Before the
U.S. Food and Drug Administration
Rockville, MD

In the Matter Of:	)	**Docket No. 2003N-0344**
Consumer-Directed Promotion	)	

COMMENTS OF PFIZER INC

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Pfizer Inc ("Pfizer") respectfully submits that two paramount facts emerge forcefully from the substantial record amassed at FDA's September 2003 open hearing on "direct to consumer" promotional communications ("DTC").[1] First, DTC significantly advances the public health. Second, allegations of harms arising from DTC are just that—allegations lacking a factual basis.[2]

In short, the agency's current DTC rules and policies are working as they should: the regulations foster messages that motivate and enable consumers to engage in thoughtful, constructive dialogue with doctors about their health conditions and treatment options. FDA would be ill-advised to embark on any precipitous change to the current regime without first having confidence, grounded in solid research, that any such revision would not threaten these substantial public health interests.

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[1] Consumer-Directed Promotion; Notice of Public Meeting and Request for Comments, 68 Fed. Reg. 47920 (Aug. 12, 2003).

[2] We use the term "DTC advertisements" or "DTC advertising" herein to refer to DTC messages presented through traditional 30-second broadcast spots and magazine and newspaper print advertisements. We use the term "DTC communications" or "DTC" to refer to the larger body of DTC messages generally, which include not only traditional advertisements but also brochures, websites, audio presentations, etc. The term "regulations" herein refers to all FDA rules, policies, and guidances governing DTC communications.

STATEMENT OF INTEREST

Pfizer is the world's leading research-based pharmaceutical company. Our prescription drug products are approved as safe and effective by FDA. They make major, and in many cases unique, contributions to human health. Expanding access to Pfizer products by disseminating knowledge about the conditions they treat and the benefits they afford—*i.e.*, marketing—serves our corporate interest, our customers' interest, and the public health interest which FDA is charged to protect.

Pfizer markets its products at all levels of the health care system. Our primary marketing focus is educating physicians about disease and treatment options. By current law, and appropriately so, only doctors and associated health-care professionals may make the decision to prescribe drugs for their patients. Because these professionals assess and diagnose the individual patient, we believe this relationship is central to the public health. We also expend substantial resources on DTC communications because we believe that

- reaching and motivating the under-diagnosed and under-treated increases and enhances the appropriate use of our products and the health of our customers;
- enhancing the consumer's understanding of conditions and available treatments can promote doctor visits and a better exchange between physicians and empowered patients; and
- reminding consumers of drug therapies enhances compliance with use prescribed by the physician and other elements of a successful therapeutic regime.

We therefore believe that DTC communication is a paradigm case of the "invisible hand" guiding private self-interest to serve the public health interest.

In framing our DTC communications, Pfizer seeks to support and not to supplant the role of treating physicians. By arousing interest and motivating doctor-patient interactions, we accentuate our repeated admonitions that no drug is right for all patients, that all drugs have some potential adverse effects which must be evaluated in individual cases, and that only an

informed decision made by a physician justifies a prescription. We gladly make information available to interested consumers via print advertisements, web sites, and toll-free telephone numbers. We believe that those consumers with sufficient interest to pursue this information will use it to engage more thoughtfully with their physicians. We would be concerned, however, about any regulatory requirement that might require presentation of risk information in a manner that might intimidate untreated consumers or otherwise deter doctor-patient contacts.

As a substantial generator of DTC communications, we are very much interested in their effect and effectiveness. Pfizer witnesses made themselves and the data they had accumulated available to FDA at the September 22-23 hearing. Pfizer has also engaged in, and supported, many other consumer health care information efforts. These include our own Clear Health Communications Initiative, through which Pfizer is developing a number of tools that both consumers and health-care professionals can use to further patient comprehension of medical conditions and medications. We also partner with health-care entities such as the American Medical Association Foundation and the National Coalition for Literacy in the "Ask Me 3" Initiative, an innovative program designed to encourage consumers to ask good questions of their health-care providers and to improve doctor-patient dialogue. Pfizer also reaches out to non-English speakers through such efforts as our new "Amigos En Salud" consumer education initiative, in which we work with a local health center in Texas to assist low-income Hispanic consumers in understanding how to appropriately treat—and live successfully with—diabetes.

Pfizer believes that DTC presents a remarkable alignment of private interests with FDA's interest in advancing the public health. If FDA should seek to more closely examine the impact of discrete elements of DTC communications on patients and physicians to fill the gaps in the existing record, Pfizer would be pleased to contribute to that ongoing process.

SUMMARY

The data collected in this docket corroborate the wisdom of FDA's 1997 decision to ease earlier restrictions on DTC broadcast advertising. That decision, along with the agency's growing understanding of the value of DTC communications, has brought significant advances to the public health. First, advertising of prescription medicines brings important public health information to many millions of Americans. The information plainly serves as a catalyst that prompts many consumers to visit their physicians. Moreover, advertising-initiated consultations are characterized by an enriched exchange of information and views between patients and physicians, as well as treatment of previously under-diagnosed or under-treated conditions. In addition, DTC advertising supplies these public health benefits with no expenditure of public funds.

Many studies in the record corroborate the positive impact of DTC on consumer health:

- DTC advertisements are making patients more aware of medical conditions they or family members might have, and of new treatment options that are available. *(FDA, Prevention, Hausman, Kassan, Verispan (Scott/Levin),[3] Market Measures/Cozint, Pfizer/Magee, NCL)*

- DTC advertisements are motivating consumers to talk to their doctors about their medical conditions and ask more questions about their health care. *(FDA, Prevention, COSHAR, NCL, Hallberg, Pfizer/Magee, Verispan (Scott/Levin), Market Measures/Cozint)*

- Advertising-driven conversations are resulting in new diagnoses of important conditions. *(FDA, Weissman (Harvard/Harris))*

- Patients report positive interactions with their physicians when discussing advertised drugs *(FDA, Prevention, COSHAR, NCL)*, and physicians report that DTC advertising has either helped or not harmed their interaction with patients. *(FDA, NMA/COSHAR, Market Measures/Cozint)*

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[3] Pfizer will file shortly an addendum providing the material referenced in these comments that is not otherwise in this record or readily available to the agency.

- Physicians report that patients ask about products that are appropriate for them and their condition *(FDA, Market Measures/Cozint)*, and empirical evidence confirms that DTC advertising does not result in improper prescribing. *(Dubois, Calfee)*

- Patients report that seeing DTC advertisements makes them more likely to comply with treatment, and makes them feel better about the treatment they have been prescribed. *(FDA, Prevention, COSHAR, NCL, Smith, Pfizer/Magee)*

- Physicians also believe that patients who participate in treatment decisions are more compliant. *(FDA, Weissman (Harvard/Harris))*

In short, the record demonstrates that DTC messages initiate a critical communications cycle that benefits the public health by spurring interested consumers to seek out additional information about prescription drugs and the conditions they address, to consult their doctors for diagnoses and proper treatment, and to stay on the drug and/or other therapy regimen that their doctors prescribe.

Conversely, those who broadly criticize DTC as leading to wasteful or "second best" prescriptions—by raising the costs of individual drugs or overall drug therapy and by evading regulatory disclosure limitations—failed to present any data significantly supporting their positions. The image of patients overriding the medical judgment of doctors to gain access to advertised drugs that they do not need might have political traction, but it lacks empirical foundation. The concept that advertising costs must cause drug price increases is conjectural and unsupported. Advertising costs are better recovered by increased sales, and data in the record confirm that advertising and price increases do not correlate. There is a valid premise to the argument that persuading the under-diagnosed and under-treated to seek help raises overall drug expenditures, but improving the health of more consumers is a social benefit, not a social cost. This is particularly true when outpatient drug treatment substitutes for far more expensive therapies and hospitalization.

In addition to the data on the public health benefits of DTC communications, the record here contains evidence that, to be effective, health messages to consumers must be presented clearly and concisely. This suggests that consumers might benefit from an agency reevaluation of some of the more arcane linguistic formulations contained in the current brief summary provided in DTC print communications. FDA should bear in mind that the quantity and wording of information designed for physicians is not necessarily appropriate or useful for patients.

The record is not developed on the effectiveness of the current risk disclosures mandated by FDA. Although both witnesses and FDA officials discussed supplementing risk information requirements at the September hearing, there is little or no data before the agency at this point concerning how such information should be presented effectively in DTC communications. Actual evidence was lacking on several key points—including rather basic but important issues such as how to avoid the "cacophony of data" problem that FDA, in its Strategic Action Plan of August 2003, already has identified.

Even more fundamentally, it is not clear that FDA has fully determined the *effect* it seeks to achieve by risk disclosure. Before the agency makes any effort to amend its beneficial regulatory approach to DTC, it must address a key preliminary question: What specific goal might FDA seek to achieve by requiring DTC communications to more comprehensively present risk information? Informing consumers obviously is a potential goal, but to what end? Pfizer respectfully suggests that FDA's regulatory objective cannot stop at simply "better informing consumers." In the context of prescription drugs, informing consumers can only be a first step because the consumer alone cannot act on whatever information—benefit or risk—is presented. A physician must prescribe the product before a patient can use it. Therefore, FDA's ultimate objective, like that of Pfizer, should be to motivate consumers to *act* by consulting their doctors

and engaging in better dialogue with them about their individual health situations. Focusing explicit attention on this consumer behavior goal will help FDA in fashioning better DTC policies and also assist it in compiling an empirical record that comports with legal requirements.[4]

Pfizer understands that for consumers to be meaningfully "empowered" within today's doctor-patient relationship, they must have a meaningful interchange with their physicians. Consumers should understand that every drug carries risks—and be prepared to assess, in consultation with the doctor, the risks of any drug that might be prescribed for them. Nevertheless, consumers cannot be expected (or induced) to believe that they are sufficiently informed to make judgments about relative benefit and risk without the assistance of their physicians.

Similarly, more burdensome disclosure requirements might have the unintended consequence of materially decreasing manufacturer incentives to direct resources to DTC communications. FDA should not take actions that induce manufacturers to move away from a form of communication that provides significant public health benefits.

The lodestar for fashioning an effective risk disclosure policy, Pfizer believes, is to neither under-inform nor over-deter consumers—a balancing act that keeps its focus on giving consumers enough information to appreciate the basic issues and to comprehend the desirability

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[4] Pfizer already has commented in detail on the relevant legal issues in its response to FDA's First Amendment Inquiry last year. *See* Comments of Pfizer Inc, Request for Comment on First Amendment Issues, Docket No. 02N-0209 (filed Sept. 13, 2002) (hereinafter "Pfizer First Amendment Comments"). Pfizer devoted a significant portion of these comments to the constitutional framework governing FDA's ability to regulate promotional speech about FDA-approved products when directed to either professional or consumer audiences. *See id.* at 107-154. *See also* George W. Evans & Arnold I. Friede, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 Food & Drug L. J. 365, 408-31 (2003). This submission supplements the statutory and constitutional analysis in Pfizer's earlier comments by identifying relevant facts relating to the public health interests FDA should seek to advance and the impact of regulatory policies on those interests.

of exploring them in more detail with a doctor. Before FDA considers upsetting the current regulations, which have served this purpose, it must gather data on what consumers actually "take away" from current risk disclosures and any potential regulatory alternatives, as well as data showing how that take-away actually affects consumer behavior. Wherever the resulting data might lead, Pfizer believes that FDA should strive for a disclosure policy that does not (1) deter consumers from seeking appropriate drug therapy, or (2) return to the pre-1997 era when disclosure requirements effectively foreclosed DTC advertising on television and thereby deprived many consumers of useful information about conditions and their treatments.

Thus, Pfizer believes that the factual record and governing First Amendment principles strongly counsel that FDA maintain the current DTC regulatory regime while it seeks better data on consumer comprehension of, and behavioral responses to, differing levels and methods of risk disclosure.

I. THE RECORD ESTABLISHES THAT FDA'S CURRENT APPROACH TO DTC COMMUNICATIONS ADVANCES IMPORTANT PUBLIC HEALTH INTERESTS

FDA's broad call for research data provided any entity with relevant factual information concerning DTC communications an opportunity to present it.[5] The result is a record full of evidence submitted by a wide variety of entities, including medical associations, the pharmaceutical industry, consumer groups, academics, marketing organizations, and the media. The evidence in this docket should put to rest any doubts as to the value of DTC communications in motivating consumers to take better care of their health by working with their physicians to obtain appropriate diagnoses and treatments.

[5] Although the docket remains open as of this writing, the lack of significant negative evidence concerning the effects of DTC is another strong indication of the positive impact on public health of consumer-directed communications concerning prescription drugs.

Therefore, guided by its obligations under the Administrative Procedure Act,[6] FDA now must conclude—both as a matter of policy and law—that its current DTC policies advance the public health. Moreover, because of the demonstrable benefits of DTC, the agency would be constrained by the First Amendment were it to consider adding new regulations that would unnecessarily burden or effectively suppress this protected commercial speech.[7]

A. Data Show That DTC Helps Consumers To Recognize Ways In Which They Can Improve Their Health Through Drug Treatments

The vast majority of studies presented at the September hearing demonstrated the beneficial impact that DTC is having on the increasingly significant "consumer empowerment" movement within the American system of health care. FDA is well aware of the factors that make it important for consumers to become aware of medical conditions that might affect them or their loved ones and of the treatment options that are available.[8] Pfizer, which has been tracking consumer empowerment trends for some time, has submitted data showing that consumer-directed information about pharmaceutical treatment options helps consumers feel better prepared to ask their doctors informed questions about their healthcare and, as a result, develop a health partnership with their doctors.[9]

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[6] *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983) (agency action must be "product of reasoned decisionmaking"); *id.* at 43 ("agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made") (Internal quotation marks and citation omitted).

[7] *See* Pfizer First Amendment Comments at 52-63, 141-154 (discussing, *e.g., Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980), and its progeny).

[8] Hearing Transcript, Direct-To-Consumer Promotion: Public Meeting, at 13,18-19 (Sept. 22, 2003), *available at* http://www.fda.gov/cder/ddmac/DTCmeetingTranscript.doc, (hereinafter "Hearing Transcript, Sept. 22, 2003").

[9] Mike Magee, M.D., *Physician-Patient Relationships, Patient Empowerment and the Role of Information*, at slides 3, 4,13 (Sept. 23, 2003) (citing Magee, "Relationship-Based Health Care in the US, UK, Canada, Germany, S. Africa, and Japan," 2003; *FDA Patient Survey, FDA Physician Survey, Market Measures/Cozint DTC Monitor*), *available at* http://www.fda.gov/cder/ddmac/p6magee/index.htm, (hereinafter "Magee presentation"); Cliff Thumma, *DTC Advertising and Doctor-Patient Interactions*, at slides 11, 22, 25 (Sept. 23, 2003) (citing Prevention Magazine, 5th Annual Survey of Consumer Reaction to Direct-to-Consumer Advertising of Prescription

Discussion during the September hearing indicated that FDA officials and other participants accept consumers' increasingly important role in alerting their physicians to their own health conditions, especially in an era when physicians are grappling with time pressures arising from both the financial and scientific aspects of modern medical practices.[10] The evidence shows that 80% of adults feel they need to be more active in managing their health care.[11]

In keeping with what appears to be a changing health care paradigm,[12] there are undisputed facts before the agency showing that consumers want access to more information about prescription drugs and related medical conditions that may be relevant to their own health and that of family members. The evidence also shows that DTC provides consumers with that information—and that while DTC advertising alone cannot be expected to provide all the information necessary to justify issuance of a particular prescription, direct-to-consumer ads motivate consumers to consult their doctors, and other available resources, to learn more about the benefits and risks of treatment alternatives.[13] Pfizer believes that a communication effort that

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Medications (2002); General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations* (Oct. 2002); *Harvard/Harris Study* (2003) *FDA Patient Survey* (2002)), *available at* http://www.fda.gov/cder/ddmac/p6thumma/index.htm, (hereinafter "Thumma presentation").

[10] Hearing Transcript, Sept. 22, 2003, at 19, 121-122; Hearing Transcript, Direct-To-Consumer Promotion: Public Meeting, at 68-69 (Sept. 23, 2003), *available at* http://www.fda.gov/cder/ddmac/DTCmeetingTranscript2.doc, (hereinafter "Hearing Transcript, Sept. 23, 2003").

[11] Magee presentation, at slide 5 (citing *Yankelovitch Monitor*, 2002).

[12] Pfizer First Amendment Comments at 3-17.

[13] In annual studies conducted by Prevention Magazine, 85% of patients surveyed agreed that DTC advertisements encourage people to find out more about the advertised drug, while 83% agreed the advertisements encourage people to find out more about the condition the drug treats. Edwin Slaughter, *Consumer Reaction to DTC Advertising of Prescription Medicines 1997 to 2002*, at slide 8 (Sept. 22, 2003) (citing *Prevention Annual Survey* (2002)), *available at* http://www.fda.gov/cder/ddmac/P1Slaughter/index.htm, (hereinafter "Slaughter presentation").

results in more thoughtful doctor-patient dialogue is a significant benefit to individual consumers and, through them, to the public health.

1. DTC communications alert consumers to information they want about health conditions that can be treated and drugs that can help them

Record data submitted by various entities, including FDA, confirm that DTC is increasing consumer awareness of conditions that may affect them and motivating them to seek professional guidance on drugs that may improve their health. The first step in the process requires raising consumer awareness of health conditions and the options for treating them. DTC communications are valuable in this regard, according to consumers themselves. FDA found that 77% of patients agree strongly or somewhat that DTC ads make them aware of new drugs.[14] Studies conducted by Prevention Magazine corroborate that finding: 80% agree that DTC ads alert people to symptoms related to a condition they might have; 78% agree strongly or somewhat that DTC ads allow people to be more involved with their health care, and 84% of patients surveyed agree strongly or somewhat that DTC ads tell people about new treatments that are available.[15]

Evidence shows that consumers particularly appreciate DTC as a valuable resource for keeping up-to-date on new treatment options. FDA surveys indicate that approximately half of those consumers who saw print ads had seen one that "especially interested" them.[16] This is consistent with the Parade survey, which found that, by a 2-1 margin, consumers suffering from

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[14] Kathryn Aikin, Ph.D., *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, at slide 18 (Sept. 22, 2003) (citing *FDA Patient Survey* (2002)), *available at* http://www.fda.gov/cder/ddmac/aikin/index.htm, (hereinafter "Aikin presentation").

[15] Slaughter presentation, at slides 8-9 (citing *Prevention Annual Survey* (2002)).

[16] Kathryn Aikin, Ph.D., *Direct-to-Consumer Advertising of Prescription Drugs: Patient Survey Results*, at slide 20 (Sept. 19, 2002), *available at* http://www.fda.gov/cder/ddmac/Presentations/KitHMCC2002out/, (hereinafter "2002 Aikin presentation").

a condition believe that DTC advertising is a good idea—and an even larger number of the people who care for the ill agree.[17] In a similar vein, the evidence shows that minority populations in particular are well served by the information provided through DTC advertising and would like to see more of it directed to them.[18]

The caregiver response is particularly noteworthy because, as the Parade study indicated, patients who have a caregiver participating in their health care are more likely to receive some form of treatment for their conditions and to actually comply with that treatment.[19] The data here show that caregivers in particular look to DTC communications as a key source of information; 77% of caregivers believe that DTC targeted directly at *them* would be valuable.[20]

That data also demonstrate that American consumers recognize the commercial motives of DTC advertising and weigh them appropriately. The National Consumer League ("NCL") survey, for example, found that 60% of patients recognize that DTC advertisements are intended

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[17] Gay Kassan, *Compliance, Caregivers, and the Consumers: New Perspectives on Health Management*, at slide 19 (Sept. 23, 2003) (citing *Parade Magazine Survey* (2003)), a*vailable at* http://www.fda.gov/cder/ddmac/p7kassan/index.htm, (hereinafter "Kassan presentation"). The researchers defined a "caregiver" as "a relative or friend who is concerned and involved in some way in helping manage [a sufferer's] condition." *Id.* at slide 4.

[18] Hearing Transcript, Sept. 22, 2003, at 56 (NMA/COSHAR encourages cultural diversity and sensitivity in DTC advertisements, given that African Americans suffer disproportionately from conditions such as heart disease). Studies consistently show that serious health conditions such as hypertension, diabetes, and stroke are more prevalent among African-Americans than in the white population, and that age-adjusted death rates due to heart disease and stroke are higher for African-Americans than for whites. *See, e.g.*, *Racial Differences in Cardiovascular Health: Findings from the National Health and Nutrition Examination Survey (NHANES) III and 1999-2000*, at slides 9-10, 13-14, 31, 37 (Pfizer Facts publication Aug. 7, 2003), *available at* http://www.pfizer.com/download/health/pubs_facts_racialdiff_CV.pdf, (citing *National Health and Nutrition Examination Surveys* (NHANES) III and 1999-2000; *Compressed Mortality File* (CMF)) (hereinafter "*Racial Differences in Cardiovascular Health*"). Accordingly, FDA should value any communications that can prompt minorities and other under-diagnosed and under-treated demographic groups to seek and obtain appropriate treatment.

[19] Kassan presentation, at slides 8-10 (citing *Parade Magazine Survey*).

[20] Hearing Transcript, Sept. 23, 2003, at 217-218.

to sell pharmaceutical products.[21] This should not be surprising, given the large body of evidence that the government has recognized elsewhere showing appropriate consumer awareness of the potential bias and appreciation for the information presented in advertising generally.[22] Nevertheless, consumers still want such messages communicated directly to them: essentially the same 60% of respondents in the NCL survey oppose limiting prescription drug ads to professional magazines targeted to doctors, and 42% of them feel strongly about it.[23]

2. Physicians confirm the value of DTC communications in prompting better patient interchange about conditions and treatment options

Consumers are not alone in perceiving the health benefits of DTC communications. There is now substantial evidence on the record showing physicians see the positive effect of DTC on their patients. In FDA's own studies, 72% of physicians agree DTC advertisements provide greater awareness of treatments; 44% agree DTC helps make patients aware of their health problems earlier; 58% think that DTC made their patients more involved in their health care; and 54% said the advertisements make the average patient more concerned about health.[24]

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[21] Linda Golodner, *Effectiveness of and Attitude Toward Medication Advertising*, at slide 19 (Sept. 22, 2003) (citing *NCL Patient Survey*), *available at* http://www.fda.gov/cder/ddmac/P1golodner/index.htm, (hereinafter "Golodner presentation").

[22] *See, e.g.,* Comments of the Staff of the Bureau of Economics, et al., Request for Comment on First Amendment Issues, Docket No. 02N-0209, 21-31 (filed Sept. 13, 2002) (discussing the positive effects to consumer behavior that result from information presented in advertising), *available at* http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091902/02N-0209_emc-000163-01.pdf, (hereinafter "FTC Comments"). The Federal Trade Commission has noted that, in the case of food advertising, health and nutrient content claims can have the effect of making consumers more aware of the significance of nutrients in foods and will prompt them to obtain more information; this in turn creates an incentive for marketers to create healthier products in order to retain customers. *Id.* at 23. *See also*, J. Howard Beales and Timothy J. Muris, *State and Federal Regulation of National Advertising*, 16-17, 38 (1993) (hereinafter "Beales/Muris").

[23] Golodner presentation, at slide 19 (citing *NCL Patient Survey*); Press Release, The National Consumers League, *Survey: Direct-to-Consumer Advertising of Prescription Drugs, Executive Summary* (Jan. 9, 2003), *available at* http://www.nclnet.org/dtcsurvey.htm.

[24] Aikin presentation, at slide 49 (citing *FDA Physician Survey* (2002)).

Other surveys also show a majority of physicians recognize the positive impact of DTC on consumer awareness:

- The Harvard/Harris study found that 72% of physicians somewhat or strongly agree that DTC ads help educate and inform patients about treatments available to them.[25]
- The National Medical Association/COSHAR ("NMA/COSHAR") study of member physicians found that 55% agree that DTC ads are beneficial to patients, 64% indicate that the ads have no negative effect on anyone, and 53% agree that ads promote patient education about disease states.[26]

B. Data Show That DTC Prompts Patients To Act On Their Newly Acquired Knowledge By Seeking Physician Advice On Conditions And Possible Treatment

As noted above, Pfizer believes that public health goals for DTC communications only begin with better informed consumers. An equally important objective is fostering DTC messages that motivate consumers to actually contact their doctors, engage in better dialogue about their health concerns, and receive appropriate treatment. The evidence now before FDA demonstrates that DTC is succeeding in helping consumers initiate useful conversations with their doctors that lead to appropriate diagnoses and treatments—whether or not the treatment includes the drug whose advertisement prompted the initial dialogue.

1. DTC advances doctor-patient communication by prompting consumers to consult with their doctors

As FDA Commissioner Mark McClellan recently noted, "DTC ads are one factor that helps get people into the doctor's office."[27] Pfizer also has consistently emphasized that the

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[25] Joel S. Weissman, Ph.D., et al., *Consumer and Physician Reports on the Health Effects of DCTA*, at slide 10 (Sept. 22, 2003) (citing *Harvard/Harris Study* (2003)), *available at* http://www.fda.gov/cder/ddmac/P1weissman/index.htm, (hereinafter "Weissman presentation").

[26] Sharon Allison-Ottey, M.D., *DTC and AA Physician and Patient*, at slides 9, 16, 22 (Sept. 22, 2003) (citing *NMA/COSHAR Physician Survey*), *available at* http://www.fda.gov/cder/ddmac/P1AllisonOttey/index.htm, (hereinafter "Allison-Ottey presentation").

[27] Rich Thomaselli, *FDA Holds Hearing For DTC Guidelines; New Rules By Year's End, But McClellan Says DTC Here To Stay,* Advertising Age, Sept. 22, 2003, at 3.

doctor must continue to be responsible for the diagnosis of health conditions and administration of appropriate care.[28] Consequently, DTC's role as a catalyst in prompting patient engagement with physicians is of paramount importance to good health care.

The data plainly show that DTC spurs millions of patients to act on their newly acquired knowledge by seeking out their physicians for advice on conditions and possible treatments.[29] The National Consumers League found that of the patients who sought additional information in response to seeing a DTC ad, 64% contacted their doctor, by either calling or visiting.[30] Thirty-six percent of physicians who serve a predominantly minority patient population report that patients have come into their offices *solely* because of DTC ads.[31]

Indeed, under-diagnosis of health conditions—many of them chronic but treatable—is a significant problem across all sectors of the U.S. population. Public health officials have shown concern over the increasing incidence of undetected or untreated incidence of diabetes, obesity, high cholesterol, hypertension, depression, asthma, Alzheimer's disease, and many other conditions.[32] According to the U.S. Centers for Disease Control and Prevention, millions of adults suffering from serious conditions such as hypertension or diabetes have not been diagnosed—and even of those who have been diagnosed, millions are not being treated to

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[28] *See* Hearing Transcript, Sept. 23, 2003, at 190; *see also* Mike Magee, *Relationship-Based Health Care in the United States, United Kingdom, Canada, Germany, South Africa and Japan: A Comparative Study of Patient and Physician Perceptions Worldwide*, at 12-14 (Sept. 11, 2003) (Paper presented at the World Medical Association meeting on Patient Safety in Care and Research); Pfizer First Amendment Comments at 6-10.

[29] In 2002, nearly 65 million consumers talked to their physicians about an advertised medicine because of an ad. *See* Slaughter presentation, at slide 16 (citing *Prevention Annual Surveys*).

[30] Golodner presentation, at slide 13 (citing *NCL Patient Surveys*).

[31] Allison-Ottey presentation, at slide 18 (citing *NMA/COSHAR Physician Survey*).

[32] Paul H. Rubin, *The Economics and Impact of Pharmaceutical Promotion*, at 9 n.9 (to be published in 3 Economic Realities in Health Care Policy, Dec. 2003) (citing *NHANES III*) (hereinafter "Rubin"); NIH News Release, Dep't of Health and Human Services, National Institutes of Health, *NCEP Issues Major New Cholesterol Guidelines* (May 15, 2001), *available at* http://www.nih.gov/news/pr/may2001/nhlbi-15.htm).

target.[33] This problem is particularly acute in minority populations.[34] When DTC induces the victims of those conditions to consult a physician, the benefit extends far beyond the specific inquiry that prompts the visit.[35] In fact, hearing testimony suggested that product-oriented DTC communication, with its emphasis on both conditions and specific available treatment options, is a powerful force in generating additional doctor-patient contact.[36] The data in this record indicates that DTC communications have a positive impact on the under-diagnosis and under-treatment problem by serving as continual reminders to consumers that health issues warrant their attention.[37]

DTC also appears to aid in overcoming some psychological impediments to seeking treatment that go beyond just inertia or inattention. For example, NCL reported that 42% of patients agree that DTC ads helped to de-stigmatize many conditions, such as depression, that may have gone untreated due to patient embarrassment.[38] FDA itself found that 30% of

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[33] Rubin, at 8 n.12 (citing *NHANES III*).

[34] Hearing Transcript, Sept. 22, 2003, at 56; *see also Racial Differences in Cardiovascular Health*, at 18.

[35] *See supra*, footnote 18.

[36] Hearing Transcript, Sept. 23, 2003, at 177-81. As the discussion at the hearing reflected, brand-specific DTC ads may reach some consumers who are not moved by more general "help-seeking" messages that do not identify a specific drug therapy.

[37] *See infra,* Section I.D.

[38] Golodner presentation, at slide 19 (citing *NCL Patient Survey*). *See also* National Mental Health Association ("NMHA") News Release, *Depression Survey Reveals Dramatic Change in Public Opinion: Disease or State of Mind?* (July 11, 2001) (concluding that, "[w]ith almost one-third of respondents (31 percent) in the general public sample saying they believe depression is a 'state of mind you can snap out of,' people with depression may be misunderstood and stigmatized."), *available at* http://www.nmha.org/newsroom/system/public_opinion_7_11_01.cfm; NMHA News Release, *Barriers to Diagnoses for Common Mental Illnesses Could Prolong Suffering, According to New National Survey* (June 6, 2001) (stating that, "only 18 percent of all adult Americans who appear to have met the diagnostic criteria for clinical depression and/or generalized anxiety disorder at some point in their lives have ever received an official diagnosis or treatment for either condition."), *available at* http://www.nmha.org/newsroom/system/news.vw.cfm?do=vw&rid=309; Michael M. Faenza, President and Chief Executive, NMHA, *Letter to the Editor*, N.Y. Times, June 25, 2003, at A24 (noting that "advertising," among other

physicians surveyed said that DTC ads persuade hard-to-reach patients come into their offices for treatment.[39]

Pfizer has had direct experience with this phenomenon in recent years with respect to the introduction of Viagra® as a treatment for erectile dysfunction ("ED"). By destigmatizing erectile dysfunction through DTC, Pfizer assisted in persuading millions of men to consult physicians about a condition which previously was both untreated and not effectively treatable.[40] Furthermore, because erectile dysfunction is associated with, and often caused by, other serious medical problems, such as cardiovascular disease and diabetes, these new doctor-patient contacts had benefits far beyond the relief of ED itself.[41]

2. DTC advances doctor-patient communication by helping consumers to engage in better dialogue with their doctors

The evidence in the record demonstrates that once a consumer has contacted his or her doctor, DTC communications such as broadcast and print advertisements help to spark better doctor-patient exchanges—as both sides recognize.[42] Improving the quality of those communications has obvious benefits. Even the most skilled diagnosticians require patient input

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sources, "seem[s] to be driving" an increase in consumer awareness of depression and is "helping people recognize their symptoms and empowering them to seek help.").

[39] Aikin presentation, at slide 49 (citing *FDA Physician Survey* (2002)).

[40] Paper by Dale Glasser, Ph.D., Medical Director, Pfizer Sexual Health (July 16, 2001) (originally prepared for submission to FDA and the Federal Trade Commission) (hereinafter "Glasser") (on file with author). In July 2001, Dr. Glasser reported that approximately 9 million men had filled a prescription for Viagra in the three years since approval.

[41] See infra, Section I.C.

[42] *See, e.g.*, Aikin presentation, at slides 19, 29 (citing *FDA Patient Survey* (43% of patients agree strongly or somewhat that seeing advertisements for prescription drugs helps them have better discussions with their doctors); *FDA Physician Survey* (53% of physicians reported having better discussions with patients who had seen DTC advertisements)).

to reach proper conclusions and decide upon the best treatment regimen for each individual.[43] Furthermore, patients who understand why treatment is necessary are more likely to comply with the treatment regimen.

According to the evidence before FDA, DTC works in part by giving laypersons both information and confidence to engage in discussion with a highly educated health-care professional on a matter outside of the layperson's expertise.[44] For example, the NMA COSHAR study found that, of doctors serving a largely minority population, 90% of those surveyed said that patients have consulted them about health issues because of DTC ads, whether the advertisements prompted the visit or not.[45] Data from Pfizer's own multi-country study of changing patient attitudes found that 91% of patients are asking more questions of their physicians and 87% are making more health care choices and actively evaluating benefit and risk than they were 10 years ago—but Americans stand out particularly in this regard.[46] Patients increasingly possess the information and confidence to ask better questions of their physicians.[47]

Supporting the data showing that DTC ads prompt better doctor-patient communication, multiple surveys provide evidence on positive consumer perceptions of how DTC affected their

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[43] Courts addressing the learned intermediary doctrine in product liability cases have recognized that patients are not passive players in the diagnosis process but rather are integral in providing necessary facts to their professional caregivers. *See e.g.*, *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 838-39 (Ohio 1981) (presumption that plaintiff's injury was due to defendant's inadequate warning was rebutted because plaintiff failed to inform doctors of prior history of toxemia).

[44] Magee presentation, at slides 4-9, 13; Hearing Transcript, Sept. 23, 2003, at 177-181; Slaughter presentation, at slide 11 (citing *Prevention Annual Survey* (2002) (67% of consumers surveyed said that DTC advertisements in magazines and on television provided them with information they needed about prescription drug benefits; 68% said the ads provided information they needed about drug risks)).

[45] Allison-Ottey presentation, at slide 19 (citing *NMA/COSHAR Physician Survey*).

[46] Magee presentation, at slide 4 (citing Magee, "Relationship-Based Health Care in the US, UK, Canada, Germany, S. Africa, and Japan," 2003).

[47] Magee presentation, at slide 13 (citing *FDA Patient Survey*, *FDA Physician Survey*, *Market Measures/Cozint DTC Monitor*).

interactions with their physicians. With numbers ranging from just above the 50% mark to past the 90th percentile, studies indicate that consumers find that their physicians respond positively to questions spurred by DTC ads and treat them like questions triggered by any other source.[48] The data also suggest that such questions have become a normal and accepted aspect of doctor-patient communication, with a vast majority of consumers reporting that DTC-prompted questions do not disrupt their relationships with their physicians.[49]

Data from the physician side of the equation also are positive. While some doctors may harbor reservations about DTC's benefits, a large number of physicians report that DTC advertising helps their interaction with patients—and very few report any negative experiences. For example, 41% of doctors surveyed told FDA that a patient's exposure to DTC communications has a beneficial effect on their interaction with patients; 53% have better discussions with their patients; and 56% agree that the patient asks more thoughtful questions.[50] Approximately 82% of physicians said that DTC communications create no problems for the

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[48] 2002 Aikin presentation, at slide 36 (93% of patients report physicians welcomed questions about prescription drugs, 86% said their doctor discussed the drug with them, and 83% said the doctor reacted like it was an ordinary part of the visit); Slaughter presentation, at slide 25 (citing *Prevention Annual Surveys*, 2001 (79% of patients who spoke to a doctor about an advertised prescription medicine reported that doctor was "very willing" to discuss it)); Allison-Ottey presentation, at slides 40-41 (citing *COSHAR Patient Survey* (54% of patients reported that interaction with doctor was positive, while 0% reported any negative effect; majority felt physician would treat question or request in the same manner as other medical questions)).

[49] 2002 Aikin presentation, at slide 49 (77% of patients who asked about a drug reported that their relationship with their doctor stayed the same, 20% said it improved, and only 2% said it got worse); Slaughter presentation, at slide 26 (citing *Prevention Annual Surveys*, 2001 (72% of patients who asked about an advertised drug said that their relationship with their doctor stayed the same, 27% said it improved, only 1% said it got worse)).

[50] Aikin presentation, at slides 28, 29, 49 (citing *FDA Physician Survey* (2002)).

interaction.[51] Moreover, multiple studies by other researchers corroborate that doctors recognize that DTC helps to improve their communication with patients.[52]

C. Data Show That DTC-Informed Doctor-Patient Dialogue Results In Appropriate Diagnoses And Treatments, Many Of Which Involve Newly Identified Conditions Raising Serious Health Concerns

The record evidence demonstrates that DTC communications are having a positive effect on both the diagnosis and treatment of health conditions. According to the empirical evidence, consumers who ask for particular drug products actually have the condition that the product is approved to treat. FDA's own studies indicate that in 88% of cases in which patients asked about a drug, physicians determined that the person had the condition that the drug treated.[53] Other studies confirm that conclusion.[54]

Moreover, there is substantial record evidence that DTC-informed consultations do not constrain treatment decisions. Both FDA and Harvard/Harris found that only 50% of patients who asked about a specific drug were issued a prescription for the drug.[55] Data indicate that

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[51] Aikin presentation, at slide 30 (citing *FDA Physician Survey* (2002)).

[52] Weissman presentation, at slide 10 (citing *Harvard/Harris Study* (66% of physicians somewhat or strongly agree that DTC ads help them have better discussions with their patients)); Allison-Ottey presentation, at slide 21 (citing *NMA/COSHAR Physician Survey* (48% of NMA member physicians surveyed agree that ads promote increased communication between doctors and patients)).

[53] Aikin presentation, at slide 34 (citing *FDA Physician Survey* (2002)).

[54] Thumma presentation, at slide 13 (citing *Market Measures/Cozint DTC Monitor* (in inquiries for drugs treating high cholesterol and mood/anxiety disorders, physicians reported that, in over 80% of cases, patients asked about medicines that were appropriate to them)); Cliff Thumma, "DTC Benefits Consumers All Along The Treatment Path", at n.15 (hereinafter "Thumma, The Treatment Path") (on file with author) (citing Kaiser Family Foundation, "Understanding the Effects of Direct-to-Consumer Advertising," November 2001 (study found that consumers who respond to DTC ads tend to be "those with the greatest health need [and] those who are affected by a relevant medical condition.")).

[55] Aikin presentation, at slide 16 (citing *FDA Patient Survey* (2002)); Weissman presentation, at slide 6 (citing *Health Affairs* (2003).

doctors believe these prescriptions were appropriate therapeutic choices, [56] and that patients had a realistic layperson's understanding about the drugs generally.[57]

In fact, the data show that these prescribed drug therapies are not only medically appropriate but also successful. According to the Harvard/Harris study, more than 80% of the patients receiving prescriptions for advertised drugs said their health is much or somewhat better as a result, and laboratory results confirm that patient perception.[58] The National Consumer League survey results are consistent: 71% of patients who received a prescription after inquiring about a DTC ad said the prescribed medication improved their condition.[59]

In addition, the record shows that DTC communications prompt many millions of consumers to talk to their physicians about a health condition for the first time. Patient surveys indicate that almost 20% of consumers report that DTC advertising motivated them to talk to a physician about a condition that they had not raised before.[60]

Physician responses also demonstrate that the positive impact of DTC on new diagnoses involves serious health issues. The Harvard/Harris study reported that 25% of advertising-driven conversations resulted in new diagnoses, 43% of which were "high priority" conditions.[61]

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[56] Weissman presentation, at slide 15 (citing *Harvard/Harris Study*, 2003 (where advertised drugs were prescribed, physicians reported that in 46% of the cases, the drug was the most effective one for the patient; in 48% of the cases, it was as effective as other drugs)).

[57] Aikin presentation, at slide 46 (citing *FDA Physician Survey* (2002) (80% of physicians believed patients understood very well or somewhat what condition the drug treats, and 58% said patients understood very well or somewhat who could use the drug)).

[58] Weissman presentation, at slide 7 (citing ACHR (2002)).

[59] Golodner presentation, at slide 17 (citing *NCL Patient Survey*).

[60] Slaughter presentation, at slide 21 (citing *Prevention Annual Surveys*); Aikin presentation, at slide 11 (citing *FDA Patient Survey* (2002)).

[61] Weissman presentation, at slide 5 (citing *Harvard/Harris Study* (2003)). FDA's own study found generally consistent data: a still consequential 6% of cases in which patients raised DTC-prompted questions that resulted in diagnosis of a new condition. Aikin presentation, at slide 29 (citing *FDA Physician Survey* (2002)).

FDA's own data are consistent, with 44% of physicians reporting that DTC advertisements cause patients to seek treatment for potentially serious health problems.[62]

The effect of DTC on new diagnoses may be linked in part to the impact that DTC ads have in motivating reluctant consumers to seek a consultation in the first place. The ensuing dialogue then may lead to the detection and treatment of serious but generally asymptomatic conditions. For example, as noted above, the advertised availability of drugs to treat erectile dysfunction is leading otherwise reluctant men to consult their physicians for treatment.[63] In conducting the medical check-ups necessary to diagnose and treat ED, doctors have discovered and made earlier diagnoses of serious illnesses such as cardiovascular disease, hypertension, depression, diabetes, renal failure, prostate cancer, and benign prostatic disease.[64]

This example is but one illustration of the fact that in-person medical examinations—as opposed to the consultations that accompany "pseudo-prescribing" via the Internet—remain

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Also, it is worth noting that what some might dismiss as mere "lifestyle" issues, such as allergy problems, can be a constant irritant to those who suffer. Such chronic conditions can be debilitating and have adverse consequences for both productivity and life enjoyment, even if sufferers are not completely incapacitated.

[62] Aikin presentation, at slide 49 (citing *FDA Physician Survey* (2002)).

[63] Glasser, at 3. As Dr. Glasser reports, "[s]tudies funded by Pfizer in several health maintenance organizations ("HMOs") found that men were more likely to be diagnosed with serious medical conditions (diabetes, dyslipidemia, heart disease, depression) shortly after presenting for a prescription for Viagra than their peers. Of approximately 1000 men newly diagnosed with ED in one HMO in the months following the launch of Viagra, 18% were diagnosed with hypertension, 16% with diabetes, 5% with ischemic heart disease and 4% with prostate cancer within a month of first visit. Thus, this effect is even apparent among men with easy access to health care and preventive services." *Id.* at 4. Empirical data show that, although men generally have much higher rates of illness and premature mortality than women, women are 100% more likely than men to visit the doctor for annual examinations and preventive services. *Men's Health: A Silent Crisis* (Men's Health Network and Pfizer publication, on file with Pfizer) (citing CDC 2001). According to a recent study, however, 21 million male consumers have consulted with a doctor as a result of seeing a DTC advertisement. *Id.* (citing "Wellness in America: Direct to Consumer Advertising," *Prevention* and *Men's Health* magazines, 2002).

[64] Glasser, at 2-4.

crucial to proper diagnoses of disease and other significant health problems.[65] DTC ads that encourage consumers to meet with their doctors obviously serve to advance the public health by, in this case, catching undetected illnesses that would otherwise fester—and add to the alarming numbers of serious medical conditions that are under-diagnosed or under-treated.

D. Data Show That DTC Communications Bolster Consumer Compliance With Drug Therapies

The record indicates that once a patient has received a prescription for drug treatment, continuing exposure to DTC communications improves their compliance with existing treatment regimens. Results gleaned from multiple surveys of consumers show that DTC advertisements help to remind many patients to follow through with their therapies.[66] The docket now provides data on a corollary point as well: many consumers report that DTC gives them greater confidence in the treatment option that their doctor has prescribed, which is likely to enhance compliance.[67]

Evidence on physician perceptions on this point is consistent. According to both FDA and Harvard/Harris, a noteworthy number of doctors believe that DTC ads increase patients'

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[65] The collateral benefits of full physician examinations underscore the point that human health is not simply a matter of addressing discrete symptoms in a vacuum. DTC communications, for all of their informative value to consumers, cannot substitute for the breadth of a physician's knowledge and judgment.

[66] *Prevention Annual Surveys*, 2001 (cited in Thumma, The Treatment Path) (17% said the ad made them more likely to take their medicine); Golodner presentation, at slides 8, 19 (citing *NCL Patient Survey* (30% said that ads remind people to take their medicines or have their prescriptions refilled; 6% who had the condition advertised said the ad reminded them how important it is to take the medication)); Allison-Ottey presentation, at slide 40 (citing *COSHAR Patient Survey* (23% are more likely to continue to take a medication if they heard or saw it advertised)). The data gathered from U.S. consumers is consistent with the findings of consumer surveys in New Zealand, the one other nation that permits DTC advertising. *See* Presentation of Dr. Dean G. Smith, University of Michigan, discussing New Zealand consumer survey results. Hearing Transcript, Sept. 23, 2003, at 163 (15% indicated that seeing an ad would make them more likely to refill a prescription; 18% indicated that it would make them more likely to take a medication more regularly).

[67] *Prevention Annual Surveys*, 2001 (cited in Thumma, The Treatment Path) (40% of patients who saw an ad for a drug they were taking said the ad made them feel better about the benefits of taking the drug; 34% said the ad made them feel better about the safety of the drug); Golodner presentation, at slide 19 (citing *NCL Patient Survey* (24% said ads made them feel good about the medicines they were already taking)).

compliance with their doctors' recommendations, tests, or prescriptions.[68] The data therefore supports the conclusion that DTC communications assist in convincing patients to be more willing to undertake and complete appropriate drug therapy.

E. Data Show That DTC Communications Provide Substantial Additional Benefits To The Public By Accelerating Acceptance And Use Of New Drug Products

DTC advertising has particular utility in disseminating information about newly approved drug products. Just as FDA has expressed a public health interest in accelerating approval of beneficial new products,[69] manufacturers have an interest in seeing that physicians and patients have meaningful access to these products. Without adequate dissemination of information, the therapeutic benefit of newly approved drugs could be substantially deferred. And while dissemination of that information to physicians is critical, DTC advertising alerts patients to new options that can, in turn, stimulate busy physicians to scrutinize them.

The record before FDA confirms that accelerated acceptance of newly approved drugs has substantial public health benefits. Several related studies conducted by Dr. Frank Lichtenberg, the Courtney C. Brown Professor of Business at Columbia University, have demonstrated that the introduction of new drugs has a strong positive impact on the probability

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[68] Aikin presentation, at slide 49 (citing *FDA Physician Survey* (34% said DTC makes patients more likely to use medications properly; 32% said ads make patients more likely to adhere to treatment regimens)); Weissman presentation, at slide 10 (citing *Harvard/Harris Study*, 2003 (45% of physicians somewhat or strongly agree that DTC ads increase patient compliance)). Empirical data also show that patients who initiate a conversation with their doctor about a prescription drug as a result of seeing a DTC ad are most likely to comply with their therapy. *See* Pfizer Inc and RxRemedy Information Services, *Impact of DTC Advertising Relative to Patient Compliance* (June 2001) (study showed that after 6-months of drug treatment, a greater percentage of patients who had asked about a drug with prompting from an ad remained on therapy than did those who asked about a drug without prompting from an ad and those that did not ask about a drug; this was true in all drug categories surveyed, including medications for allergies, arthritis, elevated cholesterol, depression, and diabetes) (hereinafter "*RxRemedy DTC/Compliance*").

[69] *See*, Center for Drug Evaluation and Research, et al., FDA, Procedural No. 9, Guidance for Industry: Fast Track Development Programs – Designation, Development and Application Review (Sept. 1998), *available at* http://www.fda.gov/cber/gdlns/fsttrk.pdf.

of survival from medical conditions and on life expectancy in general. Of the two-year increase in life expectancy that occurred during the period 1986-2000 within the countries surveyed, which included the United States, approximately 40% was attributable to the introduction of new drugs.[70] Lichtenberg also determined that, in countries that see frequent introduction of new drugs, longevity is increasing by about three weeks per year as a result of those advances.[71] It is also noteworthy that the increased longevity comes at a cost of about $250 per person, which means about $4,500 in drug expenditures for a one-year increase in life expectancy—a figure well below the amount that estimates indicate most people would be willing to pay to live an additional year.[72] Related findings include:

- An increase in the number of priority review drugs available in the period between 1983 and 1996 reduced the probability of employees being unable to work by 21%.[73]
- Over a 15-year period, the probability of a person being completely unable to work dropped from almost 8% to 6.5% as a result of new drugs, a development that corresponds to a value of approximately $500 per year in increased wages.[74]

F. Data Show That DTC's Ability To Increase Treatment For Under-Diagnosed And Under-Treated Conditions Yields Substantial Macroeconomic Benefits

Improvements in the length and quality of life arising from DTC's ability to increase recognition of medical conditions and available therapeutic options have undeniable benefits to affected patients and their families. In addition, data presented at the hearing showed that society at large benefits from enhanced drug treatment in at least three quantifiable ways:

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[70] Frank R. Lichtenberg, Ph.D., *DTC Advertising and Public Health*, at slide 14 (Sept. 23, 2003), *available at* http://www.fda.gov/cder/ddmac/P4Lichtenberg/index.htm, (hereinafter "Lichtenberg presentation").

[71] Lichtenberg presentation, at slide 14.

[72] Lichtenberg presentation, at slide 16.

[73] Lichtenberg presentation, at slide 26 (citing *National Health Interview Surveys*).

[74] Lichtenberg presentation, at slide 27 (citing *National Health Interview Surveys*).

(1) reduction in individual lost work days attributable to medical conditions;[75] (2) reduction of work days lost to permanent disability;[76] and (3) reduction of expenditures for more expensive hospitalizations and surgical treatments for conditions now treatable by outpatient drug therapies.[77] President Bush recently addressed these specific issues in advocating a prescription drug benefit in Medicare.[78]

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The September hearing proved that DTC communications are an important and useful aid in the information cycle that eventually leads to health improvements for Americans. Study after

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[75] Hearing Transcript, Sept. 23, 2003, at 40-42; Lichtenberg presentation, at slides 26-30; *see also* Pharmaceutical Research and Manufacturers of America ("PhRMA"), *The Value of Medicines*, at 10-11 (2001) (studies showed that absenteeism due to depression dropped by nine days when workers were treated with prescription medications; absenteeism due to influenza among the non-elderly population is as high as 75 million lost work days per year), *available at* http://www.phrma.org/publications/publications/value2001/value2001.pdf, (hereinafter "*The Value of Medicines*"); PhRMA, *Why Do Prescription Drugs Cost So Much and Other Questions About Your Medicines*, at 4-5 (June 2002) (study showed that a new drug treating migraine headaches saved employers $435 per month per employee due to a reduction in lost productivity costs, while the cost was only $44; for every $1 spent on prescription medications for allergies, corporations saved $3.07 in increased productivity, decreased sick time, and reduced accident costs), *available at* http://www.phrma.org/publications/publications/brochure/questions/.

[76] Hearing Transcript, Sept. 23, 2003, at 40-42; Lichtenberg presentation, at slides 26-30; *see also The Value of Medicines*, at 18 (study of 1,100 patients suffering from congestive heart failure showed that savings due to increased use of medicines totaled $9.3 million; in addition, the patients had a 15% increase in their ability to perform the activities of daily living).

[77] Neal Masia, Ph.D., *Economic Impact of DTC Advertising*, at slide 10 (Sept. 23, 2003) (citing Frank Lichtenberg, "Benefits and Costs of Newer Drugs: An Update," NBER *Working Paper* 8996, June 2002), *available at* http://www.fda.gov/cder/ddmac/p4masia/index.htm, (hereinafter "Masia presentation"); *see also The Value of Medicines,* at 6, 12 (savings in hospital expenses for AIDS patients due to new drug treatments could be as high as $8,000 per year; a drug treatment available for women at high-risk for breast cancer costs approximately $1,050 per year, while the average cost for surgery or other invasive treatments is $14,000 per year).

[78] Remarks by The President, President Calls on Congress to Complete Work on Medicare Bill, Presidential Hall, Dwight D Eisenhower Executive Office Building (Oct. 29, 2003), *available at* http://www.whitehouse.gov/news/releases/2003/10/20031029-1.html (noting the lower cost of preventive treatments as compared to medical interventions once a condition has become serious: "[S]eniors relying exclusively on Medicare do not have coverage for most prescription drugs and many forms of preventative care. This is not good; it's not cost-effective medicine. Medicare today will pay for extended hospital stays for ulcer surgery, at a cost of about $28,000 per patient. . . . Yet Medicare will not pay for the drugs that eliminate the cause of ulcers—drugs that cost about $500 a year. So anytime you talk about cost savings, there's an example of cost savings. Medicare will pay many of the costs to treat a stroke, including bills from hospital and rehab center, doctors, home health aides and out-patient care. Those costs can run more than $100,000. . . . Yet Medicare does not cover the blood-thinning drugs that could prevent strokes, drugs that cost less than $1,000 a year.").

study produced data showing that (1) consumers want and need clear, comprehensible information about health issues and treatments that concern them; (2) once armed with this information, consumers use it to engage in deeper, more thoughtful dialogue with their physicians about conditions and treatment options; (3) as a result of this communication, the doctor is better equipped to diagnose conditions and counsel the patient; and (4) together, the doctor and patient arrive at a treatment plan that is best suited to that individual's needs. DTC advertising has a demonstrable impact at the beginning of this cycle, and many forms of DTC communications support the dynamic throughout the process. Furthermore, as Section II outlines, the record contains no persuasive evidence of any countervailing harms.

II. THE RECORD DOES NOT SUPPORT THE CRITICISMS THAT SOME HAVE DIRECTED AT DTC ADVERTISING

FDA certainly is aware that DTC advertising has been the subject of vocal criticism by those who seek to curtail it severely—by regulation or taxation—or to ban it altogether. The principal arguments raised against it are that DTC advertising leads doctors to write unnecessary or "second best" prescriptions under patient pressure; that DTC advertising necessarily increases the cost of prescription drugs; and that FDA is insufficiently policing DTC advertising and, particularly in the case of "reminder" ads, allowing misleading messages to reach the public.

In Section I of these comments, we discussed the actual, beneficial impact of DTC advertising as developed in the record. In Section II, we address the criticisms directly in light of the record evidence to demonstrate that they are unfounded and therefore provide no basis for regulatory action.

A. There Is No Credible Evidence That DTC Advertising Creates Pressure On Doctors That Leads To Improper Prescribing

Critics of DTC advertising contend that the ads prompt consumers to demand that their doctors issue prescriptions for specific advertised drugs—and that those physicians comply without regard to either their professional judgment or knowledge of alternatives.[79] The empirical record contains no meaningful evidence to substantiate this contention. To the contrary, as noted above in Section I.C, the data show overwhelmingly that patients are receiving appropriate diagnoses and, when warranted, prescriptions for drugs to treat those conditions. There is no evidence to justify claims of excessive prescribing or anything reliable to substantiate fears concerning "second best" prescribing.[80]

1. The record does not support the criticism that patients pressure doctors to inappropriately prescribe specific drugs

Multiple studies corroborate that most consumers who consult their doctor about advertised drugs are seeking more information about an underlying condition and available treatment, rather than a prescription for a specific advertised drug.[81] For example, Prevention found that where a condition is being discussed for the first time, only 17% of patients ask their

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[79] *See, e.g.*, Hearing Transcript, Sept. 22, 2003, at 43-44; *id.*, Sept. 23, 2003, at 68-69, 174.

[80] Given the consumer demand for information about prescription drugs, the clear public health benefits that flow from answering that demand, and the role of the learned intermediary as the prescriber in the process, FDA would face significant constitutional impediments in attempting to justify new restraints on DTC based solely on fears that a few doctors may not prescribe prescription drugs appropriately. *See* Pfizer First Amendment Comments at 147-51.

[81] 2002 Aikin presentation, at slide 34 (23% of those surveyed asked their physicians about treatment for a condition, while only 7% asked about a specific brand); Henry N. Young, Ph.D., et al., *Does Direct-to-Consumer Advertising (DCTA) Promote Shared Decision Making? A Preliminary Study*, at slide 15 (Sept. 22, 2003) (93.5% of respondents were more likely to seek additional information about advertised drugs than a prescription), *available at* http://www.fda.gov/cder/ddmac/p3young/index.htm, (hereinafter "Young presentation"); Golodner presentation, at slide 14 (citing *NCL Patient Survey* (half of patients who visited a doctor after seeing an ad said they wanted to find out if the medication was right for them, 33% said they wanted to find the best way to treat their condition, and only 10% said they wanted the advertised drug)); Allison-Ottey presentation, at slide 38 (citing *COSHAR Patient Survey* (21% of patients wanted to discuss a specific drug with their doctor after seeing a DTC ad, but only 11% planned to ask for a specific prescription)).

doctor to prescribe a medicine that treated the condition.[82] Studies also show that most consumers do not expect their doctor to prescribe a drug for them simply because they raise a question about a DTC ad—but that if the consumer does expect a prescription, it appears to correlate most strongly with the fact that he or she previously had a "script" for the same pharmaceutical.[83] In short, the data indicate that most patients prompted by DTC advertisements to consult their doctors ask about a condition and do not demand a particular drug.[84]

2. The record does not support the criticism that physicians feel pressured to prescribe as a result of DTC ads

Several studies also demonstrate that the vast majority of physicians do not feel that DTC advertising has pressured them to prescribe inappropriate medications—or, indeed, that it has pressured them to prescribe anything at all.[85] According to FDA's own survey, only 7% of GPs and 1% of specialists reported feeling very pressured by patient requests for drugs.[86] Moreover, it is not clear from the study reports that patient requests about advertised drugs are a significant issue compared to other factors that likely impose "pressure" on today's practitioners.[87]

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[82] Slaughter presentation, at slide 22 (citing *Prevention Annual Surveys*).

[83] Aikin presentation, at slides 14-15 (citing *FDA Patient Survey* (2002) (57% of patients did not expect their doctors to prescribe a drug for them; of the remainder, 63% expected it because they had a previous prescription for the same condition, only 6% expected it because they had seen an ad on the TV or radio, and only 4% expected it because they had seen a magazine ad)).

[84] As discussed, *supra*, Section I.C, the vast majority of patients asking about a drug are found to have the condition that the drug treats.

[85] Aikin presentation, at slides 30, 43, 44 (citing *FDA Physician Survey* (2002) (82% said that DTC ads did not create any problems for their interaction with patients; 91% said the patient did not try to influence the course of treatment in a way that would have been harmful; 48% of GPs and 58% of specialists felt "not at all" pressured to prescribe a specific brand name drug when asked about it)); Allison-Ottey presentation, at slides 24-25 (citing *NMA/COSHAR Physician Survey* (61% did not feel additional pressure to justify their prescriptions based on patient requests; 89% said they had not changed their prescribing habits as a result of DTC ads)).

[86] Aikin presentation, at slide 44 (citing *FDA Physician Survey* (2002)).

[87] It does not appear that the studies attempted to determine whether doctors feel more pressure from patient requests for drugs generally than they do from other factors affecting modern practice, including productivity demands,

The apparent logic underlying the concern about patient "pressure" is that it is wrong for consumers to ask questions of their doctors. The notion that doctors are unable or unwilling to accommodate patient questions is at odds with the modern trend toward patient empowerment, which recognizes that "[p]atients and their families believe they are entitled to at least the same level of customer service [in the doctor/patient relationship] as they demand in other important transactions."[88] Pfizer believes that, as a public health matter, it is important for patients to ask their doctors questions about health conditions and potential treatment, and that consumers deserve access to sufficient information to ask those questions thoughtfully. Were FDA to base further limitations on DTC on the need to protect doctors from patient questions—appropriate or inappropriate—it would have substantial difficulty in asserting this rationale as a substantial government interest that justified new regulations.[89]

3. The record does not substantiate the fear that physicians prescribe improperly because of DTC ads

Some critics contend that DTC advertising automatically leads to the issuance of a prescription for the advertised drug, whether or not the individual patient needs that product. The data in this record prove to the contrary.[90] First, as noted above, there is substantial

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paperwork burdens, and the need to keep up with current medical research and clinical developments. As several FDA officials and witnesses at the hearing indicated, those aspects of practice likely do impose some stress on physicians, but they are not linked to DTC. Hearing Transcript, Sept. 22, 2003, at 43-44; *id.*, Sept. 23, 2003, at 68-69, 174.

[88] Amy Dockser Marcus, *Saving Baby Dalton: Doctors, Nurse—And Mom and Dad,* Wall St. J., Oct. 22, 2003, at 1.

[89] *See* Pfizer First Amendment Comments at 3-17 (discussing patient empowerment); *id.* at 147-51 (discussing paternalism).

[90] In certain cases, DTC advertising does not even lead to higher sales volume—*i.e.*, some DTC advertising campaigns can "fail" if doctors and their patients do not find the drug beneficial. Masia presentation, at slide 5.

evidence demonstrating that DTC advertising prompts doctor-patient conversations that lead to proper treatment regimens following diagnoses.[91]

Second, the data also show that patients who ask their doctors about advertised drugs receive information on a variety of treatment options available to them—such as other brands of pharmaceuticals, both prescription and over-the-counter drugs, as well as counseling about behavioral or lifestyle changes that might improve their conditions. Several studies corroborate FDA's own findings in this area. For example, both FDA and Harvard/Harris found that about 30% or more of patients who ask about one drug end up with a prescription for a different pharmaceutical.[92] In addition, three separate studies determined that in a significant percentage of cases, ranging from 45% to 60%, consumers who ask about a drug receive a recommendation for a behavioral or lifestyle change, whether or not they obtain a prescription.[93]

Third, the available evidence on prescription patterns for certain classes of drugs confirms physician reports that DTC advertising is not resulting in inappropriate prescribing. The Calfee study of the effect of statin drug advertisements found no evidence of a tendency toward over-prescribing; physicians appear to be issuing prescriptions when patients reach a

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[91] Weissman presentation, at slides 6, 15 (citing *Health Affairs* (2003) and *Harvard/Harris Study* (2003)) (for patients visits where advertised drugs were actually prescribed—which accounted for only 47% of recent DTC-prompted visits—physicians reported that in 46% of the cases, the drug was the most effective one for the patient; in 48% of the cases, it was as effective as other drugs)). Moreover, physicians reported that patients have a realistic layperson's expectations about the condition that the advertised drug treats, its limitations, and the type of patient who should be using it. *See* Aikin presentation, at slides 46-47 (citing *FDA Physician Survey* (2002)).

[92] Aikin presentation, at slide 16 (citing *FDA Patient Survey* (2002)); Weissman presentation, at slide 6 (citing *Health Affairs* (2003)).

[93] Aikin presentation, at slide 16 (citing *FDA Patient Survey* (2002)); Weissman presentation, at slide 6 (citing *Health Affairs* (2003)); Slaughter presentation, at slide 20 (citing *Prevention Annual Surveys* (2001)). According to the Harvard/Harris findings, doctors in only 5.5% of cases reported prescribing an advertised drug where another treatment option would have been more effective, but where they wanted to accommodate a patient's request. *See* Weissman presentation, at slide 15 (citing *Harvard/Harris Study* (2003)). The study provided no indication, even in these cases, that the prescription was issued without foundation.

certain cholesterol level, regardless of whether patients have viewed DTC ads for statin drugs.[94] The Dubois study on statins produced results that are consistent: an increase in DTC ads for statins coincided with a 60% increase in the number of patients using them, but statistics consistently indicated that the prescriptions were appropriate.[95]

Of the research presented during the September hearing, only two studies drew any negative (or at least equivocal) conclusions about connections between DTC communications and physician prescribing practices. However, both studies suffer from patent flaws in design. The larger of the two was conducted under the auspices of the University of British Columbia ("UBC").[96] The UBC study concluded that DTC ads were leading some doctors to prescribe drugs in which they "lacked confidence" to patients who requested them.[97] This conclusion rested on a comparison of statistics concerning physician attitudes toward the drugs they had prescribed for two sets of patients—(1) patients who asked for a DTC-advertised drug, and (2) patients who did not ask for a drug. The UBC researchers asked doctors to indicate in both cases whether the same drug would have been only a "possible" or "unlikely" choice for other similar patients. Doctors reported that the drug given to patients in the first group was a "possible" or "unlikely" choice more often than drugs given to patients in the second group.[98]

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[94] Hearing Transcript, Sept. 23, 2003, at 16-17; John E. Calfee, Ph.D., *Presentation To The Food And Drug Administration's Workshop On Direct-To-Consumer Advertising Of Prescription Drugs*, at slide 13 (Sept. 23, 2003) (citing *IMS HEALTH Retail and Provider Perspective*), *available* at http://www.fda.gov/cder/ddmac/p4calfee/index.htm, (hereinafter "Calfee presentation").

[95] Robert N. Dubois, M.D., Ph.D., *Pharmaceutical Promotion: Perhaps Don't Throw The Baby Out With The Bathwater*, at slides 8-10 (Sept. 22, 2003), *available at*, http://www.fda.gov/cder/ddmac/p2dubois/index.htm, (hereinafter "Dubois presentation").

[96] University of British Columbia, *How Does Direct-To-Consumer Advertising (DTCA) Affect Prescribing? A Survey In Primary Care Environments With And Without Legal DTCA* (Sept. 22, 2003), *available at* http://www.fda.gov/cder/ddmac/ATT424066/index.htm, (hereinafter "UBC presentation").

[97] UBC presentation at slide 19; Hearing Transcript, Sept. 22, 2003, at 164.

[98] UBC presentation, at slide 16.

FDA officials at the September hearing, however, properly cast significant doubt on both the UBC numbers and the conclusion drawn from them. As Dr. Robert Temple, FDA's Director of the Office of Medical Policy, pointed out, the phrasing of the survey left open a rather basic question: it is not at all clear "why" physicians might have felt that a particular drug was only a possible or unlikely choice for other patients.[99] In response, the UBC faculty member presenting the data conceded that physicians might have meant their prescription choice for a particular patient was based on that individual's particular medical history, tolerance for risk, or insurance coverage.[100] Most significantly, even with these research design weaknesses, physicians in the UBC study reported feeling some pressure in only 3% of cases overall, and in only 6% of cases in which a drug was actually prescribed.[101] Thus, the studies could not rule out the possibility that advertising-based inquiries enhanced, rather than overrode, the doctor's judgment.[102]

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[99] Hearing Transcript, Sept. 22, 2003, at 176-179. Dr. Temple also commented on the oddity of the results indicating that in a relatively high percentage of cases—even when physicians faced no patient request for a drug—the doctor still apparently "lacked confidence," as the UBC researchers defined it, in their prescription decisions.

[100] Hearing Transcript, Sept. 22, 2003, at 176-179. In addition, the individual physicians participating in the UBC study reported on an average of eighteen patient interactions each—a study design that might skew the results. As Dr. Kathryn Aikin of DDMAC noted during the September hearing, study data on physicians' attitudes toward DTC-prompted patient interactions can be affected by the physicians' own negative personal opinions of DTC, regardless of the actual impact of DTC on their patients. *Id.* at 40-41. If one of the physicians participating in the UBC study was inherently distrusting of patient requests for drugs, this individual's distrust would have been factored into the analysis multiple times over.

[101] UBC presentation, at slide 17. These percentages are even smaller than those resulting from similar questions in FDA's own studies. *See supra,* footnote 86; Hearing Transcript, Sept. 22, 2003, at 164.

[102] The other study offering a similarly flawed conclusion was presented by a research pharmacist on staff at the Mayo Clinic in Jacksonville, Florida. *See Assessment Of The Impact Of Direct-To-Consumer Advertising Of Prescription Drugs On Consumers And Prescribers* (Sept. 22, 2003), *available at* http://www.fda.gov/cder/ddmac/P2schultz/index.htm, (hereinafter "Fla. Mayo presentation"). Those survey results, drawn from her previous association with a public hospital in Jacksonville, indicated that approximately one-third of prescribers at that institution might not have prescribed a drug if the patient had not asked for it. *Id.* at slide 22. But, by the presenter's own admission, her survey sample was very small (Hearing Transcript, Sept. 22, 2003, at 171-172); it is not at all clear that the resulting data is statistically significant. It also should be noted that most of the responding physicians were residents or interns within their first five years of practice. Fla. Mayo presentation, at slide 17; Hearing Transcript, Sept. 22, 2003, at 172. Nevertheless, 64% of the respondents said they would have prescribed the drug without the patient's request some or most of the time. Fla. Mayo presentation, at slide 22.

In sum, while a few studies of record suggest that some physicians feel pressure in dealing with patient requests for prescription drugs, none of the research shows that doctors are incapable of dealing with it. Regardless of what may be behind the reported pressure—which may have nothing to do with the validity of patient requests—the positive benefits of DTC-inspired conversations between consumers and their doctors far outweigh any perceived negative impact on a few doctors. As Dr. Temple pointed out during the September hearing, DTC advertising has in many cases resulted in patients getting treatment where they otherwise would not have consulted a physician about their condition.[103]

4. The record does not support the criticism that consumers wrongly believe that DTC advertising contains complete information about prescription drugs

Several critics who challenge the public health benefits of DTC advertising apparently are concerned that consumers have neither access nor the inclination to seek out more information about prescription drugs. The data in the record demonstrate that this contention is not well founded. To the contrary, surveys show that DTC advertising—which under current requirements explicitly directs consumers to consult their doctors and also directs consumers to how to obtain more detailed facts elsewhere from the manufacturer—encourages consumers to seek out additional information. Data show that the sources to which many consumers turn include not only their doctors but also pharmacists, medical reference books, specialty media such as health-oriented magazines, and websites and toll-free numbers provided by pharmaceutical manufacturers. The evidence also demonstrates that the Internet has become a key conduit, where information may be exchanged through e-mail groups, chat rooms, or specialty websites of entities ranging from disease-oriented interest groups to health insurers.

[103] Hearing Transcript, Sept. 22, 2003, at 192-193. Dr. Temple also noted that in such cases, it is better that the patient received some drug therapy, even if not the optimum choice, rather than no treatment at all.

FDA has found that more than 40% of consumers who are exposed to DTC advertising search for more information about a condition or treatment because of the ad, a finding corroborated elsewhere.[104] FDA data indicate that physicians remain by far consumers' leading source for follow-up information—at 89%—followed by other health-care professionals, pharmacists (51%) and nurses (40%).[105] Surveys by other entities corroborate that professional caregivers remain the top information source sought out by patients exposed to DTC advertising.[106]

The research data also indicate that consumers make good use of other sources of follow-up information. Based on its survey, Prevention projects that 37 million Americans who see a DTC advertisement subsequently consult a website, print ad, or toll-free number.[107] Another study reported that more than 12 million people visited drug company websites during the first quarter of 2003 alone.[108] These results are consistent with research showing that consumers have a growing appreciation for the wealth of detail available to them online: Prevention's surveys indicate that nearly 40% of consumers who tapped into the Internet last year were looking for

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[104] Aikin presentation, at slide 8 (citing *FDA Patient Survey* (2002)); Allison-Ottey presentation, at slide 38 (citing *COSHAR Patient Survey*).

[105] Aikin presentation, at slide 9 (citing *FDA Patient Survey* (2002)).

[106] According to the NCL, 31% of patients decided to talk with their doctor about the drug or condition at their next appointment; 26% sought more information; 16% contacted their doctor immediately. Golodner presentation, at slides 9-10 (citing *NCL Patient Survey*). When seeking more information 16% of patients turned to a pharmacist; 14% looked to a medical or drug reference book; 14% visited general information on the Internet; 10% talked to a nurse or called an 800 number. *Id.* at slide 11 (citing *NCL Patient Survey*). Parade Magazine reports that patients seek information from doctors or other health professionals more frequently than from any other source, with 62% saying they use their doctor as an information source and 37% saying they use the Internet as an information source. Kassan presentation, at slide 12 (citing *Parade Magazine Survey*).

[107] Slaughter presentation, at slide 12 (citing *Prevention Annual Surveys* (2001, 2002)).

[108] Alan Goldhammer, Ph.D., *The Internet and Useful Patient Information*, at slide 7 (Sept. 22, 2003) (citing *Nielsen/Net Ratings*), *available at* http://www.fda.gov/cder/ddmac/P7Goldhammer/index.htm, (hereinafter "Goldhammer presentation").

prescription drug information—and of those, a whopping 96% said the information they found online was useful.[109] Indeed, caregivers (who may not always have direct access to the patient's doctor) treat the Internet as a vital source of information. Data show that almost 60% of them use the web to gather information relevant to the ill person's health, a percentage slightly higher than the caregiver's consultations with the ill person's doctor or other treating health professional.[110]

Based on this record, FDA plainly could not conclude that DTC advertisements are the sole source of information about prescription drugs that is available to consumers.[111]

B. There Is No Evidence That DTC Advertising Increases Drug Prices

Some critics of DTC advertisements also contend that these communications waste money. The arguments tend to fall into one of two categories: (1) either advertisers must be passing through the costs of DTC ads to consumers in the form of higher prices for individual

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[109] Slaughter presentation, at slides 30, 32 (citing *Prevention Annual Surveys* (2002)).

[110] Kassan presentation, at slide 12 (citing *Parade Magazine Survey*).

[111] The record evidence here has more implications for FDA's DTC regulatory scheme than may be immediately obvious. DTC communications do benefit the public health by spurring interested consumers to seek out additional information about prescription drugs and the conditions they address. At the same time, however, it is clear that DTC advertising—or any other speech by pharmaceutical manufacturers—is far from being consumers' only outlet for information about prescription drugs. Therefore, the agency faces certain legal limitations in regulating the speech of only one entity among many information sources that speak to consumers on the subject of drugs. *See* Pfizer First Amendment Comments at 151-53.

Furthermore, as FDA's own regulatory approach to broadcast ads reflects, each medium of communication has different strengths and weaknesses in effectively conveying information. *See* Center for Drug Evaluation and Research, DDMAC, Guidance for Industry - Consumer-Directed Broadcast Advertisements, 1 (Aug. 1999), *available at* http://www.fda.gov/cder/guidance/1804fnl.htm ("The prescription drug advertising regulations (21 CFR 202.1) distinguish between print and broadcast advertisements. Print advertisements must include the brief summary.... Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks...[and] also ... make 'adequate provision ... for dissemination of the approved or permitted package labeling'...."). Thus, even with respect to a single speaker, an effective and legally supportable DTC policy should reflect these distinctions.

drugs, or (2) DTC ads increase aggregate drug spending by placing prescriptions into the hands of people who do not need them. The data in the record demonstrate that neither is true.

Moreover, Pfizer believes that successfully encouraging under-diagnosed and under-treated consumers to visit their doctors is both a boon to the individual's health and of benefit to the collective public health. Therefore, to the degree that some may seek to use the policy debate surrounding DTC communications to raise questions before FDA about total expenditures on drugs, such efforts are inappropriate. Funding the cost of necessary health care is a matter being addressed by the Congress and other agencies, and there is no warrant for FDA to suppress DTC advertising as a means of dealing with their budgetary issues. Similarly, the argument that DTC expenditures limit commitments that would, or should, otherwise be made to research and development of new drugs involves economic issues outside FDA's public health mandate. In any event, the record has no evidence supporting this contention, and research and development expenditures dwarf DTC expenses.[112]

1. The record contains no empirical evidence that DTC advertising costs raise per-prescription drug prices

Some have posited that manufacturer spending on DTC advertisements causes individual prescription drugs to be more expensive for consumers than they otherwise would be if manufacturers did not engage in such marketing. Even if FDA had authority to pursue drug-pricing issues, this contention is wrong both theoretically and empirically.

The data in this record is consistent with the well-accepted economic theory that the costs of advertising can be recovered by the increased sales that the advertisements help to generate.[113]

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[112] Masia presentation, at slide 2. Research and development expenditures for the pharmaceutical industry in 2002 exceeded $30 billion, while spending on DTC advertising was less than $3 billion.

[113] *See, e.g.*, Rubin, at 14-17.

Although some assume the cost of advertising any product necessarily leads to increased prices to recover the marketing costs, economic studies show that the dynamic between advertising costs and sales prices is more complex.[114] Sellers typically engage in advertising in order to increase sales—and when that occurs, the cost of advertising is spread over a larger pool of sales units, thereby reducing the per-unit overhead costs accordingly.[115] Moreover, increased sales can both recover advertising costs and increase the total return to the manufacturer of the advertised drug.[116]

The evidentiary record proves the latter theory to be correct here: The data shows no correlation between DTC ad spending and changes in per-prescription prices. An analysis of data drawn from across the pharmaceutical industry demonstrates that consumer-directed advertising does not correlate to greater price increases for an advertised drug as compared to a non-advertised product. In 2002, the average sale price of top-selling prescription drugs promoted through DTC advertising was $102, while the average sale price of such products not promoted through DTC advertising was $127.[117] Data show that the correlation between advertising levels and price levels is actually somewhat negative.[118] Similarly, the correlation between advertising levels and changes in price also is somewhat negative.[119] Research

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[114] *See* Rubin at 14-15; *see also* Beales/Muris, at 7-10.

[115] *See, e.g.*, Rubin, at 14-16.

[116] *See id.* at 15.

[117] Masia presentation, at slide 6. The majority of Pfizer products with more than $250 million in sales per year are not promoted through DTC ads.

[118] Masia presentation, at slide 7.

[119] Masia presentation, at slide 9.

presented by Dr. Calfee on the effect of DTC ads on statin drug prices produced results consistent with these findings.[120]

In sum, there is no factual basis for the concern that DTC advertising necessarily drives up the per-prescription cost of drugs for consumers.

2. The record contains no empirical evidence that DTC ads improperly increase overall spending on drugs by unnecessarily expanding the number of patients who receive drug treatments

Critics also claim that DTC advertising leads to inappropriate prescribing and thus unnecessarily expands aggregate spending on drugs. As discussed above, however, there is no credible evidence that inappropriate prescribing is occurring.[121] To the contrary, DTC advertising is making some headway in helping to solve widely recognized under-diagnosis and under-treatment of serious health conditions, although much still remains to be done on these fronts.[122]

Accordingly, the data in the record supports the conclusion that DTC advertisements are spreading information about conditions and treatments to people who legitimately should act on that information—and that many of them are doing so by consulting their doctors and obtaining proper medical care, including but not limited to drug therapies. Evidence also indicates that appropriate drug therapies benefit the health of individuals and, through them, have a positive effect on total health care expenditures.[123] The Pharmaceutical Research and Manufacturers of America ("PhRMA") have reported on the wide body of evidence that exists regarding the

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[120] Calfee presentation, at slides 13-14.

[121] *See supra,* Section II.A.

[122] *See supra,* Sections I.C. and I.D.

[123] As noted above, usage of new drugs, as well as those that have been available for some time, contributes to societal benefits. *See supra,* Sections I.E. and I.F.

savings to individuals, employers, and society at large that result from utilization of drug therapies.[124] In the case of vaccines that have been developed to treat children's diseases, substantial savings in both individual health care costs and more general societal costs are attributable to the available drug regimens.[125] Studies also indicate that use of prescription drugs among workers results in significant benefits to the employers, as well as the workers themselves, due to reduced absenteeism.[126]

Moreover, other data show that DTC advertising, in and of itself, is far from the only factor behind increased aggregate spending on prescription drugs. According to a recent Kaiser Family Foundation analysis, even if DTC costs are assumed to be an added element of aggregate drug expenditures, 88% of the *increase* in prescription spending over a one-year period (1999-2000) was due to non-DTC factors, such as the availability of new products and the aging population.[127] The Kaiser study's attribution of only 12% of the increase to DTC advertising,

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[124] *See The Value of Medicines*; PhRMA, *Pharmaceutical Industry Profile - 2003*, 28-34, *available at* http://www.phrma.org/publications/publications/profile02/index.cfm and http:///publications/publications/profile02/2003%20CHAPTER%203.pdf, (hereinafter "*Pharmaceutical Industry Profile – 2003*").

[125] *The Value of Medicines*, at 3 (citing studies estimating that for every $1 spent on vaccines for measles-mumps-rubella, the health care system saves $21; for every $1 spent on vaccines for diptheria-tetanus-pertussis, the health care system saves $30; during the first 11 years following the introduction of a vaccine for bacterial meningitis, cases among young children dropped nearly 80%, resulting in $135 million per year in savings due to avoided hospital costs).

[126] *Pharmaceutical Industry Profile - 2003*, at 31 (workers with chronic conditions such as hypertension, heart disease, type 2 diabetes, and depression frequently lose hourly wages due to days absent from work, which also results in financial losses to their employers; annual net savings per employee due to use of drug treatments were $276 per employee with hypertension, $633 per employee with heart disease, $822 per employee suffering from depression, and $1,475 per employee with diabetes).

[127] Masia presentation, at slide 4 (citing Rosenthal, et al., Kaiser Family Found., *Demand Effects of Recent Changes in Prescription Drug Promotion* (June 2003)).

under unfavorable assumptions, refuted the contention that DTC was the "primary" factor affecting the rise in aggregate spending.[128]

In short, DTC advertising operates as a beneficial market-expanding mechanism, spreading awareness of newly available drug therapies more quickly than might otherwise occur and helping to speed appropriate treatment to patients who need it. Those who raise objections over increases in aggregate spending on prescription drugs apparently do not grasp the significance of these gains for particular patients, much less the greater commonweal. Nor is it clear that critics grasp the implications of their criticisms. Efforts to control aggregate drug spending by depriving some people—often the less educated or motivated ones—of information that they could use to improve their health, as others with better access to data already do, is not a viable policy objective. Open advocacy of this notion obviously is unseemly, but FDA should not ignore the clear implications of the argument that is being made *sub rosa*.[129]

C. There Is No Evidence That DTC Advertising Is Abusing Regulatory Disclosure Standards

Critics of DTC ads have argued that the advertising is suspect because it allegedly does a poor job in communicating risk information to consumers. Others question what they perceive as overuse of FDA-sanctioned reminder ads. As discussed below and in Section III, although the effectiveness of any communication is likely amenable to improvement, the record does not contain empirical evidence showing that the ads in their current form are confusing consumers,

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[128] Meredith B. Rosenthal, Ph.D., et al., Kaiser Family Found., *Demand Effects of Recent Changes in Prescription Drug Promotion*, 18 (June 2003), *available at* http://dev.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14380.

[129] *See* Bert W. Rein et al., Wash. Legal Found., *Proposed Limits on Prescription Drug Ads: A Constitutional Analysis* (July 2002).

deterring them from seeking professional advice, engaging in thoughtful dialogue with physicians, or otherwise imposing harm.[130]

1. The record contains no empirical evidence that current disclosures are insufficient to spur appropriate doctor-patient dialogue about the risks of prescription drugs

Pfizer agrees that the presentation of adequate risk information to consumers is an important issue and so addresses the matter in some detail in Section III, below. At this point, however, it is appropriate to note that the evidence in the record does not substantiate critics' arguments that consumers today are unaware that prescription drugs carry risks. To the contrary, the data show that consumers grasp the key fact that drug therapy poses some risk as well as benefit—and, for that reason, they understand that the doctor should be the final decision-maker in issuing a prescription.[131] Thus, it appears that today's DTC communications, even if imperfect, are achieving the ultimate regulatory objective upon which FDA should focus here: they are succeeding at motivating patients to engage in constructive benefit/risk dialogue with physicians about whether a particular drug is suitable for the patient.

2. The record contains no empirical evidence that reminder ads are misleading consumers about drug benefits

Some have questioned the use of reminder ads, which by definition feature the brand name of a prescription drug but no information about the specific indications for which it was

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[130] *See* Pfizer First Amendment Comments at 104 n.341, 150 (agency must justify new burdens on speech with evidence that the harms it seeks to address are "real" and that proposed restraints will "directly and materially" address the identified problems) (citing, *e.g.*, *Edenfield v. Fane*, 507 U.S. 761, 770-73 (1993)).

[131] Aikin presentation, at slide 46 (citing *FDA Physician Survey* (92% of physicians say that patients seeing DTC ads understand very well or somewhat that the drugs are only available by prescription; 82% say that patients understand very well or somewhat that only the doctor can decide if the drug is right)).

approved.[132] The concern appears to be that reminder ads are being used to signal messages about efficacy while avoiding disclosures, but the record contains no data to substantiate suspicions that manufacturers are seeking to evade current regulatory requirements.

Reminder ads have been and remain a valid and useful component of manufacturers' multi-media, multi-message effort to reach consumers. The record demonstrates that both consumers and doctors believe DTC ads assist in reminding patients to continue with existing prescriptions.[133]

Unless FDA amasses more evidence to prove that systematic abuses are occurring and cannot be addressed by individual enforcement actions, the agency would be hard-pressed to demonstrate that reminder ads are inherently misleading and therefore justify additional regulatory intervention.[134] If manufacturers choose to include in their communication mix some advertisements that simply name the product, with no representations on effectiveness, there is no basis to find those ads false or misleading—because they have not, in fact, "claimed" benefits which require offsetting risk disclosures.

Pfizer routinely exceeds the regulatory disclosure mandates for reminder ads because we believe that including some additional information best serves consumers' interests in learning more about our products and the conditions they treat. To be specific, we typically devote time or space in our reminder ads to (1) a general directive urging consumers to consult a doctor to

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[132] As defined in FDA regulations, "reminder" advertisements ". . . call attention to the name of the drug product but do not include indications or dosage recommendations for use of the drug product . . . and, optionally, information . . . containing no representation or suggestion relating to the advertised drug product." 21 C.F.R. §202.1(e)(2)(i).

[133] *See supra,* Section I.D. It is not clear that researchers distinguished between ads that presented efficacy information and those that did not. If FDA wishes to concentrate specifically on the effectiveness of reminder ads, it appears that further research is necessary.

[134] *See* Pfizer First Amendment Comments at 107-154. Indeed, the only relevant data in this docket appears to indicate that reminder ads are working as the regulatory construct contemplates. *See supra,* Section I.D.

discuss the drug, and (2) a referral to a Pfizer website or toll-free number through which the consumer can obtain both specific risk and benefit information. Refashioning reminder ad regulations to require both these elements would appear to preserve their utility to consumers while also addressing any concerns, however unsupported in the record, about adequate communication of drug risks. Such ads could not be reasonably accused of abusing either the letter or sprit of the reminder ad regulations or otherwise harming consumers.

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In sum, the empirical evidence in the record does not substantiate any of the criticisms or concerns that have been raised—in this proceeding or elsewhere—about the impact of DTC advertising on prescriber practices, drug costs, or risk assessment. Any claimed adverse impact is vastly outweighed by DTC's success in motivating consumers to contact their physicians and, once contact is made, engaging in better dialogue with doctors about health concerns and potential treatment options. Accordingly, current regulatory policies on DTC clearly advance the public health.

III. FDA CAN CONSIDER AMENDING CURRENT DTC REGULATIONS ONLY IF IT GATHERS EVIDENCE TO SHOW THAT CHANGES WILL FURTHER ENHANCE THE PUBLIC HEALTH

Because the record demonstrates the overwhelmingly positive impact of DTC communications, it is not surprising that attitudes toward DTC have, in the words of Peter Pitts, FDA Associate Commissioner for External Relations, undergone "an incredible sea change, from 'Is it a good thing?' to 'This is a good thing, and how can we make it better?'"[135] The agency should note, however, that it has not been presented with empirical evidence demonstrating that

[135] Nat Ives, *The Media Business: Advertising; FDA Ponders Pros And Cons Of The Ways Prescription Drugs Are Promoted To Consumers*, N.Y. Times, Sept. 29, 2003, at C11.

any perceived weaknesses in the current rules and policies are "real" or have created "real" problems—or, just as important, that any particular change to the existing requirements would "*in fact* alleviate" the asserted problem "to a material degree."[136]

Considerable discussion at the September hearing concerned risk information in DTC advertising.[137] But the record lacks data that could guide FDA were it to seek to change the current disclosure regime. Empirical evidence is meager on the key issues of how—and even whether—risk information in DTC advertising actually affects consumer behavior. It is noteworthy that witnesses at the hearing suggested that providing less, rather than more, detail in DTC advertising might better motivate consumers to consult their physicians, as long as the information that is provided is clear, concise, and well organized.[138] Data in the docket also suggest that untested changes to the disclosure requirements, however well intentioned, could overwhelm consumers and even deter many of them from raising a health issue with a doctor.[139] For these reasons, Pfizer believes that before FDA may increase disclosure requirements, the agency must more clearly determine the goals of risk disclosure and gather more data about consumer response to risk information.

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[136] *Edenfield v. Fane*, 507 U.S. at 770-71 (emphasis added); *accord, e.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476, 486-87 (1995). To pass constitutional muster, a government agency must demonstrate both the existence of a harm and that its proposed speech remedy will cure it.

[137] *See, e.g.*, Hearing Transcript, Sept. 22, 2003, at 124-131, 242-255.

[138] *See, e.g.*, Hearing Transcript, Sept. 22, 2003, at 247; Hearing Transcript, Sept. 23, 2003, at 113.

[139] *See, e.g.*, Hearing Transcript, Sept. 23, 2003, at 113, 133-135; Hearing Transcript, Sept. 22, 2003, at 229-230.

A. FDA Should Clarify That Its Regulation Of DTC Communications Achieves Its Purpose When Consumers Are Motivated And Enabled To Consult Intelligently With Their Doctors About Their Health Concerns And Available Treatment Options

The information gaps in the agency's factual record concerning effective risk disclosures may be due in part to a lack of consensus—or perhaps merely a lack of clarity—among policymakers as to the informational and behavioral goals that FDA seeks to achieve through mandated DTC disclosures. If FDA wishes to stimulate research to address the data gaps, it should come to consensus and state plainly its ultimate objectives for requiring DTC risk information. Articulating a clear consumer-behavior goal for risk disclosures is a requisite first step to designing an appropriate research protocol.

The Notice in this proceeding provides a basis for clarifying the agency's objectives. Numbered Paragraph 5 in the Notice asks:

> Can consumers understand and accurately assess claims regarding the efficacy of prescription drugs? Can consumers understand and accurately assess claims regarding the risks of prescription drugs? ... *Given the fact that prescription drug use requires participation of a learned intermediary*, how important is imperfect understanding [on the part of consumers]?[140]

The italicized language highlights the key question. Unlike over-the-counter drugs, where a consumer must rely on his or her own understanding to assess and choose among OTC options, the consumer in the prescription drug context is not a final decision maker. Congress has required that consumers engage with a physician in order to obtain and use a prescription drug.[141] Consequently, FDA's ultimate goal for regulating DTC communications must go beyond the rote invocation of better informing consumers about the risks of prescription drugs—

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[140] Consumer-Directed Promotion; Notice of Public Meeting and Request for Comments, 68 Fed. Reg. 47920, 47922 (Aug. 12, 2003) (emphasis added).

[141] Federal Food, Drug and Cosmetic Act ("FDCA") 21 U.S.C. §353.

because most consumers cannot fully appreciate that knowledge without the intervention and guidance of a learned intermediary and because misinterpretation can unnecessarily deter doctor-patient communications. Informing the consumer about risk can only be a single element of FDA's primary objective: motivating the consumer to use his or her knowledge by consulting a physician and engaging in meaningful dialogue about health conditions and treatment options.

B. Any Changes To Current Risk Disclosure Requirements Should Empower Consumers To Engage With Their Doctors About Health Issues While Also Respecting The Role Of The Learned Intermediary

Once FDA's regulatory focus is clearly directed at bettering the doctor-patient dialogue, any agency effort to improve upon existing risk disclosures must take into account the different perspectives and abilities that patients and doctors bring to those discussions. As discussed below, to support the consumer side of the dialogue, the agency should aim to foster DTC communications that neither under-inform laypersons about important risk considerations nor over-deter them from visiting their physicians to discuss their concerns and questions in more detail. To support the physician side of the dialogue, FDA should rely on the doctor's professional training and experience with the patient as the best means to ensure that patients receive a therapy option well suited to them—a reliance that the data discussed above demonstrates is warranted.[142]

1. Empowered consumers need to have a basic understanding of drug benefits and risks in order to participate in the best possible doctor-patient dialogue

In its First Amendment Comments, Pfizer discussed at some length the historical emergence of today's consumer empowerment movement in the health-care field—and the ramifications of having more engaged laypersons work in partnership with their physicians in

[142] *See supra,* Section I.C.

addressing health issues.[143] Pfizer understands that consumer empowerment supports some risk disclosure in DTC communications. For consumers to be "empowered" to engage intelligently with their physicians, they must appreciate that drug therapy has risks—and be prepared to assess, in consultation with the doctor, the risks they face individually in pursuing the prospective benefits of any treatment regime. However, consumers cannot be expected, and should not be induced to believe, that they are sufficiently informed to make judgments about relative benefit and risk without the assistance of their physicians. Empowering the consumer cannot mean supplanting the doctor.

The function of risk disclosures to consumers therefore should not be confused with the function of risk disclosures to prescribers. Pfizer is concerned that the historical basis of risk disclosure regulation—which originated in the context of ensuring that doctors had all details necessary to determine whether to issue a prescription—may blur that critical distinction. As Thomas Abrams, Director of FDA's Division of Drug Marketing, Advertising and Communication noted in a humorous aside during the September hearing, the roots of today's DTC regulation go back to a time when the regulated information was limited to the official drug labeling and was intended to be incomprehensible to laypersons.[144]

Pfizer has already submitted, in its related First Amendment Comments, an analysis that traces FDA's speech regulations forward from that time to the present day. As explained there, regulations originally intended to provide physicians with the detailed scientific information necessary to make prescribing decisions can be excessive or even counter-productive in the

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[143] *See* Pfizer First Amendment Comments at 12-17 (discussing the multi-source information environment and consumers' use of available information to interact with their physicians in a less paternalistic fashion than was once the norm).

[144] Hearing Transcript, Sept. 22, 2003, at 12-13.

context of communicating with consumers.[145] The data in this docket indicates that, on the whole, consumers do not—and in all likelihood cannot—make use of current DTC advertising disclosures in the way that physicians are expected to make use of the same material.[146]

In short, it is neither appropriate nor possible to ensure that consumers obtain comprehensive information from DTC advertising about the risks or benefits of a prescription drug as it may apply to a particular individual.[147] Rather, the licensed professional who prescribes the drug must serve that critical function.

2. DTC regulations should reflect the centrality of the learned intermediary's role in assessing the benefits and risks of treatment options for the individual patient

Were FDA to consider simply requiring an expanded list of detailed risk disclosures in DTC advertising, such a rule—if not tested with consumers—might work at cross purposes with two important policy considerations. First, it might stymie the primary objective of motivating consumers to discuss their health concerns with their doctors. Second, it could undermine the critical role that physicians must continue to play in the doctor/patient relationship.

It should be obvious that the policy need to provide comprehensive and detailed information about prescription drugs to physicians is distinct from the policy need to provide consumers enough information about a drug and the condition it treats to initiate a thoughtful

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[145] Pfizer First Amendment Comments at 26-35, 74-79, and 107-54.

[146] Aikin presentation, at slide 5 (citing *FDA Patient Survey* (2002) (41% of patients 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 Surveys* (1999) (46% of patients were not aware of or did not recall seeing the brief summary in DTC print ads; of the 54% who did recall see the brief summary, 12% read it thoroughly, 12% looked for key information, 15% skimmed it, and 10% did not read it)).

[147] FDA has been grappling with the issue of optimal information disclosure in the context of health claims for food products, with the understanding that consumers want access to health-related information and that this information will contribute to positive health outcomes for consumers; FDA is still engaged in efforts to determine the best possible way to ensure appropriate provision of health claim information to consumers. *See Food Labeling: Health Claims; Dietary Guidance*, 68 Fed. Reg. 66040 (proposed Nov. 25, 2003).

conversation with a doctor about the products risks and benefits. To paraphrase Dr. Sharon Allison-Ottey, FDA's regulations should let the "doctor be the doctor" by motivating patients to consult them about diagnoses and treatments.[148] It is the doctor's job to discuss the risks and benefits of therapy options with individual patients, taking into account the person's medical history, life situation, past adherence to treatment regimens, and any other relevant factors.

This policy approach is plainly consistent with the law: Congress through the FDCA already has determined that certain pharmaceuticals are sufficiently risky that they must be used only under the direction of a physician.[149] Both good policy and the nation's court-made law put the trained professional at the center of this process.[150] The government has been appropriately loathe to interfere with a physician's treatment decisions, because the licensed professional is deemed to be in the best position to assess an individual's health problems and provide the best possible advice on how to address them. Given the physician's role and professional sophistication with respect to overseeing prescription drug therapies, it is highly appropriate for FDA to require extensive risk/benefit information on the official package insert—or what Pfizer has called in its First Amendment Comments the "operative labeling"—that doctors use in making prescribing decisions.

But patients are not doctors. Accordingly, any agency effort to change DTC risk disclosures should not, even inadvertently, suggest that a theoretically perfect DTC ad could educate consumers fully about all the relevant risks and benefits of a prescription drug. It is not

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[148] Hearing Transcript, Sept. 22, 2003, at 132.

[149] FDCA, 21 U.S.C. §353(b).

[150] *See, e.g., Conant v. Walters*, 309 F.3d 629, 637-639 (9th Cir. 2002), *cert. denied*, 124 S. Ct. 387 (2003) (recognizing primacy of licensed professional in providing health-care services, including directives with respect to use of drugs).

possible or desirable to replicate professional medical understanding through any one list of drug disclosures, no matter how extensive.

As discussed in the next section, FDA needs more consumer-tested data to determine whether it could modify existing risk disclosure requirements. But in assessing that research, FDA also must consider that expanded recitations of risk information might actually be counter-productive and work to undermine the role of the learned intermediary. It is not illogical to worry that certain unintended negative consequences might very well flow from the provision of physician-oriented disclosures to laypersons. Beyond simply deterring some consumers from consulting their physicians, certain types of detailed disclosures might persuade other consumers that it would be safe to bypass real physician consultations and improperly obtain prescription drugs elsewhere. FDA should be concerned about drug seeking behavior—such as unlawful Internet-based "pseudo-prescribing"—that should be discouraged, not encouraged.[151]

Finally, if it were to consider revising current DTC risk disclosure policies, FDA should aim to preserve and enhance the important consumer-behavior objective that is within its grasp. DTC communications demonstrably help consumers acquire both the information and

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[151] *See* Letter of Pfizer Inc to Craig Jackson, R.Ph., Director, Division of Occupational and Professional Licensing, Utah Department of Commerce (Apr. 25, 2003) (citing Medical Board of California, *Internet Prescribing: Ordering Prescriptions Through the Internet? Buyer Beware!*, *available at* http://www.medbd.ca.gov/buyerbeaware.htm (explaining that "drugs should only be prescribed after an examination is performed and the cause of the problem or condition is diagnosed. On-line 'consultations' cannot, with any certainty, provide enough information to make a verifiable diagnosis."); Federation of State Medical Boards, *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* (adopted Apr. 2002), *available at* http://www.fsmb.org/ (stating, "[t]reatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.")); Press Release, U.S. Attorney's Office, District of Nevada, *Las Vegas Man Pleads Guilty to Unlawful Distribution of Controlled Substances on the Internet* (Aug. 5, 2003), *available at* http://www.fda.gov/bbs/topics/NEWS/2003/NEW00930.html (quoting FDA Commissioner Mark B. McClellan, M.D., Ph.D., who commended the Department of Justice for prosecuting illegal online marketers of controlled substances, and recognized the serious danger posed by Internet-based pseudo-prescribing: "This [case] highlights the serious risks posed by internet sites that bypass important safeguards for assuring that patients are properly treated with medicines of known safety and efficacy. Today's action sends a clear message that the U.S. Department of Justice and the FDA will aggressively pursue those who endanger the public by operating such illegal sites.").

confidence to actively engage their doctors in conversations about important health concerns. Much of the time, but not in every instance, those conversations will lead to diagnoses and treatment. In the aggregate, these interactions plainly advance the public health. However, even a conversation that leads to the determination that the patient is *not* suffering from a particular condition or would *not* benefit from a particular treatment is also of benefit to that individual, and to the public health as well.

C. Before FDA Could Consider Amending Its Current Regulatory Approach To Risk Disclosures, More Data Are Required To Determine How Various Alternatives Would Affect Consumer Behavior

FDA now has the empirical data it requested to demonstrate the beneficial impact that DTC communications under existing policies have had—especially since the agency's 1997 revision of its requirements for broadcast advertisements—on patients, doctors, and the public health. Before the agency changes those policies, FDA should hold itself to the same evidentiary standard for assessing risk disclosures that it has used to assess the benefits of existing DTC communications.

It is in the interest of research-based pharmaceutical companies, as well as FDA, for DTC communications to effectively inform consumers about the risks and benefits of prescription drugs. Both witnesses and FDA officials raised questions and posed hypotheses about DTC risk information during the September hearing.[152] Those comments highlighted that the agency still lacks an empirical basis for determining what consumers "take away" from various alternative approaches to disclosures. The record also lacks substantial evidence as to how that take-away understanding actually affects consumer behavior—specifically, what impact it might have on consumers acting to contact physicians to discuss the risks and benefits of treatment alternatives.

[152] Hearing Transcript, Sept. 22, 2003, at 253; *id.* at 246-249, 251-252.

Recent experience in Europe, where regulators devised a sliding scale of "risk descriptors" for consumer-directed information about pharmaceuticals, demonstrates the dangers of adopting new approaches to risk disclosure without having first conducted the research necessary to inform the decision. The European Commission developed a set of risk guidelines that grouped side effect incidence into verbal probability ranges—*e.g.*, very common, common, uncommon, rare, and very rare.[153] Although this tiered approach to risk warning was meant to better inform consumers, it worked instead to frighten and confuse them: data indicated that laypersons perceived the risks to health of these side effects as significantly higher than they were, and therefore they would be less likely to take the medication.[154] This failed attempt to improve risk messages indicates why any changes to U.S. regulation on consumer-directed risk disclosures need to be validated in advance by empirical research. FDA needs data, rather than intuition, to better understand the behavioral effects of its current disclosure mandates as well as any potential alternatives.

As the agency has recognized in other proceedings,[155] overloading consumers with too much risk information at an early stage in their awareness of a health issue has the potential to

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[153] Diane C. Berry, et al., *Patients' Understanding of Risk Associated with Medication Use: Impact of European Commission Guidelines and Other Risk Scales*, 26 Drug Safety 1-11 (2003).

[154] *Id.* at 3-7.

[155] *See* Brief of the United States of America, *In Re Paxil Litigation*, No. CV01-07937, at 3 (C.D. Cal. filed Sept. 4, 2002) ("FDA must consider not only whether adequate information of any risks is disclosed, but also whether such information is presented in such a way that does not overemphasize dangers such that useful drugs are unnecessarily avoided by consumers."). Even if consumers are not actually frightened away, they can be deterred by being given so much information that overwhelms them—and thus ignore it. In the context of considering labeling requirements for over-the-counter ("OTC") medications, FDA recognized that "consumers are becoming more actively involved in their own health care" and "are more likely to practice self-diagnosis and self-medication with OTC drug products." *Over-the-Counter Human Drugs; Proposed Labeling Requirements*, 62 Fed. Reg. 9024, 9027 (Feb. 27, 1997). As a result, FDA concluded that "it is increasingly important that OTC drug product labeling provide consumers with *uniform and understandable* information for the safe and effective use of these products." *Id.* (emphasis added). *See also* Karen Lechter, J.D., Ph.D., FDA Division of Surveillance, Research, and Communication Support, Office of Drug Safety, *Communicating Risks and Benefits Through Labeling and Leaflets*, at slides 12-19 (June 2002), *available at* http://www.fda.gov/cder/present/DIA62002/risks/sld001.htm.

frighten rather than inform them. Intimidating disclosures may deter consumers from even raising their concerns about a condition with their doctor, much less engaging in a thoughtful discussion about the appropriateness of treatment alternatives. Evidence presented at the public hearing indicates that even the existing disclosure mandates may be having this unintended effect. In FDA's own surveys, 47% of general practitioners and 42% of specialists agree that DTC advertisements create anxiety in their patients regarding the potential side effects of drug treatments.[156] Another researcher reported that patient surveys conducted by the University of Texas indicated that some consumers found the presentation of risks and side effects in DTC promotion off-putting.[157] In certain cases, this went so far as to convince patients that they should stop taking their current prescription drugs because of the potential side effects.[158]

The Texas findings dovetail with other comments at the hearing, as well as other research data, that reflect an ongoing need to overcome consumer reluctance to address health-care issues.[159] Empirical evidence also indicates that many consumers often are reluctant to complete a course of drug therapy once it has begun.[160] Ill-conceived risk disclosures seem likely to exacerbate these problems.

Gathering additional data on effective risk disclosures may touch upon both content ("How much information is enough but not too much?") and format ("How do the format strengths and weaknesses of different media affect consumer comprehension?"). With respect to

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[156] Aikin presentation, at slide 54 (citing *FDA Physician Survey* (2002)).

[157] Hausman presentation, at slide 7.

[158] Hearing Transcript, Sept. 22, 2003, at 229-30.

[159] Hearing Transcript, Sept. 23, 2003, at 63-64, 150.

[160] *RxRemedy DTC/Compliance* (finding that 40% of patients don't take their medicines as directed). By contrast, evidence indicates that DTC advertisements have a positive effect on patient compliance. *See supra*, footnote 67.

the latter, FDA should bear in mind the existing research-based understandings about the communicative power and limitations of advertising.[161] Ads are particularly well suited to serve a basic attention-getting function.[162] Thus, in the DTC context, they draw consumer attention to the existence of a medical condition and the availability of treatment options. In this way, advertising serves to inform consumers and to begin the consumer-education process concerning a particular condition and therapy option. But data in the record also indicate that people use a mix of information sources to learn about prescription drugs and the conditions they address.[163] DTC advertising plainly is not the only informational vehicle by which consumers come to comprehend complex topics such as the risk/benefit balance of prescription drug usage. DTC vehicles such as brochures and web pages are better suited to providing important information that is detailed and requires nuanced comprehension.

Any effort to revise the current disclosure requirements also must abide by the constraints that the First Amendment places upon the agency. FDA must first identify the substantial interests at stake and then show how the form and substance of any proposed disclosure

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[161] *See supra*, footnote 22.

[162] Hearing Transcript, Sept. 22, 2003, at 37. Summarizing the findings of FDA research, Dr. Aikin noted, "DTC ads are very good at increasing awareness of potential treatments but they are not very good at equally conveying information about risks and benefits." *See also id.* at 55-56 (Dr. Allison-Ottey of Coshar Medical, Inc., commenting that a particular benefit of DTC was its ability to increase awareness); *id.* at 200 (Ms. Benzing of Patient Marketing Group, Inc., noting that "DTC may be best simply at driving awareness and getting consumers to raise their hand and say 'I want to know more.'"); Hearing Transcript, Sept. 23, 2003, at 198 (Dr. Goldhammer of PhRMA stating that "given its broad-reach capabilities, mass-reach vehicles such as broadcast TV are effective at generating broad awareness of disease states and products.").

[163] *See supra*, Section II.A.4. The data on record now support the conclusion that consumers who are interested in the subject matter of a DTC broadcast advertisement are willing and able to turn to other media and speakers to find more detailed discussion on matters such as the risks and benefits of particular treatment options. As indicated in our Statement of Interest, Pfizer sees DTC ads as only one part of a bigger continuum of consumer-directed communications. Along with most manufacturers, we speak to consumers through an array of outlets because we understand that effective communication to laypeople about sometimes-complex health issues (including appropriate uses of, and expectations for, drug therapies) requires the use of multiple messages in different formats.

requirement directly and materially advances the identified goals.[164] Given the record in this docket, FDA may not require disclosures so onerous that they make DTC advertisements counter-productive—or actually work to suppress them.[165]

The record demonstrates that there would be societal losses if DTC advertising were to be suppressed, even inadvertently, via ill-conceived and untested disclosure mandates. In the case of prescription drugs, data indicate that a lack of DTC advertising could have meant the loss of up to 65 million conversations between patients and their doctors about health concerns and treatment options.[166] Therefore, if and when FDA considers revising its disclosure requirements, it should strive for a policy that would neither (1) unnecessarily deter consumers from seeking appropriate drug therapy, nor (2) return to the pre-1997 era when disclosure requirements effectively foreclosed DTC advertising in broadcast media and thereby deprived many consumers of useful information about conditions and their treatments. As demonstrated in the September 22-23 hearing, public participation in gathering empirical evidence needed to evaluate DTC risk disclosure policies would enhance the process and its ultimate result.

D. The Constitutional Requirement Of "Narrow Tailoring" Requires That FDA Be Especially Sensitive To Research That Suggests That Changes In Current Regulations Could Reduce The Amount Of DTC Advertising

Should FDA consider amending its current risk disclosure requirements, it also must consider the impact that additional obligations might have on the volume of consumer-directed information about pharmaceuticals and the conditions they treat. Drug manufacturers, like other rational actors in a marketplace, make economic choices about whether and how to spend on

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[164] *See* Pfizer First Amendment Comments at 141-154.

[165] *See* Pfizer First Amendment Comments at 147.

[166] *See* Slaughter presentation, at slide 16 (citing *Prevention Annual Surveys*).

promotion. Particularly burdensome mandates—such as the pre-1997 requirements for broadcast advertising—could persuade manufacturers that consumer-directed communications are inefficient investments, thereby depriving many laypersons of easily accessible, valuable information.

Data in this docket show that, from a pharmaceutical company's perspective, DTC is not the only means of expanding the market. While the data in the docket show that physician-directed information campaigns have a direct and positive impact with respect to interbrand competition,[167] these activities also combat under-treatment. The percentage of manufacturer revenues devoted to all marketing activities remained relatively constant over the last five years and DTC expenditures appear to have peaked.[168] If FDA were to impose disclosure burdens on DTC, it could lead manufacturers to reconsider their current allocation of resources to consumer-directed communications such as broadcast advertising.

As a hypothetical illustration of this point, consider the paradigm DTC advertisement—the 30-second TV spot—and how changes in the current regime might affect the advertiser. Assume that about five seconds of a television ad today discloses a list of specific risks. Should FDA require a more extensive discussion of risks that would require 10 seconds of time—*i.e.*, 33% of the spot—that mandate would limit the advertiser's opportunity to inform the public of indications and treatment options, and reduce the return on promotional investment. But it is not at all clear from the evidence in this docket that thus limiting the flow of valuable truthful communications to consumers would, in fact, lead to consumers being twice as informed about

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[167] *See* Julie M. Donohue, *Effects of DTC Advertising of Prescription Drugs on the Treatment of Depression*, at slide 9 (Sept. 22, 2003), *available at* http://www.fda.gov/cder/ddmac/P2donohue/index.htm, (hereinafter "Donohue presentation"); Calfee presentation, at slide 6. Consumer-directed communications, in contrast, appear to make their biggest impact by expanding the overall market for drugs in a class. *See* Donohue presentation, at slide 2; Lichtenberg presentation, at slide 5 (citing *Wosinska*; *Rosenthal, et al.*).

[168] Masia presentation, at slide 3 (citing GAO marketing data; PhRMA sales data).

the risks of the drug.[169] Nor does the docket to date contain any evidence that doubling disclosure time would actually alter consumer behavior.

At a certain point in the time calculus, the reduction of seconds available for its own preferred message in DTC spots could lead the pharmaceutical advertiser to reduce its DTC spending.[170] This outcome would result in fewer consumers being informed about conditions and treatment options and denying a benefit *unique* to DTC: encouraging patients to visit doctors and raise specific questions that lead to new diagnoses and treatment. Therefore, in any consideration of the need for more burdensome risk disclosures, FDA should weigh—as the Constitution compels—the potential for unintended restrictions on valuable information flows. Pfizer believes that on the present record such requirements would not be "narrowly tailored" to avoid undue restrictions on constitutionally protected information flows.[171]

In sum, the disclosure interests of FDA and advertisers should be aligned. Both want to assure that any additional disclosure requirements are fully supported by empirical research for two reasons: (1) to show that the requirements will affect consumer behavior in a way that is consistent with the public interest in encouraging consumers to contact their physicians; and (2) to ensure that there is no loss of the substantial benefits that the public, FDA, and the industry together derive from the information flow stimulated by the current DTC regime.

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[169] Evidence submitted in this docket suggests that placement in the ad, for example, may be more important than the length of the disclosures. *See, e.g.*, Hearing Transcript, Sept. 22, 2003, at 247.

[170] Form and language are likewise pertinent. An FDA requirement to present risk information in a way that might unduly frighten some consumers would not simply impede the goal of motivating them to consult their doctors for diagnoses and discussion about potential treatments. It also could deter manufacturers from devoting resources to DTC communications.

[171] *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 371-73 (2002).

CONCLUSION

Pfizer appreciates this opportunity to comment upon the data now on record before FDA concerning DTC communications, and we look forward to engaging in future discussions with the agency concerning the benefits of consumer-directed messages about prescription drugs.

Respectfully submitted,

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