



1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • [www.citizen.org](http://www.citizen.org)

October 27, 2020

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Comments on Knowledge Ecology International’s August 3, 2020, Citizen Petition Requesting the Food and Drug Administration to Issue a Rule Banning the Use of Background Music During the Presentation of the Risks in Direct-to-Consumer Drug Advertising; Docket No. FDA-2020-P-1725**

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, strongly endorses Knowledge Ecology International’s (KEI’s) August 3, 2020, citizen petition requesting that the Food and Drug Administration (FDA) amend 21 C.F.R. § 202.1 (Prescription-drug advertisements) to include a provision that bans background music from the presentation of the risks section of direct-to-consumer (DTC) broadcast prescription drug advertising (docket no. FDA-2020-P-1725).<sup>1</sup>

In addition, we urge the FDA to go further by promptly issuing a long-overdue final rule — mandated by the Food and Drug Administration Amendments Act of 2007 (FDAAA) — amending the regulations governing DTC advertisements for prescription drugs (21 C.F.R. § 202.1) to require that the disclosure of risk information in the major statement of DTC broadcast ads be clear, conspicuous, and neutral. In addition to including a provision that bans background music from the presentation of the risks section of DTC broadcast prescription drug advertising, as requested by KEI, the amended regulations should include the following elements:

- (1) Maintain current FDA requirements regarding which risks must be disclosed in DTC broadcast prescription drug ads. In particular, the FDA should continue to require “a brief summary of all necessary information related to side effects and contraindications,” which may include certain important nonsevere, nonserious, and non-actionable risks, while also requiring that severe, serious, or actionable risks be disclosed more prominently.

---

<sup>1</sup> Knowledge Ecology International. Citizen petition requesting the Food and Drug Administration (FDA) to issue a rule banning the use of background music during the presentation of the risks in direct to consumer drug advertising. August 3, 2020. <https://beta.regulations.gov/document/FDA-2020-P-1725-0001>. Accessed October 27, 2020.

- (2) Require all risk information in DTC broadcast prescription drug ads to be presented simultaneously in both audio and visual formats.
- (3) Ban the use of distracting imagery and sounds — both musical and nonmusical — during the disclosure of risk information in DTC broadcast prescription drug ads.
- (4) Regarding the disclosure of “serious” risks in DTC broadcast prescription drug ads, the amended rule should clarify that the scope of “serious risks” extends beyond those adverse drug reactions that may result in inpatient hospitalization or prolonged existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect.

Below is a more detailed explanation of our comments.

#### **A. Existing FDA regulations for DTC prescription drug advertisements**

Section 502(n) of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §352(n)) requires that sponsors who advertise prescription human drugs, including biological products, disclose in advertisements certain information about the advertised product’s uses and risks. For prescription drugs and biologics, section 502(n) 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 the FDA.

Current FDA regulations regarding prescription-drug advertisements include the following provision at 21 C.F.R. § 202.1(e):

(e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(1) *When required.* All advertisements for any prescription drug... shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section “side effects, contraindications” include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness.

**Advertisements broadcast through media such as radio, television, or telephone communications systems** shall include information relating to the major side effects and contraindications of the advertised drugs **in the audio or audio and visual parts of the presentation** and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation **shall contain a brief summary of all necessary information related to side effects and contraindications.** [Bolded emphasis added; italics in original]

The above disclosure required for DTC broadcast ads is known as the “major statement.”

## B. 2007 FDAAA required final improved FDA regulations for DTC broadcast prescription drug ads by 2010

Section 901(d)(3)(A) of FDAAA (Public Law 110-85), which was enacted on September 27, 2007,<sup>2</sup> amended section 502(n) of the FDCA to require that the major statement relating to side effects and contraindications in DTC broadcast ads for prescription drugs be presented in a “**clear, conspicuous, and neutral manner**” [emphasis added]. Section 901(d)(3)(A) of FDAAA required that the FDA promulgate regulations implementing the requirements of Section 901(d)(3)(A) of FDAAA within 30 months.

On March 29, 2010, the FDA issued a notice of proposed rulemaking (NPRM) (docket No. FDA-2009-N-0582; RIN 0910-AG27) that would have implemented the requirements of Section 901(d)(3)(A) of FDAAA.<sup>3</sup> The NPRM proposed that 21 C.F.R. § 202.1(e) be revised to read as follows:

(e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(1) *When required.* All advertisements for any prescription drug... must present a true **statement of information in brief summary relating to side effects, contraindications... and effectiveness.**

(i) *Broadcast advertisements.* Advertisements broadcast through media such as radio, television, or telephone communications systems must include information relating to the **major side effects and contraindications (“major statement”)** of the advertised drugs in the audio or audio and visual parts of the presentation and, unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation, **must contain a brief summary of all necessary information related to side effects and contraindications.**

(ii) *Clear, conspicuous, and neutral manner.* Advertisements for prescription drugs intended for use by humans presented directly to consumers in television or radio format must present the major statement in a clear, conspicuous, and neutral manner. A major statement is clear, conspicuous, and neutral if:

(A) Information is presented in language that is readily understandable by consumers;

(B) Audio information is understandable in terms of the volume, articulation, and pacing used;

(C) Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and

(D) **The advertisement does not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.**

[Bolded emphasis added; italics in original]

---

<sup>2</sup> Food and Drug Administration. Food and Drug Administration Amendments Act (FDAAA) of 2007. <https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstotheftdcact/foodanddrugadministrationamendmentsactof2007/default.htm>. October 27, 2020.

<sup>3</sup> 75 FR 15376.

In the preamble of the March 29, 2010, NPRM, the FDA discussed the standards of other federal agencies for “clear and conspicuous” disclosures and highlighted the Federal Trade Commission’s (FTC’s) standards. In particular, the FDA noted a 1970 FTC enforcement statement that set forth the following standards, among others, for determining whether an affirmative disclosure in a television advertisement is “clear and conspicuous”:

- (1) The disclosure should be presented simultaneously in both the audio and video portions of the television commercial (dual modality);
- (2) The video portion of the disclosure should contain letters of a color or shade that readily contrast with the background, and the background should consist of only one color or shade; and
- (3) No other sounds, including music, should occur during the audio portion of the disclosure.

In the preamble of its 2010 NPRM, the FDA also stated that the agency believed that “presenting the major statement in both the audio and visual portions of television ads could enhance the clarity, conspicuousness, and neutrality of this information.” Although the proposed rule did not include such a standard, the FDA asked the public to comment on whether the final rule should include it.

The comment period for the NPRM originally closed on June 28, 2010. In Public Citizen’s June 28, 2010, comments on the proposed rule (copy enclosed), we strongly endorsed a requirement that the major statement in DTC broadcast ads be presented in both audio and visual formats.

On January 27, 2012, the FDA reopened Docket No. FDA-2009-N-0582 to allow comments on a study added to the docket entitled “Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television Advertisements” (Distraction Study).<sup>4</sup> This study, dated May 2011, was “designed to investigate some advertising factors that could influence consumers’ understanding of a drug’s risks.” Public Citizen submitted comments dated February 27, 2012 (copy enclosed), in which we noted our belief that although there is strong support in the Distraction Study and elsewhere for the use of superimposed text accompanying the audio presentation of risks in DTC prescription-drug ads on television, the study was so flawed that any conclusions or lack thereof as to the other variables studied would be of negligible value in fashioning a regulation that would adequately protect consumers.

Disturbingly, now more than 13 years after the passage of the FDAAA, the FDA has failed to finalize the rule that was mandated by Congress in 2007 and proposed by the agency in 2010.

### **C. Long-standing concerns about allowing DTC ads**

Public Citizen does not support any DTC advertising of pharmaceutical products on broadcast media. The United States is one of only two countries in the world that permit it (the other being

---

<sup>4</sup> 77 FR 4273

New Zealand), and Public Citizen believes that DTC broadcast ads for prescription drugs have not advanced and may actually harm public health in both countries.<sup>5</sup>

We reiterate here our serious concerns about DTC broadcast ads, primarily because they often supplant the knowledge and judgment of the physician in determining whether a particular drug is most suitable for a particular patient. Although a physician must actually prescribe an advertised prescription drug product, there is ample support for the idea that patient pressure increases the likelihood that a physician will prescribe a particular product, even if another product or even non-pharmacologic treatment might have a superior result. This, coupled with the effect of aggressive marketing targeting physicians, practically ensures that prescriptions will be written without adequate attention to important information relating to risk or alternative treatment options. DTC advertising may thus supplant the knowledge and judgment of the physician in determining whether a patient will ultimately use the drug in question.

Acknowledging that DTC broadcast ads will continue in the U.S. for the foreseeable future, we encourage the FDA to implement much stronger requirements for companies to assure that, after viewing such commercials, consumers understand the drugs' risks, benefits, and comparability to other pharmaceutical and non-pharmaceutical interventions.

#### **D. FDA-commissioned study failed to determine the optimal format and content for disclosure of important risk information**

In 2014, the FDA announced that it had commissioned a study to evaluate the effectiveness of disclosing serious, actionable, and other risks versus disclosing only serious and actionable risks in DTC ads.<sup>6</sup> The intended purpose of the study, the results of which were published online by Betts et al in 2017,<sup>7</sup> was to examine the impact of a more limited risk statement on the comprehension and recall of risks disclosed in standard pharmaceutical DTC television ads. The study's methodology, however, had several flaws that call into question the validity and relevance of the results to patients who view DTC broadcast ads. In addition, the study results with regard to the primary outcome are not meaningful when viewed from the perspective of absolute, rather than relative, differences between study arms, and other results strikingly demonstrate that, regardless of how much risk information is presented in the major statement, recall of key risks in general is very poor.

##### **1. Fundamental flaws of study methodology**

The Betts et al study was designed primarily to determine the extent to which patients with self-reported depression, insomnia, or high cholesterol remembered and recognized the most important risks disclosed in the major statements in actual DTC television ads. The study compared two different types of major statements disclosing risk information:

---

<sup>5</sup> Lurie P. DTC advertising harms patients and should be tightly regulated. *J Law Med Ethics*. 2009;37(3):444-450.

<sup>6</sup> 79 FR 9217.

<sup>7</sup> Betts KR, Boudewyns V, Aikin KJ, et al. Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. *Res Social Adm Pharm*. 2018;14(10):951-963.

- (1) Major statements disclosing all major risks associated with a particular drug as presented in the original ads (unedited-risk-statement ads); and
- (2) Major statements disclosing only the “serious and actionable” risks (abbreviated revised-risk-statement ads).

To be able to meaningfully compare these two types of major statements, the presentation of these two different major statements should have been identical, with the only variable consisting of the presence or absence of the risks that were not serious and actionable. However, this study was not designed in this way. Instead, the presentation of the serious and actionable risks differed in other substantial ways between the two study arms, as explained by the study’s authors:<sup>8</sup>

The revised statements began by alerting consumers that the drug can cause “serious reactions” or, in the case of the depression ad, “severe, life-threatening reactions,” whereas the first sentence of the unedited risk statement noted that this drug is not appropriate for some people (e.g., “Crestor is not right for everyone”).

Thus, the abbreviated revised-risk-statement ads presented the serious and actionable risks with more severe-sounding introductory language than the unedited-risk-statement ads that opened the risk disclosure portion of the ad with a more banal statement that the drug might not be appropriate for all patients. The more severe-sounding introductory language in the revised-risk-statement ads may have contributed to heightened attention to, and recall and recognition of, the serious and actionable risks (as seen in the depression, insomnia, and high-cholesterol groups) and an increased tendency to perceive such risks as severe (as seen in the depression group) among the subjects in the revised-risk-statement arms.

The Betts et al study also was not designed to sufficiently answer the key question of what would be the ideal format for the risk-information disclosure in DTC ads to maximize recall, retention, and comprehension of risk information. All arms in the study provided only audio disclosure of information about specific risks. This is ironic because in order to maximize the chances that the subjects of the study would pay attention to a brief introductory statement about the fact that not all risks were being disclosed (for those subjects assigned to groups exposed to ads with this statement) that preceded the audio-only disclosure of specific risks, this brief introductory statement itself was always simultaneously provided in both audio and visual formats. To justify the decision to include the disclosure statement in simultaneous visual and audio formats, Betts et al, in the methods section, cited a 2014 study demonstrating that presenting risk information in this combined format “produced the highest recall and recognition.”<sup>9</sup>

Indeed, the FDA’s own earlier Distraction Study, published in 2011, had demonstrated the superiority of combined visual-audio presentation of risks, with the agency concluding the following:<sup>10</sup>

---

<sup>8</sup> *Ibid.*

<sup>9</sup> Wogalter MS, Shaver EF, Kalsher MJ. Effect of presentation modality in direct-to-consumer (DTC) prescription drug television advertisements. *Appl Ergon.* 2014;45(5):1330-1336.

<sup>10</sup> Food and Drug Administration. Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television

In summary, we found strong support for presenting risk information at the same time in text and in audio because doing so improves risk comprehension... This finding is consistent with previous research and with standards maintained by the Federal Trade Commission. Sponsors could help ensure the effective communication of risk information in DTC ads by presenting the spoken risk concepts simultaneously in text. Furthermore, an increase in risk comprehension was *not* associated with any reduction in benefit comprehension. ...

This study made a clear contribution to our understanding of the role of visuals in DTC advertising. The study demonstrated that reinforcing audio-delivered risk information with consistent text during the major statement of an advertisement improves consumers' risk comprehension and does not impede their comprehension of benefit. The results of this study will be helpful as FDA continues to encourage the truthful and nonmisleading presentation of prescription drug information.

It is not clear why the authors of the Betts et al study did not realize that including both visual and auditory presentations of the risks actually disclosed (or testing this combined presentation with either visual-only or auditory-only presentations) was warranted. The difference in rates of recall and retention of serious and actionable risks between subjects viewing unedited risk statements and those viewing revised risk statements may have been smaller had risk information been presented simultaneously in both visual and audio modes.

Another important variable not examined in the Betts et al study was the effect of distracting, positive imagery accompanying the auditory-only presentation of risk information in any of the study arms (see discussion of the Sullivan et al study below).

## **2. Study results: Over-interpretation of small absolute differences**

The authors of the Betts et al study concluded that “[t]he revised risk statement improved overall processing of the television ad, as evidenced by improved risk recall and recognition.”<sup>11</sup> This conclusion, however, is based on very small absolute differences in the proportions of recalled and recognized serious and actionable risk information between subjects viewing unedited-risk-statement ads and those viewing abbreviated revised-risk-statement ads, as shown in the following table (taken from Table 2 of the FDA-commissioned Betts et al study):

---

Advertisements: Technical Research Report. May 2011. <https://www.regulations.gov/document?D=FDA-2009-N-0582-0040>. Accessed October 27, 2020.

<sup>11</sup> Betts KR, Boudewyns V, Aikin KJ, et al. Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. *Res Social Adm Pharm.* 2018;14(10):951-963.

<b>Illness Population and Variable Being Measured</b>	<b>Unedited Risk Statement</b>	<b>Revised Risk Statement</b>
<b>Depression</b>		
Proportion of key risks recalled	0.12	0.16
Proportion of key risks correctly recognized	0.68	0.73
<b>Insomnia</b>		
Proportion of key risks recalled	0.20	0.24
Proportion of key risks correctly recognized	0.70	0.75
<b>High Cholesterol</b>		
Proportion of key risks recalled	0.28	0.33
Proportion of key risks correctly recognized	0.72	0.73*

\* This difference between the unedited-risk-statement and revised-risk-statement groups was not statistically significant. All other differences between the two groups were statistically significant.

As shown above, the absolute differences in the proportions of both recalled and recognized key (serious and actionable) risks between subjects viewing unedited risk statements and those reviewing revised risk statements were never greater than 5%, regardless of the condition studied. These differences would likely have been smaller, and would likely have approached statistical insignificance, had the key risks in both the unedited- and revised-risk-statement groups been presented with identical, appropriately severe language (as explained above, only the revised risk statement was introduced with such language) as well as with simultaneous visual risk information.

The above results also serve as further confirmation of the utter failure of DTC broadcast ads to effectively convey fair balance between benefits and risks of a given medication. Subjects in the study demonstrated extremely poor recall of the disclosed risks, regardless of the amount of risk information provided in the audio-only disclosures. Subjects viewing the unedited risk statements recalled just 12-28% of the serious and actionable risks presented, and subjects viewing revised risk statements did not fare much better, with recall rates of 16-33%. Although the study did not separately assess recall of the disclosed benefits of each advertised medication, it is likely that nearly all subjects recalled the overarching benefit claim, namely that the drug is generally effective for the condition that was the subject of the advertisement. Thus, this study confirms that DTC ads achieve their intended selling purpose for the drugs' manufacturers: clearly and compellingly conveying benefit information while effectively minimizing the recollection of risks.

#### **E. Another FDA-commissioned study documented that simultaneous visual distraction impairs retention of risk information**

In an another FDA-commissioned study published by Sullivan et al, 300 subjects were randomly assigned to view one of two DTC ads: a "low-distraction" ad or a "high-distraction" ad.<sup>12</sup> Both ads presented risk information in audio format with superimposed text (combined audio-visual format). The study found that, despite the presence of superimposed text, "...distracting elements during risk presentation drew attention away from the risk text and, in turn, reduced retention of drug risk information." Risk perceptions were not affected by distracting imagery. The authors

<sup>12</sup> Sullivan HW, Boudewyns V, O'Donoghue A, et al. Attention to and distraction from risk information in prescription drug advertising: An eye-tracking study. *J Public Pol Marketing*. 2017;36(2):236-245.



concluded that “even if dual modality is used to increase consumers’ comprehension of drug risk information, distracting visuals should still be avoided to help consumers focus on key information in the ad.”

These results further call into question the validity and utility of the aforementioned Betts et al study that varied the amount of risk information presented (in audio-only format) to subjects. Had that study removed distracting positive imagery from the sample DTC ads viewed by all subjects, the rates of recall and recognition of key risk information likely would have been higher across all study groups, and the differences between the groups may have decreased.

#### **F. Highlighting most important risks with diluting risk information disclosure**

A 2017 study published by Sivanathan et al found that subjects who viewed prescription drug ads that presented more comprehensive risk information but highlighted the most important risks more prominently (hereafter referred to as “emphasized but complete risk statement”) rated the most important risks as severely as subjects that were shown only the most important risks with more minor risks omitted.<sup>13</sup> The authors of that study pointed out that one therefore may not have to sacrifice transparency in order to ensure that the most important risks are understood and remembered (and not “diluted” by presentation of more minor risks) by viewers of DTC ads:

The choice of information architecture employed in [the emphasized but complete risk statement], which affords consumers the ability to compartmentalize and assign appropriate weights to major versus minor side effects, presents one possible avenue by which pharmaceutical companies and regulators may look to attenuate the argument dilution effect while maintaining transparency.

#### **G. The FDA’s proposed definition of “serious” risks is too narrow**

In the FDA’s August 21, 2017, request for information titled “Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements,” the agency definitively included within its definition of serious risks only those adverse reactions “that may result in inpatient hospitalization or prolonged existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect.”<sup>14</sup> The FDA equivocated on including other potentially serious reactions within this definition by stating that reactions that do not result in any of the above outcomes but nevertheless “based on appropriate medical judgment...may jeopardize the patient and may require medical or surgical intervention to prevent one of [these] outcomes” *may* (rather than *should*) also be considered serious risks.

Many risks that do not result in hospitalization, disability, or incapacity are nevertheless serious enough to result in medical intervention in the emergency room or outpatient setting, discontinuation of the drug in question, or impairment of patients’ quality of life. In addition, frequent side effects that are associated with nonserious but uncomfortable or distressing symptoms often can lead patients to stop taking their drug without consulting a health care provider, which can, in turn, result in serious adverse health outcomes if no other treatment is

---

<sup>13</sup> Sivanathan N, Kakkar H. The unintended consequences of argument dilution in direct-to-consumer drug advertisements. *Nat Hum Behav.* 2017;1(11):797-802.

<sup>14</sup> 82 FR 39598.

provided. We therefore believe that all such reactions should be disclosed in the major statement in DTC broadcast ads.

#### **H. Our recommendations for a final rule amending 21 C.F.R. § 202.1**

As we stated in our November 20, 2017, comments (copy enclosed) responding to the FDA's August 21, 2017, request for information titled "Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements,"<sup>15</sup> it is imperative that the FDA, as mandated by FDAAA, issue a final rule that amends the regulations governing DTC advertisements for prescription drugs (21 C.F.R. § 202.1) to require that the disclosure of risk information in the major statement of DTC broadcast ads be clear, conspicuous, and neutral.

For the aforementioned reasons, the final rule amending 21 C.F.R. § 202.1(e)(1) should include the following elements:

- (1) Maintain current FDA requirements regarding which risks must be disclosed in DTC broadcast prescription drug ads. In particular, the FDA should continue to require "a brief summary of all necessary information related to side effects and contraindications," which may include certain important nonsevere, nonserious, and non-actionable risks, while also requiring that severe, serious, or actionable risks be disclosed more prominently.
- (2) Require all risk information in DTC broadcast prescription drug ads to be presented simultaneously in both audio and visual formats.
- (3) Ban the use of distracting imagery and sounds — both musical and nonmusical — during the disclosure of risk information in DTC broadcast prescription drug ads.
- (4) Regarding the disclosure of "serious" risks in DTC broadcast prescription drug ads, the amended rule should clarify that the scope of "serious risks" extends beyond those adverse drug reactions that may result in inpatient hospitalization or prolonged existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect.

Thank you for considering our comments on this important public health issue.



Michael A. Carome, M.D.  
Director  
Public Citizen's Health Research Group

Enclosures

---

<sup>15</sup> 82 FR 39598.