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# Snake Oil Speech

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## SNAKE OIL SPEECH

#### Jane R. Bambauer\*

Abstract: Snake oil is dangerous only by way of the claims that are made about its healing powers. It is a speech problem, and its remedy involves speech restrictions. But First Amendment doctrine has struggled to find equilibrium in the balance between free speech and the reduction of junk science. Regulation requires the government to take an authoritative position about which factual claims are "true" and "false," which is anathema to open inquiry. As a result, free speech jurisprudence overprotects factual claims made in public discourse out of respect for any remote possibility that the scientific consensus might be wrong but has given wide latitude to state actors to regulate all but the most accepted and well supported claims in advertising. This Article shows that the interests in speech and safety alike would be better served by switching from the truth-oriented set of rules that apply today to a risk orientation. While risk and falsity are obviously related, they are not substitutes. The transition to a risk analysis would better match longstanding First Amendment traditions that permit state interests in avoiding harm to outweigh speech interests while maintaining epistemic modesty. The practical effect of this shift would be to permit more regulation in public discourse and less in commercial speech.

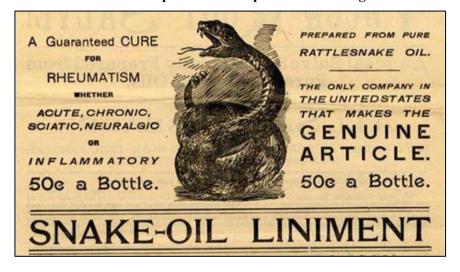
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Figure 1: The Great Yaquis Snake Oil promotional design<sup>1</sup>



#### INTRODUCTION

Snake oil is dangerous not because of what it *is*, but because of what is said about it. The metaphor is used for a wide range of pseudoscientific

<sup>1.</sup> Chip Hines, *The Medicine Show Syndrome—Are We Guilty?*, ON PASTURE (Jan. 13, 2014), https://onpasture.com/2014/01/13/the-medicine-show-syndrome-are-we-guilty/ [https://perma.cc/UD6T-PEBJ].

claims about products, services, lifestyles, and even socio-political theories.<sup>2</sup> Snake oil, in other words, is speech.<sup>3</sup>

It is not surprising, then, that the government has an interest in regulating factual claims to avoid the propagation of junk science, and the First Amendment sometimes permits it to do so. For commercial speakers, truth is a prerequisite for any First Amendment coverage at all. By contrast, the popular press is often insulated from any government assessment of falsity. For all speakers, the First Amendment rules are organized around theories of truth.<sup>4</sup>

These free speech traditions are not sustainable. One major source of incoherence is a failure in both law and the scholarly literature to differentiate two sorts of factual claims that are importantly distinct: accepted knowledge and contested knowledge.<sup>5</sup>

<sup>2.</sup> See generally DAN HURLEY, NATURAL CAUSES: DEATH, LIES, AND POLITICS IN AMERICA'S VITAMIN AND HERBAL SUPPLEMENT INDUSTRY (2006) (products) (using snake oil as an example and a metaphor for the herbal supplement industry); Snake Oil for the 21st Century: Health Claims that Are Too Good to Be True, CONSUMER REPS. (2013), https://www.consumerreports.org/cro/magazine/2013/11/health-claims-too-good-to-be-true/index.htm [https://perma.cc/HMY6-AP4J] (range of products); C. E. Evans, Letter, Modern Snake Oil, 24 CANADIAN FAM. PHYSICIAN 644, 644 (1978) (education services); Kristen Houghton, A Snake Oil Salesman Alive and Well in Dr. Oz, HUFFPOST (June 30, 2014, 5:19 PM), https://www.huffingtonpost.com/kristen-houghton/snakeoil-salesman-alive-a\_b\_5537666.html [https://perma.cc/Y8XJ-SGPF] (lifestyle); Dani Rodrik, Economics: Science, Craft, or Snake Oil?, INST. FOR ADVANCED STUDY: INST. LETTER, Fall 2013, at 1, 14–15, https://www.ias.edu/sites/default/files/documents/publications/IL\_FALL2013\_FINAL.pdf [https://perma.cc/3X73-UUDB] (political theory); Amie Parnes, President Obama Slams Romney, Ryan Tax Plans as 'Trickle-Down Snake Oil,' HILL (Aug. 15, 2012, 7:23 PM), http://thehill.com/homenews/campaign/243857-obama-slams-romney-ryan-tax-plans-as-trickle-down-snake-oil [https://perma.cc/T8P8-68KK] (political theory).

<sup>3.</sup> See Jim Edwards, Lesson from Pfizer: Don't Describe Your Product as "Snake Oil" in Internal Email, CBS MONEYWATCH (Mar. 26, 2010, 12:05 PM), https://www.cbsnews.com/news/lesson-from-pfizer-dont-describe-your-product-as-snake-oil-in-internal-email/ [https://perma.cc/P456-HU V4].

<sup>4.</sup> Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980). This Article therefore disagrees with Fred Schauer's assessment that "surprisingly little of the free speech tradition is addressed directly to the question of the relationship between a regime of freedom of speech and the goal of increasing public knowledge of facts or decreasing public belief in false factual propositions." Frederick Schauer, *Facts and the First Amendment*, 57 UCLA L. REV. 897, 902 (2010) [hereinafter Schauer, *Facts and the First Amendment*].

<sup>5.</sup> See, e.g., Paul Horwitz, The First Amendment's Epistemological Problem, 87 WASH. L. REV. 445, 467–70 (2012) (carefully laying out the unsettled epistemological role of the First Amendment but treating all statement of facts as a single category). The closest might be Justice Breyer's distinction between "easily verifiable facts" and "false statements about philosophy, religion, history, the social sciences, the arts, and the like." United States v. Alvarez, 567 U.S. 709, 731 (2012) (Breyer, J., concurring). Helen Norton adopts Justice Breyer's distinction in arguing that falsehoods about "objectively verifiable facts" should receive lighter constitutional scrutiny. Helen Norton, Lies and the Constitution, 2012 SUP. CT. REV. 161, 200–01 [hereinafter Norton, Lies and the Constitution]. But some scholars claim that scientific speech is in fact the easiest speech to evaluate. See, e.g., FREDERICK SCHAUER, FREE SPEECH: A PHILOSOPHICAL ENQUIRY 30–33 (1982); Christopher P.

Accepted knowledge, whether it pertains to highly specific facts that rely on instruments of measurement (like the temperature of a room) or to more general claims like Einstein's theory of relativity, can be verified using a high standard of evidence. These claims are verifiable and valid to the relevant community of experts. Although accepted knowledge is fallible, little is lost and much is gained when the law treats these claims as "true" (and their opposites as "false").

Contested knowledge, by contrast, is known to be presently unverifiable and subject to debate and speculation by the relevant expert community. A contested claim will assert a hypothesis that may be substantiated by empirical evidence, but not enough to have itself accepted as irrefutable. The accumulation of evidence around some general claims that have become accepted knowledge, like Einstein's theory of relativity or the theory of global warming, tends to obscure the fact that most of the scientific claims that are relevant to consumers and voters are tentative and have an insufficient base of evidence to deem them either true or false.

First Amendment doctrine has fastidiously denied the importance of contested factual claims. We see the consequences of this oversight by observing the effects on First Amendment case law as a whole. A true/false dichotomy that fails to account for contested claims is bound to be incoherent and pretentious. Low standards for "truth" will hamstring government efforts to support public safety, but high standards screen out most of the available information. Free speech law has not wrestled with the problems of a falsity approach to junk science. Instead, the First Amendment jealously guards public discourse against nearly all government intrusion no matter how noxious the claims, but permits the

Guzelian, *True and False Speech*, 51 B.C. L. REV. 669, 696–700 (2010). But note that in later work, Schauer uses a seemingly narrower category of "demonstrable facts." Schauer, *Facts and the First Amendment*, *supra* note 4.

<sup>6.</sup> This is sometimes referred to as "scientific speech" in First Amendment cases. *E.g.*, United States v. Harkonen, No. C 08-00164 MHP, 2010 WL 2985257, at \*15 (N.D. Cal. July 27, 2010); *cf.* Reilly v. Pinkus, 338 U.S. 269, 273–74 (1949) (discussing speech about "medical practices in fields where knowledge has not yet been crystallized in the crucible of experience"). Scientific speech has not been recognized as a speech category with unique properties and protections. "To ask what constitutional constraints should apply to government regulations of 'scientific speech' presupposes that there is something called 'scientific speech' that merits distinctive constitutional treatment. There is no such discrete constitutional category of 'scientific speech.'" Robert Post, *Constitutional Restraints on the Regulations of Scientific Speech and Scientific Research: Commentary on "Democracy, Individual Rights and the Regulation of Science*," 15 Sci. Engineering Ethics 431, 431 (2009).

<sup>7.</sup> See David Strauss, Persuasion, Autonomy, and Freedom of Expression, 91 COLUM. L. REV. 334, 366 (1991) ("If the category of false statements of fact is not defined very narrowly, it can, of course, become highly problematic.").

government to define scientific truth however it likes for commercial and professional speakers. The result is a hodgepodge of constitutional rules explained (but not entirely justified) by speaker type.<sup>8</sup>

But the quiet chaos of the falsity doctrine has started to break out into noisy protests, both from corporate and commercial speakers and from public outcry against "fake news." Moreover, as courts have come to appreciate the uncertainty in scientific discovery, they are increasingly skeptical of truth as an organizing principle for factual claims because it invites the government to settle live debates, to deny ambiguities in the evidence, and to foster public confidence where it may not be warranted. And it is a recipe for embarrassment and perceived hypocrisy when the government must retract previous truths.

The history of the lowly egg provides one example. For much of American history, eggs were regarded as a wholesome food staple. But their good standing withered in the 1960s when cholesterol was linked to cardiovascular disease. To counteract plummeting demand, the egg industry launched a campaign claiming that there was "no competent and reliable scientific evidence that eating eggs, even in quantity, increases the risk of heart attacks" and that competent studies suggested the opposite—that "avoiding dietary cholesterol, including that in eggs, increases the risk of heart disease."<sup>11</sup>

The Federal Trade Commission (FTC) disagreed. It alleged that the egg industry violated the unfair and deceptive practices clause of the FTC Act because "[i]n truth and in fact, . . . [t]here is competent and reliable scientific evidence that eating eggs does increase the risk of heart attacks." The Seventh Circuit partially ratified the Commission's findings, <sup>13</sup> and ads like this were permanently enjoined:

<sup>8.</sup> See infra Part II for a full account.

<sup>9.</sup> See Mark Verstraete, Derek E. Bambauer & Jane R. Bambauer, Identifying and Countering Fake News, 2 ARIZ. L.J. EMERGING TECHS. (forthcoming 2018), https://law.arizona.edu/sites/default/files/asset/document/fakenewsfinal\_0.pdf [https://perma.cc/ WV2H-93ZR]; Niraj Chokshi, How to Fight 'Fake News' (Warning: It Isn't Easy), N.Y. TIMES (Sept. 18, 2017), https://www.nytimes.com/2017/09/18/business/media/fight-fake-news.html?\_=0 [https://perma.cc/3V3S-XXS6].

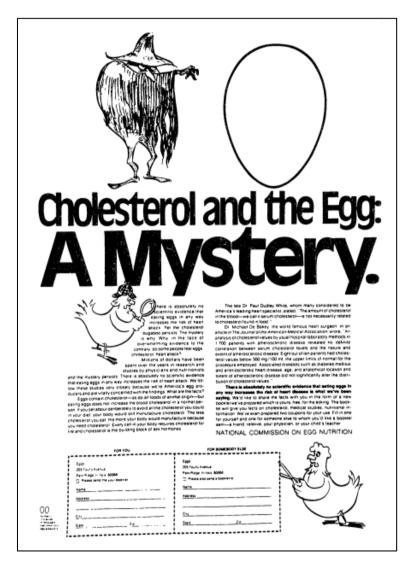
<sup>10.</sup> See Alvarez, 567 U.S. at 752 ("[I]t is perilous to permit the state to be the arbiter of truth."). Before the Roberts Court, First Amendment precedent more or less permitted the government to retain the power to determine whether specific statements are true or false. See Mark Tushnet, "Telling Me Lies": The Constitutionality of Regulating False Statements of Fact 22 (Harvard Law Sch. Pub. Law & Legal Theory Working Paper Series, Working Paper No. 11-02, 2011), https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1737930 [https://perma.cc/CC79-7DL6]. But this, too, is changing. See the discussion of the POM Wonderful case in Infra section II.E.

<sup>11.</sup> In re Nat'l Comm'n on Egg Nutrition, 88 F.T.C. 89, 95–96 (1976), enforced in part, Nat'l Comm'n on Egg Nutrition v. FTC, 570 F.2d 157 (7th Cir. 1977).

<sup>12.</sup> Id.

<sup>13.</sup> Nat'l Comm'n on Egg Nutrition v. FTC, 570 F.2d at 159.

Figure 2: National Commission on Egg Nutrition Advertisement<sup>14</sup>



At the time, the FTC's position reflected a widely shared understanding in the public health community. The majority of published health studies

<sup>14.</sup> In re Nat'l Comm'n on Egg Nutrition, 88 F.T.C. at 91.

and the conclusions drawn from them by health experts conflicted with the claims made in the egg industry ads. <sup>15</sup> Worse still, the egg industry's ads seemed to serve the interests of the egg industry at the expense of the consumer's health. This was an easy case of deception.

The trouble is, self-interested as they were, the egg industry's claims now appear to be more correct than the FTC's. The FTC had been relying on an assumption (which it called a "fact" in its briefing) that high cholesterol foods cause high levels of cholesterol in the bloodstream.<sup>16</sup> The ads challenged this assumption, pointing out that the link was an extrapolation with little supporting evidence. Indeed, the link between dietary and blood stream cholesterol has been fairly well falsified in the intervening decades.<sup>17</sup> Health experts and the FTC had been thrown off by a few poorly designed observational studies finding an association between eggs and cardiovascular disease without controlling for confounding factors like smoking, poor physical fitness, and the consumption of red meats (which egg-eaters seem to have a greater propensity to do). 18 Subsequent studies failed to produce any causal relationship between eating high-cholesterol foods and having high cholesterol, and many organizations including the American Heart Association, the Harvard School of Public Health, and the 2015 U.S. Dietary Guidelines are now reviving the egg's bedraggled reputation.<sup>19</sup>

It may be tempting to brush off this example as unrepresentative of the typical problems caused by unsubstantiated advertising. Perhaps, some would argue, selenium is a more apt example. Selenium is a supplement that had been promoted for treating prostate cancer based on early clinical

<sup>15.</sup> Nat'l Comm'n on Egg Nutrition v. FTC, 570 F.2d at 160-61.

<sup>16.</sup> See In re Nat'l Comm'n on Egg Nutrition, 88 F.T.C. at 95.

<sup>17.</sup> The majority of studies with reliable data have found no association between egg consumption and risks of heart attack or stroke. See Ying Rong et al., Egg Consumption and Risk of Coronary Heart Disease and Stroke: Dose-Response Meta-Analysis of Prospective Cohort Studies, BMJ, Jan. 7, 2013, at 5. Note that many studies found that the consumption of eggs appears to have an adverse effect on some subpopulations of Americans with health problems, including diabetics. Id. Also, the authors used the Begg & Egger regression test to check for publication bias. Id. at 3. They reported this fact without comment, but the delightful serendipity of these names was too great for me to do the same.

<sup>18.</sup> *Id.* at 4 (citing Frank B. Hu et al., *A Prospective Study of Egg Consumption and Risk of Cardiovascular Disease in Men and Women*, 281 JAMA 1387 (1999)); *see also* Larry Husten, *Stop Trashing Eggs: Large Study Finds No Harm*, FORBES (Jan. 15, 2013, 12:41 PM), https://www.forbes.com/sites/larryhusten/2013/01/15/large-meta-analysis-finds-no-harm-associated-with-eggs/#17d890ab307d [https://perma.cc/Z4RG-VYJA].

<sup>19.</sup> Eggs, HARV. T.H. CHAN SCH. PUB. HEALTH, http://www.hsph.harvard.edu/nutritionsource/eggs/ [https://perma.cc/CUS2-Q5P2]; Ben Tinker, Cholesterol in Food Not a Concern, New Report Says, CNN (Feb. 19, 2015, 7:18 PM), http://www.cnn.com/2015/02/19/health/dietary-guidelines/index.html [https://perma.cc/7E5S-8X4N].

results even after later, more robust evidence suggested that selenium not only fails to reduce cancer patients' risk of death but actually increases it.<sup>20</sup> For every egg case, there may be several selenium cases. Wouldn't it be better to let consumer protection and public health agencies punish the occasional, coincidental truth than to permit companies to pollute the consumer information environment?

This is, in a nutshell, the position taken by the majority of legal scholars who have written on the issue.<sup>21</sup> But the argument overlooks real problems in the specific case of eggs and the general case of a truth-centered speech doctrine. The problems, briefly, are the following: (1) government standards for falsity do not reliably sort good and bad information; and (2) in any case, falsity is a poor proxy for harm.

First, the problems with sorting good and bad factual information. Scientific debates have a volatile relationship with factual truth where the evidentiary record is thin or mixed (which is to say, most of the time). In areas with contested knowledge—and nutrition and health is dominated by them—weakly supported factual claims are as good as it gets. And weakly supported factual claims are often better for consumers than the alternative messages that will be used in advertising. They induce curiosity and salience, and spur attempts by competitors and other organizations to falsify the claims. Statements running against a robust record of evidence (contradicting accepted knowledge) can safely be

<sup>20.</sup> Pam Harrison, *More Evidence of Harm from Selenium in Prostate Cancer*, MEDSCAPE (Jan. 8, 2015), https://www.medscape.com/viewarticle/837761 [perma.cc/6T5S-83WW].

<sup>21.</sup> See Susan Crawford, First Amendment Common Sense, 127 HARV. L. REV. 2343, 2344-45 (making a similar institutional competence argument in the context of regulating internet service providers); Stephanie M. Greene & Lars Noah, Debate, Off-Label Drug Promotion and the First Amendment, 162 U. PA. L. REV. ONLINE 239, 255-56 (2014); Aaron S. Kesselheim & Michelle M. Mello, Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection, 92 N.C. L. REV. 1539, 1585-89 (2014); Chris Robertson, When Truth Cannot Be Presumed, 94 B.U. L. REV. 545, 551 (2014) ("One might see the FDCA regime as a reasonable compromise between the competing needs for FDA to regulate the safety and efficacy of drugs at the threshold when they come onto the market, while also allowing physicians and their patients a measure of discretion to try drugs for new indications that are not yet proven effective."). Rebecca Tushnet has gone further still, arguing that fact-finders of every sort (federal agencies, juries, state legislatures) should be able to decide which statements are false because although they "make mistakes about what is false, those costs are similar to the harms of other mistaken economic policies. We are better off overall in a system that regulates false and misleading commercial speech without heightened First Amendment scrutiny." Rebecca Tushnet, It Depends on What the Meaning of "False" Is: Falsity and Misleadingness in Commercial Speech Doctrine, 41 LOY. L.A. L. REV. 227, 229 (2007) [hereinafter Tushnet, It Depends on What the Meaning of "False" Is]. But see Jennifer L. Herbst, Off-Label 'Promotion' May Not Be Merely Commercial Speech, 88 TEMPLE L. REV. 43, 48 (2015); Mark Spottswood, Falsity, Insincerity, and the Freedom of Expression, 16 WM. & MARY BILL RTS. J. 1203, 1204-06 (2008) (arguing that all falsehoods spoken with sincere belief should be protected).

treated as false facts by the government without doing great damage to open inquiry,<sup>22</sup> but regulators penalize and ban contested knowledge without sufficient appreciation for the consequences to the information ecosystem.

The egg case illustrates the problem. The pro-egg advertisements may have contradicted the popular advice of the American Heart Association and other public health groups, but the egg industry correctly described the state of the cholesterol debate: there was not much evidence against the egg (nor for it, for that matter), and no expert consensus had formed.<sup>23</sup> When the state of evidence on an issue is in disarray, allowing the fight to spill into the advertising arena can promote evidence-based consumer decisions. At the very least, the freedom of debate has the virtue of creating salience and demand for more research.

The second set of problems concern harm. Regulators who target pseudoscientific claims use falsity (or lack of substantiation) as a proxy for risk. But under conditions of uncertainty, the probability that a statement is false is only part of the risk analysis. It also requires regulators to compare the likely consequences if the statement is false to the consequences of censorship if it later proves to be true.<sup>24</sup> This cannot be estimated with precision, but an attempt must be made.<sup>25</sup> Without constitutional bumpers, regulators tend to look myopically at only the chance of falsity and ignore the comparative risks of screening out truth versus failing to screen out falsity.<sup>26</sup> These risks are often asymmetric.

Again, the egg case is instructive. The FTC was understandably nervous about letting the egg industry coax consumers back into purchasing more eggs when public health experts feared they could increase the risk of heart attack, but it spent no energy considering the health risks that could result from *dissuading* egg purchases. If it had tried to learn a little about the consumption patterns of egg-eaters, the FTC may have anticipated that the marginal consumer who is turned off from a

<sup>22.</sup> Although this alone will not necessarily justify regulation. See discussion infra Part I.

<sup>23.</sup> Indeed, scientific texts on heart disease from the 1970s acknowledged that "the relationship of diet to prevention is not yet proven." See Wm. Alex McIntosh, The Symbolization of Eggs in American Culture: A Sociologic Analysis, 19 J. Am. C. NUTRITION 532S, 536S tbl.3 (2013) (quoting O.E. BYRD & T.R. BYRD, MEDICAL READINGS ON THE HEART (1973)).

<sup>24.</sup> Where chances draw Bayesian inferences from the available evidence.

<sup>25.</sup> Among the relevant variables are the likelihood that the statement is true, the likelihood that the statement will induce the listener to act in a certain way, and the scale of harm or benefit if they do

<sup>26.</sup> See infra Part I.

carton of eggs would choose a clearly worse substitute like beef or pork.<sup>27</sup> Not only would egg consumers be better off if eggs turned out to be as harmless as the industry claimed, but hearing the claims may have made consumers better off even if the egg industry's claims were false.<sup>28</sup>

The specter of returning to the era of the snake oil salesman has pushed the government to place rote rules of scientific substantiation over the practical effects on consumers. But even snake oil is unfairly maligned. The oils made from Chinese water snakes that were used in liniments in the nineteenth century actually did reduce inflammation.<sup>29</sup> Compared to the drivel that passed for medicine at the turn of the twentieth century,<sup>30</sup> snake oil was legitimately promising. (Compare, for example, the doctor's orders that Marcel Proust followed for his treatment of severe asthma, which consisted mostly of smoking.<sup>31</sup>)

When federal investigators shut down the production of Stanley's Snake Oil in 1917, they did so because Stanley's Snake Oil did not actually contain any snake oil. Its labeling and promotion contained a verifiably false claim about contents.<sup>32</sup> It is ironic, given snake oil's genuine medicinal advantages over other patent medicines of the day, that the episode is remembered as a valuable clearing-out of false therapeutic claims.<sup>33</sup>

Commercial speech is not the only area of First Amendment jurisprudence that suffers from a truth orientation. Factual claims in the

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<sup>27.</sup> Note, though, that the link between saturated fat and heart disease is also not terribly well supported. Nina Teicholz, *The Questionable Link Between Saturated Fats and Heart Disease*, WALL ST. J. (May 6, 2014, 10:25 AM), https://www.wsj.com/articles/the-questionable-link-between-saturated-fat-and-heart-disease-1399070926 [https://perma.cc/89SW-SYNJ].

<sup>28.</sup> Moreover, it is entirely possible that the egg industry's ads refuting the theory that dietary cholesterol causes heart disease *reduced* egg consumption rather than increasing it by directing attention to a debate that scared consumers. *See generally* McIntosh, *supra* note 23.

<sup>29.</sup> Lakshmi Gandhi, *A History of 'Snake Oil Salesmen*,' NPR (Aug. 26, 2013, 11:55 AM), https://www.npr.org/sections/codeswitch/2013/08/26/215761377/a-history-of-snake-oil-salesmen [https://perma.cc/F6WZ-JJ3T].

<sup>30.</sup> See STEVEN BRILL, AMERICA'S BITTER PILL 19–20 (2015) (describing the primitive state of hospital care in the early twentieth century).

<sup>31.</sup> Mark Jackson, "Divine Stramonium": The Rise and Fall of Smoking for Asthma, 54 MED. HIST. 171, 171–72 (2010).

<sup>32.</sup> Prosecutions for false claims that are relatively simple to invalidate protect "consumers' interest in getting what they paid for." Rebecca Tushnet, *Fighting Freestyle: The First Amendment, Fairness, and Corporate Reputation*, 50 B.C. L. REV. 1457, 1463 (2009) [hereinafter Tushnet, *Fighting Freestyle*].

<sup>33.</sup> The federal complaint alleged that Stanley misbranded his oil by "falsely and fraudulently represent[ing] it as a remedy for all pain," but the investigation was prompted by an analysis of the oil itself, which found that the product was made mostly from mineral oil and a few other substances, none of which were snake oil. Gandhi, *supra* note 29.

public discourse are given too much protection out of fear that the claim may have a tiny chance of turning out to be correct someday. Courts have effectively immunized even unqualified claims that contradict accepted knowledge and have a high chance of causing foreseeable harm unless they fall into traditionally exempted categories like fraud or defamation.<sup>34</sup> While courts deserve credit for recognizing the dangers of censoring debates in the public sphere, these concerns have blinded courts to regulatory solutions that sound in risk. If claims that are very likely to be false are also likely to cause harm, the state can intervene on behalf of public safety without imposing a singular and authoritative definition of truth.<sup>35</sup>

This Article takes a system-wide look at the First Amendment treatment of contested factual claims and lays the groundwork to moor free speech theory to concrete harm. The shift requires reversal of some of the precedents that had minimized the importance of epistemic uncertainty for commercial speakers and essentialized it for public speakers. But these are necessary corrections. The more enduring trend in free speech analysis is one that allows government restrictions on speech when (and only when) the government has credible proof of harm.<sup>36</sup>

The Article proceeds in four parts. Part I clarifies the scope of the project and defines sets and subsets of factual claims that will be used throughout the Article. Part II describes how free speech law protects contested knowledge today, and how those protections depend in large part on the type of speaker. Part III addresses the flaws in an obsessively truth-oriented approach to free speech, particularly with respect to the most and least protected speakers—the press and commercial speakers, respectively. Finally, Part IV anticipates where the law is headed. It uses a risk-oriented approach to show that government regulation can expand in the public discourse but must be reined in, to some extent, in the commercial speech doctrine.

<sup>34.</sup> See discussions infra sections II.A, II.B, and III.B.

<sup>35.</sup> Defamation and fraud laws provide a roadmap, combining a likelihood of falsity with negative consequences to a subject or listener. RESTATEMENT (SECOND) OF TORTS § 162 (AM. LAW INST. 1965) (defining fraudulent misstatements); RESTATEMENT (SECOND) OF TORTS § 559 (AM. LAW INST. 1977) (defining defamatory communications).

<sup>36.</sup> See generally Joseph Russomanno, Cause and Effect: The Free Speech Transformation as Scientific Revolution, 20 COMM. L. & POL'Y 213 (2015) (documenting a history of growing skepticism for the harms the government claims the speech will cause).

#### I. FACTUAL CLAIMS

This Part will mark the parameters of the Article. It defines the category of speech that consists of factual claims, and further subdivides this category into subcategories that have important legal implications. The definitions I provide here will not fully satisfy philosophers of science, but they will be precise enough to be serviceable.

First, free speech law already makes a distinction between factual and non-factual statements. Factual claims are falsifiable. They can theoretically, at least, be compared to objective reality.<sup>37</sup> Non-factual speech includes political ideologies, moral philosophies, artistic expression, opinions about subjective subjects, and nonsense that asserts no claims about the observable world and therefore cannot be proven false.

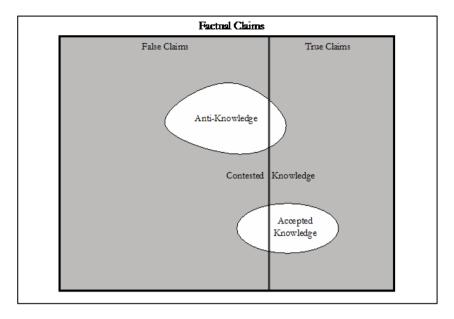
Dividing the domains of the factual and nonfactual sometimes depends on context and linguistics. For example, consider the question, "when does human life begin?" A response to this question will depend very much on what the question-poser means by the word "life." If life is determined based on spiritual or moral considerations, answers will be nonfactual claims. If life is defined as the point in fetal development at which the fetus is more than 50% likely to have the pain receptors and memory necessary to experience pain, answers will be factual claims. Even if we do not currently have the relevant empirical evidence, there is an answer, however inaccessible.<sup>38</sup> Courts may occasionally err when categorizing statements as fact or opinion,<sup>39</sup> but the distinction is frequently used in First Amendment law.

<sup>37.</sup> I should note that by recognizing the difference between fact and opinion, I am embracing the notion that an objective reality exists. This is controversial in some circles; Nietzsche, for example, thought that all human conceptions are "only an interpretation and arrangement of the world (according to our own requirements, if I may say so!)—and not an explanation of the world." FRIEDRICH NIETZSCHE, BEYOND GOOD AND EVIL (W. Kaufmann trans., 1996) (1886). But courts and lawmakers have rejected strong forms of relativism.

<sup>38.</sup> For an excellent account of the relationship between legal, scientific, and religious debates and how policy debates are converted into empirical questions, see David Faigman, *Where Law and Science (and Religion?) Meet*, 93 TEX. L. REV. 1659 (2015).

<sup>39.</sup> For example, I believe the Supreme Court miscategorized the statements leading to defamation liability in *Bose Corp. v. Consumers Union*, 466 U.S. 485 (1984) (upholding the district court's conclusion that the phrase "individual instruments heard through the Bose system seemed to grow to gigantic proportions and tended to wander about the room" was a factual claim).

Figure 3: Diagram of Factual Claims



Within the vast and diverse universe of factual claims, there are a few critical subcategories. First, there is accepted knowledge, which is comprised of factual propositions that are believed to be correct based on some epistemological standard. This is what we believe we know. As shown in Figure 1, not all accepted knowledge is true. Statements that fall into the accepted knowledge category might not be true because the epistemological standard may be premised on an overlooked assumption that turns out to be wrong, or because the standard has, by necessity, a little bit of tolerance for error. But statements that are part of accepted knowledge are supported by enough observations and credible evidence to clear the high bar established by the relevant experts and standardbearers. As long as accepted knowledge is well defined, the category of anti-knowledge can also be used. Anti-knowledge includes statements that are in direct conflict with the statements contained in accepted knowledge. If knowledge is the functional proxy for truth, then anti-knowledge is the functional proxy for falsehoods. These are the sets of claims that have been proven, based on prevailing scientific standards, to be incorrect.

Determining what should fall inside and outside the subcategory of accepted knowledge is an act with well-known hazards. 40 If public law is going to use the category of accepted knowledge to determine the truth of a statement, it will invariably have to rely on experts to define and apply the standards. And those experts may have culturally or politically induced blind spots and are also susceptible to self-interested biases, particularly if their status as experts is put at risk. Thus, because there will always be disagreement about how knowledge should be defined, the outer edges of the accepted knowledge category will be jittery. Nevertheless, even if there is no timeless and universally accepted standard for determining knowledge, even people who disagree on the standards can agree that much of what makes up scientific discussion and debate falls outside of both the accepted knowledge and anti-knowledge circles, no matter how they are defined.

That leaves the residual—contested knowledge. It forms a wide terrain of claims that may have some evidence in support, and perhaps some evidence in conflict, but not enough of either sort to conclusively place the statement into the accepted knowledge or anti-knowledge buckets. <sup>41</sup> This is the fog of science, and it is where our current set of constitutional rules tends to falter by using a true/false dichotomy.

This is not to suggest that contested claims have equal chances of becoming accepted knowledge. Statements in this category can be moreor less-well supported, and people may rationally rely on the better supported statements even if they do not meet the high standards for knowledge, and may reject baseless speculation until some evidence is produced. <sup>42</sup> The chances that contested claims are correct, given current

<sup>40.</sup> See THOMAS KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 77–91 (2012). Note that throughout this Article, I analyze the application of law to contested claims assuming that the evidence that may accumulate for those claims are part of the uncontroversial process of "normal science." Id. at 10. The recommendations from this Article may also apply to claims that so challenge accepted knowledge that they would require a paradigm shift, but it would require more analysis to be sure. For one thing, claims that demand a paradigm shift usually mount their attack from the "anti-knowledge" category of speech (the functional equivalent of false speech), and thus will have trouble receiving a hearing not only from the scientific community but also from the courts.

<sup>41.</sup> For example, in climate science, the statement that the earth's temperature is steadily warming, and that humans have contributed to the rate of warming, will usually be categorized as established *knowledge*. Denials of these claims are therefore *anti-knowledge*. But there is conflicting evidence and bona fide debate about the rate and acceleration of warming, so reasonable estimates of these figures fall outside all of the subcategories of *knowledge*, *anti-knowledge*, and *baseless claims*.

<sup>42.</sup> Claims can vary both by the quality of the methodology and the quality of the execution of the study. I embrace the hierarchy of methodology that the scientific community currently uses, with randomized experiments at the top, natural experiments and instrumental variables next, followed by well-controlled regressions, and uncontrolled time series, graphs, and statistics last. John J. Donohue,

evidence, will vary widely. The only thing that these claims have in common is that we currently lack the empirical power to confidently count them as accepted knowledge or anti-knowledge.<sup>43</sup>

Because there is wide variation in the quality of contested claims, the opportunity for havoc is both obvious and alarming. Poorly supported claims can grow a disproportionate amount of attention and can steer people into making bad decisions. As John Donohue has put it, "[w]hat the scholarly review . . . properly deemed to be an absence of evidence can appear in the hands of advocates and the press to be overwhelming econometric support." Clearly the First Amendment should not shield all weakly supported factual claims from regulation. But treating claims in this category as either true or false, as courts and other regulators often do, is a disservice to sustainable speech law.

The next Part describes how factual claims, particularly those falling within the contested-knowledge category, are protected by the First Amendment today. Free speech protection relies heavily on the type of speaker and a true/false dichotomy. Later Parts will argue that for restrictions on pure speech, falsity should annul First Amendment protection only for *anti-knowledge*. For partially substantiated claims (which are related to, but not the same as, insufficiently substantiated claims), speech interests should be balanced against.

#### II. PROTECTION TODAY

Free speech doctrine has long permitted courts and other regulators, fallible as they are, to determine the truth and falsity of a speaker's statements. In some contexts, such as fraud, the falsity of a statement simultaneously fulfills an element of the charge and helps remove the charge from the ambit of First Amendment protection. But fraud, deceit, and other conscious lies are the easy cases for a falsity approach to speech. When speakers do not actually believe the statements they make, the

Empirical Evaluation of Law: The Dream and the Nightmare, 17 Am. L. & Econ. Rev. 313, 324 (2015).

<sup>43.</sup> Two related concepts from statistics provide a helpful metaphor here: power and confidence. In statistical studies, a large number of observations will increase the power of a hypothesis test—it will make it more likely that a false null hypothesis is rejected. By analogy, a large number of empirical studies and replication efforts, or a smaller number of more methodologically strong studies, can make a factual claim increasingly credible, particularly if the evidence converges on a consistent answer.

<sup>44.</sup> Donohue, supra note 42, at 334.

state's determination that the statements are "false" does not pose serious intellectual impositions on the speaker.<sup>45</sup>

Courts tread more lightly when a speaker lacks specific intent to deceive the audience, which is typically the case for contested claims. Constitutional constraints on the law of defamation, for example, permit recovery against a speaker who makes negligent statements only in certain narrow conditions.<sup>46</sup>

This Part explains how First Amendment law currently applies to contested knowledge. Courts draw strong First Amendment distinctions based not only on the potential falsity of the speech, but on the type of speaker making the claim. For the most part, the current approach has an internal logic. Courts use speaker type as a stand in for a set of factors that have a rational connection to the likelihood that a listener will act on the claim without further deliberation.

The players in the Constitutional drama are the *press*, the *politician*, the *peer*, the *protector*, the *peddler*, and the *public authority*. This Part will explore the free speech case law applying to each.

# A. The Press

The press consists of all speakers who offer a noncommercial message for wide distribution.<sup>47</sup> There is a popular misconception that Fox News successfully won a legal "right to lie" in a 1990s case involving reporting about dairy farms.<sup>48</sup> Although that folk legal analysis is not correct, it is

<sup>45.</sup> The regulation of lies may contravene the constitution or be a very bad idea for other reasons unrelated to the determination of falsity, though. See Alan Chen & Justin Marceau, High Value Lies, Ugly Truths, and the First Amendment, 68 VAND. L. REV. 1435 (2015); Spottswood, supra note 21; Strauss, supra note 7 (on the importance of sincerity). My more limited point here is that within the category of factual claims, it is less problematic to categorize a knowing lie as a false statement than other claims made in good faith.

<sup>46.</sup> *E.g.*, Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749 (1985); Gertz v. Robert Welch, Inc., 418 U.S. 323 (1974). The Article does not engage with the interesting question of when a technically true statement may be misleading and therefore treated as false. For more on that, see Seana Valentine Shiffrin, *Deceptive Advertising and Taking Responsibility for Others, in* THE OXFORD HANDBOOK OF FOOD ETHICS 470 (Anne Barnhill et al. eds., 2018); Tushnet, *It Depends on What the Meaning of "False" Is, supra* note 21.

<sup>47.</sup> Speakers who may be peers, protectors, or peddlers in other contexts will be treated as press speakers when their non-commercial message is made as a contribution to public discourse. This of course puts quite a lot of pressure on courts to define what a "commercial message" and "public discourse" are.

<sup>48.</sup> *Did Fox News Sue for the 'Right to Lie'*?, SNOPES (Oct. 2, 2014), http://www.snopes.com/politics/business/foxlies.asp [https://perma.cc/H97D-LNLA] (describing the rumors and misinterpretations of New World Comm. of Tampa, Inc. v. Akre, 866 So. 2d 1231 (Fla. Dist. Ct. App. 2003)).

undeniable that contested claims and even anti-knowledge are strongly protected from government interference when a person speaks to a broad, indiscriminate audience.<sup>49</sup> There are well-known exceptions, such as the law of defamation,<sup>50</sup> but their strict constitutional limits only underscore the strength of protection for press speech.<sup>51</sup>

Even in instances where a speaker should know that his claims have little scientific validity, where the claims, if acted on, are likely to cause harm, and where the reaction of the audience is entirely foreseeable, First Amendment case law immunizes the speaker from government intervention. Public speakers have no duty to ensure that factual claims are accurate or well supported by the evidentiary record available at the time. This is the rule that permits the Atkins Diet book and website to continue promoting an aggressively low carbohydrate diet despite evidence that the fats and proteins taking their place seem to pose greater risks of illness and death.<sup>52</sup> It is the rule that protected a publisher from liability when a nursing school textbook gave improper instructions for the use of an enema, causing injury to a student who tried the technique on herself.<sup>53</sup> In the most famous case along these lines—Winter v. G.P. Putnam's Sons<sup>54</sup>—the rule protected the publisher of an encyclopedia of mushrooms that assured readers a particular type of mushroom was safe to eat when in fact it was toxic. 55 And it is the rule that protects celebrities, pundits, and us all when we make a wide range of pseudoscientific statements in traditional and social media.<sup>56</sup>

<sup>49.</sup> NAACP v. Button, 371 U.S. 415, 445 (1963) ("[T]he Constitution protects expression and association without regard . . . to the truth, popularity, or social utility of the ideas and beliefs which are offered.").

<sup>50.</sup> See Gertz, 418 U.S. at 340.

<sup>51.</sup> A public figure must prove actual knowledge on the part of the speaker that the defamatory statement was false. N.Y. Times Co. v. Sullivan, 376 U.S. 254, 279–80 (1964). Moreover, courts will not assume that every factually verifiable statement is likely to be taken seriously enough to constitute defamatory speech. Hustler v. Falwell, 485 U.S. 46, 57 (1988).

<sup>52.</sup> Gorran v. Atkins Nutritionals, Inc., 464 F. Supp. 2d 315, 326–28 (S.D.N.Y. 2006), aff'd, 279 F. App'x 40 (2d Cir. 2008).

<sup>53.</sup> Jones v. J.B. Lippincott Co., 694 F. Supp. 1216, 1216–18 (D. Md. 1988).

<sup>54. 938</sup> F.2d 1033 (9th Cir. 1991). The contents of books were not suitable subjects for product liability claims. *Id.* at 1034–36.

<sup>55.</sup> Id. at 1037-38.

<sup>56.</sup> For example, the movie *Vaxxed* contained a number of dubious claims about the risks of vaccination. Ariana E. Cha, *7 Things About Vaccines and Autism that the Movie 'Vaxxed' Won't Tell You*, WASH. POST (May 25, 2016), https://www.washingtonpost.com/news/to-your-health/wp/2016/05/25/7-things-about-vaccines-and-autism-that-the-movie-vaxxed-wont-tell-you/?utm\_term=.cb7d0a0c671f [https://perma.cc/M46K-B73J].

Liability for dubious scientific claims made in public discourse has been tested over and over, always with the same constitutional result: the speakers and publishers win.<sup>57</sup> Courts nestle their analysis in the rhetoric of the Marketplace of Ideas.<sup>58</sup> That conceit was practically made for scientific debate, where competing claims use increasingly elaborate proof to vie for the beliefs of experts and laymen alike.<sup>59</sup> As with defamation, the First Amendment must leave "breathing space" for falsehoods made in the course of public discussion because the alternative would raise the cost of discourse and inquiry and could chill a good deal of true speech.<sup>60</sup>

These principles are so fixed in American legal culture that the First Amendment does not often have to be pushed into service. Liability for false factual claims frequently fails within the prima facie case. In tort law, plaintiffs lose the duty and causation elements when they are injured

<sup>57.</sup> See McMillan v. Togus Reg'l Office, Dep't of Veterans Affairs, 120 F. App'x 849 (2d Cir. 2005) (incorrect statements about Agent Orange in National Academy of Sciences publication); Barden v. HarperCollins Publishers, Inc., 863 F. Supp. 41 (D. Mass. 1994) (false qualifications of attorneys listed in book about civil remedies for victims of child abuse); Jones v. J.B. Lippincott Co., 694 F. Supp. 1216 (D. Md. 1988) (poor advice about the treatment of constipation in nursing textbook); Pittman v. Dow Jones & Co., 662 F. Supp. 921 (E.D. La. 1987) (published fraudulent advertisements of third party bank); Lewin v. McCreight, 655 F. Supp. 282 (E.D. Mich. 1987) (published bad instructions for mixing mordant, causing an explosion); Cardozo v. True, 342 So. 2d 1053 (Fla. Dist. Ct. App. 1977) (poisonous ingredients listed in cook book recipe); Alm v. Van Nostrand Reinhold Co., 480 N.E.2d 1263 (Ill. App. Ct. 1985) (poor instructions in how-to book about tool-making that caused injuries); Gutter v. Dow Jones, Inc., 490 N.E.2d 898 (Ohio 1986) (negligent misrepresentation that certain securities were trading with interest when in fact they were trading flat).

<sup>58.</sup> See, e.g., Winter v. G.P. Putnam's Sons, 938 F.2d 1033, 1035 (1991) ("We place a high priority on the unfettered exchange of ideas.").

<sup>59.</sup> The version of the marketplace that best explains the contest of hypotheses in pursuit of scientific truth is John Stuart Mill's rather than Oliver Wendell Holmes's because the former believed disagreement promotes individuals' interest in and capacity for knowledge while Holmes's may have been more post-modern, regarding the prevailing truth as a collective, political process. Irene M. Ten Cate, Speech Truth, and Freedom: An Examination of John Stuart Mill's and Justice Oliver Wendell Holmes's Free Speech Defenses, 22 YALE J.L. & HUMAN. 35 (2010).

<sup>60.</sup> Gertz v. Robert Welch, Inc., 418 U.S. 323, 341–42 (1974); N.Y. Times Co. v. Sullivan, 376 U.S. 254, 271–72 (1964).

by their own credulity.<sup>61</sup> Fraud claims against publishers and authors often fail on the reliance element.<sup>62</sup>

Modern regulatory agencies do not have the same long tradition of constitutional avoidance. For example, in the 1990s, the Food & Drug Administration (FDA) and the public health community were caught by surprise when the FDA guidance limiting "Industry-Supported Scientific and Educational Activities" was struck down by a federal court, 63 but from a First Amendment perspective, it was an easy case. If the heirs of Dr. Atkins can engage in public debate about diet and nutrition, all the while making revenue off official Atkins Diet products and supplements, then surely a pharmaceutical company can engage in public discourse by publishing and distributing serious original research and by organizing educational symposia. 64

Given the strength of protection for the press in all its forms, one exception to the general free speech immunity stands out: technical documents. Maps that promise to provide complete and accurate topologies have been treated as defective products when inaccuracies in the map cause physical harm to a pilot.<sup>65</sup> This exception has been carefully cabined and has resisted attempts to expand it to materials like nonfiction books.<sup>66</sup> Courts have limited the exception to informational products that

<sup>61.</sup> For example, the Atkins diet case described above faltered on the element of duty. The court found that the Atkins company did not owe its subscribers a duty to refrain from negligent misrepresentation. Gorran v. Atkins Nutritionals, Inc., 464 F. Supp. 2d 315, 325 (S.D.N.Y. 2006), aff'd, 279 F. App'x 40 (2d Cir. 2008); see also Underwager v. Salter, 22 F.3d 730, 733–34 (7th Cir. 1994) (denying defamation claims brought by and against authors in a scientific debate on the grounds that all authors believe what they have said and lack the requisite mental state for common law defamation claims).

<sup>62.</sup> See, e.g., Pfau v. Mortenson, 858 F. Supp. 2d 1150, 1158–59 (D. Mont. 2012), aff'd mem., 542 F. App'x 557 (9th Cir. 2013).

<sup>63.</sup> Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997) (Guidance); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) (striking it down), *vacated in part sub nom.* Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

<sup>64.</sup> *Gorran*, 464 F. Supp. 2d at 327–28; *see also* Oxycal Labs., Inc. v. Jeffers, 909 F. Supp. 719, 722 (S.D. Cal. 1995) (limiting liability for misrepresentations to commercial advertising speech and dismissing claims brought against publishers of a book who also sold products promoted by the book); Smith v. Linn, 563 A.2d 123, 125 (Pa. Super. Ct. 1989) (negligent suit against authors of a diet book coming to the same result). Distinguishing between public discourse and commercial speech can be both difficult and highly consequential for free speech law.

<sup>65.</sup> See, e.g., Saloomey v. Jeppesen & Co., 707 F.2d 671 (2d Cir. 1983).

<sup>66.</sup> *Pfau*, 858 F. Supp. 2d at 1160–61 (finding that the publisher of two nonfiction books was immune from suit for alleged misstatements even if the misstatements were intentional despite advertising on their website that the book was "nonfiction" and "true").

are used more like instruments than intellectual fodder.<sup>67</sup> Other instruments that convey information such as blood pressure cuffs and speedometers are similarly concerned with verifiable accuracy. The exception for instruments mark the possibility that regulation might be able to expand to other forms of anti-knowledge if the rules are carefully crafted.

#### B. The Politician

Political candidates, activists, and lobbyists are a special case of the "press" category described in section A. The First Amendment protects these speakers as much as, and possibly more than, the general category of speakers who direct their comments to a wide audience. Their faulty statements, even deliberate lies, are practically untouchable.<sup>68</sup>

Political speakers merit their own treatment because the stakes are quite high. Political ignorance and influential political lies can cause policy changes with sweeping ramifications and externalities of the sort that bad diet books do not. Two explanations for this heightened protection stand out because they provide insights that will reverberate later in this Article. Moreover, although they lead to the same result, they are exact opposites.

The first explanation comes from the democratic self-government theory of the First Amendment explained and refined by Alexander Meiklejohn and Robert Post, among others.<sup>69</sup> A healthy democracy requires freedom of public discourse so that voters as agents of the political process can speak freely and make their decisions without government tampering. Yet one may fairly ask whether democratic legitimacy would increase, rather than decrease, if the government had

<sup>67.</sup> Moreover, the exception might be narrower even than the universe of technical maps because, for example, at least one state court immunized Google from negligence liability when its Google Maps application directed a pedestrian to cross a busy rural highway. Rosenberg v. Harwood, No. 100916536, 2011 WL 3153314 (Utah Dist. Ct. May 27, 2011).

<sup>68.</sup> United States v. Alvarez, 567 U.S. 709, 734 (2012) (requiring actual harm); Brown v. Hartlage, 456 U.S. 45 (1982) (requiring actual malice to regulate misstatements made during campaigns); Schauer, *Facts and the First Amendment, supra* note 4, at 898–99. The Supreme Court left open the possibility that regulations of some verifiable lies could withstand strict scrutiny as long as the government was prepared to show that the law was "actually necessary" to prevent harm. But the favored remedy for the multitude of scenarios in which proof of necessity is lacking is to encourage more speech. *Alvarez*, 567 U.S. at 729.

<sup>69.</sup> See generally ALEXANDER MEIKLEJOHN, FREE SPEECH AND ITS RELATION TO SELF-GOVERNMENT (1948); Robert Post, Reconciling Theory and Doctrine in First Amendment Jurisprudence, 88 CALIF. L. REV. 2353, 2367–71 (defining a "participatory theory" of free speech similar to Meiklejohn's but widening the scope to include the whole discursive process).

limited powers to ban falsehoods perpetuated by political movements and candidates who stand to gain from the deception.

There are some good responses consistent with the democratic self-government theory of free speech. First, ideological debates are often propelled through anecdotes and statistics that may be wrong in their specifics but nevertheless resonate with important values. The Black Lives Matter movement may be wrong about the scale of racial disparities in police shootings, and the Blue Lives Matter movement may be wrong about the trends in on-the-job fatalities of law enforcement officers, but fixating on the accuracy of specific claims misses the general, accurate assertions about racial disparity in criminal enforcement and danger in police work. It also misses the conflict in nonfactual values. Moreover, a government that can censor falsehoods can exploit that power to corrupt the political process and horde power.

The second reason to relieve political speakers from liabilities for lies is pragmatic rather than aspirational. Democracy tends to demand lying, no matter how principled or well informed the politicians are. Recent elections provide enough proof of this: Senator Ted Cruz lied about his record on immigration-related voting,<sup>74</sup> presidential candidate Carly Fiorina claimed that the number of abortions increases every year,<sup>75</sup>

<sup>70. &</sup>quot;Even irrational and abusive speech can, within particular circumstances, serve as a vehicle for the construction of democratic legitimacy." Post, *supra* note 69, at 2371.

<sup>71.</sup> Compare Roland G. Fryer, Jr., An Empirical Analysis of Racial Differences in Police Use of Force (Nat'l Bureau of Econ. Research, Working Paper No. 22,399, 2016) (finding no racial disparity in officer-involved shootings, but finding a significant disparity in other uses of force that were not explained with a large set of behavioral and circumstantial controls), with Herstory, BLACK LIVES MATTER, https://blacklivesmatter.com/about/herstory/ [perma.cc/Y9C8-HMXJ] ("Black Lives Matter is an ideological and political intervention in a world where Black lives are systematically and intentionally targeted for demise.").

<sup>72.</sup> Compare Causes of Law Enforcement Deaths, NAT'L L. ENFORCEMENT OFFICERS MEMORIAL FUND, http://www.nleomf.org/facts/officer-fatalities-data/causes.html [https://perma.cc/ A3UM-WBNM] (last updated Apr. 10, 2017), with About Blue Lives Matter, Blue Lives Matter (May 14, 2017), https://www.themaven.net/bluelivesmatter/pages/rF54b2VNMUOrl7wfh8vRXQ [https://perma.cc/4E6B-5DRR] ("Unjust attacks from the new media, celebrities and politicians have damaged community relations and endanger the lives and safety of law enforcement officers.").

<sup>73.</sup> See Jane Bambauer & Derek Bambauer, Information Libertarianism, 105 CALIF. L. REV. 335, 386–88 (2017).

<sup>74.</sup> Ilya Somin, *Ted Cruz and the Use of Deception to Exploit Political Ignorance*, WASH. POST: VOLOKH CONSPIRACY (Jan. 11, 2016), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2016/01/11/ted-cruz-and-the-use-of-deception-to-exploit-political-ignorance/?utm\_term=.8ce74f706e77 [https://perma.cc/JEF2-R8LE].

<sup>75.</sup> Louis Jacobson, *Carly Fiorina Incorrect that U.S. Has a 'Record Number of Abortions Year After Year*,' POLITIFACT (Jan. 20, 2016), www.politifact.com/truth-o-meter/statements/2016/jan/20/carly-fiorina-incorrect-us-has-record-number-abort/ [https://perma.cc/YF59-58KF].

President Obama lied about his support of gay marriage in 2008,<sup>76</sup> and President Trump surely did not believe his own campaign rhetoric about the feasibility of rapid deportations or building a continuous wall along the entire Mexican border.<sup>77</sup> But the phenomenon is not new. Abraham Lincoln had to falsely disavow the Republican Party platform (which pursued the goal of equal political rights for freed slaves) in order to get his foot in the door for national office.<sup>78</sup> Good politicians understand that the electorate can take only so much truth at a time. They understand, to borrow Emily Dickinson, that they must "[t]ell all the truth but tell it slant."<sup>79</sup>

Under this theory, free speech does not facilitate democratic self-government, it saves us from it.<sup>80</sup> In politics, the audience is less inclined to change ideology based on new information and more inclined to choose information based on preexisting ideology.<sup>81</sup> Factual accuracy has limited positive influence on political audiences, and conversely, the stakes from factual inaccuracy are not as grave as they may seem.

The public and political marketplace of ideas lags behind the progress of scientific knowledge. Politicians continue to deny the existence of global warming well after a consensus has formed among scientists that it does exist. But even if it does not conform to the best available science, public discourse still makes progress. Pro-life politicians can say many

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<sup>76.</sup> Zeke J. Miller, *Axelrod: Obama Misled Nation When He Opposed Gay Marriage in 2008*, TIME (Feb. 10, 2015), http://time.com/3702584/gay-marriage-axelrod-obama/ [https://perma.cc/42EM-3MI/S1

<sup>77.</sup> Julia Preston et al., *What Would It Take for Donald Trump to Deport 11 Million and Build a Wall?*, N.Y. TIMES (May 19, 2016), https://www.nytimes.com/2016/05/20/us/politics/donald-trump-immigration.html?\_=0 [https://perma.cc/6XJY-22ZZ].

<sup>78.</sup> THE LINCOLN-DOUGLAS DEBATES: THE FIRST COMPLETE, UNEXPURGATED TEXT 40–44 (Harold Holzer ed., 2004).

<sup>79.</sup> Emily Dickinson, *Tell All the Truth but Tell It Slant*, POETRY FOUND., https://www.poetryfoundation.org/poems/56824/tell-all-the-truth-but-tell-it-slant-1263 [https://perma.cc/Q5TP-R5ZU] ("Tell all the truth but tell it slant— / Success in Circuit lies / Too bright for our infirm Delight / The Truth's superb surprise / As Lightning to the Children eased / With explanation kind / The Truth must dazzle gradually / Or every man be blind—.").

<sup>80.</sup> Peter H. Aronson et al., *A Theory of Legislative Delegation*, 68 CORNELL L. REV. 1, 63–67 (1982) (describing how Congress rationally and routinely delegates hard decisions to avoid political accountability for them).

<sup>81.</sup> Dan M. Kahan & Donald Braman, *Cultural Cognition and Public Policy*, 24 YALE L. & POL'Y REV. 147, 148 (2006).

<sup>82.</sup> See Coral Davenport & Eric Lipton, How G.O.P. Leaders Came to View Climate Change as Fake Science, N.Y. TIMES (June 3, 2017), https://www.nytimes.com/2017/06/03/us/politics/republican-leaders-climate-change.html [https://perma.cc/JLA5-6FGG]. For a detailed history of the building of scientific consensus through climate modeling, see PAUL N. EDWARDS, A VAST MACHINE: COMPUTER MODELS, CLIMATE DATA, AND THE POLITICS OF GLOBAL WARMING (2010).

things about abortion that have dubious factual support, but when Todd Akin, a candidate for the U.S. Senate, said that the female body will avoid pregnancy if "it's a legitimate rape,"<sup>83</sup> his support even among conservatives collapsed.<sup>84</sup> Public debate, the messiest form of all possible discourses, still places some self-regulated limits on junk science.<sup>85</sup>

### C. The Peer

The peer speaker is the business or social acquaintance who provides information to a private audience rather than a public one. It is what most of us are most of the time when we speak.

Peer speakers receive fewer protections from the First Amendment than the press. Under the common law, peer speakers who gave bad factual information in a context in which they should have known that the listener was vulnerable or was reasonably relying on it could be sued for negligence if the listener suffered physical or financial injury as a result. 86 Legal obligations to give accurate information can grow from the reliance

<sup>83.</sup> Chris Gentilviso, *Todd Akin on Abortion: 'Legitimate Rape' Victims Have 'Ways to Try to Shut That Whole Thing Down' (VIDEO)*, HUFFPOST (Aug. 19, 2012, 3:25 PM), https://www.huffingtonpost.com/2012/08/19/todd-akin-abortion-legitimate-rape\_n\_1807381.html [https://perma.cc/VN2L-6M2M].

<sup>84.</sup> Jennifer Haberkorn, *Abortion, Rape Shaped Key Races*, POLITICO (Nov. 6, 2012, 11:54 PM), https://www.politico.com/story/2012/11/abortion-rape-controversy-shaped-key-races-083449 [https://perma.cc/GR24-EE6N].

<sup>85.</sup> Some observers of the 2016 presidential election are beginning to doubt that norms and democratic processes provide enough incentive to tell the truth. But the First Amendment should not be held responsible for the rhetoric of the 2016 election. After all, the United Kingdom, the Netherlands, and France are going through similarly reactionary political moments, *see* James Poulos, *Younger Le Pen's Reactionary Politics Tap into Pan-American Sentiment*, ORANGE COUNTY REG. (Apr. 4, 2017, 4:53 PM), https://www.ocregister.com/2017/04/01/younger-le-pens-reactionary-politics-tap-into-pan-european-sentiment/ [https://perma.cc/62KG-XEFS], and those countries operate under significantly more restrictive speech laws, *see Comparing Hate Speech Laws in the U.S. and Abroad*, NPR (Mar. 3, 2011, 3:00 PM), https://www.npr.org/2011/03/03/134239713/France-Isnt-The-Only-Country-To-Prohibit-Hate-Speech [https://perma.cc/QDV9-CSTZ]. The 2016 election seems to be a good example of voters demanding rhetoric rather than being shaped by it.

<sup>86.</sup> For physical harm: Jurgens v. Poling Transp. Corp., 113 F. Supp. 2d 388, 398 (E.D.N.Y. 2000); Isham v. PADI Worldwide Corp., Nos. 06-00382 DAE BMK, 06-00386 DAE BMK, 2008 WL 2051546 (D. Haw. May 13, 2008); Apollo Capital Fund LLC v. Roth Capital Partners, LLC, 70 Cal. Rptr. 3d 199 (Cal. Ct. App. 2007); Birmingham v. Fodor's Travel Publ'ns, Inc., 833 P.2d 70, 75 n.4 (Haw. 1992); RESTATEMENT (SECOND) OF TORTS § 311 (AM. LAW INST. 1965) (a party who negligently provides false information to another may be liable for "physical harm caused by action taken by the other in reasonable reliance upon such information" whether the harm occurs to the listener or to a third party foreseeably in harm's way). The plaintiff must prove that the speaker knew the listener was relying on his statement. For financial harm, see RESTATEMENT (SECOND) OF TORTS § 552 (AM. LAW INST. 1977).

induced in employment and consumer contractual relationships.<sup>87</sup> But the basic rules also apply to peers who are not in any form of contractual privity. Landowners providing information to visitors or adults giving instructions to children can be held responsible for the harm caused by their advice.<sup>88</sup> As a matter of substantive law, peer speech has been regulated only if specific negligent or malicious false claims cause actual financial or physical injury,<sup>89</sup> so for now, the law for peer speakers is anchored to harm.

Courts have only occasionally distinguished between verifiable (accepted) knowledge and contested knowledge in the context of peer speech. When they do, they explain that factual predictions are not actionable. However, existing negligence law and First Amendment doctrine does not entirely rule out the possibility that a person or company could be held liable for a poorly supported contested claim that foreseeably leads to harm. For one thing, the defamation case law strongly suggests that private conversations will always receive less protection than public discourse, and the rules for negligent misstatements seem readily applicable to risky contested knowledge.

#### D. The Protector

Protectors are professionals with fiduciary responsibilities to their clients and patients. They are engaged to guide or even take over the judgment of their clients, and they have legal obligations to do so competently. Like peers, protectors speak to private rather than public

<sup>87.</sup> Isham, 2008 WL 2051546, at \*4; Helen Norton, Truth and Lies in the Workplace: Employer Speech and the First Amendment, 101 MINN. L. REV. 31, 33 (2016).

<sup>88.</sup> See Yania v. Bigan, 155 A.2d 343, 345-46 (Pa. 1959).

<sup>89.</sup> RESTATEMENT (SECOND) OF TORTS § 912 (AM. LAW INST. 1979). Some states have ruled this out using common law tort duty principles. Deana Pollard Sacks, *Constitutionalized Negligence*, 89 WASH. L. REV. 1065, 1085–92 (2012).

<sup>90.</sup> Presidio Enters., Inc., v. Warner Bros. Distrib. Corp., 784 F.2d 674, 680 (5th Cir. 1986); Barden v. HarperCollins Publishers, Inc., 863 F. Supp. 41, 43 (D. Mass. 1994); Logan Equip. Corp. v. Simon Aerials, Inc., 736 F. Supp. 1188, 1200 (D. Mass. 1990); S.F. Design Ctr. Assocs. v. Portman Cos., 50 Cal. Rptr. 2d 716, 724 (Cal. Ct. App. 1995) ("It is hornbook law that an actionable misrepresentation must be made about past or existing facts; statements regarding future events are merely deemed opinions."). The exceptions involve statements about the future where the predicted act is entirely in the control of the speaker. *See* Barrett Assocs., Inc. v. Aronson, 190 N.E.2d 867, 868 (Mass. 1963); Cellucci v. Sun Oil Co., 320 N.E.2d 919, 924 (Mass. App. Ct. 1974).

<sup>91.</sup> Snyder v. Phelps, 562 U.S. 443, 451–52 (2011); Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749, 758–59 (1985).

audiences, so fiduciary duties wind up being critical. These special duties are the only things separating protectors from peers.<sup>92</sup>

Protectors can be held responsible for contested claims when their advice is poorly supported by contemporary scientific evidence. <sup>93</sup> Low-quality scientific opinions, be they misdiagnoses, recommendations, or doctors' orders, were historically treated as conduct rather than speech and rarely got the attention of constitutional lawyers. But common law courts were also reserved when regulating protectors' judgment in areas of epistemic uncertainty. Under the common law, malpractice through negligent guidance was only penalized in extreme cases. First, as with all forms of malpractice, opinion malpractice could lead to liability only after harm materialized and could be causally linked to the doctor's advice. <sup>94</sup> Even then, a doctor's advice breached a duty of care only if it was based on a theory that failed to have a substantial minority of subscribers. <sup>95</sup> On subjects with known areas of disagreement or uncertainty, doctors can satisfy the custom-based standard of care so long as they do not give advice that is outside the range where reasonable minds disagree.

The laxity in the standard for breach is a natural byproduct of the uncertainty that pervades the medical and professional fields. Sometimes the standard of care that a doctor *must* conform to includes a treatment that has not been well studied or a drug that has not been approved by the FDA to treat the condition. <sup>96</sup> Even with this flexibility, though, protectors are regulated more than peers, who are usually free to give bad advice.

It may seem odd that the speech of a professional advisor, who is paid by clients and therefore has the incentives to serve their interests, can be more heavily regulated than the speech of a peer who may have any number of motivations.<sup>97</sup> But the paradox is explained by reliance.

<sup>92.</sup> It is possible that, with more attention, we may find a sliding scale of free speech protection that is relatively strong for contractual parties, less strong for employer-employee relationships, and weaker still for fiduciaries.

<sup>93.</sup> Other scholars have explained in greater detail than I do here the logic and residual puzzles in the regulation of professional speech. *See generally* Marc Jonathan Blitz, *Free Speech, Occupational Speech, and Psychotherapy*, 44 HOFSTRA L. REV. 681 (2016); Daniel Halberstam, *Commercial Speech, Professional Speech, and the Constitutional Status of Social Institutions*, 147 U. PA. L. REV. 772, 845 (1999); Claudia Haupt, *Professional Speech*, 125 YALE L. REV. 1150 (2016).

<sup>94.</sup> RESTATEMENT (SECOND) OF TORTS § 433B cmt. a (Am. LAW INST. 1965).

<sup>95.</sup> Note, though, that courts are increasingly willing to deviate from the custom standard and using an assessment of reasonableness used for other forms of negligence. For a discussion of the traditional custom standard and the shift away, see Philip G. Peters, *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163 (2000).

<sup>96.</sup> See Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989).

<sup>97.</sup> See JOHN C. COFFEE JR., GATEKEEPERS: THE PROFESSIONS AND CORPORATE GOVERNANCE 289 (2006) (ratings agencies and the race to the bottom).

Professionals speak in a context where the audience is most likely to act on their advice without second-guessing. The free speech rule for protectors is therefore consistent with the rules for peers because they, too, can be held liable for speech if they know a listener is reasonably relying on its accuracy. Protectors are a special case of the peer rule where the reasonableness of reliance is automatically presumed.

The free speech rules for protectors are also consistent with a set of normative goals. Generally speaking, the law is designed to facilitate trust with professionals who work as the listener's agents. Government has no such interest in facilitating trust in public debate. In fact, the public interest is better served by promoting a healthy skepticism for information that does not come through a regulated professional relationship.

As a general matter, First Amendment jurisprudence has not disrupted the traditional approach to regulating professional speech.<sup>99</sup> But there are two sources of First Amendment tension.

The first comes from defining fiduciaries. Fiduciary duties maintain the boundary between protectors and peers, ensuring that the latter do not have to take on the burdens of education and self-censorship. But fiduciary duties are purely legal constructs. The coherence of the information policy described above depends on the state doing a good job applying fiduciary duties to speakers who induce reasonable reliance of their clients without wrapping in others. In practice, there has been quite a lot of slippage between the peer and protector categories because of the ipse dixit nature of defining fiduciary responsibilities.

Sometimes the state can too easily convert a peer speaker into a heavily regulated protector based solely on the type of advice a peer attempts to give. For example, advice about legal strategy, even when it is good advice, will violate the business and professions codes in most states that prohibit the unauthorized practice of law if the speaker is unlicensed. 100

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<sup>98.</sup> See generally Wendy G. Couture, The Collision Between the First Amendment and Securities Fraud, 65 ALA. L. REV. 903 (2014) (persuasively showing why a malice standard should apply to securities analysts, credit agencies, and financial journalists who make public comments about corporate securities); Spottswood, supra note 21, at 1250 ("there are situations in which false statements are not very likely to produce any sort of useful argument, but instead are expected to be relied upon by a listener without a great deal of reflection," such as attorney advice).

<sup>99.</sup> See, e.g., Shea v. Bd. of Med. Exam'rs, 146 Cal. Rptr. 653, 662 (Cal. Ct. App. 1978) ("The state's obligation and power to protect its citizens by regulation of the professional conduct of its health practitioners is well settled. . . . [T]he First Amendment . . . does not insulate the verbal charlatan from responsibility for his conduct; nor does it impede the State in the proper exercise of its regulatory functions."). Courts have occasionally nibbled on the edges by forcing licensing boards to relax advertising restrictions. See Renee Knake, Legal Information, the Consumer Law Market, and the First Amendment, 82 FORDHAM L. REV. 2843 (2014).

<sup>100.</sup> RESTATEMENT (THIRD) OF THE LAW GOVERNING LAWYERS § 4 cmt. c (Am. Law Inst. 2000).

These rules can stray too far from the theory of reasonable reliance that undergirds the information restrictions. 101

Other times, the scope of fiduciary responsibilities is under-inclusive. Law professors, to take an example close to home, cannot be sued for educational malpractice no matter how much and how reasonably their students rely on their teaching. <sup>102</sup> Financial interest and actual reliance are not sufficient to predict when fiduciary duties will be recognized. Much depends on the types of trust that the state wants to promote and actively support. <sup>103</sup>

First Amendment challenges gain force when fiduciary duties are expanded to cover more and more services, including pure speech. The proportion of Americans who are members of licensed professions has grown six-fold since the 1950s, 104 each potentially facing a set of restrictions on their advice and contested claims. As professional regulation expands, so do the incentives to bring constitutional challenges. Courts are likely to find that some forms of professional regulation are insufficiently tailored to the exceptional special relationships that once justified special First Amendment treatment.

New technology will make this First Amendment battle zone even more salient. Many new apps and software products are designed to give customized advice and predictions to their users. These communications technologies can be used not only to enhance doctorpatient, lawyer-client, and accountant-client relationships, but to substitute them. Courts will have to decide whether the state can treat

<sup>101.</sup> What it means for reliance to be "reasonable" also invites courts to expand the application of fiduciary duties. For example, a California court recently allowed a negligent misrepresentation claim against Moody's rating agency to proceed because Moody's held itself out as "possessing superior knowledge or special information or expertise regarding the subject matter" even though the particular financial goods at issue in the case were restricted for sale only to sophisticated market participants. Cal. Pub. Emps.' Ret. Sys. v. Moody's Inv'rs Serv., 172 Cal. Rptr. 3d 238, 253–54 (Cal. Ct. App. 2014).

<sup>102.</sup> RONALD STANDLER, EDUCATIONAL MALPRACTICE LAW IN THE USA 10, 39 (2013) ("Plaintiff (nearly) always loses.").

<sup>103.</sup> Jane Bambauer, *The Relationships Between Speech and Conduct*, 49 U.C. DAVIS L. REV. 1941, 1948–49 (2016).

<sup>104.</sup> Brad Hershein et al., Nearly 30 Percent of Workers in the U.S. Need a License to Perform Their Job: It Is Time to Examine Occupational Licensing Practices, BROOKINGS (Jan. 27, 2015), https://www.brookings.edu/blog/up-front/2015/01/27/nearly-30-percent-of-workers-in-the-u-s-need-a-license-to-perform-their-job-it-is-time-to-examine-occupational-licensing-practices/ [https://perma.cc/QW72-Y29P].

<sup>105.</sup> U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 6–7 (2015) [hereinafter FDA, MOBILE MEDICAL APPLICATIONS].

these emerging information services as fiduciaries (protectors) or must let them pass as cut-rate peer alternatives. 106

The second source of constitutional pressure comes from the burdens of the regulations that apply to professionals. The common law approach to malpractice tethered the law to harm by limiting liability to plaintiffs who suffered damages and by holding doctors and other professionals to a low standard of care. These restrictions were probably too friendly to defendants from an accident deterrence standpoint, but they managed to avoid free speech pitfalls by ensuring that a penalized defendant not only said something dubious but also caused harm. Recent free speech controversies in the realm of professional speech proceed without as much evidence that clients will be harmed.

For example, four states and the District of Columbia have banned licensed therapists from practicing "Sexual Orientation Change Efforts" (SOCE)—a set of protocols that some clinicians use to try to change the sexual orientation of their clients. 108 SOCE is typically practiced by religiously motivated therapists who treat homosexuality as an ailment that can or should be cured. 109 Two federal circuits have upheld the bans against constitutional challenge, one of them (the Ninth Circuit) without applying any First Amendment scrutiny. 110 Marc Blitz summarized the thinking: "[w]hat matters, for First Amendment purposes, is not that the 'talking cure' involves talking, but that it aims at curing."<sup>111</sup> The states banning SOCE practices view them as the worst sort of snake oil—as a promise that is destined to fail, in an attempt to treat a condition that is not even an ailment. Indeed, there is no strong evidence that SOCE practices achieve their desired ends. But as the American Psychological Association report on SOCE acknowledged, there is no strong evidence that SOCE causes physical or emotional distress to the patients receiving them, either. 112

<sup>106.</sup> Elsewhere I argue that regulating these apps and services as fiduciaries is more appropriate and more welfare-enhancing than regulating them as products, but that public choice problems are likely to lead to over-regulation. *See* Jane Bambauer, *Dr. Robot*, 51 U.C. DAVIS L. REV. 383 (2017).

<sup>107.</sup> See generally B. Sonny Bal, An Introduction to Medical Malpractice in the United States, 467 CLINICAL ORTHOPAEDICS & RELATED RES. 339 (2008).

<sup>108.</sup> Blitz, supra note 93, at 682.

<sup>109.</sup> See id. at 752-53.

<sup>110.</sup> Pickup v. Brown, 740 F.3d 1208 (9th Cir. 2014); King v. Governor of N.J., 767 F.3d 216 (3d Cir. 2014). In *Pickup*, the Ninth Circuit makes a lazy comparison to traditional malpractice liability of the sort I criticize earlier in this Part. *Pickup*, 740 F.3d at 1054–55.

<sup>111.</sup> Blitz, supra note 93, at 683.

<sup>112.</sup> AM. PSYCHOLOGICAL ASS'N, REPORT OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION TASK FORCE ON APPROPRIATE THERAPEUTIC RESPONSES TO SEXUAL ORIENTATION 42 (2009) ("We

The restrictions on SOCE differ from traditional malpractice liability not only because the rules apply prospectively, but because the rules operate in an area of known evidentiary uncertainty. The SOCE laws permit the government, rather than therapists, to determine the best advice on a topic where the science is underdeveloped. These laws are distinguishable from a potential law (which Italy has adopted but no U.S. state has) banning pediatricians from advising patients against vaccination. A ban on vaccination dissuasion would target anti-knowledge since that therapeutic advice conflicts with a large body of high quality studies. By contrast, the SOCE laws settle a debate where empirical evidence is thin and highly politically charged, and without credible proof of harm. They set a precedent that for professional speakers, contested knowledge can be restricted.

#### E. The Peddler

The peddler is the commercial speaker whose statements are directed at potential customers. Speakers fall into the "peddler" category only when they are engaging in commercial speech—that is, when they are promoting sales. Under *Central Hudson Gas & Electric Corp. v. Public Service Commission*,<sup>114</sup> commercial speech receives a lower form of First Amendment protection even when it is true,<sup>115</sup> and no protection at all when it is false or misleading.<sup>116</sup>

As we have seen already, speakers with a financial interest in their speech are not automatically engaging in commercial speech; they can be members of the press, peer, or protector categories when their public or private statements concern something other than advertising. Thus, the "peddler" category is dependent on how courts distinguish commercial from non-commercial speech.

conclude that there is a dearth of scientifically sound research on the safety of SOCE. Early and recent research studies provide no clear indication of the prevalence of harmful outcomes among people who have undergone efforts to change their sexual orientation or the frequency of occurrence of harm because no study to date of adequate scientific rigor has been explicitly designed to do so.").

<sup>113.</sup> Laura Cuppini, *Doctors Advising Against Vaccines Risk Disciplinary Action*, CORRIERE DELLA SERA (July 20, 2016), http://www.corriere.it/english/16\_luglio\_20/doctors-advising-against-vaccines-risk-disciplinary-action-e2455216-4e75-11e6-8e8b-1212ced41b8e.shtml [https://perma.cc/PP8X-F2T8].

<sup>114. 447</sup> U.S. 557 (1980).

<sup>115.</sup> Id. at 562-63.

<sup>116.</sup> Id. at 564.

<sup>117.</sup> Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 66–67 (1983); Groden v. Random House, Inc., 61 F.3d 1045, 1052 (2d Cir. 1995) (distinguishing between content of a book and advertisements promoting sales of the book).

This categorization is contentious at the margins. <sup>118</sup> For example, when a company funds or distributes favorable research published in peer-reviewed science journals, the dissemination of the articles is usually treated as non-commercial speech. <sup>119</sup> But the Second Circuit has suggested that a research publication theoretically could be actionable false advertising if the authors fail to disclose industry compensation or other conflicts of interest. <sup>120</sup> The FDA guidelines permit drug companies to distribute journal articles only if they are accompanied with a comprehensive bibliography and copies of publications that reach contrary results. <sup>121</sup> But for our purposes we will set aside hard cases and focus on communications that are clear advertisements.

Because false commercial speech receives no constitutional protection whatsoever, the methods for determining whether a statement is "true" have high stakes. True facts and opinions receive constitutional protection with quite probing intermediate scrutiny while false claims can be banned for any plausible rational basis. The job of identifying false facts has been left up to regulators of every sort—federal agencies, local governments, judges, and juries—without much comment from the Supreme Court. Indeed, the Court has intentionally left some fluidity between these categories of statements by recognizing that some statements phrased as opinions (e.g., "I believe X") can imply not only the fact that the speaker holds the belief, but also certain unstated facts that would be necessary to justify such a belief. 122

Some of the rules limiting what commercial speakers can say are designed to clear out verifiably false statements. For example, the FTC

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<sup>118.</sup> Hard cases: City of Cincinnati v. Discovery Network, Inc. 507 U.S. 410, 419–21 (1993) (finding that a single document can contain both commercial and noncommercial parts); *Bolger*, 463 U.S. at 67 (pamphlet sent by mail by non-profit organization is commercial speech); Semco, Inc. v. Amcast, Inc., 52 F.3d 108, 112 (6th Cir. 1995) (article written for trade magazine classified as commercial speech); Birthright v. Birthright, Inc., 827 F. Supp. 1114, 1138 (D.N.J. 1993) (nonprofit fundraising letter is commercial advertising); Nat'l Artists Mgmt. Co. v. Weaving, 769 F. Supp. 1224, 1234 (S.D.N.Y. 1991) (former employee's negative commentary about employer can be commercial speech).

<sup>119.</sup> See, e.g., Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 62 (D.D.C. 1998), vacated in part sub nom. Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

<sup>120.</sup> ONY, Inc. v. Cornerstone Therapeutics, Inc., 720 F.3d 490, 498 (2d Cir. 2013).

<sup>121.</sup> Revised Draft Guidance for Industry on Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices; Availability, 79 Fed. Reg. 11,793, 11,794–95 (Mar. 3, 2014).

<sup>122.</sup> Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, \_\_ U.S. \_\_, 135 S. Ct. 1318, 1331–32 (2015) (discussing factual omissions that rendered a statement misleading in the firm's SEC filings); Virginia Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1092 (1991); Rebecca Tushnet, Running the Gamut from A to B, 159 U. PA. L. REV. 1305, 1321–23 [hereinafter Tushnet, Running the Gamut] (discussing false implied claims from technically true statements).

filed complaints against Nordstrom, Bed Bath & Beyond, and a few other retailers for labeling products "made from bamboo" when they were in fact made from rayon. Another group of rules creates and enforces certain terms of art like "gluten-free" or "recycled," and restricts statements that verifiably conflict with the definition. Each of these regulate anti-knowledge. But commercial speakers can run afoul of the law by making contested claims, too.

Regulators take varying tacks to control junk science within their sector. On one end of the spectrum, federal securities law has been interpreted in a way that largely avoids First Amendment turmoil. SEC actions are limited for the most part to fraud and negligence based on verifiably false statements. In areas of contested knowledge, firms are free to promote the findings of research in a contested area that puts the firm in good light. While a publicly traded firm can be sued for deceit by misstating the findings of an empirical study, it will not be held liable for accurately describing the results of a study that used objectionable research methodology. Moreover, even when firms make an actionable false statement, they have the opportunity to raise a "truth on the market" defense by showing that a fulsome, truthful disclosure would not have "significantly altered the total mix of information available to a reasonable investor." 126

<sup>123.</sup> Press Release, Fed. Trade Comm'n, Nordstrom, Bed Bath & Beyond, Backcountry.com, and J.C. Penney to Pay Penalties Totaling \$1.3 Million for Falsely Labeling Rayon Textiles as Made of "Bamboo" (Dec. 9, 2015), https://www.ftc.gov/news-events/press-releases/2015/12/nordstrom-bed-bath-beyond-backcountrycom-jc-penney-pay-penalties [https://perma.cc/YF3F-GNAS]. The firms had used bamboo as a raw material, but this still violated the FTC's guidance on bamboo fabric labeling. *See 'Bamboo' Fabrics*, FED. TRADE COMM'N, https://www.consumer.ftc.gov/articles/0122-bamboo-fabrics [https://perma.cc/V3Y3-3LT4].

<sup>124.</sup> Food Labeling; Gluten-Free Labeling of Foods, 78 Fed. Reg. 47,154 (Aug. 5, 2013) (codified at 21 C.F.R. pt. 101); Guides for the Use of Environmental Marketing Claims, 77 Fed. Reg. 62,122 (Oct. 11, 2012) (codified at 16 C.F.R. pt. 260); see also Tushnet, It Depends on What the Meaning of "False" Is, supra note 21, at 248–52 (giving other examples of term-of-art meaning-making, including "organic," "Made in the U.S.A.," and "dolphin-safe").

<sup>125.</sup> *In re* Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 878–79 (9th Cir. 2012); *In re* Adolor Corp. Sec. Litig., 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009); DeMarco v. DepoTech Corp., 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001); Padnes v. Scios Nova Inc., No. C 95-1693 MHP, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996). Moreover, liability also hinges on the plaintiff's ability to show actual reliance, causation, and economic loss. *Rigel*, 697 F.3d at 876. However, a firm can run afoul of SEC law by failing to disclose studies—even studies that fail to achieve statistical significance—that foretell serious risk of liability. Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38–44 (2011).

<sup>126.</sup> Rand v. Cullinet Software, Inc., 847 F. Supp. 200, 206 (D. Mass. 1991); see also Raab v. Gen. Physics Corp., 4 F.3d 286, 289 (4th Cir. 1993) ("[P]resumption that the market price has internalized all publicly available information cuts both ways."); Pei v. Speiser, 806 F.2d 1154, 1161 (3d Cir. 1986) ("[D]efendants are . . . free to assert appropriate defenses, including . . . that the market did not respond to the misrepresentation.").

The very purpose of having and enforcing SEC disclosure laws is to remove cheap talk from the securities market, so securities law could have been fertile ground for regulating overly optimistic claims about contested knowledge. But perhaps because securities are products that by their nature require speculation, the law has taken a relatively restrained approach to the determination of falsity.<sup>127</sup>

For other industries, peddlers' scientific claims are policed more heavily, and until recently the case law showed little of the anxiety about state-determined truth in scientific debates that pervades the analysis of other types of speakers. To the contrary, advertisements that are "unsupported by accepted authority or research . . . may be deemed false on their face and actionable" under the false advertising provisions of the Lanham Act. <sup>128</sup> Contested knowledge is therefore likely to be received as "false or misleading" by regulators, and to fall outside the scope of First Amendment protection.

The FDA and the FTC are particularly hostile to contested claims, in part because the stakes of bad science are greatest in the realm of public health. Both agencies set high and specific standards for the sort of evidence that can substantiate a claim about the health benefits of products. Any claim that is not supported with at least two randomized controlled human trials falls outside the agencies' standards for accepted knowledge and is treated as false or misleading advertising. First Amendment challenges to these regulations used to be rebuffed by the courts, as we saw in the Egg Council case described in the Introduction. Courts gave the FDA and the FTC wide latitude to define the meaning of "misleading" and to manage health claims as the expert agencies thought best. But recent, successful challenges suggest the era of agency discretion is over.

In *United States v. Caronia*, <sup>130</sup> the Second Circuit vacated the conviction of a pharmaceutical representative. <sup>131</sup> The drug rep had told doctors (undercover agents, as it turned out) that a drug, Xyrem, which was approved to treat only narcolepsy, could also be prescribed to patients

<sup>127.</sup> Alternatively, perhaps securities investors for even publicly traded securities are presumed to be more sophisticated and alert than other consumers.

<sup>128.</sup> McNeil-PCC, Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991); ALPO Petfoods, Inc. v. Ralston Purina Co., 720 F. Supp. 194, 213 (D.D.C. 1989), *aff'd in part, rev'd in part*, 913 F.2d 958 (D.C. Cir. 1990).

<sup>129.</sup> See The Drug Development Process: Step 3: Clinical Research, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm [https://perma.cc/TL3B-2Y2Z].

<sup>130. 703</sup> F.3d 149 (2d Cir. 2012).

<sup>131.</sup> Id. at 152.

suffering from insomnia and restless leg syndrome. <sup>132</sup> On appeal, Caronia argued that he had been convicted for his non-misleading speech. The evidence supporting Caronia's recommendations for off-label uses was spotty, certainly falling short of the two clinical trials required for FDA approval, but the FDA did not argue that Caronia's statements were false. Instead, the agency insisted that the First Amendment did not extend to Caronia because his speech was used as mere evidence of conduct (specifically, introducing a "misbranded" or "mislabeled" drug into the market). <sup>133</sup> The Second Circuit rejected the argument, pointing out that the FDA had insisted throughout the case that speech alone was sufficient to violate the criminal statute. <sup>134</sup>

The role of speech in product regulation is more complicated than the Second Circuit suggests, <sup>135</sup> but the court was right to find that the First Amendment covered this case. The FDA's position was always difficult to defend because Caronia's liability hinged on selling a "mislabeled" or "misbranded" product rather than on some physical quality of the product. Moreover, the cases that the FDA does *not* bring are telling. The FDA does not enforce the mislabeling laws in the extremely common scenario in which a drug is sold in large quantities for off-label purposes with the knowledge of its manufacturers. Over 20% of prescriptions are written for off-label purposes. <sup>136</sup> For some populations, like children, most drugs are prescribed and used off-label since children are rarely recruited into

<sup>132.</sup> *Id.* at 156. The drug rep also said the drug could be used for minors under age sixteen when FDA approval was for patients sixteen and older. *Id.* at 157.

<sup>133.</sup> Id. at 160-61.

<sup>134.</sup> Id. at 161-62.

<sup>135.</sup> Chris Robertson has laid out more clearly than the FDA itself why speech can be used as evidence of intent for a regulatory scheme that targets conduct or products as a whole. See Chris Robertson, The Tip of the Iceberg: A First Amendment Right to Promote Drugs Off-Label, 78 OHIO ST. L.J. 1019 (2017). Nevertheless, in this case, the FDA's enforcement practices do not use speech as mere evidence of intent. If that were the case, intent could be proved using non-speech evidence, such as the fact that a large portion of sales are to consumers who will use the product for an off-label purpose. The vitamin industry for all practical purposes *intends* to sell its wares for the prevention and treatment of health conditions. Even FDA guidance clarifies that "intent" is used to mean—and only mean—speech. See U.S. FOOD & DRUG ADMIN., MEMORANDUM: PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT CONSIDERATIONS RELATED TO MANUFACTURER COMMUNICATIONS REGARDING UNAPPROVED USES OF APPROVED OR CLEARED MEDICAL PRODUCTS 21-22 (2017) [hereinafter FDA, PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT]; FDA, MOBILE MEDICAL APPLICATIONS, supra note 105, at 10 (excluding from the scope of regulation "[m]anufacturers or distributors of mobile platforms who solely distribute or market their platform and do not intend (by marketing claims—e.g., labeling claims or advertising material) the platform to be used for medical device functions").

<sup>136.</sup> Randall S. Stafford, Regulating Off-Label Drug Use: Rethinking the Role of the FDA, 358 New Eng. J. Med. 1427, 1427 (2008).

clinical trials. And for some specialties, off-label drugs account for the majority of prescriptions. 137

All of these common off-label prescribing patterns should give the FDA ample evidence for mislabeling prosecutions since they show that the manufacturer knew, expected, and desired for the drug to be used for off-label purposes. <sup>138</sup> Yet the FDA does not enforce the law against drug manufacturers in these cases. To the contrary, the FDA recognizes that off-label prescribing is a common and valuable practice. <sup>139</sup> The FDA never enforces the misbranding law unless the manufacturer uses commercial speech to promote off-label uses. <sup>140</sup> Since speech is not just a sufficient condition but a necessary one, the theory that FDA misbranding does not regulate speech is unacceptable. <sup>141</sup> *Caronia* has exposed the uncomfortable fact that much of the FDA's work is geared toward regulating information, not products.

Following *Caronia*, many commentators in the public health field argued that any drug promotion advocating off-label use is inherently and automatically misleading.<sup>142</sup> The argument was explicitly considered and

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<sup>137.</sup> Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982, 983–85 (2012); Euni Lee et al., *Off-Label Prescribing Patterns of Antidepressants in Children and Adolescents*, 21 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 137, 137–38 (2012).

<sup>138. 21</sup> C.F.R. § 201.128 (2017) ("Meaning of 'intended uses' . . . [objective intent] may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. . . . [I]f a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.").

<sup>139. &</sup>quot;The term 'unapproved uses' is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. . . . [A]ccepted medical practice often includes drug use that is not reflected in approved drug labeling. With respect to its role in medical practice, the package insert is *informational only*." *Use of Approved Drugs for Unlabeled Indications*, FDA DRUG BULL., Apr. 1982, at 4, 5 (1982) (emphasis added). Moreover, although the FDA and the states could ban the prescribing of drugs for off-label uses, they have done so only for a few drugs. 21 U.S.C. § 333(e)(1) (2012) (banning the off-label distribution of human growth hormone); Greene & Noah, *supra* note 21, at 262–63.

<sup>140.</sup> FDA, PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT, *supra* note 135, at 21–22 (describing promotion as the key to the FDA's interpretation of "intent" to introduce an unapproved or misbranded medical product).

<sup>141.</sup> For a similar critique of attempts to regulate speech through corporate governance regulations, see Larry E. Ribstein, *First Amendment and Corporate Governance*, 27 GA. St. U. L. Rev. 1019, 1022 (2011).

<sup>142.</sup> Greene & Noah, supra note 21, at 257.

rejected in *Caronia*<sup>143</sup> and well before, <sup>144</sup> because the FDA itself acknowledges that "off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care." <sup>145</sup> And in a subsequent case, *Amarin Pharma, Inc. v. FDA*, <sup>146</sup> the FDA was forced to acknowledge that at least some off-label promotion was not misleading. <sup>147</sup> In Amarin's case, the drug manufacturer wished to promote off-label uses that the FDA itself had researched and publicly recommended. <sup>148</sup>

But neither *Caronia* nor *Amarin* provided clear guidance on how the First Amendment constrains the standards the government can use to regulate contested claims. <sup>149</sup> Rather than setting general principles, the *Amarin* court itself reviewed and revised the contested statements about off-label uses. The court concluded that commercial speech reporting scientific findings must be "studiously neutral" in order to avoid being misleading (and thus unprotected), and it hand-crafted statements that Amarin could use in order to meet this exacting standard. <sup>150</sup>

*POM Wonderful v. Federal Trade Commission*<sup>151</sup> raised more directly the First Amendment's constraints on agency standards for truth (in this case, the FTC's). POM Wonderful had designed an advertising campaign

<sup>143.</sup> United States v. Caronia, 703 F.3d 149, 165-66 (2d Cir. 2012).

<sup>144.</sup> Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999); see also Greene & Noah, supra note 21, at 261.

<sup>145.</sup> Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, U.S. FOOD & DRUG ADMIN. (Jan. 2009), https://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm [https://perma.cc/3TNE-Y7C6].

<sup>146. 119</sup> F. Supp. 3d 196 (S.D.N.Y. 2015).

<sup>147.</sup> See id. at 227.

<sup>148.</sup> *Id.* at 209–11, 229. The case involved the drug Vascepa, which had been approved to treat some cardiovascular conditions, but which many studies (including an FDA-funded study) had shown was effective for treating other heart conditions. *Id.* at 209. Although the studies did not conform to the strict requirements for FDA approval of a new use of an existing drug, *see id.* at 203–05, promotion for these off-label uses was presumed by the court to be truthful and non-misleading, *id.* at 198. The FDA maintained, however, that disclosures could be misleading by failing to communicate the limitations of the study. *Id.* at 216.

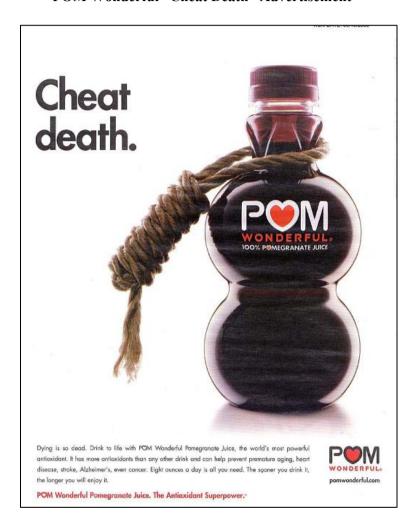
<sup>149.</sup> See id. at 228 (noting that the Caronia decision is limited to truthful and non-misleading speech).

<sup>150.</sup> *Id.* ("one-sided"); *id.* at 230 ("studiously neutral"); *id.* at 232–33 (showing that the court is hand-crafting such a studiously neutral statement for the parties). The court described its methods as "err[ing] on the side of caution." *Id.* at 233.

<sup>151. 777</sup> F.3d 478 (2015).

around weak evidence that pomegranate juice reduces heart disease, prostate cancer, and erectile dysfunction, among other things. 152

Figure 4: POM Wonderful "Cheat Death" Advertisement<sup>153</sup>



<sup>152.</sup> *Id.* at 484. Some of the advertisements misreported results from studies. *Id.* at 487. Because these ads make false *observational* claims, they do not raise the more interesting epistemological questions about speculative claims, so I will put them aside for this discussion.

<sup>153.</sup> POM Figures Appendix (Appendix B) at fig.7, *In re* POM Wonderful LLC, 155 F.T.C. 1 (2013) (No. D-9344), https://www.ftc.gov/sites/default/files/documents/cases/2013/01/ 130116pom appendixb.pdf [https://perma.cc/XC7X-89QN].

The FTC filed a complaint because the statements had not been substantiated using two randomized controlled human clinical trials, which the FTC required in order for food advertising to make a non-misleading health claim.<sup>154</sup> The D.C. Circuit found that the FTC's standard for non-misleading statements was too onerous, finding that one randomized trial would be enough. POM Wonderful had only observational studies rather than experimental trials,<sup>155</sup> so the FTC won the case, but at the price of lost control over the meaning of "misleading."<sup>156</sup>

These judicial developments are fraught with controversy because the stakes seem very high. On one hand, loosening agency grip over advertising and promotion could amplify a lot of junk science. One study that looked at a sample of statements supporting off-label use of drugs found that only 27% of them were supported by strong scientific evidence. If courts protect claims that have a weaker scientific basis, it could affect consumers and patients in unpredictable ways.

On the other hand, the standards that currently apply to commercial speakers regulated by the FDA and FTC even after *Amarin* and *POM Wonderful* are very demanding. A drug manufacturer cannot place an advertisement in a medical journal that accurately describes the results of a high quality scientific study without significant risk. The standards for drug promotion are higher than those that apply to doctors, who are held to a forgiving industry custom standard and often report the results

<sup>154.</sup> *Id.* Note that the FTC and FDA share authority over the regulation of food. Through a memorandum of understanding, they have divided the labor by having the FTC regulate claims made in advertising and having the FDA regulate the labeling of food. Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971).

<sup>155.</sup> Moreover, the observational studies conflicted with a controlled experiment that resulted in no pomegranate juice effect.

<sup>156.</sup> On the other hand, the POM case seems to be less protective than a previous case decided by the same circuit that found the FDA could not ban any health claim consistent with the First Amendment if the "evidence in support of the claim is *qualitatively* weaker than evidence against the claim." Pearson v. Shalala, 164 F.3d 650, 659 n.10 (D.C. Cir. 1999) (emphasis in original). The district court then further elaborated that a claim cannot be banned if there was any "credible evidence" supporting it unless that evidence was "outweighed by evidence against the claim" or was "qualitatively weaker." Pearson v. Shalala, 130 F. Supp. 2d 105, 114–15 (D.D.C. 2001); *see also* Whitaker v. Thompson, 248 F.Supp.2d 1, 9–13 (D.D.C. 2002) (analyzing the weight of the available evidence, finding that the support was mixed, and concluding that the FDA's outright rejection of a claim was not constitutionally permissible).

<sup>157.</sup> David C. Radley et al., Off-Label Prescribing Among Office-Based Physicians, 166 ARCHIVES INTERNAL MED. 121, 123 (2006).

<sup>158.</sup> Greene & Noah, supra note 21, at 266.

of non-rigorous studies to their patients.<sup>159</sup> Indeed, in some areas, the standard of care to which a doctor *must* conform is based on scientific evidence that falls short of the FDA's and FTC's standards for food and drug promotion.<sup>160</sup> But this may be defensible; advertising is never strictly necessary whereas doctors have to give opinions and advice even when there is very little reliable research.

Even if expert federal agencies are making the best possible tradeoffs between information flows and consumer protection (which in the next Part I will argue they do not), the expert agencies are not the only source of commercial speech restrictions. Federal and state courts decide false advertising claims brought by competitors and consumers, meaning that judges and juries must assess whether a statement is false. Faith in regulator expertise may be misplaced in these cases. <sup>161</sup>

The constitutionality of false advertising law was challenged recently in *Eastman Chemical Co. v. Plastipure*. <sup>162</sup> Eastman brought a Lanham Act claim for false advertising against Plastipure for promoting the results of a study published in a peer-reviewed journal of the National Institutes of Health. <sup>163</sup> The study was authored by the company's founder, a professor of neurobiology at the University of Texas. The study had tested several plastic resins for evidence of risk of estrogenic activity caused by chemicals used in plastics like bisphenol-A (BPA). <sup>164</sup> Some of the products that produced evidence of estrogenic activity were made with Tritan, a resin manufactured by the Eastman Chemical Company. Plastipure sent out brochures touting the findings. The only difference between the conclusions of the journal article and the description in the promotional material was that the brochure identified Eastman's Tritan products by name. <sup>165</sup> Eastman sued Plastipure, and a jury (using a

<sup>159.</sup> See discussion supra section II.D.

<sup>160.</sup> Complaint for Declaratory and Injunctive Relief at 9–15, Par Pharm., Inc. v. United States, No. 1:11-cv-01820 (D.D.C. 2011); Luke Dawson, *A Spoonful of Free Speech Helps the Medicine Go Down: Off-Label Speech & the First Amendment*, 99 IOWA L. REV. 803 (2014).

<sup>161.</sup> For example, in *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2007), a district court refused to dismiss a false advertising claim brought against the maker of Lipitor for advertising the drug not only for the FDA-approved purpose of lowering cholesterol but also for reducing the risk of heart disease. Shortly after the order, the FDA did approve Lipitor for the treatment of heart disease. So, Pfizer was exposed to liability for statements that were true under the FDA's high standards for drug approval.

<sup>162. 775</sup> F.3d 230 (5th Cir. 2014).

<sup>163.</sup> Id. at 233-34.

<sup>164.</sup> *Id*.

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

preponderance of the evidence standard) found that the claims made in the promotional materials, and hence in the scientific study, were false. 166

On appeal, the Fifth Circuit applied an "especially deferential" standard of review to jury findings in the Lanham Act case. <sup>167</sup> "Advertisements," the court explained, "do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate." <sup>168</sup>

The Lanham Act poses significant risk to any company wishing to advertise using research results because highly motivated competitors can bring false advertising claims based on any alleged methodological flaw. One strand of the "false by necessary implication" doctrine holds that any statement that misstates the scope of a study's valid implications is automatically "literally false" within the meaning of the Lanham Act. 170

The courts' inconsistent deference to fact-finders in determining the standard for non-misleading speech has left the bounds of commercial speech doctrine in disarray. Peddlers are much better protected when they use puffery than when they use contested factual claims.

# F. The Public Authority

The least protected speaker of all is the public authority—one who speaks on behalf of the government. The First Amendment protects the interests of the governed, not the state, so government entities can put limits on their own speech.<sup>171</sup>

The government can forbid itself from making false statements of fact, and on rare occasions it has done so.<sup>172</sup> But when it comes to contested

<sup>166.</sup> Id. at 234.

<sup>167.</sup> Id. at 238 (citation omitted).

<sup>168.</sup> Id. at 236.

<sup>169.</sup> Tushnet, *It Depends on What the Meaning of "False" Is, supra* note 21, at 102 (describing murkiness between true and false).

<sup>170.</sup> Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 947 (3d Cir. 1993); Church & Dwight Co. v. Clorox Co., 840 F. Supp. 2d 717, 721 (S.D.N.Y. 2012). However, unlike FTC actions, Lanham Act plaintiffs must still prove consumer deception and harm. Tushnet, *Running the Gamut, supra* 122, at 1339.

<sup>171.</sup> Columbia Broad. Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. 94, 139 (1973) (Stewart, J., concurring) ("The First Amendment protects the press from governmental interference; it confers no analogous protection on the Government."). Note that this is distinguishable from the Government Speech Doctrine, which holds that the First Amendment rights of constituents does not require the government to take viewpoint neutral stances in the government's own speech. Rust v. Sullivan, 500 U.S. 173, 192–93 (1991).

<sup>172.</sup> For an example of such a constraint, see Privacy Act of 1974, 5 U.S.C. § 552a (2012) (requiring the maintenance of truthful information); Freedom of Information Act, 5 U.S.C. § 552 (requiring accurate disclosures/reproductions of government records).

knowledge, governments have declined to limit themselves the way they limit professional and commercial speakers.

Examples of the government's mischaracterization of science abound. At the executive level, President George W. Bush tampered with agency reports in order to inject more ambiguity into the research verifying global temperature increases than was warranted. President Barack Obama's report on campus sexual assault states that one in five women is sexually assaulted in college, when the figure is nearly impossible to measure with confidence and might be closer to one in fifty if "assault" is defined narrowly. And the Trump administration made up entire terrorist massacres within its first three weeks in power.

Federal agencies are also responsible for spreading misinformation. <sup>177</sup> Given the nature of its work, it is not surprising that the FDA often makes health claims that are later debunked as more evidence accumulates. But the FDA does not have a great track record for responding to new evidence quickly.

For example, there is only scant evidence that salt consumption is bad for health. 178 Nevertheless, the FDA maintains rules to encourage foods

<sup>173.</sup> Distorting and Suppressing Climate Change Research, SCI. INTEGRITY POLICYMAKING, http://www.webexhibits.org/bush/5.html [https://perma.cc/3832-A8Q5].

<sup>174.</sup> White House Council on Women & Girls, White House, Rape and Sexual Assault: A Renewed Call to Action 1 (2014).

<sup>175.</sup> Alia Wong, *Why the Prevalence of Campus Sexual Assault Is So Hard to Quantify*, ATLANTIC (Jan. 26, 2016), https://www.theatlantic.com/education/archive/2016/01/why-the-prevalence-of-campus-sexual-assault-is-so-hard-to-quantify/427002/ [https://perma.cc/UVF5-L65R].

<sup>176.</sup> See Aaron Blake, Kellyanne Conway's 'Bowling Green Massacre' Wasn't a Slip of the Tongue. She Has Said It Before., WASH. POST (Feb. 6, 2017), https://www.washingtonpost.com/news/the-fix/wp/2017/02/06/kellyanne-conways-bowling-green-massacre-wasnt-a-slip-of-the-tongue-shes-said-it-before/?utm\_term=.4096e115b261 [https://perma.cc/ACK7-GG5U]. For a more comprehensive list of the Trump Administration's false claims, see David Leonhardt & Stuart A. Thompson, Trump's Lies, N.Y. TIMES (Dec. 14, 2017), https://www.nytimes.com/interactive/2017/06/23/opinion/trumps-lies.html [https://perma.cc/8QK6-LQUL].

<sup>177.</sup> For example, the Environmental Protection Agency had to remove saccharine from its list of carcinogens. Scott Hensley, *Saccharin Sweet Now Comes Without Hazardous Baggage*, NPR (Dec. 15, 2010, 2:33 PM), https://www.npr.org/sections/health-shots/2010/12/15/132078283/saccharin-sweet-now-comes-without-hazardous-baggage [https://perma.cc/3SJ7-4Z6L].

<sup>178.</sup> INST. OF MED., SODIUM INTAKE IN POPULATIONS: ASSESSMENT OF EVIDENCE (2013). In fact, the dietary recommendations of the federal government may pose health risks from too little salt. Margin O'Donnell et al., *Urinary Sodium and Potassium Excretion, Mortality, and Cardiovascular Events*, 371 NEW ENG. J. MED. 612 (2014). The original research implicating salt as a contributor to heart disease was based on low-quality methodologies that compared salt consumption and heart health patterns at the nation-state level. Melinda Wenner Moyer, *It's Time to End the War on Salt*, SCI. AM. (July 8, 2011), https://www.scientificamerican.com/article/its-time-to-end-the-war-on-salt/[https://perma.cc/5RSY-9SWM]. Suzanne Oparil, former president of the American Heart Association, explained "[t]he current [salt] guidelines are based on almost nothing." Peter Whoriskey, *Is the American Diet Too Salty? Scientists Challenge the Longstanding Government Warning*, WASH.

to label themselves as "low sodium" even though the designation is likely to steer consumers to foods that taste worse without offering any health advantages.<sup>179</sup>

The federal agencies' information campaigns on dietary cholesterol are similarly flawed. Recall from the Introduction that the FTC inferred from studies identifying blood cholesterol as a culprit for cardiovascular problems that foods containing cholesterol must increase cholesterol levels in the bloodstream. Using the Lanham Act's false by necessary implication doctrine, the FTC's position on dietary cholesterol would be considered "literally false" since it extrapolated a conclusion beyond what was demonstrated by the empirical studies. <sup>180</sup> Since the *In re National Commission on Egg Nutrition* <sup>181</sup> case, the link between dietary cholesterol and blood cholesterol has been seriously undermined, <sup>182</sup> yet the FDA has held tight to the old position against cholesterol. It has failed to change the mandatory nutrition panel (which mandates reporting of dietary cholesterol) and it continues to peg terms like "lean" in its labeling guidelines to low dietary cholesterol. <sup>183</sup>

The FDA will also have to modernize its stance against fat in all forms. For decades, the agency has allowed low-fat, nutrition-poor foods like Snackwell cookies to parade as "healthy" while denying nut-packed competitor snacks the opportunity to use that word on their packaging. <sup>184</sup> The FDA's sluggishness to reflect the current state of knowledge is striking because the agency would not accept a comparable lag from the food and drug producers it regulates.

POST (Apr. 6, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/04/06/more-scientists-doubt-salt-is-as-bad-for-you-as-the-government-says/?utm\_term=.4df06b5355d6 [https://perma.cc/KCX9-98YB].

<sup>179. 21</sup> C.F.R. § 101.61 (2017).

<sup>180.</sup> See discussion supra Introduction.

<sup>181. 88</sup> F.T.C. 89 (1976), enforced in part, Nat'l Comm'n on Egg Nutrition v. FTC, 570 F.2d 157 (7th Cir. 1977).

<sup>182.</sup> Other agencies have finally responded to the current state of research. The federal "Dietary Guidelines" for 2015–2020 have eliminated dietary cholesterol as a food to avoid. U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., 2015–2020 DIETARY GUIDELINES FOR AMERICANS 32 (8th ed. 2015), https://health.gov/dietaryguidelines/2015/resources/2015-2020\_Dietary Guidelines.pdf [https://perma.cc/BB4D-9LRS].

<sup>183.</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., A FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY 92 (2013), https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf [https://perma.cc/9MQ4-GQMJ].

<sup>184.</sup> The FDA's enforcement against KIND bars shows the folly in their current definition of "healthy" (which largely excludes foods that have nuts). Chris Weller, FDA Criticizes KIND Snacks over False Health Claims, Names Saturated Fats as Culprit, MED. DAILY (Apr. 15, 2015, 10:13 AM), http://www.medicaldaily.com/fda-criticizes-kind-snacks-over-false-health-claims-names-saturated-fats-culprit-329316 [https://perma.cc/4PBR-9J6B].

Federal statutory law and its supporting regulations can also convey misleading information about the state of scientific knowledge. For example, under the Controlled Substances Act, marijuana is classified as a Schedule I drug for which there is "no currently accepted medical use" even though there have been a number of well-controlled studies published in the top medical journals showing the efficacy of marijuana for the treatment of nausea, pain, and the symptoms of multiple sclerosis. 186

State lawmakers create a crazy quilt of scientific misinformation. Some make unsupported statements about fetal pain in the preambles to abortion-restriction legislation. Others require food producers to label genetically modified organisms, perpetuating the myth that they carry additional health risks. Still others actively promote quackery by

186. See, e.g., D.I. Abrams et al., Cannabis in Painful HIV-Associated Sensory Neuropathy: A Randomized Placebo-Controlled Trial, 68 NEUROLOGY 515 (2007); Jody Corey-Bloom et al., Smoked Cannabis for Spasticity in Multiple Sclerosis: A Randomized, Placebo-Controlled Trial, CANADIAN MED. ASS'N J., July 10, 2012; Ronald J. Ellis et al., Smoked Medicinal Cannabis for Neuropathic Pain in HIV: A Randomized, Crossover Clinical Trial, 34 NEUROPSYCHOPHARMACOLOGY 672 (2009); Penny F. Whiting et al., Cannabinoids for Medical Use: A Systematic Review and Meta-Analysis, 313 JAMA 2456 (2015).

187. Seventeen states have banned abortion after twenty weeks of gestation on the grounds that the fetus is able to feel pain at or before twenty weeks, yet this position is inconsistent with the medical consensus that pain cannot be felt prior to the formation of the cortex, which begins at the twenty-sixth week at the earliest. See State Policies on Later Abortions, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/state-policies-later-abortions [https://perma.cc/7FMW-HLL2] (last updated Feb. 1, 2018). For a description of the consensus that pain can be felt at twenty-six weeks at the earliest, see John A. Robertson, Science Disputes in Abortion Law, 93 TEX. L. REV. 1849 (2015).

188. Jonathan H. Adler, Compelled Commercial Speech and the Consumer "Right to Know," 58 ARIZ. L. REV. 421, 463 (2016) ("Vermont's Act 120 requires the 'clear and conspicuous' labeling of all food intended for human consumption 'produced entirely or in part from genetic engineering.' In enacting this requirement, the Vermont legislature declared that such foods 'potentially pose risks to health, safety, agriculture, and the environment,' citing an alleged 'lack of consensus regarding the validity of the research and science surrounding the safety of genetically engineered foods."") In fact, after diligent searching by many researchers, there is no evidence that genetic modification poses risks. The closest the evidence comes to showing any danger from GMO foods are studies on Roundup-Ready GMO crops that could indirectly cause harm by increasing the use of Roundup pesticides instead of alternatives. However, even the best studies on the health effects of Roundup require extrapolation from tests on rats and human placentas, and they fail to provide a comparison to other chemicals and mechanisms that would be used in lieu of Roundup. See, e.g., N. Benachour et al., Time- and Dose-Dependent Effects of Roundup on Human Embryonic and Placental Cells, 53 ARCHIVES ENVIL. CONTAMINATION & TOXICOLOGY 126 (2007). At one time the FDA had even considered the voluntary labeling of foods as "non-GMO" to be potentially misleading. See U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING: DRAFT GUIDANCE (2001).

<sup>185. 21</sup> U.S.C. § 812 (2012).

forming state-run licensing boards for fortune-tellers and practitioners of holistic medicine. 189

Many scholars have criticized the Supreme Court precedent's simplistic approach to government speech.<sup>190</sup> For the very reasons that free speech doctrine has constrained the government from attempting to resolve scientific disputes in the public discourse, good policy (if not the First Amendment itself) should arguably keep the government from polluting public discourse with anti-knowledge and weakly supported contested knowledge.<sup>191</sup>

For the purposes of this Article, though, the government's promotion of flawed science is more important in comparative than absolute terms. The government has the resources and opportunity to be an influential speaker. If it places no requirements to substantiate its own speculative claims with credible scientific studies, then the state's interest in screening out unsubstantiated claims of other speakers is demonstrably weak.

This is principally a normative critique rather than a constitutional one. However, to the extent a speaker receives any First Amendment protection (which all but commercial speakers automatically do), the critique can buttress a constitutional challenge. One California district court used precisely this comparative reasoning in striking down a

<sup>189.</sup> See License Application Form for Fortune-Telling in Mesa, AZ, http://www.mesaaz.gov/home/showdocument?id=4972 [https://perma.cc/3M4P-ZDQ4]; John M. Glionna, Fortuneteller License Law Called Biased, L.A. TIMES (July 21, 2003), http://articles.latimes.com/2003/jul/21/local/me-fortune21 [https://perma.cc/DKP6-94Y9]; CAL. DEPT. OF CONSUMER AFFAIRS: NATUROPATHIC MEDICINE COMMITTEE, http://www.naturopathic.ca.gov [https://perma.cc/YRL2-X7CY].

<sup>190.</sup> Jess Alderman, Words to Live By: Public Health, the First Amendment, and Government Speech, 57 BUFF. L. REV. 161, 170–74 (2009); Jeffrey M. Cohen, The Right to Learn: Intellectual Honesty and the First Amendment, 39 HAST. CONST. L.Q. 659, 659 (2012) (deceit in public education); David Cole, Beyond Unconstitutional Conditions: Charting Spheres of Neutrality in Government-Funded Speech, 67 N.Y.U. L. REV. 675, 703 (1992); David Fagundes, State Actors as First Amendment Speakers, 100 NW. U. L. REV. 1637, 1638 (2006); Abner S. Greene, Government of the Good, 53 VAND. L. REV. 1, 35–37 (2000); Robert D. Kamenshine, The First Amendment's Implied Political Establishment Clause, 67 CALIF. L. REV. 1104, 1104 (1979); Helen Norton, The Government's Lies and the Constitution, 91 IND. L.J. 73, 100 (2015) (noting, among other things, that government lies can impede democratic self-determination).

<sup>191.</sup> In extreme cases, a government actor's claims can be a form of soft censorship by intimidating other speakers. For example, in a particularly ironic example, an Idaho prosecutor told his constituents that "the spread of false information or inflammatory or threatening statements . . . may violate federal law" when of course such statements are in most cases constitutionally protected. Eugene Volokh, Opinion, *Chief Idaho Federal Prosecutor Warns: "The Spread of False Information or Inflammatory or Threatening Statements . . . May Violate Federal Law,"* WASH. POST: VOLOKH CONSPIRACY (June 26, 2016), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2016/06/26/chief-idaho-federal-prosecutor-warns-the-spread-of-false-information-or-inflammatory-or-threatening-statements-may-violate-federal-law/?utm\_term=.5f999b7b1cbe [https://perma.cc/BKF5-PCDC].

regulation on pricing information that exempted the government from the rule, asking, "[i]f this speech is so deceptive and harmful, why is the government allowed to engage in it?" 192

### G. Synthesis

This elaborate tour through the state of law for factual claims can now yield its payoffs.

In the public discourse, because courts are understandably reluctant to decide what the "truth" is, all factual claims are protected with something approaching complete immunity except for the historically unprotected categories of lies like defamation and fraud. The listener, rather than the government, has both the right and the responsibility to weed out bad claims and decide what is correct. Outside public discourse, however, the government has a freer hand. It can use the latitude to clear out anti-knowledge and many contested claims as well.

This hybrid structure combines the benefits of two very different styles of truth-seeking: a free-for-all (press, politicians, public authority) and an expert approach (protectors, peddlers). The free-for-all ensures that nothing that might be true is rejected. The expert approach ensures that only the claims that are likely to be true are accepted. 193

Given that free speech law uses these two distinct and often contradictory models, the categorization of speakers into these models makes intuitive sense. For example, the expert model seems entirely appropriate for the protector category since the clients will relinquish their own efforts and independent judgments about the relevant scientific debates. Because the listener has a preference for avoiding junk science as demonstrated by his seeking out an expert advisor, the free-for-all model is a mismatch. It likewise makes intuitive sense that other private speakers might have more legal impositions if, in context, the listener will be dependent on them for information (as with a landowner and a visitor).

Commercial speakers, however, are a misfit. Advertisers address the public through the same media as the press and politicians, yet when one message ("pomegranate juice reduces heart attacks") is paired with another ("so buy my pomegranate juice"), the statement shifts from

<sup>192.</sup> Italian Colors Rest. v. Harris, 99 F. Supp. 3d 1199, 1209 (E.D. Cal. 2015) (citing City of Ladue v. Gilleo, 512 U.S. 43, 52 (1994), for the proposition that exemptions from an otherwise legitimate regulation of speech could diminish the credibility of the government's interest for regulating the speech in the first place), *aff'd sub nom*. Italian Colors Rest. v. Becerra, 878 F.3d 1165 (9th Cir. 2018).

<sup>193.</sup> This is quite consistent with Robert Post's argument that information law is designed to do two mutually inconsistent things depending on context: encourage democratic participation or foster the development of expertise. *See generally* ROBERT C. POST, DEMOCRACY, EXPERTISE, AND ACADEMIC FREEDOM: A FIRST AMENDMENT JURISPRUDENCE FOR THE MODERN STATE (2012).

maximally protected to wholly unprotected. The self-interested motivations of commercial speakers can partly explain why a free-for-all model would frustrate the pursuit of truth. Regulations of advertising use an expansive version of falsity in which all contested claims are vulnerable.

Moreover, falsity is often treated as a harm in itself. Lack of proper substantiation is sufficient on its own for commercial speakers to run afoul of the law, and when First Amendment challenges are brought, the courts, too, focus only on the validity of the government's assessment of truth without analyzing the risks of a possible falsehood. 194

Of course, falsity is related to risk, but it is no substitute. The relationship between falsity and risk is not strong enough to bear the full weight of today's speech rules, especially since contested knowledge comes with a broad range of evidentiary support. Many of the commercial claims that are screened out by modern advertising laws have a good chance of being true, and in some cases, the harm even if they are false is quite limited. Meanwhile, the free-for-all model for public discourse goes too far by preserving any remote chance that poorly substantiated speech may turn out to be true. Risk-centered free speech law would permit some claims in public discourse to be subjected to government restrictions even though we know, ex ante, that there is always a chance they may be true.

Free speech doctrine can be readjusted to use risk, rather than falsity, as the basis for non-protection of scientific opinion. The next Part explains why today's truth-oriented free speech doctrine does a poor job tracking risk, particularly for the press and the peddlers—the most loved and most loathed speakers. Part IV will then show how free speech doctrine can be tweaked to balance speech interests against risk.

#### III. PROBLEMS

The First Amendment provides formidable, but qualified, protection to speakers. Risk, particularly physical risk, is an entirely appropriate counterweight to the heavy constitutional commitment to free speech. Unfortunately, the emphasis on falsity has caused First Amendment doctrine to drift apart from a risk analysis in some respects.

The doctrine under-protects commercial speakers by treating all factual claims that lack a high level of substantiation as false (or, at least potentially false) and unprotected. This treatment is not in line with a risk assessment because sometimes the consequences of censorship if a

<sup>194.</sup> Sometimes giving great deference to the government's assessment, as in *In re National Committee on Egg Nutrition*, and sometimes imposing limits on the government's assessment, as in *POM Wonderful. See supra* section II.E.

statement turns out to be true are much greater than the consequences if a statement is false. The risks are not symmetric.

At the same time, First Amendment doctrine overprotects speakers in the public discourse by shielding anti-knowledge from regulation no matter how foreseeable ensuing harm may be. This, too, is explained by the courts' nearsighted focus on truth. Since statements even within the anti-knowledge category have a chance of being true despite the body of persuasive evidence running against them, First Amendment precedent has guarded that moonshot chance. But this deprives the public of protection against foreseeable risks and culpable inflictions of harm that should be able to withstand strict scrutiny.

This Part explores the problems caused by truth-centered free speech law for commercial speakers and public discourse.

## A. Truth and Commercial Speech

The Supreme Court has found it harder and harder to maintain the lower status of commercial speech in a way that is consistent with its essentially libertarian approach to free speech, <sup>195</sup> but at the same time, it would be foolish to pretend that advertising is equivalent to broader public discourse. Advertisers are not the only speakers who have self-serving motivations, but they *always* have self-serving motivations. <sup>196</sup> Peddlers will find, produce, and share scientific evidence of any quality that helps the bottom line.

Constitutional precedent sensibly leaves more room for regulating misleading advertising claims than other types of speech. <sup>197</sup> But the self-interest of commercial speakers does not necessarily conflict with the goals of consumers or even of scientific progress. Advertising may be a danger when factual claims happen to be wrong, but it is an unmatched educator when the claims happen to be right. And in the meantime, while

<sup>195.</sup> See Sorrell v. IMS Health Inc., 564 U.S. 552, 565 (2011) (treating the statute as viewpoint discrimination instead of commercial speech regulation).

<sup>196.</sup> See generally Joanna K. Sax, Protecting Scientific Integrity: The Commercial Speech Doctrine Applied to Industry Publications, 37 Am. J.L. & MED. 203 (2011) (describing bias in corporate-funded research and reporting of results). Regulators may also worry about the harms from fly-by-night commercial operations that willingly promote a good or service on a false premise only to go bankrupt or leave the jurisdiction before harm can be identified and redressed.

<sup>197.</sup> In other words, I largely agree with Rebecca Tushnet's argument that commercial speech and consumer speech about corporations deserve different First Amendment treatment. Tushnet, *Fighting Freestyle*, *supra* note 32, at 1458.

scientific evidence is in dispute, advertising can be an instigator, drawing more attention and research to the area. 198

The FDA and FTC apply very stringent standards on advertising, requiring substantiation consistent with the standards for scientific peer-reviewed journals in order for a commercial claim to be considered non-misleading. Private causes of action based on false advertising and unfair competition use less defined and more uncertain standards, allowing recovery to a plaintiff based on a mere preponderance of evidence. And compliance with the FDA's guidelines for advertising does not provide a safe harbor in these private lawsuits. In all cases, the agency and statutory rules regulate speech based on truth rather than risk. In fact, the FDA has explicitly rejected the recommendation to use risk as the basis for regulating speech. And false advertising claims can be brought "without reference to the advertisement's impact on the buying public."<sup>203</sup>

These standards have deleterious effects. First, poorly substantiated factual claims may be more valuable to consumers than the alternative: no factual claims at all. Second, commercial regulations can induce too much confidence in the claims that are sufficiently substantiated. And third, overly high standards for truth can sap the incentives for producers to conduct research and for consumers to demand more evidence. Each problem is considered in turn.

#### 1. Restricting Good Information

False advertising law uses very high standards for substantiation. The FTC and the FDA require health claims to be supported with two randomized controlled trials (RCTs). Courts interpreting the Lanham Act have penalized advertisers for relying on independent studies that do not precisely match their claims, even when the studies are the best available

<sup>198.</sup> Which may or may not be a good thing, depending on where that effort would have gone otherwise.

<sup>199.</sup> See supra section II.E for a full description.

<sup>200.</sup> Moreover, plaintiffs demanding censorship may have an advantage because they present their cases first and capitalize on the "primacy effect" since juries' understanding of the case and the strength of evidence favors the evidence that is presented first. See Mark Spottswood, Ordering Proof: Beyond Adversarial and Inquisitorial Trial Structures, 83 TENN. L. REV. 291, 293–94 (2015).

<sup>201.</sup> POM Wonderful, LLC v. Coca Cola Co., 573 U.S. , 134 S. Ct. 2228, 2233 (2014).

<sup>202.</sup> FDA, PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT, *supra* note 135, at 28 (rejecting a risk-based approach to drug regulation).

<sup>203.</sup> McNeil-PPC, Inc. v. Pfizer Inc., 351 F. Supp. 2d 226, 247 (S.D.N.Y. 2005).

evidence on the topic.<sup>204</sup> (U.S. regulators are not alone; the European Union has banned claims that bottled water can prevent dehydration due to lack of substantiation.<sup>205</sup>)

High standards for truth screen out valuable information. Stringent standards, like placebo controls and double-blind experiments, are appropriate for studies published in scientific journals, but consumers in the real world need information more quickly than can be produced under such demanding standards. Providing some information is usually in consumers' best interest, even if the data would not satisfy rigorous scientific standards. At a critical point in time, information that makes for lousy science is usually better than no information at all.<sup>206</sup>

The current high standards are premised on two assumptions. First, by removing less substantiated claims from marketing, consumers will have to use better information from other sources.<sup>207</sup> And second, the high standards will prompt companies to invest resources into running two RCTs in order to meet the substantiation requirements.<sup>208</sup> Neither assumption is well founded. Generally speaking, no firms will invest the resources required to perform RCTs unless they hold a patent or some other form of exclusive control over a product. And as for the information that consumers will use when less-substantiated advertising is brushed away, better information may not exist. Even if it does exist, consumers may not search for it.

Put in economic terms, for most products,<sup>209</sup> the marginal utility of advertising is likely to be positive if regulators reduce the requirements for substantiation. This is true only because the standards we have are so high. With a low enough standard of substantiation, consumers would be better off by raising the standard so that it screens out the weakest claims.

<sup>204.</sup> See, e.g., McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991).

<sup>205.</sup> Nadia Arumugam, *EU Bans Bottled Water Claim that Water Prevents Dehydration: Ludicrous or Just?*, FORBES (Dec. 1, 2011, 1:11 PM), https://www.forbes.com/sites/nadiaarumugam/2011/12/01/eu-bans-bottled-water-claim-that-water-prevents-dehydration-ludicrous-or-just/#12c57ff152d9 [https://perma.cc/3ACT-8GJJ].

<sup>206.</sup> This is the point that Fred Schauer makes when he asks whether bad science can be good evidence. *See generally* Frederick Schauer, *Can Bad Science Be Good Evidence? Neuroscience, Lie Detection, and Beyond*, 95 CORNELL L. REV. 1191 (2010).

<sup>207.</sup> See FDA, PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT, supra note 133, at 6 (framing as avoiding indirect harms from directing attention away from better products, presumably where the better information would have steered them).

<sup>208.</sup> See id. at 4.

<sup>209.</sup> See my discussion of drug off-label promotion, *infra* Part IV, for an example where the current standards may be appropriate.

But the inflection point where the standard switches from being too onerous to too weak is below the rules in place today.

Let's focus on the randomized controlled trial for a moment. RCTs are experiments that randomly assign a treatment (e.g., pomegranate juice) or a control (e.g., a placebo juice that resembles pomegranate juice) to each subject, and then measure a range of outcomes to investigate the effects. RCTs are rightly regarded as the gold standard for empirical evidence because other factors that might explain a good outcome should be controlled by the control group. This makes them much more powerful than observational evidence because a person's choice to drink pomegranate juice out in the real world is not at all random and can be influenced by preexisting health, socioeconomic status, demographics, and other things. But nobody can or should rely on RCTs alone to understand how the world works. Even if RCTs are well run, they are often impossible to perform. We will never randomly assign experimental treatments to babies or pregnant women unless they have a health condition that is already threatening their lives.

By using RCTs as the sole acceptable standard, the FDA and the FTC have guaranteed that many scientific debates cannot be discussed in advertising because most studies use observations from the real world rather than an experiment. Andrew Gelman explains the problem like this: "[g]iven the manifest virtues of experiments, why do I almost always analyze observational data? The short answer is that almost all the data out there are observational."<sup>213</sup>

Standard-setting has bedeviled the expert agencies for decades. The FTC and the FDA sparred over the problem in the 1980s, when the FTC supported the Kellogg company for making ads promoting high-fiber cereals for health in violation of FDA regulations. Howard Beales and his coauthors have summarized the episode:

Consider, for example, the Kellogg claim about the relationship between diets high in fiber and the risk of colon cancer. Although the FDA now believes that there is "substantial scientific agreement" that the claim is correct, uncertainty remains. There are, after all, no randomized clinical trials measuring the incidence of cancer at different levels of fiber intake, and such

<sup>210.</sup> See Randomized Control Trial (RCT), PUBMED HEALTH, https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0025811/ [https://perma.cc/EV2U-REBM].

<sup>211.</sup> *Id.*; see also Andrew Gelman, *Experimental Reasoning in Social Science*, in Field Experiments and Their Critics: Essays on the Uses and Abuses of Experimentation in the Social Sciences 185 (Dawn Langan Teele ed., 2014).

<sup>212.</sup> The next subsection explains why they often are not well designed.

<sup>213.</sup> Gelman, supra note 211, at 192-93.

trials would surely increase our confidence in the truth of the claim. If the claim is true, however, waiting for the results of such trials would impose substantial costs on consumers, who would lose an important source of information about the likely relationship between fiber consumption and cancer risk. Before such claims were allowed, consumers ate less fiber, and as a result incurred a higher risk of cancer than necessary. On the other hand, if the claim turns out to be false, the consequences to consumers are relatively small. They may give up the better taste of another cereal, or pay a little more for a higher-fiber product. It seems clear that, in this case, the far more serious error is mistakenly to prohibit truthful claims.<sup>214</sup>

Identical reasoning can be applied to the POM Wonderful case; the harm from consuming pomegranate juice, particularly if it substitutes for some other juice or soda beverage, is negligible, so even weak evidence of benefit should be brought to consumers' attention. But this sort of marginal analysis has fallen out of favor, and the FTC has, over time, raised its standards to conform to the FDA.<sup>215</sup>

In addition to screening out positive information, the FDA standards have also interfered with advertising that can enlighten the public about the dangers of unhealthy products even if the claims are not technically accurate. Consumption of fats and saturated fats dropped precipitously between 1985 and 1990, during a period when a growing proportion of food advertisements used health claims (most often, claims that linked saturated fat to heart disease and then proudly boasted that the product

<sup>214.</sup> J. Howard Beales III et al., *In Defense of the* Pfizer *Factors, in* The REGULATORY REVOLUTION AT THE FTC: A THIRTY-YEAR PERSPECTIVE ON COMPETITION AND CONSUMER PROTECTION 83, 90 (James Campbell Cooper ed., 2013). *See generally* PAULINE M. IPPOLITO & ALAN D. MATHIOS, U.S. FED. TRADE COMM'N, HEALTH CLAIMS IN ADVERTISING AND LABELING: A STUDY OF THE CEREAL MARKET (1989), https://www.ftc.gov/sites/default/files/documents/reports/health-claims-advertising-and-labeling-study-cereal-market/232187.pdf [https://perma.cc/N47L-GKT9] (a study showing that when an advertising ban on the health benefits of fiber in cereal was lifted, consumers and producers shifted their habits to incorporate more fiber); Pauline M. Ippolito & Alan D. Mathios, *Information, Advertising and Health Choices: A Study of the Cereal Market*, 21 RAND J. ECON. 459 (1990) (same).

<sup>215.</sup> Another way to understand how high the FDA and FTC standards are, consider as a comparison what the government itself must have in terms of an empirical basis in order to meet First Amendment strict scrutiny review:

We do not, however, require that "empirical data come ... accompanied by a surfeit of background information....[W]e have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense."

Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 555 (2001) (quoting Fla. Bar v. Went For It, Inc., 515 U.S. 618, 628 (1995)).

contained no saturated fats).<sup>216</sup> But the Nutritional Labeling and Education Act of 1990 required FDA preclearance for these claims, and the advertising that differentiated between oils and fats dried up as a result.<sup>217</sup> Without the ability to make health claims, food producers had little incentive to swap saturated fats for healthier oils, and sure enough consumption of saturated fats rose again.<sup>218</sup>

More recently, false advertising law has interfered with public education about the dangers of sweeteners. When the sugar and corn industries settled their false advertising claims against each other, they ended a negative advertising battle that disputed whether high-fructose corn syrup was as "healthy" as sugar or not. 219 Both industries had viable claims because each had only weak scientific support; a bench trial could have gone either way. 220 In terms of legal strategy, the settlement was sound, but the consumers will suffer from it. Sugar and corn were stuck in a "less bad" advertising campaign. 221 The advertisements may have been inaccurate in the specifics (whether sugar is better than high fructose corn syrup), but this was secondary to the more illuminating message that both sweeteners are bad. If the sugar and corn industries had agreed long ago to refrain from producing advertisements that point out the negative health effects of the other's product, the collusion would arouse the suspicions of antitrust regulators, yet the Lanham Act's false advertising provisions steered them to the same result.<sup>222</sup>

<sup>216.</sup> Beales III et al., supra note 214, at 89-90.

<sup>217.</sup> Id.

<sup>218.</sup> Id.

<sup>219.</sup> E.J. Schultz, *Sugar and Corn Industries Settle False Ad Lawsuit*, AD AGE (Nov. 20, 2015), http://adage.com/article/cmo-strategy/sugar-corn-industries-settle-false-ad-lawsuit/301469/ [https://perma.cc/WYN9-KRH3]; Complaint at 2, W. Sugar Coop. v. Archer-Daniels-Midland Co., 98 F. Supp. 3d 1074 (C.D. Cal. 2015) (No. CV11-3473 CBM (MANx)).

<sup>220.</sup> The corn syrup industry's claim that the sweeteners were equivalent is more consistent with the evidence (some of which was funded by the corn industry). Kathleen Doheny, *How Sugar Compares with High Fructose Corn Syrup*, WEBMD (Oct. 11, 2010), https://www.webmd.com/diet/news/20101011/how-sugar-compares-with-high-fructose-corn-syrup#1 [https://perma.cc/X8CL-9DTS]; *Is High Fructose Corn Syrup (HFCS) Worse than Sugar*?, EXAMINE.COM, https://examine.com/nutrition/is-hfcs-high-fructose-corn-syrup-worse-than-sugar/ [https://perma.cc/N8H6-XFUD] (last updated Sept. 21, 2017) (surveying relevant literature); Gary Taubes, *Is Sugar Toxic*, N.Y. TIMES MAG. (Apr. 13, 2011), http://www.nytimes.com/2011/04/17/ magazine/mag-17Sugar-t.html [https://perma.cc/8V5G-DAVU]. However, high-fructose corn syrup does contain a slightly higher percentage of fructose, the obesity-promoting element. Since juries can determine truth using a preponderance standard, the corn industry had justified doubts about the outcome. *See* discussion of false advertising standards *infra* section I.E.

<sup>221.</sup> JOHN E. CALFEE, FEAR OF PERSUASION 46-57 (1997).

<sup>222. &</sup>quot;Less bad" advertising effects have been documented with cigarette advertising, too, during the famous tar wars in which the manufacturers claimed to have cigarettes that were less harmful than

Regulators and the Supreme Court often take it on faith that advertising always increases demand for the product advertised, <sup>223</sup> but this is an incomplete understanding of the consumer response to advertising. The more important point is that when reasonable but less-than-fully-substantiated health claims are screened out of advertising, consumers are poorly served.

## 2. Breeding Overconfidence

The last section focused on the strength of the claims that are screened out by current law, but the converse is that current law hides the weaknesses of claims that are condoned by it. By pruning away cheap talk and poorly supported scientific claims, the government induces reliance on the claims that do make it to the market. This is, in fact, one of the purposes of false advertising law. It gives consumers more confidence in the claims that are made by responsible companies.<sup>224</sup> But this confidence may be misplaced, particularly if the law is too effective in removing doubt.

Finality and authoritative truth are at odds with the scientific process.<sup>225</sup> That is not to say that every claim should be treated as equally credible as every other—as Part I explained, there are better and worse forms of substantiation. Still, consumers and experts alike often forget how hard it is to collect meaningful data about complex social, environmental, and health problems. Even the most reliable scientific processes will lead researchers astray. We can get a sense of this just by considering the

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competitors. The overwhelming message that consumers got, before the FTC stepped in and prohibited the health claims, was that cigarettes are dangerous. *Id.*; *see also* James L. Hamilton, *The Demand for Cigarettes*, 54 REV. ECON. & STAT. 401, 401 (1972) (describing how advertising bans were counterintuitively harmful because while advertising caused a small increase in consumption, that effect was swamped by the effects of the health scare from responsive advertising).

<sup>223.</sup> See Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 557–58 (2001); Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995). Regulators are also susceptible to biases from serving high moral purposes that can get in the way of dispassionate analysis. Lee Jussim et al., Can High Moral Purposes Undermine Scientific Integrity?, in THE SOCIAL PSYCHOLOGY OF MORALITY 173 (Joseph P. Forgas et al. eds., 2016).

<sup>224.</sup> David Vinjamuri, *POM Wonderful's Deception Is the Tip of the Iceberg*, FORBES (May 23, 2012, 4:06 PM), https://www.forbes.com/sites/davidvinjamuri/2012/05/23/judge-finds-pomwonderful-advertising-deceptive-but-thats-just-the-tip-of-the-iceberg/#2f1188421619 [https://perma.cc/LZ5N-UJ58] ("Faced with a barrage of sensational claims relating to everything from weight loss to impotence, we lose a measure of trust in all brands. This loss of goodwill effectively becomes a tax born by ethical brands as well as dodgy ones, as gaining consumer trust and loyalty become more difficult and more expensive for all.").

<sup>225.</sup> STUART FIRESTEIN, IGNORANCE: HOW IT DRIVES SCIENCE 22 (2012) ("[t]here are cases where knowledge, or apparent knowledge, stands in the way of ignorance" and productive exploration).

generally accepted 5% standard for statistical significance. Statistical significance usually indicates that the chance that the results would have occurred by pure randomness is only 5%. But as soon as fifteen different statistically significant findings are pulled together, the chances are greater than 50% that at least one finding is random noise. Add to this the fact that much public health research cannot be replicated when independent researchers try, and we get a humbling picture. Even when we make rational, evidence-based decisions, we are fumbling in the dark.

A few sobering examples will get the point across. A recent meta-study examined the prevalence of medical reversals—events where a current standard of care used by doctors is found to be ineffective or harmful. 226 The meta-study found that out of 363 studies that rigorously retested an accepted standard of care, 146 (40%) resulted in reversal. 227 Only 38% of the studies validated the standard of care, and the rest were inconclusive. 228 Of course, the medical standards that were selected for study may not have been representative—they may have been chosen because there was some doubt in the field about their value—but the results are chilling nevertheless.

The journal *Perspectives on Psychological Science* has been producing a special type of article that it calls a "registered replication report" that retests a highly influential study in the field.<sup>229</sup> So far, only one out of five retested studies have produced results consistent with the original study.<sup>230</sup> And in 2012, the pharmaceutical company Amgen announced that it attempted to replicate fifty-three landmark cancer studies and failed to reproduce the findings for forty-seven of them, despite going to unusual lengths to contact and work with the original authors.<sup>231</sup> And among the thirty-six cancer drugs approved by the FDA between 2008 and 2012,

<sup>226.</sup> Vinay Prisad et al., A Decade of Reversal: An Analysis of 146 Contradicted Medical Practices, 88 MAYO CLINIC PROC. 790, 790 (2013).

<sup>227.</sup> Id. at 792.

<sup>228.</sup> Id.

<sup>229.</sup> Registered Replication Reports, ASS'N FOR PSYCHOL. SCI., http://www.psychologicalscience.org/publications/replication [https://perma.cc/34XU-TD49].

<sup>230.</sup> The Replication Game: How Well Do Psychology Studies Hold Up?, SCI. FRIDAY (Aug. 5, 2016), https://www.sciencefriday.com/segments/the-replication-game-how-well-do-psychology-studies-hold-up/ [https://perma.cc/8VDC-V547].

<sup>231.</sup> Sharon Begley, *In Cancer Science, Many "Discoveries" Don't Hold Up*, REUTERS (Mar. 28, 2012, 10:10 AM), https://www.reuters.com/article/us-science-cancer/in-cancer-science-many-discoveries-dont-hold-up-idUSBRE82R12P20120328 [https://perma.cc/PD3A-R6U2]. More recently, Amgen has started to publish data from its failed replication efforts. Monya Baker, *Biotech Giant Publishes Failures to Confirm High-Profile Science*, NATURE (Feb. 4, 2016), http://www.nature.com/news/biotech-giant-publishes-failures-to-confirm-high-profile-science-1.19269 [https://perma.cc/ED3C-6KH3].

only five have exhibited success in the field. The other thirty-one did not extend their patients' survival.<sup>232</sup> This means that even the FDA's high standards for drug approval, requiring two RCTs, are prone to error.

There are a few explanations for the various replication crises breaking out in these fields, even when controlled experiments are used as the basis for knowledge. First, when it comes to clinical drug trials, those in charge of the trials (drug companies) have a stake in the outcome and are therefore likely to do a number of things that help improve the odds of finding efficacy. They may, for example, limit the pool of research subjects to patients who are relatively young and healthy.<sup>233</sup> Or for pragmatic reasons, they may look for early outcomes that are used as proxies for improved health—lower cholesterol or smaller tumors—rather than waiting to see how long-term health is affected.<sup>234</sup> So even when an RCT is well run and well designed, if its real-world implications rely on a faulty assumption (e.g., that lowering blood cholesterol will cause a reduction in heart attack risk) it is going to be misleading.

Decision-makers put more weight than they should on FDA approval processes. Doctors believe drugs are more effective than they really are, <sup>235</sup> possibly because the FDA is involved as a gate-keeper. In at least one sense, the non-experimental observational studies often used in epidemiology and economics have an advantage over experimental evidence: their flaws are so well known and so often pointed out that nobody puts much faith in a single study. As Rogert Peng put it, "[i]t's difficult to have a replication crisis when nobody believes the findings in the first place."

None of these issues seriously compromises the high status of RCTs. RCT experiments should be treated as a weighty form of evidence, particularly when they use a representative sample of subjects and directly

<sup>232.</sup> Chul Kim & Vinay Prasad, Research Letter, Cancer Drugs Approved on the Basis of a Surrogate End Point and Subsequent Overall Survival: An Analysis of Five Years of US Food and Drug Administration Approvals, 175 JAMA INTERNAL MED. 1992, 1992–94 (2015).

<sup>233.</sup> See Keith Humphreys et al., Subject Eligibility Criteria Can Substantially Influence the Results of Alcohol-Treatment Outcome Research, 69 J. STUD. ALCOHOL & DRUGS 757, 757 (2008). Note that academic researchers are also likely to want positive results rather than null results because their measure of success (publication) is also dependent on significant findings.

<sup>234.</sup> Kim & Prasad, supra note 232, at 1992-94.

<sup>235.</sup> Tammy C. Hoffman & Chris Del Mar, Clinicians' Expectations of the Benefits and Harms of Treatments, Screening, and Tests, 177 JAMA INTERNAL MED. 407, 407 (2017).

<sup>236.</sup> Roger Peng, A Simple Explanation for the Replication Crisis in Science, SIMPLY STAT. (Aug. 24, 2016), https://simplystatistics.org/2016/08/24/replication-crisis/[https://perma.cc/AE5H-HNJ4].

measure the outcome of interest.<sup>237</sup> But they should not be mistaken for truth.

Overconfidence in RCTs and other standards maintained by regulators does not necessarily cause trouble in the short term. At any given moment, a consumer decision made on the basis of those standards is probably the best choice. But the standards can cause frustration and backlash if the government suggests that the scientific evidence creates a solid ground when it is more like shifting sands. Consumers are exasperated by health and nutrition trends that rise and fall too quickly. When the government oversells the science behind health and nutritional claims in order to urge consumers to make decisions that are rational in the present, it undermines the chances that consumers will make updated, rational decisions in the future.

The long-term solution is for Americans to become more science-literate, to accept epistemic uncertainty, and to optimize their choices under those conditions. Financial regulators are starting to move in that direction. After decades of regulatory responses that ratcheted up the duties imposed on information intermediaries like accountants and credit agencies, the SEC is now considering opportunities to reduce reliance on credit-ratings agencies to bring back more consumer skepticism.<sup>238</sup> But this is an unusual trend. In most areas of law, false advertising regulation leaves no room for ambiguity. Ads are either false or, presumptively, true.

## 3. Thwarting Salience and Dynamism

Advertising law must balance two important goals that work at crosspurposes: developing consumer trust in a message, and developing consumer appetite for more evidence.

Advertising claims are helpful in part because they are taken at face value. If an audience had to go find all the underlying facts and develop the analytical skills to form his or her own opinion about the validity of a claim, advertising wouldn't provide any informational efficiencies.<sup>239</sup> On

<sup>237.</sup> RCTs may also be more risky than necessary. An alternative to randomizing is to assign the treatment until there is a failure, and then assign the control until there is a failure, and back and forth. This "one-armed bandit" method of testing will distribute the treatment in proportion to its efficacy (relative to the control). See BRIAN CHRISTIAN & TOM GRIFFITHS, ALGORITHMS TO LIVE BY: THE COMPUTER SCIENCE OF HUMAN DECISIONS 45–52 (2016). Machine learning may eventually bring a paradigm shift to the fields that currently rely on RCTs. With machine learning, experiments are initially designed using observational data (training data) and constantly altered and tweaked based on ongoing outcomes.

<sup>238.</sup> Onnig H. Dombalagian, *Investment Recommendations and the Essence of Duty*, 60 AM. U. L. REV. 59, 62 (2011).

<sup>239.</sup> Robert Ahdieh, Beyond Individualism in Law and Economics, 91 B.U. L. REV. 43, 77 (2011).

the other hand, advertising is part of a dynamic process, often with multiple points of decision-making. Access to weak science at  $T_0$  can generate demand for better evidence at  $T_1$ .<sup>240</sup> As Julie Cohen has said, "exposure to information shapes demand for additional information."

False advertising law can interfere with evidence-based decision-making and with the incentives to produce that evidence base. For example, a doctor, who was also the CEO of a drug company, was convicted of fraud for enthusiastically promoting the results of a study of the company's drug for treatment of a deadly disease, IPF.<sup>242</sup> Although the study was published in the prestigious *New England Journal of Medicine*, the government successfully argued that the study design was flawed by choosing a subset of research subjects after data had been collected and analyzed.<sup>243</sup> On retesting, the drug performed no better than placebo and caused mild side effects.<sup>244</sup> But given that there are no known effective treatments for IPF,<sup>245</sup> the promotion of a potentially promising treatment was arguably better than silence. It stimulated demand for more testing and caused relatively little harm in the interim.

In a case with lower stakes, a court barred Clorox's advertising that claimed its kitty litter eliminates odors better than baking-soda-based kitty litters. Clorox had tested the effects on odor based on cat waste that had spent twenty-two to twenty-six hours sealed in jars, but the court thought this experiment did not substantiate Clorox's claims because cat litter is usually left in the open air, rather than sealed in jars.<sup>246</sup> The legal

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<sup>240.</sup> Many scholars have made this point in the broader context of speech if not the specific context of advertising. Norton, *Lies and the Constitution*, *supra* note 5, at 165 ("[L]ies that trigger confrontation and rebuttal may lead to increased public awareness and understanding of the truth."); Spottswood, *supra* note 21, at 1238 ("Erroneous speech as a Means of Increasing Our Evidence."); Jonathan Varat, *Deception and the First Amendment: A Central, Complex, and Somewhat Curious Relationship*, 53 UCLA L. REV. 1107, 1119 (2006).

<sup>241.</sup> Julie E. Cohen, Copyright and the Perfect Curve, 53 VAND. L. REV. 1799, 1818 (2000).

<sup>242.</sup> United States v. Harkonen, No. CR08-0164MHP, 2009 WL 5166246, at \*1 (N.D. Cal. Apr. 15, 2009).

<sup>243.</sup> United States v. Harkonen, 510 F. App'x 633, 636 (9th Cir. 2013); see also Patti Zettler, U.S. v. Harkonen: Should Scientists Worry About Being Prosecuted for How They Interpret Their Research Results?, STAN. L. SCH.: L. & BIOSCIENCES BLOG (Oct. 7, 2013), https://law.stanford.edu/2013/10/07/lawandbiosciences-2013-10-07-u-s-v-harkonen-should-scientists-worry-about-being-prosecuted-for-how-they-interpret-their-research-results/ [https://perma.cc/ZPG3-3FKE].

<sup>244.</sup> Talmadge E. King Jr. et al., Effect of Interferon Gamma-1b on Survival in Patients with Idiopathic Pulmonary Fibrosis (INSPIRE): A Multicentre, Randomized, Placebo-Controlled Trial, 374 LANCET 222, 222 (2009).

<sup>245.</sup> See Idiopathic Pulmonary Fibrosis, NAT'L HEART, LUNG, & BLOOD INST., https://www.nhlbi.nih.gov/health/health-topics/topics/ipf/treatment [https://perma.cc/KCZ4-NNR5].

<sup>246.</sup> Church & Dwight Co. v. Clorox Co., 840 F. Supp. 2d 717, 721-22 (S.D.N.Y. 2012).

intervention made the perfect the enemy of the good and reduced incentives to design advertising campaigns around product testing.

This is not to say that advertising is a great source for scientific education. The charts, graphs, and technical-looking mumbo-jumbo used in commercials are often silly and meaningless. It's easy to get cynical about the types of evidence that consumers find convincing. Commercials too often have only the veneer of science without the methodological soundness. But the steady increase in scientific claims over the last century, including pseudoscientific claims, show something hopeful: consumers want to make decisions on the basis of evidence. They want to see that one diaper holds more blue liquid than another without leaking, or that four dentists out of five recommend their toothpaste. It is easy to overlook how much progress the human population has made. Not long ago even well-educated consumers did not understand the value of an experiment and empirical evidence.<sup>247</sup>

Less well-supported scientific claims, even those that verge on the pseudoscientific, have the virtue of focusing consumer attention on the product attributes that they should value most when making their purchasing decision—health, efficacy, and safety. When these claims are reduced by regulation, they are not necessarily replaced by better-substantiated claims. Consumers will not consult PubMed when health claims are purged from advertisements. Instead, advertising will focus on legally immune puffery, on vague concepts like "smooth" and "manly" in the 1960s or "green" and "natural" today.<sup>248</sup> Advertisers will make imprecise health claims because precision is a liability.<sup>249</sup> And they will make claims that are easier to support empirically, even if those attributes do not deserve the same salience as health, efficacy, and safety.<sup>250</sup>

For these reasons—because good information is screened out, because substantiated information is given too much weight, and because censorship can reduce salience of the important attributes—factual claims

<sup>247.</sup> For example, in the Middle Ages, an unusually enlightened noble tried to show others that torture would always extract a confession by killing his own ox and then torturing a farm hand to confession. But the meaning of the experiment was lost on his peers. STEVEN PINKER, THE BETTER ANGELS OF OUR NATURE: WHY VIOLENCE HAS DECLINED 140 (2011).

<sup>248.</sup> See CALFEE, supra note 221, at 51.

<sup>249.</sup> Groden v. Random House, Inc., 61 F.3d 1045, 1052 (2d Cir. 1995); Phantom Touring, Inc. v. Affiliated Publ'ns, 953 F.2d 724, 728 n.7 (1st Cir. 1992) (claim was "subjective and imprecise, and therefore not capable of verification or refutation by means of objective proof").

<sup>250.</sup> Moreover, the claims that can be substantiated can cause the product to enjoy an undeserved "halo effect," where consumers infer that if a product is good for them in one way, it is better for them in other ways, too. Brian Roe et al., *The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Results from FDA Experimental Data*, 18 J. Pub. Pol'y & Marketing 89, 99 (1999).

made in commercial speech that are neither very likely to be true nor very likely to be false should be given some intermediate free speech protection.

The problems discussed here do not suggest that the law of false advertising should be scrapped or significantly rewritten. Advertisers can create a lot of havoc using influential contested claims. But as Part IV will explain, regulators should be steered by the First Amendment to design their restrictions around risk rather than truth.

#### B. Truth and the Public Discourse Free-For-All

If the First Amendment does too little to protect the claims made by commercial speakers, it does too much to shield the claims made in mass media.

For example, a study of eighty randomly selected medical recommendations that were made on the hit TV show, *Dr. Oz*, found that less than half had any evidence base whatsoever, even a single case study. Fifteen percent of the recommendations contradicted the existing evidence base, meaning that the show broadcasts not just contested claims but anti-knowledge. (Recommendations from *The Doctors* were slightly better supported. The website *Natural News* is similarly flawed (if less influential). *Natural News* claimed that the Zika virus is a conspiracy made up by the pharmaceutical industry, and that the Zikarelated birth defects are actually caused by exposure to mosquito repellants and insecticides. To the extent these reports steer their audiences to take action that they would not otherwise take, and to the extent those actions make the audience worse off, these public statements create foreseeable and unnecessary risks.

Courts have shied away from legal interventions that would repress or punish these types of scientific debates, even when some statements are

<sup>251.</sup> Christina Korownyk et al., *Televised Medical Talk Shows—What They Recommend and the Evidence to Support Their Recommendations: A Prospective Observational Study*, BMJ, Dec. 17, 2014, at 1.

<sup>252.</sup> Id.

<sup>253.</sup> Id.

<sup>254.</sup> Mike Adams, Ten Shocking Reasons Why Zika Virus Fear Is Another Fraudulent Medical Hoax and Vaccine Industry Funding Scam, NAT. NEWS (June 3, 2016), https://www.naturalnews.com/054248\_Zika\_virus\_medical\_hoax\_vaccine\_industry.html [https://perma.cc/5S7C-GJTC]. The article refers to the author, Mike Adams, as "the Health Ranger." Id. A study of Facebook posts about the Zika virus found that misinformation about Zika was more prevalent than accurate information. Megha Sharma et al., Zika Virus Pandemic—Analysis of Facebook as a Social Media Health Information Platform, 45 AM. J. INFECTION CONTROL 301–02 (2017).

highly likely to be false, because of commitments to open discourse.<sup>255</sup> But, as the law of fraud, defamation, privacy, right of publicity, and even incitement illustrate, the constitutional right to free speech will bend when there is a credible threat to the audience or the subject of the speech. Fraud, incitement, and defamation have the advantage of being historical and traditional exceptions to the scope of First Amendment coverage—an attribute that has great influence over whether the government will prevail in a free speech challenge.<sup>256</sup> Privacy and the right of publicity, however, are not among the historically recognized exceptions and have nevertheless survived judicial scrutiny, albeit sometimes in pared-down form.<sup>257</sup>

These areas of law have withstood constitutional challenge because courts have a mental model of how listeners will interpret and react to speech, and what harms will flow from those reactions. That same model should support a narrow set of restrictions on scientific and health claims in the popular press—particularly where the statements are forcefully contradicted by a strong body of evidence and are likely to result in harmful conduct by the audience. Restrictions of this sort do not rely on falsity alone. (After all, privacy and right of publicity claims do not involve falsehoods.) Rather, restrictions on dangerous scientific claims can be justified because of risk.

The next Part shows how First Amendment law can be reshaped to bend for risk rather than falsity and what implications this shift will have.

#### IV. PROTECTION TOMORROW

First Amendment law is in the process of correcting the misstep of using a true/false dichotomy for factual claims. As a category, factual claims share the quality that they are capable of being proven or disproven. But only a subset of them are *presently* capable of validation. The rest are caught up in a free speech paradox, simultaneously condemned for being possibly false (and of "low value") and endorsed for being possibly true.<sup>258</sup>

<sup>255.</sup> And the mantra that "there is no such thing as a false idea." Gertz v. Robert Welch, Inc., 418 U.S. 323, 339 (1974).

<sup>256.</sup> See United States v. Stevens, 559 U.S. 460, 468-69 (2010).

<sup>257.</sup> Sorrell v. IMS Health Inc., 564 U.S. 552, 580 (2011) (striking down a law prohibiting the sale of health data but assuring that narrower privacy laws would survive scrutiny); Zacchini v. Scripps-Howard Broad. Co., 433 U.S. 562, 578 (1977) (finding that a tort claim based on the right of publicity survives a First Amendment challenge).

<sup>258.</sup> This is most famously and beautifully captured in Justice Holmes's dissenting opinion in Abrams v. United States. "Persecution for the expression of opinions seems to me perfectly

The judiciary is beginning to recognize the limits of the true/false dichotomy. As the Second Circuit observed,

[I]t is the very premise of the scientific enterprise that it engages with empirically verifiable facts about the universe. At the same time, however, it is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation.<sup>259</sup>

The best way to preserve what is working in the truth-oriented case law while fixing what is not is to shift from falsity to risk as the basis for regulation. Falsity and risk are often in sync—in many contexts, they rise and fall together. Their close relationship helps preserve the benefits of our current system in the commercial speech realm while opening up some routes for the reasonable regulation of public discourse. But where they tack apart, the falsity orientation gets in the way of free speech without sufficient justification.

This Part describes a risk-centered approach, and illustrates how it would affect current law

## A. The Harm-Centered Approach to Factual Claims

If the First Amendment protection of factual claims centered around risk, it would distinguish between two categories of unverified factual claims that are currently treated as one: *contested* claims (for which no solid base of evidence exists to validate or refute the claim), and *anti-knowledge* (which is contradicted by a solid base of evidence). Contested knowledge is speculation and debate, while anti-knowledge is the set of factual claims that can be verified, to a reasonable extent, as false.

# 1. Anti-Knowledge

Anti-knowledge from a commercial speaker serves little public value, and the precedents that restrict false claims from the scope of First Amendment protection require no overhaul. Commercial speakers will not contribute meaningfully to consumer education when their claims are exceedingly likely to misinform their audience.

logical. . . . 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 . . ." Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).

<sup>259.</sup> ONY, Inc. v. Cornerstone Therapeutics, Inc., 720 F.3d 490, 494 (2d Cir. 2013).

More controversially, the government should also be permitted to regulate anti-knowledge within the public discourse so long as the claim is likely to cause the listeners to take action that puts themselves or others in serious risk of harm, and the speaker has a sufficiently culpable mental state. <sup>260</sup> No modern case law suggests that the caution used in *Winter v. G.P. Putnam's Sons* is constitutionally required. <sup>261</sup> When a speaker recklessly provides misinformation that is likely to cause foreseeable risk of even physical harm, legal redress should be able to withstand free speech scrutiny. The state action could not cover claims that make clear, in context, that the speaker is taking an outlier position on the topic. <sup>262</sup> A responsible regime could also develop a notice system whereby a speaker responsible for a dangerously false claim is given adequate time to correct or remove the claim before liability or other consequences attach.

## 2. Contested Knowledge

Contested knowledge that is not currently capable of being verified with strong evidence is a different matter. Whether contested claims are made by commercial or public speakers, these claims should be covered by the First Amendment and afforded some amount of protection. They cannot be treated as presumptively false without overstretching the meaning of the word and without abandoning the theory that free speech provides a robust market for competing claims to vie for acceptance.

But just because an unverified factual claim isn't "false" doesn't mean it is automatically immunized from regulation. So under what conditions would regulators have sufficient justification to restrict an unverifiable claim?

A wholly utilitarian model for screening factual claims would compare the risks of censorship to the risks of speech. A formula would look like this:

<sup>260.</sup> Precedents across a broad spectrum of speech restrictions consistently require a heightened mental state before a speaker can be punished. Elonis v. United States, 575 U.S. \_\_\_, 135 S. Ct. 2001, 2009–11 (2015); *Gertz*, 418 U.S. at 347; Brandenburg v. Ohio, 395 U.S. 444, 447–48 (1969); N.Y. Times Co. v. Sullivan, 376 U.S. 254, 279–80 (1964). By comparing the mental state requirements of defamation required for public and private figures, I assume that the higher "malice" mental state would be required for a claim against dangerous anti-knowledge because of the ample opportunity for counter-speech.

<sup>261.</sup> The reasoning of *Alvarez* suggests the opposite. United States v. Alvarez, 567 U.S. 709, 724 (2012) (suggesting that laws might survive First Amendment strict scrutiny if there is "a direct causal link between the restriction imposed and the injury to be prevented").

<sup>262.</sup> For example, when *Natural News* publishes stories claiming that the Centers for Disease Control is deceitful, the claim itself announces that the publisher is taking a position that contradicts the standard authorities (including the CDC).

Risk of Claim C =

[(Estimated *Losses* if *C* is false) x (*Probability* that *C* is false)] - [(Estimated *Benefits* if *C* is true) x (*Probability* that *C* is true)]

This formula is somewhat simplified because it does not account for the incentives or disincentives to conduct more research, but given the difficulty of estimating each of these variables it is complex enough.<sup>263</sup>

For contested claims that are part of a public discussion, the constitution requires a heaping serving of doubt that the government has the competence or motivation to estimate losses, benefits, and probabilities in a dispassionate way. Thus, factual claims that are presently unverifiable must be fully protected in the public discourse. Indeed, the public sphere is where battles over the better interpretation of the available evidence should be hashed out.

But free speech law need not be as skeptical about the competence and motivation of the government with respect to commercial speakers. First Amendment doctrine continues to make allowances for the efficient regulation of marketplace actors by applying the lower, *Central Hudson* form of scrutiny. This should allow regulators to restrict unverified claims in the commercial sphere if the estimated risks outweigh the estimated benefits.

The risk analysis is clearly influenced by the level of substantiation a claim has. If a claim is baseless or close to it, then the probability that the claim is false will typically be high, and even a small loss can suffice to justify regulation. But where the evidence is stronger, much will depend on whether the commercial claim induces a benign gamble or a dangerous one. In fact, it is the benefits and losses that should often drive the outcome, and those estimates are made not from expertise about the support for a particular claim but from expertise on consumption patterns and substitutions.

To illustrate, consider the health claims made by POM Wonderful. One of the advertisements that caught the attention of the FTC claimed that drinking pomegranate juice could reduce the chance of heart disease. <sup>264</sup> The FTC's case against POM was concerned solely with the assessment of probability of truth—the quality of the substantiating evidence. But let's set that aside for a moment and ask what the consequences to consumers would be under both the condition that the claim is true and that it's false. If the claim is true, the increase in pomegranate

<sup>263.</sup> The formula is also consistent with the FTC's original understanding of its enforcement authority under the "unfairness" prong of the FTC Act as described in the "Pfizer factors." See In re Pfizer, Inc., 81 F.T.C. 23 (1972); Randal Shaheen & Amy R. Mudge, Has the FTC Changed the Game on Advertising Substantiation?, 25 CONSUMER PROT. DEV. 65, 65 (2010).

<sup>264.</sup> POM Figures Appendix (Appendix B), supra note 153, at fig.12.

consumption should be beneficial. If the claim is false, the increase in pomegranate consumption probably has negligible health effects. If the marginal consumer who buys POM because of the advertising campaign is substituting pomegranate juice for a quinoa and kale salad, their heart health will probably suffer, but the more likely scenario is that the marginal consumer substituted pomegranate juice for orange juice or even soda. The health effect is a wash.<sup>265</sup> It is a benign gamble.

There are non-health losses of course—perhaps the consumer would have preferred the taste of a different beverage, or would have paid less for it. If POM's statements were anti-knowledge, or so devoid of support that the chance of being false is high, these types of losses would tip the scales toward regulation. But the links between pomegranates, antioxidants, and heart health are established well enough to differentiate this from a quasi-fraud style of claim. The losses and benefits should be measured in terms of the consequences to health—the attribute that was decisive for the marginal purchaser.

On the other hand, a re-analysis of the *Caronia* case (involving the off-label promotion of a drug) is likely to come out in favor of the FDA. Caronia was advocating use of the drug Xyrem for off-label purposes including for relatively minor diseases like restless leg syndrome.<sup>266</sup> The basis for assessing the probability that Xyrem was effective for the off-label uses was mixed—for some uses, the evidence consisted merely of reported uses by other doctors,<sup>267</sup> while for other uses, clinical trials proved the efficacy.<sup>268</sup> However, the drug Xyrem causes a number of side effects, including nausea, depression, and pain in a substantial number of patients.<sup>269</sup> While the doctors who heard Caronia's pitch would have understood that the recommendation was off-label and therefore was probably not supported by a surfeit of evidence, the risk to patients may outweigh the benefits of the information exchange if (and this is a big "if") the involvement of physicians cannot provide sufficient protection.

<sup>265.</sup> Perhaps we could imagine a particularly impressionable consumer who drinks POM Wonderful in lieu of exercising and taking his heart medication. I doubt any consumer would put this much stock in an advertising campaign, but even if one did, this type of absurd substitution would be harmful even if the POM Wonderful advertising was true and strongly substantiated.

<sup>266.</sup> See United States v. Caronia, 703 F.3d 149, 156 (2d Cir. 2012).

<sup>267.</sup> Id. at 156-57.

<sup>268.</sup> Todd J. Swick, Sodium Oxybate: A Potential New Pharmacological Option for the Treatment of Fibromyalgia Syndrome, 3 THERAPEUTIC ADVANCES MUSCULOSKELETAL DISEASE 167, 167 (2011); Matt McMillen, FDA Panel Rejects Xyrem as Fibromyalgia Treatment, WEBMD (Aug. 20, 2010), https://www.webmd.com/fibromyalgia/news/20100820/fda-panel-rejects-xyrem-as-fibromyalgia-treatment#1 [https://perma.cc/43LR-3GRK].

<sup>269.</sup> *Xyrem Side Effects*, DRUGS.COM, https://www.drugs.com/sfx/xyrem-side-effects.html [https://perma.cc/866F-UVV2] (nausea (up to 20%), depression (1–10%), and pain (1–10%)).

If there is a difference in the outcome of an analysis between Xyrem and pomegranate juice, it has much more to do with the relative safety profiles of the two substances than it does the relative efficacy profiles. At a greater level of generality, it might be safe to say that a utilitarian approach would allow contested claims about foods but disallow them about drugs. In the short term, except in the case of allergies, foods consumed in standard quantities do not cause risks, while drugs consumed in standard dosages often do.

This raises the issue of pragmatism. Although the utility analysis would ideally apply claim by claim, resource constraints may require regulators to make broad categories of claims that are more or less likely to cause harm without making fine-grain distinctions within those categories. Thus, at least at this time, it may be constitutionally sufficient to justify speech restrictions on drugs categorically, even if no categorical explanation could be offered for restrictions on food claims.

Nothing in the recommendations here remove the practical deference that courts have historically given to expert agencies like the FDA.<sup>270</sup> Although in time the courts will probably need to increase their competence and do independent constitutional fact-finding in order to ensure the protection of individual rights,<sup>271</sup> I expect in the medium term the courts will value and largely follow the scientific assessments of agencies with respect to risk, just as they have for truth. However, whatever deference is paid to agencies, the recommendations here mark an important change in the substance of the law for factual claims. Lawmakers and expert agencies must make their regulatory decisions on the basis of harm and risk, rather than truth, and they must be prepared to defend them on that basis, too. This will require a shift in current agency practices, as the next subsection will explain.

## B. Implications for Contested Knowledge in Commercial Claims

Contested knowledge creates First Amendment heartburn because it is a widely varying category. It includes claims that fall just shy of the relevant standards for accepted knowledge as well as claims that have only anecdotal evidence. Today's false advertising law is largely explained by a fear that without intervention, the marketplace would be saturated with advertising that encourages magical thinking.

For both cynical and optimistic reasons, I believe these fears are unfounded. The cynical explanation is that advertising is already

<sup>270.</sup> See All. for Nat. Health U.S. v. Sebelius, 714 F. Supp. 2d 48, 57 (D.D.C. 2010).

<sup>271.</sup> See Justin Sevier, Redesigning the Science Court, 73 MD. L. REV. 770, 775–76 (2014) (describing the crisis in expert evidentiary fact-finding and some proposals to correct it).

brimming with incredible and misleading claims that take advantage of shoppers' hopes, fears, and ignorance that evade regulatory control. Claims that a product is "non-GMO," "natural," or "local," for example, can avoid regulation by being technically true even if they are less safe, worse for the environment, and cost more.<sup>272</sup> And yet (and here's the optimistic explanation), consumers greatly discount cheap talk and navigate their options in a way that is mostly consistent with their personal philosophies and preferences.<sup>273</sup> Thus, the stakes are not as high as they appear.

Contested knowledge will create the most trouble for tradeoff products—things that expose consumers to some risks that may be outweighed, at least for some consumers, by the benefits. Sugar cereals, for example, are unhealthy, but parents well-educated about the drawbacks of sugar may rationally decide to buy and treat their kids to them. E-cigarettes are another good example. E-cigarettes are associated with some heightened risks of depression and lung disease, but they are vastly superior to cigarettes when it comes to safety. <sup>274</sup> So the risk analysis depends very much on who the consumer is. If the consumer is a non-smoker, the risk is moderately high. If the consumer is a current smoker, the risk is negative and very large. The FDA currently restricts the promotion of e-cigarettes in order to avoid enticing nonsmokers to use e-cigarettes. But the net effect on public health from e-cigarette promotion would probably be positive. <sup>275</sup> Thus, unless the FDA generates better

<sup>272.</sup> E.g., Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants, U.S. FOOD & DRUG ADMIN. (Nov. 2015), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm05 9098.htm [https://perma.cc/FD86-QXLA] (explaining that the FDA is not aware of any safety concerns related to genetically modified foods, but providing guidance for labeling foods as "not genetically modified" anyway in order to meet consumer demand).

<sup>273.</sup> Individuals spend more time and effort acquiring information about the things they buy than who to support in their local and national elections because they intuitively know that the effort spent deciding which television to buy will make a difference in the outcome while the effort spent on selecting a candidate will not. *See* CALFEE, *supra* note 221, at 37–42 (describing evidence of consumer skepticism); BRYAN CAPLAN, THE MYTH OF THE RATIONAL VOTER: WHY DEMOCRACIES CHOOSE BAD POLICIES 14 (2007); Ilya Somin, *Foot Voting vs. Ballot Box Voting*, BALKINIZATION (Oct. 7, 2013), https://balkin.blogspot.com/2013/10/foot-voting-vs-ballot-box-voting.html [https://perma.cc/TYM6-3CPQ] ("That doesn't mean that foot voters are always well-informed or perfectly unbiased in their evaluation of information. Far from it. But, on average, they do a much better job than ballot box voters do.").

<sup>274.</sup> ROYAL COLL. OF PHYSICIANS, NICOTINE WITHOUT SMOKE: TOBACCO HARM REDUCTION 189–90 (2016).

<sup>275.</sup> Jonathan Adler et al., *Baptists, Bootleggers & Electronic Cigarettes*, 33 YALE J. REG. 313, 348–49, 361 (2016).

evidence about the marginal effects of advertising, the current regulations should fail under intermediate scrutiny.

But the FDA has resisted reform to use risk as the basis for advertising restrictions. In fact, in a recent memo that addresses the First Amendment implications for off-label promotion, the FDA rejected the suggestion that regulatory controls vary based on the safety profile of the drug. According to the memo, risk-oriented regulations "would be inadequate by themselves to protect the public safety because the required safety assessment depends on the generation of data regarding product dangers before any controls can be applied" and "the acceptability of product risks can only be properly evaluated in the context of robust data about the efficacy of the product."<sup>276</sup>

This is a sort of risk-based defense of the current law. The FDA is essentially arguing that without more testing, the default assumption for drugs is that they are too dangerous. This is a plausible position for unapproved drugs, but it is a peculiar position with respect to off-label promotion of drugs. Drugs that have already been approved for one medical purpose have a history of clinical trials and field experience that can inform a safety assessment. Approved drugs with serious side effects and contraindications could therefore require more testing, perhaps even the currently required approval process for labeling, in order to ensure the risks are outweighed by efficacy for the new purpose. But for approved drugs with only mild or rare side effects, the FDA should be able to tolerate a lower standard for the evidence of efficacy.

The FDA might be implicitly arguing that drugs, as a class, are a product that involve great risk of danger to patients, and therefore the promotion for any particular purpose requires iron-clad proof of efficacy for not only the first approved use, but all additional uses of the drug. But three things cast doubt on this logic. First, doctors can and do prescribe drugs off-label without strong evidence of efficacy.<sup>277</sup> If off-label prescribing were dangerous without premarket testing, the off-label prescribing should be just as troublesome as off-label promotion. Second, many drugs, including virtually all over-the-counter drugs, have a well-established track record of causing very few or only mild side effects.<sup>278</sup>

<sup>276.</sup> FDA, PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT, supra note 135, at 28.

<sup>277.</sup> United States v. Caronia, 703 F.3d 149, 153 (2d Cir. 2012).

<sup>278.</sup> Drugs can be approved for over-the-counter use only through a special FDA application process with heightened standards for safety or only after the drug has proven over time to be "generally recognized as safe and effective (GRASE)." See U.S. FOOD & DRUG ADMIN., REGULATION OF NONPRESCRIPTION DRUG PRODUCTS, https://www.fda.gov/downloads/AboutFDA/CentersOffices/Offices/OfficeofMedicalProductsandTobacco/CDER/UCM148055.pdf [https://perma.cc/

And third, relatedly, the category of products that are treated as "drugs" is defined (at least in part) by the products' *benefits* rather than their risks. Any substance that is promoted to diagnose, treat, or cure a disease is classified as a drug no matter how safe it may be.<sup>279</sup>

The FDA Act definitions of drugs, food, and dietary supplements are not well-matched to a risk-oriented approach to speech restrictions. Producers of foods and supplements with well-known medicinal properties and strong safety records, such as some mushroom supplements, 280 must refrain from educating the consumer about their potential to treat or prevent a disease because otherwise the product will be reclassified as a drug and have to undergo clinical trials. Where there is no opportunity to patent the product or maintain exclusive control in some other way, clinical trials will be prohibitively expensive. Meanwhile, a manufacturer that aggressively promotes its product using general health and wellness claims or using any other enticement is under no obligation whatsoever to prove the safety of its product even though many supplements have known, serious side effects. 281 The current rules, therefore, will be hard for the FDA to defend unless the definitions of "foods" and "drugs" are altered to differentiate based on safety rather than efficacy.<sup>282</sup>

Another justification for the current apparatus of FDA drug approval is to create incentives for manufacturers to create more high-value studies.<sup>283</sup> The theory that this will work for any off-patent product is dubious.<sup>284</sup> The

Z9DU-FHBK]; GRASE, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/training/OTC/topic3/topic3/da 01 03 0040.htm [https://perma.cc/2EDR-HSLK].

<sup>279.</sup> Id.

<sup>280.</sup> See generally Solomon P. Wasser, Medical Mushroom Science: Current Perspectives, Advances, Evidences, and Challenges, 37 BIOMED J. 345 (2014).

<sup>281.</sup> Dietary supplements can make health claims about reducing risks of specific diseases without triggering the requirements for drug testing. FDA 101: Dietary Supplements, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm050803.htm [https://perma.cc/HYD2-UJD3] (last updated July 15, 2015). They are treated as special types of food. FDA Regulation of Drugs Versus Dietary Supplements, AM. CANCER SOC'Y, https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/fda-regulations.html [https://perma.cc/B4W8-M9GN] (last updated Mar. 31, 2015).

<sup>282.</sup> With this type of adjustment, sugar and alcohol may be better categorized as "drugs." GARY TAUBES, THE CASE AGAINST SUGAR 31 (2016).

<sup>283.</sup> This was one of the FDA's arguments in the *Amarin* case. Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 217 (S.D.N.Y. 2015); *see also* Greene & Noah, *supra* note 21, at 255–56.

<sup>284.</sup> Also, the companies that can afford to do the research create studies of questionable value anyway, since even the integrity of studies that may seem methodologically sound can be tangled up with the purse strings.

interest in both public safety and the production of research can be served using the following, more direct alternatives to speech restrictions:

Increased support for research. The government could fund more independent research on the efficacy and safety of products, and it could offer rewards for the discovery of unknown benefits and risks. It could also alleviate some of the burdens of formal research by simplifying informed consent and Institutional Review Board rules.

Ex post liability and safe harbors. The government could facilitate post-market liability or fines when a product causes harm and could offer safe harbor from liability if the product has gone through high-quality premarket testing.

*Increased consumer information collection*. The government can incentivize the tracking, in de-identified form, of consumer information in order to facilitate post-market observational studies. It could also require companies and doctors to report adverse events. Monitoring would be especially feasible for medical devices and drugs that require a doctor's approval.<sup>285</sup>

*Seals of approval.* Government agencies can use their own influential voices by offering seals of approval or certifications to products that undergo a high level of safety and efficacy testing.

Sin taxes and health subsidies. Governments can impose taxes on dangerous products roughly proportional to the cost of the "internality."<sup>286</sup> By driving up prices artificially, the government can ensure that the market price exceeds the reserve prices for consumers who do not receive sufficient value from the product. Sin taxes have had greater success than advertising limitations in curbing the consumption of tobacco and junk food.<sup>287</sup> Similarly, subsidies for healthy products can more effectively influence consumption decisions, too.<sup>288</sup>

<sup>285.</sup> Eric Topol has proposed a probationary status for new devices so that they can be introduced to the market while sending comprehensive data to health regulators. Brian Buntz, *Dr. Eric Topol on IBM's Watson, Twitter, and the "Medical Cocoon,"* MED. DEVICE & DIAGNOSTIC INDUSTRY (Apr. 25, 2012), https://www.mddionline.com/dr-eric-topol-ibms-watson-twitter-and-medical-cocoon [https://perma.cc/9DP5-EDUL].

<sup>286.</sup> Saul Levmore, *Internality Regulation Through Public Choice*, 15 THEORETICAL INQUIRIES L. 447, 448–49 (2014).

<sup>287.</sup> See Pearl Bader et al., Effects of Tobacco Taxation and Pricing on Smoking Behavior in High Risk Populations: A Knowledge Synthesis, 8 INT'L J. ENVTL. RES. & PUB. HEALTH 4118, 4130–31 (2011).

<sup>288.</sup> See generally Ruopeng An et al., Eating Better for Less: A National Discount Program for Healthy Food Purchases in South Africa, 37 Am. J. HEALTH BEHAV. 56 (2013).

Compelled disclosures. The government can require advertisers to make substantiating and contradicting evidence available on their websites.

*Product removals.* Finally, while extreme, there may be some classes of products that simply shouldn't be sold based on its current popular usage. Raw milk, for example, makes up less than 1% of the milk market but accounts for over 60% of the milk-related infectious disease.<sup>289</sup> This product may not offer value above pasteurized milk that can justify its lower safety profile.

The FDA, the FTC, and false advertising law use advertising restrictions as a means of product and safety regulation. False advertising law is the paradigmatic example of a truth-oriented regime that would have to change to develop new elements in order to support a state interest in reducing risk. As for the expert agencies, it may very well be the case that the elaborate set of FTC and FDA rules are a reasonably efficient way to reduce public safety risks. This possibility cannot be ruled out, given that the courts applying constitutional scrutiny have not, until recently, demanded a risk-based accounting of the advertising restrictions. But neither agency has done the introspection and evidence-gathering to defend its rules on the basis of risk. They have relied on falsity as its proxy.

#### CONCLUSION

In the era of "alternative facts" and "fake news," it will be tempting for courts to tighten their grip on the truth orientation of factual claims. Many public intellectuals are understandably concerned that the public cannot agree on a basic body of facts from which to make reasoned arguments. They recommend trust in expert and scientific institutions through slogans like "science is not just a matter of opinion" or "science is not a liberal conspiracy" in the hopes of restoring a shared understanding of the evidence. While a greater aptitude for critical thinking and for sober

<sup>289.</sup> Bill Marler, Comparing the Food Safety Record of Pasteurized and Raw Milk Products—Part 3, MARLER BLOG (Oct. 10, 2009), http://www.marlerblog.com/lawyer-oped/comparing-the-food-safety-record-of-pasteurized-and-raw-milk-products-part-3/ [https://perma.cc/6PDT-ZBTC] (analyzing CDC data; I include queso fresco among the non-pasteurized milk products); see also Elisabeth A. Mungai et al., Increased Outbreaks Associated with Nonpasteurized Milk, United States, 2007–2012, 21 EMERGING INFECTIOUS DISEASES 119 (2015).

<sup>290.</sup> Allen J. Frances, *Science Is Not Just a Matter of Opinion*, PSYCHOL. TODAY (Dec. 2, 2016), https://www.psychologytoday.com/blog/saving-normal/201612/science-is-not-just-matter-opinion [https://perma.cc/VE97-45H8].

<sup>291.</sup> T-shirts available on Amazon, at https://www.amazon.com/Science-Not-Liberal-Conspiracy-T-Shirt/dp/B01LK594SW [https://perma.cc/89YM-AF2U].

analysis of evidence would certainly improve society, I do not think that this is the time to be sloppy about what "science" and "facts" are, and the ambiguity that haunts them.

In a perfectly transparent world, all facts would be described with confidence intervals and a reference to the relevant supporting and contradicting evidence. Rather than saying that flying saucers do not exist, we would explain the basis of our conclusion the way Richard Feynman did to a UFO enthusiast he met on a plane. To defend his belief that UFOs are not real, Feynman said, "I mean that from my knowledge of the world that I see around me, I think that it is much more likely that the reports of flying saucers are the results of the known irrational characteristics of terrestrial intelligence than of the unknown rational efforts of extraterrestrial intelligence."

Unfortunately, humans cannot communicate this way in very many contexts. So the law must make allowances for the imprecision and diverse convictions of speakers, as well as the skepticism or the credulity of audiences. This is no easy task, but an earnest attempt to link speech restrictions to risk will improve many of the more chaotic areas of speech regulation today.

With this adjustment, commercial speech will contain more contested factual claims. What is lost in terms of technical substantiation will be made up with increased consumer focus and greater incentive for research on product attributes that are testable. In the public discourse, on the other hand, the First Amendment should tolerate more (rather than less) regulation, at least when a speaker knows that a claim is contradicted by the accepted knowledge and when the claim is likely to cause harm to the audience or third parties.

The system proposed in this Article is not foolproof. It relies on human judgment to categorize factual claims into contested knowledge, accepted knowledge, and anti-knowledge. For commercial speech, it requires additional consideration about contested claims to assess whether they encourage dangerous or benign gambles based on supporting evidence and predicted effects. The regulators who make these determinations will not make them perfectly. There will be error, and the decision-maker will be biased by his own prior beliefs.<sup>293</sup> As Bertrand Russell wrote, "[e]very man, wherever he goes, is encompassed by a cloud of comforting convictions, which move with him like flies on a summer day."<sup>294</sup> But the

<sup>292.</sup> RICHARD P. FEYNMAN, THE CHARACTER OF PHYSICAL LAW 166 (1965).

<sup>293.</sup> This does, however, sidestep the objection that courts are less qualified to make factual determinations of scientific fact by forcing courts only to ensure that the government actor has done an analysis, and has done it without any obvious defects.

<sup>294.</sup> BERTRAND RUSSELL, SCEPTICAL ESSAYS 16 (Routledge 2004) (1928).

exercise of making and justifying the categorization can screen out some of the flies. As long as the categorization is done reasonably well, this system provides a more honest accounting of the state of knowledge than our current set of free speech rules.

First Amendment law can transition to a risk-oriented approach to factual claims without creating an existential threat to the regulatory state. A "gentle tug" will put the law of factual claims on a trajectory that can be sustained in the long term.<sup>295</sup>

 $<sup>295.\</sup> Winter\ v.\ G.P.\ Putnam's Sons, 938\ F.2d\ 1033, 1037\ (9th\ Cir.\ 1991)$  (referring to the "gentle tug of the First Amendment").