



Jim Davidson

A New Administration Will Have Many Options to Restrict Ads

Powerful House Chairman Promises More Work on DTC Advertising

By Jim Davidson

I am frequently asked, “What is going to happen next year?” And there generally is about as much apprehension in the questioner’s voice about a John McCain presidency as there is about Barack Obama occupying the White House.

Neither senator has the aversion to regulating businesses that initially was expressed by the Bush Administration. However, it should be noted that the current White House has issued more regulations than any of its predecessors. McCain has been chairman of the Senate Commerce Committee and has advocated government restrictions on another form of speech – political advertising. Sen. Obama has had a shorter time in the federal government, but supports the role of the FTC and FDA in their oversight of advertising. He voted last year to support the two-year moratorium and other advertising restrictions proposed by Sen. Edward Kennedy (D-Mass.).

In order to predict the future, we have to look to the immediate past. You know that once they regained the majority in Congress after a 12-year hiatus, Democrats quickly enacted legislation to overhaul the drug approval process at FDA. As most of you know, two congressional chairmen also proposed moratoriums on ads for new drugs, pre-clearance of the content of ads, and inclusion of wide ranging warnings in ads without identifying a specific side effect. These were defeated by members of Congress who argued that the First Amendment takes precedence and protects advertising from censorship and prior restraint by the government.

Asking for CEO’s to take the pledge

But the advocates for change have not given up. Recently, the House Committee on Energy and Commerce asked the chief executives of Merck, Johnson & Johnson, Pfizer, Schering-Plough and the Pharmaceutical Research and Manufacturers of America (PhRMA) if they would pledge to do many of the things that Congress last year rejected in legislation – most notably suspend advertising new products for up to two years. The letters and the company responses suggest Congress has not given up on efforts to rein in DTC ads, and a new administration might give them support for such restraints.

Letters from chairman John Dingell (D-Mich.) urged companies to follow guidelines developed by the Energy and Commerce Committee and not by FDA. There are six requirements the committee asked the companies to “voluntarily” accept:

- *The American Medical Association’s guidelines on the use of actors and health professionals in DTC ads.*
- *No DTC advertisements until completion of a “valid outcomes study” of a product.*
- *Two-year moratorium on DTC ads for new prescription drugs.*
- *No marketing off-label uses in DTC ads.*
- *Display FDA MedWatch telephone number in all DTC ads (2007 law required it for print ads and called for a study of its use in television ads).*
- *If FDA requires a “black box” warning in its labeling, add that warning to DTC ads.*

In their responses, all four companies opposed adoption of a two-year moratorium on advertising of new prescription drugs. Each said it waits an appropriate period – often six months – before advertising in order to educate doctors and pharmacists about new drugs.

Johnson & Johnson agreed to add the MedWatch number to its broadcast ads. Merck said it includes an 800 number to inform consumers where to obtain more information, and a second number could be confusing to the public. Merck said it relays caller inquiries to the FDA. Pfizer said it would defer to FDA on use of the MedWatch number.

The final question dealt with the inclusion of black box warnings for DTC advertising. All the companies stated they would continue to work with the FDA to comply with the current mandated requirements.

The four pharmaceutical companies agreed to voluntarily accept two of the six specific requests – to follow the AMA guidelines regarding the use of doctors and actors portraying doctors in DTC ads and not to advertise off-label uses in DTC ads.

Revising the Guiding Principles?

PhRMA took a different approach in responding to the committee’s letter. The association informed the committee that it was conducting an internal review of its Guiding Principles. PhRMA stated it would welcome the opportunity to have the committee provide feedback on any changes

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CARE Media Holdings Corp	23	caremediaholdings.com	813-888-7330	Elaine K. Mann	emann@kidcaretv.com
Catalina Health Resource	2	catalinahealthresource.com	800-803-9360		
DestinationRx, Inc.	19	drx.com	800-379-9060 x2590	Bob Ohr	bob.ohr@destinationrx.com
DTC INSIGHTS	50	dtcperspectives.com	973-377-2106	Jennifer Haug	jennifer@dtcperspectives.com
DTC Perspectives Fall Conference	46	dtcperspectives.com	973-377-2106	Christine Franklin	christine@dtcperspectives.com
Google	27	google.com	212-565-4875	Neha Parekh	nparekh@google.com
HealthiNation	11	healthination.com	212-633-0007	John Piccone	john@healthination.com
Healthmonitor	60	healthmonitornetwork.com	201-649-9918	Alex Dong	alex@healthmonitor.com
ICOM	33	i-com.com	800-603-4555 x2495	Denise Indovina	dindovina@i-com.com
InfoMedics, Inc.	9	infomedics.com	888-225-4852		
Lippincott Williams & Wilkins	5, 39	lww.com/advertising	215-521-8443	Dana Butler	dana.butler@wolterskluwer.com
Medizine	13	medizine.com	212-695-2223	Suzanne Polizzi	suzanne@medizine.com
Parade	59	parade.com	212-450-7141	Connie Gallo	connie_gallo@parade.com
Real Age	17	realage.com	215-836-0397	Mike Wojcek	mwojcek@realage.com
Saatchi & Saatchi	41	saatchihealthcare.com	212-463-3519		
The Nielsen Company	49	nielsen.com	646-654-8691	Anne Saini	anne.saini@nielsen.com
Thomson Reuters	29	pdr.net	201-358-7136	Kim Marich	kim.marich@thomsonreuters.com
TNS Healthcare	35	tnsglobal.com	410-559-0291	Wes Michael	wes.michael@tns-global.com
Waterfront Media	7	everydayhealth.com			

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to those guidelines. PhRMA pointed out that its Guiding Principles had been updated in January of 2006.

Chairman Dingell said the committee was “pleased with PhRMA’s response, and we accept their invitation to discuss revisions to its DTC Guiding Principles.” He added, “Regardless, our investigation is not over, as more work clearly needs to be done on this issue.” Rep. Bart Stupak (D-Mich.), who chairs a key subcommittee under Energy and Commerce, was much less charitable – he said these companies “continued to ignore” the provisions the committee asked them to abide by – even though these supposedly are voluntary.

Update on the DeLauro-Emerson legislation

Rep. Rosa L. DeLauro (D-Conn.), chair of the Agriculture, Rural Development, Food and Drug Administration Appropriations Subcommittee, and Rep. Jo Ann Emerson (R-Mo.), a senior Republican member of the Appropriations Committee, introduced the Responsibility in Drug and Device Advertising Act of 2008 (H.R. 6151). The bill would require many of the same changes in direct-to-consumer advertising that The Advertising Coalition worked to defeat last year, including:

- A three-year moratorium on DTC ads with a possible waiver if the Secretary agrees that the product is of affirmative value to public health
- New FDA authority to require companies to distribute “corrective materials” if they violate the advertising moratorium
- Stronger civil penalties that apply to the first and subsequent violations of the advertising provisions or other requirements of the Act
- A requirement that ads display prominently information about the potential side effects of drugs and devices
- A federal public education campaign that describes the risks of certain drugs.

A McCain or an Obama Administration are not going to have to look very far if they want to add additional FDA advertising reforms on their legislative agendas. ■

Jim Davidson is an attorney and founder of the public policy firm, Davidson & Co. As of July 1, Davidson & Company has become part of the Washington-based firm Polsinelli Shalton Flanigan Suelthaus. Davidson can be reached by e-mail at jhd@davidsondc.com.