

Healthcare Communication

September 18, 2002

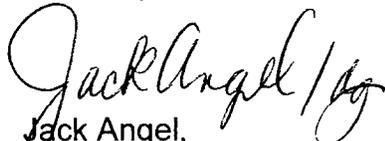
Document Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 67 Fed. Reg. 34942
Docket No. 02N-0209
REQUEST FOR COMMENT ON
FIRST AMENDMENT ISSUES

Dear Docket Manager:

In our haste to submit our Comment before the September 13th deadline, certain citation information and some last minute manuscript changes were inadvertently omitted that have been corrected in this draft. We respectfully request that this Manuscript, dated September 18, replace the original submission, forwarded to you on September 10, 2002.

Sincerely,


Jack Angel,
Executive Director, etc.

02N-0209

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To Whom It May Concern:

On behalf of the Coalition for Healthcare Communication (Coalition), the following comments are submitted in response to the request for comments that appeared in the above referenced Federal Register Notice (Notice) of May 16, 2002.

BACKGROUND

The Coalition is a not-for-profit organization representing eleven major communications organizations whose members are engaged in medical and healthcare communications including publishing, continuing medical education, and the dissemination of information on healthcare products and services. The Coalition's mission is to ensure that such communications are as robust and open as possible, so as to ensure that healthcare professionals and patients have open access to important health information.

As an active voice on various issues relating to the regulation of medical communications, the Coalition consistently seeks to achieve a common goal with the Food and Drug Administration, the medical community, policy makers, and the American public: to optimize the flow of medical and health information. To accomplish this goal, healthcare professionals need to have available current, important scientific information concerning disease, its diagnosis and its treatment so that they can make fully informed decisions concerning patient care.

It is in this context that the FDA's efforts to reexamine its regulation of medical and healthcare communications, as announced in the Notice, should be recognized as an extremely constructive and valuable regulatory initiative. Not only does the Notice provide an opportunity for FDA to receive comments from interested parties "to ensure that its regulations, guidances, policies and practices continue to comply with the governing First Amendment case law" and do not impose "unnecessary restrictions on

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speech,” but it also permits the reevaluation of whether current regulations unnecessarily obstruct the free flow of medical information thereby having a potentially adverse impact on the public health.

While some critics may attack FDA’s efforts to examine whether its regulatory actions are consistent with the First Amendment, to members of the Coalition and many others it is a long overdue recognition that even FDA regulation of advertising, promotional labeling and other forms of medical communications has its limitations.

While the Notice outlines nine questions relating to foods, dietary supplements and prescription drugs, the comments that follow are limited to address several key aspects of the Notice that are of particular interest and, in some cases, of deep concern to the Coalition and its members.

COMMENTS

Direct to Consumer Advertising **(Questions 1-2, 4-5, and 7-9)**

Direct-to-consumer advertising (DTCA) of prescription drugs has been a particularly contentious undertaking since its inception. The extensive set of questions on DTC advertising in the Notice is an indication of both the number and complexity of issues surrounding the topic. Of particular interest to FDA are the empirical effects of such advertising on patient compliance, physician visits, discovery of undiagnosed disease, prescribing habits, and the like.

Empirical research of DTCA is in its infancy. “Currently there are more opinions than facts in the scientific and lay literature,” writes one student of the subject.³² Yet, evidence is beginning to emerge on the important and positive impact of DTCA.

What is the effect of DTCA on the public health? This question, posed by FDA in its Request for Comments, stands at the heart of the debate over DTCA. In the policy arena and the public press, however, two distinct kinds of effects are inextricably linked – health effects and economic effects.

Health effects include the effects of DTCA on patients, on physicians and other healthcare providers, on the patient-physician relationship, and on specific health outcomes such as morbidity and mortality. Economic effects include costs for prescription drugs and costs for doctor visits, diagnostic tests, hospitalizations and other elements of the total costs of healthcare.

Economic Effects

While the Agency’s wide-ranging Request for Comments focuses appropriately on its mission to protect the public *health*, it would be naïve for the Coalition to ignore the unsubstantiated claims of critics who assert that not only does DTCA harm the

public health, but also that it has a negative impact on the public *pocketbook*, a paramount public policy issue today. Accordingly, our Comment on DTCA addresses both issues. First, we briefly consider the economic effects of DTCA – both fact and fiction.

DTC advertising has been under attack by health insurers, managed care organizations and some consumer groups and physicians as one of the driving forces for higher healthcare costs. Some critics have noisily asserted that the costs of advertising on television and radio result in consumers paying more for prescription drugs in the pharmacy and inflating the overall costs of health care.

To the credit of both institutions, so far neither the Congress nor FDA has overreacted to such arguments, although individual members of Congress have advanced a wide range of proposals – some, perhaps, unconstitutional -- to curb DTCA, largely based on economic arguments made during the prescription drug Medicare benefit debate. Perhaps because no credible data has been provided to support these claims, however, many policy makers have taken a more restrained approach. On the other hand, there is credible, new data suggesting some very positive economic effects from DTCA that will be discussed below.^{19-24,45}

Economic Effects of DTCA Assuming, as many DTCA opponents do, that there is a causal linkage between advertising and the increased use of prescription drugs,^{28, 30, 31, 39, 44} then critics should welcome new econometric studies that suggest that increased prescription drug use leads to cost reductions in other health services, a very positive effect from DTCA. In short, the critics have been wrong about DTCA leading to increased healthcare costs; it appears that DTCA actually helps lower them.

- 1) One set of reports suggests how DTCA helps *reduce* drug prices at the retail level.^{17,18} In a study of 13 different, “DTC advertised,” prescription drug categories reported in the *Journal of Public Policy and Marketing*, Kopp and Sheffet demonstrate that retail pharmacists behaved exactly as “dual-stage” economic theory predicted they would, reducing prices for prescription drugs that had been advertised directly to consumers.¹⁸
- 2) A series of extensive studies by Columbia University Graduate School of Business professor and economist, Frank R. Lichtenberg, indicates that increased use of prescription drugs leads to overall cost *savings* to the U.S. healthcare system.^{19,22} Contrary to the claims of some critics of the pharmaceutical industry, using health statistics from major U.S. government sources, Professor Lichtenberg’s model demonstrated for the first time that increased use of pharmaceutical medications actually reduces hospitalization costs (both number of patient visits and length of stay) and improves mortality statistics.²²
- 3) Even more surprisingly, later Lichtenberg studies suggest that the use of newer, branded prescription drugs – despite their higher costs – may

provide even greater savings than the use of older drugs.^{19,20} It is interesting to speculate that this might be the case not only because newer drugs may be more effective, but also because they tend to have fewer side effects requiring doctor visits or hospitalizations.

- 4) Furthermore, and again, contrary to the claims of some industry critics that DTCA would tend to defeat the efforts of managed care organizations to maintain cost-saving, prescription drug formularies,^{30,31} another new study from the University of California at Berkeley suggests that DTCA has *not* undermined such efforts.⁴⁵ A primary effect of DTCA, suggests Wosinska, is to expand the use of advertised drugs that already are on a managed care formulary.⁴⁵

Taken together, these studies are strongly supportive of the very positive effects that increased prescription drug use can have on the economics of U.S. health care. Coupled with evidence from the five-year, longitudinal surveys of *Prevention* magazine³⁷ the two comprehensive FDA surveys of 1999^{11,12} and 2002¹³, and other recent reports of the effectiveness of DTCA in promoting positive consumer and professional behaviors discussed below.

Health Effects

It is clear, as American Enterprise Institute resident scholar and author of *Fear of Persuasion: A New Perspective on Advertising and Regulation*, John E. Calfee, PhD, has noted, that in addition to the benefits of DTCA that might accrue to industry sponsors of DTCA, there are many public health effects of DTCA that “spill over” to the benefit of patients and consumers, generally, and not to the pharmaceutical industry.⁷

It has been claimed that DTCA would encourage patients to ask for drugs they do not need, putting undue pressure on physicians, resulting in overprescribing, and leading to a deterioration of patient-physician relations.²⁵ Results of several rigorously conducted surveys and studies during the past five years refute these largely unsupported claims and should begin to assuage any lingering concerns over potentially deleterious effects of DTCA.

Empirical studies of DTCA during the 1980s and early 1990s were based in large part upon hypothetical circumstances, relied on expert medical *opinions* and not actual *effects* on intended audiences – professional or consumer – and were subject to serious methodological flaws. In contrast, more recent evaluations have been carefully planned and executed, leading to more credible data to assist policy makers in their decision making. A review of this data leads to the following conclusions:

DTC advertising does not lead to over-prescribing. While empirical research on the effects of DTC advertising on pharmaceutical consumption is scarce, no evidence of over-prescribing as a result of DTCA has been established. One unpublished study examined DTC advertising for a single drug category, cholesterol-reducing statins (such as Pravachol, Lipitor, Zocor, and their market competitors). Using data compiled over five years (1995-2000), and analyzing numerous dependent variables and lagged

structures, Calfee, Winston, & Stempski (2001) could find no causal relationship between DTC advertising and either sales or prescriptions.⁶

Other studies have found such a relationship. While not, strictly speaking, an evaluation of prescription drug DTC advertising, in a 1996 report Basara, demonstrated that an “*informational DTCA campaign significantly and positively influenced the number of prescriptions for the implied product.*”⁵

Basara’s work is corroborated by a report from Zacary et al who examined five categories of drugs in a quasi-experimental, time-series study. “*The results of the study,*” Zacary et al reported, “*suggest that a relationship exists between direct-to-consumer advertising expenditure and prescribing for some conditions . . . but not all. These results are important because they suggest that this type of advertising is related to the provision of health care for people with certain diseases . . . and that direct-to-consumer advertising may not be a factor in the provision of care for every condition.* (Emphasis added.)⁴⁶

Two additional studies, one from the National Center for Health Statistics and Centers for Disease Control and Prevention (CDC) and one from the Blue Cross and Blue Shield-sponsored, National Institute for Health Care Management, each found a relationship between DTC-advertised drugs and increases in prescriptions and/or drug sales. Neither of these studies provided any evidence of “inappropriate” prescribing.^{8,30}

Appropriate prescribing by physicians, even when requested by patients, also is underscored by the results of the 5th consumer survey (2001/2002) conducted by *Prevention*, which found that among those who spoke with physicians about a drug as a result of a DTC ad, nearly three out of four patients did not request a prescription and, alternative, non-drug therapies were discussed about half the time.³⁴

DTC advertising does not impair the ability of physicians to give optimal medical advice or prescribe optimal treatment. Critics have hypothesized that DTCA would interfere with the physician-patient relationship, suggesting that DTCA might drive patients to make inappropriate demands, forcing harried doctors to waste valuable time in unproductive explanations, or feeling pressured to acquiesce to patients.²⁵ Evidence now is accumulating, however, which suggests that DTC ads do seem to make patient-physician interactions more productive.

For instance, the *Prevention* 2001 consumer survey found that 62% of the respondents felt that information in the DTC ads was sufficient to prepare them to discuss prescription drug risks with their doctor, and 68% felt that information in the ads was sufficient to prepare them to speak with a physician about drug benefits.³⁴

Furthermore, there is evidence that physicians generally do acknowledge the positive consumer educational benefits of DTC advertising. For instance, a survey of African-American physicians released in 2002 by the National Medical Association (the oldest and largest African-American medical association) found that a majority (55%) of the physicians surveyed felt that DTC ads were beneficial to their patients, more than twice as many as those who felt that the ads were not beneficial.⁴

DTC advertising does not damage patient-physician relationships. The results of FDA's own consumer surveys in 1999 and 2002 suggest that patients' relationships with their physicians are not harmed by visits prompted by DTC advertisements.^{12,13} In 1999, for instance, when patients were asked how they felt about their doctor's reaction to a discussion about an advertised prescription drug, 85% were satisfied or very satisfied; only 5% were unsatisfied and even fewer (2%) were very unsatisfied.¹⁰ Three years later, 20% of patients reported that their relationship with their physician had improved and 78% said it stayed the same; again, only 2% stated that they believed their relationship had worsened.¹³

These results compare quite favorably with the 2001/2002 *Prevention* survey in which 27% of patients reported an improvement in their relationship with their doctor, 71% remained the same, and only 1% reported a worsening.³⁴

DTC advertising appears to lead to an increase in patient compliance with medication regimens. DTC advertising seems to play a prominent role in increasing patient compliance with drug therapies. In 1998, 69% of patients in the *Prevention* survey reported that advertising would make no difference in taking their medicines more regularly, presumably because they believed that they already were compliant with their physicians' instructions; 27% said that the advertising made them more likely to comply.³⁶ By 2001, 81% of patients believed that they were doing the right thing (a 12-point improvement), while 17% said that advertising made their compliance more likely, versus only 2% of consumers who said that seeing such ads made them less likely to take their medicine regularly.³⁴ Similarly, while only 2% stated that seeing such ads make them less likely to refill their prescriptions, 12% said that the ads make them more likely to have their prescriptions refilled.³⁴

Data from a two-year, outcomes research study monitoring drug utilization rates for cardiovascular and estrogen medications by Prescription Drug Benefits Management company, Express Scripts, showed an improvement in "across the board compliance rates" from about 50% to about 80% for these chronic medications with heavy DTC advertising.¹⁵

An analysis of five medical conditions – arthritis, depression, nasal allergies, diabetes and high cholesterol – by Rx Remedy from a 25,000 patient, nationally representative database for Pfizer Laboratories, showed that patients who requested a specific drug as the result of a DTC ad were significantly more likely to stay on their medication than those who did not. Improvements ranged from 10% to 16% for diabetes and high cholesterol sufferers, to 37% for depressed patients, 75% for arthritis sufferers; patients with nasal allergies were more than twice as likely to stay on their medication.³³

Much of the specific data on prescription refills by brand is proprietary. Nevertheless, it is the belief of Coalition members that the “likely to refill” data from the well-constructed consumer surveys is strongly suggestive of a significant link to the now well-established increases in prescriptions and retail sales for certain DTC advertised drugs, which may be understood as better persistence and compliance by patients with their physician’s instructions.

DTC advertising promotes patient visits for undiagnosed and underdiagnosed diseases. According to the FDA 1999 consumer survey, 27% of the respondents who recalled seeing DTC ads stated that DTC ads had spurred them to discuss with their doctor a specific medical condition or illness for the first time.¹¹ This was verified to a lesser extent by the results of the FDA’s 2002 consumer survey, which found that 18% of those recalling DTC ads stated that the ads prompted them to speak with their physician about a condition/illness for the first time.¹³ Thus, the most recent FDA survey results suggest that roughly one sixth of the population surveyed had been influenced by a DTC ad to have a novel medical discussion with their provider.

Scott-Levin Associates reports that six of the top ten conditions with increased office visits in the first year after FDA relaxed its broadcast advertising policy were for DTC advertised products. DTCA “is not only raising consumer awareness of available treatment options, [but also is] driving patients to see their physicians to further discuss those options,” said a Scott-Levin executive, who added, “consumers also want more information about the drugs they are taking and other potential treatment options.”⁴²

In addition, a five-year trend of empirical evidence from Rodale, Inc., publishers of *Prevention*, now exists that suggests that DTC advertising may be helping consumers recognize and identify symptoms of medical conditions mentioned in such advertising with symptoms of their own, prompting them to discuss such conditions with their physician for the first time.³⁴⁻³⁸

“DTC advertising’s role in encouraging consumers to talk with their doctors about undiagnosed health problems could have a significant impact on public health,” writes *Prevention* magazine’s Corporate Director of Market Research, Ed Slaughter. Of the top 10 health conditions and illnesses studied in the most recent survey, in all but one condition, patients are undertreated or remain undiagnosed according to the

survey findings, including conditions requiring chemotherapy, and such chronic or recurrent conditions as osteoporosis, arthritis, diabetes, and depression.³⁴

One key finding of the *Prevention* 2001/2002 survey is that consumers who respond to DTC advertising are not overburdening the healthcare system. Seventy-five percent of these consumers wait until their next regularly scheduled doctor's appointment to talk about these health problems.³⁴

DTC advertising helps patients understand the potential risks associated with use of prescription drugs. Again, contrary to the hypotheses of its critics, DTC advertising does not seem to emphasize benefits at the expense of risk information. For instance, FDA's 2002 survey indicates that 90% of respondents, when asked what kinds of information they saw in DTC TV ads, stated "the benefits of the drug" while 90% also confirmed that they had seen "risks or side effects" information.¹³

The *Prevention* 2001/2002 survey reported that more than 60% of the respondents found that the risk and benefit information in DTC ads was sufficient to prepare them to further discuss the matter with their healthcare provider.³⁴ While concern still may exist about how much risk information is presented or how well it is communicated^{16, 26, 27, 40, 41}, findings from this year's *Prevention* survey suggest that the presence of risk information might play an important role in encouraging patient compliance – a major public health objective.³⁴

In summary, the Coalition agrees with the sentiments expressed by the National Health Council in its January 2002 statement in support of its extensive review of direct-to-consumer prescription drug advertising. DTCA, the Council says:

" . . . is an effective tool for educating consumers and patients about health conditions and possible treatments. . . . DTC advertising deserves continued, thoughtful study focused on how such advertising might be optimized."

*"DTC advertising encourages consumers to take action – visit their physician, seek information, and ask questions. It improves some patients' willingness and ability to follow through with their drug treatment regimens. And it can enhance communication or begin dialogue between patients and their health care professional. The preponderance of evidence indicates that most consumers and many physicians, as well as FDA, support DTC advertising as long as it complies with FDA regulations and guidelines and refers consumers to their physicians."*²⁹

“Off Label” Communications

With respect to “off label” communications, FDA’s position is well known. Regulated companies are not allowed to engage in “off label” speech about their products except in response to unsolicited questions or under very limited conditions.

FDA’s stated rationale for its position varies widely from 1) a concern for the public health to 2) an undermining of regulatory authority, to 3) a legalistic view that the law requires FDA to ban off-label speech. Until now, FDA has never, publicly, taken a step back and asked what limits the First Amendment places on its authority, and what makes practical sense.

Clearly there is some tension between the dissemination of information about unapproved uses and protection of the public health. Absolutely unregulated speech might lead to adverse public health consequences since information, once disseminated, can never completely be recalled, even if later found to be false. We would concede that the consequences of false information about pharmaceuticals could be much greater than the consequences of false information about a refrigerator or computer for example. However, the agency is unable to point to any cases of widespread harm due to “off label” communications supported by the regulated industry, and in the absence of an actual demonstration of such harm, the government’s interest in absolute suppression of such speech appears to be in violation of First Amendment rights.

There is much room for discussion of the differences between a policy that recognizes absolutely unfettered and unregulated speech and FDA’s existing policy, which substantially inhibits the discussion of truthful, but unapproved (“off-label”) information. It is the opinion of the Coalition that in matters of scientific and clinical speech there may be an appropriate line to be drawn; that line should, however, be closer to the border of “fully protected” speech than “completely regulated” speech.

The practical problem for policy makers is a legal paradox that enables physicians to prescribe any pharmaceutical medication for any condition, leaving “enforcement” of acceptable medical standards to the tort bar, but that requires manufacturers to refrain from communicating with physicians about unapproved uses or risk regulatory sanction from FDA.

In other words, by legislative or regulatory fiat, the scientific or clinical speech of investigators, whether academic, independent, or members of industry is, *de facto*, turned into “commercial” speech, simply because such speech is disseminated by industry. It is the belief of the members of our Coalition that this interpretation is in error, ignores First Amendment rights, and should be rectified by FDA.

The Supreme Court, in the Central Hudson case set out its test for determining whether regulation of commercial speech complies with the First Amendment.¹ Among those tests

was whether a regulation was reasonable under the circumstances, or whether a lesser degree of regulation would be sufficient to meet the government's legitimate interests. Put most appropriately by the Supreme Court in the recently decided *Western States* case "If the First Amendment means anything, it means that regulating speech must be a last – not first – resort."⁴³

Classification of Communications FDA is to be commended for finally ... some might say, at long last ... asking whether lesser degrees of regulation might work. In deciding whether a policy change is in order, it would be useful for the agency to begin considering the application of different standards to different types of information.

For example, prescription drug labels probably ought to be written much as they are now. Some additional flexibility ought to be permitted in advertising and promotion materials, perhaps involving application of FTC standards and due process procedures to advertising claims. And, some types of truthful material essentially ought to be beyond government regulation.

As to this last category, the agency might well consider the district court opinion in the Washington Legal Foundation (WLF) case as a good starting point.^{13,14} Certain kinds of truthful information, such as peer reviewed journal articles, continuing medical education, and medical textbooks, deserve the highest degree of protection under the First Amendment regardless of the source of their dissemination. And, it is difficult to think of any circumstances under which their dissemination should be prohibited. Suppression of such speech not only is forbidden under the U.S. Constitution, but also is bad policy. Congress and FDA should be seeking to foster discussion and dissemination of information about scientific and clinical developments, not suppressing or restricting it. In addition, FDA's apparent position that all scientific or educational activities funded by industry are necessarily "commercial" neglects important Supreme Court case law. The Supreme Court has repeatedly held that just because speech is made in a commercial context does not make that speech "commercial." Books and newspapers make money for their publishers and authors, but the speech contained in them is not therefore commercial. See, for example, *Smith v. California*, 361 U.S. 147, 150 (1959); *Ginzburg v. United States*, 383 U.S. 463, 474-75 (1966); *New York Times Co. v. Sullivan*, 376 U.S. 254, 265-66 (1964) (advertisements dealing with political and social matters which newspapers carry for a fee); *United States v. Paramount Pictures*, 334 U.S. 131, 166 (1948) (motion pictures which are exhibited for an admission fee).

Full Disclosure Policy As an alternative to prohibition of unapproved speech, as the Coalition has proposed to FDA in the past, the Agency might require a Full Disclosure policy where reasonable disclaimers would accompany the material. Such disclaimers would focus on disclosure that the materials may contain information on potential uses of prescription drugs that have not been approved by FDA, and identify a manufacturer's role in the dissemination of the information.

FDA also might enforce the law regarding false and misleading information more stringently, provided that the terms "false" and "misleading" are given their common

dictionary definitions and are not subject to Agency interpretation to mean simply “any information that FDA has not approved”. Such an alternative seems appropriate and is fully consistent with the Federal District Court’s opinion in *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D. DC. 1998) where the Court outlined these considerations as acceptable regulatory parameters, parameters that should meet the test of Western States as well.

As the Coalition has noted in its submission to FDA concerning the appropriateness of its proposed “Full Disclosure” policy: [November 8, 2001, Docket No. 01P – 0250, Citizen Petition Regarding Manufacturers Dissemination of Information Concerning Off-Label Uses of FDA-Approved Products at p 10]⁹:

“Equally important to its constitutional legitimacy, a Full Disclosure policy protects the interests of all concerned parties. First, the policy immediately notifies the reader of the source of the information being conveyed, putting the reader on notice to review the information with inherent skepticism based on his or her education, background and experience. The FDA’s enforcement powers are preserved if a manufacturer fails to disclose the nature of the information being communicated, since the FDA could then argue that the information is “inherently misleading.”⁹

And, as is recognized by the District Court in the WLF case, FDA still can move against a manufacturer if the information is, in fact, false or misleading. Nor would such an approach undermine the need to seek approval for additional claims, for as we said then:

“Manufacturers would also continue to have an incentive to seek supplemental labeling approval from FDA for “off label” uses, since that may pave the way for robust promotion of the product, facilitate reimbursement, and limit exposure to product liability claims. At the same time, a Full Disclosure policy would demonstrate FDA’s respect for drug manufacturers’ constitutional rights and the agency’s willingness to work with industry by entertaining less burdensome alternatives in its pursuit of promoting the public health and safety.”⁹

Interestingly, the above comments, provided to FDA a year before the Supreme Court’s decision in *Western States*, would seem to closely track the considerations noted in the Supreme Court’s decision. Furthermore, the Coalition’s previous comments also noted the benefits of such a policy both for physicians and for the public health:

“Moreover, physicians would benefit from a Full Disclosure policy because it would promote the continuous flow of information they need to make proper diagnoses and evaluate treatment options for patients. Also, physicians would have knowledge that indications described in the materials may not be approved by FDA, and that the entity providing the materials likely has an indirect financial stake in promoting a particular

*drug's "off label" use. A disclosure statement may also encourage physicians to consult their colleagues or seek additional information prior to using a drug for unapproved indications, in the interest of guarding the safety of their patients when considering non-approved treatments."*⁹

FDA's recent Notice inquires about the effect of FDA's regulation of the dissemination of "off label" information on the public health. The Coalition acknowledges that FDA has made very narrow exceptions for dissemination of "off label" information, most recently after other government officials publicly discussed the utility of certain antibiotics "off label" for the treatment of anthrax. However, we respectfully submit that, in general, this is not FDA policy, and that FDA's current enforcement efforts on the dissemination of "off-label" information hinder, rather than advance, public health interests. As the Coalition noted in a previous comment:

*"Perhaps one of the most compelling demonstrations of an area of medicine and patient care in which FDA's Notice (referring to its current policy) can have a detrimental effect is the treatment of a life-threatening disease such as cancer. "Off label" use of drugs is both pervasive and indispensable in anti-cancer regimens and therapies, and has arguably become the standard of care. In fact, the Government estimates that over 50% of cancer patients have been administered a drug for an unapproved indication, with one expert estimating that 95% of all oncology drugs are used "off label."*⁹

Interestingly, our comment also noted that:

*"Even FDA has acknowledged that "off label" uses can be of great value, with some having great historical importance, such as the "off label" use of beta blockers in hypertension and angina. ...] Indeed, FDA has recognized that physicians confronted with patient needs may seek information regarding effective "off label" uses of drugs, especially in the absence of effective remedies. However, FDA restrictions on the discussion of "off label" uses significantly impede physicians' ability to acquire this information and, similarly, encumber the advancement of medical science."*⁹

*"The Coalition objects to FDA's maintenance of a policy that can keep the most critical patients from receiving the best therapies. Physicians that learn of new diseases, diagnoses, and treatments through manufacturer-distributed scientific materials and manufacturer-sponsored educational programs are in a better position to treat cancer patients."*⁹

Certainly this is a much better public policy than keeping physicians (and their patients) in the dark. It is in the best interest of individual patients, as well as the public health, that FDA should advocate significant change in its current policy concerning the dissemination of unapproved ("off label") prescription drug information.

A New Standard for the Regulation of Promotional Claims for Prescription Drugs

For almost any advertising claim, FDA currently requires substantial data, a term usually interpreted to mean that support for a claim must be supported by two adequate and well-controlled clinical studies. This standard, while appropriate for purposes of new drug approvals, seems too high and burdensome for other advertising claims.

The bulk of advertising in the United States is regulated by the Federal Trade Commission under a different standard, a standard that permits product claims for which a “reasonable basis” exists. There is no evidentiary data to establish that the FTC standard would not be perfectly appropriate for pharmaceutical products. The U.S. Congress seems to agree with the conclusion that different standards might be applied on an audience-dependent basis, since it adopted the FTC standard in the Food and Drug Administration Modernization Act of 1997 (FDAMA)² for communication of pharmacoeconomic data by drug manufacturers to managed care executives, formulary committees and the like.³

Accordingly, the Coalition requests that FDA consider changing its standard for promotional claims for advertising and other promotional materials to a requirement that supportive data or studies for advertising claims provide a “reasonable basis” for such claims.

Regulatory Considerations for the Future

While FDA is reviewing current policies and procedures, it also might consider establishing a threshold burden of proof that must be met by FDA advertising reviewers before raising objections to promotion materials. Until recently, FDA “untitled” letters or “warning” letters could be issued without any review outside of the Division of Drug Marketing, Advertising and Communications (DDMAC).

The current practice of review of such letters for legal sufficiency by the general counsel’s office is admirable progress. However, the addition of oral notification to a manufacturer before such letters issue with, perhaps, an informal, conference-call hearing and opportunity to respond to FDA assertions might save considerable costs, and turn what is now an adversarial process into a valuable learning experience for all parties. Additionally, such an approach could prevent adverse publicity about minor issues from potentially frightening patients into abrupt, unilateral discontinuation of medication without consultation with their physician or pharmacist.

While FDA’s ad review workload might increase under such an approach so, also, might the perception of fairness by the regulated industry and, we believe, so also would the quality of agency decision-making concerning prescription drug promotion claims.

Another policy that FDA should examine involves its interpretation of the Court of Appeals decision in the WLF case.¹⁴ The agency has said that the use of an “off-label,” peer-reviewed journal article, in and of itself, is not the basis for an enforcement action, but may be used as evidence of intent to promote “off-label,” if the company is engaging in other activities that are seen as encouraging “off-label” use.

There is a strong feeling among medical publishers and others in the health communications sector that this policy has had a chilling effect on the dissemination of journal articles by drug manufacturers. Most marketers, when faced with the possibility that dissemination of a journal article might come back to haunt them in an enforcement proceeding, will take the position that sending the article out is just not worth the risk of arbitrary enforcement. FDA should seek empirical data on whether or not its policies have had such a chilling effect.²⁹

Finally, the Coalition believes that, in addition to reconsidering constitutional limits on its regulation of “off-label” activities, the FDA should reconsider the scope of its statutory authority. While the Food, Drug & Cosmetic Act does provide FDA with some authority over promotional activities, it does so only through specific statutory provisions. These provisions are not sufficient to support the agency’s attempt to assert general jurisdiction over the entire field of industry-supported scientific and educational activities and materials, or to regulate speech based on vague concerns about the quality of the physician-patient relationship. The Coalition recognizes that the FDA’s regulation of prescription drugs is an important part of the legal structure that protects the health and safety of individuals. The fact that FDA is a health and safety agency does not, however, give the agency the general authority to regulate any information that comes from the manufacturer of a drug.

Addressing the Internet

Interestingly, FDA has said nothing in these questions about the Internet, and yet the Internet has become a principal communications tool for many. Initially, FDA stated that it would issue a comprehensive guidance on regulation of Internet communications. Then, the Agency reversed its position, suggesting that no guidance was necessary because existing rules could be applied to the Internet.

When requested by the Washington Legal Foundation to indicate whether Internet materials were labeling – and, therefore, subject to FDA regulation – or advertising, which, except for prescription drugs, would be subject to FTC regulation – the agency finessed the question, and simply responded “it depends,” without giving any real guidance as to its position on the basis for any Internet decisions.

The Coalition suggests that FDA should deal with regulation of the Internet by providing appropriate guidance to the regulated industries. It is true that many FDA regulations can be applied to Internet communications without change, but rules (in the non-technical sense of the term) designed in the 1960s for medical journal print advertising are a poor

fit for 21st century Internet communications, which involve such activities as personal communications through chat rooms and on-line support groups.

Does FDA want to regulate all Internet communications as labeling? Should it? Is FDA willing to provide any guidance, at all, regarding issues that are peculiar to the Internet, such as links, or international access to web sites? Nothing in the current FDA Notice addresses the Internet, and yet it is considered by communications experts to be a critical component of any company's communications strategy with the public and healthcare professionals.

CONCLUSION

Finally, and most importantly, FDA should conduct a wide-ranging review, seeking outside input to redefine the various kinds of communication that constitute modern pharmaceutical information. Specifically, new definitions are needed to define and distinguish between "advertising," "promotion," "scientific and clinical communications" and "education."

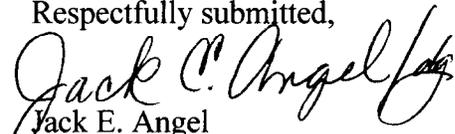
The Coalition believes that this is an appropriate time to revisit current interpretations and definitions for more than just First Amendment purposes. It simply is not true that every time a company subject to FDA regulation exercises some control over the development of information that it disseminates that the company is engaging in the promotion of a product, rather than an informational or educational activity. FDA should conduct a wide-ranging review, seeking outside input to redefine the various kinds of communication that constitute modern pharmaceutical information. Specifically, new definitions are needed to define and distinguish between "advertising," "promotion," "scientific and clinical communications," and "education." This initiative would be consistent with the long-promised rewrite of all agency policies and guidances administered by the Division of Drug Marketing, Advertising and Communications.

FDA's current approaches may make enforcement easier, but they have a tendency to stifle industry-sponsored educational initiatives. While pharmaceutical manufacturers have strong financial incentives to promote their products, they also have strong product liability incentives to avoid the stimulation of inappropriate use, which is best done by informing physicians and patients about the diseases and conditions best treated by their products.

FDA should be encouraging industry to do so, rather than placing impediments in the way. Obviously, this sort of sweeping change in policy requires careful, multidisciplinary thought and discussion. The Coalition believes that FDA may be the organization in the best position today to ask the question "Isn't there a better way?" and to lead both the healthcare professions and the industry to develop workable solutions to the problems. The Coalition and its members stand ready to actively participate in any future discussions and to contribute whatever time and ideas are necessary to create a modern communications regulatory model for the 21st century.

In conclusion, the Coalition again commends FDA for undertaking this current initiative to evaluate its regulation of medical communications under the First Amendment. Interested parties, as well as the Courts, will be watching carefully to help assure that appropriate follow-up steps and changes in FDA policy actually take place.

Respectfully submitted,


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Executive Director

Coalition for Healthcare Communications

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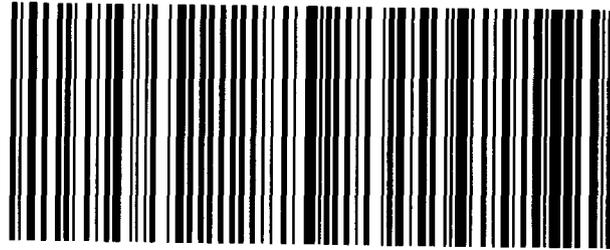
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