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DIRECT-TO-CONSUMER ADS ARE MISLEADING: CONCISE STATEMENTS OF EFFECTIVENESS SHOULD BE REQUIRED

ROBERT A. BOHRER, J.D., LL.M.*

INTRODUCTION: THE PROBLEM WITH PHARMACEUTICAL ADVERTISING

The issue of required disclaimers in direct-to-consumer (DTC) advertising of pharmaceuticals boiled to the surface in May 2019, when the Centers for Medicare and Medicaid Services (CMS) published a final rule requiring the disclosure of a drug's price in DTC ads.¹ The idea is not a new one—the American Medical Association (AMA) adopted a resolution recommending just such a required disclosure in June 2017.² For a number of reasons, even if the proposal is implemented it may not have much effect.³ Consumers may see price as an indicator of effectiveness, just as a high-priced car is expected to be superior to a lower-priced car, and insurance coverage may reduce patients'

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1. Centers for Medicare and Medicaid Services (CMS), Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency, 83 Fed. Reg. 52,789 (proposed Oct. 18, 2018) (to be codified at 42 C.F.R. pt. 403) [hereinafter CMS]. The CMS rule was struck down as violative of pharmaceutical companies' commercial speech rights in *Merck v.H.H.S.* 385 F. Supp. 3d 81 (D. D.C. 2019). The agency filed a notice of appeal from the lower court's decision on August 21, 2019. The court's decision focused on the issue of whether the Secretary of H.H.S. had the authority to regulate drug advertising under the Social Security Act. (<https://1.next.westlaw.com/Document/IB2CD0786C54411E99B14F2EE541CF11A/View/FullText.html?listSource=RelatedInfo&list=NegativeCitingReferoritences&rank=0&originationContext=docHeader&transitionType=NegativeTreatment&contextData=%28sc.Search%290>). See also Steven Woloshin, *Ask Whether A Drug Works Before Worrying About What It Costs*, L.A. Times (July 26, 2019).

2. Press Release, AMA Adopts Policy Aimed to Bolster Transparency of Prescription Costs (June 17, 2018), <https://www.ama-assn.org/ama-adopts-policy-aimed-bolster-transparency-prescription-costs#>.

3. Robert Pear, *Would Requiring Ads For Drugs to Cite Costs Really Lower the Prices?*, N. Y. TIMES (May 19, 2018), <https://www.nytimes.com/2018/05/19/us/politics/drug-prices-ads.html>; Jace B. Garrett et al., *Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising*, 179 JAMA INTERNAL MED. 435 (2019).

concerns about a high-price for a drug.⁴ The significance of drug prices to consumers is further complicated both by the “market-distorting effects of third-party payors”⁵ and the requirement for consultation with and prescription by a licensed physician whose decisions may also be impacted by third-party payors, but is not necessarily affected by the list prices of drugs. However, the thesis of this article is not that disclosing prices in DTC ads is a bad idea, but that providing consumers with information about how effective advertised drugs are likely to be for them would provide information that patients need regardless of their insurance or financial status. Additionally, it would likely have a greater impact on the pharmaceutical marketplace. If the problem with DTC ads, as the AMA stated in its proposal to require price disclosures, is that “patients pressure physicians to prescribe certain medications that cost more than lower-cost alternatives and are not necessarily as efficacious,”⁶ then requiring DTC ads to provide consumers with clear information about the effectiveness of the advertised drug would be an even more powerful solution.

There is a growing awareness of the need to require disclosures of expected effectiveness in pharmaceutical DTC marketing. Currently, consumers are told about the general condition for which a drug is used: e.g. “Drug X is approved for the treatment of major depressive disorder,” or “Drug X has been proven effective for the treatment of depression”; but rarely are consumers given information about the average benefit achieved in clinical trials or in post-market studies. This is a particular problem in DTC advertising for prescription pharmaceuticals. An article, in *The New York Times* by Elizabeth Rosen, highlighted the problem of DTC ads that are likely to mislead consumers about a drug’s effectiveness and provided this example: “Another ad promoted Jublia, a new topical drug for toenail fungus that costs thousands of dollars for a full course of treatment. Complete cure rates in studies—under 20 percent after 48 weeks of use—aren’t mentioned in the ads.”⁷

While the problem is becoming well known, as the *New York Times* article illustrates, the FDA regulation of pharmaceutical marketing is significantly constrained by the First Amendment’s protection of commercial speech, which would almost certainly make a ban on DTC pharmaceutical ads unconstitutional.⁸ This article provides an approach to FDA regulation of DTC ads that would address the problem within the limits of the First Amendment’s protection for commercial speech and provide patients with the information they

4. Garrett et al., *supra* note 3, at 436.

5. CMS, *supra* note 1 at 52,790.

6. Press Release, *supra* note 2.

7. Elizabeth Rosen, *Ask Your Doctor If This Ad Is Right for You*, N.Y. TIMES (Feb. 27, 2016), <https://www.nytimes.com/2016/02/28/sunday-review/ask-your-doctor-if-this-ad-is-right-for-you.html>.

8. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 544 (2011).

need most to sort through the glossy promotional advertisements created by pharmaceutical companies and their ad agencies.

The issue of advertising drugs to consumers is just one aspect, albeit the most visible, of the general problem of pharmaceutical companies' efforts to sell drugs without substantive support for the choices to which their marketing efforts are directed. For example, in 2005 *The New York Times* published an article entitled *Gimme an Rx! Cheerleaders Pep Up Drug Sales*.⁹ The article documented the efforts of pharmaceutical companies to recruit college cheerleaders for pharmaceutical sales positions. Why do Pharmaceutical companies recruit cheerleaders to market their drugs to physicians? The reason why is not, in my opinion, the obvious one. I believe that the real reason for hiring energetic and attractive salespeople who may not have a background in science¹⁰ is because for most drugs, the pharmaceutical companies do not have the data that would make choosing their drug a rational, rather than subjective or arbitrary, choice. The strategies used to market drugs to doctors and to consumers are largely driven by the lack of more complete data. So while attractive, high energy sales representatives with rolling bags head towards doctors' offices, butterflies (Lunesta),¹¹ weird, letter-shaped cats and dogs (Belsomra),¹² serene patients with bi-polar depression (Latuda),¹³ and attractive, apparently sexually satisfied women lounging on beds (Viagra)¹⁴ fill the TV screens of America's households. What's the message? "If you have this problem, we can fix it." Or, rather, "If you have the indication for which the FDA approved this drug, this is an effective treatment that is the best choice for you." My proposed solution is that the FDA use its power to regulate drug labeling¹⁵ to require that DTC ads contain a concise and clear statement of the expected benefit provided by the drug. The required disclosure would be based on data from trials that supported the FDA approval of the advertised indication or post-marketing studies that have been reviewed by the FDA, in a format that follows the recommendations of the

9. Stephanie Saul, *Gimme an Rx! Cheerleaders Pep up Drug Sales*, N.Y. TIMES (Nov. 28, 2005), http://www.nytimes.com/2005/11/28/business/gimme-an-rx-cheerleaders-pep-up-drug-sales.html?_r=0.

10. *Id.* Dr. Dan Foster, a West Virginia legislator, introduced a bill that would have required pharmaceutical reps to have a science degree, but the bill was not enacted.

11. Haydenriggsnz, *LUNESTA® (Eszopiclone) Sleeping Pill Commercial Ad—USA (Real One)*, YOUTUBE (Feb. 3, 2012), <https://www.youtube.com/watch?v=vu0rXFhsM8w> (last visited Dec. 11, 2019).

12. Belsomra TV Commercial, 'Cats and Dogs,' ISPOT.TV (2015), <https://www.ispot.tv/ad/7UYo/belsomra-cats-and-dogs>.

13. Latuda TV Commercial, 'Maya's Story,' ISPOT.TV (2016), <https://www.ispot.tv/ad/ANW0/latuda-mayas-story>.

14. Viagra TV Commercial, 'Save 50 Percent,' ISPOT.TV (2017), <https://www.ispot.tv/ad/A82U/viagra-save-50-percent>.

15. See Prescription-Drug Advertisements, 21 C.F.R. § 202.1(e) (2018).

FDA's just-released Draft Guidance for "Presenting Quantitative Efficacy and Risk Information" in DTC advertising.¹⁶

In Part I of this Article I illustrate the problem of misleading DTC ads with the advertisements for two widely advertised drugs. In analyzing the ad content, my focus is on whether the images and the language of the ad could reasonably be construed to imply that the drug is likely to provide a significant benefit to most patients. I also discuss whether the ad suggests that the drug would be the best choice among all available drugs for that condition. I use the data that supported the FDA's decision to approve the drugs to address the extent to which patients are actually likely to experience significant benefits from use of the drug. I compare the data for the advertised drug with one other drug approved for its indication to determine whether there is a rational, objective reason to prefer the advertised drugs with implied claims of superiority. After examining the ads and the actual data for those drugs, in Part II of this Article I briefly discuss the concept of "pragmatic implications,"¹⁷ which is an important concept in marketing and central to understanding the issue of whether DTC advertising is generally misleading (and therefore subject to some governmental regulation under the *Central Hudson* test for commercial speech).¹⁸ There is a plausible basis for finding each of these commercials to be misleading, as would be the case with most DTC ads. In Part III, I conclude by analyzing the application of *Central Hudson* to DTC ads to support my argument that the FDA can and should require a concise summary statement of expected benefit in DTC ads.¹⁹

I. THE PRODUCTS, THE COMMERCIALS, THE IMAGES, AND THE DATA.

The two drug commercials analyzed in detail are Latuda's commercial promoting the use of the drug for bi-polar depression²⁰ and Belsomra's ad promoting its use for insomnia.²¹ The images in both ads present a similar story to the potential consumer. In both commercials the images at the beginning show a person who has the indication or medical condition targeted by the drug. In the Latuda commercial we see a woman who talks about being sad and looks sad. The background narrator says, "Latuda is FDA approved to treat Bipolar Depression, which is different from other forms of depression." After the on-screen actress portraying a patient meets with her doctor, she is out walking, playing with her dog, and smiling. The story from the images is clear—Latuda

16. U.S. FDA, Draft Guidance: Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements Guidance for Industry (2018).

17. See Richard J. Harris, *Comprehension of Pragmatic Implications in Advertising*, 62 J. APPLIED PSYCHOL. 603 (1977).

18. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n. of N.Y.*, 447 U.S. 557, 564 (1980).

19. See *supra* note 13.

20. Belsomra TV Commercial, *supra* note 12.

21. *Id.*

takes away your depression and helps you feel good. The images provide the context for the other key language in the Latuda commercial: “In clinical studies, once-a-day Latuda was proven effective for people with bipolar depression.” The message is clear: If you suffer from this condition (bipolar depression), you will get better if you take Latuda. There is no “perhaps you will” or “there is a 50/50 chance you will.” Furthermore, if a viewer follows the standard advice to “ask your doctor” about Latuda, the full prescribing information for the drug upon which the doctor may rely for information shows that patients receiving Latuda as a monotherapy (the only drug for that condition) in the pivotal clinical trial achieved about a median 4.6 point greater improvement in the MADRS depression rating scale compared with patients receiving a placebo. This 4.6 point difference is from a median baseline score of just over 30 points, where a score “greater than 30 or 35 on the MADRS indicates severe depression, while a score of 10 or below indicates remission.”²² Because Latuda is unlikely to be the only drug used by many patients with bipolar disorder and depression, the study also provided results for patients given either Latuda or a placebo in addition to either Lithium or Valproate, two commonly prescribed drugs for bipolar disorder.²³ Those results showed a smaller difference between the patients receiving Latuda and those receiving a placebo. However, even though a 15 point or greater median improvement (or the slightly smaller improvement achieved by the placebo group) is certainly meaningful, that data—the only data on the prescribing information—does not inform the physician (or the patient) how likely the patient is to achieve remission (a score below 10 on the MADRS scale used in the trial). If the image in the commercial strongly suggests that the post-treatment patient is now free from depression that is unlikely to be true. The only way to know how likely patients prescribed Latuda are to be free from depression is to go beyond the label or prescribing information and look into the NIH’s PubMed database to find the studies that supported Latuda’s approval. Here is additional data from the trials that supported the approval of Latuda (lurasidone) for bipolar depression, but were not in the prescribing information:

A significantly greater proportion of subjects met a priori response criteria after 6 weeks of treatment with lurasidone 20–60 mg (53%; $p < 0.001$ [number needed to treat=5]) and lurasidone 80–120 mg (51%; $p < 0.001$ [number needed to treat=5]) compared with placebo (30%).

The proportion of subjects achieving remission at end-point was significantly greater in the lurasidone 20–60 mg group (42%; $p = 0.001$ [number needed to treat=6]) and the lurasidone 80–120 mg group

22. Christina Cusin et al., *Handbook of Clinical Rating Scales and Assessment in Psychiatry and Mental Health* (chapter 2) 13 (Lee Blair & Mark Blais, eds., 2009).

23. Mark Watanabe, *Pharmacotherapy for Bipolar Disorder: An Updated Review*, 32 U.S. PHARMACIST 26–32 (2007), <https://www.uspharmacist.com/article/pharmacotherapy-for-bipolar-disorder>.

(40%; $p=0.004$ [number needed to treat=7]) compared with the placebo group (25%).²⁴

While the images of a smiling, active woman and the words “proven effective” suggest more than a roughly 50% likelihood of clinical improvement and a 42% likelihood of at least temporary complete relief, the data supporting Latuda’s approval shows no more than that 50% likelihood of clinical improvement. And the ad does not tell the viewer anything about the effectiveness of Latuda as compared to other drugs for the same indication.

Symbyax is another drug approved for the treatment of bipolar depression and as such, the clinical trial data associated with Symbyax can be compared to that for Latuda. The comparable data for Symbyax as in bipolar depression is shown below:

The response rate . . . for the placebo group . . . [was] 30.4%[data on olanzapine only arm omitted]. . . The response rate for the [Symbyax] olanzapine-fluoxetine group was 56.1% . . . which was significantly higher than that for the placebo . . .

The remission rate for . . . the placebo group . . . [was] 24.5% . . . The remission rate for the olanzapine-fluoxetine group was 48.8% . . .²⁵

It is important to note when looking at the two data sets that no definitive conclusion can be reached in terms of the relative effectiveness of Latuda and Symbyax based on the results achieved in these separately run trials, despite the better numbers for Symbyax in its study compared with the results for Latuda in its study. The results of different trials at different times by different investigators at different sites (and countries) cannot be directly compared. Furthermore, the safety issues of each of the drugs does not support any meaningful comparison based on the top-line results simply measuring the effectiveness of the two drugs. A clear answer to the superiority of competing drugs can only be answered by a well-designed head-to-head study.²⁶ However, any commercial that implies that most patients who take Latuda will achieve remission, or that the great majority of patients achieve meaningful relief, or even that Latuda is THE appropriate choice for patients with bipolar depression is misleading.

Does the “ask your doctor” clause provide an effective remedy for any misleading impression created by the advertisement because that misleading impression would be corrected by the doctor? No, because the labeling information summarizing the clinical effectiveness data for Latuda only shows

24. Antony Loebel et al., *Lurasidone Monotherapy in the Treatment of Bipolar I Depression: A Randomized, Double-Blind, Placebo-Controlled Study*, 171 AM. J. PSYCHIATRY 160, 160–68 (2014).

25. Mauricio Tohen et al., *Efficacy of Olanzapine And Olanzapine-Fluoxetine Combination in the Treatment of Bipolar I Depression*, 60 ARCHIVES GEN. PSYCHIATRY 1079–88 (2003).

26. Robert A. Bohrer, *The Need For Publicly Funded Trials to Get Unbiased Comparative Effectiveness Data*, HEALTH AFF.: HEALTH 'POL'Y LAB (Feb. 20, 2015), <http://healthaffairs/blog/2015/02/20/the-need-for-publicly-funded-trials-to-get-unbiased-comparative-effectiveness-data/>.

changes in the median difference in depression score for the patients receiving the drug. This is compared with the changes in depression score for the patients receiving the placebo, but contains nothing about the percentage of patients who achieved remission. The real answer to one of the most important questions that a patient might want ask a doctor before choosing a drug—“How likely am I to be helped?”—is not answered by the label. The doctor would have to search through the literature to find the answer and even then the doctor would be unable to answer the question of how Latuda’s effectiveness compares to that of other drugs that treat the same problem.

Imagine that same commercial with the clear printed message and background narration stating that, “Approximately 53% of patients in the clinical trial achieved a significant benefit from Latuda compared with 30% of patients receiving a pill with no active ingredients. About 40% of patients receiving Latuda achieved remission or relief from depression compared with 25% of patients who took a pill with no active ingredients. No evidence suggests that Latuda works better than other drugs for bipolar depression.” That ad would almost certainly be less effective in persuading patients to “ask their doctor” if Latuda is the right drug for them and may not be worth broadcasting at all.

If the analysis of Latuda’s data has not put you to sleep yet, Belsomra, a drug designed to treat insomnia, is marketed to do just that. The visual images generated for the ad are fascinating. Zoomorphic furry letters spelling “sleep” and “wake” romp around the bedroom setting for the opening of the Belsomra commercial.²⁷ Don Draper would be rolling on the floor laughing.²⁸ Beyond the complete surrealist fantasy of animated furry letters representing sleep and wake messages, the images again imply more or less complete effectiveness. The woman at the beginning of the ad looks tired and is searching for sleep. Having taken Belsomra, she finally is seen sleeping soundly (and somehow a male has magically appeared in her bed to suggest some additional benefit to the drug). The story from the images is clear: if you suffer from insomnia and take Belsomra you will start sleeping well and feeling rested, and your love life might benefit as well.

The key language for Belsomra is that it can “turn down wake messages” by “targeting and inhibiting the action of orexin, a neurotransmitter that plays a central role in sending wake messages. Only Belsomra works this way.” This central verbal message of the Belsomra ad points to its first-in-class mechanism of action—“Only Belsomra works this way.” It is subtler than the “proven effective” message of the Latuda ad, but it is hard to infer any other motivation for featuring its unique mechanism or action other than the suggestion that this new mechanism of action provides greater effectiveness than the older classes of

27. Belsomra TV Commercial, *supra* note 12.

28. Don Draper was the character portrayed by Jon Hamm in *Mad Men*, the television drama about the advertising agency world of the 1960s. *Mad Men* (AMC television 2007–2015).

drugs that work on other pathways. It is reasonable to conclude that the purpose of including it in the ad is that market research indicated that including that information does suggest superiority. So, is it superior? And if it is, how effective is it?

There are other non-benzodiazepine drugs for insomnia to which Belsomra's effectiveness can be compared, such as Lunesta (eszopiclone).²⁹ Is there evidence that supports the suggestion that by working this way Belsomra is more effective than Lunesta or other non-benzodiazepene drugs for insomnia? Shown below is the data from Table 3 of the Belsomra prescribing information—the polysomnographic measurement of “time to sleep onset” from two studies.³⁰

Table 3: Polysomnographic Assessment of Time to Sleep Onset in Studies 1 and 2

	Mean Baseline and Change from Baseline [†] After 1 and 3 Months (minutes)		Difference [†] Between BELSOMRA and Placebo (minutes)
Study 1			
	Placebo (n=290)	BELSOMRA 15-20 mg [‡] (n=193)	
Baseline	66	69	
Change from Baseline			
Month 1	- 23	- 34	- 10***
Month 3	- 27	- 35	- 8**
Study 2			
	Placebo (n=286)	BELSOMRA 15-20 mg [‡] (n=145)	
Baseline	69	65	
Change from Baseline			
Month 1	- 25	- 33	- 8*
Month 3	- 29	- 29	0

[†] Change from baseline and treatment differences based upon estimated means.

[‡] 15 mg in elderly and 20 mg in non-elderly patients

* p<0.05; **p<0.01; ***p<0.001

While there is also data on “sleep maintenance” in the Belsomra prescribing information, for purposes of comparisons to Lunesta it is reasonable to use this top line primary efficacy measure—8 to 10 minutes less time to fall asleep as measured at 30 days. To be generous in this context, I will ignore the 0 difference compared to placebo at month 3 in study 2.

How does data for Lunesta, which does not target orexin but does have exactly the same indication, compare? Here, the data is not in the label but can be found in a journal article reporting on one of the clinical trials relied on for

29. Gregory M. Asnis, Thomas Manju and Margaret A. Henderson. *Pharmacotherapy Treatment Options For Insomnia: A Primer For Clinicians*, 17 int. j. of molecular sciences 50 (2015) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4730295/pdf/ijms-17-00050.pdf>.

30. Merck, *Belsomra Full Prescribing Information*, https://www.merck.com/product/usa/pi_circulars/b/belsomra/belsomra_pi.pdf (last visited July 11, 2018).

approval.³¹ All the label states is that the drug was more effective than the placebo on these measures. It is fairly clear that following the ad's recommendation to "ask your doctor" would not be likely to provide a patient with any information about how well the competing drug actually works, as the doctor would be unable to know from the prescribing information. Here is the data from the actual research article:³²

Table 2. Summary of PSG Sleep Efficacy Results

Measure		Baseline		Night 1		Night 15		Night 29		Double-blind Average	
		Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median
LPS (min)	PBO	38.4 (35.1)	27.5	35.2 (28)	28.6	34.0 (28)	27.0	30.2 (28.2)	20.5	33(22.6)	29.0
	ESZ 2mg	39.5 (36.1)	30	21.4 (27.6)	11.8	21.9 (21.1)	15.5	24 (35.8)	12.9	23 (24.9)	15.0
	ESZ 3mg	42.8 (41.6)	30.1	17.5 (20.2)	12.3	19.5(19.6)	13.8	18.1 (26.1)	11.5	18 (15.7)	13.1

The endpoint shown here is "LPS," defined by the investigators "as the time from lights out to the first 20 consecutive epochs (10 consecutive minutes) of sleep." For the purpose of this analysis, LPS is a fairly close comparator to the "time to sleep onset" measured for Belsomra. The data on this difference in "the time to sleep" for subjects who received the test drug rather than placebo was between 10 minutes less time to fall asleep for Belsomra at 30 days compared to 7 to 8.5 minutes less for Lunesta patients at 29 days. However, to further emphasize the point about not using the data from a study of one drug to draw a conclusion about its comparative effectiveness to another drug,³³ the other endpoints in the Lunesta study were different from the endpoints used for Belsomra. It is not possible to conclude which drug is more effective (or safer) from these disparate studies, and any implicit message that either drug is the drug of choice for patients with insomnia is obviously not supported by the data, nor would heeding the ad's suggestion to "ask your doctor" likely provide the answer. Although the prescribing information for Belsomra does contain some effectiveness data about Belsomra, the prescribing information for Lunesta does not.

31. Gary K. Zammit et al., *Efficacy and Safety of Eszopiclone Across 6-Weeks of Treatment for Primary Insomnia*, 20 CURRENT MED. RES. & OPINION 1979-1991 (2004).

32. *Id.*

33. See Bohrer, *supra* note 26.

II: PRAGMATIC IMPLICATIONS AS A MARKETING STRATEGY

The phenomenon of pragmatic implications has been well-studied and repeatedly demonstrated in marketing literature.³⁴ Searleman and Carter defined 'pragmatic implications' as "statements that lead a person to believe something that is neither explicitly stated nor necessarily implied."³⁵ Advertisers rely on the general beliefs of consumers to interact with the content of an advertisement to create consumer perceptions about the product without any direct assertions about the product's effectiveness or performance. Such perceptions are 'pragmatically implied' and ads designed to create such factually unsupported pragmatic implications are misleading.³⁶ While an advertisement that contains a false pragmatic implication can be tested by researchers, the goal of every marketer is to persuade the consumer that the product advertised is the best choice for a particular function.

Having a doctor as a required intermediary would seem to provide a corrective function for unsupported implications. However, it is clear that in many cases the doctor is unlikely to have the information needed to correct the impressions created by the ad. For example, the prescribing information for Lunesta (a competitor of Belsomra) and for Symbyax (a competitor of Latuda) contain no precise quantitative or comparative data for effectiveness. Instead, the only statement made in the prescribing information for those competitor drugs is that the drug in question was more effective than the placebo control in clinical trials prior to FDA approval. Furthermore, the prescribing information for the advertised drugs does not contain any comparative effectiveness data to inform the doctor.

There have been numerous studies on the effect of direct-to-consumer advertising on healthcare. There is strong evidence that direct-to-consumer advertising increases the number of doctor's visits.³⁷ There is also evidence that the number of prescriptions for an advertised indication increases.³⁸ Although an FDA survey found that 58% of physicians "agreed strongly that DTC ads make the drugs seem better than they really are," there is no consensus about the percentage of prescriptions that result for the advertised product. The FDA finding concerning physicians' views of patients' perceptions created by DTC ads strongly supports the position taken here, which is that DTC ads are

34. See e.g. Alan Searleman & Helen Carter, *The Effectiveness of Different Types of Pragmatic Implications Found in Commercials to Mislead Subjects*, 2 APPLIED COGNITIVE PSYCHOL. 265 (1988); Harris, *supra* note 17.

35. *Id.*

36. Harris, *supra* note 17.

37. E.g. Toshiaki Iizuka & Ginger Zhe Jin, *The Effect of Prescription Drug Advertising on Doctor Visits*, 14 J. ECON. & MGMT STRATEGY 701 (2005).

38. Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995 (2005).

implicitly misleading. The pragmatic implication of superior effectiveness is pharmaceutical marketers' tool of choice: DTC ads are used because they succeed. The ads increase sales of the advertised drugs, almost always without any support for the conclusion that the advertised drugs are in any way better than the other drugs that might be used.

III: A REQUIRED CONCISE STATEMENT OF BENEFIT AND CENTRAL HUDSON

The regulatory remedy for the pragmatic, misleading implications of direct-to-consumer advertising proposed here is a concise statement of the average benefit that patients taking the advertised drug receive. For example, in the Belsomra commercial, just before the required summary of potential adverse effects, the voice actor narrating the ad would be required to say, "In clinical studies, patients taking Belsomra for insomnia fell asleep 8 to 10 minutes more quickly than patients taking a placebo." That is, of course, what the pharmaceutical company's own studies showed. And, like any other pharmaceutical ad or part of a pharmaceutical ad, the accuracy of the concise statement of average benefit could be reviewed by the FDA and any inaccurate or misleading statements would be subject to regulatory action or sanction.³⁹ However, since pharmaceutical marketing is commercial speech,⁴⁰ the question presented here is whether or not an FDA-required concise statement of average benefit would be constitutional if analyzed under *Central Hudson*.⁴¹

In *Central Hudson*, the Supreme Court held that under the First Amendment, governmental regulation of commercial speech is subject to a three-part test:

For commercial speech to come within that provision [i.e. be protected by the First Amendment], it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.⁴²

Applying *Central Hudson* to direct-to-consumer pharmaceutical ads, the required disclaimers would be upheld if the ads are inherently misleading in suggesting either that the drugs are more effective than their data shows, or that

39. E.g., Meena Ramachandra & Melinda McLawhorn, *Orexigen Therapeutics, Inc. (Contrave) Untitled Letter 5/18/2017*, U.S. Food & Drug Administration, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm560127.htm> (last visited June 1, 2017) (letter of Meena Ramachandra (FDA) to Stacy Hennings, Sr. Director, Regulatory Affairs Advertising & Promotions Orexigen Therapeutics, Inc.).

40. See *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011).

41. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n. of N.Y.*, 447 U.S. at 564.

42. *Id.*

the advertised drug is the best drug for the advertised indication. Even the language “proven effective” of the Latuda commercial⁴³ would be likely to mislead the ordinary television viewer even though the word “effective” has a specialized meaning in the context of the FDA.⁴⁴ To the average viewer of a television advertisement the word “effective” is most likely to have its ordinary English language meaning, which is “[s]uccessful in producing a desired or intended result.”⁴⁵

However, it is unlikely that a court facing a challenge to the regulation would stop there. If the advertisement is not overtly or expressly misleading, then it is likely that commercial speech protection would apply and that it is necessary to proceed to the remaining steps of the *Central Hudson* analysis. If the governmental interest is to counteract the *potential* implication of superior or even significant effectiveness for most patients, then a concise statement of the actual effectiveness of the drug would directly advance that governmental interest. That leads to the final step in *Central Hudson*: Would a required disclaimer be more extensive than is necessary to counteract the potentially misleading nature of the ad? It is difficult to imagine a governmental regulation that would be less extensive and accomplish that goal. In the recent First Amendment decision by the Supreme Court, *National Institute of Family Life Advocates v. Becerra*,⁴⁶ a case striking down required disclosures in the very different context of religious organizations and abortions, Justice Thomas’s majority opinion went on to affirm that “we do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products.”⁴⁷ The required disclaimers suggested here are both health directed and purely factual and uncontroversial—they are the advertisers’ own data used in support of the approval of their products.

Would a required disclaimer of any superiority to other drugs for that indication (in the absence of FDA-reviewed comparative effectiveness studies) be less extensive or objectionable to the pharmaceutical industry? It is doubtful, as advertising a product and stating that it is no better than other products for that function defeats the purpose of advertising at all. And that is the precisely the point: A concise statement of the effectiveness of DTC-advertised drugs would go a long way towards curing the problems that DTC advertising creates. With the current clamor about pharmaceutical prices and prescription drug advertising, now is the time for the FDA to take action and require pharmaceutical companies

43. Latuda TV Commercial, *supra* note 13.

44. Adequate and Well-Controlled Studies, 21 C.F.R. § 314.126 (2018).

45. *Effective*, OXFORD LIVING DICTIONARIES, <https://en.oxforddictionaries.com/definition/effective>.

46. *Nat'l. Inst. of Family Life Advocates v. Becerra*, 138 S.Ct. 2361(2018).

47. *Id.* at 2376.

to provide patients with a concise statement of how effective their drugs have been proven to be.

