THE PHARMA PERSPECTIVE:

THE DOUBLE-EDGED SWORD OF DIRECT-TO-CONSUMER ADVERTISING

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I. Introduction

Unlike most industries, the successes and growth of pharmaceutical companies (pharma companies) can often lead to the pharma companies' own vilification by consumers and health care practitioners alike.[1] The role of pharma companies serving as 'Public Enemy Number One'[2] is perpetuated by stigmas associated with the great unknown of drug research and production.[3] This animosity towards these companies also arises from lingering questions the general public has when considering the long-term effects of prescription drug use.[4] Some patients further fear that big pharma is out to get the bottom dollar, or that pharma companies are not worried about

[1] *See*, Stephanie Sutton, *Why is the Pharma Industry Public Enemy No. 1?* (Dec. 12, 2019, 2:29PM), LINKEDIN, https://www.linkedin.com/pulse/why-pharma-industry-public-enemy-1-stephanie-sutton/.
[2] *Id.*
[3] *Id.*
[4] *See*, Luis Villalba, *Pharmaceutical companies and medical practitioners or "the beast and the beauty"?*, 37 CLINICS IN DERMATOLOGY 1, 16-20 (2019) (discussing the relationships between pharmaceutical companies, physicians, and consumers in digital media platforms).

misleading consumers into buying the ever-increasing amounts of drugs pumped into the market.[5]

In general, pharma companies have a problem with their reputations in the United States ("U.S."). [6] The U.S. is one of only two countries in the world that legally allows pharmaceutical companies to advertise directly to consumers through the use of direct-to-consumer advertisements ("DTC ads").[7] While patient-consumers are inundated with a wave of different drug advertisements each day, it is possible that consumers can forget who and what is behind all these ads. Pharma companies invest time, money, and resources in their research, development, manufacturing, marketing, advertising, and selling of drugs.[8]

All of these investments can be viewed as a means to support and maintain an interest many pharma companies have – equalizing and bettering public health.[9] While this is not the only goal of pharma companies when they make the necessary investments to create and launch drugs into the market; indeed, it is still one that links pharma companies' interests with considering the greater public health.[10] DTC ads are pivotal to the promotional successes of

[5] *See*, Sarah Van den Bogaert, et al., *In the land of pharma: A qualitative analysis of the reputational discourse of the pharmaceutical industry*, 7 SAGE J. 2, 127-47 (2018) (discussing Bad Pharma discourse and unrealistic standards society has set forth for pharmaceutical companies).
[6] *Id.*
[7] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 12, 2019, 3:03PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/].
[8] *See*, Sarah Van den Bogaert, et al., *In the land of pharma: A qualitative analysis of the reputational discourse of the pharmaceutical industry*, 7 SAGE J. 2, 127-47 (2018).
[9] *See*, C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 P.T. 10, 669-74, 681-84 (2011) (discussing direct-to-consumer advertising, regulatory requirements, and the difficulty of enforcing these ads in the media by the FDA).
[10] *Id.*

pharmaceuticals.[11] Unfortunately, the hazards of misrepresenting public safety and health risks in these short bursts of audial/visual persuasion continues to put DTC ads in the hot seat.[12]

DTC ads for pharmaceuticals are not only valuable to the success of pharma companies but they are also key in the empowerment of consumer-patients.[13] DTC ads have increased conversations between physicians and patients, and normalized inquiries about ailments and diseases that would otherwise go unnoticed or undiscussed between physicians and patients.[14] Furthermore, due to an extensive history of legislation, regulation, and case law, the commercial speech of DTC ads is locked down in U.S. history books indefinitely as protected commercial speech under the First Amendment (so long as it is truthful and non-misleading).[15] This article seeks to look at historical attempts to regulate DTC ads in efforts to determine whether regulatory agencies and guidelines can reduce the negative effects of DTC ads, while still enjoying the ads' benefits.

II. What is Direct-to-Consumer ("DTC") Advertising and How is it Related to Public Health?

DTC ads are a powerful tool and method of communication used by pharmaceutical companies to broadcast prescription drug information (including the major statement, risks associated, any boxed warnings, counterindications, and other vital information) via different media outlets (such as radio, television, or the Internet).[16] These ads are a key resource aiding in

[11] *See*, Zaheer-Ud-Din Babar, et al., *A review of DTCA techniques: Appraising their success and potential impact on medication users*, 14 R.S.A.P. 3, 218-27 (2018) (discussing a search and survey of seven electronic databases that found DTC ads to be beneficial to the DTC promotion of a drug).
[12] *See*, Elizabeth A. Almasi, et al., *What are the Public Health Effects of Direct-to-Consumer Drug Advertising?*, PLoS Med. (2006).
[13] C. Lee Ventola, 36 P.T. 10, 669-74, 681-84 (2011).
[14] *Id.*
[15] *Id.*
[16] *See*, Michael S. Wilkes, et al., *Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, And Implications*, 19 HEALTH AFFAIRS 2, (2000) (discussing the impact of direct-to-consumer advertising on consumers historically and how drug producers have benefited from them).

the success of pharma drug campaigns, as prescription drug information is shared directly to consumers to promote and educate patients on alternative treatments and drug options.[17] These ad campaigns are often exceedingly expensive for pharma companies, and require marketing and advertising personnel, as well as legal advisors to ensure compliance with FDA regulatory standards.[18]

Due to unclear and contradicting standards from the FDA, pharma companies often must fill in the gaps in DTC ad development.[19] As standards can be confusing, it comes as no surprise that DTC ads can frequently lead to misunderstanding for consumers who struggle to digest and comprehend the material transmitted through these ads.[20] From the pharma perspective, DTC ad production requires a great amount of time and effort that is often filled with pressures to successfully release an ad campaign that passes muster for both regulating agencies and public opinion alike.[21] Unlike general product advertisements, DTC ads demand the utmost care and management, as the product at hand can have potentially detrimental consequences to society: a drug impacting public health and safety.[22]

Public health is often defined as "the science and art of preventing disease, prolonging life, and promoting physical health and efficiency through organized efforts of society."[23] It is

[17] *See*, Michael S. Wilkes, et al., *Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, And Implications*, 19 HEALTH AFFAIRS 2, (2000).
[18] *See*, Lisa M. Schwartz and Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, 321 J.A.M.A 1, 80-96 (2019) (discussing the analysis that from 1997 through 2016, spending on medical marketing of drugs, disease awareness campaigns, health services, and laboratory testing increased from $17.7 to $29.9 billion. The most rapid increase was in direct-to-consumer (DTC) advertising, which increased from $2.1 billion (11.9%) of total spending in 1997 to $9.6 billion (32.0%) of total spending in 2016. Further explains some of the reasoning behind costs).
[19] *See*, Sarah Van den Bogaert, et al., *In the land of pharma: A qualitative analysis of the reputational discourse of the pharmaceutical industry*, 7 SAGE J. 2, 127-47 (2018).
[20] *See*, C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 P.T. 10, 669-74, 681-84 (2011).
[21] *See*, Sarah Van den Bogaert, et al., *In the land of pharma: A qualitative analysis of the reputational discourse of the pharmaceutical industry*, 7 SAGE J. 2, 127-47 (2018).
[22] *Id*.
[23] WENDY K. MARINER, ET AL., PUBLIC HEALTH LAW 17 (3rd ed. 2019).

true that the end goal of pharma companies' is often to sell their product(s) on the market, and utilize DTC ads to increase sales.[24] However, with these ads and sales comes a greater interaction between pharma companies and consumers that can lead to a change in the public health of the nation. This change and development must be observed and regulated. Placing the onus of mitigating the negative effects of DTC ads on pharma companies can be far too great a burden for a single industry to do on its own. It is also important to note that when consumers purchase drugs and increase the profits of pharma companies it can lead to a greater amount of funding that can go into continued research and development of alternative treatments and drugs.

What is unique about DTC ads, their regulations, and the impacts they have on public health is the time sensitive nature of the development of ads as well as the regulations.[25] With each moment of time that passes, a facet of a disease or disorder is developing and morphing.[26] New drugs are being researched, tested, manufactured, and released onto the market. Messages and ideas are being shared to a broad audience that carry varied intentions and meanings pertaining to pharmaceuticals and their uses. The conditions for creating and enforcing regulations in this field are so adaptable and volatile, that it can seem as if law and regulations are two steps behind the progress of medicine, working to catch up with the constant evolution and innovation. All these factors amount to a high-stake, high-stress environment of working to balance the public health and safety risks and benefits in regulations, while allowing pharma companies to successfully sell and create more products.

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[24] *See*, Lisa M. Schwartz and Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, 321 J.A.M.A 1, 80-96 (2019).
[25] *See*, Richard G. Frank and Paul B. Ginsburg, *Pharmaceutical Industry Profits And Research And Development* (Dec. 12, 2019, 4:12PM), HEALTH AFFAIRS BLOG, [https://www.healthaffairs.org/do/10.1377/hblog20171113.880918/full/].
[26] *Id.*

How DTC ads are viewed and interpreted can vary based on individual experiences, and ultimately raises the public health concern of what role these ads play in "inform[ing], educat[ing], and empower[ing] people about health issues" to the community at large.[27] Admittedly, consumer comprehension of these drugs' risks and benefits can be impacted by pharma companies' own efforts to downplay risk or oversell benefits.[28] At the same time, pharma companies can struggle with meeting FDA guidelines for simple language in their ads to limit consumer confusion, which can also lead to obfuscating the risks and benefits of the drug(s).[29] The tangled webs and balancing act of satisfying both the FDA and the consumer can appear next to impossible to navigate for pharma companies.

The benefits of DTC ads are not just for the pharma company. DTC ads lead to the direct targeting of patient-consumers, which has increased the dialogue between patients and their physicians.[30] Patients are empowered to seek medical advice from physicians pertaining to diseases and ailments that have been brought to their attention by these DTC ads.[31] Patients feel more equipped and more confident to reach out to their physician and speak about diseases and disorders that they were either previously unknowledgeable about, or too afraid/insecure to bring forward to the table.[32] Viewing the symptoms of a disorder on a DTC ad can also normalize and decrease the stigmas associated with diseases and disorders, especially 'invisible disabilities'

[27] WENDY K. MARINER, ET AL., PUBLIC HEALTH LAW 22 (3rd ed. 2019).
[28] *See*, Niro Sivanathan and Hemant Kakkar, *Pharmaceutical Industry Profits And Research And Development* (Dec. 12, 2019, 4:33PM), SCIENTIFIC AMERICAN, [https://www.scientificamerican.com/article/how-drug-company-ads-downplay-risks/].
[29] *See*, C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 P.T. 10, 669-74, 681-84 (2011).
[30] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 12, 2019, 4:53PM), PROCON.ORG, https://prescriptiondrugs.procon.org/.
[31] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 12, 2019, 4:58PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/].
[32] *Id.*

regarding mental health.[33] This can ease the stress that patient-physician conversations could generate for individuals seeking medical help.

Normalizing these discussions is also particularly helpful in achieving the public health interest of equalizing health treatment and access to patients of different socioeconomic backgrounds.[34] Indeed, "patients with lower incomes and education levels who are less likely to seek medical care, in general, were more likely to see a doctor after seeing DTC prescription drug ads."[35] This increased dialogue also suggests that patients are more informed about diseases/conditions and possible or alternative medical treatments.[36] In fact, 48% of doctors agree that DTC ads "inform, educate, and empower" patients, as established in an FDA survey.[37] DTC ads also serve as reminders to patients to stay on track of medication/treatment plans as well as seek out alternative treatment methods that they might not otherwise have known about.[38] This is extremely beneficial in achieving a public health goal of increasing the quality of care and quality of health of the general population.[39]

Unfortunately, positive effects can also bring negatives ones as well, and that is certainly the case for DTC ads. For one, DTC ads can lead to misinformed patients.[40] DTC ads serve as a double-edged sword by providing consumers with a wide breadth of new and valuable information about pharmaceutical products.[41] All the while, this influx of data (often riddled with

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[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] Taylor Tyler, *Direct-to-Consumer Drug Ads Should Be Scaled Back, Doctors Say*, (Dec. 12, 2019, 5:03PM), INDEPENDENT VOTER NEWS, [https://ivn.us/2013/06/03/direct-to-consumer-drug-ads-should-be-scaled-back-doctors-say].
[38] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 12, 2019, 5:05PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/].
[39] WENDY K. MARINER, ET AL., PUBLIC HEALTH LAW 22 (3rd ed. 2019).
[40] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 12, 2019, 6:05PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/].
[41] *See*, C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 P.T. 10, 669-74, 681-84 (2011).

necessary but complicated medical and legal jargon) can increase the chances that this information can also be misinterpreted or misunderstood.[42] Despite FDA efforts to regulate the vocabulary and verbiage used in these advertisements, the brief duration of the advertisements, coupled with often flashy and distracting storylines, can divert the consumer and detract from information comprehension and retention.[43] The general population does not take the time to assess the accuracy and representation of facts shared in pharmaceutical ads, and is likely to be susceptible to misunderstanding and misinterpretation of the risks that are associated with the drugs seen on the ads.[44] This reality increases the risk of misleading and deceptive information being shared with all consumers – both informed and uninformed.

Additionally, long-term health and safety risks of prescription drugs are often not determined upon the release of DTC ad campaigns.[45] This can lead to a misunderstanding of the current and future harms and counterindications that could arise in the consumption of the advertised drugs.[46] In 2011, a survey found that 43% of patients believed drugs advertised on DTC ads were 100% safe when being marketed.[47] This suggests that portions of the general population have misinterpreted the risks of the drug advertised, and could be placing their health at risk because of this misguided trust in what consumers hear and see in DTC ads.[48]

Another concern is raised that the popularization of DTC ads results in the over-filling and over-consumption of prescription drugs.[49] This concern has been raised for attention deficit

[42] *Id.*
[43] *Id.*
[44] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 12, 2019, 6:10PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/].
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 12, 2019, 6:15PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/].

hyperactivity disorder (ADHD).[50] In 2014, ADHD medication prescriptions were written approximately 25 times more frequently in the United States than in the United Kingdom (where DTC ads are not allowed), and this number keeps rising.[51] This one example reflects the growing concern in the public health field that there could be an increase in the usage of prescription medication correlated to the increase in patient-physician conversations about these drugs.

While some experts argue that the dramatic rise in prescription filling is clear evidence that the ADHD indication is being diagnosed and medically treated (for children, in particular) far surpassing reasonable rates, proponents of DTC ads argue otherwise.[52] These individuals argue that the risk of overfilling prescriptions is outweighed by the triumphs of prevention, early detection, mitigation, and treatment of illnesses and disorders.[53] Proponents argue that DTC ads have normalized symptoms of ADHD and have empowered children and adults to approach physicians and seek pharmaceutical drug assistance with these ailments.[54] In the end, DTC ads for ADHD drugs and other pharmaceuticals must fight to balance the public health and safety risks and benefits, and how to best share that information with the public.

III. FDA guidelines and regulation

Since the information shared through DTC ads implicates the general public health, this information is regulated in a somewhat similar fashion as public health programs would be regulated. Public health programs are influenced, if not generally controlled, by a federal

[50] *See*, Alan Schwarz, *Report Says Medication Use Is Rising for Adults with Attention Disorder*, (Dec. 13, 2018, 7:22PM), NYTIMES, [https://www.nytimes.com/2014/03/12/us/report-says-medication-use-is-rising-for-adults-with-attention-disorder.html/].
[51] *See*, Alan Schwarz, *Report Says Medication Use Is Rising for Adults with Attention Disorder*, (Dec. 13, 2018, 7:22PM), NYTIMES.
[52] *Id.*
[53] *See*, Steven Woloshin, et al., *The Value Of Benefit Data In Direct-To-Consumer Drug Ads*, HEALTH AFFAIRS, (Dec. 13, 2019 7:26PM), [https://www.healthaffairs.org/doi/full/10.1377/hlthaff.W4.234].
[54] *See*, Alan Schwarz, *Report Says Medication Use Is Rising for Adults with Attention Disorder*, (Dec. 13, 2019, 7:29PM), NYTIMES.

government agency.[55] In this case, the Food and Drug Administration ("FDA") is the leading government agency that regulates DTC ads pursuant to the Food, Drugs & Cosmetics Act ("FDCA").[56] It is the FDA's responsibility to oversee advertising for prescription drugs (to note, this is not applicable for over-the-counter medication).[57] Furthermore, the FDA's Office of Prescription Drug Promotion ("OPDP") is the subsection of the FDA that reviews and provides advisory comments (oftentimes, in the form of either Untitled or Warning enforcement letters) regarding these pharmaceutical DTC ads.[58]

In efforts to hold pharmaceutical companies accountable, the FDA has set forth standards for what drug ads must tell consumers.[59] DTC ads are required to: "(1) Not be false or misleading; (2) Present a fair balance of risk and benefit information; (3) Include facts that are material to the product's advertised uses; and (4) Include a brief summary of every risk described in the product's labeling."[60] This can be done by requiring drugs ads to express to consumers three key things: "(1) at least one approved use for the drug; (2) the generic name of the drug; (3) and all the risks of using the drug (or under certain circumstances, only the most important)."

Though these standards and criteria can be useful in mitigating some of the negative consequences of DTC ads, scholars argue that retrospective review of these ads can be injurious to the consumers and pharma alike.[61] Consumers, empowered by what they view in DTC ads, are often persuaded by the images and storyline that provide hopes for a 'cure-all' or at least a

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[55] WENDY K. MARINER, ET AL., PUBLIC HEALTH LAW 11 (3rd ed. 2019).
[56] *See*, Food and Drug Administration, *Prescription Drug Advertising: Questions and Answers*, (Dec. 13, 2019 7:36PM), FDA.GOV, [https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers].
[57] *See*, Food and Drug Administration, *Prescription Drug Advertising: Questions and Answers*, (Dec. 13, 2019 7:36PM), FDA.GOV.
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *See*, Rachel Groman, *Direct-to-Consumer Prescription Drug Advertising*, AMERICAN COLLEGE OF PHYSICIANS, 12 (2006).

potential solution to the ailments they are facing. Patients are often eager to reach out to their physicians about a new treatment, rather than wait for a period of time in hopes that the FDA has gotten around to reviewing and assessing these ads for any misleading information presented. If OPDP was to review DTC ads prior to their initial release, it could circumvent much of the confusing conversations that are held between physicians and patients.

In the meantime, pharma companies make great investments in DTC ad campaigns, and often feel it necessary to release these ads as soon as possible to have their product gain traction and sell in the market.[62] A delay in the release of an ad campaign could be detrimental to the success of the product launch and lead to financial struggles for the company. The costs incurred can escalate even more when the FDA then issues an enforcement letter demanding the company take down these expensive ad campaigns and release new ones.[63] The requirement to apologize and clarify for mistakes made by the company in the initial DTC ad campaigns in a later ad campaign can also cost the pharma company credibility and reputation points.[64] This is especially detrimental where pharmaceutical companies already struggle with maintaining positive reputations and credibility in the eye of the consumers.[65]

All of these costs incurred by pharma companies implies that they are unlikely to want to continuously recreate drug ads repeatedly. It is in both to the pharma companies' and the consumers' benefit to work with FDA regulations and guidelines to prepare and disseminate meaningful and truthful advertisements the first time around. Unfortunately, the history of DTC ads regulations and guidelines has been as complicated, if not more, than it is now.

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[62] *See*, Rachel Groman, *Direct-to-Consumer Prescription Drug Advertising*, AMERICAN COLLEGE OF PHYSICIANS, 7 (2006).
[63] *See*, The FDA Group, *5 Indirect Costs of an FDA Warning Letter*, (Dec. 13, 2019 7:51PM), THEFDAGROUP.COM, [https://www.thefdagroup.com/blog/2016/02/5-indirect-costs-of-an-fda-warning-letter/].
[64] *Id.*
[65] *Id.*

IV. A Look at Pharmaceutical Advertising Regulations Over Time

It is critical to look at the history of pharma advertising to identify patterns and efforts that can be used presently to reduce the negative effects DTC ads may have. The start of federal DTC drug regulations can be seen in the Progressive Era, as a means to regulate the few 'ethical' and 'on the book' drugs that were then on the market.[66] At this time, the 1906 Pure Food and Drug Act[67] applied, as it prohibited interstate transport of unlawful drugs.[68] Elements reminiscent of portions of this statute will continue and evolve into modern regulations to date.

The Pure Food and Drug Act is rooted in protections of proper (or rather, inappropriate) labeling on food and drugs.[69] While modern FDA regulations often relates to premarket approval and uses, recently there has been a shift of concern once again towards labeling (e.g., off-label uses of pharmaceuticals).[70] The Pure Food and Drug Act also required that "no detail of a drug label could be false or misleading and even required labels to list the existence and/or concentration of eleven different 'dangerous substances'.[71] Some controversy arose early on regarding the reliability of therapeutic claims of drugs, as *U.S. v. Johnson* ruled that it was not prohibited to falsely advertise therapeutic claims.[72] Ultimately, in a showing of the push and pull between the Court and Congress, the Shirley Amendment overruled *Johnson* by prohibiting

[66] See, Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 PMC 4, 659-99 (2006).
[67] *Id.*
[68] *Id.*
[69] 34 Stat. at L. 768.
[70] *See*, Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 PMC 4, 659-99 (2006).
[71] 34 Stat. at L. 768.
[72] *U.S. v. Johnson*, 952 F.2d 565 (1st Cir. 1991).

claims that could 'defraud the purchaser'.[73] This debate continues into modern day concerns of how to best avoid having DTC ads misrepresent the risks and benefits of a drug.[74]

In 1938, the FDCA was passed as a statutory recognition that consumers, who were generally self-medicating at the time, brought about public health concerns in their use of pharmaceuticals without the presence of further federal regulations.[75] While the FDA had recognized over twenty dangerous substances that could not be obtained over-the-counter ("OTC") or without prescription, it had become apparent that patients obtaining pharmaceuticals were at risk. In turn, the FDCA worked to expand the FDA's authority in drug regulation and mandated, for the first time, that drugs be proven safe for consumers by obtaining approval before being marketed.[76] FDCA also continued to expand FDA drug labeling requirements to include more than the name and ingredients of the drug.[77] The initial FDCA labeling requirements can be likened to labels consumers see today in OTC drug labels.[78] Unfortunately, the FDA's effectiveness in regulating through the FDCA was greatly limited by the passage of the Wheeler Lea Act in 1938[79], which granted jurisdiction and authority of drug advertising to the Federal Trade Commission ("FTC").[80]

Historically, pharmaceutical companies could only advertise their products to physicians.[81] This prevented direct communication and education to the patients, who were left

[73] *See*, Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 PMC 4, 659-99 (2006).
[74] *Id*.
[75] *Id*.
[76] *Id*.
[77] *Id*.
[78] *Id*.
[79] 15 U.S.C.S. § 45(l).
[80] *See*, Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 PMC 4, 659-99 (2006).
[81] *See*, ProCon.org, *History of Prescription Drug Ads* (Dec. 13, 2019, 7:50PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/history-of-prescription-drug-ads/].

underinformed of potential diagnoses and treatments to the ailments they were facing.[82] This also made diversifying the pool of consumers and broadening the base of patients limited at the start of pharmaceutical development.[83] Now, with a broader pool of consumers, there is the chance of increased understanding in the uses and effects of prescription drug consumption, if and when post-marketing research is conducted. With a larger pool of consumers, research findings could be considered more inclusive and more in-depth.

Additionally, the unclear distinction between OTC and prescription drugs in regulations led to general confusion and varied uses of drugs prescribed by the physicians.[84] It was with the passage of the Durham Humphreys Amendments ("DHAs") to the FDCA that a statutory definition of prescription drugs was finally passed and could lend itself to better regulations of the drugs in the future.[85] However, the DHAs backfired in that pharmaceuticals classified as prescription drugs soon saw less of the full product labeling required of OTC drugs.[86] The struggle to regulate what safety risks and drug information was being shared to consumers has, and always will be, a battle for pharma companies and the FDA as a regulatory agency.

A. Federal Policy on Pharmaceutical Marketing in the 1960s and Beyond

Ultimately, the involvement and regulation of the FDA in DTC ads is one of the reasons these ads have become so omnipresent in the American market system.[87] The FDA garnered its expansive authority in advertising regulations in 1969, when it passed a regulation requiring advertisements contain a "true statement of information in brief summary relating to side effects,

[82] *Id.*
[83] *See*, The FDA Group, *5 Indirect Costs of an FDA Warning Letter*, (Dec. 13, 2019 7:51PM), THEFDAGROUP.COM, [https://www.thefdagroup.com/blog/2016/02/5-indirect-costs-of-an-fda-warning-letter/].
[84] *See*, Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 PMC 4, 659-99 (2006).
[85] *Id.*
[86] *Id.*
[87] *Id.*

contraindications, and effectiveness" (FDA/DHHS 1969)[88]. Additionally, DTC ads must present a "fair balance" between information presented about the drug's side effects and contraindications and the drug's effectiveness.[89] The regulations even go so far as to explain to consumers and pharma companies how an advertisement could be considered false, unbalanced, or otherwise misleading.[90]

The FDA's authority in regulating pharma drugs is one of the agency's primary means in meeting a main goal the FDA has in safeguarding public health and safety in the use of pharmaceuticals.[91] This interest, coupled with the growing Patient's Rights Movement in the 1970s (whose goal was to require physicians to provide patients with alternative treatment plans) launched the wave of pharma advertising that is regulated in part by the consideration of the overall public health and well-being.[92]

B. First Amendment Protections

DTC ads are here to stay in the American market system, with both their pros and cons, largely because these ads can be considered protected speech under the First Amendment.[93] The First Amendment is implicated in the use of DTC ads, as the FDA seeks to regulate meaningful and truthful information pharma companies share within these ads, in hopes to limit the negative public health effects these ads can have.[94] With DTC ads right at the fingertips of consumers, concerns about mass sharing of complicated and risky medical information compete against First

[88] *Id.*
[89] *Id.*
[90] *See*, Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 PMC 4, 659-99 (2006).
[91] *Id.*
[92] *Id.*
[93] *See*, ProCon.org, *Should Prescription Drugs Be Advertised Directly to Consumers?*, (Dec. 13, 2019, 8:15PM), PROCON.ORG, [https://prescriptiondrugs.procon.org/].
[94] *See*, Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 PMC 4, 659-99 (2006).

Amendment guarantees and protections of freedom of speech (advertisements as forms of commercial speech).[95]

First Amendment protections extend to commercial speech, or speech related to the economic interests of the speaker and its audience.[96] A complete ban of commercial speech not only injures the commercial interests of the producer of speech, but also that of the consumers who have a societal interest in obtaining the fullest amount of information and then choosing what they do and do not agree with.[97]It is not only in the pharma's interests to advertise their drugs, but also in the consumers, who have their best interests in mind, in digesting information within advertisements.[98]

In considering how DTC ads can now be better regulated to minimize the negative effects that they can have on the general public health, it is important to look at how the regulation of commercial speech is treated in general. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York* sets forth a standard that if commercial speech is "neither misleading nor related to unlawful activity", government and agency's regulatory authority is limited.[99] If the State then asserts a substantial interest in restricting this commercial speech, the method of regulation must then be in proportion to that interest, specifically designed to meet that particular State goal.[100] A framework of these criteria is as follows: "(1) the restriction must directly advance the State interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose; and (2) if the governmental interest

[95] *Id.*
[96] *See*, *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 748 (1976).
[97] *See*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 561–62 (1980).
[98] *See*, *Central Hudson*, 447 U.S. 557, 561–62 (1980).
[99] *See*, 447 U.S. 557, 564 (1980).
[100] *Id.*

could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive".[101]

While *Central Hudson* is an electrical utilities company that brought suit against the NY Public Service Commissioner for regulations that wholly banned promotional electrical advertising, the concept against banning commercial speech has also extended its application to include DTC ads.[102] A brief outline of *Central Hudson* framework from above for application in future considerations of commercial speech is as follows: whether,

> "(1) the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading; (2) the asserted governmental interest is substantial; and if both inquiries yield positive answers, (3) the regulation directly advances the governmental interest asserted, and (4) it is not more extensive than is necessary to serve that interest."[103]

In *Thompson v. Western States Medical Center,*[104] the Supreme Court applied the *Central Hudson*[105] framework in determining whether FDA regulations on compounded drug advertising was a violation of First Amendment protections.[106] *Thompson* notes that it is the burden of the party wishing to uphold the restriction on the commercial speech to justify such a restriction.[107] *Thompson* stands out as a valuable case for future DTC ad regulations, as the court explicitly states that hypothesized justifications for State's interests are not sufficient to impose heightened

[101] *Id.*
[102] *Id.*
[103] *See*, 447 U.S. 557, 566 (1980).
[104] *See*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).
[105] *See*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Commn.*, 447 U.S. 557 (1980).
[106]*See*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).
[107] 535 U.S. 357, 373 (2002).

restrictions on commercial speech, unless used on a rational basis review.[108] The *Central Hudson* standard of review for commercial speech is stricter than rational basis.[109] In the case of *Thompson*, the court notes that even if the fear that these advertisements would motivate patients (even those who did not need to risk being exposed to the consumption of unneeded drugs) to convince their physicians to prescribe these drugs, it still fails as justification for narrow restriction of advertising as commercial speech.[110]

This concern of overprescribing without a founded need is one that is still raised amongst consumers and physicians observing the trends of increased prescription writing and filling today.[111] It can be argued that there is an increased public health and safety risk generated from the rise in patients seeking prescriptions for drugs that they might not otherwise have needed or wanted prior to viewing a DTC ad.[112] However, proponents of stricter monitoring and regulation of DTC ads must show that any such interest argued must first surpass that which is found insufficient here in *Thompson*, which can be challenging.[113]

i. First Amendment Application to Off-Label Use Advertisements

Pharma companies are generally prohibited from marketing and advertising off-label uses (uses of drugs not authorized or recognized within the indications and uses of the formal FDA-approved label).[114] Therefore, an off-label use of a drug is any use in which has not been authorized by the FDA. While pharma companies can try to be cautious in any advertising of off-

[108] *Id*.
[109] *Id*.
[110] *Id*.
[111] *See*, Robert H. Shmerling, *Harvard Health Ad Watch: What you should know about direct-to-consumer ads*, (Dec. 13, 2019, 8:18PM), HARVARD HEALTH BLOG, [https://www.health.harvard.edu/blog/harvard-health-ad-watch-what-you-should-know-about-direct-to-consumer-ads-2019092017848].
[112] *Id*.
[113] *See*, 535 U.S. at 360.
[114] *See*, Elizabeth Richardson, *Off-Label Drug Promotion*, (Dec. 12, 2019 8:20PM), HEALTH AFFAIRS, [https://www.healthaffairs.org/do/10.1377/hpb20160630.920075/full/].

label uses, in fear of repercussions faced by FDA enforcement, it is quite common and very legal for physicians to prescribe these drugs for off-label uses.[115] In fact, "an estimated one in five prescriptions filled" are for the purposes of off-label uses of prescription drugs.[116] Prescribing off-label is not as peculiar as it may sound; in fact, many times uses of pharmaceuticals are identified after a drug has underwent FDA approval and label authorization.[117]

Still, off-label prescribing is not clinically ethical, as the side effects and general implications of off-label uses have not been extensively studied in FDA-approved studies like on-label uses have.[118] Off label-uses and unintentional advertisements can also expose pharma companies to legal problems.[119] For example, in 2012, GlaxoSmithKline ("GSK") was fined $3 billion by the federal government, partially due to off-label promotion of several of its drugs.[120] This can be particularly challenging for pharma companies that wish to inform consumers and physicians alike of the potential risks and benefits of off-label uses, especially noting that physicians legally can, and often, do prescribe medication for off-label uses.[121]

In *Sorrell v. IMS Health*[122], the Supreme Court ruled a state statute prohibiting the sale, disclosure, or use of physician prescribing records for the purpose of marketing violated the First Amendment.[123] The court found that the restrictions did not advance a substantial government interest and that the statute placed an undue burden on commercial speech.[124] This line of case

[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] *Id.*
[120] *See*, Elizabeth Richardson, *Off-Label Drug Promotion*, (Dec. 12, 2019 8:20PM), HEALTH AFFAIRS, [https://www.healthaffairs.org/do/10.1377/hpb20160630.920075/full/].
[121] *Id.*
[122] *See*, *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011).
[123] *See*, 564 U.S. 552, 567-68 (2011).
[124] *Id.*

law continues with *United States v. Caronia*.[125] In *Caronia*, the defendant appealed a conviction where he is found "guilty of conspiracy to introduce a misbranded drug into interstate commerce… [by promoting] the drug…for 'off-label use'…for a purpose not approved by the…FDA."[126] Defendant Coronia argued the conviction violated his First Amendment freedom of speech protection, and the Supreme Court agreed.[127] The FDCA prohibits misbranding of a drug (e.g., product labeling fails to bear "adequate directions for use").[128] This prohibition not only extends to DTC ads, but, as *Caronia* shows, representations of off-label uses of drugs as well.

In *Amarin Pharma Inc. v. United States FDA*, the court shows a great interest in promoting the sharing of truthful, non-misleading information, free from the threat of misbranding charges against the pharmaceutical company by federal regulatory agencies (i.e. the FDA).[129] This interest is similar to that found in the use of DTC ads. Pharma companies advertise to the general public alternative treatment methods via DTC ads.[130] The naturally restrictive nature of timed DTC ads, combined with the complex subject matter, can render the danger of misleading risk information a concern, no matter how many restrictions and regulations are put in place. In the end, the court tends to favor the least restrictive manner of regulating commercial speech, as applied here.[131] In attempts to mitigate the negative effects of DTC ads, it is important to assess and determine how restrictive the effort would be to the commercial speech, and if it was 'more extensive than necessary'.[132]

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[125] *United States v. Caronia*, 703 F.3d 149, 152 (2d Cir. 2012).
[126] *Id.*
[127] *Id.*
[128] 21 U.S.C. § 352(f).
[129] *Amarin Pharma, Inc. v United States FDA*, 119 F. Supp. 3d 196, 198 (S.D.N.Y. 2015).
[130] *Id.* at 198.
[131] *Id.* at 226.
[132] *Id.*

Hypothetically, if Congress was to pass a law that prohibited pharma companies from advertising directly to consumers, then a claim for violation of the First Amendment protection of freedom of speech would have to be brought to court. Using the *Central Hudson* framework, legal representation, including attorneys representing pharma companies, would argue first and foremost that a DTC ad is an expression protected by the First Amendment. DTC ads contain valuable advertising information on new drugs that is intended to inform consumers of alternative treatments on the market. The content of DTC ads has been established to be lawful activity, and so long as this information is truthful and not misleading by following FDA guidelines, the first step of the *Central Hudson* framework can be considered satisfied.

The second step would then be to consider if the asserted governmental interest is substantial. With support from *Thompson*, concerns about consumer enthusiasm for new drugs that could lead to overprescribing medication is not a justified argument. Such an argument belittles the reality that physicians are skilled in their profession as to not be swayed by patient persuasion, and at the same time, patients are entitled to speak their minds and interests to physicians. Another possible governmental interest, misinterpreting risks of drugs in DTC ads, can be considered substantial as it is a public health implication that consumers are not comprehending the extent and degree of risks presented in DTC ads.

The third and fourth steps would be to consider whether the regulation directly advances the governmental interest asserted, and whether such a regulation is not more restrictive than necessary to serve that interest. Case law suggests that a total ban on commercial speech violates protected First Amendment freedom of speech rights. Even in the event that a regulation was to restrict and not totally ban pharma companies from advertising directly to consumers, the Court will still refer to commercial speech case law when overruling prohibitions on advertising of

drugs. For these reasons, it is unlikely that legislative regulations of DTC ads will be successful in achieving the desired result of reducing the harmful effects viewing DTC ads can have on consumers.

ii. Counter-advertising

When it comes to the advertising of products that prove to be a heightened public health risk, the tobacco industry and counter-advertising created against its products, shines as an example of mitigating health risks. When the FDA recognized the public harm caused by tobacco and tobacco-based products, it took measures in passing the Family Smoking Prevention and Tobacco Control Act.[133] The landmark case of *Discount Tobacco City & Lottery, Inc. v. U.S.* held that under the *Central Hudson* test, the deceptive nature of tobacco products advertisements that deceitfully promoted health claims, outweighed the interest of protected commercial speech.[134] This can be a case to look at in the future for examples of restricting First Amendment protected speech.

In 2014, the Centers for Disease Control and Prevention ("CDC") identified smoking and the use of tobacco products as a health and safety concern, which encouraged the agency to launch and release a national tobacco education campaign.[135] A twelve-week campaign had been previously released in 2012 but was not nearly as effective because of the manner in which the counter-advertisements were presented then.[136] The latest method created two phases that provided a succession of new and interesting counter-advertisements that educated the public in smoking risks and health-related issues.[137] Then-CDC Director, Tom Frieden, M.D., M.P.H.,

[133] 21 U.S.C. § 387k(b)(2)(A).
[134] *See*, *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 533 (6th Cir. 2012).
[135] *See*, Centers for Disease Control and Prevention, *Tips from Former Smokers*, (Dec. 13, 2019, 8:38PM), CDC.GOV, [https://www.cdc.gov/tobacco/campaign/tips/about/index.html].
[136] *Id.*
[137] *Id.*

argued the "TIPS" campaign was extremely cost-effective because it saved not only money, but also lives.[138] In fact, "approximately 17,000 premature deaths from smoking were estimated to be averted, and 179,000 years of healthy life gained."[139]

The CDC was one of, if not the only, agency/company that was able to compete with the billion-dollar tobacco advertising industry because of its own financial standing, prominence, and value.[140] The CDC triumphed because the effective and constant release of these informative advertisements was difficult for consumers to avoid and easy to recall back into memory when consumers were tempted to later reach for that cigarette.

Comparatively, the pharmaceutical industry and its use of DTC ads plays a different role than that of the tobacco companies' ads. The objective of pharma companies is not to mass-produce and sell a specific product for the use, enjoyment, and entertainment of the general population, regardless of the health implications as tobacco products posed. DTC ads are used as a tool to inform consumers of new and innovative products on the market intended to assist and aid in diseases and disorders that otherwise hamper the greater level of public health within the U.S. population.[141] Therefore, the purpose of the products being advertised in the information within DTC ads is to aid the public health. The side effects and risks that come with the use of these drugs are issues that will arise in continuum as far as advancements of medicine is concerned. But to truly identify DTC ads in the same light as tobacco-products, is to completely ignore the intents and purposes of medicine and pharmaceutical drugs for the public health as a whole. While it is also the goal of pharma companies to obtain profits from selling drugs to

[138] *Id.*
[139] *Id.*
[140] *Id.*
[141] *See*, Luis Villalba, *Pharmaceutical companies and medical practitioners or "the beast and the beauty"?*, 37 CLINICS IN DERMATOLOGY 1, 16-20 (2019).

patients, it is ultimately at the choice of the consumer who must still go to a physician and obtain a prescription for these drugs. To note, while both products largely come down to consumer choice, ultimately, medications can have both positive and negative effects, while science has now deduced that tobacco-based products simply have negative side effects.

All these elements considered are important to keep in mind when thinking about what kind of information and tactics can be utilized in any form of counter-advertising for DTC ads. At this time, in reviewing all the effectiveness and success found in the scientific promotion and production fostered by the pharmaceutical industry, it is unlikely that the CDC will determine an emergent health risk here as it did with the tobacco industry.

Instead of counter advertising against DTC ads, members of the medical profession should be further expected to clarify and assist in comprehension of information in DTC ads for the consumers. When it comes to advertising prescription drugs, physicians have notified the FDA and CDC in different FDA-approved studies that DTC ads are one of many factors influencing how the doctors will practice and interact with patients.[142] DTC ads have empowered patients to make their own health care decisions and ask far more thoughtful and engaging questions with their physicians.[143] Furthermore, in these studies, physicians have acknowledged a general industry belief that patients understand "they need to consult a health care professional about appropriate treatment."[144] With all this considered, it is advisable, and would be greatly beneficial, if physicians used their duty of care and trusted physician-patient relationship to take on some of the onus of DTC ad clarification. That is, pharma companies are restricted to a short

[142] See, Carol Lewis, *The Impact of Direct-to-Consumer Advertising*, 37-38 FDA CONSUMER 1, 9 (2003).
[143] *Id.*
[144] *Id.*

period of time and often confusing guidelines in trying to truthfully represent the risks and benefits of drugs advertised in DTC ads.

When a patient engages in inquiries regarding drugs seen on DTC ads, a physician could then further explain the potential risks and benefits of the drug in efforts to clarify any misunderstandings the patient may have. This can be done in hopes of educating the public further and clarifying any misconceptions or misunderstandings from viewing the initial DTC ads. While this might be difficult to accomplish, it could be one of the more successful alternatives for minimizing the negative effects of DTC ads, without hampering the successes pharma companies see in the utilization of DTC ads.

C. FDA Enforcement Letters

One struggle the FDA has in supervision and regulation of DTC ads is that the agency does not review DTC ads prior to their release and viewing by the general public.[145] Unfortunately, the parameters set forth by the First Amendment guarantee of freedom of speech thus far prevents the regulation of information before it has even been disseminated.[146] Instead, the FDA is forced to act quickly (though that is often difficult due to the high submissions and reviews of different DTC ads) and view the streaming ads for any misleading information or misrepresentation of risks right alongside the consumers viewing the ads.[147] This heightens the risk of consumers viewing inappropriate ads for violating standards or providing misleading information. The FDA acknowledges similar sentiments found by the Court in *Thompson* that consumers should operate under the impression that not all information has been vetted for the

[145] *See*, U.S. Food and Drug Administration, *Types of FDA Enforcement Actions*, (Dec. 13, 2019, 8:59PM), FDA.GOV, [https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions].
[146] *See*, The FDA Group, *5 Indirect Costs of an FDA Warning Letter*, (Dec. 13, 2019 9:01PM), THEFDAGROUP.COM, [https://www.thefdagroup.com/blog/2016/02/5-indirect-costs-of-an-fda-warning-letter/].
[147] *Id.*

absence of misleading or misinforming presentation of risks associated. While the dangers of having ads viewed by both the FDA and consumers for the first time simultaneously could significantly support altering the rules set forth to allow the FDA to review advertisements proactively, it is unlikely to happen given the court precedents.[148]

The FDA releases warning letters and letters of notice of violation (otherwise known as untitled letters) to pharmaceutical companies when they are in violation of the criteria set forth by OPDP.[149] When an untitled letter is presented to a pharmaceutical company, the company is expected to cease distribution of the misleading or misrepresentative information and proceed with sharing amended information to clarify any misunderstandings in new DTC ad campaigns.[150] Warning letters, as the name suggests, take reprimanding a step further, and require the pharma company to issue a letter and/or plan of action to the FDA detailing how the company will remediate any potentially deceptive messages they have shared, and any consumer mistrust engendered by these ads.[151]

Enforcement letters fall short in effectiveness because of an agency requirement where, in order to issue a letter and deem speech to be false or misleading in a DTC ad, OPDP must first find evidentiary support that the speech is false or misleading.[152] This is especially challenging given that the quantification of false or misleading information can vary greatly, depending on the level of how informed a consumer is when viewing and processing the advertisement. For this reason, it seems wise and altogether more productive to create FDA pre-approved language templates or a form of guidance that pharma companies can use and abide by when initially

[148] *See*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Commn.*, 447 U.S. 557 (1980). *See also*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).
[149] *See*, U.S. Food and Drug Administration, *Types of FDA Enforcement Actions*, (Dec. 13, 2019, 9:07PM), FDA.GOV, [https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions].
[150] *Id.*
[151] *Id.*
[152] *Id.*

constructing their DTC ad campaigns. If these guidelines and frameworks were then made public to be used as pre-sets for DTC ads, it could hopefully provide consistency and avoid misrepresentation or confusion in the future.

Oftentimes, consumers are not even aware that some of the most popular DTC ad campaigns are taken down or altered in response to the issuance of an FDA Enforcement Letter.[153] Requiring pharma companies to notify consumers of any changes made to their DTC ad campaigns, pursuant to violations cited by the FDA, can increase the level of awareness and understanding for the patient-consumer. Making note of these changes in newer campaigns on top of having pharma companies explaining these changes further in letters released on their website and social media could likely better inform consumers that there have been changes made to any misleading information previously presented. This is one way to hopefully mitigate some of the negative consequences that come with misleading information presented in DTC ads, in hopes of also maintaining the pharma company's credibility and success rate.

V. Where Do We Go From Here?

Pharma companies are not the enemies simply because they seek to make a profit in a challenging industry. DTC ads are used to promote new and innovative drugs in hopes of appealing to consumers. Exciting messages and catchy music found in all kinds of advertisements are also found in DTC ads. However, as has already been discussed, a key component to the pharma industry is the necessity of care in presenting the product facts and information within these advertisements. While legislation might seem like the best way to regulate these ads, any state or federal law passed is likely to struggle against the *Central*

[153] *See*, Martin T. Gahart, et al., *Examining the FDA's Oversight of Direct-to-Consumer Advertising*, (Jun. 12, 2020 12:25PM), HEALTH AFFAIRS, [https://www.healthaffairs.org/doi/full/10.1377/hlthaff.W3.120].

Hudson framework, which protects First Amendment commercial speech when it is truthful and not misleading.

Additionally, for the members of the public who are concerned with the risk DTC ads may pose in popularizing prescription drugs, and potentially leading to the abuse of these drugs, the FDA released a statement on July 1, 2019.[154] In this statement, the FDA promises to work towards a new goal related to this new topic: Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products - Content and Format.[155] One of the goals of this new guidance is to inform consumers about ways to interpret product labels and advertisements that will hopefully be updated with safety information regarding abuse, misuse, addiction, physical dependence and tolerance of the drugs.[156] This clear guidance, when submitted and finalized, could be greatly helpful in clarifying how pharma companies can be accountable in advertising the warnings and risks associated with their pharmaceuticals, without hurting the success of their promotional campaigns.

VII. Conclusion

Despite persistent attempts to improve and develop the standard of health in the general public, pharma companies do not have the best reputations with American consumers. These companies are leading sponsors and promoters of innovative drug research and development. With the use of DTC ads, pharma companies work to reach a broad base of consumers, looking to sell their products for the intended purpose and use advertised. Due to the fact that DTC ads, as a form of commercial speech, are likely to remain protected by First Amendment, it is

[154] *See*, United States Department of Health and Human Services, et al., *Draft Guidance: Guidance for Industry Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products — Content and Format*, (Dec. 13, 2019, 9:13PM), FDA.GOV, [https://www.fda.gov/media/128443/download].
[155] *Id*.
[156] *Id*.

important for these ads to be meticulously regulated. With these ads, arise concerns of misrepresentation or misunderstanding of risks and benefits presented. But as is the nature of medical and pharmaceutical development, the benefits of advertising these products seem to outweigh the risks.

Most of all, these ads have equalized access to alternative treatment information, by empowering and educating consumers of all socioeconomic backgrounds of new drugs. Furthermore, it is in the pharma companies' interests to produce information that is as accurate as possible so that the companies can avoid additional expenditure in resources for amended advertisements and injured reputations. This article seeks to demonstrate the evolution of regulations, case law, and public awareness to show a path towards mutual sharing of information and responsibilities for pharmaceutical drug risks and benefits information between pharma companies, physicians, and patients.