

further funding for clinical trials, and an extensive amount of time to even reach the stage of applying to the FDA for approval. The regulatory approval process itself can also be time-consuming as the FDA reviews the volume of material and data a company submits in support of its application.

#### *The Consent Agreement*

The Consent Agreement remedies the competitive concerns raised by Abbott's proposed acquisition of St. Jude by requiring that the parties divest to Terumo all of the assets and resources needed for it to become an independent, viable, and effective competitor in the U.S. markets for vascular closure devices and steerable sheaths. It also requires Abbott to provide notice if it intends to acquire ACT's lesion-assessing ablation catheter assets.

Terumo possesses the industry experience and reputation necessary to replace competition that would be lost in the U.S. markets for vascular closure devices and steerable sheaths. Terumo is headquartered in Tokyo, Japan. It has been active in the U.S. medical device market for over thirty years and has a U.S. subsidiary based in Somerset, New Jersey. Terumo offers a portfolio of products that are highly complementary to the vascular closure and steerable sheath products being acquired but does not sell any competing products. Through its Interventional Systems business unit, Terumo manufactures and sells guidewires, catheters, and sheaths, as well as other vascular access devices. As a result, it currently sells its products to many of the same customers as Abbott and St. Jude. Terumo is thus well positioned to restore the benefits of competition that would be lost through the Proposed Acquisition.

Pursuant to the Order, Terumo will receive all rights and assets related to St. Jude's vascular closure device business and Abbott's steerable sheath business, including all of the intellectual property used in those businesses. In addition, Terumo will take over part of the facility in Caguas, Puerto Rico where St. Jude currently manufactures most of its vascular closure device products. In order to ensure continuity of supply for certain vascular closure devices and components that are not currently manufactured in the Puerto Rico facility, the Order requires that St. Jude supply Terumo with finished vascular closure devices and components for up to two years while Terumo transitions to independent manufacturing.

To ensure that the divestiture is successful, the Order requires the parties to enter into a transitional services agreement with Terumo to

assist the company in establishing its manufacturing capabilities. Further, the Order requires that the parties transfer all confidential business information to Terumo, as well as provide access to employees who possess or are able to identify such information. Terumo also will have the right to interview and offer employment to employees associated with St. Jude's vascular closure device business and Abbott's steerable sheath business.

The parties must accomplish the divestiture no later than forty-five days after the consummation of the Proposed Acquisition. If the Commission determines that Terumo is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires the parties to unwind the sale and accomplish the divestiture within 180 days of the date the Order becomes final to another Commission-approved acquirer.

To ensure compliance with the Order, the Commission has agreed to appoint an Interim Monitor to ensure that Abbott and St. Jude comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Terumo. Further, the Order allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture should the parties fail to comply with their divestiture obligations. Lastly, the Order terminates after ten years.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

**April J. Tabor,**

*Acting Secretary.*

[FR Doc. 2016-31800 Filed 12-30-16; 8:45 am]

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#### **GENERAL SERVICES ADMINISTRATION**

**[Notice-MA-2016-08; Docket No. 2016-0002; Sequence No. 31]**

#### **Federal Management Regulations; Transportation Prepayment Audit Requirements**

**AGENCY:** Office of Government-wide Policy, General Services Administration (GSA).

**ACTION:** Notice of a bulletin.

**SUMMARY:** GSA has issued a guidance for agencies and wholly-owned Government corporations, which

provides a deadline to comply with recent regulatory changes that prohibit agencies from using prepayment auditors that have any affiliation with, or financial interest, in the transportation company (providing the transportation services) for which a prepayment audit is being conducted.

**DATES:** *Effective:* January 3, 2017.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ron Siegel, Program Analyst, Office of Government-wide Policy (MAF), Office of Asset and Transportation Management, General Services Administration at 202-357-9540, or via email at [ron.siegel@gsa.gov](mailto:ron.siegel@gsa.gov). Please cite FMR Bulletin D-03.

**SUPPLEMENTARY INFORMATION:** FMR Bulletin D-03 provides guidance to all agencies (including the Department of Defense) and wholly-owned Government corporations as defined in 31 United States Code (U.S.C.) 101, *et seq.* and 31 U.S.C. 9101(3). This bulletin provides agencies notice of a governmentwide policy revision for mandatory transportation prepayment audit plans, and provides a deadline for compliance with regulatory changes provided in FMR 102-118, Transportation Payment and Audit. FMR Bulletin D-03 and all other FMR bulletins are located at <http://www.gsa.gov/fmrbulletins>.

**Kevin Kampschroer,**

*Associate Administrator (Acting), Office of Government-wide Policy, General Services Administration.*

[FR Doc. 2016-31786 Filed 12-30-16; 8:45 am]

**BILLING CODE 6820-14-P**

#### **OFFICE OF GOVERNMENT ETHICS**

#### **Request for Public Input on the Application of the Criminal Conflict of Interest Prohibition to Certain Beneficial Interests in Discretionary Trusts.**

**AGENCY:** Office of Government Ethics (OGE).

**ACTION:** Notice of request for public comments.

**SUMMARY:** This notice and request seeks input from members of the public with expertise in trust law concerning the following question: Are there any circumstances under which an eligible income beneficiary of a discretionary trust might, in the absence of a vested remainder interest, be able to compel the trust to make a distribution or payment? OGE will take into consideration all relevant expert input submitted by the public within 60 days of the date of this notice. To be

considered, any submission exceeding five (5) pages in length must include a one-page summary of key points and conclusions. Commenters are requested to state briefly the nature of their expertise in trust law.

**DATES:** To be assured consideration, comments must be received at the address provided below, by no later than 5:00 p.m. on March 6, 2017.

**ADDRESSES:** You may submit comments, in writing, to OGE regarding this notice and request by any of the following methods:

*E-Mail:* [usoge@oge.gov](mailto:usoge@oge.gov). Include the reference "Request for Input on Discretionary Trusts" in the subject line of the message.

*Fax:* (202) 482-9237.

*Mail/Hand Delivery/Courier:* U.S. Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005-3917, Attention: "Request for Input on Discretionary Trusts."

*Instructions:* All submissions must include OGE's agency name and the words "Discretionary Trusts." All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Comments may be posted on OGE's Web site, [www.oge.gov](http://www.oge.gov). Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

**FOR FURTHER INFORMATION CONTACT:** Jennifer A. Matis, Assistant Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005-3917; Telephone: 202-482-9300; TTY: 800-877-8339; FAX: 202-482-9237.

**SUPPLEMENTARY INFORMATION:** During the administration of President George W. Bush, a former Director of the U.S. Office of Government Ethics (OGE), Hon. Robert I. Cusick, issued a guidance memorandum addressing a novel legal issue concerning the application of the primary criminal conflict of interest statute to the interests of eligible income beneficiaries of discretionary trusts who lack vested remainder interests. *Discretionary Trusts*, DO-08-024 (2008). That conflict of interest statute, 18 U.S.C. 208, prohibits an executive branch employee from participating personally and substantially in any particular matter that directly and predictably affects a "financial interest" of either the employee or a person whose interests are imputed to the employee (e.g., the employee's spouse or minor child). See 5 CFR part 2640,

subpart A. The 2008 memorandum articulated OGE's conclusion that, for purposes of the conflict of interest statute, an eligible income beneficiary of a discretionary trust would not be considered to have a financial interest in the holdings of the trust, provided that the beneficiary was not the grantor and did not have a vested remainder interest. *Discretionary Trusts*, DO-08-024 (2008). The premise underlying OGE's conclusion was that such a beneficiary could never have an "enforceable right to payment." *Id.* at 1. For this premise OGE relied upon the American Law Institute's Second Restatement of the Law of Trusts. *Id.* (citing Restatement of the Law (Second) Trusts, § 155).

In 2013, OGE issued a second guidance memorandum on the topic of reporting requirements applicable to a beneficiary who could meet the requirements articulated in its 2008 memorandum. The 2013 memorandum clarified that such a beneficiary would not have to report the holdings of the discretionary trust in an executive branch financial disclosure report filed under the Ethics in Government Act, 5 U.S.C. app. 101, *et seq.*, in the event that the beneficiary were to receive income from the trust during the reporting period, though the beneficiary would have to report the income itself. *Reporting Requirements for Discretionary Trusts*, LA-13-04 (April 9, 2013). The 2013 memorandum did not otherwise modify the 2008 memorandum or revisit its underlying premise.

The 2008 memorandum, which OGE has continued to apply, is based wholly on the premise that there are no circumstances under which such a beneficiary could ever compel a distribution or payment from a discretionary trust. This month, however, OGE learned that the American Law Institute's Third Restatement of the Law of Trusts may suggest a contrary analysis as to the financial interests of eligible income beneficiaries of discretionary trusts, at least in some jurisdictions. See Restatement of the Law (Third) Trusts, § 60, cmt. e (Am. Law Inst. 2003) ("A transferee or creditor of a trust beneficiary cannot compel the trustee to make discretionary distributions if the beneficiary personally could not do so. It is rare, however, that the beneficiary's circumstances, the terms of the discretionary power, and the purposes of the trust leave the beneficiary so powerless. The exercise or nonexercise of fiduciary discretion is always subject to judicial review to prevent abuse.").

This discovery drew OGE's attention to an article in the *Quinnipiac Probate Law Journal* by Alan Newman, Professor of Law for the University of Akron School of Law. See Newman, Alan, *Trust Law in the Twenty-First Century: Challenges to Fiduciary Accountability*, 29 *Quinnipiac Prob. L.J.* 261 (2016). Professor Newman writes,

"[I]f, in fact, the beneficiary of a discretionary trust had only an expectancy with respect to the trust, arguably the beneficiary would be unable to hold the trustee accountable to enforce the trust. However, as noted elsewhere, 'the difficulty with this theory is that it is not true.' Although there is a longstanding debate whether a beneficiary of a trust has a property interest in the trust assets, merely a claim against the trustee, or both, it is well-established that: (i) the beneficiary's interest in the trust itself is property, regardless of whether the trust terms provide that distributions to the beneficiary are at the trustee's discretion; and (ii) the beneficiary may enforce them.

*Id.* at 282 (quoting Jesse Dukeminier & Robert H. Sitkoff, *Wills, Trusts, and Estates* 689 (9th ed. 2013)).

Professor Newman further explains that cases denying the claims of a beneficiary's creditors against the trust reflect only a "policy-oriented" approach to addressing the claims of creditors and do not necessarily stand as evidence that the beneficiary lacks "an enforceable property interest with respect to the trust." *Id.* at 283. At the time of its 2008 memorandum, OGE's research focused on cases addressing the rights of creditors or the eligibility of beneficiaries for public assistance, but Professor Newman's article raises a question as to whether OGE should have focused instead on cases addressing the rights of beneficiaries as to trustees of discretionary trusts. See, e.g., *id.* at 284 ("[R]ecently enacted statutes stating that beneficiaries of discretionary trusts do not have property interests with respect to those trusts are part of the enacting jurisdictions' trust codes addressing the rights of beneficiaries' creditors, not the relationship between the trustee and beneficiaries, and appear intended to apply only in the creditors' rights context.").

OGE reviewed one of the cases cited in Professor Newman's article. In that case, the Seventh Circuit wrote,

We see no reason why a beneficiary, simply by virtue of being the beneficiary of discretionary trust, should be denied the ordinary equitable rights that flow from the fiduciary duty that runs from a trustee to a beneficiary. Included in those rights is the right to bring an action for breach of trust.

*Scanlan v. Eisenberg*, 669 F.3d 838, 844 (7th Cir. Ill. 2012). The plaintiff in

that case, a beneficiary of several trusts, sued for malpractice and breach of fiduciary duty after the trusts invested millions of dollars in a real estate investment trust that later went bankrupt. The Seventh Circuit found that an eligible beneficiary possessed the required stake to establish standing as a result of her interest in the trust. *Id.* at 846. To the extent that the plaintiff had standing by virtue of being affected by the trust's potential for gain or loss, that "stake" would appear to meet OGE's definition of a disqualifying financial interest for purposes of the conflict of interest prohibition. See 5 CFR 2640.103(b) ("the term financial interest means the potential for gain or loss").

Other cases also seem to lead to this conclusion. For example, a New York court similarly provided the following guidance, under the trust law of that state, as to the rights of the beneficiary of a discretionary trust:

In the present case, the trustees' discretion is absolute and not limited by any standard. However, even in such a case, the trustees may be compelled to distribute funds to the beneficiary if they abuse their discretion in refusing to make distribution.

*Estate of Gilbert*, 156 Misc. 2d 379, 383 (N.Y. Sur. Ct. 1992). Likewise, a California court held that, under that state's trust law, a trustee who has discretion to make or withhold a payment, may not withhold a payment with the intent of avoiding child support. *Ventura County Dept. of Child Support Services v. Brown*, 117 Cal. App. 4th 144, 150 (Cal. App. 2d Dist. 2004) (quoting Prof. Russell Niles, consultant to Cal. Law Revision Com., Memo Re Spendthrift and Related Trusts (Nov. 6, 1984)). In the California case, the outcome may well have been determined in part by language in the trust instrument requiring that the trust be administered for the benefit of the beneficiary's children in the event of the beneficiary's death, see *id.* at 148; however, this contributing factor would serve only to complicate the issue for OGE by leaving open the possibility that subtle variations in trust language may be relevant in determining the existence of a financial interest for purposes of the conflict of interest law.

Because it is not clear to OGE whether these materials represent the rule, an exception, or differing approaches to trust law in various jurisdictions, OGE would benefit from the input of members of the public who have expertise in trust law. Specifically, OGE seeks expert input concerning the following question: *Are there any circumstances under which an eligible*

*income beneficiary of a discretionary trust might, in the absence of a vested remainder interest, be able to compel the trust to make a distribution or payment?* Should this question be appropriately answered in the affirmative, OGE may need to revisit the premise underlying its 2008 guidance memorandum on discretionary trusts—*i.e.*, that such a beneficiary could never have enforceable right to a distribution or payment from the trust. OGE will take into consideration all relevant expert input submitted by the public within 60 days of the date of this notice in response to the question posed before evaluating the continuing validity of OGE's guidance memorandum, *Discretionary Trusts*, DO-08-024 (2008). To be considered, any submission exceeding five (5) pages in length must include a one-page summary of key points and conclusions. Commenters are requested to state briefly the nature of their expertise in trust law.

Approved: December 23, 2016.

**Walter M. Shaub, Jr.**

*Director, U.S. Office of Government Ethics.*

[FR Doc. 2016-31583 Filed 12-30-16; 8:45 am]

**BILLING CODE 6345-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[60Day-17-171Y; Docket No. ATSDR-2016-0007]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on "Biomonitoring of Great Lakes Populations Program III." The purpose of the proposed study is to evaluate body burden levels of priority contaminants in Great Lakes residents,

particularly those who are at high exposure risk, in the Milwaukee Bay Estuary Area of Concern (AOC) area that was not previously addressed in ATSDR's previous biomonitoring programs around the Great Lakes.

**DATES:** Written comments must be received on or before March 6, 2017.

**ADDRESSES:** You may submit comments, identified by Docket No. ATSDR-2016-0007 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov*. Follow the instructions for submitting comments.

- **Mail:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

**Please note:** All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have