Nos. 13-435

In The Supreme Court of the United States

OMNICARE, INC., *ET AL.*,

Petitioners

v.

LABORERS DISTRICT COUNCIL CONSTRUCTION INDUSTRY PENSION FUND, *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF OF THE WYOMING RETIREMENT SYSTEM AND THE INDIANA PUBLIC RETIREMENT SYSTEM AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

JOE KENDALL
KENDALL LAW GROUP, LLP
3232 McKinney Ave., Ste. 700
Dallas, Texas 75204
(214) 744-3000
jkendall@kendalllawgroup.com

Counsel for Amicus Curiae

ERIK S. JAFFE
(Counsel of Record)
ERIK S. JAFFE, P.C.
5101 34th Street, N.W.
Washington, DC 20008
(202) 237-8165
jaffe@esjpc.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTEREST OF *AMICI CURIAE* [1]

Amicus curiae the Wyoming Retirement System ('WRS") was established in 1953 and is administered by an 11-member board that is responsible for retirement benefits for nearly 42,000 active members, 23,000 retirement members and approximately 20,510 inactive members. The active membership is comprised of employees from school districts, the University of Wyoming and community colleges, state and local government and various other political subdivisions. With approximately $7 billion in assets under management, WRS consists of nine separate defined benefit pension plans.

WRS purchased over 90,000 shares of Omnicare stock during the period of the wrongdoing and, as a result of the subsequent disclosure of Omnicare's illegal activities, suffered a substantial loss. It thus has a particular interest in this case and, more generally, in the standards to be applied to statements made by issuers of publicly traded stock.

Amicus curiae the Indiana Public Retirement System ("IPRS") was established by legislation as an independent body, corporate and politic. INPRS manages the retirement assets of seven different retirement funds which includes seven Defined Benefit Plans and one Defined Contribution Plan. INPRS has approximately $27 billion in assets under manage-

---

[1] No counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *Amici* or their counsel, make a monetary contribution intended to fund the preparation or submission of this brief. This brief is submitted pursuant to the blanket consent letters of the parties, on file with this Court.

ment. It serves the pension needs of 450,000 members and retirees representing more than 1,187 employers including public universities and other municipalities and state agencies.

INPRS purchased over 250,000 shares of Omnicare stock during the period of the wrongdoing and, as a result of the subsequent disclosure of Omnicare's illegal activities, suffered a substantial loss. It thus has a particular interest in this case and, more generally, in the standards to be applied to statements made by issuers of publicly traded stock.

SUMMARY OF ARGUMENT

1. Section 11 of the Securities Act of 1933 provides remedies for untrue or misleading statements in registration statements. 15 U.S.C. § 77k(a). Prefacing a statement with the phrase "we believe" neither adds nor detracts from the truth or falsity of a statement insofar as such belief is implicit in every assertion of fact in any event, and may in fact enhance the misleading quality of a statement where the basis for such belief is omitted and left to be assumed by the listener. *Amici* thus agree with Respondents that even statements of opinion can be misleading if they lack a reasonable basis and false if they imply a reasonable inquiry resulting in a reasonable basis for the claimed opinion.

2. The actual facts of Omnicare's agreements with drug manufacturers and its pharmacy practices, undisclosed at the time of its registration statement and the beliefs professed therein, make it wholly unreasonable to claim that such agreements and practices were legal, regardless of Omnicare's subjective views

on the subject. Omnicare's agreements and conduct regarding drugs manufactured by Johnson & Johnson (J&J) involved express payments for promoting J&J drugs, covert payments later designed to conceal portions of those kickbacks and deny price reductions to the Medicaid program, numerous deceptive efforts to cause doctors to switch prescriptions to drugs more profitable to Omnicare but more expensive or more dangerous to patients and nursing home purchasers, and often outright falsification or prescription records. Omnicare engaged in similar conduct with a wide variety of other manufacturers, in some instances even withholding material facts from its own attorneys in order to get approval for agreements that had already raised significant red flags.

Reviewing even the abbreviated sampling of such facts discussed in this brief amply illustrates that no reasonable inquiry and analysis of those facts could have led to the reasonable conclusion that Omnicare's contracts and practices were lawful. Its promotional and market-share rebate agreements with manufacturers such as J&J fall squarely within the behavior expressly forbidden by the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(1). Its receipt of so-called consulting, data, and educational payments in lieu of such kickbacks, its alteration of prescriptions, and its deception of physicians involve a myriad of false statements to the federal and state governments. And, lest we forget, its conduct risked patient safety by pushing inappropriate drugs for unapproved uses.

Had the actual facts of Omnicare's agreements and conduct been disclosed at the time of its registration

statement, no reasonable investor or analyst would have given any credence to Omnicare's professed belief in the legality of its agreements and practices. Having omitted such material facts, however, Omnicare's statements of "belief" were, at a minimum, misleading, regardless of Omnicare's subjective state of mind or whether Omnicare itself unreasonably believed its own "press." Its statements of belief were likewise false in that they implied a reasonable basis for such belief that the facts demonstrate did not and could not have existed.

Viewed in light of the underlying facts, Omnicare's statements of belief did more than simply describe its subjective state of mind, they misled investors by omission and they implied false facts regarding the basis for such purported beliefs. Omnicare's statements thus are properly subject to, and violate, Section 11 of the '33 Act.

ARGUMENT

I. Statements Regarding an Issuer's Unreasonable Beliefs Are Misleading If They Omit Material Facts and False If They Imply the Further Fact that the Issuer Had a Reasonable Basis for Such Beliefs, Regardless of the Speaker's Subjective State of Mind.

Section 11 of the Securities Act of 1933 provides a private right of action against issuers and other responsible parties who file a registration statement that

> contained an untrue statement of material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.

15 U.S.C. § 77k(a).

For defendants other than the issuer, however, the statute provides an affirmative defense to liability if such defendant proves that

> he had, after reasonable investigation, reasonable ground to believe and did believe, at the time such part of the registration statement became effective, that the statements therein were true and that there was no omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading

Id. § 77k(b)(3).

For an issuer, it is no defense under the statute that it believed its statements to be true and had reasonable grounds for such belief. As Respondents correctly point out, at 49-51, allowing an issuer unilaterally to grant itself that defense by adding the words "we believe" to an otherwise actionable statement it would render the statute's expressly limited defense nonsensical. Indeed, *every* factual statement by an issuer necessarily implies that the issuer *believes* the statement to be true, and making that implied belief express adds nothing that materially alters the statement.

Even if this Court were to assume that an issuer's addition of the words "we believe" could somehow diminish the asserted substantive fact to an assertion

regarding the issuer's subjective state of mind, it still makes no sense to excuse the issuer from having performed a "reasonable investigation" and from having a "reasonable ground" to believe the substance of its statement. That bizarre construction of the statute by Petitioners would in fact grant an issuer *broader* protection from liability than given to non-issuers – precisely the opposite outcome than that provided by the expressly limited affirmative defense.

In any event, even assuming an issuer's statement of belief is to be treated differently than a bare statement of the underlying substantive assertion, *Amici* agree with Respondents that statements of opinion or belief can still be false or misleading regardless of the issuer's subjective state of mind. Such statements can often imply additional substantive facts that may be false regardless of defendant's subjective state of mind. Or they can be misleading if a defendant fails to disclose material facts that would allow a listener to evaluate the basis for and degree of uncertainty, doubt, or contraindications regarding such opinion or belief. *See* RESTATEMENT (SECOND) CONTRACTS § 169 cmt. a ("assertion of opinion as to facts not known to the [listener] may, in proper circumstances, reasonably be interpreted to include an assertion as to those facts themselves"); Resp. Br. at 30 (if "the facts are not equally known to both sides, then a statement of opinion by the one who knows the facts best involves very often a statement of a material fact, for he impliedly states that he knows facts which justify his opinion," *citing Smith v. Land and House Prop. Corp.*, (C.A. 1884) 28 Ch. D. 7, 15); Resp. Br. at 27 (opinion's potential to mislead may be miti-

gated "by fully disclosing its underlying basis," *citing* RESTATEMENT (SECOND) CONTRACTS § 539(1)).

Misleading statements may often be literally true within the four corners of the statement, but are simply incomplete in a manner that misleads the listener and are actionable under the Securities Act of 1933. *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 207-08 (1976). Statements of belief in a fact or condition that is otherwise falsifiable are prime examples of such circumstances. Unlike belief in abstract concepts or principles – "I believe in truth, justice, and the American Way"; "I believe in the Golden Rule" – statements of belief in substantive matters having objective criteria for determination can often be misleading if the basis for such belief is omitted. Telling a parking valet "I believe that is my car" can be misleading if the basis for your belief is that the actual owner owes you money and this is your extra-judicial attempt to collect it. Likewise, telling a police officer "I believe that man stole my wallet" can be misleading if the only reason you so believe is some generalized or specific prejudice against the fellow, a mere hunch, or some similarly flimsy basis.

So too in the legal and financial world, an accountant's statement "I believe this company's books and records comply with GAAP" would be misleading if the basis for that belief was that the President of the Company had an honest face, rather than an actual and diligent examination of the company's books and records. And a lawyer's statement "I believe this contract is lawful" would be misleading if the lawyer failed to disclose case law suggesting just the oppo-

site, but simply thought all of the courts to consider the issue had gotten it wrong.

In this case, Omnicare's professed belief in the legality of its contractual arrangements and practices proved to be shockingly misplaced. Whether it justified such claimed beliefs on wishful thinking, a theory of it's-not-wrong-if-we-don't-get-caught, or even some marvelously subtle legal distinction transforming payments to promote certain drugs into something other than a kickback, what matters here is that it omitted the, at best, thin-to-non-existent basis for its professed beliefs.

II. Omnicare's Omission of Material Facts Regarding Its Illegal Contracts and Practices Made Its Statements of Belief Misleading and False Regarding the Implied Reasonable Basis for Such Beliefs.

As explained in Respondents' opening brief, at 6-9, Omnicare engaged in a scheme of switching patients from less-profitable to more profitable drugs in order to (i) obtain kickbacks from drug manufacturers and (ii) overcharge Medicaid. The Third Amended Complaint (the "Complaint"), the facts of which must be accepted as true at this stage of the litigation, describes various aspects of this scheme. One prominent aspect of the scheme was a contract with Johnson & Johnson (J&J) that paid Omnicare millions of dollars to increase the market share of an antipsychotic medication called Risperdal, which Omnicare accomplished by improperly and dangerously causing the drug to be prescribed to inappropriate elderly patients in long-term care facilities. JA 207-08, 214

(Complaint ¶¶ 55, 67); Resp. Br. at 7-8. This arrangement violated the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(1).

While this scheme was in operation, and in conjunction with its 2005 public offering of $765 million of stock sold to *Amici* and other investors, Omnicare made a number of statements relating to the nature and legality of its business operations that hid the true nature of its illegal activities. Of particular relevance here, Omnicare stated that:

> We believe that our contracts with pharmaceutical manufacturers are legally and economically valid arrangements that bring value to the healthcare system and the patients that we serve.

JA 137. It further stated:

> We believe our contract arrangements with other healthcare providers, our pharmaceutical suppliers and our pharmacy practices are in compliance with applicable federal and state laws.

JA 95-96.

To more fully appreciate how such statements were misleading by omission and false in their implied factual assertion of a reasonable basis for Omnicare's opinions, a brief examination of the underlying illegality is useful.

A. Kickbacks for Promoting Drugs.

The federal anti-kickback statute provides criminal penalties for, in relevant part:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> * * *
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(1).

There is no dispute that Omnicare received cash remuneration from J&J and other companies in the form of rebates, so-called consulting and data fees in lieu of rebates, and other payments for supposed educational activities. There is likewise no dispute that Omnicare arranged for and recommended the purchase of drugs manufactured by J&J and others, for which payment was made in whole or in part under the Medicaid program. And, as is apparent from the facts described below, such payments were "in return for" arranging for and recommending – indeed, aggressively and improperly promoting and manipulating – the purchase of such drugs. *United States* v. *McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) ("a person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals."); *United States* v. *Bay State Ambulance and Hospital Rental Service*, 874 F.2d 20, 30 (1st Cir. 1989) ("The gravamen of Medicare Fraud [under the anti-kickback provisions] is inducement");

United States v. Greber, 760 F.2d 68, 69-72 (3d Cir. 1985) (doctor who owned diagnostic laboratory violated Act because he paid "interpretation fees" to other physicians to induce them to refer Medicare patients to use his laboratory's services); *United States* v. *Shaw*, 106 F. Supp.2d 103, 121 (D. Mass. 2000) (whether a payment is an illegal kickback or a valid discount turns on "whether the reason for offering or accepting the 'discount or other reduction in price' was to induce referrals of or be reimbursed for federal health care program business.").

The Complaint in this case and related federal civil and criminal suits show that Omnicare had in its possession overwhelming facts and information that would have demonstrated to any reasonable issuer or investor that the payments Omnicare received were indeed "in return for" its active promotion of various drugs and hence were illegal kickbacks under the statute.

For example, Omnicare's contracts with J&J between 1997 and 2004, which led to criminal charges against J&J in 2010, provided that Omnicare would endeavor to increase the "market share" of certain J&J drugs in return for "rebates" if Omnicare purchases of those drugs (to fill prescriptions for Omnicare customers) gained market share over competing drugs. The greater the market share of a particular drug relative to Omnicare's total purchases of drugs in the same class, the greater the rebate. JA 206-07 (Complaint ¶¶ 53-54).

The contracts also provided for "performance" rebates and incentives by which Omnicare was paid to actively promote – *i.e.*, recommend and arrange for

the ordering of – particular J&J products. JA 208-09 (Complaint ¶ 56). For an annual payment of 1% to 2% of purchases, Omnicare agreed to implement a so-called "Active Intervention Program (AIP)" or "Appropriate Use Program (AUP)" targeting particular drugs. According to the contracts,

> a) "Active Intervention Program" shall mean a program, applied by Manager and accepted by Supplier 16 in writing, which is designed to appropriately *shift market share* to Supplier's Product. Active interventions can include, but are not limited to, disease management initiatives, written correspondence to Participating Providers prescribing or dispensing pharmaceutical products, educating nursing home staff regarding Supplier's Products, conducting clinical intervention programs though which consultant pharmacists *recommend Supplier's Products* when appropriate.
>
> b) "Appropriate Utilization Program" or "AUP" shall mean a program applied by Manager, and accepted in writing by Supplier, *designed to cause the appropriate use* of Supplier's Product(s).

Id. (quoting contracts) (emphasis added); *see also* JA 209 (Complaint ¶ 57) ("Pursuant to the AIP or AUP, Omnicare and J&J designated certain drugs as 'Selected,' meaning Omnicare and its pharmacy consultants 'favored' those drugs over other brands for certain clinical indications. *Id*. at JNJ001043. * * * Omnicare personnel 'actively participate[d] in educational and promotional programs discussing [the Selected drugs]' and 'work[ed] with [J&J] to implement com-

munication effort to inform attending physicians of ' a drug's 'favored' status. *Id.*").[2]

Both types of rebates and incentives were, on their face, "overt" "remuneration" and "rebate[s]" received "in return for" Omnicare's "purchasing" "ordering" and "arranging for or recommending" the purchase and order of specified drugs paid for under Medicaid. They thus constitute conduct prohibited by the express terms of the anti-kickback statute.

In addition to these "overt" kickbacks, Omnicare received indirect or "covert" kickbacks that were designed as a substitute for the rebates where such rebates might have the effect of altering the "Best Price" under Medicaid rules and hence forcing J&J to provide comparable rebates to Medicaid. JA 210 (Complaint ¶¶ 59-59).

Under the Medicaid Drug Rebate Statute, 42 U.S.C. § 1296r-8, if a pharmaceutical manufacturer provides rebates to a favored purchaser that lower the "Best Price" for a drug paid for by Medicaid, it must inform Medicaid of the new lowest price and give comparable rebates to Medicaid as well. Because the illegal and growing kickbacks to Omnicare began to lower the "Best Price" for certain drugs, J&J and Omnicare agreed to mask such payments by recharacterizing them as, *inter alia*, consulting and data fees. As explained in an internal J&J memo-

---

[2] That the programs were couched in terms of "appropriate" use is irrelevant to the anti-kickback statute, which prohibits receiving payment for any recommending or arranging of purchase. And, as will be discussed below, Omnicare's efforts were hardly limited to recommending and arranging the "appropriate" use of favored drugs.

randum describing a new "Consulting Services Agreement" with Omnicare:

> a. Risperdal Rebates have been pushing towards Best Price
>
> b. To avoid Best Price, the Strategic Overlay for Risperdal (2% of sales) had to be eliminated
>
> c. In order to balance this, an agreement was established with Omnicare to purchase data, roughly at the cost of the Strategic Overlay for Risperdal.

JA 212 (Complaint ¶ 61) (quoting Ex. 26).

Omnicare and J&J entered into a similar arrangement concerning payments to promote the drug Sporanox. A 2002 e-mail from J&J noted that because

> the 25% rebate on Omnicare Sporanox purchases sets the best price, and the next best price is 20%, the Medicaid cost impact is about $1 million per year (avg $200k per % point) for the additional 5%. It may make sense for us approach Omnicare about reducing the rebate to 20%.
>
> * * *
>
> I would recommend to try to make up the loss of rebates in another way. Ex. 28 at JNJ347031-32.

JA 213 (Complaint ¶ 64).

These various alternative forms of kickback amounted to millions of dollars paid by J&J to Omnicare. JA 212, 214 (Complaint ¶¶ 62, 65).

Once again, these payments, made expressly "to balance" and "make up for" the express kickbacks and rebates that J&J wished to hide from Medicaid, violated the express terms of the anti-kickback statute.

Rather than acting as a neutral intermediary between doctors and drug manufacturers, Omnicare instead became the marketing arm of J&J and others in return for millions of dollars in kickbacks. As an internal J&J memo noted, "Omnicare, Inc. has demonstrated its ability to partner in a true sense of the word and has generated well over 100 million dollars of Johnson & Johnson pharmaceuticals annually." JA 219 (Complaint ¶ 74) (quoting Ex. 37). J&J executives recognized the power Omnicare wielded as a faux-intermediary, noting that Omnicare's success in causing physicians to switch to the drugs it was being paid to promote was "Incredible: good for us but scary on the power to do this." JA 220 (Complaint ¶76) (quoting Ex. 38). Accordingly, J&J correctly viewed Omnicare as an "Extension of [the J&J] Sales Force," *id*. (quoting Ex. 39), which is precisely the role Omnicare was being paid for and precisely what the anti-kickback statute means when referring to being paid "in return for" arranging or recommending the sale of a product.

While J&J was Omnicare's largest patron, providing Omnicare with tens of millions of dollars in payments, Omnicare had similar agreements with many other companies as well. Such companies included many of the largest names in the pharmaceutical industry, including Abbott Laboratories, AstraZeneca Pharmaceuticals, Bayer Corporation, Eli Lily & Co., Merck & Co., Inc., Novartis, Novo Nordisk, Pharma-

cia, and Ivax Pharmaceuticals, Inc. JA 221-26 (Complaint ¶¶ 79-90).

Any suggestion by Omnicare that these agreements merely provided for normal or legal discounts is fanciful. As the United States noted in another case in response to such claims, while ordinary price reductions or discounts may qualify for a safe-harbor under 42 U.S.C. § 1320a-7b(b)(3)(A), payments "to pharmacies for switching patients from one drug to another, and for other efforts to increase a drug's utilization do not qualify as protected price reductions simply because the payments are labeled as 'rebates' or 'discounts.'" Statement of Interest on Behalf of the United States of America in Response to Defendants' Motions to Dismiss the Complaint, *United States* ex rel. *Banigan & Templin, et al.* v. *Organon USA Inc., Omnicare, inc. and Pharmacia, Inc.*, No. 07-12153-RWZ, Doc. 144 (9/30/2011), at 5. The central issue is " 'is whether the reason for offering or accepting the "discount or other reduction in price" was to induce referrals of or be reimbursed for federal health care business.' " *Id*. (quoting *Shaw*, 106 F. Supp.2d at 121). As the facts here and in the separate *Organon* case illustrate, the payments to Omnicare

> were not mere price reductions because [the manufacturer] allegedly conditioned the payments on Omnicare * * * not only purchasing its products, but also engaging in "therapeutic interchange programs" or switching efforts to promote utilization of [the manufacturer's] drugs at the nursing facilities where Omnicare * * * filled prescriptions. As such, the payments were not true price discounts, but ra-

> ther were remuneration that [the manufacturer] offered and paid to induce Omnicare * * * to recommend its products.

Id. at 6. In short, while across-the-board discounts are permissible, conditioning such discounts on recommending or ordering certain amounts or market shares of the manufacturer's products converts them into illegal kickbacks.[3]

B. False Statements and Illegal Overcharge of Medicaid.

Omnicare's pharmacy practices likewise demonstrated that it was acting aggressively to arrange for and recommend the purchase and ordering of specific prescription drugs that were the subject of the agreements for the payments it received. And often its practices in pushing favored drugs were illegal independent of whether they were the result of the kickbacks.

---

[3] Nor could the market-share rebates plausibly be viewed as volume discounts, which, by themselves, could be legal. Omnicare's market-share bonus payments were not in fact tied to volume, but rather to market percentage relative to competing drugs. Thus, had Omnicare doubled its customer base and hence bought twice as many drugs in the same market proportions, it would not have received a market-share rebate despite the vastly increased volume of purchases. Likewise, doubling sales without implementing an AIP/AUP to promote J&J products would not have provided Omnicare with a performance rebate. Conversely, if Omnicare simply ceased buying competing products but kept its purchases of J&J products the same, it would have indeed increased market share and obtained a rebate despite no increase in volume. To pretend these contractual arrangements are akin to volume discounts is simply not credible.

For example, Omnicare deceived physicians with regard to the efficacy and cost effectiveness of drugs in order to convince them to change their prescriptions to a drug that Omnicare was being paid to promote. JA 198 (Complaint ¶¶ 37-38). It did so by manufacturing false clinical case studies that purported to show cost greater cost effectiveness for a favored drug over a competitor's drug and by using such false comparisons to obtain blanket authorization to substitute the favored drug for the competing drug. *Id.*

Omnicare also engaged in various other means of promoting and recommending J&J drugs in order to increase market share and hence increase its kickbacks. With the J&J antibiotic Levaquin, for example, Omnicare began a lobbying effort to persuade physicians to switch away from the typically prescribed antibiotic Cipro to the less prescribed Levaquin. JA 217 (Complaint ¶ 72). It did so, in part, by seeking pre-authorization for a change in antibiotics and, when it did not receive such authorization would call physicians to persuade them to allow the substitution of Levaquin when it received a prescription for Cipro. Again, the driving force behind such efforts was Omnicare's agreement with J&J to actively favor Levaquin over Cipro and the payments Omnicare received for such promotion and for increasing market share. *Id.*

Omnicare's actions also resulted in one of the primary evils the anti-kickback statute was intended to eliminate: distorting medical decisions in the service of profit-maximization. Because Omnicare received payments in return for increasing the market share

of particular drugs, it engaged in various efforts to increase the use of such drugs notwithstanding their inappropriateness for many patients. Risperdal is a prime example of such behavior. Risperdal is an atypical antipsychotic that has only been approved for the treatment of schizophrenia. But few patients in the Long Term Care Facilities with which Omnicare had contracts in fact had schizophrenia. Many of them, however, had dementia and various dementia-related behavioral issues. Because J&J's payments to Omnicare turned in part on successful promotion of Risperdal, Omnicare thus began to promote Risperdal for the treatment of those conditions and behaviors, even though it was not approved for such use, had been shown to increase the risks of strokes and other cerebrovascular incidents, and had resulted in fatalities among dementia patients. JA 215 (Complaint ¶ 69).

Omnicare also broke a variety of laws in connection with its systematic effort to distribute a more expensive form of the drug Ranitidine (the generic form of Zantac). While traditionally prescribed in tablet form and often subject to state price caps for Medicaid reimbursement, the capsule form – considered a different drug used in certain unusual situations – often is not subject to the same price caps. The capsule form thus can be many times more expensive despite no therapeutic advantage in ordinary cases.

In order to profit from such price discrepancy, Omnicare caused prescriptions to be altered to make it appear that the physician had ordered the capsule rather than the tablet. It did so in various and illegal

ways, including by modifying its staff's computers to make it impossible for its clerical staff to even enter an order for the tablet, by having the clerical staff physically alter physician orders to make it appear they had ordered the capsule rather than the tablet, and misleading doctors into signing post-hoc approval by having them sign altered confirmations without noting the alteration. JA 199-201 (Complaint ¶¶ 40-45). Internal documents made clear that the sole purpose of the changes was to avoid the price limits on the tablets and not for any therapeutic benefit. JA 194-99 (Complaint ¶¶ 31-38) (describing how clinical initiatives and drug-switching efforts were based on internal reports regarding profitability to Omnicare of particular drugs rather than their value to patients or purchasers). Indeed, when pricing conditions changed, Omnicare would direct its pharmacists to switch back to the tablet if that was more profitable, again without physician approval for the further switch. JA 201 (Complaint ¶ 44).

C. Omnicare's Undisclosed Illegal Conduct Rendered Its Statements of Belief Misleading and Its Implied Statement of a Reasonable Basis for Its Professed Beliefs False.

In light of all these self-evidently material facts, none of which were made available to investors reading the registration statement, Omnicare's asserted belief that its contracts with manufacturers and its pharmacy practices were "legally and economically valid arrangements" or "in compliance with applicable federal and state laws," JA 137; JA 95-96, was, at a minimum, misleading and falsely implied a reason-

able basis for such a belief and the absence of known facts tending to contradict Omnicare's belief.

Indeed, having expressly told investors of the existence of the anti-kickback statute and other limits on the manner in which Omnicare could legally operate its business, JA 136-37 (Complaint ¶ 46), Omnicare's omission of material facts regarding its drug-promotion agreements and drug-switching activities was necessarily misleading and necessarily implied that Omnicare had conducted a reasonable inquiry into the very issue it had highlighted.

Had Omnicare said more, and provided the underlying facts regarding its agreements and practices, investors might have been able to evaluate the reasonableness of Omnicare's stated beliefs for themselves. For example, if Omnicare had disclosed the content of its drug promotion contracts in conjunction with its statements regarding their legality, investors or analysts could have seen for themselves whether the payments were indeed in exchange for Omnicare's drug promotion initiatives. They would have quickly concluded that they were indeed kickbacks and, at a minimum doubted Omnicare's judgment and the degree of risk involved to Omnicare's earnings, even had they assumed the genuineness of Omnicare's stated beliefs.

In fact, in at least one instance that we know of, Omnicare did show one of its agreements to an attorney who concluded that "the proposed arrangement, on its face, has all the characteristics of a kickback." JA 225 (Complaint ¶ 89) (quoting attorney memorandum discussing proposed agreement with Ivax Pharmaceuticals, Inc.). Omnicare had reached an agree-

ment with Ivax in 1999 whereby it was paid an $8 million signing bonus and a 5% post-purchase rebate in exchange for committing to buy $50 million worth of certain generic drugs produced by Ivax. The attorney reviewing the agreement found it problematic on its face, specifically warned that the "lump-sum cash payment (the stated 'signing bonus') intended as an incentive to win Omnicare's business" created a "*heightened* risk" that it would be seen as violating the anti-kickback statute. *Id.*

Rather than take the advice it had received and decline to enter into an illegal agreement, Omnicare instead sought the opinion of a different attorney, conveniently failing to advise the attorney of the signing bonus and the fact that it would be received in advance of any purchases. JA 225-26 (Complaint ¶ 90). Having withheld such material information, Omnicare received a green light from the new attorney and proceeded with the agreement. *Id.*

Not only do the different results illustrate the materiality of the information Omnicare withheld from the second attorney (and, of course, from investors), it also illustrates how a claimed belief in the legality of an agreement that omits the facts and reasoning underlying that belief can be deeply misleading. No interested listener with access to all the material facts would have given any significant weight to Omnicare's beliefs, whether genuine or not.

Similarly, any reasonable observer who was aware of Omnicare's systematic alteration of prescriptions without consent would have understood that such changes constituted false claims for reimbursement of medications not actually prescribed by the doctor and

violated a host of laws regarding medical practices. Certainly any investor or analyst apprised of such conduct would have had serious qualms about any claim that Omnicare was complying with applicable state and federal laws, regardless whether Omnicare genuinely (but absurdly) believed that it was.

The legal fallout from the eventual disclosure of Omnicare's agreements and practices likewise confirms that Omnicare's claimed beliefs lacked a reasonable basis and were misleading for having omitted numerous material facts that contradicted the substance of those claimed beliefs. For example, when the details of Omnicare's agreements and practices were brought to light by various whistle-blowers, Omnicare, J&J, and others were faced with a host of lawsuits charging that such agreements and practices violated the anti-kickback statute, the False Claims Act, and other laws. Resp. Br. at 12-13. In the cold light of day, the facts of these cases were far less comforting than Omnicare's sanguine prior assurances to investors regarding the legality of its conduct. Indeed, forced to examine its conduct with actual due diligence and candor, Omnicare itself apparently lacked the comfort it had previously expressed to investors and accordingly settled many of the cases against it for over $300 million and counting.[4] That

---

[4] *See* Resp. Br. at 13 (describing various settlements by Omnicare of $98 million plus interest, $49.5 million, and $49.0 million to the United States and various States); Barrett J. Brunsman, *Omnicare Agrees to $16.7 Million Settlement Over Kickbacks*, Cincinnati Business Courier, August 16, 2013, http://www.bizjournals.com/cincinnati/news/2013/08/16/omnicare-agrees-to-167-million.html?page=all (last visited Sept. 1, 2014); *Omnicare Reports Third Quarter 2013 Financial Results*,

the eventual disclosure of the facts of Omnicare's agreements and practices led to such massive payments seems more than sufficient to demonstrate their materiality. And it likewise demonstrates that the omission of such powerful facts rendered Omnicare's claimed belief in the legality of its agreements and practices, at a minimum, profoundly misleading.

Having in its registration statement omitted the material facts that subsequently came to light, and having allowed a critical information imbalance to exist, Omnicare's statement of belief necessarily created a false sense of security in investors who were mislead into believing that Omnicare's professed belief had a reasonable factual and legal basis. The misleading quality of Omnicare's statements has nothing to do with Omnicare's subjective state of mind, but rather its likely (and eminently predictable) effect on and interpretation by investors.

For similar reasons, Omnicare's statement of belief implied the further fact that it had indeed come to those beliefs based on a reasonable inquiry into the facts and the law regarding its kickback contracts and drug-switching practices and that the company was not aware of any material facts that contradicted the stated beliefs. Based on the facts described above and the allegations of the Complaint, those implied

---

at 3-4, 10 n. (a)(1), http://www.sec.gov/Archives/edgar/data/353230/000035323013000061/ocrerex991q32013.htm (last visited Sept. 1, 2014) (disclosing $120 million settlement in *United States ex rel. Gale v. Omnicare*, No. 1:10-cv-00127); DOJ Press Release, *Omnicare to Pay Government $4.19 Million to Resolve False Claims Act Allegations of Kickbacks* (Feb. 27, 2014), http://www.justice.gov/opa/pr/2014/February/14-civ-216.html (last visited Sept. 1, 2014).

factual statements were necessarily false in that no reasonable factual and legal inquiry could have reasonably concluded that such conduct was legal. Even if one were to assume that Omnicare indeed held an actual belief in the legality of its conduct, it does not change the fact that such belief is simply unreasonable. And it does not alter the falsity of the implied factual assertions that its beliefs were reasonable and based upon reasonable inquiry and analysis.

Under such circumstances, investors would have assumed that Omnicare's stated belief about an important matter such as the legality of its business practices would be held only based on reasonable due diligence into the facts and law that would indeed support such a belief in a reasonable person. Given that investors would recognize the threat of severe penalties for violating the law and the superior knowledge of Omnicare and its executives, Omnicare certainly should and would have expected such an investor response to its professed beliefs. Indeed, the only point of Omnicare making its statement of belief at all is to lead investors precisely to that conclusion and to give them comfort in their decision to purchase stock. Unfortunately, such intended comfort, while effective, proved false and misleading. Section 11 of the '33 Act is the appropriate remedy in such a case.

CONCLUSION

For the foregoing reasons, this Court should affirm the decision of the Sixth Circuit in favor of Respondents and remand for further proceedings.

Respectfully submitted,

ERIK S. JAFFE
(Counsel of Record)
ERIK S. JAFFE, P.C.
5101 34th Street, N.W.
Washington, D.C. 20008
(202) 237-8165
jaffe@esjpc.com

JOE KENDALL
KENDALL LAW GROUP, LLP
3232 McKinney Ave., Ste. 700
Dallas, Texas 75204
(214) 744-3000
jkendall@kendalllawgroup.com

Counsel for Amici Curiae

Dated: September 2, 2014