Adam L. Hoeflich
Carolyn J. Frantz
Georgia N. Alexakis
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 W. Hubbard St.
Chicago, IL 60654
Tel: (312) 494-4400

[Additional Counsel listed below]

Attorneys for Defendant Bayer HealthCare LLC

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------	**BAYER HEALTHCARE LLC'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS THE MASTER COMPLAINT UNDER FED. R. CIV. P. 8(A), 9(B), 12(B)(1) AND 12(B)(6)**
IN RE: BAYER CORP. COMBINATION ASPIRIN PRODUCTS MARKETING AND SALES PRACTICES LITIGATION	**09-MD-2023 (BMC)**
	THIS DOCUMENT RELATES TO: All Actions

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes & Regulations

Rules

Other Authorities

Plaintiffs are consumers who claim to have purchased Bayer combination aspirin and dietary supplement products. They do not claim that they were injured by these products or that the products were ineffective. Instead, plaintiffs seek damages because they say they would not have purchased these products if they had known that Bayer, instead of submitting a New Drug Application ("NDA") for each of these products, relied on the preexisting regulatory review of aspirin and the supplements. Plaintiffs' claims fail, first, because they are, in essence, private attempts to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") (2009). 21 U.S.C. § 301 *et seq.* Courts have repeatedly refused to construe such private attempts to enforce the FDCA as violations of the state-law causes of action that plaintiffs have brought in this litigation. Even if a state were to recognize it, a cause of action based on a failure to obtain FDA approval would be preempted as interfering with the FDA's approval processes. Additionally, plaintiffs, who do not claim harm or that their products did not work, have not alleged a cognizable injury. Accordingly, plaintiffs have not stated a claim for any of the causes of action they have brought, and, in fact, lack constitutional standing.

Under Fed. R. Civ. P. 12(b)(6), a complaint must be dismissed if it fails to articulate grounds upon which relief can be granted. Under Rule 8(a), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 US 544, 555 (2007) (internal citations omitted). A plaintiff's claim must be "plausible on its face." *Id.* at 570. It cannot be speculative. *Id*. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level."). The Supreme Court recently reaffirmed these principles in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009) (reaffirming that the pleading standard set forth in *Twombly* applies to all civil actions).

These standards apply to injury and loss requirements as well as to other elements of a claim. As the Second Circuit recently explained, to state a claim for relief, a plaintiff must do more than simply allege an injury or loss – that theory must be "plausible." *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 227 (2d Cir. 2008) (dismissing RICO claims). Legally cognizable theories of injury must also not require a court to "engage in a series of speculative calculations to ascertain whether, or in what amount, plaintiffs suffered a loss." *Id.* at 230.

Causes of action based in fraud require even more specificity in pleading. A plaintiff must state "with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Where, as here, plaintiffs attempt to base their claims on allegations of fraud, state consumer fraud laws – including the laws of New Jersey and California – typically require satisfaction of the pleading requirements of Fed. R. Civ. P. 9(b); plaintiffs must "state with particularity" all of the circumstances surrounding Bayer's alleged fraud. *Parker v. Howmedica Osteonics Corp.*, 2008 U.S. Dist. LEXIS 2570, at *10-11 (D.N.J. Jan. 14, 2008) (applying Rule 9(b) to the New Jersey Consumer Fraud Act); *Kearns v. Ford*, 567 F.3d 1120, 1125 (9th Cir. 2009) (applying Rule 9(b) to the California consumer fraud statutes). A further burden lies on plaintiffs not only to allege, but also to demonstrate, the existence of constitutional standing. 5B Charles A. Wright, *et al.*, FED. PRAC. AND PROC. CIV. 3D, § 1350; Fed. R. Civ. P. 12(b)(1).

Plaintiffs' Master Complaint fails to meet these requirements for each of the causes of action they assert.

I. Factual Background

This litigation involves two Bayer products that combine low-dose aspirin, widely recognized as effective in the prevention of heart attacks and strokes, with dietary supplements whose safety and effectiveness the FDA has recognized. Bayer Women's Low Dose Aspirin + Calcium ("Bayer Calcium") combines low-dose aspirin with calcium and makes claims

regarding cardiovascular benefits and reduction of risk of osteoporosis. The FDA has approved an unqualified health claim for calcium, after finding that it reduces the risk of osteoporosis. 21 C.F.R. § 101.72 (2009). Bayer Aspirin with Heart Advantage combines low-dose aspirin with phytosterols and makes claims regarding cardiovascular benefits. The FDA has approved an unqualified health claim for phytosterols, after finding that they reduce the risk of heart disease by lowering blood cholesterol. 21 C.F.R. § 101.83 (2009).

Before approving these unqualified health claims (also known as "authorized health claims") for calcium and phytosterols, the FDA had to find:

> based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 U.S.C. § 343(r)(3)(B) & 21 C.F.R. § 101.14(c) (2009) (applying this standard to dietary supplements); *see also* Ex. A. (FDA, *Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, at 2 (Dec. 22, 1999)) ("The significant scientific agreement standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship.").[1]

---

[1] This document is available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059132.htm. The concurrently filed request for Judicial Notice encompasses this fact and other facts reflected in documents Bayer asks the Court to consider when deciding this Motion to Dismiss. Documents incorporated into the complaint by reference, or documents upon which the complaint "relies heavily," may be considered even without Judicial Notice. *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (internal citation and quotation omitted). When referencing those documents, Bayer will note the paragraph(s) of the Complaint that rely upon them.

The FDA has approved only twelve unqualified health claims under this rigorous standard. Calcium and phytosterols are the subjects of two of those twelve claims. 21 C.F.R. §§ 101.70-101.83 (2009) (listing approved unqualified health claims).

Aspirin has been sold in the United States for more than a hundred years.[2] Ex. B (David B. Jack, *One Hundred Years of Aspirin*, 350 The Lancet 437 (1997)). A daily regimen of low-dose aspirin is widely recognized as useful in preventing heart attacks and strokes. *See, e.g.*, Ex. C (American Heart Association website).[3] The FDA-approved professional labeling (labeling intended for healthcare providers) for aspirin includes such proposed cardiovascular uses. 21 C.F.R. § 343.80 (2009). The practice of marketing aspirin to consumers for cardiovascular uses is widespread. Ex. D (St. Joseph's and Ecotrin websites).[4] The Federal Trade Commission, which has responsibility for enforcing the advertising requirements that are parallel to the FDA's labeling requirements, has agreed to allow Bayer to place statements describing aspirin's cardiovascular benefits on consumer aspirin materials so long as they are accompanied by a

---

[2] Aspirin, like many over-the-counter medications, is sold under an FDA monograph, which establishes the conditions under which it is generally recognized as safe and effective. For the marketing of a drug that is subject to a monograph, an NDA approved by the FDA is not required. 21 C.F.R. § 330.13 (2009). The monograph that governs aspirin is tentative. Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 53 Fed Reg. 46,204 (Nov. 16, 1988).

[3] This document is available at: www.americanheart.org/presenter.jhtml?identifier=4456.

[4] The materials in this exhibit are available at: www.stjosephaspirin.com/page.jhtml?id=/stjoseph/include/2_0.inc and http://www.ecotrin.com/about-ecotrin/why_ecotrin.aspx.

The two non-Bayer low-dose aspirin products to which plaintiffs refer in their Complaint in fact contain labeling intended for users of a daily regimen. Although plaintiffs characterize these aspirin products as not "mak[ing] similar unapproved and deceptive claims," the Walgreens product features a red heart on the label and states that it is "For Aspirin Regimen Users"; the RiteAid product states that it is for "For Daily Aspirin Users." *Compare* Cmplt. ¶¶ 82-83 *with* Ex. E.

statement encouraging consumers to consult their physicians. Ex. F (*Sterling* consent decree), *discussed at* Cmplt. ¶ 53.[5] The packaging for Heart Advantage and Bayer Calcium contains just such language. Ex. G, *discussed* Cmplt. *passim*; *see also* Cmplt. ¶ 40 (acknowledging this statement on Bayer Calcium packaging).[6]

The FDA issued warning letters for both Bayer Calcium and Heart Advantage in late 2008, seven years after the first of these products, Bayer Calcium, had been launched. Ex. H, *discussed* Cmplt. *passim*. These warning letters expressed the view that, under the requirements of the FDCA, the combination of an over-the-counter ("OTC") drug and a dietary supplement formed a new drug for which the submission and approval of an NDA was required. The warning letters also stated that Bayer Calcium and Heart Advantage were misbranded under the FDCA because, *inter alia*, cardiovascular indications are permissible only in the professional (not OTC) labeling for aspirin. These warning letters were not final agency actions. *Perez v. Nidek Co. Ltd*, 2009 U.S. Dist. LEXIS 78214, at *7 (S.D. Cal. Aug. 31, 2009) (warning letters do not constitute a final agency action); *Genendo Pharm. N.V. v. Thompson*, 308 F. Supp. 2d 881, 885 (N.D. Ill. 2003) (same).

II. Plaintiffs Have Not Met Even the Most Basic Pleading Requirements for Most of the Causes of Action They Have Asserted

Though the Complaint alleges a large number of state-specific causes of action, plaintiffs make little to no effort to plead the requirements of most of them. As an initial matter, plaintiffs allege that the New Jersey Consumer Fraud Act ("NJCFA) applies to all plaintiffs' claims. Cmplt. ¶¶ 99-106; *see generally* N.J. STAT. § 56:8 *et seq*. (2009). Plaintiffs plead in the

---

[5] This document is available at: www.ftc.gov/os/2000/01/sterlingdecree.htm.

[6] In fact, this is the precise language agreed to by the Federal Trade Commission in the action mentioned in paragraph 53 of plaintiffs' Complaint. *Compare* Cmplt. ¶¶ 40, 53 *with* Ex. F.

alternative that the consumer-fraud laws of 43 other jurisdictions would apply. Cmplt. ¶¶ 107-112. They seek relief under the express and implied warranty laws of more than 30 jurisdictions, and plead a cause of action for "unjust enrichment" without naming any particular jurisdiction's law. *Id.* ¶¶ 113-24 (express warranty); ¶¶ 125-38 (implied warranty); ¶¶ 139-45 (unjust enrichment). Although causes of action differ significantly from state to state, plaintiffs make no attempt to articulate separately and specifically the particular requirements of any state-law cause of action for unjust enrichment or warranty, or of any consumer-fraud statutes other than the NJCFA and three California statutes. *Id.* at ¶¶ 99-164. *See generally* CAL BUS. & PROF. CODE § 17200 *et seq.* (2009) ("UCL"); CAL BUS. & PROF. CODE § 17500 *et seq.* (2009) ("FAL"); CAL CIV. CODE § 1750 *et seq.* (2009) ("CLRA"). Plaintiffs do not propose a subclass of residents of any state other than California, and do not even name plaintiffs in the master complaint for any state other than New York (Goldberg), New Jersey (Blank), Illinois (Robert and Lynne Nosbich), and California (Vinson). Cmplt. ¶¶ 9-13, 87. *See Suarez v. Playtex Prods., Inc.*, 2009 U.S. Dist. LEXIS 63771, at *6-7 (N.D. Ill. July 24, 2009) (holding that a plaintiff from one state does not state a claim for relief under another state's law); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821-22 (1985) (constitutional due process requires a connection between the parties and the state law to be applied). The vast majority of the causes of action listed in plaintiffs' Complaint therefore lack either a plaintiff, any basic attempt at meeting pleading requirements, or both. The remainder should be dismissed for the reasons described below.

III. Plaintiffs' Allegations, Which are Based on Alleged Violations of the FDCA for Which There is No Private Right of Action, Do Not State a Claim Under State Law

The Complaint, from the opening paragraph forward, makes clear that this entire litigation is based on the allegation that Bayer failed to obtain FDA approval for its combination aspirin and dietary supplement products:

> [Bayer] sold and marketed directly to the Class, two over-the-counter ("OTC") pharmaceutical products which were not approved by the Food and Drug Administration ("FDA") and never should have been sold to *any* consumer. Bayer marketed these two products . . . as combination OTC drugs and dietary supplements without the required regulatory approval. Thus, the safety and effectiveness of the drugs has not been reviewed, nor approved, by the FDA.

Cmplt. ¶ 1.

Under the FDCA, the United States government has the exclusive power to enforce the FDA's regulatory requirements (which include provisions relating to the approval of new prescription and over-the-counter drugs, as well as regulation of dietary supplements and food additives). The FDCA provides that "[a]ll such proceedings for the enforcement, or to restrain violations, of this Act, shall be by and in the name of the United States." 21 U.S.C. § 337(a) (2009). The FDA has extensive discretion in deciding whether, and how, to pursue enforcement of the statute's requirements, including the explicit discretion not to prosecute violations that the agency believes are "minor" and can be resolved satisfactorily by a written notice or warning. *See* 21 U.S.C. § 336 (2009). The Supreme Court has held that the FDCA's enforcement regime is "clear evidence that Congress intended the [Act to] be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (citing 21 U.S.C. § 337(a) in medical device context).

Courts have accordingly held that there is no private right of action under the FDCA. Affirming a dismissal of an action brought under a state consumer-fraud statute and the Lanham Act, the United States Court of Appeals for the Second Circuit stated: "Friedlander's dogged insistence that PDK's products are sold without proper FDA approval suggests . . . that Friedlander's true goal is to privately enforce alleged violations of the FDCA. However, no such private right of action exists." *PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (citations omitted); *see also Barr Labs v. Quantum Pharmics, Inc.*, 1994 U.S. Dist. LEXIS 2197,

at *29-30, *34 (E.D.N.Y. Feb 2, 1994); *Merck & Co. v. Mediplan Health Consulting, Inc.*, 425 F. Supp. 2d 402, 418 (S.D.N.Y. 2006) ("*Mediplan*").

Regardless of the cause of action plaintiffs have asserted, courts have repeatedly held that private plaintiffs fail to state a claim where they, in essence, seek redress for a violation of the FDCA. Courts have applied this doctrine to dismiss a variety of causes of action, from RICO and the Lanham Act, to state law unfair competition and consumer fraud act claims. *See, e.g.*, *Mylan Labs. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (dismissing Lanham Act claim where plaintiff's true intention was "to enforce independently the FDCA"); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) ("*Amgen I*") (dismissing state consumer fraud and false advertising and RICO claims); *Ethex v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (dismissing state deceptive trade practices claims and Lanham Act claim); *Braintree Labs v. Nephro-Tech, Inc.*, 1997 U.S. Dist. LEXIS 2372, at *21-24 (D. Kan. Feb. 26, 1997) (dismissing state unfair competition and Lanham Act claims).

Courts assessing claims like plaintiffs' must therefore scrutinize whether plaintiffs have independently, and sufficiently, pled the requirements of the causes of action they have brought, or whether they are instead trying to obscure the deficiencies in their complaint by alleging FDCA violations, for which there is no private cause of action. Plaintiffs may not "by ingenious pleading, []escape one principle of law" – that there is no private right of action under the FDCA – "by making it appear that another not truly appropriate rule is applicable." *Mylan Labs.*, 7 F.3d at 1139. Plaintiffs here attempt to do exactly that.

A. Plaintiffs do not allege the elements of their consumer fraud causes of action, only violations of the FDCA

Plaintiffs' consumer-fraud actions also rest only on alleged violations of the FDCA, which are insufficient to state a claim under any of the causes of action they have asserted. There is nothing inherently "unconscionable," "unfair," "deceptive," or "fraudulent" about selling a product that allegedly lacks proper FDA approval. N.J. STAT. at § 56: 8-2; CAL. BUS. & PROF. CODE at § 17200; CAL BUS. & PROF. CODE at § 17500; CAL CIV. CODE at § 1770. Such an act may violate the FDCA, but it does not violate state consumer fraud statutes. Nor have plaintiffs alleged any other basis for consumer fraud – they have not alleged that they were deceived by any Bayer statement, and cannot plausibly claim that merely placing these products for sale implies anything false about the particular regulatory process the products underwent.

1. There is nothing inherently unfair or fraudulent about selling or marketing a product without proper FDA approval

There is nothing inherently unfair about selling a product that, allegedly, has not undergone proper FDA review procedures. The Northern District of Illinois (affirmed by the Seventh Circuit in an unpublished opinion) reached just that conclusion, dismissing claims strikingly similar to the claims plaintiffs make in this case. *Anthony v. Country Life Mfg.*, 2002 U.S. Dist. LEXIS 19445 (N.D. Ill. Oct. 9, 2002), *aff'd* by 2003 U.S. App. LEXIS 13622 (7th Cir. July 2, 2003) (unpublished opinion).[7] Under the Illinois Consumer Fraud Act, plaintiffs had sought relief based on the inclusion of stevia and cholecaliciferol in food. 2003 U.S. App.

---

[7] Because the United States Court of Appeals for the Seventh Circuit does not allow citation to its unpublished opinions issued prior to 2007, Bayer has cited to the District Court opinion in *Anthony*, "noting the affirmance[] as relevant subsequent history." *Giano v. Senkowski*, 54 F.3d 1050, 1054 n.1 (2d Cir. 1995). Any citations to the unpublished Seventh Circuit opinion itself are merely to establish background facts about the litigation, not as an attempt to rely on the reasoning of the Court of Appeals opinion itself. *But see id.* ("We are not . . . quick . . . to disregard the judgment of other federal courts that have passed on [the issue].").

LEXIS 13622, at *9-10. Like the labeling of the products at issue here, the labeling of the products at issue in *Anthony* made clear what ingredients the products contained. *Id*. Like the dietary supplements at issue here, the ingredients in *Anthony* had been subject to an FDA review procedure (as "nutritional supplements"). The *Anthony* plaintiffs alleged only that the ingredients needed to also undergo a different regulatory procedure, the one required for inclusion in food. *Id.* The Northern District of Illinois found that producing and marketing the products at issue in *Anthony* without proper FDA review was only an FDCA violation and did not constitute an "unfair trade practice" under Illinois law. 2002 U.S. Dist. LEXIS 19445, at *4-7. There is similarly nothing inherently unfair about the mere act of selling Bayer Calcium and Heart Advantage, even if they allegedly lacked proper FDA approval.

Nor is the marketing of products without proper FDA approval inherently fraudulent. In the *Amgen* litigation, the Central District of California dismissed just such claims brought under two of the consumer fraud statutes at issue in this case. *In re Epogen & Aranesp Off-Label Marketing and Sales Practices Litig.*, 2009 U.S. Dist. LEXIS 58697 (C.D. Cal. June 17, 2009) ("*Amgen II*"); *see also generally Amgen I*, 590 F. Supp. 2d at 1282. Plaintiffs attempted to base California UCL and FAL claims on allegations that "off-label" marketing – marketing drugs for purposes that the FDA had not approved – was "false and misleading." *Amgen II*, 2009 U.S. Dist. LEXIS 58697, at *19. The court dismissed the action for failure to state a claim under California law. *Id.* at *17-20. In doing so, the Court noted that marketing a drug for uses for which it had not been approved is not "inherently fraudulent" – that the FDA has not approved a drug does not mean it does not work, and so asserting its effectiveness is not necessarily false. *Id.* at *20 n.3; *see also Amgen I*, 590 F. Supp. 2d at 1289; *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900, at *47 (D.N.J. July 10,

2009). That marketing drugs without proper FDA approval may violate the FDCA does not mean that it violates consumer fraud laws. Similarly, here, there is nothing inherently fraudulent or unfair about marketing or selling these products, even if they, allegedly, should have been the subject of an NDA.

2. Plaintiffs do not state a claim that Bayer deceived them regarding these products

Nor have plaintiffs alleged that Bayer made any actually false statement to which they were exposed. Each named plaintiff claims to have been deceived into believing that the sale of the combination aspirin and dietary supplement products was "the result of an FDA approval process." Complaint ¶¶ 9-13. But none alleges a connection between any Bayer statement and that belief.

Plaintiffs' Complaint fails to allege that Bayer anywhere affirmatively stated that these products had been separately submitted to the FDA as part of an NDA, or even that they were "FDA-approved." *Mylan Labs.*, 7 F.3d at 1139 (dismissing claims where claimant had not "point[ed] to any statement or representation in the defendants' advertising which declared 'proper FDA approval'"); *Eli Lilly & Co. v. Roussel*, 23 F. Supp. 2d 460, 478 (D.N.J. 1998) (same). *See also* CAL CIV. CODE §1770 (making actionable under the CLRA only false "representation[s]" of approval).

Plaintiffs attempt to link two types of Bayer statements to their assertion that Bayer deceived them regarding the regulatory status of these products. The first is a list of undisputedly true statements about the need for, and benefits of, aspirin, which appeared on a piece of paper inside a package of Bayer Calcium – statements such as "Bayer Aspirin can help prevent recurrent heart attacks and ischemic strokes." Cmplt. ¶¶ 41-42. The second is an undisputed statement about phytosterols – that "the FDA has recognized the use of phytosterols

(at least 800mg a day in divided doses) as part of a low-fat diet to cut the risk of heart disease" – which appeared on a Bayer website. *Id.* ¶ 65.

Plaintiffs do not allege that they saw these statements prior to purchasing their products (and, in fact, the placement of the paper *inside* the Bayer Calcium package makes that very unlikely). That failure, alone, justifies dismissal. *Suarez*, 2009 U.S. Dist. LEXIS 63771, at *10 (dismissing claims under New York and Illinois consumer-fraud laws where "plaintiffs quote statements on Playtex's website assuring customers that its products 'surpass the most stringent domestic and international regulatory guidelines on . . . safety matters,' . . . but fail to allege whether or when they relied on, or even saw, these statements prior to purchasing the coolers").

Even if a plaintiff had seen these statements, they cannot not form the basis for a consumer-fraud claim. Plaintiffs allege that the statements about aspirin inside the packaging for Bayer Calcium "misrepresent the fact that these statements pertain to the FDA approved Bayer Aspirin and not to . . . Bayer Calcium." Cmplt. ¶ 42. But plaintiffs do not deny that these statements about aspirin are also true of the aspirin component of Bayer Calcium, and they do not present any basis for believing that they convey any false information about Bayer Calcium's FDA approval. This is not a sufficient allegation of fraud. *Twombly*, 550 U.S. at 555.

Plaintiffs' allegation that accurately stating the existence of an FDA-approved unqualified health claim for phytosterols is "designed to confuse consumers that Bayer Heart Advantage – and specifically the phytosterols in combination with aspirin – has received regulatory approval" also fails to state an actionable claim. Cmplt. ¶ 65. Plaintiffs have failed to provide any plausible explanation for why a true statement about the regulatory status of phytosterols on the website for a product that contains phytosterols invites any false inference at all about the regulatory process the entire product has undergone. Plaintiffs' Complaint must do

more than claim that Bayer's statements were deceptive; it must present a plausible account of why. *Twombly*, 550 U.S. at 555. The Complaint here fails to do that.

3. Claims based on bare assertions of implied FDA approval are not actionable

Plaintiffs cannot state a claim for relief based on an allegation that, without making any false representation about FDA approval, Bayer has implied that its combination aspirin and dietary supplement products were subject to an NDA process. Courts have repeatedly held that the Lanham Act, an act aiming to prohibit many of the same kinds of practices addressed by state consumer-fraud acts, does not allow claims based on allegations that the marketing of a product constitutes an implied representation of agency approval of the product. *See Ethex*, 228 F. Supp. 2d at 1055 (courts have repeatedly "refused to allow plaintiffs to state a claim based on implicit representations of FDA approval"); *Barr Labs.*, 1994 U.S. Dist. LEXIS 2197, at *35-36 (dismissing claim where plaintiffs "allege[d] that certain words or phrases implied FDA approval"); *Mediplan*, 425 F. Supp. 2d at 418 (dismissing claims that "rely on the proposition that defendants have made implied misrepresentations about FDA approval"); *Braintree*, 1997 U.S. Dist. LEXIS 2372, at *18-19 ("It is clear that a plaintiff may not maintain a Lanham Act claim alleging only that the defendant has failed to disclose that the FDA has not approved its product."). *See also Avon Prods. v. S.C. Johnson & Sons, Inc.*, 984 F Supp. 768, 796 (S.D.N.Y. 1997) (with respect to EPA approval: "the law does not impute representations of government approval . . . in the absence of explicit claims").

Addressing a claim that selling a drug with the sort of package inserts that typically accompany FDA-approved products is misleading, the Fourth Circuit held that such a claim is "simply, too great a stretch under the Lanham Act." *Mylan Labs.*, 7 F.3d at 1139. Plaintiffs' claims here similarly are too much of a stretch under any statute at issue.

Plaintiffs cannot state a plausible claim that Bayer's act of selling its combination aspirin and dietary supplement products implied that they had been subject to an NDA. Such a claim would depend on the implausible assumption that "the relevant market is wise to either the status of an entity with the FDA or to the tangled web of the [FDCA] and the FDA regulations." *Hoffman-La Roche Inc. v. Medisca, Inc.*, 1999 U.S. Dist. LEXIS 2380, at *5 (N.D.N.Y. Mar. 3, 1999). Although plaintiffs allege that they believed the products were "the result of an FDA process," they have not alleged precisely which approval process or processes each believed the products had undergone. *See Daugherty v. Am. Honda Motor Co., Inc.*, 144 Cal. App. 4th 824, 838 (Ct. App. Cal. 2006) (no actionable deception under the CLRA and the UCL where plaintiffs could not point to any particular misrepresentation, or establish that the public had specific contrary expectations about the product).

Plaintiffs have not even alleged whether they knew about the previous FDA regulatory actions involving aspirin, phytosterols, and calcium, or how this knowledge would have affected, or did affect, their choices. Plaintiffs' allegations, therefore, do not differentiate the named plaintiffs from consumers who would have considered the FDA aspirin monograph and FDA-approved unqualified health claims for phytosterols and calcium reason enough to purchase these products.[8] Such consumers would suffer no injury as defined by any relevant cause of action. *See, e.g., Heindel v. Pfizer*, 381 F. Supp. 2d 364, 379 (D.N.J. 2004) (noting that plaintiffs who

---

[8] The statement of by Margaret Dotzel quoted at Complaint ¶ 26 does not specifically apply to combination products where the dietary supplement is the subject of an unqualified health claim like calcium and phytosterols. The "disclaimer" to which she refers – that "[t]his statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" – is not required with respect to unqualified health claims. *See* 21 U.S.C. § 343(r)(6)(C) (2009).

"continued to use [the products]" after learning the information on which they base their claims suffer no loss).

Basing a claim for consumer fraud on implications, unsupported by any representation, regarding something as complex as an FDA approval process does not, therefore, state a claim for a violation of state consumer-fraud statutes. Accordingly, several of the courts dismissing Lanham Act claims based on allegations of implied agency approval have also dismissed state-law consumer-fraud, unfair-competition, and deceptive-trade-practice causes of action based on the same allegations. *See, e.g.*, *Mediplan*, 425 F. Supp. 2d at 418, 421 ("The false advertising and unfair competition claims against all defendants based on the alleged implication of governmental approval of the importation of defendants' products into the United States . . . are dismissed. These rulings apply to the claims under both state and federal law."); *Ethex*, 228 F. Supp. 2d at 1058-59. *See also Avon*, 984 F. Supp. at 800 (with respect to EPA approval: dismissing New York consumer fraud claims for the same reasons as Lanham Act claims). This court should do the same.

B. Plaintiffs do not allege the elements of their warranty causes of action, only violations of the FDCA

Plaintiffs' express and implied warranty claims rest entirely on the allegation that Bayer was required to obtain separate FDA approvals for its combination aspirin and dietary supplement products, and that it was inappropriate for Bayer instead to rely on the FDA's prior review of aspirin and the dietary supplements in its products. Plaintiffs' claim for breach of express warranty is that "Defendant expressly warranted that Bayer Heart Advantage and Bayer Calcium were safe and effective," and that "[t]he Combination Aspirins do not conform to these express representations *because they have not been approved by the FDA* as safe and effective medications." Cmplt. ¶¶ 116-117 (emphasis added). Similarly, plaintiffs' implied warranty

claims are based on the allegation that "[d]efendant's representations and warranties were false, misleading, and inaccurate, in that the Combination Aspirins were not of merchantable quality *because they had not been approved by the FDA*." Cmplt. ¶ 130 (emphasis added).

But alleging that the FDA has not appropriately determined the safety and effectiveness of a product is not the same as alleging that the product is, in fact, not safe and effective. The latter – which plaintiffs do not allege as the basis for their warranty claims – would be required to state a claim for the express or implied warranty causes of action that plaintiffs bring. A breach of an alleged express warranty that a product is "safe and effective" would require that it not be so; implied warranty of merchantability causes of action similarly require the existence of some sort of defect. *See, e.g.*, *Am. Suzuki Motor Corp. v. Carney*, 37 Cal. App. 4th 1291, 1297-99 (Cal. App. 1995) (California law); *State Farm Fire & Casualty Co. v. Miller Electric Co.*, 562 N.E.2d 589, 595-96 (Ill. Ct. App. 1990) (Illinois law); *Adams v. Peter Tramontin Motor Sales, Inc.*, 42 N.J. Super. 313, 325 (N.J. App. Div. 1956) (New Jersey law); *Ryion v. Len-Co Lumber Corp.*, 152 A.D. 2d 978, 979 (N.Y. App. Div. 1989) (New York law).

Following this reasoning, the District Court of New Jersey in *Schering-Plough* dismissed a similar action based on "off-label" marketing (marketing a drug for purposes other than those for which it has received FDA approval) in violation of the FDCA. *Schering-Plough*, 2009 U.S. Dist. LEXIS 58900, at *6-7, *45-46. Seeking relief under the New Jersey Consumer Fraud Act, unjust enrichment, and other causes of action, the *Schering-Plough* plaintiffs had alleged various theories of economic injury based on the money they had paid for drugs for purposes that were not FDA-approved. But plaintiffs did not claim that the drugs did not actually work for those purposes, only that the FDA had not approved them, and that the manufacturer did not have sufficient evidence to substantiate claims of effectiveness (in this case, plaintiffs do not even

claim that Bayer did not have sufficient evidence to support the safety and effectiveness of Heart Advantage and Bayer Calcium). *Id.* at *45-46. Dismissing plaintiffs' complaint, the *Schering-Plough* court said: "there is a clear and decisive difference between allegations that actually contest the safety or effectiveness of the Subject Drugs and claims that merely recite violations of the FDCA, for which there is no private right of action." *Id.* at *47; *Eli Lilly*, 23 F. Supp. 2d at 479 (holding that allegations that a product has not met FDA's review standards is not the same as allegations that it is unsafe or ineffective). *See also Avon Prods.*, 984 F. Supp. at 797 (same, with EPA approval).

Here, plaintiffs' warranty claims are based entirely on an alleged lack of FDA review under an NDA process. If this states a claim, it is under the FDCA, not state warranty law. Plaintiffs' warranty claims should therefore be dismissed.

C. Plaintiffs' unjust-enrichment cause of action fails as a matter of law

Plaintiffs' unjust-enrichment claim should be dismissed for the same reasons as plaintiffs' other claims. Plaintiffs have not adequately alleged that Bayer's conduct was unfair, only that it violated the FDCA. *See supra* at 9-10. Conduct that is not unfair is also not unjust under any state's law. *See, e.g.*, *Schering-Plough*, 2009 U.S. Dist. LEXIS 58900, at *120-122; *In re Canon Cameras Litig.*, 237 F.R.D. 357, 359-60 (S.D.N.Y. 2006).

III. Plaintiffs' Claims Are Preempted

Plaintiffs' claims are based on the allegation that Bayer inappropriately relied on the preexisting regulatory status of aspirin and the supplements in its combination aspirin and dietary supplement products, instead of submitting NDAs for them as allegedly required by the FDCA. Such an allegation does not state a claim under any cause of action at issue in this litigation. Any attempt at state-law recovery based on such a claim, moreover, would be preempted.

The Southern District of California recently dismissed as preempted claims very similar to plaintiffs'. In *Perez v. Nidek*, plaintiffs had sought to recover for economic injuries based on their payment for treatment with laser equipment that had not received proper FDA approval. *Perez v. Nidek Co. Ltd*, 2009 U.S. Dist. LEXIS 78214, at *5. Specifically, they sought damages under the CLRA and the UCL based on defendant's use of an "adulterated" device under the FDCA, the failure to properly certify the devices under a related regulatory requirement, and the failure to inform patients that the devices used were not FDA-approved or properly certified. *Id.* at *20-21. The court found those claims preempted because the task of applying FDA requirements was more properly left to the FDA. *Id.* at *8, *19.

Addressing another very similar claim in *Anthony*, the Northern District of Illinois found that, had the state consumer-fraud statute applied to a claim based on alleged unfairness from marketing a product without proper FDA approval, such a claim would have been preempted. 2002 U.S. Dist. LEXIS 19445, at *8-9 ("Anthony's claim must fail because it is preempted by the FDCA . . . . Anthony's claim . . . is premised solely upon a violation of the FDCA – that defendant sold nutrition bars containing ingredients that the FDA had not approved. She does not allege that she was injured after consuming the bars."). The same analysis applies here.

State law actions are preempted when they stand as "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000) (citation omitted). *Buckman v. Plaintiffs' Legal Committee* is directly on point. There, a unanimous Supreme Court held that the FDCA preempted a state-law action based on a "fraud-on-the-FDA" theory. 531 U.S. at 348. The *Buckman* plaintiffs had argued that, "had the [allegedly fraudulent] representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* at 343. The Court

noted that the existence of the FDCA requirements formed a "critical element in [the plaintiffs'] case." *Id.* at 353. Because "state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives," the Court held such claims impliedly preempted. *Id*. at 350.

Similarly in this case, plaintiffs claim that, had Bayer not committed the alleged FDCA violation, they would not have purchased the product. And, as in *Buckman*, the alleged FDCA violations form a "critical element" in plaintiffs' case – "the state claim would not exist if the FDCA did not exist." *Riley v. Cordis*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) ("[A] private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA."). Like the plaintiffs in *Perez* and *Anthony*, plaintiffs' claims in this case rely on the existence of the FDCA. *Perez*, 2009 U.S. Dist. LEXIS 78214, at *18-22; *Anthony*, 2002 U.S. Dist. LEXIS 19445, at *8-9.

Like policing fraud on the FDA, ensuring compliance with an FDA approval process "is hardly 'a field which the States have traditionally occupied.'" *Buckman*, 531 U.S. at 347. As the *Buckman* court observed:

> The relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law. . . . Accordingly – and in contrast to situations implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety" – no presumption against preemption obtains in this case.

Id. at 347-48 (citation omitted).

Plaintiffs' action in this case focuses directly on the relationship between the FDA and the entities it regulates. Plaintiffs' asserted causes of action do not merely attempt to impose requirements that overlap to some extent with those imposed by the FDA; like *Buckman*, the wrongdoing they allege exists only by virtue of Bayer's relationship with the FDA.

The fundamental rationale of *Buckman* also applies. Both as to fraud-on-the-FDA and as to compliance with the FDCA's approval requirements, Congress has delegated to the FDA (through the Department of Health and Human Services) the authority to determine appropriate enforcement, including an express statutory provision for resolution of these and other types of enforcement matters, in the FDA's discretion, by "written notice or warning." 21 U.S.C. § 336 (2009). *See generally* 21 U.S.C. § 393 (2009); FDA, Staff Manual Guides § 1410.10 (2005).[9] The same agency – the FDA – is empowered to balance competing statutory objectives related to its own approval procedures. *Cf. Buckman*, 531 U.S. at 348. Accordingly, the Agency may choose from among a range of options to address drug-approval deficiencies, including issuing warning letters, obtaining consent decrees, and even engaging in criminal prosecutions. *See generally* FDA, The Enforcement Story, Ch. 3 (Fiscal Year 2008).[10] As in *Buckman*, "this flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349.

Also as in *Buckman*, state-law causes of action based on an alleged failure to obtain FDA approval "inevitably conflict with the FDA's responsibility to police" its own requirements. *Id.* at 350. "As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of the 50 States' [laws] will dramatically increase the burdens facing [regulated firms] – burdens not contemplated by Congress in enacting the FDCA." *Id.*

Claims based on failure to obtain FDA approval "would also cause [regulated firms] to fear that their [conduct], although deemed appropriate by the Agency, will later be judged

---

[9] This document is available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm.

[10] This document is available at: www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129812.pdf.

insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Agency neither wants nor needs, resulting in additional burdens on the FDA[] . . . ." *Id*. at 351.

Here, the FDA made a non-final determination that Bayer Calcium and Heart Advantage required approval under an NDA process. *Genendo*, 308 F. Supp. 2d at 885 (FDA warning letters do not constitute final agency action). But there is no requirement that the state-law causes of action plaintiffs propose be limited to circumstances in which the Agency has concluded that the products lack proper approval – and in fact, here, since the FDA has issued only non-final warning letters, any such requirement would not be met. The *Perez* court held California consumer fraud act claims that were based on an alleged lack of FDA-approval to be preempted despite the existence of FDA warning letters, noting that these letters do not constitute a "final" agency decision. *Perez*, 2009 U.S. Dist. LEXIS 78214, at *21.

Neither *Wyeth v. Levine* nor *Desiano v. Warner-Lambert* affects this analysis. *Wyeth v. Levine*, 129 S.Ct. 1187 (2009); *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006), *aff'd by an equally divided Court sub nom. Warner-Lambert v. Kent*, 128 S.Ct. 1168 (2008). Each involved an attempt by a physically injured party to recover by satisfying the elements of a traditional cause of action for personal injury, rather than an attempt to ground economic recovery on nothing more than an alleged failure to follow FDA procedures. In neither case was the entire claim based on an alleged failure to comply with a federal regulatory scheme – here, plaintiffs' claims, if allowed to proceed, would constitute an improper "state[] attempt to police" the FDA's approval requirements. *Desiano*, 467 F.3d at 94-95 (*Buckman* rule applies where there are "no freestanding allegations of wrongdoing apart from the defendants' purported failure to comply with FDA disclosure requirements").

Like the fraud-on-the-FDA claims at issue in *Buckman*, plaintiffs' claims here are based on, and cannot exist without, alleged FDCA violations, and interfere with the FDA's discretion over its own requirements, procedures, enforcement policies, and strategies. They are therefore preempted.

IV. Plaintiffs Have Not Alleged Cognizable Injury

Plaintiffs do not allege an injury sufficient to state a claim under any of the causes of action at issue in this litigation, or, indeed, to justify constitutional standing. First, plaintiffs have not alleged that Heart Advantage or Bayer Calcium harmed them, or that they were ineffective. Plaintiffs who use an effective product that does not harm them do not suffer any injury, and their claims must be dismissed. Second, even if plaintiffs had suffered injury, plaintiffs' theory of damage is legally untenable. Plaintiffs' theory is based on an allegation that Bayer's allegedly wrongful conduct enabled it to charge a premium price as compared to the price of low-dose aspirin uncombined with any dietary supplement. Price inflation theories are not cognizable under the causes of action plaintiffs have brought. Plaintiffs' particular theory, moreover, is too speculative to form the basis for relief, particularly as the price of uncombined low-dose aspirin, which does not contain calcium or phytosterols, and is the source of the only side-effects plaintiffs allege, is a meaningless comparison to the price of a product containing both aspirin and a supplement.

A. Where plaintiffs have used an effective product without harm, they have suffered no injury or loss

1. Individual causes of action require that a product was either ineffective or caused harm

Plaintiffs have not alleged an injury or loss necessary to recover under any cause of action where they took a medication they do not allege was ineffective or harmful to them. In *Whitson v. Bumbo*, the Northern District of California found the injury requirements of

California consumer-fraud statutes and warranty law unmet where a "product serves its purpose throughout its useful life." 2009 U.S. Dist. LEXIS 32282, at *22-24 (N.D. Cal. Apr. 15, 2009); *see also Am. Suzuki*, 37 Cal. App. 4th at 1298 (no claim under California warranty law where products "did what they were supposed to do for as long as they were supposed to do it") (citation and quotation omitted). The same analysis applies in New Jersey: "New Jersey courts have never allowed recovery based on a product that is and has been working normally." *Walus v. Pfizer*, 812 F. Supp. 41, 44 (D.N.J. 1993) (citations omitted); *Yost v. Gen. Motors Corp.*, 651 F. Supp. 656, 657 (D.N.J. 1986) (same, with warranty law). *See also In re Canon Cameras Litig.*, 237 F.R.D. at 359-60 (New York law); *Yu v. Int'l Bus. Mach. Corp.*, 314 Ill. App. 3d 892 (Ill. App. Dist. 2000) (Illinois law).

Even where, unlike here, plaintiffs have alleged that they continue to own a product that may yet malfunction in the future, courts have found that plaintiffs failed to allege a cognizable injury or loss where their complaint alleges merely a defect that has not manifested itself in their individual product. The Eighth Circuit recently affirmed dismissal of state consumer-fraud, warranty, and unjust-enrichment claims where plaintiffs sought to recover on the basis of their purchase of a defective drop-side crib that had harmed other children but had, thus far, worked normally for them. *O'Neil v. Simplicity Inc.*, 2009 U.S. App. LEXIS 16072, at *5 (8th Cir. July 22, 2009) ("It is not enough to allege that a product line contains a defect or that a product is at risk for manifesting this defect; rather, the plaintiffs must allege that their product actually exhibited the alleged defect."). Many other courts have done the same. *See, e.g.*, *Briehl v. Gen. Motors*, 172 F.3d 623, 626-29 (8th Cir. 1999) ("Where, as in this case, a product performs satisfactorily and never exhibits an alleged defect, no cause of action lies."); *In re Canon Cameras Litig.*, 237 F.R.D. at 359-60; *Yost*, 651 F. Supp. at 657; *In re Bridgestone/Firestone*,

Inc., Tires Prods. Liab. Litig., 288 F.3d 1012, 1017 (7th Cir. 2002). This Court need not go as far as these courts, however, to conclude that, where, as here, a plaintiff has used up a consumable product and has not alleged that it did not work or that it caused any harm, that plaintiff has failed to allege injury or loss sufficient to be the basis for a claim for relief.

2. A plaintiff who uses an effective product without harm lacks standing

Courts have also taken this principle a step further by holding that a plaintiff who receives an effective, non-harmful, product lacks constitutional standing. Under Fed. R. Civ. P. 12(b)(1), plaintiffs bear the burden of establishing the existence of constitutional standing, including the existence of a "concrete and particularized" "injury in fact" that is "fairly trace[able] to the challenged action of the Defendant." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (internal citations and quotation omitted).

In *Rivera v. Wyeth*, the Fifth Circuit held that plaintiffs who alleged violations of a state consumer-fraud act, breach of implied warranty, and unjust enrichment based on the defendants' alleged failure to disclose side effects of a pain reliever lacked constitutional standing to sue where they "[did] *not* claim [the drug] caused them physical or emotional injury, was ineffective as a pain killer, or has any future health consequence to users." 283 F. 3d 315, 319 (5th Cir. 2002). There, the plaintiffs' claim of economic injury failed to establish standing because "Rivera paid for an effective pain killer, and she received just that – the benefit of her bargain." *Id.* at 320.

Similarly, the U.S. District Court for the District of Columbia found that plaintiffs lacked standing to sue because they did not allege that the product at issue "failed to provide them effective pain relief or that they suffered any adverse consequences from their use" of it. *Williams v. Purdue Pharm. Co.*, 297 F. Supp. 2d 171, 175-1176 (D.D.C. 2003). The court reached that conclusion despite plaintiffs' claims that they had suffered "economic damages

because they purchased a pain-relief drug whose price was unjustifiably inflated due to Defendants' misrepresentations." *Id.* at 175.

A plaintiff also lacked standing to bring a proposed consumer-fraud, warranty, and unjust-enrichment class action based on her purchase of a baby seat that allegedly lacked proper warnings, when no child had been harmed by using her seat. *Whitson*, 2009 U.S. Dist. LEXIS 32282, at *10-19.

3. Plaintiffs have not alleged that they were harmed, or that these products were actually ineffective

Like the plaintiffs in the cases just described, the plaintiffs here have not alleged that the products they used manifested any defect as to them. Plaintiffs have not alleged that they were harmed, or that these products were actually ineffective at reducing their risk of heart disease, heart attacks, strokes, or osteoporosis. Allegations that a product's safety or effectiveness has not been reviewed by the FDA are not the same as allegations that it is actually unsafe or ineffective. *See supra* at 16-17.

Plaintiffs do not allege that they suffered any side effects from the use of Heart Advantage or Bayer Calcium without physician supervision. *See* Pretrial Order #7 (memorializing the parties' agreement that any complaints transferred into this MDL that "relate to claims for physical personal injury" receive different treatment). They have not even alleged whether they consulted their physicians about use of these products, as they acknowledge the product packaging recommends. Cmplt. ¶ 40 (quoting the packaging for Bayer Calcium: "Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.").

Nor does plaintiffs' allegation of a dosage conflict – which relates only to Heart Advantage – allege that the product was ineffective in reducing their risks of heart disease, heart attacks, and strokes. Plaintiffs claim that:

> [t]o provide any putative benefit, the dosage of phytosterols necessary to be consumed equals 2 tablets of Bayer Heart Advantage. By contrast, a daily aspirin regimen consists of a single 81 mg tablet. Thus, a person cannot simultaneously ingest the recommended dose of aspirin while obtaining any purported cholesterol lowering effects of phytosterols.

Cmplt. ¶ 67. The named plaintiffs do not allege whether they took one or two capsules each day. If they took two duo-caps daily, they face the further problem that they have not alleged that taking two 81 mg duo-caps (162 mg) of aspirin daily is ineffective. This could be because 162 mg is within the FDA-recommended daily dose.[11] If, notwithstanding the fact that the packaging clearly states that the FDA-recommended dosage of phytosterols requires two duo-caps daily, a named plaintiff took only one cap, the Complaint is further deficient in not having alleged that 400 mg of phytosterols daily fails to provide whatever benefit the product promised at that dose. *See* Cmplt. ¶ 64 (quoting packaging as recommending "400 mg per serving of free phytosterols, eaten twice a day with meals for a daily total intake of at least 800 mg"). The only source plaintiffs provide for the "dose of phytosterols necessary to be consumed" is based on the FDA-approved unqualified health claim. Cmplt. ¶ 64 & 67 (citing 21 C.F.R. § 101.83). Where "the only standard of proof of efficacy [to which] Plaintiffs point [] is FDA approval," they have not alleged actual inefficacy. *Amgen II*, 2009 U.S. Dist. LEXIS 58697, at *19-20.

In sum, plaintiffs fail to claim that the products they took were either ineffective, or harmed them, and so fail to state a claim under any cause of action.

---

[11] The FDA describes the recommended daily dose of aspirin for "prevention of recurrent [heart attack]," among other cardio-protective uses, as 75-325 mg. 21 C.F.R. § 343.80 (2009).

B. Even if they had been injured, plaintiffs' damage theory is legally insufficient

Even if plaintiffs were permitted to recover in the absence of an injury, their theory of damage is legally insufficient. Plaintiffs' stated damages theory is that Bayer's alleged misconduct allowed it to "charge a premium . . . over the costs of approved OTC aspirins." Cmplt. ¶ 81. In an effort to support this price-impact theory, plaintiffs compare the price of Heart Advantage and Bayer Calcium to those of particular brands of uncombined low-dose aspirin. *Id.* ¶¶ 82-83. Concluding, they seek a "full refund for their purchases." *Id.* ¶ 84.

It is difficult even to understand this theory of injury or to conceive how it satisfies federal pleading standards, which require claims to be plausible and non-speculative. What justifies a full refund if the theory of injury is based on a price premium? And how does the price of low-dose aspirin uncombined with any other product demonstrate that the prices of Heart Advantage and Bayer Calcium, which were combination products, were improperly inflated? Low-dose aspirin alone is not a plausible equally-effective alternative to Heart Advantage or Bayer Calcium, because it does not include either phytosterols or calcium, ingredients whose benefits plaintiffs do not dispute.

Moreover, and significantly, "price-impact" theories of injury are not legally cognizable outside the context of securities fraud. The New Jersey Supreme Court has held, for example, that the NJCFA's ascertainable-loss requirements may not be met by claims of price impact. *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 192 N.J. 372, 392 (N.J. 2007) ("[T]o the extent that plaintiff seeks to prove only that the price charged for Vioxx was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail."); *see also New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178 (N.J. Sup. Ct. 2003) (denying relief on a claim under the NJCFA based on a

theory that the alleged wrongful conduct "caused the prices to rise both for the ones that are effective, and for these, allegedly ineffective, products as well"). The *Schering-Plough* court has recently relied on the New Jersey Supreme Court's ruling to find price-impact claims related to off-label marketing insufficient to state a claim under the NJCFA. *Schering-Plough*, 2009 U.S. Dist. LEXIS 58900, at *110-12.

Nor does anything in plaintiffs' theory provide a plausible explanation for why Bayer's alleged misconduct would cause its products to have an inflated price. As another court has explained, "price-impact" arguments also do not make sense in contexts like this one:

> The suggestion that consumers might be inclined to take a drug with certain side effects if they could pay less for it, or that drugs with certain side effects should cost less, defies both reality and common sense. It is also out of place in this lawsuit, where it is clear that neither plaintiff suffered any adverse effects.

Heindel, 381 F. Supp. 2d at 380; *see also McLaughlin*, 522 F.3d at 229 ("Defendants' misrepresentations could in no way have reduced the value of the cigarettes that plaintiffs actually purchased; they simply could have induced plaintiffs to buy Lights instead of full-flavored cigarettes."). In this case, the claim is even more nonsensical, because plaintiffs base their damages theory on the price of low-dose aspirin, which is the source of the only potential side effects they allege. Cmplt. ¶ 4.

Any attempt to base recovery on a theory of price inflation with respect to these products, moreover, is too speculative, and so must fail. Even where plaintiffs alleged that the product they purchased was not as effective as had been promised, the Second Circuit dismissed as too speculative a "price-impact" claim of injury. The court noted in particular the "number of exogenous variables" bearing on the price of consumer goods. *McLaughlin*, 522 F.3d at 230 (interpreting RICO requirements); *see also Parker*, 2008 U.S. Dist. LEXIS 2570, at *8 ("Courts [interpreting the NJCFA] expect a plaintiff to 'establish [the amount of loss] with reasonable

certainty.'") (citation omitted). The same is true here. There are a host of reasons why a 500-tablet bottle of Rite-Aid brand aspirin, which does not contain phytosterols, might be less expensive per tablet than a 60 duo-cap bottle of Bayer Heart Advantage. Those reasons have nothing at all to do with the claims asserted here – the value of the Bayer brand and the impact of quantity pricing, to name just two. *See* Ex. I (screenshot of webpage cited at Cmplt. ¶ 82 n.4).

Plaintiffs have therefore stated no legally adequate basis for a finding for injury, and no legally adequate basis for recovery. Their claims should be dismissed.

Conclusion

Bayer respectfully asks this Court to dismiss the entirety of Plaintiffs' action under Fed. R. Civ. P. 8(a), 9(b), 12(b)(1) and 12(b)(6).

Dated: September 15, 2009

/s/

Adam L. Hoeflich
Carolyn J. Frantz
Georgia N. Alexakis
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 W. Hubbard St., Suite 300
Chicago, IL 60654
Tel: (312) 494-4400
Fax: (312) 494-4440

Scott M. Zimmerman
HEIDELL, PITTONI, MURPHY & BACH, LLP
99 Park Avenue
New York, NY 10016
Tel: (212) 286-8585
Fax: (212) 490-8966

Timothy S. Coon
ECKERT SEAMANS CHERIN & MELLOTT, LLC
600 Grant Street, 44th Flr.
Pittsburgh, PA 15219
Tel: (412) 566-6000
Fax: (412) 566-6099

Counsel for Defendant Bayer HealthCare LLC