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November 8, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Rm. 1-23
Rockville, MD 20857

Re: Docket No. 01P-0250
Citizen Petition Regarding Manufacturer Dissemination of Information
Concerning Off-Label Uses of FDA-Approved Products

On behalf of the Coalition for Healthcare Communication (the Coalition), Bennett, Turner & Coleman, LLP submits these comments in support of the Citizen Petition of May 23, 2001 filed by the Washington Legal Foundation (WLF) with the Food and Drug Administration (FDA). The petition concerns a request by WLF that FDA withdraw its Federal Register Notice (Notice) published on March 16, 2000, entitled "Decision in Washington Legal Foundation v. Henney."

The Coalition is a not-for-profit organization representing nine major communications organizations whose members are engaged in medical communications including publishing, continuing medical education, and the dissemination of information on health care products and services. The Coalition's mission is to ensure that medical communication is as robust and open as possible, so as to ensure that health care professionals and patients have open access to essential 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 FDA, the medical community, policy makers, and the American public: to optimize the flow of medical information. To accomplish this goal, health care professionals need to have available important scientific information concerning disease, its diagnosis, and its treatment so that they can make fully informed decisions concerning patient care.

The following comments note the concerns of the Coalition and its members regarding the subject Notice. We respectfully submit that the subject Notice should be withdrawn and in its place a corrective Notice should be issued consistent with current law regarding free speech under the First Amendment.

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I. Background

In 1993, WLF filed a Citizen Petition requesting FDA to change its policies restricting the flow of truthful information pertaining to unapproved, or unlabeled (off-label), uses of drugs and medical devices that have been approved by FDA for other indications or uses.¹ WLF was concerned with the increase in FDA letters and telephone calls to drug manufacturers warning against the unsolicited distribution of independent medical textbooks and peer-reviewed journal articles (enduring materials) in which off-label uses of their products were discussed. FDA had advised that such activities constituted unauthorized "labeling" and exposed the manufacturers to potential agency enforcement actions. The Coalition shared WLF's concerns at this early stage, and submitted comments to FDA in favor of the petition. After FDA's denial of the Citizen Petition, WLF filed suit against FDA in 1994 in the U.S. District Court for the District of Columbia, alleging that FDA's policies violated the First Amendment of the U.S. Constitution.

In October 1996, during the discovery period of WLF's pending lawsuit, FDA issued two guidance documents designed to restrict drug and medical device manufacturer distribution of enduring materials.² In December 1997, FDA issued another guidance document that severely limited the ability of manufacturers to provide financial support for continuing medical education (CME) activities.³ The Coalition had submitted comments prior to the issuance of that guidance document urging FDA to refrain from imposing restrictions on manufacturer participation in CME activities, citing First Amendment concerns. On July 30, 1998, the district court granted WLF's motion for summary judgment and held that both of FDA's guidance documents unconstitutionally burdened the right of manufacturers to engage in commercial speech.⁴ The court further enjoined FDA from prohibiting, restricting, sanctioning, or otherwise seeking to

¹ See Citizen Petition by the Washington Legal Foundation (Oct. 22, 1993), *in* Docket No. 92N-0434/CP1.

² See Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996).

³ See Guidance for Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093 (Dec. 3, 1997).

⁴ See *WLF v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *motion to alter or amend judgment denied*, 36 F. Supp. 2d 16 (D.D.C. 1999), *inj. modified*, 56 F. Supp. 2d 81 (D.D.C. 1999), *vacated as moot*, 202 F.3d 331 (D.C. Cir. 2000).

limit any manufacturer from disseminating enduring materials or participating in independent CME activities.⁵

Between the time WLF filed its motion for summary judgment and the time the court granted that motion, Congress passed the Food and Drug Administration Modernization Act (FDAMA). Section 401 of the Act allows for manufacturer dissemination of enduring materials that discuss off-label uses, provided that the manufacturer satisfy certain requirements.⁶ The Coalition responded to FDA regulations implementing § 401 by submitting comments voicing concern over FDA's interpretation of Congress' intent to encourage dissemination of peer-reviewed medical information.⁷ Subsequent to the district court's holding, FDA asked the court to qualify its injunction to exclude FDAMA § 401. The court refused, and clarified that its injunction applied to the underlying policies of FDA, and not merely to the express provisions of the guidance documents and FDAMA § 401 and its implementing regulations.⁸

FDA appealed the district court's decisions to the U.S. Court of Appeals for the District of Columbia Circuit. The brief that FDA filed with the court argued that the guidance documents and FDAMA § 401 provided FDA with independent legal authorization to restrict manufacturer speech. At oral argument, however, FDA shifted its position and maintained that (1) the enduring materials guidance documents were superseded by FDAMA § 401, and (2) that § 401 and the CME guidance document represented "safe harbors" that imposed no independent obligations on manufacturers, merely offering them guidance for avoiding sanctions that might otherwise be imposed through enforcement actions under other provisions of the Food, Drug, and Cosmetics Act (FDCA).⁹ Based on FDA's changed position, the Court of Appeals dismissed

⁵ See *WLF v. Friedman*, 13 F. Supp. 2d at 73-74.

⁶ See 21 U.S.C. 360aaa *et seq.* Some pertinent requirements include: (1) submitting a copy of the materials at least 60 days prior to dissemination; (2) submitting a supplemental New Drug Application to FDA no later than 6 months after dissemination of materials; and (3) displaying a prominent statement disclosing that the materials contain information regarding uses not approved by FDA.

⁷ See Letter from the Coalition for Healthcare Communication (July 22, 1998), *in* Docket No. 98N-0222.

⁸ See *WLF v. Friedman*, 36 F. Supp. 2d at 18; *WLF v. Henney*, 56 F. Supp. 2d at 88.

⁹ See *WLF v. Henney*, 202 F.3d at 334-36.

FDA's appeal as moot and vacated the district court's decisions and injunctions insofar as they declared FDAMA § 401 and the CME guidance document unconstitutional.¹⁰

In response to the Court of Appeals' decision, FDA issued the subject Notice. The subject Notice begins by reviewing the FDCA's prohibitions on the distribution of products in interstate commerce for any intended use that FDA has not approved as safe and effective, and follows with a background summary of the WLF lawsuit. The subject Notice reaffirms FDA's courtroom position that FDAMA § 401 and the CME guidance document represent "safe harbors," and that a manufacturer's failure to abide by them does not, by itself, constitute an independent violation of law.¹¹ Of more concern to the Coalition, however, is the subject Notice's statement that "if a manufacturer does not comply [with FDAMA § 401 and its implementing regulations], FDA may bring an enforcement action under the FDCA, and seek to use journal articles and reference texts disseminated by the manufacturer as evidence that an approved product is intended for a 'new use'."¹² The subject Notice also advises manufacturers to become familiar with the CME guidance document previously released by FDA, which details factors FDA may take into account in determining whether industry-supported scientific and education activities rise to the level of promoting off-label uses of drugs.

Since the subject Notice was published, FDA has already sent an Untitled Letter to a drug manufacturer for distributing copies of an abstract taken from a peer-reviewed medical journal that discussed the off-label use of an oncology drug.¹³ The implications made in the subject Notice, and in FDA's recent action to apply the subject Notice, clearly have a chilling effect on the rights of drug and medical device manufacturers to engage in truthful, non-misleading speech, and the rights of physicians and other health care professionals to hear such speech.

¹⁰ *See id.* at 336. In its opinion, the Court of Appeals noted that FDA did not appeal the district court's decision pertaining to the FDA guidance documents on enduring materials. Accordingly, the court viewed this section of the district court's injunction as remaining in effect. *See id.* at 337 n.7.

¹¹ *See* Decision in *WLF v. Henney*, 65 Fed. Reg. 14286, 14287 (Mar. 16, 2000).

¹² *See id.* at 14287.

¹³ *See* FDA Untitled Letter to AstraZeneca Pharmaceuticals (July 9, 2001), *posted on* www.fda.gov/cder/warn/2001/10135.pdf.

II. Application of the Notice Would Violate the First Amendment Rights of Drug and Medical Device Manufacturers.

The Coalition believes that independent medical textbooks, peer-reviewed journal articles, and CME activities constitute classic scientific and academic speech that is afforded full protection under the First Amendment of the U.S. Constitution.¹⁴ This is true as long as the speech was prepared by independent third parties, even if it contains discussions of off-label use for a particular manufacturer's products and is redistributed by that manufacturer. Since these activities involve the communication of truthful, non-misleading, exclusively science-oriented information, any governmental attempt to regulate or restrict the activities requires a compelling reason.¹⁵ The level of constitutional scrutiny should not change merely because a manufacturer, rather than a scientist or physician, chooses to disseminate the information, even if the manufacturer has an indirect financial stake in the distribution of the information.¹⁶ In merely disseminating the information, without anything more, the manufacturer is not proposing a commercial transaction, but simply redistributing the non-commercial speech of scientists, physicians, and other academics.¹⁷ The U.S. Supreme Court has stated numerous times that only a compelling government interest, such as "preventing the flow of substantive evils from an entity's activities," can justify limiting First Amendment freedoms.¹⁸ Although FDA may have a

¹⁴ See, e.g., *Keyishian v. Board of Regents of the Univ. of the State of New York*, 385 U.S. 589, 603-04 (1967) (Court recognizing academic speech as an essential freedom); *Gordon & Breach Science Publishers v. American Inst. of Physics*, 859 F. Supp. 1521, 1539-41 (S.D.N.Y. 1994) (court adopting defendants' position that articles found in scientific journals are expressions of disinterested academic inquiry, which serve to inform the scientific community on an issue of public significance); *Board of Trustees of Stanford Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) (court noting that the First Amendment protects scientific expression and debate just as it protects political and artistic expression); see also Glenn C. Smith, *Avoiding Awkward Alchemy – In the Off-Label Drug Context and Beyond: Fully-Protected Independent Research Should Not Transmogrify Into Mere Commercial Speech Just Because Product Manufacturers Distribute It*, 34 WAKE FOREST L. REV. 963 (1999).

¹⁵ See, e.g., *Keyishian*, 385 U.S. at 603-04.

¹⁶ See Smith, *supra* note 2. at 1017-18.

¹⁷ See *id.* at 1019-20.

¹⁸ See, e.g., *NAACP v. Button*, 371 U.S. 415, 439, 444 (1963); *Bates v. Little Rock*, 361 U.S. 516, 524 (1960) (Court declaring that where there is a significant encroachment upon personal liberty, the government may prevail only upon showing a subordinating interest which is compelling).

substantial interest in requiring manufacturers to obtain approval for new drug uses, the Coalition asserts that the agency has not demonstrated that such an interest rises to the level of being "compelling."

Even if the manufacturer's activities are not fully protected as classic scientific speech, the activities at a minimum enjoy strong constitutional protection as commercial speech.¹⁹ Accordingly, FDA would be violating the manufacturer's First Amendment right to engage in commercial speech if it uses the manufacturer's dissemination of enduring materials, or the manufacturer's sponsorship of CME activities, as evidence that the manufacturer intended that a drug be used for unapproved indications, or that the manufacturer has misbranded a drug's labeling. Likewise, manifestations of FDA's policies on enduring materials and CME activities, whether in the form of enforcement actions, warning letters, guidance documents, or Federal Register Notices, will deter manufacturers from engaging in speech to which they are entitled under the Constitution.

In *WLF v. Friedman*, the District Court for the District of Columbia considered FDA's underlying policies on enduring materials and CME activities to be an unconstitutional burden upon a manufacturer's First Amendment rights.²⁰ Applying the standard set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n* for commercial speech,²¹ the court held that FDA's restrictive policies as outlined in its guidance documents were considerably more extensive than were necessary to further the substantial government interest of encouraging manufacturers to file supplemental new drug applications. The court based its holding in large part upon the existence of less-burdensome alternatives, such as full disclosure by manufacturers that the enduring materials being disseminated, or CME activities being financed, contained off-label use information. The court expressed its distaste not only for the guidance documents themselves, but also for FDA's threats to use manufacturer dissemination of enduring materials or sponsorship of CME activities as evidence in a separate enforcement action.²² Accordingly, the court found the enduring materials and CME guidance documents, and the policies underlying the documents, to be unconstitutional.²³

¹⁹ See *WLF v. Friedman*, 13 F. Supp. 2d at 66.

²⁰ See *WLF v. Friedman*, 13 F. Supp. 2d at 73-74.

²¹ 447 U.S. 557 (1980).

²² See *WLF v. Friedman*, 36 F. Supp. 2d at 17-18.

²³ See *id.* at 18.

While the Court of Appeals for the District of Columbia Circuit ultimately vacated the district court's holding as a result of FDA reversing its position at oral argument, thereby effectively making that particular litigation moot, the court nevertheless went out of its way to note that it did not criticize the reasoning or conclusions of the district court by declining to address the merits of WLF's constitutional arguments.²⁴ The Coalition acknowledges that the district court vacated all remaining portions of its injunction subsequent to the Court of Appeals' holding.²⁵ However, FDA should not view the dismissal of WLF's constitutional arguments based on procedural grounds as creating a mandate for it to reinforce its legally questionable policies through the subject Notice. The district court's holding sent a clear signal that the government should be protective and solicitous of the subject speech. FDA takes an opposite view by using the Court of Appeals' narrow holding to justify the posting of the subject Notice. In any case, the district court recognized after the Court of Appeals' decision that the issue remains unresolved, and that the country's drug manufacturers are still without clear guidance as to their permissible conduct. Moreover, the district court believes that the subject Notice "specifically invites a constitutional challenge to each and every one of [FDA's] enforcement actions," and that it "will be called on to [decide the underlying issue] again before the controversy is concluded."²⁶

The Supreme Court has also shown little hesitation in striking down government attempts to unduly restrict commercial speech.²⁷ The Court's decision in *Lorillard Tobacco Co. v. Reilly*²⁸ represents a recent iteration of the long line of cases invalidating such restrictions, and further supports the Coalition's view that the subject Notice violates the commercial speech rights of manufacturers. In *Lorillard*, the Court struck down certain Massachusetts regulations governing the advertising of tobacco products as being violative of commercial speech protections under the First Amendment.²⁹ In striking down regulations prohibiting indoor and

²⁴ See *WLF v. Henney*, 202 F.3d at 337 n.7.

²⁵ See *WLF v. Henney*, 128 F. Supp. 2d 11, 15 (D.D.C. 2000).

²⁶ See *id.*

²⁷ See, e.g., *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 195-96 (1999); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516 (1996); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 430-32 (1993).

²⁸ 121 S. Ct. 2404 (2001).

²⁹ The Court was presented with two questions: (1) whether comprehensive state regulations that greatly restricted the advertising and sales practices of tobacco companies were preempted by federal law, and (2) whether the regulations violated the companies' constitutional right to engage in commercial speech. The Court held that federal law only preempted the state

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outdoor smokeless tobacco and cigar advertising within certain geographical areas and heights easily accessible by children, the Court held that the regulations failed to satisfy *Central Hudson's* fourth step: whether a government regulation is more extensive than necessary to achieve a substantial government interest.³⁰ The Court viewed the regulations' uniformly broad scope as demonstrating a lack of tailoring by the State to its objectives. The Court also asserted that the State did not sufficiently calculate the costs and benefits associated with the regulations' burden on commercial speech. Notably, the Court advised that speech regulation must not unduly impinge on a speaker's ability to propose a commercial transaction and an adult listener's opportunity to obtain information about the speaker's products. As the Court put it, "tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products."³¹

The Coalition maintains that the policies set forth by FDA in the subject Notice would not pass constitutional muster if applied to the commercial speech principles articulated in *Central Hudson*, and more recently reemphasized in *Lorillard*. The Court's decision requires a policy change by FDA that recognizes the First Amendment right of manufacturers to freely disseminate independently prepared truthful information related to their products, and the right of physicians and other health care professionals to receive such information.³² The Coalition does not disagree that FDA has a substantial interest in protecting the health and safety of the public. However, the Coalition believes that FDA has not adequately calculated the constitutional burdens imposed by the policies put forward to protect those interests. As a consequence, its policies restricting off-label use communications have not been narrowly tailored to serve those interests.

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regulations related to *cigarette* advertising. The Court employed a First Amendment analysis in determining whether state regulations related to smokeless tobacco and cigar products were also invalid.

³⁰ *Lorillard*, 121 S. Ct. at 2425. The Court found the regulations prohibiting indoor advertising of smokeless tobacco and cigars lower than five feet from the floor of a retail establishment located within 1,000 feet of a school or playground as also failing the third step of *Central Hudson* - by not directly advancing the governmental interest asserted.

³¹ *Lorillard*, 121 S. Ct. at 2425-27.

³² See *id.* at 26; see also 44 *Liquormart*, 517 U.S. at 503-04, citing *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (Court recognizing the right of consumers to assess the value of information being presented to them within the context of the commercial marketplace).

Thus, the Coalition strongly urges FDA to replace the subject Notice with a Notice such as that proposed by WLF that still achieves its primary objective of preventing the communication of false or misleading information, but that is not so overly broad as to restrict a manufacturer's right to engage in lawful, non-misleading communications, and to interfere with a physician's interest in accessing such information. If FDA chooses a policy of suppression over one of disclosure, especially when the agency has yet to demonstrate that disclosure would fail to realize its objective, it disregards a far less restrictive means of achieving its policy interests.³³

III. An FDA Policy Requiring Full Disclosure Is Constitutionally Sound and Would Protect the Interests of the FDA, Manufacturers, and Physicians.

The Coalition would support an FDA policy requiring full, complete, and unambiguous disclosure by a manufacturer that the enduring materials it disseminates, or the CME activities it participates in, contain discussion of off-label uses not approved by the FDA, and that the manufacturer produces and markets the subject product. As the district court pointed out, such a policy is less restrictive on speech, and is more narrowly tailored to achieve the objectives of FDA and Congress concerning off-label use of drugs. Likewise, it is consistent with the Supreme Court's recent decision in *Lorillard* and reconciles with the Court's view that disclaimers are constitutionally preferable to outright suppression.³⁴ The Court of Appeals for the District of Columbia Circuit has also stated that "if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression."³⁵

³³ See, e.g., *Board of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 479 (1989).

³⁴ See, e.g., *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 110 (1990).

³⁵ See *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999), *reconsideration denied*, *Pearson v. Thompson*, 141 F. Supp. 2d 105, 112 (D.D.C. 2001). In this case, the court interpreted a provision in the Nutrition Labeling and Education Act of 1990, codified at 21 U.S.C. §§ 301, 321, 337, 343, 371, relating to disease or health-related claims of dietary supplements. FDA had denied authorization for dietary supplement manufacturers to include on their labels claims characterizing the relationship of the supplement to a disease or health-related condition. FDA claimed that the supporting evidence was inconclusive and thus failed to give rise to "significant scientific agreement." The manufacturers asserted that FDA violated their commercial speech rights under the First Amendment by declining to employ a less burdensome method, such as the use of disclaimers, to serve the government's interests. The court agreed with the manufacturers.

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." And as recognized by the district court, FDA can still move against a manufacturer if the information being conveyed is in fact false or misleading. 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 the industry by entertaining less-burdensome alternatives in its pursuit of promoting the public's health and safety.

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 their 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.

IV. FDA Acquiescence to the Dissemination of Off-label Information Embodies Sensible Health Policy.

The Coalition agrees with WLF's assessment that the off-label use of FDA-approved drug products plays a vital role in the effective and efficient delivery of adequate health care to patients across the United States. As noted by WLF, the U.S. Supreme Court has even recognized the importance of off-label treatments in current medical practice, noting that "off-label usage of medical devices is an accepted and necessary corollary of FDA's mission to regulate in this area without directly interfering with the practice of medicine."³⁶ The district court in *WLF v. Friedman* repeatedly noted that off-label prescriptions constitute the most effective treatment available for some conditions. The court stated that FDA's efforts to prevent misleading information from being communicated may concurrently stifle truthful life-saving

³⁶ See *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2000).

information, or information that can make someone with a debilitating condition more comfortable.³⁷

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.³⁸ Most recently, government officials have commented on the availability of certain antibiotics for the off-label treatment of anthrax.³⁹ 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 alternatives. 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.

Perhaps one of the most compelling fields of medicine in which FDA's Notice can have a detrimental impact 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.⁴⁰ 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 a cancer patient.

V. FDA Should Espouse the Equal Treatment of Off-label Use Discussion.

Finally, a formal change in FDA policy would also eliminate the singling out of drug and medical device manufacturers in the restriction of off-label use discussion. The Court of Appeals for the District of Columbia Circuit recognized this disparate treatment in *WLF v.*

³⁷ See *WLF v. Friedman*, 13 F. Supp. 2d at 73.

³⁸ See Testimony by Michael Friedman, FDA Deputy Commissioner for Operations, before the House Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations, September 12, 1996.

³⁹ See, e.g., Gina Kolata, *Cipro Isn't the Only Drug That Can Be Prescribed, Anthrax Experts Say*, N.Y. TIMES, Oct. 17, 2001.

⁴⁰ See General Accounting Office, *Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies* (September 1991); *ASCO Daily News*, May 14, 2001.

Henney, observing that neither Congress nor the FDA has attempted to regulate the off-label use of drugs by doctors and consumers. The District Court for the District of Columbia also noted FDA's desire to refrain from interfering with physicians' pursuit of current and reliable information concerning off-label uses of drugs. The FDA has even acknowledged the suitability of physicians receiving off-label use information from a variety of sources, including journal articles, independent CME activities, on-line databases, textbooks, and discussions with colleagues.⁴¹

It should not matter to FDA where a physician receives truthful, non-misleading off-label use information. Rather, FDA should treat manufacturers like any other source of breaking medical research and treatment information that physicians utilize as part of their effort to achieve the highest standards of care. Physicians are capable of critically evaluating enduring materials that are given to them, or the findings presented at CME seminars; their ability to process new information is not dependent on the nature of the source of such information.

* * * * *

In summary, the Coalition urges FDA to remove the subject Notice and replace it with a notice or policy statement similar to the one submitted by WLF with its petition that acknowledges the right of drug and medical device manufacturers to communicate non-misleading information to physicians and other health care providers concerning the off-label use of FDA-approved drugs. The Coalition believes that a different policy is necessary because of (1) the subject Notice's chilling effect on constitutionally-protected speech, (2) the alternative means available to ensure that manufacturers do not convey misleading information, and (3) the prudent policy reasons supporting the right of all parties to openly discuss off-label uses of drugs.

The Coalition recognizes FDA's vital role in regulating information a manufacturer seeks to include in a drug product's labeling, advertisements, and promotional materials. The Coalition does not seek to alter or undermine FDA's core authority to restrict materials created by or on behalf of the manufacturer itself. The Coalition strongly believes that FDA should monitor and prosecute manufacturer labeling and promotional activities that are false or misleading. Rather, the Coalition contends that only a modest change in FDA policy is necessary to achieve a proper balance that permits manufacturers to communicate truthful, non-

⁴¹ See *WLF v. Friedman*, 13 F. Supp. 2d at 56; Testimony by Michael Friedman, *supra* note 12.

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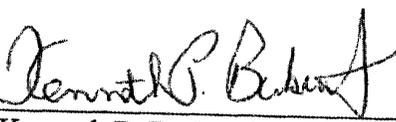
misleading medical information published by independent third parties to physicians and other health care providers.

Thank you for your consideration of these comments.

Sincerely,
BENNETT, TURNER & COLEMAN

By 

Alan R. Bennett

By 

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