Feature Article

The Changing Policy Landscape

Prepare Now for Coming FDA and Pharmaceutical Marketing Reforms

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Prior to the 2008 presidential election, Dan Jaffe, Executive VP of Governmental Relations at the Association of National Advertisers, quipped that the drug industry and its advertising partners were facing a new disease: EAD or Election Anxiety Disorder. He made these comments at the DTC in the Era of Consumer Choice Conference.

Also speaking at that conference was Mark S. Senak, J.D., SVP, Fleishman-Hillard Washington D.C. and author of Eye On FDA Blog (see: http://www.linkedin.com/in/mssen).

Mark Senak, JD

Senak calmed the audience by saying "what happens in the Presidential election on Tuesday is of very little consequence to the drug industry—it is the Congress that counts." He also said that pharmaceutical marketing will not be recognizable three years from now because of the new regulatory environment likely to be ushered in by this election.

Senak made this argument: due to the leadership void and low employee morale at the overwhelmed FDA, Congress feels the need to step in and "micromanage" the agency (eg, see "FDA Paralyzed: Who Will Protect Us?": http://tinyurl.com/6qjnqb).

The FDA void, according to Senak, is part of the "virtual shutdown of the domestic government" wrought by the Bush administration. Members of Congress—on both sides of the aisle—are "extremely anxious" about the "dramatic drop off of enforcement of domestic laws," said Senak.

This article is a summary of Senak’s presentation made at the DTC meeting and later expanded upon and available on YouTube (see http://www.youtube.com/user/eyeonfda).

Changing Policy Landscape
“The two traditional means by which pharmaceutical marketers have relied on for many, many years to encourage the uptake of new pharmaceutical products—direct-to-consumer advertising and physician marketing—are about to change,” Senak warned.

To anticipate what changes to expect from the new 111th Congress, Senak began by looking at what the 110th was up to.

That’s exactly what Henry Waxman, the California Democrat who will soon head the House Energy & Commerce Committee, suggested to attendees of a conference sponsored by The Prescription Project, a group critical of industry marketing.

“I’ve been amused of late,” said Waxman, “when a lot of people started to speculate about how I would be in legislating. I think if people want to know how I’m going to act as Chairman, they should look back to what I did back then as Chair of the Health & Environment subcommittee” (see “Rep.Waxman addresses Prescription Project conference”: http://tinyurl.com/5p2yo6).

Looking back himself, Senak listed the investigations, letters, press releases that the Committee on Energy and Commerce generated in the single month of October, 2008:

- GAO Report Finds FDA’s Foreign Drug Inspection Program Needs Significant Improvement
- Dingell, Stupak Request Interview with von Eschenbach on Bisphenol A
- Dingell, Stupak on FDA’s Warning Letter on Bayer Aspirin with Heart Advantage
- Dingell, Stupak Continue Investigation into FDA’s Questionable Handling of Bisphenol A
- Dingell, Stupak Continue DTC Ad Investigation
- Dingell, Stupak Question Whether FDA Knowingly Allowed Dangerous Drugs to be Sold to U.S. Consumers
- Dingell, Stupak Question FDA’s No-Bid Contract with a PR Firm
- Dingell, Stupak to Investigate Melamine Contamination in Chinese Milk Products

Aside from this activity, the 110th Congress also brought forth several pieces of legislation aimed at the pharmaceutical industry. “Some of the proposed legislation of the 110th Congress is probably going to come back in the 111th Congress with a great deal more potency,” predicted Senak.

Changes Ahead for DTC Marketing
“Although certain pharmaceutical companies have announced a voluntary 6-month moratorium on DTC advertising for newly-approved drugs, I think that is not enough for many members of Congress,” said Senak. Indeed, Waxman supported efforts in 2007 to allow the FDA to ban television...
ads for new drugs for up to three years, if it was necessary to protect the public health. "That concept makes a great deal of sense and can provide FDA an important tool to protect the public health," Waxman said.

Meanwhile, on December 10, 2008, the Pharmaceutical Research and Manufacturers of America (PhRMA) revealed revisions to its Guiding Principles on Direct to Consumer Advertisements (see PhRMA PR: http://tinyurl.com/69yfnp). The revisions highlighted by PhRMA include:

- Actors portraying health-care professionals should be identified as actors. If actual health-care professionals are used and compensated, the ad should say they were compensated;
- Ads featuring a celebrity endorser should accurately reflect the opinions, findings, beliefs or experience of the endorser;
- Ads should include the FDA’s MedWatch number;
- Companies should consider setting specific periods of time for education for health professionals before launching a branded DTC campaign;
- Ads with adult-oriented content should be placed where it is expected to draw an audience of approximately 90 percent adults;
- Ads should include strengthened risk-benefit balance.

No mention was made of a DTC advertising moratorium of any length. This must have come as a surprise to many attendees of the DTC in the Era of Consumer Choice Conference who listened as Hugh O’Neil, VP and Head of Market Access at Sanofi-Aventis, stated that PhRMA’s members are likely to agree on a DTC advertising moratorium for newly approved drugs (see "An Experiment: Ban All DTC Broadcast Advertising for One Year"; see http://tinyurl.com/65empr). O’Neil said there was a debate about the exact length of the moratorium—whether it should be 6 months, one year, or longer. Most experts in attendance expected PhRMA to recommend a 1-year moratorium.

It is likely that PhRMA did not include any mention of a moratorium because it did not want to open a crack into which Henry Waxman could insert a crowbar. Better to wait and see what Congress proposed.

**Adverse Event Reporting Info in TV Ads**

“Americans must face an inconvenient truth about drug safety,” said Waxman who acknowledged the

FDA let drugs on the market whose full safety profiles aren’t known.

Senak said to look for requirements for companies to be more proactive than reactive in finding adverse events. He cited as an example running toll-free telephone numbers in advertisements to provide consumers with a means to report an adverse event with the drug. Congress required the MedWatch adverse event reporting information (ie, toll-free phone number) in all print drug ads when it approved a major overhaul of drug safety laws last fall. This does not apply to broadcast TV ads and the PhRMA Code states:

“DTC print advertisements for prescription medicines should include FDA’s toll-free MedWatch telephone number and website for reporting potential adverse events. DTC television advertisements for prescription medicines should direct patients to a print advertisement containing FDA’s toll-free MedWatch telephone number and website, and/or should provide the company’s toll-free telephone number.”

In other words, a “two-click” rule applies to TV requiring that viewers first find the relevant print ad to get to the phone number. Consumers Union (CU)—the nonprofit publisher of Consumer Reports—petitioned the FDA asking that a toll-free number and website be included in all TV drug ads so people can easily report their serious side effects to the agency (see “TV Prescription Drug Ads Should Include How to Report Serious Side Effects to FDA”; http://tinyurl.com/627v7g).

In a consumer poll, CU found that a strong majority of consumers favored requiring the inclusion of FDA’s Web site and toll-free telephone number for reporting serious side effects in drug advertisements. Specifically:

- Magazines or newspapers: 90% agreed that print ads should be required to list the information, including 70% who strongly agreed.
- Television: 87% agreed that drug ads in TV broadcasts should be required to list the information, including 67% who strongly agreed.

**Physician Marketing**

In the new Congress, Senak predicted you’ll see a greater emphasis on transparency of relations between the pharmaceutical industry and physicians and medical societies. Back in September 2007, Senator Charles Grassley (R-IA), the ranking member of the Committee on Finance, and Senator Herb Kohl (D-WI), the Chair of the Special

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Committee on Aging, introduced the Physician Payment Sunshine Act, which includes a national registry of payments made by pharma companies to physicians for speaking and consulting services. Several pharmaceutical companies recently announced plans to publicly disclose certain payments to physicians (see http://tinyurl.com/5sx5ds).

Senak warned that Congress has an “unanswered hunger” for greater sanctions imposed for off-label promotion and he suggested that there will be proposals to regulate or eliminate industry-sponsored CME.

Waxman said at the Prescription Project Conference that Congress needs to address physician marketing, because the “most persuasive, effective advertising” really goes on in the doctor’s office. According to the Project’s blog post, Waxman “discussed industry’s attempts to conduct off-label marketing, cherry-picked industry information, and his support of Kohl’s academic detailing initiative, the Independent Drug Education and Outreach Act.”

Drug Safety
“We’ve seen a great deal of legislative interest in drug safety,” said Senak. “and we are likely to see more of it—certainly by providing the FDA with greater oversight teeth” in the following areas:

- Post-marketing commitments
- Timely publication trials
- Clinical study publication
- Public access to trials
- Foreign manufacturer inspections
- Split up the approval office and safety office and recommend that the safety office hold greater sway.

Pricing Pressure
“There is no question,” said Senak, “that Medicare Part D reform to allow price negotiations on behalf of the government” will be pursued by Congress. Other areas of legislation affecting pricing include:

- Importation
- Generic promotion, including a pathway for biosimilars regulatory authority
- Costs of marketing as premise for marketing reforms

“Congress is quite pregnant with the idea of reform and much more unfettered than in the past to see those reforms co me to fruition,” said Senak. “Many changes that have been proposed directly impact pharmaceutical marketing. The traditional means of reaching out to physicians AND consumers is very likely to change in the near future. In particular, DTC advertising will change greatly with mor atoria lasting two to three years after launch—a critical period in the lifecycle of drugs. This will have a direct impact on the uptake of new products.”

Changing Communications Landscape
As outlined above, policy changes are probably going to increasingly restrict traditional means of pharmaceutical company outreach to key targets (ie, physicians and patients). Meanwhile, communications is moving from broadcasting to niche-casting where people are seeking information of their own choosing, not what is chosen for them.

“Direct to consumer advertising in its traditional form is becoming less relevant due to a number of factors, including technological changes and changes in the media viewing patterns of the target population,” said Senak. As evidence, Senak presented a chart from comScore US MediaMetrix showing that online news circulation greatly surpasses print news circulation (see Figure 1, pg. 5).

Senak characterized this as a flow away from “broadcasting” towards “niche-casting” where consumers are getting their information from trusted sources in the blogosphere, twitter, and other social network sites. These sources speak specifically to niche interests and not broadly to the least common denominator. Journalists themselves are increasingly participating in the blogosphere. Even the New York Times, Washington Post, and BBC “twitter!” “All the social media have been recognized as news outlets by the major news organizations,” said Senak.

Mainstream Media Moving into Digital
- Journalists increasingly active participants in blogosphere
- 70% read blogs on a regular basis
- 75% use blogs for story ideas, angles, insight and tone
- 1 in 4 have their own blogs

Not only are consumers and journalists migrating online, healthcare professionals are fully digital. Ninety-three percent (93%) of Healthcare professionals are online every day and 54% claim that the “Internet has increased adoption of recommended practice.”

Physicians are also participating in online communities such as Sermo, which has a user base of...
nearly 100,000 physicians. On Sermo, physicians are not only communicating with each other, but are also communicating with pharmaceutical companies—through MSLs and other physician employees—and outside investors about brands.

There have been other forays by pharmaceutical companies into social media—YouTube channels, Facebook Affinity pages, and blogs—with varying degrees of commitment, noted Senak. Johnson & Johnson has been especially aggressive in this area, employing a very integrated strategy. Some of the ground-breaking blogs established by pharmaceutical companies, however, have been dormant for quite some time; e.g., GSK’s alliconnect (see “Has the alliconnect Blog Been Abandoned?”: http://tinyurl.com/5f25c8) and Centocor’s CNT04111.

While digital is becoming the pre-eminent source of news and information, it’s a well-known fact that the drug industry is far behind other industries in exploiting digital media where branding is substantially taking shape and reshaped.

**Suggestions for Action**

To prepare for policy changes, Senak suggested that pharmaceutical companies “have their ducks in a row” by staking out a position and creating messaging to answer the following questions.

- What’s your track record on post marketing commitments?
- What is your policy on the future of sponsored CME programs?
- Why don’t you publish your clinical trials?
- Why don’t you reveal your payments to doctors?

Senak focused mostly on creating a digital communications strategy. His first piece of advice is to develop an integrated approach. “Digital media is constantly spawning new ways to communicate,” Senak said. The evolution of digital media is very rapid and the uptake by stakeholders—patients and physicians—is “breathtaking.”

**Overcoming Regulatory Roadblocks**

“I understand that there’s a great deal of digital media conservatism among pharma legal/regulatory folk,” admitted Senak. “These traditional concerns will crumble in the face of coming reforms that demand new approaches. Besides, there are a number of things pharma marketers can do online that are no risk whatsoever.”

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Senak offered RSS news feeds for corporate communications and Youtube for patient education as examples.

Senak reiterated that the FDA’s position that it does not regulate e-media per se. The regulatory parameters for the pharmaceutical industry generally apply to any type of media in which communications occurs whether it’s television, radio, print, or social media. “There is potential for future FDA regulations or guidance for Internet communications,” said Senak. The one variable that always needs to be considered is the regulatory culture of the company (see “Pharma’s Social Media Marketing Readiness Score,” PMN-Reprint #73-05; http://tinyurl.com/5ulryr).

Recently, however, the FDA issued a little-noticed warning letter that applies specifically to Internet display ads (see “Death of the One-Click ‘Rule’ or ‘Received Precedent’ or Whatever!”: http://tinyurl.com/6j8s3n).

Overcome the Fear of Adverse Event Reporting

When asked why they do not engage their audience via social media, most pharmaceutical marketers mention the burden of reporting adverse events they may learn about from user-generated comments.

“I believe that there will be pressure on pharmaceutical companies to be more aggressive or proactive about the discovery of adverse events,” said Senak. “However, whether monitoring blogs or comments to the editor of newspapers, the same adverse event reporting rules apply. By not monitoring the media where consumers are migrating is simply pennywise and pound foolish,” said Senak.

In conclusion, Senak said that the drug industry needs to develop an integrated, strategic and proactive approach to use digital tools to not only build brands but to meet the coming policy challenges, which will limit the current avenues available to the industry for marketing and developing relationships with health professionals and consumers.