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A NEW DISEASE BORN EVERY MINUTE: THE MARKETING OF PATHOLOGY AND THE EXPLOITATION OF GENDER-BASED INSECURITIES AND SEXUALITY TO SELL DRUGS

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> You take the blue pill and the story ends. You wake in your bed and believe whatever you want to believe. You take the red pill and you stay in Wonderland and I show you how deep the rabbit-hole goes. Remember—all I am offering is the truth, nothing more. – The Matrix[1]

I. INTRODUCTION

The quote above from the science fiction movie *The Matrix,* refers to a scene where the character Morpheus whittles down the main character, Neo's, future life path and fate into nothing more than a choice between two pills.[2] While this certainly seems like little more than an element of a science fiction plot, it is in fact a parallel and symbolic representation of a trend in American culture where consumers have begun to accept the message that they can reshape, rework, and change their lives for the better if they have access to the "right" medication. With a change in guidelines for pharmaceutical direct-to-consumer advertising implemented in 1997 by the Food and Drug Administration (FDA)[3] and subsequent Supreme Court decisions such as *Thompson v. Western States Medical Center*,[4] protection of commercial speech under the First Amendment has trumped the government's interest in protecting consumers from the potential dangers of prescription pharmaceuticals. This has resulted in an amazing expansion of what is known as the "lifestyle drug" market.

Even the most naïve consumer today recognizes that the majority of branding, marketing, and advertising campaigns succeed through utilization of

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1 THE MATRIX (Warner Bros. 1999).

2 *Id.*

3 *See* 62 Fed. Reg. 43, 171 and 62 Fed. Reg. at 43, 172 (Aug. 12, 1972).

4 535 U.S. 357 (2002).

sexual desires and insecurities to sell products. Consumers are inundated almost constantly with messages that suggest the acquisition of the right products will make them look like or make them attractive to the models being used to sell them. Through billboards, radio, TV, signs on public transportation, and guerrilla marketing, these messages have become so ubiquitous that their sales pitch is barely registered by the conscious mind anymore. While ads clearly target both men and women, in an age where Paris Hilton gyrating on a car and dousing herself with a fire hose seems a logical way to sell cheeseburgers,[5] there is no question that the female body and over-sexualized libido are the favored vehicle by which advertisers capture their audiences.[6]

What is particularly disturbing about the proliferation of the lifestyle drug industry's direct-to-consumer advertising is not the standard subliminal use of sex in the ads themselves, but the manipulation of gender-based insecurities and sexuality to literally expand the market through the conversion of common human concerns into new pathologies. The strategy appears to be working extremely well. The global market for lifestyle drugs was assessed to be about $20 billion in 1999 and has been estimated to reach $29 billion by 2007.[7] But the expansion of the market for the pharmaceutical companies may be coming at a cost to U.S. citizens, both through increased demand for insurance coverage of new pills, and an increased dependency on pills to make individuals feel complete.[8] Various imperfections and discomforts that have been traditionally accepted as part of the life process are now being repackaged and billed as ailments which should be treated or cured through consumption of new products.[9]

In Part II, this Note will attempt to define the lifestyle drug market and use various examples of drugs to show how direct-to-consumer marketing has evolved and grown by promulgating sexual anxiety and repackaging typical gender-based insecurities as "pathology." Part III will discuss the history of the Food and Drug Administration's role in regulating pharmaceutical sales and marketing. This section will show how advocates within the pharmaceutical industry successfully lobbied for changes in the Federal Food, Drug, and Cosmetic Act (FDCA) opening

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[5] Carl's Jr., *at* http://www.carlsjr.com/news/11 (last visited Feb. 17, 2006).

[6] Tamara R. Piety, *"Merchants of Discontent": An Exploration of the Psychology of Advertising, Addiction and the Implications for Commercial Speech*, 25 SEATTLE U. L. REV. 377, 446 (2001) ("One of the most obvious social ills fueled or exacerbated by advertising and media is the objectification of women. Women's bodies are used to sell everything from cars to fishing lures.").

[7] Tim Atkinson, *Lifestyle Drug Market Booming*, NATURE MEDICINE 8, 909 (2002), *available at* http://www.nature.com/nm/journal/v8/n9/full/nm0902-909.html.

[8] R. Flower, *Lifestyle Drugs: Pharmacology and the Social Agenda*, TRENDS. PHARMACOL. SCI. Apr. 25(4), 182-5 (2004) ("The increasing availability of drugs that can be used to alter our appearance, our physical and mental capabilities or even our characters is changing the social fabric of our culture and poses a difficult challenge to our healthcare systems.").

[9] *Do We Need Lifestyle Drugs?*, BBC NEWS, Jan. 3, 2003, http://news.bbc.co.uk/1/hi/health/2624547.stm (last visited Feb. 16, 2006) ("The creation of these pathologies is resulting in ever narrowing definitions of what is 'normal' which help turn complaints of the healthy into conditions of the sick.").

both television airwaves and print mediums as acceptable formats for advancing the direct-to-consumer marketing of drugs. These changes resulted in a complete revolution in how drugs are perceived by the public and redefined the doctor/patient relationship. These changes also primed the public for the explosion of lifestyle drugs, which would shortly thereafter take over the marketplace.

Part IV explores the repercussions of cases such as *Thompson*, which have upheld the pharmaceutical industry's right to free commercial speech based on a strict scrutiny standard over the government's interest in protecting consumers from the potentially dangerous side-effects of prescription drugs. Part V will ask how the medical professional's role has evolved in the face of these changes in helping society draw the line between enhancement and treatment. Do physicians have a responsibility to take on a more paternalistic role as gatekeepers when it comes to granting access for drugs that are more a product of consumerism than actual medication?

Finally, in Part VI this Note will investigate some of the concerns that have been raised regarding direct-to-consumer marketing and who is raising these concerns. It will also look at the range of suggestions that have been made as to how direct-to-consumer advertising may be better regulated. The American Medical Association and various politicians—among others—have addressed concerns about the proliferation of drug advertisements and the affect they may be having on the collective psyche of the American people, as well as how they may be impacting the cost of healthcare.[10] Much resistance remains within the advertising and pharmaceutical companies towards any mandatory reform and thus the range of ideas on how potential problems should be addressed remains very broad. In light of the legal framework that has evolved over the last few decades, which offers a very high level protection to drug manufacturer's based on their right to commercial free speech under the First Amendment, it is important to ask what might be the most viable alternative to the current system and how can we implement it?

II. WHAT ARE LIFESTYLE DRUGS AND HOW DO WE DEFINE PATHOLOGIES?

The precise definition of "lifestyle drugs" is subject to debate but "they are generally defined as drugs taken to satisfy a non-medical or non-health related goal."[11] Perhaps some of the difficulty in defining this group of drugs more precisely is based on the fact that the term "drug" itself can often be imprecise in its application, its relevance depending frequently on the context of how something is actually being consumed.[12] For example, food and beverages that are consumed in

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[10] Rich Daley, *FDA Reviews Rules Governing Drug Ads for Consumers* 40 PSYCHIATRIC NEWS 1, Dec. 2, 2005, *available at* http://pn.psychiatryonline.org/cgi/content/full/40/23/1.

[11] Flower, *supra* note 8.

[12] Dictionary.LaborLawTalk.com, *available at* http://encyclopedia.laborlawtalk.com/Drug (last visited Feb. 16, 2006).

the normal course of the day as meals for sustenance would not be labeled "drugs." But, when the same food item is consumed in an attempt to illicit certain physiological or physiological effects, as is if often the case with food items like alcohol and caffeine, then the notions of that item shift from food to drug.[13] In other words, we may consume beer and coffee as food items but their role as depressant and stimulant respectively also make them drugs.

The lines are admittedly blurred between drugs that conform more strictly to the traditional notion of medication and those that fall into the category of "lifestyle drug." These ambiguities do little to hide the reality that there is a growing market in the pharmaceutical industry for drugs that have purposes extending beyond the treatment of life threatening disease.[14] With the consumer's increased accessibility to information through the "Big Pharma" funded media campaigns; a perception of increased availability of drugs—whether true or false—has been created.[15] This demystifies the drugs and in many ways alters the way society perceives the role of these drugs in their lives, impacting both the individual and the social constructs of society in general.[16] Not surprisingly the "symptoms" most of these lifestyle drugs purport to cure, almost universally involve issues relating to body image, sexual insecurities, and the glorification of youth.[17]

A. "Curing" Obesity, Baldness, and Wrinkles

Probably one of the earliest accepted uses of drugs for cosmetic purposes was the consumption of diet pills and other drugs in order to promote weight loss.[18] Controlled substances such as amphetamines were widely prescribed in the 1960s as diet pills until their potential to cause habit-forming addictions in users was recognized and physicians began prescribing them more cautiously by the mid 1970s.[19] Over-the-counter sales of appetite suppressants and ephedrine—an

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[13] *Id.*

[14] *See* Flower, *supra* note 8, at 182.

[15] *Id.*

[16] *Id.*

[17] Ray Moynihan & Alan Cassels, *A Disease for Every Pill*, THE NATION, Oct. 17, 2005, *available at* http://www.thenation.com/doc/20051017/moynihan

> Two doctors from Dartmouth Medical School recently analyzed seventy drug company ads in ten popular magazines. They found that almost half tried to encourage consumers to consider medical causes for their common experiences, most often urging them to consult a physician. The ads targeted aspects of ordinary life including sneezing, hair loss and being overweight—things many people could clearly manage without seeing a doctor—and portrayed them as though they were part of a medical condition.

[18] HeartCenterOnline.com, Diet Pills: Summary, http://heart.healthcentersonline.com/weightobesity/dietpills.cfm (last visited Feb. 12, 2006) ("Various forms of diet pills have been used since the 1960's and a number of them are no longer used due to potential health risks.").

[19] HeartCenterOnline.com, History of Diet Pills, http://heart.healthcentersonline.com/weightobesity/dietpills4.cfm (last visited Feb. 12, 2006).

amphetamine-like drug—based pills remained common practice even after doctors began prescribing amphetamines with more caution.[20] However, not until the 1997 changes to the FDA guidelines did prescription-based diet pills begin to have the consumer audience they have today.[21] Now consumers possess greater awareness as to what drugs can help them lose weight and can go to the doctor to specifically request them by name; in many cases obtaining them without a comprehensive physical examination.[22]

The two most notable diet pills to hit the market after 1997 were Redux and Xenical.[23] Redux was actually a derivative of fenfluramine, the main ingredient in the fen phen diet pill, which became extremely popular in the 1990s despite knowledge that it often caused pulmonary hypertension that could become so serious as to cause death.[24] However, the drug was approved despite the risk because at the time the obesity "epidemic" was considered to be a much greater threat to the general public than potential fatalities from the drug due to the hypertension it caused. The drug became readily available not just to those who met the medical definition of obese, but also to those seeking to lose weight for simple cosmetic reasons.[25] As expected, hypertension complications occurred, in addition to another unanticipated side effect called cardiac valvulopathy, and it had to be taken off the market in its first year of distribution.[26]

Today the weight-loss business has created a market estimated to be valued at $30 billion.[27] This is a somewhat confusing field to navigate, because the passage of the Dietary Supplement Health and Education Act (DSHEA)[28] in 1994 created a new regulatory framework in which certain dietary supplements fell outside the realm of the FDA. Specifically, the FDA monitors only diet "drugs," so after the implementation of the DSHEA, the dietary supplements were beyond the reach of the FDA and were instead classified as food supplements or over the

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[20] *Id.*

[21] Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD DRUG L.J. 489, 497 (1999) ("The 'draft guidance' lead to more television advertising . . . DTC advertising grew to $579,000,00 in 1998.").

[22] Apryl A. Ference, *Rushing to Judgment on Fen-Phen and Redux: Were the FDA, Drug Manufacturers, and Doctors Too Quick to Respond to American's Infatuation with a Cure-All Diet Pill for Weight Loss?*, 9 ALB. L.J. SCI & TECH 77, 85 (1998) ("Some physicians prescribed the drug over the Internet or to patients they had not met. Other patients received the diet pills through centers run by nurses, with the doctor seen only on videotape.").

[23] TheSite.org, Diet Pills, http://www.thesite.org/healthandwellbeing/fitnessanddiet/healthyeating/dietpills (last visited Feb. 16, 2006).

[24] Jerry Avorn, M.D., *FDA Standards – Good Enough for Government Work?*, 353 NEW ENG. J. MED. 969, 972 (2005).

[25] *Id.*

[26] Avorn, *supra* note 24.

[27] Jodie Sopher, *Weight-Loss Advertising Too Good to Be True: Are Manufacturers or the Media to Blame?*, 22 CARDOZO ARTS & ENT L.J. 933, 934 (2005).

[28] *Id.* at 938.

counter products.[29] Even though the DSHEA has separated "supplements" from "drugs" for the purpose of government regulation of the product, the Federal Trade Commission (FTC) still has the final say on the validity of advertising for both types of product.[30] Some might argue that given the potentially dangerous side effects of even these over the counter supplements, perhaps they should be more highly regulated and their sales and approval process should remain under the scrutiny of the FDA. Perhaps there really is a difference in safety that should warrant different tiers of regulation for different classes of substances. The public arguably has much more cause for concern regarding the side effects of prescription drugs like Redux then it does regarding over the counter supplements, which actually are safer. If that is the case, and there truly are different levels of safety between the two groups of diet aids, then why are both groups being advertised in magazines and on television in a manner that makes it almost impossible for the public to differentiate between the two?

The way these two categories are lumped together perfectly illustrates how everyday consumer goods and the concept of actual drugs have been combined in the minds of consumers, particularly when it comes to weight loss and the cosmetic industry.[31] By granting increased accessibility to the availability of information regarding drugs, direct-to-consumer marketing has in many ways stripped drugs of their traditional association with medication, making them more accessible to patients. Patients who experience advertisements regarding the drugs first hand, instead of through consultation with a doctor, may tend to approach them with less caution. After all, the ads suggest that weight-loss drugs do the same thing as over-the-counter ones, they just do it better.

Efforts to treat baldness with prescription drugs demonstrate another area where drug companies have found that insecurities about appearance could have a very profitable influence on drug sales.[32] In fact, baldness treatments arose inadvertently. Rogaine, the first available drug on the market to treat baldness, was initially created by Upjohn–now a subsidiary of Pfizer–to treat hypertension.[33]

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[29] *Id.* at 939-940.

[30] *Id.* at 938.

[31] GREG CRITSER, GENERATION RX: HOW PRESCRIPTION DRUGS ARE ALTERING AMERICAN LIVES, MINDS, AND BODIES 52 (2005).

> The whole thing [DTC] was a bit much for Irv Lerner, the head of Roche. 'I thought it was a huge mistake then and I think the same now. It whittles down the power of the physician and, frankly it hurts the image of the industry by lining pharma up with beer and tobacco and cosmetics.'

Id.

[32] Pines, *supra* note 21, at 494 ("The classic example of the first type of commercial was for Upjohn's hair restorer Rogaine. Commercials showed men with male-pattern baldness, and urged them to see their physicians or obtain further information by calling an 800 number.").

[33] The Hair Transplant Network, http://www.hairtransplantnetwork.com/Hair-Loss-Treatments/rogaine.asp (last visited Feb. 17, 2006) (Minoxidil, Rogaine's active ingredient, was originally created as a drug for treating hypertension (high blood pressure). It was then discovered that one of its side effects was growing hair. Minoxidil was then tested for use as a topical application

This mistake turned out to be a very profitable one, however, as Upjohn quickly began to re-brand the drug and pump advertising dollars into this product.[34] Anecdotally, it is interesting to note that it was actually a rather simple problem posed by Rogaine when it hit the market in the late 1980s, which highlighted the potential value of direct-to-consumer marketing to executives at Upjohn, serving as a catalyst for them to consider the prospect of such marketing in earnest.[35] When doctors prescribed Rogaine they simply reiterated the instructions to the patient as they were literally written on the package information provided by Upjohn.[36] The instructions stated the cream should be applied first thing in the morning.[37] Many of the male consumers took this literally, applying it as soon as they woke up and then proceeded to shower, diluting the medication and rendering it ineffective.[38] This problem inspired Dr. Theodore Cooper, the head of Upjohn at the time, to contact Jim Sammons, the Executive Vice-President of the AMA for a meeting along with the AMA's Vice-President of Marketing Wendy Borow-Johnson, to discuss some of the challenges the industry faced by not being able to provide information freely to consumers.[39] At the time the AMA endorsed the ban on all direct-to-consumer marketing, but it was during this meeting that executives began to see some of the true potential value in speaking directly to customers. As Critser explains, Borow-Johnson began to argue, "Why not DTC drug ads?"[40]

Despite the initial problems with its application, Rogaine was eventually accepted on the market as one of the best, if not the only, option for men with hair loss. In 1996, Minoxidil, the generic version of Rogaine, became available without prescription and sales are estimated today at $162 million per year.[41]

Similar to the inadvertent discovery that Rogaine could be used as a treatment for baldness, Propecia, a more recently available prescription baldness medication, was also initially intended for another use— the treatment of enlarged prostates. However, when it was discovered that it also helped treat hair loss, it was soon branded and marketed for this purpose instead.[42]

Botox also was a "mistake." It was developed in the 1970s and purchased by Allergan in the 1980's to help treat eye spasms.[43] In 2002, however, the FDA

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for re-growing hair. The results were sufficiently impressive that the FDA approved it as a treatment for hair loss.).

34 Pines, *supra* note 21, at 494.

35 CRITSER, *supra* note 31, at 45.

36 *Id.*

37 *Id.*

38 *Id.*

39 *Id.*

40 CRITSER, *supra* note 31, at 46. (DTC is an abbreviation for to direct-to-consumer.).

41 *See* Dean Thomas Scow, Robert S. Nolte & Allen F. Shaughnessy, *Medical Treatments for Balding Men*, AMERICAN FAMILY PHYSICIAN, 2189 (1999).

42 New Hair Institute, http://www.newhair.com/treatment/other-medications.asp (last visited Feb. 17, 2006) (Finasteride, (the active ingredient in Propecia), was originally marketed for use in prostate enlargement in men over 50.).

43 Whole Health MD,

approved it for cosmetic use once it was discovered that if injected into wrinkles the drug eliminated them.[44] This was yet another example of how marketing, media and rebranding have allowed drug companies to capitalize on unpredicted side effects of a drug that they may have initially pumped significant research and development dollars into for another purpose. But have these drugs actually filled a void, or simply magnified the concept of these cosmetic problems in the minds of the public through their marketing?

B. Viagra

One of the most widely known and discussed lifestyle drugs is Viagra®. Initially developed to treat angina, it was approved as a treatment for impotence in men and introduced to consumers as such in 1998.[45] The introduction of Viagra to the market created a storm of unprecedented media hype as consumer interest in this little blue pill soared.[46] Health industry pundits and regulators alike speculated how demand for this drug might impact various aspects of the healthcare system.[47] It seems much of the curiosity about this drug was stimulated by the mixed message it seemed to create. The "drug" was after all prescribed for the legitimate medical condition erectile dysfunction (ED) but it also was gaining a mystique for its ability to enhance sexual performance even in the healthy.[48]

In fact, this image of Viagra as a "recreational" or "party" drug is one that Pfizer itself has arguably tried to perpetuate, particularly in the last few years as the initial demand for the new drug has leveled off.[49] In a recent press release issued by the AIDS Healthcare Foundation, the organization criticized Pfizer for employing a "reckless" and "irresponsible" ad campaign, and accusing them of purposely promoting the image of Viagra as a party drug.[50] The AIDS Healthcare

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http://www.wholehealthmd.com/refshelf/substances_view/1,1525,10170,00.html (last visited Feb. 17, 2006).

[44] *Id.* (First studied and put to use in the treatment of eye disorders, botulinum toxin type A's dominant use is currently for the temporary reduction of wrinkles.)

[45] Kim H. Finley, *Life, Liberty and the Pursuit of Viagra? Demand for "Lifestyle" Drugs Raises Legal and Public Policy Issues*, 28 CAP. U. L. REV. 837, 844 (2000).

[46] Rudolf Klein and Heidrun Sturm, *Viagra: A Success Story for Rationing?*, HEALTH AFFAIRS, Nov. 25, 2002, http://www.medscape.com/viewarticle/445003

[47] *Id.*

[48] *Id.* ("[I]t was difficult to draw a clear line between prescribing Viagra® to treat a defined medical condition or to enhance normal sexual performance, a difficulty compounded by the fact that ED is a self-reported condition and that the notion of normal sexual performance is itself ambiguous."); *see also* Weber et al., *The New Era of Lifestyle Drugs*, BUSINESSWEEK, May 11, 1998, *available at* http://www.businessweek.com/1998/19/topstory.htm (last visited Sept. 22, 2005) ("Viagra is special. It's the epitome of a brand new market.").

[49] Aaron Smith, *Lilly's Sex Drug Sales Jump in 2005*, CNNMONEY.COM, (2006), http://money.cnn.com/2006/01/20/news/companies/cialis/ ("While Cialis sales ramped up in 2005, Viagra sales wound down. Viagra sales declined 2 percent to $1.6 billion in 2005, said Pfizer in its earnings report on Thursday. Viagra sales dropped 8 percent in the fourth quarter to $430 million. Pfizer attributed the sales decline to 'slower growth in the overall erectile-dysfunction market and competition from other products.'").

[50] *Pfizer's Super Bowl Viagra Ad: 'Reckless and Irresponsible,' Says AHF*, AIDS HEALTHCARE

Foundation drew attention to the timing of Pfizer's placement of certain Viagra ads, which surfaced right before holidays known for binge drinking, over indulgence and excess such as the Super Bowl and New Year's Eve.[51] The group was particularly concerned with the tagline on the ads, which read "ED is an issue with half of all men over 40."[52] It pointed out how using the word "issue" instead of referring to ED as a "medical condition" created an ambiguity designed to manipulate male consumers based on sexual insecurities.[53]

These criticisms of Pfizer highlight exactly how powerful direct-to-consumer advertising can be when shaping perceptions of drugs in the consumer psyche. By blurring lines between treatment and enhancement, and fabricating demand based on gender-based insecurities instead of simply providing the relevant information, these types of ad campaigns have refashioned lifestyle drugs into consumer goods rather than medication in the eyes of the public.

The success of Viagra and society's quickness to embrace it as both a cure-all for sexual dysfunction and a recreational libido enhancer have led to a campaign by pharmaceutical companies to define and develop the concept of female sexual dysfunction as an illness as well.[54] Perhaps, awakened by reports that women were also experimenting with Viagra in an effort to achieve the same heightened sexual sensations promised to their male counterparts, companies such as Pfizer realized an entirely untapped market was equally anxious for a magic pill to fix its sex lives.[55]

In their rush for a piece of the female market, however, pharmaceutical companies have opened themselves up to some valid criticisms. It is the "discovery" of potential cures for this particular "pathology" that has raised the question of whether the industry has gone too far in pushing drugs to solve everyday problems.[56] Female sexual dysfunction offers one of the clearest examples of an area where some of the physiological deficiencies society is trying to cure with pills are actually rooted more strongly in emotional and cultural issues then they are in medicine.[57] A legitimate concern about how couples may turn to a drug to solve sexual difficulties that may ultimately be rooted in individual psychological

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FOUNDATION PRESS RELEASE, Feb. 6, 2006, http://www.aidshealth.org/02-news/02-3-prls-content/02-06-06a.html (last visited Feb. 16, 2006) ("Pfizer continues to employ a reckless and irresponsible marketing that encourages the use of Viagra as a 'party drug.'").

[51] *Id.*

[52] *Id.*

[53] *Id.* ("The use of the word 'issue' seems designed to capitalize on men's fears, while giving Pfizer wide latitude to imply as many as half of all men over 40 are afflicted with the medical condition, Erectile Dysfunction and could benefit from their problem.").

[54] Moynihan & Cassel, *supra* note 17.

[55] *See* Finley, *supra* note 45, at 845 ("Women too are already experimenting with the drug [Viagra], although the FDA has not approved its use by females.") A doctor reported he knew of several women who had taken their partners pills—all reported increased sensation in the vagina and more intense orgasms. *Id.*

[56] Sarah Boseley, *Drug Firms "Invented" Female Sexual Problem*, THE GUARDIAN, Jan. 3, 2003, available at http://www.guardian.co.uk/uk_news/story/0,3604,867828,00.html (last visited Sept. 22, 2006).

[57] *Id.*

problems or relationship issues suggests an ugly attempt by drug companies to perpetuate a false idea about what sexual dysfunction in women really is.[58]

In short, the Viagra phenomenon and the parallel "diseasification" of female sexual dysfunction represent the clearest example of how wrapping sexual insecurities into neat marketing packages have resulted in large profits for Big Pharma. While there is undoubtedly a very genuine concern regarding the medical condition of ED, it is not far-fetched to speculate that the forces driving the sales of these drugs are rooted as much in the fears of inadequacy in the healthy as in the population of individuals actually afflicted with ED.

C. Shyness and Other Mental Disorders as Disease

Other drugs such as Zoloft and Paxil CR extend beyond treating cosmetic and physical complaints.[59] They represent another financial boom for the pharmaceutical companies that peddle these pills directly to consumers in print and television ads promising to fix complaints that have traditionally fallen into the realm of psychology.[60] Paxil CR is in fact a new one-dose-a-day version of Paxil introduced to extend sales after the loss of the initial patent.[61] New names such as "anxiety disorder," "acute shyness," and "social phobia" have been coined to recognize certain behaviors or emotions as pathological that historically had been acceptable as common human traits.[62] Roger Brownsword refers to a report written by the Neffield Council of Bioethics when quite eloquently summing up this new trend that tends to "medicalise" conditions that up until this point of history, may

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[58] *Id.* John Bancroft, director of the Kinsey Institute stated, "The danger of portraying sexual difficulties as a dysfunction is that it is likely to encourage doctors to prescribe drugs to change sexual function, when the attention should be paid to other aspects of the woman's life."

[59] Zoloft Product Website, http://www.zoloft.com/zoloft/zoloft.portal?_nfpb=true&_pageLabel=default_home (last visited Feb. 16, 2006) ("Zoloft is FDA approved to treat depression, social anxiety disorder, posttraumatic stress disorder (PTSD), panic disorder, obsessive-compulsive disorder (OCD), and premenstrual dysphoric disorder (PMDD) in adults over age 18. It is also approved for OCD in children and adolescents age 6-17 years."); *see also* Paxil Product Website, www.paxil.com (last visited Feb. 17, 2006) ("Paxil CR treats social anxiety disorder, depression and panic disorder. Paxil CR has been proven effective in the treatment of social anxiety disorder, depression, and panic disorder. Paxil CR helps you get your balance back and get back to being you.").

[60] Pfizer Inc. First Quarter 2005 Performance Report, http://www.pfizer.com/pfizer/are/investors_releases/2005pr/mn_2005_0419.jsp (last visited Feb. 16, 2006) (Worldwide Zoloft sales reached $845 million, ahead four percent compared to the same period in 2004. It has been the number-one prescribed antidepressant in the U.S. since 2000.).

[61] *See* Steve Goldstein, *GlaxoSmithKline Earnings Rise 45%*, Marketwatch, Feb. 8, 2006, http://www.marketwatch.com/News/Story/Story.aspx (last visited Feb. 16, 2006); *see also*, Rich Duprey, *Will Acquisitions Patch Merck's Pipeline?*, The Motley Fool.com, Jan. 26, 2006, http://www.fool.com/News/mft/2006/mft06012614.htm (last visited Feb. 16, 2006) (Paxil CR was in fact created to stave off competition from generics which resulted in loss of sales for regular Paxil when the patent ran out.).

[62] Roger Brownsword, *Causes for Concern and Causes of Action: A Comment on "Pushing Drugs,"* 42 WASHBURN L.J. 601, 603 (2003).

have been viewed negatively but still fell in the purview of what society considered just normal aspects of day-to-day existence.[63]

Again the overlying phenomena in the direct-to-consumer marketing of these types of drugs are marketing campaigns that manipulate consumers' fears that they are not "normal" and thus need a pill to fix their "pathologies." While disorders such as shyness and anxiety are not patently gender-based or sexual in nature, it is valid to consider how instilling sentiments of inadequacy about one's ability to socialize could indirectly become linked to feelings of sexual inadequacy. It is not too difficult to imagine targeted consumers visualizing a quick-fix that eradicates a barrier between themselves and the rest of the normal world: a barrier that may be the reason they haven't met the "right" man, the "right" woman, or made the "right" friends.[64]

A drug called Sarafem is on the other hand very gender specific.[65] It is marketed to young females to "cure" a recently "discovered" medical condition called premenstrual dysphoric disorder (PMDD).[66] The history of this drug's development and the marketing campaign behind it are perhaps the most pointed example of ads that sell pathology as much as the drug itself in an attempt to morph a common female life experience into a sickness.

In the late 1990s Eli Lilly's antidepressant Prozac was about to lose its patent, opening the market to generic competitors.[67] The company realized, however, that if it could get the drug approved in order to treat an entirely different or "new" disease then it could counterbalance this attack from generic competitors by boosting sales of the drug in a whole new area.[68] In 1998, Lilly funded a "roundtable" that concluded PMDD existed and there was enough evidence to support the use of Prozac to treat it.[69] Once the drug was approved to treat PMDD, Pfizer initiated an awareness campaign to inform the general public about the

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[63] *Id.*

> [A]s the Council remarks, "the producers of new 'anti-shyness' drugs such as Paxil and Luvox, have been accused of applying to normal behavior, interventions developed for pathological traits. What is more, individuals who think that they might have a General Anxiety Disorder or Social Anxiety Disorder can take an online self-test which sets a suitably low threshold for professional advice to be recommended . . . Before you can say, 'Please write me a prescription,' we find that once normal anxieties are re-classified as pathological and with the commercial and social pressure, medical intervention is advised."

Id.

[64] Editorial, *Happier, Hornier, Hairier,* NATURE BIOTECHNOLOGY 21, 1 (2003) ("Increasingly, companies are persuading patients that nature has cursed them with a new disease that only their drugs can cure. Some have called this the medicalization of life. *The British Medical Journal* has called it 'disease mongering.'").

[65] *See* WanerChilcott.com, http://www.warnerchilcott.com/products/sarafem.php (last visited Feb. 17, 2006).

[66] *Id.*

[67] Moynihan & Cassels, *supra* note 17.

[68] *Id.*

[69] *Id.*

existence of this "disease" and made several changes to the Prozac packaging and look to re-brand the pill with women specifically in mind.[70]

Many have criticized Lilly's commercials for Sarafem as an effort to "sell a disease and not the drug," and complain that there is no regulatory check to claims made about the disease for which the drug is being advertised.[71] Critics have noted with particular concern that Lilly has conspicuously geared its marketing efforts to young women by placing many of its ads in magazines commonly read by teenagers.[72] Targeting such a vulnerable group at a time when they are only just beginning to understand their bodies and the various implications of their menstrual cycle might be interpreted as an attempt on the part of Lilly to take advantage of the naïveté of this particular consumer group.[73] After all, it might be easier to convince this group that certain symptoms are pathological since they have not yet had a chance to become accustomed to them as a normal part of womanhood.[74]

The story of Serafem is an extreme but common example of how the drug companies aim to get more return on their research dollars by trying to find multiple uses for one drug.[75] Unfortunately, many of these "pathologies" which manufacturers claim the drug can cure could be interpreted as a mere exaggeration of symptoms that are a normal part of life. As with a large portion of advertising in general, the key to selling the idea of the pathology and creating demand for it is often manipulating consumer insecurities about self.

III. THE BIRTH OF BROADCAST DIRECT-TO-CONSUMER ADVERTISING OF DRUGS: HOW THE FDA CHANGED THE PLAYING FIELD AND EXPANDED THE LIFESTYLE DRUG MARKET

In 1995, the FDA sent out a notice to individuals in various healthcare professions, as well as to consumers and special interest groups, in order to collect

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[70] *Id.* "The subsequent campaign to 'build awareness for both the condition and the drug' included changing the name of Prozac to Sarafem, changing the color of pill to lavender, and promoting it with 'images of sunflowers and smart women.' *Id.* "Lilly created a brand that better aligned with the personality of the condition for a hand-in-glove fit." Moynihan & Cassels, *supra* note 17 (quoting Vince Parry, marketing specialist).

[71] Moynihan & Cassell, *supra* note 17 ("While the advertising claims made about the benefits and risks of medicines are regulated by law—albeit very loosely—claims about disease remain a virtual free-for-all.").

[72] *Id.*

[73] *Id.*

[74] *Id.* ("[Targeting young women] . . . seems designed to make younger women feel there is something wrong with the normal emotional fluctuations they experience in the lead up to their monthly period . . . the ads paint a shallow picture of what it means to be a young woman.").

[75] CRITSER, *supra* note 31, at 71-72 (discussing the ad campaign to "inform" about the disease known as gastroesophaegeal reflux disease (GERD) when it found that Zantac, originally marketed to treat ulcers was effective on GERD. Critser explains, "The answer was to medicalize, and by extension popularize, GERD . . . [t]he tactic worked so well, sending Zantac sales into the heavens, that it has since become a textbook example of what the industry now routinely called "branding a condition.").

data regarding their views on the state of direct-to-consumer marketing of drugs.[76]

At that time of the request, direct-to-consumer marketing was a nascent and growing concept within the pharmaceutical industry, but was not yet the industry norm.[77] The FDA still required the inclusion of very detailed information in broadcast ads giving specific information on both the benefits and risks of the medication, a practice that was very prohibitive to making effective ads.[78] Among the information manufacturers were required to include were directions for use and the purpose, efficacy, and risks of the drug itself.[79] This imposed a very difficult burden on advertisers because in order to meet the specification they generally had to display the equivalent of the entire package insert that they were required to include in the product itself.[80] These are generally pages long and contain very scientific and technical language.[81] It was certainly not a requirement that was easy to satisfy in a thirty second on-air spot or on a single magazine page.

At the time of this request for information, the FDA sought to address a wide range of concerns about the current state of direct-to-consumer advertising that fell on very disparate sides of the spectrum.[82] On the one hand was criticism that the regulations were not strict enough because consumers lacked the requisite knowledge needed to fully understand their medical conditions or the drugs that might be used to treat them.[83] Another concern focused on the inherently misleading nature of advertising and how this could interfere with the consumers' ability to process the information they were receiving.[84] Still others worried that ads directed at consumers could damage the doctor/patient relationship, increase demand for certain drugs, drive prices upward, and also lead to increased drug abuse.[85]

On the flip side lay the groups who believed consumer-directed prescription drug advertising should not be regulated at all.[86] They argued that until the FDA

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[76] Direct-to-Consumer Promotion, Public Hearing, 60 Fed. Reg. 42581 (Aug. 16, 1995). (The FDA set out to "solicit information from, and the views of interested persons, including health care professionals, scientists, professional groups, and consumers, on the issues and concerns relating to the promotion of prescription drugs directly to consumers through print, broadcast, and other types of media.").

[77] Pines, *supra* note 21, at 491 ("The traditional marketing program by pharmaceutical companies consisted of: 1) a strong sales force that sought to 'educate' doctors about the company's latest offerings; 2) advertising in medical journals; and 3) the provision to physicians, either through the sales force or by mail, of information about a company's drugs.").

[78] *Id.* at 493 ("As interpreted by FDA, the requirement for 'adequate provision' essentially made it impossible for television advertisements.").

[79] Direct-to-Consumer Promotion, Public Hearing, 60 Fed. Reg. 42581, (Aug. 16, 1995) *citing* 21 U.S.C.§ 352(n) (2000).

[80] Elizabeth C. Melby, *The Psychological Manipulation of the Consumer–Patient Population Through Direct-to-Consumer Prescription Drug Advertising*, 5 SCHOLAR 325, 332-333 (2003).

[81] *Id.*

[82] Direct-to-Consumer Promotion, Public Hearing, 60 Fed. Reg. 42581 (Aug. 16, 1995).

[83] *Id.*

[84] *Id.*

[85] *Id.*

[86] *Id.*

addressed the overly burdensome restrictions in place, prescription drug advertisements directed to the general public should be free from the hindrance of all advertising regulations.[87] The ideologues that supported loosening restrictions argued that the current regulatory scheme governing pharmaceutical ads violated the manufacturers' First Amendment right to free commercial speech.[88] As a result of these hearings, the FDA did not go so far as to remove regulations, but it did make some very significant concessions, which swung the pendulum in favor of the manufacturers and those who supported unfettered direct-to-consumer advertising of drugs.[89] With the changes to the Food, Drug and Cosmetic Act as of 1997,[90] sponsors of broadcast advertisements were allowed to forgo the "brief summary" section that they were previously required to air and were instead permitted to make "adequate provisions" for the labeling to be dispersed through another outlet.[91] For example, an advertiser could simply air an 800 number and direct customers to call for more information about the product.[92] This change in section 202.1(e)(1) of the Food, Drug and Cosmetic Act came to be known as the "adequate provision" clause.[93] The FDA recognized that the previous "brief summary" requirement was extremely burdensome on pharmaceutical advertisers, essentially robbing them of the ability to make effective commercials that could fit in the time and space restrictions imposed by electronic media.[94]

This small change to the legislation opened the floodgates for the direct-to-consumer broadcast advertisement of drugs.[95] Today, the value of the ad market itself relating to these campaigns is estimated at $4 billion.[96] Currently, the U.S.

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[87] Public Hearing, *supra* note 82.

[88] Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43171 (Aug. 12, 1997).

[89] Food, Drug and Cosmetic Act, 21 U.S.C.§ 352(n) (2000).

[90] 21 U.S.C. Ch. 9 (2000).

[91] Draft Guidance, *supra* note 88.

[92] Pines, *supra* note 21, at 494

> Because such advertising could not be product specific, drug companies used two other kinds of advertisements. One was a television version of a help-seeking advertisement in which disease symptoms were described with the mention of any specific product . . . . The classic example of the first type of commercial was for Upjohn's hair-restorer Rogaine. Commercials showed men with male pattern baldness and urged them to see their physicians or obtain further information by calling an 800 number.

[93] 21 U.S.C. 202.1(e)(1) (2000).

[94] *Id.*

[95] Pines, *supra* note 21, at 497 ("The 'draft guidance' lead to more television advertising. Drug companies, on issuance of the draft guidance, immediately redirected some of their advertising spending from print to television. In subsequent budget cycles, they directed most of the increased spending to television. DTC advertising on television grew to $579,000,000 in 1998.").

[96] Center For Media and Democracy, http://www.sourcewatch.org/index.php?title=Direct-to-consumer_advertising (last visited Feb. 16, 2006).

> The Food and Drug Administration will hold a public hearing on direct-to-consumer (DTC) drug advertising, 'more than two years after the last public hearing . . . failed to produce any guidelines to regulate the $4 billion ad category,' notes *AdAge*. In announcing the November 1 and 2, 2005 meeting in Washington, DC, the FDA said it 'believes the agency, the industry and other members of the public now have enough

and New Zealand are the only countries that permit this practice for the advertising of drugs.[97]

The rapid speeds with which the airwaves have become inundated with these advertisements and their effect on the doctor/patient relationship have seemingly resulted in a sense of entitlement to drugs if and when a patient desires them. The patient is no longer dependent on the physician as his or her sole source of information regarding treatment options or available drugs. In fact, the patient now has even been given the impression—perhaps falsely—that he or she may even be capable of diagnosing him or herself with certain diseases and may now be the one to suggest a certain drug to the doctor instead of the other way around.[98] The mysterious world of medicine in which the medical professionals held all the secrets, all of sudden seemed accessible to the masses. This phenomenon created a power shift between patient and doctor, arguably resulting in more autonomy for the patient, or on the flip side, limiting the doctor in her or his ability to effectively do her or his job.[99]

IV. *THOMPSON V. WESTERN MEDICAL CENTER*: THE BATTLE FOR GOVERNMENT INTEREST IN REGULATING DRUG ADVERTISING VS. THE FIRST AMENDMENT RIGHT TO FREE COMMERCIAL SPEECH

Despite concerns over the development of an on-demand drug culture and an ever increasing awareness that we seem to be trying to medicate our bodies, our personalities, and our sex drives to some abstract ideal of perfection, the Supreme Court issued a decision in 2002 that reaffirmed the pharmaceutical industry's right to advertise freely. The Supreme Court in *Thompson* stated that any interests the government may have in regulating the pharmaceutical industry must pass strict scrutiny if the regulating activity would interfere with the pharmaceutical industry's right to free commercial speech under the First Amendment.[99]

The case itself does not deal specifically with advertising in the lifestyle drug market but rather with soliciting and advertising in an even smaller and more specialized practice within the pharmaceutical industry known as drug compounding.[100] Drug compounding is a practice in which a pharmacist makes

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> experience with DTC promotion to understand what regulatory issues may need to be addressed.'

Id.

[97] *Id.*

[98] Pines, *supra* note 21, at 513 ("In addition, companies continue to look for methods to evaluate whether a drug is suitable for DTC advertising and promotion. Among the questions asked are: Is the kind of drug that patient sill call to the physician's attention?").

[99] Melby, *supra* note 80, at 331 (quoting an American Medical Association delegate saying, "The big issue is medication by demand vs. [sic] medication by need . . . the more knowledge the patient gets, the better this is [for drug companies]. Ob the other hand, the advertising 'de-professionalizes' the profession [of medicine] to some degree.").

[99] Thompson v. Western States Med. Center, 535 U.S. 357, 374 (2002).

[100] *Thompson*, 535 U.S. at 360-361.

small alterations to a commercial drug that does not change its efficacy or potency but addresses a special need in a small group of patients.[101] They are in essence creating a new drug that is not available commercially.[102] The implications of the Supreme Court weighing the right to free commercial speech so heavily over the government's interest in regulating how pharmacists advertise to the public on a large-scale basis would be felt significantly in the future as consumer interest groups began to speak out against the marketing of lifestyle drugs. Compounding is a very small segment of the entire pharmaceutical market and a relatively esoteric practice that applies only to a small portion of the patient population.[103] But the reasoning behind the Supreme Court's holding could easily be applied to much more widespread practices. It is a powerful weapon, which the pharmaceutical industry could use to challenge any future attempt by the federal government to rein in some of the freedom the industry was granted in 1997.

The respondents in *Thompson* were made up of a group of pharmacies, which specialized in the practice of compounding drugs.[104] They sued in an attempt to enjoin enforcement of the subsections of the Food and Drug and Drug Administration Modernization Act of 1997 (FDAMA)[105] dealing with advertising and solicitation.[106] They argued that those provisions violated the First Amendment's free speech guarantee.[107] Both the district and the appellate courts ruled that section 503(a) of FDAMA, regarding advertisement and promotion, was an unconstitutional restriction on commercial speech.[108]

In affirming this ruling, the Supreme Court relied heavily on *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, the first case in which it explicitly held that commercial speech fell under the umbrella of the First Amendment.[109] The majority in *Virginia Board of Pharmacy* vocalized a strong government interest in the protection of commercial speech, stating the public had a right to make informed decisions based on the information that commercial entities could provide.[110] It highlighted the importance of consumer access to this information as an integral part of the market economy.[111]

The Supreme Court outlined a four-prong test set out by an earlier case,

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[101] *Id.* at 361 ("Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product.").

[102] *Id.*

[103] *Id.*

[104] *Id.* at 360.

[105] 21 U.S.C. § 353(a) (2000).

[106] *Thompson*, 535 U.S. at 360.

[107] *Id.*

[108] *Id.*

[109] *Id.* at 366.

[110] *Id.* at 366-367 (citing Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 765 (1976)).

[111] *Thompson*, 535 U.S. at 370.

Central Hudson Gas and Electric Corp. v. Public Service Commission, for determining whether certain types of regulation on commercial speech were permissible under the Constitution.[112] The test, which the Court applied in *Thompson*, dictated that unless the commercial speech in question is deemed misleading, it is protected under the First Amendment and may not be regulated by the state unless the reason the state purports for the restriction is tied "to a 'substantial' governmental interest," and further that the regulation it has implemented "'directly advances' that interest," in a way that it "is 'not more extensive than necessary' to serve the interest."[113] This test in essence raises the level of protection for commercial speech to the same level given to noncommercial speech under the First Amendment.[114]

Because the government did not argue in *Thompson* that the advertising content for the compound drugs was misleading, it had to prove the other three prongs of the *Central Hudson* test.[115] The *Thompson* Court held that the substantial interests asserted by the government were not significant enough to support the passage of legislation restricting the constitutional right of free speech.[116] Most notably the Court stated that the government's interest in regulating advertising could be met in the alternative by either restricting sales, or putting tighter restrictions on the FDA approval process of such drugs through testing.[117] In other words, if the government wanted to advance its interest in protecting consumers by preventing patients from obtaining compound drugs when they were not considered medically necessary, then it had to do so more directly by stepping in during the approval, manufacturing or sales process, not by limiting the public's right to information.[118] Justice Breyer authored the lone dissent.[119] Weighing the importance of the government's interest in protecting free commercial speech with its interest in protecting the welfare and safety of its citizens, he felt that the latter should come out on top.[120] He focused on a nuance of the analysis, which he felt the majority missed and that is of particular relevance to the ongoing public discourse over the lifestyle drug market.[121] Justice Breyer argued that in addition to the government's goal of trying to limit the amount of compound drugs supplied to the public, it was equally important to evaluate whether the demand for

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112 Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 591 (1980).

113 *Id.*

114 *Id.*

115 *Thompson*, 535 U.S. at 367

116 *Id.* at 371 ("Even assuming that it does [have substantial interest], however, the Government has failed to demonstrate that the speech restrictions are 'not more extensive than is necessary to serve [those] interests'".).

117 *Id.* at 373.

118 *Id.*

119 *Thompson*, 535 U.S. at 378 (Breyer, J., dissenting).

120 *Id.* at 379 (Breyer, J., dissenting).

121 *Id.* (Breyer, J., dissenting).

these drugs was based on convenience, or whether there was a legitimate need for them.[122]

The majority directly addressed Justice Breyer's concern and used it as an opening to suggest that he was entering into dangerous territory by advocating a federal government that is overly paternalistic.[123] The general message of the holding addressed the issue of government overreaching into lives of private citizens; specifically stating that to restrict this kind of speech was an unnecessary regulation rooted in an unfounded distrust of the general public's ability to make sound decisions about their own general welfare.[124]

In her opinion, Justice O'Connor specifically addresses a statement made in *Virginia Board of Pharmacy*, where the Court addressed similar concerns that sum up the Court's stand on these issues.[125] Here she argues that the government should work off of a premise that citizens, given the proper tools and information, are capable of making decisions for themselves.[126] She then suggests that working from this point of view creates a presumption that the more information made available to consumers, the better protected they are because they can make better decisions for themselves.[127]

The need for balance between paternalism and autonomy enters the discussion on various levels. It is clearly relevant on a macro scale when analyzing the role of the federal government in their legislation of the personal lives of its citizens at the expense of curtailing their decision-making capacity or infringing upon their right to privacy. The argument made by Justice O'Connor seems valid when analyzed in a vacuum, but reeks of hypocrisy when considered in light of decisions such as *Gonzales v. Raich.*[128] This case succinctly exemplifies the federal government's

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[122] *Id.* (Breyer J., dissenting).

[123] *Id.* at 374.

[124] *Thompson*, 535 U.S. at 374.

> Even if the Government had argued (as does the dissent) that the FDAMA's speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions. This concern rests on the questionable assumption that doctors would prescribe unnecessary medications and amounts to a fear that people would make bad decisions if given truthful information.

Id.

[125] *See Va. Bd. of Pharmacy* 425 U.S. at 770.

[126] *Thompson*, 535 U.S. at 374.

> There is . . . an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.

Id.

[127] *Id.*

[128] Gonzales v. Raich, 545 U.S. 1, 125 S. Ct. 2195 (2005) (holding that the regulation of marijuana under the CSA was squarely within Congress' commerce power because production of marijuana meant for home consumption had a substantial effect on supply and demand in the national market.).

tendency to intervene in both state sovereignty and in the personal lives of citizens when it comes to matters of regulating controlled substances, particularly in the area of medicinal marijuana.[129] In this area the Supreme Court expresses little concern about the federal government placing restrictive paternalistic guidelines on citizens themselves at the expense of their constitutional rights to Due Process and Privacy, but balks when the restrictions come instead at the expense of large pharmaceutical manufacturers.

In 1996, the voters of California passed Proposition 215, now known as the Compassionate Use Act (CUA),[130] which gave seriously ill patients within the state legal access to marijuana for medical purposes.[131] Respondents Raich and Monroe, citizens of California, cultivated and ingested marijuana as prescribed by their doctor and in compliance with the CUA. However, despite the conclusion by county officials that said the use was a lawful act, federal agents seized and destroyed all of Monroe's plants.[132] Raich and Monroe then sued.[133]

Raich and Monroe did not challenge Congress's right under the Commerce Clause to regulate marijuana generally.[134] They argued instead that the over-inclusive application of the Federal Controlled Substance Act (FCSA) to regulate marijuana as a Schedule-I drug even for purposes of medical use, went beyond the commerce power.[135] Furthermore, they argued that the enforcement of the FCSA violated the "*Due Process Clause* of the *Fifth Amendment*, the *Ninth* and *Tenth Amendments of the Constitution* and the doctrine of medical necessity."[136]

The Court classified the "main objective of the FCSA" as the desire to generally control the problem of drug abuse in the United States through its strict regulation on both legal and illegal sales of all narcotics."[137] It applied rational basis review, giving deference to Congress' objective and the role that the FCSA plays in fulfilling that goal.[138]

While it is difficult to compare *Gonzales* and *Thompson* directly because the respective laws in each are challenged on two different constitutional bases, it is

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[129] *Id.*

[130] CAL. HEALTH & SAFETY CODE § 11362.5 (2006).

[131] *Gonzales*, 125 S. Ct. at 2198 ("The Act creates an exemption from criminal prosecution for physicians as well as for patients and primary caregivers who possess or cultivate marijuana for medicinal purposes with the recommendation or approval of a physician.").

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] U.S. CONSTITUTION, ART. I, § 8; *see also Gonzales*, 125 S. Ct. at 2204 ("They argue that the CSA's categorical prohibition of the manufacture and possession of marijuana for medical purposes pursuant to California law exceeds Congress's authority under the Commerce Clause.").

[136] *Gonzales*, 125 S. Ct. at 2198.

[137] *Id.* at 2203 (The objective was cited as a desire to "conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels.").

[138] *Id.* at 2208 ("We need not determine whether respondents activities, taken in aggregate, substantially affect interstate commerce in fact, but only whether a "rational basis" exists for so concluding.").

telling that the majority in *Gonzales* focused entirely on the Commerce Clause challenge and did not address the Due Process or doctrine of medical necessity arguments.[139] Could these challenges to the FCSA have triggered the strict scrutiny protection afforded the pharmacists in *Thompson?* Could the Court have concluded that there were better ways for Congress to actually achieve its narrowly tailored objective that would not interfere with the rights granted to California citizens under this state legislation? Alternate means of keeping medical marijuana out of the stream of commerce surely exist which do not violate the respondents' rights under Due Process or doctrine of medical necessity, i.e. better labeling, policing, and safeguards. Why didn't the Court suggest the federal government utilize these means to regulate the sale of drugs in the same way as it did in *Thompson*?

The point of these questions is not to second guess the legitimacy of the Supreme Court's ruling in *Gonzales*, but rather to show that Congress has acted and continues to act paternally when it comes to other areas of drug legislation and the Supreme Court is willing to uphold those decisions. It seems an odd inconsistency that several of thees same governmental objectives existed in the FDAMA (i.e. to keep potentially dangerous drugs out of the hands of customers who sought them based on convenience instead of necessity) and yet in this case the First Amendment rights of the pharmaceutical companies won out. One might ask why the pharmaceutical companies are a more highly protected group than the sick.

V. ADDRESSING THE ISSUES OF GATE KEEPING IN THE CURRENT DIRECT-TO-CONSUMER MARKET CLIMATE

Of course the tension between autonomy and paternalism in drug legislation is not just an issue that faces the Supreme Court, but is also the crux of the ongoing struggle of bioethicists and other professionals entrenched in the medical industry. For now, the practice of direct-to-consumer marketing of lifestyle drugs has become an accepted common practice, and thus it is important to analyze how the role of physicians and pharmacists may likely evolve in the current climate.

The study of bioethics is born from a long tradition in the medical field in which health providers are forced to balance several conflicting principles which create a natural tension in the day-to-day practice of medicine.[140] Among these principles, the two most prevalent and difficult to balance are notably those of paternalism and autonomy.[141] As patients gain greater access to information about

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[139] *See generally Gonzales*, 125 S. Ct. at 2195.

[140] FURROW, ET AL., BIOETHICS: HEALTH CARE LAW AND ETHICS, 4-5 (2001), *citing* K. Danner Clouser and Bernard Gert, *A Critique of Principlism*, 15 J. MED. & PHIL. 200 (1990).

[141] *Id.*

> Bioethics has assumed a kind of 'principalist' orientation over the past 30 years, in which ethical principles, 'at best . . . operate primarily as checklists naming issues worth

available drugs, many questions arise about whether they are equipped to answer questions on their own about the differences between treatment and enhancement.

If, for example, an individual sees an advertisement for a pill that treats sexual dysfunction, obesity, or even anxiety disorder, and is convinced that he or she needs it, how does the physician asses whether this is indeed the case? Does he or she have a responsibility to withhold this drug from a patient if he or she believes it to be unnecessary? Logically, it would seem that much of the power and/or trust historically bestowed upon physicians stemmed from their unique position of having more information than patients about disease and treatment. If patients believe, even incorrectly, that he or she now owns some of that knowledge personally, the power dynamic has shifted and the physician may be put in the position where his or her decision to grant or withhold certain medications is likely to be questioned.[142] The purpose of advertising has traditionally been to create demand and make it seem as if the consumer *needs* the product being sold. Thus, if Madison Avenue advertising executives tell patients they need to be less shy, less wrinkly, skinnier, and last longer during intercourse, a doctor's role in telling them that they may not, becomes much more difficult.[143]

Some may ask, however, if it is even the doctor's role to vigorously police these types of scenarios in the first place. If patients desire a certain treatment, even if it really only amounts to enhancement and they are fully aware of the risks, is it not their prerogative to receive it? Still, those who worry about the inherently exploitative potential for manipulation within consumer ads say the ads create a false sense of autonomy and this is exactly why the medical profession exists—to prescribe medications only where necessary.[144]

While this Note does not attempt to offer any answers to the questions direct-to-consumer marketing raises about the doctor/patient relationship, these are questions worth addressing as they are fundamental in demonstrating how advertising drugs to consumers has so profoundly impacted the status quo. At best, the ads have empowered patients with information that frees them from being at the mercy of physicians when it comes to making life-altering medical decisions.

> remembering when considering a biomedical moral issue' . . . such a checklist of principles includes: 1. Autonomy 2. Non-Maleficence (Do No Harm) 3. Beneficence 4. Confidentiality 5. Distributive Justice 6. Honesty.

Id.

[142] BBC News, *supra* note 9 ("Debate is not over whether people experience these conditions. Instead it is about how they should be defined and whether they are diseases which can be treated by a pill.").

[143] Daley, *supra* note 10 ("[R]esearch has found that the ads tend to improve communication between physicians and patients, but a subset of patients will insist a physician prescribe a specific drug due to advertising.).

[144] Aaron Smith, *Banning Drug Ads Could Cost $10 Billion*, CNNMONEY.COM *available at* http://money.cnn.com/2005/08/01/news/fortune500/directconsumer/index.htm, Aug. 1, 2005 (last visited Sept. 22, 2006) ("Dr. John Abramson, clinical instructor at Harvard University, former family doctor and author . . . said that direct-to-consumer advertising is 'detrimental' to health care because it 'drives a wedge' between patients and physicians by playing on the patients 'sense of autonomy.'").

At worst, the ads have engendered a false sense of competency in patients who now mistakenly believe they have sufficient information to make their own medical decisions. In the face of this tension, physicians must learn to balance both the positive and negative effects that direct-to-consumer advertising has had on their profession, and learn how to best fulfill their obligations in the face of the new climate.

VI. WHERE DO WE GO FROM HERE?

The concerns and problems addressed in this Note have not gone unrecognized by the public, medical professionals, and politicians. At the urging of vocal groups of physicians, the FDA has recently considered whether to modify its policy on direct-to-consumer advertising.[145] However, in light of the protection afforded the pharmaceutical industry in cases like *Thompson* and the financial resources at its disposal, which will allow them to fight such an overhaul, these changes seem very unlikely.

The FDA held a public hearing on direct-to-consumer promotion of medical products on November 1 and 2, 2005.[146] The hearing was organized to address the impact of direct-to-consumer marketing of drugs and medical devices upon consumers by giving various interest groups and concerned citizens a forum to address concerns about the practice.[147] The organization of the hearing in and of itself represents the growing interest in direct-to-consumer marketing in this industry and recognizes that perhaps there may be a better way to regulate the current practices.[148] The fact that the registration for the conference was at full capacity underscores this level of interest even more.[149]

The two days of testimony were comprised of seven panels that addressed a wide range of issues and viewpoints surrounding the current state of direct-to-consumer advertising of medical products.[150] While a wide range of issues were addressed, the two presentations most relevant to the current discussion were given by James H. Davidson, founder of Davidson & Company and executive director of

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[145] Daley, *supra* note 10.

[146] U.S. Food and Drug Administration Website, http://www.fda.gov/Cder/ddmac/dtc2005/default.htm (last visited Mar. 9, 2006).

[147] *Id.*

> FDA is particularly interested in hearing the views of individuals and groups most affected by DTC promotion, including consumers, patients, caretakers, health professionals (physicians, physicians' assistants, dentists, nurses, pharmacists, veterinarians, and veterinarian technicians), managed care organizations, and insurers, as well as the regulated industry. FDA is seeking input on a number of specific questions, but is interested in any other pertinent information participants in the hearing would like to share.

Id.

[148] *Id.*

[149] *Id.*

[150] FDA Website, http://www.fda.gov/Cder/ddmac/dtc2005/presentations.htm (last visited Mar. 9, 2006).

The Advertising Coalition, and Alex Sugarman-Brozan of Prescription Access Litigation (PAL), "A Community Catalyst Initiative."[151] These presentations were products of two very different special interest groups, each trying to support very polarized goals.[152] Thus, the two presentations offered an interesting snapshot of the direct-to-consumer marketing climate in its present state and offer a succinct summary on two of the more extreme standpoints lobbying the FDA on this matter.

On the one hand, Davidson's presentation sought to point out the many benefits of direct-to-consumer advertising. He focused primarily on statistics which supported the notion that more consumers have been prompted to seek medical condition for "high priority conditions," that otherwise they would have let go untreated.[153] He also suggested that certain diseases such as osteoporosis and depression, often called "the silent killer," are on the whole under-diagnosed and that the use of direct-to-consumer advertising has helped to bring this problem to the attention of the general public.[154] Lastly, he proposed that a large reason for the disparity in access to health care between whites and minorities could not solely be attributed to differences in income or level of health insurance coverage. He stated that the minority groups' lack of information about the diseases themselves and the various drugs that can treat them also contribute to the inferior

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[151] *Id.*

[152] *See* The Advertising Coalition Website, http://www.theadvertisingcoalition.com (last visited Mar. 9, 2006)

> The Advertising Coalition (TAC) is comprised of national trade associations whose members are advertisers, advertising agencies, broadcast companies, cable operators and program networks, and newspaper and magazine publishers. These associations and their members share a common objective—they oppose proposals in Congress or from the Executive branch of government to limit or restrict advertising content or volume, or to limit the ability of businesses to deduct the cost of advertising as an ordinary and necessary business expense.

Id.; *compare with* Community Catalyst—Prescription Access Litigation Project Website, http://www.prescriptionaccess.org (last visited Mar. 9, 2006)

> The Prescription Access Litigation (PAL) Project works to make prescription drug prices more affordable for consumers, using class action litigation and public education. Community Catalyst created PAL in 2001. Since then, PAL has been involved in over 20 class action lawsuits challenging drug industry tactics to illegally raise the price of prescription drugs. In just 3 years, 4 of these cases have settled, allowing consumers who were illegally overcharged to be reimbursed and putting drug companies on notice that their illegal tactics will not go unopposed. PAL is a national coalition of over 100 organizations, including consumers, seniors, heath care, labor, legal services, women's health and human services groups in 35 states and the District of Columbia.

[153] FDA Website, *supra* note 151 (Based on a Harvard, Massachusetts General Hospital, and Harris Interactive study, thirty-five percent of 3000 patients sought medical advice after seeing an advertisement, twenty-five percent of those received a new diagnosis and forty-three percent of those were for high priority conditions. Also, "between 25 and 30 million Americans have been prompted by an ad to talk to their physician for the first time about a medical condition.").

[154] *Id.* ("From 1987 to 1997, the percent of Americans treated for depression tripled from .7% to 2.3%. The private sector's financial resources and ability to reach a huge market can be brought to bear on the public health issue of bone health.").

healthcare they receive on the whole.[155]

Davidson cited both *Virginia State Board of Pharmacy* and *Thompson* to emphasize the clear-cut precedent in the Supreme Court, which has held that direct-to-consumer advertising is strongly protected under the First Amendment as commercial speech.[156] He concluded his presentation by advocating for increased reliance on self-regulation by the pharmaceutical industry of its own advertising and marketing practices as the best vehicle for improving the advertising climate if and when rehabilitation is needed.[157]

Sugarman-Brozan presented the flipside to direct-to-consumer advertising as viewed by concerned citizens and interest groups who believe it is having a profound and negative impact on U.S. society.[158] Her testimony suggested that drug companies actively manipulate consumers in order to sell drugs that are not entirely safe and may not even be necessary. On the whole, she argued that direct-to-consumer advertising interferes with the doctor/patient relationship, promotes brand name drugs over generic medications and other treatment alternatives such as diet and exercise, acts as a force in driving up costs of drugs, and negatively affects research priorities.[159]

Sugarman-Brozan pointed out that allowing the pharmaceutical companies to use direct-to-consumer marketing to sell drugs while at the same time expecting them to self-regulate by simultaneously offering objective information on their potential side effects and dangers creates a conflict of interest that comes at the expense of the consumer in the same way that ads by manufacturers of certain consumer goods such as beer and cigarettes do.[160] She also pointed out that the direct-to-consumer marketing is most important to a pharmaceutical companies' bottom line in cases where there is actually less demand for a drug because in order to generate sales, pharmaceutical companies synthesize need through advertising rather than relying on that need to develop organically.[161]

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[155] *Id.* ("Access to information is a critical piece in the access picture for Hispanic and other under served communities."). In a study conducted by the Commonwealth Fund found data to suggest that minorities lag behind in health care quality and are more likely to have communication problems with their doctors than Caucasian patients. *Id.*

[156] FDA Website, *supra* note 151.

[157] *Id.*

[158] *Id.*

[159] *Id.* Sugarman-Brozan's presentation stated that over 20 million consumers took Vioxx "mostly due to ads" and that 70% of Cox 2 users didn't actually need them. *Id.* She asked the panel to consider "How many heart attacks were caused by these ads" and "How many billions of dollars were wasted?" FDA Website, *supra* note 151. She also specifically cited a drug called Nexium to highlight her stance stating that it is actually no more effective than the drug Prilosec but it is actually seven times more expensive. *Id.* She estimated that the $4.6 billion of sales estimated to have been generated by Nexium in the year 2005 were made possible only through direct-to-consumer marketing. *Id.*

[160] *Id.* (quoting Marcia Angell, MD, "To rely on the drug companies for unbiased evaluations of their products makes about as much sense as relying on beer companies to teach us about alcoholism.").

[161] *Id* (quoting Marcia Angell, MD, "The fact is that marketing is meant to sell drugs, and the less important the drug, the more marketing it takes to sell it. Important new drugs do not need much

Not surprisingly, Sugarman-Brozan and PAL are not content to rely on the self-regulation within the pharmaceutical company to police the climate and to voluntarily implement necessary changes in direct-to-consumer marketing practices.[162] The group instead recommends increased enforcement of the direct-to-consumer ads by ensuring adequate FDA staff to review all promotions.[163] They also made a call to the Chief Counsel to review all enforcement letters sent out to pharmaceutical companies in the instances where advertisements don't meet FDA regulations and asked the FDA to require pre-broadcast review of all advertisement submissions.[164] Finally, they called for Congress to impose monetary penalties where appropriate for advertising violations, an outright prohibition of "reminder" ads, increased regulation of "disease awareness" ads, increased regulation of drug ads aimed specifically at children, a prohibition of coupons for drugs, and an overall return to the pre-1997 requirements in the Food, Drug and Cosmetic Act, which initially were set out to regulate direct-to-consumer marketing.[165]

It is unclear how the widely disparate testimony at these hearings impacted the FDA and what the next action steps will be. In his report, written in December 2005, Daley predicted that if recommendations from the panel were to come they would not surface until February 2006.[166] As of late winter 2006, they have not yet arisen.

Even without the end results, one can see from the two extreme stances presented that strong forces are at play on both sides of the debate. In light of the *Thompson* decision, however, and the strong First Amendment argument available to the pharmaceutical industry to support its right to continue its direct-to-consumer advertising practices unfettered, it seems unlikely that the FDA will attempt any actions as extreme as those embraced by groups like PAL.

An alternative to immediately implementing mandatory action has been suggested, and even traditionally pro-pharma groups such as the AMA are considering supporting it. Under this framework, the pharmaceutical companies would agree to a voluntary moratorium on ads while the FDA took time to further study and investigate their impact on consumers.[167]

Perhaps one of the biggest advocates for change has been U.S. Senate Majority Leader Dr. Bill Frist, a former surgeon. He has made a public request for such a voluntarily moratorium on direct-to-consumer advertising, suggesting that the acknowledgements made to date regarding its dangers and the need for an

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promotion. Me-too drugs do.").

162 FDA Website, *supra* note 151.

163 *Id.*

164 *Id.*

165 *Id.*

166 Daley, *supra* note 10.

167 *Id.* (Joseph Cranston, Ph.D., Director of Science, Research and Technology at AMA, testified that DTC advertising has been a topic of debate among his organization's membership, which is considering recommending a ban on the ads.").

overhaul have done little to address the problem.[168] He has stated that he believes the 1997 changes to the guidelines were a failure and that they have resulted in a climate where pharmaceutical companies can sell drugs by misrepresenting both the benefits and drawbacks to their products.[169]

It has been estimated that such a moratorium could cost the pharmaceutical industry as much as $10 million if it ever became a reality.[170] Despite an impact economically, specialists such as Dr. John Abramson speculate that such a moratorium "is not impossible, but it would require an outcry from the public and physicians."[171] Survey information suggests that public concern about direct-to-consumer marketing exists but does not indicate whether this is a cause over which the public possesses enough concern to organize around, generating any significant momentum.[172]

With politicians like Sen. Frist speaking out, the public may now have the rallying point that has been so far lacking. Despite potential obstacles in the courts, the public could exert enough pressure to encourage the industry itself to embrace a voluntary moratorium and reassess its own practices. It is after all the goodwill of its consumers on which so much of the pharmaceutical revenue from direct-to-consumer advertising depends. If the public no longer believes that the drugs being sold to it in the ads it sees on TV really live up to the claims being made, than direct-to-consumer advertising may lose some of its potency organically. In a situation like this, Big Pharma would be forced to reassess its marketing strategies regardless of pressure from the government.

Sen. Frist has specifically warned about how direct-to-consumer marketing practices have led to irresponsible prescribing practices on the parts of doctors, jeopardizing patient safety.[173] While it may ultimately be out of the hands of the courts and the FDA to impose harsher restrictions on direct-to-consumer

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[168] Senator Bill Frist, http://frist.senate.gov (last visited Feb. 17, 2006).

[169] *Id.*

> Along with the FDA's long overdue plan to review the failed Clinton-Era DTC guidelines, these announcements are encouraging signs that the industry and FDA both recognize that DTC advertising frequently oversells benefits and undersells risks of prescription drugs, and that substantive steps must be taken to rein in this potentially harmful form of marketing. While I wish the PhRMA guidelines would have gone farther and proposed a moratorium on DTC advertising of newly approved drugs, I hope individual pharmaceutical manufacturers will seriously consider such a measure.

Id.

[170] Smith, *supra* note 145 ("It would have a multi-billion impact . . . $10 billion is not an unreasonable number.").

[171] *Id.*

[172] *Id.* (The research firm Harris Interactive released a survey showing more than half of its respondents would support a temporary advertising ban on newly-approved direct-to-consumer drugs and another survey which revealed 51% believe "it is a good idea to forbid direct-to-consumer advertising for new prescription drugs for some period of time after the FDA approved a new drug, so that doctors have time to become familiar with the new drug.")

[173] *Id.* (quoting Frist, "Research evidence indicates that this blitz in direct-to-consumer advertising has unwittingly led to inappropriate prescribing which most importantly can compromise patient safety and care.").

advertising, if the public continues to hear statements such as Sen. Frist's, it is highly likely that it will be able to initiate reform on its own, as the pendulum of public perception swings from one of acceptance to suspicion in the realm of direct-to-consumer advertising.