DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS & THE WORLD OF SOCIAL MEDIA: THE PARADOX OF ADVERTISE FIRST, ENSURE SAFETY SECOND

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I. Intro

Pharmaceutical manufacturers spend millions of dollars annually in an effort to persuade consumers to use their drugs.\(^1\) A host of marketing techniques are used to reach the optimal amount of consumers, increase demand, and raise profits. Additionally, consumers demand a nonstop flow of information while also expecting that promoted products are safe for consumption. However, when rapidly expanding technology meets consumerism, it is often difficult for regulators to stay ahead of the regulatory curve.

The Food and Drug Administration (“FDA”) and Federal Trade Commission (“FTC”) are charged with balancing the interests of consumers and advertisers by securing a safe pharmaceutical industry. With limited resources, the FDA and FTC seek to maintain “fair and balanced” advertising standards in an effort to protect society from potentially harmful drugs while still allowing individual autonomy in healthcare decisions and companies the ability to advertise their products.\(^2\)

\(^1\) See infra notes 16-18 and accompanying text (stating the current DTCA spending levels by pharmaceutical manufacturers).
\(^2\) See infra notes 46-51 and accompanying text (explaining the roles of FDA and FTC with regard to direct-to-consumer advertising).
In light of these competing interests, how best to regulate direct-to-consumer advertising (“DTCA”), including electronic forms of it (“eDTCA”), is a contentious topic.\(^3\) With conflicting ideologies of government paternalism, free access to information, and patient autonomy, how best to regulate DTCA implicates a range of concerns.\(^4\) Further, with the expansion of internet-capable technologies, regulators are left wondering how to best regulate emerging forms of advertising.

While there are many problems associated with DTCA, there is also great potential, especially with eDTCA, to inform patients about disease and treatment options.\(^5\) Current regulations, however, are insufficient to adequately protect the public from the harms proven to stem from DTCA, including the adverse effect on patient knowledge through the receipt of misinformation; uninformed and inappropriate demand for brand name drugs; the lessening of individual autonomy; and the transfer of prescribing power from the physician to the patient.\(^6\) Thus, with regard to promulgating new regulations for eDTCA, FDA should abandon its current protocol of promulgating regulations based on specific platforms and should instead promulgate comprehensive regulations based on the restraints imposed by eDTCA platforms, such as space limitations and third-party created information. Further, FDA can also incorporate this concept of addressing the problems rather than platforms to its current DTCA regulations by regulating entire marketing programs or by limiting advertising upon the initial launch of a new prescription drug. These comprehensive, rather than piecemeal, solutions will better protect the public from the problems caused by DTCA while also not stifling the potential of DTCA to provide information to consumers. While these suggestions may require extensive effort on the part of

\(^3\) *See generally* Part II.B.
\(^4\) *See generally* Part II.B.
\(^5\) *See infra* notes 39-43 and accompanying text (highlighting the benefits associated with DTCA).
\(^6\) *See* Part II.C.
FDA and FTC, they are imperative if the current problems are to be solved with a long-term frame in mind.

Part II of this paper provides brief background on DTCA in the United States and addresses several of the problems associated with DTCA. Part III discusses traditional DTCA (print and television), and outlines the current regulatory framework of FDA and FTC, including current enforcement and post-surveillance mechanisms. To close, the weaknesses of the current regulatory scheme are discussed. In Part IV, this paper discusses the role of eDTCA, its current regulation and associated problems. It will show how print and broadcast media differ significantly from online media, and therefore, applying current print and broadcast regulations to eDTCA is insufficient to properly regulate this media. In Part V, this paper proposes solutions including: regulating marketing campaigns rather than individual components; requiring advertising to focus on disease prevention rather than individual drugs; limiting advertising on new drugs; encouraging education; and regulating the problems with eDTCA platforms, rather than the platforms themselves. If implemented, these suggestions would effectively regulate DTCA and eDTCA and adequately protect the public from the harms of DTCA.

II. DTCA Background

A. Trends in DTCA Spending

DTCA involves various types of advertising methods, including television, radio, magazine, and Internet, that are directed toward consumers and promote prescription and non-
prescription drugs.12 DTCA tends to be concentrated on a small number of brands with majority of spending focused on the top twenty selling drugs, which are often new drugs used to treat chronic conditions.13 Campaigns typically begin within one year of the introduction of the pharmaceutical into the market.14 Currently, only the United States and New Zealand allow DTCA of pharmaceutical drugs.15

DTCA spending increased 330% between 1996 and 2005, growing to over $4.2 billion annually, and it continues to grow.16 Data from 2008 shows that drug manufactures spent $4.8 billion of a total $2.4 trillion advertising expenditure on DTCA.17 While DTCA represents a small percentage of total advertising spending, DTCA spending is increasingly becoming a larger percentage of overall advertising expenditures.18

Further, DTCA generates a substantial amount of revenue for drug manufacturers because it works.19 According to a recent study conducted by the Harvard School of Public Health, increases in “DTCA were associated with significant growth in sales for the classes of

14 See Donohue, supra note 13, at 678. “In 2006, DTCA accounted for 35% of promotion of drugs approved within the previous two years.” Mintzes, supra note 13, at 261.
16 See Donohue, supra note 13, at 676.
18 See Donohue, supra note 13, at 676.
drugs studied: for every 10% increase in DTCA, drug sales within the classes studied increased on average by 1%.”\textsuperscript{20} For every additional dollar spent on DTCA, an additional $4.20 in sales was yielded.\textsuperscript{21} These figures lead critics to contend that requests for advertised medications result in increased health care costs, because oftentimes the advertised drugs are more expensive than similar or generic alternatives.\textsuperscript{22}

\textbf{B. Potential and Problems with Advertising Prescription Drugs Directly to Consumers}

DTCA has the potential to provide patients with important health care information, such as information regarding available prescription drug treatment or disease pathology and prevention. Despite these potential benefits, there is reason for concern regarding how DTCA affects patient populations, and how it is regulated.

To begin, consumers persuaded by DTCA. Almost a third of adults say that they have spoken to their doctor about a drug they saw advertised on television and forty-four percent of those patients were prescribed the medication.\textsuperscript{23} However, studies have shown that DTCA provides incomplete and inaccurate knowledge to patients, thus adversely affecting their knowledge and understanding of disease and treatment. A study conducted by FDA found that “60% of patients thought that the advertisements provide[d] insufficient information about drug


risks and 44% felt similar about the benefits.”

Further, “[f]ifty-eight percent believed that advertisements made the drugs appear better than they are.”

Pharmaceutical companies market their drugs in the most favorable light, oftentimes mitigating rare but significant side effects.

Most provide typical product information, along with vague descriptions of benefits; however, significantly fewer provide the “prevalence of, risk factors for, or causes of the condition.”

Further, the language used in these ads exceeds the recommended eighth-grade level for the general public, so it is likely that many consumers do not fully understand the advertisements. Moreover, alternative treatments are rarely included—a recent study found that less than one third of ads mentioned alternative treatments, and “[o]nly a minority of ads acknowledge variations in product effectiveness.”

These factors combined lead to misinformed and oftentimes confused consumers.

Further, DTCA leads directly to uninformed demand which detrimentally impacts public safety. Exposure to DTCA encourages patients to request drugs, as “[p]atients are no longer viewed as passive recipients of medical care, but instead as active participants who play a key role in making clinical decisions with their health care providers.”

However, the content of print and television ads is insufficient for patient self-diagnosis. If patients base knowledge on

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24 See Lurie, supra note 17, at 446-47.
25 Id.
26 Dominick Frosch, et al., A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising, 100 AM. J. PUB. HEALTH 24, 30 (Jan. 1, 2010).
27 Id.
28 Id.
29 See id.
30 Id.
31 See Dominick L. Frosch, et al., Living in the “land of no”? Consumer perceptions of healthy lifestyle portrayals in direct-to-consumer advertisements of prescription drugs, 73 SOCIAL SCIENCE & MEDICINE 995 (2011).

[N]arratives in advertisements can potentially influence specific perceptions of causality, further shaping forces of medicalization in DTCA. Several participants perceived the Vytorin advertisement as suggesting that high cholesterol was primarily a hereditary issue, thereby shifting responsibility from something an individual can control (dietary habits) to something they cannot control (genetics) and placing the solution squarely into the medical domain.

Id. at 1001.
improper information, it lessens the individual autonomy of those patients, because decisions
which are supposedly made in the best interests of the patient might not actually be the optimal
decision due to the incorrect information. Thus, bias in advertisements can lead to prescribing
drugs to patients that who lack full knowledge of the side effects, thereby implicating public
health and safety.\textsuperscript{32} While the government must be mindful that patients have autonomy
regarding personal healthcare, allowing misleading advertisements directly impairs this
autonomy. Misleading DTCA is thus a risk to public health, because it could lead to individuals
unknowingly making detrimental decisions.\textsuperscript{33}

Lastly, no regulatory safeguards exist to mitigate the effects of the increased consumer
demand based on incomplete information, which leads directly to the transfer of prescribing
power from the physician to the patient. Where at one time patients went in to physician’s office
for the physician’s expert opinion, patients now feel empowered by knowledge gained from
DTCA. This can decrease dependence on physician objectivity and have a detrimental impact on
patient care. While patients may request certain medications because of DTCA, the idea of
laypersons stepping into role of expert is paradoxical, since patients lack the requisite level of
education to make complex medical decision and cannot ultimately make a prescribing decision.

\textsuperscript{32} See Frosch, A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug
Advertising, supra note 26, at 24-25.

Physician surveys find that DTCA increases prescription volume and that some of these
prescriptions are clinically inappropriate. Eighty-one percent of physicians believe that DTCA
prompts medication requests, and one quarter report resulting changes in their prescribing habits.
A survey of physicians and their patients found that 7\% of patients made a prescription request
and that DTCA exposure increased such requests. Although 78\% of the requests were fulfilled, the
prescribing physician judged half of these prescriptions as possible or unlikely choices for a
similar patient with the same condition. In another survey, physicians judged half of DTCA-
prompted requests to be clinically inappropriate. However, 69\% of these requests were at least
partially fulfilled, with a small but significant percentage of these requests (6\%) judged as
potentially harmful choices. Physicians often said they fulfilled such requests to accommodate
patients.

\textsuperscript{33} See generally Cali. Dental Assoc. v. F.T.C., 119 S.Ct. 1604 (1999) (noting that allowing false or misleading
advertising could actually harm consumers).
Thus, physicians should be seen as a safeguard between the public and DTCA. As the American Medical Association (“AMA”) points out:

Physicians must maintain professional standards of informed consent when prescribing. When a patient comes to a physician with a request for a drug he or she has seen advertised, the physician and the patient should engage in a dialogue that would assess and enhance the patient’s understanding of the treatment. . . . Physicians should deny requests for inappropriate prescriptions and educate patients as to why certain advertised drugs may not be suitable treatment options, providing, when available, information on the cost effectiveness of different options . . . Physicians must remain vigilant to assure that direct-to-consumer advertising does not promote false expectations.34

Physicians worry, however, that DTCA may still cause harm, because it “promotes longer, unnecessary visits and inappropriate medication requests.”35 Further, some physicians feel pressured to comply with patient requests for drugs, because the patient may simply go elsewhere if the physician does not comply.36 Yet, if physicians write clinically inappropriate prescriptions due to this compelling pressure, it could result in harmful prescribing.37 Moreover, DTCA can lead to medicalization—where drugs are used on patients without regard to other non-drug alternatives—resulting in increased medical cost and potential patient harm.38

35 Frosch, A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising, supra note 26, at 26.
36 See U.S. FOOD AND DRUG ADMINISTRATION - THE IMPACT OF DIRECT-TO-CONSUMER ADVERTISING, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm (“Eight percent of physicians said they felt pressured to prescribe the specific brand-name drug when asked.”).
37 Frosch, A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising, supra note 26, at 25. A study of patients in a California HMO showed that of those who were exposed to DTCA for COX-2 inhibitors, there was a significant increase of both appropriate and inappropriate prescribing. Another study found “higher rates of switching to an advertised brand of proton pump inhibitor among patients living in television markets with high DTCA volume for these drugs.” Id. at 27.
38 Id. at 27.

Fifty-five percent of online adults have looked online for information about at least one of the following three methods of health treatment: prescription or over-the-counter drugs, alternative treatments or medicines, or experimental treatments or medicines. Of those who look online for drug or treatment information: 42% have looked for information about only one method of treatment, 58% have weighed at least two methods of treatment, and
Therefore, physicians are not an adequate safeguard to counter the impact of DTCA. A lack of safeguard coupled with insufficient information could have a detrimental effect on society, because it improperly removes a level of expertise which is necessary in the context of medical decision-making.

While the use of DTCA has significant public health drawbacks, it may also provide benefits to consumer. Studies show that DTCA “increases classwide sales [and] helps to avert underuse of medicines to treat chronic conditions.” Further, DTCA studies show that it may increase productive discussions between patients and physicians, which can be beneficial to patient autonomy. Because of the information provided by DTCA, patients believe they make better health decisions and have increased confidence to converse with their physicians. Moreover, increased patient participation contributes to patient adherence. One study showed that more than half of the participating physicians felt that DTCA educates patients and improves

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23% have looked into all three: prescription or over-the-counter drugs, alternative treatments or medicines, and experimental treatments or medicines.

While most adults looking online for information about specific treatments weigh many different options, those seeking prescription or over-the-counter drug information are less likely to look at alternative or experimental treatments.

Fox, supra note 121.

“[T]he primary forces of medicalization in contemporary society are no longer the medical professions, but increasingly commercial interests, among which DTCA is perhaps the most visible.” Frosch, Living in the “land of no”, supra note 31, at 995.

“Predictably, the cost of health care is driven up, as patients are induced to request newer, more expensive medications instead of equally effective, generic alternatives.” See Lurie, supra note 17, at 446-47.

39 See Frosch, A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising, supra note 26, at 26 (“the overall effects of DTCA on physician-patient communication are unclear, and the effects on quality of care appear mixed.”).

40 Donohue, supra note 13, at 674.

41 See Frosch, A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising, supra note 26, at 26; Victor E. Schwartz, et al., Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising, 32 HARV. J.L. & PUB. POL’Y 333, 353 (Winter 2009) (detailing one of the most comprehensive DTC studies done to date, which was conducted by FDA and “included 250 general practitioners and 250 specialists in the fields of dermatology, allergy, endocrinology, and psychiatry.”).

42 Frosch, A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising, supra note 26, at 25.
patient understanding of diseases and treatments.\textsuperscript{43} Again, however, information obtained through DTCA must be accurate and reliable in order to increase patient autonomy and provide societal benefits.

III. The Regulatory Framework of Print and Broadcast DTCA

A. Current Regulations: Print and Broadcast DTCA

DTCA regulations differ from typical consumer product advertising regulations, because pharmaceuticals have inherent health risks.\textsuperscript{44} These risks include known side effects, as well as the risk of prescribing errors, “unintended or accidental exposure, intentional misuse, abuse and self-harm.”\textsuperscript{45} Pharmaceutical drug DTCA is currently subject to various regulations promulgated by both FDA and FTC. FDA regulates DTCA of prescription drugs through its Division of Drug Market, Advertising and Communications,\textsuperscript{46} while FTC regulates non-prescription drugs.\textsuperscript{47} FDA garners its power from the Federal Food, Drug and Cosmetic Act.\textsuperscript{48} The agency is charged with ensuring “prescription drug information provided by drug firms is truthful, balanced, and accurately communicated.”\textsuperscript{49} FDA does not review and approve all advertising prior to

\textsuperscript{43} Id.


\textsuperscript{48} 21 U.S.C. § 301; see 21 C.F.R. § 202.1 (West 2011) (listing the specific requirements for prescription drug advertisements, including required ingredient information, as well as how to handle information related to side effects, dosage, effectiveness, etc.).

\textsuperscript{49} 21 U.S.C.A. § 352 (West 2012); see U.S. FOOD AND DRUG ADMINISTRATION – THE IMPACT OF DIRECT-TO- CONSUMER ADVERTISING, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm (last visited April 11, 2012). “FDA’s primary responsibility is to protect the American people from unsafe or mislabeled food, drugs, and other medical products and to make sure consumers have access to accurate, science-based information about the products they need and rely on every day.” U.S. FOOD AND DRUG ADMINISTRATION, Strategic Priorities 2011-2015,
Instead, FDA has promulgated regulations which require that prescription drug advertisements achieve fair balance by presenting a “true statement of information in a brief summary relating to side effects, contraindication, and effectiveness.”

DTCA can take various forms, from the traditional methods of print and broadcast to the emerging methods of social media advertising. Print methods include media like magazines and newspapers. Broadcast includes both radio and television media. FDA recognizes three types of DTCA for broadcast and print media. The first, referred to as reminder advertisements, name the drug and manufacturer but not the disease. The second, called “help-seeking” advertisements mentioned the disease and manufacture but not the name of the drug. Finally, the third, called a “product claim” advertisement, includes the drug name, the condition it treats and discusses the benefits and risks of the drug.

Broadcast and print media are regulated similarly, but not identically. Print materials are subject to strict requirements regarding information that must be included in the advertisement; broadcast media require less detailed information regarding side effects and precautions than its print counterpart.

51 See 21 C.F.R. § 202.1(e)(1) (Side effects are defined to include: “side effects, warnings, precautions.”)
53 See id.
Print advertisements must include a “brief summary of the package insert detailing full product information required by law.” It must “describe the drug’s adverse experience profile, contraindications, warnings, and precautions, as well as the indications for the drug’s use from the approved product labeling.” Effectiveness information shall include specific indications for use of the drug for purposes claimed in the advertisement. Side effects and contraindications information must disclose each specific side effect or contraindication but can be limited to the indication for which the drug is being advertised. The brief summary may only discuss FDA approved indications and cannot recommend any off-label use.

Broadcast advertisements must include a “major statement” along with either a “brief summary,” as described above, or, alternatively, an “adequate provision.” The major statement must disclose the product’s “major risks in either the audio or audio and visual parts of the presentation.” The adequate provision must contain one of the following options for consumers to obtain approved package labeling: a toll-free phone number; a print advertisement which appears concurrently in publications which reach the exposed audience; product information brochures at publicly accessible sites; or web page or disclosure that physicians may provide additional product information.

57 Id.
60 21 C.F.R. § 202.1(e)(4).
62 Id.
Congress recently granted FDA additional power through the Food and Drug Administration Amendments Act (“FDAAA”) of 2007. Under FDAAA, FDA has the authority to require the submission of television DTCA prior to their being broadcast. FDA can make recommendations to improve compliance with regulations; however, drug companies are not required to implement suggestions. Guidelines which further clarified what types of advertisements would be subject to preapproval and also described “how FDA plans to implement the requirement for the pre-dissemination review of [DTCA]” were issued in March 2012.

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The Agency intends to require sponsors to submit TV ads for pre-dissemination review in the following categories:

Category 1: The initial TV ad for any prescription drug or the initial TV ad for a new or expanded approved indication for any prescription drug
Category 2: All TV ads for prescription drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) with elements to assure safe use (see section 505-1(f) of the FD&C Act)
Category 3: All TV ads for Schedule II controlled substances
Category 4: The first TV ad for a prescription drug following a safety labeling update that affects the Boxed Warning, Contraindications, or Warnings & Precautions section of its labeling
Category 5: The first TV ad for a prescription drug following the receipt by the sponsor of an enforcement letter (i.e. a Warning or untitled letter) for that product that either cites a TV ad or causes a TV ad to be discontinued because the TV ad contained violations similar to the ones cited in the enforcement letter
Category 6: Any TV ad that is otherwise identified by FDA as subject to the pre-dissemination review provision

These categories reflect a risk-based approach that will enable the Agency to leverage its limited resources to best protect the public health by ensuring that certain high risk and high impact TV ads accurately and effectively communicate key information about advertised products, including their major risks and indications.

Id. at 2.


FDA intends to notify drug sponsors of the requirement to submit their TV ads for pre-dissemination review in several different ways. For drugs approved in the future and for approved drugs for which an expanded indication is approved in the future (Category 1), for approved drugs
Both print and broadcast DTCA require fair balance throughout the entire advertisement.\textsuperscript{67} Therefore, no part of the advertisement is allowed to be false or misleading.\textsuperscript{68}

An advertisement does not satisfy the true statement requirements if it fails to provide fair balance between the side effects, contraindications and effectiveness information; is false or misleading with respect to any of the aforementioned information; or fails to reveal facts material to the drug indication being advertised.\textsuperscript{69} The regulations further delineate specific instances when an advertisement is considered false, lacking in fair balance or otherwise misleading.\textsuperscript{70} Instances include: if it promotes off-label uses; suggests a drug is safer or more effective than another drug without required evidence; references literature that misrepresent effectiveness; or uses a quote out of context to convey a false or misleading idea.\textsuperscript{71}

\textbf{B. Enforcement and Post-Marketing Surveillance}

FDA ensures fair balance in DTCA by employing a “comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and that fall under Categories 4 and 5 as described in this guidance, and for any other drugs for which FDA determines pre-dissemination review of TV ads is required (Category 6), FDA intends to notify sponsors in the letter approving the application or supplement, in the approval of the labeling update, in the enforcement letter, or in other correspondence. For drugs already approved prior to the issuance of this guidance that fall under Categories 1, 2, and 3, FDA intends to publish a notice in the Federal Register notifying sponsors that their products will be subject to pre-dissemination review in accordance with section 503B of the FD&C Act. However, if a sponsor is developing a TV ad for a product that falls into one of the categories described above and has not yet received written notification, we recommend that the sponsor submit the TV ad for pre-dissemination review as described in this guidance.

\textit{Id. at 4-5.} \\
\textsuperscript{67} See Avery, supra note 56, at 252. \\
\textsuperscript{68} 21 C.F.R. § 202.1. \\
\textsuperscript{69} 21 C.F.R. § 202.1(e)(6). \\
\textsuperscript{70} 21 C.F.R. § 202.1(e)(6) (noting that an advertisement may be considered false or misleading for a host of reasons including if it “[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience” or if it “[c]ontains favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contains literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience). \\
\textsuperscript{71} See 21 C.F.R. § 202.1(e)(6).
promotional information to both health professionals and consumers. All drug labels must be approved by FDA prior to the drugs being marketed; however, advertisements do not require agency approval prior to being run. Instead, marketing materials must be sent to FDA upon a drug’s launch. The Obama Administration adopted a stricter stance on DTCA, and granted more power and resources to FDA so that the agency can enhance its regulation. FDA can now impose civil monetary penalties (up to $250,000) for false or misleading advertisements. Additionally, the FDAAA amendments added six million dollars annually to FDA’s funding so that it may implement these changes.

FDA also conducts post-market surveillance in an effort to further its mission of ensuring the safety and effectiveness of prescription drugs. FDA’s main surveillance initiative is the “Bad Ad” Program. Under the program, FDA educates health care providers about their roles in ensuring prescription drug advertising and promotions are truthful and not misleading. Healthcare providers are encouraged to report misleading drug advertisements to FDA. After receiving a report, the Office of Prescription Drug Promotion reviews and evaluates an advertisement to determine if enforcement action or additional monitoring is necessary. If an advertisement is found to pose a “clear risk to the public health,” FDA will intervene.

Inventions such as this benefit the public by requiring false or misleading advertisements to be

73 Id.
76 FDA ’Bad Ad’ Plan Debuts, 32 CHAIN DRUG REV., June 7, 2010.
78 See id.
79 Id.
removed and/or corrective advertisements to be run. Unfortunately, the “Bad Ad” Program is understaffed, which cuts directly to the effectiveness of these regulatory efforts.  

[T]he number of staff members who are dedicated to reviewing advertisements has remained relatively stable, whereas the use of such advertising has grown substantially. In 2002, three FDA staff members were dedicated to reviewing direct-to-consumer advertisements. In 2004, four staffers were reviewing such advertisements, even though spending on this form of advertising . . . had increased by 45%. . . .  

FTC requires that advertising be truthful and non-deceptive, fair and backed by substantial evidence. “FTC defines deception as a misrepresentation or omission likely to mislead reasonably acting consumers to their detriment.” Under the Federal Trade Commission Act, FTC has the power to prohibit deceptive and unfair practices, as well as false advertising of non-prescription drugs. In recent years, FTC has paid increasingly close attention to DTCA. In late 2009, FTC issued new guidance regarding company-affiliation disclosures to incorporate the use of social media advertising.  

The FTC expects companies to make reasonable efforts to educate the celebrities, bloggers, employees and others promoting their brand at their behest regarding disclosing their connection to the advertiser and not making false or misleading statements or claims. The guidance specifically singles out celebrity spokespeople, requiring them to disclose financial connections to brands when promoting them other than in ads and commercials, such as on talk shows or via social media, and making them personally liable for false claims made about a product.

81 See Donohue, supra note 13, at 679.  
83 Truth in Advertising, Offline or Online, N.Y. TIMES, Oct. 13, 2009, at A.  
C. Weaknesses in the Current Regulatory Framework

i. Drug Failures

While there is considerable debate over how far regulations should go in restricting DTCA, what is equally important is whether current regulations are effective. Several recent examples of large-scale, problematic drug releases indicate a lack of effectiveness. FDA allowed drugs to be heavily marketed to the public despite an awareness of life-threatening side effects. While DTCA is one of many factors affecting whether a patient receives a drug, the causal connection between DTCA and increased sales means that DTCA exacerbates the potential public harm of dangerous drugs.85

One such example of a major drug failure is Rofecoxib, also known as Vioxx. Merck received FDA drug approval in May 1999 and began marketing Vioxx to treat osteoarthritis. Physicians were quick to endorse the drug, in part due to the success of Merck’s huge advertising campaign in positioning Vioxx to be the next blockbuster drug.86 Worldwide, over 80 million people were prescribed Vioxx at some time.87 After concerns of increased risk of heart attack came to light, the drug was withdrawn from the market. However, the recall was not immediate and “[i]ntensive advertising continued for four years after the first rigorous evidence of an increase heart attack risk” was exposed.88 Prior to its withdrawal, Merck had annual sales revenue of $2.5 billion from Vioxx.89 Its recall resulted in one of the largest to date. In all, Vioxx

85 See supra notes 19-21 and accompanying text (describing studies which prove the efficacy of DTCA on increased sales).
86 See Business Week, Lessons from the Vioxx Fiasco, http://www.businessweek.com/magazine/content/04_48/b3910055_mz011.htm (last visited April 11, 2012). See also Donohue, supra note 13, at 674.
88 See Mintzes, supra note 13, at 260.
Vioxx is a prime example of how the current approval process fails to properly address false or misleading DTCA upon discover of potentially deadly side effects, and how that system failure can harm a vast portion of the population. This failure is attributable to lackluster regulations enforced by an overburdened system. The most frightening aspect of the Vioxx drug recall is that scientists knew of the detrimental side effects prior to Vioxx’s entrance onto the market but did not implement special requirements with regard to DTCA. Critics blame FDA’s failure to take the risks seriously—No new warnings were issued with regard to Vioxx, and DTCA was allowed to continue for years after FDA discovered the harmful side effects.

Despite the disastrous events which unfolded with Vioxx, FDA continues to allow many controversial drugs to be heavily, and improperly, advertised. For example, the birth control pill, Yaz. In 2007, Bayer, the manufacture of Yaz, spent over $83 million dollars on DTCA for Yaz, and sales in 2007 topped $254 million. However, when compared with other birth control prescription drugs, Yaz has been linked with a much higher risk of deadly side effects, including blood clots and strokes. The drug ran into trouble with FDA because advertisements promoted off-label uses which were not approved by FDA. In order to remedy the misconceptions to the public, FDA mandated that Bayer:

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90 See Mintzes, supra note 13, at 260.
91 Business Week, supra note 86.
92 Id.
93 CONSUMER REPORTS, 2008.
95 See Matthew Arnold, Flat is the New Up, MED. MKT. & MEDIA, April 1, 2010 (“In February 2009, even before Hamburg signed on, Bayer announced it would run $20 million worth of "corrective" advertising for its birth control pill Yaz and submit to preclearance of all advertising for six years as part of a settlement with FDA and 27 states attorneys general. At issue were two Yaz TV ads that the states and the agency said effectively marketed the drug..."
Implement a $20 million dollar campaign to ‘remedy’ the misinformation it promoted and must submit all subsequent television advertisements to FDA for pre-approval; comply with FDA on TV and print advertisement suggestions; and “clearly and conspicuously” disclose for what FDA has approved when discussing—in its print ads—those symptoms Yaz can treat.\(^\text{96}\)

However, when false and misleading information is disseminated to consumers, the harms that stem from improper DTCA are done and it is virtually impossible to undue that damage.

It is impossible to predict whether Yaz will become the next Rofecoxib. However, these are only two examples of prescription drugs which have slipped through the cracks in our regulatory framework. What is of greater concern is that Yaz and Rofecoxib are only two out of tens of thousands of prescription drugs on the market. Many more drugs are of concern—FDA data shows that there were 1,742 drug recalls in 2009 alone.\(^\text{97}\)

\textit{ii. Diminishing Enforcement Efforts}

Warning letters are one of FDA’s primary ways of policing pharmaceutical drug DTCA. However, when comparing the number of warnings letters in the past decade with those of the late 1990s, from over 200 letters annually to approximately thirty letters annually, respectively, it is clear that this enforcement mechanism has declined.\(^\text{98}\) It is uncertain whether this decline is off-label, minimized risk information and plastered over side effects with distracting visuals and other “competing modalities.”\(^\text{99}\). The off-label uses include treatment for all types of premenstrual syndrome when Yaz was only FDA approved for the most severe PMS. Feeley, \textit{supra}, note 94.


\(^{98}\) See Donohue, \textit{supra} note 13, at 676. “The number of regulatory actions taken by the FDA against companies marketing prescription drugs to consumers has fallen dramatically in recent years.” \textit{Id.} at 679.

The number of letters sent by the FDA to pharmaceutical manufacturers notifying them that they had violated regulations for prescription-drug advertising fell from 142 in 1997 to only 21 in 2006. During the same period, the proportion of promotion-related regulatory letters citing problems with direct-to-consumer advertisements (as opposed to promotional material aimed at health professionals) increased from 15.5% of all letters in 1997 to 33.3% in 2006. And during the years 2003–2004, nearly half of the FDA’s promotion-related regulatory letters were focused on direct-to-consumer advertisements. From 1997 to 2006, nearly 84% of regulatory letters regarding direct-to-consumer advertising cited advertisements for either minimizing risks (e.g., minimizing or
due to better compliance by pharmaceutical companies or weakened oversight by FDA.\textsuperscript{99} Evidence points to the fact that FDA is understaffed when it comes to policing DTCA, especially when compared with the growth in spending on DTCA.\textsuperscript{100} In 2010, Congress authorized a “handful more staffers to help tackle the growing flood of ads, but the agency still has just 57 officials charged with reviewing roughly 75,000 marketing items a year.”\textsuperscript{101} Another problem is that letters are often issued after marketing campaigns have already disseminated false and misleading information and thus impacted consumers.\textsuperscript{102} Therefore, the problems often associated with DTCA, such as negative impact on the physician-patient relationship and consumer demand have already occurred. Moreover, information on the Internet can never truly be deleted. Consumers may save information or copy certain pages. Thus, catching a misleading advertisement and removing it from the Internet is not a complete remedy.

\textbf{iii. Insufficiency of the “Bad Ad” Program}

The Bad Ad Program is a step in the right direction for policing DTCA; however, it is insufficient as a means of prohibiting false and/or misleading DTCA from reaching the public. The goal of this program is to heighten public and medical community awareness of the potential for false and misleading promotion.\textsuperscript{103} According to data compiled after the program’s first year, there were “328 reports of potentially untruthful or misleading promotion.”\textsuperscript{104} Of these, 125 were

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\textit{omitting information on side effects), exaggerating effectiveness (e.g., portraying the indication too broadly or making unsubstantiated claims of superiority over other drugs), or both.}

\textsuperscript{99} See Donohue, supra note 13, at 676.

\textsuperscript{100} See supra note 81.

\textsuperscript{101} Id.

\textsuperscript{102} See Donohue, supra note 13, at 676. There is an average five-month delay before removal of illegal advertising.

\textsuperscript{103} See Mintzes, supra note 13, at 261.

identified for comprehensive review.\textsuperscript{105} Because the program is targeted primarily at healthcare providers, the level of heightened awareness outside of the health community is uncertain. Thus, only a small percentage of the population is being educated on the potential for DTCA to be false and misleading. Another problem with this program is that “bad ads” were discovered only after they were disseminated to the public. The Bad Ad Program helps fill a gap in the regulatory framework, but it is insufficient at prohibiting “bad” ads from entering the marketing altogether.

\textit{iv. Incentive to Pay Fines Instead of Restricting DTCA}

FDA has the power to impose civil monetary fines when DTCA is false or misleading; however, the fines imposed for violating DTCA regulations often pale in comparison to the potential windfall from marketing these blockbuster drugs. While the sale of drugs can mean millions of dollars for drug companies, fines are only $250,000.\textsuperscript{106} Because of the low price tag associated with fines and the large amount of increased sales that stem from DTCA, pharmaceutical companies are incentivized to view fines as a cost of doing business rather than a restriction on DTCA.\textsuperscript{107}

\textbf{IV. The World of eDTCA}

\textbf{A. Overview of eDTCA, Including Social Media}

New online advertising methods, referred to as eDTCA, have emerged with the transition of the Internet from “Web 1.0” to “Web 2.0” technologies—including that of social media marketing.\textsuperscript{108} Where the Internet was once viewed as a passive way to receive information, Web 2.0 provides a more “interactive, dynamic, and custom-built relationship” experience through the

\footnotesize{\textsuperscript{105} Id.  
\textsuperscript{106} See 21 U.S.C. § 333(b).  
\textsuperscript{107} See Lurie, \textit{supra} note 17, at 448.  
Information can be transmitted instantaneously to a large audience. Online platforms are not limited to stationary computers, but can now be accessed by laptop, mobile phone, and tablets. Currently, multiple avenues for social media exist, including social platforms like Twitter, Google+, and Facebook; multimedia channels like YouTube; rating and review sites like Yelp; and personalized blogs. These platforms are powerful when it comes to interacting with consumers. For instance, when combined, Facebook and Twitter have over 350 million users worldwide.

Social media and other eDTCA provide advantages for advertisers when compared with traditional DTCA forms. Pharmaceutical manufacturers can reach large audiences while also targeting specific patient populations. Internet sites are flexible, because they allow for information to be quickly updated, removed, or adapted, and provide analytics information, including website traffic patterns. Moreover, an increasing number of patients are tech-savvy and

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109 Id. Social media has a broad definition, often involving the intersection of the Internet and consumers. One scholar defined it as “text, words, pictures, video, and the like created with the intention of sharing. In the context of the marketplace, it is the thoughts and experiences of participants . . . that relate to their experiences with brands, products or services. DAVE EVANS, SOCIAL MEDIA MARKETING: AN HOUR A DAY Chap. 3 (2012). Webster’s defines it as “[w]eb sites and other online means of communication that are used by large groups of people to share information and to develop social and professional contacts. Dictionary.com, dictionary.reference.com (last visited April 11, 2012).

110 Twitter is a “social networking and microblog site using short Internet posts.” Liang, Prevalence and Global Health Implications of Social Media in Direct-to-Consumer Drug Advertising, supra note 108.


113 YOUTUBE, www.youtube.com (last visited April 11, 2012). “YouTube provides a forum for people to connect, inform, and inspire others across the globe and acts as a distribution platform for original content creators and advertisers large and small.” Id.

114 YELP, www.yelp.com (last visited April 11, 2012). Yelp states its purpose as connecting “people with great local businesses.” Id.

115 See Evans, supra note 109.


117 Liang, Prevalence and Global Health Implications of Social Media in Direct-to-Consumer Drug Advertising, supra note 108.
have easy access to the Internet. Lastly, social media allows for viral marketing. Instead of drug companies choosing to run print or broadcast advertisements at particular times, social media allows users to do the sharing. The goal of Internet and social media campaigns is actually that individuals will further the messages on social media, thus creating a viral marketing campaign.

Of all the forms of DTCA, eDTCA has the greatest potential to benefit patients by reaching users on a variety platforms and providing up-to-date information about health care, disease, and treatment options. In fact, several studies have shown that patients turn to the Internet for health care information before consulting with a medical professional, and the information they receive from the Internet and social media platforms impacts their health decisions. In a recent DTCA study regarding online social media technologies, researchers

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119 Id.

120 Id.

121 Id. “A Harris poll estimated 175 million adults use the Internet for health care information.” Id. “The National Center for Health Statistics reported 51% of adults searched for health information on the Internet” during the first half of 2009. Id. Further, another survey indicates that 60% of Americans turn to the Internet first when searching for health-related information. See Greene, supra note 116. “Over 60 million consumers used social media to communicate and research health and medical information in 2008.” FDA POLICY ON SOCIAL MEDIA AND PRODUCT PROMOTION, http://www.corporatecomplianceinsights.com/fda-policy-social-media-product-promotion/ (last visited April 11, 2012).

E-patients are using the internet to compare their options, just as they do with other major decisions, and to find the "just-in-time someone-like-me" who can aid their decision-making.

Fifty-nine percent of e-patients have done at least one of the following activities:

- 41% of e-patients have read someone else's commentary or experience about health or medical issues on an online news group, website, or blog. About half of e-patients between the ages of 18-49 have read someone else’s commentary online, compared with about one-third of e-patients ages 50 and older.
- 24% of e-patients have consulted rankings or reviews online of doctors or other providers.
discovered that each of the ten largest pharmaceutical companies had an eDTCA presence, and many were active on multiple social media platforms. This included 70% with dedicated Facebook pages, 90% with websites, 80% with YouTube channels, and 80% with health care communication mobile applications. Further, some pharmaceutical manufacturers also host blogs where consumers can get drug and health care information.

- 24% of e-patients have consulted rankings or reviews online of hospitals or other medical facilities.
- 19% of e-patients have signed up to receive updates about health or medical issues. Customized health bulletins are especially popular among e-patients age 50-64: 23% have signed up to receive such updates, compared with 14% of e-patients ages 18-29, for example.
- 13% of e-patients have listened to a podcast about health or medical issues.


Among the six in ten e-patients who say their most recent search had an impact, mostly minor, on their own health or the way they care for someone else:
- 60% say the information found online affected a decision about how to treat an illness or condition.
- 56% say it changed their overall approach to maintaining their health or the health of someone they help take care of.
- 53% say it lead them to ask a doctor new questions, or to get a second opinion from another doctor.
- 49% say it changed the way they think about diet, exercise, or stress management.
- 38% say it affected a decision about whether to see a doctor.
- 38% say it changed the way they cope with a chronic condition or manage pain.

Id.

When asked, “Did the health information you found in the last time online have a major impact on your own health care or the way you care for someone else, a minor impact, or no impact at all?”
- 13% of e-patients say their most recent inquiry had a major impact.
- 44% of e-patients say it had a minor impact.
- 41% of e-patients say their most recent inquiry had no impact.

Id.

Liang, Prevalence and Global Health Implications of Social Media in Direct-to-Consumer Drug Advertising, supra note 108.

Companies include Pfizer (having a comprehensive Facebook page with over 51,000 “likes” and includes photos, commentary and adverse events (https://www.facebook.com/Pfizer)); Astrazeneca (https://www.facebook.com/pages/AstraZeneca/33255586863); and Eli Lilly (https://www.facebook.com/pages/Eli-Lilly-and-Company/112432178772737).


See GlaxoKlineSmith’s blog at http://www.morethanmedicine.us.gsk.com/blog/about-this-blog.html (“Our goal is to encourage an open, productive discussion about a range of topics related to the US healthcare system and how it can be improved. And we're going to try and do our best to provide a GSK perspective that doesn't sound like it's written in 'legalese.' But, be sure to read our Comments Policy to be familiar with the rules.”); Pfizer’s blog at http://www.thinksciencenow.com/feature/.
Despite its advertising potential, social media plays a small role in DTCA budgets. In 2008, less than 4% of DTCA expenditures were spent on Internet outlets. Many speculate that the low spending levels are a direct result of the lack of FDA guidance and regulations on social media platforms. It is unlikely, however, that social media expenditures will remain nominal for long. Growth projections estimate that pharmaceutical drug online ad spending will reach $1.52 billion in 2014. “Marketers are deliberately creating campaigns, and use what they call ‘digital buzz’ techniques’ to get their message out.” These campaigns embrace everything from comical YouTube videos, in hopes that viewers will share them with others, to support group websites for particular diseases. Further, pharmaceutical companies will want to ensure that the information promulgated on social media is portraying the correct message and is “accurate, transparent, [and] high-quality.” Thus, it is only a matter of time before pharmaceutical companies tap into the various resources of Web 2.0 and increase social media

126 See Greene, supra note 116; see also Liang, Prevalence and Global Health Implications of Social Media in Direct-to-Consumer Drug Advertising, supra note 108 (stating that 2009 total online DTCA spending was projected between $117 and $1 billion). “Prescription products are being marketed through more controlled, non-interactive strategies using conventional Internet outlets, such as fixed websites, and links to and from websites – which, by today’s standards, are antiquated avenues for advertising. Accordingly, FDA-regulated industries have yet to harness the potential of social media.” FDA POLICY ON SOCIAL MEDIA AND PRODUCT PROMOTION, http://www.corporatecomplianceinsights.com/fda-policy-social-media-product-promotion/ (last visited April 11, 2012).


128 “Big Pharma, which spent $1 billion in online promotion last year and was expected to reach $1.52 billion in spending by 2014, has been somewhat inhibited by the lack of guidance and ambiguity on social-media use.” AD AGE DIGITAL, http://adage.com/article/digital/fda-s-social-media-guidelines-befuddle-big-pharma/231855/ (last visited April 11, 2012). “No company wants a warning letter from the F.D.A., so they’re going to comply,” he said, “but it will mean there won’t be as effective search advertising; it’ll be harder to do in an effective way. But F.D.A.-regulated companies can only stay in business if they’re on the right side of the F.D.A.” N.Y. TIMES, F.D.A. Rules on Drug Ads Sow Confusion as Applied to Web, http://www.nytimes.com/2009/04/17/business/media/17adco.html (last visited April 11, 2012).


131 Id.

and other eDTCA expenditures.\textsuperscript{133} While eDTCA may be a great resource for patients, it also has the potential to create immense problems for regulators trying to keep up with its constant evolution.

\textbf{B. Current Regulations: eDTCA}

While FDA has regulations in place for print and television media, FDA has not yet promulgated comprehensive media-specific regulations for eDTCA. Instead, eDTCA is subject to print and broadcast media regulations. In light of the obvious difference between print and broadcast media and Internet platforms, FDA has wisely endeavored to develop guidelines specifically applicable to eDTCA.\textsuperscript{134} This task, however, has proved challenging, and FDA has yet to offer a complete set of guidelines for eDTCA, including social media.\textsuperscript{135} In the fall of 2009, FDA held public hearings in an effort to engage pharmaceutical and biotechnology companies and receive suggestions for how to handle the challenges presented by social media.

\textsuperscript{133} As one leading advertising agency blog stated, the pharmaceutical industry should engage in social media but albeit in a careful manner.

\begin{quote}
“Instead, pharma marketing that promises to leverage social channels should voluntarily be transparent, useful, not overly promotional and serve a real need. Doing things right in this area doesn’t always mean looking for permission or waiting for someone else to do it first. Efforts launched in an ethical and non-manipulative way can and do work - and should be a part of your planning efforts for 2011, whether the social media guidelines from the FDA come in early 2011 or not.”
\end{quote}


\textsuperscript{134} Industry is frightened that FDA will try to apply current regulations to social media.

\begin{quote}
“Now, as the companies change their search ads to comply with the letters, industry executives say the solution is worse than the problem: their ads are even more confusing and misleading now, they say. And they worry that regulators will enforce standards that were created for magazines and television, rather than making new rules that acknowledge how Internet ads have evolved.
\end{quote}

\textsc{Stephanie Clifford}, \textit{F.D.A. Rules on Drug Ads Sow Confusion as Applied to Web}, \textsc{N.Y. Times} (April 16, 2009).


In 1999, FDA further delayed taking a position by informing the industry that it would “look at [Internet] issues on a case-by-case basis” while reserving the right to reevaluate the need for regulations in the future. As a result, to glean FDA’s Internet policy, the industry has been forced to scrutinize individual enforcement actions against companies who have created and used Internet websites for improper promotion of their products.

\textit{Id.}
platforms and the Internet.\textsuperscript{136} FDA solicited written comments so it could better develop
regulations and policies.\textsuperscript{137} Post hearings, FDA announced its intention to issue guidance for
social media;\textsuperscript{138} however, it was not until December 2011 when FDA released its first
guidance.\textsuperscript{139}

Unfortunately, the draft guidance does not provide a comprehensive regulatory
framework for eDTCA, but instead gives examples of how social media may be implicated with
regard to unsolicited requests for off-label use.\textsuperscript{140} It states that companies are not required to
respond to unsolicited requests for off-label information and also provides clear requirements for
how they are to handle unsolicited requests for off-label information if they choose to respond.\textsuperscript{141}

\textsuperscript{136} See MEDIAPOST PUBLICATIONS, http://www.mediapost.com/publications/article/167499/the-fda-social-media-
guidance-the-path-forward.html (last visited April 11, 2012); BIG THINK, http://bigthink.com/ideas/41144 (last
visited April 11, 2012).
\textsuperscript{137} See FDA POLICY ON SOCIAL MEDIA AND PRODUCT PROMOTION,
2012).
\textsuperscript{138} See MEDIAPOST PUBLICATIONS, http://www.mediapost.com/publications/article/167499/the-fda-social-media-
guidance-the-path-forward.html (last visited April 11, 2012)
\textsuperscript{139} See U.S. FOOD AND DRUG ADMINISTRATION – GUIDANCE FOR INDUSTRY, RESPONDING TO UNSOLICITED
REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES,
(last visited April 11, 2012).
\textsuperscript{140} See SOCIALMEDIATODAY, http://socialmediatoday.com/emoderation/431738/fda-guidance-pharma-social-media-
and-label-use (last visited April 11, 2012); AD AGE DIGITAL, http://adage.com/article/digital/fda-s-social-media-
guidelines-befuddle-big-pharma/231855/ (last visited April 11, 2012).
\textsuperscript{141} See U.S. FOOD AND DRUG ADMINISTRATION – GUIDANCE FOR INDUSTRY, RESPONDING TO UNSOLICITED
REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES,
(last visited April 11, 2012). If companies chose to respond, FDA provided a clear procedure for how to handle the
response. For non-public responses, the following criteria should be met:

1. Information should only be provided to the individual making the request
2. Information should be tailored to answer the specific question(s) only.
3. Information must be “truthful, non-misleading, accurate, and balanced.”
4. Information should be scientific in nature
5. Responses should be made by medical or scientific personnel, not marketing personnel
6. Information must include a copy of FDA-required labeling; a statement that FDA has not approved product
   as safe and effective for the off-label use; a statement disclosing approved or cleared uses; safety
   information; list of references for the information provided.
7. Company should maintain records of the request and the information provided

\textit{Id.} at 7-9.

For public unsolicited requests for off-label information, the company do the following:

1. Only respond if the request is for their specific product
2. The public response should be limited to the provision of the company’s contact information

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The guidance wades into the world of social media by making clear that solicited bloggers will be treated as extensions of the company and any off-label discussion will be considered solicited.\textsuperscript{142} While the guidance is not as comprehensive as the industry may have sought, it provides some guidance regarding social media and foreshadows future regulation.\textsuperscript{143}

C. Enforcement: Warning Letters

Electronic DTCA regulations are enforced using the same methods as the other forms of DTCA, such as through warning letters and civil monetary fines.\textsuperscript{144} However, because there are fewer regulations for eDTCA, the majority of FDA response has been through warning letters. In April of 2009, FDA issued fourteen letters to pharmaceutical companies regarding their use of Internet search engine sponsored links.\textsuperscript{145} The letters were in response to an industry assumption that online advertisements that contained only benefit information were in compliance with regulations as long as the risk information was provided within “one-click” of the benefits information.\textsuperscript{146} FDA’s letters made clear that there was no such “one-click” rule, and that DTCA

\begin{itemize}
\item \textsuperscript{144} See supra notes 72-83 and accompanying text (discussing FDA and FTC enforcement efforts).
\item \textsuperscript{145} HEALTHCARE ENGAGEMENT STRATEGY, http://creationhealthcare.com/articles/fda-warns-pharmaceuticals-about-google-advertising/ (last visited April 11, 2012).
\item \textsuperscript{146} See Clifford, supra note 134.
\end{itemize}
must contain both benefit and risk information together.\textsuperscript{147} The companies were ordered to discontinue the advertisements immediately.\textsuperscript{148}

Further, in 2010, FDA issued a warning letter to drug maker Novartis regarding its advertising of prescription drugs on Facebook.\textsuperscript{149} Novartis was cited for misusing the “Share” widget.\textsuperscript{150} The problem, according to FDA, was that the widget “didn’t share enough information” and therefore lacked fair balance.\textsuperscript{151} These warning letters may provide some guidance for industry; however, it still is far from the needed comprehensive framework.

D. Problems with eDTCA and its Current Regulatory Framework

Unfortunately, current print and broadcast media regulations do not completely align with online advertising. The variety of social media platforms poses difficulties in regards to regulatory efforts, because a blanket regulation is unlikely to work within the vast array of social media. Some platforms do not allow for the required listing of side effects and other information because of formats with space constraints. For instance, Twitter allows only 140 characters per “tweet”, which is inadequate to fit the required information for print advertisements.\textsuperscript{152}

FDA has been slow to react to new forms of social media.\textsuperscript{153} Because of the lack of social media guidance, many problems have emerged with regard to consumers and industry and

\textsuperscript{147} Id. The letters addressed five specific warnings that the advertisements violated regulations, including: 1) omission of risk information; 2) minimization of risk information; 3) inadequate communication of indication; 4) overstatement of efficacy; and 5) failure to use established brand names.


\textsuperscript{150} Id. The share widget is used by clicking on it to promote a page, in this case a page for the drug Tasigna, to your Facebook friends. Id.


\textsuperscript{152} Id.

eDTCA, including: uncertainty regarding the quality of the information available on social media; how to handle space constraints and achieve fair balance; off-label discussions; and whether industry will push the envelope and use eDTCA despite a lack of media-specific regulation.\(^{154}\)

\(i.\) **Uncertainty Regarding the Quality of Information Available on Social Media**

Consumers should be concerned with information garnered from eDTCA, because advertisers can easily use online platforms to confuse or coerce consumers. For example, product websites usually have benefits information available on the front page of the site; however, risk information is often incomplete and is usually buried within the website.\(^{155}\) Further, online platforms make it difficult for consumers to discern what information is reliable and accurate, because they are unable to decipher the origin of the information.\(^{156}\) Some social media platforms often make it difficult for manufacturers to control DTCA content, such as when users are allowed to post comments but manufacturers cannot remove or edit that information. Apps like Sidewiki—where advertisements are placed on websites based on consumer searches and without company decision—makes the distinction between company-controlled content and independent content difficult because it “can layer a social network of commentary onto any existing static Web site, with or without the site owner’s consent.”\(^{157}\) Lastly, because search

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\(^{154}\) See Frosch, *A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising*, supra note 27. While there are many problems associated with social media and eDTCA, there are also potential benefits including: 1) Communication of health information to patients; 2) Risk evaluation and mitigation strategies; and 3) Coordination with existing regulatory tools. *Id.* However, while these potential benefits exist, it is still imperative that FDA issue social media guidance for industry in order to meet one of the objectives with which it is charged—ensuring the public is provided fair and balanced information with regard to DTCA. *Id.*

\(^{155}\) See *id.*

\(^{156}\) See Liang, *Prevalence and Global Health Implications of Social Media in Direct-to-Consumer Drug Advertising*, *supra* note 108. “While offline conversation about health information may be robust, it seems that the online conversation about health may be lopsided. There are many more readers and listeners than there are writers and creators of online content.” Fox, *supra* note 121.

\(^{157}\) See Greene, *supra* note 116.
engines drive consumers to content, eDTCA may receive higher traffic because of repeat use or other website links. This can cause sites to appear higher in search results, allowing these DTCA sites to become a dominant source of health information.  

Companies are also concerned about the quality of information on the Internet. Many companies are unsure whether they are allowed to participate in online discussion of its drugs, such as on a blog, without being held responsible for all of the content created. Thus, many patient questions go unanswered. Moreover, companies are concerned with whether they are responsible for correcting misinformation posted by third-parties. Because of the lack of certainty, many companies do not address misinformation and it remains online for consumers to view.

**ii. How to Handle Space Constraints and Achieve Fair Balance**

Another concern with the lack of eDTCA guidance is that not all online platforms are equivalent, and it is difficult to apply current regulations consistently in an online environment. Problems can arise, because advertisers try to fit regulations to a media for which they were not created. Patient safety may be compromised due to the fact that some eDTCA may overemphasize benefits while underemphasizing risk. Industry would like to see some type of guidance for space constraints with regard to social media. For instance, “many in the industry are calling for FDA to formally adopt the rule and allow a company to present a brief


162 See Liang, *Direct-to-Consumer Advertising With Interactive Internet Media*, supra note 158, at 825.

163 See FDA POLICY ON SOCIAL MEDIA AND PRODUCT PROMOTION, http://www.corporatecomplianceinsights.com/fda-policy-social-media-product-promotion/ (last visited April 11, 2012). “The industry wants FDA to account for the evolving nature of social media and space constraints. Guidelines or regulations regarding dissemination of risk information should be principal based and applicable to multiple social media formats.” *Id.*
introduction of its product (e.g., an abbreviated reference to the product’s indication and its most significant risks) based on the space constraints of the social media itself, provided there is easy access to full product information through a hyperlink.”

iii. Off-label Discussions

Electronic DTCA on social media platforms poses a problem with regard to off-label discussions, because of the fact that social media encompasses many platforms where the public can openly contribute opinions and information. Again, companies wonder if they will be held responsible for any information involving their products, even if it was not disseminated by them. “There is trepidation that any off-label discussion or reference on an interactive social media site will impute knowledge and consent of an unapproved use to the manufacturer.”

iv. Whether Industry Will Push the Envelope

The lack of social media guidance incentivizes an unguided industry to push the bounds of advertising in the realm of social media. Advertisers are not deterred by the lack of specific regulation, and DTCA has appeared on the Internet from blogs to social media sites. In fact, spending on social networking sites reached over $1 billion in 2008, and that amount appears to be increasing.

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164 Id.
165 See supra notes 108-124 and accompanying text (describing various social media platforms and how consumers utilize them).
168 Truth in Advertising, Offline or Online, N.Y. TIMES, Oct. 13, 2009, at A.
V. Proposals for a Comprehensive DTCA Regulatory Framework

To best protect the public, the problems of DTCA must be mitigated while the potential is maximized.\textsuperscript{169} This can be accomplished through improved regulation, which will lead to better information being presented to the public. Scholarly research indicates that current regulations are insufficient to ensure public safety;\textsuperscript{170} however, a balance must be struck between governmental oversight and the rights of pharmaceutical manufacturers to advertise. On one hand, a complete ban would offer the greatest protection to the public, but it would be heavily paternalistic and infringe on individual autonomy. Further, it might run afoul of the First Amendment.\textsuperscript{171} On the other side of the spectrum, allowing unrestricted DTCA would likely have drastically harmful effects. Consumers could be wholly misled by DTCA that only features benefits, drugs would likely be overprescribed, and deaths could occur. Therefore, an approach in the middle would produce the most optimal result.

Scholars have proposed a host of regulatory alternatives and additions which would improve the current regulatory scheme, including: regulating marketing campaigns rather than individual components; focusing advertising on disease prevention rather than individual drugs; limiting advertising of new drugs; and encouraging education.

\textsuperscript{169} See Frosch, \textit{A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising}, supra note 27.
\textsuperscript{170} See supra Part II.B.
\textsuperscript{171} See Frosch, \textit{A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising}, supra note 27, at 30 (noting that the government must be mindful of the First Amendment and commercial speech when regulating advertising). It cannot be said with certainty that a ban on DTCA would be found unconstitutional. Commercial speech regulation is governed by the 4-part test set forth in \textit{Central Hudson Gas & Elec. Corp. v. Public Services Comm. of N.Y.}, which includes: (1) whether the speech at issue concerns lawful activity and is not misleading; (2) whether the asserted government interest is substantial; and, if so, (3) whether the regulation directly advances the governmental interest asserted; and (4) whether it is not more extensive than is necessary to serve that interest. While this is an important consideration when contemplating advertising restrictions, it will not be covered in depth in this paper. For a more in-depth analysis regarding the constitutionality of a restriction on DTCA, see Mark I. Schwartz, \textit{To Ban or Not to Ban-That is the Question: The Constitutionality of a Moratorium on Consumer Drug Advertising}, 63 FOOD & DRUG L.J. 1 (2008); David C. Vladeck, \textit{The Difficult Case of Direct-to-Consumer Drug Advertising}, 41 LOY. L.A. L. REV. 259 (Fall 2007).
A. Regulate Marketing Campaigns Rather than Individual Components

The regulations promulgated by FDA are currently inadequate to capture the vast array of advertising platforms and the rapid development of new social media platforms. To best alleviate the problem, new regulation could focus on regulating marketing programs, rather than individual types of marketing. FDA could focus on the message of the overall program, checking to ensure it is fair and balanced, and then approve information which advertisers could use in DTCA. As one scholar noted, “[o]nly by knowing this informational landscape—by considering it holistically in terms of the packaging and circulation of ideas, rather than by defining particular kinds of marketing to focus on can observers hope to evaluate and ultimately regulate its many traffickers.” Campaign reviews could be accomplished more quickly when compared with individual marketing piece reviews, because FDA would approve the overall information, rather than approving the information on each piece. The advertiser would then be responsible for using only the approved information. Improved approval times would increase the amount of reviewed material on the market and heighten consumer protection. This idea appears encouraging, because it does not require a complete overhaul of the system, but rather a modification of existing regulations.

B. Focus Advertising on Disease Prevention Rather than Individual Drugs

Rather than centering campaigns on advertising individual drugs, pharmaceutical companies could collaborate on campaigns that encourage consumers to talk to their physicians about a particular condition or disease. This alternative may lead to a decrease in advertising

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172 See Greene & Kesselheim, Hidden in Plain Sight, supra note 15.
173 See Lurie, supra note 17, at 448.
174 Greene & Kesselheim, Hidden in Plain Sight, supra note 15.
175 See Avery, supra note 56, at 252. “Several opponents to DTCA have expressed strong concerns about potential bias in the presentation of health information in DTCA, noting the use of strongly promotion-oriented communications and ad text formats designed to sell branded products rather than foster understanding of complex medical information.” Id.
expenditures; however, it would result in a more informed and less biased public.\(^{176}\) Also, by encouraging patients to consult with their physicians about overall health, rather than a particular medication, patient autonomy is encouraged. Physicians will feel less pressured to succumb to patient’s demands for particular medications, and can also focus on non-medication alternatives.\(^{177}\) Most helpfully, this approach returns prescribing power to physicians.

C. Limit New Drug Advertising

The Institute of Medicine has recommended that FDA restrict advertising for new prescription drugs.\(^{178}\) Representative Henry Waxman has gone so far as to support a “two-year DTC moratorium for new drugs.”\(^{179}\) “‘Americans must face an inconvenient truth about drug safety’ . . . . ‘The truth is that we inevitably allow drugs on the market whose risks are not fully known.’”\(^{180}\) Allowing DTCA means consumers are exposed to drug information before the risks associated with entering the market are fully understood. A limited restriction on pharmaceutical drugs DTCA would result in increased public safety, because it would minimize over prescription.\(^{181}\) Also, while drug manufactures could continue marketing to physicians, physicians would be able to prescribe medications without external pressure from patients.

Further, this moratorium on DTCA could allow FDA more time to review marketing materials prior to a drug’s launch. A regulation banning DTCA for a certain period of time would provide an adequate balance of oversight without infringing on patient autonomy.

At least one pharmaceutical manufacture has voluntarily adopted this model. Bristol-Myers Squibb “recently announced a voluntary moratorium on direct-to-consumer advertising


\(^{177}\) See supra notes 35-38 and accompanying text (describing the current pressures that physicians are under to prescribed requested brand name drugs even though they may not be the best treatment option available).

\(^{178}\) Donohue, supra note 13, at 674.


\(^{180}\) Id. (quoting House Representative Henry Waxman).

\(^{181}\) Matthew Arnold, Waxman Says DTC Ad Ban Should be a Priority, 44 MED. MARKETING & MEDIA, Jan. 1, 2009.
for drugs in the first year after FDA approval.” 182 Additionally, PhRMA, the industry trade group, has recommended that manufacturers delay such campaigns for new drugs until after health professionals have been sufficiently educated.” 183 Even a year moratorium will limit overprescribing and help ensure that only patients who need certain prescription drugs receive them. It will also allow pharmaceutical manufactures to learn how the marketplace reacts to drugs and can prevent drug failure disasters.

D. Encourage Education

Lastly, FDA should encourage both physician and patient education. Physicians should educate themselves outside of the literature received from drug companies. FDA could recommend that physicians are cautious in prescribing newly approved drugs until long-term effects in the marketplace develop and are more fully understood. The AMA encourages physicians to open a dialogue with their patients when they ask for DTC advertised drugs. 184 Further, it asks that physicians report advertisements that are inaccurate, incomplete, or imbalanced. Ethical mandates may, however, fall flat in the face of patient demand. A comprehensive physician education program is essential to decrease the impact of uninformed demand and empower physicians to report misleading advertising.

In order to better educate the patient population, FDA could require increased transparency by requiring drug manufacturers to disclose “all material information that allows a meaningful comparison to existing therapies . . . .” 185 While this may be difficult in current print or broadcast realms, it is something that could be disseminated easily through the Internet.

182 Donohue, supra note 13, at 679.
183 Id.
185 Liang, Reforming direct-to-consumer advertising, supra note 50 at 398.
E. Social Media: Addressing the Problems Instead of the Platforms

“What everybody was looking for was never going to happen. If you’re waiting for divine guidance, you’re still waiting.”186

The onset of rapidly evolving social media advertising formats demands new regulations. This proves a difficult task for FDA and FTC. While some of the aforementioned suggestions for modification to current DTCA guidelines also apply to social media, social media should be specifically considered and incorporated into the current regulatory framework. In order to best incorporate social media guidelines, it is “important to note the differences between the utilization and communication factors within each online platform. The FDA must develop a series of strategic regulations that apply to company-controlled online communications, company-controlled and hosted online communications, as well as real-time, social media communications.”187

Rather than trying to develop regulations for the various forms of social media, an unlikely scenario, FDA should address and regulate the problems that industry currently faces. These problems, as noted above, include: ensuring third-party information is accurate; addressing inadequate space issues; off-label discussions; and defining for what information companies are responsible. To date, scholars have proposed a variety of solutions for eDTCA, many of which could be implemented as long-term fixes. In addition to these scholarly proposed solutions, I have also included solutions which I believe will aid FDA with eDTCA regulations.

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i. **Third-Party Information**

To address third-party information, FDA could require sponsorship identification on any site that is affiliated with pharmaceutical manufacturers. This would alert consumers that the information they receive is linked to companies and may be bias. The identification could be in the form of a FDA and/or company branded seal.\(^{188}\) FDA could require that this seal be linked to the company’s webpage or that the company have a page on their website that is devoted to disclosing any relationships with online third parties, such as bloggers.\(^{189}\) Lastly, FDA might find it helpful to turn to guidance from FTC in regulating third-party disclosures.\(^{190}\)

ii. **Space Limitations**

When dealing with space limitations, FDA could allow companies a link to a product website and/or only a graphic depicting the name of the product. Thus, neither benefits nor risk information is presented in a misleading manner. FDA could also require that if space limitations prohibit listing side effects, benefits may not be listed. Both of these suggestions facilitate fair and balanced eDTCA while still allowing companies to engage in DTCA.

iii. **Off-label Discussions**

Off-label discussions with regard to unsolicited requests for information have been addressed in part by recent FDA guidance;\(^{191}\) however, FDA should also make clear to the industry whether it is responsible for all off-label discussion on the Internet. While the current

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\(^{188}\) See Greene, *supra* note 116.
Second, it is crucial to address the problem of disclosure of financial interests in social media. Although most Internet users can often (but not always) find data on drugs’ risks and benefits within a few keystrokes, it is hard to determine whether the source is credible and disinterested. It is now recognized that the ghostwriting of medical research articles can have important public health implications; financial disclosures should be just as explicit for leading providers of social media content as for authors of articles in peer-reviewed journals.

\(^{189}\) Id.

\(^{190}\) Id.

\(^{191}\) See *supra* note 84 and accompanying text (detailing FTC’s latest social media regulations).

\(^{191}\) See *supra* notes 140-143 and accompanying text (discussing most recent FDA guidance regarding eDTCA).
guidelines provide helpful example scenarios, because social media is a constantly changing environment and off-label discussions can appear in a variety of settings, FDA must continue to provide informative guidance regarding industry content responsibility.\textsuperscript{192} It seems an impossible task to provide a blanket long-term solution for this area.

\textit{iv. Pharmaceutical Manufacturer Responsibility for Information}

Lastly, FDA could offer guidance regarding the types of information for which companies are responsible. This could include treating company-controlled or sponsored sites similarly to print media.\textsuperscript{193} It is practical and responsible to require companies to control their websites to ensure there is no misinformation or false or misleading DTCA. If a site is not company-controlled, it will be difficult for FDA to require companies to police that information, as they will likely have no control over changing content. However, companies could be required to maintain a webpage that discloses which third-party sites are watched to ensure accurate information. This would facilitate customer knowledge and promote acceptance of reliable information.

These are all only pieces of the social media puzzle. While the FTC amended its guidelines to include “blogs, Twitter and other forms of online communication”\textsuperscript{194} there is still substantial need for FDA and FTC regulation with regards to eDTCA and social media. It is imperative that both agencies develop regulations because of the current increase in social media DTCA and its forecasted growth in the future. If regulations are not created, the dissemination of inaccurate information could soon overwhelm consumer protections currently in place under current DTCA regulations.

\textsuperscript{192} See supra notes 140-143 and accompanying text (discussing most recent FDA guidance regarding eDTCA).

\textsuperscript{193} \textsc{Big Think}, http://bigthink.com/ideas/41144 (last visited April 11, 2012).

\textsuperscript{194} \textit{Truth in Advertising, Offline or Online}, N.Y. TIMES, Oct. 13, 2009, at A.
VI. Conclusion

DTCA, especially eDTCA, has the potential to be a great resource for consumers. Information regarding diseases, treatments, and even prevention is provided through a variety of platforms, thus increasing consumer access. With great potential, however, comes great responsibility. DTCA has been proven to cause harm to consumers. It often provides false or misleading information, creates uninformed demand, and causes the transfer of physicians prescribing power into the hands of the laymen. Further, blockbuster drugs are typically more expensive than alternatives already on the market and only offer marginal benefits over existing drugs.

It is surprising that DTCA can run without FDA approval of its content. Once information is released, it is difficult, if not impossible, to correct consumer misconception. While FDA imposes fines for “bad ads,” penalties are often insignificant compared to the profits drug manufactures stand to make. Allowing drug manufactures to advertise without prior approval gives them free reign over advertising and leaves the public vulnerable to misleading or false information.

As it stands, DTCA is insufficiently regulated. Rather than fixing the DTCA problems after they have occurred, it is imperative that FDA and FTC to take preemptive action and promulgate regulations that address the various problems associated with DTCA, and especially eDTCA, before harmful advertisements reach the public. Further, FDA is understaffed and underfunded. The Obama Administration should continue to increase funding, and FDA should find more efficient ways of approving advertisements. After all, the public depends on FDA and FTC to protect its health by ensuring prescription drugs advertising is fair and balanced.