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Commentary

Consumer Advertisements for Psychostimulants in the United States:

A Long Record of Misleading Promotion

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The prescription of psychotropic medications for children continues to be a controversial area of medical practice. In the United States, academic medical centers, medical researchers, prescribers, and the FDA are all ostensibly committed to the common goal of disseminating accurate information and promoting treatment based on scientific evidence. In the United States, however, medical treatment takes place in the context of legal and pervasive direct-to-consumer advertising (DTCA). There are concerns about the potential for DTCA to affect public health negatively and to increase health care costs.[1,2]

In 2005, we wrote to the FDA regarding a perceived disconnect between widespread DTCA for attention-deficit/hyperactivity disorder (ADHD) medications and the peer-reviewed scientific literature.[3] Such a disconnect is important because FDA regulations require that DTCA be consistent with the FDA-approved product label.[4] The FDA notified us that it would further evaluate our concerns,[5] but the advertisements continued. Three years later (on September 26, 2008), the FDA issued letters to 5 pharmaceutical companies that sell psychostimulants (eg, methylphenidate and mixed amphetamine salts), warning them to cease misleading promotion—including advertisements to both prescribers and consumers.6 The warning letters state that among other alleged infractions, the targeted advertisements overstate the efficacy of psychostimulants.

Some might question the delay in regulatory response. However, our central question is, where has the mainstream medical community been over the past 3 years while—as the FDA has now acknowledged—Americans were being misled about psychiatric drugs for children?

As anyone familiar with the treatment of children with an ADHD diagnosis already knows, psychostimulant medications represent but 1 type of intervention used with this population and are by no means a "magic bullet" treatment. Both the evidence-based literature and even the prescribing labels for psychostimulants acknowledge the need for a comprehensive treatment program in the treatment of ADHD.[7,8] There is also a paucity of research demonstrating that the prescription of stimulants predictably results in enhanced socioemotional development.

Therefore, when we wrote to the FDA in 2005, we were concerned about a highly visible US advertising campaign for Adderall that featured smiling children and their parents. The advertisements were widely distributed in popular periodicals, such as People magazine, and they claimed that Adderall was a "trusted solution for ADHD" that would lead to "friends that ask him to join the group" and a "family hour that lasts for hours." The Web site featured a celebrity endorsement by television personality Ty Pennington, in which he claimed that Adderall did not affect his appetite or sleep.[9] All of these advertising claims exaggerated the positive impact of this medication as measured by scientific evidence.[10]

For instance, academic difficulties are often a precipitating factor in the diagnosis and treatment of ADHD, and thus parents may find claims that psychostimulants increase academic performance particularly compelling. For years, Adderall advertisements have used the slogan, "Schoolwork that matches his intelligence."[9] In 2005, we wrote to Shire Pharmaceuticals regarding this claim, pointing out that the experimental evidence was limited to improvement on a 10-minute math test, and questioning whether this was equivalent to the more global concept of "schoolwork."[11] At the time, Shire defended its advertising campaign.[12] The FDA has subsequently clamped down on the gap between peer-reviewed scientific evidence and such claims, noting that an improvement on ADHD measures does not necessarily correlate with improved academic outcomes, and warning Shire directly that "improvement in attention, as evidenced by increased numbers of math problems answered correctly, has not been correlated with an improvement in academic performance throughout the day, an end point which has not been studied."[13]

This chain of events raises several important issues. First, we wonder how many parents have been "driven to the doctor" and made the difficult decision to medicate their child under the influence of misleading advertising. However, there is a larger problem. There were few (if any) dissenting voices raised from rank-and-file academic psychiatrists who objected to these misleading advertisements. How is it that over the past 3 years, we have not seen strong public objections to the widespread dissemination of obviously inaccurate information? Beyond academia, practicing child psychiatrists and pediatricians who treat patients with ADHD must also be aware of the disconnect between these highly visible advertisements and the scientific evidence.

While we have focused here on Adderall, for years we have also noted questionable promotional materials for several other ADHD medications.[10] Yet, the voice of mainstream practicing and academic psychiatrists has seemingly been silent. Why?

It is easy—perhaps too easy—to blame the FDA for inefficient regulation, but at least the agency has finally acted. This is in stark contrast to the many professional societies and representative bodies made up of physicians who study ADHD or who treat affected patients, from which we have seen no public objections. Certainly, a public outcry from prominent academic psychiatrists could have influenced the FDA to act sooner. Is it possible that the flow of money from the pharmaceutical companies to influential academic psychiatrists (a situation now being investigated by Congress)[14] has brought with it a certain willingness to remain silent?

Intriguingly, a recent federally funded, controlled long-term study found the clinical utility of psychostimulants to be limited,[15] and recent evidence-based treatment guidelines in the United Kingdom now recommend their prescription only for children with the most severe behaviors.[16] A recent study found that stimulants are prescribed at a rate 3 times higher for children in the United States than for their counterparts in Germany and the Netherlands.[17] According to the researchers, DTCA is one likely reason for the higher rate of drug use in the United States. Obviously, advertisements that exaggerate the efficacy of stimulants are intended to increase sales, and therefore, the rate at which we medicate our children.

Children with behavioral disorders are a vulnerable population. Certainly, their welfare—and the science behind our efforts to help—should come before commercial interests. The policies, practices, and advocacy of the medical profession should clearly demonstrate a preference for evidence-based information over commercial advertising.

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