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DTC Pros and Cons Presented at FDA Hearing

By **John Mack**

People are polite in Washington, DC. They don't rush and knock you down in the Metro (subway) like people do in NYC. Similarly, FDA staffers and presenters at the recent public hearing on DTC were very polite too. The nice FDA people asked nice questions and the nice presenters, for the most part, didn't blast the FDA for not doing anything to reign in DTC or for doing too much.

This article presents a summary of what these nice people had to say at the FDA hearing, comments by members of the Pharma Marketing Roundtable (PM Roundtable), which met by conference call on November 10, 2005 to discuss DTC issues, and results from the ongoing DTC Issues Online Survey being conducted by Pharma Marketing News.

FDA Inside the Beltway

The 2-day meeting was held on November 1 and 2 at the National Transportation Safety Board Boardroom and Conference Center in Washington, DC rather than closer to FDA headquarters in Rockville, Maryland. Perhaps this made it more convenient for Washington beat reporters and staffers from Capitol Hill.

John Kamp, PM Roundtable member and Executive Director of the Coalition for Healthcare Communication, offered an "inside the beltway" take on FDA's motives for holding this hearing. "One clear purpose of the meeting was to remind other people inside the beltway, especially Congress, that FDA is in charge, is aggressively regulating DTC, and is doing fine, thank you."

Some presenters at the hearing, however, disagreed and criticized the FDA for dropping the ball. These critics were balanced by an equl number of DTC supporters. Harry Sweeney, PM Roundtable member and CEO/Chief Creative Officer at Dorland Global Health Communications, counted 21 Pro presentations and 17 Con presentations.

Generally, the critics were much more entertaining at the hearing than were the supporters. They were more lively and often used multimedia presentations. In contrast, most supports were dry and boring. It was as if they left all their marketing skills at the office! "The Cons ranged from balanced to incendiary," said Sweeney, "with heart-rending, over-the-top presentations that they used to muckrake."

Pfizer Research

Pfizer perhaps has done more than any other pharma company to study how to balance communication of benefits and risks in DTC ads and presented some results from its studies at the hearing.

In August, 2005, Pfizer announced its commitment to "fundamentally change our approach to communicating risk and benefit information to improve educational value while continuing to motivate people to overcome barriers to healthy behavior."

Part of this commitment is to test and improve consumer-friendly approaches to risk communication:

- Pfizer has submitted to the FDA for review a new consumer-friendly and consumer-tested print brief summary, the part of the print ad that extensively lists the risks of a medicine (see Figure 3 on page 5). Should the FDA approve this new version, Pfizer will use this new format in all its print advertising and on all of its product Web sites.
- Pfizer will fund research to find ways to further improve risk communication in DTC TV advertising. Pfizer will conduct this research with input from the FDA and third parties and will adjust its communications based on the results.

The first presenter at the FDA meeting—Sharon D. Allison-Ottey of COSHAR Inc.—summarized the qualitative research that Pfizer performed in September, 2004. Based on qualitative screening, four "innovative" options that may help to provide consumers with more user friendly information via print DTC ads were recommended for quantitative testing:

- '**Empowerment**' provided both important information about the medication as well as information about the indication (e.g., high cholesterol) and lifestyle changes that can help improve a patient's outcome.

- '**Fast Facts**' provided the pertinent information in an easy to follow format, allowing the reader to quickly "scan and read" the sections that are most important to them.
- '**Questions**' provided the quick scan of important information and the format is one that is thought to potentially elicit questions to the physician.
- '**Safety Guide**' appeared to be the best option to test this finding since it has some of the elements that are important (i.e., blocking of information and color) so it has more of the variables of the other options that will be tested.

These were combined with existing brief summary versions and prototypes of those referenced by the 2004 FDA Brief Summary guidance to create the quantitative test matrix.

Five Key Learnings

1. **The Ad itself is an integral part of risk communication.** Consumers receive information about side effects and other important information from the ad alone (as demonstrated by the Ad only cell)…

Click here to navigate...

On the crucial dimension of recall and severity of side effects, three of the alternative versions prove superior to other versions tested within both therapeutic areas (Migraine and High Cholesterol): Fast Facts, Questions, safety Guide…

5. …**And, importantly, risk communication and motivation are not incompatible.** Each of these versions has motivation scores that are no worse than an ad paired with the current Brief Summary. Motivation was measured as a take action metric: visit a physician or call an 800 number. No mention was made, however, if visiting a product website was an action measured.

Motivation

Pfizer's DTC mission statement reads, in part, "to communicate motivating, useful and understandable information about medical conditions and treatment options…" Pat Kelly, President of Pfizer US Pharmaceuticals, presented data supporting the motivational role that DTC advertising plays.

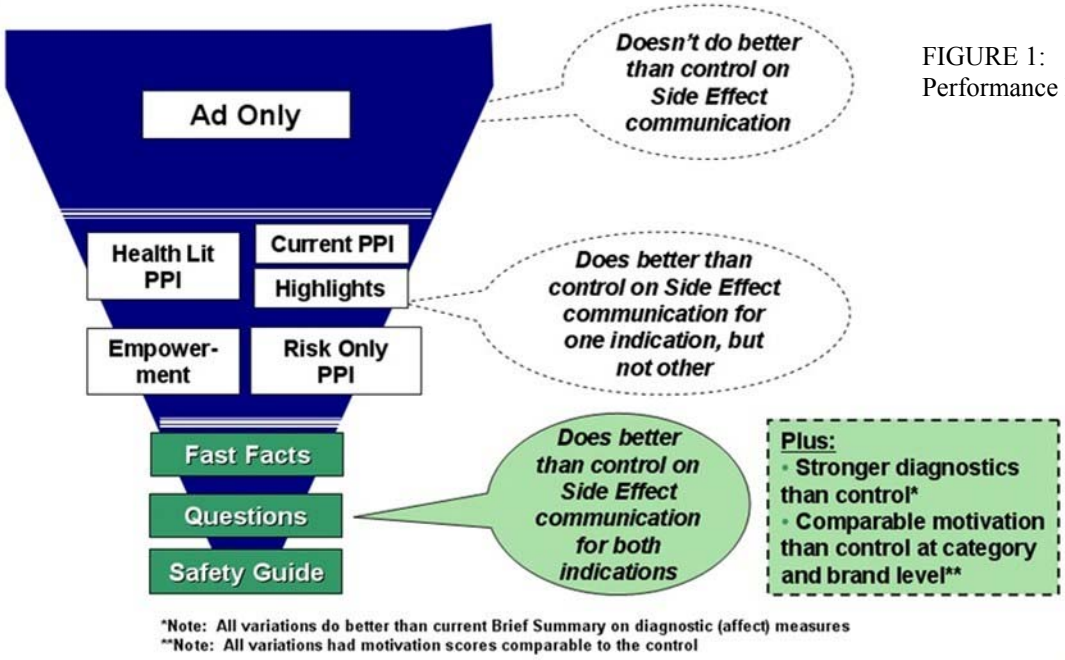


FIGURE 1:
Performance Funnel

2. …**But, the Brief Summary matters.** An ad with a Brief Summary is more effective at conveying side effect information compared to having an Ad only with no brief summary at all…
3. …**And, the Brief Summary can clearly be improved.** Current Brief Summary is clearly inferior at communicating information compared to all alternative versions tested…
4. …**We have identified several appealing** alternatives to the Current Brief Summary.

The crux of his presentation was that DTC is instrumental in motivating millions of American with undiagnosed medical conditions to speak with their physicians and that advertising leads to new diagnoses (see Figure 2 on page 4).

"We've learned that ads need to provide information that motivates consumers to overcome the significant barriers that continue to prevent millions of Americans … from starting that all-important conversation with their doctors to get the medical help they need," said Kelly. Kelly was careful to

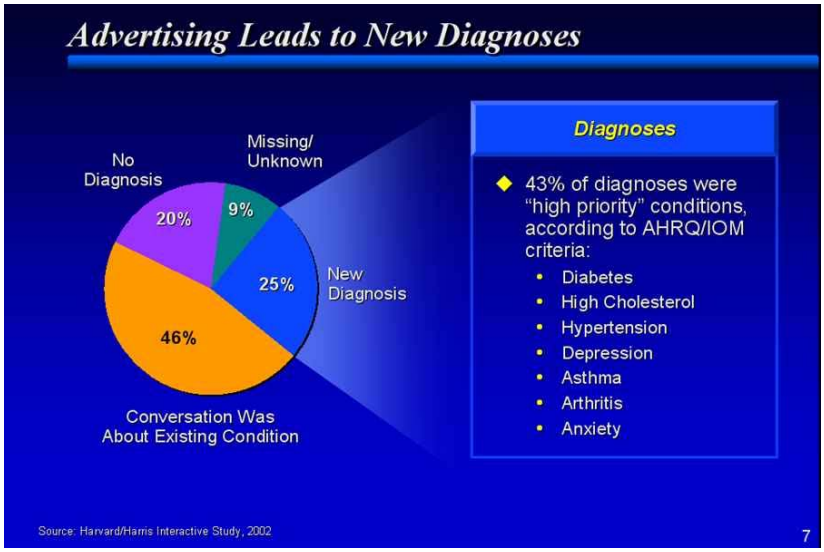


FIGURE 2: DTC advertising has helped one in four patients who asked about a DTC-advertised product during a doctor visit receive a diagnosis for a previously unknown medical condition. More than forty percent of these new diagnoses were for high priority conditions.

point out, however, that consumers seek health information from a variety of sources in addition to DTC. TV ads, for example, ranked 5th as an information source after conversation with physician, magazines/newspapers, conversations with family/friends, and conversation with pharmacist.

"If the point of DTC advertising is to get people to talk to their doctors to become more aware about diseases," said Mario Cavallini, PM Roundtable member and Manager, Competitive Intelligence at SimStar, "then DTC should talk just about that. But that's not the only goal of DTC. We should be careful in public defense of DTCA that we don't get boxed into the position that the ONLY purpose for DTCA is disease awareness and driving consumers to the doctor."

Recommendations

Kelly's recommendations to the FDA were as follows:

- Don't sacrifice proven public health benefits of DTC
  - Pursue changes in an evidence-based way
  - Critical research is needed
- Work together to ensure that communications are truly helpful, understandable and engaging to the patient
  - Focused
  - Balanced
- Expand rather than reduce information options
- Help consumers work with their healthcare providers
- Recognize people's barriers to healthy behavior and the importance of DTC in overcoming them

How Much Risk Information is Enough?

Communicating risk in DTC ads is a crucial issue for the FDA. When queried on this issue by FDA panelists, Kelly suggested that an effective standard must be set to determine how much risk information is optimal. Pfizer, as well as other pharma companies, are seeking to find the boundary beyond which risk information becomes so overwhelming that it actually deters patients from seeking help. "We need to step back," said Kelly, "and establish what is reasonable to be accomplished" within a short 30-second or 60-second DTC ad.

"How do you get the FDA to agree to put only as much information in ads as is needed to communicate risks without creating information overload?," asked Sweeney. "Some people figured out a long time ago that if industry can be forced to pile more and more information into their commercials, the DTC advertising issue would sink of its own weight."

As far as the FDA may be concerned, it "needs to quantify how well DTC ads communicate risk," said Jack Barrette, PM Roundtable member and Category Development Officer at Yahoo!. "FDA needs to find good metrics to show that risks are as well understood as benefits whereas previously there was a tremendous imbalance. They can then demonstrate that they corrected this imbalance and did their job as a regulatory authority to make DTC a worthwhile type of communication."

Disease Awareness Ads

According to Kelly, Pfizer has allocated a portion of their media budget a financial amount "equivalent to one major medicine" to address general public health as a "stand-alone brand" without mentioning any drug brand. Part of this sum may be used to develop a special category of unbranded ads: Help-seeking ads or unbranded disease-awareness ads.

Disease-awareness ads are not subject to the disclosure requirements of the Federal Food, Drug, and Cosmetics Act and FDA regulations. These ads are communications disseminated to consumers or health care practitioners that discuss

IMPORTANT FACTS

LIPITOR atorvastatin calcium (LIP-ih-tore)

LOWERING YOUR HIGH CHOLESTEROL

High cholesterol is more than just a number, it's a risk factor that should not be ignored. If your doctor said you have high cholesterol, you may be at an increased risk for heart attack. But the good news is, you can take steps to lower your cholesterol.

With the help of your doctor and a cholesterol-lowering medicine like LIPITOR along with diet and exercise, you could be on your way to lowering your cholesterol. Ready to start eating right and exercising more? Talk to your doctor and visit the American Heart Association at www.americanheart.org.

HOW TO TAKE LIPITOR

Do:
- Take LIPITOR as prescribed by your doctor.
- Try to eat heart-healthy foods while you take LIPITOR.
- Take LIPITOR at any time of day, with or without food.
- If you miss a dose, take it as soon as you remember. But if it has been more than 12 hours since your missed dose, wait. Take the next dose at your regular time.

Don't:
- Do not change or stop your dose before talking to your doctor.
- Do not start any new medicines before talking to your doctor.
- Do not give LIPITOR to other people. It may harm them even if your problems are the same.
- Do not break the tablet.

ABOUT LIPITOR

LIPITOR is a prescription medicine. Along with diet and exercise, it lowers "bad" cholesterol in your blood. It can also raise "good" cholesterol (HDL-C). In adults, it can lower the risk of heart attack in patients with multiple risk factors for heart disease - such as family history of heart disease, high blood pressure, older than 55, low "good" cholesterol, or smoking.

POSSIBLE SIDE EFFECTS OF LIPITOR

The most common side effects of LIPITOR are:
- Headache
- Constipation
- Diarrhea, gas
- Upset stomach and stomach pain
- Rash
- Muscle and joint pain

Side effects are usually mild and may go away by themselves. Less than 3 people out of 100 stopped taking LIPITOR because of side effects.

Serious side effects in a small number of people:
Muscle problems or liver problems. Muscle problems can lead to kidney problems. Symptoms of muscle or liver problems include:
- Unexplained muscle weakness or pain, especially if you have a fever or feel very tired
- Nausea or vomiting
- Stomach pain
- Brown or dark-colored urine
- Feeling more tired than usual
- Your skin and the whites of your eyes become yellow

If you take LIPITOR and have these symptoms, call your doctor immediately.

WHO IS LIPITOR FOR?

Who can take LIPITOR:
- People who can't lower their cholesterol enough with diet and exercise
- Adults and children over 10

Who should NOT take LIPITOR:
- Women who are pregnant or nursing or may become pregnant
- People with liver problems
- People allergic to anything in LIPITOR

BEFORE YOU START LIPITOR

Tell your doctor:
- About all medications you take, including prescriptions, over-the-counter medications, vitamins, and herbal supplements
- If you have muscle aches or weakness
- If you drink more than 2 alcoholic drinks a day
- If you have diabetes or kidney problems
- If you have a thyroid problem

NEED MORE INFORMATION?
- Ask your doctor or healthcare provider.
- Talk to your pharmacist
- Go to www.lipitor.com or call 1-888-LIPITOR

Rx only

Manufactured by Pfizer Ireland Pharmaceuticals
Dublin, Ireland
Distributed by Parke-Davis, Division of Pfizer Inc.
New York, NY 10017 USA
 Printed in USA July 2005

FIGURE 3: Pfizer's consumer-friendly and consumer-tested print brief summary that Pfizer will begin using with FDA's approval.

a particular disease or health condition, but do not mention any specific drug or device or make any representation or suggestion concerning a particular drug or device.

Even though Pfizer—and other pharma companies—may be spending more of their media budget in the future on disease-awareness ads, it does not believe that these ads are as effective as branded DTC in driving consumers to seek help.

According to Kelly, "general disease-awareness and help-seeking ads do not drive patients to the doctor to anywhere near the degree that information about a solution or a potential solution will." This finding is "not well understood," according to Kelly.

"What we have found," Kelly said, "is that if you express just that you should be aware that there is a medical condition or a disease that you should worry about, it doesn't generate as much action as if you then say there might be potential solutions that you should consult with your provider about. So it is the other connection that is important for motivating action."

It may be possible to design motivational disease-awareness ads that are as effective as branded ads in driving patients to seek help. After all, this is how pharmaceutical companies advertise in markets throughout the rest of the world. "It's no doubt possible to do disease awareness ads that drive consumers to see their doctors," said Barrette. "The challenge for unbranded ad campaigns is that they benefit the market leader disproportionately. So this is not an advertising and marketing strategy that is easy for the industry to support from a financial and business perspective."

David Hoo, PM Roundtable member and Marketing Director at ACNielsen, noted that, for some therapeutic categories, disease-awareness ads may be a win-win rather than a win-lose proposition. "In many large therapeutic categories," said Hoo, "the market leader does stand to gain the most from disease awareness advertising, but others should benefit proportional to their market share. The key thing for all DTC marketers to keep in mind is this should expand the market and each drug's new sales should be incremental sales with disproportionably higher incremental profits." Hoo suggested that disease awareness ads generate an acceptable ROI despite having lower response rates than branded DTC ads. "Plus," Hoo adds, "there is the PR benefit of doing disease awareness ads that are good and right for patients."

Continued on next page…

FDA Regulation of DTC Survey Results: Non-Branded Ads

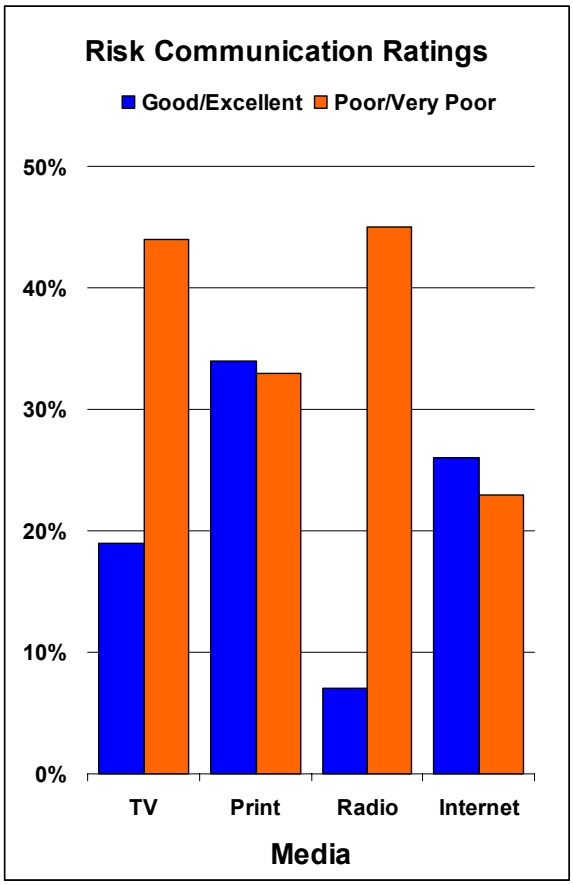
When asked if the pharma industry as a whole should adopt Pfizer's policy regarding allocation of resources to non-branded ads and make it a permanent policy, 54% of survey respondents said "yes" whereas 36% said "no."

"I do not see that it is the obligation of the pharma industry to take on this educational task," said one respondent. "It is the job of the health care authorities."

"Disease-awareness ads and adherence-to-recommendation ads are crucial for patients in this era when physician-patient communication is faltering while new medications increasingly appear in the marketplace," said another respondent.

Communicating Risk: The Bee's Wings

A study entitled "Comprehension of Benefits versus Risk: Is There Fair Balance in DTC" presented by Ruth Day of Duke University, discovered that the bee in the Nasonex TV commercial beat its wings furiously when risk information was being presented but was still when benefit information was presented. Day claimed that the beating wings divert viewers' attention from the risk information.



How devious and clever DTC advertisers must be to employ such nefarious devices to subvert the fair balance guidelines of the FDA! Not many experts actually give marketers that much credit for manipulating the elements of ads, although Hoo conceded that "there is a lot of care and attention to these things, like the blueness and clarity of the Claritin sky visuals."

Sweeney rebuffed the notion that prescription drug marketers generally are using what he calls the "mechanics of comprehension." Studies presented during the first panel at the FDA hearing "delve into a level of ivory-tower communications research that as a practical matter I think very few people in the industry have been doing," said Sweeney.

Notwithstanding the credibility of Day's studies on bee's wings, her main point was this: in TV and print DTC ads, "risk information is physically present but functionally absent." There's a sound bite for you!

Use of Celebrities

Abby Mehta of Gallup and Robinson presented data from a Pfizer-funded study of Celebrities in DTC Advertising. This study found that although ads featuring celebrities were more effective at "breaking through the clutter" and were more "likeable" by consumers, the ads generally were not more informative or believable and may or may

FDA Regulation of DTC Survey Results: Communicating Risk

When asked how good a job pharma marketers currently are doing to educate consumers about communicating risks in DTC advertisements in TV, print, radio, and Internet media, respondents thought that marketers did the best job via print (see Figure 4).

"Industry is doing a fair job when one considers that there is no consensus on what constitutes 'good' or 'excellent' communication of risk," said one respondent "As the dialogue and debate over what constitutes good risk communication continues, industry should weigh in heavily on this issue. Since 'zero-risk' is, as a practical matter, unattainable in the use of pharmaceuticals, the debate will rage over 'how much risk is acceptable?' Answers to that question will depend as much on philosophy as facts. It seems that laypeople, when adequately informed, are willing to accept much more risk than some policy makers would like. This should be an interesting topic to follow."

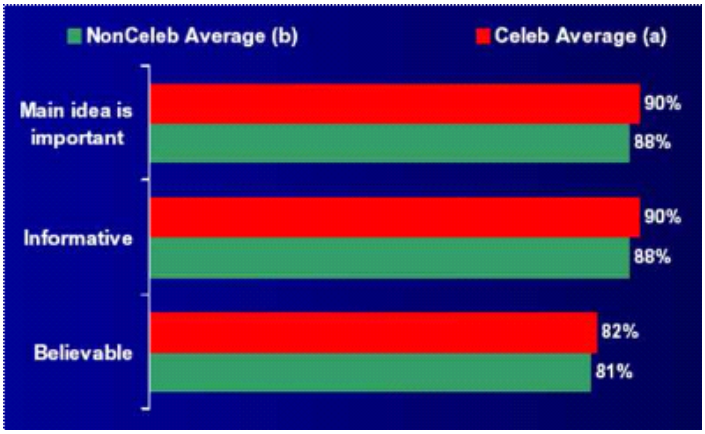
"Don't forget direct mail," said another respondent. "This medium and the Internet are the key media to move pharma messaging from passive to active, from superficial education to true education—consumer CME is what is needed and these two channels are the only ones that can do it."

"The internet has been doing an excellent job of educating consumers about both prescription and non-prescription drugs," said another respondent. "However, it is limited in its reach. In that respect, radio needs to catch up on providing crucial information on diseases, precautions to be taken, side effects of well known drugs and so on. This would benefit people living in the interiors and rural areas whose only source of information is often the radio."

not motivate consumers to seek treatment (it depends on the condition).

Results of this study show that:

- On average, celebrity DTC ads are more likely than noncelebrity ads to gain attention and break through clutter;
- Celebrities in ads, and the celebrity ad itself are rated more favorably than noncelebrities and the noncelebrity ads, but
- Celebrity ads are not seen to be providing more important messages or being more informative and believable (see Figue below);



- Celebrity ads may or may not motivate doctor consultation: various factors including health condition seem to influence celebrity effectiveness;
- While a celebrity endorsed brand may be seen as unique and sometimes improving quality of life, its efficacy and performance is not expected to be different from that in a noncelebrity ad.

Radical Ideas

Alex Sugarman-Brozan, representing a group called Prescription Access Litigation, was one of the most strident DTC critic to testify. His group represents consumers in class action lawsuits against pharmaceutical companies and claims to target deceptive marketing. He was against any DTC advertising that did not include the complete product labeling. This includes TV ads, which the FDA says are OK without the full labelling as long as "adequate provision" was made for consumers to access the labeling in other media—i.e., print and the Internet. In other words, Sugarman-Brozan is against the adequate provision regulation that allows DTC on TV and radio.

Pre-Approval of DTCA by FDA

Sugarman-Brozan also made several realistic suggestions that should be taken seriously, one of which involves mandatory pre-approval of DTC promotions by FDA. Under current FDA rules, submitting ads in advance is voluntary. Pre-approval has been recommended by PhRMA in its voluntary guidelines and several pharma

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FDA Regulation of DTC Survey Results: Use of Celebrities

When asked if the use of celebrity endorsements or actors playing doctors in DTC ads mislead consumers about the risk-benefit tradeoffs of prescription drugs, 54% of respondents said "yes" and 31% said "no."

"We need to detach the two tactics," said one respondent, "actors playing doctors is just dead wrong. Actors who may suffer from a condition, like Delta Burke form depression, is fine. We live in a society where some need to relate to others before they can accept something emotionally. Actors who suffer should be used."

Other comments:
"Key word in the question is 'mislead.' Mass marketers, social marketers and the government itself, all use celebrities to attract attention to their messages and causes. There is nothing 'misleading' about that. Communication of information concerning risk-benefit tradeoffs of prescription drugs is a separate issue. If the message is an appropriate one (the key issue), the use of celebrities only enhances the likelihood that it will be heard through the clutter."

"Celebrity endorsements or actors playing doctors is a form of fake advertising that should be banned."

"You first have to have the trust and confidence of the patient in the drug. A celebrity's cannot create trust, even if a consumer/patient may like them."

"Here, the risk-benefit trade off should be considered: How much risk the consumer takes by consuming the advertised drugs (based on the celebrity endorsement) and the benefit the company gets on account of boost in sales. This is very crucial in that consuming a particular brand of soap because it is endorsed by your favorite star is definitely less risky than doing the same with a prescription drug (without considering indications, side effects etc.)"

companies pledged to submit all their TV DTC ads to FDA before running them.

AstraZeneca stunned attendees at the FDA hearings—at least those in the know—with an announcement that it submitted written testimony proposing "a mandatory requirement for pharmaceutical companies to submit all direct-to-consumer (DTC) advertising to the U.S. Food and Drug Administration's (FDA) Division of Drug Marketing and Communication (DDMAC) for review prior to its use.

"The PhRMA guidelines are a solid first step, but the proposals we're making today make clear that AstraZeneca views the PhRMA principles as a floor, not a ceiling," said Tony Zook, Senior Vice President, Commercial Operations, and President and CEO designate, AstraZeneca Pharmaceuticals LP. "If our collective goal is to ensure that accurate and responsible information is communicated to patients and health care providers, then manufacturers, patients, physicians and policymakers ought to welcome such a review process."

AstraZeneca's proposal includes several tradeoffs and loopholes. For example, any pre-approved ad would be exempt from a subsequent finding by the FDA that the advertisement is misleading or inaccurate. Also, AstraZeneca would support legislation that would require a mandatory review of DTC advertisements by the FDA, but only where DDMAC has the necessary resources to conduct its review within a specific timeframe. This Catch-22 was noted by the November 10 Pharma Marketing Roundtable participants who unanimously agreed that the announcement was a red herring—AstraZeneca knows full-well that the FDA doesn't have the resources to pre-approve all DTC ads, including print as well as TV ads.

At the hearing, Sugarman-Brozan observed that the FDA has 40 staff members to view all drug promotions, including DTC and promotions to health care professionals. He claimed there were 53,000 such promotions in 2004. That means each FDA reviewer would need to review 5.5 promotions per day. Even if this were possible, the FDA would be hard-pressed to review all DTC promotions before airing in a timely fashion. To do so would require additional staff and funding, which are not likely to be available.

Risky Proposition

"AstraZeneca put forth a pretty risky proposition," said Sweeney. "If the agency says it doesn't have the resources, then you'll have Congressman Henry Waxman jumping up and down on the Hill promising to get additional resources for the FDA. You just don't know what will happen." Sweeney noted that there is a specific prohibition in the Food and Drug Act against pre-approval of advertising and a mandatory rule probably is unconstitutional. "A better idea," said Sweeney, "would be to create a pharmaceutical version of the National Advertising Review Board that already exists for the rest of the advertising industry to resolve disputes about advertising claims."

Another presenter at the FDA hearing suggested that a new type of "user fee" be imposed on the industry to cover this extra expense. In other words, these critics would set up a DTC promotion approval regime similar to the drug approval process. The drug industry would like that as much as the drug approval process. Think DELAY—a major sore point with the industry. According to FDLI SmartBrief, "Pharmaceutical firms now need an average 8.5 years to move a new product through clinical and approval phases, according to a study by the Tufts Center for the Study of Drug Development."

Nevertheless, Sugarman-Brozan recommended that FDA review all DTCA, including broadcast, print and online ads. He also recommended the following:

FDA should seek power to impose civil monetary penalties. He criticized the current method of issuing warning letters and likened it to British Bobbies shouting out "Stop! Or I'll shout stop again" as they pursue bad guys with no threat of force. The audience had a good laugh at that one.

End FDA Chief Counsel review of all enforcement letters. Although SB doesn't think FDA warning letters are effective, he nevertheless suggested that these letters not be impeded by FDA's chief counsel review. This issue was discussed in a post to Pharma Marketing Blog (see "WLF Watches FDA Watching Drug Ads").

Power of Images

Diana Zuckerman of the National Research Center for Women & Families suggested that the power of DTC is in the images, not the words. Images, most often used in DTC to illustrate benefits, are so powerful, she contended, that they defeat any attempt at fair balance. This left the FDA wondering how it would regulate images to achieve fair balance—how could they measure the effect of images? "How in the world are we supposed to do that?," was the FDA attitude that Cavallini said was the undertome of the meeting.

Zuckerman, however, had a solution: the only way to guarantee fair balance is to do away with images in ads.

Conclusion

Confronted by all these pros and cons and the necessity for more studies, the FDA is not likely to make any sweeping changes to DTC any time soon. "The main thrust of FDA questions was how the regulations could be tweaked one way or another," said Kamp.

Sweeney summed up the current public opinion about DTC with comments made by a speaker at a recent conference: "The real problem is that TV DTC ads have become the face of the industry to the American public, and the poster child for TV commercials is Viagra, which the public sees as inappropriate for family viewing. Self restraint on a couple of fronts would help."

Pharma Marketing News

Expert Consulted

The following expert was consulted in the preparation of this article.

- **Jack Barrette**, PM Roundtable member, Category Development Officer, Yahoo!, 617-305-5232, barrette@yahoo-inc.com
- **Mario Cavallini**, PM Roundtable member, Manager, Competitive Intelligence, SimStar, 609-689-6106, mcavallini@simstar.com
- **David Hoo**, PM Roundtable member, Marketing Director, ACNielsen, 516-682-6109, david.hoo@acnielsen.com
- **John Kamp**, PM Roundtable member, Executive Director, Coalition for Healthcare Communication, 202-719-7216, jkamp@wrf.com
- **Harry Sweeney**, PM Roundtable member, CEO/Chief Creative Officer, Dorland Global Health Communications, 215-625-0111, hsweeney@dorland.com

Pharma Marketing News

Publisher & Executive Editor

John Mack
VirSci Corporation (www.virsci.com)
215-504-4164, 215-504-5739 FAX
mailto:editor@pharmamarketingnews.com

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