

685 F.Supp.2d 186  
**(Cite as: 685 F.Supp.2d 186)**

## H

United States District Court,  
 D. Massachusetts.  
 In re PHARMACEUTICAL INDUSTRY  
 AVERAGE WHOLESALE PRICE LITIG-  
 ATION.

This Document Relates to:  
 The **City of New York**, et al., Plaintiffs,  
 v.  
**Abbott Laboratories**, et al., Defendants.

Civil Action No. 01-12257-PBS.  
 MDL No. 1456.  
 Subcategory Case No. 03-10643-PBS.  
 Feb. 9, 2010.

**Background:** City and forty-two New York counties brought suit against numerous pharmaceutical manufacturers and subsidiaries alleging Medicaid fraud in violation of the federal Best Prices Statute, and state law, including alleged violations of New York's false claims act statute, New York's consumer protection statute, and common law fraud. Plaintiffs moved for partial summary judgment against thirteen defendants as to the claims under New York's false claims act statute for nine subject drugs reimbursed at the federal upper limit (FUL). Defendants moved for partial summary judgment on all counts as to all New York Medicaid claims reimbursed on the basis of FULs.

**Holdings:** The District Court, [Saris](#), J., held that:

(1) defendants violated New York false claims act statute by knowingly submitting false average wholesale prices (AWP) and wholesale acquisition costs (WAC) that were used by Centers for Medicare and Medicaid Services (CMS) in setting FULs for nine subject drugs for purposes of cal-

ulation of Medicaid reimbursement rates, and

(2) causation element of claims under New York's consumer protection statute was established by the evidence.

Plaintiffs' motion allowed; defendants' motion denied.

West Headnotes

### [1] States 360 ↪188

360 States

360V Claims Against State

360k188 k. Making or presentation of false claims. [Most Cited Cases](#)

To prove liability under New York's false claims act statute, a plaintiff must show that defendants knowingly made a false statement or representation on behalf of themselves or others to attempt to obtain or to obtain payment from public funds. N.Y.McKinney's Social Services Law § 145-b(1).

### [2] Health 198H ↪487(4)

198H Health

198HIII Government Assistance

198HIII(B) Medical Assistance in General; Medicaid

198Hk484 Providers

198Hk487 Reimbursement

198Hk487(4) k. Costs.

[Most Cited Cases](#)

For a wholesale acquisition cost (WAC) to have been a true list price for purposes of New York's Medicaid reimbursement formula, 50% of a drug's sales each year must have been made at transaction prices that were within 5% of the manufacturer's reported WAC for that drug. N.Y.McKinney's Social Services Law § 367-a(9)(b)(i).

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**[3] States 360 ↪188**

360 States

360V Claims Against State

360k188 k. Making or presentation of false claims. [Most Cited Cases](#)

Pharmaceutical manufacturers and subsidiaries violated New York false claims act statute by knowingly submitting false average wholesale prices (AWP) and wholesale acquisition costs (WAC) that were used by Centers for Medicare and Medicaid Services (CMS) in setting federal upper limits (FUL) for nine subject drugs for purposes of calculation of Medicaid reimbursement rates; when companies published false prices, they attempted to obtain payment from public funds. N.Y.McKinney's Social Services Law § 145–b(1).

**[4] States 360 ↪188**

360 States

360V Claims Against State

360k188 k. Making or presentation of false claims. [Most Cited Cases](#)

Causation of improper payments is not an element of claim under New York false claims act statute. N.Y.McKinney's Social Services Law § 145–b(1).

**[5] Damages 115 ↪6**

115 Damages

115I Nature and Grounds in General

115k6 k. Certainty as to amount or extent of damage. [Most Cited Cases](#)

Under New York law, when the existence of damage is certain, and the only uncertainty is to its amount, the plaintiff will not be denied a recovery of substantial damages.

**[6] States 360 ↪188**

360 States

360V Claims Against State

360k188 k. Making or presentation of false claims. [Most Cited Cases](#)

Deception of government officials is not an element of claim under New York False Claims Act. N.Y.McKinney's Social Services Law § 145–b.

**[7] States 360 ↪188**

360 States

360V Claims Against State

360k188 k. Making or presentation of false claims. [Most Cited Cases](#)

Pharmaceutical companies, which allegedly violated New York false claims act statute by knowingly submitting false average wholesale prices (AWP) and wholesale acquisition costs (WAC) that were used by Centers for Medicare and Medicaid Services (CMS) in setting federal upper limits (FUL) for nine subject drugs for purposes of calculation of Medicaid reimbursement rates, were not entitled to rely on government knowledge defense since record did not contain any evidence that CMS would tie reimbursement to published prices, and specifically the lowest published price, if it knew or approved of the fact that the defendants' published prices were meaningless, neither the actual price that wholesalers paid nor even the price that any significant number of wholesalers paid. N.Y.McKinney's Social Services Law § 145–b.

**[8] Antitrust and Trade Regulation 29T ↪138**

29T Antitrust and Trade Regulation

29TIII Statutory Unfair Trade Practices and Consumer Protection

29TIII(A) In General

29Tk133 Nature and Elements

29Tk138 k. Reliance; causation; injury, loss, or damage. [Most Cited](#)

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## Cases

Causation is an essential element of claims under New York's consumer protection statute. N.Y.McKinney's General Business Law § 349.

### [9] Antitrust and Trade Regulation 29T ↪222

#### 29T Antitrust and Trade Regulation

29TIII Statutory Unfair Trade Practices and Consumer Protection

29TIII(C) Particular Subjects and Regulations

29Tk222 k. Health care and medical insurance. [Most Cited Cases](#)

Causation element of claims under New York's consumer protection statute was established by evidence that pharmaceutical companies, which violated New York False Claims Act by knowingly submitting false average wholesale prices (AWP) and wholesale acquisition costs (WAC) that were used by Centers for Medicare and Medicaid Services (CMS) in setting federal upper limits (FUL) for nine subject drugs for purposes of calculation of Medicaid reimbursement rates, not only caused FULs to be higher than necessary by inflating the array of prices that state agency relied upon in setting an appropriately priced FUL, but also by causing CMS to underestimate the quantity of drugs available at a given FUL, and thus to set higher FULs than necessary to achieve its goal of ensuring sufficient access to drugs; CMS's undisputed use of discretion and its need to balance multiple goals did not preclude a factual finding of causation. N.Y.McKinney's General Business Law § 349.

### [10] Federal Civil Procedure 170A ↪2515

170A Federal Civil Procedure  
170AXVII Judgment

#### 170AXVII(C) Summary Judgment

170AXVII(C)2 Particular Cases

170Ak2515 k. Tort cases in general. [Most Cited Cases](#)

Genuine issues of material fact existed as to whether state officials reasonably relied on false prices published by pharmaceutical companies in setting federal upper limits (FUL) for nine subject drugs for purposes of calculation of Medicaid reimbursement rates, precluding summary judgment in favor of companies on city and counties' claims under New York's consumer protection statute, and for common law fraud. N.Y.McKinney's General Business Law § 349.

### [11] Fraud 184 ↪3

184 Fraud

184I Deception Constituting Fraud, and Liability Therefor

184k2 Elements of Actual Fraud

184k3 k. In general. [Most Cited Cases](#)

In order to find liability for common law fraud under New York law, the plaintiff must prove that the defendant (1) made a material, false statement; (2) knowing that the representation was false; (3) acting with intent to defraud; and that plaintiff (4) reasonably relied on the false representation and (5) suffered damage proximately caused by the defendant's actions.

### [12] Fraud 184 ↪21

184 Fraud

184I Deception Constituting Fraud, and Liability Therefor

184k19 Reliance on Representations and Inducement to Act

184k21 k. Persons who may rely on representations. [Most Cited Cases](#)

**Fraud 184** ↪25

## 184 Fraud

184I Deception Constituting Fraud, and Liability Therefor

184k25 k. Injury and causation.

**Most Cited Cases**

Third party reliance on fraud is cognizable under New York law where there is a sufficient causal connection between a defendant's fraud and a plaintiff's injury.

**[13] Fraud 184** ↪21

## 184 Fraud

184I Deception Constituting Fraud, and Liability Therefor

184k19 Reliance on Representations and Inducement to Act

184k21 k. Persons who may rely on representations. **Most Cited Cases**

Reliance element of common law fraud under New York law was established by evidence that pharmaceutical companies submitted false wholesale pricing data to publishers, intending that the information would be relied on by Centers for Medicare and Medicaid Services (CMS) in determining federal upper limits (FUL) for nine subject drugs for purposes of calculation of Medicaid reimbursement rates.

**[14] Fraud 184** ↪25

## 184 Fraud

184I Deception Constituting Fraud, and Liability Therefor

184k25 k. Injury and causation.

**Most Cited Cases**

Causation is an essential element of New York common law fraud claims.

\*188 [Henry H. Rossbacher](#), Rossbacher & Associates, [Adam D. Miller](#), [Walter J. Lack](#), Engstrom, Lipscomb & Lack, Los Angeles, CA, [Jonathan W. Cuneo](#), Cuneo

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**AMENDED MEMORANDUM \*195 AND ORDER** <sup>FN1</sup>

**FN1.** This Memorandum and Order amends the Court's January 27 Memorandum and Order to reflect the fact that Boehringer Ingelheim Roxane Inc. f/k/a Roxane Laboratories, Inc. settled with the Plaintiffs during the pendency of the addressed motions.

**SARIS**, District Judge.

**I. INTRODUCTION**

New York City and forty-two New York counties have brought suit against numerous pharmaceutical manufacturers and subsidiaries alleging Medicaid fraud in violation of the federal Best Prices Statute, [42 U.S.C. § 1396r-8](#), and state law, including alleged violations of New York's false claims act statute, [N.Y. Soc. Serv. Law § 145-b](#), New York's consumer protection statute, [N.Y. Gen. Bus. Law § 349](#), and common law fraud. The Plaintiffs' expert has calculated spreads between the Defendants' published Wholesale Acquisition Costs ("WACs") and actual acquisition costs as consistently above 50%, frequently over 100%, and sometimes over 1000%, with spreads as high as 1841% for Barr,

3998% for Dey, 1893% for Ivax, 33641% for Mylan, 13486% for Par, 1103% for Purepac, 59936% for Sandoz, 1224% for Schering-Warrick, 2955% for Teva, 5775% for Watson, and an Average Wholesale Price ("AWP")—Average Manufacturer Price ("AMP") spread as high as 17421% for Wyeth. (Devor Decl. [Docket No. 6061] Ex. C.) Plaintiffs have moved for partial summary judgment against thirteen defendants <sup>FN2</sup> as to the claims under [Section 145-b](#) for nine subject drugs <sup>FN3</sup> reimbursed at the Federal Upper Limit ("FUL"). The Defendants have moved for partial summary judgment on all counts as to all New York Medicaid claims reimbursed on the basis of FULs.

**FN2.** The thirteen defendants were: (1) Barr Laboratories, Inc.; (2) Dey, L.P. and Dey, Inc.; (3) Ethex Corporation; (4) Ivax Corporation/Ivax Pharmaceuticals, Inc.; (5) Mylan Laboratories/Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc.; (6) Par Pharmaceuticals Companies, Inc./Par Pharmaceutical, Inc.; (7) Purepac Pharmaceutical Co.; (8) Boehringer Ingelheim Roxane Inc. f/k/a Roxane Laboratories, Inc.; (9) Sandoz, Inc.; (10) Schering Corporation/Schering-Plough Corporation/Warrick Pharmaceuticals Corporation; (11) Teva Pharmaceutical USA, Inc.; (12) Watson Pharmaceuticals, Inc./Watson Pharma, Inc.; and (13) Wyeth. Ethex and Boehringer Ingelheim Roxane have subsequently settled.

**FN3.** The nine drugs are: (1) Albuterol .90 mcg inhaler; (2) Albuterol .83 mg solution; (3) Cefadroxil 500 mg capsule; (4) Clonazepam .5 mg tablet; (5) Enalapril Maleate 20

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mg tablet; (6) Isosorbide Mononitrate 60 mg tablet; (7) Lorazepam 1 mg tablet; (8) Metoprolol 100 mg tablet; and (9) Ranitidine 150 mg tablet.

After briefing and a hearing, Plaintiffs' motion is **ALLOWED** and the Defendants' motion is **DENIED**.

## II. UNDISPUTED FACTS

This case comes as part of the massive AWP multi-district litigation concerning drug manufacturers' publishing of fraudulently inflated prices, including AWPs, WACs, and other prices.<sup>FN4</sup> These motions \*196 concern drugs reimbursed on the basis of FULs, which were affected by such published prices. The following facts are undisputed except where stated.

FN4. The general background of this case has already been fully set out by the Court. See *City of New York v. Abbott Labs.*, No. 01-cv-2257, 2007 WL 1051642 (D.Mass. Apr. 2, 2007). The Court assumes familiarity with that decision. The drug pricing schemes at issue in this case are also discussed in the Court's previous AWP-related decisions. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172 (D.Mass.2003); *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F.Supp.2d 196 (D.Mass.2004); *In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F.Supp.2d 187 (D.Mass.2004); *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d 165 (D.Mass.2004); *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61 (D.Mass.2005); *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F.Supp.2d 277

(D.Mass.2006); *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F.Supp.2d 164 (D.Mass.2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d 12 (D.Mass.2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d 20 (D.Mass.2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F.Supp.2d 367 (D.Mass.2008); *In re Pharm. Indus. Average Wholesale Price Litig.*, 252 F.R.D. 83 (D.Mass.2008); see also *Massachusetts v. Mylan Labs., Inc.*, 357 F.Supp.2d 314 (D.Mass.2005); *Massachusetts v. Mylan Labs., Inc.*, 608 F.Supp.2d 127 (D.Mass.2008).

### A. Statutory Framework for Setting FULs

The federal government pays approximately fifty percent of Medicaid's share of prescription drug costs. See 42 U.S.C. § 1396d(b). The remaining fifty percent is divided between state and local authorities according to state law. See *id.* The State of New York reimburses providers for the entire fifty percent. N.Y. Soc. Serv. Law § 367-b. Each county is then billed for fifty percent of the State's costs for prescription drugs purchased by the county's residents. *Id.* § 368-a; see also *id.* § 367-b(6). Collectively, the New York Medicaid program paid in excess of \$13 billion between 1997 and 2003 for the prescription drugs at issue in these lawsuits.

The Secretary of Health and Human Services, acting through the Centers for Medicare and Medicaid Services ("CMS") sets FULs to control state Medicaid expenditures for multiple source drugs.<sup>FN5</sup> The Secretary established the FUL in 1987 to allow "the Federal and State governments to take advantage of savings that are currently available in the marketplace for



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multiple source drugs ... [while] maintain[ing] State flexibility in the administration of the Medicaid program.” 52 Fed. Reg. at 28,648. Congress statutorily required the establishment of FULs in 1990. See Omnibus Budget Reconciliation Act of 1990, Pub.L. No. 101–508, sec. 4401(a)(3), § 1927(f)(2), 104 Stat. 1388, 1388–1430 (1990) (codified at 42 U.S.C. § 1396r–8(e)(4)).

FN5. FULs are not used in the Medicare program, and apply only to the Medicaid program. See Medicare and Medicaid Programs; Limits on Payments for Drugs, 52 Fed.Reg. 28,648, 28,653 (July 31, 1987).

FULs reflect the outer boundary of what state Medicaid agencies can reimburse retail pharmacies for outpatient multiple source drugs. Each year, states must make assurances that their aggregate Medicaid expenditures for the relevant drugs are within the FULs set by CMS, plus reasonable dispensing fees set by the state. See 42 C.F.R. § 447.333 (2007). As of December 2006, CMS had set FULs for over 500 multiple source drugs.

The statutory and regulatory framework that guides CMS in setting FULs was constant during the relevant period.<sup>FN6</sup> Under the Medicaid Act, CMS only calculates a FUL for drugs that have at least three \*197 therapeutic and pharmaceutical equivalents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (know as the “Orange Book”). See 42 U.S.C. § 1396r–8(e)(4); 42 C.F.R. § 447.332(a)(1)(i) (2007). Further, the drug must have at least three suppliers, as reflected in “all listings contained in current editions (or updates) of published compendia of cost information for drugs available for

sale nationally.” 42 C.F.R. § 447.332 (a)(1)(ii) (2007). Although the regulations do not define “published compendia,” CMS considered information in the Red Book, Blue Book (published by First DataBank), and Medi-Span. See Department of Health and Human Services, Office of Inspector General, *Addition of Qualified Drugs to the Medicaid Federal Upper Limit List 20* (OEI–03–04–00320) (Dec. 2004) (“OIG 2004 Report”).

FN6. Significant changes, which took effect on January 1, 2007, were made to the FUL calculation framework as part of the Deficit Reduction Act of 2005 (“DRA”), Pub.L. No. 109–171, § 6001, 120 Stat. 4, 54–59 (2006). CMS attempted to implement these changes in a final rule published in July of 2007. 72 Fed.Reg. 39,142 (July 17, 2007). Significant portions of the rule were preliminarily enjoined in *National Association of Chain Drug Stores v. Leavitt*, Civil Action No. 07–02017–RCL (D.D.C.). Congress then suspended the relevant provisions of the Deficit Reduction Act. See Medicare Improvements for Patients and Providers Act of 2008, Pub.L. No. 110–275, § 203, 122 Stat. 2494, 2592 (2008). Although the suspension expired September 30, 2009, the preliminary injunction remains in effect.

CMS takes the further step of ensuring that the drugs are actually available in the marketplace. Drugs are often listed in the compendia before they are actually available nationwide, or when there is only a limited supply. CMS will verify the availability of a drug by checking with manufacturers and suppliers. See OIG 2004 Re-

port 21.

CMS also considers whether the establishment of a FUL will likely result in savings to the Medicaid program, and only sets FULs in such cases. *See* Department of Health and Human Services, Office of Inspector General, *How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List* 3 (OEI-03-05-00350) (Sept. 2005) (“[I]f a drug does not have a published price that, when multiplied by 150 percent, is lower than AWP, CMS does not include the product.”); 51 Fed. Reg. 29,560, 29563 (Aug. 19, 1986) (discussing setting FULs only where savings would justify the administrative burden on pharmacies and Federal and State governments).

According to the regulations, if a drug meets those requirements, the FUL is set at 150% of the published price for the least costly therapeutic equivalent that can be purchased in quantities of 100 tablets or capsules, or, for drugs not commonly available in quantities of 100, or for drugs in liquid form, that can be purchased in another commonly listed package size. 42 C.F.R. § 447.332(b) (2007). The “published prices” considered by CMS are AWP, WACs, and Direct Prices (“DPs”) published in the national drug pricing compendia (Red Book, Blue Book, and Medi-Span). *See* OIG Report 2004, at 20–21 (“If there are three suppliers of the drug, the FUL system selects the lowest price (Average Wholesale Price, Wholesale Acquisition Cost, or Direct Price) that can be purchased by pharmacies and multiplies it by 150 percent”).

### **B. Complexity of Setting FULs**

The method for setting FULs is far more complex than the framework suggests, and in practice, CMS must exercise significant discretion to ensure sufficient

beneficiary access to drugs while also achieving cost savings for the Medicaid program. *See* 52 Fed.Reg. at 28,653. For many FULs, CMS did not base the FUL on the lowest published price, but instead on a somewhat higher published price, such as the second, third, or fourth lowest published price. This was done to ensure that a sufficient supply of the drug could be purchased for a price less than the FUL.

Since 1990, CMS has used a database application, called the FULs System, to receive and process drug data and calculate preliminary FULs. The System downloads, processes, and groups pricing data from the compendia in accordance with \*198 criteria designed by CMS. The CMS employee who determines the FUL, the FULs analyst, will periodically request that the System download and process data for a particular drug, in a process referred to as a “cycle.” The FULs System downloads drug data from the FDA’s Orange Book and drug pricing data from the compendia. FN7 For unknown reasons, the System does not retrieve WAC price data from Medi-Span, although the Defendants here reported identical WACs for their drugs to all three compendia, and the System retrieved the data from First DataBank and Red Book. The System also retrieves labeler code information from the CMS Medicaid Drug Rebate (“MDR”) database, which contains information reported by manufacturers pursuant to the Medicaid Rebate program. FN8

FN7. Defendants argue that CMS never used their AWP. Although no FULs were set at 150% of a reported AWP due to the fact that AWP were consistently higher than reported WACs, the System retrieved, analyzed, and sorted AWP

data as well as WAC data.

**FN8.** Although the MDR database contains the Average Manufacturer Price (“AMP”) information reported by manufacturers, this information is not used in the FULs System, nor is it provided to the FULs analyst.

The FULs System takes the drug data from the Orange Book and compares the labeler code data, which identifies the drug's manufacturer, against a data file in the MDR that identifies the manufacturers that have effective Rebate Agreements with the Secretary of Health and Human Services, and thus products covered by the Medicaid program. The System excludes any products from manufacturers that do not have an active Rebate Agreement.

The System also excludes NDCs that are not regularly available. If an NDC is designated by Medi-Span as “inactive” or “deleted,” or by First DataBank as “obsolete” either currently or in the next six months, the System excludes the NDC. This is done because FULs are to be based on cost information “for drugs available for sale nationally.” 42 C.F.R. § 447.332 (a)(1)(ii) (2007). Since 1999, the FULs analyst has had the ability to exclude NDCs that are temporarily or permanently unavailable by marking the products with exclusion codes of “T” or “P,” based on his communications with the manufacturer. Manually excluded NDCs, unlike NDCs excluded by the FULs System, still appear on the FULs System's online displays, as well as in its printouts, but are marked with their exclusion codes and are not considered when the FUL is set.

The System also excludes NDCs when two or more of the compendia specify that the NDC is a unit dose form of the drug.

This is done because CMS understood that the unit dose form of a drug is not generally the most commonly used package size of a drug, and FULs are to be set based on a commonly available package size. **FN9** 42 C.F.R. § 447.332(b) (2007).

**FN9.** The unit dose form of a drug is typically used only in hospital settings, and is thus less commonly used.

After the data is received and the NDCs are culled, the remaining NDCs are assigned to Product Groups, or groups of NDCs with the same ingredient, strength, dosage form, and route of administration. Some NDCs cannot be matched with their appropriate Product Groups, and the System places such products into an “unmatched” table. These products must be manually reviewed and assigned to Product Groups, a process that is done somewhat infrequently. Since 1999, the FULs analyst has had the ability to manually redesignate products from an incorrect \*199 Product Group to the correct Product Group when errors have occurred in the matching process.

Because of the System's method of sorting NDCs into Product Groups, as well as the earlier culling of NDCs, each FULs System Product Group does not perfectly correlate to First DataBank's “Generic Code Number” (“GCN”) groupings or Medi-Span's “Generic Product Identifier” (“GPI”) groupings.

The FULs System's final step is to sort the NDCs in each Product Group from highest to lowest price and calculate a preliminary FUL for the Product Group, which it does by taking the lowest price and multiplying it by 1.5.

Once the cycle is completed, its output is available to the FULs analyst either online or in the form of print-outs. The FULs analyst will review the data and ensure that the preliminary FUL is consistent with CMS' program objectives. Part of this review is semi-automatic: for instance, the FULs analyst must ensure that the preliminary FUL set by the FULs System is based on a product sold in quantities of 100 tablets or capsules, or, if the drug is not commonly available in quantities of 100, in the package size commonly listed. Part of the review is based on communications with the manufacturer. For instance, Product Groups frequently contain entries with different prices for the same NDC. Where one of the conflicting prices is important to setting the FUL, CMS will contact the manufacturer to determine the correct price. More generally, for all prices that are considered when setting the FUL, the FULs analyst will typically contact the manufacturer to verify that the prices are valid and that the products are widely available in the market.

Finally, part of the review is significantly more discretionary. If the preliminary FUL is at such a level that CMS deems that an insufficient supply of the drug can be purchased nationwide for a price less than the FUL, the FULs analyst will reject that FUL and recalculate a new FUL on the basis of the next lowest price. The analyst typically repeats this process until the FUL is such that he believes a sufficient supply of the drug can be purchased nationwide for less than the FUL. (See Supplemental Br. of U.S. on the Federal Upper Limit [Docket No. 6693] 1–9.)

Defendants' expert argues that during the relevant time period, CMS would have established a lower FUL in 23 out of 31

cases if it had simply followed the rule set out in the target regulation. They also present evidence that CMS' deviation from the regulation does not follow any systematic pattern. (Defs.' Joint Reply in Supp. of Mot. for Summ. J. [Docket No. 6218] 5–13.) Plaintiffs respond that a frequent strategy employed by CMS was to base the FUL on a published price such that the FUL would be higher than the published WACs of the available products of three manufacturers. (Supplemental Br. of U.S. on the Federal Upper Limit 2–3.) Playing wac-a-mole, Defendants argue that the “three WAC rule-of-thumb” only explains three of the twenty-three deviations. (Defs.' Joint Reply in Supp. of Mot. for Summ. J. 7.) Plaintiffs respond by pointing out significant flaws in the Defendants' expert's data and proffering other reasons why certain prices were rejected or accepted. (Supplemental Br. of U.S. on the Federal Upper Limit 9–11.) Regardless, while there may be no rigid algorithms, as a general matter, if the FUL calculated from the lowest published price was not higher than the WACs of what CMS deemed to be a sufficient quantity of manufacturers' products to ensure availability, CMS would consider rejecting the FUL and instead calculating the FUL on the next lowest price, repeating the process until the FUL \*200 was higher than the WACs of a sufficient quantity of drugs.

### ***C. FULs in New York Medicaid Reimbursement***

Once set, the FUL for a particular drug applies to all therapeutically equivalent versions of that drug. That is, the FUL for a drug governs all of a state's reimbursement for therapeutically equivalent versions of the drug, regardless of which manufacturer's version is ultimately dispensed by the pharmacist. Moreover, although the



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FUL is set as an aggregate cap on spending for a particular drug, most states have incorporated FUL into their reimbursement formulas at the level of each individual drug reimbursement.

From 1997 to 2005, the New York Medicaid reimbursement formula, set by the New York Legislature, specified that if a FUL was in place for a drug, providers were to be reimbursed based on the FUL. See *N.Y. Soc. Serv. Law* § 367-a(9)(b)(i) (2005). As required, the Federal Government approved New York's state Medicaid Plan throughout the period. See 42 C.F.R. § 447.333 (2007).

#### D. Defendants' Pricing Practices

All of the Defendants entered into Medicaid Rebate agreements.<sup>FN10</sup> All of the Defendants reported WACs (or WAC equivalents) and most reported AWP.<sup>FN11</sup> With isolated exceptions, the Defendants' AWP were not tethered to its actual prices and were easily more than 30% above the actual prices charged. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d at 95.<sup>FN12</sup> Likewise, the WACs they reported were uniformly not “the actual cost at which wholesalers acquired a drug,” and were “far, far higher than the price ... actually paid.” *Mylan*, 608 F.Supp.2d at 144.<sup>FN13</sup> Employees of the Defendants have admitted that the WACs and AWP they reported were not the prices typically paid to acquire their drugs, and thus that their WACs were not even true list prices under the list price test requiring that “50% of a drug's sales each year [be] made at transaction prices that were within 5% of the manufacturer's reported [WAC] for that drug.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 672 F.Supp.2d 211, 215 (D.Mass.2009).<sup>FN14</sup> The Defendants knew that CMS \*201 con-

sidered their prices in setting FULs.<sup>FN15</sup> Finally, the Defendants also knew that providers would obtain reimbursement from Medicaid for their drugs.<sup>FN16</sup>

**FN10.** See Barr 56.1 at ¶ 4; Dey 56.1 at ¶ 3; Ivax 56.1 at ¶ 3; Mylan 56.1 at ¶ 3; Par 56.1 at ¶ 3; Purepac 56.1 at ¶ 3; Sandoz 56.1 at ¶ 7; Schering–Warrick 56.1 at ¶ 3; Teva 56.1 at ¶ 3; Watson 56.1 at ¶ 4; and Wyeth 56.1 at ¶ 4.

**FN11.** See Barr 56.1 at ¶¶ 5–15; Dey 56.1 at ¶¶ 13–14; Ivax 56.1 at ¶¶ 14–17; Mylan 56.1 at ¶¶ 9–13; Par 56.1 at ¶¶ 7–17; Purepac 56.1 at ¶¶ 7–14; Sandoz 56.1 at ¶¶ 11–20; Schering–Warrick 56.1 at ¶¶ 7–16; Teva 56.1 at ¶¶ 17–20; Watson 56.1 at ¶¶ 11–12; and Wyeth 56.1 at ¶¶ 6–12.

**FN12.** See Barr 56.1 at ¶¶ 18–22; Dey 56.1 at ¶¶ 17–23; Ivax 56.1 at ¶¶ 8–10, 18–22; Mylan 56.1 at ¶¶ 9, 18, 20; Par 56.1 at ¶¶ 8–9, 18–19; Purepac 56.1 at ¶¶ 15–19, 22; Sandoz 56.1 at ¶¶ 24–31, 34–44; Schering–Warrick 56.1 at ¶¶ 17–23; Teva 56.1 at ¶¶ 9–13, 16, 21–22; Watson 56.1 at ¶¶ 9, 14–23; and Wyeth 56.1 at ¶¶ 15–18, 22–27.

**FN13.** See Barr 56.1 at ¶¶ 18–30; Dey 56.1 at ¶¶ 17–23; Ivax 56.1 at ¶¶ 11–13, 19–27; Mylan 56.1 at ¶¶ 10, 15–25; Par 56.1 at ¶¶ 10, 20–22; Purepac 56.1 at ¶¶ 19–33; Sandoz 56.1 at ¶¶ 29, 32–44; Schering–Warrick 56.1 at ¶¶ 17–23; Teva 56.1 at ¶¶ 14, 23–26; Watson 56.1 at ¶¶ 10, 14–23; and Wyeth 56.1 at ¶¶ 19–27.

**FN14.** See Barr 56.1 at ¶¶ 18–30;

Dey 56.1 at ¶¶ 17–23; Ivax 56.1 at ¶¶ 11–13, 18–27; Mylan 56.1 at ¶¶ 9–10, 15–25; Par 56.1 at ¶¶ 8–10, 18–22; Purepac 56.1 at ¶¶ 15–33; Sandoz 56.1 at ¶¶ 24–44; Schering–Warrick 56.1 at ¶¶ 17–23; Teva 56.1 at ¶¶ 9–26; Watson 56.1 at ¶¶ 9–10, 14–23; and Wyeth 56.1 at ¶¶ 15–27.

FN15. See Barr 56.1 at ¶ 17; Dey 56.1 at ¶ 16; Ivax 56.1 at ¶¶ 3, 38; Mylan 56.1 at ¶¶ 3, 4, 6, 14; Par 56.1 at ¶¶ 3, 6, 17; Purepac 56.1 at ¶¶ 3–6; Sandoz 56.1 at ¶¶ 7, 21–23; Schering–Warrick 56.1 at ¶ 3; Teva 56.1 at ¶¶ 3, 6–7; Watson 56.1 at ¶¶ 4–6, 8, 13, 23; and Wyeth 56.1 at ¶¶ 4, 14; see also *Mylan*, 608 F.Supp.2d at 154.

FN16. See Barr 56.1 at ¶ 16; Dey 56.1 at ¶¶ 4–5, 11; Ivax 56.1 at ¶¶ 4–7; Mylan 56.1 at ¶¶ 5–8; Par 56.1 at ¶¶ 5–6; Purepac 56.1 at ¶¶ 5–6; Sandoz 56.1 at ¶¶ 8–10, 21–23; Schering–Warrick 56.1 at ¶¶ 5–6; Teva 56.1 at ¶¶ 5–7; Watson 56.1 at ¶¶ 7–8; and Wyeth 56.1 at ¶¶ 13–14.

### III. DISCUSSION

#### A. Standard of Review

“Summary judgment is appropriate when ‘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 judgment as a matter of law.’ ” *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36–37 (1st Cir.1995) (quoting Fed.R.Civ.P. 56(c)). “To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party’s

position.” *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir.1990); see also *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

“Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who ‘may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.’ ” *Barbour*, 63 F.3d at 37 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)). “There must be ‘sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted.’ ” *Rogers*, 902 F.2d at 143 (quoting *Anderson*, 477 U.S. at 249–50, 106 S.Ct. 2505). The Court must “view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party’s favor.” *Barbour*, 63 F.3d at 36.

#### B. New York False Claims Act

Plaintiffs bring claims under N.Y. Soc. Serv. Law § 145–b alleging that defendants obtained public funds by means of false statements. Section 145–b(1) provides:

(a) It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

(b) For purposes of this section, “statement or representation” includes,

but is not limited to: a claim for payment made to the state, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment, financial information whether in a cost report or otherwise, health care services available or rendered, and the \*202 qualifications of a person that is or has rendered health care services.

(c) For purposes of this section, a person, firm or corporation has attempted to obtain or has obtained public funds when any portion of the funds from which payment was attempted or obtained are public funds, or any public funds are used to reimburse or make prospective payment to an entity from which payment was attempted or obtained.

N.Y. Soc. Serv. Law § 145–b(1).

[1] The plain language of the statute establishes that to prove liability under [Section 145–b](#), Plaintiffs must show that Defendants knowingly made a false statement or representation on behalf of themselves or others to attempt to obtain or to obtain payment from public funds.

### 1. False Statements

[2][3] Plaintiffs contend that Defendants reported false WACs to the publishing compendia, knowing that CMS would use those WACs to establish FULs, and that New York Medicaid (and the federal Medicaid program and the Medicaid programs of other states) would reimburse on the basis of those FULs. A true WAC is “the price that wholesalers actually paid to acquire the drug.” *Mylan*, 608 F.Supp.2d at 144. For a WAC to have been a true list

price, “50% of a drug's sales each year [must have been] made at transaction prices that were within 5% of the manufacturer's reported [WAC] for that drug.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 672 F.Supp.2d 211, 215. Plaintiffs have presented undisputed evidence that the WACs the Defendants reported were not the prices that wholesalers actually paid to acquire their drugs and that fewer than 50% of their sales were made within 5% of their reported WACs. Defendants do not contend that their reported prices were the prices actually paid by providers or wholesalers or that more than 50% of their sales were made within 5% of them. As such, Plaintiffs have established that the Defendants reported false WACs.

### 2. Knowledge of Falsity

A harder issue is whether there is undisputed evidence of scienter. Defendants' only plausible claim regarding their failure to report true WACs is that they believed they were meant only to report list prices. For purposes of summary judgment, the Court must assume this contention contained in Defendants' deposition testimony is true. But there is simply no evidence that Defendants believed that the prices they reported were even true list prices. As discussed at the Track One trial, the FTC's Guides Against Deceptive Pricing provide that a list price “will not be deemed fictitious if it is the price at which substantial (that is, not isolated or insignificant) sales are made.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d at 105 (quoting 16 C.F.R. § 233.3(d)). After a review of the case law, the Court then held that “if more than 50 percent of all sales were made at or about the list price, the list price will not be deemed fictitious.” *Id.* Defendants have presented no evidence that a significant percentage (and certainly not

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more than 50%) of their sales were made within 5% of their reported WACs, and Defendants were aware that only a very small percentage of their sales were made within that range. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 672 F.Supp.2d 211, 214–15; see also *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 185–86 (1st Cir.2009). As such, even viewing the facts in the light most favorable to the Defendants, and drawing all reasonable inferences in their favor, the Defendants knew that the list \*203 prices they reported were fictitious list prices.

This case presents substantially similar facts to those discussed in *Massachusetts v. Mylan Labs., Inc.*, 608 F.Supp.2d 127. There the Court declined to issue summary judgment in the plaintiff's favor as to the defendants' knowledge of falsity. However, the parties did not focus on the issue of the FTC's list price test as an aid to assessing scienter in their briefs.

### 3. On Behalf of Himself or Others/Payment from Public Funds

Defendants do not dispute that the payments made by New York Medicaid constitute “payment from public funds.” Likewise, the Defendants' reporting of inflated prices with the effect of increasing reimbursement to providers constitutes false statements made “on behalf of providers.” See *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d at 179.

### 4. Attempt to Obtain Payment

[4] Defendants argue that Plaintiffs cannot prove their case because Plaintiffs cannot prove that any false statement caused improper payments. Causation of improper payments, however, is not an element of Section 145–b. The plain language of Section 145–b makes clear that liability

attaches upon an “attempt to obtain” improper payments. Nothing more is required. Defendants look to Section 145–b(1)(b) to impose a causation requirement, but that section merely defines the meaning of “statement or representation” in Section b(1)(a). The “statement or representation” here, the reported WACs, constitute “report[s] of data which serve[ ] as the basis for a claim or a rate of payment,” although they could also be understood as “financial information whether in a cost report or otherwise.”

Defendants argue that the use of the phrase “which serves as the basis” adds a causation requirement to the statute. This is not a reasonable interpretation. First, the definition of “statement or representation” is expansive, not limiting, beginning by noting that the term “includes, but is not limited to” the types of statements and representations that follow. Moreover, the canon of *noscitur a sociis* makes clear that the “report[s] of data” do not come with a causation requirement as the other listed statements or representations, “a claim for payment,” “financial information whether in a cost report or otherwise,” “health care services available or rendered,” and “the qualifications of a person that is or has rendered health care services,” do no such thing.

More fundamentally, and unsurprisingly given that Section 145–b(1)(b) is a definitional section, when the definition is read into Section 145–b(1)(a), the meaning of the section does not change. Reading the definition of “statement or representation” into Section 145–b(1)(a), the statute reads: “It shall be unlawful for any ... corporation knowingly by means of a false report of data which serves as the basis for a claim or a rate of payment ... on behalf of himself



or others, to attempt to obtain or to obtain payment from public funds....” In context, the language of the statute makes clear that liability still attaches upon an *attempt* to obtain funds. The data must “serve [ ] as the basis for a claim or a rate of payment,” only in the sense of being material, that is, the type of data which serves as the basis for a claim or rate of payment, as opposed to other types of data which do not. *See Mylan*, 608 F.Supp.2d at 152–53.

The remainder of the statute supports this reading. A second definitional section, [Section 145–b\(1\)\(c\)](#), which defines “attempt to obtain or to obtain payment from \*204 public funds,” reaffirms that the section imposes liability “when any portion of the funds from which payment was attempted or obtained are public funds,” with no limitation imposing a causation requirement when the false statement is a “report of data.” Similarly, the damages section of the statute, [Section 145–b\(2\)](#), allows the plaintiff to recover on the basis of “the amount by which any figure is falsely overstated,” rather than on the basis of actual injuries incurred, belying the existence of any causation requirement.

This reading of the statute based on its plain language is also consistent with the purpose of every false reporting act—to prevent false reporting—which is best served by creating liability when a false statement is made, rather than only in cases where the scheme succeeds. *See Mylan*, 608 F.Supp.2d at 153. This statute serves the same purpose as other false claims acts, which, like the federal False Claims Act, evaluate claims “based on the potential effect rather than actual result [because that] is more consistent with the underlying purpose of the FCA. The United States Supreme Court has broadly interpreted the

[FCA] to cover ‘all fraudulent attempts to cause the Government to pay out sums of money.’ ” *Id.* (quotation marks and citations omitted).

When the Defendants published false prices, they “attempt[ed] to obtain ... payment from public funds,” all that is required under the statute. The data they submitted was the type of data which “serves as the basis for a claim or a rate of payment,” as it was exactly that data that CMS analyzed and relied upon as the starting point in setting FULs, and the FULs were based upon that data. This is all that is required by [Section 145–b](#). Even viewing the facts in the light most favorable to the Defendants, and drawing all reasonable inferences in the Defendants’ favor, the Defendants attempted to obtain payment from public funds on behalf of providers by means of a material false statement or representation. Accordingly, Plaintiffs’ motion for summary judgment for liability under [Section 145–b](#) must succeed.

[5] Defendants alternatively argue that because the FUL-setting process was discretionary and not mechanistic, the calculation of damages is rendered too complicated. But the question of calculating damages is separate from the question of liability. As a general matter, some uncertainty in the calculation of damages does not bar their award. “[U]nder the long-standing New York rule, when the existence of damage is certain, and the only uncertainty is to its amount, the plaintiff will not be denied a recovery of substantial damages.” *Contemporary Mission, Inc. v. Famous Music Corp.*, 557 F.2d 918, 926 (2d Cir.1977).

[I]t is defendants ... who must bear the risk of any uncertainty which their wrong has created. Where the complained of injury ‘is of such a nature as to preclude

the ascertainment of the amount of damages with certainty', it would be a perversion of fundamental principles of justice to deny all relief to the injured person, and thereby relieve the wrongdoer from making any amend for his acts.

*Schoenholtz v. Doniger*, 657 F.Supp. 899, 908 (S.D.N.Y.1987) (quoting *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563, 51 S.Ct. 248, 75 L.Ed. 544 (1931)).

Moreover, Section 145–b specifically provides formulas for calculating both damages and penalties. As for damages, “[f]or any violation of [the law], the local social services district or the state shall have a right to recover civil damages equal to three times the amount by which the \*205 figure is falsely overstated....” N.Y. Soc. Serv. Law § 145–b(2).

Section 145–b also provides for penalties for each overpayment that the Defendants caused:

In addition, the department of health is also authorized to recover any overpayment, unauthorized payment, or otherwise inappropriate payment and impose a monetary penalty against any person or persons ... who caused the overpayment, unauthorized payment, or otherwise inappropriate payment to be received by the other person or persons. All of the foregoing actions may be taken by the department of health for the same claim.

N.Y. Soc. Serv. Law § 145–b(4)(b). New York law has not addressed the question of causation as a prerequisite for the award of penalties.<sup>FN17</sup> While calculating penalties and damages may well be a daunting task, the Court will address issues relating to the calculation of damages and

penalties following further briefing.

FN17. Case law interpreting the similarly motivated federal False Claims Act (“FCA”) indicates that the government can recover civil penalties even without proving any damages. See *United States ex rel. Luther v. Consol. Indus., Inc.*, 720 F.Supp. 919, 922 (N.D.Ala.1989); *United States v. Rapoport*, 514 F.Supp. 519, 523 (S.D.N.Y.1981); *Fleming v. United States*, 336 F.2d 475, 480 (10th Cir.1964).

## 5. Deception

[6] Defendants also argue that Plaintiffs cannot establish liability because Plaintiffs cannot establish that either CMS or New York Medicaid was deceived because they had access to the Defendants' AMP data and because they knew the Defendants reported prices were merely list prices. Deception of government officials, however, is not an element of Section 145–b. The plain language of the statute makes clear that liability attaches upon the attempt to obtain payment, as discussed above. Because the Defendants attempted to obtain payment by making false statements, the statutory inquiry is complete.

[7] To prevail on a government knowledge defense, Defendants must produce admissible evidence that New York or its agencies knew the actual true facts, and that they ordered, asked for, approved, or decided as a policy matter to acquiesce in the Defendants' reporting of false prices. See generally, *Mylan*, 608 F.Supp.2d at 148–152. The evidence cited by the Defendants does not show anything close to such knowledge or approval, and is misleading to boot. For instance, the Defendants attempt to rest their hat on a 1986 letter from Cesar Perales, the head of the New

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York State Department of Social Services, to CMS' predecessor that setting FULs on "advertised" prices for 100-unit packages of drugs will not lead to cost savings. (Perales Aff. [Docket No. 6057] Ex. A.) But Perales' concern was based on the fact that most pharmacies buy in larger, cheaper quantities, and he says nothing about inflation or falsity of WACs and nothing about the extent of any WAC inflation. (*Id.*) He likewise does not in any way indicate an affirmative approval of the Defendants' false WACs. (*Id.*)

With respect to the federal government, the Defendants contend that CMS officials knew about the price inflation because they spoke of building in a "profit margin" for pharmacists in setting FULs and expressed concerns that CMS might miss out on potential cost savings by setting FULs on the basis of the Defendants' published prices. 52 Fed.Reg. at 28,650, 28,655–28,656. A profit margin was built in: by setting FULs at WAC times 150% as opposed to setting them at WAC. Likewise, \*206 the concern about missed price savings was based on the fact that "using published prices as a basis for determining payment levels may cause wholesalers to invent new ways of offering discounts.... The drawback is that neither State programs nor the Federal Medicaid program will benefit from such reductions in wholesale prices." *Id.* at 28,656. This statement thus relates not to concerns of manufacturer price inflation, but to concerns of missing out on discounts offered by wholesalers. If anything, the use of the term "profit margin" indicates that CMS did not understand the massive inflation in prices reported by the Defendants. Needless to say, it would be torturing language to interpret expressed concerns of missing out on potential lost savings as embracing enormous overpayments.

The rest of the evidence presented by the Defendants is the same as that presented in *Mylan*, and here, as there, it is clear that:

[a]lmost all publicly available information appearing through the end of the Damage Period suggested that participants and informed analysts of these markets believed that WAC + x%, where x% was reasonably small, provided a good approximation of the actual drug acquisition cost for retail pharmacies. The only information that I have seen to the contrary is that found in the March 2002 OIG Report discussed ... above. That information was certainly insufficient to have altered [CMS'] reimbursement practices through 2003:Q1.

*Mylan*, 608 F.Supp.2d at 157–58 (citation omitted).

Defendants' strongest argument to show actual federal government knowledge is that CMS knew about and possessed AMPs. The Medicaid Rebate Agreement defines AMP as "the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade.... Specifically, it is calculated as Net Sales divided by number of units sold." Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer § I(a). "Net Sales" is defined in the Agreement as "quarterly gross sales revenue less cash discounts allowed and all other price reductions ... which reduce the actual price paid." *Id.* § I(p).

Because CMS had access to AMPs, the Defendants reason that CMS should have known that the Defendants' published prices were false. But AMPs are statutorily prohibited from being used for reimburse-

ment and must be held confidentially, and thus CMS could not have used AMP data in this way, and there is no evidence that it did. *See* Medicare Improvements for Patients and Providers Act of 2008, [Pub.L. No. 110-275](#), 122 Stat. 2494 (2008); 42 U.S.C. § 1396r-8(b)(3)(D). Moreover, the Medicaid statute required CMS to set its prices on the basis of the Defendants' published prices, not the Defendants' AMPs, and thus there is no reason to believe that CMS looked to the Defendants' AMP data in analyzing its reimbursements.

Defendants also argue that CMS has access to other sources of information that informed CMS that the manufacturers' published prices were higher than actual transaction prices. CMS gathered information from manufacturers, wholesalers, pharmacies, and state Medicaid agencies to ensure that drugs were available, that drugs were assigned to the appropriate Product Group, that the FUL was at a reasonable level, and that the FUL was such that sufficient quantities of the drug could still be obtained. Despite extensive discovery, there is no evidence that CMS' efforts revealed that the Defendants' reported\*207 prices suffered from such mega-spreads or that CMS ordered or approved of such reporting practices.

The record does not contain any evidence from which a factfinder could reasonably infer that CMS would tie reimbursement to published prices, and specifically the lowest published price, if it knew or approved of the fact that the Defendants' published prices were meaningless, neither the actual price that wholesalers paid nor even the price that any significant number of wholesalers paid. It would be irrational for CMS to subtitle the rule creating FULs “Limits on Payments for Drugs,” if CMS

believed that payments would be limitless, reflecting published prices completely disconnected from reality, or to state that the purpose of the rule was “to take advantage of savings that are currently available in the marketplace for multiple source drugs,” if it knew that it was setting FULs in such a way as to make that impossible. 52 [Fed.Reg.](#) at 28,648. Likewise, Defendants cannot explain why CMS would have done its best to set FULs on the basis of the lowest published price that it believed would ensure sufficient availability of drugs if CMS knew or approved of the Defendants' meaningless WACs, or why New York Medicaid would have worried about failing to capture every last available discount if it knew that at the same time it was signing off on payments based on numbers crafted from thin air. The Defendants' government knowledge defense cannot prevail.

Under [Section 145-b](#), Plaintiffs must show that Defendants knowingly made false statements or representations on behalf of themselves or others to attempt to obtain payment from public funds. Even viewing the facts in the light most favorable to the Defendants, and drawing all reasonable inferences in their favor, the Plaintiffs have proved that Defendants, by submitting false AWP and WACs that were used by CMS in setting FULs, have done just that. As such, the Plaintiffs' partial motion for summary judgment related to liability on their [Section 145-b](#) claims is **ALLOWED** and the Defendants' partial motion for summary judgment as to the Plaintiffs' [Section 145-b](#) claims is **DENIED**.

### ***C. Unfair Trade Practices***

Plaintiffs also bring claims alleging that Defendants' conduct constituted an unfair trade practice under New York's consumer



protection statute, General Business Law § 349. Defendants have moved for summary judgment on the claims. <sup>FN18</sup>

**FN18.** Plaintiffs moved for summary judgment only on their claims under Section 145–b.

The statute provides monetary relief for any person injured by reason of “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.” N.Y. Gen. Bus. Law § 349. “A plaintiff under section 349 must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that plaintiff suffered injury as a result of the deceptive act.” *Stutman v. Chemical Bank*, 95 N.Y.2d 24, 29, 709 N.Y.S.2d 892, 731 N.E.2d 608, 611 (2000).

[8] Defendants argue that Plaintiffs cannot prove their claim because they cannot prove causation. Causation is an essential element of Section 349 claims. See *Gaidon v. Guardian Life Ins. Co. of Am.*, 94 N.Y.2d 330, 344, 704 N.Y.S.2d 177, 725 N.E.2d 598, 604 (1999) (injury must occur “by reason” of Section 349 violation).

**\*208 [9]** Defendants argue that because CMS exercised discretion in setting FULs, it is impossible for Plaintiffs to show that had the Defendants published lower prices, those lower prices would have resulted in setting lower FULs, and thus it is impossible for Plaintiffs to prove causation. It is true that the exercise of discretion makes it impossible for Plaintiffs to prove causation to a logical certainty. However, the law merely requires that the Plaintiffs prove that it is more likely than not that the Defendants' false prices caused CMS to set

higher FULs.

When the facts are viewed in the light most favorable to the Plaintiffs and all reasonable inferences are drawn in the Plaintiffs' favor, the Plaintiffs have presented sufficient evidence to demonstrate causation. CMS did not “disregard” lower prices but used them as a starting point. CMS chose, based on the price information reported by the Defendants, to set FULs such that sufficient quantities of drugs could be purchased for less than the FULs it set, something the Defendants regard as a “sound policy reason[ ].” Had the Defendants reported true WACs, CMS would likely have had lower FULs. CMS may have kept a similar number of published prices below the FUL, but it would likely have set the FUL at a lower price. <sup>FN19</sup>

**FN19.** Defendants also point to other decisions by CMS that they think prevent liability. Sometimes CMS did not set a FUL when enabled to by the regulatory criteria. CMS sometimes set FULs based on prices obtained by double-checking published prices with the manufacturer and declined to set FULs if it knew that there was a shortage of a drug's raw material or that the drug was not widely enough available in all of the states. Errors were made where FULs were based on products that were not therapeutically equivalent, based on products not in the most commonly available package size, and based on prices that were outdated. While these issues may make the calculation of damages difficult, they do not defeat liability.

In fact, CMS' goal, ensuring that sufficient quantities of drugs were available,

bolsters, and does not hurt, Plaintiffs' case. CMS did not always base its FULs on the lowest reported price not because it simply disregarded such prices, or actively desired to set FULs higher than it could, but because it wanted to ensure sufficient drug availability. Had the Defendants reported truthful prices, CMS would have known that it could accomplish this goal with lower FULs, and accordingly would likely have set FULs lower.

In many cases, had any single Defendant reported the truth in any instance, it is more likely than not that the FUL for that drug would have come down. CMS was attempting to ensure that sufficient quantities of drugs were available for less than the FUL. Had any defendant reported a truthful price, that price would likely have been the lowest price reported. While the FUL may not have been based off of that price, CMS would likely have taken into account the availability of that manufacturer's drug for less than the FUL. In many cases, this availability likely would have caused CMS to set its FUL on the basis of a reported price that was lower than the reported price on which it in fact set the FUL. <sup>FN20</sup>

<sup>FN20</sup>. And, of course, had significant numbers of the manufacturers of therapeutically equivalent drugs reported truthful prices—many of whom are Defendants here—the FUL would have been dramatically lower.

As such, the Defendants not only caused FULs to be higher than necessary by inflating the array of prices that CMS relied upon in setting an appropriately priced FUL, but also by causing CMS to underestimate the quantity of drugs available at a given FUL, and thus to set higher FULs than necessary to achieve its goal of

ensuring\*<sup>209</sup> sufficient access to drugs. CMS' undisputed use of discretion and its need to balance multiple goals thus does not preclude a factual finding of causation or necessitate granting summary judgment in Defendants' favor.

[10] Defendants also argue that Plaintiffs cannot establish liability because Plaintiffs cannot establish reasonable reliance. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d at 182 (violation of the statute requires a showing that Defendants' actions were “likely to mislead a reasonable consumer acting reasonably under the circumstances”). When viewing the facts in the light most favorable to the Plaintiffs and drawing all reasonable inferences in the Plaintiffs' favor, there remains a dispute of fact as to whether state officials reasonably relied on the prices published by the Defendants. As such, Defendants' motion for partial summary judgment as to Plaintiffs' [Section 349](#) claims is **DENIED**.

#### **D. Common Law Fraud**

Plaintiffs also bring fraud claims under state common law. Defendants have moved for summary judgment on the claims. <sup>FN21</sup>

<sup>FN21</sup>. Plaintiffs moved for summary judgment only on their claims under [Section 145–b](#).

[11] In order to find liability for common law fraud, the plaintiff must prove that the defendant “(1) made a material, false statement; (2) knowing that the representation was false; (3) acting with intent to defraud; and that plaintiff (4) reasonably relied on the false representation and (5) suffered damage proximately caused by the defendant's actions.” *Morris v. Castle Rock Entm't, Inc.*, 246 F.Supp.2d 290, 296 (S.D.N.Y.2003).

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[12][13] “Third party reliance on fraud is ... cognizable under New York law where there is a sufficient causal connection between a defendant's fraud and a plaintiff's injury.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1051642, at \*13 (citing *Desser v. Schatz*, 182 A.D.2d 478, 479–80, 581 N.Y.S.2d 796 (N.Y.App.Div.1992)). “Fraud exists ‘where a false representation is made to a third party, resulting in injury to the plaintiff.’ ” *Id.* (quoting *Buxton Mfg. Co. v. Valiant Moving & Storage*, 239 A.D.2d 452, 454, 657 N.Y.S.2d 450 (N.Y.App.Div.1997)). Here, CMS “relied on the defendants' submission of false ... pricing information to the detriment of” New York State and its counties. *Id.* at \*14. Defendants “submitted wholesale pricing data to publishers, intending that the information would be relied on by” CMS in determining FULs. *Id.* CMS “relied on the accuracy of that information” in determining FULs, and New York State and its counties “were injured when they overpaid for prescription drugs purchased through [Medicaid].” *Id.* “Under New York law, because the misrepresentations relied on by [CMS] caused the [state and] counties direct harm, plaintiffs' claim of fraud is viable.” *Id.*

[14] Defendants argue that Plaintiffs cannot prove their claim because they cannot prove causation. Causation is an essential element of New York common law fraud claims. See *Wall St. Transcript Corp. v. Ziff Commc'ns Co.*, 225 A.D.2d 322, 322, 638 N.Y.S.2d 640 (N.Y.App.Div.1996) (misrepresentation must be the direct and proximate cause of the injury). For the reasons discussed above, however, when viewing the facts in the light most favorable to the Plaintiffs and drawing all reasonable inferences in

their favor, Plaintiffs have presented sufficient evidence to demonstrate causation.

\*210 Defendants also argue that Plaintiffs cannot establish liability because Plaintiffs cannot establish reasonable reliance. See *Channel Master Corp. v. Aluminum Ltd. Sales, Inc.*, 4 N.Y.2d 403, 407, 176 N.Y.S.2d 259, 151 N.E.2d 833, 835 (1958) (fraud requires proof that the plaintiff was “deceived and damaged” by the alleged misrepresentation). When viewing the facts in the light most favorable to the Plaintiffs and drawing all reasonable inferences in the Plaintiffs' favor, there remains a dispute of fact as to whether state officials reasonably relied on the prices published by the Defendants. As such, Defendants' motion for partial summary judgment as to Plaintiffs' common law fraud claims is **DENIED**.

#### ORDER

Plaintiffs' motion for partial summary judgment [Docket No. 6076] is **ALLOWED** and the Defendants' motion for partial summary judgment [Docket No. 6052] is **DENIED**.

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