PRESCRIPTION DRUG LABELS: COMPELLED COMMERCIAL SPEECH AND ITS EFFECT ON PUBLIC HEALTH CONCERNING PRESCRIPTION DRUGS AND THE OPIOID CRISIS

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We are not afraid to entrust the American people with unpleasant facts, foreign ideas, alien philosophies, and competitive values. For a nation that is afraid to let its people judge the truth and falsehood in an open market is a nation that is afraid of its people.

John F. Kennedy[1]

I. INTRODUCTION

Today, our communications environment is a marketplace, spewing ideas and messages everywhere.[2] Many ideas and messages are prescription drug advertisements.[3] Pharmaceutical companies will spend millions, openly offering a solution to a health problem, even if people do not have a health problem; prescription marketing is big business.[4] Some argue the primary goal of pharmaceutical companies is not helping consumers but, rather, selling a product.[5] Recently, methods for the

1. *See* FreeMediaOnline, *John F. Kennedy on the 20th Anniversary of the Voice of America and Its Mission*, YOUTUBE (Mar. 24, 2018), https://www.youtube.com/watch?v=XFl1x2veHx0 [https://web.archive.org/web/20201121192648/https://www.youtube.com/watch?v=XFl1x2veHx0]. This speech by John F. Kennedy was inspired by events of the Cold War and is archived in the Cold War Radio Museum. *Id.* President Kennedy touched on how freedom of information is a fundamental human right and how it affects individuals with decision making. *Id.*

2. *See* Mary-Rose Papandrea, *The Missing Marketplace of Ideas Theory*, 94 NOTRE DAME L. REV. 1725, 1726 (2019).

3. *See* Harvard Men's Health Watch, *Do Not Get Sold on Drug Advertising*, HARV. HEALTH PUB. (Feb. 14, 2017), https://www.health.harvard.edu/drugs-and-medications/do-not-get-sold-on-drug-advertising [https://web.archive.org/web/20201121192715/https://www.health.harvard.edu/drugs-and-medications/do-not-get-sold-on-drug-advertising].

4. *See id.*

5. *See id.*

marketing of prescription drugs shifted from marketing to physicians towards marketing to consumers.[6]

Although prescription drugs are beneficial, when misused, they can lead to public health problems, such as today's opioid crisis in the United States.[7] Many blame physicians and pharmaceutical companies for fueling the opioid crisis by using aggressive marketing schemes and by prescribing high volumes of opioid pain pills;[8] direct-to-consumer (DTC) advertising is known to be a part of the cause.[9] Drug overdose accounts for more accidental deaths in the United States than any other cause.[10] In fact, many opioid crisis victims sued big pharmaceutical companies, such as Purdue Pharma, Mallinkrodt, and Insys Therapeutics, because of their aggressive marketing schemes.[11] Purdue Pharma tentatively reached a comprehensive settlement for thousands of cases across the country,[12]

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6. *See* Praveen Tipireni, *Methods for Marketing Drugs Are Changing. Here's What That Means for the Pharma Industry*, MEDIUM (Oct. 16, 2018), https://tincture.io/methods-for-marketing-drugs-are-changing-heres-what-that-means-for-the-pharma-industry-f050e4c52337 [https://web.archive.org/web/20201121192822/https://tincture.io/methods-for-marketing-drugs-are-changing-heres-what-that-means-for-the-pharma-industry-f050e4c52337?gi=cc42b8a28758].

7. *See* Hilary Homenko, Note, *Rehabilitating Opioid Regulation: A Prescription for the FDA's Next Proposal of an Opioid Risk Evaluation and Mitigation Strategy (REMS)*, 22 HEALTH MATRIX 273, 274–75 (2012).

8. *See generally* Joseph R. Schottenfeld et al., *Pain and Addiction in Specialty and Primary Care: The Bookends of a Crisis*, 46 J. L. MED. & ETHICS 220 (2018).

9. *See* IRETA, *Pills for Your Ills: Exploring the Relationship Between Direct-to-Consumer Pharmaceutical Marketing and Addiction*, INST. FOR RSCH., EDUC. & TRAINING ADDICTIONS (July 3, 2013), https://ireta.org/resources/pills-for-your-ills/ [https://web.archive.org /web/20210105055300/https://ireta.org/resources/pills-for-your-ills/]; *see also* Reenita Das, *Are Direct-to-Consumer Ads for Drugs Doing More Harm Than Good?*, FORBES (May 14, 2019), https://www.forbes.com/sites/reenitadas/2019/05/14/direct-to-consumer-drug-ads-are-they-doing-more-harm-than-good/#675295634dfc [https://web.archive.org/web/20201121192909/https://www.forbes.com/sites/reenitadas/2019/05/14/direct-to-consumer-drug-ads-are-they-doing-more-harm-than-good/].

10. *See* Schottenfeld et al., *supra* note 8, at 221.

11. *See* Muscogee (Creek) Nation v. Purdue Pharma. L.P. (*In re* Nat'l Prescription Opiate Litig.), No. 1:18-op-45459, 2019 WL 2468267 (N.D. Ohio Apr. 1, 2019); *see also In re* Nat'l Prescription Opiate Litig., MDL No. 2804, 2019 U.S. Dist. LEXIS 58890 (J.P.M.L. Apr. 4, 2019); Jason B. Binimow, Annotation, *Opioid Marketing, Promoting, and Distributing Claims Against Manufacturers and Distributors*, 39 A.L.R. 4 (2018).

12. *See* Jan Hoffman, *Purdue Pharma Tentatively Settles Thousands of Opioid Cases*, N.Y. TIMES (Sept. 11, 2019), https://www.nytimes.com/2019/09/11/health/purdue-pharma-opioids-settlement.html [https://web.archive.org/web/20201121192943/https://www.nytimes.com/2019/09/11/health/purdue-pharma-opioids-settlement.html].

while Mallinkrodt reached settlements with various counties;[13] there are more settlements to come.[14]

However, while aggressive marketing schemes lead to overprescribing, the FDA compels companies to disclose important information about products to address public health concerns via compelled commercial speech.[15] For example, the FDA wanted to compel tobacco companies to put graphic warning labels on their cigarette packs to help deter smoking.[16] There are various tests to see if the government may compel an entity to reveal certain information, which this Note will discuss later.[17]

The legal challenges to FDA-imposed compelled speech raises two important issues that this Note will consider: (1) the level of constitutional scrutiny the government should have to overcome to compel an entity to disclose information that the entity does not want to disclose; and (2) how the FDA can overcome this constitutional scrutiny standard while effectively accomplishing public health goals that concern prescription drugs, primarily prescription opioids.

This Note argues that the best-suited scrutiny test is the *Zauderer* test based on precedent, factors discussing which test is controlling, and promotion of public health.[18] In the public health world, the public benefits from a good flow in the marketplace of ideas. This spreads beneficial information, allowing people to make well-informed decisions. The FDA should be able to compel pharmaceutical companies to provide inserts that discuss the harmful side effects of drugs and, for opioids specifically, that provide information regarding the opioid crisis. This additional compelled commercial speech could be inserts that

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13. *See* Lenny Bernstein et al., *Mallinckrodt Reaches Settlement With 'Bellwether' Counties in Mammoth Opioid Lawsuit*, WASH. POST (Sept. 6, 2019), https://www.washingtonpost.com/health/mallinckrodt-reaches-settlement-with-bellwether-counties-in-mammoth-opioid-lawsuit/2019/09/06/1e8a19f8-d0d9-11e9-b29b-a528dc82154a_story.html [https://web.archive.org/web/20191204084517/https://www.washingtonpost.com/health/mallinckrodt-reaches-settlement-with-bellwether-counties-in-mammoth-opioid-lawsuit/2019/09/06/1e8a19f8-d0d9-11e9-b29b-a528dc82154a_story.html].

14. *See id.*

15. *See, e.g.*, Bryan M. Haynes et al., *Compelled Commercial Speech: The Food and Drug Administration's Effort to Smoke Out the Tobacco Industry Through Graphic Warning Labels*, 68 FOOD & DRUG L.J. 329 (2013).

16. *See id.*

17. *See* 1B HAROLD S. BLOOMENTHAL & SAMUEL WOLFF, *Standard of Review for Compelled Commercial Speech*, *in* GOING PUBLIC AND THE PUBLIC CORPORATION § 7:70.46 (2019).

18. *See infra* Part III.B.

discuss previous cases or other ideas that could be suggested by the FDA or scholars.

Part II.A will discuss the current public health issues that arise from aggressive marketing schemes, showing why compelled commercial speech is relevant to combating public health issues.[19] Part II.B will give background on the development of the law of compelled commercial speech and how it functions in our information-driven society.[20] Part III.A defines what a substantial government interest is in relation to the First Amendment.[21] Part III.B discusses what standard of scrutiny the government must overcome to pass laws and regulations that promote compelled commercial speech.[22] Part III.C discusses various methods of compelled commercial speech and whether those methods fit within the tension of the *Zauderer* and *Central Hudson* tests.[23] This section also discusses the likely impact on consumers.[24] Part IV reaffirms that *Zauderer* should be the controlling scrutiny standard.[25] Part IV calls out to other scholars to research and help find the best method of compelled commercial speech to achieve public health goals and restates the importance of the flow of information.[26]

II. BACKGROUND

A. Current Public Health Issues with Prescription Drugs and Big Pharma's Aggressive Marketing Schemes

There is a tremendous prescription drug abuse problem in the United States, and it continues to worsen.[27] Today, Americans are taking more

19. *See infra* Part II.A.
20. *See infra* Part II.B.
21. *See infra* Part III.A.
22. *See infra* Part III.B.
23. *See infra* Part III.C.
24. *Id.*
25. *See infra* Part IV.
26. *Id.*
27. *See* J. Baxter Oliphant, *Prescription Drug Abuse Increasingly Seen as a Major U.S. Public Health Problem*, FACT TANK: NEWS NUMBERS (Nov. 15, 2017), https://www.pewresearch.org/fact-tank/2017/11/15/prescription-drug-abuse-increasingly-seen-as-a-major-u-s-public-health-problem/ [https://web.archive.org/web/20201121193401/https://www.pewresearch.org/fact-tank/2017/11/15/prescription-drug-abuse-increasingly-seen-as-a-major-u-s-public-health-problem/]. This study compared prescription drug abuse with other current public health issues in the United States, such as mental illness, obesity, cancer, alcohol abuse, cigarette smoking, and AIDS. *Id.* When comparing these public health issues, Americans said that it is the biggest public health issue today aside from cancer. *Id.* However, the

prescription drugs than ever before.[28] Much of the drug abuse comes from aggressive marketing tactics that push sales of prescription drugs.[29] Beginning in the early 1990s, many drug manufacturers began to target consumers with advertising due to, in part, an aging population and an increase in patients who participate in their own health care decisions.[30] This trend of advertising continues today.[31]

1. Advantages and Disadvantages of Direct-to-Consumer (DTC) Advertising

In 2017, the United States pharmaceutical industry spent $6.1 billion on advertising prescription drugs directly to consumers.[32] Direct-to-consumer (DTC) advertising is relatively new, and there is no federal law that bans DTC advertising.[33] In 2016, 771,638 prescription drug

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concern for cancer stayed the same as it was five years ago, while the concern for prescription drug abuse increased. *Id.*

28. *See* Robert Preidt, *Americans Taking More Prescription Drugs Than Ever: Consumer Reports Says Many May Be Doing More Harm Than Good*, WEBMD (Aug. 3, 2017), https://www.webmd.com/drug-medication/news/20170803/americans-taking-more-prescription-drugs-than-ever-survey [https://web.archive.org/web/20201121193427/https://www.webmd.com/drug-medication/news/20170803/americans-taking-more-prescription-drugs-than-ever-survey]. Fifty-five percent of Americans regularly take prescription drugs. *Id.* On average, a prescription drug user takes four different prescription drugs regularly, and that user may also take other over-the-counter drugs. *Id.*

29. *See* Michelle Llamas, *Selling Side Effects: Big Pharma's Marketing Machine*, DRUG WATCH (Aug. 30, 2019), https://www.drugwatch.com/featured/big-pharma-marketing/ [https://web.archive.org/web/20201121193529/https://www.drugwatch.com/featured/big-pharma-marketing/].

30. *See The Impact of Direct-to-Consumer Advertising,* FDA.GOV, https://www.fda.gov/drugs/drug-information-consumers/impact-direct-consumer-advertising [https://web.archive.org/web/20201121193556/https://www.fda.gov/drugs/drug-information-consumers/impact-direct-consumer-advertising] (last visited Feb. 29, 2020) [hereinafter *Impact*].

31. *See id.*

32. *See Should Prescription Drugs Be Advertised Directly to Consumers?*, PROCON.ORG, https://prescriptiondrugs.procon.org/ [https://web.archive.org/web/20201121193632/https://prescriptiondrugs.procon.org/] (last updated on Oct. 23, 2018).

33. *See Background on Drug Advertising*, FDA.GOV, https://www.fda.gov/drugs/prescription-drug-advertising/background-drug-advertising [https://web.archive.org/web/20201121193856/https://www.fda.gov/drugs/prescription-drug-advertising/background-drug-advertising] (last visited Oct. 5, 2019).

advertisements were shown, which is a sixty-five percent increase since 2012.[34]

There are advantages and disadvantages that come from DTC advertising of prescription drugs.[35] One advantage is that DTC advertising helps inform patients about drugs[36]—and some doctors agree,[37] knowing the FDA requires that ads include risks of drugs to inform patients.[38] Ads also encourage patient compliance with treatment instructions.[39] Lastly, ads are a form of freedom of speech for pharmaceutical companies.[40] Commercial advertisements were considered outside the protection of the First Amendment until *Bigelow v. Virginia* and *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*;[41] in these cases, the Supreme Court held that

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34. *See* 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 [https://web.archive.org/web/20201121194135/https://www.nytimes.com/2017/12/24/business/media/prescription-drugs-advertising-tv.html].

35. *See id.*

36. *See* ASHISH PAREKH ET AL., RISKS AND BENEFITS OF DIRECT TO CONSUMER ADVERTISING ON PATIENT PROVIDER RELATIONSHIPS—REPORT OF THE ISPOR DIRECT TO CONSUMER ADVERTISEMENTS WORKING GROUP (2012), https://www.researchgate.net/profile/Melissa_Roberts3/publication/336147704_Risks_and_Benefits_of_Direct_To_Consumer_Advertising_On_Patient-Provider_Relationships-Report_of_the_ISPOR_Direct_to_Consumer_Advertisements_Working_Group/links/5d92cb9e299bf10cff1cd019/Risks-and-Benefits-of-Direct-To-Consumer-Advertising-On-Patient-Provider-Relationships-Report-of-the-ISPOR-Direct-to-Consumer-Advertisements-Working-Group.pdf [https://web.archive.org/web/20210105070159/https://www.researchgate.net/profile/Melissa_Roberts3/publication/336147704_Risks_and_Benefits_of_Direct_To_Consumer_Advertising_On_Patient-Provider_Relationships-Report_of_the_ISPOR_Direct_to_Consumer_Advertisements_Working_Group/links/5d92cb9e299bf10cff1cd019/Risks-and-Benefits-of-Direct-To-Consumer-Advertising-On-Patient-Provider-Relationships-Report-of-the-ISPOR-Direct-to-Consumer-Advertisements-Working-Group.pdf].

37. *See* Taylor Tyler, *Direct-to-Consumer Drug Ads Should Be Scaled Back, Doctors Say*, INDEP. VOTER NEWS (June 3. 2013), https://ivn.us/2013/06/03/direct-to-consumer-drug-ads-should-be-scaled-back-doctors-say [https://web.archive.org/web/20201121194420/https://ivn.us/2013/06/03/direct-to-consumer-drug-ads-should-be-scaled-back-doctors-say].

38. *See Basics of Drug Ads*, FDA.GOV, https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads [https://web.archive.org/web/20201121194804/https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads] (last updated June 19, 2015) [hereinafter *Basics*].

39. See PAREKH ET AL., *supra* note 36.

40. *See Should Prescription Drugs Be Advertised Directly to Consumers?*, *supra* note 32.

41. *See* Ann K. Wooster, *Protection of Commercial Speech Under First Amendment—Supreme Court Cases*, 164 A.L.R. FED.1 § 2 (2000).

speech proposing no more than commercial transactions enjoys a substantial degree of First Amendment protection.[42]

Commercial speech is important for fundamental rights such as free speech, liberty, free markets, and other reasons that the founders envisioned.[43] It is important for companies to have commercial speech protection because commercial speech is beneficial for profitability, which motivates companies to market their products well.[44] However, the Supreme Court has held that the Constitution gives less protection to commercial speech than other forms of speech, saying the government may regulate the content of commercial speech to prevent the distribution of information that is false, deceptive, and misleading, or that proposes illegal transactions.[45] Businesses fear that regulation of their speech will lower profits.[46] Although companies' profits will degrade, the Court wants to protect consumers from deception or coercion, which leads to harm;[47] this harm could derive from DTC advertising.

While there are many negative implications of DTC advertising, there are some positives. In a survey conducted by the FDA, most physicians believed because a patient saw a DTC ad, the patient asked thoughtful questions.[48] Physicians also "thought that DTC ads made patients more involved in their healthcare."[49] This study demonstrated that when a patient inquired about a particular drug, the patient had that condition eighty-eight percent of the time, and "eighty percent of physicians believed that their patients understood what condition the advertised drug treat[ed]."[50] When asked if patients understood that only a doctor could decide whether a drug was appropriate for them, eighty-two percent of physicians answered that patients either "very well" or "somewhat" understood.[51]

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42. *See* Bigelow v. Virginia, 421 U.S. 809 (1975); Virginia State Bd. Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

43. *See* U.S. CONST. pmbl.

44. Colin R. Munro, *The Value of Commercial Speech*, 62 CAMBRIDGE L.J. 134, 154 (2003).

45. *See* Wooster, *supra* note 41, at § 2.

46. *See* Matthew Blum, *Freedom of Speech in Business: Does It exist? Is It Important?*, VANCOUVER BUS. J. (July 29, 2016), https://www.vbjusa.com/opinion/columns/law-column/freedom-speech-business-exist-important/ [https://web.archive.org/web/20201121194800/https://www.vbjusa.com/opinion/columns/law-column/freedom-speech-business-exist-important/].

47. *See* Wooster, *supra* note 41.

48. *See Basics*, *supra* note 38.

49. *See id.*

50. *See id.*

51. *See id.*

However, other physicians said they thought DTC ads did not relay information about the upsides and downsides of drugs equally well.[52] Many ads misinform patients by overemphasizing benefits of the drug;[53] most ads have potentially misleading information, and some are even false.[54] The FDA tries to counter the harm that comes from misleading ads with its Bad Ad Program,[55] but public health issues remain because these advertisements still reduce rational prescribing and consumer decision making.[56] Eight percent of prescribers said that they even feel pressure to prescribe a specific drug when a patient asks about that drug.[57] Although prescription opioids are important for pain treatment in the short term,[58] drug ads promote drug usage before long-term safety

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52. *See id.*

53. *See* Richard Meyer, *Majority of Physicians Believe DTC Ads Should Be Cut Back*, WORLDOFDTCMARKETING.COM (Apr. 30, 2019), https://worldofdtcmarketing.com/majority-of-physicians-believe-dtc-ads-should-be-cut-back/ [https://web.archive.org/web/20201121194927/https://worldofdtcmarketing.com/majority-of-physicians-believe-dtc-ads-should-be-cut-back/].

54. *See generally* Adrienne E. Farber & David H. Kreling, *Content Analysis of False and Misleading Claims in Television Advertising for Prescription and Nonprescription Drugs*, 29 J. INTERNAL MED. 110 (2014).

55. *See The Bad Ad Program*, FDA.GOV, https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program [https://web.archive.org/web/20201121195001/https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program] (last updated June 19, 2015) [hereinafter *Bad Ad Program*]. The FDA uses the Bad Ad Program to educate healthcare providers about their role in ensuring that prescription drug advertising and promotions are truthful and not misleading. *Id.* Prescription drug advertising must: (1) be accurate; (2) balance the risk and benefit information; (3) be consistent with the prescribing information approved by the FDA; and (4) include only information that is supported by strong evidence. *Id.* The types of promotion that are regulated are: (1) TV and radio advertisements; (2) all written or printed promotional materials; (3) speaker presentations; and (4) sales presentations. *Id.* The common violations with drug promotion include: (1) omitting or downplaying the risk of the drug; (2) overstating the effectiveness of the drug; and (3) misleading drug comparisons. *Id.*

56. *See* Jennifer C. Middleton, *Direct-to-Consumer Advertising of Prescription Drugs and The World of Social Media: The Paradox of Advertise First, Ensure Safety Second*, 2014 MINN. ST. B. ASS'N 1 (2014); *see also* Faerber & Kreling, *supra* note 54; David Lazarus, *Column: TV Commercials for Prescription Drugs 'Doing More Harm Than Good'*, L.A. TIMES (Apr. 10, 2018), https://www.latimes.com/business/lazarus/la-fi-lazarus-direct-to-consumer-drug-ads-20180410-story.html [https://web.archive.org/web/20201121195449/https://www.latimes.com/business/lazarus/la-fi-lazarus-direct-to-consumer-drug-ads-20180410-story.html].

57. *See Impact*, *supra* note 30.

58. *See* CTR. FOR DISEASE CONTROL & PREVENTION, CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN (2014), https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf [https://web.archive.org/web/20201115001050/https://www.cdc.gov/drugoverdose/pdf/Guidelines_At-A-Glance-a.pdf].

information is known, as exemplified in today's opioid crisis.[59] Every country bans DTC ads except for the United States and New Zealand.[60] The World Health Organization (WHO) states, "advertisements to the general public should . . . not generally be permitted for prescription drugs."[61]

DTC ads depict people who are happy or contain celebrities, such as Ray Liotta from the motion picture *Good Fellas*, which may mislead consumers.[62] Because of aggressive marketing schemes, disgruntled plaintiffs are bringing claims against opioid manufacturers for marketers using fraudulent misrepresentations about the drug's efficacy and selling without providing adequate instructions and warnings.[63] There are cases today that exemplify various aggressive marketing schemes.[64]

2. Examples of Aggressive Marketing Schemes

It is important for companies to have protected commercial speech to help advertise products, but sometimes marketing schemes can be too aggressive.[65] The Prescription Drug Marketing Act of 1987 (PDMA) was

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59. *See* Meyer, *supra* note 53.

60. *See* Tyler, *supra* note 37.

61. *See* WORLD HEALTH ORG., GUIDELINES FOR THE REGULATORY ASSESSMENT OF MEDICINAL PRODUCTS FOR USE IN SELF-MEDICATION 24 (2000), https://apps.who.int/iris/bitstream/handle/10665/66154/WHO_EDM_QSM_00.1_eng.pdf?sequence=1&isAllowed [https://web.archive.org/web/20201121195709/https://apps.who.int/iris/bitstream/handle/10665/66154/WHO_EDM_QSM_00.1_eng.pdf?sequence=1&isAllowed=].

62. *See* hockey14822, *Chantix….This Is an Actual Commercial*, YOUTUBE (Jan. 5, 2010), https://www.youtube.com/watch?v=3hp_y0wDFz0 [https://web.archive.org/web/20201121195738if_/https://www.youtube.com/watch?v=3hp_y0wDFz0]; *see also* Jamee Stein, *Cialis Commercial*, YOUTUBE (Aug. 30, 2016), https://www.youtube.com/watch?v=jJwx6vUzfuE [https://web.archive.org/web/20201121200416/https://www.youtube.com/watch?v=jJwx6vUzfuE]; XJ Gaming, *1996 Oxycontin Commercial, Very Sad*, YOUTUBE (Apr. 17, 2018), https://www.youtube.com/watch?v=Ad-_v7_i0Hc [https://web.archive.org/web/20201121200437/https://www.youtube.com/watch?v=Ad-_v7_i0Hc]; *see also* mentallo, *Chantix TV Commercial, 'Until I Tried' Featuring Ray Liotta*, YOUTUBE (Dec. 4, 2018), https://www.youtube.com/watch?v=VPIcz6jcK2k [https://web.archive.org/web/20201121200540/https://www.youtube.com/watch?v=VPIcz6jcK2k].

63. *See* Binimow, *supra* note 11, at 4.

64. *See, e.g.*, *In re* Nat'l Prescription Opiate Litig., 406 F. Supp. 3d 672 (N.D. Ohio 2019); *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-2804, 2020 WL 871539 (N.D. Ohio 2020); Perry v. Insys Therapeutics, Inc., No. 18-cv-1190-JD, 2019 WL 2106391 (D.N.H. May 14, 2019); Inge v. McClelland, 725 F.App'x 634 (10th Cir. 2018).

65. *See infra* Part II.A.2.

signed into law in 1988.[66] The two goals of the PDMA were to: "(1) ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs."[67] At the time, the legislation was necessary to increase safeguards in the drug distribution system that was prone to retail sale of substandard, ineffective, or counterfeit drugs; this legislation was aimed to protect consumers.[68] Despite that enactment, there are still issues with prescription drug marketing today.

In re Opioid Litigation shows the negative public health effects that derive from aggressive marketing.[69] Many issues come from pharmaceutical companies pushing prescriptions on physicians to increase sales.[70] In particular, Purdue Pharma misrepresented its product to consumers, trying to downplay the addictiveness of its high-selling opioid, OxyContin.[71] After using literature and audiotapes for physicians and brochures and videotapes for patients along with its "Partners Against Pain" website to downplay OxyContin's addictiveness, the drug's sales jumped from $44 million to nearly $3 billion.[72] However, the commercial success came with a price as rates of drug abuse and addiction skyrocketed, and drug manufacturers found trouble with numerous lawsuits.[73]

Another aggressive marketing scheme is the "multi-tiered strategy" used by Mallinkrodt to "bribe" doctors for prescribing Acthar.[74] According to the whistleblower lawsuit:

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66. *See Prescription Drug Marketing Act of 1987*, FDA.GOV, https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/prescription-drug-marketing-act-1987 [https://web.archive.org/web/20201121200652/https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/prescription-drug-marketing-act-1987] (last visited Feb. 29, 2020).

67. *See id.*

68. *See id.*; Patricia Jankowski, *Prescription Drug Marketing Act of 1987*, STUDY.COM, https://study.com/academy/lesson/prescription-drug-marketing-act-of-1987.html [https://web.archive.org/web/20201121200716/https://study.com/academy/lesson/prescription-drug-marketing-act-of-1987.html] (last visited Feb. 29, 2020).

69. *See In re* Opioid Litig., No. 400000/2017, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018).

70. *See* Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 222 (2009).

71. *See id.* at 223.

72. *See id.*

73. *See id.*

74. *See* Wayne Drash, *Whistleblowers: Company at Heart of 97,000% Drug Price Hike Bribed Doctors to Boost Sales*, CNN HEALTH (Apr. 30, 2019), https://www.cnn.com/2019/04/30/health/mallinckrodt-whistleblower-lawsuit-

> Mallinkrodt intentionally engaged in an illegal scheme to increase its sales and profits by engaging in . . . illegal activity, including: [(1)] . . . using valuable incentives, rewards[,] and other forms of remuneration to induce healthcare providers to promote and prescribe Acthar[;] [(2)] [s]ystematically promoting and marketing H.P. Acthar Gel for unapproved, off-label uses[;] [and] [(3)] [c]ausing hundreds or thousands of false claims for reimbursement of H.P. Acthar Gel to be submitted to, and paid by, federal healthcare programs.[75]

Insys Therapeutics used another aggressive marketing scheme, pushing opioids on consumers.[76] According to Yale Law Professor Abbe Gluck, "[This] case paints a picture of the kind of troubling industry practices that helped fuel the opioid epidemic."[77] Insys representatives took pride in aggressively marketing opioids by making rap videos,

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acthar/index.html
[https://web.archive.org/web/20201121200845/https://www.cnn.com/2019/04/30/health/mallinckrodt-whistleblower-lawsuit-acthar/index.html].

75. *See id.* (internal quotations omitted). This is an example of an Anti-Kickback situation, and Congress passed the federal Anti-Kickback statute to address situations like these ones. *See* Thomas S. Crane et al., *What Is the Anti-Kickback Statute?*, AM. B. ASS'N https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/
[https://web.archive.org/web/20210105081557/https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/] (last visited Jan. 5, 2021). There is also a violation of fraud and abuse laws when entities make false claims for reimbursement from federal healthcare programs, such as Medicare or Medicaid for example. *See* David E. Matyas, *View on Fraud and Abuse*, AHLA-PAPERS P10059803 (1998) (unpublished presentation) (on file with author); *see also Health Care Fraud and Abuse*, JOHN HOPKINS MED., https://www.hopkinsmedicine.org/johns_hopkins_healthcare/providers_physicians/health_care_fraud_and_abuse/
[https://web.archive.org/web/20201121200907/https://www.hopkinsmedicine.org/johns_hopkins_healthcare/providers_physicians/health_care_fraud_and_abuse/] (last visited Feb. 29, 2020).

76. INSYS THERAPEUTICS, https://www.insysrx.com/
[https://web.archive.org/web/20191213133743/https://www.insysrx.com/] (last visited Jan. 20, 2020). Insys said on its homepage that its "vision is to improve the quality of patient care by building a special pharmaceutical company . . . [and to] to improve the lives of patients." *Id.*

77. *See* Gabrielle Emanuel & Katie Thomas, *Top Executives of Insys, an Opioid Company, Are Found Guilty of Racketeering*, N.Y. TIMES (May 2, 2019), https://www.nytimes.com/2019/05/02/health/insys-trial-verdict-kapoor.html
[https://web.archive.org/web/20201121201031/https://www.nytimes.com/2019/05/02/health/insys-trial-verdict-kapoor.html].

glorifying their aggressive and harmful marketing scheme.[78] There is even a video where an Insys sales representative dressed up as a pill bottle.[79] During the trial, federal prosecutors laid out Insys's marketing plan to pay "doctors for sham educational talks and luring others with lap dances—to spur sales of Subsys."[80]

Many times, the events became solely social affairs with no educational presentation about the drug;[81] prescribers were paid thousands of dollars to "'speak' to an audience of zero" while doing cocaine in the bathroom at their own events.[82] This would induce doctors to turn their practices into pill mills that only accepted cash; they only wrote their names on prescription pads to get the drugs to consumers.[83] The hiring tactics helped fuel Insys's marketing scheme.[84] Insys hired good-looking and attractive people—mostly women—who were not only inexperienced with pharmaceutical sales, but were also motivated and naïve, working hard to meet Insys's objectives.[85] Today, there are still physicians being charged from this debacle, facing career-ending charges

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78. *See* WVURxMan, *Subsys Rap Video Created by Insys Pharmaceuticals (More Info in Description)*, YOUTUBE (Feb. 18, 2019), https://www.youtube.com/watch?v=mtwFZwjCSTE [https://web.archive.org/web/20201121201050/https://www.youtube.com/watch?v=mtwFZwjCSTE]. "This is an actual music video created by Insys Pharmaceuticals. This video was played for the jury in a case in which Insys [was] charged with creating a kickback scheme for physicians who prescribed the drug." *Id.*

79. *See* Janelle Lawrence*, Insys Sales Chief Gets to 26 Months in Opioid-Fraud Case*, BLOOMBERG (Jan. 23, 2020), https://www.bloomberg.com/news/articles/2020-01-23/insys-sales-chief-sentenced-to-26-months-in-opioid-fraud-case [https://web.archive.org/web/20201121202216/https://www.bloomberg.com/tosv2.html?vid=&uuid=3f2ed7b0-2c37-11eb-866f-45c318953e76&url=L25ld3MvYXJ0aWNsZXMvMjAyMC0wMS0yMy9pbnN5cy1zYWxlcy1jaGllZi1zZW50ZW5jZWQtdG8tMjYtbW9udGhzLWluLW9waW9pZC1mcmF1ZC1jYXNl].

80. *See* Emanuel & Thomas, *supra* note 77.

81. *See* Larry Neumeister, *Doctor Gets 2 Years Prison in Bribe Scam over Painkiller*, ASSOCIATED PRESS (Oct. 28, 2019), https://apnews.com/article/05483fc590bc4a1fb6d761b9d0e6552a [https://web.archive.org/web/20201121202239/https://apnews.com/article/05483fc590bc4a1fb6d761b9d0e6552a]. In this case, after the "presentation," the doctor and a few others with Insys went on a trip to a strip club where they were given a private room, drinks, and lap dances. *Id.* The doctor later said, "I'll be embarrassed for the rest of my life . . . It's been devastating on my life in every way possible." *Id.*

82. *See* Evan Hughes, *The Pain Hustlers*, N.Y. TIMES MAG. (May 2, 2018), https://www.nytimes.com/interactive/2018/05/02/magazine/money-issue-insys-opioids-kickbacks.html [https://web.archive.org/web/20201121202341/https://www.nytimes.com/interactive/2018/05/02/magazine/money-issue-insys-opioids-kickbacks.html].

83. *See id.*

84. *See id.*

85. *See id.*

after reaping benefits from this kickback scheme.[86] While Congress may take action to disincentivize physicians from acting heinously, there are ways that the FDA can prevent pharmaceutical companies from acting heinously, too.

3. What the Government Can Do to Combat Aggressive Marketing Schemes

In 1962, Dr. Frances Kelsey from the FDA prevented marketing of Thalidomide, a sleeping pill that caused "severe birth defects of the arms and legs in thousands of babies in Western Europe."[87] This occurrence helped stir up support for tougher drug laws and provides an example of the FDA protecting public health by regulating drug marketing.[88] Recently, public outcries emerged over health concerns with the tobacco vaping company, Juul.[89] The high number of teens and young adults using Juul is causing health issues among the youth; the marketing schemes of Juul are known to target teens and young adults.[90] The FDA

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86. *See* Press Release, U.S. Attorney's Office S. Dist. of N.Y., Manhattan Doctor Convicted in Manhattan Federal Court of Accepting Bribes and Kickbacks from a Pharmaceutical Company in Exchange for Prescribing Fentanyl Drug (Dec. 5, 2019), https://www.justice.gov/usao-sdny/pr/manhattan-doctor-convicted-manhattan-federal-court-accepting-bribes-and-kickbacks [https://web.archive.org/web/20201121202424/https://www.justice.gov/usao-sdny/pr/manhattan-doctor-convicted-manhattan-federal-court-accepting-bribes-and-kickbacks]; *see also* Clary Estes, *Doctor Pleads Guilty to Accepting Bribes to Prescribe Powerful Opioid Fentanyl*, FORBES (Nov. 27, 2019), https://www.forbes.com/sites/claryestes/2019/11/27/new-jerseypennsylvania-doctor-pleads-guilty-to-accepting-bribes-to-prescribe-fentanyl/#155f4aca70a8 [https://web.archive.org/web/20201121202503/https://www.forbes.com/sites/claryestes/2019/11/27/new-jerseypennsylvania-doctor-pleads-guilty-to-accepting-bribes-to-prescribe-fentanyl/].

87. *See* U.S. FOOD & DRUG ADMIN., A HISTORY OF THE FDA AND DRUG REGULATION IN THE UNITED STATES (2006), https://www.fda.gov/media/73549/download [https://web.archive.org/web/20201112022645/https://www.fda.gov/media/73549/download].

88. *See id.*

89. *See* Jamie Ducharme, *How Juul Hooked Kids and Ignited a Public Health Crisis*, TIME (Sept. 19, 2019), https://time.com/5680988/juul-vaping-health-crisis/ [https://web.archive.org/web/20201121202607/https://time.com/5680988/juul-vaping-health-crisis/].

90. Susan Weisman, *Public Health Concerns About Youth and Young Adult Use of JUUL*, PUB. HEALTH L. CTR. MITCHELL HAMLINE SCH. L. (Apr. 30, 2018), https://www.publichealthlawcenter.org/blogs/2018-02-19/public-health-concerns-about-youth-young-adult-use-juul [https://web.archive.org/web/20200502031007/https://www.publichealthlawcenter.org/blogs/2018-02-19/public-health-concerns-about-youth-young-adult-use-juul]. Juul markets its product to teens and young adults by providing appealing flavors. *Id.* Some of the

took action by putting the industry on notice, informing Juul of the various public health issues that arise from its marketing schemes, hoping that companies such as Juul will comply with the FDA's wishes moving forward.[91] While there are various ways the government can combat aggressive marketing schemes, one specific way to combat current aggressive marketing schemes of prescription drugs is compelled commercial speech.[92]

B. History of Compelled Commercial Speech and Its Relation to the First Amendment

1. Compelled Commercial Speech and Its Connection with Society's Interests

Compelled commercial speech is a form of government-mandated messaging that commercial entities must disclose on advertisements, products, or elsewhere.[93] Compelled commercial speech warns the public about public health dangers.[94] Examples of products that carry compelled commercial speech, or disclosed warnings, are alcohol, tobacco, and marijuana.[95] Compelled commercial speech relates to what society wants out of the First Amendment. [96]

While there may be no single principle that answers the question of what speech the First Amendment covers, what society wants with

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appealing flavors are mango, cool mint, crème brûlée, and fruit medley. *Id.* There is also a persistent belief that vaping is less harmful than other products such as traditional cigarettes. *Id.* The design of the Juul is also appealing to teens and young adults as it resembles a USB flash drive, making it easy to hide it and use it discretely. *Id.*

91. *See* Leah Rosenbaum, *FDA Warns Juul About Deceptive Marketing Tactics*, FORBES (Sept. 9, 2019), https://www.forbes.com/sites/leahrosenbaum/2019/09/09/fda-warns-juul-about-deceptive-marketing-tactics/#e0d9f6d168fd [https://web.archive.org/web/20201121202738/https://www.forbes.com/sites/leahrosenbaum/2019/09/09/fda-warns-juul-about-deceptive-marketing-tactics/]. The FDA told Juul that it markets its product to children and that Juul tried to make the impression that "Juul products [were] 'totally safe' and '[ninety-nine percent] safer than cigarettes.'" *Id.*

92. *See infra* Parts II.B.1, II.B.2, II.B.3.

93. *See* Micah L. Berman, *Clarifying Standards for Compelled Commercial Speech*, 50 WASH. U.J.L. & POL'Y 53, 55–56 (2016); *see also* Ellen P. Goodman, *Visual Gut Punch: Persuasion, Emotion, and the Constitutional Meaning of Graphic Disclosure*, 99 CORNELL L. REV. 513, 515 (2014).

94. *See* Leslie Gielow Jacobs, *Regulating Marijuana Advertising and Marketing to Promote Public Health: Navigating the Constitutional Minefield*, 21 LEWIS & CLARK L. REV. 1081, 1088 (2017); *see also* LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 361–65 (2d ed. 2008).

95. *See* Jacobs, *supra* note 94, at 1088–91.

96. *See* Victor Brudney, *The First Amendment and Commercial Speech*, 53 B.C. L. REV. 1153, 1161 (2012).

protection of free speech is based on its communal interests.[97] These "communal interests include (1) the making of (or declining to make) collective decisions in electoral matters, or more broadly in matters of public policy, and (2) the generation of the society's collective values, tastes, and vision of itself in matters capaciously characterized as 'cultural.'"[98] Aside from these communal interests, the First Amendment functions to protect speech that improves the quality of a democratic and free society.[99] Commercial speech is protected by the First Amendment, but it has less protection than other forms of speech.[100] Also, government entities may compel entities to engage in commercial speech more liberally than they may compel individuals to utter fully protected speech.[101]

While the government may restrain certain commercial speech, the government has more freedom to compel commercial speech and require entities to disclose information.[102] However, as of late, the Supreme Court made it more difficult for government entities to impose restrictions on commercial advertising by subjecting these restrictions to strict scrutiny.[103] This led to more use of compelled commercial speech instead of hindering protected commercial speech.[104]

2. Groundbreaking Cases for Compelled Commercial Speech and the Differing Levels of Scrutiny

There are three tests to see if the government may compel an entity to reveal certain information: (1) the strict scrutiny test from the D.C. District Court in *R.J. Reynolds Tobacco v. FDA*;[105] (2) the intermediate scrutiny test from *Central Hudson Gas & Electric Corp. v. Public*

97. *See id*
98. *Id.* at 1161–62.
99. *Id.* at 1163.
100. *See also* Leslie Gielow Jacobs, *Compelled Commercial Speech as Compelled Consent Speech*, 29 J.L. & POL. 517 (2014).
101. *Id.*
102. *Id.*
103. *See* Samantha Rauer, *When the First Amendment and Public Health Collide: The Court's Increasingly Strict Constitutional Scrutiny of Health Regulations That Restrict Commercial Speech*, 38 AM. J.L. & MED. 690, 702 (2012); Sorrell v. IMS Health Inc., 564 U.S. 552 (2011).
104. *See* Berman, *supra* note 93, at 55; *see also* Jennifer L. Pomeranz, *Compelled Speech Under the Commercial Speech Doctrine: The Case of Menu Label Laws*, 12 J. HEALTH CARE L. & POL'Y 159, 181–82 (2009).
105. R.J. Reynolds Tobacco Co. v. FDA, 845 F. Supp. 2d 266, 272 (D.D.C. 2012), *aff'd*, 696 F.3d 1205 (D.C. Cir. 2012).

Service Commission of New York[106] that was also used by the D.C. Circuit Court in *R.J. Reynolds*;[107] and (3) the rational basis review test from *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*.[108] Scrutiny standards are important because they show how much freedom the government has with making laws without affecting constitutional rights of citizens.[109] This Section discusses the scrutiny standards affecting compelled commercial speech.

In *Central Hudson Gas & Electric Corp. v. Public Service Commission*, the Supreme Court established the basic test for the government regulating commercial speech: commercial speech receives protection from governmental regulation if it concerns lawful activity and is not misleading.[110] The Court came up with a four-prong test to determine whether the commercial speech regulation is consistent with the First Amendment: (1) speech "must concern lawful activity and not be misleading"; (2) government interest must be substantial; (3) the regulation must directly advance the interest; and (4) the regulation must be narrowly drawn and not more extensive than necessary.[111]

In *Central Hudson*, the Court dealt with suppressing commercial speech rather than compelling commercial speech; the government wanted to cease all advertisements by an electrical utility that promoted the use of electricity.[112] The New York Public Service Commission (NYPSC) tried to ban an electrical utility company from advertising to promote the use of electricity.[113] The NYPSC thought its "interconnected utility system in New York State [did] not have sufficient fuel stocks or sources of supply to continue furnishing all customer demands for the 1973–1974 winter."[114] The Court ruled the regulation unconstitutional, stating commercial speech is afforded less protection than other constitutionally guaranteed expression but that this regulation was still unconstitutional.[115] In short, the Court ruled if commercial speech is not

106. Cent. Hudson Gas & Elec. Corp. v. Publ. Serv. Comm'n of N.Y., 447 U.S. 557 (1980).

107. *R.J. Reynolds*, 696 F.3d at 1205.

108. Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 (1985); *see also* Melissa M. Card, *America, You Are Digging Your Grave with Your Spoon—Should the FDA Tell You That on Food Labels?*, 68 FOOD & DRUG L.J. 309, 315–18 (2013).

109. *See* Elke C. Meeùs, *The Second Amendment in Need of a Shot in the Arm: Overhauling the Courts' Standards of Scrutiny*, 45 W. ST. L. REV. 29, 54 (2017).

110. *See Central Hudson*, 447 U.S. at 566.

111. *See id.*

112. *See id* at 558.

113. *See id.*

114. *Id.* at 559.

115. *Id.* at 562–63.

misleading or unlawful, prohibiting commercial speech is only constitutional if it advances a substantial government interest and the prohibition of commercial speech is narrowly tailored to achieve that interest.[116] The Court found that the regulation imposed by the government bore a tenuous relationship to the government's purported interest, and the government had not narrowly tailored its regulation in support of its putative interest.[117] The First Amendment's regards for commercial speech comes from informational functions of advertising.[118] Ceasing ads that promote the use of electricity is not connected to the government's interest in fair, efficient utility pricing, and ceasing ads was not narrowly tailored to that interest.[119] However, as discussed before, prohibiting commercial speech and compelling commercial speech are treated differently.

In *Zauderer v. Office of Disciplinary Counsel*, the Supreme Court allowed an exception, in certain circumstances, to permit rational basis review of compelled commercial speech that was factual.[120] The government wanted an attorney who advertised his services on a contingent fee basis to disclose that clients will have to pay costs even if the lawsuit is unsuccessful.[121] The government reasoned that the public is unaware of the technical difference between "fees" and "costs."[122] The Court determined that compelled commercial speech regulations are permissible as long as they are not unduly burdensome and are reasonably related to the state's interest in preventing consumer deception.[123] The reasoning behind this decision—that the constitutionally protected interest that comes from not providing factual information is minimal—gives the government a less stringent standard to overcome.[124]

In *R.J. Reynolds Tobacco Co. v. FDA*, the District Court for the District of Columbia Circuit applied strict scrutiny.[125] The government did not satisfy this burden.[126] This case dealt with the possibility of requiring cigarette companies to put graphic warning labels on cigarette

116. *See id.*
117. *See id.* at 569–70.
118. *See id.* at 563.
119. *See id.*
120. *See* Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 651 (1985).
121. *See id.* at 652–53.
122. *See id.* at 652.
123. *See id.* at 651.
124. *See id.*
125. *See* R.J. Reynolds Tobacco Co. v. FDA, 845 F. Supp. 2d 266, 274 (D.D.C. 2012), *aff'd*, 696 F.3d 1205 (D.C. Cir. 2012).
126. *See id.* at 274–77.

packages depicting the harmful side effects of smoking.[127] The government contended its compelling interest was conveying to consumers, especially adolescents, the devastating consequences of smoking and nicotine addiction.[128] The court believed the actual purpose of these graphic warning labels was not to inform or educate, but rather to advocate for a change in behavior, encouraging smoking cessation and discouraging potential new smokers from starting.[129] The court concluded that educating the public about the dangers of smoking might be compelling, but simply persuading the public not to purchase a legal product is not.[130] Under strict scrutiny, the government carries the burden of proving that a compelled commercial speech regulation is narrowly tailored to achieving a compelling government interest, which is the highest burden.[131] However, on appeal, the government got a better chance at having its regulation survive under a less stringent standard.[132]

At the federal appellate level in *R.J. Reynolds*, the D.C. Circuit lowered the standard to *Central Hudson*'s intermediate scrutiny, but it veered away from the Supreme Court and stated that compelled commercial speech is limited to a narrow situation where the entity's commercial message is misleading or incomplete.[133] Despite having a standard with a lesser burden, the government still failed to satisfy it.[134] Tobacco companies are known for having strong judicial ties to help themselves in the courtroom.[135]

In his concurrence in *Milavetz, Gallop & Milavetz, P.A. v. United States*, Justice Clarence Thomas said that *Zauderer* did "not stand for the proposition that the government can constitutionally compel the use of a scripted disclaimer in any circumstance in which its interest in preventing consumer deception might plausibly be at stake."[136]

Judge Janice Brown of the D.C. Circuit took Justice Thomas's reasoning and declined to apply the *Zauderer* rational basis test because the Supreme Court never applied this test to disclosure requirements that were not designed to correct misleading commercial speech;[137] the D.C.

127. *See id.* at 268.
128. *See id.* at 274.
129. *See id.* at 275.
130. *See id.*
131. *Id.* at 274.
132. *See* R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012).
133. *Id.* at 1213, 1217.
134. *Id.*at 1219–21.
135. *See* LC Friedman, *Tobacco Industry Use of Judicial Seminars to Influence Rulings in Products Liability Litigation*, 15 TOBACCO CONTROL 120 (2006).
136. *See* Milavetz, Gallop & Milavetz, P.A. v. United States, 558 U.S. 229, 257 (2010) (Thomas, J., concurring).
137. *See R.J. Reynolds Tobacco Co.*, 696 F.3d at 1215.

Circuit decided to apply *Central Hudson*'s intermediate scrutiny test instead, holding the government to a tougher standard.[138] The FDA did not prove that graphic images on cigarette packages advanced its goal of lowering smoking rates.[139] The D.C. Circuit noted the "FDA framed the warnings as general disclosures about negative health effects of smoking. The warnings [were not] a measure designed to combat specific deceptive claims."[140] Also, the court highlighted that the graphic warning labels were not the type of "purely factual and uncontroversial" information where *Zauderer* would apply.[141]

In *American Meat Institute v. Department of Agriculture*, there was an *en banc* hearing where the panel of judges of the D.C. Circuit determined that the *Zauderer* should be applied instead of *Central Hudson*, following the footsteps of other circuits in correcting consumer deception.[142] The D.C. Circuit previously ruled in favor of applying *Central Hudson*.[143] The panel overruled previous cases saying otherwise.[144]

3. Legal Precedent and How It Relates to Prescription Drug Advertising

a. Regulating Commercial Speech and Drug Advertising

Since the *Central Hudson* test was formed, the Supreme Court has expressed doubts on whether *Central Hudson*'s intermediate scrutiny test is the correct test in two groundbreaking cases, *Thompson v. Western States Medical Center* [145] and *44 Liquormart, Inc. v. Rhode Island*.[146] In *44 Liquormart*, Rhode Island passed a law that prohibited alcohol providers and news media from advertising the retail prices of alcohol.[147] 44 Liquormart got in trouble after it advertised in a newspaper that it sold liquor at a cheap price.[148] The Court of Appeals reversed the District Court, holding that the statute was constitutional despite applying the

138. *See id*. at 1217.
139. *See id.* at 1222.
140. *Id.* at 1216.
141. *See id.*
142. Am. Meat Inst. v. Dep't of Agric., 746 F.3d 1065 (D.C. Cir. 2014) (en banc).
143. *See id.* at 22.
144. *See id.* at 22–23.
145. Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002).
146. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996).
147. *Id.* at 489.
148. *Id.* at 493.

Central Hudson test instead of the *Zauderer* rational basis test.[149] However, although the Supreme Court still applied the *Central Hudson* test instead of applying strict scrutiny, it found that the statute was unconstitutional, finding that the statute abridged the First Amendment rights of 44 Liquormart.[150] The Court reasoned that the government had an interest in protecting consumers, which is why commercial speech is subject to more government control than non-commercial speech.[151] Here, the second prong of the *Central Hudson* test was satisfied because there was a substantial government interest in protecting consumers from alcohol abuse.[152] However, the other three prongs were not satisfied.[153]

In *Thompson*, the FDA passed a law known as the Modernization Act of 1997, prohibiting pharmaceutical companies from advertising or promoting compound prescription medication, which is a combination of drugs in one drug.[154] The government wanted to impose this prohibition to maintain the small-scale availability of compounded drugs for the benefit of unique patients while preventing mass-production of unregulated drug combinations that had not been submitted to the FDA for safety testing.[155] Just like in *44 Liquormart*, the Court applied the *Central Hudson* test.[156] Here, the Court emphasized the fourth prong, stating that there were less restrictive ways for the government to advance its interest.[157] For example, instead of prohibiting advertising,

149. 44 Liquormart, Inc. v. Rhode Island, 39 F.3d 5 (1st Cir. 1994), *rev'd*, 517 U.S. 484 (1996).

150. *44 Liquormart, Inc.*, 517 U.S. at 516.

151. *Id.* at 502.

152. *Id.* at 504–05.

153. *Id.* at 487. In regard to the first prong, the proposed speech by 44 Liquormart did not promote illegal activities nor did it constitute false and deceptive practices, meaning that this speech should be protected by the First Amendment; all 44 Liquormart said was its liquor prices were cheap, which is not necessarily false when it could be mere sales puffery, and it did not promote any illegal activity to be conducted with its liquor. *Id.* In regard to the third prong, the law did not necessarily advance the government's interest of protecting consumers of alcohol abuse; there was no evidence that prohibiting 44 Liquormart to engage in this type of commercial speech would advance the government's interest. *Id.* In regard to the fourth prong, the Court went on to say that there were other avenues to advance the government's interest of protecting consumers of alcohol abuse that were less extensive than its prohibition on 44 Liquormart's advertising. *Id.*

154. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002). *See generally* Ronilee Shye, *What Are Compounded Medications?*, GOODRX (Oct. 4, 2019), https://www.goodrx.com/blog/what-are-compounded-medications/ [https://web.archive.org/web/20201121202755/https://www.goodrx.com/blog/what-are-compounded-medications/].

155. *Thompson*, 535 U.S. at 368–70.

156. *Id.* at 367.

157. *Id.* at 376.

the government could require warning labels that compounded drugs had not gone through FDA testing.[158]

In his dissent, Justice Stephen Breyer stated the Court could reasonably conclude from the evidence that doctors would be more inclined to prescribe drug compounds that had higher consumer demand, which was driven by advertisement.[159] Justice Breyer also stated untested compound drugs posed risks to consumers that were best addressed in the context of a physician-patient relationship without the increased demand that was driven by advertisements.[160] Justice Breyer concluded that the Court applied the commercial speech doctrine too strictly, undervaluing the importance of the government's interest in regulating the misuse of prescription drugs.[161]

It is important to think about how cases like *Thompson* and *44 Liquormart* would turn out if, instead of regulating the commercial speech that is freely given by an entity, the government would instead compel speech. In fact, the *Thompson* Court stated that the better alternative was to compel speech rather than inhibit it, ensuring that no one's First Amendment rights were harmed.[162] In the end, it is best to advance the government's interests without abridging the rights of its citizens. However, this is not always conceivable, which the next section discusses.

b. Compelled Commercial Speech and Prescription Drug Advertising

When looking at legal precedent with compelled commercial speech and how it relates to prescription drug advertising, an important question is whether *Central Hudson*'s intermediate-scrutiny test or *Zauderer*'s rational basis review test will apply. A big factor in the outcome of cases is the level of scrutiny the government must overcome to win its case.[163] The D.C. Circuit said that the *Zauderer* test was the exception and not the rule in First Amendment cases, implying that the *Central Hudson* test was the controlling test in *National Ass'n of Manufacturers v. SEC*.[164] In that case, the Securities and Exchange Commission (SEC) drafted a rule that imposed certain disclosure requirements for companies that used

158. *Id.*
159. *Id.* at 382 (Breyer, J., dissenting).
160. *Id.* (Breyer, J., dissenting).
161. *Id.* (Breyer, J., dissenting).
162. *Id.* at 376.
163. *See* Marisa Lopez, *Constitutional Law: Lowering the Standard of Strict Scrutiny*, 56 FLA. L. REV. 841, 851 (2004).
164. *See* Nat'l Ass'n of Mfrs. v. SEC, 748 F.3d 359, 369–72 (D.C. Cir. 2014).

gold, tantalum, tin, and tungsten originating in or near the Democratic Republic of Congo.[165] The SEC's rule of compelled commercial speech did not survive the *Central Hudson* test,[166] and the court emphasized that the Supreme Court stated that rational basis review was limited to disclosures that were purely factual and uncontroversial.[167] The court also stated that the *Zauderer* test was limited to cases where disclosures were reasonably related to the government's interest in preventing consumer deception.[168]

However, today it is arguable whether *Zauderer* or *Central Hudson* is the controlling test. *American Meat* changed the course of the D.C. Circuit on which test will be applied. However, it is possible that the facts of any case will cause the D.C. Circuit to switch back to the *Central Hudson* test if the D.C. Circuit finds it more just. Regardless, compelled commercial speech and prescription drug advertising are topics that affect the marketplace of ideas theory.

4. Marketplace of Ideas

The marketplace of ideas is a test for the truth.[169] In his famous dissent in *Abrams v. United States*, Justice Oliver Wendell Holmes stated:

> But when men have realized that time has upset many fighting faiths, they may come to believe even more than they believe the very foundations of their own conduct that the ultimate good desired is better reached by free trade in ideas—that the best truth is the power of the thought to get itself accepted in the competition of the market, and that trust is only ground upon which their wishes safely can be carried out.[170]

Holmes's dissent revealed important guiding principles for considering the scope of First Amendment protection, primarily the ability to speak.[171] This famous dissent influenced many, including

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165. *See id.* at 362–63.
166. *Id.* at 370–71.
167. *Id.*
168. *Id.* at 371.
169. *See* David Schultz, *Marketplace of Ideas*, FIRST AMEND. ENCYCLOPEDIA, https://www.mtsu.edu/first-amendment/article/999/marketplace-of-ideas [https://web.archive.org/web/20201121203029/https://www.mtsu.edu/first-amendment/article/999/marketplace-of-ideas] (last updated June 2017).
170. Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).
171. *See* Papandrea, *supra* note 2, at 1729.

Justice Anthony Kennedy, who advocated striking down government regulations that restricted speech during his time as a Supreme Court Justice.[172]

In terms of commercial speech, Justice Kennedy also said restricting corporate speech to level the field was foreign to the First Amendment.[173] He said that speaker-based restrictions were just as suspect as content-based restrictions because "[s]peech restrictions based on the identity of the speaker [were] all too often simply a means to control content."[174] In conclusion, Justice Kennedy believed that commercial speech restrictions undoubtedly "interfere[d] with the 'open marketplace of ideas' protected by the First Amendment."[175] On the other side, there is a fear that false information will spread, misleading listeners.[176]

For example, in today's political climate, there is a fear that "fake news" will spread instead of truthful information.[177] There is also a fear that the elite and powerful control the marketplace, skewing what information is shown in the marketplace and inhibiting its purported purpose.[178] Those who support the government controlling what can be said at times can control the imbalance that, they believe, is rooted in laissez-faire economics.[179] Pharmaceutical companies are known for being powerful.[180] It is argued that voices "with more power, wealth, or fame (or all three) are not only louder and more visible, but they are also amplified in both new and traditional media."[181] Critics of laissez-faire economics conclude that state intervention is needed to correct communicative failures that derive from a complete free-flow of ideas.[182]

While people, such as Justice Kennedy, advocate for the free-flow of ideas by disallowing prohibitions on speech, it is important to know how

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172. *See id.*

173. *See id.* at 1731.

174. *See id.* (quoting Citizens United v. FEC, 558 U.S. 310, 340 (2010)) (alteration in original).

175. *See id.* (quoting *Citizens United*, 558 U.S. at 354)

176. *See id.* at 1743.

177. *See* Ari Era Waldman, *The Marketplace of Fake News*, 20 U. PA. CONST. L. 845 (2018). Waldman pointed out that "[f]ake news [was] a new name for an old problem. Disinformation, misinformation, hoaxes, conspiracy theories, and lies have long tried to influence public opinion." *Id.* at 846. Waldman argued that the "marketplace of ideas was always meant to be the marketplace of *ideas*, not *facts*." *Id* at 869. Therefore, there will be information that is not factual from time-to-time. *Id.*

178. *See generally* Stanley Ingber, *The Marketplace of Ideas: A Legitimatizing Myth*, 1984 DUKE L.J. 1 (1984). Ingber stated that a high-quality democratic government depended upon the caliber of a public exchange in ideas. *Id.* at 4.

179. *See id.*

180. *See infra* Part II.A.2.

181. *See* Papandrea, *supra* note 2, at 1727.

182. *See generally* Ingber, *supra* note 178.

the marketplace of ideas operates in hindered speech. For new and upcoming drugs, there is no effective marketplace of ideas if pharmaceutical companies do not have to publicly disclose clinical data.[183] An area where compelled commercial speech often arises is prescription drug labeling.

C. History of Prescription Labels

In *Thompson*, the Supreme Court of the United States stated that instead of a restriction on advertising for compound drugs, the government's interest could be far less restrictive if the government required labels disclosing information.[184] Prescription labels have a long history going back to 1890; in 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act.[185] The Act divided controlled substances "into five schedules . . . on the basis of their abuse potential, accepted medical use, and accepted safety under medical supervision."[186] Medicine bottles contain labels with the schedule of the drug.[187] The schedules of drugs range from Schedule I to Schedule V. [188] Schedule I drugs are defined as drugs with no currently-accepted medical use and have a high potential for abuse, while Schedule V drugs have currently-accepted medical uses with very low potential for abuse.[189] Most opioid prescription drugs are currently in Schedule II.[190]

Not only was the Comprehensive Drug Abuse Prevention and Control Act passed in 1970, but the FDA also required the first patient

183. Cynthia M. Ho, *A Dangerous Concoction: Pharmaceutical Marketing, Cognitive Biases, and First Amendment Overprotection*, 94 IND. L.J. 773, 777 (2019).

184. Thompson v. W. States Med. Ctr., 535 U.S. 357, 376 (2002).

185. *See The History of Prescription Drugs*, GOOD MED., BAD BEHAVIOR, http://www.goodmedicinebadbehavior.org/explore/history_of_prescription_drugs.html [https://web.archive.org/web/20201121203047/http://www.goodmedicinebadbehavior.org/explore/history_of_prescription_drugs.html] (last visited Oct. 7, 2019).

186. *Id.*

187. *See id.*

188. *See Drug Scheduling*, DEA, https://www.dea.gov/drug-scheduling [https://web.archive.org/web/20201121203558/https://www.dea.gov/drug-scheduling] (last visited Oct. 7, 2019). Examples include: Schedule I (heroin, marijuana, LSD, and ecstasy); Schedule II (Vicodin, hydrocodone, and oxycodone); Schedule III (Tylenol, ketamine, anabolic steroids, and testosterone); Schedule IV (Xanax, Valium, and Ativan); Schedule V (Lomotil, Motofen, and Lyrica). *Id.*

189. *See id.*; *see also* Jacobs, *supra* note 94, at 1091. Although marijuana is considered to have medical uses, the Drug Enforcement Agency (DEA) refuses to reconsider marijuana's classification. *Id.*

190. *See Drug Scheduling*, *supra* note 188.

package insert.[191] The inserts aimed to inform a patient about the risks and benefits of a drug.[192] The primary purpose of prescription drug labeling was actually to give healthcare professionals the information needed to prescribe drugs appropriately rather than informing patients about useful information and harmful effects of the drug.[193] Drug labeling has changed over time in many facets, and it continues to change today.[194] An example of pharmaceutical companies not having to disclose information is found in the context of off-label prescription drug use.[195]

Off-label prescription drug use occurs when physicians prescribe a prescription drug "in a manner not specified in the FDA's approved packaging label or insert."[196] Doctors say off-label prescription drug use has its role in medical practice but also admit that off-label use increases the risk of litigation when a patient has unwelcome or serious side effects.[197] Misunderstandings regarding a drug's FDA-approved use or potential side-effects increase patients' risks of medication blunders and hazardous outcomes.[198] *United States v. Caronia* held that prohibiting truthful off-label promotion violated the First Amendment.[199] What needs to be addressed is whether the FDA can compel pharmaceutical companies to disclose information regarding dangers of off-label use of prescription drugs.[200]

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191. *See A Brief History of the Center for Drug Evaluation and Research*, FDA, https://www.fda.gov/about-fda/virtual-exhibits-fda-history/brief-history-center-drug-evaluation-and-research [https://web.archive.org/web/20201121203615/https://www.fda.gov/about-fda/virtual-exhibits-fda-history/brief-history-center-drug-evaluation-and-research] (last updated Jan. 31, 2018).

192. *See id.*

193. *See* Mary E. Kremzner, Pharm.D., Deputy Dir., U.S. Food & Drug Admin. & Steven F. Osborne, M.D., Med. Officer, U.S. Food & Drug Admin., An Introduction to the Improved FDA Prescription Drug Labeling, https://www.fda.gov/media/72979/download [https://web.archive.org/web/20201121203653/https://www.fda.gov/media/72979/download] (last visited Oct. 7, 2019) (PowerPoint presentation available at link provided).

194. *See id.*

195. *See* Kelli Miller, *Off-Label Drug Use: What You Need to Know*, WEBMD, https://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know#1 [https://web.archive.org/web/20201121203747/https://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know] (last visited Nov. 2, 2019).

196. *See id.*

197. *See id.*

198. *See id.*

199. United States v. Caronia, 703 F.3d 149, 152 (2d Cir. 2012).

200. *See infra* Part III.

Prescription drug labels still need to be perfected to combat public health issues, especially today's opioid crisis.[201] There is a proper amount of opioid prescription use that needs to be obtained to optimize chronic pain treatment without harmful effects to public welfare.[202] It is important to know how the FDA can attack these issues while staying within the confines of the United States Constitution.[203] For consumers, it is important for them to learn about prescription drugs, specifically prescription opioids, and know the risks and other alternative treatments.[204] Opioid prescription bottles today have labels stating that there is a risk of overdose and addiction and that opioids may cause drowsiness and dizziness that require avoiding the operation of a vehicle or dangerous machine.[205] It is essential to know how prescription drug labels should be scrutinized and what compelled commercial speech the FDA should use on prescription drug labels to combat public health issues.[206]

III. ANALYSIS

First, I will consider what a substantial government interest is and how it relates to compelled commercial speech. Then, I will discuss what the appropriate level of scrutiny is when a government-mandated message gets litigated. Lastly, I will propose a few methods of compelled commercial speech and test how they will be judged in court.

A. What Is a Substantial Government Interest?

1. Fears of Allowing Compelled Commercial Speech

As shown in *Thompson* and *44 Liquormart*, it can be favorable to society if the government chooses to compel commercial speech rather

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201. *See supra* Part II.A.

202. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 58.

203. *See supra* Part II.A.

204. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 58. Some alternative treatments include physician therapy; exercise; non-opioid medications such as acetaminophen or ibuprofen; and Cognitive Behavioral Therapy (CBT). *Id.*

205. *See* Christopher Conover, *Tackling Opioid Addiction with Treatment, Not Arrest*, ARIZ. PUB. MEDIA (Jan. 16, 2020), https://news.azpm.org/p/azaddicted-news/2020/1/16/164529-tackling-opioid-addiction-with-treatment-not-arrest/ [https://web.archive.org/web/20201121204201/https://news.azpm.org/p/azaddicted-news/2020/1/16/164529-tackling-opioid-addiction-with-treatment-not-arrest/].

206. *See infra* Part III.

than prohibit forms of commercial speech in certain situations.[207] However, there are some concerns with giving freedom to the government with compelled commercial speech.[208] As shown in his concurrence in *American Meat*, then-Judge Brett Kavanaugh said setting a low bar may provide the government leeway to spread its preferred messages instead of facilitating a healthy marketplace.[209] Then-Judge Kavanaugh also said if the government was authorized to compel commercial speech due to mere consumer interest, then the government could over-demand disclosure of information that related to "every whimsical, irrelevant question that might come into a consumer's head."[210] This could lead to detrimental and unnecessary costs to pharmaceutical companies.[211] Bad forms of compelled speech include when people could discriminate against others on the basis of race; [212] the Court in *Anderson v. Martin* struck down a Louisiana law that required ballots to identify a candidate's race, which allowed voters to discriminate against a candidate on the basis of race.[213] There is also a concern that too many disclosures may invade privacy, which shows how bad forms of commercial speech could venture into personal freedoms.[214]

However, in many areas of commercial law, a common aim is promoting public welfare.[215] In fact, that aim is a big reason why we have a government as shown in the Constitution.[216] In regard to compelled commercial speech, what is contingent on whether mandated disclosures actually increase welfare depends on if the benefit to consumers receiving the compelled information outweighs the costs to

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207. *See* 44 Liquormart, Inc. v, Rhode Island, 517 U.S. 484 (1996); Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002).

208. *See* Robert Post, *Compelled Commercial Speech*, 117 W. VA. L. REV. 867, 889–96 (2015).

209. Am. Meat Inst. v. Dep't of Agric., 746 F.3d 1065 (D.C. Cir. 2014) (Kavanaugh, J., concurring).

210. *See* Post, *supra* note 208, at 895.

211. *See id.*

212. *See* Anderson v. Martin, 375 U.S. 399 (1964). This case took place during the height of the Civil Rights Movement of the 1960s where racial tensions were significantly high. In this scenario, compelled speech would have harmed public welfare rather than benefiting it. *Id.*

213. *See id.*

214. *See* Post, *supra* note 208, at 895.

215. *See id.* at 891. *See generally* Peter J. Hammer, *Antitrust Beyond Competition: Market Failures, Total Welfare, and the Challenge of Intramarket Second-Best Tradeoffs*, 98 MICH. L. REV. 849 (2000).

216. *See* Post, *supra* note 208, at 891–92; *see also* Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489, 1488 (2002). *See also* U.S. CONST. pmbl.

producers in distributing that information.[217] In reality, the costs of labeling products is typically quite low, so compelled commercial speech may produce benefits for public welfare when the benefit to consumers is greater than the costs to producers.[218] While it is important to be cognizant of issues that may arise from misuse of compelled commercial speech—just like it is important to be cognizant of issues that arise from misuse of prescription drugs—there are substantial government interests that exist.

2. Prescription Drug Abuse as a Substantial Government Interest

With prescription opioids, there is a proper amount of usage that society aims for, so that there is treatment for pain without drug abuse.[219] Again, it is essential to treat chronic pain for individuals with various treatments, including prescription opioids.[220] In the government's view, it is important to treat pain,[221] but there is also a substantial government interest in ensuring prescription drugs are used correctly without drug abuse harming public welfare.[222]

Substantial government interest is important for the second and third prongs of the *Central Hudson* test.[223] Government interests can range from a wide variety of different interests.[224] The extra costs for

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217. *See* Post, *supra* note 208, at 892.

218. *See id.* at 892–93. *See also* ELISE GOLAN ET AL., U.S. DEP'T AGRIC., THE ECONOMICS OF FOOD LABELING, AGRICULTURAL ECONOMIC REPORT No. 793 (2000), https://www.ers.usda.gov/webdocs/publications/41203/18885_aer793.pdf?v=9419.4 [https://web.archive.org/web/20201121204201/https://www.ers.usda.gov/webdocs/publications/41203/18885_aer793.pdf?v=9419.4]. This report discussed the costs and benefits of mandatory labeling—a form of compelled commercial speech—with food labeling on food products that contain GMOs. *Id.* While the costs may not be significant for large producers, it could raise some issues with small producers. *Id.* However, when looking at public health issues that arise from big pharmaceutical companies, there is no need to worry about the extra costs that shadow small producers since big pharma is full of large producers in a market that carries many barriers to entry. *Id.*

219. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 58, at 3.

220. *See id*. at 2.

221. *See id.*

222. *See id.* at 3–4.

223. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York 447 U.S. 557, 577 (1980). As a refresher, the two prongs dealing with substantial government interests are: 2) government interest must be substantial and 3) the regulation must directly advance the interest. *Id.*

224. *See* Post, *supra* note 208, at 899; *see also* Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 410 (1993) (balancing the facts of the case with the government's interest in the esthetics of the city atmosphere); Edenfield v. Fane, 507 U.S. 761, 769 (1993) (balancing the facts of the case with the government's interest in the accuracy of commercial information in a marketplace); Bd. of Trs. of State Univ. of N.Y. v. Fox, 492

compelled commercial speech will not be much for big pharmaceutical companies compared with expenses from other parts of the business, as shown in various audited financial statements and labeling studies,[225] and the government interest in combating public health issues from prescription drug abuse is substantial.[226] As discussed in the beginning of this Note, consumers are put in a vulnerable position with aggressive marketing schemes that are utilized over them.[227] There is very little regulation of what can and cannot be said when advertising prescription drugs.[228] It is also known that there are public health crises, such as the opioid crisis, that continue to haunt consumers today.[229] As shown in the *Purdue Pharma*, *Mallinkrodt*, and *Insys* cases, prescription drug companies take advantage of vulnerable consumers, and those companies hope to reap the benefits of sales at the expense of the health of consumers.[230]

U.S. 469, 475 (1989) ("the governmental interests asserted . . . are substantial: promoting an education rather than commercial atmosphere . . . preventing commercial exploitation of students, and preserving residential tranquility."); *Central Hudson*, 447 U.S. at 568 (balancing the facts of the case with the government's interest in energy conservation); POM Wonderful, LLC v. FTC, 777 F.3d 478 (D.C. Cir. 2015) (balancing the facts of the case with the government's interest in the accuracy of commercial information in a marketplace).

225. *See* Laura Johnson, *Pharmaceutical Labeling Improves Efficiencies in a Highly Complex Supply Chain*, MATERIAL HANDLING & LOGISTICS (Aug. 22, 2017), https://www.mhlnews.com/technology-automation/article/22054517/pharmaceutical-labeling-improves-efficiencies-in-a-highly-complex-supply-chain [https://web.archive.org/web/20201121204333/https://www.mhlnews.com/technology-automation/article/22054517/pharmaceutical-labeling-improves-efficiencies-in-a-highly-complex-supply-chain]; *Warning Labels*, HEALTHY FOOD AM., http://www.healthyfoodamerica.org/warninglabels [https://web.archive.org/web/20201121204327/http://www.healthyfoodamerica.org/warninglabels] (last visited Nov. 16, 2020). *See also* MARY K. MUTH ET AL., FDA LABELING COST MODEL, RTI INTERNATIONAL (2003), https://www.foodrisk.org/files/labeling_cost_model.pdf [https://web.archive.org/web/20210105142914/https://www.foodrisk.org/files/labeling_cost_model.pdf]; Transcept Pharmaceuticals, Inc., Annual Report (Form 10-K) (Mar. 30, 2011); FUTURESCRIPTS SECURE, LLC, AUDITED FINANCIAL STATEMENT (2009); DELOITTE & TOUCHE LLP AUDITED FINANCIAL STATEMENT (2009); Express Scripts Holding Co., Annual Report (Form 10-K) (Feb. 2, 2017).

226. *See supra* Part II.A.

227. *See supra* Part II.A.2.

228. *See* Benita Lee, *How Is Consumer Drug Advertising Regulated in the United States?*, GOODRX (June 17, 2019), https://www.goodrx.com/blog/prescription-drug-advertising-regulation-united-states/ [https://web.archive.org/web/20201121204533/https://www.goodrx.com/blog/prescription-drug-advertising-regulation-united-states/].

229. *See supra* Part I.

230. *See supra* Part II.A.2.

The public health concerns with opioids are beyond the concerns that Kavanaugh listed in his concurrence in *American Meat*. There is no risk of discrimination, there is no fear of irrelevant questions that waste time when there are necessary questions to keep a proper flow of information, and there are no detrimental and substantial costs to prescription drug producers. This relates to the public welfare discussion, and this shows that prescription drug abuse is a substantial government interest that is valid when discussing whether the government can compel commercial speech upon a prescription drug manufacturer.

B. The Appropriate Level of Scrutiny

Compelled commercial speech deals with companies rather than people. The companies are large pharmaceutical companies that have dialogue that falls under commercial speech. Strict scrutiny arises if the government were to compel speech out of individual citizens.[231] This is because the First Amendment rights of individuals are greater than those of corporate entities.[232] Strict scrutiny is a very high bar to overcome, and it exists to systematically ensure that all citizens have their First Amendment rights.[233] This gives near-full autonomy of speech to individual citizens. On the other hand, the large pharmaceutical companies will not be treated the same way as individual citizens. If large corporations were autonomous when communicating in the commercial marketplace, it would be tough to govern them as they carry much more power than a consumer.[234] This also helps to protect consumers as commercial speech informs consumers about the availability, nature, and prices of products.[235]

When discussing what the appropriate level of scrutiny is for the government to overcome, there is a tension between the *Zauderer* and *Central Hudson* tests.[236] The *Zauderer* test is a rational basis review test that applies to compelled commercial speech that is purely factual and uncontroversial.[237] This test is limited to cases where the mandated disclosures are "reasonably related to the State's interest in preventing

231. *See* Post, *supra* note 208, at 910–11.
232. *Id.*
233. *See* Richard H. Fallon, Jr., *Strict Judicial Scrutiny*, 54 UCLA L. REV. 1267, 1288 (2007).
234. *See* Robert Post, *Recuperating First Amendment Doctrine*, 47 STAN. L. REV. 1249, 1278 (1995).
235. *See* Bates v. State Bar of Ariz., 433 U.S. 350, 364 (1977).
236. *See* Post, *supra* note 208, at 881–82.
237. *See* Nat'l Ass'n of Mfrs. v. SEC, 748 F.3d 359, 370–71 (D.C. Cir. 2014).

deception of consumers."[238] While strict scrutiny is out of the question, *Central Hudson* is considered the stable test, yet there are times where it looks as if *Zauderer* will overrule *Central Hudson*.[239] In reality, it seems as if the determining test is applied on a case-by-case basis, discerning from factors that the Court thinks is more just at the time of the case.

Although the *Zauderer* test appears to be the exception to the *Central Hudson* test, the *Zauderer* test should be the one that is applied when dealing with situations such as horrendous public health crises that derive from heinous acts of large pharmaceutical companies. In *R.J. Reynolds Tobacco Co.*, the main reason the FDA's regulations of compelling graphic warning labels on cigarette packages failed was because the FDA conceded that these labels were not to inform or educate consumers of possible health risks that come with smoking, but, rather, to advocate for a change in behavior that was completely legal.[240]

This situation differs from the one in *R.J. Reynolds* because it does not necessarily advocate for a change in behavior but does inform and educate consumers of risks they take on when using prescription medication, and it informs consumers how to properly use the medication without creating drug abuse. Of course, physicians are typically the ones who select the drugs patients take, and they are ethically obligated to select the correct drug. However, consumers can influence the discussions about what kind of drug they should take, and, as shown in the *Insys* case, physicians can be incentivized to make immoral choices when prescribing drugs.[241] Also, when consumers buy prescription drugs legally, they do so with the comfort that a physician prescribed the drug, which is a drastic contrast to purchasing cigarettes on their own at a local gas station.[242] From a public health policy perspective, there is an appropriate level of usage of prescription medication;[243] for example, it is ideal for consumers to consume the correct amount of opioids to treat for pain and other health issues without suffering from addiction or abusing the drug.[244]

American Meat discussed *Zauderer*'s "reasonably related" test and its three preconditions necessary for a court to implement the *Zauderer* test instead of the *Central Hudson* test.[245] The first precondition is the

238. *See id.* at 371.
239. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 360 (2002).
240. *See* R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1218–19 (D.C. Cir. 2012).
241. *See supra* Part II.A.2.
242. *See id.*
243. *See* CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 58.
244. *See id.*
245. *See* Post, *supra* note 208, at 900–01.

government's compelled commercial speech must relate to the goods or services provided by the entity, which was inherent in *Zauderer*'s facts because it dealt with the attorney advertising his contingent fee.[246] Obviously, the compelled speech deals with the prescription drugs, as it would discuss the public health issues that derived from the drug. The second precondition is the government's compelled commercial speech must not be so burdensome that it essentially becomes a restriction on constitutionally protected speech.[247] Large pharmaceutical companies would still carry the same commercial speech rights they did before; all that would be done would be to ensure they do not engage in heinous activity that pushes their sales while harming the lives of others.[248] The third precondition is the government's compelled commercial speech must contain "purely factual and uncontroversial information" about the entity's product.[249] Some will argue that although this information is factual, the commercial speech the government will compel is indeed controversial; however, comparing it to *R.J. Reynolds*, the nature of this compelled speech is not as gruesome as a graphic of a black-coated lung or of a tracheotomy on someone's neck. This information is simply to inform the consumer of the harm derived from the drug.

The government wants consumers to use prescription drug medication the correct way. Unlike smoking, the government wants people to use prescription medicine in some respects. With added information, the world of prescription medicine would get closer to the goal of properly treating pain without causing additional harms to society. This additional compelled commercial speech would not completely change behavior, but it would inform and educate, which avoids the fears that were expressed in *R.J. Reynolds*.

C. Methods of Compelled Commercial Speech That Help Prevent Prescription Drug Abuse

Before discussing various methods, it is important to remember why the marketplace of ideas is important. A paradigm for why information is important is the Securities and Exchange Commission (SEC).[250] A pivotal moment in how information would operate in the American stock system was the stock market crash leading to the Great Depression in

246. Am. Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18, 26 (D.C. Cir. 2014)

247. *See id.* at 27 (citing Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 146–47 (1994); *see also* Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 651 (1985).

248. *See supra* Part II.A.2.

249. *Am. Meat*, 130 F.3d at 21.

250. *See* Post, *supra* note 208, at 883–84.

September of 1929.[251] This propelled the United States to start the SEC and to create laws to help facilitate the flow information important for protecting investors and keeping the market afloat.[252] The stock market has laws and rules that are governed from a simple and straightforward concept: every investor, whether sophisticated or unsophisticated, should have access to certain facts about an investment prior to investing in it and for as long as that investor holds that investment.[253]

This information flow results in a far more active, efficient, and transparent capital market that benefits investors.[254] The SEC and the laws that operate with it helped make the stock markets in the United States "the envy of the world" instead of the depressing state it was during the 1930s.[255] Just as investors are persuaded to make the correct decision when information is disclosed to them, consumers are persuaded in the same way when making decisions regarding healthcare and prescription pills.[256] The extra-needed information helps prescription drug consumers make proper decisions just like information helps investors make proper investments.

While there are various methods that make the American stock market function efficiently, it is essential to explore the methods that will work well to avoid public health crises. There are two proposed solutions that will be discussed: (1) inserts discussing previous cases; and (2) graphic labels describing health complications arising from prescription drug abuse. The first proposed solution is an example of something that should be applied under the *Zauderer* test. The second proposed solution is an example that faces the tension between *Zauderer* and *Central Hudson*, emphasizing the importance of scrutiny standards.

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251. *See* History.com Editors, *Great Depression History*, HIST., https://www.history.com/topics/great-depression/great-depression-history [https://web.archive.org/web/20201121204626/https://www.history.com/topics/great-depression/great-depression-history] (last updated Oct. 17, 2019).

252. *See* History.com Editors, *SEC: Securities and Exchange Commission*, HIST., https://www.history.com/topics/us-government/securities-and-exchange-commission [https://web.archive.org/web/20201121204811/https://www.history.com/topics/us-government/securities-and-exchange-commission] (last updated Dec. 6, 2019).

253. *See What We Do*, SEC.GOV, https://www.sec.gov/Article/whatwedo.html [https://web.archive.org/web/20201121204844/https://www.sec.gov/about/what-we-do] (last visited Jan. 24, 2020).

254. *See id.*

255. *See* Post, *supra* note 208, at 884.

256. *See id.*

1. Inserts Discussing Previous Cases

a. What This Proposed Solution Would Entail

As a patient gets his or her pill bottle, he or she would then get a prescription bottle containing at least thirty pills, which is a hazard for addiction and opioid diversion. In this hypothetical, this is a prescription bottle of hydrocodone. This would be an addition to what is already on the prescription bottle label.[257] Aside from the external label, there would be an additional insert.[258] This extra insert would discuss previous debacles like *Purdue Pharma*, *Mallinkrodt*, and *Insys Therapeutics*.[259]

This additional, detailed info would inform the consumer beyond just labeling a certain prescription drug with a general risk of addiction and overdose;[260] a consumer would know that there are incentives, such as increased profitability and other benefits, for prescribing opioids that may lead to his or her own personal harm. Instead of the subtle notice of the prescribed drug being an addictive drug, a consumer would know there is an incentive against him or her, emphasizing the importance of using the opioid correctly.

b. Application Under the Zauderer *Test*

This example fits the three preconditions: (1) it relates to the entity's goods that are provided by pharmaceutical companies; (2) it is not so burdensome that it essentially becomes a restriction on constitutionally protected speech; and (3) it contains purely factual and uncontroversial information about the product.[261] For the first precondition, the previous cases relate to the goods provided. For the second precondition, pharmaceutical companies would still be able to exercise other forms of commercial speech. The third precondition is debatable. Some may argue that the inserts are similar to the graphic images exemplified in *R.J. Reynolds*.[262] However, this is not an image of a black-coated lung that is aimed to change behavior; this is a warning to show previous malicious practices of the pharmaceutical industry and to inform the consumer of what he or she risks when taking prescription drugs. In the end, adding an additional insert would help achieve the goal of consumers taking the correct amount of a drug to accomplish its purpose, such as treating pain,

257. *See supra* Part II.C.
258. *See id.*
259. See *supra* Part II.A.2 for a summary of the cases involving these companies.
260. *See supra* Part II.C.
261. *See supra* Part II.C.
262. *See supra* Part II.A.2.

without abusing it. Companies would also still be able to exercise their commercial speech rights, and, while companies may not enjoy the profitability that was experienced during malicious schemes, they would still have an opportunity to make a good profit.

2. Graphic Labels Describing Health Complications Arising from Prescription Drug Abuse

a. What This Proposed Solution Would Entail

This proposed solution would entail inserts that contain photos such as: a overdosed couple in the front seat of a car with a child in the back;[263] a person passed out on the floor with pills in his or her hand; a person with his face in his hands while sitting down next to a giant pill bottle; and a person with one of his hands cuffed to a pill bottle. These images aim for the same result as the first proposed solution: send a message to the consumer about the dangers of prescription opioids. However, this proposed solution would not fare as well in court as the first proposed solution.

b. Application Based on the Tension Between the Zauderer *Test and the* Central Hudson *Test*

The first two preconditions of the *Central Hudson* test are met because this proposed solution relates to the product, and it would not hinder the commercial speech of a pharmaceutical company. What makes this proposed solution different from the first proposed solution is that it advocates for a change in behavior rather than merely informing the consumer,[264] and when comparing it to other cases, it is very similar to *R.J. Reynolds*. As discussed before, prescription bottles already have a warning saying that drugs are addictive and may cause an overdose.[265] These images would try to "scare" the consumer away from using the product just like the black-coated lung image that was shown in *R.J. Reynolds*.

What these images do not accomplish is informing the consumer. The images may emphasize the harms, but they do not inform the consumer like the inserts do in the first proposed solution. There would

263. *See* Casey Ross, *Behind the Photo: How Heroin Took Over an Ohio Town*, STAT (Sept. 21, 2016), https://statnews.com/2016/09/21/photo-heroin-ohio/ [https://web.archive.org/web/20210105155140/https://www.statnews.com/2016/09/21/photo-heroin-ohio/].

264. *See supra* Part II.A.2.

265. *See supra* Part II.C.

be no increased flow of information; this proposed solution would just place emphasis on information that is already disclosed. The Court would rule this proposed solution unconstitutional.

3. The Future of Direct-to-Consumer Advertising

Some academics at the Kellogg School of Management at Northwestern University "find the value to society of direct-to-consumer advertising is positive on the whole."[266] While that may or may not be true, the increased flow of information that is derived from commercial speech will help increase public welfare and value to society regardless of the previous impact of DTC advertising. The First Amendment is full of constitutional questions, and as stated in the preamble, one of its end goals is to promote the general welfare.[267]

IV. CONCLUSION

This Note does not argue that there should be no DTC advertising but rather that it needs to be regulated in the appropriate manner. While there is a tension between *Central Hudson*'s intermediate scrutiny test and *Zauderer*'s rational basis review test, the *Zauderer* test must apply for DTC ads regarding prescription drugs because it deals with compelled factual speech—that is, unless there are needless graphic images. There needs to be inserts that actually give out information about malicious big pharma practices and the opioid crisis. It is the more just decision, which would help avoid public health issues in the future. These proposed solutions are only the beginning. They are the start of other ideas that will help overcome information asymmetry barriers and allow consumers to know the proper way of using drugs; the marketplace of ideas theory shows the importance of this.

In cases involving opioid prescription pills, many times, a consumer is overprescribed, getting thirty or more capsules of an opioid for something small, like wisdom teeth removal. At that point, a consumer is given great power to either destroy his or her own life or to supply pills to others, destroying their lives. There are also issues with aggressive marketing schemes from the likes of big pharmaceutical companies such as Purdue Pharma, Mallinkrodt, and Insys Therapeutics. If there were

266. *See* Michael Sinkinson & Amanda Starc, *The Hidden Benefits of TV Drug Ads*, KELLOGG INSIGHT (Dec. 2, 2016), https://insight.kellogg.northwestern.edu/article/the-hidden-benefits-of-tv-drug-ads1 [https://web.archive.org/web/20210105160643/https://insight.kellogg.northwestern.edu/article/the-hidden-benefits-of-tv-drug-ads1].

267. U.S. CONST. pmbl.

proper government-mandated disclosures, the harm to consumers' health may have been avoided because they would have known the hidden harms of opioids.

Lastly, both legal scholars and scholars in other areas of academia should research further the best way to use compelled commercial speech to help prevent public health harms. It is not feasible to stop using opioids just to avoid prescription pill use; people are in pain, and they need treatment for pain. What is important is that society uses prescription pills, such as opioids, in the correct and most efficient manner.