

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

UNITED STATES OF AMERICA, *

Plaintiff, *

v. *

KORANGY RADIOLOGY ASSOC., *
P.A., trading as BALTIMORE *
IMAGING CENTER, a corporation *
and AMILE A. KORANGY, M.D., *
an individual, *

NO. RDB-09-cv-0623

Defendants. *

* * * * *

MEMORANDUM OPINION

The United States filed this action to collect civil money penalties (“civil penalties”) that were first assessed by an Administrative Law Judge (“ALJ”) at the Food and Drug Administration (“FDA” or “agency”) in December 2004 against Amile A. Korangy, M.D., a radiologist, and Korangy Radiology Associates, P.A. (“KRA”), a Maryland corporation of which Dr. Korangy is a 100% shareholder and which owns and operates Baltimore Imaging Center, a mammography facility (collectively, “Defendants”). This debt – which stands at \$1,013,000 plus outstanding interest – resulted from Defendants’ violations of the Mammography Quality Standards Act of 1992 (“MQSA”), 42 U.S.C. § 263b, and their breach of a payment agreement that they entered into with FDA. Currently pending before this Court is the Government’s Motion for Summary Judgment (Paper No. 14). The parties’ submissions have been reviewed and no hearing is necessary. *See* Local Rule 105.6 (D. Md. 2008). For the reasons stated below, the Government’s Motion for Summary Judgment is GRANTED.

BACKGROUND

The complete factual and procedural background of this case has been fully set forth by the United States Court of Appeals for the Fourth Circuit in *Korangy v. FDA*, 498 F.3d 272 (4th Cir. 2007), in which the Fourth Circuit affirmed administrative rulings. Therefore a lengthy discussion herein is not necessary.

Under the Mammography Quality Standards Act of 1992, no mammography facility may conduct a mammography examination or procedure unless it possesses an effective certificate that has been issued or renewed by FDA. 42 U.S.C. § 263b(b)(1). Although Defendant Dr. Amile A. Korangy was aware that the mammography equipment he was using had a certificate that expired on May 6, 2002, he used the equipment through July 25, 2002, performing 192 mammograms in violation of the MQSA. 42 U.S.C. § 263b(h)(3)(D).

The ALJ assessed a civil penalty of \$579,000 against each Defendant, Korangy and KRA, for their violations, for a total penalty of \$1,158,000. On appeal, the Department of Health and Human Services' Departmental Appeals Board (the "Board") upheld the propriety of the ALJ's liability finding and civil penalty computation. The Fourth Circuit affirmed the Board's ruling on August 17, 2007. Finally, the Supreme Court denied Defendants' petition for a writ of *certiorari*.

After exhausting all of their administrative and judicial appeals, Defendants voluntarily entered into an agreement with FDA to pay the agency the total penalty of \$1,158,000 over the course of fifteen months. Under the agreement, Defendants are jointly and severally liable for the full amount. Defendants breached that agreement when they failed to make the first required

payment of \$579,000, which was due on or before June 12, 2008.¹ FDA then sent Defendants a notice of default, stating that the entire \$1,158,000 plus interest was immediately due and payable. Compl. Ex. 12 at 2.

STANDARD OF REVIEW

Rule 56 of the Federal Rules of Civil Procedure provides that summary judgment “shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). A material fact is one that “might affect the outcome of the suit under the governing law.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A genuine issue over a material fact exists “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* In considering a motion for summary judgment, a judge’s function is limited to determining whether sufficient evidence exists on a claimed factual dispute to warrant submission of the matter to a jury for resolution at trial. *Id.* at 249.

In undertaking this inquiry, a court must consider the facts and all reasonable inferences in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). After the moving party has established the absence of a genuine issue of material fact, the nonmoving party must present evidence in the record demonstrating an issue of fact to be resolved at trial. *Pension Ben. Guar. Corp. v. Beverley*, 404 F.3d 243, 246-47 (4th Cir. 2005) (citing *Pine Ridge Coal Co. v. Local 8377, UMW*, 187 F.3d 415, 422 (4th Cir. 1999)). Summary judgment will be granted if the nonmoving party “fails to

¹ Defendants made three subsequent payments totaling \$145,000 towards their initial debt, but have made no payments since January 8, 2009.

make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

This Court has an affirmative obligation to prevent factually unsupported claims and defenses from going to trial. *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993) (quoting *Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987)). If the evidence presented by the nonmoving party is merely colorable, or is not significantly probative, summary judgment must be granted. *Anderson*, 477 U.S. at 249-50. This Court has previously explained that a "party cannot create a genuine dispute of material fact through mere speculation or compilation of inferences." *Shin v. Shalala*, 166 F. Supp. 2d 373, 375 (D. Md. 2001) (citations omitted).

ANALYSIS

I. Full and Final Decision

As an initial matter, whether Defendants' MQSA violations and the civil penalties assessed against them were appropriate has been fully and finally decided. The ALJ found Defendants were liable for the violations and assessed a civil penalty that was upheld by the Board on appeal. *Korangy Radiology Assoc., P.A. v. FDA*, No. A-05-35, 2005 HHSDAB LEXIS 131, at *12-61 (Sept. 26, 2005). The United States Court of Appeals for the Fourth Circuit affirmed the Board's ruling. *Korangy v. FDA*, 498 F.3d 272, 278 (4th Cir. 2007), rendering the agency's action final, subject to review by the Supreme Court. The Supreme Court denied Defendants' petition for a writ of *certiorari*. *Korangy Radiology Assoc. v. FDA*, 128 U.S. 1110 (Jan. 14, 2008).

II. Defendants' Affirmative Defenses

Defendants raise eighteen affirmative defenses in their Answer to the Government's Complaint, none of which are meritorious. Notably, Defendants do not substantiate – or even reference – almost any of these defenses in their Opposition to the Government's pending Motion for Summary Judgment.

A. Failure to State a Claim Upon Which Relief May Be Granted

Defendants' first affirmative defense is that the Amended Complaint fails to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6). Am. Answer at 6. The Government's Amended Complaint contends that the Defendants owe FDA the civil penalties plus interest under the Agreement. These facts raise a right to relief far above the speculative level and state a claim to relief that is plausible on its face. *Robinson v. Am. Honda Motor Co., Inc.*, 551 F.3d 218, 222 (4th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Accordingly, this affirmative defense is groundless.

B. Civil Penalty Assessment Challenge

Defendants raise four baseless affirmative defenses challenging the underlying penalty assessment against them: to wit that the Government did not have authority to assess the civil penalties against them, that they were denied due process of law, that the penalties were punitive and excessive, and that they were unable to pay the penalties and were entitled to mitigation. Am. Answer at 6.

These defenses cannot succeed for two reasons. First, the Court of Appeals has exclusive jurisdiction for judicial review of a civil assessment under the MQSA. 42 U.S.C. § 263b(k)(1) (“If the Secretary imposes a sanction on a facility under [the MQSA] . . . , the owner or operator of the facility may . . . file a petition with the *United States court of appeals* for the circuit in which the facility is situated for judicial review of the action.”) (emphasis added). *See also*

United States v. Holcomb, 651 F.2d 231, 236 (4th Cir. 1981) (holding that the District Court lacked jurisdiction to review the validity of an administrative finding under the Horse Protection Act because the Act stated the forum for judicial review of a civil assessment was the Court of Appeals). Therefore, this Court lacks jurisdiction to review the validity of the civil penalty assessment that has been affirmed by the Fourth Circuit.

Second, as explained above, Defendants have had several full and fair opportunities to raise these defenses, which have been fully litigated and finally decided against them in numerous administrative and judicial proceedings. Thus, these defenses are barred by the doctrines of collateral estoppel and *res judicata*.

C. Accord and Satisfaction, Payment, Release, and Waiver

Defendants' raise four unsubstantiated affirmative defenses that require proving certain facts regarding their civil penalty debt and/or the Agreement: accord and satisfaction, payment, release, and waiver. Am. Answer at 6-7.

To prevail on the defense of accord and satisfaction, Defendants need to prove that the parties entered into a compromise agreement whereby Defendants agreed to pay more than they believed they owed and FDA agreed accept a sum less than it believed it was due. *See Parker v. Prudential Ins. Co.*, 900 F.2d 772, 776 (4th Cir. 1990). The Agreement itself makes clear, however, that FDA never agreed to accept a sum less than it believed it was due; rather, the agency agreed to give Defendants fifteen months to pay the *full amount* of civil penalties that they owed FDA.

Defendants' payment defense has no merit because it is undisputed that Defendants have not fully paid the \$1,158,000, plus applicable interest, owed to FDA. Defendants cannot show that their obligation to pay the civil penalties has been released by FDA, because it has not been. Defendants also cannot show that FDA waived its right to recovery by an express or implied

agreement in which the agency manifested its intent to relinquish its right to be paid, because there is no such agreement. *See American Hardware Mut. Ins. Co. v. BIM, Inc.*, 885 F.2d 132, 138 (4th Cir. 1989). Consequently, each of these defenses cannot succeed.

D. Duress, Fraud, and Estoppel

Defendants' attempts to void the Agreement under the defenses of duress, fraud, and estoppel, all of which require a showing of improper behavior on FDA's part, and their defense of illegality, also must fail. *See Am. Answer at 7.*

To void an agreement on the grounds of duress, Defendants must show that they assented to the Agreement under an improper threat which left them with no reasonable alternative but to agree. *United States v. Vanhorn*, 20 F.3d 104, 112 (4th Cir. 1994). There is no evidence of any improper threats made by FDA.

In order to support their fraud defense, Defendants must prove, among other things, that FDA made false representations to them for the purpose of defrauding them, and that they acted in reliance on the misrepresentation. *See Learning Works, Inc. v. Learning Annex, Inc.*, 830 F.2d 541, 545 (4th Cir. 1987). Defendants' estoppel defense requires a showing that they were misled by someone at FDA, that this person had the authority to make such a representation, and that, in reliance on the misleading statement, Defendants changed their position for the worse. *OPM v. Richmond*, 496 U.S. 414, 419-20 (1990); *see also Hartford Fire Ins. Co. v. Annapolis Bay Charters, Inc.*, 69 F. Supp. 2d 756, 763 (D. Md. 1999). There is no evidence that FDA made any false, fraudulent, or misleading representations to Defendants in this matter; therefore, all of these defenses are groundless.²

² Moreover, estoppel generally does not lie against the federal government. *Richmond*, 496 U.S. at 426-27.

Defendants' illegality defense requires them to show that the Agreement is unenforceable on public policy grounds. However, the public policy arguments here cut against Defendants and warrant holding them responsible for their MQSA violations and for their breach of the Agreement, requiring them to pay the full penalty assessment against them. Thus, this defense has no merit.

E. Laches and Statute of Limitations

Defendants raise the related defenses of laches and statute of limitations, but both are unavailing to them in this case. Am. Answer at 7. To prove that laches bars this case, Defendants must show, among other things, that the Government was negligent or lacked diligence in asserting its right to payment. *Hartford Fire Ins. Co.*, 69 F. Supp. 2d at 763. The timeline of events in this matter show that the Government was neither negligent nor lacked diligence in its actions against Defendants.

Defendants do not state what applicable statute of limitations allegedly bars this case. The Government's right to file this action to collect the civil penalties owed to it did not accrue until the Supreme Court denied *certiorari*. See 42 U.S.C. § 263b(k)(4). The Government filed this action less than one year after the Defendants breached the agreement. Furthermore, Defendants made a payment to FDA on the civil penalty just two months before the Government brought this action. Thus, the statute of limitations does not bar the Government's claims in this case.

F. Res Judicata and the Statute of Frauds

Defendants' affirmative defense of *res judicata* and the statute of frauds are without foundation. In order to prevail on a *res judicata* defense, Defendants must show, among other

things, a final judgment on the merits in their favor in a prior suit. *Andrews v. Daw*, 201 F.3d 521, 524 (4th Cir. 2000). FDA, however, has prevailed in *all* earlier proceedings against Defendants, and there is no final judgment in Defendants' favor that would support an affirmative defense of *res judicata*. Defendants also assert a "statute of frauds" defense. The statute of frauds is completely inapplicable to the written Agreement that is at issue in this case.³ Thus, both of these defenses fail.

III. Defendants' Contract Claim

In their Opposition to the Government's Motion for Summary Judgment, Defendants contend that the Agreement they voluntarily entered into with the FDA is unenforceable because two of its terms lacked consideration and the Government implicitly waived its right to enforce the Agreement.

A. Consideration

Defendants seek to have the entire Agreement declared unenforceable because there was no consideration for two specific provisions in the contract: the provision wherein they agreed to be held jointly and severally liable for the full \$1.158 million civil penalty, and the provision that provides for interest payments in the event of their default.⁴ Opp. at 5-6; Agreement at ¶¶ D, F.

The Agreement at issue in this case provided both a benefit to the Defendants and a detriment to the Government. *Harford County v. Town of Bel Air*, 704 A.2d 421, 430 (Md.

³ The statute of frauds provides that contracts for the sale of *land* are unenforceable unless they are in writing and signed by the parties to be charged. *Sports Auth. v. Chesapeake Assocs.*, No. 97-1833, 20 1998 U.S. App. LEXIS 9554, at *19 (4th Cir. May 12, 1998).

⁴ Notably, Maryland law provides that "a party who signs a contract is presumed to have read and understood its terms and as such will be bound by its execution." *Holloman v. Circuit City Stores, Inc.*, 894 A.2d 547, 556 (Md. 2006); *see also Binder v. Benson*, 171 A.2d 248, 250 (Md. 1961) ("[T]he usual rule is that . . . one who has the capacity to understand a written document who reads and signs it, or, without reading it or having it read to him, signs it, is bound by his signature as to all of its terms.") (citations omitted).

1998) (explaining that consideration is established by showing either a benefit to the promisor or a detriment to the promise). The obvious benefit to the Defendants was the fifteen additional months to pay the Government the full civil penalty amount. Although the Government need only show a benefit to Defendants to establish that there was valuable consideration for the Agreement, there was also a detriment to the Government, which itself is sufficient to uphold the validity of the Agreement's terms. The practical effect of the Government's agreement was that, if Defendants were paying the civil penalty in full compliance with the Agreement, any attempt by the Government to bring a collection action would be forestalled. *Cheek v. United HealthCare of Mid-Atlantic, Inc.*, 835 A.2d 656, 661 (Md. 2003) (explaining that forbearance to exercise a right or pursue a claim constitutes sufficient consideration to support an agreement). Thus, the Agreement and all promises made therein had consideration and are binding and enforceable.

B. Waiver

Defendants contend that there is a dispute of material fact as to whether the Government impliedly waived its rights under the Agreement because it waited over eight months from the notice of default to institute this case and accepted three payments from Defendants after their default. Opp. at 10. However, all of the facts of this case taken together plainly show that the Government has not waived its rights to enforce the Agreement.

First, the Government has actively litigated this matter against Defendants since 2003. Second, the Government's notice of default made clear that "any change in the terms of the Payment Agreement was unacceptable to FDA" and that the agency was "referring this matter to appropriate authorities to ensure enforcement of the agreement and collection of the entire

amount, plus all interest due upon collection.” Compl. Ex. 12 at 1-2; *BarGale Indus., Inc. v. Robert Realty Co., Inc.*, 343 A.2d 529, 533 (Md. 1975) (“A waiver . . . may result from an express agreement or be inferred from circumstances. Acts relied upon as constituting a waiver of the provisions of a contract must be inconsistent with an intention to insist upon enforcing such provisions.”) (internal quotations omitted). Third, an eight month delay in filing this case is well within the applicable statute of limitations. Moreover, once the case was referred to the Department of Justice, Government counsel engaged in extended discussions with Defendants’ attorneys to try to avoid filing this collection action. Memo. in Supp. Summ. J. at 4. Fourth, at no time has the Government ever suggested that anything less than full payment of the civil penalty, plus applicable interest in accordance with the Agreement, was acceptable. *Nichols v. Cities Serv. Oil Co.*, 171 F. Supp. 400, 409 (D. Md. 1959), *aff’d* 273 F.2d 415 (4th Cir. 1960) (“[Waiver] is a voluntary act which implies a choice by the party to dispense with something of value or to forego some advantage which he might, at his option, have demanded and insisted on.”) (citations omitted). The fact that the Government accepted from Defendants three payments totaling \$145,000 on a total debt amount of over \$1.158 million does not give any credence to Defendants’ argument that the United States voluntarily waived its right to collect the full amount owed in accordance with the Agreement. Defendants’ claim that the Government has waived the Agreement is entirely unsubstantiated.

CONCLUSION

For the reasons stated above, the Government’s Motion for Summary Judgment (Paper No. 14) is GRANTED and judgment is entered against Defendants in the amount of \$1,013,000, plus all applicable interest and costs. A separate Order follows.

Dated: December 17, 2009

/s/
Richard D. Bennett
United States District Judge