Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Devices and Radiological Health,

Complainant,

v.

Brigitte Alzate,

Respondent.

Docket No. C-14-866
FDA Docket No. FDA-2014-H-0361

Decision No. CR3395

Date: September 30, 2014

DECISION

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) filed an administrative complaint (Complaint) against Respondent, Brigitte Alzate, alleging that she and three other respondents violated the Mammography Quality Standards Act of 1992 (MQSA), codified at 42 U.S.C. § 263b, and its implementing regulations. CDRH sought to impose an $83,750 civil money penalty against Respondent. Respondent filed an answer to the Complaint that generally denied CDRH's allegations. Respondent also moved to dismiss the Complaint for lack of subject-matter jurisdiction. CDRH subsequently moved for summary decision, which Respondent has not opposed.

I consider the facts stated in CDRH's motion for summary decision and its supporting exhibits to be undisputed. Based on those undisputed facts, and as explained below, I deny Respondent's motion to dismiss the Complaint (R. Mot.), grant CDRH's motion for a summary decision, and impose an $83,750 civil money penalty on Respondent.

I. Background and Procedural History

CDRH issued a Complaint dated March 24, 2014, that named the following as respondents: Brigitte Alzate, Oscar Alzate, Digital Radiology Center, Inc. (DRC), and William B. Smith, M.D.[1] The Complaint alleged, among other things, that DRC violated several provisions of the MQSA and that Respondent, as an operator and employee of DRC, was also liable under the MQSA and subject to a civil money penalty. CDRH sought imposition of an $83,750 civil money penalty on Respondent. On April 22, 2014, Respondents Brigitte Alzate, Oscar Alzate, and DRC filed, pro se, a joint request for an extension to file their answers to the Complaint. In my April 30, 2014 Acknowledgment and Pre-hearing Order, I granted a 30-day extension and set May 27, 2014, as the date on which those three respondents had to file their answers. Respondents Brigitte Alzate and Oscar Alzate, now represented by the same attorney, filed a joint answer on May 27, 2014, which generally denied the allegations in CDRH's Complaint. Respondent DRC, however, did not timely answer the Complaint.[2]

On June 2, 2014, Respondents Brigitte Alzate and Oscar Alzate, through their attorney, filed a motion to dismiss CDRH's Complaint. Following a series of additional motions from the parties, on June 27, 2014, I issued an omnibus order (June 27 Order), that addressed several procedural deadlines as well as a request from Respondent's attorney (who also represented Oscar Alzate) to withdraw as counsel. I acknowledged the attorney's withdrawal and directed him to "ensure that his withdrawal is not [done] in a way that interferes with the speedy, orderly, or fair conduct of this proceeding," and to "fully [comply] with his ethical obligations as a Florida attorney under Rule 4-1.16 for the Florida Rules of Professional Conduct." June 27 Order at 2. Based on CDRH's stated intent to file a motion for summary decision, I also ordered that CDRH had until

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[1] The Director of the Civil Remedies Division (CRD) of the Departmental Appeals Board docketed each respondent under a separate CRD docket number. Respondent Smith filed a timely answer to the Complaint as well as a motion to dismiss the Complaint as it pertained to him. CDRH did not oppose the dismissal. It appears that Respondents Brigette Alzate and Oscar Alzate had been using Respondent Smith's name, without authorization, in matters related to DRC in order to make it appear that Respondent Smith owned DRC. The Alzates apparently did this to avoid needing a Florida license for DRC. If DRC had been owned by a physician, such as Respondent Smith, the Alzates believed that Florida law did not require DRC to have a state license. CDRH Ex. C. However, Respondent Smith did not own DRC. Therefore, on June 6, 2014, I dismissed the Complaint against Respondent Smith (CRD Docket No. C-14-868).

[2] On June 24, 2014, I issued an Initial Decision and Default Judgment in which I concluded that DRC was liable under the MQSA and imposed a $2,920,000 civil money penalty against DRC. *See Ctr. for Digital & Radiological Health v. Digital Radiology Ctr., Inc.*, DAB CR3270 (2014).

July 2, 2014 to respond to Respondent's motion to dismiss, and until July 25, 2014 to file a motion for summary decision. June 27 Order at 2. I provided both Respondent and Oscar Alzate 30 days to respond to any CDRH motion for summary decision. June 27 Order at 2. I stayed responses to any open discovery requests as well as all future prehearing submissions pending the resolution of any dispositive motion. June 27 Order at 2-3. A copy of the June 27 Order was served by U.S. mail to Respondent's home and business addresses in addition to her recently withdrawn attorney.

On July 3, 2014, CDRH filed a motion for summary decision and supporting brief (CDRH Br.), which also included its opposition to Respondent's motion to dismiss.[3] Counsel for CDRH certified that she served Respondent with a copy of the motion by first-class mail to both Respondent's withdrawn attorney and Respondent's known business address. Pursuant to my June 27 Order and applicable regulation, Respondent had until August 7, 2014, to respond to CDRH's motion for a summary decision. June 27 Order at 2; *see* 21 C.F.R. § 17.30(c) (providing an additional five days to respond if a document was served by mail). Respondent did not oppose or respond in any way to the motion for a summary decision.

II. Issues

This case presents the following issues:

1. Whether I have subject-matter jurisdiction to decide if Respondent Brigitte Alzate is liable for a civil money penalty under 42 U.S.C. § 263b(h);

2. Whether the undisputed facts establish Respondent Brigitte Alzate is liable under 42 U.S.C. § 263b(h) for a civil money penalty; and

3. If there is a basis to impose a civil money penalty, whether an $83,750 civil money penalty against Respondent Brigitte Alzate is an appropriate amount.

[3] CDRH filed its opposition to Respondent's motion to dismiss one day later than the deadline I established in my June 27 Order. However, CDRH likely did not receive the June 27 Order in the mail until after the deadline set for CDRH to file its opposition. *See* 21 C.F.R. § 17.30(c). This is supported by the fact that CDRH's opposition contains language indicating it had not yet received my *June 24* Initial Decision and Default Judgment against DRC (DAB CR3270), and, therefore, likely had also not received the *June 27* Order at that time. *See* CDRH Motion for a Summary Decision at 2 n.1. Further, Respondent has not moved to strike CDRH's opposition. Therefore, I accept CDRH's opposition.

III. Statutory and Regulatory Framework

The MQSA requires a mammography facility to have a valid certificate to perform mammography scans. 42 U.S.C. § 263b(b)(1). The Secretary of Health and Human Services (Secretary) may issue a certificate for a maximum of three years to a facility only after its owner or lessor provides statutorily-required information, including the types of machines used for mammography scans, procedures used in the facility to provide mammography, proof of an on-site medical physicist, and proof of accreditation by an accreditation body that the Secretary, acting through the FDA, has approved. 42 U.S.C. § 263b(c), (d)(1); 21 C.F.R. § 900.11(a), (b)(1). FDA performs annual inspections of facilities certified to perform mammography to ensure the facility's compliance with the MQSA including all of the "quality standards" set forth in 42 U.S.C. § 263b(f). 42 U.S.C. § 263b(g)(1)(E).

If upon inspection FDA determines that the quality of mammograms performed in a facility is inconsistent with the requirements in the MQSA, FDA may impose a variety of sanctions in lieu of suspending or revoking a valid certificate. *Id.* § 263b(h)(1). The MQSA authorizes FDA to, among other things, require the facility to notify patients who received mammograms at the facility of the deficiencies posing a risk, the potential harm, and any remedial steps to be taken. *Id.* § 263b(h)(2). The MQSA also permits FDA to assess a civil money penalty not to exceed $11,000 for:

> (A) failure to obtain a certificate as required by subsection (b) of this section,
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> (B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) of this section or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii) of this section,
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> (C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and
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> (D) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

42 U.S.C. § 263(h)(3); *see* 21 C.F.R. § 17.2. The MQSA requires the Secretary to "develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) through (3)," which must include proper notice to the facility owner or operator as well as an opportunity to respond and appeal a sanction determination. 42 U.S.C. § 263(h)(4). The Secretary has promulgated these procedures in 21 C.F.R. pt. 17.

IV. Jurisdiction

Respondent argues in her motion to dismiss the Complaint that I do not have "subject matter jurisdiction" over her case. R. Mot. at 3. Respondent asserts that she is making a "factual attack on the tribunal's power to consider this matter," because she was never the "owner, operator, or employee" of DRC, and therefore cannot be the subject of a civil money penalty action taken pursuant to the MQSA. R. Mot. at 4.

"Subject matter jurisdiction" refers to a tribunal's jurisdiction "over the nature of the case and the type of relief sought." *Black's Law Dictionary* 870 (8th ed. 2004). In a "factual attack" of a tribunal's subject-matter jurisdiction, "the presumption of truthfulness afforded a plaintiff under Federal Rule of Civil Procedure 12(b)(6) does not attach, and the [tribunal] is free to weigh the evidence." *Lawrence v. Dunbar*, 919 F.2d 1525, 1529 (11th Cir. 1990). However, if a factual attack of subject-matter jurisdiction implicates an element of the underlying claim then the "proper course of action for the [tribunal] . . . is to find that jurisdiction exists and deal with the objection as a direct attack on the merits of the plaintiff's case . . . . Judicial economy is best promoted when the existence of a federal right is directly reached and, where no claim is found to exist, the case is dismissed on the merits." *Id.* (quoting *Williamson v. Tucker*, 645 F.2d 404, 412 (5th Cir. 1981)).

The Secretary may impose civil money penalties on a facility that conducts breast cancer screening or diagnosis through mammography activities if it fails to comply with MQSA requirements. 42 U.S.C. § 263b(h)(3). The Secretary may also impose civil money penalties on the "owner, operator, or any employee of a facility required to have a [MQSA] certificate" if that individual aids and abets a facility's violation of the MQSA. *Id.* § 263b(h)(3)(D).

The Secretary has delegated her authority to bring civil money penalty actions under the MQSA to FDA, and, in turn, CDRH. If CDRH files a Complaint seeking a civil money penalty under the MQSA, then the procedures in 21 C.F.R. pt. 17 apply. 21 C.F.R. § 17.1(h); *see also* 42 U.S.C. § 263b(h)(4). Those regulations require that an administrative law judge, qualified under the Administrative Procedure Act, be assigned to preside over any case initiated with the filing of a Complaint. 21 C.F.R. §§ 17.3(c), 17.5(d). Under an agreement between FDA and the Departmental Appeals Board, CDRH filed its Complaint against Respondent with the Civil Remedies Division (CRD). The

CRD director administratively assigned this case to me for adjudication. The regulations vest me with subject-matter jurisdiction to determine whether CDRH has a basis to impose a civil money penalty under the MQSA.

In considering this motion, I note that the regulations governing this proceeding do not include a provision for dismissal of the Complaint, except as a sanction. *See* 21 C.F.R. § 17.35(e). Although this does not mean that I do not have authority to dismiss a case for reasons other than as a sanction, I am mindful that the regulations do not provide a standard for dismissal, and I will not do so unless it appears entirely appropriate. In the present case, Respondent premises her motion to dismiss on the fact that she was never an owner, operator, or employee of DRC, yet she did not present any evidence with her motion that supports her assertions. More importantly, whether an individual is an owner, operator, or employee of a facility subject to MQSA requirements is a critical element of a civil money penalty claim against that individual. 42 U.S.C. § 263b(h)(3)(D). Respondent's argument directly questions the merits of CDRH's claims against her, which cannot be disposed of through dismissal for want of jurisdiction. *See Lawrence*, 919 F.2d at 1529. CDRH has the authority to bring an action for a civil money penalty pursuant to the MQSA and, as discussed above, I have the authority to hear and decide such a case. Respondent's factual challenge to my subject-matter jurisdiction is unsupported and hinges on an element of CDRH's claim against her. Therefore, I deny Respondent's motion to dismiss for lack of subject-matter jurisdiction.

V. Discussion of the Merits

A. Summary decision is appropriate.

Summary decision is appropriate if "the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the [moving] party is entitled to summary decision as a matter of law." 21 C.F.R. § 17.17(b). Here, CDRH moved for a summary decision and provided affidavits and supporting exhibits. Respondent did not respond to or, in any other way, dispute the affiants' claims or any of the supporting documentation, even though she expressly has the right to do so. *See id*. § 17.17(a). Thus, this evidence is undisputed. The only remaining issue is whether the facts established by this undisputed evidence demonstrate that CDRH is entitled to judgment as a matter of law. As discussed below, I conclude that it does. Therefore, summary decision is proper in this case.

B. The undisputed facts demonstrate that Respondent Brigitte Alzate violated the MQSA and is subject to a civil money penalty.

As noted above, Respondent did not oppose CDRH's motion for a summary decision. But even if a motion is unopposed, "the moving party still bears the burden of identifying 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrates the absence of a genuine issue of material fact." *Mann v. Taser Intl., Inc.*, 588 F.3d 1291, 1301 (11th Cir. 2009) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). A tribunal cannot merely grant summary disposition because a motion is unopposed, but "must consider the merits of the motion." *United States v. One Piece of Real Property Located at 5800 SW 74th Ave., Miami, Florida*, 363 F.3d 1099, 1101 (11th Cir. 2004). The tribunal "need not *sua sponte* review all of the evidentiary materials on file at the time the motion is granted, but must ensure that the motion itself is supported by evidentiary materials. At the least, the [tribunal] must review all of the evidentiary materials submitted in support of the motion for summary judgment." *Id.* at 1101-02.

The motion for summary decision, supporting brief, and supporting exhibits establish the following facts: DRC was incorporated on August 2, 2010, in Florida, with Respondent listed as DRC's President until May 2012.[4] DRC, Inc. is the corporate owner of the DRC facility that requires MQSA certification. Oscar Alzate told the FDA that he was the manager and Respondent the assistant manager of the DRC facility. CDRH Ex. B ¶ 10. Respondent was also listed on corporate documents as DRC's treasurer. *See* R. First Request for Judicial Notice, Ex. D. On August 19, 2010, FDA issued a provisional certificate to the DRC facility so that it could obtain clinical images and test materials as part of the accreditation process. CDRH Ex. A ¶ 23. On February 16, 2011, FDA notified DRC that the DRC facility failed the initial accreditation process and had to cease performing mammography services. CDRH Ex. A ¶ 24, Attach. 7. Soon thereafter, DRC sought reinstatement from the American College of Radiology (ACR) an FDA-approved accreditation body. In the reinstatement application, Respondent was

[4] CDRH provided evidence that Respondent and Oscar Alzate previously managed a mammography facility named Medisound, but the Medisound facility did not comply with MQSA standards. CDRH Ex. A ¶¶ 15-19; CDRH Ex. B, Attach. 2. In 2009 and 2010, inspectors found that the Medisound facility performed mammography 213 times after its MQSA certificate expired. CDRH Ex. A ¶ 19. FDA directed Medisound to notify all at-risk patients of the risk problems, but Medisound failed to do so. CDRH Ex. A ¶ 20. FDA then issued a "Safety Notification" about the mammography issues at the Medisound facility. CDRH Ex. A ¶ 20. Medisound notified the American College of Radiology on August 10, 2010, that it had ceased performing mammography. CDRH Ex. A ¶ 21. CDRH points out that the DRC facility is at the same location as the Medisound facility, but uses a different side of the building for its street address. CDRH Br. at 9; CDRH Ex. B ¶ 7.

listed as the "Facility president or CEO" and as the facility contact. CDRH Ex. A ¶ 25, Attach. 8, at 4. On April 20, 2011, the Florida Bureau of Radiation Control, under contract with FDA, conducted an inspection of the DRC facility to ensure compliance with MQSA. The inspectors found that the DRC facility did not comply with the MQSA and provided Respondent with a copy of the inspection report and noncompliance finding. CDRH Ex. B ¶ 8, Attach. 4. On May 12, 2011, Respondent sent a facsimile to ACR under the DRC letterhead, which stated that in August 2010, DRC had purchased the mammography equipment from Medisound, Inc., and that DRC "continued to employ Brigitte Alzate . . . ." CDRH Ex. A ¶ 26, Attach. 9, at 2.

ACR notified DRC on May 24, 2011, that the DRC facility's MQSA accreditation was denied effective June 3, 2011, and recommended that DRC cease conducting mammography services. CDRH Ex. A ¶ 27, Attach. 10. ACR copied Respondent on the notice letter. ACR determined that the DRC facility was "essentially operating as the previously revoked mammography facility, Medisound, Inc." CDRH Ex. A ¶ 27. On June 6, 2011, FDA notified DRC that it was no longer certified because it did not meet the MQSA certification requirement and that it must cease performing mammography. CDRH Ex. A ¶ 28. FDA also warned DRC that if the facility continued to perform mammography without the appropriate certification, it could be subject to a civil money penalty of up to $10,000 per day. CDRH Ex. A, Attach. 11, at 2. The DRC facility received the FDA notice letter on June 8, 2011, which was signed for by "ALZATE." CDRH Ex. A, Attach 11, at 4.

One year later, on June 6, 2012, Respondent and Oscar Alzate faxed a letter to ACR titled "LETTER DISPUTING INFORMATION ON OUR FACILITY"; Respondent's and Oscar Alzate's names are both on the letter, although Oscar Alzate was listed as the DRC facility's manager. CDRH Ex. A, Attach. 12.

From September 6 to September 12, 2012, two FDA investigators, along with an inspector from the Florida Bureau of Radiation Control, conducted an unannounced inspection of DRC. CDRH Ex. B ¶ 10. Oscar Alzate identified himself to the investigators as the manager of DRC and Respondent as the assistant manager of DRC, who assisted him in the day-to-day operations of the facility, "including requesting and receiving mammography assessment results needed to correlate biopsy results with the interpreting physician's findings, working the front desk, taking phone calls, and helping check in patients." CDRH Ex. B ¶ 10. Oscar Alzate provided the FDA inspectors with a report showing that the DRC facility performed at least 1,922 mammograms between August 1, 2011, and September 10, 2012, the period that the DRC facility did not have the required MQSA certificate. Oscar Alzate told investigators that approximately ten percent of the patients provided mammography films from another facility to the DRC facility for review. CDRH Ex. B, Attach. 6. The investigators concluded that the DRC

facility performed 1,730 mammograms from June 8, 2011, when the DRC facility received the FDA's notice letter, to September 6, 2012, the last date the DRC facility performed mammography, for a total of 315 business days. CDRH Ex. B ¶ 11.

The FDA investigators also determined that DRC failed to implement and document a quality assurance and quality control program that substantially complied with MQSA quality standards. CDRH Br. 12; CDRH Ex. B ¶¶ 12-14. The investigators documented 15 "Level 2" observations[5] including: the use of an unaccredited mammography unit; the failure to follow the manufacturer-recommended quality control procedures for the mammography unit, monitor, and laser printer; the failure to obtain biopsy results for mammograms performed; and the failure to produce documents verifying that training requirements for interpreting physicians had been met. Investigators also found documents in a shred bin that DRC was required to maintain. CDRH Ex. B ¶ 14. The inspectors found three "Level 3" violations. The FDA investigators provided Oscar Alzate with a copy of the inspection report on September 12, 2012. CDRH Ex. B ¶ 15.

On September 12, 2012, Oscar Alzate provided the FDA investigators with a written affidavit, in which he again identified himself as the manager of the DRC facility and "responsible for all of the activities related to mammography at this location." CDRH Ex. B, Attach. 5.[6] He acknowledged that he was responsible for all of the administrative duties of the facility as well as for its day-to-day operations. He admitted in the affidavit that he "knowingly allowed Digital Radiology Center to conduct mammography without certification from August 2011 until September 6, 2012." CDRH Ex. B, Attach. 5. Oscar Alzate again stated that Respondent was the DRC facility's assistant manager. CDRH Ex. B, Attach. 5, at 1.

On October 15, 2012, FDA directed the DRC facility to notify all patients that received mammography services between June 8, 2011 and September 12, 2012, that DRC had performed the mammograms without proper certification. CDRH Ex. A, Attach. 16. However, the DRC facility never provided the required notifications. CDRH Ex. A ¶ 36.

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[5] A "Level 1" observation occurs when a facility fails in a key MQSA requirement that may compromise mammography quality (for example, operating without accreditation or certification). A "Level 2" observation occurs when a facility fails to meet at least one significant mammography quality item. A "Level 3" observation occurs when a facility meets all major MQSA requirements with only minor problems. CDRH Ex. A ¶ 11.

[6] It is not clear from Oscar Alzate's affidavit whether he drafted the language himself or simply agreed to it. He handwrote on the last page: "I read this Statement and agree. It is truth [*sic*]." CDRH Ex. B, Attach. 5, at 4.

CDRH alleged in its Complaint that Respondent violated the MQSA because she was the owner, operator, or an employee of DRC and, in that role, aided and abetted the DRC facility's multiple violations of the MQSA. CDRH has sought to impose the following civil money penalties against Respondent:

- $5,000 pursuant to 42 U.S.C. § 263b(h)(3)(D), for Respondent's aiding and abetting DRC's failure to obtain an MQSA certification; and

- $78,750, pursuant to 42 U.S.C. § 263b(h)(3)(D) for Respondent's aiding and abetting DRC's failure to comply substantially with MQSA quality standards on each of at least 315 business days ($250 per day for 315 days).

CDRH Br. at 3.

As explained above, the MQSA permits CDRH to assess a civil money penalty not to exceed $11,000 "for each aiding and abetting in a violation of, any provision of, or regulation promulgated under [42 U.S.C. § 263b] by an owner, operator, or any employee of a facility required to have a certificate." 42 U.S.C. § 263b(h)(3); 21 C.F.R. § 17.2. The DRC facility was an entity that conducted breast cancer screening through mammography activities, and was thus a "facility" that required certification pursuant to the MQSA. 42 U.S.C. § 263b(a)(3)(A), (b)(1). It is undisputed that the DRC facility violated the MQSA by performing mammography without obtaining a required MQSA certificate for 315 business days, and failing to notify 1,730 at-risk patients of the risk posed, which the FDA required it to do. *Id.* § 263b(d)(1)(A)(iv); CDRH Ex. B ¶ 11, Attach. 5-8. The DRC facility also violated the MQSA by using an unaccredited mammography unit, failing to implement and document a quality assurance and quality control program that complied with MQSA standards, failing to follow the manufacturer-recommended quality control procedures for the mammography unit, monitor, and laser printer, and failing to obtain biopsy results for mammograms performed. CDRH Ex. B ¶¶ 14-15, Attach. 8.

The undisputed evidence further establishes that Respondent was an operator and employee of the DRC facility. An "operator" is "a person who uses and controls something (such as a machine, device, or business) . . . ." *Merriam-Webster Dictionary (Online)*, at http://www.merriam-webster.com/dictionary/operator (last visited Sept. 29, 2014). Respondent signed documents as the President or CEO of the DRC facility. CDRH Ex. A ¶¶ 22, 25, Attachs. 6, at 3, 4, 6; 8, at 1, 4. She also submitted letters to ACR as the contact person for the DRC facility. CDRH Ex. A ¶ 28, Attach. 8. Respondent's father, Oscar Alzate, admitted in a sworn affidavit to FDA investigators that he was the manager responsible for the day-to-day activities of the DRC facility and that Respondent, as assistant manager, helped him with those day-to-day tasks. CDRH Ex. B ¶ 10, Attach. 5, at 1; *see also* CDRH Ex. C ¶ 14; Whether Respondent had an ownership interest in the facility is not dispositive. Respondent's role as "assistant

manager," which including helping with the day-to-day activities of the DRC facility, establishes that she exercised some control over the DRC facility, and was therefore its "operator" during the period CDRH has cited. In addition, documents that DRC submitted to ACR and FDA described Respondent as an "employee" of the DRC facility. CDRH Ex. A, Attach. 9, at 2; *see also* CDRH Ex. A, Attachs. 6, at 12 (signing document on DRC's behalf); 12, at 2 (signing letter on DRC's behalf); CDRH Ex. B, Attach. 3, at 6 (designated to provide DRC records to an investigator).

As an operator and employee of the DRC facility who exerted some control over its day-to-day activities, Respondent was in a position to, and in fact did, aid and abet the numerous violations of the MQSA that the DRC facility committed. The MQSA does not define the elements of "aiding and abetting," although the ordinary meaning of "aid and abet" is to "assist or facilitate the commission of a crime, or to promote its accomplishment." *Black's Law Dictionary* 76 (8th ed. 2004). Respondent was part of the facility's failed attempts to obtain certification and accreditation and aware of FDA's direction to cease all mammography activities. CDRH Ex. A ¶¶ 25-27. Oscar Alzate acknowledged to FDA investigators that he (as manager) and Respondent (as assistant manager) allowed the DRC facility to continue performing mammography for 315 days without having the required MQSA certificate. CDRH Ex. B ¶ 10, Attach. 5. By assisting the DRC facility in performing mammography despite being aware of the FDA's order to cease such activities, Respondent facilitated the DRC facility's ongoing violations of the MQSA from June 8, 2011 to September 6, 2012.

While the MQSA applies to mammography facilities, and so the DRC facility was the entity that directly violated the statute (*see* 42 U.S.C. § 263b(a)(3), (b)(1)), Respondent, as assistant manager, was undoubtedly directly involved in the facility's administrative functions and therefore "aiding and abetting" the DRC facility's significant violations of various MQSA requirements. I conclude that the undisputed facts establish that Respondent aided and abetted the DRC facility's violations the MQSA while she was an operator and employee of that facility, and therefore subject to a civil money penalty pursuant to the MQSA. *See* 42 U.S.C. § 263b(b)(1), (f), (h)(3)(D).

C. An $83,750 civil money penalty against Respondent Brigitte Alzate is appropriate.

The civil money penalty that CDRH has sought to impose, $83,750, may appear as a substantial sum but is comparatively low when faced with the possible civil money penalty that the MQSA authorizes. Respondent facilitated the DRC facility's operation without an MQSA certificate or accreditation for 315 days. For each day that an operator

aids and abets a facility in violating the statute, the MQSA authorizes an $11,000 civil money penalty against that operator. Thus, for those 315 violations Respondent could be liable for $3,465,000 in the form of a civil money penalty.

Addressing violations similar to the current case, a federal circuit court of appeal stated:

> Moreover, KRA lost its certification not because of a failure to comply with a reporting requirement or some similar "technicality," but because its equipment did not produce an image of adequate quality. The seriousness of that deficiency cannot be over-emphasized. Breast cancer is most curable at its earliest stages. If mammography equipment does not produce an image of acceptable quality, early-stage breast cancer may not be detected, thus depriving the patient of the best chance for cure. Under these circumstances, it would be impossible to conclude that a single $3,000 penalty would be grossly disproportionate to the gravity of a single offense.
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> This case, of course, does not involve a single violation of the MQSA. It involves 193 violations committed by Korangy and 193 violations committed by KRA, resulting in a combined penalty of more than $1,000,000. While we recognize that this is a substantial penalty, the amount of the penalty is the direct result of the number of individual offenses committed by Korangy and KRA. Contrary to the suggestion of the petitioners, the gravity of their offenses does not diminish because they repeatedly committed the same offense. To the contrary, the repeat offenses mean that more early cancers may have been missed and more patients may have missed their best chance for a cure. Because the petitioners committed very grave violations of the MQSA, a substantial penalty was warranted.

Korangy v. United States Food & Drug Admin., 498 F.3d 272, 278 (4th Cir. 2007) (internal citations omitted). I agree that a substantial penalty is warranted in the present case as well.

However, instead of imposing the substantial penalties available, CDRH has sought the relatively minor amount of $250 for each day Respondent aided and abetted the facility in performing mammography without certification. Indeed, the $83,750 civil money penalty is less than two and a half percent of the total authorized civil money penalty. The mere fact that the total civil money penalty is large only serves to demonstrate the broad and prolonged scope of Respondent's improper conduct. Each individual civil

money penalty is modest when considering that Respondent permitted the DRC facility to conduct mammography knowing that it did so without the required accreditation and certification. Respondent repeatedly, and with full knowledge of the circumstances, thwarted the requirements of the MQSA and put a substantial number of individuals at risk by doing so. Mammography provides a potentially life-saving function; Respondent's repeated and knowing disregard of the law that Congress enacted to ensure quality mammography services demonstrates a callous indifference for the lives and safety of the DRC facility's patients. The lenience of CDRH in this case is difficult to understand given that Respondent was already involved in committing the same offense at the same address using a different business name. CDRH Ex. B ¶¶ 4-7, Attachs. 2, 3.

Respondent argued in her motion to dismiss that the civil money penalty is "penal in nature." R. Mot. at 5. CDRH responded that "MQSA civil money penalties are intended to promote compliance with the MQSA by taking the profit out of non-compliance, not to punish violators." CDRH Br. at 22 (citing 60 Fed. Reg. 38,612, 38,613 (July 27, 1995)). I agree with CDRH. The plain language of the MQSA provides that violators are subject to a "civil money penalty," not a criminal fine, which demonstrates Congress' intent that the sanctions are of a civil, rather than penal nature. The MQSA on its face is remedial and the actions taken pursuant to it are the same.

Although comparatively low, I conclude that CDRH's request to impose an $83,750 civil money penalty against Respondent is not inappropriate. *See* 42 U.S.C. § 263b(h)(3)(A)-(C); 21 C.F.R. § 17.34.

VI. Conclusion

Based on the foregoing, I conclude that the undisputed facts of this case establish that Respondent was an operator or employee of the DRC facility and aided and abetted that facility's violations of the MQSA. I also conclude that an $83,750 civil money penalty against Respondent is appropriate. Therefore, I order Respondent to pay a civil money penalty in the amount of $83,750.[7]

/s/
Scott Anderson
Administrative Law Judge

[7] Respondent must make payment to CDRH and the FDA in the manner specified in 21 C.F.R. § 17.54.