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December 21, 2016

Honorable Susan M. Collins
Chairman
U.S. Senate Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, D.C. 20510

Honorable Claire McCaskill
Ranking Member
U.S. Senate Special Committee on Aging
628 Hart Senate Office Building
Washington, D.C. 20510

Dear Senators Collins and McCaskill:

Having followed and appreciated the Committee's hearings and investigations into pharmaceutical pricing and other industry abuses that have proven extremely burdensome to patients, U.S. taxpayers and investors, I commend you for uncovering unethical and sometimes criminal behavior on the part of unscrupulous pharmaceutical companies.

I write to call your attention to a similar but even more egregious case than those the Committee has evaluated to date: Ligand Pharmaceuticals, a publicly-traded U.S. pharmaceutical company. Ligand may be the industry's most significant abuser of these standards and laws. These include multiple abuses and violations of existing pharmaceutical classification, reimbursement, and accounting statutes and standards by Ligand. In particular, Ligand Pharmaceuticals' so-called "licensing" model is a nexus for a new breed of unethical pharmaceutical companies whose primary goal is to reap extraordinary profits on the backs of patients, taxpayers and shareholders by (among other things) abusing the Orphan Drug Act of 1983 as well as a litany of accounting loopholes.

Under this model, Ligand essentially plays the role of a special purpose acquisition company to licensees that, with superior resources, stifle access to these drugs by generic drug companies through misuse of the Orphan Drug Act, ensuring these drugs are sourced and licensed by Ligand, a company that now lies at the heart of this new, unethical breed of pharmaceutical companies. In turn, Ligand receives excessive royalties from the enormous increase in revenues generated from these drugs' price increases.

The Ligand business model is very much at the center of the larger, emerging crisis in spiraling health care costs that is threatening patients and the fiscal stability of our country.

Public policy must be constructed and enforced in ways that account not only for the companies driving these unethical and likely illegal entities, but also their enablers, who work for a cut of the profits. In addition to investigating these abuses by Ligand, Congress must act swiftly to tighten the Orphan Drug Act to ensure drugs meet the legitimate purpose intended under this statute to prevent these abuses, and ensure policy reforms to fast-track the approval of generics are passed.

Separately, this past January, after several years of research into Ligand, a whistleblower report was filed with the U.S. Securities and Exchange Commission (SEC) regarding Ligand's material misrepresentations to investors.

I am attaching a more detailed report on Ligand's extensive abuses of pharmaceutical classification, pricing, accounting and other regulations, standards and statutes.

I strongly encourage the Committee to commence an investigation into Ligand. I also will gladly make myself available to the Committee to review and understand these abuses and to testify under Congressional oath on them.

Thank you for your attention to this important matter.

Sincerely,

Rev. Fr. Emmanuel Lemelson

Rev. Fr. Emmanuel Lemelson
Founder and President
The Lantern Foundation

Enclosure

cc:
U.S. Senate Special Committee on Aging members
Kevin L. Kelley, Staff Director
Derron Reynard Parks, Staff Director
Mia Lenee Woodward, Investigative Counsel

Background

Ligand Pharmaceuticals' so-called "licensing" model is a nexus for a new breed of unethical pharmaceutical companies whose primary goal is to reap extraordinary profits on the backs of patients, taxpayers and shareholders by (among other things) abusing the Orphan Drug Act of 1983 as well as a litany of accounting standards. In fact, it is Ligand that systemized the monopoly pricing practices that has given rise to similar accounting and regulatory abuses subsequently adopted by Valeant, Martin Shkreli's Retrophin, Mylan and other pharmaceutical companies, which the Committee previously has called as witnesses.

The Ligand business model is not based on finding the best drugs to cure or treat rare conditions, as the Orphan Drug Act, which Ligand is exploiting, encourages. Instead, Ligand's model consists of locating drugs whose price, through the Orphan Drug Act, can be continually and radically increased with negligible benefit to patients with these rare conditions.

Exploiting the Orphan Drug Act of 1983: An Overview

Ligand is in the business of locating drugs that are candidates for orphan drug status. Once the enhanced patent-like protections under the Orphan Drug Act of 1983 are granted, providing seven years of protection against generic competition, these drugs are then pre-packaged as drug monopolies for licensees. When Ligand engages in this activity, the U.S. taxpayer underwrites the cost of the subsidies and incentives that are granted to Ligand through the orphan drug designation program. Then, in turn, Ligand through its licensees drastically increases the price of these drugs, which are then billed (under federal Medicare and state Medicaid programs), to the very same taxpayers.

The Orphan Drug Act was enacted by Congress with laudable intentions, namely to incentivize research-based pharmaceutical companies to invest in clinical research and development of therapies to treat rare diseases that (absent the Act) would not likely be discovered or developed. However, under the leadership of Ligand CEO John Higgins, who has run the company since 2007, Ligand's research and development spending, which the Act was designed to stimulate, has been gutted from $44.6 million in 2007 to $13.4 million in 2015, a decrease of seventy percent, even though the company now has substantially more drugs under orphan drug status today than it did in 2007.

Ligand's fleecing patients and taxpayers

The structure of Ligand's business model consists of:

(1) Ligand acquires licensing rights to older, sole-sourced drugs that face no generic competition. These usually include drugs that serve a small patient population since few patients typically means less regulatory scrutiny and less motivation for competitors to enter the market;

(2) Ligand then misrepresents these drugs as the "gold standard" for the condition or symptoms it treats, so that health care providers are dissuaded from prescribing equally and often more suitable substitutes at lower prices;

(3) Ligand seeks and obtains "orphan drug" designation for these drugs, which then bars generic competition and enables virtually unlimited price increases because of the veritable monopoly the designation creates for these drugs; and

(4) Ligand then licenses these monopolistic drugs to companies that raise the price on these low-profile medications, which are now protected from competition due to their orphan drug status.

What sets Ligand apart from Retrophin, Turing, Valeant, Mylan and others is that, unlike these companies which have exploited the opportunity for nearly limitless price increases on some of their drugs, this is Ligand's exclusive mission and function. In fact, no company is currently more engaged than Ligand in abusing the Orphan Drug Act for the purpose of grossly increasing drug prices that are ultimately absorbed by taxpayers.

As is the case with both of Ligand's primary royalty-generating drugs, both of which have been granted orphan drug status, Ligand is generating massive royalties from drugs for which vastly cheaper and typically equally and if not more effective alternatives exist.

The first disgraceful example is Ligand's licensing of Kyprolis[1], a failed oncology drug that has shown no progression-free survival benefit over its much less expensive competitors.[2] Despite Kyprolis' lack of clinical efficacy, however, the federal Medicare program was billed roughly $280,000 per round of treatment per patient for Kyprolis for a total of $228 million in 2015 alone, an increase of 43 percent over 2014, and $387 million over 2014 and 2015. Outrageously and unjustifiably, this now makes Kyprolis one of the most expense drugs billed to the Centers for Medicare and Medicaid Services (CMS).[3] [4]

A second outrageous example can be found in Ligand's other primary revenue-generating drug Promacta[5]. Ligand represents that Promacta is primarily used to treat idiopathic thrombocytopenic purpura (ITP), an extremely rare condition. In these cases, Promacta is sold to these patients at the exorbitant price of $10,196 for 30 75 mg. tablets. Promacta is not a cure for ITP and it will not make a patient's platelet counts normal if the patient has this condition[6].

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[1] Kyprolis is a drug that uses Captisol (a Ligand product) in its formulation. Ligand has a license agreement with Amgen and receives royalties on Kyprolis sales.

[2] Lemelson Capital reported in August 2014 that Kyprolis was facing extraordinary competitive threats from two entrenched multiple myloma (MM) indications, Celgene's Revlimid and Takeda Pharmaceutical's Velcade. The Lemelson Capital report was subsequently proven correct when Amgen Executive Vice President of Research and Development Sean Harper noted recently that a late-stage Kyrprolis study did not meet its goal in improving progression-free survival versus Velcade in patients who had not yet been treated for the disease.

See "Update: Lemelson Capital Further Increases Short Stake in Ligand Pharmaceuticals (NASDAQ: LGND) as LGND EPS Plunges 76 percent in Q2 2014," available here: Link

[3] See: "Rough Month: A Closer Look at Ligand's Fall From All-Time Highs," available here: Link

[4] See: "How Much Will Amgen's Carfilzomib for Multiple Myeloma Cost?" available here: Link

[5] Promacta is an oral thrombopoietin receptor agonist

[6] See: "What is Promacta?" Drugs.com, (available here: Link).

Accounting, fiduciary and corporate governance violations

In addition to Ligand's abuse of the Orphan Drug Act, its gross overpricing of drugs billed to public payers systems under the Act, and the clinically unconvincing value and designation of these extraordinarily expensive drugs, our organization has previously uncovered and reported on Ligand's clear violations of Sections 10(b) of the Securities Exchange Act of 1934, which prohibits any act or omission resulting in fraud or deceit in connection with the purchase or sale of a public security.[7] Specifically, in 2014, we reported that much of Ligand management's commentary was knowingly and materially false and misleading.[8]

Over the past several weeks, ten U.S. law firms have announced investigations into Ligand for breaching their fiduciary duties to shareholders and for securities fraud. During this same period, eleven U.S. law firms have filed class action lawsuits against Ligand, alleging materially false and misleading statements by the company and its management.

Ligand has made demonstrably false and misleading statements and failed to disclose other negative material facts, including:

(1) In 2015, Ligand grossly overstated the value of certain deferred tax assets by approximately $27.5 million;
(2) As of December 31, 2015, Ligand's outstanding convertible senior unsecured notes, due 2019, were misleadingly misclassified as long-term debt rather than (as the company stated over a year later) short-term debt; and
(3) In November 2016, Ligand acknowledged that it did not maintain effective controls over the accuracy and presentation of its accounting and financial reporting, as is required of publicly-traded companies such as Ligand.

Since Higgins' appointment in 2007 as Ligand CEO, stock option awards and compensation packages to Ligand executives and board members have increased exponentially. These insiders have then methodically sold their stock awards at prices artificially inflated as a direct byproduct of their unduly optimistic misrepresentations of the company's financial condition. Ligand executives and board members have thus benefited directly from their material misrepresentation of the company's value. Based largely on these and other misrepresentations, Ligand stock price rocketed 1,550 percent higher between January 1, 2011 and June 30, 2016, a period of just five and half years, even as the company's GAAP earnings declined dramatically in recent years.

Further, Ligand has made materially misleading statements to investors regarding its debt expense and made excessive use of non-GAAP measures to disguise the true cost of the company's stock awards to its management. Ligand's unethical engineering of its financial statements has allowed the company to raise more capital from public markets both directly and indirectly through proxies, which has allowed the company to obtain the rights to even more orphan drug candidates whose prices can be unjustifiably increased under the respective market monopolies afforded them.

[7] Lemelson Capital Management, LLC published five research reports between June and August of 2014 outlining materially misleading statements made by Ligand Pharmaceuticals.
[8] Since 2011, Ligand has amended their quarterly and annual reports an extraordinary 14 times

In addition to these substantial abuses and misrepresentations, a significant part of the proceeds from Ligand's misclassified 2014 debt offering was used to acquire one of Ligand's largest investors' (BVF Partners) stake in Ligand in a private transaction at extraordinary and misrepresented expense to Ligand shareholders.

Finally, Grant Thornton, Ligand's auditor, has also been complicit in these abuses, wrongly providing a clean audit opinion to Ligand's material misrepresentations.

Ligand's documentable record of accounting, regulatory and ethical abuses is one of the worst in the history of modern public markets. Further, the company's management team and board of directors are operating consistently in ways that represent exclusively their own self-interests and not, as is required of fiduciaries, those of the company's shareholders.

Variable interest entity abuses and conflicts of interest

Ligand also has significantly abused other accounting standards, including the variable interest entity (VIE) standard. Ligand's abuse of the VIE has been designed to disguise the company's true operating expenses and create phantom profits in ways very much like Enron criminally misused special purpose entities (SPEs).

On May 4, 2015, Viking Therapeutics, a pharmaceutical startup closely intertwined with Ligand and initially a tenant in its La Jolla, California office building, began trading publicly on the NASDAQ stock exchange. Ligand is mentioned 348 times in Viking's 2015 10-K[9] . At the time of this IPO, Viking was operating effectively as a Ligand proxy with Ligand sponsorship. As part of the offering, Viking sold three million shares of its common stock at a public offering price of $8.00 per share. In connection with the IPO, Ligand received 3.4 million Viking shares in part for agreeing to purchase $9 million worth of Viking's stock, or 38 percent of the total offering, creating both a market for the shares and a trading price that were both engineered in advance.

Shortly after the IPO, Ligand then deconsolidated its equity stake in Viking off their balance sheet, claiming the company was no longer a VIE. Ligand recorded a $28.2 million gain on the deconsolidation for the year ended December 31, 2015 related primarily to the equity milestone received from Viking upon the close of the IPO. However, Ligand retained the intellectual property in the Viking transaction and virtually controlled Vikings stock and board[10] while Viking booked the significant losses related to developing the Ligand assets it licensed to Viking.

In 2015, Viking went on to lose approximately $23.4 million, or $3.68 per share, developing assets owned by Ligand.

Despite the IPO support from the Ligand purchases, Viking shares recently traded as low as $0.94 per share, a decline in value of 88.25 percent from its offering price, while Ligand's 49.4 percent initial stake in Viking common stock virtually eliminated the ability of other shareholders to influence corporate

[9] Viking Therapeutics, Inc. Form 10-K available here: Link
[10] Matthew Foehr, Ligand's Executive Vice President and Chief Operating Officer serves on Viking's board of directors.

matters at the company, contradicting Ligand's claim that Viking was no longer a VIE at the time of its deconsolidation off their balance sheet. Barely a year and a half later, Viking now faces almost certain delisting from the NASDAQ stock exchange.

As of October 31, 2016, Viking had a market capitalization of approximately $21 million (roughly 23 percent less than the value of the approximately $28 million initial entry on Ligand's statement of income), which was to represent only 49.4 percent of the company's outstanding shares.

The unethically cozy relationship between Ligand and Viking's IPO underwriter Roth Capital also has developed into a glaring conflict of interest with Roth Capital receiving transactional banking fees for Ligand's proxy Viking while absurdly placing "strong buy" ratings on Ligand stock and predicting even higher future trading prices for it. In so doing, Roth Capital fails to disclose clearly its conflict of interest to existing and prospective investors, driving Ligand stock higher and enabling stock awards and subsequent sales by Ligand insiders.

Ligand has used Viking and other equity partners, such as Shkreli's Retrophin and TG Therapeutics, to create a pyramid-type equity scheme used to indirectly harvest capital from public markets. This, in turn, has been fed upstream to the effective sponsor, Ligand, which has used the entries to artificially buttress their statement of income while their legitimate expenses have been disavowed and attributed to surrogates further down the pyramid. Absent any scrutiny of this unethical practice by regulators or lawmakers, Ligand now appears ready to conduct a similar transaction with Seelos Therapeutics, a company whose website consists of just one page with an indiscernible logo and 18 characters of text (their name) and their address[11]. Yet, Ligand is already representing to investors that it stands to make millions from the licensing arrangement with Seelos and undoubtedly a future IPO.

Material misrepresentations lead to vast overvaluation

Based on Ligand's multiple misrepresentations and omissions, even though the company's total revenue increased a very modest $7 million between 2014 and 2015, its market capitalization more than doubled (by 104 percent) from roughly $1.04 billion at FYE 2014 to approximately $2.16 billion at FYE 2015, and recently has exploded further to nearly $3 billion. Further, in the first nine months of 2016, Ligand's income from continuing operations was just $759,000 against a market capitalization at September 30 of $2.1 billion, or an extraordinary 2,800 times trailing nine-month income from continuing operations.

Ligand's real income (excluding non-cash items) is down 80.8 percent[12] year over year through year-end 2015, cash and cash equivalents have dropped by roughly 40 percent year over year[13], and the company's long-term debt has increased from $196 million to $205 million in the same timeframe.

[11]Available here: Link

[12] When the roughly $255 million non-cash entry (deferred tax asset of $219.6 million from the release of valuation allowance, a $28.2 million gain on deconsolidation of Viking) are removed from the statement of operations, Ligand's income fell from $12 million at FYE 2014 to approximately $2.3 million at FYE 2015, representing a decrease of 80.8 percent. The deferred tax assets were recently further written down.

[13] Cash and cash equivalents fell from approximately $160 million at FYE 2014 to roughly $97 million at FYE 2015, representing a drop of approximately 40 percent.

Meanwhile, Ligand has taken equity in three companies (not including its recent transaction announced with Seelos Therapeutics) with combined deficits of $268.9 million and combined losses in 2015 of $137.1 million while representing its stake in these companies as $30.4 million in income on its statement of operations, an accounting abuse that is entirely misleading.

Ligand CEO Higgins' ties with Shkreli

The U.S. Senate Special Committee on Aging, led by Senators Susan Collins (R-ME) and Claire McCaskill (D-MO), has properly investigated the fraudulent schemes of Martin Shkreli and the companies he founded, Retrophin (a Ligand partner) and Turing Pharmaceuticals, which set out to obtain licenses on out-of-patent medicines and increase the prices on them dramatically in pursuit of windfall profits without either of Shkreli's companies needing to develop and bring its own drugs to market. Since markets for out-of-patent drugs are often small, and obtaining regulatory approval to manufacture a generic version is expensive, Shkreli calculated or perhaps was shown that, with closed distribution for the product and no competition, his companies could set nearly limitlessly high prices for these drugs.

Less known, however, is the fact that it was Ligand CEO John Higgins who set Shkreli up as a biotech executive in 2012,[14] helping Shkreli establish this monopoly business model [15] at Retrophin through the licensing of DARA (dual acting receptor antagonist of angiotensin and endothelin receptors) intended to be developed for orphan indications of severe kidney disease[16] from Ligand.

In fact, in 2012, announcing his partnership with Shkreli, Ligand's Higgins issued a press release praising Shkreli and the unethical monopoly business model that he helped Shkreli establish, stating:

""This is an attractive deal for Ligand and our shareholders. We have partnered DARA with a team that has great credentials, is highly motivated to advance the program and has a compelling development plan. This is another valuable asset in our late-stage portfolio." [17] and

"The leadership at Retrophin has shown tremendous passion and commitment to advance this important program, working with the FDA and raising additional capital." [18]

Shkreli, in turn, recently appeared as cognoscenti in an interview, praising Ligand as "a very well run business."[19] In fact, Ligand's relationship with Shkreli's is so close that Retrophin director John W. Kozarich

[14] See: "The next Sage? Shkreli partner Ligand puts together another sweet startup package deal for Seelos" available here: Link
[15] See: "Sudden Price Spikes in Decades-Old Rx Drugs: Inside the Monopoly Business Model" available here: Link
[16] See: Ligand Licenses DARA Program to Retrophin, available here: Link
[17] See: Ligand Licenses DARA Program to Retrophin, available here: Link
[18] See: Ligand receives equity milestone payment from Retrophin: Link
[19] See: "Martin Shkreli Thinks Jazz Pharmaceuticals Could Be Worth $20 Billion, While Mast Therapeutics Is 'Worthless" available at the 10 minute, 45 second mark here: Link

simultaneously serves as Ligand's chairman of the board. However, Higgins has been even more deceptive than Shkreli since price hikes of Ligand drugs such as DARA are both carried out and buried in third-party licensees, allowing Ligand to focus almost singularly on the task of sourcing new drug monopolies under the Orphan Drug Act.

After the publication of our June 16, 2014 report criticizing Ligand, Roth Capital (a firm both Ligand surrogate Viking[20] and Shkreli's Retrophin utilize for underwriting[21]) vigorously defended Ligand's unethical business model. About two weeks later, on July 1, 2014, Roth Capital appeared as an underwriter of the Viking IPO, which later would directly account for $28 million in ghost profits on Ligand's income statement as described above.

Conclusion

Ligand Pharmaceuticals' free-for-all money grab, like Shkreli's Retrophin, Valeant and Mylan, has not played out in a vacuum; it has real public policy and health-care ramifications for real patients, real taxpayers and real shareholders.

The company's licensing model has multiplied its price gauging scheme exponentially and has, in turn, held patient's hostage, burdening the U.S. taxpayer, preventing generic competition, fleecing shareholders and enriching Ligand executives. Even with Shkreli and former Valeant executives having been arrested and charged with fraud in what the U.S. Department of Justice correctly labeled "a trifecta of lies, deceit and greed,"[22] and the Justice Department engaged in an ongoing multi-year federal antitrust investigation into anticompetitive conduct in the pharmaceutical industry, Ligand CEO John Higgins, who is the key node in this web of pharmaceutical industry malfeasance, is still shamelessly pushing the unethical Ligand model forward at astonishing cost to patients, taxpayers, and investors.

[20] See: Page 153 of the Viking S-1 available here: Link.

[21] "Shkreli began with receiving a $4 million series A funding round, followed by a pipe deal with Roth Capital Partners valued at $10 million that was raised at a deep discount and had warrants attached. From here, Shkreli was able to acquire the rights to Thiola and Chenodal, and subsequently raise the price of each drug. Thiola was marked up nearly 20 times its original price, while Chenodal was raised around five times its beginning price," See: "Exclusive: Why Martin Shkreli Feels He Has Been Vindicated" available here: Link

[22] See: Former Hedge Fund Manager And New York Attorney Indicted In Multimillion Dollar Fraud Scheme, available here: Link