

American University Washington College of Law

## Digital Commons @ American University Washington College of Law

---

Upper Level Writing Requirement Research Papers

Student Works

---

2021

### **Please Consult Your Lawyer before Taking Sorrell: How the FDA Should Approach Social Media for Prescription Drug Advertising**

Steven Valentino

Follow this and additional works at: [https://digitalcommons.wcl.american.edu/stu\\_upperlevel\\_papers](https://digitalcommons.wcl.american.edu/stu_upperlevel_papers)



Part of the [Food and Drug Law Commons](#)

---

Comment

PLEASE CONSULT YOUR LAWYER BEFORE TAKING *SORRELL*:  
HOW THE FDA SHOULD APPROACH SOCIAL MEDIA FOR PRESCRIPTION DRUG  
ADVERTISING

## TABLE OF CONTENTS

Introduction.....	1
I. The Development and Provisions of the FDCA.....	5
A. Development of the FDCA .....	5
B. Labeling, Misbranding, and Advertising a Prescription Drug.....	9
II. Social Media Guidance and the First Amendment.....	14
A. FDA’s Social Media Guidance .....	14
1. Third-Party Misinformation Guidance.....	16
2. Character Limit Guidance .....	18
B. The First Amendment .....	23
1. Commercial Speech Doctrine.....	23
2. Character Limit Guidance First Amendment Analysis .....	29
C. Off-Label Promotion Roadblocks.....	34
III. Recommendations .....	37
A. Social Media Functions and Advertising.....	38
B. Issuing Further and Updated Guidance Documents .....	42
C. Notice-and-Comment Rulemaking.....	46
Conclusion .....	49

## INTRODUCTION

The colloquial phrase that urges a consumer to “talk to [their] doctor about [insert drug here]” is a hallmark of drug advertising.<sup>1</sup> Television and print advertising are likely the most common media sources where consumers are exposed to that phrase.<sup>2</sup> However, consumers are not exposed to these advertisements as aggressively on their social media platforms, but this is changing.<sup>3</sup> This is likely due to a lingering challenge the Food and Drug Administration (FDA) has grappled with for direct-to-consumer (DTC) advertising of prescription drug products.<sup>4</sup> However, consumers are active about their health and over half of the United States population

---

<sup>1</sup> See, e.g., *The Ambien Brand: Where Millions Have Turned When Having Trouble Falling Asleep*, SANOFI (last visited July 1, 2020), <https://www.ambien.com/>.

<sup>2</sup> Joanne Kaufman, *Think You’re Seeing More Drug Ads on TV? You Are, and Here’s Why*, N.Y. TIMES (Dec. 24, 2017), <https://www.nytimes.com/2017/12/24/business/media/prescription-drugs-advertising-tv.html>. This is most likely a result of the existing regulations addressing broadcast, radio, and print mediums directly. Prescription Drug Advertisements, 21 C.F.R. § 202.1 (2019).

<sup>3</sup> Nitasha Tiku, *Facebook has a Prescription: More Pharmaceutical Ads*, WASH. POST (Mar. 4, 2020), <https://www.washingtonpost.com/technology/2020/03/03/facebook-pharma-ads/> (finding companies are beginning to ramp up their social media advertising).

<sup>4</sup> Direct-to-consumer (DTC) advertising is where a company advertises its product information to the consumer instead of healthcare professionals. *Direct-to-Consumer (DTC) Advertisements, Drug Advertising: A Glossary of Terms*, U.S. FOOD & DRUG ADMIN. (last visited July 20, 2020), <https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#dtc>.

has performed health research online.<sup>5</sup> Thirty-seven percent of internet users specifically looked for information on prescription drugs.<sup>6</sup> With these levels of consumer activism about their health, it is unsurprising to see a proliferation of DTC advertising to users on the Internet, and specifically placing these advertisements to social media.<sup>7</sup>

In 2018, the pharmaceutical industry spent \$6.1 billion on advertising, with \$5.1 billion spent on television ads.<sup>8</sup> In 2019, the healthcare and pharmaceutical industry spent \$3.62 billion on digital advertising.<sup>9</sup> As indicated by these figures, advertising is of immense scale. With the advent of social media platforms, pharmaceutical companies could reach new and existing consumers through these new types of forums and media outlets. However, this medium has remained in regulatory limbo since 2014—the last time the FDA issued a guidance document

---

<sup>5</sup> *Most Internet Users Start at a Search Engine When Looking for Health Information Online*, PEW RES. CTR. (Oct. 29, 2006), <https://www.pewresearch.org/internet/2006/10/29/online-health-search-2006/> (finding eighty percent of American internet users searched for health information).

<sup>6</sup> *Id.*

<sup>7</sup> See Tiku, *supra* note 3 (commenting industry is now beginning to advertise more heavily on social media).

<sup>8</sup> Alison Kanski, *Nielsen: Pfizer Tops List of Biggest Pharma Advertisers in 2018*, MED., MKTG, & MEDIA (Apr. 2, 2019), <https://www.mmmonline.com/home/channel/nielsen-pfizer-tops-list-of-biggest-pharma-advertisers-in-2018/>.

<sup>9</sup> Ross Benes, *Digital Ad Spending by Industry 2019*, EMARKETER (Aug. 1, 2019), <https://www.emarketer.com/content/digital-ad-spending-by-industry-2019>.

pertaining by name to social media.<sup>10</sup> Enforcement against companies advertising prescription drugs using social media began with a warning letter issued in 2010 against Novartis Pharmaceuticals for developing a shareable Facebook widget.<sup>11</sup> This letter highlighted an important theme for existing guidance and regulations— presentation of the risk information.<sup>12</sup>

“Social media” describes a burgeoning set of platforms where people can share ideas and communicate with one another.<sup>13</sup> User bases vary across platforms, with Facebook as a clear

---

<sup>10</sup> U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: INTERNET/SOCIAL MEDIA PLATFORMS: CORRECTING THIRD-PARTY MISINFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES (2014) [hereinafter THIRD-PARTY MISINFORMATION GUIDANCE]; U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS—PRESENTING RISK AND BENEFIT INFORMATION FOR PRESCRIPTION DRUGS AND MEDICAL DEVICES (2014) [hereinafter CHARACTER LIMIT GUIDANCE].

<sup>11</sup> Letter to Lisa Drucker, Novartis Pharm. Corp., from Karen R. Rulli, FDA, 2–3 (July 29, 2010),

<http://wayback.archiveit.org/7993/20170112062707/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf> (accessed May 23, 2020) [hereinafter Tasinga Warning Letter] (the Tasinga widget omitted the risk information).

<sup>12</sup> *Id.* at 2–4.

<sup>13</sup> See *Social Media*, BLACK’S LAW DICTIONARY (11th ed. 2019); *Social Media*, MERRIAM WEBSTER (last visited July 3, 2020). Scholars have characterized applications from networking sites like Facebook to virtual game worlds like World of Warcraft as social media. Andreas M.

leader with nearly two-and-a-half billion users.<sup>14</sup> Some other familiar platforms like YouTube and Twitter have two billion and 386 million users, respectively.<sup>15</sup> These high usage statistics also have a tremendous variance in the age of the user.<sup>16</sup> Each of these platforms has a unique way of allowing users to interact and collaborate, and useful for businesses, targeted advertising services, which this Comment refers collectively as “functionality.”<sup>17</sup>

---

Kaplan & Michael Haenlein, *Users of the World, Unite! The Challenges and Opportunities of Social Media*, 53 BUS. HORIZONS 59, 62 (2010).

<sup>14</sup> J. Clement, *Most Popular Social Networks Worldwide as of April 2020, Ranked by Number of Active Users*, STATISTA (Apr. 24, 2020), <https://www.statista.com/statistics/272014/global-social-networks-ranked-by-number-ofusers/> (also reporting other platforms, like TikTok and Snapchat have ascertained 800 million users and 398 million users respectively).

<sup>15</sup> *Id.*

<sup>16</sup> *Social Media Fact Sheet*, PEW RES. CTR. (last visited Aug. 21, 2020), <https://www.pewresearch.org/internet/fact-sheet/social-media/> (finding that over fifty percent of individuals aged eighteen to sixty-five years old have at least one social media account).

<sup>17</sup> *Facebook for Business*, FACEBOOK (last visited Aug. 21, 2020), <https://www.facebook.com/business/ads/ad-targeting>; *Twitter Ads Targeting*, TWITTER (last visited Aug. 21, 2020), <https://business.twitter.com/en/advertising/targeting.html>. For the purposes of this Comment, functionality also includes constraints in the ability to express and manifest an idea. *See, e.g.*, “Tweet,” *Glossary*, TWITTER, <https://help.twitter.com/en/glossary> (last visited July 8, 2020) (where a tweet is limited to 280 characters and may contain photos and video content); “Single Image or Video Ads,” *Snapchat Ad Specs*, SNAPCHAT,

This Comment will explore how to address social media as a new medium for advertising in three parts. Part I discusses the creation and evolution of the Food, Drug, and Cosmetics Act's (FDCA's) drug approval scheme and relevant statutory provisions for protecting the public health. Part II discusses the guidance documents the FDA has issued on social media and discusses the weaknesses of each one. It then includes a discussion of the critical First Amendment case law in the realm of drugs, with a comprehensive analysis of how one of the guidance documents would stand with the First Amendment jurisprudence if challenged. Finally, Part III offers guidance to the FDA for how it should consider social media functionality in its thinking. It then offers practical methods for how the FDA could update existing guidance or issue new guidance and use its notice-and-comment rulemaking procedures to update existing provisions when approaching social media functionality and DTC prescription drug advertising.

## I. THE DEVELOPMENT AND PROVISIONS OF THE FDCA

### A. Development of the FDCA

Congress took one of its first major steps to enhance food and drug regulation in 1906, when it created a criminal offense for individuals who were misbranding food and drugs.<sup>18</sup> This

---

<https://businesshelp.snapchat.com/en-US/article/top-snap-specs> (last visited July 8, 2020) (where ads may be single image or videos and last from three seconds to three minutes).

<sup>18</sup> Pub. L. No. 59-384 (1906). *See generally* Jillian London, *Tragedy, Transformation, and Triumph: Comparing the Factors and Forces that Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States*, 69 *FOOD & DRUG L.J.* 315, 327–29, 336–41 (2014) (comparing the factors leading to England and the United States

legislation, however, did not include evaluation requirements for safety and efficacy; a change that arrived over the next few decades.<sup>19</sup> However, the legislation’s intent and purpose of protecting the public health persisted as food and drug regulation evolved.<sup>20</sup> In 1906, a “drug” was “all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary . . . to be used for the cure, mitigation, or prevention of disease either by man or other animals,” but was amended to include additional definitions of what a drug could be.<sup>21</sup>

---

drug regulatory regimes); *infra* Part I(B) (explaining misbranding). Present provisions on food and drug misbranding can be found at FDCA §§ 403, 502, 21 U.S.C §§ 343, 352 (2018).

<sup>19</sup> Pub. L. No. 59-384.

<sup>20</sup> *See* H.R. REP. NO. 2139, at 1–2 (1938) (commenting that the Food, Drug, and Cosmetic Act’s (FDCA’s) purpose “amplifies and strengthens the provisions designed to safeguard the public health and prevent deception . . .”).

<sup>21</sup> *Compare* Pub. L. No. 59-384, § 6 (defining drug as “all medicines and preparations” recognized by the National Formulary (NF) to be used in the treatment of disease), *with* 21 U.S.C. § 321(g)(1)–(2) (2018) (which includes, in part, medicines recognized in the NF, but adds the definition of a “counterfeit drug”), *and* 21 U.S.C. § 321(p) (2018) (where the drug definition describes a “new drug”). *See also* Lewis A. Grossman, *Food, Drugs, and Droids: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 1104–8, 1112–18 (2008) (exploring the differences between the definitions of “drug” in the 1906 Pure Food and Drug Act and the FDCA).

Congress members began drafting a replacement law beginning as early as 1933.<sup>22</sup> However, passage would come after a paradigmatic moment in 1937 when an estimated ninety people died as a result of the S. E. Massengill Company distributing more than 240 gallons of a drug containing deadly chemical.<sup>23</sup> The replacement of the 1906 Act occurred in 1938 with the introduction of the FDCA on January 6, 1937.<sup>24</sup> Senator Royal Copeland, urging the passage of a new law, emphasized the purpose of a new food and drug bill was to protect society from such tragedies.<sup>25</sup> This major update included the beginning of what would evolve into the robust premarket review of drugs that exists today.<sup>26</sup> The existing model for premarket review came after the Thalidomide crisis in Europe.<sup>27</sup> Following the crisis, Representative Oren Harris of Arkansas proposed amendments to the FDCA in 1962.<sup>28</sup> These amendments created the

---

<sup>22</sup> David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 L. & CONTEMP. PROBS. 2, 6 (1939).

<sup>23</sup> PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 642 (4th ed. 2013); Cavers, *supra* note 22, at 20.

<sup>24</sup> Federal Food, Drug, and Cosmetic Act, S. 5, 75th Cong. (1937).

<sup>25</sup> 83 CONG. REC. 6264 (1938).

<sup>26</sup> Federal Food, Drug, and Cosmetic Act, S. 5, 75th Cong., § 505 (1938). *See also* Hutt, *supra* note 23, at 642 (noting that the process at this time functioned as a “notification” system).

<sup>27</sup> Hutt, *supra* note 23, at 642. *See generally* Anita Bernstein, *Formed by Thalidomide: Mass Torts as a False Cure for Toxic Exposure*, 97 COLUM. L. REV. 2153 (1997).

<sup>28</sup> H.R. REP. NO. 87-2464, at 1–2 (1962). Some additional objectives included factory inspections and new procedures to follow for testing new drugs. *Id.* at 1–2.

comprehensive drug review process that exists today with the “[r]equirement that new drugs be shown to be effective as well as safe.”<sup>29</sup> For prescription drugs, these amendments also conferred important authority to the FDA with control over the advertising of such products.<sup>30</sup>

This history is here to highlight an oft-cited objective for the FDA to serve as protector of the public health.<sup>31</sup> Social media adds another dimension of complexity to the FDA’s pursuit of this objective.<sup>32</sup> On the one hand, consumer deception is at the forefront.<sup>33</sup> In a similar vein, DTC advertising on social media likely revives similar challenges the FDA faced when it first began regulating DTC ads.<sup>34</sup> The other side of the equation involves the possibility of a direct

---

<sup>29</sup> *Id.* at 1. *See also* FDCA § 505(b)(1)(A), 21 U.S.C. § 355(b)(1)(A) (2018) (requiring a manufacturer to prove whether the drug is safe and effective for intended use).

<sup>30</sup> Hutt, *supra* note 23, at 907.

<sup>31</sup> *See, e.g.*, *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012); *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 217 (S.D.N.Y. 2015); *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 57 (D.C. Cir. 1998).

<sup>32</sup> Social media presents variable functionality industry could use to interact and engage consumers. Tiku, *supra* note 3 (finding companies are beginning to promote on social media).

<sup>33</sup> *See* THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 3 (commenting that third-party content may be hazardous to public health); CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5 (claiming that “truthful, accurate, non-misleading, and balanced product information” will best serve the public health).

<sup>34</sup> *See* Jacqueline West, *National Marketing Gone Unintentionally Global: Direct-to-Consumer Advertising of Pharmaceutical Products and the Internet*, 11 J. INT’L BUS. & L. 405, 412 (2012)

challenge to the very core of the drug approval process: an avenue that could lead to off-label promotion.<sup>35</sup> Clear from the history, however, are that drugs come under close scrutiny and with this scrutiny comes an agency charged with monitoring the commercial posture taken by manufacturers on these products.<sup>36</sup>

#### B. Labeling, Misbranding, and Advertising a Prescription Drug

In the current model of the FDCA, several provisions directly address the rules regarding the labeling and advertising of a drug.<sup>37</sup> Further, additional rules are outlined in the CFR to help expound on the expectations set by the FDA.<sup>38</sup> The FDCA defines a label as “a display of written, printed, or graphic matter upon the immediate container of any article . . . .”<sup>39</sup> It then

---

(summarizing how the “brief summary” requirement was a challenge for the FDA for broadcast advertising).

<sup>35</sup> See *infra* Parts I(B), II(C) (defining off-label promotion and exploring the challenges courts have placed in the FDA’s path).

<sup>36</sup> See *infra* Part I(B) (covering the statutory and regulatory tools the FDA has to review the potential misbranding of a drug).

<sup>37</sup> See, e.g., FDCA §502(f), (n), 21 U.S.C. § 352(f), (n) (2018). Inversely, the labeling requirements might be easy to understand by seeing what the labeling should avoid for fear of being deemed misbranded (a topic that will be discussed shortly). See, e.g., § 352(a)(1) (“a drug . . . shall be deemed to be misbranded if its labeling is false or misleading in any particular”).

<sup>38</sup> 21 C.F.R. §§ 201.1, 201.100, 202.1 (2019).

<sup>39</sup> FDCA § 201(k), 21 U.S.C. § 321(k).

classifies “labeling” to include “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”<sup>40</sup>

For enforcement and compliance with the FDCA, misbranding is a common cause of action.<sup>41</sup> The FDCA grants the FDA many tools to make a case about an article being misbranded.<sup>42</sup> One tool is section 201(n), which allows the FDA to review “not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material . . . under the conditions of use . . . .”<sup>43</sup> In *Kordel v. United States*, the Court gave the language of section 201(m) a very liberal construction, holding “it is the textual relationship that counts.”<sup>44</sup> These two provisions plus *Kordel* are valuable for the FDA when determining a misbranding violation.

---

<sup>40</sup> FDCA § 201(m), 21 U.S.C. § 321(m).

<sup>41</sup> *See, e.g.*, *United States v. Evers*, 643 F.2d 1043, 1044 (5th Cir. 1981) (suit against a physician for misbranding a drug when giving information about its use to his patients); *Alberty Food Products v. United States*, 194 F.2d 462, 463 (9th Cir. 1952) (literature distributed to prospective consumers failed to demonstrate, among other things, diseases the drug was intended to cure).

<sup>42</sup> FDCA §§ 201(n), 301(a)–(b), 502(a)(1), (n), 21 U.S.C §§ 321(n), 331(a)–(b), 352(a)(1), (n).

<sup>43</sup> FDCA § 201(n), 21 U.S.C. § 321(n).

<sup>44</sup> 335 U.S. 345, 350 (1948) (finding articles and accompanying literature can “supplement” each other and no physical attachment to the article is necessary).

Section 502 of the FDCA is devoted specifically to drugs.<sup>45</sup> Under this section, misbranding can occur when the “labeling is false or misleading in any particular.”<sup>46</sup> Another form of misbranding occurs when a label fails to reveal material facts, for example, “adequate directions for use.”<sup>47</sup> These adequate directions for use are defined as “directions for which the layman can use a drug safely and for the purposes for which it is intended.”<sup>48</sup> These directions may be found inadequate because “of omission . . . or incorrect specification of (a) statements of all conditions, purposes, or uses for which such drug is intended . . . (b) quantity of dose . . . (c) frequency of administration . . . .”<sup>49</sup>

A drug that is not approved for a specific use, under which there is no general recognition by scientists qualified to evaluate safety and efficacy of the drug for that use, is considered a “new drug.”<sup>50</sup> Promoting a drug as such violates section 505(a) for “introduction into interstate commerce any new drug, unless approval of an application . . . is effective with respect to such

---

<sup>45</sup> FDCA § 502, 21 U.S.C. § 352.

<sup>46</sup> § 352(a)(1).

<sup>47</sup> FDCA §§ 201(n), 502(f)(1), 21 U.S.C. §§ 321(n), 352(f)(1).

<sup>48</sup> Labeling, 21 C.F.R. § 201.5 (2019). For example, a failure to include how to properly prepare the drug for use could be found inadequate. § 201.5(g).

<sup>49</sup> § 201.5(a)–(c). The regulation also provides that other factors, like the method of administration and information about preparation, are some other possibilities. § 201.5(f), (g).

<sup>50</sup> FDCA § 201(p)(1), 21 U.S.C. § 321(p)(1).

drug.”<sup>51</sup> This in conjunction with FDCA section 301(a), creates the prohibition against what is known as “off-label promotion” because promotion must be consistent with the FDA approved labeling.<sup>52</sup> These prohibitions are important for social media considerations because if a firm is going to promote its product, it must do so in accord with the FDA approval of its product.<sup>53</sup> Failure to do so will likely result in a misbranding action taken by the FDA against the offending party.<sup>54</sup>

The FDA recognizes several types of advertisements manufacturers may employ to promote their products.<sup>55</sup> The main types of advertisements are “Product Claim” advertisements, “Reminder” advertisements, and “Help-seeking” advertisements.<sup>56</sup> A “Product Claim” advertisement is one that names the drug and discusses the benefits and risks.<sup>57</sup> In a print medium, these advertisements must include a “brief summary,” which includes all the known

---

<sup>51</sup> FDCA § 505(a), 21 U.S.C. § 355(a). The basic elements of what a new drug application looks like can be found under subsection (b)(1) of the same statute.

<sup>52</sup> FDCA § 301(a), 21 U.S.C. § 331(a).

<sup>53</sup> *Id.*

<sup>54</sup> *See, e.g.,* United States v. Caronia, 703 F.3d 149, 157 (2d Cir. 2012) (one of the counts against Mr. Caronia was a conspiracy to introduce a drug into interstate commerce that was misbranded).

<sup>55</sup> *Basics of Drug Ads*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads> (last visited July 5, 2020).

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* This will be the most pivotal type of advertisement discussed by this Comment in Part III.

risks posed by the drug.<sup>58</sup> If done through a broadcast medium, the advertisement must include a “major statement,” which is a communication of the most important risks and how viewers may locate more risk information.<sup>59</sup> A “Reminder” advertisement does not disclose risk information, but simply provides the audience the name of the drug without including indications the drug is approved for.<sup>60</sup> “Help-seeking” advertisements are interesting because when created “properly,” they are not supposed to be drug advertisements.<sup>61</sup> These types of ads fall under the Federal Trade Commission’s (FTC’s) purview.<sup>62</sup> Lastly, FDA states that “Other Product Claim Promotional Material” is “promotional labeling” and if these materials mention a drug’s benefits, they must also include the prescribing information.<sup>63</sup>

---

<sup>58</sup> FDCA § 502(n)(3), 21 U.S.C § 352(n)(3); Prescription Drug Advertisements, 21 C.F.R. § 202.1(e)(1) (2019); *Basics of Drug Ads*, *supra* note 55. The “brief summary” forbids advertisers from suggesting the use of the drug for an unapproved indication. § 202.1(e)(iii)(4)(i)(a).

<sup>59</sup> § 202.1(e)(1); *Basics of Drug Ads*, *supra* note 55. The CFR provides that the major statement applies to broadcasts through radio, television, or telephone. § 202.1(e)(1).

<sup>60</sup> § 202.1(e)(2)(i); *Basics of Drug Ads*, *supra* note 55. Prescription drugs that contain boxed warnings in their labeling are prohibited from using these advertisements. § 202.1(e)(2)(i).

<sup>61</sup> *Basics of Drug Ads*, *supra* note 55.

<sup>62</sup> *Id.* However, if they mention or suggest a specific drug, the FDA will retain purview. *Id.*

<sup>63</sup> *Id.* The FDA defines “promotional labeling” as items distributed to consumers, like brochures and cups, among other things. “Promotional Labeling,” *Drug Advertising: A Glossary of Terms*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#P> (last visited July 7, 2020).

These types of advertisements are important because each type comes with unique requirements.<sup>64</sup> When considering these for social media functions, some may be better suited than others for certain mediums.<sup>65</sup> If the advertisement form is a “Help-Seeking” advertisement, then the jurisdiction itself shifts from the FDA to the FTC, which can be a limitation on the FDA’s capacity to review an advertisement.<sup>66</sup> An important challenge to consider with “Product Claim” advertisements are how social media functions can be used to navigate the “brief summary” requirement.<sup>67</sup>

## II. SOCIAL MEDIA GUIDANCE AND THE FIRST AMENDMENT

### A. FDA’s Social Media Guidance

In furtherance of this statutory evolution as an arbiter of the public health, the Administrative Procedure Act (APA) creates a process the FDA must adhere to when promulgating new rules that carry the force of law.<sup>68</sup> However, there is also an exemption for it to issue “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.”<sup>69</sup> It is precisely this exemption in the process that allows the FDA to

---

<sup>64</sup> See *Basics of Drug Ads*, *supra* note 55.

<sup>65</sup> The FDA acknowledges this for reminder advertisements because those ads do not require the same amount of disclosure. CHARACTER LIMIT GUIDANCE, *supra* note 10, at 4.

<sup>66</sup> *Basics of Drug Ads*, *supra* note 55.

<sup>67</sup> FDCA § 502(n)(3), 21 U.S.C. § 352(n)(3) (2018).

<sup>68</sup> Administrative Procedure Act (APA), 5 U.S.C. § 553 (2018).

<sup>69</sup> APA, § 553(b)(A).

issue a guidance document, which consists of its thinking on a particular subject and how it believes case law and statute apply.<sup>70</sup>

Although the FDA presently maintains two guidance documents with the term “social media” in the title, the agency has otherwise minimally addressed the subject.<sup>71</sup> The two documents focus on two main points: (1) how the FDA believes firms should approach correcting misinformation disseminated by third parties and (2) how firms should approach using social media sites and advertising mediums with character constraints.<sup>72</sup> Both of these documents draw their strength from similar roots—the labeling and misbranding provisions granted by the FDCA.<sup>73</sup> Discussion of these documents in depth will demonstrate that the FDA is thematically concerned with the public health and making sure the public has the best information to make informed decisions related to their health.<sup>74</sup> However, these guidance

---

<sup>70</sup> See, e.g., THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 1; CHARACTER LIMIT GUIDANCE, *supra* note 10, at 1.

<sup>71</sup> THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10; CHARACTER LIMIT GUIDANCE, *supra* note 10.

<sup>72</sup> THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10; CHARACTER LIMIT GUIDANCE, *supra* note 10.

<sup>73</sup> See THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 2–3; CHARACTER LIMIT GUIDANCE, *supra* note 10, at 2–3; see also *supra* Part I(B) (discussing the relevant provisions).

<sup>74</sup> THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 3; CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5.

documents fall short of addressing the First Amendment case law and commercial speech protections in issuing these guidance documents, which will be important for future guidance.

### 1. *Third-Party Misinformation Guidance*

The third-party misinformation guidance suggests how firms “should respond, if they choose . . . to misinformation related to a firm’s own FDA-approved or -cleared products . . . when that information is created or disseminated by *independent* third parties.”<sup>75</sup> The FDA recognizes that firms are “generally not responsible” for third-party content about their product, but could be if it “solicit[ed] or influence[d]” the content.<sup>76</sup> Section four of the guidance indicates how firms should communicate a correction request.<sup>77</sup> Among the suggestions, the FDA highlights firms be “non-promotional in nature” and “consistent with the FDA-required labeling for the product.”<sup>78</sup> The FDA also suggests firms include the approved labeling in their communications.<sup>79</sup> If the product is a prescription drug, it should be “supported by sufficient evidence, including substantial evidence.”<sup>80</sup>

---

<sup>75</sup> THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 1 (emphasis added).

<sup>76</sup> *Id.* at 5.

<sup>77</sup> *Id.* at 5–6.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at 6.

<sup>80</sup> *Id.* “Substantial evidence” means “adequate and well-controlled investigations . . . to evaluate the effectiveness of the drug” FDCA § 505(d), 21 U.S.C. § 355(d) (2018).

The FDA recognizes the challenge that exists in trying to correct an entire forum due to the vast amount of information.<sup>81</sup> The FDA does not expect a firm to seek to correct every piece of information that exists on a particular site.<sup>82</sup> If a firm elects to correct some of the misinformation, it should “clearly identify the misinformation it is correcting, define the portion of the forum . . . and should correct all the misinformation that appears in that clearly defined portion.”<sup>83</sup> However, a firm may not correct only some of the misinformation in a defined section; it must address it all.<sup>84</sup> In addressing the defined section, the FDA offers several suggestions.<sup>85</sup> Some of the methods include directly correcting the misinformation on the forum, providing corrective information to the author, requesting removal of the post, or contacting a site administrator.<sup>86</sup> If the posts cannot be removed, the FDA requests firms keep records about its efforts addressing the misinformation.<sup>87</sup>

---

<sup>81</sup> THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 6.

<sup>82</sup> *Id.* at 7.

<sup>83</sup> *Id.*

<sup>84</sup> For example, if the firm chooses to correct information that negatively publicizes its product and ignores a clear overstatement of the product’s benefits in the same defined section, the firm has failed to adhere to the guidance. *Id.*

<sup>85</sup> *Id.* at 7–8.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at 9.

With all guidance documents, they are merely suggestions with no force of law and offer, at best as the name suggests, guidance on a topic.<sup>88</sup> Dodging enforcement action, however, is valuable to a firm, so these documents do come with some bite.<sup>89</sup> One of the challenging elements of this guidance is that, if a firm chooses to engage in correcting misinformation, it should do so in a manner that narrowly limits itself to the specific element that is creating the misinformation.<sup>90</sup> This creates a content-based burden, which could prove problematic if the FDA is going to suggest a limit to a firm’s ability to respond to misinformation.<sup>91</sup> Additionally, it offers that a firm not be “promotional in nature or tone,” which suggests a speaker-based burden, which is subject to a rigorous review under existing case law.<sup>92</sup>

## 2. *Character Limit Guidance*

The character limit guidance applies to a firm presenting the benefit information of its drug and stating it should also incorporate the risk information of it in “electronic/digital

---

<sup>88</sup> FDCA § 701(h)(1)(A), 21 U.S.C. § 371(h)(1)(A) (2018); *see also* Hutt, *supra* note 23, at 30 (highlighting how the FDA has increasingly used this tool).

<sup>89</sup> *See generally* Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 122–24 (2014) (surveying the value of compliance with guidance).

<sup>90</sup> *See, e.g.*, THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 6 (where example 5 discusses that information should be limited to the indication in question); *see also infra* Part II(B)(1) (discussing burdens on speech and applicable case law).

<sup>91</sup> *See Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 581 (2011) (“content-based burdens on protected expression are sufficient to justify an application of heightened scrutiny”).

<sup>92</sup> *Sorrell*, 564 U.S. at 572; THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 5.

platforms that are associated with character space limitations—specifically on the Internet and through social media . . . .”<sup>93</sup> The document provides two mediums for examples, namely Twitter’s “tweet” and Google’s sponsored link service.<sup>94</sup> It is not intended to apply to promotions on “product websites” or webpages that appear on social media (like product pages on Facebook, Twitter, or YouTube) because the FDA believes the same constraints do not exist.<sup>95</sup>

In a character-limited platform, if a firm presents the benefit information, it should also discuss the risks.<sup>96</sup> In presenting these two elements, the presentation should be of comparable “content and prominence.”<sup>97</sup> Additionally, the FDA advises firms to provide a link to a place where a “more complete discussion” of the risk information.<sup>98</sup> The guidance further highlights when crafting an advertisement or promotional statement, the “benefit information should be accurate and non-misleading and reveal material facts within . . . .”<sup>99</sup>

---

<sup>93</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 1.

<sup>94</sup> *Id.* at 1–2.

<sup>95</sup> *Id.* at 2.

<sup>96</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5.

<sup>97</sup> *Id.* at 4; *see also* Prescription Drug Advertisements, 21 C.F.R. § 202.1(e)(5)(ii) (2019) (requiring the information be presented as a fair balance).

<sup>98</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5.

<sup>99</sup> Material facts are about the use could be limitations to an indication or relevant population for treatment. *Id.* at 6.

The FDA offers two factors to evaluate the comparability in presentation of the risk versus the benefit: (1) whether the risk qualifies a representation about the product and (2) whether the risk has the same prominence and readability as the benefit information.<sup>100</sup> At a minimum, the FDA suggests “the most serious risks associated with the product” be communicated.<sup>101</sup> For prescription drugs, “the most serious risks” are those in a “boxed warning,” either fatal or life-threatening, or all contraindications found within the approved labeling.<sup>102</sup> When providing a mechanism to communicate information beyond the tweet, the FDA suggests a “direct” hyperlink to a page that is “devoted exclusively to comprehensive risk information . . . .”<sup>103</sup>

To help emphasize the comparability of the risk and benefit disclosures, the FDA suggests firms use the same emphasis that highlights the benefit information on the risk

---

<sup>100</sup> *Id.* at 8.

<sup>101</sup> *Id.* at 9.

<sup>102</sup> *Id.* A “boxed warning” is a warning that a drug “may lead to death or serious injury . . . .” Labeling, 21 C.F.R. § 201.57(c)(1) (2019). A “contraindication” is a condition when the drug “should not be used . . . .” “Contraindication,” MEDLINEPLUS, <https://medlineplus.gov/ency/article/002314.htm> (last visited July 21, 2020).

<sup>103</sup> Some examples of direct information offered are “landing pages” with information exclusively focused on risks or a PDF outlining the information. CHARACTER LIMIT GUIDANCE, *supra* note 10, at 10. Firms may use URL condensing services to help fit the information. CHARACTER LIMIT GUIDANCE, *supra* note 10, at 10.

information as well.<sup>104</sup> If the medium offers the ability to accentuate or reformat specific parts of the message, the FDA advises firms to use that formatting to highlight significant risk information.<sup>105</sup> In formulation of the messages, the FDA permits the use of commonly utilized acronyms and symbols to assist with shrinking the size of the message to permit the balance of benefits and risks.<sup>106</sup>

While these guidance documents begin tackling social media to ensure drugs are characterized in a consistent and balanced manner, they leave room for improvement. An important shortcoming of the character limit guidance is its failure to explore the First Amendment jurisprudence in suggesting certain manufacturers avoid using those character-limited platforms.<sup>107</sup> This is further exacerbated since the suggestions made by the FDA create a speaker-based burden that suggests manufacturers try to comply with rigid requirements in a

---

<sup>104</sup> *Id.* at 10–11.

<sup>105</sup> For prescription drug messages, one example is reformatting a boxed warning for more prominence. *Id.* at 11.

<sup>106</sup> *Id.* at 14.

<sup>107</sup> Industry highlights this case in its comments. *See* Washington Legal Foundation, Comment Letter Concerning Draft Guidance for Industry on Internet/Social Media Platforms with Space Character Limitations, 4–6 (Sept. 16, 2014), <https://www.regulations.gov/document?D=FDA-2014-D-0397-0019> [hereinafter WLF Letter]; Medical Information Working Group, Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations (Docket No. FDA-2014-D-0397), 4–5 (Sept. 16, 2014) [hereinafter MIWG Letter].

narrowly defined space.<sup>108</sup> While leveraging how the failure to reveal material facts could lead to the misbranding of a drug, the guidance does not clearly demonstrate a nexus as to how a consumer is more likely to be misled by an advertisement on this platform.<sup>109</sup> A larger takeaway is that both guidance documents do not address the differing functionality that social media provides.<sup>110</sup> While the documents were issued in the advent of social media, silence on the

---

<sup>108</sup> See *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 571 (2011) (finding content- and- speaker based burdens on expression warrant heightened judicial scrutiny and subsequently applying *Central Hudson* to that effect); Pharmaceutical Research and Manufacturers of America, Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations (Docket No. FDA-2014-D0397), 8, n. 29 (Sept. 16, 2014) [hereinafter PhRMA Letter] (commenting that risk disclosures creates a speaker-based burden, subject to heightened scrutiny under *Sorrell*).

<sup>109</sup> The guidance relies heavily on section 201(n), but a reviewing court or industry challenge would likely assert mere probability of deception is insufficient. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 563 (1980) (“government may ban forms for communication *more likely* to deceive the public . . . .”) (emphasis added).

<sup>110</sup> See Cook Group, Inc., Docket No. FDA-2014-D-0447 Draft Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation, 3 (Sept. 16, 2014) [hereinafter Cook Letter] (commenting that the FDA should more “broadly reflect” the differing social media platforms that exist); Advanced Medical Technology Association, Docket No. FDA-2014-D-0397; Draft Guidance for Industry on Internet/Social Media Platforms with

matter since then provides room for amending or issuing new guidance to address the evolving platforms and address existing industry concerns.<sup>111</sup>

## B. The First Amendment

### 1. *Commercial Speech Doctrine*

Commercial speech protections were not readily recognized until *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*<sup>112</sup> This case originated from a state law that prohibited pharmacists from publishing, advertising, or promoting information about the pricing of a prescription drug.<sup>113</sup> Justice Blackmun found “society . . . may have a strong interest in the free flow of commercial information.”<sup>114</sup> He observed that “the poor, the sick, and particularly the aged” are most afflicted by the hiding of prescription drug prices.<sup>115</sup>

In recognizing the legal protection of commercial speech, Justice Blackmun offered that “we of course do not hold that it can never be regulated in any way.”<sup>116</sup> He then listed typically

---

Character Space Limitations, 2 (Sept. 16, 2014) [hereinafter AdvaMed Letter] (noting the FDA should take an approach that better reflects the “unique” attributes of social media).

<sup>111</sup> See *infra* Part III(B) (discussing how the FDA could issue new guidance to address this).

<sup>112</sup> 425 U.S. 748, 770 (1976). “Commercial Speech” is defined as “[c]ommunication (such as advertising and marketing) that involves only the commercial interests of the speaker and the audience . . . .” *Speech*, BLACK’S LAW DICTIONARY (11th ed. 2019).

<sup>113</sup> 425 U.S. at 749–50 (quoting VA. CODE ANN. § 54-524.35 (1974)).

<sup>114</sup> *Id.* at 764.

<sup>115</sup> *Id.* at 763.

<sup>116</sup> *Id.* at 770.

upheld restrictions, namely: those that are not content restrictive, serve an important government interest, or leave open ample alternative channels for communication.<sup>117</sup> The lone dissenter, Justice Rehnquist, explained his disagreement with the majority, believing the First Amendment services “public decisionmaking as to political, social, and other public issues” and not the “purchase one or another kind of shampoo.”<sup>118</sup>

This case has several important considerations for applicability to social media functions. First, Justice Blackmun recognizes that commercial speech is not immune to speech restrictions, which provides supportive language for the FDA to continue to regulate advertising and do so for information posted by a manufacturer on social media or equivocated through a function of social media.<sup>119</sup> Justice Blackmun was keen to note that “society . . . may have a strong interest in the free flow of commercial information” and that, while advertising might be viewed as “excessive,” dissemination of this information is useful for consumer decisions.<sup>120</sup> Social media

---

<sup>117</sup> *Id.* at 771.

<sup>118</sup> *Id.* at 787 (Rehnquist, J., dissenting). Justice Rehnquist feared this ruling would go beyond simple display of price information, instead leading to “active promotion of prescription drugs, liquor, cigarettes, and other products . . . thought desirable to discourage.” *Id.* at 781 (Rehnquist, J., dissenting). *See, e.g.,* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 526 (2001) (striking down a law prohibiting outdoor and point-of-sale promotion of smokeless tobacco products and cigars); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 516 (1996) (striking down a law prohibiting the promotion of liquor prices).

<sup>119</sup> *Va. St. Bd. of Pharm.*, 425 U.S. at 770.

<sup>120</sup> *Id.* at 764–65.

can easily become a vehicle for these advertisements, which provides an important rationale for both industry and the FDA to come together and identify meaningful methods of regulation.<sup>121</sup>

The signature test for commercial speech analysis came with *Central Hudson Gas and Electric Corp. v. Public Service Commission of New York*.<sup>122</sup> The Court created a four-part legal inquiry into commercial speech restrictions.<sup>123</sup> To evaluate the permissibility of a commercial speech burden, a court must first determine whether the speech is false or misleading.<sup>124</sup> If the speech is found truthful and not misleading or concerns lawful activity, the court must find the government asserted a substantial interest.<sup>125</sup> To sustain the speech restriction, the burden on speech must directly advance that interest and be no more extensive than necessary to achieve

---

<sup>121</sup> See *infra* Part III (explaining how the FDA can provide meaningful solutions and address existing industry concerns). Justice Blackmun also highlighted the “the poor, the sick, and elderly” are often disproportionately affected by suppression of price information. *Va. St. Bd. of Pharm.*, 425 U.S. at 764. With digital platforms becoming a cheaper alternative, there could be incentive for firms to reduce costs. See Brent Gleeson, “TV Advertising vs. Digital Marketing,” FORBES (Nov. 20, 2012, 1:39 PM), <https://www.forbes.com/sites/brentgleeson/2012/11/20/tv-advertising-vs-digital-marketing/#2ee1129037f8> (stating some advantages to digital advertising are that it is cheaper and has better capacity to target specific consumer demographics).

<sup>122</sup> 447 U.S. 557 (1980).

<sup>123</sup> *Id.* at 564, 572.

<sup>124</sup> *Id.* at 564.

<sup>125</sup> *Id.*

that interest.<sup>126</sup> In practice, the protection will not apply if the speech in question is false or misleading.<sup>127</sup> If the speech concerns lawful activity, is not misleading, and the government asserts a substantial interest, then the court must review whether the asserted interest is directly advanced by the regulation and whether it is more extensive than necessary.<sup>128</sup>

*Central Hudson* is the oft cited case when a commercial speech restriction is at issue.<sup>129</sup> Addressing this case in guidance is imperative because it is a consistent topic industry mentions when there are limitations and requirements present in proposed guidance.<sup>130</sup> *Central Hudson*

---

<sup>126</sup> *Id.*

<sup>127</sup> *See Id.* at 566 (identifying speech that is unlawful or misleading is not protected). Recall a drug is misbranded if “its labeling is false or misleading in any particular.” FDCA § 502(a)(1), 21 U.S.C. § 352(a)(1) (2018).

<sup>128</sup> *Central Hudson*, 447 U.S. at 566. *See, e.g.,* United States v. Caronia, 703 F.3d 149, 165–68 (2d Cir. 2012) (applying *Central Hudson*’s test in this manner).

<sup>129</sup> *See e.g.,* Thompson v. W. Sts. Med. Ctr., 535 U.S. 357 (2002) (challenging a provision of the Food and Drug Administration Act of 1997 that exempts compounded drug manufacturers from advertising); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (challenging a statute prohibiting the advertising of tobacco and smokeless tobacco products); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996) (challenging a state law prohibiting the advertising of alcohol prices); Rubin v. Coors Brewing Co., 514 U.S. 476 (1995) (challenging the Federal Alcohol Administration Act’s prohibition on beer labels displaying alcohol content).

<sup>130</sup> *See* WLF Letter, *supra* note 107, at 4–6 (discussing that the First Amendment jurisprudence grants constitutional protections to manufacturers); MIWG Letter, *supra* note 107, at 4.

can help aide the FDA because if the speech in question does not concern lawful activity or is misleading, it gives the FDA an opportunity to challenge the offending speech before needing to defend its limitations on speech.<sup>131</sup> Additionally, the FDA can use guidance to offer alternative “channels” of communication on social media to show its restriction is not “more extensive than necessary.”<sup>132</sup> Performing these actions would demonstrate that the FDA is crafting policy in a manner that shows it is trying to be as minimally restrictive as possible, a central element in reviewing commercial speech inquiries.<sup>133</sup>

In the same vein of commercial speech, *Sorrell v. IMS Health, Inc.*<sup>134</sup> articulated “heightened scrutiny” analysis applies when there are content- and speaker-based burdens on protected expression.<sup>135</sup> This analysis is triggered by a “regulation of speech because of disagreement with the message it conveys.”<sup>136</sup> To survive the inquiry, the state must

---

<sup>131</sup> *Central Hudson*, 447 U.S. at 566. If the FDA can successfully prove the speech is unlawful or misleading, then the manufacturer that promoted its product in that manner will not be afforded First Amendment protection. *Id.*

<sup>132</sup> *Id.*; *Va. St. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976). By doing this, the FDA can address First Amendment jurisprudence, which neither existing draft guidance does.

<sup>133</sup> *See Central Hudson*, 446 U.S. at 566 (where a court will review if the government’s restriction is more extensive than necessary).

<sup>134</sup> 546 U.S. 552 (2011).

<sup>135</sup> *Id.* at 571 (2011).

<sup>136</sup> *Id.* at 566 (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989)).

demonstrate “the statute directly advances a substantial government interest and that the measure is drawn to achieve that interest.”<sup>137</sup> In *Sorrell*, the Court struck down a Vermont law that failed to meet this standard.<sup>138</sup> While a small victory, the Court agreed that the public policy objectives of promoting public health and lowering the costs of medical services were “proper.”<sup>139</sup>

This case has become foundational for its line “[s]peech in aid of pharmaceutical marketing, however, is a form of expression protected by . . . the First Amendment.”<sup>140</sup> This line is now used against the FDA in both public comments on guidance as well as case law.<sup>141</sup> Neither existing guidance targeting social media makes mention of this principle, which is opportunity for improvement if the FDA decides to update these documents.<sup>142</sup> Additionally, if the FDA creates new guidance or rules surrounding social media usage, *Sorrell* is important to address because its language appears inextricably linked to prescription drugs and

---

<sup>137</sup> This “ensure[s]” the burden is proportional to the government’s interest(s). *Id.* at 572. *See also Central Hudson*, 477 U.S. at 566 (listing the four-part intermediate scrutiny analysis).

<sup>138</sup> *Sorrell*. 564 U.S. at 557.

<sup>139</sup> *Id.* at 576.

<sup>140</sup> *Id.* at 557.

<sup>141</sup> *See* MIWG Letter, *supra* note 107, at 4 (commenting that the Character-Limit Guidance creates a prohibition on some firm’s trying to use character limited platforms in violation of *Sorrell*); *infra* Part II(C) (the cases discussing off-label promotion).

<sup>142</sup> Doing so could quell the concern of the FDA’s lack of position on how these documents comply with existing case law. *See, e.g.*, MIWG Letter, *supra* note 107, at 4 (discussing the constitutional issues).

representations made about them.<sup>143</sup> If the FDA chooses to pursue more formal rulemaking related to prescription drug marketing on digital platforms broadly, this case certainly needs to be addressed.<sup>144</sup>

## 2. *Character Limit Guidance First Amendment Analysis*

It is useful to run the FDA’s current thinking through existing legal frameworks to evaluate whether it would stand under current precedent. While the FDA notes what a firm “should” do, an enforcement action might be sufficient to trigger a First Amendment inquiry.<sup>145</sup> The predominant standards to consider here are *Sorrell* and the *Central Hudson*, four-step inquiry about commercial speech restrictions.<sup>146</sup> The provision under review here is the FDA’s suggestion that firms who cannot meet the “fair balance” requirement “reconsider” using a platform with a character limit.<sup>147</sup> A content-based burden on speech is created by enforcing

---

<sup>143</sup> See *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 557 (2011) (“[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the . . . First Amendment.”).

<sup>144</sup> If there is a regulation of speech based on content, “heightened scrutiny” is going to apply. *Sorrell*, 564 U.S. at 566; see *infra* Part III(B) (discussing how this could be done).

<sup>145</sup> See, e.g., *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 222 (S.D.N.Y. 2015) (where a warning letter sufficiently allowed Amarin to seek relief).

<sup>146</sup> See *supra* Part II(B)(1) (discussing the commercial speech doctrine).

<sup>147</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5. Additionally, this analysis is done as if the firm wants to use a “Product Claim” advertisement because the guidance was not intended to be used on “Reminder” advertisements. CHARACTER LIMIT GUIDANCE, *supra* note 10, at 4, n. 10.

The “fair balance” requirement states that a firm must present information of comparable detail

that, in a character limited space, if a firm discusses the benefits it must also discuss the risks.<sup>148</sup> If a firm cannot meet such requirement, then it should avoid using the platform.<sup>149</sup> The criteria used by a reviewing court will require the government to maintain a “substantial government interest” and that “the measure is drawn to achieve that interest” in addition to the other *Central Hudson* factors.<sup>150</sup>

On the *Central Hudson* question of whether the speech is false or misleading, the FDA’s argument will be that tweets or other character limited posts are misleading because they do not adequately disclose sufficient risk information against the benefits.<sup>151</sup> Industry will rebuke the FDA’s argument as impermissible because the FDA cannot restrict speech based on the notion that the speech is not more likely to deceive the public than not.<sup>152</sup> Industry might invoke the

---

between the side effects and contraindications and the effectiveness and safety. Prescription Drug Advertisements, 21 C.F.R. § 202.1(e)(5)(ii) (2019).

<sup>148</sup> *Sorrell*, 564 U.S. at 565; § 202.1(e)(5)(ii).

<sup>149</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5.

<sup>150</sup> *Sorrell*, 564 U.S. at 572 (stating how the government must justify its content-based burden and applying *Central Hudson* to evaluate that justification); *see also* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y., 447 U.S. 557, 566 (1980) (laying out the four-part commercial speech inquiry).

<sup>151</sup> FDCA § 201(n), 21 U.S.C. § 321(n) (2018) (omitting risk information is a failure to reveal a material fact); *Central Hudson*, 447 U.S. at 566.

<sup>152</sup> *See also* Thompson v. W. Sts. Med. Ctr., 535 U.S. 357, 367 (2002) (explaining *Central Hudson* does not apply if the speech concerns lawful activity and is not misleading); *Central*

FDA’s prior thinking about a reasonable consumer.<sup>153</sup> They would argue under this concept that a single tweet demonstrating benefits and leaving either only the risks or a link to refer to them is not inherently misleading.<sup>154</sup> Based on the language from the guidance and existing case law, the most applicable substantial government interest would be the protection of public health.<sup>155</sup> In defense of this interest, the FDA would assert that the FDCA’s purpose is to protect public health, that it should be afforded a “liberal construction,” and guidance is one of the informal tools it has to perpetuate that purpose.<sup>156</sup>

---

*Hudson*, 447 U.S. at 563 (government may prohibit speech that is more likely to deceive the public than inform it).

<sup>153</sup> In a guidance document, the FDA entertained the “reasonable consumer standard.” The standard looks through the eyes of a prospective consumer “acting reasonably in the circumstances.” See U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: PRESENTING RISK INFORMATION IN PRESCRIPTION DRUG AND MEDICAL DEVICE PROMOTION 5 (2009) [hereinafter PRESENTING RISK INFORMATION GUIDANCE].

<sup>154</sup> *Id.*

<sup>155</sup> See *id.* at 576 (finding a policy objective of public health to be “proper”); *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012) (finding that drug safety and public health are substantial interests); see also CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5 (stating the public is best served through “truthful, non-misleading, and balanced” promotions).

<sup>156</sup> See *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969) (stating that a court should give “effect” to the congressional intent in making the FDCA with an “overriding purpose” of protecting the public health).

Even if a reviewing court upheld this interest, the next big challenge is determining whether the measure is drawn sufficiently.<sup>157</sup> The guidance initially suggests that a firm seeking to discuss benefits must also discuss the risks associated with the drug.<sup>158</sup> It also permits a manufacturer to use a link to expand upon the risks associated with the promoted drug, but it still must include risks in the character limited message.<sup>159</sup> The FDA would argue that disclosure of information and a balanced presentation will best serve the public health.<sup>160</sup> By requiring both a showing of the risks and a link addressing them further, that objective is achieved. Further, they would assert that they have left “open ample alternative channels for communication of information” by allowing the risk discussion to continue elsewhere or simply allowing the firm to choose an alternative advertising platform.<sup>161</sup>

---

<sup>157</sup> In reviewing this element, the court is looking for a “fit between the legislature’s end and the means chosen to accomplish those ends.” *Sorrell*, 564 U.S. at 572 (quoting *Bd. of Trs. of St. U. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989)).

<sup>158</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 1.

<sup>159</sup> *Id.* at 10.

<sup>160</sup> *See Va. St. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976) (discussing people will make the best choices when they have the information available to them); CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5.

<sup>161</sup> *Va. St. Bd. of Pharm.*, 564 U.S. at 771.

Conversely, industry would challenge that a listing of known risks and a link discussing them further is imbalanced.<sup>162</sup> Further, it would similarly argue that the public health might be best served by simply only using a link for risk information because instead of a few words, consumers might be more willing to view an entire landing page than a tweet alone for the drug information.<sup>163</sup> In doing so, they would contend under section 201(n) that they are revealing material facts about a drug because the link provides the information and is textually related to the article.<sup>164</sup> Under statute and regulation, industry would also contend they are presenting more than a fair balance of the risks because a character-limited post containing a brief statement of benefit can be outweighed by a comprehensive discussion of the potential hazards under use provided within a link.<sup>165</sup> In terms of a less restrictive means, industry would likely assert that

---

<sup>162</sup> See, e.g., PhRMA Letter, *supra* note 108, at 8–9 (stating that alternative means, such as using “introductory phrases” and providing a link or using a “universal graphic[al] symbols” could create a balanced presentation of information).

<sup>163</sup> A reasonable consumer under the circumstances might not consider a single tweet as the definitive authority on a drug’s information. See PRESENTING RISK INFORMATION GUIDANCE, *supra* note 153, at 5 (articulating the standard for what a reasonable consumer does).

<sup>164</sup> FDCA § 201(n), 21 U.S.C. § 321(n) (2018). This provision is also mentioned in the background of the guidance as a place where the guidance draws its strength. CHARACTER LIMIT GUIDANCE, *supra* note 10, at 3.

<sup>165</sup> See FDCA § 502(n)(3), 21 U.S.C. § 352(n)(3) (advertisements or other descriptive matter shall include information in brief summary pertaining to “side effects, contraindications, and

the “One-Click Rule” is a less burdensome alternative than guidance suggestion of both risks and a link, which could lead to the consequential decision of a firm “reconsider[ing]” use of the platform.<sup>166</sup> The question will hinge on whether the content within the link satisfies the fair balance without the listing of the risks in the character-limited message.<sup>167</sup>

### C. Off-Label Promotion Roadblocks

In a Second Circuit case, as the dissent puts it, “the majority calls into question the very foundations of our century-old system of drug regulation.”<sup>168</sup> In statements made to a government informant, Mr. Caronia broadened the application of Xyrem beyond the contents of the approved labeling.<sup>169</sup> Unfortunately for the FDA, the majority found *Sorrell*’s application of “heightened scrutiny” was warranted and the subsequent *Central Hudson* application yielded negative results for the agency.<sup>170</sup> The court found that the prohibitions on off-label promotion

---

effectiveness . . . .”); Prescription Drug Advertisements, 21 C.F.R. § 202.1(e)(5)(ii) (2019) (violation of this regulation will not be found when presentation of information is comparable).

<sup>166</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5. The “One-Click Rule” was an industry developed initiative to provide a URL in a limited space to provide information instead of listing it all out. See Randy Gray, Note, *One Click is Enough: Satisfying FDA’s Fair Balance in the Highly-Regulated Marketplace*, 39 RUTGERS COMPUTER & TECH. L.J. 95, 103–4 (2013); West, *supra* note 34, at 422.

<sup>167</sup> CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5.

<sup>168</sup> *United States v. Caronia*, 704 F.3d 149, 169 (2d Cir. 2012) (Livingston, J., dissenting).

<sup>169</sup> *Id.* at 156–57.

<sup>170</sup> *Id.* at 164–69.

were content-based.<sup>171</sup> The court also ruled that the restrictions were speaker-based because they targeted pharmaceutical manufacturers without restricting everyone else from discussing off-label uses.<sup>172</sup>

Perhaps most critical to potential issues related to social media promotion, under *Central Hudson*'s first element, the court found off-label promotion concerned lawful activity because off-label drug use is legal.<sup>173</sup> It also stated that off-label drug promotion is “not in and of itself false or misleading.”<sup>174</sup> While the FDA asserted the protection of the FDCA’s drug approval process as a substantial interest, the court reasoned the FDA was overly burdensome.<sup>175</sup>

This problem for the FDA was further exacerbated a few years later with *Amarin Pharma, Inc. v. United States Food and Drug Administration*.<sup>176</sup> Here, the court rejected the FDA’s argument that *Caronia* should be reviewed narrowly on its facts.<sup>177</sup> Reemphasizing the *Caronia* decision, the *Amarin* court stated the “considered and firm view is that, under *Caronia*,

---

<sup>171</sup> *Id.* at 165.

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* Drugs go through extensive testing to reach FDA approval status and to claim that off-label discussion is lawful strikes an interesting counterbalance. *See* FDCA § 505(b)(1), 21 U.S.C. § 355(b)(1) (2018) (FDA drug approval requirements).

<sup>174</sup> *Caronia*, 703 F.3d at 165.

<sup>175</sup> *Id.* at 167–68 (reasoning the government could educate physicians to discern information or develop a disclaimer system).

<sup>176</sup> 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

<sup>177</sup> *Id.* at 224.

the FDA may *not* bring such an action based on truthful promotional speech alone, consistent with the First Amendment.”<sup>178</sup> The majority highlighted neither false nor misleading speech is protected and that expression, but not conduct, is protected.<sup>179</sup>

This opinion highlights an integral challenge the FDA faces: protected expression.<sup>180</sup> This makes the FDA’s regulatory job harder with respect to social media functions because retweeting or sharing a post from a consumer in support of a product, even if the content is off-label, will likely result in a comprehensive First Amendment analysis.<sup>181</sup> While *Amarin* finds that “*Caronia* leaves room for prosecuting off-label marketing as misbranding,” it still seems to narrow the gap the FDA could prosecute by also stating “a manufacturer that engages in *non-communicative activities* . . . cannot use the First Amendment as a shield.”<sup>182</sup> A manufacturer could raise that a post that is shared, retweeted, or liked is a communicative activity, and therefore, behind a First Amendment shield.

---

<sup>178</sup> *Id.*

<sup>179</sup> *Id.* at 228.

<sup>180</sup> *Id.*

<sup>181</sup> This could be argued as expression in pursuit of pharmaceutical marketing, bringing it under the umbrella of protection. *See Sorrell v. IMS Health, Inc.*, 546 U.S. 552, 557 (2011) (“[s]peech in aid of pharmaceutical marketing, however, is a form of expression protected by . . . the First Amendment”); *United States v. Caronia*, 704 F.3d 149, 161–62 (2d Cir. 2012) (prosecution of an individual for aiding pharmaceutical marketing).

<sup>182</sup> *Amarin*, 119 F. Supp. 3d at 228 (emphasis added).

### III. RECOMMENDATIONS

Social media is an evolving platform that shifts the way people and business can interact. To some extent, there is a hidden genius to the FDA remaining silent on the subject for so long. It could be the sole reason there has not been a proliferation of advertising for prescription drugs on your Facebook page.<sup>183</sup> However, industry will not remain idle as these sites and apps become more attractive for reaching consumers.<sup>184</sup> Facebook used to be just a place for people to post their own thoughts and share articles or media. Now, it has a marketplace where businesses and people can post goods and services they have for sale.<sup>185</sup> These types of technological evolutions in social media spaces might continue and business are attracted to it.<sup>186</sup> The FDA should see this as an opportunity to update existing regulations and issue more guidance in furtherance of its statutory calling. The following analyses will explore how the FDA should consider social media functions in advertising and how this thinking could apply to promulgating updated or new guidance issuances and rulemaking.

---

<sup>183</sup> Kassity Liu, *FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising*, Jolt Dig. (Apr. 17, 2012), <https://jolt.law.harvard.edu/digest/fda-and-social-media-the-impact-of-social-media-on-prescription-drug-advertisin>.

<sup>184</sup> Tiku, *supra* note 3.

<sup>185</sup> *About Marketplace for Business*, FACEBOOK, (last visited July 11, 2020) <https://www.facebook.com/business/help/289268564912664?id=150605362430228>.

<sup>186</sup> Tiku, *supra* note 3.

## A. Social Media Functions and Advertising

The FDA should directly address the functions of social media platforms to clarify the regulatory gap that exists.<sup>187</sup> To begin, it should invoke the FDCA and *Kordel* as authority over such communications.<sup>188</sup> It should continue to take an expansive view of the labeling provisions because communications about an article ultimately supplement the article, which can synchronously function as advertising information since the FDCA also addresses advertising in a similar manner.<sup>189</sup> For example, the FDA should indicate if a company “likes” or “retweets” a statement about a product, that symbolic gesture should indicate the contents of the post “accompany such article” consistent with the content of the affirmed post.<sup>190</sup> This should be seen as a “representation” of the product because it can evince an intent about a firm’s

---

<sup>187</sup> See, e.g., Prescription Drug Advertisements, § 202.1 (2019) (where social media is not addressed, or the words “digital,” “internet,” and “online” do not appear either).

<sup>188</sup> See FDCA § 201(n), 21 U.S.C. § 321(n) (2018); 335 U.S. 345, 350 (1948) (holding the textual relationship matters).

<sup>189</sup> See FDCA § 201(m), (n) 21 U.S.C. 321(m), (n) (in considering whether there is a misbranding, the labeling or advertising shall be considered to evaluate the representations made about the product); *Kordel v. United States*, 335 U.S. 345, 349 (1948) (finding that an article is accompanied when something “supplements or explains it.”). See also PRESENTING RISK INFORMATION GUIDANCE, *supra* note 153, n. 9 (defining “promotional piece, promotional materials, and promotional communications” to include Internet web sites).

<sup>190</sup> FDCA § 201(m), 21 U.S.C. § 321(m) (where labeling means “all written, printed or graphic matter . . . accompanying such article”).

understanding and beliefs about the product since it reaffirms one of its consumers endorsements or other representations related to its use.<sup>191</sup> If the post being “liked” or “retweeted” is in relation to a use off-label, then a misbranding action could be brought against the firm.<sup>192</sup>

If the source of the firm’s engagement appears in a comment or user reply where character limits are not a concern, then the FDCA and paired regulations provide the FDA with a strong framework for regulating such representations.<sup>193</sup> Under FDCA § 502(n)(3), for example, the firm must provide the “brief summary” of the drug and if limits are of no concern, then the inclusion of such should be required.<sup>194</sup> These regulations should become more feasible because in a space where one can place text and other media, without constraint, satisfying this

---

<sup>191</sup> *Id.*; FDCA § 201(n), 21 U.S.C. § 321(n) (“there shall be taken into account . . . representations made or suggested by statement, word, design, device, or any combination thereof” in consideration of misbranding). *See generally* Chang Zhou, *Consumers as Marketers: An Analysis of the Facebook “Like” Feature as an Endorsement*, 41 W. ST. U.L. REV. 115, 117–18, 126–129 (2014) (arguing how the “like” feature on Facebook could operate as an endorsement under the Federal Trade Commission Act and related guides).

<sup>192</sup> FDCA §§ 301(a), 502(a)(1), 21 U.S.C. §§ 331(a), 352(a)(1) (introducing into interstate commerce a drug that is misbranded is a prohibited act). *See also* *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 228 (2015) (holding *Caronia* leaves room for off-label marketing to be considered misbranding).

<sup>193</sup> *See* FDCA §§ 201(m), (n), 502(n), 21 U.S.C. §§ 321(m), (n), 352(n).

<sup>194</sup> FDCA § 502(n)(3), 21 U.S.C. § 352(n)(3). The requirements for how to meet this are expounded on in the CFR. Prescription Drug Advertisements, 21 C.F.R. § 202.1(e)(1) (2019).

requirement should be simple. Similar to the objectives of the third-party misinformation guidance, a comment section provides opportunity to correct statements made about a product to be consistent with the FDA approved labeling.<sup>195</sup> Further, these limits provide firms the ability to adequately clarify or specify important information, which can help shield from potential misbranding violations that might arise from terse or unclear comments.<sup>196</sup>

The off-label promotion jurisprudence thus far does create some important concerns for the FDA to monitor.<sup>197</sup> Whereas *Wisconsin v. Mitchell* held the “First Amendment . . . does not prohibit the evidentiary use of speech to establish elements of a crime,” *Caronia* offered stark contrast, instead, prohibiting the FDA from doing as such.<sup>198</sup> The best hope for the FDA in this dichotomy is that the Supreme Court rejects *Caronia* or at least the Second Circuit overrules itself with other circuits declining to accept the holding. However, a trend seems to indicate whenever the means by which the government seeks to achieve its substantial interest in the sphere of drug regulation, the reviewing court finds less restrictive means that could be

---

<sup>195</sup> THIRD-PARTY MISINFORMATION GUIDANCE, *supra* note 10, at 1.

<sup>196</sup> See FDCA §§ 201(n), 502(a)(1), 21 U.S.C. §§ 321(n), 352(a)(1) (elaboration could help ensure the drug is not misbranded from terse and unclear statements about it).

<sup>197</sup> *Supra* Part II(C).

<sup>198</sup> See 508 U.S. 476, 489 (1993); *United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012) (Livingston, J., dissenting). *But see Caronia*, 703 F.3d at 162, 165 (concluding the government’s prosecution of Mr. Caronia for his speech did not comport with the First Amendment).

employed, or an exception is carved out.<sup>199</sup> These precedents seem to have eroded the government’s capacity to win on the first element of *Central Hudson*.<sup>200</sup>

Nonetheless, the FDA should incorporate a direct discussion about how social media functions can lead to a drug becoming misbranded.<sup>201</sup> Since social media provides the ability to use differing forms of media, this can create a diverse array of options for which the FDA can evaluate claims made by a company.<sup>202</sup> An example could be for video mediums, like Snapchat, advertising videos that illustrate someone using a drug for an indication unapproved by the FDA could be grounds for a misbranding action, especially if the post also provides a link to information unsupported by the FDA labeling.<sup>203</sup> If a firm repeatedly likes and shares customer testimonials, without influencing or soliciting the information, then the FDA might find the product as a “new drug” that, unsupported by an approved FDA application, is illegal.<sup>204</sup>

---

<sup>199</sup> See *supra* Part II(B) (exploring the First Amendment jurisprudence and drug intersections).

<sup>200</sup> See *supra* Part II(C) (discussing that discussion of off-label information is not necessarily unlawful or misleading); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980) (inquiring whether the challenged speech burden concerns lawful activity).

<sup>201</sup> FDCA § 201(m), (n), 21 U.S.C. § 321(m), (n).

<sup>202</sup> *Id.*

<sup>203</sup> See FDCA §§ 201(n), 502(a), 21 U.S.C. §§ 321(n) (considering the representations made), 352(a) (labeling becoming false because of inconsistency with the approved labeling).

<sup>204</sup> FDCA §§ 201(p), 505(a), 21 U.S.C. §§ 321(p), 355(a).

## B. Issuing Further and Updated Guidance Documents

The FDA should update or issue final guidance on the presently titled social media guidance documents. Six years of public availability should present a reasonable window of time to update existing thinking. Industry has shared its perspective on the guidance documents and found several problems.<sup>205</sup> First Amendment issues, especially *Sorrell*, were a major source of concern over the character limit guidance.<sup>206</sup> Since the FDA failed to address the First Amendment in its current thinking, it should update existing guidance to include a discussion of this. *Central Hudson* and *Sorrell* should be the focus since they lay the foundation for review.<sup>207</sup>

For the third-party misinformation guidance, the FDA should permit the corrective material to be promotional in nature. This serves the purpose of becoming less-restrictive than necessary and would give creative latitude to manufacturers to send corrective information using

---

<sup>205</sup> See WLF Letter, *supra* note 107, at 8, 11, 15 (exploring how the character limit guidance is overly broadens FDA authority and constrains speech); MIWG Letter, *supra* note 107 (exploring the failure to account for *Sorrell*); PhRMA Letter, *supra* note 108, at 5 (noting that heightened scrutiny will apply).

<sup>206</sup> See WLF Letter, *supra* note 107; MIWG Letter, *supra* note 107; PhRMA Letter, *supra* note 108.

<sup>207</sup> See *supra* Part II(B)(1) (discussing the commercial speech doctrine and when burdens on speech call for analysis).

advertisements containing either the major statement or brief summary for the prescription drug that needs its information corrected in a medium.<sup>208</sup>

In taking the path to update the character limit guidance, it should consider adopting less-restrictive means and include the First Amendment jurisprudence. For instance, it should consider lightening up the suggestion that a firm incorporate both important risks and a URL to address them further.<sup>209</sup> Industry offers a good suggestion for the adoption of universal iconography, which could make research easier on the consumer.<sup>210</sup> It could pair this with the creation of its own education materials for consumers to teach them the important aspects of drug labeling and advertising and what to look for.<sup>211</sup> This will serve an important purpose for the First Amendment jurisprudence because the courts have continued to find ways the government could be less restrictive when creating burdens on speech.<sup>212</sup> To address this case,

---

<sup>208</sup> For example, a company could have a television advertisement or a direct copy of a magazine ad it ran, which would need to comport with the “brief summary” or “major statement” requirement. FDCA § 502(n), 21 U.S.C. §352(n); *see* *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 564 (1980) (government restriction cannot be more burdensome than necessary).

<sup>209</sup> *See* CHARACTER LIMIT GUIDANCE, *supra* note 10, at 10 (suggesting the inclusion of a URL to help comprehensively address the totality of the risk information).

<sup>210</sup> PhRMA Letter, *supra* note 108, at 8–9.

<sup>211</sup> *See, e.g., United States v. Caronia*, 703 F.3d 149, 167–68 (2d Cir. 2012) (finding the government could address off-label promotion through education programs).

<sup>212</sup> *Id.*

the FDA should continue to explain that the public health is the core of its rationale for providing such guidance.<sup>213</sup> If it is going to suggest a firm not use a particular platform due to inability to meet the “fair balance” requirement, it should afford thinking as to why the suggested prohibition is permissible and give explanation to alternative means for the firm to use.<sup>214</sup> In doing so, the FDA would take into account both *Sorrell* and *Central Hudson* by explaining the measures taken are “not more extensive than necessary” to achieve the protection of the public health.<sup>215</sup> The use of a link in addition to the risk information poses one of the places for elaborating on this thinking.<sup>216</sup> In addition to how character-limited spaces might impact a consumer becoming misled, the guidance should incorporate consumer studies to help provide further guidance and context for what factors most directly contribute to consumer understandings.<sup>217</sup>

---

<sup>213</sup> See CHARACTER LIMIT GUIDANCE, *supra* note 10, at 5 (emphasizing the public health is best served by clear information).

<sup>214</sup> Industry might be successful in arguing that prohibition on a character-limited platform would violate principles of “leav[ing] open ample alternative channels” because it is a chilling effect on an entire type of platform. *Va. St. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976).

<sup>215</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980).

<sup>216</sup> See *supra* Part II(B)(2) (exploring how commercial speech restrictions could be less burdensome using a link instead of a balanced representation of risk and benefit information).

<sup>217</sup> While statute permits the FDA to evaluate misbranding based on material omission, a clearer discussion of factors to look for would benefit both industry in crafting better advertisements, but

The FDA should take this as an opportunity to provide new and direct guidance about how it believes user interactions will fall within the scope of the FDCA. For example, new guidance could explain that liking posts about a product creates a “textual relationship” that can be considered reviewed in a misbranding action.<sup>218</sup> Videos that can reach the same length as other broadcast mediums can also fall under the same guidelines imposed on those mediums.<sup>219</sup> New guidance could also address how DTC advertising and using targeted advertising tools on social media could be regulated.<sup>220</sup> For instance, the FDA explore how demographic tools among other factors could lead to a drug becoming misbranded because the promotion of such drug is “false or misleading” because the targeted group of individuals is not within the scope of the FDA approved labeling.<sup>221</sup> It could also directly address First Amendment jurisprudence because the first element of *Central Hudson* does not protect speech that is not truthful or misleading.<sup>222</sup>

---

also meet potential legal hurdles related to a court determining if the language is definitively misleading. *See* FDCA § 201(n), 21 U.S.C. § 321(n) (2018); *Central Hudson*, 447 U.S. at 563 (government may ban speech more likely to deceive than not).

<sup>218</sup> *United States v. Kordel*, 335 U.S. 345, 350 (1948); *supra* Part III(A).

<sup>219</sup> Recall Snapchat allows advertisements of 3 to 180 seconds in either images or video. “Single Image or Video Ads,” *supra* note 17.

<sup>220</sup> *See* Tiku, *supra* note 3 (noting the concerns both manufacturers and consumers have about targeted advertising).

<sup>221</sup> FDCA § 502(a)(1), 21 U.S.C. § 352(a)(1) (2018).

<sup>222</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980).

Additionally, this creates a prime opportunity to obtain comments on its statutory and case law interpretations. In the wake of either new or updated guidance, this is a chance for government and industry to come together and grapple with these developing platforms. The FDA should consider reaching out to the creators of these platforms to gather developer insights for what these social media platforms can achieve in order to create effective rules or guidance that can address a lasting and evolving system. Like the growth of radio and television, which have run alongside print, this new medium seems to combine the two and the FDA should not continue to let it grow without documenting some form of updated thinking.

### C. Notice-and-Comment Rulemaking

Notice-and-comment rulemaking could be a more effective tool to promulgate new regulations for governing social media tools. The APA provides agencies the ability to create “rules” in furtherance of their statutory calling.<sup>223</sup> Unlike the guidance exemption, this route also provides something that guidance documents do not: a rule with a force of law.<sup>224</sup> However, the agency must adhere to several formalities.<sup>225</sup> Summarily, an agency must provide the public with an opportunity to comment on a proposed rule and consider such comments in promulgation of the final rule.<sup>226</sup>

---

<sup>223</sup> A “rule” under the APA means “the whole or a part of an agency statement of general or particular applicability and future effect designed to *implement, interpret, or prescribe law or policy . . .*” APA, 5 U.S.C. § 551(4) (2018) (emphasis added).

<sup>224</sup> APA, § 551(4).

<sup>225</sup> APA, § 553. *See supra* Part II(A) (explaining the guidance exception).

<sup>226</sup> APA, § 553(c). A rule cannot be effective within thirty days of initial notice. APA, § 553(d).

In using this method to address social media functionality, the FDA should update existing regulations to include social media and digital advertising. As an example, in the “Prescription Drug Advertisements” regulation, the current provision of the act provides “Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.”<sup>227</sup> The FDA should address this section of the CFR to include digital platforms and include language that names social media as an example. Another opportunity for update comes in the next subsection, which lists different types of descriptive matter the FDA deems to be “labeling” under the FDCA.<sup>228</sup> While it comes close to identifying digital and social media items with “similar pieces of printed, audio, or visual matter descriptive of a drug,” it could stand to benefit from a clearer definition that “similar pieces” include digital advertisements and labeling of the drug.<sup>229</sup>

The usage of notice-and-comment rulemaking has several benefits for the FDA and industry. One such advantage is the public process for issuing comments.<sup>230</sup> By utilizing this process, the FDA can obtain documented feedback for its current vacuum in social media regulation by reviewing how industry believes the agency can proceed. Another advantage to this process is that social media platforms could also provide comments and information about

---

<sup>227</sup> Prescription Drug Advertisements, 21 C.F.R. § 202.1(l)(1) (2019).

<sup>228</sup> It provides that items like brochures, bulletins, and literature, among other things, are considered labeling. § 202.1(l)(2).

<sup>229</sup> *Id.*

<sup>230</sup> APA, § 553(c).

how their platform could contribute to the success of the FDA’s progress in creating effective policy.<sup>231</sup> This highly visible public process encourages accountability, which was fundamental in the passage of the APA.<sup>232</sup> In the public sphere, industry benefits from this accountability because the FDA must consider its comments.<sup>233</sup> The FDA wins from this accountability because it gets a second-mover advantage of receiving this feedback and earning the opportunity to consider and craft around the major concerns offered by the public.<sup>234</sup> However, significant challenges exist, like the costs associated with crafting, publicizing, and finalizing review of a proposed rule.<sup>235</sup> Further, input by individuals who are not directly regulated by agency rules may not provide input, leading the agency to bend toward only the regulated interest and not the

---

<sup>231</sup> For example, discuss how targeted advertisements work on a specific platform. *See* Tiku, *supra* note 3 (discussing targeted advertising concerns).

<sup>232</sup> *See* S. Rep. No. 79-752, at 8 (1945) (“[referencing the public information section] [t]he section has been drawn upon the theory that administrative operations and procedures are public property which the general public, rather than a few specialists or lobbyists, is entitled to know or to have the ready means of knowing with definiteness and assurance”).

<sup>233</sup> APA, § 553(c).

<sup>234</sup> *Id.*

<sup>235</sup> *See* David Fontana, *Reforming the Administrative Procedure Act: Democracy Index Rulemaking*, 74 *FORDHAM L. REV.* 81, 84–85 (2005) (exploring challenges presented with notice-and-comment rulemaking).

public at-large.<sup>236</sup> Despite these costs, the ability to create a regulation with the force of law provides significant value in furthering the agency's statutory calling.<sup>237</sup>

## CONCLUSION

The advent of social media has proliferated and amalgamized itself to be a massive force in the future of the digital age.<sup>238</sup> Digital advertising expenditures by the pharmaceutical industry demonstrates a financial testament to the importance of advertising.<sup>239</sup> With a drug approval process that is both rigorous and expensive, companies finding more attractive ways to promote products will remain a priority.<sup>240</sup> By adhering to statutory provisions and updating existing regulations and thinking on the topic, the FDA will be able to successfully create and enforce guidelines designed to promote the public health. By doing so, the FDA will make significant headway in the rapidly developing digital age. In promulgating these regulations or issuing guidance documents, the FDA should make the concerted effort to address existing First

---

<sup>236</sup> *Id.* at 85 (FDA rulemakings showed greater participation by regulated interests according to a 1977 study).

<sup>237</sup> APA, § 551(4).

<sup>238</sup> *See* Clement, *supra* note 14 (social media platforms have tremendous user bases).

<sup>239</sup> Benes, *supra* note 9.

<sup>240</sup> *See* Hutt, *supra* note 23, at 643 (noting approval for a new chemical entity can cost upwards of \$2 billion over fifteen years); Keith B. Leffler, *Persuasion or Information? The Economics of Prescription Drug Advertising*, 24 J.L. & ECON. 45, 74 (1981) (concluding that promoting a newly developed product has a significant effect on the success of a new drug).

Amendment issues that have begun proliferating.<sup>241</sup> By implementing an approach that demonstrates it is not trying to be unduly burdensome, the FDA should be able to place itself in a position to thwart challenges while still implementing effective new policies in prescription drug advertising regulations.<sup>242</sup>

---

<sup>241</sup> *See supra* Part II(C) (discussing the off-label promotion roadblocks).

<sup>242</sup> *See supra* Parts II(B), III(B) (emphasizing the importance of less-burdensome alternatives in case law and how the FDA could consider navigating this requirement).