

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESAL PRICE)
LITIGATION) MDL NO. 1456

THIS DOCUMENT RELATES TO:) Civil Action No. 01-12257-PBS

State of Iowa)
)
Plaintiff)
)
v.)
)
Abbott Laboratories, Inc.,)
et al.)
)
Defendants)

MEMORANDUM AND ORDER

August 19, 2008

Saris, U.S.D.J.

INTRODUCTION

Iowa brings this action against seventy-eight brand name and generic drug manufacturers to recover money that its Medicaid Program paid to reimburse providers for the drugs manufactured by defendants. Among other things, Iowa alleges that defendants' reporting of inaccurate, false and misleading wholesale pricing information constituted deception and unfair practices prohibited by the Iowa Consumer Fraud Act ("ICFA").¹ See Iowa Code §

¹Iowa's Complaint states four other causes of action. Count I alleges that defendants violated the Federal Medicaid Statute, 42 U.S.C. § 1396r-8, by failing to comply with the Federal Medicaid rebate provision. Count II alleges that defendants breached their contracts with the Secretary of Health and Human Services by violating the rebate agreements of which Iowa was an intended third-party beneficiary. Count IV alleges a cause of action for fraud because defendants engaged in actual fraudulent

714.16.

As background, defendants report "average wholesale prices" ("AWPs") to publishing companies for certain drugs covered by Iowa's Medicaid Program. Iowa contends that the AWPs and other reported prices are fraudulently and grossly inflated above the actual acquisition costs of providers like pharmacists and physicians. The factual basis for the use of the AWP as a pricing reimbursement benchmark by federal and state governments and the private sector is set forth in numerous prior opinions by this Court, including In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007), with which the Court assumes familiarity.

After hearing and review of the submissions, the Court **ALLOWS-IN-PART** and **DENIES-IN-PART** Certain Defendants' Motion to Dismiss the Complaint [Docket No. 5078].

STANDARD OF REVIEW

For the purposes of this motion, the Court accepts the complaint's well-pleaded facts as true and indulges all reasonable inferences in the plaintiff's favor. See Cook v. Gates, 528 F.3d 42, 48 (1st Cir. 2008). "To survive a motion to dismiss, a complaint must allege a 'plausible entitlement to relief.'" Id. (quoting Bell Atl. Corp. v Twombly, __U.S.__, 127 S. Ct. 1955, 1967 (2007)); see also Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007).

reporting of pricing information on which Medicaid reimbursements are based. Count V alleges a cause of action for unjust enrichment.

DISCUSSION

A. The Iowa Consumer Fraud Act

The key question in dispute is whether Iowa, a governmental entity, may, pursuant to the ICFA, collect actual damages it suffered for reimbursing for Medicaid drugs based on allegedly deceptive and misrepresented prices. Moving to dismiss, defendants argue that "person," as used in several places in the ICFA, does not include the state of Iowa or its governmental agencies. As a result, defendants contend that the attorney general cannot bring a claim for damages under the ICFA on behalf of the state. In a related argument, defendants argue that Iowa is also prohibited from bringing certain claims under the ICFA because the state is not a "consumer."

1. Statutory Scheme

An analysis of the statutory scheme is essential to resolving this dispute, particularly in light of the sparse Iowa caselaw on point. The ICFA provides, in relevant part:

The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice.

Iowa Code § 714.16(2)(a) (emphasis added). The statute defines the underlined terms. "Person" is defined:

The term "person" includes any natural person or the person's legal representative, partnership, corporation (domestic and foreign), company, trust, business entity

or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof.

Iowa Code § 714.16(1)(j). "Deception" is defined:

"Deception" means an act or practice which has the tendency or capacity to mislead a substantial number of consumers as to a material fact or facts.

Iowa Code § 714.16(1)(f). "Unfair practice" is defined:

"Unfair practice" means an act or practice which causes substantial, unavoidable injury to consumers that is not outweighed by any consumer or competitive benefits which the practice produces.

Iowa Code § 714.16(1)(n).

The ICFA denies prospective plaintiffs a private right of action. Stepp v. State Farm Mut. Auto. Ins. Co., No. 06-CV-2027, 2006 WL 2038596, at *4 (N.D. Iowa July 19, 2006). Instead, the ICFA permits the Iowa attorney general to bring actions for equitable relief and civil penalties against persons who engage in unlawful practices under the ICFA. See id. In relevant part, section 7 provides:

A civil action pursuant to this section shall be by equitable proceedings. If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section, including the appointment of a receiver in cases of substantial and willful violation of this section. If a person has acquired moneys or property by any means declared to be unlawful by this section and if the cost of administering reimbursement outweighs the benefit to consumers or consumers entitled to the reimbursement cannot be located through reasonable efforts, the court may order disgorgement of moneys or property acquired by the person by awarding the moneys or property to the state to be used by the attorney general for the administration and implementation of this section....

In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section...Civil penalties ordered pursuant to this subsection shall be paid to the treasurer of state to be deposited in the general fund of the state.

Iowa Code § 714.16(7).

2. Definition of Person

Defendants' first contention is that the definition of "person" in Iowa Code § 714.16(1)(j) does not include the government. To support this argument, they compare the ICFA with a generic statutory provision that expressly includes governmental entities:

Unless otherwise provided by law, "person" means individual, corporation, limited liability company, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

Iowa Code § 4.1(20). In defendants' view, the omission of governmental entities in the ICFA definition of "person" in § 714.16(1)(j) as compared to their express inclusion in this general provision indicates that the omission in the ICFA was intentional.

Generally speaking, dictionaries define "include," the term used in the ICFA definition of "person," to mean "[t]o contain as a part of something." Black's Law Dictionary 777 (8th ed. 2004) (the "participle including typically indicates a partial list."). The Supreme Court has recently commented on the difference between the terms "means" and "includes:"

[T]he word "includes" is usually a term of enlargement, and not of limitation. Thus [a] term whose statutory definition declares what it "includes" is more susceptible to extension of meaning...than where...the definition declares what a term "means." [W]hen an exclusive definition is intended the word "means" is employed, . . . whereas here the word used is "includes."

Burgess v. United States, 128 S. Ct. 1572, 1578 n.3 (2008) (citing Groman v. Comm'r of Internal Revenue, 302 U.S. 82, 86 (1937)) (other citations and internal quotation marks omitted). Throughout Iowa Code § 714.16, "means" is used in certain definitions and "includes" in others, indicating that the legislature intended the words "mean" and "include" to have different meanings. Compare Iowa Code § 714.16(1)(d) (" '[c]onsummation of sale' means completion of the act of

selling, leasing, or renting") (emphasis added) with Iowa Code § 714.16(1)(i) ("[t]he term 'merchandise' includes any objects, wares, goods, commodities, intangibles, securities, bonds, debentures, stocks, real estate or services") (emphasis added). While no court in Iowa has directly addressed the issue, the better reading is that "person" in Iowa Code § 714.16(1)(j) includes the government.

3. Persons in Interest and Consumers

The next question is whether the attorney general can bring an action on behalf of the state for damages the state incurred under the ICFA. Defendants argue that Iowa cannot seek damages on behalf of itself under the ICFA because the ICFA is designed to protect consumers, not to protect the state. Conceding that the attorney general can seek injunctive relief, defendants contend: "[w]hile the Attorney General has the authority to bring a CFA case and to seek injunctive relief to stop prohibited practices or unlawful conduct, the Attorney General can only seek monetary judgments to 'restore to any person in interest any moneys or property, real or personal.' [Iowa Code § 714.16(7)] (emphasis added)." (Mem. Law Supp. Certain Defs.' Mot. Dismiss Compl. 18.)

Both parties agree that the ICFA is at its core a consumer protection statute; its definitions of both "deception" and "unfair practice" refer to "consumers." While the ICFA does not define "consumer," the Supreme Court of Iowa has set forth a broad definition of "consumer" in interpreting a tax statute.

See Cedar Valley Leasing, Inc. v. Iowa Dep't of Revenue, 274 N.W.2d 357, 360 (Iowa 1979) (holding that a farm equipment leasing company was a consumer or user of the equipment it purchased to lease). The court explained that a "'consumer' is defined as 'one that utilizes economic goods[;]'\...[company] need not exhaust, waste, or destroy the equipment to be a 'consumer or user.'" Id. (citing Webster's Third New International Dictionary 490 (1961)). Even under this capacious definition of "consumer," a governmental entity that reimburses for drugs is not a "consumer" of the drugs.

Nonetheless, plaintiff contends that the ICFA gives the attorney general standing under the ICFA when a state agency is defrauded so long as the alleged wrong is "consumer-oriented." Plaintiff relies on this Court's decision in In re Pharm. Indus. Average Wholesale Price Litig., 339 F. Supp. 2d 165 (D. Mass. 2004), interpreting New York's consumer fraud statute, N.Y. Gen. Bus. Law § 349. New York and federal courts interpreting § 349 have held that a "party has standing under Section 349 when its complaint alleges a consumer injury or harm to the public interest, regardless of whether the plaintiff is a consumer." Id. at 182 (citing Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc., 344 F.3d 211, 218 (2d Cir. 2003)) (internal quotation marks omitted). Unfortunately for plaintiff, though, there is no comparable caselaw in Iowa giving the government a clear-cut cause of action for damages when it is not itself a consumer.

In construing the ICFA, Iowa courts look for guidance to the caselaw construing the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1 et seq., because "[t]he Iowa Consumer Fraud Act was patterned after the Illinois Consumer Fraud Act." State ex rel. Miller v. Hydro Mag, Ltd., 436 N.W.2d 617, 621 (Iowa 1989). In a suit brought by the attorney general on behalf of the people and taxpayers of Illinois against public contractors based on, inter alia, their alleged misrepresentations as to compliance with minority and women business enterprise requirements, the Illinois Supreme Court held that the state attorney general could assert standing under the Illinois Consumer Fraud and Deceptive Business Practices Act, even though the allegedly defrauded parties were governmental units, not "consumers." See People ex rel. Hartigan v. E & E Hauling, Inc., 607 N.E.2d 165, 172-73 (Ill. 1992) ("Nothing in section 7 indicates that the defrauded party must be a consumer or 'person' in order for the Attorney General to have standing, nor will we read such a requirement into that section.").

This precedent from a kissing-cousin state is not a slam dunk for the plaintiff because of an important difference in the statutory schemes. The Iowa statute expressly defines two of the prohibited acts -- "deception" and "unfair practice" -- in terms of harm to consumers. See Iowa Code § 714.16(1)(f), (n). By contrast, the Illinois statute does not have comparable definitions of "unfair practice" and "deception."

The question of statutory construction is close. While the ICFA defines "unfair practice" and "deception" as consumer-based, it does not similarly limit other prohibited acts like "fraud, false pretense, false promise, or misrepresentation[.]" See Iowa Code § 714.16(2)(a). Significantly, § 714.16(2)(a) refers to "persons," not "consumers[;]" § 714.16(7) refers to both "persons" and "consumers." The Supreme Court of Iowa has described the ICFA as "a statute that serves a remedial purpose and must be interpreted liberally." State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc., 694 N.W.2d 518, 528 (Iowa 2005). Moreover, in another context, the Supreme Court of Iowa has suggested, in dicta, the right of Iowa to seek restitution on behalf of itself under the ICFA, noting the enactment of an appropriation measure that referred to "damages awarded to the state...by a civil consumer fraud judgment." State ex rel. Miller v. Santa Rosa Sales & Mktg., Inc., 475 N.W.2d 210, 219 (Iowa 1991) (citation omitted). In light of Illinois' caselaw under a similar provision, this doctrine of liberal construction, and the statutory structure which seems to distinguish between "persons" and "consumers," the Court concludes that the better reading is that the other listed practices, like fraud and misrepresentation, need not cause harm to "consumers" to be "unlawful practice[s]" under § 714.16(2)(a). Under this interpretation, at this early stage of the proceedings, the state, as a reimbursing party, is a "person" under Section 7 of the ICFA on behalf of whom the attorney general can seek injunctive

relief, reimbursement and civil penalties if the state is defrauded as the result of an “unlawful practice” that is not defined as limited to consumers.² See Iowa Code § 714.16(2)(a). Thus, the Court **DENIES-IN-PART** the motion to dismiss Count III. The Court **ALLOWS-IN-PART** the motion to dismiss Count III to the extent that certain Best Price claims have not been pled with adequate particularity, as discussed below.

B. Miscellaneous

The Court rules on the remaining issues as follows:

1. The Court **ALLOWS** the motion to dismiss Count I on the ground that there is no private right of action for the states under the Medicaid Best Prices Statute, 42 U.S.C. § 1396r-8. See Massachusetts v. Mylan Labs., 357 F. Supp. 2d 314, 326 (D. Mass. 2005).

2. The Court **ALLOWS-IN-PART** and **DENIES-IN-PART** the motion to dismiss Count II (breach of contract). Although Iowa is an intended third-party beneficiary of the rebate agreement, see Mylan, 357 F. Supp. 2d at 327-29, plaintiff has not, with respect to most defendants, tied the Best Price claims to particular drugs, discounts or other company-specific practices. Such allegations are necessary to support claims of breach of contract or fraud based on misrepresentations about prices under the notice pleading requirement in Fed. R. Civ. P. 8(a). See In re Pharm. Indus. Average Wholesale Price Litig., No. 01-12257, 2004

² Although the Court has suggested certification to the Supreme Court of Iowa, neither side has requested this option.

WL 2387125, at *2 (D. Mass. Oct. 26, 2004) (“[w]ith respect to most companies, [plaintiff] has not tied the Best Prices claims to any particular drugs, discounts or other company-specific practices which would support an inference of misrepresenting Best Prices. Therefore, the allegations fall woefully short under Rules 8(a) and 9(b).”). Defendants concede that the Best Price claims as to certain drugs were pled with sufficient particularity, but do not clearly specify which drugs. The parties shall confer and notify the Court as to the drugs for which the various Best Price claims have been adequately pled so that the record is clear.

Defendants also contend that plaintiff’s Best Price claims are barred by the filed rate doctrine, but plaintiff has the better argument that its Best Price claims should not be dismissed for this reason. See Mylan, 357 F. Supp. 2d at 329 (with respect to the filed rate doctrine, “[d]efendants’ Best Prices data submissions do not constitute ‘rates’ or ‘tariffs,’ so this doctrine is inapplicable.”).

3. The Court **ALLOWS-IN-PART** and **DENIES-IN-PART** the motion to dismiss Count IV (common law fraud). See In re Pharm. Indus. Average Wholesale Price Litig., 339 F. Supp. 2d at 180 (addressing a motion to dismiss a claim for common law fraud because, inter alia, plaintiff “was or should have been aware of the AWP fraud[,]” the court found that this argument “presents a factual issue inappropriate for resolution at this stage”). For similar reasons, this Court declines without prejudice

defendants' request to limit the damages period from 1992 to August 1997.

Defendants also move to dismiss this claim on the ground that Iowa failed to allege any false representation regarding the meaning of AWP or of any other pricing term on the part of defendants. Defendants concede that plaintiff does allege a statement by First DataBank that "AWP represents an average price which a wholesaler would charge a pharmacy for a particular product." (Compl. ¶ 98.) This Court rejects this argument and has previously rejected a similar argument. See Mylan, 357 F. Supp. 2d at 322 ("[w]hen all reasonable inferences are drawn in favor of the non-moving party during the relevant period, the term WAC was understood in the trade to mean a true price, and Defendants were misrepresenting their true prices to the government.").

Defendants also move to dismiss this and other claims involving WAC and WAC Equivalent allegations, arguing that plaintiff has not set forth its claims with sufficient particularity under Fed. R. Civ. P. 9(b). This Court has previously set forth the standard with respect to Rule 9(b) for claims regarding AWP: "the Court concludes that the plaintiffs have satisfied Rule 9(b) with respect to those drugs (1) specifically identified in the complaint as (2) purchased by [plaintiffs] in any year subject to this lawsuit along with (3) an allegedly fraudulent AWP calculated on a good faith basis, together with a spread." In re Pharm. Indus. Average Wholesale

Price Litig., No. 01-12257, 2007 WL 1051642, at *15 (D. Mass. Apr. 2, 2007). In that case, defendants also argued, in support of their motion to dismiss, that many of plaintiffs' allegations concerning wholesale pricing fraud were premised on the submission of WAC or equivalent listings. This Court held that, once plaintiffs had satisfied Rule 9(b) with respect to AWP and confirmed that their case was not about the 20 - 25% mark-up between WAC and AWP, "[g]iven the formulaic relationship between WAC and AWP, no more particularity is required." Id. Therefore, WAC and WAC equivalent claims, included in several of plaintiff's allegations, will not be dismissed on this ground as long as they satisfy this standard.

Defendants argue that any claims based on State Maximum Allowable Cost ("SMAC") should be dismissed because SMACs are based on actual purchase records, not on published pricing. In its briefing, plaintiff concedes that it will not pursue any claims for drugs reimbursed based on SMAC after SMAC became effective. Therefore, all claims based on SMAC after SMAC became effective are dismissed.

4. The Court **ALLOWS-IN-PART** and **DENIES-IN-PART** the motion to dismiss Count V (unjust enrichment). Plaintiff concedes that its unjust enrichment claims should be dismissed as to certain defendants and certain drugs. The parties shall submit a stipulation specifying the drugs for which they agree that the unjust enrichment claims were not alleged with adequate particularity.

Defendants also argue that Iowa did not sufficiently allege that it conferred a benefit on defendants. Plaintiff alleges that defendants were unjustly enriched as a result of their unlawful acts through both the increased sales of covered drugs with the greatest spreads and their failure to pay the full rebate amounts required by law. (Compl. ¶¶ 614-16, 665.) This Court denies the motion to dismiss plaintiff's unjust enrichment claims on this ground. See In re Pharm. Indus. Average Wholesale Price Litig., 339 F. Supp. 2d at 181 ("[l]eaving aside the thorny issue of whether [plaintiff] may recover from Defendants to the extent that the AWP fraud boosted their sales, the Court notes that [plaintiff's] claim that Defendants were 'saved from expense' when they fraudulently underpaid Best Prices rebates to the State, and consequentially [plaintiff], suffices to state a claim.").

5. The Court **DENIES** the motion to dismiss the "FUL" claims without prejudice. See In re Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d 402, 405 (D. Mass. 2007) ("[t]he Court denies defendants' motion to dismiss drugs subject to a Federal Upper Limit[;]...plaintiffs and defendants shall each select five drugs subject to FUL reimbursement[;]...[t]he Court will address the plaintiffs' FUL claims as to those drugs on summary judgment with expert assistance and a more complete record."). However, the Court will stay discovery as to the FUL drugs at issue in this action pending resolution of the FUL claims in the Consolidated New York Counties litigation.

6. Defendants move to dismiss any drug for which plaintiff has alleged a spread of 30% or less. This Court **DENIES** the motion to dismiss any drugs for which plaintiff has alleged a spread of 30% or less, but this Court will, with no objection by plaintiff, stay discovery for all drugs with alleged spreads of 30% or less until such time as plaintiff establishes that a lower threshold should apply. See In re Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d at 405 ("discovery is stayed for all drugs with spreads lower than 30% until such time as the plaintiffs submit an expert affidavit providing a good faith basis for a 20-25% spread threshold.").

S/PATTI B. SARIS
United States District Judge