



Wiley Rein & Fielding LLP

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1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

Virginia Office
7925 JONES BRANCH DRIVE
SUITE 6200
McLEAN, VA 22102
PHONE 703.905.2800
FAX 703.905.2820

www.wrf.com

March 31, 2006

Sarah E. Botha
202.719.7411
sbotha@wrf.com

BY HAND DELIVERY

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

Re: Submission of Citizen Petition on Behalf of the Coalition for Healthcare Communication

Dear Sir or Madam:

Please accept for filing the attached citizen petition submitted on behalf of the Coalition for Healthcare Communication in four copies pursuant to 21 C.F.R. §§ 10.20, 10.30.

Sincerely,

Sarah E. Botha

cc: Sheldon T. Bradshaw, Chief Counsel, Office of the Chief Counsel
Patrick Ronan, Chief of Staff, Office of the Commissioner
Scott Gottlieb, Deputy Commissioner for Policy
Janet Woodcock, Deputy Commissioner for Operations
Randall W. Lutter, Associate Commissioner for Policy and Planning
Steven K. Galson, Director, Center for Drug Evaluation and Research
Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research
Robert J. Temple, Director, Office of Medical Policy
Rachel E. Behrman, Deputy Director, Office of Medical Policy
Thomas W. Abrams, Director, Division of Drug Marketing, Advertising, and Communications
Kristin I. Davis, Deputy Director, Division of Drug Marketing, Advertising, and Communications
Melissa M. Moncavage, Direct-to-Consumer Review Group Leader, Division of Drug Marketing, Advertising, and Communications

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Division of Dockets Management

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Kathryn J. Aikin, Direct-to-Consumer Research Team, Division of Drug
Marketing, Advertising, and Communications

Nancy M. Ostrove, Director, Risk Communications, Office of Planning

Susan B. Bro, Office of External Relations

Healthcare Communication

March 31, 2006

0632 '06 MAR 31 A9 53

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

Re: Citizen Petition Requesting Promulgation of an Amended Regulation for Prescription Drug Advertising to Establish Separate Criteria for Practitioner-Directed and Consumer-Directed Advertising and to Establish a Standing Advisory Committee on Health Care Communications.

Dear Sir or Madam:

Pursuant to 21 C.F.R. §§ 10.20 and 10.30, the Coalition for Healthcare Communication (the "Coalition") submits this petition under Sections 502, 503 and 701 of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act") (21 U.S.C. §§ 352, 353 and 371) to request the Commissioner of Food and Drugs to amend the regulations governing prescription drug advertising to consumers ("DTC") and to create a standing advisory committee on health care communications.

The Food and Drug Administration ("FDA") has significant evidence demonstrating that DTC provides valuable information to consumers about treatment options and leads to doctor/patient conversations that improve patient care. To further FDCA goals and enhance the value of communications from the regulated industry, this Petition asks the FDA:

(1) to adopt formal DTC rules and policies that highlight the differing information needs of patients and prescribers, particularly recognizing the different and changing roles that patients and practitioners play in the course of the drug decisional process; and

(2) to create a standing Communications Advisory Committee to ensure that the agency's rules and policies are based on the best available social scientific and professional knowledge of consumer behavior and effective consumer communications.

Communication is effective only if conducted at the level recipients understand and can use. For this reason, the Coalition believes that regulation of DTC should stress the use of clear, understandable and retainable messages about benefits and safe use of prescription drugs, with an emphasis on the information that a patient needs to discuss medication options with a physician. Further, the Coalition urges new rules that provide clear, objective guidance to advertisers to enhance industry compliance and streamline FDA enforcement. Meeting these objectives will honor the "less is more" paradigm that FDA recently endorsed in its revised professional labeling regulation, will enable better communication to patients about health conditions and therapeutic options, and will advance the public health.

A. Introduction

FDA over the past decade has generated and gathered significant research on the effect of DTC. Its value is fully understood by the current FDA. For example, in announcing the release of FDA's recent Draft "Brief Summary" Guidance on DTC risk disclosures in print advertisements,¹ then-Commissioner Mark McClellan articulated the agency's growing understanding of how DTC advertising helps to support the public health: "The evidence shows that promotions directed to consumers can play a particularly important role in helping patients

¹ FDA, *Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* (posted Feb. 4, 2004), <http://www.fda.gov/cder/guidance/5669dft.pdf> (hereinafter "Draft Brief Summary Guidance").

start a discussion with their health practitioner about many conditions that are often unrecognized and are under-treated in this country.”²

Indeed, the record from the November 1 and 2, 2005 hearing confirms DTC’s public health value as a disease awareness tool and as a stimulus to beneficial consultation between patients and prescribers on diagnosis and treatment options. The record compiled by FDA demonstrates that consumer advertising works in medicine just as it does throughout the American economy. The economic incentive of drug manufacturers to promote recognition of diseases and treatment options coincides with the public interest in efficient, effective health care. Market incentives stimulate what amounts to a multi-billion dollar public information and awareness program at no cost to taxpayers. The public health will continue to be advanced by FDA policy that encourages effective, truthful and non-deceptive DTC advertising. (*See*, Coalition Testimony at FDA’s November 1, 2005 hearing for a more complete discussion) (Ex. B).

Meanwhile, expressions of public concern about drug safety and risk communications at the recent FDA hearings have highlighted the need to increase consumer understanding of drug safety, and the potential of DTC advertising to advance that understanding. Patients need to know that all drugs have risks and that prescribing decisions require a full, professional balancing of potential risks and rewards. Effective drug policy should reflect that difficult balance of priorities. Consumers must be given enough information to stimulate appropriate discussion of health conditions and therapeutic options with their physicians, but that same information should not confuse or scare them away from asking questions or remaining compliant with current treatment.

² *See* Transcript of FDA News Teleconference Announcing DTC Draft Guidances at 2 (Feb. 4, 2004) (Ex. A).

Dr. McClellan also noted the widespread consensus that the current “brief summary” approach to drug risk disclosures in print ads -- *i.e.*, verbatim reprints of the advertised drug’s FDA-approved label -- “doesn’t convey that information as effectively as it should to many consumers who find it too detailed and off-putting.”³ He correctly recognized that

[t]his may be a case where “less is more” in terms of consumer understanding....

Less is more for consumers because they can actually get more out of this information. The larger type, the clearer language, the focus on the more important risks that are a basis for further discussion with the health professional, and an appropriate basis is more beneficial to them in taking something away from the ads, rather than just skipping over a brief summary section as most consumers seem to do today.⁴

Dr. McClellan’s statements in the context of the “brief summary” have broader application in consumer communication. Indeed, they stem from fundamental principles of consumer behavior. These fundamental principles were detailed by the Coalition comment filed to FDA’s Docket No. 2003N-0344. There, Dr. Lewis Pringle explains that consumer decision-making is a complex undertaking in which the role of mass media and non-personal communications plays only a part.⁵

As detailed in Dr. Pringle’s paper, advertising is best used to create awareness and stimulate interest in gathering more information from other sources, particularly doctors and other prescribers. *Id.* at Part One: 4-6, 8-11, 24-26. DTC advertising cannot be expected to communicate effectively a litany of potential adverse events. When found to do so, such ads

³ *Id.* at 4.

⁴ *Id.* at 3, 5.

⁵ Dr. Lewis G. Pringle, *Direct-To-Consumer (DTC) Advertising: A Practical Communications Model and Commentary on Risk Communications*, Part One: 15, 21-26 (Jan. 5, 2004), submitted with Comments of the Coalition for Healthcare Communication, Request for Comment on Consumer-Directed Promotion, Docket No. 03N-0344 (FDA filed Jan. 14, 2004), available at <http://www.fda.gov/ohrms/dockets/dailys/04/jan04/012304/03n-0344-c00004-vol3.pdf> (hereinafter “CHC/Pringle Consumer-Directed Promotion Comments”).

both over warn and under inform. The result is more confusion than communication. According to Pringle, DTC's is best used to make consumers aware that help might be available, that it involves some risk, and that a physician should be consulted for more details. *Id.* Burdening an ad with too many copy points wastes time, money, and the opportunity to effectively communicate. As Dr. Pringle says "An ad that attempts to communicate *much* more than one single copy point is likely to fail in the effort." *Id.* at Part One: 5.

Pringle uses the Buyer Behavior Modeling developed by Robert J. Lavidge and Gary A. Steiner in 1961 to illustrate the now common understanding of how advertising works. *Id.* at Part One: 16-24. The Buyer Behavior Model progression of events starts with awareness, then moves to knowledge, liking, preference, conviction and purchase. DTC advertising operates in the first phase, awareness. Broadcast 30-second spots and print ads are not effective at moving consumers to the knowledge, liking, and subsequent phases in the adoption decision. For drugs, the adoption decision is made at the time of consultation with a physician prescriber. To quote Pringle again: "The regulatory mandate notwithstanding, adequate communication of risk details **is highly unlikely to be accomplished** by DTC advertising." *Id.* at Part One: 26. Advertising works in the first stage of the decision-making process through the creation of consumer awareness and motivation to consult a doctor. DTC advertising should not be crippled by policy that demands more than it can do. The FDA has taken important steps in that direction, but more needs to be done.

The Coalition believes that optimum DTC regulation requires a "back to basics" approach, based on a realistic understanding of both the potential and the limits of consumer advertising. FDA's current regulatory goals and requirements were established in 1985 when FDA, without notice and comment, simply adapted professional advertising standards to DTC.

Professional communications, however, differ from DTC both in the degree of scientific and health literacy of the intended audience and the role of different audiences in the prescribing decision. FDA's regulatory approach should recognize and accommodate these differences.

In addressing professionals, manufacturers deal with an audience of varying degrees of education and experience, including one group -- licensed prescribers -- that has the sole statutory authority to write a prescription giving patients access to a drug. Prescribers, for purposes of counseling their patients on drug use in a variety of clinical circumstances, need the type of comprehensive information available in product labeling, including: a full and complete understanding of the physical characteristics of prescription drugs; knowledge of the indications for which drugs are effective; information on methods of use; disclosure of the situations in which specific medications may be contraindicated, as well as the possibility of adverse interactions with other drugs; and, disclosure of possible side effects whose risks should be weighed against the potential benefits of the drug therapy for an individual patient.

DTC advertising, by contrast, principally addresses patients and caregivers. Law forbids consumers to obtain the advertised drug without consulting a practitioner to obtain a prescription. Congress has determined that FDA should designate certain drugs as "Rx only" precisely because it believes that consumers cannot safely use such medications without professional supervision.

While some may think it desirable to tell consumers about all side effects and contraindications, no matter how clearly this information is communicated to consumers, a significant number will lack the education or background to comprehend and act on it. They will simply not have the requisite professional skill to appropriately weigh the benefits and risks to make a prescribing decision. For example, a statement that a drug may cause liver damage may

be comprehensible in its own terms but evaluating its clinical significance for an individual patient requires professional knowledge of liver function and body chemistry. Moreover, the judgment whether a particular long-term risk or transitory side effect is worth taking requires evaluation of the potential therapeutic benefit of the drug to the individual patient, the probability that the risk will be encountered, the severity of the risk for the individual patient and the patient's ability to use alternative therapies. Consumers, no matter how clearly advised of the general characteristics of a prescription drug, cannot make, and should not try to make, these particularized judgments without practitioner guidance. *DTC advertising should not be, and should not appear to be, a substitute for patient-physician interaction, and sound drug selection by skilled physicians.*

For these reasons, regulatory requirements for risk disclosure in DTC should be markedly different from professional requirements. FDA regulations prompting maximum feasible disclosure of this information in professional advertising and professional labeling serve a public health purpose different from the information needs of patients and caregivers. DTC regulations should facilitate full disclosure by patients to physicians of personal health conditions and drug and medical history, and should stimulate a robust physician-patient exchange on the benefits and risks of using an advertised drug. In other words, effective DTC policy should let practitioners be practitioners and patients be patients. To achieve this goal, what patients need to be told about side effects in prominent and plain English is that:

- All prescription drugs, including the advertised drug, have potential benefits and risks;
- The decision to use a prescription drug requires a professional diagnosis by a licensed prescriber and discussion between patient and prescriber of the possible benefits and risks to that individual patient of taking the drug;

- Patients should fully discuss their conditions, their medical histories, and any other medications they are taking with their health care professionals in order to help inform the professional prescribing decision.

Clear and repeated delivery of these core messages should enable better prescribing decisions, and enhance doctor/patient discussions of drug benefits, side effects and risks. Petitioner's proposed amendments to FDA's prescription drug advertising regulations are designed to achieve this goal.

Petitioner also seeks to eliminate certain artifacts of the existing regulatory system, including:

- Micro-type print disclosures in scientific language reproducing professional labeling, which most patients cannot comprehend;
- Extensive "major statements" that can be difficult for consumers to evaluate and understand, and are seldom fully retained; and
- Complicated and confusing messages that suggest that consumers can self-diagnose and self-medicate notwithstanding an "Rx only" designation.

To further this goal and improve the FDA's decision making in this area, the petition also recommends the establishment of a standing advisory committee on health communications that will enable the FDA to be informed by social science and professional communication experts. This committee should be composed of professionals from the regulated industry, consumer protection officials from the Federal Trade Commission and other consumer agencies, and social science research experts from industry and academia. (For a more complete discussion, *see* Testimony presented by Peter J. Pitts, Director, Center for Medicines in the Public Interest, Senior Fellow, Pacific Research Institute, November 2, 2005) (Ex. C). Given the importance of this standing committee, the Coalition suggests that the FDA consider appointing expert consumer advertising regulators and social science researchers to co-chair the committee. For example, two recent former chairs of the Federal Trade Commission, Timothy Muris and Robert

Pitofsky, are highly respected across the spectrum of political, academic and social science experts, and could be expected to appropriately guide a committee of communication and behavioral scientists to advise the FDA. This support will not only better inform the FDA on the science and practical aspects of consumer behavior, but undoubtedly will contribute to the FDA's standing in the legal community and provide the record evidence necessary to defend FDA regulation against First Amendment challenges.⁶

The remainder of this petition first describes the proposed advertising rule and its benefits in detail. It next describes the conflict between the goals of the existing regulation and the requirements of FDCA Section 503(b), and the way in which the proposed amendment would resolve that tension. It then discusses the First Amendment issues raised by existing regulation and their resolution by the proposed amendment. Taking all these factors into account, Petitioner urges FDA to move forward with the policy changes and the advisory committee proposed in this petition.

B. Action Requested

The Coalition respectfully requests the Commissioner of Food and Drugs to take the following actions:

- Promulgate an amended regulation, pursuant to Sections 502(n) and 701(e) of the FDCA (21 U.S.C. §§ 352(n), 371(e)) and the procedural requirements of 5 U.S.C. §§ 553, 556, and 557, to revise 21 C.F.R. §§ 202.1(e) and (1) to establish separate criteria for satisfying the brief summary requirement of FDCA Section 502(n) for practitioner-directed and consumer-directed prescription drug advertisements. The exact wording of the existing regulation is attached at Exhibit E. The proposed amended regulation is attached at Exhibit F. A document displaying all of the changes to the existing regulation that are contained in the proposed amended regulation is attached at Exhibit G.

⁶ See Rosemary C. Harold & John F. Kamp, *Grounding Regulation in Behavioral Science: Strengthening FDA's Approach to DTC Risk Disclosures*, FDLI Update, Nov./Dec. 2004, at 8 (Ex. D).

- Maintain the current final guidance document entitled “Consumer-Directed Broadcast Advertisements” until such time as the proposed amended regulation is enacted and in force, at which time the guidance document should be revoked or revised to conform to the proposed amended regulation.
- Leave in place the three DTC-related draft guidances issued in February 2004, namely, “Brief Summary Disclosing Risk Information in Consumer-Directed Print Advertisements,” “Consumer-Directed Broadcast Advertising of Restricted Devices,” and “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms,” until such time as the proposed amended regulation is enacted and in force, at which time the draft guidances should be revoked or revised to conform to the proposed amended regulation.
- Create a standing Communications Advisory Committee comprised of members from a variety of communications disciplines representing all segments of the scientific and health communications industries, media, the regulated industries, academia, and government.

C. Statement of Grounds

The Coalition proposes to revise paragraphs (e) and (l) of 21 C.F.R. § 202.1 in order to create a new form of simplified, mandatory risk disclosure in DTC. These new requirements would fully satisfy the “brief summary” requirement of 21 U.S.C. § 352(n) by providing appropriate “information . . . relating to side effects [and] contraindications.”

The Coalition believes the proposed amendment will optimize the proven public health benefit of DTC. Indeed, the empirical evidence gathered at FDA’s 1995, 2003, and 2005 public hearings on DTC advertising demonstrates that DTC successfully educates consumers about the existence of medical conditions and treatment options,⁷ and prompts consumers to consult their

⁷ See Kathryn Aikin, Ph.D., *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, at slides 18, 49 (Sept. 22, 2003) (citing *FDA Patient Survey* (2002) and *FDA Physician Survey* (2002)), <http://www.fda.gov/cder/ddmac/aikin/index.htm> (last visited Mar. 28, 2006) (hereinafter Aikin presentation) (77% of patients agreed strongly or somewhat that DTC ads help make them aware of new drugs; 72% of physicians surveyed agreed strongly or somewhat that DTC makes patients aware of possible treatments; and 58% agreed that DTC makes patients more involved in their healthcare); Edwin Slaughter, *Consumer Reaction to DTC Advertising of Prescription Medicines 1997 to 2002*, at slides 8-9 (Sept. 22, 2003) (citing *Prevention Annual Survey* (2002)), <http://www.fda.gov/cder/ddmac/P1Slaughter/index.htm> (last visited Mar. 28, 2006) (hereinafter Slaughter presentation) (84% of patients surveyed agreed strongly or somewhat that DTC ads tell people about new treatments that are available; 80% of patients surveyed agreed that DTC ads alert people to symptoms related to a

health care professionals about whether an advertised treatment option could be right for them.⁸ Unfortunately, FDA's current mandatory disclosures do not communicate risk information in a form consumers can fully understand, retain or appropriately use.⁹ The findings presented at the FDA hearings thus support modified DTC disclosure requirements that encourage and equip consumers to discuss the likely benefits and risks of the advertised drug with their physicians. The Coalition's proposed amendments would enable DTC to achieve this goal.

As noted above, the Coalition's goal is to universalize patient awareness that all drugs have benefits and risks and to encourage patients to fully inform prescribers of all known pertinent information. The Coalition urges that FDA expressly disavow any reliance on DTC to fully warn patients of all possible risks and side effects. The Coalition believes that such an "educational" effort, however noble in theory, conveys a false impression that consumers can

condition they might have; and 78% agreed strongly or somewhat that DTC ads allow people to be more involved with their healthcare).

⁸ Slaughter presentation, at slides 16, 21 (citing *Prevention Annual Surveys*) (in 2002, 33% of consumers (nearly 65 million people) talked to their physicians about an advertised medicine because of an ad; 15% (29 million) talked to their physicians about a health condition for the first time because of an ad); Sharon Allison-Otley, M.D., *DTC and the AA Physician and Patient*, at slide 18 (Sept. 22, 2003) (citing *NMA/COSHAR Physician Survey*), <http://www.fda.gov/cder/ddmac/P1AllisonOtley/index.htm> (last visited Mar. 28, 2006) (36% of surveyed NMA member physicians reported that patients have come into their offices *solely* because of DTC ads); Linda Golodner, *Effectiveness of and Attitude Toward Medication Advertising*, at slides 9-10 (Sept. 22, 2003) (citing *NCL Patient Survey*), <http://www.fda.gov/cder/ddmac/P1golodner/index.htm> (last visited Mar. 28, 2006) (more than half of the adults surveyed took some action in response to seeing a DTC ad that interested them; 31% decided to talk to their doctor at their next appointment; 16% contacted their doctor immediately); Aikin presentation, at slides 9, 49 (citing *FDA Patient Survey* (2002) and *FDA Physician Survey* (2002)) (89% of patients surveyed reported consulting their doctor for more information after seeing a DTC ad; 30% of physicians surveyed said that DTC ads make hard-to-reach patients come into a doctor's office for treatment).

⁹ See Aikin presentation, at slide 5 (citing *FDA Patient Survey* (2002)) (41% of patients surveyed in 2002 reported that they did not read any part of the brief summary that accompanies print ads for prescription drugs; 32% read "a little"); Slaughter presentation, at slide 14 (citing *Prevention Annual Survey* (1999)) (46% of patients surveyed were not aware of or did not recall seeing the brief summary in DTC print ads; of the 54% who did recall seeing the brief summary, only 12% read it thoroughly, 12% looked for key information, 15% skimmed it, and 10% did not read it); FDA, *Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results* at 4 (Nov. 19, 2004), <http://www.fda.gov/cder/ddmac/Final%20Report/FRfinal111904.pdf> (hereinafter "FDA Survey Research Results") ("half of those [patients surveyed] who read at least some of the brief summary described it as difficult to read").

decide on use of the drug without professional guidance. Moreover, it is confusing to those consumers who lack the knowledge and context of the warnings and thus detracts from the achievable and critical messages that DTC can convey. Such disclosure must be left to other means. Instead, DTC advertising policy must support the role of the learned intermediary in educating consumers on the specific side effect risks of advertised drugs and the likelihood of any particular risk affecting an individual patient.

The FDA itself recognized in its recent rulemaking on simplified professional labeling that requiring extraneous disclosure is not cost free. The clutter generated by extraneous disclosure can, in fact, result in providing patients with information that is apparently extensive but realistically far less understandable and retainable than it could and should be.

1. Proposed Changes to 21 C.F.R. § 202.1

The Coalition proposes a new subparagraph to 21 C.F.R. § 202.1(e)(3)(iii) which would govern risk disclosure in all “consumer-directed” advertisements.¹⁰ New subparagraph

¹⁰ The new DTC risk disclosure requirements will apply print and broadcast ads, as well as Internet communications that promote specific drug products but are not aimed at patients who have already obtained prescriptions -- that is, Internet communications that do not provide directions for use. See Ex. F at ¶ (I)(1)(iii)(c). While Internet websites that are directed to patients who have already obtained a prescription and thus provide directions for use are properly regarded as labeling, FDA should categorize as advertising those websites that are designed only to educate the general public about new treatment options and to prompt a physician consultation. Because of the need for consumers to obtain a prescription before purchasing prescription drugs, an Internet communication directed at consumers who do not yet have prescriptions is not part of an “integrated distribution program” for the advertised drug. See *Kordel v. United States*, 335 U.S. 345, 348, 350 (1948) (holding that pamphlets were “labeling,” not advertising, when they had a common origin and common destination and were thus parts of an “integrated distribution program”); *Alberty Food Prods. Co v. United States*, 185 F.2d 321, 325 (9th Cir. 1950) (newspaper advertisements were not distributed to ultimate purchasers as a supplement to the advertised product’s package label and were therefore not part of an integrated distribution program and not “labeling”). Such Internet communications also do not serve the same function as labeling and, as a result, are properly classified as advertising. See *Kordel*, 335 U.S. at 351 (literature distributed separately from the product is properly classified as “labeling” where it “performs the same function as it would if it were on the article or on the containers or wrappers”); *United States v. Urbuteit*, 335 U.S. 355, 357 (1948) (leaflets shipped separately were labeling when they were “designed to serve and did in fact serve the purposes of labeling”); *United States v. 24 Bottles Sterling Vinegar & Honey*, 338 F.2d 157, 159 (2d Cir. 1964) (literature will not serve the “same function” as labeling merely because it promotes the sale of the food or drug; “[t]he distinguishing characteristic of a label is that, in some manner or another, it is presented to the customer in immediate connection with his view and his purchase of the product”) (emphasis added).

202.1(e)(3)(iii)(b) would not apply to any “practitioner-directed” advertisements. The Coalition also proposes an amendment to paragraph 202.1(l), which would draw a bright line between consumer and practitioner-directed advertisements, confining the latter to advertisements whose expected audience is at least 80% professional.¹¹

Under new subparagraph 202.1(e)(3)(iii)(b), advertisers would be required to deliver, in language of their own choosing, three core messages in each consumer-directed advertisement that would prominently and effectively communicate the following information:

- (1) All prescription drugs, including the one being advertised, have potential benefits and potential risks,¹²
- (2) The advertised drug requires a prescription involving a professional weighing of all the potential benefits, risks and side effects for the individual patient;¹³ and
- (3) The patient should fully inform his/her health care professional about the patient’s medical history and about other medications the patient is using

¹¹ FDA used a similar expected audience approach to distinguish adult and youth-oriented publications in its proposed cigarette labeling regulations. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,513-19, 44,617 (Aug. 28, 1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897) (setting forth the agency’s definition of an “adult publication” as any publication whose readers age 18 and older constitute 85% or more of the publication’s readership). In addition, the FTC has long used similar measures for measuring the target audience for age appropriate advertising for adult products, including alcohol beverages. See FTC, *Self-Regulation in the Alcohol Industry: A Review of Industry Efforts to Avoid Promoting Alcohol to Underage Consumers* (Sept. 1999), available at <http://www.ftc.gov/reports/alcohol/alcoholreport.htm> (recommending the alcohol industry adopt the best prevailing industry practices to avoid promotion to underage consumers, including requiring a 60 to 70 percent legal-age audience for print media for alcohol advertisements, a 55 to 60 percent legal-age audience for radio, and a 70 to 75 percent legal-age audience for television placements) (Ex. H).

¹² The sponsor will take into account the severity and frequency of the side effects listed in the approved or permitted product labeling when determining how best to advertise a product. The proposed regulation specifically provides, however, that DTC ads must describe any prescription drug whose approved or permitted labeling includes a black box warning as having serious side effects. See Ex. F ¶ (e)(3)(iii)(b)(1).

¹³ The second core message -- discussing the need to have an individualized consultation with a physician -- also relates to the advertised drug’s effectiveness because it explains that consumers must evaluate with their doctors the potential benefits to them, as well as the potential risks, of taking the advertised drug. This core message conveys that while the prescription drug has been approved by FDA, only a licensed professional can determine whether the drug is likely to produce a positive effect for any particular patient. In this way, the core message helps to ensure a balance between the risk and benefit information presented in the ad.

to ensure the health care professional can make an appropriate prescribing decision.

The proposed regulation includes exemplary language to provide further guidance on how compliance could be effected.¹⁴ Manufacturers would remain free to choose any language that conforms to the substantive requirements. However worded, the substantive requirements would provide both a regulatory floor and ceiling for risk disclosure. Advertisers could neither omit, nor go beyond, the core messages required for safety purposes. Ex. F ¶¶ (e)(3)(iii), (iv). Furthermore, the FDA should assert full preemptive authority over all other would be regulators to ensure that these are the exclusive rules applicable to all prescription drug advertising anywhere in the United States.¹⁵

Recognizing that some patients may want and be able to access the professional labeling, the proposed regulation permits (but does not require) DTC advertising to reference a website (together with a toll-free number) where the approved or permitted package labeling or approved patient labeling is available. *Id.* ¶ (e)(3)(iv). The information so provided must advise patients:

- (1) That patients should consult a licensed practitioner to decide whether the advertised drug is right for them;

¹⁴ The proposed regulation suggests the following statement as an example of how sponsors could provide the core messages: "Like all drugs, [drug name] has both benefits and risks. [Drug name] is only available by prescription, and your doctor can explain how [drug name] is likely to affect you. Be sure to tell your doctor about all of your medical conditions, and about any other medications you are taking, because this information could affect whether you should take [drug name]. Remember, only your doctor can decide if [drug name] is best for you." See Ex. F ¶ (e)(3)(iii)(b).

¹⁵ FDA recently confirmed that, as "the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading," its requirements for the content and format of prescription drug labeling preempt conflicting or contrary State law. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601). FDA's prescription drug advertising regulation must also preempt State law requirements that would conflict with FDA's determination of the proper scope of risk disclosures in DTC within the context of FDCA section 502(n)'s brief summary requirement and section 503(b)'s requirement for restricting certain drugs to sale by prescription.

- (2) That FDA requires the advertised drug to be available only by prescription because it can be used safely only under the supervision of a licensed practitioner; and
- (3) That reading the labeling is no substitute for a discussion with a licensed practitioner.

The FDA should assume that the new regulatory scheme satisfies the intent of the current “fair balance” regime of Section 202.1(e)(5). Current application of the fair balance test in the DTC context is inherently subjective, overbroad and vague. A more precise definition would better enable companies to meet the intent of the current fair balance rules and avoid these pitfalls. Further, FDA’s current fair balance test reaches far beyond the threshold prong of the Supreme Court *Central Hudson* test, which requires only that an advertisement be truthful and not misleading to qualify for First Amendment protection.¹⁶ (Once advertising meets this threshold test, the FDA may regulate only where it can carry the burden of proof to demonstrate that the other requirements of *Central Hudson* test are met.)

The FDA has full authority to redefine its fair balance policy, and there are sound First Amendment reasons to do so. Section 502(n) of the FDCA defines and limits the authority of the FDA but does not require that prescription drug ads provide “fair balance” between risk and benefit information. FDA itself created the requirement when it promulgated regulations implementing Section 502(n), which requires only that prescription drug ads contain a “true statement” of information in brief summary. FDA is therefore free to revisit its interpretation of the statute and modify the fair balance requirement in Regulation 202.1(e). Given that the “true statement” language of the FDCA fully comports with the threshold prong of the Supreme Court’s *Central Hudson* test while the existing enforcement of “fair balance” does not, the FDA should instead focus on the false and misleading criteria set forth in Regulation 202.1. Indeed, it

¹⁶ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 563-64 (1980).

is the responsibility of regulatory agencies to construe their enabling statutes in ways that comport with constitutional law, rather than, as here, persist in enforcing a regime with questionable constitutionality.¹⁷

A number of consequential regulatory changes are proposed to fully implement the new regulation. Specifically, the proposal: reorganizes the numbering of FDA Regulation Section 202.1 to distinguish requirements relating to “false and misleading” issues from those relating to “brief summary”; restricts the final sentence of subparagraph (e)(1) -- relating to the “major statement” and “adequate provision” exceptions -- to professional advertising; and deletes current subparagraph (e)(6)(xx), which is redundant with subparagraph (e)(3) and properly relates to the brief summary requirement rather than FDA’s false and misleading inquiry.

2. Statutory Support for the Proposed Revision

FDA’s existing side effect disclosure requirements are intended to implement Section 502(n) of the Act (21 U.S.C. § 352(n)). That section requires prescription drug advertising to include a “brief summary” of information “*relating to*” an advertised drug’s side effects, contraindications, and effectiveness. By its words, Section 502(n) does not require comprehensive side effect disclosure or even specific side effect disclosure. Indeed, FDA itself concluded that the term “brief summary” could be applied flexibly when it published its “adequate provision” guidance for broadcast advertising disclosure and, more recently, when it cooperated with manufacturers to develop a more limited and readable print DTC advertising disclosure format.

¹⁷ See, e.g., *NLRB v. Catholic Bishop of Chicago*, 440 U.S. 490, 500 (1979) (“an Act of Congress ought not be construed to violate the Constitution if any other possible construction remains available.”).

The Coalition believes that its proposed DTC amendment falls squarely within the express language of Section 502(n). The amendment's "core" disclosure requirements present critical risk disclosures in brief summary relating to side effects and contraindications. Moreover, the Coalition believes that its proposed DTC regulation surpasses the existing regulation in meeting public health needs and implementing the FDCA's requirements "as a symmetrical and coherent regulatory scheme" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000). The Coalition has found nothing in the legislative history of Section 502(n) or the administrative history of 21 C.F.R. § 202.1 which would preclude FDA from going forward with its proposal. Indeed, consideration of the statutory scheme as a "harmonious whole," *Brown & Williamson*, 529 U.S. at 133, strongly suggests tension between FDA's application of existing Regulation 202.1 to DTC and the statutory scheme distinguishing prescription drugs from over-the-counter ("OTC") drug products in FDCA Section 503(b)(1) (21 U.S.C. § 353(b)(1)).

a. **The Import of the Section 503(b)(1) Prescription Drug Definition**

Before 1953, FDA-approved drugs could be distributed at the discretion of the manufacturer. In enacting the Humphrey-Durham amendments to the FDCA in 1951,¹⁸ however, Congress required the FDA to identify drugs which could not be used safely "except under the supervision of a practitioner licensed by law to administer such drug" 21 U.S.C. § 353(b)(1). Those drugs must be dispensed by prescription and must bear the Rx-only mark. They are also the subjects of FDA's DTC advertising restrictions.

¹⁸ See Humphrey-Durham Drug Prescriptions Act, Pub. L. No. 82-215, 65 Stat. 648 (1951) (amending 21 U.S.C. § 353(b)) (Ex. I).

In requiring FDA to designate prescription drugs for restricted dispensing, Congress implicitly recognized and endorsed the longstanding common law “learned intermediary” doctrine. Under that rubric, courts recognize that drug manufacturers owe duties of specific side effect disclosure to practitioners, rather than patients, and that practitioners must take responsibility for understanding those risks, relating them to the clinical situation of the patient, and counseling the patient appropriately. *See, e.g., Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966); *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334, 337 (N.D.W.Va. 1995) (noting that learned intermediary doctrine is “nearly universal”). Section 503(b)(1) reinforces and clarifies the allocation of responsibility under the learned intermediary doctrine by having FDA designate those drugs that should fall within it and distinguishing them from OTC drugs that, with appropriate labeling, may be used safely by patients without medical guidance.

The “brief summary” requirement in Regulation 202.1 unfortunately works at cross purposes to Section 503(b)(1) and has caused dangerous confusion in state court application of the learned intermediary doctrine. By merging disclosure requirements for professional and DTC advertising, Regulation 202.1 strongly suggests that it would be desirable, albeit infeasible, to communicate to patients all of the side effect risk information which should be provided to practitioners. It further implies that patients are capable of applying that information to their own clinical situations and using it. It thus challenges both the Congressional health care premise underlying Section 503(b)(1) and the practitioner-patient risk communication pathway that should be the natural concomitant of Rx-only distribution.

This conceptual collision causes more than just theoretical problems. Patients may conclude innocently, but wrongly, that an FDA-endorsed brief summary tells them all they need to know about the risks of taking a particular drug. They may then have difficulty in focusing on

a different risk assessment from their practitioners and may fail to seek the comprehensive, personal risk/benefit discussion which Section 503(b)(1) should foster. Even more seriously, they may purchase the drug without prescription or meaningful diagnosis from “bargain” web sites, or other non-U.S. sources, thus endangering their health. Conversely, they may be unduly “risk-deterred” from seeking consultation with their practitioners by warnings to which they overreact. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935 (FDA recognizing that “[e]xaggeration of risk could discourage appropriate use of a beneficial drug,” and that “[o]verwarning, just like underwarning, can . . . have a negative effect on patient safety and public health.”).¹⁹

Similar misunderstandings have arisen in judicial application of the “learned intermediary” doctrine to prescription drugs which are the subject of DTC. In *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1253 (N.J. 1999), for example, the New Jersey Supreme Court held that physicians play a “much diminished role as an evaluator or decisionmaker” with respect to those drugs and that manufacturers using DTC must take responsibility for comprehensive risk disclosure to patients. To the extent that Regulation 202.1 facilitates this mistaken analysis, it exerts pressure in exactly the wrong direction causing manufacturers to refrain from beneficial DTC or to overload DTC with incomprehensible but legally protective risk disclosure.

The Coalition’s proposed revision of Regulation 202.1 would closely track the thrust of Section 503(b)(1). It would reemphasize the public health importance of the “Rx only” designation and the critical role of practitioners in the risk information channel. It would avoid both stimulation of false confidence and overdeterrence. Moreover, by setting a preemptive

¹⁹ Recent studies show that the current manner of presenting risk information leads to an overestimation of risk among patients, and a reduced intent to comply with their prescriptions. *See* Sean D. Young and Daniel M. Oppenheimer, *Different Methods of Presenting Risk Information and Their Influence on Medication Compliance Intentions: Results of Three Studies*, 28 *Clinical Therapeutics* 129, 136 (Jan. 2006) (Ex. J).

ceiling as well as a floor on risk disclosure, it would strengthen the learned intermediary doctrine in state courts and avoid having the manipulation of that doctrine from serving as a ratchet to undercut the policy of Section 503(b)(1).

b. The Legislative History of Section 502(n)

Section 502(n) was added to the FDCA by the Kefauver-Harris Drug Amendments of 1962 (Pub. L. 87-781, 76 Stat. 780) (Ex. K). At that time, constitutional protection for commercial speech was effectively non-existent and prescription drug DTC was not in use. Through Section 502(n), Congress shifted responsibility for regulating physician-directed advertising and promotion from the Federal Trade Commission to the more narrowly-focused FDA. As explained in the Senate Report on the bill, one of its key objectives was to “provide physicians with better and more adequate information about drugs and correlatively to reduce the dissemination of information which is false and misleading.” S. Rep. No. 87-1744 (1962) *reprinted in* 1962 U.S.C.C.A.N. 2884, 2898 (Ex. L); *accord* H. Rep. No. 87-2464, at 1-2 (1962) (Ex. M). Moreover, the extensive floor debate, while replete with references to enhancing the flow of information to physicians, makes no reference to patient information. *See, e.g.*, 108 Cong. Rec. 17,368, 21,084, 21,086, and 21,091 (1962) (Statements of Sen. Kefauver and Reps. Blatnik, Dingell, and Multer) (Ex. N). In short, nothing in the legislative history of Section 502(n) requires or even suggests the current “brief summary” requirement for DTC nor gives any basis for requiring parallel treatment of physician and patient advertising disclosures.

c. The Administrative History of FDA Regulation Section 202.1

FDA conducted an extended rulemaking exercise between 1963 and 1969 to implement Section 502(n).²⁰ As with the Congressional debate, FDA’s rulemaking exercise focused

²⁰ *See, e.g.*, Drugs; Statement of Ingredients; Prescription-Drug Advertisements, 28 Fed. Reg. 6375 (June 20, 1963) (initial rule as promulgated) (Ex. O); Prescription-Drug Advertisements; Confirmation of Effective Date of Order

exclusively on communications to practitioners and made no mention of DTC. See Letter of George P. Larrick, Commissioner of Food & Drugs, Oct. 1, 1963, *reprinted in* Compendium of Medical Advertising, FDA Pub. No. 40, at 7 (June 1967) (Ex. Q); Statement of James L. Goddard, M.D., Commissioner of Food & Drugs, Before the Subcommittee on Intergovernmental Relations of the House Committee on Government Operations (May 25, 1966), *reprinted in* Compendium of Medical Advertising, FDA Pub. No. 40, at 34 (June 1967) (Ex. R). With that focus, FDA decided to give an expansive interpretation to the term “brief summary,” effectively requiring reproduction of the entire risk-related text of the product labeling in all promotional communications.

FDA first began serious consideration of applying Section 502(n) to DTC in the early 1980s. At that time, expanded media outlets and the development of constitutional commercial speech doctrine created pressure for DTC and highlighted the significant impediment to economically effective DTC that would result from applying Regulation 202.1 to DTC. As candidly explained to Congress by then Commissioner Arthur Hull Hayes, Jr.:

It is true that our current regulations make broadcast advertising of prescription drugs virtually impossible on the commercial networks and impose significant impediments to effective use of print media, but this is so mainly because these regulations were not developed to govern advertising in a format aimed at lay persons. It may well be that direct advertising to lay persons is an inappropriate means of promoting prescription drugs, and that the regulations should continue to impose strict requirements on this form of advertising if it is to be conducted at all. But that result should be the product of a conscious decision, following comprehensive public discussion, and not of the adventitious fact that the current regulations do not, as a practical matter, permit something they were not intended to address.

Acting Upon Objections, 34 Fed. Reg. 11,357 (July 9, 1969) (noting effective date of order amending regulation) (Ex. P).

Letter from Arthur Hull Hayes, Jr., Commissioner of Food & Drugs, to Rep. John D. Dingell, Chairman, Subcommittee on Oversight and Investigations, August 23, 1983, at 1 (emphasis added) (Ex. S).

Commissioner Hayes, apparently of the mistaken belief that FDA could constitutionally ban DTC, went on to explain that FDA was still considering whether DTC “would be appropriate or beneficial to the public.” *Id.* at 11. He stated that FDA would make disclosure decisions in the context of its more fundamental review of the public health value of DTC and that FDA had requested a voluntary moratorium on DTC so that it could comprehensively study the issue:

We have not decided whether prescription drug advertising to consumers is appropriate and, if so what form it should take. I have appealed to the pharmaceutical community to exercise restraint in initiating prescription drug advertising campaigns to give the (FDA) time in which to study the possible effects that this form of drug promotion may have on a lay audience.

Id. at 1.

The voluntary DTC moratorium lasted until September 1985. FDA, while acknowledging that the purpose of the moratorium to have a DTC regulation which was “the product of conscious decision, following comprehensive public discussion,” *id.*, conducted no public hearings and proposed no regulations in the moratorium period. Rather, on September 9, 1985, FDA simply published a notice that it was terminating the moratorium and permitting Section 202.1 to regulate DTC by extension of its literal wording. *See Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium*, 50 Fed. Reg. 36677 (Sept. 9, 1985) (Ex. T). FDA’s terse explanation was that “for the time being, current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers.” *Id.* at 36678. Thereafter, until its most recent round of constitutional inquiry and broadly-focused public hearing on DTC’s public health contribution, FDA’s sole regulatory action -- albeit an

important one -- was issuance of its 1999 broadcast disclosure guidance which explained to advertisers how to make “adequate provision” in broadcast ads for the dissemination of package labeling in order to qualify for an exemption in Section 202.1(e) from the otherwise comprehensive “brief summary” requirement.²¹

It is at least arguable that, by its 1985 inaction, FDA created a new substantive DTC rule without the public notice and opportunity for comment required by FDCA Sections 502(n)(3) and 701(e) (21 U.S.C. §§ 352(n)(3), 371(e)) and the Administrative Procedure Act (5 U.S.C. § 553(b)). The 1963-1969 rulemaking giving rise to Regulation 202.1 gave no opportunity for public comment on the proper purposes of DTC risk disclosure because FDA’s notices never raised the issue.²² When FDA considered it in the early 1980s, it did so with no public process²³ and resolved the question by declaring that a literal fortuity gave it a pre-existing regulation on which to rely.²⁴ These actions violate the spirit, if not the letter, of mandatory rulemaking

²¹ See FDA, *Guidance For Industry, Consumer-Directed Broadcast Advertisements* (posted Aug. 6, 1999), <http://www.fda.gov/cder/guidance/1804fnl.pdf>.

²² See *Am. Med. Ass’n v. Reno*, 57 F.3d 1129, 1132 (D.C. Cir. 1995) (holding that notice “must include sufficient detail on its content and basis in law and evidence to allow for meaningful and informed comment”).

²³ Providing “notice” at the time the rule is adopted and allowing subsequent comment does not satisfy the statutory procedural requirements for notice and comment rulemaking. See *Air Transp. Ass’n v. Dep’t of Transp.*, 900 F.2d 369, 379 (D.C. Cir. 1990) (strictly enforcing the requirement that notice and an opportunity for comment precede rulemaking because “an agency is not likely to be receptive to suggested changes once the agency ‘put[s] its credibility on the line in the form of ‘final’ rules.”); *Nat’l Ass’n of Farmworkers v. Marshall*, 628 F.2d 604, 621-622 (D.C. Cir. 1980) (“ongoing sensitivity to developing knowledge is to be encouraged; it is a normal requirement of competent administration. It does not, however, justify suspension of requirements otherwise mandated for the initial promulgation of regulations.”) (citation omitted).

²⁴ FDA cannot argue that the rule was exempt from the notice and comment procedures on the ground that it was an “interpretive rule.” Extending the prescription drug advertising regulation to DTC cannot be interpretive rule because it “effects a change in existing law or policy” for DTC, it supplements, rather than construes, the brief summary rule set forth in the FDCA, and it clearly intends to “impose obligations, or produce other significant effects on private interests.” *Nat’l Family Planning and Reprod. Health Ass’n Inc. v. Sullivan*, 979 F.2d 227, 237-238 (D.C. Cir. 1992) (internal citations omitted). Moreover, the APA expressly provides that agencies may forego notice and comment procedures for interpretive rules “Te]xcept when notice or hearing is required by statute.” 5 U.S.C. § 553(b) (emphasis added). Because FDCA Section 502(n) specifically requires notice and comment with the opportunity for a hearing when FDA issues, amends or repeals regulations implementing the brief summary provision, the exemption for interpretive rules is not available. See 21 U.S.C. §§ 352(n)(3), 371(e)(3).

requirements. In any event, they clearly foreclose any contention that FDA's current "brief summary" approach is the product of a carefully considered administrative process.

3. Constitutional Considerations Favoring the Proposed Revision

In 1985, when FDA ended the moratorium and applied the professional advertising standards of Regulation 202.1 to DTC, the constitutional law of commercial speech was in its early stage of development. FDA, in fact, was of the view that *Pittsburgh Press*²⁵ gave it pervasive power over DTC as part of its comprehensive regulatory program, including the power to ban DTC altogether. Given that "greater power," FDA made no constitutional analysis whether the First Amendment restricted its authority to impose mandatory side effect disclosure requirements on DTC.

After the Supreme Court's 2002 decision in *Western States*²⁶ and a number of lower court decisions,²⁷ it is now beyond argument that FDA must respect First Amendment boundaries in regulating DTC. The Coalition believes that the comprehensive mandatory side effect disclosure requirement of Regulation 202.1 improperly crosses those boundaries.

A mandatory DTC disclosure requirement, applied without regard to the affirmative claims being made, could be justified constitutionally only if all DTC without such disclosure were "inherently misleading," which [means] 'more likely to deceive the public than to inform it.'" *Washington Legal Found. v. Friedman*, 13 F. Supp.2d 51, 66-67 (D.D.C. 1998) (internal citations omitted). The fact that a DTC advertisement provides some, but not all, truthful information about a drug would not, by itself, make the advertisement deceptive. Only if the

²⁵ *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376 (1973).

²⁶ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

²⁷ See, e.g., *Washington Legal Found. v. Friedman*, 13 F. Supp.2d 51 (D.D.C. 1998); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

advertisement were to create a false impression that the prescription drug was risk free and could be taken without a benefit/risk evaluation with a licensed prescriber could the likelihood of deception outweigh the value of truthful efficacy information. Moreover, because prescription drug DTC is designed to stimulate a patient-practitioner interaction rather than a purchase, any risk of deception is substantially lessened by the role that the learned intermediary must play under Section 503(b)(1). Thus, a general disclosure that a prescription drug has risks that need to be weighed against its therapeutic benefits clearly suffices to avoid “inherent deception” and FDA can command additional specific risk disclosure only if that disclosure can withstand constitutional review under the bellwether *Central Hudson* criteria.²⁸

Where FDA disclosure requirements are imposed on truthful and non-deceptive DTC, FDA bears the constitutional burden of defending them by showing that they serve a substantial government interest; that the government interest is directly advanced by the requirements; and that the requirements are reasonably tailored to advance that interest without unduly restricting protected speech. Regulation 202.1, as applied to DTC, may fail on each of these grounds.

First, the absence of any formal process in 1985 when the professional advertising rules were applied without change to DTC means that a substantial government interest in specific side effect disclosure cannot be gleaned from the administrative record. In the professional advertising context, there is clearly a substantial government interest in giving practitioners ready access to the information needed to inform their professional judgment. By contrast, that information is not readily understood or applied by patients who, as a matter of law, cannot make prescribing decisions. Thus, it is, at best, unclear whether the absence of specific risk disclosure creates the type of harm that constitutionally justifies a government remedy. *See Edenfield v.*

²⁸ *Cent. Hudson*, 447 U.S. at 566.

Fane, 507 U.S. 761, 770-71 (1993) (the government cannot justify speech restrictions with “mere speculation or conjecture,” but “must demonstrate that the harms it recites are real.”); accord *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001).

Second, even assuming that FDA could claim a substantial interest in mandating disclosure to better equip patients to discuss side effect risks with prescribers, demonstrating the “direct advancement” of that interest by existing brief summary requirements could be an uphill battle. Again, in the professional advertising context, the immediate availability of labeling information otherwise prepared for practitioner prescribing use directly advances enhanced prescribing decisions. In the DTC context, however, patients cannot make prescribing decisions and it is just as likely that the availability of specific risk disclosures in DTC will truncate patient-practitioner interchanges as enhance them. Both patients and busy practitioners may wrongly assume that the availability of risk information in DTC is equivalent to its comprehension.²⁹ By contrast, the simple, unequivocal messages proposed by the Coalition that risks must be discussed between patient and practitioner far more clearly advance the public health interest in meaningful patient-practitioner exchanges. As a result, the Coalition’s proposal satisfies the *Central Hudson* standard in a way the current regulation may not. See *Edenfield*, 507 U.S. at 771 (the “direct advancement” prong requires disclosures to “in fact alleviate [the asserted harm] to a material degree.”); *Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 192-93 (1999) (a regulation cannot be sustained if there is “little chance” that the restriction will advance the state’s goal in the “context of the entire regulatory scheme”).

²⁹ Anecdotal evidence demonstrates that many consumers are foregoing a doctor consultation and consider themselves sufficiently informed to decide whether or not to use any prescription drug. See Amy Harmon, *Young, Assured and Playing Pharmacist to Friends*, N.Y. Times, Nov. 16, 2005 (discussing the growing trend of consumers ordering prescription drugs on the Internet and trading prescription drugs with friends, without consulting a licensed professional) (Ex. U). The current brief summary format effectively confirms that consumers are capable of making independent decisions about whether to use a particular prescription drug.

Third, to the extent that FDA attempts to contend that existing DTC risk disclosure requirements do advance a substantial government interest in enhanced patient-practitioner risk interchanges, it remains questionable whether they are “more extensive than reasonably necessary” to further that interest. *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 476-77 (1989). Indeed when the less burdensome alternative proposed by the Coalition is considered, the costs and complexities imposed on advertisers by the existing rule are clearly not “narrowly tailored.” *Id.*; *see also Cincinnati v. Discovery Networks, Inc.* 507 U.S. 410, 418 n.13 (1993) (explaining that courts must examine whether “there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech.”).

In short, Regulation 202.1 as applied to DTC stands on shaky constitutional ground. Petitioner’s proposed revision, on the other hand, has deep constitutional roots as well as public health benefits.

4. Record Support for the Proposed Revision

In developing the proposed revisions to Regulation 202.1, the Coalition was guided by four critical communications concepts; centrality (focusing on the “main thing”); simplicity/comprehensibility; clarity and ease of administration; and retainability. Each of these concepts was explored in FDA’s recent hearings and each supports adoption of the Coalition’s proposal.

a. **Centrality**

The Coalition believes that the core messages in proposed subparagraph 202.1(e)(3)(iii)(b) convey the most important risk information a prospective patient needs at the time he/she is receiving a DTC promotional message. *See Wayne L. Pines, A New Approach to Risk Disclosure in DTC Advertising*, FDLI Update, Nov./Dec. 2004, at 4 (Ex. V). The patient must understand that the advertised drug can be harmful, as well as helpful, and that embarking

on the advertised drug therapy requires an individualized diagnostic assessment by a licensed practitioner leading to a patient-practitioner benefit/risk exchange. At the threshold point in the prescribing process where DTC has its impact, it is not possible for prospective patients fully to identify and understand specific side effect risks. The patient is the decision-maker only with respect to whether a practitioner should be approached. If, as the core messages prompt, the patient approaches a DTC-prompted interaction with the practitioner ready to discuss and apply to his/her treatment information which the practitioner can best convey, any lack of risk appreciation at the DTC reception point can be remedied.

At the September 2003 hearing, Mr. Michael Roberts of Catalina Health Resource advocated a staged approach to risk disclosure in which the amount of risk information provided would vary based on “where the consumer is in the process of learning about a prescription drug.”³⁰ The Coalition’s proposal builds on this idea. Dr. Ruth Day of Duke University, testifying at the same hearing, specifically considered a general risk statement in DTC such as “all drugs have potential benefits and risks depending on how they are used and who uses them.”³¹ Dr. Day believed that widespread dissemination of such a message could enable patients to “have a better framework for storing [the ideas], ‘I need to know about the benefits. I need to know about the potential side effects.’”³² Dr. Day’s concept also supports the Coalition’s core messages proposal.

The third core message helps condition patients to recall and disclose information uniquely in their possession that can improve prescribing decisions. The Coalition recognizes

³⁰ Hearing Transcript, Direct-To-Consumer Promotion: Public Meeting, at 76 (Sept. 23, 2003), <http://www.fda.gov/cder/ddmac/DTCmeetingTranscript2.doc> (last visited Mar. 29, 2006).

³¹ See Hearing Transcript, Direct-To-Consumer Promotion: Public Meeting, at 250 (Sept. 22, 2003), <http://www.fda.gov/cder/ddmac/DTCmeetingTranscript.doc> (last visited Mar. 29, 2006).

³² *Id.*

that skilled practitioners seek this information, and that this core message will expedite and improve these discussions when patients come prepared to disclose their current drug and condition history. Moreover, the Coalition believes that this disclosure requirement, which speaks directly to patient action, reinforces the other core messages and helps overcome the idea that patients can self-medicate with the advertised drug.³³

b. **Simplicity/Comprehensibility**

The Coalition carefully designed the core messages so that they could be conveyed in simple words and short sentences. As demonstrated by the example included in the proposed regulation,³⁴ the core messages can easily be framed so that they are comprehensible to consumers with virtually any level of reading ability and scientific background. In addition, the messages do not call upon the consumer to apply the information being conveyed. Rather, the consumer is informed that the drug has potential risks and advised to discuss these potential risks, along with his/her drug and condition history, when a prescription is being evaluated. Fewer disclosures will focus and improve the communications.

The hearing record established that patients exposed to DTC have widely varying reading comprehension skills and scientific knowledge.³⁵ Those at the high end of the continuum derive

³³ The possibility that specific side effect risk disclosures will induce a false self-medication confidence is not trivial. Physicians have expressed concern that consumers who have viewed DTC advertising do not have a clear understanding of the relative risks and benefits of advertised drugs or of an advertised drug's appropriateness for them. Aikin presentation, at slide 47 (citing *FDA Physician Survey (2002)*) (60% of physicians surveyed said that patients who have viewed DTC advertisements understand only a little or not at all the possible risks and negative effects of advertised drugs; 70% said these patients do not understand the limitations of drug efficacy; 72% said these patients do not understand who should not use a drug). A recent proposal in the New Hampshire legislature speaks directly to this concern by requiring an anti-self medication message in all drug and device DTC. H.R. 1542, 2006 Sess. (N.H. 2006) (Ex. W).

³⁴ See Ex. F ¶ (e)(3)(iii)(b); see also, *supra*, note 14.

³⁵ See Hearing Transcript, Direct-To-Consumer Promotion of Medical Products: Public Meeting, at 43-44, 48 (Nov. 1, 2005), <http://www.fda.gov/cder/ddmac/dtc2005/transcript1.pdf> (last visited Mar. 29, 2006) (Dr. Lewis Glinert of Dartmouth College discussing the impact of the listener's identity on comprehension of risk information, and noting that elderly, low-literate, and non-American groups may have a particularly difficult time understanding current risk

the greatest benefit from specific risk disclosures and are most likely to pursue in-depth knowledge from company web sites and independent sources. The proposed regulation accommodates their interests by permitting reference to a website or toll free number where complete professional labeling can be obtained. It further protects them against erroneous overconfidence by the additional disclaimers required when the professional labeling is provided.

Other consumers with different educational and economic backgrounds receive and process information at a less sophisticated level. For them, the proposed amendment more aggressively ensures equal access to information about medicines. See Pauline M. Ippolito and Alan D. Mathios, *Health Claims in Advertising and Labeling, A Study of the Cereal Market*, Bureau of Economics Staff Report, Federal Trade Commission, August 1989. FDA must be fully conscious of the possibility of elitist concepts in regulatory disclosure when regulators require information best understood at their own comprehension level. Professional advertisers begin any inquiry in persuasion by studying the targeted audience, their knowledge, understanding, attitudes and interests. Highly educated doctors, lawyers and health professionals may not be fully attuned to these basic consumer concepts. The Coalition's goal in the proposed regulation and advisory committee is to ensure that new approaches are based in the science of consumer behavior rather than regulatory intuition.

disclosures); *Id.* at 151-152 (William Person, President of 50 Plus WEBHealth, proposing that FDA's communications policy include a distinct market segmentation strategy, based on such factors as age, language, and differences in vision, reading and memory retention, to ensure the message is delivered, received and understood); William Person, *Consumer Directed Promotion of Regulated Medical Products, Presentation to FDA*, at slide 6 (Nov. 1, 2005), <http://www.fda.gov/cder/dmac/dtc2005/Personppt.ppt> (last visited Mar. 29, 2006); see also CHC/Pringle Consumer-Directed Promotion Comments at Part One: 15 (noting that "consumers' demographic/psychographic backgrounds, access to information, and health-related knowledge/experience also contribute to their ability to comprehend and the willingness to attend to information given in broadcast advertisements.").

c. **Clarity, Objectivity and Ease of Administration**

The simplicity and limited scope of the Coalition's proposed regulation will greatly facilitate compliance by DTC advertisers and supervision by DDMAC. Difficult questions relating to the parameters of "adequate provision" and the achievement of "fair balance" will be eliminated. Violators of the new "core messages" requirement will be readily identified and will have little opportunity to claim confusion or complexity as an excuse.

While the Coalition's proposal eliminates the overly subjective concept of "fair balance," it retains the false and misleading criteria FDA uses to determine whether an advertisement, either by affirmative representation or omission, is in any way untruthful. Moreover, the new brief summary requirement mandates that the core messages be effectively communicated. Thus, in accordance with FDA's current regulatory requirements, the core message requirement is applicable to the entire advertisement. *See* 21 C.F.R. § 202.1(e)(3) ("Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in another distinct part of the advertisement"). Advertisers will not satisfy the core message requirement if the messages are not a perceptible component of the ad as a whole.

d. **Retainability**

The Coalition recognizes that prospective patients exposed to DTC rarely are in a position to act on it immediately. The goal of the advertiser is to create a condition/product imprint sufficient to prompt the consumer to contact an authorized prescriber and inquire about the drug or condition. From the advertiser's perspective, that contact is the desired endpoint and it does not matter whether the consumer retains the specific efficacy information presented, so long as the DTC exposure is consultation motivating.

Under FDA's current regulatory approach, however, it is important that the patient both comprehend specific side effect disclosures and retain that information through the point when

the prescribing decision is made. Unless the patient retains the specific side effect information provided in DTC, it may play no role in the decisional process or, in a best case scenario, have to be re-conveyed by the practitioner. If the specific disclosure, in the majority of cases, has no greater impact than the Coalition's proposed core "discussion" admonitions, there is no public health benefit in retaining a complex, potentially incomprehensible, administratively burdensome disclosure regime, with all the attendant risks of false confidence, when a superior alternative is readily available.

The record has established that patients have difficulty in comprehending the encyclopedic risk disclosures in the current brief summary.³⁶ By paring down the quantity of risk-related information in DTC, and requiring the core messages to be imprinted repetitively, the Coalition's proposal better assures that the most important messages will be understood, retained, and acted upon by patients.³⁷ In addition, by reducing the clutter of product-specific side effect warnings, the Coalition's proposal will enhance the effectiveness of advertising messages. Patients will not only better understand the advertised drug's potential benefits, but also the critical safety information needed as they move to the next stage of the adoption process, including their conversations with prescribers.

³⁶ See FDA Survey Research Results at 25 (55% of patients surveyed in 2002 who read at least some of the brief summary described it as "very hard" or "somewhat hard" to read); see also CHC/Pringle Consumer-Directed Promotion Comments at Part One: 13 (discussing studies showing "a remarkable decline in the ability of [an] advertisement to communicate effectively as the number of alternatives (or attributes and/or message elements) increased."); Draft Brief Summary Guidance at 2 (acknowledging consumers' lack of "[a] technical background" and difficulty in understanding and retaining exhaustive lists of risks).

³⁷ See CHC/Pringle Consumer-Directed Promotion Comments at Part One: 9-11, 13-16, 25-27, 30 (demonstrating that consumers are more likely to understand and remember simple, generalized messages than complex, particularized messages about risk); see also *id.* at Part One: 26 ("Even though mass media advertising may be quite well suited to creating general awareness of the overall risk of Rx communications, it simply is *not* suited to accomplish the stated objective of rendering in its objects the desired levels of detailed and complex understanding.").

In sum, the Coalition believes that the extensive record FDA recently has assembled on DTC clearly supports, if not demands, a fresh look at the current DTC regulatory regime, especially the risk/disclosure paradigm. The Coalition believes that this petition presents a compelling public health and legal case for initiating such a review to examine, with full public participation, the regulation of DTC. The Coalition is confident that the outcome of such review would be a substantial increase in the public health benefits for patients already being generated by DTC.

D. Environmental Impact

As provided in 21 C.F.R. § 25.30(h), the petitioners believe this petition qualifies for a categorical exclusion from the requirement to submit an environmental assessment or environmental impact statement.

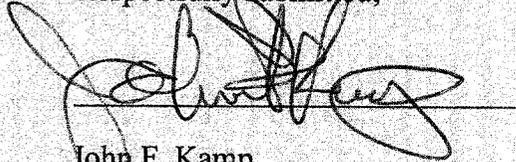
E. Economic Impact

As provided in 21 C.F.R. § 10.30(b), the petitioners will submit economic impact information upon request of the Commissioner.

F. 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 petitioners which are unfavorable to the petition.

Respectfully submitted,



John F. Kamp
Executive Director
Coalition for Healthcare Communication³⁸
405 Lexington Avenue
New York, NY 10174-1801
(212) 850-0708, (202) 719-7216

Of Counsel:

Bert W. Rein
Sarah E. Botha
WILEY REIN & FIELDING LLP
1776 K Street N.W.
Washington, D.C. 20006
(202) 719-7000

³⁸ A current list of Coalition members is provided at Exhibit X.