1-21-2009

# USA v. Carlisle HMA Inc

PRECEDENTIAL

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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NO. 07-4616

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UNITED STATES OF AMERICA
ex rel. TED D. KOSENSKE, M.D.

v.

CARLISLE HMA, INC.; HEALTH
MANAGEMENT ASSOCIATES, INC.

Ted D. Kosenske, M.D.
Appellant

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On Appeal From the United States District Court
For the Middle District of Pennsylvania
(D.C. Civil Action No. 05-cv-02184)
District Judge: Hon. Christopher C. Conner

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Argued October 31, 2008

BEFORE: SLOVITER, STAPLETON and TASHIMA,* *Circuit Judges*

(Opinion Filed January 21, 2009)

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* Hon. A. Wallace Tashima, Senior United States Circuit Judge for the Ninth Circuit, sitting by designation.

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OPINION OF THE COURT

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STAPLETON, Circuit Judge:

Appellant Ted D. Kosenske brought this *qui tam* action under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, against Carlisle HMA, Inc. ("HMA"), and its parent company, Health Management Associates, Inc. The complaint alleged that they submitted outpatient hospital claims to the Medicare program and other federal healthcare programs, falsely certifying that such claims were in compliance with the Stark Act, 42 U.S.C. § 1395nn ("the Act"), and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b. The parties filed cross-motions for summary judgment. The District Court granted the defendants' motion and denied the plaintiff's motion. This appeal followed.

This appeal presents two principal issues. First, we must decide whether the exclusive service arrangement between Kosenske's former practice, Blue Mountain Anesthesia Associates, P.C. ("BMAA"), and defendants, in which BMAA

provided pain management services at an outpatient HMA clinic, triggered the restrictions placed by the Stark and Anti-Kickback Acts on the submissions of claims for services rendered following "referrals" by a physician having a "financial relationship" with the service provider. We conclude that the Stark and Anti-Kickback Acts were implicated. Second, we must determine if the arrangement between BMAA and HMA satisfied the personal service exception to the Stark Act and the substantially identical safe harbor provision of the Anti-Kickback Act. We conclude that it did not. It follows that summary judgment was wrongly awarded to HMA. Accordingly, we will reverse and remand to the District Court for further proceedings consistent with this opinion. Because the parties agree that, in the context of this case, the requirements of the Anti-Kickback Act and its implementary regulations are indistinguishable from those of the Stark Act, we refer only to the latter in the following analysis.

I.

BMAA, a group of four physicians that practiced anesthesiology, engaged in negotiations with Carlisle Hospital and Health Systems ("CHHS"), culminating in an Anesthesiology Services Agreement ("the Agreement") dated December 31, 1992. Kosenske was a member of that group.

The purpose of the Agreement was to establish an exclusive service arrangement under which BMAA would provide all anesthesia services required by the Hospital's patients at CHHS's hospital in Carlisle, Pennsylvania (the "Hospital"). While no pain management services were being

performed by BMAA physicians at the Hospital in 1992, the Agreement contemplated that such services might be rendered in the future. The Agreement essentially provided that (1) BMAA would provide anesthesia coverage for Hospital patients on a 24/7 hour/day basis; (2) the Hospital would provide at no charge the space, equipment and supplies reasonably necessary and economical for BMAA to provide these anesthesiology services; (3) BMAA would use the personnel, space, equipment and supplies provided by the Hospital solely for the practice of anesthesiology and pain management for the Hospital's patients; (4) the Hospital would not allow anyone other than BMAA physicians to provide anesthesia or pain management services at the Hospital; and (5) BMAA physicians would not practice anesthesia or pain management at any location other than "the Hospital and . . . such other facilities and locations as may be operated by Hospital and Carlisle Hospital & Health Services ("CHHS"), the entity which owns Hospital." JA at 2.

It is helpful to note at the outset two limitations on the obligations of BMAA under the carefully drafted Agreement. First, as the section of the Agreement we have just quoted suggests and as the remainder of the Agreement confirms, "Hospital" refers only to the "Carlisle Hospital located at 246 Parker Street, Carlisle, Pennsylvania." JA at 1. Thus, the patients that BMAA committed itself to provide 24/7 hour/day anesthesia services for were the patients in the existing facility of the Carlisle Hospital. While it is true that the Agreement contains a few provisions that contemplated the possibility of BMAA services being performed elsewhere, those provisions only confirm that BMAA's commitment under *this* Agreement to provide services was limited to that facility. Section 7B, for

example, provides as follows:

> In the event that Hospital or CHHS obtains, opens, or operates another facility or location at which anesthesiology or pain management services are required or offered, Hospital and CHHS *shall offer BMAA the opportunity* to provide exclusive anesthesiology and pain management services at such new facility or location under the same terms and conditions as provided in this agreement, *to the fullest extent that the Hospital and/or CHHS is able to contract with BMAA* to provide such services on the same terms and conditions as set forth herein. *Should Hospital and/or CHHS be unable, for any lawful reason, to enter into a contract with BMAA* to provide such services on the same terms and conditions as set forth herein, then *Hospital and/or CHHS shall offer BMAA the first opportunity* to provide exclusive anesthesiology and pain management services at such new facility or location on whatever terms Hospital and/or CHHS and BMAA may negotiate and, in the event that the parties are not able to negotiate an agreement for the provision of such exclusive services by BMAA, BMAA shall have *the right of first refusal* for any proposal or contract entered, offered, or made by Hospital and/or CHHS with any other person or entity to provide anesthesiology or pain management services at such new facility. Hospital and/or

> CHHS shall not enter into any agreement with any other provider without first offering to BMAA the opportunity and right to provide such exclusive services at such facility or location on identical terms offered to or negotiated with such other provider.

JA at 8-9 (emphasis added).

Thus, understandably, BMAA was not committing itself to provide continuous 24/7 service at any new facility that the Hospital or CHHS might choose to open in the future. Rather, it insisted that if and when that happened they would either have to *"offer BMAA the opportunity* to provide exclusive anesthesiology and pain management services" in the new facility under the same terms and conditions or would have to provide BMAA with an opportunity to exercise a right of first refusal. In short, if BMAA were going to undertake the obligation of providing service beyond the patients of the then current facility, a new contract would be required.

Second, while BMAA committed itself to satisfying all of the anesthesiology needs of the patients at the Hospital, it did not similarly commit itself to provide pain management services. Not surprisingly, given that no pain management services were being provided when the Agreement was signed, BMAA only committed itself to "devote such time as necessary to provide anesthesia services to Hospital patients and provide anesthesiology consultation to other physicians in the Medical Staff as needed," including "reasonable emergency response on

a 24 hour a day, 7 day per week basis."[1] JA at 2, 4.

The Agreement, while using the terms "anesthesiology" and "pain management" as distinct fields of practice, did not define these terms. In context, however, anesthesiology is used in the traditional sense – the practice of administering anesthesia to patients undergoing a surgical procedure. Accordingly, it is a hospital- or surgery-center-based practice. The practice of "pain management," as commonly understood, involves the evaluation and management of pain symptoms. It can be, but is not required to be, hospital-based. This distinction between anesthesiology and pain management is relevant in the context of the Stark Act because it bears on the issue of referrals. As the Department of Health and Human Services ("HHS") has recognized, with traditional hospital-based practices like anesthesiology, "it is typically the hospitals that are in a position to influence the flow of business to the physicians, rather than the physicians making referrals to the hospitals." OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4867 (Jan. 31, 2005). In such situations, HHS is primarily concerned with any remuneration flowing from anesthesiologists to the hospital. With respect to a pain management practice that is not a hospital-based practice, the

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[1] It is true, as the District Court found, that the mutual exclusivity provisions, including one contained in the section entitled "Obligations of BMAA," restrict its right to practice both "anesthesiology and pain management" elsewhere, but those provisions expressly relate only to BMAA's right to practice rather than its obligation to do so.

concerns are different. Patients typically come to see pain management physicians for office visits, and the physicians frequently order tests or procedures at a hospital, lab, or other facility. Thus, in pain management, a physician in an outpatient facility is in a position to generate substantial business for a hospital. *See id*. at 4865 (noting that "[p]hysicians are the primary referral source for hospitals"). Therefore, HHS's concern would be with remuneration flowing from the hospital to the physicians in order to induce the physicians to provide business for the hospital.

Approximately fifteen months after signing the 1992 Agreement, Kosenske and a Hospital nurse began administering pain management services, in addition to traditional anesthesia, to Hospital patients. Because there was no dedicated space for pain management services, Kosenske saw these patients in space used for other hospital purposes.

In 1998, the Hospital built a new, stand-alone facility, containing an outpatient ambulatory surgery center and a pain clinic ("the Pain Clinic"), which was located about three miles away from the Hospital. From the day of its opening, BMAA provided pain management services to patients in the Pain Clinic, and the Hospital did not charge BMAA rent for the space and equipment, or a fee for the support personnel it provided to BMAA at the Pain Clinic. BMAA provided a physician to see patients in the Pain Clinic, and this physician when serving there did not have other anesthesiology duties at the Hospital. As with the anesthesia services, BMAA physicians submitted claims to Medicare for the professional services performed during these visits, and the Hospital submitted claims for the

facility and technical component of the visits. No one other than BMAA provided pain management services at the Pain Clinic. However, the parties did not amend the 1992 Agreement or enter into a new agreement.

In June 2001, HMA purchased the Hospital from CHHS, as an asset purchase, and renamed it Carlisle Regional Medical Center. The 1992 Agreement was not assigned to HMA, but both HMA and BMAA acted as if the Agreement were still in effect at the Hospital. We will assume, without deciding, that HMA was CHHS's successor under the applicable law.

II.

We review the District Court's grant of summary judgment *de novo*. *DIRECTV Inc. v. Seijas*, 508 F.3d 123, 125 (3d Cir. 2007) (citing *CAT Internet Servs. Inc. v. Providence Wash. Ins. Co.*, 333 F.3d 138, 141 (3d Cir. 2003)).[2] We apply the same standard as the District Court in determining whether summary judgment was appropriate. *Congregation Kol Ami v. Abington Twp.*, 309 F.3d 120, 130 (3d Cir. 2002). Thus, summary judgment was proper if, viewing the record in the light most favorable to the non-moving party and drawing all inferences in that party's favor, there is no genuine issue of

[2] We have jurisdiction under 28 U.S.C. § 1291, in that this is an appeal from a final judgment in favor of defendants. Judgment was entered on November 15, 2007, and Appellant timely filed a notice of appeal on December 10, 2007.

material fact and the moving party is entitled to judgment as a matter of law. *See Abramson v. William Paterson Coll.*, 260 F.3d 265, 276 (3d Cir. 2001); Fed. R. Civ. P. 56(c).

III.

Section 3729 of the False Claims Act ("FCA") imposes liability on any person or entity who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; . . . .

31 U.S.C. 3729(a)(1)-(3). Falsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) (citing *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997)); *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D.Ill. 2006).

A

Section 1395nn(a)(i) of the Stark Act provides, in pertinent part:

> if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a)(1). Under the Act, a physician has a "financial relationship" with an entity if the physician has "an ownership or investment interest in the entity," or "a compensation arrangement" with it. 42 U.S.C. § 1395nn(a)(2). A "compensation arrangement" consists, with certain exceptions not here relevant, of "any arrangement involving any remuneration between a physician . . . and an entity . . . ." 42 U.S.C. § 1395nn(h)(1)(A). "The term 'remuneration' includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(B). The Stark Act defines "referral" as "the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or

to be performed by (or under the supervision of) that other physician)." 42 U.S.C. § 1399nn(h)(5)(A). The "oft-stated goal" of the Act is "to curb overutilization of services by physicians who could profit by referring patients to facilities in which they have a financial interest." *See* Jo-Ellyn Sakowitz Klein, *The Stark Laws: Conquering Physician Conflicts of Interest?*, 87 GEO. L.J. 499, 511 (1998).

The Act contains exceptions to its broad prohibition, however, in order to exclude from the prohibition financial arrangements that exist for reasons independent of referrals. *See* 2 BARRY R. FURROW ET AL., HEALTH LAW: PRACTITIONER TREATISE SERIES, § 13-9 (2d ed. 2000). One such exception excludes "personal service arrangements" if:

> (i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,
> (ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,
> (iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,
> (iv) the term of the arrangement is for at least 1 year,
> (v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in

> subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
> (vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and
> (vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn(e)(3)(A).

The Act defines "fair market value" as "the value in arms length transactions, consistent with the general market value . . . ." 42 U.S.C. § 1395nn(h)(3). Once the plaintiff or the government has established proof of each element of a violation under the Act, the burden shifts to the defendant to establish that the conduct was protected by an exception. *Rogan*, 459 F. Supp. 2d at 716.

B

In the course of concluding that HMA was entitled to summary judgment, the District Court found that BMAA received numerous benefits as a result of its relationship to HMA which constituted "remuneration" for purposes of the Act and established a "compensation arrangement" and "financial relationship" between BMAA and HMA. The Court further

concluded that BMAA physicians had requested services from the Hospital that constituted referrals and that HMA had submitted claims to Medicare based on those services. The Court held, however, that HMA's undisputed evidence had established that its arrangement with BMAA at the Pain Clinic was within the scope of the "personal service" exception of § 1395nn(e)(3)(A).

In the course of concluding that HMA had carried its burden of demonstrating satisfaction of all elements of the personal service exception, the District Court tacitly assumed that the Agreement was applicable to BMAA's service at the Pain Clinic and held that it satisfied the "arrangement . . . in writing" requirement because "all parties intended . . . HMA to succeed CHHS under the 1992 agreement for purposes of the Stark Act." JA at 41. After concluding that the provisions of the Agreement "adequately address all of the anesthesiology and pain management services to be rendered by BMAA at the hospital and the pain management clinic," JA at 43, it turned to the issue of whether the Agreement set forth in advance compensation to be provided for those services, which did not exceed their fair market value. The Court concluded that this requirement of the "personal service" exception was satisfied even though HMA had tendered no evidence regarding the market value of the space, equipment and staff services provided to BMAA at the Pain Clinic or of the mutual exclusivity rights the parties were apparently according each other there. The Court found such evidence unnecessary because the consideration provided for in the Agreement was the result of negotiation between unrelated parties and "[b]y definition" reflected fair market value. As the Court put it:

> The mutuality of rights and responsibilities imposed by the 1992 agreement is compelling evidence that the parties engaged in a fair-market-value exchange. . . . *By definition*, the terms of the contract reflect the fair market value of the benefits conferred on each party. Therefore, the court finds that [the] agreement complies with the fair market value requirements of the personal service exception.

JA at 46-47 (emphasis added).

C

We agree with the District Court's determination that the arrangement between BMAA and HMA implicates the Stark Act. BMAA received numerous benefits as a result of its relationship with HMA, including the exclusive right to provide all anesthesia and pain management services, and the receipt of office space, medical equipment and personnel. These benefits constitute remuneration in-kind from HMA to BMAA, which is considered a compensation arrangement under the Act and establishes a financial relationship between BMAA and HMA. We cannot, however, agree with the District Court that the arrangement between BMAA and HMA at the Pain Clinic qualifies for the personal service exception.

The exception recognizes that there can be personal service arrangements involving referrals that are beneficial and seeks to take advantage of those benefits while assuring that the referrals will not result in abuses. The Act does this by insisting

on the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the remuneration to be received for those services.

In this case, the only written contract in existence between the parties is one that did not, and obviously was not intended to, apply to services at a non-existent facility. It was negotiated in 1992 in a context wholly different from the one that existed six years later after the opening of the Pain Clinic. No pain management services were being provided by BMAA in 1992, and by 1998 it was providing exclusive pain management services for a facility devoted solely to such services. Similarly, with respect to the value to be received by BMAA for those services, in 1992 no free Hospital space, staff or facilities were devoted solely to pain management, and the opening of the Pain Clinic represented a very substantial change.

In this context, it is apparent that there was no written contract setting forth the relevant arrangement at the Pain Clinic following its opening. Moreover, even if the 1992 Agreement could otherwise be read as reflecting the parties' arrangement at the Pain Clinic, that Agreement said nothing about much of the consideration that BMAA was receiving for its services. The Agreement says nothing whatsoever about the provision of free office space, equipment and staff necessary to the practice of pain management, much less about a stand-alone Pain Clinic.

Finally, it is clear that there were no arm's length negotiations that could vouch for the fair match of service and compensation that the whole statutory scheme is designed to

assure. The District Court's determination that such a match existed cannot be sustained for two reasons. First, as a factual matter, negotiations in 1992 could not possibly reflect the fair market value of the consideration given and received more than six years later under materially different circumstances. Second, as a legal matter, a negotiated agreement between interested parties does not "by definition" reflect fair market value. To the contrary, the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation.

The Act provides that "[t]he term 'fair market value' means the value in arms length transactions, consistent with the general market value . . ." 42 U.S.C. § 1395nn(h)(3). The regulations amplify this definition as follows:

> Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers *who are not otherwise in a position to generate business for the other party*, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement *who are not otherwise in a position to generate business for the other party*, on the date of acquisition of the asset or at the time of the

service agreement.

42 C.F.R. § 411.351 (emphasis added). As we have explained, BMAA and HMA are in a position to generate business for each other.

HMA makes no plausible argument in support of the District Court's analysis. Rather, it advances two alternative rationales for reaching the Court's ultimate conclusion. We find no merit in either.

First, HMA insists that there can be no fair market value issue because BMAA physicians at the Pain Clinic are compensated for their medical services directly by Medicare and HMA is compensated for its commitment of facilities directly by Medicare. The suggestion, as we understand HMA's brief, is that Medicare's evaluation should be accepted as a fair market evaluation of each. This would not help HMA, however, unless we were willing to ignore the current arrangement under which BMAA is receiving the free use of the Pain Clinic facilities and apparently the exclusive right to practice pain management there. Given the text of the Act and the concerns which prompted it, we must decline the invitation to do so.

HMA's second alternative ground for sustaining the judgment of the District Court is based on a Medicare regulation setting forth requirements "for a determination that a facility . . . has provider-based status." 42 C.F.R. § 413.65. HMA's argument is that the Act is inapplicable to referrals by BMAA to the Hospital for diagnostic tests and other services because "patients treated by BMAA physicians [at the Pain Clinic] were

*de facto* patients of the hospital, and, therefore, BMAA did not actually make any referrals." JA at 51, n.19. This argument is founded not on evidence regarding how patients get to BMAA physicians at the Clinic, but rather upon 42 C.F.R. § 413.65 which sets forth the conditions under which a facility may be considered a part of the main hospital – rather than a free standing facility unrelated to the main provider. This regulation determines whether a facility like the Pain Clinic has sufficient connections to a hospital so that it can be considered a part thereof and, for example, can submit claims under the hospital's provider number. Under § 413.65, among other things, the professional staff at the off-site facility must have clinical privileges at the main provider, medical records must be integrated into a unified retrieval system, and patients at the off-site facility who require further care must have full access to all services of the main provider. 42 C.F.R. § 413.65(d)(2). As we read § 413.65, it has nothing to do with referrals or the concerns of the Stark Act.

HMA points to one subsection of 42 C.F.R. § 413.65 relating to the requirement that the clinical services of the facility and the main provider must be "integrated as evidenced by the following," *inter alia*:

> Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and *are referred* where appropriate to the corresponding inpatient or outpatient department or service of the main

provider.

42 C.F.R. § 413.65(d)(2)(vi) (emphasis supplied by HMA).

HMA reads this sub-section as depriving physicians at the facility of any discretion in making referrals of their patients, *i.e.*, as mandating referrals to the main provider. We believe HMA reads too much into this provision. While Pain Clinic patients clearly must have access to all services provided by the Hospital in order for it to be considered a part thereof, we are unpersuaded that BMAA physicians at the Clinic have been deprived of the right to refer their patients in accordance with their best medical judgment.

The referrals of patients by BMAA physicians at the Pain Clinic to the Hospital for diagnostic tests and other treatments comes within the statutory definition of referrals and the circumstances in which they are made present the same concerns that motivated the Act. Accordingly, we conclude that that Act is implicated and that HMA had the burden of demonstrating its right to an exception, a burden that it failed to carry.

## IV

The judgment of the District Court will be reversed, and this matter will be remanded for further proceedings consistent with this opinion.[3]

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[3] Because the District Court determined that the Stark and Anti-Kickback Statutes were not violated, it did not determine

whether Kosenske satisfied the remaining elements necessary to establish a *prima facie* claim under the False Claims Act, 31 U.S.C. § 3729(a), specifically whether HMA knew its certifications were false because it was in violation of the Stark and Anti-Kickback Acts. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (To establish a *prima facie* claim under 31 U.S.C. § 3729(a)(1), a plaintiff must show that: "'(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'") (quoting *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001), *cert. denied*, 536 U.S. 906 (2002)).