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May 15, 2013

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

**Re: Final Rule on Transparency Reports and Reporting of Physician Ownership
or Investment Interests; 78 Fed. Reg. 9457 (February 8, 2013);
Failure to Include Medical Textbooks within the Definition of
“Educational Materials That Directly Benefit Patients”**

Dear Ms. Tavenner:

The Washington Legal Foundation (WLF) writes to raise concerns regarding the constitutionality of the position recently adopted by the Centers for Medicare and Medicaid Services (CMS) with respect to reporting requirements under the Physician Payment Sunshine Act (the “Act”), 42 U.S.C. § 1320a-7h. The Act provides that “payments or other transfers of value” made by pharmaceutical manufacturers to doctors must be reported annually by manufacturers to HHS, but explicitly excludes from the reporting requirement “educational materials that directly benefit patients or are intended for patient use.” 42 U.S.C. § 1320a-7h(e)(10)(B)(iii). On February 8, 2013, CMS announced its determination that medical textbooks do not fall within the statutory exclusion for “educational materials” and thus that gifts of medical textbooks are reportable under the Act.¹

WLF understands that numerous commenters urged CMS to determine that medical textbooks fall within the statutory exclusion. We further understand that following CMS’s contrary determination, a number of individuals and textbook publishers have contacted CMS to argue that: (1) CMS’s interpretation of the educational materials exclusion is based on a misunderstanding of congressional intent; (2) CMS’s classification of medical textbooks under the Act is inconsistent with its classification of other educational materials; (3) medical textbooks are impartial and important sources of medical information for doctors and thus are

¹ CMS made that announcement in connection with its issuance of final regulations implementing the Act. 78 Fed. Reg. 9456 (Feb. 8, 2013). Although the regulations themselves do not address the medical textbook issue, CMS stated in its discussion accompanying the regulations that the “educational materials” exclusion is inapplicable to textbooks because “[a]lthough these items may have downstream benefits for a patient, we believe they are not directly beneficial to patients.” See “Provisions of the Proposed Rule and Responses to Public Comments,” Sec. B(1)(j)(3), 78 Fed. Reg. at 9486.

essential for optimal patient care; and (4) if medical textbooks are deemed reportable under the Act, patient care will suffer because most drug companies will cease providing textbooks as gifts and most doctors will become unwilling to accept such gifts.

While WLF agrees with those concerns, we write separately to focus on an additional issue: applying the reporting requirements to medical textbooks would constitute a serious infringement on the First Amendment rights of pharmaceutical companies to disseminate medical texts and the First Amendment rights of doctors to receive such information. Both groups have strong reason to believe that they will be subject to harassment and/or investigation if forced to report such speech activity to CMS, with the result that their speech will be chilled considerably. The U.S. Supreme Court has repeatedly held that disclosure requirements of this sort are subject to “exacting scrutiny” and can pass muster under the First Amendment only if shown to serve important government interests that outweigh the burdens they impose on speakers. WLF has seen no indication that CMS has given *any* consideration to the First Amendment implication of its interpretation of the Act’s educational materials exclusion. For example, there is no indication that CMS is even aware that the Food and Drug Administration (FDA), as a result of its ill-considered attempts in the 1990s to restrict manufacturer dissemination of medical textbooks, is subject to a permanent federal court injunction that imposes strict limits on any such restrictions. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 73-74 (D.D.C. 1998) (“*WLF I*”), *appeal dismissed*, 202 F.3d 331 (D.C.Cir. 2000) (“*WLF III*”).

WLF has no objections to CMS’s decision to begin enforcement of other portions of the Act’s reporting requirements effective August 1, 2013; such enforcement does not raise significant First Amendment issues. WLF urges, however, that CMS delay any decision to apply the reporting requirements to medical textbooks until it has had an opportunity to examine the First Amendment implications of such a decision. In particular, CMS needs to investigate whether such a decision would (as many observers have predicted) result in a significant reduction in manufacturer dissemination of medical textbooks; if so, then CMS’s policy almost surely could not withstand First Amendment scrutiny. If CMS persists in its current policy before undertaking such an investigation, it is likely to find itself the target of a First Amendment lawsuit by affected parties.

I. Interests of WLF

The Washington Legal Foundation is a public interest law and policy center with members and supporters in all 50 States, including many patients and physicians who seek unfettered access to truthful information about well-recognized medical treatments. WLF regularly appears before federal and State courts and administrative agencies to promote economic liberty, free enterprise, and a limited and accountable government. In particular, WLF has devoted substantial resources over the years to promoting the free speech rights of the

business community, appearing before numerous federal courts in cases raising First Amendment issues. *See, e.g., Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011); *Nike v. Kasky*, 539 U.S. 654 (2003); *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). As noted above, WLF (in *WLF I*) successfully challenged the constitutionality of certain FDA restrictions on the First Amendment rights of doctors and pharmaceutical manufacturers. As a result of that litigation, FDA is subject to a permanent injunction limiting FDA authority to suppress manufacturer dissemination of medical textbooks discussing off-label uses of their FDA-approved products.

WLF also regularly participates in federal administrative proceedings in support of expanded First Amendment rights. *See, e.g.,* WLF comments to CMS, objecting to speech restrictions contained in CMS's Medicare Marketing Guidelines (submitted April 4, 2006); FDA Citizen Petition No. 2006P-0319/CPI (August 11, 2006) (documenting repeated First Amendment violations by FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) and calling on DDMAC to conform to constitutional constraints on its activities).

II. The Distribution of Medical Textbooks Is Speech Protected by the First Amendment

Pharmaceutical companies spend vast sums each year promoting the sale of their products. Much of the money is used for advertising, usually directed at either patients or doctors, or to pay the salaries of marketing representatives who make regular sales calls at doctors offices. A small portion is used to provide goods or services directly to doctors.

Some "transfers of value" made directly to doctors have been subjected to criticism in recent years. Critics fear that doctors who receive gifts from a drug company may be tempted to write prescriptions for one of the company's drugs in the hopes of receiving additional gifts rather than based on a conclusion that the drug prescribed fits the patient's needs. If the gifts are sufficiently large, they are viewed by some as a kick-back – a bribe paid with the implicit understanding that the doctor will, in return, prescribe an increased number of the company's drugs.

In recognition of those concerns, the Pharmaceutical Research and Manufacturers of America (PhRMA) has, since 2002, promulgated a "Code on Interactions with Healthcare Professionals." Virtually all of the largest drug companies subscribe to the Code. The Code commits companies to "following the highest ethical standards" in dealing with physicians. It bars gifts to doctors (*e.g.,* travel, lodging, and entertainment/recreational items) that lack an educational component. Rather, company relationships with doctors "are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education." Code at 4 (2009 ed.). The Code explicitly permits gifts

“primarily designed for the education of patients and healthcare professionals,” so long as they “they do not have value to the healthcare professionals outside of their professional responsibilities. For example, companies may provide educational items *such as a medical text book.*” *Id.* at 19 (emphasis added).

In adopting the Physician Payment Sunshine Act in 2010 (as part of the Patient Protection and Affordable Care Act, Pub.L. 11-148), Congress sought to achieve goals quite similar to those of the PhRMA Code. Although the Act does not prohibit gifts from drug companies to doctors, it is designed to expose to public inspection those gifts that lack a bona fide educational purpose – and thereby shame those involved into discontinuing such gifts.

Many of the gifts that a drug company representative might conceivably give to a doctor (*e.g.*, a meal, a ticket to a sporting event) have no communicative component, and thus do not implicate First Amendment concerns. On the other hand, a gift of a medical textbook clearly does implicate such concerns; the sole purpose of disseminating a textbook is to convey the ideas contained therein, and it possesses value solely by virtue of the value of those ideas. The U.S. Supreme Court has explicitly held that the speech of pharmaceutical companies to doctors – even speech designed solely for the purpose of selling a product – is entitled to First Amendment protection. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2665 (2011). The federal courts have repeatedly *rejected* federal government arguments that the First Amendment is inapplicable to its regulation of the expressive activity of a drug company because (the government asserts) its regulation focuses on the company’s commercial conduct, not its speech. For example, in rejecting that government argument raised in response to WLF’s challenge to FDA restrictions on dissemination of medical textbooks to doctors, a federal district court stated:

[T]he activities at issue in this case are only “conduct” to the extent that moving one’s lips is “conduct,” or to the extent that affixing a stamp and distributing information through the mails is “conduct.” . . . This court is hard-pressed to believe that the agency is seriously contending that “promotion” of an activity is conduct and not speech, or that “promotion” is entitled to no First Amendment protection.

WLF I at 59.

Moreover, the First Amendment provides particularly strong protection to the speech at issue here because all concede that medical textbooks are truthful and (because they are prepared by reputable, independent medical publishers) are unbiased. In its 1996 guidance document on dissemination of textbooks, FDA observed that “[t]hese tests typically discuss a wide range of medical diagnoses and treatments, including drug product utilization, surgical techniques, and other medical topics, and are often useful to clinicians in the practice of medicine.” *See* “Guidance for Industry Funded Dissemination of Reference Texts,” 61 Fed. Reg. 52800, 52801

(Oct. 8, 1996) (the “Textbook Guidance”).² Accordingly, any federal regulations that inhibit distribution of medical textbooks are subject to First Amendment scrutiny.

CMS should be aware that the federal courts struck down FDA’s Textbook Guidance on First Amendment grounds and permanently enjoined its enforcement. *WLF I*, 13 F. Supp. 2d at 73-74.³ The district court later clarified that its injunction applied not only to the Textbook Guidance itself but also to any subsequent documents that purported to adopt the policies of that document. *Washington Legal Found. v. Friedman*, 36 F. Supp. 2d 16, 18 (D.D.C. 1999) (“*WLF II*”) (“The Court’s decision and injunction must be read to apply to the underlying policies of the FDA, and not merely to the express provisions of the Guidance Documents.”). FDA ultimately abandoned its appeal from those decisions, and the appeals court stated explicitly that the medical textbook injunction remains in effect. *WLF III*, 202 F.3d at 334 n.4 and 337 n.7.

III. Although CMS Is Not Banning Speech, It Is Substantially Burdening Speech, and Such Burdens Are Subject to First Amendment Constraints

Although the Act’s reporting requirement includes an explicit exemption for “educational materials that directly benefit patients,” 42 U.S.C. § 1320a-7h(e)(10)(B)(iii), CMS has interpreted that exemption as being inapplicable to medical textbooks. 78 Fed. Reg. at 9486. As a result of that interpretation, drug companies will be required to report to HHS all gifts of medical

² FDA further limited the definition of what it deemed to constitute a medical textbook, as follows: “The reference text should not have been written, edited excerpted, or published specifically for, or at the request of a drug, device, or biologic firm, unless the text was prepared in a manner that results in a balanced presentation of the subject matter,” and “The content of the reference text should not have been reviewed, edited or significantly influenced by a drug, device, or biologic firm, or agent thereof, unless the text was prepared in a manner that results in a balanced presentation of the subject matter.” *Id.* That limiting definition is consistent with industry understanding of what constitutes a medical textbook. Indeed, WLF understands that textbooks produced by the publishing partners of Millennium Medical Education Resources Ltd. (*i.e.*, the firms that have expressed the greatest concerns regarding CMS’s rules) have been written totally independently of any drug company influence.

³ The injunction barred FDA from prohibiting “any pharmaceutical or medical device manufacturer . . . from disseminating or redistributing to physicians or other medical professionals any reference textbook (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on uses of drugs or medical devices other than those approved by FDA.” *Id.*

textbooks made to doctors after July 31, 2013. That reporting requirement does not, of course, flatly prohibit any speech; a manufacturer will still be free to distribute medical textbooks provided that it reports the distribution and provided that doctors will continue to accept such gifts given their knowledge of the reporting requirement. Nonetheless, courts have repeatedly held that mandatory disclosure of expressive activity imposes a burden on the expressive activity and thus is subject to First Amendment constraints.

The Supreme Court has repeatedly applied “exacting scrutiny” to disclosure requirements imposed on those who engage in expressive activity. *Citizens United v. FEC*, 558 U.S. 310, 366 (2010); *Davis v. FEC*, 554 U.S. 724, 744 (2008); *Buckley v. American Constitutional Law Found., Inc.*, 525 U.S. 182, 202 (1999); *McIntyre v. Ohio Elections Comm’n*, 514 U.S. 334, 347 (1995); *Brown v. Socialist Workers ’74 Campaign Comm.*, 459 U.S. 87, 420 (1982); *Buckley v. Valeo*, 424 U.S. 1, 64-65 (1976). The First Amendment scrutiny is at its highest when, as here, the speech is truthful and seeks to convey information that is of significant public interest – in this case, information critical to the effective delivery of medical care. Although drug manufacturers are commercial entities, there is no plausible basis for asserting that their distribution of medical textbooks constitutes “commercial speech” – a category of speech that is entitled to a lessened (but still substantial) degree of First Amendment protection.⁴ Moreover, the public importance of the information conveyed in a medical textbook is not reduced simply because a doctor receives the textbook as a gift from a drug company rather than by purchasing it with his own funds. See *McIntyre*, 514 U.S. at 353 (“the inherent worth of the speech in terms of its capacity for informing the public does not depend upon the identity of its source, whether corporation, association, union, or individual.”) (quoting *First Nat’l Bank of Boston v. Bellotti*, 435 U.S. 765, 777 (1978)).

In general, the courts have determined the constitutionality of a disclosure requirement by balancing (on the one hand) the burdens that the requirement imposes on speakers, against (on the other hand) the government interests allegedly served by the requirement. As *Davis*

⁴ See, e.g., *Central Hudson Gas & Electric Corp. v. Public Service Comm’n*, 447 U.S. 557, 562-63 (1980). In general, “commercial speech” is defined as “speech which does no more than propose a commercial transaction.” *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976). The speech contained in medical textbooks does not propose any sort of commercial transaction between a drug company and a doctor, and WLF is unaware of any government officials who contend otherwise. The fact that a drug company is a for-profit entity that may hope that its speech will create good-will that ultimately will improve profitability does not transform what otherwise would be fully protected speech into commercial speech. See *Bd. of Trustees of State University of New York v. Fox*, 492 U.S. 469, 482 (1989) (“Some of our most valued forms of fully protected speech are uttered for a profit. See, e.g., *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964).”).

explained:

We have repeatedly found that compelled disclosure, in itself, can seriously infringe on privacy of association and belief guaranteed by the First Amendment. As a result, we have closely scrutinized disclosure requirements. . . . To survive this scrutiny, significant encroachments “cannot be justified by a mere showing of some legitimate government interest.” Instead, there must be a “relevant correlation” or “substantial relation” between the governmental interest and the information required to be disclosed, and the government interest “must survive exacting scrutiny.” That is, the strength of the governmental interest *must reflect the seriousness of the actual burden on First Amendment rights*.

Davis, 554 U.S. at 744 (emphasis added) (quoting *Buckley v. Valeo*, 424 U.S. at 64, 75).

As explained below, the available evidence tips decidedly against the constitutionality of CMS’s policy. The evidence suggests that the disclosure requirement will severely burden the First Amendment right of drug and device companies to disseminate medical textbooks – even to the point of causing all such dissemination to cease. On the other hand, WLF is hard-pressed to identify *any* substantial government interest that would be served by applying the Act’s disclosure requirement to medical textbooks.

IV. The Disclosure Requirement Imposes a Substantial Burden on the Right to Speak by Distributing Medical Textbooks

WLF does not consider itself an expert on the on-going relationships between drug companies and doctors. Based on our conversations with those who possess such expertise, however, the consensus is that the Act, as interpreted by CMS, will severely burden the First Amendment right of drug and device companies to disseminate medical textbooks, as well as the First Amendment right of doctors to receive medical textbooks.

Complying with the Act’s reporting requirements is time-consuming and expensive. As interpreted by CMS, the Act will require manufacturers to keep track of *every* medical textbook they disseminate, because every textbook has a retail value that exceeds the Act’s \$10 threshold. Moreover, even if a textbook is the first gift supplied during the reporting year by a manufacturer to a doctor and even if the textbook has a retail value of less than \$100, the manufacturer will still need to keep detailed records regarding the gift so that it can determine later whether total gifts for the year exceeded \$100 in value. Doctors will similarly be forced to keep detailed records regarding any textbook they are given, so that they can be in a position, if necessary, to dispute HHS reports regarding gifts they have received. Comments filed with CMS by a coalition of 27 nationwide organizations that represent the interests of doctors, including the American Medical Association (AMA), well illustrate the burdens imposed on doctors by

CMS's interpretation of the Act:

The current Proposed Rule would require all physicians to maintain ongoing records of every activity they engage in so that they are able to ensure accurate reporting. . . . We believe that CMS has greatly underestimated the amount of time physicians would need to review cumulative reports and to challenge them before they were posted given the resources physicians would need to dispute inaccurate, false, and misleading reports. . . . Realistically, we would anticipate that the paperwork requirements of documenting all of a physician's activities could easily exceed 80 hours per year.

Comments of AMA, *et al.*, at 8-9 (Feb. 17, 2002).

Moreover, manufacturers that continue to provide gifts to doctors risk incurring substantial penalties if they are later determined to have failed to submit timely, accurate, or complete reports regarding those gifts. Each such error is subject to fines of up to \$10,000. If the error in timeliness, accuracy, or completeness is deemed by HHS to constitute a *knowing* violation, manufacturers are subject to fines of up to \$100,000 per error, with aggregate fines of up to \$1.15 million per year.

The inevitable result will be a significant reduction in speech. Manufacturers will be able to reduce compliance costs and potential fines by reducing the number of medical textbooks they disseminate. They are likely to transfer their expenditures to such non-reportable activities as continuing medical education and direct-to-consumer advertising. Similarly, doctors will be able to reduce compliance costs by declining to accept medical texts. More importantly, doctors who decline to accept medical texts can avoid inclusion of their names on public lists of doctors who are accused of being on the "payroll" of pharmaceutical companies. While many doctors wish to receive the information contained in medical textbooks, their willingness to exercise their First Amendment rights to receive such information is greatly tempered by an unwillingness to expose themselves to the potential harassment and censure that can accompany inclusion on lists of doctors who received payments from drug or device companies. Fear of such listing has been a strong motivator for doctors in recent years. As the AMA's comments to CME noted:

[P]hysicians may have their careers and professional reputations damaged as a result of one disputed report. . . . The proposed rule opens the door to the real possibility that a large number of physicians could . . . suffer significant damages including investigation by government and private entities, potential disciplinary actions, public censure, ridicule, and destruction of professional reputation and livelihood.

Id. at 3-4.

Indeed, the whole point of the Act appears to have been to discourage gifts to doctors by

publicizing the practice – and thereby: (1) holding all involved up to ridicule; and (2) providing prosecutors with evidence for potential kick-back prosecutions. The legislative history of the Act confirms that Congress required disclosure not so that patients could use the information as part of a careful evaluation of which doctors to use, but to discourage doctors from accepting gifts that lack an educational purpose. There is little evidence that Congress intended to single out textbook dissemination and other expressive activities for special disapprobation, but the effect of the Act (as interpreted by CMS) is to burden this expressive activity to such an extent that much of the activity will cease. The Supreme Court has held repeatedly that although a law is subject to particularly strict scrutiny if the government *intends* to single out expressive activity for harsh treatment,⁵ the principal focus of any First Amendment scrutiny is the extent of the burden imposed on speech, not whether the imposition of that burden was the government’s specific intent. *See, e.g., NAACP v. State of Alabama*, 357 U.S. 449, 461 (1958) (overturning an Alabama court order requiring NAACP to disclose the names of its Alabama members because disclosure would infringe on First Amendment rights by subjecting members to harassment; Court deemed it irrelevant whether Alabama acted for the purpose of abridging First Amendment rights).

The Supreme Court has been particularly wary of government-imposed burdens on speech where, as here, there is evidence that the burden will deter activity protected by the First Amendment. Thus, in *Brown v. Socialist Workers ’74 Campaign Comm.*, 459 U.S. 87 (1982), the Court struck down an Ohio law that required small political parties to disclose the names and addresses of campaign contributors and recipients of campaign disbursements. The Court concluded that the party to which the law was being applied, the Socialist Workers Party, was sufficiently unpopular that people identified as contributing to or doing business with the party were likely to be subjected to “threats, harassment, or reprisals from either Government officials or private parties,” and thus that disclosure would cause such individuals to refrain from engaging in activity protected by the First Amendment. 459 U.S. at 93. The Court concluded that this deterrent effect would be particularly strong among businesses from whom the Socialist Workers Party wanted to purchase goods or services. It explained, “Because an individual who enters into a transaction with a minor party purely for commercial reasons lacks any ideological commitment to the party, such an individual may well be deterred from providing services by even a small risk of harassment.” *Id.* at 98.

The sorts of commercial relationships described in *Brown* mirror the typical relationship between a drug or device company and a doctor. Drug companies often wish to provide truthful

⁵ *See, e.g., Grosjean v. American Press Co.*, 297 U.S. 233 (1936) (striking down on First Amendment grounds a Louisiana 2% gross receipts tax on advertising revenues of all newspapers with a weekly circulation above 20,000, where the tax was adopted following complaints by Senator Huey Long that large newspapers were attacking him unfairly).

and useful medical information to doctors by providing them with medical textbooks, but they lack any strong ideological commitment to doing so. Similarly, most doctors appreciate receiving the information provided to them by drug companies in the form of free textbooks, but (like the vendors in *Brown*) they will quickly forgo receipt of that information if they conclude that accepting the information will lead to any amount of harassment. Under those circumstances, courts are likely to view the burdens imposed by the Act on First Amendment-protected activities to be particularly onerous.

The burdens are also particularly onerous because the Act is being applied to speech whose truthfulness CMS does not contest. The Supreme Court has long applied particularly close scrutiny to burdens imposed on truthful speech. For example, in striking down an Ohio statute that required all campaign leaflets to bear the name and address of the individual sponsoring the leaflet, the Court deemed the statute to be particularly objectionable because it applied without regard to the leaflet's truthfulness; and in the case before the Court the statute was being invoked with respect to an individual whose leaflet was "not even arguably false or misleading." *McIntyre*, 514 U.S. at 351-53.

The burdens that CMS is imposing on speech rights are also subject to special scrutiny for the additional reason that they are being imposed in a selective manner. Anyone other than a drug or device company is free to distribute medical textbooks to doctors without being burdened by the Act's reporting requirements. Only the speech of drug and device companies is subjected to special disapprobation. The Supreme Court has repeatedly subjected such "speaker-based restrictions" to heightened First Amendment scrutiny. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2663-65 (2011) (applying heightened First Amendment scrutiny to, and striking down, a Vermont law that restricted truthful speech by drug companies in connection with promotion of their products but permitted identical speech by virtually all others).⁶

V. Application of the Act to Medical Textbooks Does Not Serve Any Substantial Government Interests

The application of the Act to medical textbooks does not serve any substantial government interests. Whatever government interests it may serve are far outweighed by the substantial burdens (outlined above) that CMS's interpretation of the Act imposes on First-

⁶ *Sorrell* is distinguishable in one respect: the Vermont law at issue included not only speaker-based restrictions but also content-based restrictions. In contrast, the Act (as interpreted by CMS) is not content-based: it applies to all textbooks and other communicative materials supplied to doctors without regard to their content. *Sorrell* nonetheless makes clear that the First Amendment frowns on speaker-based restrictions just as much as it frowns on content-based restrictions. *Id.*

Amendment-protected activities.

The principal government interest served by the Act is the prevention of corruption. CMS, which provides billions of dollars each year to reimburse the costs of medical devices and prescription drugs, has a strong interest in ensuring that a doctor prescribes use of medical products only when their use is indicated, and not because the doctor has been bribed to write such a prescription. By requiring drug companies to report to HHS gifts they make to doctors, the federal government can ascertain which doctors are receiving inordinately large gifts and thus can more easily ascertain whether a doctor's prescription-writing practices have been corrupted.

WLF does not question the constitutionality of the Act as applied to disclosure of large gifts that do not constitute speech. But the dissemination of medical textbooks is materially different from the sort of gifts Congress had in mind when it adopted the Act. The principal distinction is the magnitude of the gift. By their nature, gifts of travel, food, and lodging can often end up being many times more valuable than any medical textbook. For example, if a drug company provides a doctor with an all-expenses paid vacation to a Hawaiian golf resort at which the doctor is free (if he chooses) to attend a medical symposium, the gift may well be worth many thousands of dollars. In contrast, the most expensive medical textbooks supplied by drug companies to doctors cost only a small fraction of that amount. Moreover, while two vacation trips are twice as valuable as one vacation trip, a second copy of a cardiology textbook is worthless to a cardiologist after he has received the first copy – thereby in effect placing a ceiling on the value of any textbook gifts. Accordingly, the likelihood that a gift of a medical textbook could corrupt a doctor's prescribing practices is negligible.

The Supreme Court has recognized that a desire to deter corruption can, under appropriate circumstances, justify mandatory disclosure requirements that burden First Amendment rights. But it has generally limited disclosure to “large” expenditures that legitimately could be viewed as having the potential to corrupt. *See, e.g., Buckley v. Am. Constitutional Law Found., Inc.*, 525 U.S. 182, 202 (1999) (“disclosure requirements deter actual corruption and avoid the appearance of corruption by exposing *large* contributions and expenditures to the light of publicity.”) (emphasis added) (citations omitted). *Buckley* struck down a Colorado law requiring the disclosure of the names and addresses of paid petition circulators (and the amount they were paid) who had been hired to assist in getting voter initiatives placed on the election ballot. *Id.* at 203-04. The Court reasoned that amounts paid to circulators were sufficiently small, as was the potential that such payments would corrupt the circulators, that Colorado's “interest in preventing fraud” was not “significantly advanced” by the disclosure requirements, and thus that that interest could not justify the burden on First Amendment rights imposed by the disclosure requirement. *Id.* at 204 n.23.

Given the Act's expressed desire to exempt gifts that “directly benefit patients,” 42

U.S.C. § 1320a-7h(e)(10)(B)(iii), WLF finds it ironic that CMS has interpreted the Act as prohibiting dissemination of a medical text *only* if it has real medical value. A book has value only to the extent that the book contains valuable information. Thus, a drug company sales representative need not report that, during one of his sales visit to the doctor's office, he has left off a copy of a promotional brochure regarding one of his company's drugs or a Harlequin romance novel, because no doctor – or anyone else – would value the material as exceeding the Act's \$10 reporting threshold. It is only because doctors and their patients can actually make use of information contained in bona fide medical textbooks that doctors (and the market in general) assign a sufficiently large value to the textbooks to render them reportable. Yet, CMS has produced no evidence – and WLF is not aware of any – that the modest value of a single copy of a medical textbook is sufficient to tempt a doctor to adopt corrupt prescribing practices.

Other than an interest in preventing fraud, the Act serves no legitimate government interest. Congress never attempted to justify the Act based on its informational value – that is, that patients might use the information contained in HHS reports in deciding which doctor to choose. The limited experience to date with state law reporting requirements does not support claims that the Act's disclosure requirements could be justified on the basis of their informational value. In any event, the clear congressional intent of the Act was to deter *all* gifts to doctors that do not provide a direct benefit to patients, not to tolerate large gifts so long as they are fully reported.

VI. CMS Can Avoid First Amendment Difficulties by Construing the Act as Inapplicable to Medical Textbooks

As explained above, CMS's application of the Act to the dissemination of unbiased, independently-produced medical textbooks is unlikely to withstand First Amendment scrutiny if challenged in the courts. Given that the economic viability of textbook publishers is thrown into question by CMS's decision, such a challenge is likely.

Moreover, in the face of a constitutional challenge, the courts are unlikely to grant deference to CMS when interpreting the Act. At the very least, the burdens imposed on First Amendment rights by an application of the Act to medical textbooks raises a serious constitutional issue. The Supreme Court has repeatedly explained that “[w]here an administrative interpretation of a statute invokes the outer limits of Congress’ power, we expect a clear indication that Congress intended that result.” *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172 (2001). “This requirement [of a “clear indication” of congressional intent] stems from our prudential desire not to needlessly reach constitutional issues and our assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority.” *Id.* at 172-73.

There is no language in the Act that can be construed as a “clear indication” that Congress intended to require that medical textbooks be included in the reporting requirement. Although the Act requires that “payments or other transfers of value” from drug companies to doctors be included in annual reports submitted to HHS, it explicitly excludes from the reporting requirement “educational materials that directly benefit patients or are intended for patient use.” 42 U.S.C. § 1320a-7h(e)(10)(B)(iii). By all accounts, medical textbooks supplied by drug companies to doctors “directly benefit patients” – doctors regularly use information gleaned from the textbooks in their treatment of patients, and they often show the textbooks to patients while explaining treatment options. At the very least, therefore, there is a plausible statutory basis for exempting medical textbooks from the Act’s reporting requirement. By adopting that construction of the Act, courts could avoid the serious constitutional questions that they would otherwise be required to confront.

The regulations issued by CMS in final form on February 8, 2013 do not specify whether medical textbooks come within the “directly benefit patients” exclusion. They merely repeat the statutory language, stating that exclusions from the reporting requirements include “Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer’s services to educate patients regarding a covered drug, device, biological, or medical supply.” 42 C.F.R. § 403.904(i)(4). However, in its discussion accompanying the regulations, CMS stated that the “educational materials” exclusion is inapplicable to textbooks because “[a]lthough these items may have downstream benefits for a patient, we believe they are not directly beneficial to patients.” 78 Fed. Reg. at 9486. CMS provided no further explanation for its seemingly narrow construction of the word “directly.”

CMS’s construction of the Act, while plausible, is not the most natural reading of the “directly benefits patients” language – particularly in light of evidence that patients derive numerous benefits from the medical textbooks disseminated to doctors. Congress most likely included the word “directly” because it wished to make clear that it did not intend to exempt gifts that have, at most, only an attenuated relationship with benefit to patients. For example, the gift to a doctor of an all-expenses-paid trip to Hawaii to attend a medical seminar arguably is of benefit to patients because the doctor may learn something at the seminar that later benefits her patients, and she might not have attended the seminar had a drug company not paid travel and lodging expenses. But any correlation between the gift and subsequent benefits to patients is highly attenuated; most people would consider the payment of travel and lodging expenses at a luxury vacation resort to be primarily of benefit to the doctor, not her patients. On the other hand, because the only value of information contained in a medical textbook derives from a doctor’s ability to use that information in treating patients, the relationship between a medical textbook and benefits to patients is far closer – and thus is the sort of educational material that most people would consider to be of “direct” benefit to patients.

Moreover, there is considerable evidence that when it adopted the Act, Congress thought

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it was codifying PhRMA's "Code on Interactions with Healthcare Professionals." As noted above, the Code explicitly endorses gifts of "educational items such as a medical text book" because of their educational value. It is unlikely that a Congress that thought it was writing the PhRMA Code into federal law would have drafted an exclusion that covered "educational materials that directly benefit patients" if its intent was to express disagreement with the Code with respect to medical textbooks.

In light of the grave constitutional issues raised by CMS's rule, courts will not defer to CMS's reading of the Act (for the reasons explained above) even if they deem it a plausible reading. Accordingly, WLF urges CMS to re-examine the statutory issue, particularly in light of CMS's apparent failure to consider First Amendment implications of the issue the first time around. Such a re-examination would not require any change in the newly released regulations, because the regulations do not directly address the status of medical textbooks.

In particular, WLF requests that CMS delay any implementation of reporting requirements for medical textbooks until after it has an opportunity to undertake a study of whether (as many observers have predicted) applying the Act as currently proposed would result in a significant reduction in manufacturer dissemination of medical textbooks. If the study concludes that the answer is yes, then CMS should comply with First Amendment constraints by announcing that medical textbooks fall within the Act's exclusion for "educational materials that directly benefit patients." By doing so, CMS can avoid litigation that will almost surely arise if CMS persists with its current interpretation.

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Conclusion

Because CMS's decision to apply the Physician Payment Sunshine Act to dissemination of medical textbooks raises serious First Amendment concerns, the Washington Legal Foundation respectfully requests that CMS re-examine that decision. It further requests that CMS delay the Act's applicability to the dissemination of medical textbooks until the re-examination process can be completed.

Respectfully submitted,

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