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December 2, 2002

BY HAND DELIVERY

Janet Rehnquist, Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-8-CPG
Room 5426, Cohen Building
330 Independence Ave., S.W.
Washington, D.C. 20201

Re: Draft OIG Compliance Guidance for Pharmaceutical Manufacturers (OIG-8-CPG)

Dear Ms. Rehnquist:

We appreciate this opportunity to comment on the Draft Compliance Guidance for Pharmaceutical Manufacturers published in the Federal Register on October 3, 2002 ("Draft Guidance"). We submit these comments on behalf of several pharmaceutical manufacturers.

We support the OIG's issuance of compliance program guidance for various segments of the health care industry, including pharmaceutical manufacturers. However, we have several concerns with the Draft Guidance. One overarching concern is the lack of specificity in the discussion of certain risk areas. We are especially troubled by numerous vague warnings throughout the document that certain practices should be "carefully reviewed." These warnings often group together vastly different types of practices, do not acknowledge the availability of safe harbors or other ways to protect the practices at issue, and do not otherwise explain how such practices should be reviewed and evaluated. Such explanations

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are necessary for manufacturers as they attempt to develop or revise policies and procedures to assure compliance with applicable laws.

As discussed in more detail below, we urge the OIG to provide greater clarity on several issues discussed in the Draft Guidance, including the following:

- the types of price concessions that may qualify for the discount safe harbor;
- the permissibility of market share discounts;
- the permissibility of multiple product discounts;
- the permissibility of discount arrangements with pharmacy benefit management companies (PBMs);
- how to determine "fair market value";
- the circumstances under which the OIG believes that a violation of the anti-kickback statute can give rise to liability under the False Claims Act; and
- the permissibility of industry support of continuing medical education.

We address these, and other concerns, in the discussion below. We have limited our comments to certain of the "Specific Risk Areas" identified in the Draft Guidance.[1] For the sake of consistency, we follow the order of topics as set forth in the Draft Guidance.

Kickbacks and Other Illegal Remuneration

We have several concerns with the discussion in the Draft Guidance regarding kickbacks. Many of the cautionary statements made in this section of the Draft Guidance are overbroad, and there is a lack of specific guidance from the OIG that is necessary for manufacturers as they attempt to develop policies and procedures to ensure compliance with the anti-kickback law. The effect is to taint many legitimate activities which clearly are not kickbacks. The OIG owes manufacturers more precision here

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1 67 Fed. Reg. 62057, 62060-626063 (October 3, 2002).

to avoid deterring clearly lawful and beneficial activities along with those that are illegal or abusive.

Kickbacks as False Claims

The Draft Guidance states that "a violation of the anti-kickback statute may give rise to liability under the False Claims Act."[2] This is rather like saying that conspiring with a competitor in an unfair trade practice, or any number of other "bad" acts, *may* result in liability under the FCA: all may set into motion a series of events that result in presenting or causing to be presented a false claim, but none in and of themselves necessarily relates to an FCA violation. In other words, the statement is so overbroad that it is misleading. The FCA does not provide that violations of other statutes or regulations may serve as a basis for establishing FCA liability. And the Supreme Court has cautioned that "the False Claims Act was not designed to reach every kind of fraud practiced on the Government,"[3] a result that could be reached under this broad statement in the Draft Guidance.

It is clear that the existence of a kickback, by itself, does not give rise to a false claim. In perhaps the most recent case to address this issue, the court stated that "a violation of the federal antikickback provision is not a *per se* violation of the FCA."[4] That court relied in part on Thompson v. Columbia/HCA Healthcare Corp., a case in which the Fifth Circuit confirmed that violations of statutes and regulations are insufficient, in themselves, for stating a cause of action under the False Claims Act.[5]

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2 63 Fed. Reg. at 62061.

3 U.S. v. McNinch, 356 U.S. 595, 599 (1958).

4 U.S. *ex rel* Franklin v. Parke-Davis, 147 F.Supp.2d 39, 54 (D.Mass. 2001).

5 125 F.3d 899 (5th Cir. 1997).

Most courts have found that violations of statutory or regulatory requirements, by themselves, do not give rise to FCA liability.[6] A few courts have found that false certifications of compliance with statutes and regulations may give rise to FCA liability when certification is an express prerequisite to obtaining a government payment, although even this is far from a universally accepted view.[7] Moreover, even under this theory, a kickback violation can result in a false claim only if the claim form includes a (false) certification that the provider or supplier has not violated the anti-kickback statute, and the relevant payor relies on that statement in making payment on the claim.[8]

Accordingly, the current state of the law in most jurisdictions appears to be that violations of other laws do *not* give rise to FCA liability, and certainly not without an express certification of compliance that is a prerequisite to obtaining payment. The OIG's statement in the Draft Guidance is inappropriate in light of the current state of the law. We urge the OIG either to delete this reference entirely, or to revise the sentence at

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6 *See, e.g.,* U.S. *ex rel* Am. Textile Mfrs. Inst., Inc. v. The Limited, Inc., No. C2-97-776, 1997 U.S. Dist. LEXIS 18142 (S.D. Ohio 1997), *aff'd* 190 F.3d 729 (6th Cir. 1999) ("Congress, by amending the False Claims Act in 1986 [did not intend] to convert that Act into an all-inclusive vehicle for the enforcement of any federal statute or government regulation"); U.S. *ex rel* Luckey v. Baxter Health Care Corp., 2 F.Supp.2d 1034, 1045 (N.D. Ill. 1998), *aff'd* 183 F.3d 730 (7th Cir. 1999) (it is a "well-established principle that the [False Claims Act] is not a vehicle for regulatory compliance").

7 *See, e.g.,* U.S. *ex rel* Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996); U.S. *ex rel* Sharp v. Consolidated Med. Transp., Inc., No. 96C 6502, 2001 WL 1035720 (N.D. Ill. 2001). But *see, e.g.,* Thompson v. Columbia/HCA Healthcare Corp., 938 F.Supp. 399 (S.D. Tex. 1996) ("false statements in [hospital cost report] certifications do not render the claims false"); U.S. v. Hill, 676 F.Supp. 1158, 1174 (N.D. Fl. 1987) ("a false statement is not coterminous with a false claim").

8 One district court has also found "implied certification" by virtue of the defendant's participation in federal health care programs. U.S. *ex rel* Pogue v. American Healthcorp, Inc., 914 F.Supp. 1507, 1513 (M.D.Tenn.1996). However, the implied certification theory has been heavily criticized, and has been expressly rejected by a number of courts. *See, e.g.,* U.S. *ex rel* Joslin v. Community Home Health of Maryland, Inc., 984 F.Supp. 374 (D. Md. 1997); U.S. *ex rel* Hopper v. Anton, 91 F.3d 1261, 1265 (9th Cir. 1996); U.S. *ex rel* Mikes v. Strauss, 84 F.Supp.2d 427, 435 (S.D.N.Y. 1999). This theory is inconsistent with the language of the statute, and would have the effect of encouraging *qui tam* suits premised on a wide range of conduct not contemplated by the FCA.

issue to state: "Some courts have found that violations of the anti-kickback statute may give rise to liability under the False Claims Act if the defendant has certified compliance with the anti-kickback statute and such certification is a prerequisite to obtaining payment."

(1) Relationships with Purchasers

(a) Discounts and Other Terms of Sale

The discussion of discounts in the Draft Guidance should be clarified in several respects. First, the OIG should acknowledge that there are a number of ways to structure the arrangements referenced in this section to avoid liability under the anti-kickback statute. For example, discounts to many purchasers may be protected under the statutory exception for discounts[9] or the regulatory "safe harbor" for discounts[10]; payments to group purchasing organizations (GPOs) may be protected under the GPO safe harbor[11]; payments for services may be protected under the personal services safe harbor[12]; and discounts to wholesalers have been approved by the OIG under certain circumstances even if they do not technically satisfy an exception or safe harbor.[13] The Draft Guidance does not consistently acknowledge the availability of these alternatives, which are clearly applicable to many of the practices as to which the Draft Guidance suggests a concern may exist.

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9 42 U.S.C. §1320a-7b(b)(3)(A).

10 42 C.F.R. §1001.952(h).

11 42 C.F.R. §1001.952(j).

12 42 C.F.R. §1001.952(d).

13 OIG Advisory Opinion 98-2 (April 8, 1998).

Wholesalers

The Draft Guidance states that "price concessions or benefits offered to a wholesaler potentially implicate the statute."[14] However, the Draft Guidance fails to mention that the OIG has approved drug discounts to wholesalers as long as the manufacturer takes the discount into account for purposes of computing average manufacturers price (AMP) and best price (BP) under the Medicaid Rebate Statute,[15] and otherwise meets the reporting and disclosure requirements of the discount safe harbor.[16] The final guidance should specifically state that discounts to wholesalers are not problematic if they satisfy the criteria set forth by the OIG in Advisory Opinion 98-2.

GPOs and PBMs

The Draft Guidance states that "incentive payments to GPOs [and] PBMs also potentially implicate the anti-kickback statute."[17] However, administrative fees paid to GPOs are easily protected by the GPO safe harbor, if appropriate disclosures are made to the GPO's members and the entity qualifies as a GPO under the safe harbor definition. Unless and until Congress alters or eliminates the statutory exception for GPO administrative fees, there is no reason that an "incentive payment" could not meet these criteria. The final guidance should make this clear.

PBMs typically do not purchase products from manufacturers. Rather, they negotiate good prices and other favorable terms for such

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14 67 Fed. Reg. at 62061.

15 42 U.S.C. §1396r-8.

16 OIG Advisory Opinion 98-2 (April 8, 1998).

17 67 Fed. Reg. at 62061.

purchases on behalf of health plans and other payors. PBMs serve important functions in the pharmaceutical sale and distribution process, including contracting with pharmaceutical companies on behalf of health plans and aggregating purchasing power for larger rebates. Accordingly, they have the ability to significantly reduce pharmaceutical costs for plans, beneficiaries, and Federal health care programs.

If discounts or rebates obtained by PBMs are passed through to health plan purchasers, then such arrangements may be structured to qualify for protection under the discount safe harbor. Even if such rebates are not passed through to health plans, they should not be seen as abusive as long as certain safeguards are in place. Specifically, if PBMs disclose to the health plans the rebates they receive, the health plans are in a position to act as prudent purchasers, either by negotiating greater pass-throughs from the PBM, or by making the judgment that the drug prices negotiated with the PBM (and thus available to the plans) are sufficiently low that the PBM should be able to retain all or part of the rebate as part of its fee for services to the plan. Similarly, if plans acknowledge in their contracts with PBMs that disclosure of specific amounts retained is unnecessary because the plans are satisfied with the terms of the contract regardless of any rebates obtained by the PBMs, there would be no risk of abuse.[18] We urge the OIG to acknowledge in the final guidance that discounts to PBMs are protected under the discount safe harbor if they are passed through to the purchasers and meet the other requirements, and that discounts not passed through are not problematic as long as there is appropriate transparency in the PBM-plan relationship.

Other Price Concessions

We are also concerned about the statement in this section of the Draft Guidance that certain kinds of price concessions "including, but not

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18 Also, to the extent that PBMs act on behalf of capitated health plans, there is no risk of harm to Federal health care programs. These plans include Medicare+Choice organizations, Medicaid managed care plans, and other plans that receive fixed payments (*e.g.*, per member per month payments) from a Federal or State agency.

limited to, discounts on other products, other free or reduced price goods or services, 'educational' or other grants, 'conversion payments,' signing bonuses, or 'up-front payments' do not qualify for the discount exception and should be carefully reviewed."[19] This is an overbroad and imprecise statement that groups together disparate practices, many of which clearly can be protected under a safe harbor or otherwise ought to be permissible. We discuss each of these practices below.

- *Discounts on Other Products.* With respect to "discounts on other products," the statement above errs by significant omission. The discount safe harbor clearly states that one product may be offered at a discount or without charge as an inducement for the purchase of a different product as long as both products are reimbursed under the "same methodology."[20] Thus, despite the unqualified statement in the Draft Guidance that these types of arrangements may not be protected, the safe harbor expressly protects "multiple product" discounts that are reimbursed under the same reimbursement methodology. The OIG should make this clear in the final guidance.

In addition, the OIG should clarify its interpretation of the term "same methodology." In a Notice of Proposed Rulemaking from 2000, the OIG proposed a "clarification" of this term.[21] Since this proposal was in the form of a clarification, not a revision, and since the regulation would still refer to the same *methodology*, it appears that this proposed change is intended only to give examples of some of the reimbursement methodologies that may apply. This reading of the proposed clarification would appear to permit the bundling of items or services that are reimbursed under the same general payment system, regardless of whether the bundled

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19 67 Fed. Reg. at 62061.

20 42 C.F.R. §1001.952(h)(5)(ii).

21 65 Fed. Reg. 63035, 63036 (Oct. 20, 2000). The proposal would add the following parenthetical to the text of the regulation to clarify the term "same methodology": "(e.g., under the same DRG, prospective payment, or per diem, but not including fee schedules)."

items are used in separate incidents of service or are reimbursed under separate payment "codes."[22]

However, the proposal is nonetheless troubling because it might be read to suggest that bundled products could qualify for the safe harbor only if the products are reimbursed under the same code or are provided within a single incident of service. Either of those interpretations would not only run afoul of the plain language of the safe harbor, but also would be so impractical as to make the provision essentially useless. Many drugs are used across a wide range of disease states, and therefore are paid under many different DRGs and APCs. Two obvious examples are antibiotics and anti-emetics. Prohibiting bundled discounts on such products would not advance any of the objectives of the discount safe harbor, and would be likely to chill the availability of many cost-reducing discount arrangements that pose little or no risk of fraud or abuse.

As the OIG has acknowledged, multiple product discounts are problematic to the extent that they may permit parties to shift costs among reimbursement systems and to distort the true costs of items.[23] This consideration is absent if all products or services included in the discount are reimbursed using the same general reimbursement methodology. The OIG should acknowledge the legitimacy of these circumstances to avoid chilling appropriate activity while discouraging inappropriate activity.

- *Other Free or Reduced Price Goods or Services.* As discussed below in the section on "Other Terms of Sale," many "value-added" goods and services are properly viewed as included in the purchase price for a product, in part because they have no value apart from the product itself. This is true, for example, with respect to billing assistance and reimbursement consultation programs that assist customers with payment for the manufacturer's own products. The OIG has recognized that "standing alone, these services have no substantial independent value and do not

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22 For instance, DRG or APC codes.

23 OIG Advisory Opinion 02-10 (July 30, 2002).

implicate the anti-kickback law."[24] The OIG should confirm in the final guidance that these types of items and services do not raise concerns under the anti-kickback law, whether or not they qualify as "discounts."

- *Educational or Other Grants.* The anti-kickback law is implicated only if one non-incidental purpose of the arrangement is to induce purchases or referrals.[25] It is clear that a grant or donation whose sole purpose is to serve a legitimate educational function or to support a valid charitable endeavor does not implicate the anti-kickback law. In addition, many manufacturers provide support for research that may advance the general state of knowledge in an area of interest to them without providing the company with any exclusive or proprietary rights. Further, some payments that the parties denominate as "grants" may in fact reflect payments for services to be provided for the manufacturer. Such payments may be protected under the personal services safe harbor, or may otherwise be permissible if they are not intended to induce purchases. The OIG should confirm in the final guidance that educational grants are permissible if they are not intended to induce purchases, and that payments for services may be protected under the personal services safe harbor even if they are called "grants."

- *Conversion Payments.* As discussed below in the section on "Switching Arrangements," certain of these arrangements can be structured to fit within safe harbors. For example, some fee for service arrangements may be structured to satisfy the personal services safe harbor even if they result in switching. Further, to the extent that "market share" and similar

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24 OIG Advisory Opinion 00-10 (December 28, 2000).

25 U.S. v. Greber, 760 F.2d 68, 72 (3rd Cir.), *cert. denied* 474 U.S. 988 (1985) ("If the payments were intended to induce the physician to use [defendant's] services, the statute was violated, even if the payments were also intended to compensate for professional services"); U.S. v. Bay State Ambulance & Hospital Rental Serv., Inc., 874 F.2d 20,30 (1st Cir. 1989) (noting that the "issue of the sole versus primary reason for payments is irrelevant since any amount of inducement is illegal," but approving a jury instruction that prohibited conviction if the improper purpose was "incidental" or "minor"); U.S. v. Kats, 871 F.2d 105,108 (9th Cir. 1989) (approving jury instruction that guilt could be found "if you find beyond a reasonable doubt that one of the *material* purposes for the solicitation was to obtain money for the referral of services") (emphasis in original).

discounts are viewed as falling within this category, they can be structured to satisfy the discount safe harbor. The OIG's statements should acknowledge this by distinguishing payments that clearly can be protected by a safe harbor, regardless of whether they result in product "switching," from other payments.

- *Signing Bonuses.* It is unclear what is meant by the term "signing bonus." A signing bonus given as partial compensation for services provided to a manufacturer by an agent may be protected under the personal services safe harbor. In addition, a signing bonus given in connection with an agreement to purchase products may be protected under the discount safe harbor if it is properly treated as a rebate or time of sale discount under the safe harbor.[26] We encourage the OIG to clarify what it means by a "signing bonus" and to acknowledge that such payments are clearly permissible if they satisfy a safe harbor.

- *Up-Front Payments.* We are aware of the OIG's general concerns with up-front payments and "prebates."[27] However, certain types of up-front payments should not be seen as problematic. For instance, an up-front payment may reflect an estimated rebate that may be later reconciled by the parties based on actual sales volume or other specified criteria. Depending on the timing of the sale and payment, this type of arrangement could be protected as a rebate under the discount safe harbor.

Finally, the Draft Guidance appears to make no distinction between the statutory exception for discounts and the regulatory "safe harbor." This is an important point because the two provisions contain significantly different requirements for protecting certain discount arrangements from liability under the anti-kickback law. While we are aware that the OIG has in the past taken the position that the statutory

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26 This would require, among other things, that the bonus be paid other than at the time of sale. This should be feasible, however, since a "signing bonus" need not be made at the time of "signing."

27 *See* OIG correspondence (from D. McCarty Thornton) regarding "up-front rebates, prebates, and signing bonus payments" (July 17, 2000).

exception is encompassed within the safe harbor, in the only judicial decision to address this issue, the court specifically held that the statutory exception and the regulatory safe harbor "are separate and independent bases" for protecting discount arrangements.[28] Since they have now both been judicially recognized, the OIG should acknowledge these separate and independent bases.

Other Terms of Sale

The Draft Guidance suggests that certain services offered in connection with the sale of products may be problematic. Such services include product-related billing assistance and reimbursement consultation programs.[29] Specifically, the OIG is concerned about programs that "eliminate an expense that the purchaser or referral source would have otherwise incurred."[30] This statement is too broad, and should be clarified to avoid chilling protected or otherwise appropriate support programs.

As the OIG has acknowledged, billing and reimbursement assistance programs, on their own, have no independent value for providers and that the cost associated with these programs is included in the purchase price for the product. "Standing alone, these services have no substantial independent value and do not implicate the anti-kickback law."[31] CMS has also approvingly acknowledged the practice of providing such support services to customers. In a transmittal to intermediaries regarding the hospital outpatient prospective payment system, CMS stated that "[m]any device manufacturers routinely provide hospital customers with information about appropriate coding of their devices. We understand that information

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28 U.S. v. Shaw, 106 F.Supp. 103, 113 (D. Mass. 2000).

29 67 Fed. Reg. at 62061.

30 *Id.*

31 OIG Advisory Opinion 00-10 (December 28, 2000).

provided by manufacturers in this manner can significantly simplify the hospitals' task in determining how to bill . . ." [32]

We encourage the OIG to confirm that billing and reimbursement consultation programs of this kind are appropriately viewed as included in the purchase price for a product, or otherwise have no substantial value that could be viewed as "remuneration," comparable to warranties or instructions on proper use. These programs have no value apart from the purchased product, and, by themselves, should not be seen as problematic.

(2) Relationships with Physicians and Other Health Care Professionals

"Switching" Arrangements

The statements in the Draft Guidance regarding so-called "switching" arrangements are vague and potentially misleading. The OIG cautions that direct product conversion payments should be reviewed "very carefully," while programs that have the effect of rewarding switching indirectly should be reviewed "carefully."[33] These admonitions indicate generally that the OIG has concerns about these arrangements. However, the Draft Guidance offers no advice about *how* such arrangements should be reviewed, what features should avoided, or what safeguards may be implemented by manufacturers to minimize potential risk.

First, the OIG should acknowledge that not all "switching arrangements" are inherently problematic. Many of these arrangements relate to compliance with formularies developed by pharmaceutical and therapeutics (P&T) committees whose members are independent from those involved in discount and rebate negotiations. In developing formularies,

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32 CMS Program Memorandum, Transmittal A-01-41 (March 22, 2001).

33 67 Fed. Reg. at 62062.

P&T committees generally consider such factors as safety, efficacy, clinical appropriateness (including therapeutic equivalence), and cost effectiveness. Thus, many "switching programs" have the positive effects of promoting clinically appropriate care, preventing inappropriate utilization, and controlling costs to patients, health plans, and Federal health care programs. Clearly, these are laudable objectives that should be acknowledged and approved by the OIG.

Particularly troubling in this portion of the Draft Guidance is the implication that market share discounts or rebates may be considered suspect. Market share rebates are very common arrangements that closely resemble standard volume discounts. These discounts and rebates may be structured, without difficulty, to fit squarely within the discount safe harbor. In addition, fee for service arrangements with physicians, pharmacists, or others may be structured to satisfy the requirements of the personal services safe harbor. One example of such an arrangement might be a manufacturer of a medical product paying pharmacists to notify patients utilizing a competitor product that the competitor has been recalled by the FDA, and providing educational information on the non-recalled product.[34]

The OIG makes no mention of these safe harbors in this section. When an arrangement fits within a safe harbor, it is irrelevant whether such arrangement may result in "switching"; it is "immune from sanction." In fact, the OIG has acknowledged that certain "switching" arrangements are permissible if they are "fully consistent with a safe harbor regulation."[35] In the final guidance, the OIG should remove any suggestion that market share rebates are problematic, reiterate that some of these arrangements may be protected by safe harbors even if they result in product switching,[36] and acknowledge that arrangements that encourage the use of less costly therapeutic equivalents are not problematic.

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34 FDA does not require pharmacies to send recall notices in these circumstances.

35 67 Fed. Reg. at 62061.

36 OIG Fraud Alert: Prescription Drug Marketing Schemes (August 1994).

Consulting and Advisory Payments

The Draft Guidance acknowledges that consulting and advisory arrangements can be structured to satisfy the personal services safe harbor. However, an important element of that safe harbor is payment of "fair market value" compensation. Moreover, the OIG recommends that manufacturers should "take steps to ensure appropriate documentation of the fair market value determination."[37]

Despite the importance of the "fair market value" concept, the OIG has never issued guidance on how to determine fair market value for services. This is a very significant omission, as manufacturers and others frequently struggle with how to determine fair market value compensation for services. We strongly urge the OIG to address these points in detail in the final guidance.

We believe that fair market value for services should generally reflect payment for comparable services made to similarly-situated physicians (or other healthcare professionals).[38] Specifically, we believe that the following factors are relevant in determining fair market value for a physician's service:

- the value of the physician's time (measurable at least in part based on opportunity cost);
- the physical or intellectual complexity of the service;
- the amount of skill and training required to perform the service
- the risks (if any) to the physician;

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37 67 Fed. Reg. at 62062.

38 This is consistent with the tests set forth in regulations under the Internal Revenue Code (reasonable compensation of physicians by tax exempt entities is "the amount that would ordinarily be paid for like services by like enterprises under the circumstances") (Treas. Reg. § 53.4958-4T(b)(ii)), and in regulations under the physician self-referral ("Stark") law (fair market value is "compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.") (42 C.F.R. §411.351).

- the geographical locus of the service (costs of living and prevailing wages may differ depending on location);
- the availability (or unavailability) of similar services in the geographic area; and
- academic and professional training, degrees, certifications, skills and experience, professional awards and memberships, etc.

We urge the OIG to list these factors (and others, as appropriate) as points to consider in determining fair market value for services. We also ask the OIG to address with more specificity how to appropriately document the fair market value determination.

Fair market value is also an important issue for manufacturers in the context of data purchase agreements with customers. Manufacturers often enter into such agreements in order to obtain valuable information about the efficacy and use of their products, or for a variety of other legitimate purposes. We encourage the OIG to provide guidance on the determination and documentation of fair market value of data obtained from customers.

Other Remuneration

In general, we support the reference in the Draft Guidance to the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"). The PhRMA Code reflects a sincere effort on the part of the pharmaceutical industry to establish reasonable limits on various arrangements between manufacturers and healthcare professionals. However, we are concerned that the OIG views compliance with the PhRMA Code as only a "minimum" standard of conduct. The PhRMA Code itself makes clear that no benefits of any kind may be offered in exchange for prescribing products or agreeing to prescribe products. Accordingly, practices that comply with the PhRMA Code all should be permissible under the anti-kickback law.

We strongly urge the OIG to clarify that it does not consider practices that comply with the PhRMA Code to be problematic (or to indicate specifically any parts of the Code about which it thinks otherwise). We also urge the OIG to confirm that practices that fail to comply with the PhRMA Code are not *per se* violations of the law.

Sponsorship of CME

One issue in this section of the Draft Guidance warrants particular comment. The OIG notes that "sponsorship or other financing related to third-party educational conferences and meetings" potentially implicates the anti-kickback statute.[39] This is an overbroad statement that could have a chilling effect on industry support of educational meetings and conferences.

It is widely recognized that medical conferences and meetings are valuable educational forums that benefit both physicians and patients. These meetings provide physicians with the most current information on new developments related to clinical procedures, medical technology, and other issues that ensure patients are receiving the best and most appropriate care available. The PhRMA Code and the AMA Guidelines both state that continuing medical education conferences and professional meetings "can contribute to the improvement of patient care." The OIG's broad statement in the Draft Guidance could ultimately harm patient care by slowing or restricting the dissemination of important medical information to healthcare professionals.

Many educational conferences and meetings are supported with financial assistance from industry, including pharmaceutical and medical device manufacturers. This industry support is critical for the continued viability of these meetings. Without such support, medical education providers likely would be forced to curtail or stop offering such educational activities.

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39 67 Fed. Reg. at 62062.

The PhRMA Code, the AMA Guidelines, and the Standards for Commercial Support of CME promulgated by the Accreditation Council on Continuing Medical Education (ACCME) all recognize the importance and permissibility of industry support of CME. Moreover, these codes all include reasonable limits on such support that serve to eliminate risks of program abuse. For instance, the codes generally require that financial support be given to the sponsor, which can use the money to reduce overall conference registration fees for all attendees. In general, funds may not be given directly to physicians. [40] While the codes include restrictions on paying for travel expenses and entertainment for non-faculty healthcare professionals attending CME events, they do not restrict financial support for the conference provided to the sponsor. This is consistent with the position that financial support to a CME sponsor does not represent remuneration to the attendees or faculty of such events.

We strongly encourage the OIG to clarify in the final guidance that sponsorship of educational conferences and meetings does not implicate the anti-kickback law, and that the OIG agrees with the PhRMA Code's treatment of this issue.

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Thank you very much for the opportunity to comment on the Draft Guidance. We look forward to the OIG's responses to our concerns in the final guidance.

Respectfully submitted by,

Carl B. Feldbaum
President
Biotechnology Industry Organization

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40 The codes permit the provision of funds to permit medical students, residents, and fellows to attend conferences, including payment for travel expenses, under certain circumstances.