



## Introduction

When Barack Obama was elected the 44<sup>th</sup> president of the United States, it broke ground in many ways, and pundits everywhere rushed to speculate about what types of changes his administration would bring. Although the financial crises, wars in Afghanistan and Iraq, and a deeply troubled U.S. economy have been the key priorities the new administration is focusing on first, the topic of DTC advertising, and changes that may result from the Obama administration, has generated a wide array of opinions and concerns. In this imc<sup>2</sup> point of view (POV) document, we review the various opinions and explore some of the options pharmaceutical marketers may need to consider under different scenarios.

In the meantime, the FDA seems to already be responding to increasing pressure from consumer groups to increase its scrutiny of DTC advertisements across different marketing channels. In the first two quarters of 2008, the FDA issued five warning letters specific to promotional materials (as opposed to sales force activity or clinical warnings) to pharmaceutical marketers, but during the second and third quarters the FDA issued 16 warning letters. Although it is difficult to know the specific reason for the increase (increased scrutiny vs. more new promotional campaigns that violated DTC regulations), several of the letters addressed areas where the FDA had not previously issued specific guidance, as with Pfizer's Viagra online video or Novartis's Diovan's online banner advertisements. The most recent FDA action against Bayer for misleading Yaz TV commercials has resulted in Bayer committing to run \$20 million in corrective advertising.

## imc<sup>2</sup>'s Point of View

Until the new administration makes its policies clear, imc<sup>2</sup> recommends pharmaceutical marketers conduct various scenario planning for its brands. There are three likely scenarios to consider:

- *Continued increase in scrutiny* by the FDA of pharmaceutical advertising, with some additional guidance on the use of the digital channel
- *Additional regulations* in the form of further requirements on fair balance, disclosure of risks and benefits, or specific language that must be used
- *Prohibitions on DTC advertising*, either for a specific amount of time after a product launches or indefinitely for certain drug categories

## Continued Increase in Scrutiny

Under this scenario, although there would not be significant changes from the current regulations, the FDA would continue to aggressively monitor and act on infractions. *DTC Perspectives* believes that more conservative review and a continued increase in warnings and fines is the most likely outcome of the new administration ("President Obama," 07 November 2008). If more pharmaceutical marketers adopt the voluntary guidelines outlined by PhRMA, it is likely that the FDA will feel less pressure in the near term to make substantial changes to regulations.

The FDA has also indicated that it may be planning to issue some additional guidance on DTC messaging in the digital channel, which would be first. Until now, regulatory review boards have used their own judgment to interpret guidance on print and other offline channels when considering online

campaigns. For example, the recent Diovan warning letter included the following specific guidance on inclusions of risk information in online banner advertising (although this may apply only to drugs with black box warnings):

*... The banners, however, entirely omit all risk information, including the warnings, precautions, and the most frequently reported adverse events from the PI. We note that a link to the PI and Patient Product Information (PPI) is included at the bottom of the banners. However, this does not mitigate the misleading omission of risk information from the banners. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any effectiveness or safety claims made in that part. By omitting the most serious and frequently occurring risks associated with the drug, the banners misleadingly suggest that Diovan is safer than has been demonstrated (Vaswani, 28 August 2008).*

Additional guidance for the FDA might result in some pharmaceutical companies being able to pursue more communication in the digital channel than before. For example, a recent Nielsen whitepaper reviewed the FDA requirements on adverse event (AE) reporting and looked at 500 healthcare-related messages posted online, and concluded that only 1 of the 500 appeared to meet the FDA criteria for AE reporting (the major omission of the 499 others was the inclusion of an identifiable reporter as defined by the FDA). As noted by Nielsen:

*Though the FDA guideline does not specify what constitutes an identifiable reporter, the 2007 draft guideline for OTC reporting notes that in order for an AE report to be submitted to the FDA, there should be "sufficient information for the responsible person to follow-up, such as a phone number or e-mail address" (Davies, Nielsen Online August 2008).*

If the FDA issued guidance that specifically addressed AE reporting in the online channel, pharmaceutical marketers could consider specific programmatic approaches to promote consumer dialogue on conditions and treatments.

In any case, we expect to see a continuation of the trend of decreasing or flat spending levels for pharmaceutical marketing overall, and a lengthening of the time it takes between the initiation of a campaign and its launch – currently averaging more than six months. This isn't surprising, given that most regulatory groups are choosing to wait for the FDA to respond to materials submitted to DDMAC rather than launching the campaign. This means that marketers will be less flexible with campaign messages, as it will take much more time to make adjustments. In this scenario, it makes sense to spend more money on up front consumer research and concept testing, and to develop campaigns that will lend themselves well to implementations across multiple channels and to "variations" that are approved at one time but released over time or to targeted audiences to keep messaging fresh and relevant throughout the longer lifetime of specific campaigns. Lipitor's recently launched "Heart to Heart" campaign, using testimonials from real patients, is an example of just such an "extendable" campaign. The campaign, featuring "John," was rolled out simultaneously via TV, print, and online.

### Increased DTC Regulations

Under this scenario, the FDA would likely require additional patientfriendly language in all communications regarding fair balance, risks, and benefits. The largest impact of this scenario would be on the viability of TV advertisements for specific therapeutic categories or diseases – 30 second spots in particular would not have enough time to make a claim statement and also comply with the increased requirements.

Sixty second spots, or even extended long form TV units, might be a better option, but increased costs associated with 60 second spots and filming of extended commercials, as well as some of the RC challenges associated with obtaining approval for three to five minutes of content, may make it less appealing. As quoted from *DTC Perspectives*:

*...expect risk guidances to be more imposing and create more problems producing a 60 second branded ad for broadcast. . . Print, web, direct, and point of care may benefit if more risk disclosure is required ("President Obama," 07 November 2008).*

Indeed, with increased regulation, marketers would need to look at expanding print, direct mail, interactive, and other "non-mass" channels as a more viable mechanism for communicating with consumers. As a result, we would ultimately expect to see a shift in spending from TV to other channels, including print, direct, and digital. Many pharmaceutical companies are in fact already stating that they will reduce or eliminate DTC advertising on TV. GlaxoSmithKline (GSK) CEO Andrew Witty recently told the Wall Street Journal that GSK would reduce TV advertising in 2009 vs. previous levels, although he declined to say by how much ("Glaxo to Cut TV Investment," 16 January 2009).

Regardless, the impact of increased regulations in these other channels would depend on the nature of the regulations, whether more limited claims, inclusion of increased information, or tighter risk guidance.

For this scenario, it may also make sense for pharmaceutical marketers to evaluate how best to communicate to consumers around complex issues of risk and benefit. Some pharmaceutical companies such as Pfizer (content around medicine safety on its corporate site [http://www.pfizer.com/responsibility/medicine\\_safety/medicine\\_safety\\_education.jsp](http://www.pfizer.com/responsibility/medicine_safety/medicine_safety_education.jsp)) are already providing information to consumers around how to evaluate risk and benefit information more specifically. Other companies may follow suit with similar consumer education efforts to pave the way for patients and prospective patients to better understand increased language around risks.

### Prohibitions on DTC Advertising

DTC advertising is prohibited in every country except the United States and New Zealand. Many consumer groups and even some pharmaceutical leaders argue that continuing to allow DTC advertising in the United States is a mistake. William Burns, Roche's head of pharmaceuticals, told a Financial Times conference in London:

*Direct-to-consumer promotion was the single worst decision for the industry. When industry says we're spending all the money on R&D but actually it's spending it on TV advertising to preserve margins, it doesn't get much credibility (Hirschler, 02 December 2008).*

In this scenario, we might see complete prohibitions on DTC for specific time periods after initial product approval, indefinite prohibitions for certain categories, or, in the most extreme case, a complete ban on DTC advertising.

Even under a complete ban on DTC advertising, the FDA is highly unlikely to require pharmaceutical companies to take down branded websites. In fact, the Internet is likely to be the one place that pharmaceutical companies would be allowed to communicate with consumers under these extreme restrictions. As James Gardner posted after attending the November FDA hearings on DTC promotion:

*Everyone would agree that banning DTC advertising on television, radio, and print would, at least in theory, prevent U.S. consumers from being exposed to its allegedly harmful impact. Forgotten is the fact that banning DTC advertising online would only remove a currently regulated source of information and replace it with millions and millions of \*unregulated\* sources. Some have good quality content but many are marginal – and some are outright dangerous.*

*To bring it to life – consider that Cialis alone produces 6 million Google results – only one of which is currently scrutinized by the FDA. Remove that one, and you'd still have 5,999,999 sources! Likewise for any major drug on the market (Gardner, 02 November 2005).*

A ban on DTC advertising does not necessarily mean that branded communication with consumers would completely go away. Consumers are used to being able to direct their own healthcare choices, and it's unlikely that they will simply "go back" to waiting for their physician or healthcare provider to ask them questions and recommend a solution. Consumers will continue to talk to friends and family members to seek information, read publications that feature health and wellness information, and seek information online.

Branded websites will likely still need to exist, even at product launch, to provide critical information to potential patients and to patients already on therapy. Although online media to promote the product would not be allowed to drive consumers to the branded websites, natural search engine optimization would continue to allow consumers seeking both condition and treatment information to 'find' the websites. Under this scenario, it will become increasingly important for websites to have a depth of condition information to be well optimized for online search. In the most restrictive scenario, branded websites could be password protected so that only patients who have received a prescription could access the content. As Mr. Gardner points out, this would mean that the only FDA-regulated source of information for consumers would be heavily restricted, a highly unlikely possibility.

Non-branded sites, once very popular but now much less so, could see a resurgence in usage and value to both the brands and consumers should the FDA ban DTC advertising. One possibility is that non-branded sites could be used to allow consumers to opt in for branded information. Consumers, lacking access to any other branded communication, could be more likely to opt in. For some categories that have a 'watch and wait' phase before a prescription is written – like diabetes, high cholesterol, and arthritis – pharmaceutical marketers might consider pre-RX support programs that would provide patients and consumers (prospective patients) with condition information and non-specific treatment alternatives so that they could begin an early dialogue. If patients subsequently are not able to control their condition through alternatives (diet, exercise, OTC alternatives) and opt in for branded communication, direct mail or online communications could be an effective conversion tool. Pre-RX support programs that allow opt-ins for branded communications would also be a viable way to develop patient databases for categories where DTC advertising is allowed only after some specific period of time following initial drug approval.

A ban on DTC advertising would bring a whole new meaning to, and opportunities for, permission-based marketing. Pharmaceutical marketers might consider creating broad health portals where consumers could sign up for a variety of health information. Consumers interested in receiving information about when new medicines or treatments are made available could specifically request this information through a portal. Although most pharmaceutical companies might initially try to create their own proprietary databases, a national program to allow consumers to essentially opt in to DTC advertising across the industry is likely to be more effective and economical (think of this as a national "DO contact" list).

Finally, should the FDA ban DTC marketing, integrated communication to and through healthcare professionals will become even more critical. Patient support programs, already a key factor physicians consider when deciding what to prescribe, especially in conditions where adherence is a challenge, will be a key mechanism to reach consumers at the point of Rx, and drive them into opted in programs for further consideration.

### Conclusion

Although it remains unclear what changes will occur in DTC advertising, it makes sense for pharmaceutical marketers to conduct scenario planning to determine how the various changes could impact their brand specifically. Depending on the condition, stage of life cycle, and current marketing mix, pharmaceutical marketers should conduct marketing planning exercises that take into account some of the alternatives presented in this document.

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