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Side Effects of Corporate Greed: Pharmaceutical Companies Need a Dose of Corporate Social Responsibility

Martin L. Hirsch*

I. INTRODUCTION

"The point is, ladies and gentleman, that greed . . . for lack of a better word . . . is good. Greed is right. Greed works. Greed clarifies, cuts through, and captures the essence of the evolutionary spirit."¹

When it comes to health care and pharmaceuticals, greed is not good. In the world of health care, where patients rely on their doctors to do what is best for them, there is no place for greed.² Corporate governance in pharmaceutical companies that focuses on the shareholder's bottom line is completely inconsistent with health care, medicine and access to pharmaceuticals, where the patient should come first.³ This Article discusses how the corporate governance of pharmaceutical companies negatively affects health care and access to medicine world wide.⁴

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¹1. WALL STREET (Amercent Films 1987).

²2. It has long been held that the relationship of patient and physician is one of trust and confidence. See 36A CAL. JUR. 3d *Healing Arts and Institutions* § 352.

³3. The Hippocratic Oath, a pledge taken by most graduating medical students, states in part, "I will apply, for the benefit of the sick, all measures that are required, avoiding those twin traps of overtreatment and therapeutic nihilism." The Hippocratic Oath-Modern Version, http://www.pbs.org/wgbh/nova/doctors/oath_modern.html. (Last visited February 24, 2008). The Hippocratic Oath also states that "[doctors] will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug." *Id.*

⁴4. It notes that corporations are accountable to their shareholders, and that stakeholders of the corporation are not protected by corporate law, but protected by other regulatory law. In the context of this article the argument would be that pharmaceutical companies are accountable to their shareholders' interests even before their customers', and if a customer is injured by a product, that customer has a remedy under tort

By adhering to the typical shareholder model of corporate governance, the pharmaceutical companies' ethics⁵ do not always align with that which a patient might expect from their health care provider.⁶ The shareholder model of corporate governance encourages pharmaceutical companies to maximize shareholder profit. Transversely, patients and others seeking health benefits and medical care from the products of the pharmaceutical companies are concerned with their own health and well being.⁷ Therefore, a change from the shareholder model approach of corporate governance to one which aligns the interests of the company with that of their customers would better serve the medical needs the pharmaceutical companies' customers.

This Article argues that patient health is good, patient health is right, and that patient health works. Pharmaceutical companies should find value in doing what is best for patients rather than their shareholders' bank accounts. Such a system where patient health is the highest value can be implemented through corporate social responsibility⁸ which shifts the corporations' duty from maximizing shareholder profits to considering, and providing for, customer and community needs. Part I of this Article discusses several examples of the effects of the current corporate governance structure in pharmaceutical companies. Part II examines different international models of corporate governance, specifically looking at systems promulgated by the United Nations and the European Union. Part III considers whether these systems of corporate social responsibility ultimately provide a means to change the corporate governance of the pharmaceutical companies in order to recognize health as a fundamental

law. Henry Hansmann & Reinier Kraakman, *The End of History for Corporate Law*, 89 GEO. L.J. 439 (2001).

⁵5. Ethics, as used here, means the moral conviction to do what is best for the patients at all times.

⁶6. Pharmaceutical company refers to companies that produce medicine and drugs to treat various diseases, ailments and health issues, and follow the shareholder model of corporate governance.

⁷7. See Sacha Bonsor, *Trust Me I'm a Patient*, TIMES (London), May 1, 2007, at 4 (stating that patients are led to believe that doctors are right about their diagnoses and treatment recommendations).

⁸8. Corporate social responsibility refers to the dedication of businesses to the interests of its community, customers, and society at large.

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human right and shift focus from maximizing shareholder
profit to maximizing world health.

A. PROFITS VALUED OVER LIVES

A young man sits outside his house in Northern India, suffering from the effects of leishmaniasis. He shows signs of fever, has an enlarged spleen, and the whites of his eyes are yellow. This disease will attack his immune system and leave him susceptible to infection, most likely tuberculosis. If he is not treated, he will die. His father, who pulls a rickshaw, worked endlessly to save enough money to save his son. His family has already spent several months' of income on treatment, only to learn that the treatment they worked so hard to acquire would fail. The drug they could afford had lost its effectiveness, and would not save the young man. The drug that doctors formerly used to treat the disease had become outdated.⁹

A man in South Africa who contracted cerebrospinal meningitis during the annual outbreak suffers at home with no option for treatment. His family cannot afford the cost for his medication, \$65 (USD). The treatment cost more than five wage earners in the family would make in two weeks. The family did not have any money to spare after purchasing food and paying for school.¹⁰

1. Treating Diseases of the Poor

What if Scrooge had the power to cure disease, but

⁹ Drug companies stopped researching drugs for tropical diseases such as leishmaniasis due to economic reasons, not scientific ones. According to pharmaceutical companies there is not a market for medicine that treat tropical diseases. Tropical diseases such as malaria and leishmaniasis effect people in tropical areas of the world, which are overwhelmingly poor areas. There is a market for the medicine in the sense that millions of people die from these diseases every year showing how needed the drugs are. But there is not a market for these drugs in the sense that the people suffering from the diseases are poor and generally could not afford the treatment. Isabel Hilton, *A Bitter Pill for the World's Poor*, *GUARDIAN*, Jan. 5, 2000, at 20.

¹⁰ The author of the article, Mr. Boudreau, was friends with this sick man. The man's family contacted Mr. Boudreau who took the man to the hospital and paid the \$65 for treatment. After his friend received the treatment, the author asked the doctor what would have happened if he had not received treatment. The doctor's response was, "he would be allowed to die." Ned Boudreau, *Devil's Bargain: Africa and the Pharmaceutical Companies*, *ZNET DAILY COMMENT.*, Oct. 2, 2002, <http://www.zmag.org/sustainers/content/2002-10/02boudreau.cfm>.

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whereas drugs to treat the poor amount to a losing endeavor because the people who need the drugs cannot afford to pay the high prices the pharmaceuticals companies charge in order to maximize profits.¹⁹

In 1998, 6.1 million people in developing countries died from diseases that are preventable, and curable, including malaria, tuberculosis, and lower-respiratory-infections.²⁰ These people died because the drugs used to treat their diseases are either no longer effective, nonexistent, or too expensive.²¹ Pharmaceutical companies are currently discontinuing their research and development of drugs to treat tropical diseases allowing the former treatments to become outdated.²² Of the forty-one important drugs used to treat tropical diseases, diseases primarily affecting developing countries, none were discovered in the 1990s and all but six were discovered before 1985.²³ Sleeping sickness, a disease that effects 300,000 Africans each year can only be treated with the same drug that was used to treat it seventy years ago.²⁴ The last drug company that made a more effective treatment discontinued the product because it was not profitable.²⁵ The only treatment that remains is the seventy-year-old concoction of what amounts to arsenic and anti-freeze, which kills 5% of the people injected with it.²⁶

¹⁹In 2002, pharmaceutical companies that were members of the Fortune 500 out earned all the other Fortune 500 companies by a considerable margin. Profits were measured three ways, and in each category the drug companies had higher profits. Measuring profits as a percentage of revenue the drug companies earned more by nearly 14%, profits as a percentage of assets drug companies earned more by nearly 12%, and profits as a percentage of equity drug companies earned more by over 17%. NEAL PATTISON & LUKE WARREN, PUB. CITIZEN CONGRESS WATCH, 2002 DRUG INDUSTRY PROFITS: HEFTY PHARMACEUTICAL COMPANY MARGINS DWARF OTHER INDUSTRIES 1 (2003), available at http://www.citizen.org/congree/reform/drug_industry/corporate/articles.cfm?ID=9923.

²⁰Silverstein, *supra* note 17, at 13.

²¹Hilton, *supra* note 9, at 1.

²²JEAN O. LANJOUW & MARGARET MACLEOD, STATISTICAL TRENDS IN PHARMACEUTICAL RESEARCH FOR POOR COUNTRIES, 2 (2005), available at http://www.who.int/intellectualproperty/studies/en/Lanjouw_Statistical%20Trends.pdf.

²³Silverstein, *supra* note 17, at 14.

²⁴Donald G. McNeil, Jr., *Drug Companies and the Third World: A Case Study in Neglect*, N.Y. TIMES, May 21, 2000, at 1.

²⁵*Id.* at 2.

²⁶*Id.*

2. Generic Drugs and the Fight Against AIDS

*"People ask me how we could have been so stupid so as to sue Nelson Mandela . . . I say we had to, Mother Theresa was already dead."*²⁷

A pharmaceutical company representative told this joke at a conference referring to the lawsuit thirty-nine pharmaceutical companies brought to stop the South African government from importing cheap antiviral generic drugs to treat citizens infected with AIDS who otherwise could not afford treatment.²⁸ The pharmaceutical companies eventually dropped the lawsuit, but the drugs remained too expensive for the South African government to implement an effective treatment program.²⁹

The world's major pharmaceutical companies are involved in a similar fight against Brazil to stop its production of generic drugs to treat AIDS patients.³⁰ Brazil instituted a government funded medical program whereby the government would provide free AIDS treatment to those who needed it.³¹ The only way the government could afford to continue the program was by producing generic versions of the needed drugs.³² Since Brazil instituted the program it cut the death rate from AIDS in half.³³ The drug companies oppose the program because the drugs Brazil produces are protected by patents.³⁴

Some say the stance taken by the pharmaceutical companies against providing affordable treatment of AIDS shows they value wealth over health.³⁵ The problem facing poor countries fighting the AIDS epidemic is the only way to

²⁷ Amy Kapczynski, *Strict International Patent Laws Hurt Developing Countries*, YALE GLOBAL, Dec. 16, 2002, <http://yaleglobal.yale.edu/display.article?id=562>.

²⁸ *Id.*

²⁹ Philippe Riviere, *Patently Wrong: Southern Sickness, Northern Medicine*, LE MONDE DIPLOMATIQUE, July 2001, at 1, <http://mondediplo.com/2001/07/07aids>.

³⁰ Indira A.R. Lakshmanan, *Drug Costs Imperil Brazil AIDS Fight*, BOSTON GLOBE, Jan. 3, 2007, at 1, 2.

³¹ *Id.* at 1.

³² *Id.*

³³ *The Other Drug War: Pharmaceutical Companies and WTO sue Brazil and South Africa to Protect Prices and Patents* (Democracy Now! Broadcast Feb. 15, 2001), available at <http://www.democracynow.org/article.pl?sid=03/04/07/0156254>.

³⁴ *Id.*

³⁵ *Oxfam: Drug Firms Waging War on Poor*, *supra* note 15, at 1.

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provide affordable drugs to save lives is to buy or produce generic antiviral drugs.³⁶ New antiviral drugs cost \$17,000 (USD) per year, per patient, whereas older generic versions of similar treatment cost only hundreds of dollars per year.³⁷ The option seems to be to either continue producing generic treatment and save lives, or switch to patented drugs and let the people who cannot afford the treatment to die.³⁸

3. Nigeria Sues Pfizer

The drug companies are involved in another international lawsuit. This time, however, a foreign government sued a major drug company.³⁹ During an outbreak of meningitis in 1996, Pfizer provided Trovan to treat the disease.⁴⁰ The Nigerian government sued Pfizer for \$7 billion (USD) on behalf of the families of children who died or suffered side effects for alleged unauthorized testing

³⁶ See *The Other Drug War*, *supra* note 33. See generally Lakshmann, *supra* note 30, at 2.

³⁷ Lakshmanan, *supra* note 30, at 1.

³⁸ One of the major issues related to the AIDS drugs, as well as the need to provide other types of drugs to poorer nations, are the patent and intellectual property issues. To address these issues the World Trade Organization (WTO) member countries created an agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS attempt to create a balance between the long term goal of providing incentives for future research and development of new drugs by protecting patent rights, and the short term goal of allowing access to existing, patented, drugs in order to provide needed medicine. The Doha Declaration, in which participating governments agreed on the application of TRIPS, interprets TRIPS in a way to support public health. This allows governments to act in ways that are motivated by the need to protect public health. A large part of this is allowing countries the right to grant compulsory licensing in an emergency situation to either import or produce generic medicines. The countries have the freedom to decide what constitutes an emergency. See generally TRIPS and Pharmaceutical Patents: Fact Sheet, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm (last visited Feb. 28, 2008); The Doha Declaration Explained, http://www.wto.org/english/tratop_e/dda_e/doha_explained_e.htm#top (last visited Feb. 28, 2008); TRIPS and Public Health, Alternative Law Forum, <http://www.altnlawforum.org/PUBLICATIONS/document.2004-12-18.5846929564> (last visited Feb. 28, 2008) (discussing corporate social responsibility, an alternative to TRIPS); *infra* notes 87-110 and accompanying text.

³⁹ Faith Jones, *Nigeria Sues Pfizer Over Drug Trial Scandal*, SciDEV.NET, June 6, 2007, <http://www.scidev.net/content/news/eng/nigeria-sues-pfizer-over-drug-trial-scandal.cfm>.

⁴⁰ *Nigeria Sues Drugs Giant Pfizer*, BBC NEWS, June 5, 2007, <http://news.bbc.co.uk/2/hi/africa/6719141.stm>.

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of Trovan.⁴¹ Specifically, the government alleges that Pfizer administered Trovan to 233 children, killing 196 of them.⁴² Thirty-seven children survived the use of Trovan, but they all suffered serious health problems such as deafness, paralysis, brain damage, loss of sight, and slurred speech.⁴³

Pfizer argues that they obtained verbal consent from parents.⁴⁴ However, at the time, Trovan had only been approved for use by adults in the United States, and had never been given to children.⁴⁵ Regardless of which side wins the lawsuit, it is clear that children died and Trovan caused those deaths.⁴⁶ Pfizer does not argue that treating the children with Trovan was an experiment; it instead asserts that it had approval to conduct such an experiment.⁴⁷ Nonetheless the facts indicate that Pfizer experimented with those children's lives.

B. BOTTOM LINE THINKING DOES NOT SPARE U.S. PATIENTS

A fourteen-year-old boy in Michigan rides his skateboard outside his parents' house when he suddenly collapses. He had a heart attack. He later died. The chief pathologist who examined him concluded that the boy's blood vessels showed scarring and tissue growth, commonly associated with chronic stimulant use. The medical examiner said that ten years of Ritalin use was the likely cause of the gradual damage to the boy's nervous system, ultimately leading to his heart attack and his death.⁴⁸

The allegations facing drug companies are not only coming from abroad. Many stories like the one above have surfaced domestically, indicating the trend of valuing profit

⁴¹ *Id.*

⁴² Jones, *supra* note 39.

⁴³ *Id.*

⁴⁴ *Nigeria Sues Drugs Giant Pfizer*, *supra* note 40.

⁴⁵ Joe Stephens, *Panel Faults Pfizer in '96 Clinical Trial in Nigeria*, WASH. POST, May 7, 2006, at A1.

⁴⁶ *Id.*; Jones, *supra* note 39; *Nigeria Sues Drugs Giant Pfizer*, *supra* note 40.

⁴⁷ Stephens, *supra* note 45, at A1.

⁴⁸ Jeff Levine, *Boy's Death Linked to Ritalin*, WEBMD MED. NEWS, Apr. 18, 2000, <http://www.webmd.com/news/20000418/boys-death-linked-to-ritalin>; See also *Death from Ritalin*, <http://ritalindeath.com/ADHD-Drug-Deaths.htm> (last visited Feb. 10, 2008) (memorializing children whose deaths are linked to using ADD and ADHD treatment drugs such as Ritalin, Desipramine, Stratters, and Concerta whose causes of death were either heart related or suicide linked to prescription drug use).

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over public health exists in the United States. This trend is most evident in direct-to-consumer advertising, and over-prescription of potentially harmful drugs.⁴⁹

A 2005 report shows that pharmaceutical companies influence doctors' diagnoses in an effort to improve their bottom lines. Researchers at Dartmouth Medical School estimate tens of millions more Americans were diagnosed with a sickness or health problem during the 1990s than ever before.⁵⁰ The criteria used to make a diagnosis have been changed in order to classify more healthy people as sick.⁵¹ Changing the criteria of what is considered sick resulted in tens of millions more customers for drug companies.⁵² The report uncovered the fact that pharmaceutical companies give money to members of the World Health Organization, U.S. National Institute of Health and some of America's most prestigious medical societies for these institutions to promote the pharmaceutical industry's agenda.⁵³ As a result, today three in four Americans are considered to have at least one disease, but millions of these people are truly not sick, resulting in sales of drugs to people who do not need them, but can afford to pay for them.⁵⁴ Remember: the opposite is true in developing countries where people truly need the drugs, but cannot afford them.

⁴⁹ See generally Susan Kelleher & Duff Wilson, *The Hidden Big Business Behind your Doctor's Diagnosis*, SEATTLE TIMES, June 26, 2005, at A1 (describing the influences of the pharmaceutical industry on drug and treatment guidelines).

⁵⁰ See *id.*

⁵¹ For example, the threshold weight to be considered obese might be lowered by several pounds, or the threshold to be diagnosed with hypertension lowered by several blood pressure points. *Id.*

⁵² *Id.*

⁵³ *Id.* See also Jerry Avorn, *Dangerous Deception—Hiding the Evidence of Adverse Drug Effects*, 355 NEW ENG. J. MED. 2169 (2006). Doctor Avorn recalls a conversation with a hospital administrator which illustrates the effect the pharmaceutical companies have over doctors, and the prescriptions they write. Dr. Avorn remembered the Administrator describing how well the hospital's grand-rounds worked because "the drug companies find the speakers, pay their honoraria, and provide free food for the doctor which helps a lot with attendance." *Id.* Dr. Avorn goes on to explain what a good deal this actually was for the pharmaceutical companies, because the doctors who attended would go on to prescribe the drugs promoted at that grand-round. *Id.*

⁵⁴ Kelleher & Wilson, *supra* note 49.

1. Dangerous Side Effects of Commonly Used Drugs⁵⁵

Drug sales indicate that America is on its way to becoming a drug-dependent nation. Between 1998 and 2000, sales of anti-depressant drugs increased 73%, and sales of analeptics, drugs that stimulate the central nervous system like Ritalin and Adderall, increased 167%.⁵⁶ British drug officials, as well as the Food and Drug Administration, warned physicians about the risks associated with the anti-depressants Paxil, which has the potential to prompt teenagers and kids to consider suicide.⁵⁷ Moreover, there are ample documented instances of youth deaths linked to Ritalin and anti-depressants.⁵⁸ Nonetheless, use of these drugs continue to skyrocket.⁵⁹

Three independent studies tested the effects of Ritalin use in humans. The results of one test concluded that using prescription stimulants during childhood makes children more susceptible to cocaine use as young adults.⁶⁰ Another study found that children treated for ADHD with prescription stimulants had a 9% risk of developing psychotic symptoms, while the control group—children who did not use those drugs—showed zero signs of developing psychotic symptoms.⁶¹ A final study found that stimulants can cause growth retardation, depression and obsessive compulsive disorder.⁶² Critics of the use of stimulants to treat ADHD and

⁵⁵ Many commonly prescribed drugs carry harmful side effects. See generally Avorn, *supra* note 53; Consumers Union, Prescription for Change, <http://www.consumersunion.org/campaigns/prescriptionforchange/004320 indiv.html> (last visited Jan. 30, 2008). To discuss each drug and its side effects, however, is beyond the scope of this article.

⁵⁶ Lou Dobbs, *We Need a War vs. Legal Drugs*, N.Y. DAILY NEWS, Sept. 28, 2003, at 14.

⁵⁷ *Id.* The diet drug Fen-phen is yet another example of a prescription drug that manifested harmful side effects in its users. See David J. Morrow, *Fen-phen Maker to Pay Billions in Settlement of Diet-Injury Cases*, N.Y. TIMES, Oct. 8, 1999, at 1.

⁵⁸ Death from Ritalin, *supra* note 48 (describing the deaths of a number of children "as a direct result of using psychotropic drugs used for ADD and ADHD").

⁵⁹ Dobbs, *supra* note 56.

⁶⁰ Peter R. Breggin & Fred A. Baughman Jr., *Questioning the Treatment for ADHD*, 291 SCIENCE 595, 595 (2001).

⁶¹ *Id.*

⁶² *Id.* See also Gabrielle Weiss & Lily Hechtman, *The Hyperactive Child Syndrome*, 205 SCIENCE 1348, 1348-54 (1979) (discussing a study concluding that stimulant drugs can suppress growth and recommending

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ADD point to the fact that these stimulants enhance obsessive compulsive behavior while suppressing a child's spontaneous behavior, such effects are then mistaken as improved attention.⁶³

There has also been an increase in the use of statin drugs which are used to lower cholesterol in adults.⁶⁴ A change in the guidelines of what it means to have high blood pressure increased the market for statin drugs.⁶⁵ Nine experts on cholesterol wrote these guidelines.⁶⁶ Of these nine experts, six of them have financial ties to the pharmaceutical companies that produce the most commonly used statin drugs.⁶⁷ The more common side effects from statin drugs are liver damage and muscle aches.⁶⁸ Muscle symptoms are the most common side effects. This side effect is called "myopathy" and results in actual damage to muscle tissue.⁶⁹ Other less common side effects include decrease in memory or concentration, depression and irritability, pain other than muscle pain, and peripheral neuropathy or tingling and numbness.⁷⁰

In yet another example of prescription drugs harming their users, cyclo-oxygenase-2 (COX 2) inhibitors were found to be harmful. In 2005, a panel of doctors advised the FDA that all COX 2 inhibitors should come with a "black box" warning that these drugs increase chances of heart attacks and strokes.⁷¹ The most popular COX 2 inhibitors are Vioxx, Celebrex, and Bextra, which are prescribed to treat arthritis.⁷² A story from 2005 estimated that Merck alone faced nearly 7,000 state and federal lawsuits brought

lower dosages and periodic breaks in treatment to prevent the side effect from occurring).

⁶³ See, e.g., Breggin & Baughman, *supra* note 60.

⁶⁴ See generally, *Big Bucks, Big Pharma: Marketing Disease & Pushing Drugs*, (Democracy Now! broadcast Jan. 19, 2007), available at <http://www.democracynow.org/article.pl?sid=07/01/19/1432236>.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ The UCSD Statin Study, Statin Adverse Effects, http://medicine.ucsd.edu/SES/adverse_effects.htm (last visited Jan. 30, 2008).

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ Leanne Lenzer, *FDA Advisers Warn: COX 2 Inhibitors Increase Risk of Heart Attack and Stroke*, 330 *BRIT. MED. J.*, 440, 440 (2005).

⁷² *Id.*

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prescription from their doctors.⁸⁰ This effectively means that these "patients" prescribed their own treatment for what they diagnosed as a medical condition requiring that treatment. As such factors increase consumer demand, advertising budgets at the pharmaceutical companies also increase.⁸¹

Direct-to-consumer advertising also reflects the unbalanced priorities of the companies. Instead of continuing to develop and research new drugs, as well as improve old ones, the pharmaceutical companies spend overwhelming amounts of their budgets on advertising.⁸² This spending only furthers the need of the pharmaceutical companies to search for the next blockbuster drug, instead of developing more effective treatments for common diseases.⁸³ Related to this issue is the need of the pharmaceutical companies to extend patent life in order to maintain the monopoly on a certain drug.⁸⁴ In order to extend the patent, pharmaceutical companies will find a new use for an existing drug.⁸⁵ Then they market the drug for its new use. This marketing requires heavy promotion of the drug,⁸⁶ and further evidences the misalignment between the interests of the pharmaceutical companies and those who purchase the products they produce.

⁸⁰ Wilkes et al., *supra* note 76, at 110-13.

⁸¹ *Id.*

⁸² PATTISON & WARREN, *supra* note 19, at 5.

⁸³ From 1989 through 2000, of the 1,035 new drugs approved only 24% were given priority FDA review. This suggests that only those 24% were considered improvements to existing remedies, because such new developments are commonly given priority review. It is likely that the overwhelming majority of research and development focuses on so called "me-too" drugs which are copies of previously successful drugs. Me-too drugs cost much less to develop because they involve only tweaks to existing drugs. Thus, the pharmaceutical companies are able to increase their spending on advertising, as 76% of their research and development goes to drugs that cost less to develop. *Id.*

⁸⁴ A pharmaceutical company's patent on a certain drug creates a monopoly on that drug. This monopoly is quite lucrative, so much so that when Eli Lilly's patent on Prozac was cut short by three years, Lilly's stock dropped 30% on the same day. Matthew Herper, *Drug Patent Peril*, FORBES.COM, Jan. 26, 2005, http://www.forbes.com/technology/2005/01/26/cx_mh_0126patents.html.

⁸⁵ *Big Bucks, Big Pharma*, *supra* note 64.

⁸⁶ *Id.*

Pharmaceutical companies push unneeded drugs to those who can afford them, and withhold desperately needed drugs from those who cannot afford them. The power to cure and save is outweighed by the obligation to earn. Ethically, the corporate structure that mandates the responsibility to maximize profits needs to be reformed.

II. CORPORATE SOCIAL RESPONSIBILITY AS THE CURE

Corporate social responsibility (CSR) can cure the ills of the pharmaceutical companies, because it will implement new ethics in the corporate structure that recognize broader duties beyond those owed to shareholders.

A. DIVERGENT POSITIONS OF CSR

The corporate governance debate dates back to the 1930s when Adolf Berle and Merrick Dodd argued whether a corporation owes a duty to society as a whole or just to its shareholders.⁸⁷ Berle argued that managers of the corporation owed a duty to the shareholders because the shareholders own the corporation.⁸⁸ Berle saw the managers as agents, or trustees, who owed a fiduciary duty to the shareholders to maximize shareholder profits.⁸⁹ Dodd held a divergent view, arguing that the corporation should focus, not only on the interests of its shareholders, but on the interests of its employees, consumers, and the general public.⁹⁰ He noted that public opinion was causing the law to change in some areas to a view in which the corporation had a duty of social service in addition to profit making.⁹¹

The correlative modern views are known as the

⁸⁷ See generally A.A. Berle, Jr., *Corporate Powers as Powers in Trust*, 44 HARV. L. REV. 1049 (1931); E. Merrick Dodd, Jr., *For Whom Are Corporate Managers Trustees?*, 45 HARV. L. REV. 1145 (1932).

⁸⁸ Berle, *supra* note 87, at 1049 ("It is the thesis of this essay that all powers granted to a corporation are necessarily . . . exercisable only for the ratable benefit of all shareholders as their interest appears.").

⁸⁹ *Id.*

⁹⁰ See Dodd, *supra* note 87, at 1160.

⁹¹ *Id.* ("[T]he law has already reached the point . . . where it compels business enterprises to recognize to some extent the interests of other persons besides their owners.").

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standard shareholder-oriented model⁹² and the stakeholder-oriented model.⁹³ The standard shareholder-oriented model ("shareholder" model or "standard" model) adheres to Berle's view that the role of corporate managers is to maximize shareholder profits.⁹⁴ The stakeholder-oriented model adheres to Dodd's alternative construction of a corporation's duty, expanding his argument to align with CSR.⁹⁵

The stakeholder approach to corporate governance is analogous to the theory of CSR. CSR focuses on the communities in which the corporation operates or conducts business, the environment, labor rights, human rights in general, and ethics.⁹⁶ This Article focuses on the human rights and ethical aspects of CSR. These elements of CSR can change the negative aspects of pharmaceutical companies discussed in Part I. The goal is to implement CSR in the pharmaceutical companies, shifting the corporation's duty from a shareholder approach to a stakeholder approach. Such a major change would shift the focus of the pharmaceutical companies to protecting the health of their customers and providing necessary medicine to all regardless of ability to pay. A change of this sort recognizes the specific rights to medicine and health, as well as human rights in general.

1. The Standard Shareholder-Oriented Model

The ethical responsibility of the pharmaceutical companies is clear because they, along with treating physicians, provide treatments to save lives. Yet there are many instances of deaths, either because people cannot get the right treatment, or they receive the wrong treatment. There are further instances of people who receive treatment suffering from harmful side effects. Though pharmaceutical

⁹² See generally Hansmann & Kraakman, *supra* note 4, at 440-43 (discussing the dominance of the standard shareholder-oriented model for corporate governance).

⁹³ See Generally Cynthia A. Williams, *Corporate Social Responsibility in an Era of Economic Globalization*, 35 U.C. DAVIS L. REV. 705, 713-14 (2002) (discussing various positions of scholars on corporate social responsibility, as well as the stakeholder-oriented model providing insufficient accountability).

⁹⁴ *Id.* at 708.

⁹⁵ *Id.* at 716.

⁹⁶ *Id.*

companies are not solely to blame for these issues, as doctors prescribe the medicines that the FDA approves, the pharmaceutical companies are most in need of reform due to their misalignment of interests with that of their customers.

Both the United Nations and the World Health Organization recognize health as a fundamental human right.⁹⁷ In that light, adopting CSR that recognizes human rights would be an effective means to end the harmful profits-oriented approach currently found in the pharmaceutical companies. The priority of the pharmaceutical companies must change from maximizing profits to maximizing human health. To undergo this change there must be a shift away from the current model which solely requires the board of directors to provide shareholders with a fair return on their investment, and thus requires the board to focus on maximizing profits.⁹⁸

As seen from the examples discussed in Part I, when the pharmaceutical companies strive to maximize profits, they fail to always provide ethical health treatment to all those who need it. The corporate structure of maximizing profits results in an inconsistency between the pharmaceutical companies and the expectations of those who need treatment, believe their treatment will make them better, or believe that health is a human right.

The common model of corporate governance, the one found in the United States, and in U.S. pharmaceutical companies, is the shareholder model.⁹⁹ The American Law Institute's Principles of Corporate Governance state that a corporation's objective is to increase corporate profit as well as shareholder gain.¹⁰⁰ This model of corporate governance developed in the United States as business and industry grew.¹⁰¹ As their businesses grew, owners could not fully

⁹⁷UNAIDS Joint United Nations Programme on HIV/AIDS, Human Rights, <http://www.unaids.org/en/PolicyAndPractice/HumanRights/default.asp> (last visited Feb. 28, 2008); World Health Organization, Health and Human Rights, <http://www.who.int/hhr/en/> (Last visited Feb. 28, 2008) ("WHO Constitution: 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.'").

⁹⁸Williams, *supra* note 93, at 717.

⁹⁹See Hansmann & Kraakman, *supra* note 4, at 440-41.

¹⁰⁰PRINCIPLES OF CORPORATE GOVERNANCE: ANALYSIS AND RECOMMENDATIONS § 2.01(a) (1994).

¹⁰¹See Mark J. Roe, *Some Differences in Corporate Structure in*

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fund all their endeavors, so they sold shares of their businesses to any willing purchaser. This model resulted in shareholders who were distant from the operations of the business. These shareholders lacked the expertise in the business to monitor the managers. What developed was a system where the shareholders were not involved in the operations of the business but were owed a duty to ensure the managers were looking after their financial interests.¹⁰²

The most prevalent form of CSR under the shareholder model is to do everything possible, within the confines of the law, to maximize shareholder wealth.¹⁰³ This view relies on contract and regulatory law to protect the other constituencies affected by the corporation.¹⁰⁴ This type of CSR considers the corporation to have fulfilled its obligation to society by bolstering the economy and tax base.¹⁰⁵ Thus, the shareholder model does not consider it necessary for the corporation to address other societal concerns addressed by the stakeholder model of CSR.

2. The Stakeholder Model of CSR

Unlike the shareholder model, the stakeholder model mandates broader duties beyond those owed to share owners of the corporation.¹⁰⁶ CSR is recognized as a means for a company to integrate economic, environmental, and social concerns while addressing both shareholder and stakeholder concerns.¹⁰⁷ This definition embodies making

Germany, Japan, and the United States, 102 YALE L.J. 1927, 1933 (1993).

²102. See generally *id.* at 1936-41 (contrasting the shareholder structure in Germany and Japan with that of the United States in which intermediaries hold a large percentage of shares which allows these institutions to share the power structure with the corporation and its managers).

³103. See Williams, *supra* note 93, at 708.

⁴104. See *id.* at 714 (identifying employment contracts, anti-discrimination laws, and environmental protection laws, as some of those protections).

⁵105. See *id.*

⁶106. See generally, Ilias Bantekas, *Corporate Social Responsibility in International Law*, 22 B.U. INT'L L.J. 309 (2004) (explaining the sources of CER for multinational enterprises in the context of a global economy); Upendra Baxi, *Market Fundamentalism: Business Ethics at the Altar of Human Rights*, 5 HUM. RTS. L. REV. 1 (2005) (discussing the ramifications of the Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights on businesses and CSR).

⁷107. See Industry Canada, What is CSR?, http://www.ic.gc.ca/epic/site/csr-rse.nsf/en/h_rs00094e.html (last visited May 1, 2008).

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decisions not only based on economic factors, but also on the human rights and community consequences of the corporation's actions.¹⁰⁸ R. Edward Freeman suggests that the corporation owes a duty to individuals or entities who affect or are affected by corporate operations.¹⁰⁹ He recognizes this duty to be equally important to that owed to the corporation's shareholders.¹¹⁰

B. HUMAN RIGHTS AND ETHICAL ASPECTS OF STAKEHOLDER CSR

There are many international guidelines for CSR. The focus of this Article is those CSR guidelines that recognize human rights, ethics and the need for medical treatment.

1. United Nations

The United Nations (UN) Global Compact (the "Global Compact") is a voluntary global governance¹¹¹ program that focuses on implementing principles of CSR. The Global Compact promotes CSR through ten universal principles of human rights, labor, and the environment.¹¹² The idea of the Global Compact is to bring together UN agencies and civil society to support environmental and social principles.¹¹³ The Global Compact comprises ten principles, two of which focus on human rights.¹¹⁴ The principles of the UN Global Compact are derived from the Universal Declaration of Human Rights (UDHR).¹¹⁵ Article 25 of the UDHR states:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food,

⁸108.*Id.*

⁹109.R. Edward Freeman & John McVea, *A Stakeholder Approach to Strategic Management* 4 (Darden Bus. Sch. Working Paper No. 01-02), available at <http://ssrn.com/abstract=263511>.

⁰110.*Id.* at 10.

¹111.Global governance refers to voluntary world-wide regulatory systems. The most notable global governance body is the United Nations, but many other intergovernmental organizations provide guidelines, and regulations. See The Global Governance Group, <http://www.globalgovgroup.com/> (last visited Feb. 16, 2008).

²112.See United Nations Global Compact, <http://www.unglobalcompact.org/index.html> [hereinafter Global Compact].

³113.Global Compact, About the Global Compact, <http://www.unglobalcompact.org/AboutTheGC/index.html> (last visited Feb. 16, 2008).

⁴114.Global Compact, *supra* note 112.

⁵115.Global Compact, Human Rights, http://www.unglobalcompact.org/Issues/human_rights/index.html (Last visited Feb. 16, 2008).

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clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability widowhood, old age or other lack of livelihood in circumstances beyond his control.¹¹⁶

This provision of the UDHR is captured in the principles of the UN Global Compact.¹¹⁷

Principles 1 and 2 of the Global Compact originate from the 1948 UDHR. Because the UDHR and its international protections for individual human rights were established over a half century ago, the principles are now considered to be international customary law.¹¹⁸ The objectives of the Global Compact are to "mainstream the ten principles in business activities around the world, and catalyze actions in support of UN goals."¹¹⁹ The Global Compact does not include means to regulate the implementation of its objectives and principles. The Global Compact, instead, "relies on public accountability, transparency and the enlightened self-interest of companies, labour [sic] and civil society to initiate and share substantive action."¹²⁰

The UN also recognizes the need to address AIDS as a global epidemic. In particular, the UN focuses on the severity of the AIDS epidemic in sub-Saharan Africa, where seventy-five percent of the world's population infected with AIDS lives.¹²¹ Such huge numbers of people infected with AIDS imposes a major economic burden on that part of the continent.¹²²

The Declaration of Commitment on HIV/AIDS calls for action on a global scale to address the AIDS epidemic.¹²³ The Declaration further recognizes the importance of people with AIDS receiving the treatment that they need by

¹¹⁶Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. Doc. A/810 (Dec. 10, 1948), available at <http://www.un.org/Overview/rights.html> [hereinafter UDHR].

¹¹⁷See Global Compact, *supra* note 112 ("Principle 1: Business should support and respect the protection of internationally proclaimed human rights; and Principle 2: make sure that they are not complicit in human rights abuses.").

¹¹⁸Global Compact, Human Rights, *supra* note 115.

¹¹⁹Global Compact, What is the UN Global Compact?, <http://www.unglobalcompact.org/AboutTheGC/index.html> (Last visited Feb. 16, 2008).

¹²⁰*Id.*

¹²¹Declaration of Commitment on HIV/AIDS, G.A. Res. A/RES/S-26/2, at 1 (June 27, 2001).

¹²²*Id.* at 2.

¹²³*Id.* at 1.

emphasizing "that access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."¹²⁴ To implement this, and other, principles of the Declaration, the UN calls for action not only from international governments, but also from the business and civil sectors as well. Such action includes providing antiviral drugs to treat the disease.¹²⁵

The United Nations Economic and Social Council has further promulgated principles of CSR in its Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights.¹²⁶ One important initial aspect of the Norms is that they require multinational corporations (MNCs) to recognize all UN and other treaties on human rights, including the World Health Organization principles that recognize health as a human right.¹²⁷

The principles set forth in the Norms requires MNCs to "act in accordance with the fair business, marketing and advertising practices and shall take all necessary steps to ensure the safety and quality of the goods and services they provide. . . ."¹²⁸ This principle further states that MNCs shall not "produce, distribute, market, or advertise harmful or potentially harmful products for use by consumers."¹²⁹

Another aspect of the Norms that provides a model of CSR particularly helpful to effect change in the pharmaceutical companies is the definition of stakeholder. The definition of stakeholder includes a general category of people who are affected by the actions of the MNC.¹³⁰ The definition then elaborates on this general category, noting that stakeholders can include people or groups who are

⁴124.*Id.* at 3.

⁵125.*Id.* at 4.

⁶126.Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, U.N. Doc. E/CN.4/Sub.2/2003/12/Rev.2 (2003) [hereinafter Norms].

⁷127.*Id.* at ¶ 4; World Health Organization, Health and Human Rights, <http://www.who.int/hhr/en/> (last visited Feb. 16, 2008).

⁸128.Norms, *supra* note 126, at § F(13) ("Obligations with regard to consumer protection").

⁹129.*Id.*

⁰130.*Id.* at § I(22).

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directly or indirectly affected by the activities of the MNC.¹³¹

2. Organisation for Economic Co-operation and Development

The Organisation for Economic Co-operation and Development (OECD) intends to create a strong system of corporate governance around the world. Like the UN Principles and Guidelines, those of the OECD are non-binding, and voluntary.¹³² The OECD also suggests that improved corporate governance will help a business to grow and to prosper; it recognizes that business ethics and awareness of environmental and social concerns will impact a company's long term success.¹³³

The OECD principles provide a framework, or a reference, for legislators or corporations when drafting their corporate governance model.¹³⁴ The principles are not, however, a mandate to adopt any particular type of corporate governance. The principles of the OECD are intended to identify objectives of corporate governance and create various means for achieving those objectives.¹³⁵

The OECD Principles state that the board should recognize the interests of stakeholders, applying high ethical standards in doing so.¹³⁶ The OECD recognizes the important role of stakeholders in the long term success of the corporation. The Principles state that where a stakeholder's rights are established and protected by law the corporation should respect those rights.¹³⁷ Even in areas where stakeholder rights are not legislated, the Principles suggest recognition of those broader interests, pointing to the corporation's interest in maintaining a positive

¹³¹Principle 22 states that the term stakeholder includes consumer groups, customers, and others. Thus, this definition recognizes customers of drug companies—those who take the drugs—as people who should be protected by the CSR program. *Id.*

¹³²ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *OECD GUIDELINES FOR MULTINATIONAL ENTERPRISES* 17 (2000), available at <http://www.oecd.org/dataoecd/56/36/1922428.pdf> [hereinafter *OECD GUIDELINES*].

¹³³ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *OECD PRINCIPLES OF CORPORATE GOVERNANCE* 12 (2004) available at <http://www.oecd.org/dataoecd/32/18/31557724.pdf> [hereinafter *OECD PRINCIPLES*].

¹³⁴*Id.* at 11.

¹³⁵*Id.* at 13.

¹³⁶See generally, *OECD PRINCIPLES*, *supra* note 133, at 24-29.

¹³⁷See generally *id.* at 21.

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reputation.¹³⁸ The OECD omits from its definition of stakeholder, the customer and prospective customer, only recognizing investors, employees, creditors, and suppliers.¹³⁹

The OECD also recognizes the important role that good health and healthcare play in economic growth.¹⁴⁰ The OECD 2007 Annual Report mentions that insufficient healthcare causes unnecessary deaths, and poor health in general, while recognizing that gaps in the access to healthcare remain across socio-economic groups.¹⁴¹ The OECD views pharmaceutical pricing and reimbursement policies as one cause of low availability and affordability of medicine in countries with need.¹⁴² These policies are viewed as an inhibitors of "the global public good of innovation in medicine."¹⁴³

Though the OECD Principles do not recognize the same definition of a stakeholder as that of the Norms, the OECD Guidelines for Multinational Enterprises (MNEs) states that they should respect the human rights of the individuals affected by their activities.¹⁴⁴ This recognition is much closer to the stakeholder CSR policies the pharmaceuticals should adopt, because both customers and non-customers are affected by the pharmaceutical companies.¹⁴⁵ Furthermore, the OECD Guidelines recognize the importance of treating consumers in accordance with fair business, marketing, and advertising practices as well as providing safe quality goods.¹⁴⁶ The standards further state that the products should provide enough information to the customer to allow an informed decision.¹⁴⁷

The OECD Guidelines provide specific goals for MNEs to

⁸138.*Id.*

⁹139.*Id.*

⁰140.ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, ANNUAL REPORT 47-49 (2007), *available at* <http://www.oecd.org/dataoecd/1/53/38484866.pdf>.

¹141.*Id.* at 47.

²142.*Id.* at 49.

³143.*Id.*

⁴144.OECD GUIDELINES, *supra* note 132, at 19.

⁵145.As discussed in Part I, pharmaceutical companies have a great impact on the health of their customers as well as the health of sick people in poor countries who cannot afford medication for their diseases.

⁶146.OECD GUIDELINES, *supra* note 132, at 25.

⁷147.*Id.*

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meet in protecting their customers. The most relevant are the health, safety and information standards. One principle states that MNEs should ensure all products meet the required safety standards for health, including appropriate product warning labels.¹⁴⁸

The OECD Principles provide helpful guidance in the implementation of a corporate governance system. The OECD recognizes that corporate governance may be implemented in various ways, either through legislation, government regulation, self regulation, or voluntary standards.¹⁴⁹ The first step to implement the OECD principles is to establish an effective foundation of laws and regulations.¹⁵⁰ The OECD suggests monitoring the corporate governance framework to ensure it is serving its purpose of promoting ethical and transparent corporate governance practices.¹⁵¹ The OECD recommends that laws and regulations affecting corporate governance be implemented efficiently and fairly. One way to achieve this is for government and regulatory authorities to meet with corporations and their stakeholders to assess the CSR framework of the company.¹⁵²

While the OECD suggests self-regulation as possible means to implement CSR, it clearly prefers laws and regulations set by a governing body.¹⁵³ Self-regulation is certainly better than no CSR at all, but it can leave stakeholders and shareholders uncertain about the implementation and meaning of the standards.¹⁵⁴ This uncertainty contributes to the OECD's preference for national regulation that provides a framework shareholders and stakeholders can rely upon, and find redress in, if something goes wrong.¹⁵⁵

3. The European Union

The major publication that sets forth the standards of CSR in the EU, and the means to implement those

⁸148.*Id.*

⁹149.OECD PRINCIPLES, *supra* note 133, at 29-31.

⁰150.*Id.*

¹151.*Id.*

²152.*Id.*

³153.*Id.*

⁴154.*Id.*

⁵155.*Id.*

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rights policies.¹⁶⁵ A code of conduct is a set of standards together with a pledge by the company to observe the standards.¹⁶⁶ To effectively implement human rights, the codes of conduct must be established at every level of the company. A verification scheme should also be established to audit the effectiveness of the program.¹⁶⁷ The Green Paper suggests that codes of conduct emphasize continuing gradual improvements to the standards established by the company and to the code of conduct itself.¹⁶⁸

III. LESSONS LEARNED: IS CSR THE APPROPRIATE PRESCRIPTION?

One obstacle to implementing CSR is the apparent control the pharmaceutical companies have over United States lawmakers and regulators. The most recent evidence of this control is the failure of the House of Representatives to pass an effective version of The Food and Drug Administration Amendments Act of 2007.¹⁶⁹ This resolution was designed to raise the standards for disclosure of drug side effects and test results, regulate direct-to-consumer advertising, and end conflicts of interest between the FDA and pharmaceutical companies.¹⁷⁰ The bill passed by the House does none of these things; it strengthens the pharmaceutical companies' ties with the FDA.¹⁷¹ This reversal occurred as a result of coercion from the powerful pharmaceutical lobby, PhRMA.¹⁷² The pharmaceutical lobby is recognized as the most powerful lobby in Washington.¹⁷³

⁵165. GREEN PAPER, *supra* note 156, at 14-15.

⁶166.*Id.*

⁷167.*Id.*

⁸168.*Id.*

⁹169. Mike Adams, *FDA Tyranny to Become Law: HR 2900 Analysis*, NATURALNEWS.COM, July 12, 2007, <http://www.naturalnews.com/021932.html> (discussing the passage of Food and Drug Administration Amendments Act of 2007, H.R. 2900, 110th Cong. (2007)).

⁰170.*Id.*

¹171.*Id.*

²172.*Id.*

³173. "The combined worth of the world's top five drug companies is twice the combined GDP of all sub-Saharan Africa and their influence on the rules of world trade is many times stronger because they can bring their wealth to bear directly on the levers of western power." Julian Borger, *Industry that Stalks the U.S. Corridors of Power*, GUARDIAN (Manchester), Feb. 13, 2001, available at <http://www.guardian.co.uk/international/story/0,3604,437212,00.html>.

Another example of PhRMA's strength in Washington is the failure of The Prescription Drug User Fee Act (PDUFA) that was intended to strengthen the FDA system of approving drugs.¹⁷⁴ Instead the law created a sense that the FDA is actually accountable to the drug companies, which results in less drug safety regulation.¹⁷⁵ Additionally, PDUFA has minimal funding and this limits the FDA's testing and research of drug safety.¹⁷⁶ Not only does this legislation not help to regulate drug safety, but commentators argue that the Act has the opposite effect.¹⁷⁷

I raise these issues here to demonstrate the difficulties that lie ahead in mandating the adoption of CSR principles in pharmaceutical companies. To pass the laws establishing CSR guidelines, legislators will have to overcome the pharmaceutical lobby. With enough ground swell and consumer support for new CSR principles, PhrMA may be forced to consider the negative impact that opposing human rights and consumer protection laws will have on public opinion of drug companies.

A. CSR APPLIED TO PHARMACEUTICAL COMPANIES

There are two fundamental aspects of CSR to consider in examining the various models capable of addressing the problems identified with the pharmaceutical companies: who the CSR protects, and what rights CSR protects. The appropriate model of CSR will protect both customers and non-customers. CSR should protect human rights of these groups specifically recognizing that health is a human right.

The pharmaceutical companies must recognize stakeholders, not just shareholders. Adopting a system of CSR that recognizes and protects the stakeholders will shift pharmaceutical companies from the current bottom line

⁴174.Sidney Wolfe, Ben Peck & Frank Clemente, *Comments on: The Prescription Drug User Fee Act (PDUFA)*, PUBLIC CITIZEN, Jan. 25, 2002, <http://www.citizen.org/publications/release.cfm?ID=7145>.

⁵175.Avon, *supra* note 53.

⁶176.The FDA proposed to devote only \$29.3 million to the drug-safety program. This amounts to 6.7% of the \$437.8 million in user-fee revenue. Compare this to the \$188.5 billion that was spent on prescription drugs in the United States in 2004, and the \$11.9 billion spent on pharmaceutical advertising. Sean Hennessy & Brian L. Strom, *PDUFA Reauthorization—Drug Safety's Golden Moment of Opportunity?*, 356 NEW ENG. J. MED. 1703, 1703 (2007).

⁷177.*Id.*

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model to that of ethics and human rights. The stakeholder model implemented must recognize both customers and individuals affected by the companies' activities as stakeholders. The broadest recognition of a stakeholder group is found in the OECD Guidelines which states that MNC's should respect the human rights of those affected by their activities.¹⁷⁸ This broad interpretation of a stakeholder includes the groups of people who need to be protected from the pharmaceutical companies, both customers and poor people who cannot afford to be customers.

When it comes to the issues discussed in Part I, it is clear that the concern is to help customers, in addition to people who need a medicine, but who do not have access to it. Customers need protection from side effects, over-prescription, and direct-to-consumer advertising. Those who desire medication need to gain access to the drugs they need in order to live. The OECD's broad recognition covers these groups and makes for a good starting point for an appropriate model of CSR.

Both the Norms and the OECD Guidelines establish a requirement that a corporation conduct its business recognizing fair business, marketing and advertising practices, and that companies should provide safe quality products to their customers.¹⁷⁹ This principle addresses the protection of the customer. Application of this principle could be used to limit direct-to-consumer advertising, require fewer harmful side effects or increased patient notification regarding side effects, and create more stringent prescription standards to ensure the benefit to the patient outweighs the potential risks.

In the face of a fair advertising requirement, direct-to-consumer advertising will either undergo a fundamental change, or end altogether. Many do not consider this advertising to be fair due to its effects on the consumer and prescription practices.¹⁸⁰ CSR principles should make advertising more fair. Direct-to-consumer advertising would be acceptable as long as it was considered fair to the consumer. These advertisements would have to be

¹⁷⁸OECD GUIDELINES, *supra* note 132, at 19.

¹⁷⁹*Id.*; Norms, *supra* note 126.

¹⁸⁰Direct-to-consumer advertising may encourage patients to pressure their physicians to prescribe specific medications. Wilkes et al., *supra* note 76, at 120.

subjected to a heightened standard to ensure that they were not misleading and did not lead to self diagnoses. Overall, the goal of the advertising should be to improve patient health, not to improve the shareholders' bottom line. This goal is consistent with not only the fairness standard found in the OECD Guidelines and the Norms, but also with the standards of fair business practices and providing safe quality products to consumers.

Additionally, by requiring safe quality products, the consumer is protected from dangerous prescriptions. This would call for higher regulatory standards to ensure the drug's side effects did not outweigh its benefits. The CSR model could implement such regulatory standards. A standard could focus on informing patients about risks, creating a heightened scrutiny of the risks of taking the drug, and weighing the risks against the benefits. By requiring such a standard, the patient would be better informed of the risks associated with the drug, and the pharmaceutical companies would have less influence over the doctors' prescriptions. This would have a chilling effect on over-prescription and lead to overall consumer protection.

The CSR program should also protect those who are affected by the activities of the pharmaceutical companies but are not customers. Those affected by the activities of the company are recognized as stakeholders in the various models of CSR. This includes those who need drugs but do not have access to them either because the drugs are too expensive or because the needed treatments have become ineffective. This group includes the AIDS patients in Brazil and South America, the people who suffer from tropical diseases in Africa like sleep sickness, and the boy in India whose family could not afford the medicine to save him. The activities of the pharmaceutical companies affect these people because the pharmaceutical companies control the means to make them healthy and to save their lives. This profound effect on these non-customers' lives qualifies these people as affected by the activities of the pharmaceutical companies.

Non-customers are recognized as stakeholders to whom the pharmaceutical companies owe a duty, and thus companies should provide protection for these people. Coupling this recognition of non-customers as stakeholders

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with the human rights aspect of CSR truly protects these people. The human rights aspect of CSR includes the right to health and to medicine as established in both the UDHR and the WHO Health and Human Rights section.¹⁸¹ The recognition of the right to health and medicine as a human right will compel the pharmaceutical companies to protect those rights by providing treatment to those who need it. Thus, the pharmaceutical companies would, through CSR, protect human rights including the right to health and medicine. The human rights aspect of CSR coupled with the broad definition of a stakeholder, which includes non-customers, would effectively require the pharmaceutical companies to find a way to provide low cost, effective medicine to those who could not otherwise afford it.

B. CHALLENGES TO IMPLEMENTING CSR

The hurdle in the CSR debate is not whether the principles would work to cure the issues raised in Part I, as the discussion above shows that those issues would be effectively addressed through adopting the CSR principles. The hurdle is how to implement the principles. All of the CSR models discussed are voluntary. They suggest means of implementation, such as adopting codes of conduct or adhering to the laws of the host country, but they do not establish a way to mandate CSR in a country that does not recognize CSR in its corporate governance. It would be especially difficult to establish CSR as a mandatory law that applies to companies that have a powerful lobby and will fight the regulation.

The CSR rules that are applicable to the pharmaceutical companies must be mandatory. If they are voluntary, it is likely that the pharmaceutical companies will continue to value shareholder wealth over stakeholder health. As alluded to in describing HR 2900 and PDUFA, the pharmaceutical companies have an aversion to regulations. If CSR principles were promulgated, but voluntary, it seems likely that the pharmaceutical companies would not adopt a CSR program. Therefore, CSR must be mandatory.

¹⁸¹UDHR, *supra* note 116; World Health Organization, Health and Human Rights, <http://www.who.int/hhr/en/> (last visited Feb. 28, 2008).

CONCLUSION

Pharmaceutical company actions can be harmful to both their customers, by over-prescription, harmful side effects, and direct-to-consumer advertising, and to non-customers, by these people not having access to needed treatment or the treatment that they do have being ineffective. Models of CSR address these issues, and through a model of CSR that incorporates the principles discussed above, the harms of the pharmaceutical companies could be cured. The major challenge to implementing a CSR program to cure these issues is the powerful pharmaceutical lobby in Washington.

One potential way to encourage companies to adopt CSR would be for the United States Government to give corporate tax benefits for implementing CSR.¹⁸² Such a voluntary program would strike a balance between the shareholder-oriented approach and the stakeholder approach. The shareholders would benefit in that the corporation received favorable tax incentives. Stakeholders would benefit from the implementation of CSR. Though such a means of implementing CSR is not mandatory it would create motivation for pharmaceutical companies to implement CSR.

Added motivation for pharmaceutical companies to further increase CSR beyond what is adopted for tax breaks would then come from the market. If consumers began to buy products from the companies that implemented CSR, the market would drive further implementation of CSR.¹⁸³ Such increased popularity in the market would drive up sales and result in increased profits to benefit shareholders. Thus, CSR would not only benefit stakeholders, but it would also benefit shareholders.

²182. Similar tax incentives already exist for encouraging environmental friendly corporate practices. See *generally* 26 U.S.C. § 179D (2000) (deduction available for energy efficient commercial buildings); 26 U.S.C. § 48 (2000) (tax credit available for use of solar and other renewable energy sources).

³183. A study found that roughly 70% of the people polled found a company's public health impact important vs. about 40% who found it important for a company to deliver value to its shareholders. FLEISHMAN-HILLARD INT'L COMM'NS, RETHINKING CORPORATE SOCIAL RESPONSIBILITY 8-10 (2006), available at http://www.csrresults.com/FINAL_Full_Report.pdf