Big Pharma Pushes Back in Ad Medication Pricing Lawsuit

By Chuck Dinerstein, MD, MBA — June 20, 2019

It is not surprising that pharmaceutical companies have filed a lawsuit seeking to block the implementation of the FDA’s new regulations regarding pricing information in direct to consumer (DTC) pharmaceutical advertising. They make two essential arguments, that the price information will confuse and possibly harm consumers and that the new regulations are a violation of their first amendment rights. I will leave the last argument to the attorneys to discuss, for our purposes, let’s consider the harms. And there is no better place to begin than the primary documents, the lawsuit and the written testimony of their expert, Professor Ravi Dhar, a Yale marketing professor.

To understand the harms, we begin with the cited benefits.

“Members of the public health community have long recognized that direct-to-consumer advertisements are an important source of information for patients, informing them about new treatment options, raising awareness of disease, and encouraging patient discussions with healthcare providers. … 35% of respondents had discussed a medical condition with a doctor as a result of seeing a direct-to-consumer advertisement relating to a particular condition. Of those, nearly a quarter were diagnosed with a new condition following the conversation… 60% of respondents reported that seeing an advertisement for a prescription medicine led them to take a specific action to manage their health care, such as refilling a
Dr. Dhar argues that the inclusion of pricing information, in this instance, the wholesale acquisition cost or WAC, will both anchor a consumer’s expectations about their out-of-pocket costs and overestimate them. He argues that the advertised “list price” will be considered like MSRP (as I have previously suggested) and

“...while a consumer may negotiate additional discounts from the MSRP, she usually pays a sum that is close to—and directly related to—the MSRP. ...a prescription drug’s out-of-pocket costs is nothing like an MSRP, with which a consumer is likely to be familiar. ...[And] because of the complex and varying structure of individual insurance plans ... it is extremely challenging even for motivated and knowledgeable consumers to approximate their out-of-pocket costs from the advertised ‘list price.’”

But before flipping the script on Dr. Dhar’s comments, let me quote one more of his very reasonable thoughts.

“Television advertisements are characterized by “fleeting messages that have a very short life span” with little “opportunity to examine [them] in considerable detail.” WAC will be displayed for a few fleeting moments in the television advertisement, which are not likely to provide the consumer the opportunity to process the information at her own pace, much less the opportunity to process the complex detail needed to accurately understand what WAC represents. ... Likewise, WAC is to be presented to consumers while they are likely to be in a “low-involvement” state—watching television and not motivated to make much effort with respect to that information. That is, the disclosure of WAC is unlikely to trigger immediate further research or inquiry beyond the passive absorption of the information when a consumer is in a low-involvement state and not motivated to fully process the information.”

In essence, pricing information is fleeting, its complexity challenging to process, and consumers are disinclined to pursue further inquiry because they have “low involvement.” Posting drug prices will cause a patient to overestimate their out-of-pocket costs and subsequently have a chilling effect on those previously mentioned beneficial effects. But if all these problems are valid for the pricing information, then is it not equally true for the risks and benefits of the advertised pharmaceutical?

You would not get that impression from Dr. Dhar’s commentary; consumers make more
appointments to speak with their doctors, ask better questions, and are not necessarily given new prescriptions. He cites an FDA study on patient and physician perception of direct to consumer (DTC) advertising. And if he is willing to cite this in his expert testimony, the research must be very informative. [1] What did that study show?

- 77% of patients thought the ads increased their awareness of new options. 41% of the surveyed physicians [2] felt DTC ads were beneficial educating, prompting discussion and awareness.
- 4% initiated a visit to the doctor solely because of a DTC ad. The rest had scheduled appointments or concerns.
- 10% were reluctant to talk to their doctors for fear of implying a distrust of the doctor. Perhaps a well-founded fear as 28% of physicians believed that DTC advertising led to tension in the doctor-patient relationship.
- Roughly a third felt DTC ad helped generate questions, about the same percentage as questions prompted by family and friends. 73% of the surveyed physicians felt that patients asked better questions.
- 32% felt DTC ads help them make better health decisions.
- 17% of patients indicated that it just made them anxious about their health.
- 18% found that DTC ads reminded them to take their already prescribed medications.
- 40% never discuss medication cost with their healthcare provider. This may have changed in the years since the study; we do not know.

**DTC’s Brief Summary**

DTC print advertising requires a summary of risks and benefits to the patient; because of television ads “fleeting nature,” a reference to the brief summary in magazines or other sources is required. Dr. Dhar points out in his testimony that disclaimers stating the list price may be lower for some individuals “ignores a large body of academic research that shows that disclaimers are often ineffective…” But again, if it is true for a list price disclaimer, what about the brief summary, another form of disclaimer. Returning once again to the FDA study cited by Dr. Dhar, we learn.

- “45 percent of patients reported reading all or almost all of the brief summary when they were interested in the drug. Despite this desire for information, half of those who read at least some of the brief summary described it as difficult to read.”
- 44% of patients felt that the benefits were inadequately described.
- 65% of physicians felt that patients confused the risks and benefit, leading them to overestimate the efficacy of the drugs.
Remember, Dr. Dhar said overestimating out-of-pocket costs was bad; but if overestimation is bad for pricing, isn’t the same true for benefits. And if that is the case, aren’t DTC ads misleading? With all these problems, why run medication-specific DTC ads at all? Advertising to promote disease awareness and treatment options educate consumers and prompt visits and questions. As you might suspect, these medication specific ads sell drugs; otherwise, why spend $6 billion annually. [3] DTC ads prompt new prescriptions 40 to 60% of the time when patients ask for them “by name.” Physicians most frequently did not prescribe a new drug because it was “not right for the patient and that another drug [because of cost or efficacy] was more appropriate.”

The study concluded that

“...DTC advertising seems to increase awareness of conditions and treatments, motivate questions for the healthcare provider, and help patients ask better questions. Our data provided no evidence of increased visits as a result of DTC advertising …Both patients and doctors indicate that DTC advertisements overstate drug efficacy and do not present a fair balance of benefit and risk information. Patients gave only modest ratings to the understandability of the brief summary included in print advertisements, information that is meant to provide a more complete picture of the advertised product’s risks.”

DTC pharmaceutical ads sell medications, but if Big Pharma’s argument is that list prices confuse and mislead patients, then the same can be said for the ads impact upon making treatment decisions. Perhaps we should just not run the ads at all because understanding the risks and benefits of therapy are a much more critical factor than its price.

[1] Unless of course, he is cherry-picking his facts, but an expert witness wouldn’t do that, right?

[2] 500 Physicians were also surveyed, although they might not entirely reflect the views of the more than 1 million physicians practicing in the US.

[3] That is dwarfed by the $20 billion spent annually on marketing to physicians and eclipses the $600 million spent on disease awareness advertising.

Sources: Stat’s article Amgen, Merck, and Eli Lilly sue over Trump administration policy to require drug prices in TV ads [2] was the initial impetus to take a deeper dive into how the new direct to consumer pricing regulations might play out in court. Further information was obtained from the lawsuit itself [3], as well as the expert testimony [4] by Professor Ravi Dhar of Yale, who teaches marketing and management. Dr. Dhar’s deposition cited and led back to the previous survey Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription [5] performed for the FDA.