DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in a Clear, Conspicuous and Neutral Manner in Advertisements in Television and Radio Format

Docket No. FDA-2009-N-0582

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Table of Contents

I. INTRODUCTION AND SUMMARY

A. INTRODUCTION

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated costs of compliance in the first year could exceed one percent of sales revenues for the smallest affected entities, we find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more

(adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Under section 502(n) of the Federal Food, Drug and Cosmetic Act (FD&C Act), as amended by section 901(d)(3)(A) of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress has mandated that the disclosure of the major side effects and contraindications of the advertised product (known as the "major statement") in human prescription drug advertisements presented directly to consumers in television or radio format stating the name of the drug and its conditions of use (DTC TV/radio ads) be presented in a "clear, conspicuous and neutral manner." Section 901(d)(3)(B) of FDAAA mandates that FDA issue regulations that establish standards for determining whether a major statement is presented in such a manner. In accordance with this legislation, this final rule requires that the major statement in such ads be presented in a clear, conspicuous, and neutral (CCN) manner and provides standards for determining whether this is the case.

B. Summary of Costs and Benefits

The costs of this final rule include the cost to read and understand the rule, to revise company standard operating procedures, and to revise DTC TV/radio ads during the transition period leading up to the compliance date. These activities and their associated costs will occur during the first year. We also expect there to be modest ongoing costs for industry to review future DTC TV/radio ads to ensure that these advertisements comply with this final rule and an ongoing opportunity cost related to a potential change in the relative allocation of time within the ad between the presentation of the major statement and the presentation of other content. The total present value of costs over a 10-year time horizon ranges from $104.8 million to $331.8 million, with a primary estimate of $218.3 million, at a 7 percent discount rate; the present value ranges from $123.8 million to $393.0 million, with a primary estimate of $258.4 million, at a 3 percent discount rate. Annualized costs over a 10-year time horizon range from $14.9 million to $47.2 million, with a primary estimate of $31.1 million at a 7 percent discount rate; annualized costs over a 10-year time horizon range from $14.5 million to $46.1 million, with a primary estimate of $30.3 million at a 3 percent discount rate.

The benefits of this final rule stem from and include helping consumers notice, attend to, and understand the major statement in DTC TV/radio ads. The standards in the final rule help to ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug and help ensure that consumers are better informed when they participate in healthcare decision making.

Table 1 summarizes the annualized costs and describes the benefits of this final rule.

Table 1. Summary of Benefits, Costs and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Helping consumers notice, attend to, and understand the major statement in DTC TV/radio ads.						
Costs	Annualized Monetized $millions/year	31.1	14.9	47.2	2020	7%	10 years	
		30.3	14.5	46.1	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: Compliance costs in the first year may exceed one percent of revenues for the smallest affected entities. Wages: None Growth: None							

C. Comments on the Preliminary RIA and Our Responses

FDA received more than 30 submissions on the proposed rule from consumers, public interest groups, trade associations, and the drug industry during the initial comment period (March 29, 2010 to June 28, 2010). When we reopened the comment period to allow for comment on the Distraction Study report (FDA, 2011) as it relates to the proposed standards

(January 27 to February 27, 2012, and March 29 to April 9, 2012), we received nearly 40 more submissions. A subset of the submissions contain comments related to the preliminary economic analysis of impacts.

Some comments relate to the general topic of the economics of DTC advertising but are outside the scope of this final rule. For example, a few comments suggested that FDA should ban all DTC advertising for prescription drugs, asserting that doing so would reduce prescription drug prices and expenditures. Comments such as these are beyond the scope of this final rule and are not addressed here because this rule does not address whether DTC advertising for prescription drugs should exist, but instead addresses the narrower issue of establishing standards that FDA will consider in determining whether the major statement in certain DTC television or radio advertisements is presented in a clear, conspicuous, and neutral manner as required under FDAAA.

Comment 1: One comment stated that FDA's assessment of costs should be balanced by potential consumer and health savings, noting the analysis does not address potential savings that could result from even marginal reductions of any inappropriate prescriptions driven by DTC advertisements (DTCA). The comment stated that although FDA acknowledges that: "no studies have examined the impact of direct to consumer advertising on either health outcomes or examined the costs and health and social consequences of DTCA" such research must be carried out so that the positive financial impacts of these and other standards for clearer DTC advertising can be accurately assessed.

Response 1: This analysis is concerned with the effects of establishing standards for determining whether the major statement in certain DTC television or radio advertisements is presented in a clear, conspicuous, and neutral manner as required under section 502(n) of the FD&C Act as amended by FDAAA. The overall effects of DTC advertising of prescription drugs are generally beyond the scope of this rule, except that any effects on dimensions that may be meaningfully modified by this final rule would be relevant for establishing the baseline and impacts relative to that analytic baseline. To carry out primary research on the overall effects of DTC advertising of prescription drugs would be beyond the scope of this rule.

Comment 2: In the context of offering support for the rule and the dual modality requirement, one commenter argued that the costs of compliance would not outweigh the benefit of making advertisements more beneficial to consumers. In fact, the commenter argued that the advertisements are already beneficial to pharmaceutical companies and would remain beneficial under this final rule while becoming more beneficial to consumers. Finally, the commenter stated the costs of compliance should fall on the shoulders of pharmaceutical companies rather than consumers bearing the consequences of inadequate knowledge of drug risks.

Response 2: A key analytic question is whether the costs of compliance do or do not outweigh the potential benefits of establishing standards for determining whether the major statement in a DTC television or radio advertisement is presented in a CCN manner.

Pharmaceutical companies are willing to pay for radio and television advertising for certain products in order to increase the size of the market or gain market share. We fully expect pharmaceutical companies to continue to advertise on radio and television according to the standards set forth in this rule. In Section II.D of this analysis, we discuss the benefits stemming from this rule related to enhanced consumer comprehension of the major statement in DTC TV/radio ads.

Comment 3: A comment argued that proposed § 202.1(e)(ii)(B) and (C), which respectively proposed to require that audio information be understandable in terms of pacing and that textual information appear for a sufficient duration, could require increasing the length of television or radio advertisements with substantial risk information, which would increase costs to drug sponsors.

Response 3: The requirement that the major statement in certain DTC television or radio advertisements be presented in a clear, conspicuous, and neutral manner has been in effect since March 25, 2008, as a result of the enactment of FDAAA. Firms therefore have already been implementing practices to ensure that the major statement is presented in a CCN manner. We believe drugs with all types of risk information can satisfy the CCN requirement as implemented in this final rule using advertisement durations currently observed in the market. In particular, in the final rule, the standard requires that the major statement's audio information, in terms of volume, articulation, and pacing used, be at least as understandable as the audio information presented in the rest of the advertisement—a standard that we believe many current ads subject

to the CCN requirement already satisfy. Thus, generally we do not expect sponsors to have to slow down the audio portion of the major statement to satisfy the CCN criteria. Further, under the final rule, text is required to be used *concurrently* with audio to present the major statement in ads in television format, and the duration of that text is considered sufficient if the text display begins at the same time and ends at approximately the same time as the corresponding audio. Therefore, while we cannot rule out the possibility that manufacturers would ever choose to respond to these final CCN requirements by increasing the length of an advertisement, the rule itself does not dictate that result and we do not have evidence about whether manufacturers will make that choice.

Comment 4: Comments offered differing viewpoints about whether inclusion of a dual modality requirement would increase advertisement length (and therefore increase costs). One comment questioned whether inclusion of an additional requirement for dual modality would impose a greater financial burden upon drug producers and advertisers than the standards cited in the proposed rule. The comment stated that requiring dual modality would provide advertisers with more guidance on how to properly adhere to the FDAAA clear, conspicuous, and neutral requirement. Another comment stated that requiring simultaneous audio and visual presentation of the major statement would not impose additional time, but may reduce the needed time; thus, it would not impose an undue burden on pharmaceutical advertisers. Other comments argued that the dual modality requirement would increase the length of advertisements citing, for example, advertisements with substantial risk information.

Response 4: Because the requirement to present risk information in a CCN manner is already in effect under FDAAA, the issuance of defined standards should reduce regulatory uncertainty, which in turn could reduce inefficiencies in compliance. Moreover, the Agency has provided flexibility for sponsors to determine how to meet the dual modality requirement. For example, the requirement for dual modality presentation of the major statement may be met by displaying on screen the verbatim key terms or phrases from the corresponding audio; a verbatim complete transcript is not required, but is another option that sponsors can choose to use to fulfill dual modality. Thus, the agency finds that the inclusion of the major statement in both audio and visual modes in television advertisements would not generally increase the advertising time needed. However, in the analysis of this final rule, we increase by 25 percent the number of

hours at the high end of our estimated range for revising company standard operating procedures to account for planning and procedure adjustments that might be needed to produce advertisements that comply with the standards and remain within current advertising time durations.

Comment 5: While some comments supported the earliest possible effective date for implementation of the proposed standards, another comment stated that a 90-day implementation period was reasonable for DTC advertisements that have not already begun production and that 180 days would be reasonable for those that are already in production or circulation and may need modifications. The comment stated that a 90-day effective date for advertisements that have already been produced would have a significant financial impact and that FDA's one-time cost estimates for modifying existing advertisements ($100,000 - $150,000 per television advertisement and $10,000 - $20,000 per radio advertisement) appear optimistically low. The comment requested that FDA revisit these estimates and publish a more detailed analysis of the cost of modifying existing advertisements.

Response 5: For the proposed rule the Agency relied on industry sources to estimate the costs to modify existing advertisements (for example, to add superimposed text or prepare new audio). We requested detailed comments on our estimates. The comments did not provide any data to support an alternative estimate of costs. Therefore, for this final rule, we continue to rely on the information we gathered for the proposed rule (updating for inflation) but consider the cost of revising a television advertisement to add or modify text separately from the cost of making additional revisions to meet standards pertaining to the non-textual aspects of the major statement.[1] We also note that the Agency is providing a compliance date that is 365 days after publication of this final rule, which should alleviate concerns from large and small firms about the burden of having to quickly revise advertisements that are already in production or circulation.

Comment 6: Some comments request additional detail about FDA's examination of a sample of television and radio advertisements disseminated in 2008. As described in the

[1] There are five standards for clear, conspicuous, and neutral in this final rule.

Analysis of Impacts section of the proposed rulemaking document, that examination was used to develop a baseline estimate of the percentage of major statements that were not presented in a CCN manner in 2008, shortly after enactment of the statutory requirement to present the major statement in a CCN manner. Commenters requested additional detail about the methodology used for the evaluation, the criteria or standards used, and the criteria which advertisements most frequently failed to satisfy.

Response 6: We have updated our estimates of baseline conditions for this final rule to account for the specific standards that it establishes, including the requirement that the major statement in television advertisements be presented concurrently using both audio and text (dual modality). Thus, we decline to go into greater detail about the previous examination.

D. Summary of Changes to the Economic Analysis

Unlike the Analysis of Impacts prepared for the proposed rule, the primary analysis in this final Regulatory Impact Analysis includes the impacts of a standard requiring dual modality for the major statement in certain advertisements in television format and the impacts of a compliance date that is one year after publication of this final rule.[2] We have also updated the analysis throughout to reflect the updates of data sources, and changes in standards for regulatory analysis.

II. Final Regulatory Impact Analysis

A. Background and Purpose

Section 502(n) of the FD&C Act requires advertisements to contain ''a true statement'' of certain information including ''information in brief summary relating to side effects, contraindications, and effectiveness'' as required by regulations issued by FDA. FDA's longstanding prescription drug advertising regulations require advertisements broadcast through

[2] With respect to the standard requiring dual modality for the major statement in advertisements in television format, the Analysis of Impacts estimated for the proposed rule contemplated the possibility of such a standard; the estimated impacts of the dual modality standard were estimated in the Alternatives Considered section of the proposed rule's Analysis of Impacts.

television or radio to disclose the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation (21 CFR 202.1(e)(1)). This disclosure of the major side effects and contraindications has long been known as the "major statement." The regulations further specify that an advertisement does not satisfy the statutory requirement of containing a ''true statement'' of certain information if it: (1) Is false or misleading with respect to side effects, contraindications, or effectiveness; or (2) fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug; or (3) fails to reveal facts that are material in light of the representations made in the advertisement or with respect to the consequences that may result from the use of the drug as recommended or suggested in the advertisement (21 CFR 202.1(e)(5)).

With this longstanding framework as a backdrop, section 901(d)(3)(A) of FDAAA amended the FD&C Act by adding to section 502(n) the provision that ''[i]n the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a *clear, conspicuous, and neutral manner*'' (emphasis added). (As noted previously, in this document, we refer to the advertisements subject to this requirement as DTC TV/radio ads.)

Neither the statute nor our current regulations describe standards for determining whether a major statement is presented in a CCN manner, but FDAAA instructs FDA to establish such standards to address the requirements it added to section 502(n). In accordance with this, we are establishing standards for determining whether a major statement in DTC TV/radio ads is presented in a ''clear, conspicuous, and neutral manner.''

B. Need for Federal Regulatory Action

DTC advertising is characterized by asymmetric information and potentially poor processing of information by consumers. Drug manufacturers generate extensive efficacy and safety information about their products in support of applications seeking FDA marketing approval. While much information is publicly available for approved drugs, consumers would face high costs in terms of time and effort to research and understand much of this information.

Among other reasons, manufacturers advertise prescription drugs directly to consumers to increase demand and utilization; manufacturers, therefore, have an incentive to portray their drugs in a positive light, subject to applicable laws. As described above, a system of Federal oversight has been developed to help ensure that consumers receive fair, balanced, and accurate information about advertised drugs. Section 502(n) of the FD&C Act (21 U.S.C. 352(n)) specifies that prescription drug advertisements must contain ''a true statement'' of certain information, including ''such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations.'' Under those regulations, advertisements broadcast through media including TV and radio must include information relating to the major side effects and contraindications (the "major statement"), but as long as adequate provision is made for dissemination of the FDA approved or permitted labeling in conjunction with the broadcast presentation, these ads do not need a full brief summary of all necessary information related to side effects and contraindications (21 CFR 202.1(e)(1)). FDAAA added to the requirements for the major statement in advertisements for prescription drugs intended for use by humans presented directly to consumers in TV or radio format, by specifying that the major statement in these ads must be presented in a "clear, conspicuous, and neutral" manner.

Section II.C below describes how consumers process the information provided in DTC TV/radio ads in the absence of this final rule. We describe baseline TV/radio advertising practices and the extent to which recent DTC TV/radio ads include CCN presentations of risk information. We find that while major statements have generally improved since Congress amended section 502(n) and instructed FDA to establish standards to address the requirements it added to that section, some still fall short. We also discuss the resultant level of consumer understanding of product risks. Section II.D discusses the negative consequences that may result from lack of consumer understanding under the status quo. Although prescription drugs cannot be obtained by a consumer without a prescription from a licensed healthcare provider (HCP), we find empirical evidence that inadequate consumer comprehension of prescription drug risks, which this final rule helps to mitigate, may still have negative consequences.

C. Baseline Conditions

1. Baseline Advertising Practices

Industry expenditures on DTC advertisements of prescription drugs have increased dramatically since 1997. Prior to 1997, the majority of DTC promotion occurred in print; companies may have been unclear at that time about how they could comply with the requirements applicable to broadcast media (in particular, the requirement in § 202.1(e)(1) that advertisers make "adequate provision" for dissemination of the product's package labeling). In 1997, FDA issued a draft guidance, which was finalized in 1999, describing an approach for fulfilling the requirement for adequate provision in connection with broadcast advertising for prescription drugs (FDA, 1999). Following the issuance of the draft guidance, companies expanded their consumer-directed promotional efforts to include TV and radio advertisements. Advertising expenditures increased as companies began to use these costlier media to promote their products to consumers. From a reported total expenditure of less than $1 billion in 1997 (approximately $1.53 billion when adjusted for inflation) (Winstein and Vranica, 2009), prescription drug industry spending on advertising topped $6.58 billion in 2020, according to Kantar measured media (Bulik, 2021). In 2020, television advertisements accounted for the majority of advertising spending with $4.58 billion of the total $6.58 billion that drug companies spent on advertising in 2020 (Bulik, 2021). Spending on prescription drug ads in radio format is also growing, increasing from $30 million in 2007 (U.S. Congressional Research Service, 2009) to $57.4 million in 2020 (Medical Marketing and Media, 2021). For comparison, the total value of U.S. retail outlet sales for prescription drugs was $407.1 billion in 2019 (Kaiser Family Foundation, 2020).

We use advertisements submitted to FDA at the time of first publication on Form 2253[3] over the years 2014 to 2022 to estimate the total number of new DTC TV/radio ads that will be disseminated annually under this final rule. In 2022, 608 television advertisements were submitted to CDER and 2 were submitted to CBER, for a total of 610. That same year, 63 radio advertisements were submitted to CDER and 0 were submitted to CBER. An average of 444 television and 36 radio advertisements were submitted to FDA annually over this period, as shown in Table 2 below, with submissions of both types exceeding these averages in recent years. We project future submissions over the time horizon of the analysis using an average of the most recent 5 years of data, for 596 total TV ads and 47 total radio ads.

[3] See 21 CFR 314.81(b)(3)(i).

Table 2: Advertisements Submitted to FDA on Form 2253

	Average (2014-2022)	2022	2021	2020	2019	2018	2017	2016	2015	2014
TV Ads—CDER	436	608	691	564	641	444	311	276	221	167
TV Ads—CBER	8	2	3	6	6	14	12	11	12	5
TV Ads—TOTAL	**444**	**610**	**694**	**570**	**647**	**458**	**323**	**287**	**233**	**172**
Radio Ads—CDER	34	63	64	56	18	32	14	11	18	26
Radio Ads—CBER	3	0	0	2	1	0	0	11	3	7
Radio Ads--TOTAL	**36**	**63**	**64**	**58**	**19**	**32**	**14**	**22**	**21**	**33**

Prior to publication of the proposed rule, FDA's Center for Drug Evaluation and Research evaluated a sample of television and radio advertisements that had been disseminated in 2008, shortly after enactment of the statutory requirement for the major statement to be presented in a CCN manner, to estimate baseline conformity with this statutory requirement. In the combined sample, 34 percent of the ads evaluated were judged to violate the statutory requirement. This previous examination, for several reasons, may not provide a useful or accurate picture of present and future advertisements in television and radio format and their baseline conformity with the requirements of this final rule. First, as acknowledged in the proposed rule, television advertisements have a relatively short life (75 FR at 15382). Affected firms have had ample time since the 2007 enactment of FDAAA (which requires the major statement to be presented in a clear, conspicuous, and neutral manner) to refine later advertisements. Second, as also acknowledged in the proposed rule, the Pharmaceutical Research and Manufacturers of America's (PhRMA's) publication of voluntary guidelines regarding DTC advertisements was revised in December 2008, to (among other things) specify that risks and safety information in DTC advertising should be presented in a "clear, conspicuous and neutral manner, and without distraction from the content" (PhRMA, 2008). This voluntary industry-created guideline may have influenced industry performance. Finally, the prior estimates did not take account of the specific standards established in this final rule, which include the requirement that the major

statement in television advertisements be presented concurrently using both audio and text (dual modality). For these reasons, we update our estimates of baseline conditions.

Based on Agency experience over the past 10 years, we believe that the presentation of major statements has generally improved to become more clear, conspicuous, and neutral in ways that will satisfy many standards incorporated in this final rule. However, television advertisements generally do not currently satisfy the dual modality standard in the manner finalized in this rule; therefore, we estimate baseline conformity with this standard at 0 percent. Otherwise, we estimate, based on Agency experience and the reasons stated above, that baseline conformity has likely improved in the last 10 years and between 10 percent and 33 percent (approximately one-third) of DTC TV/radio ads fail to fully comply with one or more of the standards pertaining to the non-textual aspects of the major statement. A published review of 68 DTC TV advertisements airing between July 2012 and August 2014 found areas where there may still be room for improvement (Sullivan et al., 2019). We note, however, that this review was undertaken as a content analysis and not to make judgments about what would violate this final rule or any other set of standards for CCN presentation.

2. BASELINE CONSUMER UNDERSTANDING

Research suggests there is significant room for improvement in baseline consumer comprehension of drug product risks as presented in DTC advertisements. For example, 60 percent of the responding physicians in one large survey believed that DTC advertisements for prescription drugs provided patients with little or no understanding about the risks and negative effects of the products (Aikin et al., 2004). Over 65 percent of these same physicians observed that DTC advertisements may lead patients to confuse the relative risks and benefits of advertised drugs.

Research available at the time this rule was proposed showed that presenting the same information simultaneously in both the audio portion and as visual superimposed text increases comprehension compared with information presented in only one of those modes (Morris et al., 1989; Murray et al., 1998; Wang and Muehling, 2010). Subsequently, FDA's Distraction Study likewise found that presenting risk information using dual modality improves consumer comprehension (FDA, 2011). Studies have continued to confirm the positive impact of dual modality (Aikin et al., 2016; Russell et al., 2017; Sullivan et al., 2017). As stated above, DTC

television advertisements generally do not currently use dual modality to present the major statement in the manner required by this final rule.

Bringing major statements in DTC TV/radio ads up to the standards of this final rule, including the use of dual modality, will improve consumer comprehension.

D. Benefits of the Rule

1. Effects of DTC Advertising

Prescription drugs, by definition, cannot be accessed directly by the consumer; they must be prescribed by a licensed HCP. However, consumers make critical choices related to treatment with prescription drugs. They decide, for example, whether to make the initial appointment with an HCP, whether to ask the HCP about a particular drug, whether to fill a prescription, whether to take the drug, and whether to continue taking it in adherence to the prescribed regimen.

To understand the benefits of establishing standards for determining whether the major statement in a DTC television or radio advertisement is presented in a clear, conspicuous, and neutral manner, we provide a brief overview of the effects of DTC advertising. There is a growing body of research, but it has generated mixed results. For the proposed rule, the Agency contracted with Eastern Research Group (ERG) in 2008 to review and summarize the relevant peer-reviewed literature on DTC advertising published between 2004 and 2008 (Eastern Research Group, 2009). This review was an extension of work already published by FDA in 2004 summarizing its survey research results on the public health impacts of DTC advertising (Aikin et al., 2004). Highlights of some of the research findings in the ERG report and from other recent research are described below. See the ERG report for a comprehensive discussion of the literature covered by the review.

DTC prescription drug advertising raises awareness of medical conditions and potential treatments. Research has generally found that DTC advertising increases the demand for and utilization of advertised prescription drugs (Alpert et al., 2015; Avery et al., 2012; Dave and Saffer, 2012; Eastern Research Group, 2009; Frosch et al., 2010). In addition, some research has shown that DTC advertising for a particular drug increased the demand for the entire therapeutic class (Eastern Research Group, 2009). Other effects include increased rates of drug therapy compliance, although the size of this effect may be small (Eastern Research Group, 2009; Princeton Survey Research Associates International, 2017). DTC advertising has also been

shown to produce indirect, or spillover, effects on consumer behavior, such as increasing the number of physician visits that detect treatable disease (Eisenberg et al., 2022; Weissman et al., 2003). Less desirable outcomes may result when drug promotions are biased and provide an incomplete or confusing account of the drug's likely effects. Research using surveys of physicians have found that doctors associate DTC advertisements with promoting unnecessary visits and causing patients to require more of their time (Murray et al., 2003). This can encourage an increased and sometimes inappropriate demand for the advertised products (Mintzes et al., 2002; Murray et al., 2003).

2. Benefits of this Final Rule via Improved Consumer Understanding

This final rule sets standards for the manner of presentation of the major statement in DTC TV/radio ads to help ensure that this risk information is presented effectively—that is, in a way that helps consumers notice, attend to, and understand the drug's risks. The clear, conspicuous, and neutral presentation of risk information in DTC TV/radio ads helps ensure that these ads convey a truthful and non-misleading net impression about the advertised drug and that consumers are better informed when they participate in healthcare decision making.

In this final rule, FDA incorporated common themes found in other Federal standards specific to the clear and conspicuous communication of important information. These themes were: "ease of comprehension of the language used in the disclosure; the formatting and location of textual information in the disclosure; audio considerations such as pacing, volume, and qualities of speech; and the presence of any distracting elements during the disclosure" (75 FR 15376 at 15378). FDA noted in the preamble of the proposed rule that other Federal standards revealed the widespread incorporation of these common themes, which FDA in turn incorporated in its own proposed standards, and now incorporates in its final standards, because they are all factors that contribute to whether the audience will notice, attend to, and understand the risk information in the major statement (75 FR 15376 at 15378-15379).

The final rule establishes five standards that, independently and collectively, contribute to a clear, conspicuous and neutral presentation of the major statement in DTC TV/radio ads. Three of the standards for presenting the major statement address basic techniques for any communication targeting a broad consumer audience: that it uses consumer-friendly language and terminology, rather than technical language; that its audio be at least as understandable as

other audio in the same ad; and that the visual aspects of text used to present the major statement allow that text to be read easily. (See § 202.1(e)(1)(ii)(A), (B), and (e)(1)(ii)(D)). The dual modality requirement in the final rule has already been discussed (see section C.2), and as noted, research indicates that using this technique to present risk information improves consumer risk comprehension and recall, without decreasing the recall or comprehension of benefit information (Aikin et al., 2016; Russell et al., 2017; Sullivan et al., 2017). (See § 202.1(e)(1)(ii)(C)). The last standard, in § 202.1(e)(1)(ii)(E), is a common-sense measure that adds to the others to help ensure that consumers notice, attend to, and understand the major statement by prohibiting the simultaneous presentation of other audio or visual elements, alone or in combination, that are likely to interfere with comprehension of the major statement.

Bringing major statements in DTC TV/radio ads up to the standards of this final rule, including the use of dual modality, will improve consumer comprehension. The extent to which risk information in current DTC TV/radio ads is not presented in a CCN manner determines the scope for this final rule's potential generation of benefits (through helping to ensure that these ads convey a truthful and non-misleading net impression of the advertised drug as well as helping to ensure that consumers are better informed when they participate in healthcare decision making).

Even though prescription drugs cannot be accessed directly by consumers, consumers make critical choices that have effects on drug utilization. DTC advertisements encourage consumers to ask their HCPs about drugs, but consumers must decide, among other things, whether to make an initial appointment with an HCP and whether to ask about a specific drug. Improved consumer comprehension of benefits and risks helps to ensure that consumers are better informed when they participate in healthcare decision making.

E. Costs of the Rule

FDA regulations currently require that TV/radio advertisements present information relating to the major side effects and contraindications of the product, and FD&C Act section 502(n) as amended by FDAAA requires that such information be presented in a clear, conspicuous, and neutral manner for human prescription drug advertisements presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use. This final

rule would provide standards for determining what would be considered CCN, including a requirement that the major statement in television advertisements be presented concurrently using both audio and text. Once the final rule is in effect, manufacturers will have to take these standards into account when developing advertising materials for DTC TV/radio ads.

1. NUMBER OF ENTITIES AFFECTED

We use information from advertisements submitted to FDA on Form 2253 to determine the number of entities affected by this final rule. In 2022, 54 firms submitted television advertisements to CDER, 22 firms submitted radio advertisements to CDER, three firms submitted television advertisements to CBER, while zero firms submitted radio advertisements to CBER. The total number of firms was 79: therefore, we estimate that 79 entities will be affected by this final rule.

Table 3: Number of Firms Submitting Advertisements to FDA on Form 2253

	Average 2014-2022	2022	2021	2020	2019	2018	2017	2016	2015	2014
TV—CDER	39.7	54	51	37	33	32	30	41	38	41
Radio—CDER	12.7	22	20	16	4	5	8	5	15	19
TV—CBER	2.8	3	2	3	3	3	3	3	3	2
Radio—CBER	0.9	0	0	1	1	0	0	2	2	2
Total	**56**	**79**	**73**	**57**	**41**	**40**	**41**	**51**	**58**	**64**

2. COST TO READ AND UNDERSTAND THE RULE

Individuals from the 79 pharmaceutical and biologics manufacturers that currently disseminate or plan to soon disseminate television and radio advertisements will need to devote time to reading and understanding this final rule. This is a one-time cost that will be incurred in the first year after the final rule publishes. We assume that on average 3 people from each firm will read the rule: one top executive, whose time is valued at $165 per hour; one marketing manager, whose time is valued at $150 per hour; and one lawyer, whose time is valued at $159

per hour.[4,5] At an average adult reading speed of 200-250 words per minute (Trauzettel-Klosinkski et al., 2012), we estimate that it will take approximately 1 to 1.5 hours for each person to read this final rule. Including time to consider the rule, we estimate each person will spend a total of 2 to 3 hours. As shown in Table 4, this yields a cost per firm for reading and understanding the rule of $948 to $1,422 and a total cost of $74,892 to $112,338.

Table 4: Cost to Read and Understand the Rule

	Low	High
Time to Read and Consider the Rule (Hours)	2	3
Cost per Top Executive	$330	$495
Cost per Marketing Manager	$300	$450
Cost per Lawyer	$318	$477
Cost per Firm	$948	$1,422
Total Cost for 79 Firms	$74,892	$112,338

3. COST TO REVISE COMPANY STANDARD OPERATING PROCEDURES

This final rule would lead to one-time costs for pharmaceutical advertisers to set up new standard operating procedures for meeting the CCN criteria, including presentation of the major statement in television advertisements concurrently using both audio and text.

In Section H of the Preliminary Regulatory Impact Analysis, we estimated the costs of an alternative that included dual modality. For that alternative, FDA estimated that all firms who submit advertisements would bear one-time costs for developing new standard operating procedures because current standard practice is not likely to satisfy the dual modality requirement. We estimated SOP revisions would require 10 to 20 hours of upper management time, 40 to 80 hours of marketing management time, and 80 to 120 hours of technical writing time. For the proposed rule, the FDA received no substantive comments on the estimated range of costs and its components. As discussed in our response to comments that the proposed standards might increase the length of some television advertisements, we increase the high end

[4] Throughout the analysis of this final rule, we continue to base our estimate of the opportunity cost of one hour on the mean hourly wage but update to 2020 wages using the Bureau of Labor Statistics, "Occupational Employment Statistics: May 2020 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 – Pharmaceutical and Medical Manufacturing," https://www.bls.gov/oes/current/naics4_325400.htm

[5] In the analysis of the proposed rule, we escalated the wage cost by 40 percent to account for employee fringe benefits. Throughout the analysis of this final rule, we have updated our methodology in accordance with current best practices and HHS guidance, and we double the wage to account for both employee fringe benefits and overhead costs.

of the number of hours for each labor category by 25 percent to account for additional planning and procedure adjustments that might be needed to produce advertisements that comply with the standards and remain within current advertising time durations. We estimate that revisions to SOPs would require 10 to 25 hours of upper management time (top executives) at $165 per hour, 40 to 100 hours of marketing management time at a cost of $150 per hour, and 80 to 150 hours of technical writing time at a cost of $74 per hour.[6] As shown in Table 5, the cost per firm to revise SOPs would range from $13,570 to $30,225; the total one-time costs of SOP revisions would range from approximately $1.1 million to $2.4 million.

Table 5: Time and Cost to Revise Standard Operating Procedures

	Low	High
Top Executive Time (Hours)	10	25
Marketing Management Time (Hours)	40	100
Technical Writing Time (Hours)	80	150
Top Executive Cost ($165/hour)	$1,650	$4,125
Marketing Management Cost ($150/ hour)	$6,000	$15,000
Technical Writing Cost ($74/ hour)	$5,920	$11,100
Total Cost per Firm	$13,570	$30,225
Number of Firms	79.00	79.00
Total Cost	$1,072,030	$2,387,775

4. Cost to Revise Existing Advertisements During the Transition Period

If the compliance period for this final rule is not sufficient to encompass the life cycle of an advertisement that is already in production or in use, the likely response would be for the firm to revise the advertisement, if noncompliant. There are two potential costs of this revision: the direct costs of revising the advertisement and the indirect costs that may arise due to quickly making changes that were not anticipated from the start. Such indirect costs may arise, for example, due to changes to media placement decisions made far in advance or due to the need for booking talent far in advance. We provide a compliance date of one year (365 days) after publication of this final rule, which we believe is sufficiently long to minimize any indirect costs

[6] Bureau of Labor Statistics, "Occupational Employment Statistics: May 2020 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 – Pharmaceutical and Medical Manufacturing," https://www.bls.gov/oes/current/naics4_325400.htm. Wages are doubled to account for employee benefits and overhead costs.

that could possibly arise. Therefore, we expect the primary cost for revising advertisements to be the direct costs of revision during the transition period, which is the year between the publication date of this final rule and the compliance date.

a. Television

We use a Monte Carlo simulation to model the number of potentially affected television advertisements (advertisements that will need to be revised if noncompliant). The basic assumptions are as follows. See Appendix A for a detailed description of the simulation.

- We expect 596 new television advertisements for human prescription drugs to be disseminated each year, as stated above.
- The lifespan (how long advertisements will remain in use after first dissemination) of DTC television advertisements is as described by the GAO (2002). Based on the GAO distribution, the maximum lifespan of DTC television advertisements is 28 months, or 840 days based on a 30-day month.
- Lacking detailed information about the distribution of production time for advertisements, we assume production time from development of the storyboard to initial dissemination is uniformly distributed in whole-month increments between 6 and 12 months, and that prior production activities are not meaningfully affected by this final rule. While initial development of the concept for an advertisement may begin further in advance, only starting with the storyboard phase would decisions be made that might require subsequent revision to satisfy the requirements of this final rule.

Based on this, we estimate that a total of 179 to 226 television advertisements are potentially affected during the transition period, corresponding to the 90 percent confidence interval from the Monte Carlo simulation. We believe one year should provide sufficient time to revise noncompliant advertisements and replace them with compliant versions so they can be disseminated (or continue to be disseminated) as scheduled without interruption.

In the absence of this final rule, television advertisements are not required to present the major statement in the manner set forth in its dual modality provision, so we assume that all will require addition or modification of text. As described above, we also estimate based on recent

Agency experience that between 10 to 33 percent of television advertisements would fail to fully comply with one or more of the standards pertaining to the non-textual aspects of the major statement.

For the proposed rule and its alternatives, we estimated that modifications to television advertisements would cost on average $100,000 to $150,000 per advertisement but did not separately estimate the cost of adding or revising text to satisfy dual modality and the cost of making changes to non-textual aspects of the major statement. The Agency requested detailed comment on the estimates of the costs of compliance. One comment stated that the estimates were optimistically low, but the comment did not provide any alternative cost estimates. With no new information provided, we rely on the underlying information we gathered for the proposed rule based on discussions with industry sources. However, we update our use of that information and evaluate the cost of revising a television advertisement's text to satisfy dual modality and standard #4 separately from the cost of making additional revisions to meet any of the other standards pertaining to non-textual aspects of the major statement. We estimate that adding or revising text would cost $80,000 to $150,000 in 2008 dollars, where the lower end of the range would apply when it is only necessary to add and move text, and the upper end of the range would apply when it is necessary to change some background visuals. In 2020 dollars, this ranges from $96,429 to $180,805.[7] We estimate that additional revisions to meet any of the other standards pertaining to non-textual aspects of the major statement would cost $150,000 to $200,000 in 2008 dollars. In 2020 dollars, this ranges from $180,805 to $241,073. With these estimates, we assume that reshooting will not typically be necessary to achieve compliance with this final rule.

We combine all the information discussed above to estimate the total (direct) cost for revising television advertisements, as shown in Table 6.

Table 6: Total Cost for Revising Television Advertisements

	Low	High
Number of ads potentially affected	179	226
Proportion needing revision of text	100%	100%
Number needing revision of text	179	226

[7] Throughout this analysis we use the Implicit Price Deflator for Gross Domestic Product to adjust for inflation.

Cost per ad of revising text	$96,429	$180,805
Total cost of revision of text	$17,260,851	$40,861,931
Proportion needing revision to satisfy the other CCN criteria	10%	33%
Number needing revision to satisfy other CCN criteria	18	75
Cost per ad of revising to satisfy other CCN criteria	$180,805	$241,073
Total cost of revisions to satisfy other CCN criteria	$3,254,490	$18,080,501
Total costs for revising television ads	$20,515,341	$58,942,432

b. Radio

We model the number of radio advertisements potentially affected by this final rule in a similar manner to the number of television advertisements. We expect 47 new radio advertisements to be disseminated each year. We lack information to modify the advertisement lifespan distribution and production duration distribution for radio, so we continue to use the same assumptions we use for television. Based on this, we estimate using a Monte Carlo simulation that a total of 10 to 23 radio advertisements are potentially affected during the transition period. (See Appendix B for additional detail.) We believe one year should provide sufficient time to revise noncompliant advertisements and replace them with compliant versions so they can be disseminated (or continue to be disseminated) as scheduled without interruption.

As described above, we estimate that under the status quo, only about 10 to 33 percent of radio advertisements fail to meet the CCN standards in this final rule. Therefore, we estimate that about 1 to 8 of the 10 to 23 potentially affected radio advertisements will need to be revised during the transition period for this final rule.

For the proposed rule, we relied on information from industry sources that indicated these revisions would cost on average $10,000 to $20,000 per radio advertisement. Updating from 2008 dollars to 2020 dollars, we estimate that these revisions would now cost $12,054 to $24,107 per radio advertisement.

We combine all this information to estimate the total (direct) cost for revising radio advertisements, as shown in Table 7.

Table 7: Total Cost for Revising Radio Advertisements

	Low	High
Number of ads potentially affected	10	23
Proportion needing revision to satisfy CCN criteria	10%	33%
Number needing revision to satisfy CCN criteria	1	8
Cost per ad of revising to satisfy CCN criteria	$12,054	$24,107
Total cost of revisions to satisfy CCN criteria	$12,054	$192,859

5. Ongoing Cost to Produce Advertisements that Meet the Standards of this Final Rule

As with the proposed rule, FDA believes that this final rule will not increase the length of DTC TV/radio ads. The Agency has provided flexibility for sponsors to determine how to meet the objective of the dual modality requirement. Dual modality may be met without increasing the length of the TV ads using techniques such as displaying on screen the verbatim key terms or phrases from the corresponding audio; a verbatim complete transcript is not required. Furthermore, we do not expect sponsors to have to slow down the audio portion of the major statement to satisfy the CCN criteria. Therefore, we assume that firms will generally continue to produce new DTC TV/radio ads using time slots of the same duration that they currently purchase. However, if sponsors choose to slow down the presentation of the major statement, they could incur an additional cost, which we do not quantify here. This cost could manifest as an increase in advertising expenditures if the sponsor chooses to increase ad duration.[8]

If the sponsor chooses to slow down the presentation of the major statement, but does not choose to change ad duration, an opportunity cost could arise from the relative allocation of time within the ad between the presentation of the major statement and the presentation of other content. Sullivan et al. (2019) estimate that, for their examined sample, the major statement averages 33 seconds, out of total television advertisement length of 70.2 seconds, with reading speed differing between the major statement (3.17 words per minute) and the preceding ad content (2.86 words per minute). If, for purposes of an illustrative estimate, we consider a scenario where a firm chooses to bring their television ad into compliance with the CCN final rule by slowing the speed of the major statement to match the preceding content's speed, then the

[8] The average cost for a 30-second spot on network prime time television was nearly $110,000 in 2011 (Crupi, 2012). Ad Age reports prices for 30-second advertisements shown during specific prime time shows in 2018 that vary widely between shows but are broadly consistent with this level (Poggi, 2018).

104.6 words of a major statement (=3.17 x 33) would require 36.6 seconds (=104.6/2.86), or a 3.6-second increase relative to the prevailing average. As noted elsewhere in this regulatory impact analysis, annual TV ad spending is approximately $4.58 billion, representing both audio and visual value (50% each, in the absence of a better estimate[9]). As previously stated, between 10% and 33% of TV ads require revisions in order to satisfy one or more of the standards pertaining to the non-textual elements of the major statement, which include a standard for pacing of the audio. The resulting illustrative estimate of the opportunity cost if firms choose to shift audio content for 3.6 seconds of advertisements that average 70.2 seconds would be between $11.7 million (= 10%*50%*$4.58 billion*3.6 / 70.2) and $38.7 million (=33%*50%*$4.58 billion*3.6/70.2).

The requirement to present the major statement in a CCN manner is already in effect in accordance with FD&C Act section 502(n) as amended. The final standards for determining whether the major statement is presented in a CCN manner will provide direction that should reduce regulatory uncertainty in developing major statements. Although the standards for presenting the major statement in a CCN manner might constrain some design choices, the creation of compliant DTC TV/radio ads would not generally require the use of a significantly greater quantity of productive resources. Advertising agencies take great pains to create promotional programs that portray product attributes in the most favorable way. Key advertising agencies would be aware of the pertinent rules and would tailor their compositions accordingly. For the most part, advertising messages are crafted to be as persuasive as possible, while complying with applicable regulatory restrictions. In the design stage, advertisement developers consider and evaluate a variety of facts, features, layouts, and formats before making a final decision. While in the short term, some additional draft submissions might occur as industry becomes familiar with the final standards, this incremental effort is assumed to be minimal.

We expect that after the transition period during which some advertisements will need to be revised, future advertisements should cost about the same to produce once firms' standard operating procedures for CCN manner of presenting the major statement are in place. However, industry is likely to build-in additional review to ensure that each advertisement complies with

[9] In addition to the uncertainty introduced by this assumption about the component values of audio and video, we further note a general assumption in this illustrative estimate of linearity of opportunity cost across time units of advertising.

this final rule. We estimate this review of each advertisement would require 3 hours of marketing specialists time at $75 per hour and 2 hours of marketing management time at a cost of $150 per hour.[10] Table 8 shows the incremental ongoing cost for ensuring advertisements meet the standards of this final rule. These costs would be incurred annually after the one-year compliance period for this final rule.

Table 8 Annual Cost for Ensuring Advertisements Meet the Standards of this Final Rule

Marketing specialist time per ad	3
Marketing manager time per ad	2
Marketing specialist cost per ad ($75/hr)	$225
Marketing manager cost per ad ($150/hr)	$300
Total cost per ad ($)	$525
Number of television ads per year	596
Cost for television ads ($)	$312,900
Number of radio ads per year	47
Cost for radio ads ($)	$24,675
Total cost per year ($)	$337,575

6. SUMMARY OF COSTS

Table 9 summarizes the upfront and ongoing costs of this final rule. Table 10 shows the present value and annualized value of costs over a 10-year time horizon at both 7 percent and 3 percent discount rates.

Table 9: Costs of this Final Rule ($ Thousands)

	Year 1 (Low)	Year 1 (Med)	Year 1 (High)	Years 2-10
Read and understand the rule	$75	$94	$112	$0
Revise SOPs	$1,072	$1,730	$2,388	$0
Revise television ads during transition	$20,515	$39,729	$58,942	$0
Revise radio ads during transition	$12	$102	$193	$0
Opportunity Cost Associated with Potential Change in Allocation of Time to the Major Statement	$11,744	$25,249	$38,754	$25,249

[10] Bureau of Labor Statistics, "Occupational Employment Statistics: May 2020 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 – Pharmaceutical and Medical Manufacturing," https://www.bls.gov/oes/current/naics4_325400.htm. Wages are doubled to account for employee benefits and overhead costs.

Ensure ads meet the standards of this final rule	$0	$0	$0	$338
Total costs	$33,418	$66,904	$100,389	$25,586

Note: Medium estimates are calculated as the midpoint of the low and high estimates.

Table 10: Present and Annualized Value of Total Costs Over a 10-Year Time Horizon ($ Millions)

	7% (Low)	7% (Med)	7% (High)	3% (Low)	3% (Med)	3% (High)
Present Value	$104.79	$218.32	$331.85	$123.77	$258.37	$392.97
Annualized Value	$14.92	$31.08	$47.25	$14.51	$30.29	$46.07

Note: Medium estimates are calculated as the midpoint of the low and high estimates.

F. Distributional Effects

The distributional effects of this final rule on underserved populations is uncertain. A number of empirical studies have found that underserved populations are often exposed to disparate levels of DTCA (Duerksen, et al., 2005; Lee and Begley, 2010). Age has also been found to be a factor in DTCA exposure (Ball et al., 2011; Mehta & Purvis, 2003; Yuan, 2008). Specifically, research has shown that older adults watch more television than younger adults, resulting in higher exposure levels to DTC TV ads (Depp et al., 2010).

G. International Effects

The requirements of this final rule apply to all firms that create DTC TV/radio ads for the U.S., including both domestic and foreign firms. As pharmaceutical products are increasingly manufactured outside of the United States by foreign or domestic firms (US Department of Commerce, 2011), some potential effects borne by producers may be borne by foreign producers. Additionally, many domestic producers of pharmaceutical products are subsidiaries of foreign firms. Overall, of all the firms that submitted Form 2253 to FDA in 2022, approximately 51% were either a foreign firm or a subsidiary of a foreign firm.

H. Analysis of Regulatory Alternatives to the Rule

As directed by Section 901(d)(3)(B) of FDAAA, the Agency is establishing standards for determining whether the major statement in DTC TV/ radio ads is presented in a CCN manner. Below we assess three alternatives to this final rule.

1. Exclude the Dual Modality Requirement

In the proposed rule, FDA indicated that it was considering whether the final rule should include a requirement for the major statement in television advertisements to be presented in dual modality, and requested comment on this issue. As reflected above, FDA has chosen to include the dual modality requirement in the final rule. However, we considered as an alternative to this final rule one that excludes the dual modality requirement. The preamble to this final rule and Section II.C.2 of this analysis discuss FDA's reasons for including dual modality and the expected improvements in consumer recall and comprehension it would bring. By excluding the dual modality requirement, we would forgo the expected improvements associated with the dual modality requirement.

Two costs change under this alternative. First, the cost for developing new standard operating procedures is reduced. In our response to comments, we state that we increase our high estimates of the time spent on developing standard operating procedures by 25 percent relative to our estimates from the proposed rule to account for planning and procedure adjustments that might be needed to produce advertisements that comply with the standards, including dual modality, and remain within current advertising time durations. For this alternative, we revert to the proposed high estimates of 20 hours for top executives, 80 hours for marketing managers, and 120 hours for technical writers. In addition, because we estimate that only 10 to 33 percent of current television advertisements fail to meet standards pertaining to the non-textual aspects of the major statement, we estimate on the low end that only 8 of the 79 affected firms (roughly 10 percent) will need to revise their standard operating procedures. On the high end, we continue to estimate that all 79 affected firms will make some revisions to their standard operating procedures.

Second, DTC television advertisements have not generally been required to satisfy the dual modality requirement set forth in the final rule, and consequently, we assume that every television advertisement potentially affected by this final rule during the transition period would require revisions to text. Removing this requirement eliminates a substantial portion of the cost of revising television advertisements, leaving only the cost for revising a subset to satisfy the other CCN standards. (See the subtotals for each type of revision in Table 6 above.) Table 11 presents the estimated costs under this alternative.

Table 11: Costs for Alternative 1 (Thousands)

	Year 1 (Low)	Year 1 (Med)	Year 1 (High)	Years 2-10
Read and understand the rule	$75	$94	$112	$0
Revise SOPs	$109	$1,009	$1,910	$0
Revise television ads during the transition period	$3,254	$10,667	$18,081	$0
Revise radio ads during the transition period	$12	$102	$193	$0
Opportunity Cost Associated with Potential Change in Allocation of Time to the Major Statement	$11,744	$25,249	$38,754	$25,249
Ensure ads meet the standards of this final rule	$0	$0	$0	$338
Total costs	$15,194	$37,122	$59,050	$25,586
Change in total costs from final rule	-$18,224	-$29,782	-$41,339	$13,505

2. 90-DAY EFFECTIVE DATE WITH NO ADDITIONAL COMPLIANCE PERIOD

The proposed rule had a proposed effective date of 90 days with no additional compliance period. Under this proposed approach, 90 days after publication of a final rule, the major statement in any DTC TV/radio ads would have to comply with the standards for presentation in a CCN manner put forth in the final rule. Therefore, this would hasten the potential benefits described above of having standards for determining whether a major statement is presented in a CCN manner. However, a 90-day effective date with no additional compliance period would result in many more advertisement revisions because 90 days is a relatively short time period compared to the range of lifespans for advertisements.

We estimate the cost of this alternative by re-running our simulations of the number of television and radio advertisements potentially requiring revision (if noncompliant) using a 90-day effective date. We estimate that 561 to 641 television and 36 to 59 radio advertisements would potentially be affected. (See Appendix C for a more detailed description.) The proportions of potentially affected advertisements requiring revision do not change. Under this alternative, the ongoing cost of ensuring advertisements released after the transition period meet the standards of this final rule also begins at the 90-day effective date rather than at the end of the first year.

Table 12 summarizes costs under this alternative. We note that these estimates likely understate the true costs of this alternative because we have not incorporated the potential indirect costs associated with revising advertisements, such as costs that arise from making changes to media placement or talent booking decisions made far in advance. We note that such indirect costs are far more likely to arise under this relatively short compliance deadline than with the one-year compliance period provided in this final rule.

Table 12: Costs for Alternative 2 (Thousands)

	Year 1 (Low)	Year 1 (Med)	Year 1 (High)	Years 2-10
Read and understand the rule	$75	$94	$112	$0
Revise SOPs	$1,072	$1,730	$2,388	$0
Revise television ads during the transition period	$64,222	$115,613	$167,004	$0
Revise radio ads during the transition period	$48	$253	$458	$0
Opportunity Cost Associated with Potential Change in Allocation of Time to the Major Statement	$11,744	$25,249	$38,754	$25,249
Ensure ads meet the standards of this final rule	$253	$253	$253	$338
Total costs	$77,414	$143,191	$208,969	$25,586
Change in total costs from final rule	$43,996	$76,288	$108,579	$0

3. 90-Day Effective Date With No Additional Compliance Period -and- Exclude the Dual Modality Requirement

Alternative 3 combines the effects of Alternative 1 and Alternative 2. Specifically, we consider the impact of a 90-day effective date with no additional compliance period while simultaneously excluding the dual modality requirement.

As seen above, removing the dual modality requirement eliminates a substantial portion of the cost of revising television advertisements. Conversely, a 90-day effective date with no additional compliance period would, in isolation, increase costs because it would result in many more advertisement revisions than the effective date of this final rule. The same factors contributing to the potential underestimation of costs discussed in Alternative 2 also apply here.

However, the overall effect on net benefits is ambiguous. As noted above, the 90-day effective date would hasten the potential benefits of having standards for determining whether a major statement is presented in a CCN manner. Excluding the dual modality requirement would forgo the expected improvements associated with adopting the dual modality requirement.

Table 13 summarizes the costs under this alternative. When both Alternative 1 and Alternative 2 are implemented simultaneously the effect is not equal to the sum of their individual effects. This is because excluding the dual modality requirement eliminates a substantial portion of the total costs associated with revising television advertisements.

Table 13: Costs for Alternative 3 (Thousands)

	Year 1 (Low)	Year 1 (Med)	Year 1 (High)	Years 2-10
Read and understand the rule	$75	$94	$112	$0
Revise SOPs	$109	$1,009	$1,910	$0
Revise television ads during the transition period	$10,125	$30,616	$51,108	$0
Revise radio ads during the transition period	$48	$253	$458	$0
Opportunity Cost Associated with Potential Change in Allocation of Time to the Major Statement	$11,744	$25,249	$38,754	$25,249
Ensure ads meet the standards of this final rule	$0	$0	$0	$338
Total costs	$22,100	$57,221	$92,342	$25,586
Change in total costs from final rule	-$11,318	-$9,682	-$8,047	$0

3. Summary of Regulatory Alternatives

Table 14 summarizes the present value of costs for this final rule and its regulatory alternatives at 7 percent and 3 percent discount rates. Alternative 1 would cost between approximately 12 and 16 percent less than the final rule. Alternative 2 would cost between approximately 30 and 39 percent more than the final rule. Alternative 3 would cost between approximately 2 and 10 percent less than the final rule.

Table 14: Summary of Cost of Regulatory Alternatives (Present Values, $ million)

	7%			3%		
	Low	Med	High	Low	Med	High
Alternative 1 – Exclude dual modality requirement	$87.76	$190.49	$293.21	$106.08	$229.46	$352.83
Alternative 2 – 90-day effective date	$145.91	$289.62	$433.33	$166.48	$332.44	$498.39
Alternative 3 – 90-day effective date -AND- Exclude dual modality requirement	$94.22	$209.27	$324.33	$112.78	$248.97	$385.16
Final Rule	$104.79	$218.32	$331.85	$123.77	$258.37	$392.97

III. FINAL SMALL ENTITY ANALYSIS

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated costs of compliance in the first year could exceed one percent of sales revenues for the smallest entities, we find that the final rule will have a significant economic impact on a substantial number of small entities. This analysis, as well as other relevant sections in this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. DESCRIPTION AND NUMBER OF AFFECTED SMALL ENTITIES

The Small Business Administration (SBA) size standards determine the threshold, by industry, for a business to qualify as small for the purposes of this small entity analysis. All domestic and foreign affiliates are considered in establishing whether a business qualifies as small. The current thresholds for both the Pharmaceutical Preparation Manufacturing and Biological Product Manufacturing industries are 1,250 employees. These thresholds have been in effect since February 26, 2016; the previous thresholds were 750 employees for Pharmaceutical Preparation Manufacturing and 500 employees for Biological Product Manufacturing (81 FR 4469).

As described above, we use information submitted to FDA on Form 2253 to determine the number of entities affected by this final rule. To determine how many of the entities are small, we looked up the number of employees in each firm (or the parent firm, when applicable) using

such sources as company web sites and annual reports, Forms 10-K filed with the Securities and Exchange Commission, and Dun & Bradstreet data. We then compare the number of employees to the SBA size standard in effect for that year. (For years 2014 and 2015, we use a size standard of 750 employees.[11]) In so doing, we find that 3 out of 34 firms submitting a Form 2253 in 2017 qualified as small. The number and proportion qualifying as small was considerably higher in 2014, as shown below in Table 15.

Table 15: Entities submitting Form 2253

	2017	2016	2015	2014
Total	34	45	46	50
Small	3	3	5	16
Proportion Small	9%	7%	11%	32%

B. DESCRIPTION OF THE POTENTIAL IMPACTS OF THE RULE ON SMALL ENTITIES

To examine the potential impacts of the rule on small entities, we estimate the cost for the average small firm and compare those costs to average sales within small business size categories.

All small firms affected by this rule will bear upfront costs to read and understand the rule and to revise standard operating procedures, as described above. These costs are estimated based on the average cost per firm, and we assume the average cost per small firm is the same as for all firms.

If the compliance period for this rule is not sufficiently long to encompass the life cycle of their advertisements, small firms submitting television advertisements would bear the cost of adding or revising text and would possibly bear additional costs to meet other CCN manner criteria related to the non-textual aspects of the major statement. Likewise, small firms submitting radio advertisements may bear the cost of making revisions to satisfy CCN manner criteria if the compliance period is not sufficiently long to encompass the life cycle of their advertisements. These costs would be incurred during the transition period in the first year.

To estimate the cost per small firm to revise television and radio advertisements, we use data from Forms 2253 submitted to FDA. For each year from 2014 through 2017, we calculate the

[11] We identified 3 firms in 2014 with employment between 500 to 749 and 0 firms in 2015. Based on reviewing the company websites and looking up specific products in the *Drugs@FDA: FDA Approved Drug Products* database, none of the 3 firms appear to have biologics manufacturing as the primary business activity.

proportion of television and the proportion of radio advertisements submitted by small businesses and multiply these proportions by both the low and high estimates of the total estimated cost of revising advertisements of that type; this generates low and high estimates of the total costs to small businesses. Then we divide by the number of small firms submitting that type of advertisement, which yields a low and high estimate of the cost per small business based on information from that year. We use the minimum low estimate and maximum high estimate over the years 2014 to 2017 to generate our overall range of costs per small entity. Table 16 shows the calculations for television advertisements, and Table 17 shows the calculations for radio.

Table 16: Costs per small entity to revise television advertisements

	2017	2016	2015	2014	Min	Max
Proportion of ads submitted by small businesses	2.17%	1.74%	2.15%	8.14%		
Total cost to small businesses (low)	$444,605	$357,410	$440,243	$1,669,853		
Total cost to small businesses (high)	$1,277,390	$1,026,872	$1,264,859	$4,797,640		
Number of small firms submitting ads	3	2	3	11		
Cost per small business (low)	$148,202	$178,705	$146,748	$151,805	$146,748	$178,705
Cost per small business (high)	$425,797	$513,436	$421,620	$436,149	$421,620	$513,436

Table 17: Costs per small entity to revise radio advertisements

	2017	2016	2015	2014	Min	Max
Proportion of ads submitted by small businesses	0.00%	4.55%	19.05%	18.18%		
Total cost to small businesses (low)	$0	$548	$2,296	$2,192		
Total cost to small businesses (high)	$0	$8,766	$36,735	$35,065		
Number of small firms submitting ads	0	1	3	5		
Cost per small business (low)	Not Applicable	$548	$765	$438	$438	$765

Cost per small business (high)	Not Applicable	$8,766	$12,245	$7,013	$7,013	$12,245

Finally, small firms who continue disseminating advertisements in the future, after the transition period, would spend time reviewing those advertisements to ensure compliance with the standards of this final rule. To estimate the cost for the average small firm, we calculate the proportion of all advertisements (television or radio) submitted by small businesses on Form 2253 for each year from 2014 to 2017. For each year, we multiply this proportion by the total estimated cost for this activity; this generates an estimate of the total cost to small businesses. Finally, we divide by the number of small firms submitting advertisements. We use the minimum estimate over the years 2014 to 2017 as our low estimate and the maximum estimate as our high estimate. Table 18 shows these calculations.

Table 18: Ongoing Cost Per Small Entity to Ensure Future Advertisements Meet the Standards of this Final Rule

	2017	2016	2015	2014	Min	Max
Proportion of *all* ads submitted by small businesses	2.08%	1.94%	3.54%	9.76%		
Total cost to small businesses	$7,012	$6,555	$11,961	$32,934		
Number of small firms submitting ads	3	3	5	16		
Cost per small business	$2,337	$2,185	$2,392	$2,058	$2,058	$2,392

Table 19 summarizes the various cost components, including the opportunity cost associated with a potential change in relative allocation within the ad between the presentation of the major statement and the presentation of other content, and shows the average total cost per small entity.

Table 19: Average Cost Per Small Entity

	Year 1 (Low)	Year 1 (High)	Years 2-10 (Low)	Years 2-10 (High)
Cost to read the rule	$948	$1,422	$0	$0
Cost to revise guidance or SOPs	$13,570	$30,225	$0	$0
Cost to revise television ads	$146,748	$513,436	$0	$0
Cost to revise radio ads	$438	$12,245	$0	$0

Opportunity Cost Associated with Potential Change in Allocation of Time to the Major Statement	$252,008	$3,154,383	$252,008	$3,154,383
Cost to ensure future ads meet the standards of this final rule	$0	$0	$2,058	$2,392
Total	$413,712	$3,711,711	$254,067	$3,156,775

Using 2017 Statistics of US Businesses Data (US Census Bureau, 2017), we estimate the average revenue for biologics and pharmaceutical manufacturing entities within small employment size categories by dividing estimated receipts (sales) by the number of enterprises in the size category.[12] We then inflate these values to 2020 dollars using the GDP deflator, as shown in Table 20. Finally, we calculate the average first-year and subsequent-year cost per small entity as a proportion of sales revenue. This information is summarized in Table 21, which shows that the first-year cost per small entity could be over 24.6 percent of revenues for the smallest entities, those with fewer than 500 employees.

Table 20: Average Sales Per Small Entity

Number of Employees	Estimated Receipts (Millions, 2017 $)	Number of Enterprises (Firms)	Average Sales (Millions, 2017 $)	Average Sales (Millions, 2020 $)
<500	$24,055	1,679	$14	$15
500 to 999	$8,420	47	$179	$189
1,000-4,999	$26,928	73	$369	$389

Table 21: Average Costs Per Small Entity as a Proportion of Average Sales

Number of Employees	Year 1 Cost as a Proportion of Avg. Sales (Low)	Year 1 Cost as a Proportion of Avg. Sales (High)	Years 2-10 Cost as a Proportion of Avg. Sales (Low)	Years 2-10 Cost as a Proportion of Avg. Sales (High)
<500	2.7%	24.6%	1.7%	20.9%
500 to 999	0.2%	2.0%	0.1%	1.7%
1,000-4,999	0.1%	1.0%	0.1%	0.8%

Source: Table 19 and Table 20.

C. Alternatives to Minimize the Burden on Small Entities

[12] These data are provided for the Pharmaceutical and Medicine Manufacturing industry, NAICS 3254, which encompasses 4 categories including both pharmaceutical and biologics manufacturing. More recent data provide revenue at the establishment level but not at the enterprise level, as needed for this analysis.

Regulatory alternative 1, which excludes the dual modality requirement, would reduce the burden on small entities. Table 22 shows the average cost per small entity under this alternative, calculated in a similar manner as described above for calculating the average cost per small entity of the final rule. Table 23 shows the average first-year and subsequent-year cost per small entity as a percentage of sales. Under this alternative, the high estimate of first-year costs per small entity is reduced to approximately 20.8 percent of revenues for the smallest entities, those with fewer than 500 employees.

As discussed above, however, excluding the dual modality requirement would mean forgoing the expected improvements in consumer recall and comprehension that would be associated with the use of dual modality.

Table 22: Average Cost Per Small Entity for Alternative 1, Excluding Dual Modality

	Year 1 (Low)	Year 1 (High)	Years 2-10 (Low)	Years 2-10 (High)
Cost to read the rule	$948	$1,422	$0	$0
Cost to revise guidance or SOPs	$13,570	$24,180	$0	$0
Cost to revise television ads	$23,280	$157,496	$0	$0
Cost to revise radio ads	$438	$12,245	$0	$0
Opportunity Cost Associated with Potential Change in Allocation of Time to the Major Statement	$252,008	$3,154,383	$252,008	$3,154,383
Cost to ensure future ads meet the standards of this final rule	$0	$0	$2,058	$2,392
Total	$290,244	$3,349,725	$254,067	$3,156,775
Change from final rule	-$123,468	-$361,985	$0	$0

Table 21: Average Costs Per Small Entity for Alternative 1, Excluding Dual Modality, as a Proportion of Average Sales

Number of Employees	Year 1 Cost as a Proportion of Avg. Sales (Low)	Year 1 Cost as a Proportion of Avg. Sales (High)	Years 2-10 Cost as a Proportion of Avg. Sales (Low)	Years 2-10 Cost as a Proportion of Avg. Sales (High)
<500	1.8%	20.8%	1.6%	19.6%
500 to 999	0.1%	1.7%	0.1%	1.6%

1,000-4,999	0.1%	0.8%	0.1%	0.8%

Source: Table 20 and Table 22.

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APPENDIX A: MONTE CARLO SIMULATION OF TELEVISION ADVERTISEMENTS POTENTIALLY AFFECTED BY THIS FINAL RULE

The simulation is set up as follows:

- We designate the day of publication of this final rule as day 0 and designate all other days relative to 0. A negative day represents the number of days prior to publication, while a positive day represents the number of days after publication.
- Our simulation covers each day from 480 days prior to publication (day -480) to 360 days after publication (day +360).

- For simplicity, we assume all months consist of 30 days and a year consists of 360 days. We do this in part because our estimate of advertisement lifespan (how long advertisements remain in use after first dissemination) is measured in months.
- An average of 596 new television advertisements are disseminated each year. We assume the daily rate at which television advertisements are initially disseminated is constant and that initial disseminations arrive independently from each other. This enables us to model the daily arrival of initial disseminations using a Poisson distribution with Lambda = (596/360).[13] The Poisson distribution is a discrete probability distribution that returns non-negative integer values; thus, our model allows any non-negative integer number of initial disseminations to occur on a given day (0, 1, 2, …), but the average will be 596 initial disseminations over the course of a year.
- The lifespan (how long advertisements will remain in use after first dissemination) of DTC television advertisements is as described by the GAO (2002) and shown in Table Appendix Table 1.[14] Based on the GAO distribution, the maximum lifespan of DTC television advertisements is 28 months, or 840 days assuming 30-day months.
- Lacking detailed information about the distribution of production time for advertisements, we assume production time from development of the storyboard to initial dissemination is distributed uniformly between 6 and 12 months and that prior production activities are not meaningfully affected by this final rule. (While initial development of the concept for an advertisement may begin further in advance, only starting with the storyboard phase would decisions be made that might require subsequent revision to satisfy the requirements of this final rule.)

Table Appendix Table 1: Lifespan of DTC Television Advertisements

Months in use	Percentage
1	22%
2	10%
3-6	30%

[13] Lambda is the mean number of events per interval, in this case the mean number of television advertisements initially disseminated per day.

[14] Within bins that encompass several months, we assume an even distribution among months. For example, since 30 percent of advertisements remain in use for 3 to 6 months, we assume that 7.5 percent of all advertisements remain in use for 3 months, 7.5 percent for 4 months, 7.5 percent for 5 months, and 7.5 percent for 6 months.

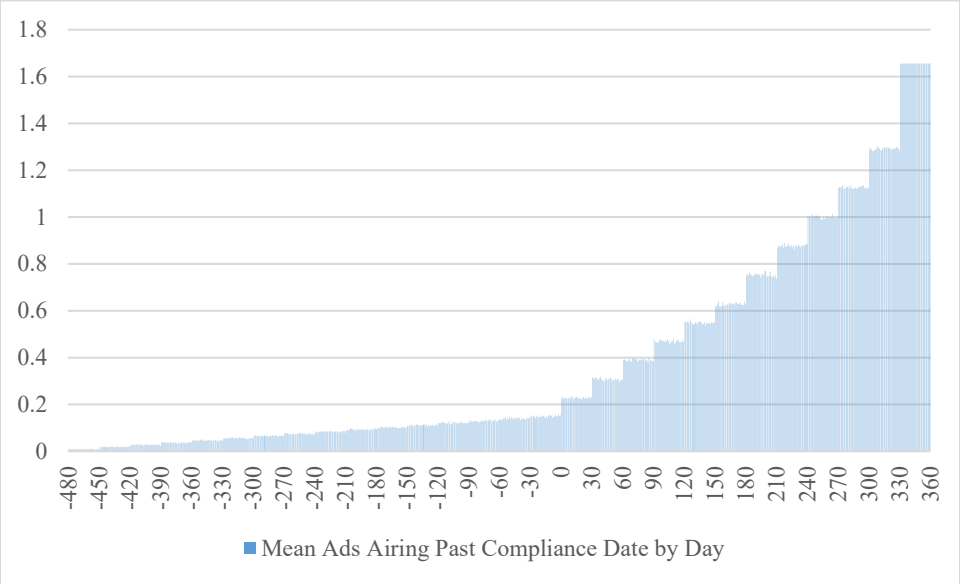
7-12	29%
13-28	9%

Source: GAO (2002)

Our simulation consists of the following steps. We run 5,000 iterations and calculate the total number of potentially affected advertisements at the 5th percentile and 95th percentile to generate low and high estimates corresponding to a 90 percent confidence interval.

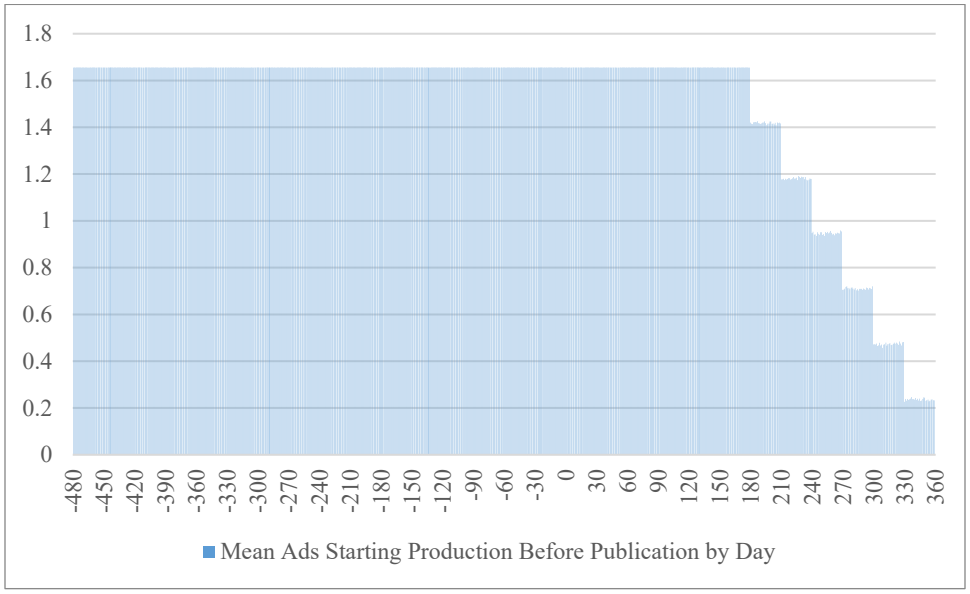
1. We first simulate the number of advertisements initially disseminated each day from day -480 to day 360. This is achieved by making a separate draw from the Poisson distribution described above, designated in @Risk as *RiskPoisson(596/360)*, for each day from -480 through 360.
2. For each day, for *i=1,2,3,…10* we check whether the *ith* potential advertisement exists by evaluating whether the expression *i<=NumberofAds* is true, where *NumberofAds* is the number of advertisements initially disseminated that day based on Step 1. (Ten is a sufficient number to evaluate because in no iteration did the number of advertisements initially disseminated on any given day ever exceed 10.)
3. For each day, for each newly disseminated advertisement that exists, we simulate whether the advertisement will continue in use beyond the compliance date by drawing its lifespan in months from the GAO lifespan distribution and evaluating whether the expression *Day+Lifespan*30>360* is true. (*Day* is the day number and *Lifespan* is the lifespan of the advertisement in months.) Figure 1 shows the mean number of new television advertisements being disseminated past the compliance date by day, across all iterations.

Appendix Figure 1: Mean Number of New Television Advertisements being Disseminated Past the Compliance Date, by Day



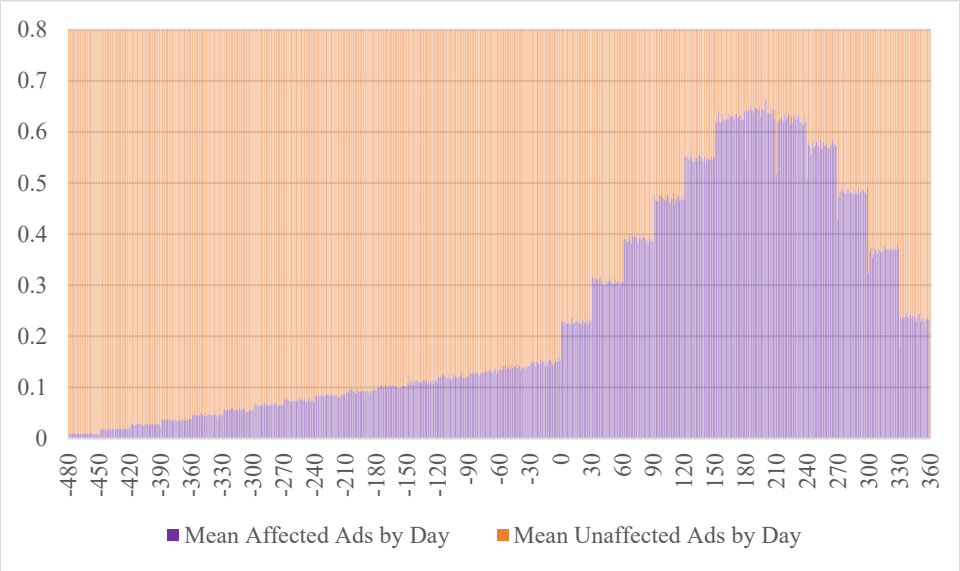
4. For each day, for each newly disseminated advertisement that exists, we simulate whether the advertisement began significant production prior to the publication date by drawing its production duration from the uniform distribution of whole-month increments between 6 and 12 months (*RiskIntUniform(6,12)* in *@Risk*) and evaluating whether the expression *ProductionDuration*30>Day* is true. (*ProductionDuration* is the advertisement's production duration and *Day* is the day number.) Appendix Figure 2 shows the mean number of new television advertisements starting significant production before publication by day, across all iterations.

Appendix Figure 2: Mean Number of New Television Advertisements Starting Production Before Publication, by Day



5. We determine whether an advertisement is potentially affected by this final rule by evaluating whether it exists based on Step 2, it would continue to remain in use beyond the compliance date based on Step 3, and it would have begun significant production prior to the publication date based on Step 4. (All three conditions must hold.) Appendix Figure 3 shows the mean number of potentially affected and unaffected television advertisements initially disseminated by day, across all iterations.

Appendix Figure 3: Mean Number of Affected and Unaffected Television Advertisements Initially Disseminated by Day



6. Finally, we sum the number of potentially affected advertisements across all days.

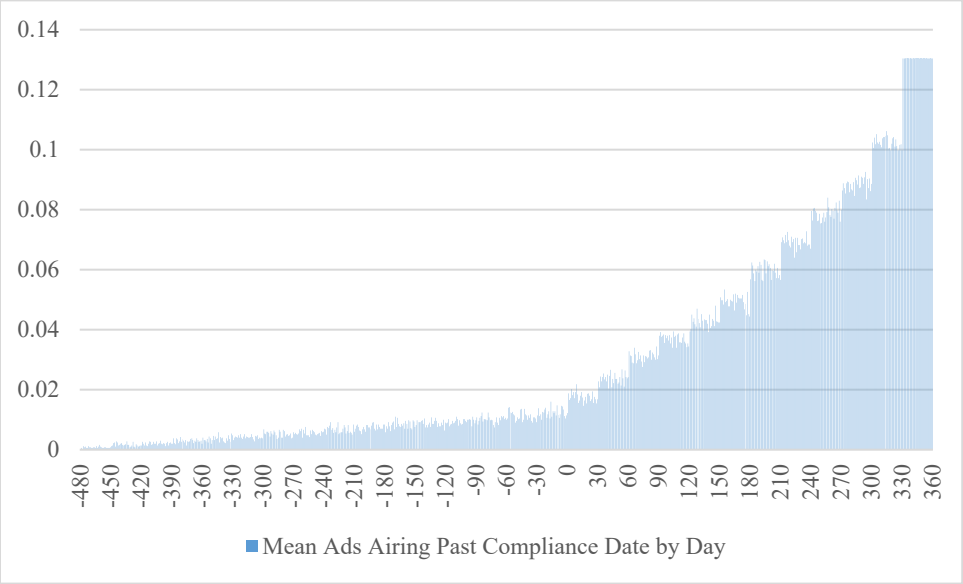
Based on this, we estimate that a total of 179 to 226 television advertisements are potentially affected during the transition period. This encompasses advertisements initially disseminated before the publication date as well as advertisements initially disseminated after the publication date but before the compliance date. Because we do not believe that the relevant production time for a television advertisement, from development of the storyboard to initial dissemination, would regularly exceed one year, we do not estimate that any advertisements released after the compliance date would require revision.

APPENDIX B: MONTE CARLO SIMULATION OF RADIO ADVERTISEMENTS POTENTIALLY AFFECTED BY THIS FINAL RULE

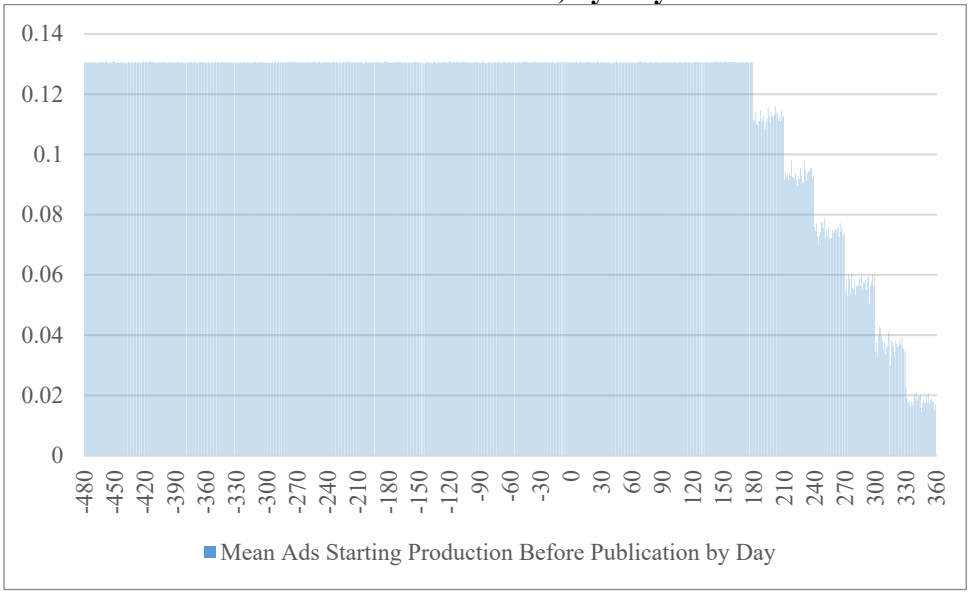
We model the number of radio advertisements potentially affected by this final rule in a similar manner to the number of television advertisements. An average of 47 new radio advertisements are disseminated each year. Therefore, we modify the Poisson distribution for daily arrival to Lamba = (47/360). This means that any non-negative integer number of initial advertisement disseminations can occur on a given day (0, 1, 2, …), but the average will be 47 initial disseminations over the course of a year. The rest of the simulation setup and procedures are identical. (We lack information to modify the advertisement lifespan distribution and production duration distribution for radio, so we continue to use the same distributions as for television.)

Averaging across all iterations, Appendix Figure 4 shows the mean number of new radio advertisements being disseminated past the compliance date by day, Appendix Figure 5 shows the mean number of new advertisements starting production before publication by day, and Appendix Figure 6 shows the mean number of affected and unaffected radio advertisements initially disseminated by day. The patterns are the same as for television, but the number of ads is lower. Summing across all days, we estimate that 10 to 23 radio advertisements will potentially be affected during the transition period, corresponding to the 5th and 95th percentiles in our simulation.

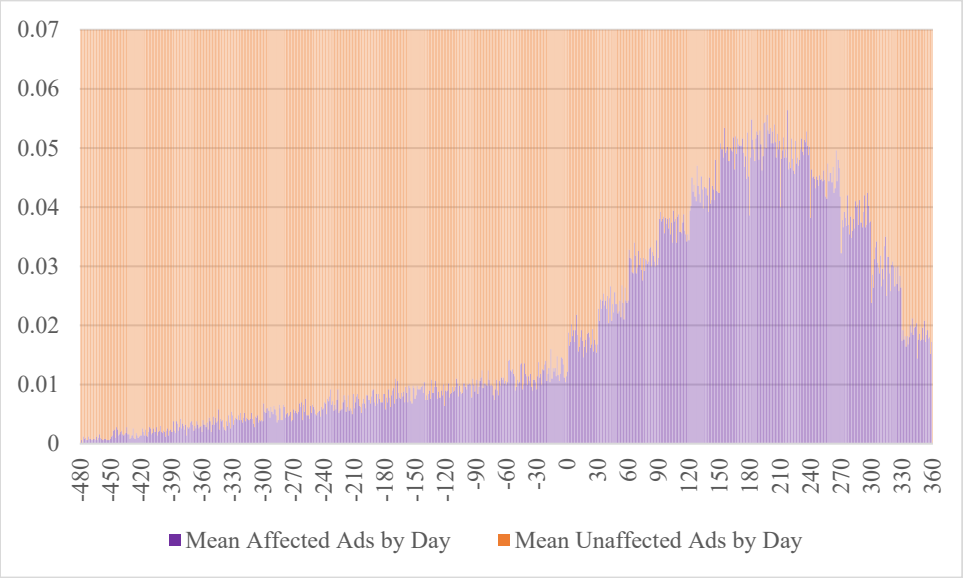
Appendix Figure 4: Mean Number of New Radio Advertisements Disseminated Past the Compliance Date, by Day



Appendix Figure 5: Mean Number of New Radio Advertisements Starting Production Before Publication, by Day



Appendix Figure 6: Mean Number of Affected and Unaffected Radio Advertisements Initially Disseminated by Day


0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
-480
-450
-420
-390
-360
-330
-300
-270
-240
-210
-180
-150
-120
-90
-60
-30
0
30
60
90
120
150
180
210
240
270
300
330
360
Mean Affected Ads by Day
Mean Unaffected Ads by Day

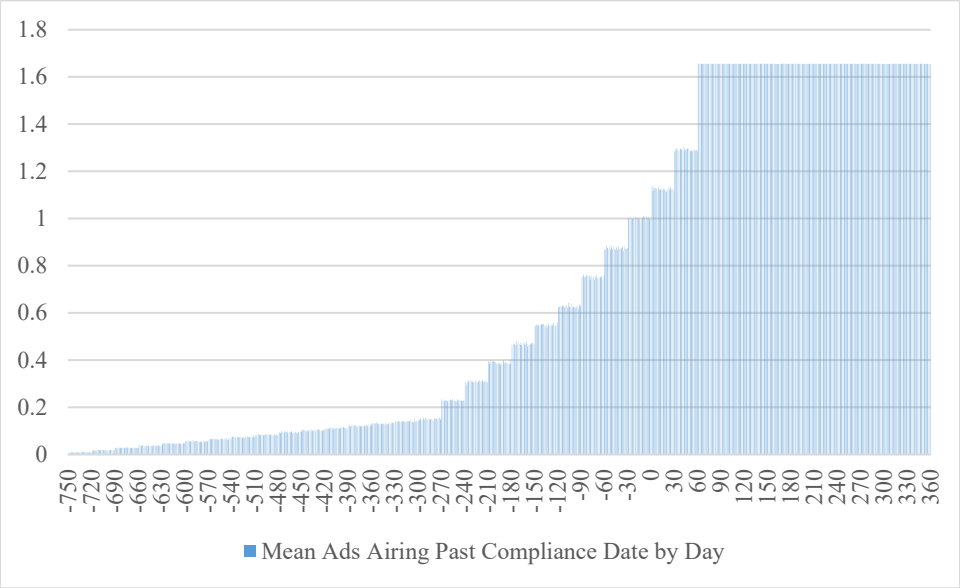
APPENDIX C: MONTE CARLO SIMULATION OF TELEVISION AND RADIO ADVERTISEMENTS POTENTIALLY AFFECTED WITH A 90-DAY EFFECTIVE DATE AND NO ADDITIONAL COMPLIANCE PERIOD

For a 90-day effective date with no additional compliance period, we modify the simulation as follows:

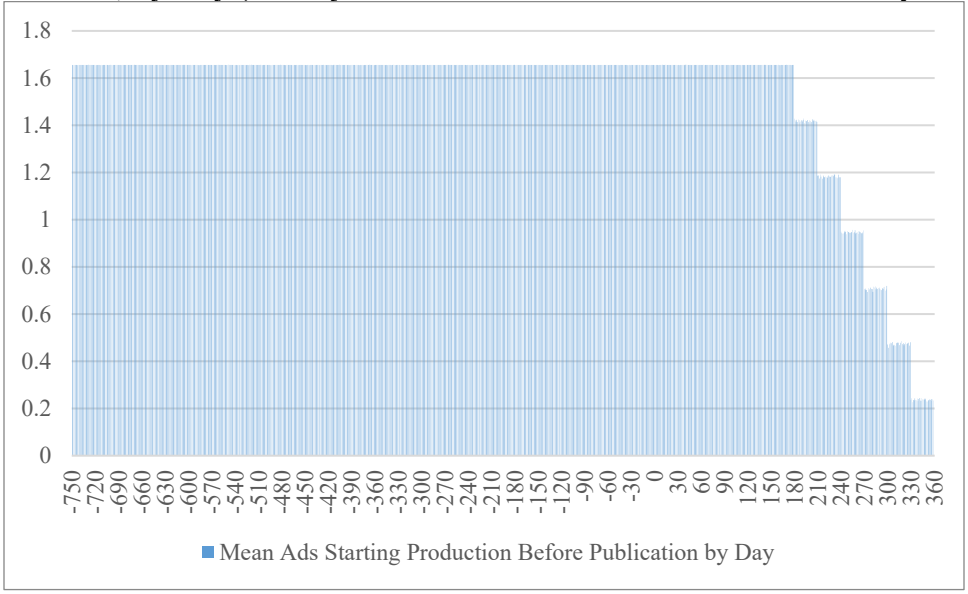
- The simulation covers each day from 750 days prior to publication of this final rule (day -750) to 360 days after publication (day +360). This modification is necessary because day -750 is the first day an advertisement could initially be disseminated and possibly still be in use on the compliance date (-750 days + 28 months * 30 days = 90).
- For each day, for each newly disseminated advertisement that exists, we simulate whether the advertisement will continue to be used beyond the effective date by drawing its lifespan in months from the GAO lifespan distribution and evaluating whether the expression *Day+Lifespan*30>90* is true. (*Day* is the day number and *Lifespan* is the lifespan of the advertisement in months.)

Everything else follows the television and radio simulations for a 360-day compliance period. Appendix Figure 7 shows the mean number of new television advertisements disseminated past the compliance date by day, Appendix Figure 8 shows the mean number of new television advertisements starting production before publication by day, and Appendix Figure 9 shows the mean number of affected and unaffected television advertisements initially disseminated by day. Note that with a 90-day effective date and no additional compliance period, there is a period of time over which every new advertisement would need to be revised (if noncompliant). Summing across all days, we estimate that 561 to 641 television advertisements will potentially be affected during the transition period, corresponding to the 5th and 95th percentiles in our simulation.

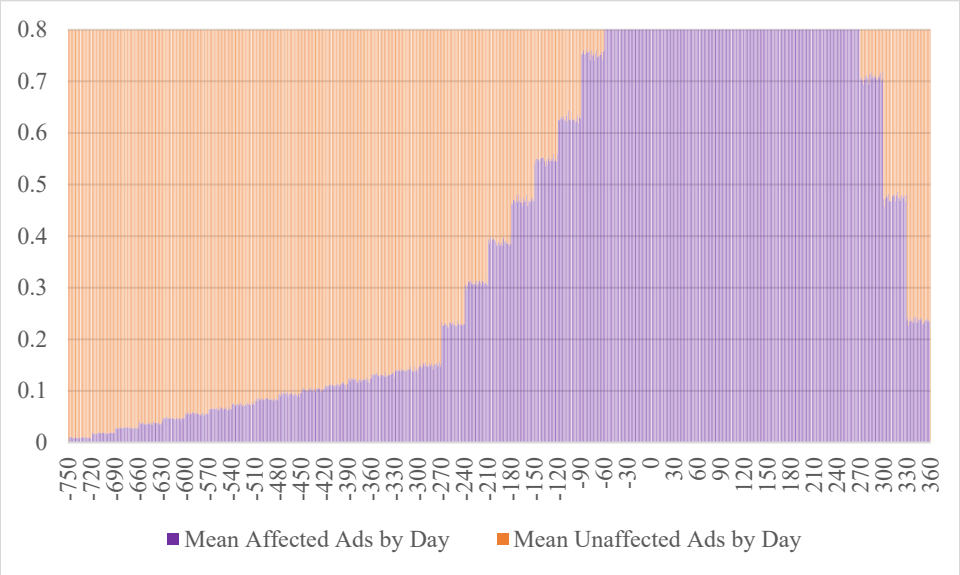
Appendix Figure 7: Mean Number of New Television Advertisements Disseminated Past the Compliance Date, by Day (90-Day Effective Date With No Additional Compliance Period)



Appendix Figure 8: Mean Number of New Television Advertisements Starting Production Before Publication, by Day (90-Day Effective Date With No Additional Compliance Period)

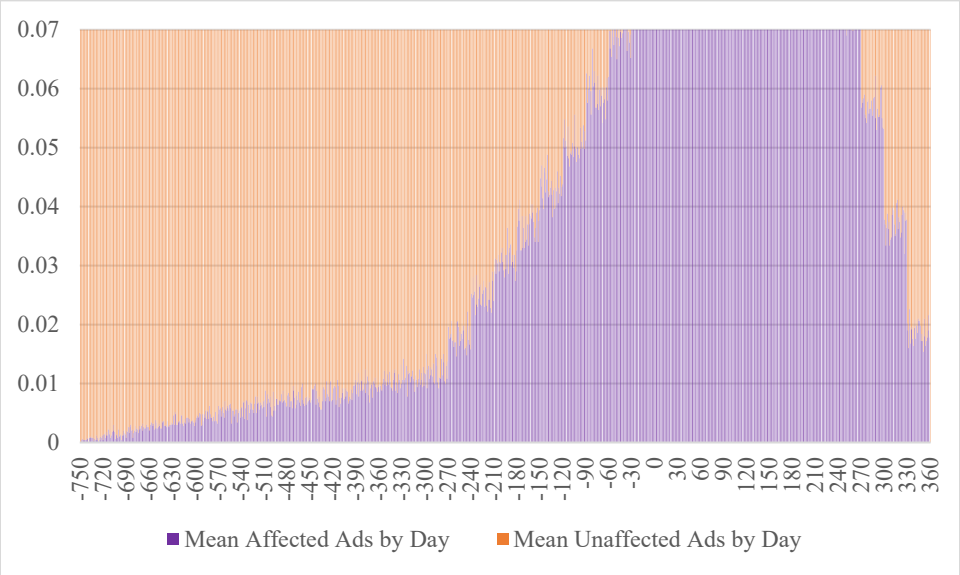


Appendix Figure 9: Mean Number of Affected and Unaffected Television Advertisements Initially Disseminated by Day (90-Day Effective Date With No Additional Compliance Period)



The pattern for radio is the same as for television, but the number of advertisements is lower. Appendix Figure 10 shows the mean number of affected and unaffected television advertisements initially disseminated by day. Again, with a 90-day effective date and no additional compliance period, there is a period of time over which every new advertisement would need to be revised (if noncompliant). Summing across all days, we estimate that 36 to 59 radio advertisements will potentially be affected during the transition period, corresponding to the 5th and 95th percentiles in our simulation.

Appendix Figure 10: Mean Number of Affected and Unaffected Radio Advertisements Initially Disseminated by Day (90-Day Effective Date With No Additional Compliance Period)


0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
-750
-720
-690
-660
-630
-600
-570
-540
-510
-480
-450
-420
-390
-360
-330
-300
-270
-240
-210
-180
-150
-120
-90
-60
-30
0
30
60
90
120
150
180
210
240
270
300
330
360
Mean Affected Ads by Day
Mean Unaffected Ads by Day