I disagree with this use of means and instrumentalities. To be liable of deception under means and instrumentalities requires that the party *itself* must make a misrepresentation, as the Commission detailed in *Shell Oil Company*.[2] According to the majority in that case, ''[T]he means and instrumentalities doctrine is intended to apply in cases . . . where the originator of the **unlawful material** is not in privity with consumers'' and ''it is well settled law that the originator is liable if it passes on a **false or misleading representation** with knowledge or reason to expect that consumers may possibly be deceived as a result.'' [3] For example, in *FTC* v. *Magui Publishers, Inc.,* the court found the defendant directly liable for providing the means and instrumentalities to violate Section 5 when it sold Salvador Dali prints with forged signatures to retail customers, who then sold the prints to consumers.[4]

Unlike *Shell* and *Magui Publishers,* the statement that TRUSTe provided to its clients was indisputably truthful at the time. During the period in which TRUSTe required client privacy policies to state that TRUSTe was a non-profit, TRUSTe was, in fact, a non-profit. Once TRUSTe changed to for-profit status, it no longer required clients to state its non-profit status and actively encouraged clients to correct their privacy policies. TRUSTe did not pass to clients any false or misleading representations regarding its for-profit status. Nor was TRUSTe's recertification of Web sites a misrepresentation of TRUSTe's non-profit status to its clients; during recertification TRUSTe again clearly communicated its for-profit status to clients by requesting that its clients update their privacy policies. Because TRUSTe accurately represented its non-profit status to its clients, TRUSTe cannot be primarily liable for deceiving consumers under a means and instrumentalities theory.

TRUSTe's alleged recertifications of untrue statements are more properly analyzed as secondary liability for aiding and abetting.[5] In *Magui Publishers* the court found that the defendant forgers were not only directly liable for their own misstatements, but also secondarily liable for the retailers' fraudulent misrepresentations to consumers because defendants ''supplied their deceptive art work, certificates and promotional materials to their retail customers with full knowledge these customers would use the materials to deceive consumers.'' [6] The court explained that aiding and abetting has three components: ''(1) The existence of an independent primary wrong; (2) actual knowledge by the alleged aider and abettor of the wrong and of his or her role in furthering it; and (3) substantial assistance in the commission of the wrong.'' [7]

It is not clear that TRUSTe's clients committed an independent primary wrong. However, TRUSTe certainly had knowledge of the misstatements in the privacy policies and of TRUSTe's role in facilitating those misstatements. And, arguably, its certifications may have provided substantial assistance in deceiving consumers. Regardless, because TRUSTe never misrepresented its corporate status, TRUSTe's actions regarding its corporate status at most comprise aiding and abetting its clients' actions.

Perhaps all this seems like legal hairsplitting, but it is not. Under the Supreme Court's decision in *Central Bank of Denver* v. *First Interstate Bank of Denver,*[8] the FTC ''may well be precluded from bringing Section 5 cases under an aiding and abetting theory.'' [9] By prosecuting activities more properly analyzed as aiding and abetting under the guise of means and instrumentalities liability, I am concerned that we are stepping beyond the limits the Supreme Court has established. I therefore dissent from Count II.

[FR Doc. 2014–27733 Filed 11–21–14; 8:45 am]

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Brill, and Commissioner Terrell McSweeny, at 2 (Nov. 17, 2014).

[2] *In the Matter of Shell Oil Co.,* 128 F.T.C. 749 (1999).

[3] *Id.* at *10 (Public Statement of Chairman Pitofsky, Commissioner Anthony and Commissioner Thompson) (emphasis added). Similarly, Commissioner Orson Swindle's dissent stated that under FTC precedent, ''means and instrumentalities is a form of primary liability in which the respondent was using another party as the conduit for disseminating **the respondent's misrepresentations** to consumers.'' *Id.* at *14–15 (Dissenting Statement of Commissioner Orson Swindle) (emphasis added). Swindle's dissent likewise emphasized that a defendant ''may not be held primarily liable unless it has actually made a misrepresentation.'' *Id.* (quoting *In re JWP Inc. Securities Lit.,* 928 F. Supp. 1239, 1256 (S.D.N.Y. 1996)). *See also FTC* v. *Magui Publishers, Inc.,* Civ. No. 89–3818RSWL(GX), 1991 WL 90895, at *14, (C.D. Cal. 1991), *aff'd,* 9 F.3d 1551 (9th Cir. 1993) (''One who places in the hands of another a means or instrumentality to be used by another to deceive the public in violation of the FTC Act is directly liable for violating the Act.'').

[4] *Magui Publishers, Inc.,* 1991 WL 90895, at *17.

[5] ''[A] respondent who has provided assistance to another party that has made misrepresentations is at most secondarily liable—in particular, for aiding and abetting another's misrepresentations.'' *Shell Oil Co.,* 128 F.T.C. 749, *15 (1999) (Swindle Dissent) (citing *Wright* v. *Ernst & Young LLP,* 152 F.3d 169, 175 (2d Cir. 1998), *cert. denied,* 119 S.Ct. 870 (1999); *Shapiro* v. *Cantor,* 123 F.3d 717, 720 (2d Cir. 1997); *Anixter* v. *Home-Stake Production Co.,* 77 F.3d 1215, 1225 (10th Cir. 1996) (''the critical element separating primary from aiding and abetting violations is the existence of a representation, made by the defendant.'')).

[6] *Magui Publishers, Inc.,* 1991 WL 90895, at *15.

[7] *Id.* at *14.

[8] *Cent. Bank, N.A.* v. *First Interstate Bank, N.A.,* 511 U.S. 164 (1994).

[9] *Shell Oil Co.,* 128 F.T.C. 749, *19 (Swindle Dissent).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2014–0015]

Request for Comment on Draft Vaccines Adverse Event Reporting System (VAERS) 2.0 Form

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of request for public comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is publishing this notice requesting public comment on the proposed VAERS 2.0 form, which is intended to replace the current VAERS–1 form (*https://vaers.hhs.gov/resources/vaers_form.pdf*). CDC and the U.S. Food and Drug Administration (FDA) co-administer the Vaccines Adverse Event Reporting System (VAERS), a post-licensure (i.e., after vaccines have been licensed by the FDA and are being used in the community) reporting system that accepts submitted reports of adverse events that occur after vaccination from healthcare providers, manufacturers, and the public. Healthcare providers and vaccine manufacturers are required to submit VAERS reports. The National Childhood Vaccine Injury Act of 1986, section 2125 of the Public Health Service Act (42 U.S.C. 300aa–25) authorized VAERS. The current VAERS form has been used since 1990.

DATES: Written comments must be received on or before January 23, 2015.

ADDRESSES: You may submit comments, identified by docket number CDC–2014–0015 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* You may also submit written comments to the following address: Centers for Disease Control and Prevention, (CDC), National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Immunization Safety Office, Attn: VAERS 2.0 form Docket No. CDC–

2014–0015, 1600 Clifton Rd. NE., Mailstop A–07, Atlanta, Georgia, 30333.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* All materials submitted will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Standard Time, at 1600 Clifton Road NE., Atlanta, Georgia 30333. Please call ahead to (404) 639–4000 and ask for a representative from Immunization Safety Office to schedule your visit. You should be aware that this office is in a Federal government building; therefore, Federal security measures are applicable. For additional information, please see Roybal Campus Security Guidelines under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Tiffany Suragh; Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Immunization Safety Office, l600 Clifton Road NE., Mailstop D–26; Atlanta, Georgia, 30329–4018; Telephone: (404) 639–4000.

SUPPLEMENTARY INFORMATION: VAERS is an important and critical ''early warning system'' in the federal vaccine safety infrastructure for identifying adverse events after receipt of childhood, adolescent, and adult vaccines licensed for use in the United States (US). Healthcare providers and vaccine manufacturers are required under section 2125(b) of the Public Health Service Act (42 U.S.C. 300aa–25(b)) to file VAERS reports regarding the occurrence of any event set forth in the Vaccine Injury Table which occurs within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table and the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert. VAERS also accepts reports on adverse events following receipt of other vaccines. Patients, parents and others aware of adverse events can also file VAERS reports. Although VAERS is not designed to assess if a vaccine caused an adverse event, VAERS provides CDC and FDA with important early information that might signal a potential problem. If the VAERS data suggest a possible association between an adverse event and vaccination, the relationship will be further assessed. In recent years VAERS has received approximately 30,000 US reports annually.

VAERS is a mandated activity for the U.S. Department of Health and Human Services (HHS) and VAERS data are used by federal agencies, state health officials, health care providers, manufacturers, and the public, therefore it is important to maximize the usefulness of this system. The information collected by the proposed VAERS 2.0 form will be similar to that on the current VAERS–1 form so historical comparisons can be made; however, the changes in the draft VAERS 2.0 form should improve reporting efficiency and data quality. VAERS 2.0 offers standardized responses, clearer instructions and guidance, and improved online reporting. Select questions have been updated, with questions added, removed, and reorganized to decrease response burden and maximize usability. The draft VAERS 2.0 form can be found at *http://www.regulations.gov.*

During the development of the draft VAERS 2.0 form, CDC and FDA sought input from key stakeholders in the federal government, state health officials involved in vaccine safety and vaccine programs, and other public health partners. In addition, the VAERS 2.0 form was presented to three federal advisory committees, the Advisory Commission on Childhood Vaccines (September 5, 2014), the National Vaccine Advisory Committee (September 9, 2014), and the Advisory Committee on Immunization Practices (October, 2014) and was tested with potential reporters (e.g., physicians, nurses, pharmacists, patients, and parents). All public comments will be reviewed and considered prior to finalizing the VAERS 2.0 form.

Roybal Campus Security Guidelines: The Edward R. Roybal Campus is the headquarters of the U.S. Centers for Disease Control and Prevention and is located at 1600 Clifton Road NE., Atlanta, Georgia. The Immunization Safety Office is in a Federal government building; therefore, Federal security measures are applicable.

In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Roybal Campus through the entrance on Clifton Road; the guard force will direct visitors to the designated parking area. Upon arrival at the facility, visitors must present government issued photo identification (e.g., a valid federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-United States citizens must complete the required security paperwork prior to the visit date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor's ID badge at the entrance to Building 19 and will be escorted to a room to view the available materials. All items brought to HHS/CDC are subject to inspection.

Dated: November 18, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2014–27678 Filed 11–21–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10407 and CMS–R–245]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HSS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.