Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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Comments of
Prescription Access Litigation/Community Catalyst, Inc.,
and

Alliance for Retired Americans, American Federation of State, County and Municipal Employees, (AFSCME), American Medical Student Association (AMSA), Breast Cancer Action, California Alliance for Retired Americans (CARA), CALPIRG, Coalition of Wisconsin Aging Groups, Consumers Advancing Patient Safety (CAPS), Connecticut Center for Patient Safety, Connecticut Citizen Action Group, Health Care for All, IUOE Local 4 Funds, Long Island Health Access Monitoring Project, MASSPIRG, National Women's Health Network, New England Carpenters Health Fund, National Legislative Association on Prescription Drug Prices (NLARx), Oregon Health Action Campaign, Prescription Policy Choices, TeamstersCare, US PIRG, VPIRG

Concerning

The United States Food and Drug Administration Notice "Direct–to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner"

Docket No. FDA-2009-N-0582, RIN 0910-AG27

June 24, 2010

DESCRIPTIONS OF ORGANIZATIONS SUBMITTING COMMENTS:

Prescription Access Litigation, LLC, is a non-profit organization representing consumer interests, with a coalition of over 130 senior, labor, patient, and consumer advocacy organizations. Prescription Access Litigation is a project of **Community Catalyst**, Inc., a non-profit health care advocacy organization working nationally and in over 40 states to make quality, affordable health care, including prescription drugs, accessible to everyone. Our work exposes inappropriate and illegal pharmaceutical marketing and pricing practices by industry and promotes an increased reliance on independent evidence of drug effectiveness by physicians, health care programs, and consumers. Community Catalyst has engaged a broad range of stakeholders in campaigns to pass state and federal prescription drug statutes, promote policies at Academic Medical Centers, and challenge industry practices through litigation and legal action.

The mission of the four million member **Alliance for Retired Americans** is to ensure social and economic justice and full civil rights for all citizens so that they may enjoy lives of dignity, personal and family fulfillment and security. The Alliance believes that all older and retired Americans have a responsibility to strive to create a society that incorporates these goals and rights and that retirement provides them with opportunities to pursue new and expanded activities with their unions, civic organizations and their communities.

The **American Federation of State, County and Municipal Employees**, AFSCME, is a union of 1.6 million members who provide the vital services that make America happen. With members in hundreds of different occupations – from nurses to corrections officers, child care providers to sanitation workers – AFSCME advocates for fairness in the workplace, excellence in public services and prosperity and opportunity for all working families.

The **American Medical Student Association** (AMSA), with a half-century history of medical student activism, is the oldest and largest independent association of physicians-in-training in the United States, representing more than 60,000 physicians and physicians-in-training.

Breast Cancer Action is a national, grassroots education and advocacy organization that carries the voices of people affected by breast cancer to inspire and compel the changes necessary to end the breast cancer epidemic.

CALPIRG is a non-profit, non-partisan member-based public interest advocacy organization, taking on powerful interests on behalf of Californians to win concrete results for our health and our well-being. With a strong network of researchers, advocates, organizers and students across the state, we stand up to powerful special interests on a range of consumer and public health issues including measures to provide safe and affordable prescription drugs, and improve the quality and lower the cost of health care.

Consumers Advancing Patient Safety (CAPS) is a consumer-led nonprofit organization formed to be a collective voice for individuals, families and healers who wish to prevent harm in healthcare encounters through partnership and collaboration. Membership in CAPS is free and open to anyone that shares our values. Our website (www.patientsafety.org) provides free access to a searchable database of resources, tools and education materials, as well as downloadable consumer engagement toolkits.

The **California Alliance for Retired Americans** (CARA) is a statewide nonprofit organization that unites retired workers and community groups to win social and economic justice, full civil rights, and a better, more secure future for ourselves, our families, and future generations. As an umbrella organization for more than 175 affiliated groups, CARA serves a combined membership of over 850,000 Californians. Our priority issues include advocating for health care for all, safe and affordable prescription drugs, access to affordable long term care services, especially community based services, affordable housing, and protecting pensions and retirement security.

The **Coalition of Wisconsin Aging Groups** is a nonprofit, nonpartisan, statewide membership organization that was founded in 1978. CWAG's mission is to improve the quality of life for people of all ages through: Intergenerational Understanding and Leadership Development, Public Education, Legal and Legislative Advocacy and Public Policy Development. We believe there are too many conflicts of interest between the pharmaceutical industry and physicians, undermining evidence based health care decisions and contributing to the skyrocketing costs of prescription drugs.

The **Connecticut Center for Patient Safety** represents the voice of the health care consumer. We work toward creating a culture of patient safety and improving the quality of care. There is no place for direct to consumer marketing in a culture of safety. Care should not be about profits but about improving health and health outcomes.

Connecticut Citizen Action Group (CCAG) is a statewide membership organization, with over 20,000 members, dedicated to building a more just society. CCAG has played a leading role on health policy in Connecticut and on national issues.

Health Care For All (HCFA) seeks to create a consumer-centered health care system that provides comprehensive, affordable, accessible, culturally competent, high quality care and consumer education for everyone, especially the most vulnerable. One of our main areas of concern is with pharmaceutical and medical device company marketing. The Massachusetts Prescription Reform Coalition, founded by HCFA, works to control manipulative industry marketing practices so that patients can have access to necessary medication and devices at a price they can afford.

IUOE Local 4 Funds administers the Health & Welfare, Pension and Annuity Funds for the 8000 members and dependents of Operating Engineers Local 4. With our health benefits under a self-insured, self-administered program we are especially concerned about the cost spiral resulting from advertising of prescription drug benefits and the impact on demand and utilization by our members.

MASSPIRG is non-profit, non-partisan member supported public interest advocacy group working on behalf of Massachusetts citizens to win concrete results for our health and our well-being, With a strong network of researchers, advocates, organizers and students across the state, we stand up to powerful special interests on a range of consumer and public health issues including measures to provide safe and affordable prescription drugs, and improve the quality and lower the cost of health care.

The **National Women's Health Network** (NWHN) works to improve the health of all women by influencing policy and supporting informed consumer decision-making. We are committed to eliminating economic and political barriers to health care and to ending women's exposure to unnecessary drug and medical treatment risks. We are guided in our work by core values including the belief that that evidence rather than profit should drive the services offered and information that is made available to women to inform their health decision-making and practices. The NWHN is supported by our members and we do not accept financial support from drug companies, tobacco companies or medical device manufacturers.

The **New England Carpenters Health Fund** is a self-insured, self-administered health plan covering 22,000 members and their dependents. Our members continually look to us to provide a comprehensive, high quality health care program that will serve their needs, at an affordable price. The plan participants trust in us to administer the health benefits program effectively and efficiently. We continue to focus on encouraging consumerism amongst our group and look to provide safe and affordable prescription drug benefits to our members and their families.

The **National Legislative Association on Prescription Drug Prices** (www.reducedrugprices.org) is a nonpartisan, nonprofit organization founded in 2000. Directed by state legislators and funded through state and member dues, the Association assists state legislators in working jointly to make prescription drugs more affordable and accessible, while serving as a national clearinghouse for research and information on drug pricing, marketing and conflicts of interest in pricing and a forum to develop and defend innovative public policies.

Prescription Policy Choices is a nonprofit, nonpartisan 501-c-3 educational and public policy organization which provides objective research, information and on-the-ground expertise on prescription drug policy in an effort to improve access to safe, effective and affordable medicine in the US.

TeamstersCare is a Taft-Hartley Trust Fund providing health and welfare benefits to 6,000 Teamsters and their 15,000 dependents and to 1,200 retirees and spouses. We are committed to promoting wellness, prevention and member education so that our members are able to make informed health care decisions. We believe Direct-to-Consumer prescription drug advertising undermines our educational efforts by inappropriately influencing the beliefs and demands of our members on both their physicians and their Health Plan.

U.S. PIRG, the federation of state Public Interest Research Groups (PIRGs), stands up to powerful special interests on behalf of the American public, working to win concrete results for our health and our well-being. With a strong network of researchers, advocates, organizers and students in state capitols across the country, we take on the special interests on issues, such as product safety, political corruption, prescription drugs and voting rights, where these interests stand in the way of reform and progress.

Founded in 1972, **VPIRG** is the largest nonprofit consumer and environmental advocacy organization in Vermont, with over 15,000 members and supporters. Our mission is to promote and protect the health of Vermont's people, environment and locally-based economy by informing and mobilizing citizens statewide.

COMMENTS:

We submit these comments in support of the FDA's five proposed standards implementing the requirement under section 901(d)(3)(a) of FDAAA that "the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner" in any "advertisement for a drug . . . presented directly to consumers in television or radio format."[1]

1. **As consumer, senior, labor, non-profit health plans, patient safety, and other advocacy organizations, we strongly support the five proposed standards to protect consumers from misleading DTC advertising.**

We wholeheartedly support these standards, which will promote public health by providing consumers with more accessible, accurate information in broadcast prescription drug ads. These standards will also prevent ads from using distraction to minimize or undermine consumers' ability to appreciate the very real risks of prescription drugs communicated in these ads.

There are no studies showing positive public health outcomes resulting from DTC advertising. In contrast, there is ample evidence that DTC "advertising is used to drive choice [toward expensive brand-name drugs] rather than [to] inform [consumers]."[2]

There are potentially very serious health consequences associated with the use of nearly every drug – from Acetaminophen to Zetia. Newly approved drugs are often promoted by Direct-to-Consumer (DTC) advertising before the public and the FDA can know how much of a risk the drug poses when used by millions of new patients. One example is Avandia, a drug used by millions before its significant side-effects became widely known. Another example of unsafe over-promotion of a new drug concerned Vioxx, one of the most aggressively advertised new drugs, taken by tens of millions of patients. Vioxx was ultimately linked to between 35,200 to 52,800 deaths and 88,000 to 140,000 heart attacks in the US.[3]

(Neither Vioxx or Avandia are actual examples of drugs whose risks are "unknowable." In the case of Avandia, there is emerging evidence that its manufacturer Glaxo-Smith Kline not only knew of the drug's risks of cardiac events for years before they were made public in a 2007 New England Journal of Medicine study, but that their "executives attempted to intimidate independent physicians, focused on strategies to minimize or misrepresent findings that Avandia may increase cardiovascular risk, and sought ways to downplay findings that a competing drug might reduce cardiovascular risk." [4] Similarly, there is compelling proof unearthed through

[1] *See* 21 U.S.C. § 352(n)(2010).
[2] *Direct-to-consumer advertising under fire*, 87 Bulletin of the World Health Organization 8, 565-644, http://www.who.int/bulletin/volumes/87/8/09-040809/en/index.html (last visited June 18, 2010). (*quoting* Dr. Dee Mangin, Associate Professor at the Christchurch School of Medicine and Health Sciences, Christchurch, New Zealand).
[3] D.J. Graham, *Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs: Nested case-control study*, 365 The Lancet 475-481 (2005).
[4] .STAFF REPORT ON GLAXOSMITHKLINE AND THE DIABETES DRUG AVANDIA, Committee on Finance, U.S. Senate, at 1, Jan. 2010, available at http://finance.senate.gov/library/prints/.

litigation which revealed that Vioxx's risks were actually know by its manufacturer Merck as early as 1996, and subsequently confirmed by Merck's own internal studies in 2000. Merck failed to disclose these risks at any time before a public study lead to Vioxx's withdrawal from the market in September 2004. Merck ultimately settled legal claims related to their 'failure to warn' consumers of these risks for a record-breaking 4.85 billion dollars in 2007.[5])

Prescription Access Litigation has testified before the FDA that, aside from putting patients at risk, deceptive marketing by pharmaceutical companies is one of the primary factors fueling inappropriate use of prescription drugs and driving up drug costs in the United States.[6] Our testimony has cautioned that "[m]anufacturer-sponsored television advertisements, in particular are ill-suited to effective communication of risk-benefit information about prescription drugs."[7]

We strongly agree with the FDA's recognition that positive health outcomes from the use of prescription drugs "are less probable when drug promotions are biased and provide an incomplete or confusing account of the drug's likely effects."[8] As such, we applaud the FDA's new proposed standards as a strong step to advance public health.

Re proposed rule 1: "Information is presented in language that is readily understandable by consumers;"

2. Consumer-friendly language using 'every day words' better informs consumers

When choosing to use a prescription drug, consumers face complex medical issues beyond their comprehension. To help ensure that consumers are better informed in this process, we wholeheartedly support the FDA's proposal to make explicit the requirement that a drug's risk information be 'presented in language that is readily understandable by consumers." The FDA Notice in the *Federal Register* further clarified that this would require that ads "use everyday words or terms that are understandable to consumers" i.e. using words like "fainting" rather than medical terms such as "syncope."[9] The importance of this requirement cannot be overstated.

The FDA's review of scientific studies on DTC advertising [10] ("ERG Report") notes that "overall consumers want side effect reporting to be information rich and easily accessible."[11] This ERG Report notes a number of studies showing why it is necessary to establish DTC advertising standards in relation to consumer understanding:

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[5] See http://www.merck.com/newsroom/news-release-archive/corporate/2007_1109.html
[6] Testimony of Alex Sugerman-Brozan, Director of Prescription Access Litigation/Community Catalyst, FDA Public Hearing on Direct-to-Consumer Advertising (November 2, 2005).
[7] Comments of The Prescription Project, Community Catalyst and Prescription Access Litigation, Community Catalyst, September 26, 2008, concerning Docket No. FDA-22080N-0226.
[8] Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner, 75 Fed. Reg. 15376 at 15382 (proposed March 29, 2010)("FDA proposed rules").
[9] Id. at 15379.
[10] John Eyraud et al., Scientific Literature on Direct-to-Consumer Advertising of Prescription Pharmaceuticals, 2004-2008, Literature Review, Eastern Research Group, Inc. (January 10, 2009).
[11] Eyraud, *supra* note 10, at 17. (*Citing* J.J. Davis, Consumers' preferences for the communication of risk information in drug advertising, 26 Health Aff. 863-870, 2007).

- 60 percent of physicians in one large study believed that DTC advertisements for prescription drugs provided patients with little or no understanding of the risks and negative effects of these drugs;
- 65 percent of physicians said that DTC advertisements may lead patients to confuse the relative risks and benefits of advertised drugs.

a. Use of scientific language in DTC advertising may be inherently misleading

The ERG Report documents the significant effects of the *type of language used in an ad* on consumer understanding of drug risks and side effects. One study found that the use of 'scientific language' in DTC ads lead to lower expectations of side-effects by consumers.[12] Conversely, consumers provided with fuller descriptions of side effects were better able to consider and evaluate these risks.[13] These results imply that using scientific language in ads may mislead consumers by creating a false impression that the drug has been more rigorously tested, and is thus safer than has actually been shown. The proposed FDA requirement that all drug ads present information in consumer-friendly language will likely reduce any such false perception of safety.

b. The proposed "readily understandable" standard should protect the most vulnerable consumer likely to view, and be influenced by, an ad

The FDA's non-binding May 2009 Draft Guidance Presenting Risk Information in Prescription Drug and Medical Device Promotion notes that FDA evaluates drug promotions by industry "from the perspective of a reasonable consumer"[14] or "a reasonable member of the targeted population."[15] This standard is meant to be generally applicable to both print and broadcast DTC advertising. While some targeting of a specific patient population is possible by placing print ads in magazines with better defined readerships, it is nearly impossible for broadcast DTC advertising by drug makers to target any specific group of consumers. Television ads are accessible to anyone, and are seen by millions of consumers. Therefore, requiring a standard that protects *all viewers of the broadcast ad* from being misled is warranted.

In order to protect all consumers likely to see and be influenced by a broadcast DTC ad, we urge the FDA to define this standard of 'understandability' relative to a consumer who is *the least informed person of limited literacy likely to view and be influenced by an ad.* In considering whether language is 'readily understandable' the FDA should consider that public health experts recommend that ads directed to the general public should use language at an eighth-grade reading comprehension level, and that currently the majority of ad content exceeds this recommended level.[16] Other studies have shown that adults with limited literacy were much less

[12] Id.
[13] Id.
[14] FDA, Draft Guidance "Presenting Risk Information in Prescription Drug and Medical Device Promotion" at 5 (May 2009).
[15] Id. at 12.
[16] Dominick L. Frosch et al., A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising, 100 Am. J. of Pub. Health 24, 25 (January 2010).

likely to understand risk information compared with the company's positive messaging in DTC ads.[17]

Other federal agencies have adopted such a standard to protect consumers from being misled by DTC advertising. For instance, FTC has adopted a "least sophisticated consumer" standard when determining whether a debt collector's communication violates the Federal Debt Collection Practices Act's proscription of false or misleading representations.[18] Courts have described this 'least sophisticated consumer' as someone who is "uninformed, naïve or trusting" but who has a "rudimentary knowledge [about the subject] and who is capable of making logical deduction[s] and inferences."[19] If such a standard is warranted in the context of protecting consumers' financial well-being from debt collectors, then we suggest it is even more appropriate where a consumer's lack of understanding could endanger their health.

In the proposed rules, the FDA notes that the agency is studying whether the elderly, children, minorities, or other vulnerable population subsets warrant different standards with respect to DTC advertising. We recommend that, until this study or other research provides FDA with a scientific basis for a different standard, the agency should adopt a 'least sophisticated consumer' standard in order to adequately protect all consumers likely to view a DTC broadcast drug ad.

c. To be "clear" and avoid vagueness, ads should quantify known risks and side effects where possible to any frequency above a certain amount

We fully support the FDA's interpretation that a 'clear' presentation of risk means that ads should "avoid the use of vague terms or explanations" and that the major statement "should accurately convey the frequency of [a] risk."[20] Studies demonstrate that when drug ads quantify a drug's effects, this information reduces exaggerated perceptions and promotes more accurate assessments of drug effects by consumers.[21]

We recommend that the FDA include in the final rule clarification of appropriate threshold levels for quantifying risks for bothersome, significant, serious or life threatening risks attributable to the drug. These thresholds should be based on current research in the field of Risk Communication in order to ensure that patients can interpret risk at the most optimal level.

Describing risks in quantitative terms may also increase the conspicuousness of the risk information, by drawing a consumer's attention to the reality of the risk described. A quantitative description of risk also provides consumers with an evidence-based presentation that is scientifically justifiable, increasing the neutrality of the ad.

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[17] K.A. Kaphingst et al., Comprehension of information in three direct-to-consumer television prescription drug advertisements among adults with limited literacy, 10 J. Health Commc'n 609-619 (2005).
[18] 15 U.S.C. §1692g (2010).
[19] Sims v. GC Serv. L.P., 445 F.3d 959, 963 (7th Cir. 2006).
[20] FDA proposed rules, 75 Fed. Reg. 15376 at 15379.
[21] D. Frosch, et al, A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising. Amer. J. Public Health. Jan. 2010, vol. 100, No. 1, at 26, (noting that "[r]igorous experimental evidence indicates that exaggerated perceptions of benefit can be corrected with quantitative information not typically provided in current ads."). citing Woloshin S, Schwartz LM, Welch HG. The value of benefit data in direct-to consumer drug ads. Health Aff (Millwood).2004 (Suppl Web Exclusives):W4-234–245.

For all of the above reasons, we think that requiring consumer-friendly language that includes a quantification of risk information is a vital addition to current FDA regulations, and will help increase the clarity, conspicuousness, and neutrality of broadcast DTC drug ads.

d. Health education materials developed by the Agency for Healthcare Research and Quality (AHRQ) provide an appropriate model of consumer-oriented language quantifying health risks.

A useful resource for standards on presenting risk information to patients may be the Agency for Healthcare Research and Quality's Effective Health Care Program guides for patients and consumers.[22] These guides are written at a 6th grade literacy level and present benefits and risks of medical treatments.

For example, one guide compares two kinds of blood pressure medications as follows:

> It is rare, but sometimes people get a drug reaction called angiodema (pronounced "An-gee-o-uh-DEE-muh.") In research comparing [these two medications] about 1 out of 10,000 people gets angiodema."

Re proposed rule 2: "Audio information is understandable in terms of the volume, articulation, and pacing used;"

3. Audio information should be understandable by a reasonable consumer in terms of volume, articulation, and pacing

We support the FDA's proposed requirements for the presentation of audio information. This proposed standard is necessary because advertisers commonly minimized consumer perceptions of risk relative to benefits by presenting the risk information more quickly, despite the former requirement that risks and benefits be presented in 'fair balance.' [23] One study found this to be true for an alarming 91 percent of DTC ads reviewed.[24] As the FDA noted in the *Federal Register*, the FTC implemented this same requirement for DTC advertising of over-the-counter (OTC) drugs for more than a decade ago.[25] Given that over-the-counter drugs are considered safe enough to use without the advice of a licensed prescriber, certainly no lesser standard should be applied to the promotion of prescription drugs.

FDA should take into account the fact nearly all of the top selling brand-name drugs are heavily advertised, and that a large percentage of these drugs are used by seniors. This proposed standard is especially important to seniors, or to other consumers who, as a result of their literacy, visual or other limitations, may rely more heavily on the audio portions of an ad.

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[22] See http://www.effectivehealthcare.ahrq.gov/index.cfm/guides-for-patients-and-consumers/

[23] This 2004 study cited in note 24, supra, was conducted when the former 'fair balance' requirements were in place. under 21 U.S.C. §352(n).

[24] Eyraud, *supra* note 10, at 15. (*Citing* KA Kaphingst et al., A content analysis of direct-to-consumer television prescription drug advertisements, 9 J. Health Commc'n 6, 515-528 (2004)).

[25] 63 Fed. Reg. 87, 24996 at 25002 (May 6, 1998).

Though it is possible that requiring risk information to be presented at a slower pace could result in longer ads, the potential public health and consumer safety benefits warrant such a requirement.

Re proposed rule 3: "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;"

4. The placement, size, style, contrast, and duration of the text used should allow the text to be "read easily"

We support the FDA's proposed requirement that the text in a broadcast ad be 'easily read' in terms of its size, style, contrast, and duration on the screen. This requirement will help to address the fact that, compared to benefits, a drug's risks may require more explanation. The FDA should also take into account the fact that seniors use nearly all of the best selling and most advertised drugs. In addition, drugs that treat conditions such as diabetes may require a heightened standard because vision impairment and loss are commonly associated with the disease. Thus, the advertiser should know that many patients seeing such an ad may require even larger letters or other considerations to effectively communicate risk information in a clear, conspicuous, and neutral manner.

Re proposed rule 4: "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."

5. Risk information must be presented without audio or visual distraction

We support the FDA's requirement that risk information cannot be considered to be neutral if it is "presented in competition with other elements if these elements would arrest the attention and distract consumers from the presentation of the risk information." This standard will help improve the clarity, conspicuousness, and neutrality of the major statement.

This requirement is particularly important because, as noted in the ERG Report, benefit information is often presented visually "in the form of happy and symptom-free 'patients' engaged joyfully in normal daily activities."[26] In contrast, risk are never illustrated using visual images showing patients undergoing adverse events.[27] This is because visual imagery is more powerful than verbal messages. One study states that "when visual and verbal messages are discordant, visual messages tend to dominate information processing, which could lead to inadequate processing of verbal risk information."[28] As a result, visual depiction of benefits distracts from, and undermines, any simultaneous verbal presentation of risks.

[26] Eyraud, *supra* note 10, at 15.
[27] Id.
[28] Frosch, *supra* note 21, at 29-30.

The FDA has caught advertisers using broadcast ads that have this effect. For instance, an FDA warning letter concerning a DTC TV ad for the drug YAZ states that "the overall effect of . . . distracting visuals, graphics, concurrent [superimpositions] and background music is to undermine the communication of important risk information, minimizing these risks and misleadingly suggesting that YAZ is safer than has been demonstrated by substantial evidence."[29] The letter notes that in the drug's TV advertising, "fast paced visuals depict[ing] various women looking at pictures, trying on clothes, chatting at a café, stretching/exercising in a park, and walking down the street" were shown while the audio component described the major, sometimes life-threatening, risks associated with YAZ.[30] The FDA said that the audio communication of these serious risk disclosures during the major statement was minimized by these "distracting visuals, numerous scene changes, and other competing modalities such as the background music which combine to interfere with the presentation of the risk information."[31]

As demonstrated by this warning letter, distracting images or sounds can seriously undermine the clarity and conspicuousness of the presentation of risk information and can present a non-neutral perspective of the drug being advertised. In support of this proposed requirement, the FDA noted that, since 1970, the FTC has required that DTC ads for OTC drugs be presented without distracting sounds during the audio portion of the ad.[32] Again, no lesser standard should apply to prescription drugs.

Re proposed rule 5 to present risk information in 'dual modality'

6. Risk information should be presented in simultaneous audio and visual presentation ("dual modality") to enhance consumer understanding

We support the proposed 'dual-modality' requirement that risk be presented simultaneously in audio and text-based visual modes. Requiring dual modality in direct-to-consumer advertising will aid in improving consumer understanding. As stated in the FDA Notice, "presenting the information in two modes reduces possible interference from other messages that might be present on the screen at the time of the ad" and thus dual modality could "enhance the clarity, conspicuousness, and neutrality" of the information presented.[33]

As another leading national consumer organization commented, "[p]roviding an audio warning with other things happening in the background is, no matter how hard one tries, distracting" while "[p]roviding the same, simultaneous audio and visual warning is the single best way to make a lasting impression that will be helpful to patient-consumers."[34]

[29] FDA Warning Letter re: NDA # 21-676, 21-873, 22-045, October 3, 2008, concerning DTC ads for the drug YAZ.
[30] Id.
[31] Id.
[32] As noted in the FDA proposed rules, 75 Fed. Reg. 15376 at 15377, citing a 1970 FTC enforcement policy statement; later codified by FTC at 63 Fed. Reg. 87, 24996 at 25002 (May 6, 1998).
[33] FDA proposed rules, 75 Fed. Reg. 15376 at 15380.
[34] Comments by Consumers Union, June 4, 2010, concerning Docket No. FDA-2009-N-0582-0023 (March 29, 2010).

Such a 'dual mode' presentation of risk information has been required by the FTC for the direct-to-consumer advertising of OTC drugs for over four decades.[35] Again, no lesser standard should apply to prescription drugs, which require a prescription and physician supervision due to their greater dangerousness.

Furthermore, the ERG Report notes a 2005 study finding that "using captions with oral messages improved the overall recall of side effect information, resulted in lower levels of distraction, and lessened the cases of sensory overload for high risk severity medication."[36] This study supports the use dual modality is an effective mechanism to improve comprehension, draw attention to the importance of the information, and reduce distraction. For these reasons, we feel that requiring dual-modality in DTC broadcast advertising will contribute greatly to the clarity and conspicuousness of risk information in drug ads.

7. Additional recommendations to provide a 'neutral' presentation of risks to consumer viewing DTC ads.

As the FDA stated in the notice, there is no standard definition for the statutory term "neutral." The FDA has provided the interpretation that it means "unbiased" under the FDAAA amendments. We caution that the industry bias in designing drug ads is profound. This advertising drives billions of dollars of annual profits for the most widely advertised drugs. One prominent commentator has admonished:

> "[t]o rely on the drug companies for unbiased evaluations of their products makes about as much sense as relying on beer companies to teach us about alcoholism . . . . The fact is that marketing is meant to sell drugs …." [37]

Numerous lawsuits[38] have documented how the drug industry's powerful profit incentive has resulted in a shameful track record of putting drug promotions and resulting profits first, at the expense patient safety achieved through a full, fair, and adequate disclosure of known drug risks or benefits. The fact that the drug industry's profit incentives are at such odds with consumers and providers reliance on the industry for accurate, unbiased information supports the strongest possible oversight, regulation, and enforcement by the FDA. More specifically, the FDA's oversight of the communication of risks, through explicit standards such as those proposed, is vital to protecting the health and well being of the millions of consumers taking prescription drugs.

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[35] CCH Trade Regulation Reporter, Paragraph 7569.09 "Clear, Conspicuous Disclosure," October 21, 1970.
[36] Eyraud, *supra* note 10, at 18.
[37] Angell, M. The Pharmaceutical Industry -- To Whom Is It Accountable? New England Journal of Medicine, 2000; 342:1902-4.
[38] Lawsuits concerning the drug Vioxx revealed emails dated as early as 1996 and clinical trial data from 2000 revealing that drug manufacturer Merck had knowledge of the risks of cardiac events; the drug was not withdrawn form the market until 2004. The litigation resulted in a $4.85 Billion global settlement of personal injury claims alleging that Merck had breached their duty to warn consumers of these risks. See also descriptions of litigation concerning the drugs Vytorin-Zetia, Ketek, and Zyprexa, available at www.prescriptionacces.org.

We believe that to ensure a "neutral" presentation of risks, the FDA should look not only at the bias that the manufacturer has in promoting their drug, but also at any widely held biases by consumers as well. For this reason, we urge the FDA to:

a. Require a disclosure that "The FDA has not approved this ad."

Requiring a statement that "The FDA has not approved this ad" would start to correct two widely held but highly misleading beliefs that consumers have concerning drugs and drug ads, namely:

(i) that the FDA both approves all ads, and [39]

(ii) that only drugs that are proven to be 'very safe' can be advertised on TV.

Including such a required disclosure makes the major statement more 'neutral' by disassociating the ad from any government imprimatur regarding the safety of the drug, or whether such safety is adequately described by the ad the consumer is seeing.

b. Require that the Medwatch 1-800-FDA-1088 hotline be included in all DTC broadcast ads

Similarly, we suggest that the 1-800-FDA-1088 Medwatch adverse event hotline be presented in all television and radio broadcast ads, just as it is required for all print advertisements.[40] Including this hotline would help communicate that, overall, the drug being advertised is not known to be risk free. We are aware that the FDA is currently looking into whether including this number in television ads is appropriate, but we believe that the FDA's inclusion of this requirement is warranted until such time as there is evidence that such a disclosure is not necessary. (For example, including this hotline may be less necessary after a drug has been on the market for years and has been taken by millions of patients without the discovery of any new or long-term negative health consequences.)

Though neither of the above recommendations were explicitly proposed in the FDA Notice, we propose that the FDA adopt them in order to further ensure that the clear, conspicuous, and neutral standard is achieved. We feel that these additional recommendations are well within the character, scope, and scheme of the original rule proposal, and therefore can be included within the final regulations.

8. Comment on the proposed effective date of these new standards

We support the earliest possible implementation of these standards. Drug manufacturers have had over two and a half years since the enactment of the statutory requirement of a 'clear, conspicuous, and neutral' presentation of risks under FDAAA.[41]

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[39] *See* FDA Draft Guidance, Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009)("[c]onsumers have preconceived ideas about the amount of scrutiny these ads undergo. Many believe FDA exercises tight regulatory control over the content of these ads and to some extent, believe that all ads have been pre-reviewed prior to airing.")

[40] 21 U.S.C. §352(n) (2010) (DTC print ads must contain the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.")

[41] FDAAA was enacted September 27, 2007.

9. Comment on FDA resources to enforce these new requirements

We applaud the FDA's return to their vital role protecting consumers through more rapid review and more aggressive responses to false, misleading, or inaccurate statements in broadcast and other DTC drug advertising.[42] Nevertheless, we recognize that FDA is vastly underfunded to adequately regulate promotional conduct related to prescription drugs. Consider: the annual spending of $2.6 Billion by the federal governments Medicare Part B program on just one drug – Epoetin alfa -- in 2007 was greater than the entire FDA budget of $2.6 billion for its 10,000 employees in 2008.[43]

As a result, even the fastest possible response by FDA still means that millions of consumers will likely see any deficient ad. Television ad campaigns are designed to have their impact over very short periods of time – a few weeks to a few months. If a misleading ad runs even once, some consumers could be misled, and the damage is done.

Though the FDA was given the statutory authority[44] to require a prior 'advisory review' of broadcast DTC ads in 2007, the agency did receive the necessary Congressional funding for this program. This paltry amount of funds – $11 million dollars – combined with user-fees, would have allowed FDA to work with industry to catch misleading or confusing broadcast ads before they lead consumers to inappropriate decisions about their prescription drug needs.

Until such time as Congress addresses this under-resourcing of the FDA, we support the Agency's continued efforts to quickly identify inaccurate or misleading ads. Furthermore, in light of the risks to public health and the absence of this 'advisory review' program, we urge the FDA to enforce these new standards through the civil fines for misleading DTC advertising authorized under 21 U.S.C. § 333(g)(1).[45]

10. Comment on the FDA's assessment of the costs of implementation

The FDA's assessment of the "Cost of Compliance" should be balanced by potential consumer and health system savings. The FDA addresses various costs of industry compliance, but does not comment on potential savings that could result from even marginal reductions of any inappropriate prescriptions for drugs driven by DTC advertising. The FDA acknowledges that "no studies have examined the impact of direct to consumer advertising on either health

[42] These efforts include the FDA increased regulation of DTC ads through warning and untitled letters since the start of 2009, as well as the "Bad Ad" program initiated in May of 2010. See http://blog.prescriptionaccess.org/?p=825

[43] Bonnie M. Cramer, Chair, AARP Board of Directors, Testimony before Energy and Commerce Health Subcommittee, Dec. 8, 2009.

[44] 21 U.S.C. § 353b (2010)(" The Secretary may require the submission of any television advertisement for a drug . . . for review under this section not later than 45 days before dissemination of the television advertisement.")

[45] 21 U.S.C. § 333(g)(1)(2010) ("[A]ny such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period.")

outcomes or examined the costs and health and social consequences of DTCA."[46] This research must be carried so that the positive financial impacts of these and other standards for clearer DTC advertising can be accurately assessed.

Thank you for your consideration of these comments.

Sincerely,

Wells G. Wilkinson
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Staff Attorney, Community Catalyst

Rob Restuccia
Executive Director
Community Catalyst

[46] FDA proposed rules, 75 Fed. Reg. 15376 at 15382 (citing Gilbody, S., P. Wilson, and I. Watt, Benefits and Harms of Direct to Consumer Advertising: A Systematic Review,' Quality and Safety in Health Care, 14:246–250, 2005.)