IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WASHINGTON COUNTY HEALTH CARE AUTHORITY, INC., CESAR CASTILLO, INC., WARREN GENERAL HOSPITAL, and ERIE COUNTY MEDICAL CENTER CORPORATION, Plaintiffs, v. BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, HOSPIRA, INC., and HOSPIRA WORLDWIDE, INC., Defendants.	)	No. 16 CV 10324 Judge John J. Tharp, Jr.

MEMORANDUM OPINION AND ORDER

Salt water composes almost three-fourths of the planet, so some may be surprised to learn that the United States has a salt water shortage, of sorts. Specifically, for the last several years, the US has lacked sufficient quantities of intravenous saline solution, a medical product used to treat dehydration that consists of sodium chloride (or, as it is commonly known, salt) dissolved in water. The plaintiffs in this antitrust suit allege that the shortage was no accident; they assert that it was artificially manufactured by intravenous saline solution suppliers in an effort to increase prices. The complaint posits that the defendants, the two largest producers of intravenous saline products, violated Section 1 of the Sherman Act by colluding to increase prices by initiating a series of bogus voluntary recalls that depleted the saline inventories of health care facilities throughout the nation, precipitating a health care crisis. Defendants assert that this theory is implausible and move to dismiss the complaint. This Court agrees and grants the defendants' motions without prejudice.

BACKGROUND[1]

With over one billion units used in the United States each year, intravenous saline solution ("IV saline") is among the most ubiquitous and essential products in emergency medicine. Consolidated Amended Complaint ("CAC"), ECF No. 35 at ¶¶ 4, 106. Consisting of various concentrations (0.9% being the most prevalent) of sodium chloride dissolved in water, IV saline is used to prevent and treat dehydration and to dilute other intravenous medications. *Id*. ¶¶ 39-40. Hospitals, predictably, are the largest purchasers of IV saline. Defendants Baxter and Hospira are the biggest sellers, each with about 45% market share. *Id*. ¶ 43. One other seller, B. Braun Medical Inc., has the remaining 10%. *Id*. ¶ 96. In part because there are so few sellers, the Department of Justice and the Federal Trade Commission classify the IV saline market as highly concentrated. *Id*. ¶ 98.

The IV saline market also has high barriers to entry, as a new manufacturer would have to build or develop manufacturing plants that meet strict FDA requirements. *Id*. ¶ 100. An FDA economist estimated that it would take three to five years and hundreds of millions of dollars to open a new IV saline plant. *Id*. Moreover, because Baxter and Hospira are vertically integrated with respect to the production of IV saline (*i.e.*, they acquired companies providing goods and performing services in the IV saline supply chain), it would be onerous for a competitor to gain the economies of scale necessary to compete. *Id*. ¶ 101.

In November 2013, Baxter informed customers that there was an IV saline shortage, purportedly resulting from a harsher than expected flu season. *Id*. ¶ 44. No previous major flu outbreak, however, had resulted in an IV saline shortage, including the 2009-2010 swine flu

[1] As this is a motion to dismiss, the Court accepts all well-pleaded facts as true and construes all inferences in favor of the plaintiff. *Zemeckis v. Global Credit & Collection Corp.*, 679 F.3d 632, 634 (7th Cir. 2012).

outbreak that hospitalized 274,000 people in the United States in addition to those hospitalized for the common flu. *Id*. ¶¶ 126-128. Two months after Baxter's letter, the Food and Drug Administration publicly acknowledged the shortage and gave new approval for certain foreign plants—including one owned by Baxter—to ship IV saline to the United States. *Id*. ¶ 46. The new imports, however, were unable to eliminate the shortage. *Id*. ¶ 47. Health care facilities, including those operated by the Veterans Health Administration, subsequently implemented policies designed to conserve IV saline supplies. *Id*. ¶ 50-51. This included use of oral hydration whenever possible and flushing central venous access devices less frequently. *Id*. ¶ 50. There is, however, no true substitute for IV saline, and the FDA has indicated that the IV saline shortage "poses a serious threat to patients." *Id*. ¶¶ 49, 107-108.

Concurrent with the shortage, Baxter and Hospira issued a number of voluntary recalls of IV saline, which are summarized in the following table:[2]

Recall Date	No. of Bags: Baxter	No. of Bags: Hospira	Reason for Recall
05/21/13	845,520		Leakage
06/06/13		676,872	Leakage
10/14/14		16,500,000	Punctures
12/08/14	542,080		Particulate Matter
12/22/14		30,840	Leakage
03/18/15	597,498		Missing closures/Leakage
04/07/15		128,050	Leakage
07/02/15		314,600	Leakage
07/17/15	322,720		Particulate Matter
Total Recalls	2,307,818	17,650,362	19,958,180
Percentage	11.56%	88.44%	

[2] The complaint (¶ 61) identifies the number of bags recalled for only four of the nine recalls. Nevertheless, the Court takes judicial notice of the number of units recalled during each recall, as such information is publicly available on the FDA's recall database. *See* FOOD AND DRUG ADMINISTRATION, FDA RECALL INFORMATION SEARCH, https://www.accessdata.fda.gov/scripts/ires/index.cfm.

The summary reflects that in May and June 2013, Baxter and Hospira both recalled hundreds of thousands of IV saline bags, citing a potential for leakage. *Id.* ¶ 61. Neither company, however, followed up with any recall of IV saline solution for more than 16 months. Then, in October 2014, Hospira recalled 16.5 million IV saline bags due to the potential for punctures; Baxter, however, did not announce another recall until December, when it recalled half a million bags because particulate matter had been discovered floating inside a sealed bag of saline solution. Later that month, Hospira issued a small recall of about 31,000 bags due to leakage. *Id.* And finally, within three weeks of each other in both the spring and summer of 2015, Baxter and Hospira again issued voluntary recalls, due to leaks and the presence of particulate matter (specifically, Baxter recalled two lots of saline bags after a customer reported a free-floating insect in one of the bags).[3]

The complaint alleges that these recalls substantially reduced the supply of IV saline solution and resulted in a dramatic increase in IV saline prices. The complaint includes no allegations about the defendants' production levels during this time period, but alleges that in the fourth quarter of 2014 Baxter and Hospira's collective recalls removed approximately 28.5% of IV saline bags from the U.S. market. *Id.* ¶ 62.[4] The complaint further alleges that prices rose 36%

[3] *See* FOOD AND DRUG ADMINISTRATION, FDA RECALL INFORMATION SEARCH, Recall Nos. D-1335-2015 and D-1336-2015, https:// www.accessdata.fda.gov/scripts/ires/index.cfm.

[4] The complaint does not identify a source for this statistic, but it can be derived using the Q4 2014 recall numbers on the summary chart and the estimate of monthly IV saline use in the United States that the plaintiffs cite in paragraph 62 of the complaint: 20 million bags/month x 3 months = 60 million bags x 28.5% = 17.1 million bags, the amount recalled in Q4 2014. Elsewhere in the complaint, however, the plaintiffs allege that "[o]ver a billion units of IV Saline Solution are used in the United States every year." AC ¶ 4. Using that estimate, the Q4 2014 recalls would amount to only 6.8% of the IV saline solution used in the United States over that period: 1 billion/year = 250 million/quarter; 17.1 million/250 million = 6.8%). The plaintiffs offer no explanation for why they use a higher estimate of saline use when describing the IV saline shortage as a public health crisis and a lower estimate when calculating the impact of the defendants' recalls.

for the U.S. government between late 2014 and late 2015, and 200-300% for private customers. *Id*. ¶ 64.

During this period, Hospira and Baxter submitted information to the FDA's publicly accessible drug shortage database. *Id.* ¶ 66. The database includes information from manufacturers on the availability of certain drugs, including the estimated duration of an expected shortage and the reason for the shortage. *Id.* ¶ 67. Baxter used the database in December 2013 to indicate that it was suspending the manufacturing of 150 mL IV saline bags to meet higher demand for 250 mL IV saline bags. *Id.* ¶ 69. On the same day, January 17, 2014, Hospira and Baxter both submitted shortage letters to the FDA indicating that IV saline customers would be put on allocation. *Id*. ¶ 70.

Hospira and Baxter used the IV saline shortage to bolster other areas of their businesses. Hospira and Baxter informed some purchasers that they would not be able to purchase IV saline at any price unless they also purchased other Baxter or Hospira products, and imposed greater price increases on other customers who declined to purchase non-saline products. *Id*. ¶ 77. Baxter and Hospira also used the IV saline shortage to lock their customers into long term contracts. *Id*. Baxter's CEO, Robert L. Parkinson, Jr., indicated that he thought the IV saline shortage "sensitized a lot of people to the value of these products." *Id*. ¶ 86. Baxter subsequently saw an 8% increase in its "Fluid Systems" franchise (a business unit which includes IV saline), driven in part by "pricing for IV solutions." *Id*. ¶ 88. Hospira similarly indicated that it saw an "uptick in IV solutions prices," which drove a 19% increase in net sales in the division that included IV saline. *Id*. ¶ 89. Hospira's CEO noted that the increase in sales was "primarily driven by the strong performance from our solutions products, which benefitted from the continued strong demand from protracted market shortages." *Id*. The price of IV saline rose even though

the price of plastic—the primary raw material in IV saline bags—remained stable or fell. *Id*. ¶¶ 122-125.

Plaintiffs, purchasers of IV saline, filed suit against Baxter and Hospira on behalf of themselves and others similarly situated, alleging that Baxter and Hospira violated the Sherman Act, 15 U.S.C. § 1, by conspiring to restrict output and thereby increase prices in the IV saline market. In addition to the allegations detailed above, the complaint alleges that Baxter and Hospira had the opportunity to manufacture an IV saline shortage by conspiring at trade conferences, including those put on by the Advanced Medical Technology Association and Generic Pharmaceutical Association. *Id*. ¶¶ 113-116. The complaint further alleges that Baxter and Hospira had unique incentives to spur a shortage and/or keep IV saline prices high: both companies had expiring long-term contracts that they sought to re-negotiate at higher prices, and Baxter hoped to use the shortage to get approval to import IV saline from its foreign plants. *Id*. ¶¶ 118-120.

Baxter and Hospira now move to dismiss the complaint, asserting that it does not plausibly allege that they colluded to restrict the output and increase the price of IV saline solution. Because the facts to which the plaintiffs point do not plausibly support the existence of "a preceding agreement" distinguishable from "mere[] parallel conduct that could just as well be independent action," *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007), the complaint fails to state a claim for restraint trade in violation of Section 1.

DISCUSSION

I. Existence of an Agreement

Section 1 of the Sherman Act, 15 U.S.C. § 1, prohibits "[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce." The Act "is designed to prevent businesses from entering into collusive agreements," and "[a]greements to fix prices unambiguously fall

within the ambit of § 1." *Omnicare, Inc. v. UnitedHealth Group, Inc.*, 629 F.3d 697, 705 (7th Cir. 2011). To state a claim under § 1, a plaintiff must allege the existence of "(1) a contract combination, or conspiracy; (2) a resultant unreasonable restraint of trade in a relevant market; and (3) an accompanying injury." *Agnew v. National Collegiate Athletic Ass'n*, 683 F.3d 328, 335 (7th Cir. 2012). There must be "an explicit agreement, not merely a tacit one." *In re High Fructose Corn Syrup Antitrust Litig.*, 295 F.3d 651, 661 (7th Cir. 2002). A typical price-fixing scheme features "sellers who collude to set their prices above or below prevailing market prices." *Omnicare*, 629 F.3d at 705. This case concerns price-fixing's first cousin, output restriction, a scheme in which market participants agree to reduce the amount of a product in the marketplace, thereby "reducing supply below demand" and "rais[ing] prices above a competitive level." *United States v. Andreas*, 216 F.3d 645, 667 (7th Cir. 2000).

The focus in this case is on the first element of a Section 1 claim. Defendants maintain that that the complaint does not adequately allege the existence of agreement to restrain the supply and increase the price of IV saline. The Supreme Court set forth the framework for evaluating the adequacy of a complaint alleging unlawful collusion in *Twombly*. As the Supreme Court there explained, a § 1 claim "requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made." 550 U.S. at 556. "A statement of parallel conduct, even conduct consciously undertaken, needs some setting suggesting the agreement necessary to make out a § 1 claim; without that further circumstance pointing toward a meeting of the minds, an account of a defendant's commercial efforts stays in neutral territory." *Id*. at 557. "[A] conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Id*. at 556-57. The plaintiffs argue that the amended complaint identifies parallel behaviors (sending shortages notices to the FDA and initiating voluntary product recalls), as well

as "plus-factors" (industry structure, defendants' membership in trade organizations, falling raw material costs, and past misconduct) that, in combination, suffice to push the alleged conspiracy across the line separating the possible from the plausible. But these factors, standing alone or considered collectively, are no more probative of an agreement than of independent self-interested conduct and, as such, *Twombly* instructs that they are inadequate to state a claim.

To see this, it will be helpful to consider along the way what a complaint that adequately alleges an agreement would look like. In *Twombly*, the Supreme Court endorsed the views of commentators who suggested that agreements to restrain trade can be differentiated from mere parallel conduct by considering whether the behavior at issue "would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties," and whether the conduct at issue is suggestive of "the sort of restricted freedom of action and sense of obligation that one generally associates with agreement." 550 U.S. at 556 n. 4 (citations and internal quotation marks omitted). For example, "complex and historically unprecedented changes in pricing structure made at the very same time by multiple competitors, and made for no other discernable reason, would support a plausible inference of conspiracy." *Id*. (internal quotation marks omitted). No such circumstances exist in this case.

A. Parallel Conduct

Plaintiffs' theory is that Baxter and Hospira used the FDA shortage reporting mechanism to signal forthcoming output restrictions to each other, and that they subsequently initiated product recalls under false pretenses, all in an effort to increase the price of IV saline. While the parties spill much ink debating the finer points of the relevant FDA regulations (which the Court will address in turn), a sound analysis of the complaint must begin with *Twombly*—specifically,

Twombly's admonition that "lawful parallel conduct fails to bespeak unlawful agreement. . . . [A]n allegation of parallel conduct and a bare assertion of conspiracy will not suffice." 550 U.S. at 556. So, even in the best case scenario for plaintiffs—wherein the FDA notifications and recalls showed the defendants moving in lockstep—the allegations of parallel conduct in the complaint, standing alone, would be insufficient to overcome a motion to dismiss, even where collusion is a possible explanation for the parallelism. It bears noting, moreover, that not all allegations of parallel conduct are created equal; the context in which the alleged parallel conduct occurs, and the nature of that conduct, can be important to an assessment of the complaint's plausibility. Where context suggests that, notwithstanding parallel conduct, agreement is unlikely, or unnecessary, the probative force of the parallel conduct is less substantial. *See, e.g.*, *In re Text Messaging Antitrust Litigation* ("*Text Messaging I*"), 630 F.3d 622 (7th Cir. 2010) ("An accusation that the thousands of children who set up makeshift lemonade stands all over the country on hot summer days were fixing prices would be laughed out of court because the retail sale of lemonade from lemonade stands constitutes so dispersed and heterogeneous and uncommercial a market as to make a nationwide conspiracy of the sellers utterly implausible.").

For several reasons, the probative force of plaintiffs' allegations of parallel conduct is particularly weak. Chief among them is that the IV saline market is an oligopoly in which "conscious parallelism"—"a common reaction of firms in a concentrated market that recognize their shared economic interests and their interdependence with respect to price and output decisions"—is to be expected. *Twombly*, 550 U.S. at 553. In other words, absent additional factual allegations, the mere fact that Baxter and Hospira restricted their own production of IV saline solution output after learning of output reductions by the other sheds little light on the

existence *vel non* of an unlawful agreement. Yes, it is possible that Baxter and Hospira's behavior stemmed from a violation of the antitrust laws—*i.e.*, that it was the result of an agreement. But the nature of an oligopoly makes it such that there is a substantial likelihood that—even absent an agreement—Baxter and Hospira would have tried to capitalize on output restrictions signaled by the other, as it was in their independent interests to restrict supply and drive up prices. In short, parallel conduct in an oligopolistic market is not particularly probative of collusion.

The complaint also has problems that arise not from market structure, but from its allegations describing how the purported output restriction conspiracy occurred. These problems—which affect both the alleged instrument of output restriction (voluntary recalls) and the alleged signaling mechanism (shortage letters sent to the FDA)—also undermine the plausibility of the plaintiffs' theory.

1. Voluntary Recalls

Plaintiffs' theory that Baxter and Hospira used voluntary recalls to manufacture a shortage is quite implausible in light of the gaping factual deficiencies in the complaint, affirmative allegations that undermine the purported scheme, and the regulatory landscape in which IV saline producers operate. As an initial matter, the complaint contains no allegations suggesting that the reasons Baxter and Hospira provided for the recalls were false. Further, the complaint demonstrates that Hospira recalled about eight times as many units as Baxter, incurring substantially greater costs despite roughly equal market share. And even were it plausible to believe that one schemer would agree to absorb wildly disproportionate costs for no additional benefit, the odds that it would agree to ***this*** scheme are minute, as voluntary recalls

impose high upfront costs and invite FDA scrutiny of the very instrument of the unlawful agreement.

a. No Allegations That the Recalls Were Bogus

To begin, it must be recognized that the plaintiffs' theory about how the defendants colluded to increase the price of IV saline solution rests on the premise that the product recalls the defendants made were bogus. Plaintiffs charge the defendants with "creating a public health crisis that denied medical providers and others the IV Saline Solution necessary to treat . . . the hospitalized and those needing emergency medical attention." Resp. at 1, ECF No. 83. The defendants did this, the plaintiffs allege, "by restraining supply and fixing the price of IV Saline Solution." *Id*. More specifically, the plaintiffs allege that the defendants colluded to cause "the purported IV Saline shortage" by engaging in parallel recalls of IV Saline Solution and "signal[ing] their output restrictions and price increases to each other through publicly available communications with customers and the FDA." Resp. at 3.

The necessary implication of these allegations is that the product recalls announced by the defendants were phony—that is, unnecessary because the products were not defective. If the recalls were legitimate—*i.e.*, if the products were, in fact, defective—then the resulting shortages they caused could not have been the product of collusion (*i.e.*, agreement). There is certainly no plausible basis to conclude that the defendants colluded ***to create*** actual defects in their products so that they could then coordinate recalls of those products. The recalls could only have operated as an unlawful collusive "output restriction" device, then, if the defects were fictitious; recalls are required when defects may compromise the safety of the product. *See* 21 U.S.C. § 331(a) (prohibiting "the introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded"); *see also* 21 C.F.R.

§ 7.40 (noting that "recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products").

Yet, as Hospira observes (Mem. at 2, 9, ECF No. 58), the complaint contains not a single allegation of fact to support an inference that the recalls were shams—no allegations that the bags were not prone to leakage and puncture, as reported; no assertions that the reports of missing closures were feigned; no claim that particulates were not found in the bags recalled on that basis.[5] And without any fact allegations to plausibly establish that the recalls were shams, the plaintiffs' theory that the defendants raised prices by artificially restricting output by conducting a series of spurious recalls collapses: no sham recalls means no collusive scheme to restrict output means no agreement to charge supracompetitive prices.

In attempting to respond to this argument, the plaintiffs try to have it both ways, contesting the claim that they have not alleged that the recalls were phony while also acknowledging, both implicitly and expressly, that they were not. As to the former, the plaintiffs point to no allegations of fact that, if true, would support a plausible inference that the recalls were shams. Instead, they actually assert, in complete disregard of *Twombly*'s teaching that conclusory labels do not fact allegations make, that they have adequately pleaded the false nature of the recalls because the complaint "uses the words 'purported' or 'purportedly' in referencing the alleged reasons for every one of the recalls." Resp. at 37. There could not be a more textbook

[5] To the contrary, to the extent that the complaint alleges facts relevant to the legitimacy of the recalls, those facts support the validity of the recalls. The complaint acknowledges that recalls are necessary if sterility is compromised by punctures or the solution contains particulates, both reasons that the defendants provided for their recalls. CAC ¶ 41. And in discussing the defendants' "purported justifications for the IV Saline Solution shortage," the complaint omits any reference to the recalls whatsoever; what it describes as the defendants' pretextual justifications for the saline shortages are the claim that shortfalls today cannot be explained by a harsh 2013-14 flu season and that saline price increases are anomalous in light of declining prices for plastic, a principal component of the product. *See* CAC ¶¶ 18-19.

illustration of the sort of inadequate reliance on "mere conclusory statements" that *Twombly* disparaged. The plaintiffs then implicitly concede their failure to plead any facts to support an inference that the recalls were shams in acknowledging that they are "unable to prove either that Defendants' recalls were unnecessary or what they cost Defendants." Resp. at 38 n.23. The plaintiffs, of course, point out that they are not required to ***prove*** that the recalls were unwarranted. *Id*. That is true, but of no help to the plaintiffs, as it simply ignores the requirement that the complaint plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Twombly*, 550 U.S. at 556. "Rule 8(a)(2) still requires a 'showing,' rather than a blanket assertion, of entitlement to relief." *Id*. at 555 n.3.[6]

The plaintiffs also argue, in grudging but inconsistent acknowledgment that the defects that prompted the recalls were genuine, that the defects were nevertheless "inconsequential" or "technical" and thus permitted the defendants to engage in the recalls "without significant business or reputational risks." Resp. 5, 35-36. But this contention is belied by the FDA's findings when it evaluated Baxter and Hospira's recalls. Each of Baxter and Hospira's recalls were classified as either Class I or Class II recalls by the FDA.[7] These are the two most serious recall designations. A Class I recall occurs when "there is a reasonable probability that the use of, or exposure to, a violative product will cause serious and adverse health consequences or death." 21 C.F.R. § 7.3(m)(1). A Class II recall "is a situation in which use of, or exposure to, a

[6] Nor is this an impossible requirement; the plaintiffs acknowledge, for instance, that there is public information that would bear on the question (and which they intend to pursue). What they don't explain is why they didn't do so before alleging that the defendants' manufactured a public health crisis by means of sham recalls.

[7] Baxter's recalls related to particulate matter in IV saline bags—including one initiated after a customer reported a free floating insect inside an IV saline bag—were designated as Class I. Baxter and Hospira's recalls related to punctures and leakage were designated as Class II. *See* FOOD AND DRUG ADMINISTRATION, FDA RECALL INFORMATION SEARCH, https:// www.accessdata.fda.gov/ scripts/ires/index.cfm.

violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote." 21 C.F.R. § 7.3(m)(2). According to the FDA, then, all of the recalled products posed health risks to the public, and some of the products posed grave risks. While plaintiffs suggest that the recalls were based on mere technicalities, the FDA did not assign any of the recalls to Class III, which covers products that technically violate FDA standards but are "not likely to cause adverse health consequences." 21 C.F.R. § 7.3(m)(3). And to the extent plaintiffs assert that Baxter and Hospira defrauded the FDA to obtain Class I and II designations, the complaint contains few if any facts supporting that conclusion, and certainly fails to comport with the Federal Rule of Civil Procedure 9's demand for particularity. See Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.").[8]

For other reasons, too, the rigorous regulatory framework in which Baxter and Hospira operate undermines the plausibility of the plaintiffs' theory. The FDA only considers a removal of a product from the market to be a voluntary recall if it "regards the product as involving a violation that is subject to legal action, e.g., seizure." 21 C.F.R. § 7.46(a). A recall triggers an "evaluation of the health hazard presented by a product being recalled or considered for recall . . . conducted by an ad hoc committee of Food and Drug Administration scientists." 21 C.F.R. § 7.41(a). In so doing, the FDA evaluates "whether any existing conditions could contribute to a

[8] It does not matter that the plaintiffs have not asserted a claim of fraud; "the dictates of Rule 9(b) apply to allegations of fraud, not claims of fraud." *Pirelli Armstrong Tire Corp. Retiree Medical Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 446 (7th Cir. 2011). It is also unclear whether the Court could even entertain such an argument absent a finding by the FDA itself that it was defrauded by the defendants. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that state law "fraud-on-the-FDA" claims are pre-empted because "the federal statutory scheme [governing drugs and medical devices] amply empowers the FDA to punish and deter fraud against the Administration, and [] this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives.").

clinical situation that could expose humans or animals to a health hazard," and assesses the likelihood and seriousness of the consequences posed by the hazard. *Id*. At the end of the evaluation, the FDA assigns the recall a classification of either Class I, II, or III, "to indicate the relative degree of health hazard" posed by the product being recalled. 21 C.F.R. § 7.41(b). As the defendants point out, by initiating a fake recall in furtherance of an illegal agreement to restrict output would invite—require, actually—the government to scrutinize the artifice through which the unlawful collusion occurred. This is yet another strike against the plausibility of plaintiffs' theory.[9]

A complaint premised on a theory that the defendants intentionally manufactured a public health crisis by orchestrating bogus product recalls that would, despite the public health crisis and rigorous regulatory oversight of product recalls, escape the FDA's attention, lacks facial plausibility. To survive a motion to dismiss, it requires (among other things) some factual allegations which, taken as true, suggest that the output restricting recalls were, in fact, a sham. But the complaint in this case includes no such allegations and, for that reason alone, the complaint is implausible and must be dismissed.

b. The Recalls Were Not Parallel

In view of the complaint's implicit concession that the recalls were not bogus, it is not surprising to see that, in fact, the recalls were not really "parallel," as the plaintiffs allege. Nor is

[9] Plaintiffs cite *In re Plasma-Derivative Protein Therapies Antitrust Litigation*, 764 F. Supp. 2d 991, 996 (N.D. Ill. 2011), for the proposition that allegations of efforts to mislead the FDA add plausibility to a complaint. But in *Plasma Therapies*, the allegations were that defendants reported false data to the government in an effort "to avoid another government investigation." *Id*. Here, by contrast, initiating a voluntary recall automatically triggers an FDA investigation. It is much more likely that a company would provide false data to the FDA to head off an investigation than it is that a company would mislead the FDA in a way it knows will trigger scrutiny of the precise artifice of its deceit.

the defendants' alleged conduct consistent with the plaintiffs' theory that product recalls were used to create shortages.

For starters, the initial recalls alleged in the complaint did not create any shortage. There are no allegations of shortages existing until the 2013-14 flu season, *see* CAC ¶ 10, and the defendants in May/June 2013 collectively recalled only about 1.5 million bags. Indeed, plaintiffs effectively acknowledge that 2013-14 flu season was, in fact, unexpectedly harsh and that shortages reported in November 2013 could be explained by that fact. *Id. at* ¶¶ 18, 44-45; 126 ("2013 to 2014 flu season alone cannot justify the extended IV Saline Solution shortages experienced through today."). Even assuming none of 1.5 million bags recalled in May/June 2013 were timely replaced, these recalls amounted to less than 4% of even the plaintiffs' low-end estimate of 40 million bags of saline solution usage over that two month period (and less than 1% of the bags purchased during that period using plaintiffs' high-end estimate of 1 billion bags per year). The plaintiffs allege no facts to suggest that it is plausible that so small a temporary shortfall would drive prices significantly higher. The omission is particularly problematic because the data shows that ***there were no further recalls over the course of the next 16 months***. It is hardly plausible to infer that, having supposedly agreed on a scheme to create a shortfall by means of bogus product recalls, the defendants then sat on their hands for the next 16 months without making any product recalls.[10]

[10] Baxter contends that the IV saline solution shortage was caused not by recalls but by "a perfect storm" of events that adversely affected production. Baxter Mot. to Dismiss 2-3, 7, ECF No. 60. Its assertion relies on information outside the limited record the Court may consider, however—specifically sources on which the plaintiffs rely for some of the allegations in the complaint. The plaintiffs' limited citation to news articles addressing the saline shortage, however, permits the Court to consider other material in the same sources as is necessary to place the statements cited by the plaintiffs in context; it does not authorize the wholesale consideration of all information set forth in those sources as established fact. The cause of the IV saline shortage is, undoubtedly, a fact-intensive question that cannot be appropriately answered

To be sure, one could argue that certain aspects of the defendants' recalls and shortage notices were parallel: the notices, and subsequently the recalls, were relatively close in time to one another, and comparable recalls were unprecedented in the IV saline industry.[11] But these similarities warrant no inference of collusion in light of the disproportionate size of the recalls. The IV solution recalls by Baxter and Hospira were not remotely parallel in magnitude: in the recalls identified in the complaint, Baxter recalled approximately 2.3 million IV saline bags. By contrast, Hospira recalled over 17.5 million bags—about eight times as many bags as did Baxter. The vast bulk of Hospira's recalled product, moreover, was the subject of a single recall notice for 16.5 million bags in October 2014. That single recall was almost 20 times larger than Baxter's largest recall, and amounted to more than 82 percent of the total IV saline solution recalled over the alleged life of the conspiracy.

Nor does the timing of the recalls support a plausible inference of collusion. Although the first recalls by each defendant occurred within a few weeks of each other, and were of comparable size, thereafter the recalls do not occur in a predictable pattern or scale, much less move in lockstep. After the 16-month delay noted previously, Hospira then made its recall of 16.5 million bags, but that recall was not, as one might expect were there a collusive scheme, followed by a series of Baxter recalls closing the gap; rather, Baxter followed two months later with a recall that was a third ***smaller*** than its first recall and which was necessitated by an entirely different problem. Oddly—if the recalls were phony—Hospira then followed up its massive October 2014 recall with a miniscule recall of 30,000 bags that could have contributed

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in the context of evaluating a motion to dismiss, but it is not necessary to answer that question in the context of the defendants' motions. While they fall short of definitively establishing the cause of the shortage, the defendants succeed in demonstrating that the plaintiffs have not plausibly alleged that the shortfall was the product of a collusive output restriction scheme.

[11] The complaint acknowledges that Hospira, in particular, conducted voluntary recalls of IV saline solution between 2010 and 2012, before the alleged conspiracy began. CAC ¶ 60.

nothing to an allegedly collusive scheme. Just as odd is the fact that in April and July of 2015, Hospira conducted back-to-back recalls, without an intervening recall by Baxter—despite the fact that those recalls widened the gap between the number of recalls conducted by Hospira and Baxter by another 400,000 bags. This chronology is difficult to reconcile with the plaintiffs' collusion theory; if anything, it tends to undermine, rather than support, the notion that the defendants engaged in parallel conduct.

Even if the disparities in the magnitude and timing of the defendants' recalls does not, in and of itself, render plaintiffs' complaint implausible (*see Kleen Prods., LLC v. Packaging Corp. of Am.*, 775 F. Supp. 2d 1071, 1077 (N.D. Ill. 2011) (concluding that the complaint stated an antitrust claim notwithstanding that the defendants' capacity "reductions were made in varying amounts and not all at the same time")), it is yet another strike against the complaint's plausibility. *See In re Baby Food Antitrust Litig.*, 166 F.3d 112 (3d Cir. 1999) (affirming grant of summary judgment in favor of defendants on price fixing claim in part due to substantial differences in the amount of defendants' price increases). It makes little sense that Hospira—which the plaintiffs concede has the same market share as Baxter—would agree to recall eight times as much product as Baxter (and therefore incur substantially greater costs) given their equal market shares.[12] The plaintiffs offer no explanation, much less a plausible one, for why

[12] Both Baxter and Hospira argue at length that they would risk severe business consequences as a result of recalls, *i.e.*, customers would purchase IV saline elsewhere. The complaint, however, contains factual allegations suggesting that customers may not necessarily have other options: Baxter and Hospira account for 90% of the IV saline market, there is only one other manufacturer, the cost of entry into the IV saline market are astronomically high, and Baxter and Hospira both lock customers into long term contracts. The problem posed by the complaint is not that customers would stray from Baxter and Hospira collectively; it's that Hospira risks losing customers to Baxter by recalling eight times as much product. It is implausible that Hospira would agree to suffer substantial reputational harm and allow Baxter to escape comparatively unscathed.

Hospira would agree to structure a scheme to coordinate voluntary recalls in a manner that gave such a lop-sided benefit to its competitor.

c. Voluntary Recalls Are an Implausible Means of Restricting Output

If plaintiffs' theory is accurate, then Baxter and Hospira took a remarkably circuitous and pricy route to hiking IV saline prices.[13] Product recalls are expensive and draw attention from regulators, especially in the pharmaceutical industry. Even drawing all inferences in plaintiffs' favor, as the court must, there is virtually no chance that recalls of millions of IV saline bags (by Baxter) or tens of millions of bags (by Hospira) imposed no cost on the defendants. While it is possible that many, or even most, of the recalled IV saline bags had already been used, a recall of bags already used could not contribute to a shortage and it strains credulity to believe that Baxter and Hospira collectively recalled millions of IV saline bags and paid no refunds. Indeed, plaintiffs tacitly concede that the recalls imposed substantial costs on Baxter and Hospira by noting that the defendants "reduced their customers' on-hand supply below demand by repeatedly removing IV Saline from their customers' inventories." Resp. to Motions to Dismiss 10-11, ECF No. 83. Moreover, as the defendants point out, voluntary recalls have associated costs aside from refunds: the recalling company must submit a detailed recall strategy for evaluation by the FDA, must actually implement recall notifications, and must vigilantly monitor the recall and provide periodic updates to the FDA (tracking the number of purchasers notified of the recall and their responses, among other things). 21 C.F.R. § 7.42; 21 C.F.R. § 7.53. This is

[13] The defendants point out as well that the complaint's allegations about price increases are not robust. The Court does not agree, however, that the absence of specific allegations regarding the prices the plaintiffs themselves paid for IV saline solution renders the complaint implausible given the statements by executives of the defendants, quoted in the complaint, acknowledging that IV saline solution prices did rise during at least some portion of the relevant period, even if the complaint's allegations do not allege the magnitude of the increase. *See* CAC ¶¶ 85-90.

not to say that the high costs of a purported agreement to initiate product recalls necessarily render the existence of the agreement implausible, *per se*. It is possible that multiple companies would collude in such a way because they stood to gain more from the resulting price increases than they would lose from the costs of product recalls, and the complaint alleges that is precisely what happened here. But the merely possible does not rise to the level of the plausible. The high initial expense of the purported agreement weighs against its plausibility. *See High Fructose Corn Syrup*, 295 F.3d at 661 (describing an alleged collusive agreement as "implausible" where "it would mean that losses would be incurred in the near term in exchange for the speculative possibility of more than making them up in the uncertain and perhaps remote future"). That there exist simpler and more effective means of achieving the objective further diminishes the plausibility of the alleged scheme. As discussed above, if Baxter or Hospira wanted to signal their interest in raising the price of IV saline solution, they didn't need a complex scheme that imposed significant upfront costs. All they had to do was raise their price of saline solution and see if the other followed suit: "it is well-established . . . that the mere existence of an oligopolistic market structure in which a small group of manufacturers engage in consciously parallel pricing of an identical product does not violate the antitrust laws." *Reserve Suply Corp. v. Owens-Corning Feberglas Corp.*, 971 F.2d 37, 50 (7th Cir. 1992).

Beyond that, the notion that the recalls themselves had a material effect on the price of IV saline solution over the multi-year life of the alleged conspiracy is fanciful. As noted, Hospira's October 2014 was the single largest recall conducted and accounted for 82% of the total product recalled. The complaint credibly alleges that a recall of that size affected availability during the fourth quarter of 2014, but that's as far as it goes. During the rest of the period from May 2013 to July 2015, only 3.4 million bags were recalled. The complaint affords no basis to support the

inference that a shortage of 3.4 million bags—which, even using plaintiffs' low-end volume estimate, consists of only 17% of one month's supply of IV saline solution—would cause a significant rise in prices over the course of more than two years. The complaint alleges no facts concerning the defendants' total production or capacity; no facts addressing the number of bags that were ordered from the defendants; and no facts detailing how many bags were ordered that the defendants were unable to supply. And although the complaint acknowledges that in response to the saline solution shortage, the FDA permitted saline to be imported from foreign manufacturers—another fact that illustrates the implausibility of the plaintiffs' theory that the defendants colluded in a manner that convinced their regulator to allow imports from foreign competitors—it provides no allegations about the number of units supplied by such foreign competitors. Plaintiffs' theory, then, rests almost entirely on a single act—Hospira's October 2014 recall—taken by only one member of the alleged conspiracy, and begs the question: if the defendants adopted a scheme to create shortages by recalls, why was there only one recall, involving only one party, that was reasonably capable of materially raising IV saline solution prices? Neither the complaint nor the plaintiffs' briefs provides a discernable answer.

2. Shortage Notices

The signaling mechanism alleged in the complaint is also suspect. Plaintiffs posit that the defendants sent letters to the FDA to inform customers of upcoming IV saline shortages. The complaint suggests that the defendants came to an accord wherein each would further restrict output—via voluntary recalls—when the other indicated to the FDA that a shortage was imminent. There are two principal problems with this theory. First, shortage letters are not necessarily made public and the decision to publish them rests with the FDA, not with the company submitting them. The regulation addressing publication of shortage notices indicates

that the "FDA may choose not to make information collected [concerning shortages] available on the drug shortages list . . . if FDA determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the drug to patients." 21 C.F.R. § 314.81(b)(3)(iii)(d)(2). Plaintiffs argue that the defendants knew the FDA would publish their shortages letters because the circumstances under which the FDA could have declined to publish them were narrow. But the facts alleged in the complaint bely that assertion; the ubiquity and importance of IV saline—which the complaint alleges has no adequate substitute—suggests that an IV saline shortage may be precisely the sort of situation in which public notification would lead to hoarding. According to plaintiffs, then, defendants left the linchpin of their conspiracy to the discretion of FDA regulators.

In addition, the timing of the shortage notices calls plaintiffs' signaling theory into doubt. The complaint notes that Baxter sent the "first relevant" shortage letter to the FDA on December 16, 2013. CAC ¶ 69. But the complaint also alleges that Baxter and Hospira's conspiratorial recalls began in May 2013, seven months ***before*** the first shortage letter. *Id*. ¶ 61. The plaintiffs do not explain how the shortage notices triggered a steady stream of voluntary recalls if some of the allegedly coordinated recalls occurred before the notices?[14] Further, the complaint identifies a total of only four shortage letters, all of which were sent within the four-month window of December 2013 to March 2014, and none of which was sent within six months of any subsequent

[14] Defendants also argue that because the shortage letters were legally required, they could not have been used to signal output restrictions. But there is no reason that is the case; Baxter and Hospira could easily have agreed to pursue output restrictions upon receipt of a legally required notice. The problem with the complaint is not that legally-required public notices are inherently implausible signaling mechanisms, it's that the complaint contains paltry factual support for—and indeed undermines—the proposition that the shortage letters at issue in this case actually functioned as a signaling mechanism.

recall by either of the defendants. The complaint alleges that the conspiracy continued unabated for years after the last shortage-letter-signal was sent, suggesting either that the shortage letters were not, in fact, a signaling mechanism or that those responsible for implementing the alleged conspiracy must have been sleeping while on watch. In neither case is the plausibility of the plaintiffs' theory enhanced.

In short, the "parallel" conduct alleged by the complaint is not parallel and does not support an inference of unlawful agreement. The facts affirmatively pled in the complaint establish that the recalls were overwhelmingly one-sided, subject to federal scrutiny, and timed in a way that would render agreement unlikely. The complaint's silence speaks volumes as well. The failure to plead any facts suggesting that the recalls were bogus, failure to grapple with the complex regulatory framework in which defendants operate, and failure to allege facts indicating that all but one of the recalls could have meaningfully affected the marketplace reinforce the inadequacy of the theory set forth in the complaint. On these pleadings, the inference that the parties colluded together to raise IV saline solution prices by coordinating product recalls is quite implausible.[15]

[15] Plaintiffs, in asserting that the defendants unlawfully colluded, also point to the ways in which Baxter and Hospira used the saline shortage. Specifically, plaintiffs maintain that Baxter and Hospira both pressured customers to purchase other products in conjunction with their IV saline purchases in exchange for discounts on saline. Although tying arrangements often run afoul of the antitrust laws, plaintiffs concede that they are not pursuing standalone tying claims against either defendant. Resp. at 24. The plaintiffs instead posit that the defendants' conduct is merely another factor that points toward coordination. But there is no basis to draw that inference. At best, plaintiffs' allegations bespeak efforts by the defendants to use the shortage to bolster other areas of their business. The complaint contains no facts suggesting that these efforts were the product of an agreement, and not the result of independent strategies designed to expand defendants' business relationships.

B. Plus Factors

Plaintiffs also identify "plus factors" that, they say, push their claim into the realm of plausibility. Defendants counter that plausible allegations of parallel conduct are required to state a Section 1 claim in the absence of direct evidence. In defendants' view, because the complaint does not plausibly allege parallel conduct, the Court need not even consider the additional factors the plaintiffs argue render their theory plausible. In that, the defendants are mistaken. The plaintiffs' only burden at the pleadings stage is to "allege facts from which the Court can plausibly infer that the defendants had a conscious commitment to a common scheme designed to achieve an unlawful objective." *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 772, 789 (N.D. Ill. 2017). "That is, the circumstances of the case must reveal a unity of purpose or a common design and understanding, or a meeting of the minds in an unlawful arrangement." *Id*. Parallel conduct is but one of many varieties of circumstantial evidence plaintiffs can employ to state a claim. *See, e.g.*, *Hogan v. Cleveland Ave Restaurant Inc.*, No. 2:15-CV-2883, 2018 WL 1475398, at *4 (S.D. Ohio Mar. 26, 2018) ("Plaintiffs are not required to show parallel conduct; it is merely a vehicle . . . that can be used to show circumstantial evidence of a conspiracy.").

Ultimately, however, whether plaintiffs are required to plead plausible parallel conduct does not matter: Even if the plaintiffs' allegations sufficed to establish a strong inference of parallel conduct (and, as discussed above, it does not), the complaint would still fall short because the "plus factors" the plaintiffs identify do not make the inference of an express agreement between Baxter and Hospira any more plausible. The "plus factors" the plaintiffs identify—industry structure, trade association membership, and Baxter's settlement of an unrelated price-fixing law suit—are no more probative of an express agreement between the defendants than are the plaintiffs' allegations of parallel conduct. While consistent with the

possibility of collusion, they do not provide factual support that makes a finding of collusion plausible rather than merely possible.

The plaintiffs' arguments about "plus factors" rely heavily on the Seventh Circuit's application of *Twombly* in *Text Messaging I*, where the court addressed the adequacy of price-fixing allegations that included "a mixture of parallel behaviors, details of industry structure, and industry practices[] that facilitate collusion." *Id.* at 627. Like the IV saline industry, the text messaging industry was highly concentrated, with the four defendants to the suit providing 90% of all U.S. text messaging services. *Id.* at 628. The text messaging service providers attended trade meetings where they directly exchanged price information and participated in an organization whose "stated mission was to urge its members to substitute 'co-opetition' for competition." *Id.* Each of the service providers simultaneously shifted their heterogeneous and complex price structures to a uniform price structure featuring a one third increase in prices. *Id.* The price increases coincided with steadily falling costs. *Id.* The court concluded that, taken together, these facts constituted "parallel plus" allegations sufficient to survive a motion to dismiss. *Id.*

Although this case bears some resemblance to *Text Messaging I* (the IV saline industry is also highly concentrated, the product at issue is homogenous, and demand is inelastic), we know from *Twombly* and its progeny that industry structure alone cannot get the complaint across the finish line. If the complaint's allegations must render it more than merely possible that the defendants entered into an illegal agreement, it cannot be the case that allegations that a market is oligopolistic and a product is homogeneous are sufficient to survive a motion to dismiss. If that were so, an antitrust complaint targeting any industry with those features would survive a motion to dismiss regardless of whether there were any additional facts suggesting an agreement.

Hence, while market structure can provide some evidence of an unlawful agreement, it (even combined with parallel conduct) cannot sustain plaintiffs' complaint all on its own. *See High Fructose Corn Syrup*, 295 F.3d at 661 ("There is evidence both that the HFCS market has a structure that is auspicious for price fixing and that during the period of the alleged conspiracy the defendants avoided or at least limited price competition. But . . . all of this evidence is consistent with the hypothesis that they had a merely tacit agreement.").

The second purported "plus factor" that plaintiffs identify is Baxter's alleged history of anticompetitive conduct. The complaint alleges that Baxter previously settled antitrust claims against it for price fixing in the blood plasma derivatives market. CAC ¶ 131. The plaintiffs in the previous case alleged that Baxter signaled output restrictions at meetings called by the FDA. *Id.* at ¶ 132. Although this information is of questionable admissibility, *see High Fructose Corn Syrup*, 295 F.3d at 664 (corporate defendant's "previous misconduct cannot be used as evidence that it participated in a [different] conspiracy" to fix prices), even if considered now, at the motion to dismiss stage, evidence that Baxter's settled a prior price-fixing claim adds nothing to the plausibility of the claim in this case. The plaintiffs allege no admissions by Baxter in the prior suit, so any inference to be drawn that Baxter had engaged in price-fixing in the prior case would depend on the evidence about that conduct, not on the parties' mutual agreement to settle the dispute about that conduct. The minimal facts alleged in the complaint do little more than invite speculation that Baxter routinely engages in price-fixing because someone else filed a price-fixing claim relating to an unrelated product. That sort of speculation lends nothing to the effort to push plaintiff's theory into the plausibility zone.[16]

[16] After briefing was completed, the plaintiffs asked the Court to take judicial notice of public records reporting the issuance of a grand jury subpoena by the Antitrust Division of the Department of Justice to an unnamed employee of Baxter seeking documents and testimony

Text Messaging and this case also feature another "plus factor," namely, seemingly anomalous price increases; in both cases, prices rose amid stagnant or falling costs. This behavior reasonably arouses suspicions, as "falling costs increase a seller's profit margin at the existing price, motivating him, in the absence of agreement, to reduce his price slightly in order to take business from his competitors, and certainly not to increase his price." *Text Messaging*, 630 F.3d at 628. But the allegations in this case are qualitatively different from the *Text Messaging I* allegations in a key respect: there, not only did the sellers increase their prices, they also simultaneously shifted from "heterogeneous and complex" pricing structures, to a single, uniform pricing structure at a heightened price point. *Id*. Here, by contrast, the complaint does not identify a simultaneous structural shift suggesting an agreement.

The absence of a structural shift is significant because anomalous price hikes in highly concentrated industries are often the result of typical, non-conspiratorial market behavior. "Oligopolies pose a special problem under § 1 because rational, independent actions taken by oligopolists can be nearly indistinguishable from horizontal price fixing." *Valspar Corp. v. E.I. Du Pont De Nemours and Co.*, 873 F.3d 185, 191 (3d Cir. 2017). This is the case because "any rational decision in an oligopoly must take into account the anticipated reaction of the other

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relating to the manufacture, sale, pricing, and shortages of intravenous solutions and containers, and to a request for similar information from the New York Attorney General's office. While the Court takes judicial notice of this information, it does not—contrary to the plaintiffs' assertion—enhance the plausibility of the plaintiffs' claim. The records in question do nothing more than report the existence of investigations; they include no information or findings concerning conduct by the defendants. The mere fact that an investigation is being conducted says nothing about whether unlawful conduct has occurred. Investigations require no minimum predication or threshold of evidence to begin; indeed, the purpose of an investigation is to determine ***whether*** there is evidence of unlawful conduct; its existence does not therefore signal that there must be such conduct. The Court therefore accords no weight to the information that is the subject of the plaintiffs' request for judicial notice.

firms." *Id*. In *Valspar*, the Third Circuit concisely explained why price increases may occur notwithstanding falling costs:

> "[O]ligopolistic rationality" can cause supracompetitive prices because it discourages price reductions while encouraging price increases. A firm is unlikely to lower its price in an effort to win market share because its competitors will quickly learn of that reduction and match it, causing the first mover's profits to decline and a subsequent decline in the overall profits of the industry. Similarly, if a firm announces a price increase, other market participants will know that if they do not increase their prices to the first-mover's level, the first-mover may be forced to reduce its price to their level. Because each of the other firms know this, each will consider whether it is better off when all are charging the old price or the new one. They will obviously choose the new price when they believe that it will maximize industry profits.

Id. (alterations and internal quotation marks and citations omitted). Indeed, when *Text Messaging* returned to the Seventh Circuit at the summary judgment phase, the court recognized that "[c]ompetitors in concentrated markets watch each other like hawks," and discerned several rational reasons why oligopolists might uniformly raise prices irrespective of costs and without an unlawful agreement. *In re Text Messaging Antitrust Litig.* ("*Text Messaging II*"), 782 F.3d 867, 874-75 (7th Cir. 2015) (describing several rationales that may lead "firms [in an oligopoly]—without any communication with the [price] leader—to raise their prices"). So, that Baxter and Hospira both raised prices in the face of falling costs does little to suggest that they engaged in actual collusion, which is illegal, as opposed to "tacit collusion," which is not. *Id*. at 872, 873-74, 879.[17]

[17] Hospira argues that plastic and resin costs are not the only drivers of the cost of an IV saline bag; specifically, Hospira asserts that the manufacturing and compliance costs required to meet strict FDA requirements also drive cost. But Hospira does not suggest that these costs increased in a way that would offset declines in the price of raw materials or would otherwise explain increases in the price of IV saline. This argument therefore merits little weight.

Unsurprisingly, then, *Text Messaging I*'s most compelling allegations supporting the existence of an agreement had little to do with industry structure, and everything to do with specific suspicious communications among the defendants: the defendants had attended industry conferences during which they exchanged price information and sought to substitute "co-opetition" for competition. 630 F.3d at 628. The plaintiffs' allegations in this case, however, do not allege any such express vows of cooperation among competitors, and the complaint stops far short of alleging that these defendants similarly exploited the opportunities for collusion that industry associations provided. The plaintiffs assert only that the defendants were members of two of the same organizations, and that those organizations held meetings attended by defendants. But this is true in virtually every industry; trade organizations are ubiquitous and serve numerous legitimate and pro-competitive purposes. *See In re Musical Instruments and Equipment Antitrust Litig.*, 798 F.3d 1186, 1196 (9th Cir. 2015) ("[T]rade associations often serve legitimate functions, such as providing information to industry members, conducting research to further the goals of the industry, and promoting demand for products and services."); *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 435 (4th Cir. 2015) (concluding that standard-setting trade organizations can have "decidedly procompetitive effects by encouraging greater product interoperability generating network effects, and building incentives to innovate" (internal quotation marks omitted)). Absent additional facts addressing the content of defendants' discussions at or the (nefarious) subjects of trade organization meetings, allegations that defendants were members of the same trade organizations are unspectacular and fail to move the needle.

The "plus factors" the plaintiffs identify here are, therefore, substantially weaker than those present in *Text Messaging I*. And the alleged collusive scheme at issue in *Text Messaging I*

was garden variety price-fixing; here, by contrast, the complaint alleges an implausibly complex and outlandish scheme to restrict output. This poses a problem for the plaintiffs, as the more complex the allegations, the more facts are required under Federal Rule of Civil Procedure 8 to "show how, in the plaintiff's mind at least, the dots should be connected." *Swanson v. Citibank, N.A.*, 614 F.3d 400, 405 (7th Cir. 2010); *see also Iqbal*, 556 U.S. at 679 (assessing plausibility is "a context-specific task"). Taking together each of the identified plus factors—market structure, Baxter's history, the price of raw materials, and membership in trade organizations—the Court is unpersuaded that plaintiff's allegations of conspiracy rise to the level of plausibility. With the exception of the allegations concerning Baxter's prior misconduct (which, again, is of dubious admissibility and probative value) each of the identified plus factors are either equally consistent with conscious parallelism, or to be expected regardless of whether the defendants unlawfully colluded. And one (potential) instance of prior misconduct on the part of one of the defendants does not convert an otherwise implausible conspiracy into a plausible one. The Court therefore dismisses plaintiffs' complaint for failure to state a claim.

II. *Noerr-Pennington* Doctrine

Although the Court dismisses the plaintiffs' complaint for failure to state a claim, for the benefit of the parties, it will address the alternative grounds for dismissal posed by defendants. Baxter argues that the *Noerr-Pennington* doctrine alternatively bars plaintiffs' claim. The *Noerr-Pennington* doctrine "extends absolute immunity under the antitrust laws to businesses and other associations when they join together to petition legislative bodies, administrative agencies, or courts for action that may have anticompetitive effects." *Mercatus Group, LLC v. Lake Forest Hosp.*, 641 F.3d 834, 841 (7th Cir. 2011) (internal quotation marks omitted). Baxter contends that its voluntary recalls and shortage notices were efforts to petition the government to take

certain courses of action, *e.g.*, to stave off potential FDA enforcement actions against the company's defective IV saline bags. Plaintiffs respond that defendants' actions were purely ministerial and were not undertaken to affect government policy, and alternatively that the *Noerr-Pennington* doctrine does not apply because the shortage notices and recalls were shams. *Id*. at 842 (recognizing an exception to the *Noerr-Pennington* doctrine where the petitioning activity is either a sham lawsuit or a fraudulent misrepresentation).

The Court finds that this issue is ill-suited for resolution on a motion to dismiss. While Baxter posits in its briefing that its recalls and shortage notices were undertaken for the purpose of petitioning the government—and not merely to fulfill a legal responsibility—the complaint, not surprisingly, contains no facts suggesting that was the case. It is possible that some, or even most, voluntary recalls and shortage notices are undertaken to petition the FDA to take a certain course of action. But nothing in the complaint indicates that the specific recalls and shortage notices at issue in this case were issued with that purpose in mind. Immunity is an affirmative defense, and at the motion to dismiss stage, "dismissal is appropriate only when the factual allegations in the complaint unambiguously establish all the elements of the defense." *Hyson USA, Inc. v. Hyson 2U, Ltd.*, 821 F.3d 935, 940 (7th Cir. 2016). The complaint does not compel the conclusion that Baxter's conduct constituted petitioning activity, and it will therefore not be dismissed on *Noerr-Pennington* grounds.

III. Antitrust Injury

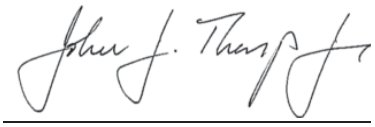
Baxter also argue that the complaint should be dismissed because it fails to allege an antitrust injury. An antitrust plaintiff must allege "that her claimed injuries are of the type the antitrust laws were intended to prevent and reflect the anticompetitive effect of either the violation of or anticompetitive acts made possible by the violation." *Kochert v. Greater Lafayette*

Health Servs., Inc., 463 F.3d 710, 716 (7th Cir. 2006). Baxter argues that the complaint does not allege antitrust injury because the alleged price increases could have resulted from a shortage wholly unrelated to collusion. But that position is inconsistent with the allegations of the complaint. Assuming, for the moment, that the collusive scheme alleged in the complaint was plausible (it is not), the complaint alleges that as a result of the scheme, "the prices of IV Saline Solution have been fixed, raised, maintained, or stabilized at artificially inflated levels." CAC ¶ 142. Accordingly, the complaint alleges that the plaintiffs "paid higher prices for IV Saline Solution than they would have paid in the absence of" defendants' unlawful conduct. Paying higher prices as a result of coordinated output restrictions is a paradigmatic antitrust injury. *See U.S. Gypsum Co. v. Indiana Gas Co., Inc.*, 350 F.3d 623, 626-627 (7th Cir. 2003) ("A private plaintiff must show antitrust injury—which is to say, injury by reason of those things that make the practice unlawful, such as reduced output and higher prices."). A shortage without collusion may result in price increases, but the complaint alleges that the defendants' scheme resulted in the plaintiffs paying higher prices than they otherwise would have. Consequently, had plaintiffs' theory of collusion been plausible, plaintiffs would have successfully pled antitrust injury.

* * *

For the foregoing reasons, the consolidated amended complaint is dismissed without prejudice. Although there is reason to doubt that plaintiffs will be able to successfully replead in light of the affirmative allegations made in the CAC, which provide ample basis to infer that the defendants' recalls ***were not*** the product of an unlawful agreement, the plaintiffs should not be foreclosed from attempting to address the issues identified in this opinion in a second amended complaint. Their first amendment was predicated not on remedying issues raised in a motion to dismiss or by the Court, but on the need to consolidate claims of multiple plaintiffs. If the

plaintiffs wish to stand on the adequacy of the CAC, however, they should so advise the Court and judgment will be entered in accordance with this ruling, thereby permitting the plaintiffs to appeal if they wish to do so.



Dated: July 5, 2018

John J. Tharp, Jr.
United States District Judge