

**PUBLISHED**  
**UNITED STATES COURT OF APPEALS**  
**FOR THE FOURTH CIRCUIT**

AMILE A. KORANGY, M.D.; KORANGY  
RADIOLOGY ASSOCIATES, P.A.,  
*Petitioners,*

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION,  
*Respondent.*

No. 05-2300

AMILE A. KORANGY, M.D.; KORANGY  
RADIOLOGY ASSOCIATES, P.A.,  
*Petitioners,*

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION,  
*Respondent.*

No. 06-1860

On Petition for Review of an Order  
of the Food and Drug Administration.  
(A-05-35)

Argued: May 24, 2007

Decided: August 17, 2007

Before WILKINSON, MOTZ, and TRAXLER, Circuit Judges.

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Petition for review denied by published opinion. Judge Traxler wrote the opinion, in which Judge Wilkinson and Judge Motz joined.

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**COUNSEL**

**ARGUED:** Timothy Cronin Lynch, OFFIT & KURMAN, Maple Lawn, Maryland, for Petitioners. Anne Lobell Murphy, UNITED STATES DEPARTMENT OF JUSTICE, Appellate Staff, Civil Division, Washington, D.C., for Respondent. **ON BRIEF:** Alex M. Allman, OFFIT & KURMAN, Maple Lawn, Maryland, for Petitioners. Daniel Meron, General Counsel, Sheldon T. Bradshaw, Chief Counsel, Food and Drug Division, Eric M. Blumberg, Deputy Chief Counsel, Litigation, Marci B. Norton, Associate Chief Counsel for Enforcement, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C.; Peter D. Keisler, Assistant Attorney General, Douglas N. Letter, Appellate Staff, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Respondent.

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**OPINION**

TRAXLER, Circuit Judge:

Dr. Amile Korangy and Korangy Radiology Associates ("KRA") petition this court for review of an order of the Food and Drug Administration imposing monetary sanctions on Korangy and KRA for allowing a statutorily-required certification to lapse and for performing mammograms after the certification expired. For the reasons that follow, we deny the petition for review.

**I.**

Under the Mammography Quality Standards Act ("MQSA"), facilities that provide mammographies must be certified by the FDA. *See* 42 U.S.C.A. § 263b(b) (West Supp. 2007). In accordance with the MQSA, the FDA in 1999 issued a certificate for the operation of a mammography facility, known as "Baltimore Imaging Center," in Catonsville, Maryland. The 1999 certificate issued by the FDA was set to expire on May 6, 2002, and the expiration date was noted on the certificate itself. By 1999, Baltimore Imaging Center was operated by KRA, which is wholly owned by Korangy.

The American College of Radiology ("ACR") is an FDA-approved accreditation body that inspects mammography equipment to determine compliance with the MQSA. ACR inspected Korangy's equipment and informed Korangy by letter in April 2002 that his mammography equipment failed the quality standards for clinical image and that he should immediately stop using the equipment. ACR's letter explained to Korangy that the failure would be reported to the FDA and that the FDA would "officially notify" Korangy to stop using the equipment. *See* J.A. 32.

Notwithstanding his knowledge that his mammography produced images of unacceptable quality, Korangy continued to use the machine. He bought a new mammography unit that was provisionally certified for use on July 25, 2002. From May 7 (the day after his original certificate expired) until July 25 (the day before the new unit was certified), Korangy was operating without the required certification. During that uncertified period, he performed 192 mammograms at the Catonsville facility.

The FDA learned that Korangy was performing mammograms without the proper certification, and it filed a complaint in September 2003 seeking civil penalties against Korangy and KRA. An administrative law judge granted partial summary judgment in favor of the FDA, concluding that KRA and Korangy were each liable for one penalty for failing to obtain the required certificate. *See* 42 U.S.C.A. § 263b(h)(3)(A) (West Supp. 2007). Because the Act prohibits conducting an examination or procedure without a certificate, the ALJ also concluded that Korangy and KRA each had committed an additional 192 separate violations by performing mammograms during the certification lapse. In a separate proceeding, the ALJ determined the appropriate amount of the sanctions. The FDA initially sought \$10,000 (the statutory maximum) for each violation by Korangy and KRA. Korangy contended, however, that he lacked the ability to pay sanctions in that amount. Although the FDA could not verify Korangy's claim because he did not come forward with all of the relevant financial information, the FDA nonetheless reduced its sanctions request from \$10,000 per violation to \$3,000 per violation. The ALJ assessed penalties in the amount sought by the FDA. The total amount of sanctions imposed was more than one million dollars—\$579,000 separately assessed against both KRA and Korangy.

Korangy and KRA appealed to the Departmental Appeals Board of the Department of Health and Human Services, and the Board affirmed the ALJ's decision. Korangy and KRA then filed this petition for review.

## II.

As noted above, the MQSA requires mammography facilities to be certified by the FDA, *see* 42 U.S.C.A. § 263b(b), and authorizes the imposition of civil monetary penalties for the "failure to obtain a certificate as required by subsection (b) of this section." 42 U.S.C.A. § 263b(h)(3)(A). A \$3,000 penalty was imposed on KRA and on Korangy for violation of this requirement. Neither KRA nor Korangy challenge that penalty on appeal. KRA (but not Korangy), however, does challenge the imposition of separate penalties for each of the 192 mammograms performed during the certification lapse.

The penalties for each of the mammograms performed were imposed under § 263b(h)(3)(D), which authorizes penalties for "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." 28 U.S.C.A. § 263b(h)(3)(D). KRA contends that it is *the facility*,<sup>1</sup> and not the owner or operator of the facility, and that the penalties were therefore not authorized under § 263b(h)(3)(D).

We agree with KRA's construction of the statute. Section 263b(h)(3)(D) unambiguously authorizes penalties to be imposed on owners, operators, and employees of the mammography facility, but it does not authorize penalties to be imposed on the facility itself. KRA's argument falters at the next step, however, because KRA's claim that it is the facility, as opposed to the owner or operator of the facility, is foreclosed, both as a matter of fact and of procedure.

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<sup>1</sup>The MQSA defines "facility" as the physical place where mammograms are performed. *See* 42 U.S.C.A. 263b(a)(3)(A) (West Supp. 2007) ("The term 'facility' means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts breast cancer screening or diagnosis through mammography activities. . . .").

The issue is foreclosed to KRA as a factual matter because it admitted in the proceedings below that it was the owner of the mammography facility. KRA's status as the owner of mammogram facility is a question of fact, and KRA cannot now be heard to challenge the ownership that it previously admitted. *See, e.g., Lucas v. Burnley*, 879 F.2d 1240, 1242 (4th Cir. 1989) ("The general rule is that a party is bound by the admissions of his pleadings." (internal quotation marks omitted)); *cf. Zinkand v. Brown*, 478 F.3d 634, 638 (4th Cir. 2007) ("Judicial estoppel is a principle developed to prevent a party from taking a position in a judicial proceeding that is inconsistent with a stance previously taken in court.").

The argument KRA seeks to raise on appeal is also barred as a procedural matter because KRA never argued below that penalties could not be imposed on it under § 263b(h)(3)(D) because it was the facility and not the owner of the facility. "[I]ssues raised for the first time on appeal are generally not considered absent exceptional circumstances. The underlying rationales for this rule are respect for the lower court, an avoidance of unfair surprise to the other party, and the need for finality in litigation and conservation of judicial resources." *Holly Hill Farm Corp. v. United States*, 447 F.3d 258, 267 (4th Cir. 2006) (internal quotation marks and alterations omitted). There are no exceptional circumstances in this case that would warrant our departure from this general rule. The language of § 263b(h)(3)(D) is abundantly clear and should have put KRA on notice from the beginning of these proceedings that the FDA was seeking to impose penalties on it in its capacity as the owner of the mammography facility. If there were doubt about KRA's ownership, it was incumbent upon KRA to raise the issue in a timely manner, when it could have been resolved by the agency charged with enforcing the MQSA. *See Lane Hollow Coal Co. v. Director, Office of Workers' Comp. Programs*, 137 F.3d 799, 806 (4th Cir. 1998) ("Simple fairness to those who are engaged in the tasks of administration, and to litigants, requires as a general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice." (internal quotation marks omitted)). Accordingly, we reject KRA's contention that the civil penalties assessed against it for the 192 mammograms performed during the certification lapse were not authorized under § 263b(h)(3)(D).

## III.

Korangy argues that an FDA guidance manual requires the FDA to give a facility, after a certification lapse, specific notice that performing mammograms could result in the imposition of civil penalties. Korangy contends that there is a factual dispute about whether he actually received the required notice. Because the ALJ expressly did not resolve the dispute, Korangy contends that the order must be vacated and the case remanded to the ALJ for resolution of the factual dispute.

The factual dispute identified by Korangy involves two letters sent by the FDA. On April 1, 2002, the FDA sent Korangy a letter informing him that his certificate was about to expire and that it would violate the statute to perform mammograms after its expiration. On May 1, 2002, the FDA sent a second letter to Korangy directing him to stop performing mammograms and stating that he would be subject to civil penalties if he continued to perform them. Korangy denied having received either letter. The ALJ did not decide whether Korangy in fact received these letters, concluding that even without them Korangy had all the notice that he needed. We agree with the ALJ's analysis on this point.

The manual upon which Korangy's argument hinges states that:

The decision as to whether a facility should receive a Warning Letter or Civil Money Penalties would depend on the severity of the situation found. *Prior notice should be established before considering Civil Money Penalties.* Factors affecting severity could include the number of patients that were examined while uncertified, whether the facility knew that it was performing mammography uncertified (i.e., was it clear from correspondence that the facility received that they were no longer certified). . . .

J.A. 81 (emphasis added). Assuming for purposes of this case that the guidance manual establishes binding standards with which the FDA must comply, we simply cannot conclude that the agency's actions were in any way inconsistent with the requirements of the manual. While the manual requires that prior notice be given, nothing in the

manual mandates that notice must come in any particular form, or that the notice must come from the FDA itself. In this case, the 1999 certificate itself shows on its face that it expires on May 6, 2002. The ACR, the entity that performed the inspection of the equipment, sent Korangy a letter on April 29, 2002, stating that the equipment had failed the accreditation examination, that he should immediately stop performing mammograms, and that continuing to perform mammograms "may result in official sanction and fines from the FDA." J.A. 32. Because Korangy acknowledges that he received this letter, the record clearly supports the ALJ's determination that Korangy received sufficient notice. *See Knox v. United States Dep't of labor*, 434 F.3d 721, 723 (4th Cir. 2006) ("Under the Administrative Procedure Act. . . , federal courts can overturn an administrative agency's decision only if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, or unsupported by substantial evidence." (internal quotation marks omitted)). The ALJ thus properly resolved the issues before it, and there is no need to remand for resolution of the factual dispute surrounding the April and May letters from the FDA.

#### IV.

Finally, Korangy and KRA contend that the penalty imposed is excessive and violates the Eighth Amendment. We disagree.

The Excessive Fines Clause of the Eighth Amendment prohibits the government from imposing excessive fines as punishment. While Eighth Amendment claims often arise in the criminal context, civil sanctions may fall within the scope of the amendment. *See Austin v. United States*, 509 U.S. 602, 610 (1993); *Thomas v. Commissioner*, 62 F.3d 97, 99 (4th Cir. 1995). Civil fines serving remedial purposes do not fall within the reach of the Eighth Amendment. However, if a civil sanction "can only be explained as serving in part to punish," then the fine is subject to the Eighth Amendment. *Austin*, 509 U.S. at 610. If the civil penalty is punitive and thus subject to the Eighth Amendment, it will be found constitutionally excessive only if it is "grossly disproportional to the gravity of [the] offense." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *see United States v. Ahmad*, 213 F.3d 805, 813 (4th Cir. 2000).

The FDA argues that the penalties authorized by the MQSA are wholly remedial and thus not subject to the Eighth Amendment. While we harbor some doubt about that characterization, *see Bajakajian*, 524 U.S. at 329 (suggesting that remedial actions are brought to obtain compensation or indemnification for lost revenues), we need not resolve that issue. Assuming that the penalties are at least partially punitive and thus subject to the Eighth Amendment, we cannot conclude that penalties imposed are grossly disproportionate to the gravity of the offense.

Preliminarily, we note that Congress authorized up to \$10,000 for each violation of the MQSA. The \$3,000 per violation penalty imposed by the FDA thus represents a substantial reduction of the penalty authorized by Congress. *See id.* at 336 (noting that "judgments about the appropriate punishment for an offense belong in the first instance to the legislature"). Moreover, KRA lost its certification not because of a failure to comply with a reporting requirement or some similar "technicality," *cf. id.* at 337 (finding forfeiture of more than \$350,000 to be constitutionally excessive where the defendant's crime was "solely a reporting offense"), 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.

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

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MQSA, a substantial penalty was warranted.<sup>2</sup> Under these circumstances, we cannot conclude that the penalties assessed against Korangy and KRA were grossly disproportional to the gravity of the offenses they committed, and we therefore reject the petitioners' Eighth Amendment claims.

V.

Accordingly, for the foregoing reasons, we hereby deny the petition for review.

*PETITION FOR REVIEW DENIED*

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<sup>2</sup>Moreover, if the FDA could not impose separate penalties for repeated violations, that would serve as perverse encouragement for out-of-compliance clinics to perform as many mammograms as possible. Clinics could put off for as long as possible purchasing expensive new equipment and continue to profit from each mammography performed, secure in the knowledge that their profits would exceed any sanctions that might ultimately be imposed.