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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.* MATTHEW CESTRA and on behalf of the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN, and the DISTRICT OF COLUMBIA Plaintiffs, -against - CEPHALON, INC., and JOHN DOES #1-100, FICTITIOUS NAMES Defendants.	Civil Action 10-6457 (SHS)

STATEMENT OF INTEREST OF PLAINTIFF THE STATE OF NEW YORK IN RESPONSE TO DEFENDANT'S MOTION TO DISMISS <u>RELATOR'S SECOND AMENDED COMPLAINT</u>

The State of New York (the "State"), by its attorney Eric T. Schneiderman, Attorney General for the State of New York, respectfully submits this Statement of Interest in opposition to the defendant's Motion to Dismiss the Second Amended Complaint ("SAC") of relator Mathew Cestra ("Relator"). The State submits this memorandum to address the two issues raised by defendant: (1) whether the New York False Claims Act ("NYFCA") applies retroactively to conduct preceding its April 2007 enactment; and (2) whether *United States v. Caronia* precludes a cause of action under the NYFCA based on a manufacturer's off-label marketing of a prescription drug that causes the submission of false claims to the Medicaid program. The State takes no position on the outcome of the other issues in defendant's motion to dismiss.

PRELIMINARY STATEMENT

On the first point, unambiguous statutory language provides that the NYFCA "shall apply to claims filed or presented before, on or after April 1, 2007." This language squarely forecloses defendant's argument that the NYFCA is not retroactive. In fact, this Court has expressly held that the NYFCA "is explicitly retroactive." *United States ex rel. Mishra v. NYSARC*, No. 03-7250, Transcript of Hearing Regarding Motion to Dismiss at 16-17 (S.D.N.Y. March 20, 2009) (attached hereto as Exhibit A).

On the second point, as made clear by the United States' Statement of Interest filed today in this case, the *Caronia* decision does not bar a cause of action under the federal False Claims Act ("FCA") based on a manufacturer's off-label marketing of a prescription drug that causes the submission of false claims to federal health care programs. The NYFCA is closely modeled on the federal FCA. The NYFCA provides that any person who knowingly presents a false or fraudulent claim to the State or a local government for payment, or who knowingly makes a false statement, is liable for treble damages and civil penalties ranging between $6,000 and $12,000. N.Y. State Fin.

Law § 189. The United States' arguments in its Statement of Interest apply with equal force to defeat the contention that *Caronia* requires dismissal of the NYFCA claims based on a manufacturer's off-label marketing of a prescription drug that causes the submission of false claims to the Medicaid program. For reasons of judicial economy, the State adopts and incorporates by reference the United States' Statement of Interest.

BACKGROUND

I. THE NEW YORK FALSE CLAIMS ACT

Section 39 of Part C of the State Governor's 2007 health and mental hygiene budget bill, enacted on April 7, 2007, added a new article 13 to the Finance Law, which is designated the New York False Claims Act. *See* State Fin. Law §§ 187-194. The budget bill expressly provides that the NYFCA "shall apply to claims filed or presented before, on or after April 1, 2007." 2007 N.Y. Sess. Laws (McKinney's) Ch. 58, S. 2108-c, § 93(5) (April 9, 2007). When the NYFCA was amended in 2010, the legislature again enacted that the NYFCA shall "apply to claims, records, or statements made or used prior to, on or after April 1, 2007." Ch. 379, § 13, 2010 McKinney's N.Y. Laws at 1165. A claim under the NYFCA shall be commenced no later than ten years after the date on which the violation of this article occurred. State Fin. Law § 192(1).

The NYFCA functions much like the federal FCA. The NYFCA permits private individuals to bring *qui tam* actions on behalf of the State. N.Y. State Fin. Law § 190(2). The NYFCA requires a *qui tam* plaintiff to file the complaint under seal, and provides that the court must maintain the complaint under seal for a period of 60 days. Within that 60-day period, or any extension of that period granted by the court, the Attorney General must inform the court whether he intends to convert the qui tam action into a civil enforcement action or intends to intervene in the *qui tam* action. If the Attorney General elects to convert the action to a civil enforcement action, the State

"shall have primary responsibility for prosecuting the action." N.Y. State Fin. Law § 190(5)(a). If the Attorney General elects merely to intervene, the State and the *qui tam* plaintiff "shall share primary responsibility" for prosecuting the case. *Id.* If the Attorney General elects not to intervene, the *qui tam* plaintiff retains responsibility for prosecuting the case, "subject to the attorney general's right to intervene at a later date upon a showing of good cause." N.Y. State Fin. Law § 190(5)(a). In cases where the State declines intervention, the *qui tam* plaintiff is entitled to between 25 and 30 percent of any ultimate recovery. N.Y. State Fin. Law § 190(6)(b).

II. PROCEDURAL HISTORY

Relator filed this action pursuant to the provisions of the federal FCA, as amended, 31 U.S.C. §§ 3729 et seq., the NYFCA, State Finance Law §§ 187 et seq., and other states' similar statutes. The State filed a notice of its decision to decline intervention on December 10, 2012, as did the United States and other named plaintiff states. Subsequently, defendant filed a motion to dismiss the relator's SAC, including the asserted NYFCA claims, on a number of grounds, including (a) the alleged "Impermissible Retroactive Application of State Law" (see Def. Mem. at p. 23 (Document # 52) and its Ex. B (Document # 52-2, p. 2); and (b) the application of *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) to the state law claims (see Def. Mem. at p. 23 (Document # 52) and its Ex. B (Document # 52-2, p. 2). As real party in interest regarding the NYFCA claims, the State submits this Statement of Interest to address defendant's arguments concerning the retroactive application of the NYFCA and the application of *Caronia* to the NYFCA claims in this case.

ARGUMENT

POINT I

THE NYFCA APPLIES TO RELATOR'S CLAIMS AGAINST DEFENDANTS

While defendant contends that application of the NYFCA represents an "Impermissible Retroactive Application of State Law," (Def's Mem. at p. 23 and Exhibit B at p. 2), defendant neither briefs the point not cites any authority in support of its contention, which is relegated to a checked box in Exhibit B. Indeed, defendant's contention is meritless. It ignores, not only the clear and unambiguous statutory language declaring that the Legislature intended that the NYFCA would apply to conduct preceding the NYFCA's enactment, but also this Court's ruling in *United States ex rel. Mishra v. NYSARC*, No. 03-7250, Transcript of Hearing Regarding Motion to Dismiss at 16-17 (S.D.N.Y. March 20, 2009).

A. This Court Has Already Held that the NYFCA Is Retroactive

In the matter of *United States of America, ex rel. Mishra v. NYSARC, et al.* Your Honor held that, "the [NYFCA] is explicitly retroactive. New York False Claims Act 2007 New York Session Law, Chapter 58 S2108-C of April 9, 2007 states that Section 39 of the New York NYSARC False Claims Act 'shall apply to claims filed or presented prior to, o [sic] or after April 1, 2007.'" *Id.*

B. Statutory Language Expressly Provides that the NYFCA Applies to Claims Presented Before Its Enactment

The Supreme Court has set forth a two-part test for determining whether applying a statute to events preceding its enactment is improper. First, a court must ascertain whether the legislature has clearly communicated its intent that the law be applied to such conduct. *INS v. St. Cyr*, 533 U.S. 289, 316 (2001); *Martin v. Hadix*, 527 U.S. 343, 352 (1999); *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). If the legislature has clearly expressed that intent, the court's inquiry ends.

Landgraf, 511 U.S. at 380; *accord Majewski v. Broadalbin-Perth Cent. Sch. Dist.*, 91 N.Y.2d 577, 584 (1998).

If there is no clear expression of legislative intent, "then the court must determine whether application of the statute to past conduct 'would have a retroactive effect, *i.e.*, whether it would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed.'" *Kuhali v. Reno*, 266 F.3d 93, 110 (2d Cir. 2001) (quoting *Landgraf*, 511 U.S. at 280); *see also St. Cyr*, 533 U.S. at 320-22; *Martin*, 527 U.S. at 352, 357-58. If it would have such an effect, the court applies a default rule, or presumption, disfavoring retroactive application "absent clear [legislative] intent" to the contrary.

This case is resolved at the first step of the analysis, because there is clear and unambiguous statutory language providing that the NYFCA applies to false claims that were presented for payment before the Act's April 2007 enactment. As discussed above, the NYFCA was added to New York law by § 39 of Part C of the Governor's 2007 health and mental hygiene budget bill. Section 93(5) of Part C of that bill specifically states that "section thirty-nine of this act shall apply to claims filed or presented prior to, on or after April 1, 2007." 2007 N.Y. Sess. Laws (McKinney's) Ch. 58, S. 2108-c, § 93(5) (April 9, 2007). That provision leaves no doubt that the Legislature intended that the NYFCA would apply to claims presented before the Act was passed, such as the Medicaid claims at issue here. *See Kuhali*, 266 F.3d at 110-11 (finding similar "before, on, or after" language to be an unambiguous expression of legislative intent to apply a statute retroactively); *accord St. Cyr*, 533 U.S. at 320 & n.43. Given this clear statutory language, the NYFCA is retroactive.

C. <u>The Retroactive Application of the NYFCA Is Constitutional</u>

The retroactive application of the NYFCA passes constitutional muster. *See People of the State of New York v. Sprint Nextel*, 970 N.Y.S.2d 164, 173-176 (Sup. Ct. NY Co. June 27, 2013).

This ruling is well-founded in analogous federal law. Where the Legislature enacts a civil regulatory scheme such as the NYFCA, "only the clearest proof" will suffice to show that the statute is so punitive in purpose or effect as to transform the retroactive application of its civil remedy into the type of criminal penalty prohibited by the Ex Post Facto Clause. *Hudson v. United States*, 522 U.S. 93, 100 (1997). The Supreme Court has provided a non-exhaustive list of factors to analyze the effect of a statute for Ex Post Facto purposes: whether the statute's sanction (1) involves an affirmative disability or restraint, (2) has historically been regarded as a punishment, (3) comes into play only on a finding of scienter, (4) promotes the traditional aims of punishment—retribution and deterrence, (5) applies to behavior that is already a crime, (6) is rationally connected to an alternative purpose, and (7) appears excessive in relation to that alternative purpose. *Smith v. Doe*, 538 U.S. 84, 97-106 (2003) (citing *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168-169 (1963)).

Applying these factors to the NYFCA, most militate against a finding that it violates the Ex Post Facto Clause. First, the NYFCA's damages provision does not impose any affirmative restraint. Second, the similar federal FCA sanctions have historically been regarded as primarily civil and remedial, rather than so punitive as to be penal. *See United States ex rel. Drake v. NSI, Inc.*, 736 F. Supp. 2d 489, 498-502 (D. Conn. 2010) (discussing historical view of federal FCA and rejecting Ex Post Facto challenge); *United States v. Ettrick Wood Prods.*, 683 F. Supp. 1262, 1264 (W.D. Wis. 1988) (finding that enhanced damages did not render federal FCA penal for purposes of Ex Post Facto Clause); *cf. United States ex rel. Marcus v. Hess*, 317 U.S. 537, 549 (1943) (penalties under the federal FCA are not criminal punishment for the purpose of the Double Jeopardy Clause); *United States v. Rogan*, 517 F.3d 449, 454 (7th Cir. 2008) (same). Third, the NYFCA's damages are rationally connected to an alternative purpose, namely, recouping losses from fraud and protecting the public fisc. *See Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 130-31 (2003);

Rogan, 517 F.3d at 452. Fourth, the FCA's damages are not excessive in relation to its alternative purpose. *See Cook Cnty.*, 538 U.S at 130 ("[S]ome liability beyond the amount of the fraud is usually necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims.") (internal quotation marks omitted).

Finally, two federal Courts of Appeal have recently considered the constitutionality of retroactive application of the federal FCA have held that it does not violate the Ex Post Facto Clause. *See United States ex rel. Miller v. Bill Harbert Int'l Constr.*, 608 F.3d 871, 878-79 (D.C. Cir. 2010), *cert. denied* 131 S.Ct. 2443 (2011); *United States ex rel. Sanders v. Allison Engine, Co., Inc.*, 703 F.3d 930, 942-948 (6th Cir. Nov. 2, 2012), *rev'g* 667 F. Supp.2d 747 (S.D. Ohio 2009), *cert. denied* 133 S.Ct. 2855 (2013). Although there is disagreement among federal district courts, a number have found that the Ex Post Facto Clause is not applicable to the federal FCA. *See, e.g., Drake*, 736 F. Supp. 2d at 498-502 (holding federal FCA is not sufficiently punitive to warrant application of the Ex Post Facto Clause); *Ettrick Wood*, 683 F. Supp. at 1264 (finding retroactive application of federal FCA did not implicate Ex Post Facto Clause); *United States v. Oakwood Downriver Med. Ctr.*, 687 F. Supp. 302, 308 (E.D. Mich. 1988) (holding Ex Post Facto Clause inapplicable to FCA claims). While the Supreme Court has not definitively determined the issue, it has made clear that the federal FCA serves legitimate remedial and compensatory purposes in addition to punitive ones. *See Cook County*, 538 U.S. at 130. So does the New York counterpart. *See New York v. Sprint Nextel*, 970 N.Y.S.2d at 173-176 (holding NYFCA is not sufficiently punitive to warrant application of the Ex Post Facto Clause).

POINT II

CARONIA DOES NOT BAR NYFCA CLAIMS BASED ON DEFENDANT'S OFF-LABEL MARKETING OF PRESCRIPTION DRUGS THAT CAUSED THE SUBMISSION OF FALSE CLAIMS TO MEDICAID

The United States' Statement of Interest sets forth the reasons that *Caronia* does not preclude a cause of action under the federal False Claims Act based on a manufacturer's off-label marketing of a prescription drug that causes the submission of false claims to federal health care programs. These reasons, which are incorporated by reference, apply with equal force to the Relator's causes of action under the NYFCA based on a manufacturer's off-label marketing of a prescription drug that causes the submission of false claims to Medicaid.

In any event, even *Caronia* makes clear that "to warrant First Amendment protection, the speech in question must not be misleading and must concern lawful activity." *United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012) (citation omitted) (emphasis added). The State also notes that to the extent the 188-page Complaint raises issues of fact as to whether defendant's alleged conduct constitutes false and/or misleading promotion of drugs (*see* Relator's Opp. Mem. at 15-16 (citing SAC ¶¶ 92-172, 200-18)), it would be appropriate at this stage on that ground alone to deny the portion of defendant's motion to dismiss that is based on *Caronia*.

* * * *

CONCLUSION

For the reasons above, the State respectfully requests that the Court deny defendant's motion to dismiss insofar as it challenges whether the NYFCA applies retroactively, and, in the event the Court reaches defendant's First Amendment argument, deny the motion to dismiss on the asserted grounds that *Caronia* requires dismissal of the NYFCA claims based on a manufacturer's off-label marketing of a prescription drug that causes the submission of false claims to the Medicaid program.

Dated: New York, New York
November 7, 2013

Respectfully submitted,

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