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Data Center

Career Center
Marketplace

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Print Edition
Customer Services
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Media Kit
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$4 BILLION DTC DRUG AD FIGHT FINDS A HUMAN FACE

Widowed Ad Exec Suing Pfizer Testifies at Charged FDA Debate

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By Rich Thomaselli

WASHINGTON (AdAge.com) -- Amid the rhetoric calling for everything from tempering direct-to-consumer drug ads to abolishing them, the Food and Drug Administration's public hearings on the merits of DTC begged for a human voice. It found one today in Kim Witczak.

The late Timothy 'Woody' Witczak and his wife, Kim Witczak. Ms. Witczak, who believes her husband's death was triggered by his use of Pfizer's antidepressant drug Zoloft, delivered an impassioned statement during the second day of the FDA hearing.

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In between presentations from pharmaceutical industry advocates hoping to keep the status quo and opponents hoping to shut down the $4 billion category, Ms. Witczak delivered an impassioned speech about the suicide of her husband -- a death she believes was triggered by his use of the antidepressant drug Zoloft, from Pfizer.

But Ms. Witczak, who is suing Pfizer, did not call for an end to DTC, only that it "be held to a higher standard."

Unique perspective

Hers was a unique perspective: She was the only one of 39 speakers during the two-day public hearings listed as a consumer, or part of the general public, but she is also in the advertising business as a senior art buyer and producer for Publicis Groupe's Fallon, Minneapolis. Standing in a near-empty room after a break scattered the crowd, Ms. Wiktczak was asked if her 15 years in the ad business stopped her from calling for an end to DTC.

"Probably a little bit. I'm a realist. I know it's big business," she said. "But I came here on my own dime to talk about Woody, and all I was hoping to do was be a voice of reason."

During her speech, Ms. Witczak relayed how in 2003 her husband of almost 10 years, Timothy "Woody"' Witczak, decided to start his own business. The prospect was giving him restless nights, and his doctor prescribed Zoloft even

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and his doctor prescribed Zoloft even though he was not diagnosed with depression. Several weeks later, after experiencing several side effects, Mr. Witczak hanged himself in the garage of their home. Ms. Witczak was on a business trip; her father found the body.

'New marketing environment'

"I believe DTC has influenced the prescribing habits on many levels," she said during her speech. "DTC has created a mind-set that there is a pill for every problem. DTC has shifted the paradigm away from the doctor to the consumer. This is the new marketing environment."

Still, she would not call for the end of the practice, only for changes. One such change she proposed would be that print promotions be done on facing pages, so the ad is the left side and the side effects, or brief summary, to the right, instead of on the back of the main ad.

"I'm looking to start small," Ms. Witczak said. "But no matter how small, DTC ads must be grounded in truth."

This might be the kind of change the industry is willing to accept because there was no happy medium otherwise during the second day of hearings, called by the FDA in order for the agency to receive data and guidance on DTC advertising that could lead to more restrictive guidelines on the practice.

Controversial compromise

One day after supporters acknowledged that DTC did need some tweaking, several opponents offered a compromise that will surely be summarily rejected: no brand ads at all.

"There are many risks to DTC advertising and the only answer is to use help-seeking ads, rather than profit-driven ads that link drugs and disease," said Dr. Peter Lurie, deputy director of the advocacy group Public Citizen and an outspoken critic of DTC. Dr. Lurie added that drug makers were turning consumers into "agents" for their own companies.

Judith Cahill, director of the Academy of Managed Care Pharmacy, said that her group supports DTC but only if the ads are educational about disease symptoms or alternative treatment options, not about specific brands. "It does a disservice to the public if its aim is to induce name recognition and increase market share," she said.

First Amendment rights

"To say that's a crazy idea is an understatement," said an executive at one of the major pharma companies who attended the hearings but did not testify. "I think everybody in our industry agrees -- and it was reiterated several times -- that DTC advertising needs to change. Not allowing us to advertise our brands is not 'change,' it's restrictive and it's against the First Amendment."

Gary Ruskin, executive director of the Portland, Ore.-based advocacy group Commercial Alert, said that argument doesn't have merit. "Only doctors can prescribe prescription medication, so there is no legitimate reason to have DTC," said Mr. Ruskin, who called for the end of all DTC.

Alex Sugarman-Brozan of the advocacy group Prescription Access Litigation asked that the FDA return to pre-1997 requirements that demand the full brief summary in TV ads, knowing that would mean the end of broadcast ads. "If [the pharmaceutical companies] can't do the summary, they shouldn't be on TV or radio," Mr. Sugarman-Brozan said.

Asked by Dr. Robert Temple, director of the FDA's Office of Medical Policy, how drug makers would overcome such difficulties, Mr. Sugarman-Brozan said with a laugh, "Maybe the industry needs to purchase larger blocks of [commercial] time."

Mr. Temple replied: "I can tell you they won't. They'll tune out."

Consumers Union, the Washington-based nonprofit publisher of *Consumer Reports,* further outlined its call for major reforms during its afternoon testimony. "Current ads often fail to present the benefits and risks of using prescription drugs or medical devices in an accurate, non-misleading,

balanced and understandable way," senior policy analyst Bill Vaughan said.

Calls for a moratorium
Consumers Union called for a 2- or 3-year moratorium on advertising of new drugs and pre-approval of ads to both consumers and physicians, among other reforms. American Advertising Federation President-CEO Wally Snyder warned against imposing moratoriums, saying that such action would dangerously hinder the public's access to quality medical treatment.

"Ultimately, the issue is not about moratoriums on advertising, it is about regulation. If a drug is not ready, by all means keep it off the market," Mr. Snyder said. "But once approved, once the stringent requirements of clinical trials and other testing are done, and the drug approved, please do not send a mixed message by banning advertising. Regulate the drug, but do not impede the flow of truthful information."

ANA rebuke
Mr. Ruskin presented a letter he made public last week, in which more than 200 medical school professors called for the end to prescription drug advertising. That drew a sharp rebuke from the Association of National Advertisers. Although the ANA did not present at the FDA hearings, the group's exec VP, Dan Jaffe, said in a release that the "Commercial Alert proposal is radical, misguided and unconstitutional. We believe that DTC advertising provides tremendous benefits to consumers and promotes the public health. Many prescription drug products provide enormous health benefits that prolong and save lives. FDA studies have found that more than 24 million Americans have discussed a health issue for the first time after seeing a prescription drug ad."

In one interesting presentation, John Calfee of the American Enterprise Institute introduced a survey comparing DTC in the U.S. and New Zealand, the only two countries to allow DTC pharma advertising. "In both nations," Mr. Calfee said, "there is very little evidence of harm coming from DTC advertising."

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