Feature Article

Congress vs. Pharma: Trouble Ahead?

By **John Mack**

Now that the elections are over, the pharmaceutical industry is left to ponder what the new Congress has in store for it. There has already been a lot of speculation in the general press and trade media as well as a few shots fired across the bow by Congress.

It's not just democrats itching to get at Pharma. For example, the Senate Committee on Health, Education, Labor, and Pensions (HELP) chaired by Sen. Michael B. Enzi (R-Wyoming), met in full session on November 16, 2006 to discuss revamping the FDA ("Hearing on Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation") and Senator Charles Grassley (R-Iowa) put a hold on the nomination of Dr. Andrew C. von Eschenbach for commissioner of the FDA.

The following is a synopsis of the issues and changes experts have predicted that the drug industry will be subjected to in the next legislative session:

Drug Price Related

- Change Medicare to specifically allow the government to directly negotiate prices with pharmaceutical companies
- Allow drug importation from Canada
- Patent Reform; ie, set limits on whether big pharmaceutical firms can make deals with generic drug makers

Marketing Related

- Enact a mandatory 6-month, one- or two-year moratorium on ads for new drugs
- Require FDA pre-clearance of all DTC ads
- Wipe out or limiting tax deductions for advertising expense
- Require a "black triangle" in ads and labels for new drugs
- Set standards for risk presentation that make broadcast ads infeasible

FDA/Drug Approval/Safety Related

- Hold up of Prescription Drug User Fee Act (PDUFA) reauthorization
- Make FDA more powerful; eg, create office of drug safety within FDA, give the FDA the power to fine companies to force them to do safety studies or change the labels of drugs (Grassley-Dodd and Enzi-Kennedy bills)

To explore these issues further and to get a better idea what actions Congress may take that may affect the industry, Pharma Marketing Network hosted an online survey and a follow-up podcast Roundtable discussion. This article summarizes what was learned from the experts who participated.

Survey Results

The "What's In Store From Congress" online survey posed the following question:

Regardless of how you feel personally about whether or not such legislation should be passed, please indicate how likely or unlikely you believe Congress will enact legislation to require or allow the following:

- Some form of a mandatory moratorium on DTC ads for new drugs
- FDA pre-clearance of all DTC ads
- Wipe out or limit tax deductions for drug advertising expenses
- A "black triangle" in ads and labels for new drugs
- Make FDA more powerful with regard to drug safety and approval (eg, create office of drug safety within FDA, give the FDA the power to fine companies to force them to do safety studies, etc.)
- As part of Medicare Part D reform, allow the federal government to directly negotiate prices with pharmaceutical companies
- Rx drug re-importation from Canada
- Through patent reform, set limits on whether big pharmaceutical firms can make deals with generic drug makers

The results are summarized in the figure on the next page.

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Podcast Discussion
The following discussion is an excerpt from the Pharma Marketing Talk Show podcast, which was broadcast live on November 28, 2006. You can download the entire audio archive at http://www.pharma-mkting.com/talk/show003.htm

Guests included:

- **Jack Barrette**, Category Development Officer, Yahoo!
- **Walter Bartus**, Sr. Program manager, Xchange
- **Mario Cavallini**, Manager, Competitive Intelligence, Rossetta Marketing
- **Neil Gray**, Managing Director, Healthcare Trends & Strategies, LLC
- **Richard Meyer**, Senior eMarketing Manager, Medtronic-Diabetes
- **Harry Sweeney**, CEO/Chief Creative Officer, Dorland Global Health Communications

In preparation for this podcast, guests had access to several articles that laid out some of the changes that Congress might have in store for the pharmaceutical industry (download here). Some of the major battles are summarized in Table 1 on page 5.

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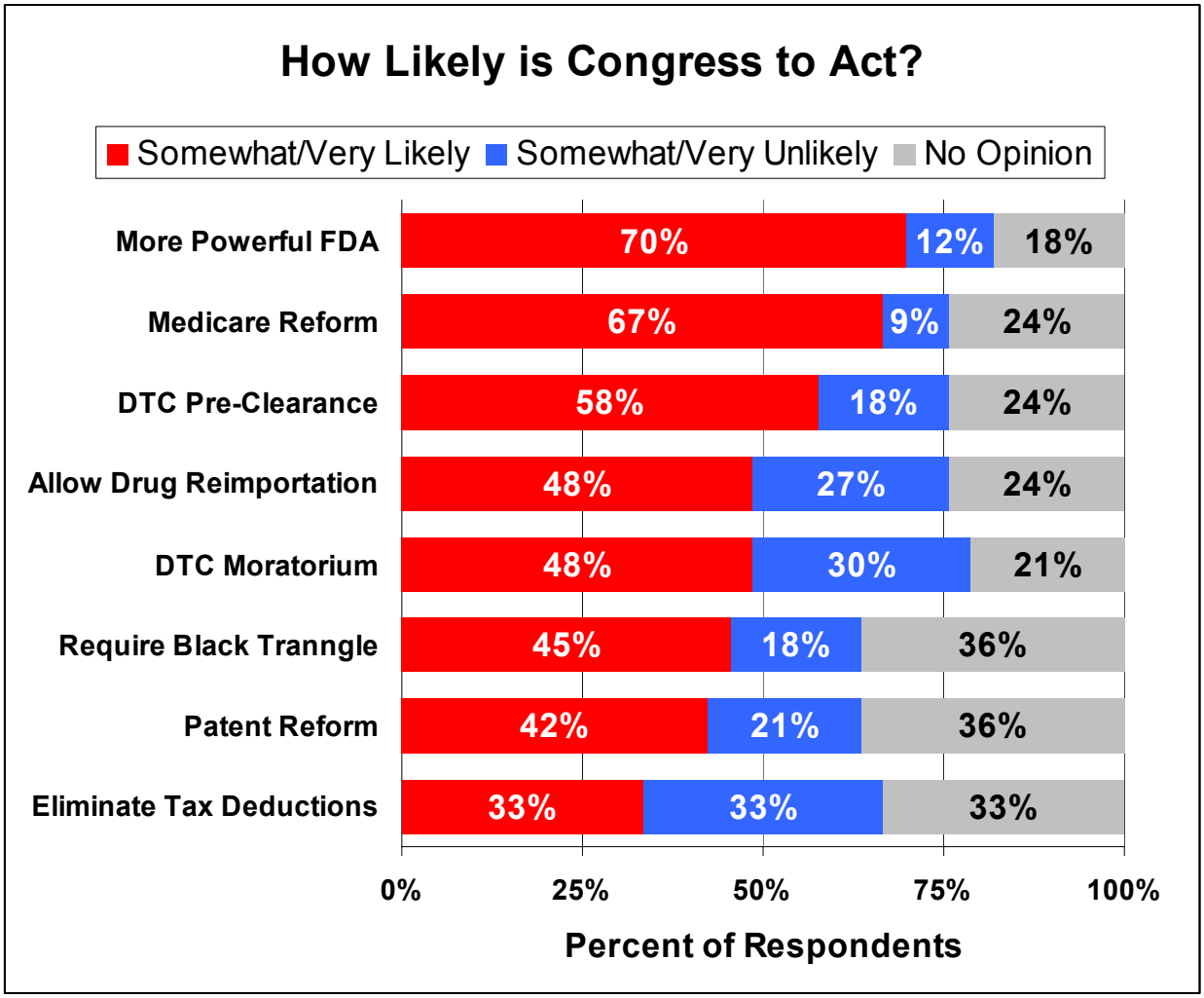

FIGURE 1: Results of the "What's In Store From Congress" online survey. Access the latest results online at http://www.surveymonkey.com/Report.asp?U=291261388846

Legislation	What it is	Impact
Medicare reform	Would remove a clause that prevents the U.S. government from negotiating directly with drug firms.	Could allow the government to force lower drug prices
Drug importation	A law allowing patients to get cheap drugs from Canada looks increasingly likely.	Probably minimal, but the industry would lose face.
Prescription Drug User Fee Act reauthorization	The law that lets the drug industry fund the FDA in return for faster drug approvals is up for review.	A delay could slow the FDA; drug safety laws could be attached to it.
Patent reform	Basic reforms might make it more difficult to file multiple patents on a drug.	Limits on whether big pharmaceutical firms can make deals with generic drug makers are possible.
Medicaid reform	The system purchases drugs for the poor. A 2005 law already sought to save money.	Many prescription drugs, like those for schizophrenia, actually have much of their market share here.
Drug safety	Two bipartisan bills aim to make the FDA more powerful.	Will likely force the drug industry to disclose more data and do more studies. Drugs may carry stronger warnings.

TABLE 1: Six Battles For Big Pharma. Source: Catherine Arnold, Credit Suisse First

Mack: Let's start our discussion with Medicare Part D reform, namely the promise that Democrats made to change the law to allow the federal government to directly negotiate prices with pharmaceutical companies. Anyone willing to comment on that?

Cavallini: I'm guessing that's not likely to happen. If it were to happen, there would be more connections between government and the pharmaceutical industry that would further magnify the issue of special interests influencing prices.

Mack: Some experts suggest that if the government were to negotiate lower prices for Medicare Part D beneficiaries, it would force pharmaceutical companies to raise prices for other purchasers.

Sweeney: History has shown that any time the government starts tinkering with prices, things go awry. Controlling drug prices is not going to fix the problem of rising healthcare costs. Drug costs are only a small fraction of the overall costs. If the objective is to save the most money, then we have to look at other parts of the healthcare system, like hospital costs, which account for over 30% of expenditures. But it is politically more correct to focus on the pharmaceutical industry, which has borne an undue level of criticism on this issue.

Mack: What about the effect on innovation? A study I've seen estimates that 100 or so less drugs per year would come to market if the government negotiated Medicare Part D prices and thereby limited pharma's profits.

Sweeney: If the private sector doesn't fund innovation, where's the money going to come from?

Meyer: You bring up some really good points. I don't think anybody believes that the government is the answer to the problems that plague the industry. People don't understand how costly it is to bring a drug to market. These costs are increasing and pharmaceutical companies have a responsibility to their shareholders.

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Medicare Reform May Hurt DTC?

"It is clear that the Medicare administration will have significant leverage with drug companies if that negotiating power is granted by Congress. Although they cannot, for first amendment reasons, prohibit DTC, they might informally give preference in negotiations to drugs that agree not to advertise. I expect most drug companies would gladly drop DTC if they get a higher price in return for a formulary preference." – Bob Ehrlich, Chairman, DTC Perspectives, Inc.

Mack: Speaking of bringing new drugs to market, what about bills in Congress that address the FDA to make it more powerful especially with regard to drug surveillance and safety issues. For example, establishing a separate drug safety office and giving the FDA the power to fine companies who do not comply with drug surveillance study requirements.

Barrette: We've seen some news about the FDA collecting fees for review of DTC advertising (see, for example, "Pay Per DTC Ad View Update"). A large portion of this money would go to collecting more drug safety information after launch. With more funding for these kinds of activities by pharmaceutical companies, there will be an increased perception that the FDA is a "client" of the industry. Is the FDA the right horse for politicians to bet on or will people look to an outside entity to monitor drug safety, which could be very dangerous?

Meyer: Would another layer of government bureaucracy really help?

Gray: We are definitely going to see the FDA strengthened greatly maybe not over the two years, but definitely after the next presidential election. There's also going to be a lot more push from the government to "encourage" the industry to get its clinical trials act together, to be more efficient and more effective. Obviously, this will help lower drug prices.

Sweeney: What level of safety are we talking about? What level of risk is the public willing to accept? Have we seen any studies or discussion on this? Even in the Vioxx case, you are talking about a fraction of one percent in terms of adverse events. In biological systems, we cannot achieve a level of zero risk. What level of risk we can accept has not even begun to come into the conversation.

Cavallini: Actually, the bill that Senators Kennedy and Enzi put up after the IOM report includes a sort of "Risk Map lite" provision for newly approved drugs (see Box below). Under this provision, each new drug must include a risk plan.

Direct-to-Consumer Advertising

Mack: Let's move on to some other issues, such as a moratorium on DTC advertising for new drugs. We've seen some pharmaceutical companies implement a voluntary moratorium of 6 months to one year. What about making this mandatory? Will that be written into law?

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S.3807: Enhancing Drug Safety and Innovation Act of 2006 Risk and Mitigation Strategy

Under the Enhancing Drug Safety and Innovation Act, FDA would begin to approve drugs and biologics, and new indications for these products with risk evaluation and mitigation strategies (REMS). The REMS is designed to be an integrated, flexible mechanism to acquire and adapt to new safety information about a drug. Sponsors would propose a REMS and FDA would approve it after structured discussions. The sponsor and FDA will assess and review the REMS at least annually for the first three years, as well as in applications for a new indication, when the sponsor suggests changes, or when FDA requests a review based on new safety information.

Every REMS would have the following elements:

- The drug's FDA-approved professional labeling;
- 15-day, quarterly, and annual reports of adverse events for the drug;
- A pharmacovigilance statement that explains and justifies whether standard adverse event reporting for the drug is adequate to assess known serious risks and to identify unexpected serious risks, or whether and what additional studies or clinical trials are needed;
- A timetable for periodic assessment of the REMS.

Cavallini: That's one of the few changes that might actually happen. Having the industry do something that won't cost them any money is going to be an easy call for politicians.

Barrette: I would agree. Everyone agrees that the idea has some merit. The industry itself cannot make guidelines stick unless it comes from an outside organization. Believe me, Yahoo! is in the business of helping pharmaceuticals companies do DTC, but it would help if the rules were clear instead of changing every time a company wants to do a press release.

Sweeney: I think it's a terrible idea to implement a fixed-term moratorium across the board for all new drugs. At the least, we should make a distinction between drugs that are truly life saving versus third or fourth drugs in a class that are not so critical from a public health perspective. Also, I can think of two cases where problems were identified with drugs because a critical mass of use was achieved in a very short period of time, which DTC advertising can only help bring about. If the promotional effort had not raised the level of use to the degree that it did, and the adoption curve dragged out for a long period, the side effects might never have been identified.

Mack: What about getting that same level of adoption through physician promotion?

Sweeney: These examples were a result of physician promotion. DTC would only increase the awareness faster.

Gray: What's the rationale for the moratorium?

Cavallini: The rationale for a moratorium publicly expressed by the industry was that the moratorium gave pharmaceutical companies more time to promote the drug to physicians so that the physicians are familiar with the drug before they start hearing about it from patients who saw it advertised on TV.

Barrette: I agree that that was the appropriate first reason for a moratorium, but there's no question that the safety issue is now inappropriately or inaccurately attached to this idea.

Cavallini: Another reason this is likely to happen is that it doesn't rely on the FDA, which as other people have mentioned, is not a high-valued stock right now.

Mandatory Pre-Clearance of DTC

Mack: Well, even so, there's the issue of mandatory pre-clearance of DTC ads by the FDA after the moratorium ends.

Gray: That may actually improve the quality of information flowing through DTC ads!

Mack: Are they talking about just broadcast and print DTC or are they also talking about online DTC?

Barrette: Depending on how you define it, only broadcast and print is DTC. Online advertising, although it may reach similar numbers of people as do broadcast and print, is not covered by separate guidelines. It has been a challenge for us not to have clearer guidelines for online DTC advertising.

Bartus: Typically, the FDA does not "approve" ads, but rather simply does not file an objection and allows them to go forward.

Mack: Last year AstraZeneca proposed pre-clearing all ads with the provision that the FDA cannot later request that "approved" ads be pulled. Any comment on that?

Sweeney: Based on past history, it is highly unlikely that the FDA would ever agree to concede their right to sanction an ad based on further consideration. By the way, although companies may agree to pre-clearance, it is a First Amendment violation. That hasn't been tested yet, but there are institutions that are interested in testing it in the courts.

Cavallini: There's another good reason why the FDA should not give away its power to sanction a pre-approved ad. When the FDA reviews ads they are looking at individual elements that are part of a general marketing plan. Recall the Dorothy Hamil Vioxx ads. You had two ads, a reminder ad that mentioned the brand but not the condition and another that talked about the condition and didn't mention the brand. They both used the same imagery, the same music, etc. Both were legitimate as separate ads, but when used together they were considered a branded ad that did not include fair balance as required by law.

Sweeney: That was obviously a gaming of the system. Most observers thought "What were they thinking?!"

Black Triangle Label for New Drugs

Mack: What about the use of a black triangle on labels of new drugs for a period after approval? It's something that's done in the UK, for example, to indicate that this new drug may have unknown side effects (see Box, next page).

Sweeney: In the abstract, it's probably a good idea, but FDA could require it for up to two years.

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Why these arbitrary dates? There's been almost no public conversation about this.

Bartus: Isn't the purpose of the black triangle to notify patients that they are "guinea pigs"?

Sweeney: That's certainly a viewpoint that's been expressed. Again, how far out do you want to test? What is the level of risk that we are willing to accept? That needs to be determined so that whatever restrictions are imposed, we know where the line has been drawn.

Black Triangle

"A black triangle appearing after the trade name of a British medicine (or vaccine) indicates that the medication is new to the market, or that an existing medicine (or vaccine) is being used for a new reason or by a new route of administration.

"The black triangle also highlights the need for surveillance of any Adverse Drug Reactions (ADRs) that might arise from the use of a new medication. The Medicines and Healthcare products Regulatory Agency (MHRA) encourage anyone to voluntarily report ADRs (however minor) via the Yellow Card Scheme to gather more information and gain more understanding of a new medication.

"After a new medicine (or vaccine) has been brought to the market there is still a lot that can be learnt about the drug from its widespread use. Similarly, if an existing drug us being used in a situation where it was not used before or if it is been given by a different route of administration a lot can still be learnt about its new or modified use.

"The black triangle label generally stays with the new drug (or new use of an existing drug) for at least 2 years, when it is reviewed, and after this time the black triangle label may or may not be discontinued." – wikipedia, http://en.wikipedia.org/wiki/Black_triangle_%28pharmacology%29

Mack: We may not have to agree what an acceptable risk is, but we need to know what the risks are and communicate that to consumers. The black triangle may be used until the drug company concludes its post-marketing safety studies.

Worst Case/Best Case Scenarios

Mack: We discussed a lot of things Congress may do that will impact the industry. Which is the worst thing it could do?

Cavallani: I think the worst thing that can happen is nothing! They may tweak around the edges, do a lot of finger pointing over the next two years, launch a number of investigations, and, in general, continue undermining of the FDA from within and without. On the other hand, the best thing that could happen would be a genuinely strong FDA.

Gray: A strong, effective, and responsible FDA would be a good outcome.

Meyer: With strong leadership!

Gray: I think that's a very under emphasized piece of the solution. The FDA really has not had consistent senior and middle management leadership for a decade. It really affects the industry quite significantly.

Barrette: The public trust in the FDA has to be restored. That comes from leadership as well as clarity for the industry so there is no question about where the lines are drawn for what's allowed and what's not.

Mack: It appears from this conversation that this is the most important issue and the others are more political issues tied to drug prices and the bad reputation of the industry.

Meyer: There's a lot of consumer anger out there that was revealed by the recent election. Until the pharmaceutical industry gets its act together and formulates a communications strategy to inform the American public about how much it costs to bring a drug to market, it will have to deal with this kind of scrutiny over and over again.

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