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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548

Decision

Matter of: Veterans Healthcare Supply Solutions, Inc.

File: B-411904

Date: November 12, 2015

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DIGEST

Protest of an award of a sole-source contract for brand name medical equipment is denied where the agency had a rational basis for standardizing such equipment to improve patient safety.

DECISION

Veterans Healthcare Supply Solutions, Inc., (VHSS) of Jacksonville, Florida, protests the award a sole-source contract to PROAIM Americas, LLC, of Grover, Missouri, under request for quotations (RFQ) No. VA246-15-Q-1045, issued by the Department of Veterans Affairs (VA) for brand name argon plasma coagulators (APC). VHSS contends that the sole-source award is not justified and is contrary to applicable procurement laws and regulations.

We deny the protest in part and dismiss it in part.

BACKGROUND

The W.G. (Bill) Hefner VA Medical Center in Salisbury, North Carolina, (VAMC) will open new healthcare centers (HCC) in Kernersville and Charlotte, North Carolina, in 2016. According to the VAMC's website, once completed, the two HCCs will provide significantly expanded outpatient services to more than 65,000 North Carolina veterans annually under the Salisbury VAMC's health care system,

including gastrointestinal endoscopy services, for which the APCs are being procured.[1] VA medical staff will rotate among the VAMC and its new HCCs, as the staff currently does among the medical center and its three community-based outpatient clinics located in Charlotte, Hickory, and Winston-Salem, North Carolina. See Contracting Officer (CO) Statement at 2.

In April 2015, the VAMC submitted purchase requests to its regional network contracting office (NCO)[2] for nine name brand ERBE APCs for the endoscopy rooms at the new HCCs. Id. at 1.

On July 7, in response to the purchase requests, the NCO posted a sources sought notice on the FedBizOpps website advising that the VA was contemplating awarding a contract for APCs for a local VAMC and that the agency was seeking information on available brands of APCs. See Agency Report (AR), Tab A, Sources Sought Notice, at 9-11. Interested firms were requested to respond to a number of questions, including whether their APCs required training; whether they were made to order, or in stock and ready to ship; their lead time for delivery; and their ease of use. Id. at 2-3. Firms were also to identify competing brands, manufacturers, and models, and essentially compare the devices' operational differences and required components. See id.

The agency received responses from five manufacturers and five authorized distributors or sellers--including VHSS, a service-disabled, veteran-owned small business that sells APCs manufactured by US Medical Innovations, LLC, (USMI) and PROAIM, a small business that is ERBE's distributor for government sales.[3] See AR, Tab A, Market Research Report, at 12-30.

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[1] An APC is an electrosurgical medical device that cuts, coagulates, and desiccates biological tissue by applying a high-frequency electric current using ionized argon gas (argon plasma); the device requires a number of components, such as an electrosurgical generator, gas tank, foot activation switch or pedal, various surgical instruments, catheters, and probes, among other things. See ERBE Elektromedizin GMBH et al. v. Canady Tech. LLC, 629 F.3d 1278, 1280-81 (Fed. Cir. 2010); 21 C.F.R. § 876.4300 (Food and Drug Administration's (FDA) classification of endoscopic electrosurgical unit and accessories).

[2] NCO 6, which is located in Hampton, Virginia, provides procurement support to VA medical centers and clinics in North Carolina and other mid-Atlantic states. See www.va.gov/plo/about/saos.asp (last visited Nov. 12, 2015).

[3] USMI is located in Takoma Park, Maryland. ERBE Elektromedizin GmbH, is located in Tübingen, Germany.

A NCO contract specialist reviewed the responses and questioned whether a brand name purchase was justified given that other APC brands were available and that the two HCCs were new facilities. AR, Tab B, NCO Contract Specialist-VAMC Admin. Officer Emails, July 13, 2015, at 1-2. The contract specialist asked the VAMC to explain its rationale for requesting ERBE brand APCs, and pointed out that four other brands of APCs were available. See id.; CO Statement at 2. The VAMC explained that all Salisbury VAMC sites of care currently have ERBE APCs, that medical staff rotate among the various sites, including the new HCCs as noted above ("someone might be in Salisbury today and Kernerville tomorrow"), and that for direct patient care, the VAMC strives to use identical equipment for the same clinical use. See AR, Tab B, NCO Contract Specialist-VAMC Admin. Officer Emails, July 13, 2015, at 1. The contract specialist then contacted the APC manufacturers and distributors and asked them to describe operational differences among APC brands with regard to dials, settings, and interfaces, and how labor-intensive they were to operate. CO Statement at 2; see AR, Tab A, Market Research Report, at 32-40.

The contract specialist prepared a detailed market research report documenting the responses to the sources sought notice; brochures, website information, and depictions of various APC models (including ERBE's and USMI's); his exchanges with industry representatives and VAMC staff; and his findings and recommendations, among other things. See AR, Tab A, Market Research Report. The report found that APCs seemed relatively complex in terms of operations and maintenance, that they required some training and an understanding of their technical requirements, and that APC operation methods, interfaces, and settings varied among brands. Id. at 1. The report concluded that market research supported the VAMC's rationale for purchasing brand name APCs, and recommended that the agency issue a sole-source contract to ERBE's government distributor, PROAIM. Id. at 3; CO Statement at 2. The contracting officer concurred and approved the report on July 24. Id.

On July 29, the VA issued the RFQ to PROAIM for nine APCs and required components.[4] See AR, Tab E, RFQ. PROAIM submitted a quotation on that same

[4] The agency states that the RFQ was not posted on FedBizOpps because ERBE had advised the contract specialist that PROAIM was its only distributor for government sales. CO Statement at 3; see AR, Tab C, Contract Specialist-ERBE Emails, July 14, 2015, at 1. To the extent that VHSS objects that the agency did not post the solicitation with the J&A, the protester's arguments in this regard are untimely because the protester failed to raise them in its initial filing. 4 C.F.R. § 21.2(a)(2) (requiring protest issues be filed within 10 days after the basis is known or should have been known); see also Lanmark Tech., Inc., B-410214.3, March 20, 2015, 2015 CPD ¶ 139 at 5 n.2 (piecemeal presentation of protest grounds, raised for the first time in comments, are untimely).

date (July 29). See AR, Tab G, PROAIM Quotation. On August 4, the VA issued a contract to PROAIM for $167,090 for four APCs for the new Kernersville HCC. See AR, Tab H, PROAIM Contract. (The separate purchase request for five APCs for the Charlotte HCC was cancelled due to lack of funding. CO Statement at 3.)

The following day (August 5), the VA posted on FedBizOpps a Notice of Justification and Approval (J&A) for Other Than Full and Open Competition.[5] AR, Tab I, J&A, at 1. The J&A advised that the NCO and VAMC had issued a sole-source contract for ERBE brand APCs under the authority of Federal Acquisition Regulation (FAR) § 6.302-1 (Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements), and stated that

> [t]he requested ERBE APCs are additional equipment to a department wide inventory of APCs. . . . Brand name only is being requested in order to standardize with existing equipment. The use of identical equipment in all endoscopy rooms decreases the possibility of human error, thereby increasing patient safety. Each brand contains a unique interface and different outputs associated with their settings. Each brand has differences in the number of settings, as well as the function and nomenclature of the settings.

Id. This protest followed.

DISCUSSION

VHSS protests the VA's decision to procure brand name APCs and challenges the agency's responsibility determination. While our decision here does not specifically discuss each of the protester's various arguments, we have considered all of VHSS's contentions and find none furnishes a basis to sustain the protest.

Sole-Source Award

VHSS contends that the VA has no rational basis for procuring this type of medical equipment on a sole-source or brand name basis, and claims that VHSS can provide a comparable APC (manufactured by USMI) that will meet the VAMC's needs at a much lower price. VHSS asserts that the agency has not presented scientifically reliable analyses or studies to support its assertion that standardizing its inventory of APCs is likely, or even necessary, to increase patient safety.[6] VHSS argues that the

[5] The contracting officer approved and executed the J&A on the same day that she approved the market research report, July 24. CO Statement at 2.

[6] According to VHSS, it "is quite common for healthcare providers to have privileges at more than one hospital or healthcare location, and each location may have equipment manufactured by different companies[; therefore] it is imperative that the (continued...)

J&A is deficient because it failed to identify any salient physical, functional, or performance characteristics for the APCs, contrary to FAR § 11.104. VHSS also argues that the agency's reliance on non-competitive procedures reflects its failure to conduct reasonable advance planning, contrary to the Competition in Contracting Act of 1984 (CICA). VHSS complains that the J&A reflects nothing more than VAMC end-users' preference for the incumbent manufacturer's equipment, and maintains that the agency did not meaningfully consider the capabilities of other APC brands.

The VA maintains that lack of consistency in the usage of medical devices is a very common source of human error, and argues that the need to minimize medical errors and enhance patient safety provides a reasonable (and compelling) justification for purchasing the same brand of APCs that is currently used by the VAMC's medical staff.[7] The VA states that the agency does not dispute that other manufacturers can meet its need for APCs generally, but asserts that only PROAIM can meet the VAMC's legitimate need for APCs that are identical in function and user interfaces to its current inventory of ERBE brand APCs.

While CICA requires agencies to obtain full and open competition in its procurements through the use of competitive procedures, CICA permits an exception to use other than competitive procedures where there is only one responsible source able to meet the agency's requirement. 41 U.S.C. §§ 3304(a)(1), 3306(a)(1) As a general matter, when an agency uses noncompetitive procedures, it is required to execute a written J&A with sufficient facts and rationale to support the use of the cited authority. 41 U.S.C. § 3304(e); FAR §§ 6.302-1, 6.303, 6.304. Our review of an agency's decision to conduct a sole-source procurement focuses on the adequacy of the rationale and conclusions set forth in the J&A. Research Analysis & Maint., Inc., B-296206, B-296206.2, July 12, 2005, 2005 CPD ¶ 182 at 4. The adequacy of the agency's justification is ascertained through examining whether the agency's explanation is reasonable, that is, whether it can withstand logical scrutiny. Columbia Imaging, Inc., B-286772.2, B-287363, Apr. 13, 2001, 2001 CPD ¶ 78 at 2-3. Where the J&A sets forth a reasonable justification for the agency's

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healthcare provider is familiar with the procedure and the use of APC technology and application generally, not just equipment supplied by one manufacturer." Protester's Comments at 9, citing exh. 12, Declaration of USMI Chief Executive Officer (CEO), at 3.

[7] See AR at 1, citing Zhang, J. et al., Evaluating & Predicting Patient Safety for Medical Devices with Integral Information Technology, in Advances in Patient Safety: From Research to Implementation, Vol 2: Concepts and Methodology (Kerm Henriksen et al. eds., Agency for Healthcare Quality and Research 2005).

actions, we will not object to the award. Global Solutions Network, Inc., B-290107, June 11, 2002, 2002 CPD ¶ 98 at 6.

In our view, the VA's rationale for standardizing medical equipment, to reduce medical errors and enhance patient safety, sets forth a reasonable basis for procuring APCs on a brand name basis under the circumstances here. The determination of the government's needs and the best method of accommodating them is primarily the responsibility of the procuring agency, since its contracting officials are most familiar with the conditions under which supplies, equipment, and services have been employed in the past and will be utilized in the future. Columbia Imaging, Inc., supra, at 2. Where, as here, a requirement relates to human safety concerns, the agency has the discretion to set its minimum needs so as to achieve not just reasonable results, but the highest possible reliability and effectiveness. McKesson Automation Sys., Inc., B-290969.2, B-290969.3, Jan. 14, 2003, 2003 CPD ¶ 24 at 8.

Our Office has held that an agency's legitimate need to standardize the equipment it uses may provide a reasonable basis for imposing restrictions on competition. Brinkman Instruments, Inc., B-309946, B-309946.2, Oct. 15, 2007, 2007 CPD ¶ 188 at 2-3 (agency's proposed award of a sole-source contract for autotitrators to be used in nuclear submarines is unobjectionable where the agency reasonably determined that it needed to acquire the same autotitrator previously fielded on other nuclear submarines for purposes of standardization and safety across the submarine fleet); Advanced Med. Sys., Inc., B-259010, Jan. 17, 1995, 1995 WL 29832 at 1-2 (agency need to standardize fetal monitors in order to maximize patient care was reasonable).

In response to the protest, the agency has provided a medical article--sponsored by the Agency for Healthcare Research and Quality, the Department of the Army, and the National Aeronautics and Space Administration--that asserts that medical device use errors are a common source of patient injury and death, and that there is a clear link between usability problems and user error. See Evaluating & Predicting Patient Safety for Medical Devices with Integral Information Technology, supra, at 324. The article, which is based on a comparison of several infusion pumps from two different manufacturers, focuses on identifying usability problems that might be potential triggers for medical errors. Id. at 323, 329. The authors of the article specifically address the impact of device features and user interfaces (such as auditory cues and warnings, display messages, key information, physical controls, specific wording and labels, and sequence of tasks) on the incidence of human errors. See id. at 331-32. The authors argue that medical device users should not have to wonder whether different words, situations, or actions mean the same thing across different devices. See id. at 327 (internal citations omitted).

VHSS does not substantively refute the article's findings, but complains that the article is not identified anywhere in the contemporaneous record and was only

provided by the VA during the course of this protest. Our Office generally considers post-protest explanations, such as the one presented here, where the explanations merely provide a detailed rationale for contemporaneous conclusions and fill in previously unrecorded details, so long as the explanations are credible and consistent with the contemporaneous record. See TaxSlayer LLC, B-411101, May 8, 2015, 2015, CPD ¶ 156 at 8; Vinculum Solutions, Inc.--Recon., B-408337.3, Dec. 3, 2013, 2013 CPD ¶ 274 at 3 n.2.

Notwithstanding the protester's objections, we find no basis to disregard the VA's reliance on this article, which affirms the agency's rationale for using identical equipment for the same clinical use and is entirely consistent with the agency's contemporaneous concerns in that regard. The record shows that the VAMC was concerned that its medical staff should not have to transition among different APCs. For example, the VAMC was concerned that its medical providers should not have to stop (while performing an endoscopy) to consider whether the APC's knobs, switches, and other user interfaces operated differently than the equipment that the provider may have used the day before at another VAMC site. See AR, Tab B, NCO Contract Specialist-VAMC Admin. Officer Emails, July 13, 2015, at 1.

The VA's market research supports such concerns. For example, with regard to operational differences between competitors' models, the respondents variously answered: very different; all models would operate differently; no competing brand offers the same setting configuration or handpiece options; models are fundamentally different in both operation and patient outcomes; all brands operate differently; there is a significant difference in settings. See AR, Tab A, Market Research at 16, 18, 21, 29, 32-33, 35, 39. Indeed, USMI's own CEO states that "APC manufacturers have unique, brand/model specific user interfaces and displays[.]" Protester's Comments at 9, citing Exh. 12, Declaration of USMI CEO, at 2. Likewise, with regard to training, the respondents variously stated that training was required, recommended, included, and/or available for their specific models. AR, Tab A, Market Research at 12, 16, 18 (equipment requires some training with an in-service), 25, 29.

On this record, we find that the procurement process here was reasonable and reflects the contracting staff's diligence in seeking to promote competition. The record shows that in response to the name brand purchase request, the NCO issued a sources sought notice, conducted broad market research, questioned the VAMC's request for brand name equipment and presented the VAMC with alternative sources, sought further information from industry regarding device operability, and prepared a detailed market research report of the agency's findings.[8]

[8] Contrary to VHSS's assertion, the VA was not required to identify salient characteristics for its APC requirement. The purpose of a solicitation's statement of salient characteristics, as set out in FAR § 11.104(b), is to define the minimum

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Bias

VHSS also alleges that the VA is biased in favor of ERBE products, and maintains that the sole-source award is an effort by the agency to "avoid" our decision in Veterans Healthcare Supply Solutions, Inc., B-407223.2, Dec. 13, 2012, 2013 CPD ¶ 3, discussed below. Protest at 7-8, 12-13. Government officials are presumed to act in good faith, and a protester's contention that contracting officials are motivated by bias or bad faith thus must be supported by convincing proof; we will not attribute unfair or prejudicial motives to procurement officials on the basis of inference or supposition. Career Innovations, LLC, B-404377.4, May 24, 2011, 2011 CPD ¶ 111 at 7-8.

Apart from its unsupported allegations, VHSS has provided no evidence, and there is none in the record, showing agency bias in favor of ERBE products. See, e.g., Protest at 4, 12 (multiple VA hospitals have purchased USMI products); AR, Tab B, NCO Contract Specialist Emails, July 13, 2015, at 1-2 (questioning the VAMC's request for ERBE brand APCs). Moreover, contrary to the protester's repeated assertions,[9] our 2012 decision in Veterans Healthcare Supply Solutions, Inc. did not hold that USMI's and ERBE's APCs are equal, substantially equivalent, or comparable. Rather, our decision in that protest (which involved an evaluation challenge under a brand name or equal procurement for APCs at a different VAMC) concluded that the agency had not reasonably evaluated whether USMI's proposed APC was significantly different from the name brand ERBE APC.[10] Veterans

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characteristics of the brand name product that an alternative "equal" product must meet. CAMSS Shelters, B-309784, B-309784.2, Oct. 19, 2007, 2007 CPD ¶ 199 at 6. As described above, the agency here reasonably determined, based on its market research, that there were no equal products that could meet the agency's need for APCs that were identical (i.e., the same brand) to the VAMC's inventory of APCs.

[9] See AR, Tab A, Market Research, at 12 (VHSS providing, in response to NCO's sources sought notice, a copy of "GAO Ruling that USMI compares to the E[RBE] product"); 37 ("The USMI Product was deemed by the GAO as a comparable product[.]"); Protest at 7-8 (asserting that GAO, in its Veterans Healthcare Supply Solutions, Inc. decision, held that USMI's and ERBE's products are "substantially equivalent"); Protester's Comments at 5-6 and Protester's Supp. Comments at 4 (both citing Veterans Healthcare Supply Solutions, Inc. for the proposition that ERBE's and USMI's products "are equal.").

[10] The same ERBE device, albeit from a different distributor, and the same proposed USMI device, were at issue in Veterans Healthcare Supply Solutions, Inc. See Supp. AR, Tab N, Mem. for Record, at 1 (stating that the instant protest and the 2012 protest involved the same manufacturers and models).

Healthcare Supply Solutions, Inc., supra, at 6. In this respect, that decision recommended that the VA "reevaluate the[] units, and determine and document whether the USMI device is significantly different from the brand name item." Id.

In sum, we conclude that the VA has established a legitimate safety need for standardizing APCs used at the VAMC and its associated HCCs, and that the contemplated sole-source award will achieve the VAMC's standardization goals.[11] Advanced Med. Sys., Inc., supra, at 1-2 (legitimate medical need to standardize fetal monitors). VHSS's disagreement with the VA's rationale does not provide a basis to sustain the protest. See Allied-Signal Inc., B-247272, May 21, 1992, 92-1 CPD ¶ 461 at 10.

Responsibility Determination

Finally, VHSS challenges the VA's responsibility determination because, according to the protester, the agency ignored available information suggesting that ERBE products may have an unsatisfactory performance record. VHSS complains that the VA failed to consider adverse events involving ERBE products that have been reported to the FDA and are publically available in the FDA's MAUDE database.[12] VHSS argues that the number of adverse medical events shows that ERBE vendors cannot be deemed to be responsible contractors, because they are supplying products with unsatisfactory performance records. This, VHSS asserts, calls into question not only the reasonableness of the VA's responsibility determination, but also its justification for purchasing ERBE brand APCs.

Our Office will consider a protest of an affirmative determination of responsibility where the protest identifies evidence raising serious concerns that, in reaching the responsibility determination, the contracting officer unreasonably failed to consider available relevant information or otherwise violated statute or regulation. 4 C.F.R. § 21.5(c); T. F. Boyle Transp., Inc., B-310708, B-310708.2, Jan. 29, 2008, 2008 CPD ¶ 52 at 5. In that context, we will review a challenge to an agency's affirmative responsibility determination where the protester presents specific evidence that the contracting officer may have ignored information that, by its nature, would be

[11] We emphasize that the ability of other manufacturers or distributors to meet the Salisbury VAMC's general need for APCs is not at issue in the instant protest. Rather, at issue here is the adequacy of the VA's justification for purchasing name brand APCs for the Salisbury VAMC's new HCCs.

[12] That is, the Manufacturer and User Facility Device Experience database, which collects medical device reports (MDR) submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as healthcare professionals, patients, and consumers. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm (last visited Nov. 12, 2015).

expected to have a strong bearing on whether the awardee should be found responsible. Verestar Gov't Servs. Group, B-291854, B-291854.2, Apr. 3, 2003, 2003 CPD ¶ 68 at 4-5.

The allegations that our Office has reviewed in the context of an affirmative determination of responsibility generally pertain to very serious matters such as potential criminal activity. For example, in FN Mfg., Inc., B-297172, B-297172.2, Dec. 1, 2005, 2005 CPD ¶ 212 at 7-8, our Office reviewed an allegation that the agency failed to consider an ongoing investigation into whether the awardee defrauded the government on a prior contract for the same requirement. In Southwestern Bell Tel. Co., B-292476, Oct. 1, 2003, 2003 CPD ¶ 177, we reviewed an allegation that the agency failed to consider that the awardee's CEO had been indicted for conspiracy and fraud by the U.S. Attorney for Southern New York. In Verestar Gov't Servs. Group, we reviewed an allegation that the agency had failed to consider that the awardee was embroiled in a massive public accounting scandal and had vastly misstated its earnings.

In contrast, MDRs of adverse events simply do not support the necessary threshold showing to trigger our Office's review of a challenge to an affirmative responsibility determination.[13] According to the FDA, MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices, and the MAUDE website contains an extensive list of disclaimers in that regard, including that:

> Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under reporting of events and lack of information about frequency of device use.
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> MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
>
> Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report.

[13] VHSS does not assert that those adverse events involved the same model of ERBE APCs or components that the VAMC is purchasing here.

> Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
>
> MAUDE data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.
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> * * * * *
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> Submission of a medical device report and the FDA's release of that information is not necessarily an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.[14]

Thus, by their nature, MDRs of adverse events reported in the FDA's MAUDE database would not, without more, be expected to have a strong bearing on whether a medical device manufacturer or distributor should be found responsible. See The GEO Group, Inc., B-405012, July 26, 2011, 2011 CPD ¶ 153 at 7; Hendry Corp., B-400224.2, Aug. 25, 2008, 2008 CPD ¶ 164 at 2-3. Accordingly, this basis of the protest is dismissed. See 4 C.F.R. § 21.5(c).

The protest is denied in part and dismissed in part.

Susan A. Poling
General Counsel

[14] www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm; www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm (last visited Nov. 12, 2015).