

Testimony of Meredith B. Rosenthal, Ph.D.

Chairman Craig, Senator Breaux, distinguished Committee members, thank you for inviting me to discuss the consequences of direct to consumer advertising (DTCA) of prescription drugs. I have been asked to summarize the scientific research in this area, highlight key findings for policy, and make note of important questions not yet answered by empirical studies.

My review will highlight three main points supported by research on the consequences of DTCA of prescription drugs. First, while consumers take notice of and sometimes act upon prescription drug advertisements, the rapid growth of DTCA has not been associated with a commensurate explosion in the rate at which consumers report that they demand and receive advertised products. Second, DTCA clearly increases spending on prescription drugs but is not the primary driver of prescription drug spending growth. Third, because most of the increase in spending caused by DTCA appears to be due to new utilization, the most crucial outstanding question for policy is: what is the magnitude of the incremental health benefit (relative to the treatment they would have received absent DTCA) obtained by these patients? Without the answer to this question we cannot know whether DTCA's effects on consumer welfare are, on net, positive or negative.

I would like to begin by noting that much of the evidence on this topic is summarized in a recent Government Accounting Office (GAO) report. In its report,<sup>1</sup> the GAO reviewed the evidence on the growth of DTCA, its scale relative to investment in research and development, and its impact on prescription drug use and spending. In terms of impact, the GAO concluded that the weight of the evidence supported the notion that DTCA increases utilization of and spending on prescription drugs. The GAO report did not address the impact of DTCA on appropriateness of

treatment or public health.

### Impact of DTCA on Spending and Patterns of Use

Because DTCA is a relatively recent phenomenon and a difficult one to study for a number of reasons, there are only a handful of studies that directly examine the impact of this form of promotion on behavior and none so far on health outcomes. There is, however, a large literature on promotion of prescription drugs to physicians, including detailing, sampling, and journal advertising. Because the findings appear to contrast with the early evidence on DTCA, I will note a few results from selected studies. Early economic studies of physician-oriented marketing of prescription drugs by Bond and Lean, Hurwitz and Caves, Leffler, and Vernon<sup>2-5</sup> considered evidence that this marketing was more "persuasive" than "informative". This distinction reflects a more general literature that viewed advertising alternatively as changing consumers' preferences,<sup>6</sup> creating or exaggerating product differences and thereby increasing barriers to entry,<sup>7</sup> or as providing information about a product's characteristics and its price.<sup>8</sup> A common finding from the empirical literature was that professional promotion of prescription drugs made it more difficult for new brands to enter a therapeutic class and decreased price competition by increasing perceived product differences.

More recent research by King<sup>9</sup> on anti-ulcer medications finds that marketing by an individual brand reduces the price responsiveness of demand for that drug, but that total industry marketing reduces the extent of product differentiation (and thus increases price competition). Rizzo<sup>10</sup> reports that for antihypertensive drugs, both current and cumulative detailing expenditures decrease the price responsiveness of demand through the development of greater brand loyalty.

Overall, promotion of prescription drugs to physicians has been found to decrease price competition and result in changes in market shares among competitors without increasing the overall size of the market for a therapeutic class. Unlike physician-oriented promotions, to the extent that DTCA raises awareness among previously untreated consumers of the existence of potentially effective treatments, DTCA could bring more patients into physician offices.

Looking at pre-1997 DTCA, in which products could only be marketed if either the name of the product or the indication for which it was intended were omitted, Berndt<sup>11</sup> examined DTCA data for branded antiulcer (H<sub>2</sub>-antagonist) prescription drugs through May 1994, along with detailing and medical journal advertising data. For the entire H<sub>2</sub> therapeutic class, detailing, medical journal advertising, and DTCA led to increased sales although detailing and journal advertising were much more effective than DTCA. Although detailing and medical journal advertising stocks positively affected market shares, DTCA had no significant impact on market share.

Two recent studies of DTCA by Wosinska<sup>12</sup> and Ling, Berndt and Kyle<sup>13</sup> incorporate data after the FDA's 1997 clarification of DTCA guidelines. Wosinska uses 1996-1999 prescription drug claims data for 4,728 patients who filled a total of 11,529 new prescriptions for cholesterol reducing drugs in the Blue Shield of California medical plans, along with national data on physician detailing, samples and DTCA. She finds that DTCA positively impacts total therapeutic class sales, but only impacts an individual brand positively if that brand has a preferred status on the third party payer's formulary.

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Once again looking at the H<sub>2</sub>-antagonist class, Ling, Berndt and Kyle studied promotion of both prescription and over-the-counter (OTC) forms of the same brands. Within the prescription market, detailing and medical journal advertising efforts have positive and long-lived impacts on prescription market share, while DTCA of the prescription brand has no significant impact on market share. DTCA efforts for prescription brands also have no significant impact on same-brand OTC shares.

Using monthly data for five therapeutic classes on the major types of drug promotion and sales from 1996 to 1999, my coauthors and I examined the impact of DTCA on the sales of these drugs.<sup>14</sup> These five classes (antidepressants, anti-cholesterol drugs, proton pump inhibitors, antihistamines, and nasal sprays) accounted for roughly 30% of DTCA spending over this period. After accounting for the fact that products with higher sales are more likely to be advertised and promoted to physicians, we found that increases in total DTCA for a therapeutic class are associated with significant growth in sales for that class. Promotion to physicians (detailing) similarly increased total sales for a therapeutic class, but to a lesser degree. No evidence was found to support the notion that DTCA was a factor in determining the market share of individual products within a class. Extrapolating the results to all drugs that advertise, these estimates imply that DTCA may account for roughly 12% of the overall growth in prescription drug spending in 2000.

Finally, in related work my coauthors and I have examined the impact of DTCA on medication use for the treatment of depression.<sup>15,16</sup> The first study looked at the impact of direct-to-consumer advertising and promotion to physicians on the likelihood that 1) medication treatment

was initiated for an individual diagnosed with depression, and 2) the duration of medication treatment was consistent with national guidelines. Our results suggest that advertising antidepressants to consumers may increase the likelihood that an individual with depression initiates medication therapy. Free samples of antidepressants, on the other hand, had no effect on medication use. We found no evidence that pharmaceutical promotion to consumers or physicians has an important impact on the likelihood that antidepressant therapy would be continued in a way that meets existing treatment guidelines. The second study again supports the notion that product-specific spending on detailing to physicians had a significant impact on drug choice while spending on direct-to-consumer advertising had no effect on the selection of antidepressant medication. Both of these studies provide further support for the notion that the primary effect of DTCA is on expanding use of a drug to previously untreated consumers.

#### Consumer and physician surveys

*Prevention* and *Men's Health* magazines, with technical assistance from the FDA, have been conducting consumer surveys about perceptions and effects of direct to consumer advertising of prescription drugs since 1997. In addition, the FDA and a number of other private entities have conducted similar surveys. The results of these surveys, across different samples and instruments as well as over time are remarkably consistent. More than 80% of Americans can recall seeing an ad for a prescription drug; roughly a third of people talked with their physician as a result of seeing an ad; and about 5% of consumers report that they received the advertised drug as a result of such discussions prompted by DTCA. While the share of Americans that is aware of prescription drug advertising has steadily increased since 1997, neither the percentage

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of consumers that reports discussing an advertised drug or receiving an advertised drug as a result of such discussions has increased over time.<sup>17</sup>

Consumer surveys have also been used to gauge consumer understanding of the health conditions described in the ad, risks and benefits of the advertised product, and perceptions about the nature and value of advertising itself.<sup>18-20</sup> Findings from these studies suggest that DTCA is not an important source of detailed public health information: even immediately after seeing advertisements consumers often do not recall information presented on disease risk factors, drug benefits or risks. In addition, consumers appear to misunderstand the extent to which advertising is regulated by the FDA. For example, one study reported that 22% of consumers agreed that advertising of drugs with serious side effects had been banned.<sup>19</sup> Finally, consumers generally view DTCA positively and value it as a source of information.

Physician surveys about DTCA have generally revealed discomfort with the idea of advertising directly to consumers, particularly among primary care physicians.<sup>21,22</sup> Perhaps of greater concern, physicians report that DTCA leads them to write prescriptions that they feel are equivocal or at least atypical.<sup>21,23</sup>

### Summary and Conclusions

Although DTCA of prescription drugs has increased rapidly since 1997, it currently accounts for only 14% of total promotional spending by the pharmaceutical industry. Meanwhile, prescription drug spending has more than doubled since 1997. Despite the fact that it is also true that spending on advertised drugs has grown roughly twice as fast as spending on unadvertised

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drugs, these statistics do not really help us to quantify the impact of DTCA on prescription drug spending. The evidence we do have regarding the causal effect of DTCA on spending suggests that DTCA is a significant driver but explains only a small share of total spending growth. This conclusion is also supported by consumer surveys conducted from 1997 to the present, in which a small but unchanging share of consumers report that they received an advertised product as a result of seeing an ad and talking to their doctor about it.

To date there is no evidence that DTCA leads to higher prices (in contrast to physician promotion), although this is admittedly hard to study. Nor is there evidence that DTCA encourages people who are already being treated with a drug in the same therapeutic class to switch brands. These last two points are important because they suggest that DTCA might have a net beneficial effect if, on average, the incremental gains from this new treatment exceed the incremental cost of providing it. It would be naïve to suggest that all of the utilization that results from DTCA is appropriate, much less cost-effective (the widespread availability of insurance coverage for prescription drugs makes this unlikely), but it would be equally unrealistic to suggest that there is no health benefit from all these prescriptions. So the critical puzzle for research and policy is to attempt to quantify, directly or indirectly, the incremental health benefits from the prescribing that results from DTCA for a broad spectrum of drugs and conditions.

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