BlueCross BlueShield Association

An Association of
Independent Blue Cross
and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
Telephone 202.626.4780
Fax 202.626.4833

July 23, 2001

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01D-0162

Dear Sir or Madam:

The Blue Cross and Blue Shield Association (BCBSA) supports the Food and Drug Administration's (FDA's) effort to clarify communication of risk information for prescription drugs advertised directly to consumers. BCBSA appreciates this opportunity to provide the FDA with comments on the agency's draft guidance for industry titled "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements," (66 FR 20468).

BCBSA is a federation of 44 independent, locally operated Blue Cross and Blue Shield Plans that collectively provide health care coverage to nearly 80 million – more than one in four – Americans. Blue Cross and Blue Shield Plans have extensive experience in providing prescription drug coverage through a variety of products and delivery mechanisms designed to meet the quality and value demands of their customers.

As the draft guidance states, direct-to-consumer (DTC) print ads often convey critical product risk information by reprinting "in small type, verbatim … labeling written for health professionals, using medical terminology." BCBSA agrees with the agency that this format presents risk information in a manner that "may be difficult for consumers to understand." BCBSA believes that both print and broadcast DTC promotion raise consumer safety issues, including inappropriate demand for and use of advertised drugs. As DTC ads for prescription drugs continue to saturate the media, the FDA must ensure that consumers receive clear and understandable information about their benefits and risks.

Summary of BCBSA Recommendations:

BCBSA believes that the FDA's draft guidance supporting the use of agency-approved patient labeling to convey risk information in DTC print ads is an important first step

01D-0162

C9

toward assuring that consumers receive comprehensive and useful information about drug risks. However, BCBSA recommends that the FDA take the following additional steps:

- Require manufacturers to use FDA-approved patient labeling to convey risk information in all types of print DTC ads when such labeling is available and appropriate; and

- Require full disclosure of all risk and benefit information in all types of print DTC ads when FDA-approved patient labeling is not available or appropriate.

Because the use of patient labeling in DTC print ads will remain voluntary under the FDA's guidance, these steps will provide drug manufacturers with an incentive to develop and seek agency approval of patient labeling and meet the FDA's goal of increasing the usefulness of labeling information for consumers.

As we outlined in our May 18, 2001 in comments concerning docket number 01N-0078 ("Assessment of Physician and Patient Attitudes Toward DTC Promotion of Prescription Drugs"), BCBSA believes that because the FDA's current policies on DTC advertising evolved from a framework intended to regulate physician-directed promotion, they do not address the unique information needs of consumers.

To ensure that consumers receive complete and accurate information about the risks and benefits associated with prescription drug use, BCBSA recommends that the FDA develop new guidance for pharmaceutical manufacturers on DTC advertising with a consumer-focused approach. Such guidance should include criteria for the level, type and presentation of information that consumers need with respect to advertised drugs.

BCBSA also has specific recommendations for clarifying the FDA's guidance on the criteria for using patient labeling. BCBSA agrees that approved patient labeling is a suitable means of communicating risk information when it comprehensively addresses the drug's most serious and most common risks. However, the FDA must protect consumer safety by ensuring that patient labeling used in DTC print ads does not minimize or omit potentially serious adverse events. BCBSA recommends that the FDA clarify its draft guidance to:

- Define the term "major precaution;"

- Define the term "frequently occurring side-effects" and state specific threshold rates of incidence of contraindications;

- Define the terms "serious effects" and "not serious effects;" and

- Require a tagline in all DTC print ads encouraging consumers to consult with health care professionals for additional information on appropriate treatments (e.g., "Your physician may recommend other appropriate treatments").

FDA Regulatory Framework for DTC Advertising

The Federal Food, Drug, and Cosmetic Act (FD&C Act) charges the FDA with ensuring that the labeling and advertising of prescription drugs is truthful and not misleading. Under Section 502(n) prescription drug labeling (including advertising) must include "a true statement of information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in the regulations." This is known as the "brief summary requirement."

The implementing regulations distinguish among three types of ads:

- "Product-claim" ads, which mention both a branded product and the disease or condition that it treats, are generally the most informative and stringently regulated.
- "See your doctor" ads typically describe the symptoms of a disease and encourage readers or viewers to see their doctor if they recognize such symptoms. These ads are not allowed to mention a branded product by name.
- "Reminder ads," mention the branded product by name but may not make any representation about its intended use.

The FDA regulates product-claim ads more rigorously than other types. All product claim ads — whether print or broadcast — must fulfill the brief summary requirement. In contrast, reminder ads and "see your doctor" ads need not include the brief summary. The FDA's draft guidance on using patient labeling in DTC print ads applies only to product-claim ads.

The FDA regulations implementing Section 502(n) require that the risk information presented in a drug ad must include each specific side effect and contraindication from the drug's approved labeling. This FDA-approved labeling is called "professional labeling" because it is written for physicians and other health care professionals (21 CFR §210.1(e)(3)(iii)). The regulation further specifies that "side effect and contraindication" refers to all categories of risk data in the drug's approved labeling, including the Warnings, Precautions and Adverse Reactions sections, so that every risk in a drug's labeling must be stated in its advertising.

The regulations do not specify a format for the brief summary in print ads. In practice, most drug manufacturers reprint in their ads the risk-related sections of the approved product labeling exactly as written for health professionals, including all medical terminology. This approach satisfies the FDA regulation, but requires consumers to scrutinize technical medical data, presented in small type, to glean critical drug risk information.

Certain drug products have FDA-approved patient labeling in addition to professional labeling. Patient labeling describes the drug's risks and benefits in consumer-friendly language so that the patient can use the product appropriately. Because it is intended to communicate key information in understandable language for the lay consumer, patient

labeling focuses on the product's more serious risks and those less serious risks that occur frequently. Although patient labeling may be included with a prescription drug when dispensed, it generally is not reprinted for use in DTC print ads because it does not always address "each specific" risk as mandated by the brief summary requirement.

Communication of Risk and Benefit Information

The volume of DTC advertising continues to increase. According to IMS Health, pharmaceutical manufacturers spent $2.5 billion on DTC advertising in 2000, up from $1.8 billion in 1999. A 1999 study by the National Institute for Healthcare Management showed that the 10 most heavily promoted drugs in 1998 accounted for over a fifth of the total growth in prescription drug expenditures from 1993 to 1998.[1] In total, these 10 drugs had 1998 sales of over $11 billion – about 12 percent of all retail drug spending. This use-inducing DTC advertising raises issues with respect to consumer safety in the absence of clear and understandable information about product benefits and risks.

Recent surveys raise questions about the effectiveness of DTC advertising in communicating pertinent information about drugs. The 1999 *Prevention* survey asked respondents who recalled seeing DTC ads to rate them on a four-point scale (with "don't know" as a possible fifth response) on how well they communicate information about risks and benefits. Just one in eight consumers thought that DTC ads do an excellent job in conveying "serious warnings about the product."[2] More than two-fifths of consumers rated magazine ads as doing "only fair" (30%) or "poor" (14%) jobs in communicating serious risks.

Half of the respondents thought that television ads do an "only fair" (30%) or "poor" (20%) job in communicating serious warnings. Similarly, one in eight consumers thought that magazine and television ads do an excellent job in communicating "annoying but not serious side effects." About half thought that DTC ads do an "only fair" or "poor" job at communicating such side effects.

Most physicians are also skeptical of the quality and objectivity of the information presented in the ads. In a 1998 survey of 3,000 doctors, Scott-Levin found that more than half of physicians disagreed with the statement, "DTC advertising is a reliable source of information." In addition, more than 60% disagreed with the statement, "DTC advertising is an objective source of information."[3]

---

[1] National Institute for Health Care Management Foundation (NIHCM), Prescription Drugs and Mass Media Advertising, (Washington, D.C.: September 2000).

[2] *Prevention Magazine*, "Year Two: A National Survey of Consumer Reactions to Direct-to-Consumer Advertising": Table 3: 21.

[3] "Half of Rx drug consumer ad spending goes to TV, Scott-Levin reports," *Business Wire via the NewsEdge Corporation*, June 2, 1998. Cf. Also "IMS Health Reports Direct-to-Consumer Advertising Increases Prescription Pharmaceutical Brand Requests and Awareness: Majority of Physicians have Negative View Toward DTC Advertising."

In June 2001, a delegation of physicians within the American Medical Association (AMA) called for the FDA to take action on DTC ads, charging that they interfere with doctor-patient relationship, and misinform the consumer about prescription drugs.[4] The AMA also advocates that DTC ads include the tagline: "Your physician may recommend other appropriate treatments."[5]

BCBSA Recommendations

The FDA's current policies on DTC advertising evolved from a framework intended to regulate physician-directed promotion. As a result, the current policies do not address the unique information needs of consumers, as the agency implicitly acknowledges by undertaking to permit the use of patient labeling in DTC print ads. As the FDA continues its effort to assure that consumers receive comprehensive and useful information about drug risks in advertisements, BCBSA asks that it consider the following comments and recommendations.

Comments on the Draft Guidance

In general, BCBSA recommends that the FDA develop new guidance for industry on DTC advertising with a consumer-focused approach, to ensure that consumers receive complete and accurate information about the risks and benefits associated with prescription drug use. Such guidance should include criteria for the level and type of information that consumers need with respect to advertised drugs.

In 1984, the FDA conducted a study of consumer response to prescription drug advertising, with a view to testing the degree to which they could understand advertising copy, how well they retained benefit and risk information, and the effect of various formats on their learning and retention.[6] The 1984 results showed that although consumers could understand advertising copy, they retained far more benefit than risk information. It also found that respondents understood risk information better if it were specific rather than general, and incorporated into the main body of the ad rather than being presented in the "brief summary" format. These findings imply that the brief summary requirement needs to be overhauled, not merely edited, for consumer audiences.

Since the 1984 publication of the FDA study, additional evidence has surfaced about the national state of health literacy. A 1999 study of over 3,200 new Medicare enrollees in four Prudential Healthcare Plans found that 33.9% of English speaking and 53.9% of Spanish speaking respondents had inadequate or marginal health literacy.[7] According to

[4] "Doctors Debate Ban on Drug Ads," *The New York Times*, June 17, 2001.

[5] Victoria Stagg Elliott, "Questions Swirl Around Drug As for Patients," *American Medical News*, July 9/16, 2001.

[6] Louis A. Morris and Lloyd G. Millstein, "Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements, " *Food Drug Cosmetic Law Journal*, Vol. 39 (1984): 497 – 505.

[7] Julie A. Gazmararian, David W. Baker, Mark V. Williams, Ruth M. Parker, Tracy L. Scott, Diane C. Green, S. Nicole Fehrenback, Junling Ren, and Jeffrey P. Koplan, "Health Literacy Among Medicare

a 1998 report by the AMA's Council on Scientific Affairs, one hospital-based study found that "42% of patients were unable to comprehend directions for taking medicine on an empty stomach, 26% could not understand information on an appointment slip, and 60% could not understand a common consent form."[8]

These findings underscore the need for clear and understandable information in DTC ads about the benefits and risks of prescription drugs. BCBSA believes that the FDA's draft guidance supporting the use of agency-approved patient labeling to convey risk information in DTC print ads is an important first step toward assuring that consumers receive comprehensive and useful information about drug risks. However, as noted earlier, BCBSA recommends that the FDA take the following additional steps:

- Require manufacturers to use FDA-approved patient labeling to convey risk information in all types of print DTC ads when such labeling is available and appropriate; and

- Require full disclosure of all risk and benefit information in all types of print DTC ads when FDA-approved patient labeling is not available or appropriate.

Conclusion

Consumers are becoming increasingly knowledgeable about their own health care and they value information that assists them in understanding both conditions and treatments. However, because consumers have different information needs regarding prescription drugs than do doctors and other health professionals, BCBSA believes that the FDA should adapt its regulatory approach to DTC advertising accordingly.

BCBSA further believes that use-inducing promotion raises issues with respect to consumer safety, including inappropriate demand and use of advertised drugs. As such, BCBSA believes that consumers faced with a barrage of advertisements for new drugs must receive clear and understandable information about their benefits and risks.

BCBSA recommends that the FDA develop new guidance for industry on DTC advertising with a consumer-focused approach. Such guidance should include criteria for the level, type and presentation of information that consumers need with respect to advertised drugs.

Enrollees in a Managed Care Organization," *JAMA* 1999: 281: 545 – 551. Cf. also Rima E. Rudd, Barbara A. Moeykens, and Tayla C. Colton, "Health and Literacy: A Review of Medical and Public Health Literature, Chapter 5 of Health and Literacy: Annual Review of Adult Learning and Literacy, ed. By John Comings, Barbara Garners, Christine Smith: (New York: Jossey-Bass, 1999). This chapter can be accessed at http://www.hsph.harvard.edu/healthliteracy/literature/html.

[8] "Missed Messages: Millions of patients lack the literacy skills to fully understand their illnesses and treatment plans," Editorial for July 20, 1998, *American Medical News*, accessed April 30, 2001 from http://www.ama-assn.org/sci-pubs/amnews/amn_98/edit0720.htm. Cf. also M.V. Williams, R.M. Parker, D.W. Baker, K. Parikh, W.C. Coates, and J.R. Nurss, "Inadequate Functional Health Literacy Among Patients at Two Public Hospitals, *JAMA* 1995: 2714 (21): 1677 – 1682.

BCBSA believes that the FDA's draft guidance supporting the use of agency-approved patient labeling to convey risk information in DTC print ads is an important first step toward meeting this goal. We applaud the FDA for addressing this critical health care issue and support the agency in its endeavors.

Sincerely,

Mary Nell Lehnhard
Senior Vice President
Office of Policy and Representation

H:\POL&REP\W01\20W\Christine\DTC\DTC Print Patient Labeling comments.final.doc