Study finds that 'Big Pharma' fails at self-policing ED drug advertising

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The pharmaceutical industry's efforts to self-regulate its direct-to-consumer (DTC) advertising are "an industry-sponsored ruse," intended to deflect criticism and collectively block new Federal regulation, a study released today in the *Journal of Health Politics, Policy and Law* found.

The paper, "The Politics and Strategy of Industry Self-Regulation: The Pharmaceutical Industry's Principles for Ethical Direct-to-Consumer Advertising as a Deceptive Blocking Strategy," was written by Denis Arnold, Associate Professor of Management and Surtman Distinguished Scholar in Business Ethics in the Belk College of Business at UNC Charlotte, with Jim Oakley, Associate Professor of Marketing at Montana State University.

Arnold and Oakley studied the marketing campaigns for erectile dysfunction (ED) drugs over a four-year period, 2006 to 2010. These products include sildenafil citrate, manufactured and marketed as Viagra in the U.S. by Pfizer; tadalafil, manufactured and marketed as Cialis in the U.S. by Eli Lilly; and vardenafil HCI, manufactured by Bayer Healthcare and jointly marketed as Levitra in the U.S. by Bayer Healthcare, GlaxoSmithKline and Merck.

All of these companies have certified compliance with the "PhRMA Guiding Principles," developed by the Pharmaceutical Research and Manufacturers of America trade organization and first introduced in 2005. Under these guidelines, a company must commit to internal

processes to ensure compliance with the principles, complete an annual certification of compliance, and submit a document to PhRMA signed by the CEO and chief compliance officer attesting to compliance.

"The Guiding Principles were introduced, as least in part, to preclude the need for additional federal regulation of broadcast drug advertising," Arnold said. "In this regard they have been largely successful."

Arnold and Oakley's analysis found that rather than a serious effort to facilitate the education of consumers, the Guiding Principles were often ignored, putting consumers at possible risk and exposing children to inappropriate content.

"Cumulatively, our data shows that ED marketing campaigns fail to responsibly educate consumers about health conditions and appropriate treatments," Arnold said. "Instead of facilitating a balancing of interests between company profits and public health, the illusion of industry self-regulation is primarily serving the interest of pharmaceutical companies at the expense of the public's interest in genuine health education and welfare."

Among the findings in the study:

- Advertising for ED drugs grew from $200 million in 2006 to $313 million in 2009, a 56 percent increase. Television advertising accounts for about 80% of the DTC ad spending.
- There was a clear pattern of non-compliance to the "Guiding Principles" for the three drugs under study, and Arnold and Oakley note that PhRMA does not make public violations of its guiding principles, nor does it sanction member violations.
    - Eli Lily's Cialis campaign consistently violated six principles, partially complied with two principles, and

fully complied with one principle.
    - Pfizer's Viagra campaign consistently violated five principles, partially complied with one principle, and fully complied with two principles.
    - Bayer Healthcare, GlaxoSmithKline, and Merck's Levitra campaign consistently violated five principles, partially complied with three principles, and fully complied with one principle.

- In the four-year time span studied, there were nearly 100,000 television advertising occurrences for ED drugs.

    - American consumers have been exposed to approximately 500 billion ED television advertising impressions since 2006, of which over 100 billion were seen by consumers under the age of 18, in violation of the Guiding Principles.
    - In response to the introduction of H.R. 2175, the Families for ED Advertising Decency Act,, in 2009 (introduced by Rep. James Moran (D-VA8), each of the companies has stated that they are in compliance with the Guiding Principles requirement that 90% of the audience for adult-themed broadcast advertisements be 18 or older, but Arnold and Oakley's analysis of AC Nielsen Monitor-Plus data documents that this claim has not been true for any quarter during the four-year period of the study.

- Patient information and print ads were consistently found to exceed recommendations for consumer legibility violating the Guiding Principles.
- Each of the drugs is presented in ads as the most appropriate first stage treatment for impotence, despite known risks such as priapism and sudden loss of hearing or vision. - None of the ED

drugs effectively informed consumers of alternative options for treatment, in violation of the Guiding Principles.
- The mechanism set up by PhRMA for consumers to make complaints does not function: the FAX machine is typically not connected and complaints go unanswered.

"We were surprised by the findings," Arnold said. "We did not expect this level of non-compliance. It is troubling to discover that executives at these companies are engaged in this level of duplicity."

Arnold and Oakley make a number of recommendations to rectify the ineffectiveness of the industry-developed self-regulation, including maintaining bans on DTC advertising where they currently exist. In countries without a ban, most notably the U.S. and New Zealand, the study recommends a more robust regulatory climate. Options might include:

- Implementing restrictions on advertising that might reach children, such as those as outlined in the Families for ED Advertising Decency Act;
- Requiring that non-pharmacological treatment options and comparative treatment costs be addressed;
- Requiring FDA approval of advertisements take place before advertisements are broadcast for the first time, as opposed to the current practice of allowing the ad to run as long as it has been submitted for review;
- Assessing a fee for each DTC advertising broadcast, to enable the National Library of Medicine to produce and widely distribute plain-English information about the benefits, harms, and cost of the drugs advertised, as well as information about the condition and non-pharmacological treatment options.

"In the case of New Zealand, some of these changes could be introduced

via amendments to the existing Code for Therapeutic Advertising by the Advertising Standards Authority, while others could be introduced by the Ministry of Health," Arnold explained. "In the U.S., the ability for Congress and FDA to implement such regulatory changes will be subject to the evolving role of the Supreme Court in assessing what constraints may be placed on commercial speech. However, Congress could empower existing agencies or departments to penalize firms for making false claims about their advertising."

Arnold and Oakley also recommend that additional resources be provided, within existing regulatory frameworks, so regulatory agencies can more rigorously enforce of statutory requirements.

"The ultimate goal of these recommendations is to better balance the interests of pharmaceutical companies and the public," Arnold said.

Provided by University of North Carolina at Charlotte