Feature Article

FDA's Good Reprint Practices Guidance

Pros and Cons of the Proposed Rules for Distribution of Off-Label Information

By **John Mack**

Medical journals may soon become the pharmaceutical industry's newest physician marketing partner. On Friday, February 15, 2008—on the eve of the three-day President's Day weekend—the FDA published its draft guidance on "Good Reprint Practices for the Distribution of Medical Journal Articles ... on Unapproved New Uses of Approved Drugs..."

A 2006 study published in the *Archives of Internal Medicine* estimated that 21 percent of all doctor-written prescriptions were for uses unapproved by the FDA.

FDA has traditionally interpreted the Federal Food, Drug, and Cosmetic Act to give it authority to consider a company's dissemination of reprints of articles about unapproved uses of the company's product as evidence that the company was engaged in illegal marketing.

The new rules FDA proposes would allow drug and device makers to provide doctors with copies of medical journal articles that discuss product uses that have not been vetted or approved by the FDA. The rules also say that drug companies do not have to promise to adequately test the unapproved use discussed in the article.

Under the proposed rules, the agency would let drug and device companies pass out articles to doctors if the articles were peer-reviewed and came from a journal with an expert editorial board. The article must be accompanied by a prominent warning that the use described is not approved or cleared by the FDA.

The agency also abandoned the requirement that drug and device makers must provide the studies to the FDA beforehand or promise to seek approval of the discussed use.

Waxman Wades In

This last relaxation of previous rules, according to many critics like Congressman Henry Waxman, Chairman of the House Committee on Oversight and Government Reform, "would carve a large loophole in the law and create a pathway by which drug and device manufacturers can promote unapproved (off-label) uses of their products without first obtaining FDA approval..." Waxman expressed this view in a letter to FDA commissioner Dr. Andrew C. von Eschenbach back in November, 2007 in response to receipt of an October 2007 internal FDA draft of the proposed new rules.

Under Section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA)—which expired in September 2006—drug companies could distribute journal articles discussing off-label uses of drugs only if they promised that they intended to do controlled studies on the off-label use and submit an application to the FDA for approval for that use.

Critics worry that without this promise, drug companies have no incentive to seek such approval for new uses of their drugs and they will just promote off-label by showering docs with reprints.

Continues on page 4...

Summary of FDA's Proposed "Good Reprint Practices"

Under the draft guidance, a drug company would be able to disseminate scientific articles on unapproved uses as long as they are:

1. Published in peer-reviewed journals, not including supplements or other publications paid for by the manufacturer;
2. Not false or misleading;
3. Not abridged or summarized by the manufacturer;
4. Accompanied by approved labeling for product, by a bibliography of previously published studies of the unapproved use, and if the article has been called into question by other articles, a representative article reaching different conclusions;
5. Distributed separately from promotional materials; and
6. Accompanied by a number of disclaimers and disclosures.

Waxman stated in his letter to FDA that the draft guidance would allow drug companies to sponsor drug trials that are "carefully constructed to deliver positive results and then use the results to influence prescribing patterns. This undercuts the prohibition on marketing of unapproved uses of drugs and devices and puts the public at risk for ineffective and dangerous uses of drugs."

Drug companies, for example, could sponsor small "investigator-initiated" trials on off-label uses and get these studies published in peer-reviewed journals so that they can distribute the reprints to physicians. Often such studies involve very small populations of special patients and do not meet the rigorous requirements FDA has for approving drugs for new uses.

These are just some of the issues raised by FDA's proposal that pundits and experts are debating on the Internet, in the press and in official comments submitted to the FDA. The remainder of this article summarizes some of these discussions and presents preliminary results of an online survey sponsored by *Pharma Marketing News*:

CLICK TO TAKE THE SURVEY NOW

After taking the survey, you will be able to view a de-identified summary of the results to date.

The Issues

The survey asks how strongly respondents agree or disagree with a number of statements that reflect the tenor of the debate. So let's look at these statements and see what survey respondents, pundits, and ex-FDA officials have to say about them

> **STATEMENT # 1**. Under NO circumstances should drug companies be permitted to hand out off-label information—including peer-reviewed journal articles—to physicians and other health care professionals.

The majority of survey respondents (60%) disagree (40% strongly disagree vs. 20% who somewhat disagree) with this statement whereas 35% strongly/somewhat agree (15%/20%) with it. About the same percentage (57%) of pharma company respondents—89% of whom are very/somewhat (33%/56%) supportive of the pharmaceutical industry—also disagree.

"Over the past year pharma has proved that it cannot police itself and has been clandestine about data and marketing," claims survey respondent **Rich Meyer**, Senior Interactive Manager at Medtronic Diabetes and blogger at World of DTC Marketing (see his PMN Forum Profile). "This is not a step in the right direction and opens the door to abuses."

An anonymous pharma company survey respondent who agreed somewhat with this statement had this to say: "Until companies, regardless of size or income, are forced to comply with regulations executives will continue to find any way possible to encourage off label use. The new guidance appears to almost give them carte blanche to promote off label without taking any risk. As it is many companies pressure employees to support off-label promotional activities; this pressure is not limited to sales & marketing or even medical affairs, it has also drifted into clinical development. The focus on big pharma has actually empowered and emboldened small bio/

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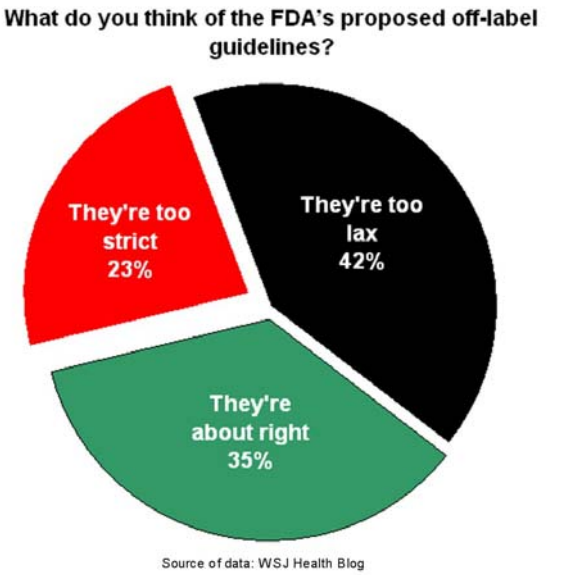

Figure 1: Results of a WSJ Health Blog poll of 231 readers.

pharma companies to set up practices that lend an appearance of compliance with no intent to comply. Execs at these companies are extremely sure neither they nor the company will be held accountable since they are acutely aware that, even if a qui tam suit is filed (getting an attorney willing to take a small case is hard), the DOJ/FDA are unlikely to be interested in the cases against 'small fish' and others that can fly below the radar."

In December 2007, the Coalition for Healthcare Communication (CHCC) supported FDA's proposal and said "Denying physicians easy access to peer reviewed information about off label usage, denies patients the likelihood of receiving the most effective therapy and goes against the sacred right of physicians and their patients to be the final arbiter of what is best for each patient."

[See "Waxman Media Blast & Letter to FDA Would Limit Medical Information, Undermine Peer Review Process"]

John Kamp, Executive Director of the CHCC, responded to the *Pharma Marketing News* Survey and left this comment: "The FDA proposal allows very limited distribution of peer review articles, and puts the FDA—rather than government investigators and others without a clear policy perspective—back in the role as the primary regulator of off-label communication. It's a careful step to put the health policy professionals back in primary policy position on these issues, and thus likely to be beneficial to the public health. Unfortunately, over the past decade these policy decisions have been made more by law enforcement personnel with little real understanding of the underlying policy consequences of their actions."

Dr. Scott Gottlieb, a practicing physician and resident fellow at the American Enterprise Institute, and previously deputy commissioner of the FDA from 2005 to 2007, wrote a *Wall Street Journal* OpEd piece in which he said "'Off label' are now dirty words in conventional lexicon, made synonymous with lawbreaking as a result of … prosecutions, even though these words describe the way more than half of cancer medicine is practiced. And the more serious the disorder," said Gottlieb, "often the more likely it is that for every right and wrong treatment choice there are many other practical decisions painted in shades of gray. Efforts to confine patients and doctors to FDA-approved uses have their own health consequences, raising the question: Just who is in the best position to make these hard choices?"

[See "Stop the War on Drugs"]

Role of American Enterprise Institute

Merrill Goozner, journalist and blogger, noted that the guidance was written by Randall Lutter, "who was at the American Enterprise Institute before taking over the agency's policy shop." Seems like the AEI has a swinging two-way door opening up to and from the FDA!

According to an entry in the wikipedia online encyclopedia, "The American Enterprise Institute for Public Policy Research (AEI) is a conservative think tank, founded in 1943. It is associated with neoconservative domestic and foreign policy views. According to the institute its mission is 'to defend the principles and improve the institutions of American freedom and democratic capitalism — limited government, private enterprise, individual liberty and responsibility, vigilant and effective defense and foreign policies, political accountability, and open debate."

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Summary of Section 401 of FDAMA

Under section 401 of FDAMA, Congress provided that company dissemination of off-label reprints would not be considered evidence of promotion of an off-label use if, among other things, the company submitted the reprints to FDA for review 60 days before dissemination and the company had submitted an application seeking approval of the new use to FDA. These conditions addressed the policy concerns underlying the prohibition against marketing of unapproved uses. Section 401 of FDAMA was enacted as a temporary provision, with a sunset date of 2006.

During the period between enactment in 1997 and2006, a number of abuses involving journal articles occurred, including the abuses involving anti-depressants, Vioxx, Celebrex, and Neurontin. There was no effort to renew section 401 when Congress passed the FDA Amendments Act of 2007. The result is that FDA's authority over dissemination of reprints reverts to its pre-FDAMA status.

Goozner asks what isn't in the FDA proposal: "It doesn't say that the studies of unapproved uses must be from randomized controlled clinical trials, which is the gold standard of medical research. All the proposed guidance says is that the studies should be 'adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training.'

"This is an open door for the drug industry to conduct more so-called seeding trials that encourage off-label uses. Because of their small size and lack of a control group, these trials are almost always of limited value in judging the true benefit of the drug in that off-label use.

"Unfortunately, there are lots of second-tier journals in every medical specialty that publish dozens of such trials every year. And they will be happier than ever to take them since, should this guidance get adopted, they are likely to see reprint requests from drug companies soar.

"As the nation grapples with how to pay for skyrocketing health care costs and policy wonks grapple with how to get more physicians to follow evidence-based medical practices, the Bush administration's FDA … has proposed opening the floodgates to wider promotion and use of unproven drugs."

[See "FDA Proposes Lack-of-Evidence-Based Medicine Policy"]

What I think: Pharmaceutical companies have been legally distributing off-label information to physicians via peer-to-peer, physician-to-physician discussions, especially when initiated by physicians rather than by drug reps. This has been done via Medical Science Liaisons (MSLs) and key opinion leaders at sponsored educational symposia (see, for example, "Give Docs What They Want").

It's not necessary for drug representatives to hand out off-label material when it is perfectly feasible to continue distribution via MSLs or via a secure online physician networks.

Sales reps clearly are trained and expected to promote the benefits of their products above all else and may be tempted to use the off-label reprints as part of their promotional sales pitch—in fact, they would be dumb NOT to do that! Overall, I would have to say that I disagree somewhat with this statement.

> **STATEMENT # 2.** As in the old rule, a drug company should be permitted to hand out such information IF the information is first reviewed by the FDA and the company declares that it intends to submit an application for FDA approval of the off-label use (ie, perform clinical trials).

Survey respondents were divided on this: 50% disagree (5% strongly disagree vs. 45% who somewhat disagree) and 50% agree (30% strongly/20% somewhat) whereas 57% of pharma respondents disagree with it (14% strongly vs. 43% somewhat).

Some critics have pointed out a long time ago that the FDA is too weak, underfunded, under staffed, or simply not inclined to properly review studies in off-label prints. Public Citizen's Health Research Group claims that as a result "Drug companies submitting selected off-label use information to a congressionally weakened FDA for review before being disseminated to health professionals will ensure that a drug's off-label benefits, if any, will be overstated and the risks of its off-label use dangerously minimized."

[See "Comments on Food and Drug Administration proposed regulation on dissemination of information on unapproved/new uses for marketed drugs, biologics and devices. (HRG Publication #1447)"]

That's what Public Citizen thought of the old law in 1998. It had this to say about FDA's current proposal: "Almost every week brings new evidence of the FDA's dangerous attitude about the public's health and demands a change in leadership at the agency, starting with the commissioner. Today's proposal, if finalized, constitutes a health threat because it encourages drug companies, who have no reason to fear FDA sanctions, to promote drugs for purposes not proven to be safe and effective."

"The 'new' regulations are not very different than the original regs for off-label promotion," says **Maltmann**, an anonymous member of the **Forums at Pharma Marketing Network** (see his profile here), "and I believe they will get the same amount of use—none or almost none. Aside from the CME method of disseminating off-label information that appears to be more arms-length than a sales representative delivering a reprint, the rules are cumbersome and still put the representative in an uncomfortable position.

"I don't believe most Pharma companies will take the risk of having a representative get involved in an off-label conversation after providing a reprint. I also don't believe the amount of pre-work necessary to get this information out is cost or time effective.

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"I, for one, would not want to be the first test-case of this type of promotion as the OIG may not see things the same way that FDA does."

What I think: The FDA cannot possibly track the promises pharmaceutical companies make and enforce these promises to do the research and submit applications for new approved uses. It's similar to the situation in which drug companies make promises about doing post-marketing surveillance trials in return for faster approval. About 65% of the time it just never happens and the FDA is virtually powerless to do anything about it (see "Spinning Bad News about FDA & Drug Safety"). So I would have to say that I strongly disagree with this statement.

> **STATEMENT # 3.** FDA is forced to relax the rules because not to do so is an infringement of commercial free-speech rights.

About 40% of survey respondents agree that this is the case whereas about 35% disagree (the remainder were undecided). A clear majority (57%) of pharma company respondents, however, disagreed and 43% agreed.

"Surprise warning letters can still come!," said **Robert Nauman**, Principal, BioPharma Advisors, and member of the Pharma Marketing Roundtable (see his PMN Forum Profile). "I think the whole thing on Free speech is spin, but when we did this practice 10-15 years ago, it helped further medical debate. The question really is who sparks the physician to medical debate and thoughts about innovative therapies? I welcome the reprints back."

"Courts have pressured the FDA to avoid restricting companies' free-speech rights," noted a December, 2007 article in the *Wall Street Journal* (see "FDA and Drug Marketing," December 1, 2007; Page A9). The article quoted **Daniel Troy**, a former FDA chief counsel who previously helped argue against the agency in a major suit over restrictions on off-label promotion: "Off-label prescribing is very often the standard of care," and companies should be able to give doctors "truthful, non-misleading information" about such uses, said Mr. Troy who now represents drug companies and others in private practice.

In a review of court decisions (the "WLF decision") written for the Healthcare Marketing & Communications Council, it was noted that "a United States district court declared several FDA Guidances covering the dissemination of off label information and the regulation of CME, as well as Section 401 of FDAMA and its implementing regulations, to be unconstitutional. In its decision, the Court in the WLF case found these FDA and Congressional efforts to be in violation of the First Amendment of the United States Constitution."

The court opinion stated that articles must come from "bona fide peer-reviewed journals", those that use "experts to objectively review and select, reject, or provide comments about proposed articles. Such experts must also be experts concerning the subject of the article and be independent from the journal."

[See "WLF Decision and Its Implications"]

Peer-Review

In his letter to von Eschenbach, Congressman Waxman stated "the draft guidance poses multiple risks. First, it appears to be based on the premise that peer-reviewed reports provide accurate, validated information and that even if individual articles are biased, the published literature as a whole can provide balance. Regrettably, recent experience shows that this is not always the case. There have been a number of high-profile instances in recent years where journal articles provided a distorted picture of a drug's safety or effectiveness. This has been in particular a problem in the case of journal articles based on studies funded by drug companies."

"Peer-review," notes the CHCC, "is a blinded process that works effectively to assure that articles that appear in medical journals meet a high standard for scientific merit, medical accuracy and fair balance. To suggest, as Congressman Waxman does, that health care practitioners and the public cannot rely on peer-reviewed journal articles as a reliable source of medical information flies in the face of decades-long practice. Like democracy, peer review is not perfect. But peer review is by far the best system available to vet new ideas in medical practice."

Waxman referenced a *PLoS Medicine* article written by **Richard Smith**, a former editor of BMJ, who claimed that the "bigger problem lies with the original studies, particularly the clinical trials, published by journals." As evidence, Smith cited "a systematic review of 30 studies comparing the outcomes of studies funded by the pharmaceutical industry with those of studies funded from other sources... Overall," said Smith, "studies funded by a company were four times more likely to have results favourable to the company than studies funded from other sources."

[See "Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies"]

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Examples of Methods for Pharmaceutical Companies to Get the Results They Want from Clinical Trials

- Conduct a trial of your drug against a treatment known to be inferior.
- Trial your drugs against too low a dose of a competitor drug.
- Conduct a trial of your drug against too high a dose of a competitor drug (making your drug seem less toxic).
- Conduct trials that are too small to show differences from competitor drugs.
- Use multiple endpoints in the trial and select for publication those that give favourable results.
- Do multicentre trials and select for publication results from centres that are favourable.
- Conduct subgroup analyses and select for publication those that are favourable.
- Present results that are most likely to impress—for example, reduction in relative rather than absolute risk.

Source: "Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies" (PLoS Medicine)

A recent study published in the *New England Journal of Medicine* purported to find a bias toward publication of positive antidepressant clinical trials. The abstract sated: "Among 74 FDA-registered studies, 31%, accounting for 3449 study participants, were not published. Whether and how the studies were published were associated with the study outcome. A total of 37 studies viewed by the FDA as having positive results were published; 1 study viewed as positive was not published. Studies viewed by the FDA as having negative or questionable results were, with 3 exceptions, either not published (22 studies) or published in a way that, in our opinion, conveyed a positive outcome (11 studies). According to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis showed that 51% were positive."

Recently the Blogosphere (eg, Pharmalot) was abuzz over a move by Pfizer to subpoena the *New England Journal of Medicine* in order to wade through confidential reviews of published studies of its Celebrex and Bextra painkillers.

Donald Kennedy, Editor-in-Chief of Science Magazine said in an editorial ("Confidential Review—Or Not?") that Pfizer's motion "is interesting in terms of its revelations about what Pfizer knows about the process of scientific publication and what it regards as the 'public interest.' For example," says Kennedy, "the motion states: 'The public has no interest in protecting the editorial process of a scientific journal…' Say what? Doesn't the public want access to credible biomedical science? If not, what was the open-access movement all about? Do medical advocacy groups really have no use for knowledge that might help their members?"

What I think: FDA doesn't think it can win in court or, at least, it has had a change of heart on this issue after Dr. von Eschenbach took over. A legal fog has been cast over limitations FDA previously placed on distribution of reprints by pharma companies. Clearly, FDA's new guidance is based on a court decision regarding a first-amendment case brought by the Washington Legal Foundation (see above). So I would have to say that I strongly agree that the FDA was forced to relax the rules because not to do so is an infringement of commercial free-speech rights, at least as far as recent court decisions are concerned.

> **STATEMENT # 4.** The new rule will stop pharmaceutical companies from underwriting expensive trials to confirm new drug uses.

Survey respondents were most adamant about disagreeing with this statement. Exactly 70% of all respondents (vs. 72% of pharma respondents) disagreed strongly (35%) or somewhat (35%) that the new rule will stop pharmaceutical companies from underwriting trials for new drug uses.

The off-label use of drugs to treat cancer has often been cited as a major benefit of allowing pharmaceutical companies to distribute information about these off-label uses. (There have been estimates that 62% of cancer patients use drugs off-label.) Gottlieb, for example, mentioned "cancer" 17 times in his OpEd piece.

"In presenting his argument," says **Ed Silverman** of the Pharmalot Blog, "[Gottlieb] cites a case two years ago in which Lilly pled guilty to a criminal indictment and paid $36 million in fines for promoting studies that its Evista cancer drug could prevent breast cancer in post-menopausal women. Back then, Evista was approved only for treating osteoporosis, not preventing cancer, he noted. But three months ago, the FDA approved the drug for use against breast cancer."

It appears, therefore, that the pharmaceutical has a long way to go to develop approved uses for its

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cancer-treating drugs and any disincentive to do the studies necessary may put cancer patients at further risk.

"There should be an immediate recognition that matchmaking between cancer and cancer treatment is one area in cancer research and treatment which is deserving of much greater attention and utilization," said **gpawelski**, an anonymous member of the Pharma Marketing Forums (see the discussion thread here)."There should be an inclusive effort to study and utilize technologies which are based on both the sub-cellular (molecular) level and at the cellular (cell function/cell culture) level. Because what may benefit one individual cancer patient may not benefit another."

What I think: Waxman said in his letter to von Eschenbach, "the draft guidance may create a disincentive for drug and device manufacturers to seek approval for unapproved uses." Overall, I would have to say that I disagree somewhat with this statement.

This argument would have more merit if sales of drugs depended solely upon promotion to physicians. Pharma companies also want to promote new uses for their products to consumers. They could do this—and DO do this—via PR, which places stories in the press about unapproved uses of drugs. But it's much more efficient and effective to use DTC advertising, which in no way allows for the promotion of off-label uses. Still, off-label use of drugs is a big source of income for the industry. Anything that would increase off-label use would be a windfall.

> **STATEMENT # 5.** Because the FDA is so slow in assessing drug and device benefits, it is imperative that drug companies be able to hand out medical journal articles so that doctors can learn immediately about life-saving uses.

About 55% of survey respondents agree that this is the case whereas about 40% disagree. Only 43% of pharma company respondents, however, agree strongly (14%) or somewhat (29%) with this statement and 43% disagree strongly.

> **STATEMENT # 6.** Doctors have many other sources of information about off-label use of drugs—the Internet and their own journal subscriptions, for example—and do not require that pharmaceutical companies provide this information to them.

Although STATEMENT #6 seems to be just another way of expressing STATEMENT #5, the survey responses were quite different.

About 45% of survey respondents agree with this statement whereas about 40% disagree. Surprisingly, a much larger percent (62%) of pharma company respondents also agree strongly or somewhat and none disagree with this statement.

Ken Johnson, senior vice president for the Pharmaceutical Research and Manufacturers of America, said that "journal articles can offer physicians valuable insight that helps them make informed decisions regarding appropriate medical treatments for their patients."

Nuno Camacho, who responded to the survey, said "[This statement] might be true but doctors are so busy that I guess it is really very helpful that pharma companies are allowed to discuss these issues with doctors."

What I think: If doctors want to learn immediately about life-saving uses of drugs, they should subscribe to and read the medical literature and take their continuing medical education more seriously. Also, pharma companies have other ways to get this information to docs—ie, by sponsoring continuing medical education! So, I would have to say that I strongly disagree with STATEMENT #5.

Physicians can easily learn about new drugs and off-label uses of old drugs from a myriad of sources—especially the Internet (see "The Professor's Straw Man Free Lunch for Physicians Argument"). Maybe they prefer the nice, glossy reprints given to them by sales reps as gifts. Anyway, I would have to say that I strongly agree with STATEMENT #6.

> **STATEMENT # 7.** Since the FDA admitted that it did not really enforce the old requirements, it is also not likely to enforce the NEW require-ments (ie, use of peer-reviewed articles only, warning label on articles). Consequently, this gives the drug industry virtual free reign to do off-label promotion.

The majority (55%) of survey respondents agree with this statement and 40% disagree. About the same percent (57%) of pharma company respondents also agree strongly or somewhat; the remainder (43%) disagree somewhat.

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What I think: According to a *NY Times* article, "An F.D.A. official said the agency did not really enforce those [old] requirements anyway." Logically, if that is true, then it is also true that the FDA would not enforce the new requirements, which would open up a lot of possibilities for the drug industry to abuse the privilege—especially, as I noted above, if sales reps are in charge of handing out reprints. So, I would have to say that I agree somewhat with this statement.

Perhaps **David Holdford**, an Associate Professor of Pharmacy at Virginia Commonwealth University and a member of the Forums at Pharma Marketing Network (see his PMN Forum Profile), summed up best what many people think:

"Philosophically, I am always in favor of the free flow of information to prescribers. I also believe that much off-label prescribing is valuable.

"However, checks and balances are needed on the dissemination of clinical studies. Currently, 21% to 60% of all drug use in the U.S. is off-label. Some of this use clearly is inappropriate and/or excessive—even with the current restrictions. So a change in the rules may be needed under the right circumstances.

"The changes suggested by the FDA do not appear to address three problems seen with off-label prescribing. One problem is that some journals do not have a rigorous review process and are simply arms of the pharmaceutical industrial complex. If articles from these journals are still allowed to serve as evidence for pre-scribing, evidence-based prescribing may not be very good. The second problem is that much of the evidence is funded by the pharmaceutical company. This ensures that most evidence is driven by the objectives of the Industry, not necessarily by social welfare. The third problem is that physicians are unable to effectively process all of the evidence out there. This makes them susceptible to helpful drug company assistance (a.k.a. promotion).

"If some less biased alternative information source were available, such as IOM's proposed National Clinical Effectiveness Program, the rule change might make sense. Therefore, any rule change should be linked to support for the IOM proposal."

What Do You Think?
CLICK TO TAKE THE SURVEY NOW

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Pharma Marketing News

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