Excerpt from Draft Scientific Literature on Direct-to-Consumer Advertising of Prescription Pharmaceuticals, 2004-2008, prepared for the FDA by Eastern Research Group, John Eyraud, Charles Goodhue, Andreas Lord, and Cynthia Whitman

4. Underserved Populations and DTCA

Only a few studies have directly addressed the impacts of DTCA of prescription medication on underserved populations, including seniors, diverse minority populations, and economically or educationally disadvantaged groups. Research among underserved populations tends to address differences in behavior and comprehension in response to DTCA between underserved groups and the general population.

In addition to these few studies, the National Medical Association (2006), as mentioned above, reported on a non-random opinion survey of African-American physicians regarding the impact of DTCA on patient behavior. Although 45 percent of the physicians surveyed believed that DTCA educationally benefits people in underserved communities, this report gave no indication whether the physicians surveyed interacted primarily with any specific underserved patient populations.

4.1 Limited-Literacy Consumers and DTCA Comprehension

In the area of DTCA comprehension, Kaphingst et al. (2005) examined comprehension of information in three typical DTC television advertisements (for Singulair, Nasacort AQ, and Zocor) among 50 U.S.-born and foreign-born participants with limited English-language literacy. After viewing the advertisements, subjects were administered a questionnaire as well as 35 true-false questions regarding the content of the advertising. Subjects answered an average of 59 percent of the questions correctly, with risk communication being the area of lowest comprehension. As one might have expected with subjects of limited English literacy, audio-only presentation of risk information was more effective than text-only presentation; however, audio-only presentation was also more effective than text-and-audio presentation ("…the odds of a correct answer were lower for risk information than other types of information, and lower if the information had been given in text, with or without accompanying audio, rather than in audio only"). The authors stated that "[b]oth our descriptive data and multivariate results indicate that these three advertisements were less successful in communicating risk information than other information."

Kaphingst et al. (2004) had earlier performed a content analysis of DTCA in which they found that a majority of the TV ads they analyzed "used both medical and lay terms to communicate medical ideas." They inferred that this meant that consumer-friendly language was not used to communicate all the important information in a given ad. The implications for the substantial portion of the audience that is of limited English literacy are clear: although FDA insists "that adequate contextual and risk information, presented in understandable language, is included [in DTCA] to fulfill the requirement

for fair balance…," Kaphingst et al. point out that "…FDA has not yet addressed how the literacy skill levels of U.S. adults are taken into account in making such a determination. A more detailed examination of DTC television advertisements is necessary to ensure that absence of contextual information or use of medical terminology does not obscure important risk information for consumers, and particularly for those millions of consumers with limited literacy skills."

In their study testing consumer comprehension of their "drug facts box," Schwartz et al. found a small but significant difference in comprehension between subjects with high school degrees or less schooling and those with college degrees or higher education levels, although "even people at the lower end of the range of educational attainment in our sample, did fairly well…." They reported that "…the mean number correct on the 5 data interpretation questions differed somewhat according to participant educational attainment: 3.4 correct (high school graduate or lower), 4.0 (some college), 4.2 (college graduates), and 4.1 (postgraduate degree)."

4.2 Seniors and Lack of Influence of DTCA

Bower et al. (2006) examined factors influencing drug preferences (specifically, switching from traditional NSAIDS to coxibs, despite higher copayments for the latter) among 127 elderly osteoarthritis sufferers in Nova Scotia. Using an unstructured, in-depth interview technique, they determined that their subjects were heavily influenced by distribution of free samples, recommendations by family physicians, and fear of side effects from traditional NSAIDS (despite the fact that there was no evidence at the time that coxibs were safer). In contrast to the several reports of DTCA impact on patient behavior mentioned below, this study found that the higher price of coxibs, information from social networks, and most particularly DTCAs were generally stated by subjects to be of little or no influence on them. Although the interview responses were coded and scored, Bower et al., in this article at least, did not present detailed statistical results, and did not address whether self-report might be a reliable method to determine the influence of all factors contributing to patient decision-making. There might be a response bias among patients against admitting the influence of media advertising.

The Bower paper highlights one difference between the elderly and other potentially underserved populations, i.e., the fact that elderly patients are more likely to be seeing a physician and taking some medication regularly, as opposed to the significant portion of non-elderly DTCA consumers who are not under a physician's care.

DeLorme et al. (2006) cite earlier studies that indicate seniors receiving "less healthcare information in general and less medication information in particular" than other age cohorts, that doctors "tend to spend less time with elderly patients, provide them with less information, and are generally less responsive to them," and that elderly patients "are less likely to challenge medical authority or to press physicians for detailed information about medical conditions." Their survey study of 284 adults in northeast Georgia found that DTCA effectively motivated older adults to ask questions of their

pharmacists, motivated younger adults most often to discuss the issue with friends and family, and sparked mature adults to speak with their physicians.

A study conducted by Huh et al. (2004) found that older consumers are neutral about the informational utility of DTC ads, whereas younger consumers are negative but see DTCA as especially beneficial to prepare them to ask their doctors intelligent questions. Balazs et al. (2000) found that DTCA leads every one in two older adults to ask a healthcare practitioner about a drug he or she saw advertised, every one in three to ask for a prescription for an advertised drug, and every one in five to ask about an illness or medical condition that was featured in a DTC ad. Barrett (2002) reported that DTCA exposure leads every one in five older adults to ask a physician for a prescription drug he or she saw advertised.

In another study of DTCA impacts on older adults, Datti and Carter (2006) extracted data for 2,601 DTCA-exposed patients from the data set of the Inter-University Consortium for Political and Social Research (ICPSR 3687). Adults 65 years old or older composed 17 percent of the study population. The authors performed statistical analyses of this patient data and found that "older adults are less likely to request a specific drug following exposure to DTCA." However, they also found that, "with increasing age, requests for prescription drugs are more likely to result in recommendations for other treatment." Among patients making drug requests, patients 65 to 74 years old were 174 percent more likely than those under 35 to be referred for further treatment, while patients 75 and over were 251 percent more likely than those under 35 to be referred.

4.3 African-American and other Minority Consumers and DTCA

The National Consumers League, in their 2006 research overview on DTCA (NCL 2006), pointed out that "the government has identified serious and chronic disparities in health outcomes and treatment patterns between whites, African-Americans, and Latino consumers." The report points out that there has been "very little research on the impact of DTCA on minority populations." One earlier study that did address DTCA impacts on African-American patients (Allison-Ottey et al. 2003) surveyed 1,065 patients (91 percent were African-American) immediately after they visited their physicians. The authors reported that 21 percent of their respondents intended to ask their physician about a prescription drug they had seen advertised; however, in a complementary survey of the respondents' physicians, the doctors reported that 9 percent of the patients had asked about a prescription.

In contrast, Murray et al. (2004) reported that African-Americans were no more likely than white non-Hispanics and Asians to seek preventive care (such as a screening or blood test) in response to information from a DTCA (the figures were 8 percent for black Americans, 7 percent for white non-Hispanics, and 7 percent for Asians). For Hispanics, 15 percent reported seeking preventive care because of information in a drug advertisement. However, 24 percent of African-Americans did report discussing health concerns with a physician because of DTCA, a figure less than half of that reported by Allison-Ottey. Murray et al. interviewed a randomly selected, weighted national sample

of 3,209 adults to obtain their results. Among people who reported that DTCA had resulted in a change in their relationship with their physician, 18 percent of African-Americans said this relationship had worsened, while the percentages of white Americans, Hispanics, and Asians who said their physician relationship had worsened were 2 percent, zero, and zero, respectively.

The Datti and Carter study (2006) mentioned above also examined DTCA impacts on African-Americans, finding that DTCA consumers in this group were 58 percent more likely to request prescriptions from their doctor than otherwise similar study counterparts. However, paralleling other research in this area (Briesacher, 2003), physicians in the Datti study were significantly less likely to comply with African-Americans' request for a prescription. The authors noted: "Specifically, the study findings suggested that the odds of African Americans receiving their prescription were reduced by 63% (OR = 0.37) in comparison with their otherwise similar counterparts. Most likely, this finding reflects a complex interaction of variables, including socioeconomic status, education, healthcare accessibility and a lack of continuity in care, as well as of systemic factors ingrained in the healthcare system." (Datti and Carter 2006).

Other researchers have presented data relating to potentially underserved groups as part of broader research efforts:

Targeting older and female consumers: Brownfield et al. (2004), in their analysis of the quantity, frequency, and placement of television DTCA, found that ads appear most frequently in the mid-afternoon and early evening, on news programs and soap operas, suggesting that these DTCA are targeting women and senior citizens.

Lower income consumers view DTCA more favorably: In a nationally representative, random sample survey of 1,695 adults ages 18 years and older, the Kaiser Family Foundation study (Kaiser 2008) of public attitudes toward pharmaceutical companies and prescription drugs indicated that "the groups who have the highest share saying they have a favorable opinion of drug companies include Hispanics (63% favorable)…those with a household income less than $25,000 (55%), [and] those with a high school education or less (52%)…" Further, consumer opinion that "Rx advertising is mostly a good thing" was found to be inversely related to income, with 59 percent of respondents with incomes under $25,000 agreeing with the statement, while less than 50 percent of respondents with incomes above $50,000 agree with it. (Interestingly, among all survey respondents, 67 percent agree that "[p]rescription drug ads educate people about available treatments and encourage them to get help for medical conditions they might not have been aware of.")

Non-white, lower income, and lower education level consumers are all more likely to say that DTCA caused them to seek medical care: Robinson et al. (2004), in a survey of 500 Colorado residents, found that respondents differed by race and economic status in their responses to the question of whether DTCA caused them to seek medical care. Among non-white respondents, 31.6 percent agreed that DTCA caused them to seek

medical care, whereas 8.8 percent of whites agreed with the statement. For respondents who did not attend college and those who did, the figures were 18.9 percent and 8.1 percent, respectively; and for lower income vs. higher income respondents, the figures were 18.2 percent vs. 8.3 percent.

In the study by Murray et al. (2004), 58 percent of people who scheduled a physician visit in response to DTCA had not graduated high school; the figure for high school graduates making an appointment because of a DTCA was 22 percent (P = .009).

Consumers with lower education levels are more likely to agree that DTCA provides enough information to decide if drug benefits outweigh risks: The seventh *Prevention* magazine survey on consumer reaction to DTCA of prescription medicines (Prevention, 2004) reported that 43 percent of consumers who did not graduate high school agreed that DTCA provided enough information to make a risk/benefit decision, as compared to 36 percent of high school graduates, 28 percent with some college, and 23 percent of college graduates.

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