusion which, inevitably, deprives the individual of her job and her livelihood is obviously a severe sanction that goes far beyond the penalties that courts have previously permitted government to impose on a strict liability basis.

Daniel R. Levinson

June 15, 2011

Page Three

Arbitrary and Inconsistent Application of the No-Fault Exclusion Provision Is Inevitable

Applied without a requirement of personal fault, exclusion of individuals under 42 U.S.C. § 1320a-7(b)(15)(ii) will inevitably be arbitrary and capricious. The statute provides OIG with discretion to exclude any officer or managing employee of a sanctioned entity, but is silent on when the exercise of such discretion is appropriate.

The recently issued OIG guidance, which purports to identify factors for invoking this authority to exclude individuals without fault, makes clear only that OIG has imposed *no* meaningful limits on its own discretion. *See Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act* (Oct. 19, 2010).

For starters, the guidance document notes that the factors it recites are nonbinding, may be subject to modification at any time, and are not intended to limit OIG's discretionary authority[.] *Id.* at 1-2. Thus, even if the factors provided any meaningful constraints on OIG's discretion and they do not they offer no assurance of a consistent approach because they may be altered or abandoned in any given case. Notably, the guidelines do *not* require OIG to consider whether the individual adequately performed pertinent duties. A senior executive may, for example, have the duty to ensure that appropriate corporate compliance protocols are in place and are properly operating, and that appropriate incentives exist to deter and report wrongdoing. But no matter how effective compliance systems may be, human beings are involved, and it is therefore impossible to ensure that no employee in an organization private or public will ever violate the law. Yet OIG's guidelines virtually ignore the question whether the individual performed her compliance-related duties properly, or how she performed any other relevant duty, and premise exclusion almost entirely on alleged violations by others².

It is safe to say, therefore, that in any case in which OIG invokes no-fault exclusion, it will have failed indeed it may have made almost no effort whatsoever to distinguish the excluded individual's conduct from the unblameworthy conduct of others who (quite properly) continue to enjoy their jobs and careers. That failure makes arbitrariness unavoidable.

Finally, arbitrariness is inevitable because, in the OIG's view, OIG's exercise of this discretion is not subject to administrative or judicial review. *Id.* at 1. Instead, according to the OIG, review of OIG's exclusion determinations is limited to two discrete issues:

² The only mention of the individual's performance of compliance-related duties appears in Section II.C.1, which states that [i]f the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion. Proving an impossibility, of course, is difficult in any circumstance, and it appears, in any event, that appropriate or diligent performance and commitment may be deemed irrelevant under this standard.

Daniel R. Levinson

June 15, 2011

Page Four

(1) whether [t]he basis for the imposition of the sanction exists, and (2) whether [t]he length of exclusion is unreasonable. 42 C.F.R. § 1001.2007. This interpretation would mean that the individual cannot obtain review of the determination that the company violated the law; or the determination that the public will benefit in some way from exclusion of the individual; or the determination that any factors favoring or disfavoring exclusion that have been articulated by the agency are in fact present or absent in the circumstances. This limitation, if correct, would be grossly unfair and would seem to preclude principled and transparent application of the no-fault exclusion sanction over time.

No-Fault Exclusion Could Impair Negotiated Resolution of Allegations of Wrongdoing Without a Corresponding Public Benefit

Use of the exclusion authority against non-culpable individuals based on their companies' settlements and plea agreements also could have adverse consequences for negotiated resolutions of allegations of wrongdoing. Resolution of disputes through settlements or negotiated agreements, as opposed to protracted litigation, saves the government and the corporate defendant money and resources; promotes more timely resolutions of complicated matters; and may entail substantial changes in business practices of settling entities in the form of Corporate Integrity Agreements that are promptly implemented and designed to guard against future violations. But if a company's settlement or guilty plea, without more, can form the basis for the exclusion of an individual, a severe additional consequence imposed after the company's liability has been resolved, companies will feel new pressure to contest allegations that might otherwise be resolved through negotiation. The OIG's policy therefore could encourage costly, protracted disputes.

Moreover, it is difficult to identify any genuine public benefit that would justify these costs. Under OIG's policies, individuals subject to no-fault exclusion may gain no benefit from a strong personal commitment to corporate compliance. They may lose their jobs and careers however devoted or effective they might be. The purely *in terrorem* effect of this extreme and untargeted policy is, for that reason among others, difficult to forecast, at best. It is possible that subjecting health care executives to this sort of no-fault potential exclusion, a potential sanction that does not meaningfully exist in most, if not all, other industries, over time will deter talented women and men from taking leadership positions within health care companies, as opposed to other industries. It is safe to say, in any event, that the policy is as likely to deter productive, lawful behavior as any other kind, and therefore cannot possibly justify its harmful effects.

Daniel R. Levinson
June 15, 2011
Page Five

* * *

We recognize that it is extraordinarily important to ensure that proper incentives exist for health care companies to comply with the law. PhRMA's members are committed to maintaining the strongest and most effective compliance programs. But with due respect, no-fault exclusion of individuals based solely on a corporate plea, without any finding of personal culpability, is unjust and arbitrary and will result in unintended and unjustifiable adverse consequences. We urge OIG to exercise its authority to exclude individuals only where it has made a reviewable finding, on the record, that the individual engaged in wrongdoing with respect to the underlying violation.

Sincerely,

Copies:

The Honorable Kathleen Sebelius, Secretary of the Department of Health and Human Services

The Honorable William Corr, Deputy Secretary, Department of Health and Human Services

William B. Schultz, Acting General Counsel, Department of Health and Human Services

DR. JOCHEN HÜCKMANN
MERZ GMBH & CO. KGAA

ECKBNHEIMER LANDSTRASSE 100
60318 FRANKFURT AM MAIN
TELEFON 0 69/15 03-212
TELEFAX 0 69/15 03-581
E-MAIL: JOCHEN.HUECKMANN@MERZ.DE

Mr. Howard Solomon
Chairman and Chief Executive Officer
Forest Laboratories, Inc.
909 Third Avenue,
New York, NY 10022-4731
USA

April 18, 2011

Dear Howard,

Thank you for your personal letter of April 15, I have absolutely no understanding for the action taken by the Inspector General of The Department of Health and Human Services. I have observed the restrictive behaviour towards the pharmaceutical industry in the past. To some extent I have an understanding for the government and social security to mind the critical cost situation. I deem it nevertheless not right that the slightest deviation from in many cases not stringently and clearly formulated compliance and regulatory rules lead to overactivities in penalisation and more.

During our negotiations to form a licensing contract it always was to me of highest importance to deal with a company of high integrity. This integrity of Forest has goverened our relationship throughout our cooperation without exemptions until today and I consider it an attitude of prudence and future orientation.

As to our personal relationship I think it was based throughout the history of our partnership on mutual trust, openness and truthfulness, I have the utmost respect for your sovereignty in leadership which excludes by itself any behaviour of the lessest unauthorized practice. You have in person earned the highest respect as a trustworthy business leader not only in the pharmaceutical industry but also in the society of New York and the United States.

Forest and yourself will overcome the present to my mind politically instrumented actions by the Department of Health and Human Services not only because you have the best defendants in your country and your excellent management on your side with their expertise and loyalty to defend Forest's and your own interests but above all you have always been guided by honesty.

All the best to you, Howard, and your company.

Sincerely

2

DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 08 2011

Office of Inspector General

Exclusions Staff

7175 Security Blvd, Ste. 210

Baltimore, MD 21244

Howard Solomon
c/o Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022

Dear Howard Solomon:

RE: OI File Number H-11-40460-9

The Department of Health and Human Services is considering excluding you from participation in any capacity in the Medicare, Medicaid, and **all** Federal health care programs as defined in section 1128B(f) of the Social Security Act (Act). The Act defines a Federal health care program as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (except for the Federal Employees Health Benefits Program). State health care programs are defined in section 1128(h) and include plans and programs under titles XIX, V, XX, and XXI of the Act. **The scope of this exclusion, if implemented, is broad and will have a significant effect on your ability to work in the health care field.** This proposed exclusion is authorized under section 1128(b)(15) of the Act (42 U.S.C. 1320a-7(b)(15)) which allows for the exclusion of any individual who has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of the Act; or is an officer or managing employee as defined in section 1126(b) of the Act, of such an entity. A sanctioned entity is defined as one that has been convicted of any offense described in section 1001.101 through 1001.401 of this part, or has been terminated or excluded from participation in the Medicare, Medicaid, and all other Federal health care programs.

Our records indicate that you are associated with Forest Pharmaceuticals, Inc, and consequently meet the criteria for exclusion.

If effectuated, your exclusion would have national effect and apply to all Federal procurement and non-procurement programs and activities. **This exclusion will affect your ability to claim payment from these programs for items or services that you render; it will not affect your right to collect benefits under these programs. You may find more information regarding exclusions on the Office of Inspector General's (OIG) website, including Frequently Asked Questions and the Special Advisory Bulletin about the Effect of Exclusion. To access this site, go to <http://oig.hhs.gov>, then click on EXCLUSIONS DATABASE, and then choose the item you would like to access.**

Page 2 Howard Solomon

The exclusion would be in addition to any sanction an individual State or other Federal agency may impose under its own authority. The State in which you provide services can apply to the OIG for a waiver of your exclusion from a Federal or State health care program if the particular program it administers can demonstrate to the OIG that a waiver would be in the public's best interest.

You have 30 days from the date of this letter to submit any information you want to the OIG to consider before a final determination is made. Send such information to this office at Office of Inspector General, Exclusions Staff, 7175 Security Boulevard, Suite 210, Baltimore, MD 21244. If you do not submit information on a timely basis, the OIG will make its decision based on currently available information. You will be informed of the decision, and if an exclusion is implemented, given your appeal rights.

Sincerely,

Peter Clark
Exclusions Director

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