**Citizen Petition**

August 3, 2020

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

**RE: A 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**

The undersigned submits this Petition pursuant to Section 21 of the Federal Food, Drug, and Cosmetic Act (the "Act") and 21 C.F.R. § 202.1 to request that the Commissioner of the Food and Drug Administration (the "Commissioner") ban the use of music during the presentation of side effects and risks of prescription drugs, in all forms of advertising with sounds (AWS) including but not limited to advertisements on television, radio, social media and Internet web pages.

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# Introduction

This petition makes a narrow and important proposal, that the FDA limit the use of music in television, radio and internet streamed advertisements of drugs and vaccines. In particular, we ask the FDA to ban the use of music during the sections of advertisements that discuss the potential side effects and other risks associated with the products.

The FDA already regulates the content of Direct to Consumer (DTC) advertisements, specifying that such ads cannot be false or misleading. It also requires that DTC advertisers give a "fair balance" of information about benefits and risks. These risks may include side effects, allergic reactions, or contraindications.

A growing body of literature is largely critical of DTC advertisements, arguing that DTC ads are designed in ways that use visuals and sound to enhance the impression of health benefits, while using images and sounds to systematically distract attention from the side effects and

contraindications of products, which, if following the FDA “fair balance” requirement, should in fact be “comparable in depth and detail with the claims for effectiveness or safety." (21 C.F.R. § 202.1).

A significant and avoidable problem is the widespread employment of distraction techniques, such as the use of background music during the presentation of the risks in television and other broadcast or streamed advertisements that include multimedia content.

This petition will refer to ads with sounds as AWS, to describe any ads that include sounds, whether the ad is delivered over broadcast television or radio, streamed on social media or Internet web pages, or disseminated through other means of reaching consumers directly.

AWS create special fair balance compliance challenges for marketers of prescription drugs and policymakers because of the interplay of two different sensory modalities (audio and visual) used to present risk and benefit information communicated in a relatively short period of time, and the incongruent nature of the two types of information presented (possible positive and negative outcomes of using the product). These characteristics of DTC AWS create opportunities for distraction of consumers from information in the message. The advertisers’ goal is to sell as much of their product as possible which means that they are incentivised to emphasize the benefits and minimize the risks.

Advertisers use background music in order to achieve an outcome that is more favorable to expanding sales than would be the case if the company honored the intent of the FDA’s current provisions, however, it comes the expense and social cost of patients having a reduced comprehension of information on the side effects and risks of products.

Broadcast prescription drug ads and other AWS are required to present major product risks in the audio portion of the ads. In a 2009 Guidance, FDA regulators recommend that risks should be "presented in clear, understandable language without distraction" (FDA, 2009, p.20). The draft guidelines do not offer a definition of distraction *per se,* but suggest that message elements such as background music, visuals and on-screen text can interfere with consumer comprehension by distracting attention away from the information being presented. This petition will focus on the audio elements alone, specifically background music, and how it works as a distraction to the presentation of risks and therefore is in conflict with the FDA's fair balance provision and should be banned.

## A. Action Required

The FDA should amend §202.1 of the Code of Federal Regulations Title 21 on Prescription-Drug Advertisements to include a provision that bans background music from the presentation of the risks section of direct to consumer prescription drug advertising. (21 C.F.R. § 202.1).

## B. Statement of Grounds

### I. Current State of DTC Drug Advertising/FDA Regulations

A 2005 Congressional Report defined direct-to-consumer (DTC) prescription drug advertising as "any promotion designed by pharmaceutical companies to communicate to the

public about prescription drugs through the lay media" (Vogt, 2005, p.1). DTC ads usually fall into one of three categories:

1. Product-claim ads contain the brand name of a drug and claims about the product's therapeutic use for a particular health condition;
2. Help-seeking ads contain information about the particular health condition that the drug treats and encourage consumers to talk to their doctor about the condition, but they do not contain the drug's brand name, nor do they mention any claims about a drug's doses;
3. Reminder ads call attention to a drug's brand name but do not mention any particular condition or make claims about the product's uses.

The Federal Food, Drug and Cosmetic Act (FFDCA) provides the statutory requirements for marketing a prescription drug in the United States. When the FFDCA was enacted in 1938, most prescription drug promotion was in the form of written material directed at physicians. In 1962, Congress added section 502(n) to the Act, giving the FDA jurisdiction over drug labeling and advertising. The section included several important requirements for the marketing of new drugs. New drugs must be proven safe and effective before they can be sold in the United States, and any claims about the product's uses or effectiveness must be substantiated by adequate clinical testing. This requirement that all claims must be substantiated is the legal framework for the FDA's jurisdiction over product claim advertising.

In 1969, the FDA issued regulations for product-claim advertising. Product-claim ads must have four characteristics:

1. They cannot be false or misleading;

2. They must present a "fair balance" of claims about the drug's therapeutic uses and effectiveness and the drug's risks
3. They must contain "facts" that are "material" to the drug's use;
4. They must include all risks from the drug's approved labeling in a "brief summary."

In August 1999, the FDA issued its Guidance for Industry: Consumer-Directed Broadcast Advertisements, which made it much easier for pharmaceutical companies to advertise prescription drugs on television. Agency guidance is not binding law, but is designed to help industry members comply with current regulations. The FDA's 1999 guidance paved the way for drug companies to use broadcast media for product-claim ads without a brief summary, provided that they included the advertised drug's most important risks, called a "major statement." (FDA, 1999, p.2). The major statement is required to be in the audio portion of the advertisement but can be in the video portion as well. The regulations also require that broadcast advertisements must "present a fair balance between information about effectiveness and information about risk." (FDA, 1999, p.2).

In assessing fair balance, the FDA not only looks at the number and quality of specific benefit and risk statements, but also at the "net impression" of all the elements communicated in the message as a whole. (FDA 2009, pg.4). In a 2009 draft guidance, the FDA responded to requests for specific guidance about how it evaluates adequate risk information in promotional messages. (FDA, 2009). The draft guidance suggests that in order to ensure comparable benefit and risk presentations, manufacturers should consider not only the time devoted to benefits and risks and the number of statements about each, but also the comprehensibility of the language

used, and the type of information provided. The 2009 draft guidance specifically warns against "the use of audio or visual components that enhance or distract from the presentation of risk or benefit information." (FDA, 2009, p.11).

Advertisers' use of background music is a distraction from the presentation of risks because the type of music they choose is incongruent with the message presented and it bombards the viewer with excess stimuli making it difficult for them to retain the information. This leads to viewers comprehending the benefits better than the risks and results in an unfair, highly positive view of advertised prescription drugs.

Patients often request particular drugs from their doctors, and the distortion created by music in pharmaceutical advertising during messages regarding potential side effects and risks results in overdiagnosis and over prescription of the American public.

## II. Incongruency

The type of background music used in DTC has an effect on what information is emphasized and subsequently retained by viewers.

The first musical property that can influence message reception is "attention-gaining value," which refers to the activation or arousal potential of musical sound. (Kroeber-Riel, 1979). Music's ability to engage a listener's attention can stem from objective traits, such as speed and loudness, or subjective traits, such as surprisingness and interestingness. (Berlyne, 1974). Slow, soft music should have a low attention-gaining value, whereas fast, loud music can be expected

to activate higher levels of attention. In an advertising context, music may contribute to message reception by attracting and holding attention. (Hecker, 1984). According to one view, attention-getting music should attract attention to an ad, thereby enhancing message reception. A paradox arises, however, in that listeners sometimes attend to the music so closely that the message is not processed. In these cases, music is a distractor that inhibits message reception and processing. Wakshlag, Reitz, and Zillman (1982) found that music that increased attention to a program inhibited learning from it. Anand and Sternthal (1990) found music to have a distracting effect in a radio advertising context. As Macklin (1988, p. 225) states, "an individual may attend to the music [and] become so enraptured by [it] that the central message of the advertiser is ignored." She suggests that music is likely to have this distracting effect when it is "extraneous to the main concept or theme." (p. 227). Whether attention-gaining music enhances or distracts from processing may therefore depend on the consistency of meaning conveyed by the music and verbal message. This incongruence between music and message is highly prevalent in television drug commercials. According to the FDA, DTC drug commercials must present a balance of the benefit and risk; however, the background music chosen for most drug commercials often distracts from the risks by being incongruent with its messaging.

Furthermore, one study by Kellaris and Cox suggests that music-message congruency can moderate the influence of music's attention-gaining value on at least some aspects of ad recall and recognition. When congruence is high, attention-gaining music seems to contribute positively to these outcomes. When congruence is low, attention-gaining music seems to serve more as a distraction from ad processing. This interactive phenomenon may help explain some of

the conflicting findings reported in previous research on the relationship between background music and ad effectiveness.

Kellaris and Cox data confirmed that when background music is both attention-gaining and message-incongruent, it will pull listeners' attention away from the message, thereby harming recall. This is the technique employed by drug advertisers. They utilize attention-gaining and message-incongruent music to distract viewers from the presented risk.

A number of studies have concluded that consumers comprehend benefit information better than risk information in DTC ads. (Abernathy & Adams-Price, 2006; Day, 2005; Glinnert & Schommer, 2005). Distracting or dividing viewers' attention from information in a message can affect how well viewers comprehend that information. Research suggests that both information load and the relevance of information presented in one channel to the other have the potential to distract consumers.

## III. Information Load

Information load refers to "the variety of stimuli (in type and number) to which the receiver must attend." (Jacoby, 1977, p. 569). Research on consumer information processing (Bettman, 1975; Jacoby, Speller, and Kohn, 1974) suggests that information overload, or too much information, may reduce subjects' attention and comprehension. Experimental studies in consumer psychology research have demonstrated a number of television advertising elements that can contribute to information load and divided attention: music (Hahn and Huang, 1999),

presentation rate (Wingfield, Lindfield & Goodglass, 2000), and animation (Hong, Thong, & Tam, 2004).

In terms of audio distraction, experimental studies have demonstrated that both music and the rate of speech can affect information load. The presence of music in advertising messages can affect message processing, and both the tempo and familiarity of the music can moderate these effects. Background music in TV advertising is information offered to viewers in addition to the main message. Fast tempo music requires more processing resources than slower tempo music. (Hahn & Hwang, 1999). While the presence of any music increases information load, unfamiliar music makes message processing more difficult because it distracts attention away from the message.

The FDA recognizes the impact of audio information load elements on the distraction potential of DTC television advertisements. The 2009 draft guidance notes several audio factors that the FDA will consider when evaluating distraction in television ads including verbal pace, volume, and the presence of background music during the presentation of both benefits and risks. (FDA, 2009).

In their definition of distraction, Hoy and Andrews incorporated the concepts of information load and irrelevant stimulation. They defined distraction as "extraneous nonverbal elements such as music, sound effects, and unrelated pictorial information." (2004, p. 173). They found that 99.5% of ads that included risk information in the form of superimposed text had some form of distraction while the superimposed text was on-screen. Almost all (99.2%) had competing sounds, including music; 33.3% had scene changes, and 86.6% had moving visuals.

Of ads with audio risk information, 97.3% included distraction during the disclosure. Thirty-seven percent had a scene change, 89.6% had moving visuals, and 95.9% had other sounds, including music occurring concurrently. Only 2.7% had no distracting elements during the audio presentation of risk information. In order to effectively educate and communicate with consumers these distractions, music, must be eliminated.

In discussing the findings about the presentation of spoken information, it is important to note that the FDA requires that the "major statement" (FDA, 1999, p.2) of the drug's most important risks be presented over the audio channel. This may mean that the FDA places greater importance on the audio channel as an information source than the video channel. If the audio channel is where the important information must be communicated, background music directly competes with the "major statement" which, according to the FDA, is the one of the most important requirements of DTC drug advertisements. The FDA has even sent a warning letter to Bayer HealthCare Pharmaceuticals regarding an ad for the Premenstrual Dysphoric Disorder (PMDD) drug YAZ stating that the audio communication of serious risk disclosures during the "major statement" is minimized by distracting visuals, numerous scene changes, and other competing modalities such as background music, which combined to interfere with the presentation of the risk information (FDA, 2009a). Additionally, the FDA has previously discontinued ads for distraction tactics in the past. Schering-Plough Corp was ordered to discontinue an ad for allergy drug Nasonex after a congressional hearing determined that background visuals in the ad had the potential to distract consumers from side effect information (FDA, 2008). The ad featured a bee that flew around during a description of side effects but

simply hovered while benefits were being explained. Banning background music from DTC drug advertisements when side effects are discussed is the logical step for the FDA to take in order to achieve the goals that they have already presented and are currently attempting to enforce. Banning music during discussions of side effects has the advantage also of being a clear bright line that is easy to enforce.

## IV. Overdiagnosis in The United States

A chief concern of critics is the potential of DTC advertising to increase inappropriate prescribing, reflecting both cost and safety concerns. (Adams, 2001) The use of background music contributes to these issues. Physician surveys find that DTC advertising increases prescription volume and that some of these prescriptions are clinically inappropriate. According to one survey, eighty-one percent of physicians believe that DTC advertising prompts medication requests, and one quarter report resulting changes in their prescribing habits. (Frosch, 2010). A survey of physicians and their patients found that 7% of patients made a prescription request and that DTC advertising (DTCA) exposure increased such requests. Although 78% of the requests were fulfilled, the prescribing physician judged half of these prescriptions as possible or unlikely choices for a similar patient with the same condition. In another survey, physicians judged half of DTCA-prompted requests to be clinically inappropriate. However, 69% of these requests were at least partially fulfilled, with a small but significant percentage of these requests (6%) judged as potentially harmful choices. (Mintzes, 2003) Physicians often said they fulfilled such requests to accommodate patients. (Weissman, 2004).

In nationally representative surveys, 39% of physicians and 30% of patients felt that DTCA interferes with the physician–patient relationship. Physicians reported more annoyance when presented with a hypothetical medication request motivated by DTC advertising than they do when the query arises from a more traditional medical reference such as the Physicians' Desk Reference. Overall, physicians are less likely than patients to endorse the positive aspects of DTC advertising and more likely to worry that DTC advertising promotes longer, unnecessary visits and inappropriate medication requests. (Murray, 2004) Additionally, patients may react negatively if their physician refuses a medication request. Nearly half of patients in one study reported feeling disappointed about not receiving a requested medication, 25% said they would try to change their physician's mind or get the drug elsewhere, and 15% considered terminating care with their physician. (Bell RA, 1999).

Exposure to prescription drug advertisements can prompt prescription requests. These requests can be driven by ads that include insufficient, inaccurate, or otherwise misleading information. By prompting requests for prescriptions, DTC advertising can promote patient participation in clinical decisions; however, the downstream effects may vary significantly depending on the quality of the information. If a request is clinically inappropriate, but physicians are unable (because of lack of knowledge, time, or other background variables) or unwilling to correct the patient's perception, it may lead to unnecessary and potentially harmful prescribing. Although high-quality information about prescription drugs is itself not sufficient to ensure appropriate prescribing decisions, it is a necessary ingredient to reduce the negative impact of DTCA-prompted prescribing for inappropriate and overtly risky uses.

Therefore, in order to ensure patients do not receive insufficient, inaccurate, or misleading information from DTC advertising the FDA is asked to ban the use of music during the presentation of the risks, for the reasons explained in sections II and III of this petition. Banning music will lead to a more informed patient and thus less clinically inappropriate prescriptions.

## V. Comment on Incentives

Drug manufacturers provide information to consumers and physicians regarding the benefits, side effects and risks of drugs. The companies have strong economic incentives to promote the benefits and downplay the side effects and risks of their products.

One of the disadvantages of encouraging use of products when risks are high are the occasional litigation from patients who experience adverse outcomes. However, management of firms often perceive that expected costs of such litigation costs are both less than the profits from expanded sales and subject to significant delays.

The incentives to downplay the role of side effects and risks are more intense for managers than shareholders, given the pressure on managers to constantly expand sales and profits in order to keep their jobs and to benefit from employment incentives that are linked to company share prices, and the limited tenure of the Chief Executive Officers (CEOs) and Directors.

Table 1 provides the names, dates of appointment, and days and years of tenure as CEO for the current CEOs of thirteen of the largest drug companies. The median tenure is 5.2 years, and six of the thirteen CEOs have been on the job less than the median. Only one of the CEOs has held that job more than ten years.

**Table 1: Names, dates of appointment, and days and years of current CEO tenure of 13 of the largest drug companies**

| Company | CEO | Date of appointment | Days CEO as of July 30, 2020 | Years CEO |
|---|---|---|---|---|
| Pfizer | Albert Bourla | Jan 2019 | 546 | 1.5 |
| Novartis | Vasant Narasimhan | Feb 1, 2018 | 880 | 2.4 |
| Roche | Severin Schwan | May 2008 | 4443 | 12.2 |
| Merck | Kenneth C. Frazier | Jan 1, 2011 | 3468 | 9.5 |
| Sanofi | Paul Hudson | Sep 1, 2019 | 303 | 0.8 |
| J&J | Alex Gorsky | April 26, 2012 | 2987 | 8.2 |
| GSK | Emma Walmsley | April 2017 | 1186 | 3.2 |
| Abbie | Richard Gonzalez | Jan 2, 2013 | 2736 | 7.5 |
| Gilead | Daniel O'Day | Mar 1, 2019 | 487 | 1.3 |
| Amgen | Robert A. Bradway | May 23, 2012 | 2960 | 8.1 |
| AstraZeneca | Pascal Soriot | Oct 1, 2012 | 2829 | 7.7 |
| BMS | Giovanni Caforio | May 2015 | 1887 | 5.2 |
| Eli Lilly | David Ricks | Jan 1, 2017 | 1276 | 3.5 |

## VI. Comment on Visual Images in DTC Advertising

There are similar and serious concerns about the distracting and incongruent nature of the use of images in pharmaceutical ad discussions of side effects and risks. Regulating the use of images is important, but beyond the scope of this petition. The elimination of music in the

sections of advertisements that present the side effects and risks can and should be implemented now, regardless of the FDA's future consideration of the problem of inappropriate visual images.

### VII. Conclusion

The current state of direct to consumer advertising for prescription drugs is not about patient empowerment. It is not about providing clarity, and it often does not enhance the physician-patient relationship. The FDA should acknowledge that music is used in AWS in order to undermine appreciation and reduce understanding of information regarding side effects and risks of drugs.

Banning music from the risks section of AWS will lead to a more clear and concise presentation of material facts that should be important to the patient. A more informed patient will lead to more accurate diagnosis and better health care for the American people overall.

## C. Environmental Impact

The action requested is subject to a categorical exemption from environmental assessment under 21 CFR 25.34.

## D. Economic Impact

Pursuant to 21 § CFR 10.30, the undersigned will provide data concerning the economic impact of the action requested should such information be requested by the FDA.

## E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

## Petitioners

Respectfully,

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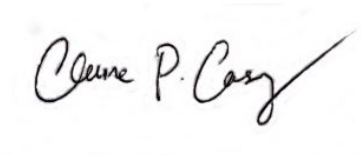

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# Examples of distracting/message-incongruent music in DTC drug advertising

1. Trelegy TV Commercial

https://www.ispot.tv/ad/ojix/trelegy-the-power-of-more

2. Jardiance TV Commercial

https://www.ispot.tv/ad/oHiG/jardiance-dimitri-is-on-it-restaurant

3. Ozempic TV Commercial

https://www.ispot.tv/ad/IepS/ozempic-arcade

4. Victoza TV Commercial

https://www.ispot.tv/ad/7xxi/victoza-across-america

5. Descovy for Prep TV Commercial

https://www.youtube.com/watch?v=nhsF7Csninw

6. Xeljanz XR TV Commercial

https://www.youtube.com/watch?v=kgIX2RwhTng

7. Xarelto TV Commercial

https://www.youtube.com/watch?v=CfFpdaY_ghU

8. Pradaxa TV Commercial

https://www.youtube.com/watch?v=1gDGRwmpD3M

9. Cosentyx TV Commercial

https://www.youtube.com/watch?v=TVXVi8VJVr4

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