[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 18-11778

D.C. Docket No. 1:17-cv-21562-DPG

JOSHUA DEBERNARDIS,
on behalf of themselves and all others similarly situated,
CHRISTINA DAMORE,
on behalf of themselves and all others similarly situated,

Plaintiffs - Appellants,

versus

IQ FORMULATIONS, LLC,
a Florida limited liability company,
EUROPA SPORTS PRODUCTS, INC.,

Defendants - Appellees.

Appeal from the United States District Court
for the Southern District of Florida

(November 14, 2019)

Before WILSON, JILL PRYOR, and SUTTON,* Circuit Judges.

JILL PRYOR, Circuit Judge:

Plaintiffs Joshua Debernardis and Christina Damore appeal the district court's dismissal of their claims against defendants IQ Formulations, LLC and Europa Sports Products, Inc. The plaintiffs argue that the district court erred in concluding they suffered no injury in fact and thus lacked standing. Their allegations that they purchased from the defendants dietary supplements that the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*, banned from sale are sufficient, they contend, to establish that they suffered an injury in fact. After careful consideration and with the benefit of oral argument, we conclude that the plaintiffs plausibly alleged that they suffered an economic loss when they purchased supplements that were worthless because the FDCA prohibited sale of the supplements. Because the plaintiffs have standing to pursue their claims, we vacate and remand.

I. FEDERAL REGULATION OF DIETARY SUPPLEMENTS

The plaintiffs' theory of standing rests on the premise that federal law prohibited the defendants from selling the supplements the plaintiffs purchased.

* Honorable Jeffrey S. Sutton, United States Circuit Judge for the Sixth Circuit, sitting by designation.

To explain why the supplements could not lawfully be sold, we begin with a brief overview of the law regulating the sale of dietary supplements.

The FDCA authorizes the Food and Drug Administration ("FDA") to regulate a variety of products—including food, drugs, and cosmetics—to "protect the public health." 21 U.S.C. § 393(b)(2); *see POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014) ("The FDCA statutory regime is designed primarily to protect the health and safety of the public at large."); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). In 1994, Congress amended the FDCA, through the Dietary Supplement Health and Education Act ("DSHEA"), to set guidelines governing the FDA's regulation of dietary supplements.[1] *See* Pub. L. No. 103-417, 108 Stat. 4325 (1994). Congress intended the DSHEA to "protect[] the right of access of consumers to *safe* dietary supplements . . . to promote wellness." *Id.* § 2(15)(A) (emphasis added). And Congress expressly imposed a duty on the FDA to "take swift action" to keep "unsafe or adulterated" dietary supplements off the market. *Id.* § 2(13).

[1] A "dietary supplement" is a product "intended to supplement the diet" that contains one of the following ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance used to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, extract, or combination of any such ingredient. 21 U.S.C. § 321(ff)(1). The product also must be intended for ingestion in tablet, capsule, powder, soft gel, gelcap, or liquid form or, if not in such a form, the product must not be represented as "conventional food" or the "sole item of a meal or . . . diet." *See id.* §§ 321(ff)(2), 350(c)(1)(B).

The sale of "adulterated" dietary supplements is expressly banned by the FDCA and the DSHEA. *See* 21 U.S.C. §§ 331(a) (prohibiting the sale of adulterated foods), 342(f) (setting forth when a dietary supplement is deemed an adulterated food). A supplement is adulterated if: (1) it "presents a significant or unreasonable risk of illness or injury" when taken as directed by its label; (2) it contains a "new dietary ingredient"; (3) the Secretary of Health and Human Services declares it to "pose an imminent hazard to public health or safety"; or (4) it contains a poisonous substance that renders it injurious to health. *See id.* § 342(f)(1).

The plaintiffs in this case alleged that the dietary supplements they purchased were adulterated because they contained "new dietary ingredients." A "new dietary ingredient" is one that was not marketed in the United States before October 15, 1994. *See id.* §§ 342(f)(1)(B); 350b.[2] Congress created a presumption that supplements containing new dietary ingredients generally should not be sold. *See id.* §§ 342(f)(1)(B); 350b. The presumption reflected Congress's determination that when a dietary ingredient had no history of use in the United States, there was "inadequate information to provide reasonable assurance that

[2] With this definition, Congress effectively grandfathered in any dietary supplements that were on the market when the DSHEA was enacted in October 1994. *See* DSHEA, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (reflecting that the DSHEA was enacted on October 25, 1994).

[the] ingredient does not present a significant or unreasonable risk of illness or injury." *Id.* § 342(f)(1)(B).

The presumption that a supplement containing a new dietary ingredient is unsafe may be overcome with sufficient proof. There are two ways to establish that a supplement containing a new dietary ingredient is safe enough to be sold. Under the first exception, a supplement containing a new dietary ingredient may be sold if it contains "only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered." *Id.* § 350b(a)(1). Under the second exception, such a supplement may be sold if there is "a history of use or other evidence of safety establishing" that when the dietary ingredient is used as recommended or suggested by its labeling it is "reasonably [] expected to be safe" *and* at least 75 days before beginning to sell the supplement, the manufacturer or distributor provided the FDA with the information that was the basis for the conclusion that the supplement is reasonably expected to be safe. *Id.* § 350b(a)(2).

Viewed as a whole, the FDCA, as amended by the DSHEA, demonstrates that Congress intended to bar the sale of dietary supplements that included ingredients posing too great a risk to public health. With this background about Congress's regulation of dietary supplements in mind, we now discuss the plaintiffs' allegations to determine whether standing has been established.

II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

This case arises out of the plaintiffs' purchase of the dietary supplement Metabolic Nutrition Synedrex ("Synedrex").[3] Since 2013, IQ has manufactured and sold Synedrex and another dietary supplement, Metabolic Nutrition E.S.P. (together, the "supplements"). Marketed to consumers as energy stimulants, both supplements contain the ingredient MethylPentane Citrate, which is more commonly known as "DMBA."

Consumers could purchase the supplements directly from IQ through its website or from Europa, IQ's exclusive distributor for the supplements. In addition to selling the supplements directly to consumers, Europa sold them to retailers throughout the United States, including Walgreens and NaturalBodyInc.com, which in turn sold the supplements in their retail stores and/or online.

Each plaintiff purchased and used Synedrex. Debernardis purchased Synedrex from Walgreens.com in September 2015. Damore purchased Synedrex from websites including NaturalBodyInc.com and eBay.com in June 2015, February 2016, and August 2016.

[3] In reviewing whether the district court erroneously dismissed the complaint for lack of standing, we look to the facts as they are alleged in the plaintiffs' complaint. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Church v. City of Huntsville*, 30 F.3d 1332, 1336 (11th Cir. 1994).

After purchasing Synedrex, the plaintiffs sued IQ and Europa in federal court, bringing a putative class action. They sought to represent three potential classes: (1) both plaintiffs sought to represent a class of all persons in the United States who purchased the supplements, (2) Debernardis sought to represent a class of all persons in Illinois who purchased the supplements, and (3) Damore sought to represent a class of all persons in New York who purchased the supplements. The plaintiffs brought claims against IQ under the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201 *et seq.*; against both defendants under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq*; against both defendants under New York General Business Law § 349, *et seq*; and against both defendants for common law fraud and unjust enrichment. As the basis for all the claims, the plaintiffs alleged that the defendants had engaged in unlawful, deceptive, and unjust conduct when they sold the supplements and failed to disclose that sale of the supplements was illegal in the United States.

According to the complaint, the FDCA prohibited the sale of the supplements because the supplements were "adulterated" and unsafe for human consumption. Specifically, DMBA, one of the ingredients in the supplements, qualified as a "new dietary ingredient." Because the supplements contained a new dietary ingredient, the plaintiffs alleged, they were adulterated for purposes of the FDCA and presumed to be unsafe for human consumption unless there were

sufficient indicia that the new dietary ingredient was safe. Here, neither party has alleged or argued that the first exception—that the supplements contained only dietary ingredients that had been present in the food supply—applied. And the plaintiffs alleged that the supplements did not meet the second exception because the defendants failed to provide the FDA with premarket information showing that DMBA had a history of harmless use or other evidence of its safety.

To further support their allegations that the FDCA banned the sale of the supplements, the plaintiffs alleged facts showing that the FDA had determined that DMBA was a new dietary ingredient and that other dietary supplements containing DMBA were adulterated. In April 2015—before the plaintiffs purchased their supplements—the FDA sent warning letters to 14 companies that sold supplements containing DMBA. The FDA warned each company that its product was adulterated because DMBA qualified as a new dietary ingredient and the company had failed to provide the FDA with the appropriate premarket notice demonstrating DMBA's safety.

The complaint further alleged that each plaintiff was harmed as a result of purchasing the supplements. Each plaintiff suffered an injury by purchasing supplements that could not be "legally sold or possessed" and had "no economic or legal value." Doc. 1 at ¶ 50. Because the supplements had no economic value, each plaintiff paid an "unwarranted amount" to purchase the supplements. *Id.*

Both defendants moved to dismiss the complaint, raising, among other arguments, that the plaintiffs lacked standing because their complaint failed to establish that they suffered an injury in fact. The defendants argued that the plaintiffs suffered no injury because the plaintiffs received the benefit of the bargain they made when purchasing the supplements. In particular, the defendants pointed out the lack of any allegation that the supplements failed to work as intended or that the plaintiffs paid a premium for the supplements. In response, the plaintiffs argued that they adequately alleged an economic injury by alleging that the supplements they purchased were worthless because the FDCA prohibited their sale.

The district court granted the defendants' motions to dismiss, concluding that the plaintiffs lacked standing because they failed to allege an injury in fact. The court acknowledged that an economic harm would qualify as a concrete injury but determined that the plaintiffs alleged no economic harm. The court explained that even if the supplements could not legally be sold, the plaintiffs received the benefit of their bargain because there was no allegation that the supplements failed to perform as advertised, that the supplements caused any adverse health effects, or that the plaintiffs paid a premium for the supplements. After concluding that the plaintiffs suffered no injury in fact and lacked standing, the court did not address

the defendants' other arguments about why the claims should be dismissed. The plaintiffs appeal the dismissal of their claims for lack of standing.

III. STANDARD OF REVIEW

Whether the plaintiffs have standing to bring suit is a threshold jurisdictional issue subject to *de novo* review. *London v. Wal-Mart Stores, Inc.*, 340 F.3d 1246, 1251 (11th Cir. 2003).

IV. ANALYSIS

The Constitution limits the power of the judiciary to "Cases" and "Controversies." U.S. Const. art. III, § 2. To satisfy the case-or-controversy requirement, a plaintiff must have standing to sue. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The standing doctrine has "developed in our case law to ensure that federal courts do not exceed their authority as it has been traditionally understood." *Id.* The doctrine "limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Id.*

To satisfy the standing requirement, a "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Id.* As the parties invoking federal court jurisdiction, the plaintiffs bear the burden of establishing these elements. *Id.* "Where, as here, a case is at the pleading stage,

the plaintiff must clearly allege facts demonstrating each element." *Id.* (alteration adopted) (internal quotation marks omitted).

The primary standing issue in this appeal is whether the plaintiffs sufficiently alleged that they suffered an injury in fact. Europa also raises a second, separate standing issue: whether the plaintiffs' allegations were sufficient to establish that their injuries were fairly traceable to Europa's conduct. We address both arguments below.

A. The Plaintiffs Alleged Sufficient Facts to Establish that Each Suffered an Injury in Fact.

We begin with the question of whether the plaintiffs' allegations were sufficient to establish that they suffered an injury in fact. To establish an injury in fact, a plaintiff must allege that he suffered "'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan v. Defenders of the Wildlife*, 504 U.S. 555, 560 (1992)). For an injury to be concrete, it "must be *de facto*; that is, it must actually exist." *Id.* (internal quotation marks omitted). The Supreme Court has explained that the injury must be "real, and not abstract." *Id.* (internal quotation marks omitted). In many cases, the question of whether the plaintiff "has a cognizable injury sufficient to confer standing is closely bound up with the question of whether and how the law will grant him relief." *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 591 (8th Cir. 2009). Yet

we must "not . . . conflate Article III's requirement of injury in fact with a plaintiff's potential causes of action, for the concepts are not coextensive." *Id.*

In this case, the plaintiffs argue that they experienced a concrete injury because they incurred an economic loss when they purchased the supplements. Certainly, an economic injury qualifies as a concrete injury. *See Clinton v. New York*, 524 U.S. 417, 432-33 (1998); *MSPA Claims 1, LLC v. Tenet Fla., Inc.*, 918 F.3d 1312, 1318 (11th Cir. 2019) (explaining that an economic injury is the "epitome" of a concrete injury). A person experiences an economic injury when, as a result of a deceptive act or an unfair practice, he is deprived of the benefit of his bargain. *See Carriuolo v. Gen. Motors Co.*, 823 F.3d 977, 986-87 (11th Cir. 2016) (holding that class members bringing Florida Deceptive and Unfair Trade Practices Act claims were denied the benefit of their bargain and thus injured when they purchased vehicles that were represented as having three perfect safety ratings but actually had no safety ratings). A plaintiff's damages under a benefit of the bargain theory are calculated based on "the difference in the market value of the product or service in the condition in which it was delivered and its market value in the condition in which it should have been delivered according to the contract of the parties." *Rollins, Inc. v. Heller*, 454 So. 2d 580, 585 (Fla. Dist. Ct. App. 1984)

(internal quotation marks omitted).[4] Ordinarily, when a plaintiff purchases a product with a defect, the product retains some value, meaning her benefit-of-the-bargain damages are less than the entire purchase price of the product. *See id.*

But "[a] notable exception" to this general rule applies when the "product is rendered valueless as a result of a defect." *Id.* When a plaintiff receives a worthless product, his benefit of the bargain damages will be equal to the entire purchase price of the product. *Id.* The benefit-of-the-bargain theory thus recognizes that a purchaser who acquires a product with significant defects may effectively receive nothing of value. *See id.*

The plaintiffs, relying on a benefit-of-the-bargain theory, argue that they have standing to press their claims because they experienced an economic loss when they paid money to purchase the supplements and in return received adulterated supplements that could not lawfully be sold and thus were worthless. To evaluate the plaintiffs' benefit-of-the-bargain theory, we must consider two questions: (1) does a purchaser acquire a worthless product when he purchases an adulterated supplement? And, if so, (2) did the plaintiffs adequately allege that the supplements they purchased were adulterated?

[4] In discussing the nature of an injury under a benefit of the bargain theory, we rely on Florida cases because the parties looked to Florida law and thus waived any argument that we should look to some other state's law or that Florida law was inconsistent with general benefit-of-the-bargain contract principles.

Beginning with the first question, we accept, at least at the motion to dismiss stage, that a dietary supplement that is deemed adulterated and cannot lawfully be sold has no value. Through the FDCA, as amended by the DSHEA, Congress banned the sale of adulterated dietary supplements because of its concern that such substances could not safely be ingested. *See* 21 U.S.C. §§ 331(a), 342(f)(1)(B), 393(b)(2). A person who purchased an adulterated dietary supplement thus received a product that Congress judged insufficiently safe for human ingestion. Given Congress's judgment, we conclude that the purchaser of such a supplement received a defective product that had no value. This conclusion is consistent with the well-established benefit-of-the-bargain theory of contract damages, which recognizes that some defects so fundamentally affect the intended use of a product as to render it valueless. *See Rollins*, 454 So. 2d at 585.

Turning to the second question, we conclude that the complaint plausibly alleged that the supplements the plaintiffs purchased were adulterated. According to the complaint, the supplements contained DMBA.[5] The complaint further alleged that DMBA was not marketed in the U.S. before 1994, and therefore it qualified as a new dietary ingredient.[6] Because the supplements contained a new

[5] The defendants argue that MethylPentane Citrate, the relevant ingredient in the supplements, is not the same as DMBA. But at the motion to dismiss stage, we must accept as true the plaintiffs' allegation that the supplements contained DMBA.

[6] Other allegations in the complaint establish the plausibility of the plaintiffs' allegation that DMBA is a new dietary ingredient. For example, before the plaintiffs purchased the

dietary ingredient, they were presumed to be adulterated. 21 U.S.C. §§ 342(f), 350b. And accepting the complaint's allegations as true, this presumption was not overcome. Neither party contends that the supplements contained only dietary ingredients that were present in the food supply. *See* 21 U.S.C. § 350b(a)(1). And the complaint alleged that before selling the supplements, neither IQ nor Europa provided any notice to the FDA showing that DMBA had a history of harmless use in food products or supplements or containing other evidence of DMBA's safety. Therefore, the plaintiffs adequately alleged that the supplements that they purchased were adulterated, meaning the FDCA banned their sale.

The district court held, and the defendants argue, that the plaintiffs' allegations were insufficient to establish standing because the complaint included no allegation that the supplements failed to perform as advertised or were purchased at a premium due to a misrepresentation about the product. To support this argument, the defendants cite a string of cases holding that plaintiffs had standing when they alleged that a product failed to perform as advertised or was

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supplements, the FDA had warned more than a dozen other companies that sold products containing DMBA that their products were adulterated because they contained a new dietary ingredient.

At oral argument, the defendants argued that these warning letters carried little significance because they were sent *after* the plaintiffs purchased the products. But the complaint alleged that the FDA sent the warning letters about DMBA on April 28, 2015 and that Debernardis purchased supplements in September 2015 and Damore purchased supplements in June 2015, February 2016, and August 2016. We need not decide and express no opinion whether the warning letters would be relevant if they were sent after the plaintiffs made their purchases.

purchased at a premium.[7] *See, e.g.*, *James v. Yamaha Motor Corp.*, No. 15-23750, 2016 WL 3083378 (S.D. Fla. May 31, 2016) (concluding that boat purchasers alleged a financial injury in the form of diminution of value by alleging that they purchased boats advertised as having "fully operational, safe, and reliable motors" but received boats with engines subject to premature failure); *Marty v. Anheuser-Busch Cos.*, 43 F. Supp. 3d 1333, 1352 (S.D. Fla. 2014) (concluding that plaintiffs adequately alleged that they suffered an economic harm when they paid a premium to purchase imported beer but received beer that was brewed domestically). But none of the defendants' cases involved allegations that the plaintiff had acquired a product that could not lawfully be sold. These cases found standing where the products did not work as advertised or where the plaintiffs had paid a premium—meaning these allegations were *sufficient* to establish standing—but they did not hold that such allegations were *necessary* to establish standing.

In contrast, our conclusion—that the plaintiffs have standing because they allegedly experienced an economic loss when they purchased a product that the FDCA banned from sale because it was presumptively unsafe—is consistent with

[7] The district court and defendants acknowledge that a plaintiff also has standing if she alleges that she was physically injured by the product. Of course, physical injuries are distinct from economic injuries. There is no requirement that a plaintiff have experienced physical harm to have an economic injury. *See Adinolfe v. United Techs. Corp.*, 768 F.3d 1161, 1172 (11th Cir. 2014) (recognizing that economic harm and physical injury are distinct types of injury that can give rise to standing). So the fact that the plaintiffs experienced no physical injury does not mean that they experienced no economic injury.

the only decision from another circuit to have addressed standing in this context. The Ninth Circuit, albeit in an unpublished opinion, held that a consumer in a similar situation adequately alleged that she suffered an injury in fact. *See Franz v. Beiersdorf, Inc.*, 745 F. App'x 47 (9th Cir. 2018) (unpublished). In *Franz*, a consumer purchased a skin lotion that was advertised as improving skin firmness. *Id.* at 48. She sued the manufacturer under California's unfair competition law, claiming that she was injured by purchasing a lotion that qualified as a "drug" under the FDCA but had not been approved by the FDA. *Id.* at 48-49. After the district court dismissed the complaint for lack of standing, the Ninth Circuit reversed, holding that the consumer had standing. *Id.* The court explained that the consumer suffered an injury in fact when she allegedly spent money to purchase a product that "should not have been sold" because it was illegal to sell the product. *Id.* at 49. Like the plaintiff in *Franz*, here the plaintiffs established an injury in fact for standing purposes by alleging that they purchased such a product.

In addition, at least one other circuit has recognized that under a benefit-of-the-bargain theory an economic injury occurs when the purchaser acquires a worthless product, even if there is no indication that she was physically harmed by the product, the product failed to work as intended, or she paid a premium for the product. *See In re Aqua Dots Products Liability Litig.*, 654 F.3d 748 (7th Cir. 2011). In *Aqua Dots*, the Seventh Circuit considered whether parents who

purchased a defective toy had standing to sue even though their children were not injured by the toy's defect. The toy consisted of small beads that could be fused together with an adhesive to create designs. *Id.* at 749-50. Some of the toys were manufactured using a substitute adhesive, which when swallowed metabolized into gamma-hydroxybutyric acid, commonly known as the "date rape" drug. *Id.* at 749. Some children were injured after playing with the toy when they swallowed the beads and ingested the drug. *Id.* at 749-50. A group of parents whose children were not injured sued the manufacturer, distributors, and retailers of the toy. *Id.* at 750. After the district court refused to certify a class, the parents brought an interlocutory appeal to the Seventh Circuit. *Id.*

The Seventh Circuit addressed as a threshold matter whether the parents had standing. The court concluded that the parents had standing because they experienced a loss when "they paid more for the toys than they would have, had they known the risks the beads posed to children." *Id.* at 751. Because the Seventh Circuit found standing where the parents sought a refund of the entire purchase price, the court necessarily accepted the parents' theory that a toy that could poison their children had no value. *See id.* at 750. The court expressly rejected the argument that the parents lacked standing because their children had not been physically injured. *Id.* at 750-51. Just like the parents in *Aqua Dots*, the

plaintiffs in this case alleged that they experienced an economic injury when they paid to purchase an unsafe and therefore worthless product.

The defendants try to distinguish *Aqua Dots* by arguing that the Seventh Circuit concluded there was standing because the parents alleged that they paid a premium to purchase the toys. We disagree with this characterization of the Seventh Circuit's decision, which does not indicate that the parents alleged they paid a premium to purchase this particular brand as compared to similar toys. The parents in *Aqua Dots* instead relied on a different theory, alleging that they paid more for the toy than they would have if they had known about the risk that it would poison children (in which case it would have been worthless to them). *See id.* at 750-51.

We acknowledge that a district court reached the opposite result in a dietary supplement case. *See Hubert v. Gen. Nutrition Corp.*, No. 15-cv-1391, 2017 WL 3971912 (W.D. Penn. Sept. 8, 2017). The plaintiffs in *Hubert* purchased nutritional supplements containing the ingredients picamilon, BMPEA, or acadia rigidula. *Id.* at *1. They sued the retailer who sold the supplements, alleging that they would not have purchased the supplements if they had known about the dangers of ingesting picamilon, BMPEA, and acadia rigidula or if they had known that FDCA banned the sale of products with these ingredients. *See id.* at *7 (explaining that the plaintiffs alleged they would not have purchased the

supplements if the seller had disclosed that they "contained mislabeled ingredients which supposedly pose serious health risks or were unlawful"). The district court concluded that the plaintiffs lacked standing because they failed to allege an injury in fact. The court explained that the plaintiffs had not been deprived of the benefit of the bargain because they consumed the supplements and alleged no adverse health consequences nor that the products failed to work for their intended purpose or to deliver the promised benefits. *Id.* at *8.

The district court in *Hubert* acknowledged the plaintiffs' allegations that they were deprived of the benefit of the bargain when they purchased supplements that could not lawfully be sold under the FDCA, but it failed to analyze whether these allegations established that the plaintiffs purchased a worthless product and thus suffered an economic injury. *See id.* at *7-9. Given the court's failure to grapple with the plaintiff's argument that the products were worthless because they could not lawfully be sold, we are unpersuaded by *Hubert*.

The defendants contend our decision will mean that any consumer who purchased a product that could not legally be sold for any reason will have acquired a worthless product and thus have standing to sue. But we are not deciding today whether a consumer who alleges he purchased a product that could not legally be sold under a different statutory scheme acquired a worthless product. We caution that our decision is limited to the specific facts alleged in this case—

that the plaintiffs purchased dietary supplements that Congress, through the FDCA and the DSHEA, had banned from sale with the purpose of preventing consumers from ingesting an unsafe product.[8]

To sum up, Congress through the FDCA and the DSHEA banned adulterated supplements to protect consumers from ingesting products that Congress judged to be insufficiently safe. The complaint's allegations establish that the plaintiffs purchased adulterated dietary supplements that they would not have purchased had they known that sale of the supplements was banned. Because the plaintiffs were deprived of the entire benefit of their bargain, we conclude they adequately alleged that they experienced economic loss.

B. The Plaintiffs Alleged Sufficient Facts to Show That Their Injuries Are Fairly Traceable to Europa.

We now consider Europa's argument that the plaintiffs lack standing because as alleged, their injuries were not fairly traceable to Europa's conduct.[9]

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[8] Nor are we addressing whether a plaintiff would have standing if she allegedly purchased a product that lawfully could be sold but came with inadequate warnings, *see In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liability Litig.*, 903 F.3d 278, 281-82 (3d Cir. 2018), or a product that was lawfully sold at the time of purchase but whose sale later was prohibited, *see O'Neil v. Simplicity, Inc.*, 574 F.3d 501, 504 (8th Cir. 2009) (holding that grandparents were not deprived of the benefit of their bargain when they purchased a drop-side crib but the crib later was subject to a recall by its manufacturer and the Consumer Product Safety Commission warned consumers not to use the crib).

[9] Europa raised this argument for the first time at oral argument. We nonetheless consider the argument because standing is "a threshold jurisdictional question which must be addressed." *AT&T Mobility, LLC v. NASCAR*, 494 F.3d 1356, 1359 (11th Cir. 2007) (internal quotation marks omitted).

To establish standing, a plaintiff must allege that her injury is "fairly traceable to the challenged conduct of the defendant." *Spokeo*, 136 S. Ct. at 1547. Under this requirement, the "line of causation" between the alleged conduct and the injury must not be "too attenuated." *Allen v. Wright*, 468 U.S. 737, 752 (1984), *abrogated on other grounds by Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014).

Europa argues that the line of causation is too attenuated because the plaintiffs never directly alleged that it distributed any of the supplements they purchased. We conclude that the plaintiffs' economic losses were fairly traceable to Europa's conduct because their factual allegations support an inference that Europa distributed the supplements each plaintiff purchased. The complaint alleged that only two entities supplied the supplements to consumers: IQ and Europa. IQ, the manufacturer, never distributed supplements to retailers, although it did sell supplements directly to consumers through its website. IQ relied on Europa to deliver its supplements to retailers, who sold the products to consumers. According to the complaint, the retailers that Europa supplied included Walgreens and NaturalBodyInc.com. The plaintiffs alleged that that Debernardis purchased IQ's supplements from Walgreens through its website and Damore purchased IQ's

supplements from NaturalBodyInc.com.[10] As the sole distributor that supplied supplements to retailers, only Europa could have provided the supplements the plaintiffs bought.[11]

V. CONCLUSION

The district court erred in concluding that the plaintiffs lacked standing. The defendants raised in the district court a number of other arguments about why the plaintiffs' claims should be dismissed. But "[b]ecause none of these issues were decided initially, we decline to address them for the first time on appeal." *Leal v. Ga. Dep't of Corrs.*, 254 F.3d 1276, 1280-81 (11th Cir. 2001). We thus vacate the district court's order granting the motion to dismiss and remand for further proceedings consistent with this opinion.

VACATED and REMANDED.

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[10] The complaint also alleged that Damore purchased supplements through the website eBay.com from a vendor named BF Nutrition but did not address how BF Nutrition acquired the supplements it sold. We need not decide, though, whether the complaint supports an inference that Europa distributed the supplements sold by BF Nutrition. The plaintiffs alleged that Damore purchased supplements multiple times, and their allegations are sufficient to support the conclusion that Europa distributed at least some of the supplements Damore purchased.

[11] We emphasize that we are deciding only that the complaint's allegations sufficiently established that the plaintiffs' injuries were fairly traceable to Europa for purposes of the motion to dismiss. At the summary judgment stage, the plaintiffs will be required to come forward with evidence to support their allegations that Debernardis purchased Synedrex from Walgreens, Damore purchased Synedrex from NaturalBodyInc.com, and Europa supplied Synedrex to Walgreens and NaturalBodyInc.com. *See Lujan*, 504 U.S. at 561 (explaining that standing is an "indispensable part of the plaintiff's case" and "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation").

SUTTON, Circuit Judge, concurring. In joining the court's opinion, I wish to add a few words about the razor's edge of Article III jurisdiction.

Just as Congress and the state legislatures do not have the final say over whether a law satisfies the First Amendment, they do not have the final say over whether something is an injury under Article III. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548–50 (2016). And just as there is not "an anything-hurts-so-long-as-Congress-says-it-hurts theory of Article III injury," *Hagy v. Demers & Adams*, 882 F.3d 616, 622 (6th Cir. 2018), there is not an anything-hurts-so-long-as-the-plaintiff-says-it-hurts theory of Article III injury, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 563 (1992). Article III sets a judicially enforceable baseline that a claimant suffer genuine harm or risk of harm, one that requires at a minimum that the injury "exist" in the real world independent of a legislature's choice to confer the right to sue and independent of the plaintiff's claim to be hurt. *Spokeo*, 136 S. Ct. at 1548–49.

What makes today's case difficult is that the plaintiffs rest a seemingly concrete injury (dollars-and-cents economic harm) on a purely procedural violation (the defendant's failure to file a notice with the federal Food and Drug Administration). Joshua Debernardis and Christine Damore say they were injured when IQ Formulations sold them dietary supplements that were illegal under federal law, a defect they say made the supplements worthless. They hang their injury in fact on what made the supplements illegal to sell—IQ Formulations' failure to notify

the Food and Drug Administration that it was adding a "new dietary ingredient" to two of its products and to provide the government with evidence that the new ingredient would be safe. *See* 21 U.S.C. §§ 342(f)(1)(B), 350b(a)(2). But neither claimant alleges any traditional injuries from buying or using IQ Formulations supplements, say that the products made them sick or did not work as advertised. Nor do they claim that the allegedly new ingredient posed any real risk of future injury, say that consumption of the product would increase the likelihood of obtaining this or that disease. *Cf. In re Aqua Dots Prods. Liab. Litig.*, 654 F.3d 748, 750–51 (7th Cir. 2011). All Debernardis and Damore say is that they would not have bought the supplements had they known that IQ Formulations failed to comply with federal law.

Debernardis and Damore nonetheless plausibly allege an injury in fact—that they paid more for IQ Formulations' dietary supplements than they would have paid had they known the company did not follow the law. This difference in price states a concrete economic harm that satisfies Article III standing's injury in fact element, no matter the label we give it. *Clinton v. New York*, 524 U.S. 417, 432–33 (1998); *Dubuisson v. Stonebridge Life Ins. Co.*, 887 F.3d 567, 575 (2d Cir. 2018); *Aqua Dots*, 654 F.3d at 751; *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012). Without the benefit of discovery, we are not in a position to second guess the harm they allege. And that suffices to permit the case to proceed.

That conclusion comes with two qualifications and one reminder. The discovery process may unearth facts that undermine Debernardis and Damore's standing to bring this claim. We reverse today in part because it is plausible for a consumer to allege that he relies on strict compliance with Food and Drug Administration regulations when making choices about what products to buy. At summary judgment, each claimant will need evidence to back the point up. Why was the product worthless to each of them? How did it deliver less than expected? Did each of them use the product even after they knew of the labeling deficiency? The answers to these questions and others will determine whether the case may proceed further and, if so, how.

At the next stages of the case, it's also a good idea to keep in mind the easy-to-miss distinctions between (1) injury in fact (a constitutional imperative), (2) statutory injury (an element of the plaintiff's cause of action), and (3) damages (a remedies calculation). Nothing guarantees that the Article III injury that gets Debernardis and Damore in the courthouse door is compensable under their legal theory or, if it is, that a jury will agree that the supplements they bought were worthless as opposed to worth less than the full purchase price.

Even if the plaintiffs' state-law claims eventually fail for lack of Article III standing at the summary judgment stage, they may be able to vindicate them in state court. The States, it's well to remember, take a variety of approaches to standing,

with many of them having no case-or-controversy requirement at all. *ASARCO, Inc. v. Kadish*, 490 U.S. 605, 617 (1989). In some States, a claimant might even be able to get an advisory opinion about whether a plaintiff alleging this kind of claim has standing to bring it. *Cf. In re Advisory Op. to the Governor*, 483 A.2d 1078, 1079 (R.I. 1984); *Duncan v. FedEx Office & Print Servs., Inc.*, 123 N.E.3d 1249, 1256–57 (Ill. App. Ct. 2019). So long as the plaintiffs choose to proceed in federal court, however, they must play by the federal rules. *See Nicklaw v. Citimortgage, Inc.*, 839 F.3d 998, 1003 (11th Cir. 2016).