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# OUTGUNNED FDA TRIES TO GET TOUGH ON DRUG ADS

AGENCY WARNINGS TO DRUGMAKERS OVER MARKETING HAVE RISEN AS COMPANIES GET CREATIVE

## SPECIAL REPORT

# FDA STRUGGLES TO KEEP UP WITH PITCHES OLD AND NEW

Under the Obama administration, the FDA has vowed to crack down on the drug industry's increasingly aggressive marketing tactics, both online and off. But with just 57 officials charged with viewing some 75,000 ads a year, there is only so much the agency can do.

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SILVER SPRING, Maryland

It wasn't what you would call a casual get-together.

In February 2009, a popular New York blogger attended a brunch with fellow "frazzled moms." They took in tips from a style expert and listened to a nurse extol the virtues of Mirena, a birth control device sold by Bayer Healthcare.

The nurse was on Bayer's payroll. In a series of events organized with the help of a women's website, Mom Central, the pharmaceutical company gathered a captive audience of young mothers. It provided the nurse with a script and had the women fill out a survey before they left.

*"THIS WAS EXTREMELY, EXTREMELY CONCERNING TO US BECAUSE THIS PRODUCT HAS RISKS."*

The sessions earned a stern rebuke from the U.S. Food and Drug Administration. In a letter to Bayer Healthcare made public earlier this year, the agency faulted the drugmaker for telling "busy moms" that using its intrauterine device (IUD) "will result in increased levels of intimacy, romance and, by implication, emotional satisfaction."

Besides hyping the product, the nurse failed to disclose potential risks. "Here you have a company hiring a third-party to invite people into a home like a Tupperware party," said Thomas Abrams, whose department oversees pharmaceutical marketing reviews at the FDA. "That was extremely, extremely concerning to us because this product has risks -- risk of infection, loss of fertility. Huge risk."



PAPERWORK: FDA officials review marketing material at their office in Silver Spring, Maryland June 9, 2010. REUTERS/JONATHAN ERNST

Under the Obama administration, the FDA has vowed to crack down on increasingly aggressive marketing tactics -- both online and off. But even Abrams acknowledges the agency lacks the resources to sharply curtail misleading drug ads.

Downturn or no, the pharmaceutical industry hasn't been skimping on advertising. In 2009, companies spent a vast \$4.8 billion to reach out to consumers in the United States -- the only country besides New Zealand that allows direct-to-consumer advertising -- up from nearly \$4.7 billion the year before, according to tracking firm Kantar Media.

To drug companies, it is all part of patient education. But consumer advocates, some lawmakers and others see the barrage of ads as a way to push medicines that people may not need as well as raise the nation's overall healthcare costs.

As media splinters into a sea of Internet blogs, on-demand television and niche publications, companies are racing to keep pace. Websites and digital technology offer powerful tools that make it easier, cheaper and quicker to target specific groups. And drugmakers are relying more on celebrities and other methods to make their products stand out.

For example, last year the FDA warned Abbott Laboratories over a promotional DVD featuring former basketball star and HIV patient Earvin "Magic" Johnson that the agency said suggested the company's HIV drug Kaletra was safer and more effective than proven.

Agency staff have also slapped Allergan Inc for its website promoting its eyelash-boosting drug Latisse, saying various webpages did not tell potential consumers about possible risks, such as extraneous hair growth if the product touches the skin elsewhere, and downplayed possible allergic reactions.

Earlier this year, Novartis earned a warning for two websites it sponsored -- www.gistalliance.com and www.cmlalliance.com -- to promote its leukemia drug Gleevec. The FDA said although the sites never used the therapy's brand name, they clearly alluded to it and yet failed to mention critical side effects.

All told, the number of warnings the agency has sent drugmakers has ballooned, despite voluntary industry guidelines established in 2005 to help curb complaints. In 2008, under the Bush administration, the FDA sent just 21 notices to companies for violating the agency's marketing standards. Last year, it sent 41 letters to companies. Already this year, it is outpacing that effort, having issued 45 warnings through Aug. 28.

**CREATIVE MARKETING**

The FDA's Division of Drug Marketing, Advertising and Communications, reviews advertisements and other promotional items before and after they run to try to ensure companies do not mislead consumers or make false claims.

Its job isn't getting any easier. "Companies have become more aggressive with their promotion, more creative," said Abrams, a former pharmaceutical salesman who spent seven years working in sales and marketing for two different companies before moving to the FDA's promotional division for the last 16 years.

The advertising universe has been transformed in other ways since his days pushing promotions in New Jersey, home to several of the nation's top drugmakers.



**MONITORING MAD MEN:** Tom Abrams, director of the US Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications (DDMAC), oversees the FDA's enforcement of rules against deceptive pharmaceuticals advertising at FDA headquarters in Silver Spring, Maryland, June 9, 2010 **REUTERS/JONATHAN ERNST**

Facebook, Twitter, YouTube and other social media networks are the new frontier in marketing, and drugmakers are dipping in like everyone else. Pfizer Inc, GlaxoSmithKline Plc, Bristol-Myers Squibb and AstraZeneca all have Twitter feeds, and some also have blogs.

*"COMPANIES HAVE BECOME MORE AGGRESSIVE WITH THEIR PROMOTION, MORE CREATIVE."*

Unlike the case for print and broadcast, the FDA has yet to lay out guidelines for industry to follow, though Abrams said the agency aims to release a draft later this year.

"We are developing separate guidance that are issue-specific and can apply to the various mediums used on the Internet," he told Reuters. For example, the agency will advise companies how to respond when consumers make an unprompted request for information on a drug.

The lack of guidelines remains a sore point for the industry. "FDA has continued enforcement actions without these clear standards," said Jeff Francer, a lawyer at the Pharmaceutical Research and Manufacturers of America (PhRMA), the industry lobby group that made the 2005 pledge to clean up ads.

In comments submitted to the FDA ahead of the expected new guidelines, drugmakers made their feelings known. Officials for diversified healthcare company Johnson & Johnson urged the agency to "keep its approach as simple and flexible as possible," in a letter this past February.

**SEPRACOR'S LUNESTA**

June 17, 2010 - FDA warned Sepracor Inc over a 60-second television commercial featuring a sleepless woman whose bed appears to be a boxing ring. She falls asleep after taking Lunesta and is tucked in by the company's trademark butterfly.



Sepracor, acquired by Dainippon Sumitomo Pharma Co Ltd in October, suggested the sleep aid was "clinically superior" to other insomnia treatments, the agency said. An announcer says: "If you've taken your sleep aid, and you're still fighting to sleep in the middle of the night, why would you go one more round using it? ...Lunesta is different." The FDA said it was unaware of data to back up the claim and called on the drugmaker to stop airing it.

## “WE DO REVIEW ADS AND CAN TAKE ACTION WHEN WE THINK THERE ARE MISREPRESENTATIONS OR INADEQUATE PRESENTATION OF RISKS.”

And Big Pharma has acquired some unlikely allies. Internet companies that thrive on online advertisements, including YouTube’s parent Google Inc and rival Yahoo! Inc, have joined forces with drugmakers in pressing the FDA for clear standards.

### ‘RUNNING TO KEEP UP’

Even without the Internet, FDA officials would have trouble keeping up.

Congress has helped deliver a handful more staffers to help tackle the growing flood of ads, but the agency still has just 57 officials charged with reviewing roughly 75,000 marketing items a year, Abrams noted. They review “thousands and thousands” but can’t get to them all, he said.

As a result, agency officials say they must prioritize which promotions get checked first. Those that could have the biggest effect on public health top the pile.

To make matters worse, Congress moved to allow industry funds to boost FDA ad reviews but never fully authorized the program. Companies could have voluntarily paid a fee to have the FDA screen their television commercials before they ran, rather than later when they could get a warning.

FDA Commissioner Margaret Hamburg, who took over in May 2009, has said staffers simply can’t cope with the volume. “We’re sort of always running to keep up,” Hamburg, a former New York City health chief and public health expert, told lawmakers at a U.S. House of Representatives appropriations subcommittee in March.

“We do review the ads and can take action when we think there are misrepresentations or inadequate presentation of risks, but the volume makes it very, very difficult,” she said. “The fact is: we don’t review them, sign off, and then they go up.”

Insufficient staff isn’t the agency’s only problem. It is also hampered by antiquated technology systems.

At a time when digital videos take seconds to upload and can reach millions of views in minutes, the FDA’s marketing reviewers read storyboards of television and Internet spots on paper, which are archived in a separate room across the agency’s 130-acre campus. As with other government entities, the division is moving toward electronic submissions but isn’t there yet.

To ease the workload, the agency recently enlisted doctors to report misleading promotions aimed at medical professionals. Its “Bad Ad” campaign seeks to teach physicians how to spot questionable promotions or statements and then report them to the agency voluntarily.

So far, it has received about 100 complaints through the effort.

Nevertheless, consumer activists say FDA’s overall approach is likely to fall short. Abrams’ office “certainly needs more money and manpower to be regularly monitoring this kind of stuff,” said Steve Findlay, a senior health policy analyst for Consumers Union, an independent non-profit group aimed at protecting buyers.

Findlay said the industry’s efforts at self-policing have helped, especially among larger companies, but some companies have clearly crossed the line.

### ABBOTT LABORATORIES’ KALETRA

July 22, 2009 - *The FDA warned Abbott Laboratories over a promotional DVD featuring former basketball player and HIV patient Earvin “Magic” Johnson.*



REUTERS/JEFF HAYNES

In it, Johnson is interviewed about what it was like to have HIV and his experience taking Abbott’s Kaletra drug. “The promotional DVD minimizes the serious risks of the drug, overstates the efficacy of Kaletra, and includes unsubstantiated claims,” the agency wrote.

Abbott has said it discontinued its use of the DVD earlier in 2009 before the warning letter was made public.

### NOVARTIS’ TASIGNA

Aug. 4, 2010 - Novartis received one of the FDA’s first warning letters targeting what the agency considered an inappropriate Facebook widget on the drugmaker’s website for Tasigna, a chronic myelogenous leukemia therapy. *FDA said the widget, which the social networking website uses to share content with its Facebook users, was misleading because it told people about the drug’s benefits but not its risks.*



“By failing to disclose any risk information for Tasigna, the shared content misleadingly suggests that Tasigna is safer than has been demonstrated,” the FDA wrote to the drugmaker.

"We're still seeing drug ads that are not completely balanced and are inappropriate or off-base," he said.

Consumer advocates worry pharmaceutical companies are increasing efforts to reach teenagers through online ads.

Allergan used a "High School Musical"-type promotion for prescription acne drug Aczone featuring "Twilight" movie actor Michael Welch. He starred in an online video series called "Aczone: The Musical."

Other companies have created stuffed animals, games and children's books to promote medicines to youth, said Susan Linn, director of the Campaign for a Commercial-Free Childhood, a group of doctors, parents, teachers and other advocates.

"It's not a good idea to start kids on a life of choosing drugs based on whether they are cool, or whether some celebrity is promoting them," said Linn, who believes marketing of medicines to children should be outlawed.

Allergan spokeswoman Caroline Van Hove said the Aczone campaign was appropriate because the drug is approved for ages 12 and older. The musical website was "just one of many informational tactics" to educate patients about what at the time was the first new FDA-approved acne medicine in a decade, she said.

PhRMA's Francer said the vast majority of ads don't merit any regulatory action. He added that it can be extremely hard, especially with television commercials, to convey all of a medication's risks. "It can be incredibly challenging for the companies to present all of the risk information that both they and the FDA want to be presented in a way that is understandable to patients," he told Reuters.

**"WE'RE STILL SEEING DRUG ADS THAT ARE NOT COMPLETELY BALANCED."**

**CROSSING THE LINE:** A pair of ads that ran afoul of the US Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications (DDMAC) rules against misleading pharmaceuticals advertising at FDA headquarters in Silver Spring, Maryland, June 9, 2010. **REUTERS/ JONATHAN ERNST**



**'AN AMAZING EVENING'**

In Bayer's case, the New York blogger and another one in Columbus, Ohio wrote about the parties immediately afterward, mentioning both the website that helped organize them as well as the birth control device being touted.

Although studies show that drug ads work -- consumers who see them are more likely to ask their doctors about the product -- it is unclear whether the company's events to promote Mirena had any impact beyond the small parties' audience.

"I went to a brunch yesterday that was hosted by Mom Central and Bayer Healthcare, and they brought in two speakers. One to talk (humorously) about their Mirena birth control product, and the other to give us 'frazzled moms' some basic style tips... The speakers knew their stuff, and did a good job," read one account on [www.sanemoms.com](http://www.sanemoms.com) that then focused only on fashion.

Another shorter post, at [chefdruck.blogspot.com](http://chefdruck.blogspot.com), also only mentioned Mirena in passing in favor of tips on shoes and husbands. "We had an amazing evening, talking about sex, fashion, and living a simpler life," it said.

Stacy DeBroff, chief executive of Mom Central, likened the parties to a focus group, but said her website won't partner with any other drugmakers until the FDA clears up its rules. "For us, it was kind of an experiment of sorts ... If we bring people into your living room what happens?" she told Reuters.

Still, the FDA did not find out about the Tupperware-like party pitch or the online posts until months after they hit the blogosphere and the agency received a complaint. Abrams declined to say who filed the grievance.

Bayer Healthcare, a unit of the German drugmaker Bayer AG, said it stopped holding the parties 10 months before it even received the agency's letter.

**BAYER'S MIRENA**

Jan. 12, 2010 - In Feb. 2009, bloggers touted Bayer-sponsored events for "frazzled moms" where a style expert offered fashion tips and a nurse gave a pitch about the company's Mirena birth control device.



FDA took issue with the script for the events, saying the nurse downplayed the intrauterine device's (IUD) risks and oversold its benefits. In a letter to Bayer Healthcare, part of Bayer AG, the agency faulted it for telling women its IUD would help boost intimacy and could help them "look and feel great." Both bloggers wrote about the events at <http://www.sanemoms.com/journal/tag/confidence> and <http://chefdruck.blogspot.com/2009/02/two-worlds-collide.html>. Bayer has said it stopped holding the gatherings 10 months before it received the agency's letter.

## ALLERGAN'S LATISSE

Sept. 16, 2009 - Allergan Inc saw a letter from the FDA last year citing the drugmaker for its website promoting its controversial eyelash-boosting drug Latisse.



FDA said various pages on the company's website did not tell consumers about possible risks like extraneous hair growth wherever the drug touches the skin and downplayed possible allergic reactions. Although Allergan pointed consumers to full prescribing details on two other webpages, that did not make up for not mentioning the risks, the FDA wrote. Allergan said it would work with the FDA to address the concerns and that one set of promotional material was no longer in use.

In comments to the FDA over social media policies, the German drugmaker said the agency should open up channels to market products and embrace the use of technology, not restrict it. "Any FDA approach should seek to maximize the dissemination of accurate healthcare information to patients and their caregivers," Bayer's senior counsel Christopher Cannon wrote earlier this year. The FDA, he added, should allow drugmakers to be "using the full spectrum of social media and other tools available via the Internet."

Abrams, age 55, said he personally uses Facebook but still relies on his younger staffers to keep up with technology. "I'm not that sophisticated," he joked.

He also said his division will continue to be aggressive in rooting out suspect marketing. One ad reviewer, he said, recently called in on her way to vacation in Florida, having seen a misleading television ad for an erectile dysfunction suppository at the airport.

As for Abrams, he keeps a pad of paper by his television for some evenings when he is watching with his wife, Maureen.

"I can be watching TV with my wife after our kids go to bed, and she knows ... when a drug commercial comes on: no talking," he said.

## NOVARTIS' GLEEVEC

May 4, 2010 - Novartis received a warning letter for two websites it sponsors that the agency said are clearly linked to its leukemia drug Gleevec even though the drug's name is never mentioned.



The sites, [www.gistalliance.com](http://www.gistalliance.com) and [www.cmlalliance.com](http://www.cmlalliance.com), made claims about the drug's benefits but failed to mention serious side effects such as congestive heart failure. They also promoted an unapproved use of the drug and made unproven claims about dosing, the FDA said. "These websites are concerning from a public health perspective," it wrote. It also sought details about Novartis' role with another website, [www.bloodleveltesting.com](http://www.bloodleveltesting.com), that the FDA said may not comply with agency rules.

**COVER PHOTO:** Employees display a pair of ads that ran afoul of the US Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications (DDMAC) rules against misleading pharmaceuticals advertising at FDA headquarters in Silver Spring, Maryland, June 9, 2010. **REUTERS/JONATHAN ERNST**

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