

Coalition Responds to DTC Study, Editorial In Annals of Family Medicine, January/February 2007

The January/February 2007 edition of the Annals of Family Medicine contains a report on a DTC research study and an accompanying editorial co-authored by former FDA Commissioner David Kessler. Although the FDA needs to ground its DTC policy on the science of consumer behavior, the study and the editorial would lead policy makers in the wrong direction.

Either editorialists Kessler and Levy didn't read the study carefully or they chose to ignore its limits. Nothing in the research supports their opinions and conclusions that more stringent DTC rules are needed. Further, the research authors largely ignore the significant body of studies on the effects of advertising on consumer beliefs and behaviors, including the FDA's own studies, that demonstrate that exposure to advertising leads to more and better doctor-patient conversations.

The authors of the study recognize its limitations, but not their own bias. They note at the end of their Introduction that the study uses "content analysis" which they say "is a well-established method of inquiry for generating research questions and hypotheses for *future* experimental and observational studies that examine the effects of advertising on consumers beliefs and behaviors." (Emphasis added) What they don't appear to recognize is that the study of DTC advertising has largely eclipsed any need for such rudimentary research. Mainline social science researchers have largely abandoned content analysis because it does little to illuminate consumer behavior and can easily mislead lay readers, policy makers, and even academic leaders.

Worse, the authors of the research appear to have designed it to confuse rather than enlighten. The authors' choice of what to code and how to interpret it, as well as their conclusions in the Discussion section, could easily lead the casual reader to believe that the ads somehow "failed" academic scrutiny and thus need to be more highly regulated. We hope policy makers read the study critically and respect its limits, rather than use it recklessly to support calls for more restrictive DTC policy.

The entire issue of DTC advertising, as well as the regulation of it by the FDA, calls for more and better social science. The Coalition for Healthcare Communication has petitioned the FDA asking the agency to develop a communication advisory committee that could bring better social science to the regulation of consumer advertising. This study would not meet any test of scientific rigor that Dr. Kessler correctly championed during his tenure at FDA. In fact, the scientific studies by the FDA to date have been much more scholarly, granular, precise and useful than this. Clearly, FDA is already well ahead of these researchers in both technique and interpretation.

Unfortunately, the study denigrates emotional appeals and calls for more fact based advertising. Facts are fine and DTC advertising provides great facts and information, particularly since the industry adopted the PhRMA DTC self-regulation Principles in 2005.

Meanwhile, emotions are a fact of life. Emotions drive much human behavior, including our eagerness to follow our doctors' instructions. Without emotion, much advertising would be wasted, and great opportunities to advance patient care would be squandered. Good DTC advertising policy demands respect for a clear understanding of consumer behavior, how patients think and act, what drives them to take the medicines that often enable longer and healthier lives. Sophisticated social scientists know this and can help the FDA use this knowledge to inform good public policy choices.

Doctors choose medications for their patients largely based on the science of medicine and the experience of other patients, making it appropriate to focus professional advertising on those facts. Patients respond to different facts and appeals. Good policy requires focus on the information needs of patients, rather than the needs of prescribers.

Today, partially because of exposure to advertising, patients are empowered to have more informed conversations with their doctors about drugs that might be useful for them. Doctors still control the prescribing decision, but look to patients as active participants in decisions and for better adherence to their instructions. DTC advertising plays an increasingly valuable role in this process.

The authors observe that advertising is not a perfect or complete communication tool. No such tool exists, including drug labels, "brief summaries," doctor/patient discussions, extensive continuing education programs and the like. If we had such a magic wand, we all would wave it and our research on DTC could end. In reality, each communication tool has a place, but none can carry the load by itself. So, let's not allow the pursuit of the authors' implied perfect model for communication impede the beneficial use of advertising.

Although interesting, this study is far from a definitive work and certainly not a basis for more stringent FDA regulation of DTC advertising.

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