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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS,
Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION;
JANET WOODCOCK, M.D., Acting Commissioner of
Food & Drugs, in her official capacity; BIOMEDICAL
ADVANCED RESEARCH & DEVELOPMENT AUTHORITY;
GARY L. DISBROW, PH.D., Director, Biomedical
Advanced Research & Development Authority, in his
official capacity; U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES; XAVIER BECERRA, Secretary of
Health & Human Services, in his official capacity,
Defendants-Appellees.

No. 20-1784

Appeal from the United States District Court
for the Western District of Michigan at Grand Rapids.
No. 1:20-cv-00493—Robert J. Jonker, District Judge.

Decided and Filed: September 9, 2021

Before: SILER, THAPAR, and MURPHY, Circuit Judges.

COUNSEL

ON BRIEF: Andrew L. Schlafly, Far Hills, New Jersey, for Appellant. Scott R. McIntosh, Lewis S. Yelin, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees.

MURPHY, J., delivered the opinion of the court in which SILER and THAPAR, JJ., joined. SILER, J. (pg. 22), delivered a separate opinion concurring in all but Part III.A.1 of the majority opinion.

OPINION

MURPHY, Circuit Judge. In *Flast v. Cohen*, 392 U.S. 83 (1968), the Supreme Court suggested that plaintiffs broadly have “standing” to sue over actions taken by the political branches whenever the litigants are sufficiently “adverse.” *See id.* at 100–01. The standing at issue in this case—associational standing—grew out of the same “judicial thinking” as *Flast*. *Nat’l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 693 (D.C. Cir. 1971). It permits an association that has suffered no injury to sue on behalf of members who have. Yet the Court has since criticized *Flast* for overlooking that standing (and, in particular, its requirement that a plaintiff identify a personal injury) represents a key part of the Constitution’s separation of powers. *Lewis v. Casey*, 518 U.S. 343, 353 n.3 (1996). It is not clear how associational standing comports with this more recent guidance. At the least, the guidance should lead us to vigilantly ensure that an association’s members have incurred a personal injury. And here, the plaintiff (an association of physicians) failed to plausibly plead that any member has been injured by the actions of the Food and Drug Administration (FDA) that it criticizes. We thus affirm the dismissal of its complaint.

I

Under the Federal Food, Drug, and Cosmetic Act, a drug manufacturer cannot distribute a drug in interstate commerce without obtaining the FDA’s approval for the uses listed on the drug’s official label. *See* 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer generally must conduct clinical trials establishing that the drug is safe and effective for those intended uses. *See id.* § 355(d). In emergency situations, however, the FDA may allow the distribution of an unapproved drug or of an approved drug for an unapproved use. *See id.* § 360bbb-3(a)(1)–(2).

Although the Act regulates a manufacturer’s distribution of drugs, it does not go further by regulating a doctor’s practice of medicine. *See Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350–51 (2001). The Act thus does not prohibit doctors from prescribing an

FDA-approved drug (say, a chemotherapy drug approved to treat leukemia) for an “off-label” use (say, treatment of other cancers). *See United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012). It instead leaves the regulation of doctors to the states. *Cf. Dent v. West Virginia*, 129 U.S. 114, 121–24 (1889).

This case involves “hydroxychloroquine.” The FDA approved this drug for distribution in 1955. It has now approved the drug to treat malaria, lupus, and arthritis. A CDC fact sheet describes the drug as “relatively well tolerated” and lists its most common side effects as “stomach pain, nausea, vomiting, and headache.” Fact Sheet, R.8-14, PageID 286. Still, a patient may not use hydroxychloroquine unless a doctor prescribes it.

The FDA has not approved hydroxychloroquine to treat COVID-19. Early in the pandemic, the FDA relied on the then-available data to conclude that the drug might help treat the disease. In March 2020, the agency issued an Emergency Use Authorization (“Authorization”) under § 360bbb-3(a). The Authorization permitted the hydroxychloroquine in the federal government’s strategic national stockpile to be distributed for treatment of COVID-19 patients. Yet it granted access to this large stockpile only in limited circumstances. The Authorization stated that the drug “may only be used to treat adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.” Auth., R.8-8, PageID 262.

The Association of American Physicians & Surgeons, a nonprofit organization with physician members, believed that the Authorization did not offer broad enough access to the federal stockpile. It sued the FDA and its Commissioner, the Biomedical Advanced Research and Development Authority and its Director, and the Department of Health and Human Services and its Secretary. (For simplicity, we will refer to all defendants as the FDA.) The Association alleged that hydroxychloroquine can help patients if taken as a prophylaxis before they get COVID-19 or as an initial treatment after such a diagnosis. It thus sought declaratory and injunctive relief against the Authorization’s restrictions barring use of hydroxychloroquine to treat COVID-19 except for hospitalized patients.

The Association pleaded three claims. It alleged that these restrictions violated the implied equal-protection guarantee in the Fifth Amendment's Due Process Clause. Compl., R.1, PageID 17, 20–22. It alleged that the restrictions violated the First Amendment right to associate by limiting access to medication useful for meeting in groups during a pandemic. *Id.*, PageID 22–23. And it alleged that the restrictions violated the Administrative Procedure Act. *Id.*, PageID 22.

The Association also pleaded three injuries. It alleged an injury to itself: The Association was considering canceling a conference purportedly due to the Authorization's restrictions. *Id.*, PageID 23. It next invoked associational standing on behalf of its physician members: It claimed that the members could not prescribe hydroxychloroquine for COVID-19 because of the restrictions. *Id.*, PageID 19. The Association lastly invoked third-party standing: It alleged that its members' patients could not obtain the drug for the treatment of COVID-19. *Id.*

The district court held that none of these injuries plausibly pleaded the Association's standing to challenge the Authorization. The court dismissed the complaint for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). *See Ass'n of Am. Physicians & Surgeons v. FDA*, 479 F. Supp. 3d 570, 579–85 (W.D. Mich. 2020). We review this decision *de novo*. *See CHKRS, LLC v. City of Dublin*, 984 F.3d 483, 488 (6th Cir. 2021).

Before doing so, we flag a mootness issue. The Authorization had a short shelf life. Within months, the FDA had rescinded it because additional data suggested that hydroxychloroquine was ineffective at treating COVID-19. 85 Fed. Reg. 56,231, 56,232 (Sept. 11, 2020). Must we ensure that these new facts do not moot the Association's suit before addressing its standing? No, the Supreme Court has told us that we have discretion to choose between non-merits grounds for dismissing a suit. *See Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007). We thus exercise our discretion to begin with standing, which, as it turns out, moots any mootness issue. *See In re 2016 Primary Election*, 836 F.3d 584, 587 (6th Cir. 2016).

II

The Association spends much of this appeal attacking the FDA's actions on their policy and legal merits. It says that it should have standing because the FDA has engaged in "anti-life conduct" that has contributed to the "deaths of many thousands of innocent Americans." Appellant's Br. 28–29. It adds that it should have standing because the FDA has committed "wrongdoing" by making "false and misleading" claims about hydroxychloroquine. *Id.* at 33, 41. These merits arguments misunderstand standing's basic function, so we start with first principles.

The Constitution separates the general powers of government: Article I vests "legislative Powers" in the Congress; Article II vests the "executive Power" in the President; and Article III vests the "judicial Power" in the Supreme Court and inferior courts. By doing so, the Constitution at once both protects and restrains the judiciary. It protects the courts from efforts by the political branches to interfere with their duty to resolve disputes between litigants. The legislative branch, for example, cannot reverse a court's final judgment. *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 225–26 (1995). And the executive branch cannot render a final judgment in a case of the type traditionally resolved by courts. *Stern v. Marshall*, 564 U.S. 462, 484 (2011).

Yet this separation of powers also protects the political branches from the courts. Courts have a specific power: to decide "Cases" or "Controversies" between litigants. U.S. Const. art. III, § 2. They do not have a standalone power to evaluate the constitutionality of every law passed by Congress or every initiative implemented by the President. *See Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 146 (2011). A court may engage in such judicial review and issue a remedy regulating the political branches only "when necessary in the execution of" its duty to decide a case. *Summers v. Earth Island Inst.*, 555 U.S. 488, 492 (2009). It may not issue an advisory interpretation of the Constitution or an advisory injunction regulating those branches whenever a concerned citizen thinks they have acted unlawfully. *See Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 473 (1982).

But this limit on the courts would be meaningless if the words “Case” and “Controversy” covered any challenge to government action dressed up in a complaint with an official-looking caption. That is where “standing” comes in. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). It ensures that the disputes resolved by courts today are the same kinds of disputes “traditionally amenable to, and resolved by, the judicial process.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 102 (1998). At its core, the judiciary has existed as the venue in which a party may seek relief for an injury caused by another party’s invasion of its rights. *See Warth v. Seldin*, 422 U.S. 490, 499 (1975). That insight leads to standing’s three elements. To establish a “case,” a plaintiff must show that the plaintiff has suffered an injury, that the defendant’s conduct likely caused the injury, and that the relief sought will likely redress the injury. *TransUnion*, 141 S. Ct. at 2203.

These separation-of-powers principles should make it obvious that the Association does nothing to establish an Article III “case” merely by criticizing the wisdom or legality of the FDA’s actions. The Association’s belief that the FDA has engaged in wrongdoing does not prove its standing because its “disagreement” with the FDA is not an injury, no matter how “sharp and acrimonious” it may be. *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013) (citation omitted). And its belief that the FDA’s policies have harmed thousands does not prove its standing unless it adequately shows that it is “among the injured.” *Sierra Club v. Morton*, 405 U.S. 727, 735 (1972).

III

Given these standing ground rules, it is notable that the Association has abandoned the only personal injury it alleged: It claimed that the restrictions on hydroxychloroquine in the FDA’s Authorization might force it to cancel a conference. The district court rejected this argument because the Association failed to plausibly plead that the Authorization—as opposed to state limits on large gatherings—would cause the injury. Because the Association does not challenge this conclusion on appeal, we need not consider whether it alleged an injury to itself. The Association instead argues that it may sue over injuries incurred by others not before the court. It claims that it may pursue this suit based on “associational standing” on behalf of its physician members or “third-party standing” on behalf of its members’ patients.

A. Associational Standing

The Association first seeks to invoke “associational standing” to sue for injuries incurred by its physician members. This doctrine sometimes permits an entity to sue over injuries suffered by its members even when (as here) the entity itself alleges no personal injury. *See, e.g., Summers*, 555 U.S. at 494; *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 552–58 (1996); *Int’l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 281–82 (1986); *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 342–43 (1977). The Court in *Hunt* adopted the current test for this type of proxy suit. 432 U.S. at 343. An organization may sue on behalf of its members if it shows that: (1) its “members would otherwise have standing to sue in their own right”; (2) the “interests” that the suit “seeks to protect are germane to the organization’s purpose”; and (3) “neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Id.*

1

Before applying this test to the Association’s claims, it is worth taking a fresh look at where the test came from. The Supreme Court developed it in the 1960s and 70s. At that time, its cases left unclear which standing elements were “prudential” limits rooted in judicial discretion and which were “constitutional” limits rooted in Article III. *See Valley Forge*, 454 U.S. at 471–76. The Court has since clarified things. But it has yet to reconcile its associational-standing test with its more recent guidance. For three reasons, moreover, the two are not obviously reconcilable.

Reason One: The “irreducible constitutional minimum” of standing requires a plaintiff to allege a particularized injury. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). How, then, can the Association sue in this case if it has *not* suffered an injury? The Court previously said that the first associational-standing factor (that an entity’s members have suffered an injury that would give them standing if they sued) satisfies this element. *Brown Grp.*, 517 U.S. at 555–56.

Yet the Court’s recent cases suggest that this nonparty injury alone does not suffice. These cases hold that historical practice should guide courts when deciding whether an injury

satisfies Article III's requirements. See *TransUnion*, 141 S. Ct. at 2204. So before authorizing other types of "representative" litigation (in which one party sues over another's injury), the Court has ensured that historical practice supported it. Cf. *Hollingsworth*, 570 U.S. at 707–14. The Court, for example, held that a private "relator" may bring a "qui tam" suit on behalf of the government based on pages of history showing that courts had long permitted that litigation. *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 773–78 (2000). It likewise held that an assignee of a claim may sue over the claim even if the assignor receives the proceeds—again based on the history surrounding those assignments. *Sprint Commc'ns Co. v. APCC Servs., Inc.*, 554 U.S. 269, 274–85 (2008). And it held that a party may sometimes sue as the "next friend" of a person subject to a legal disability based again on that practice's pedigree. *Whitmore v. Arkansas*, 495 U.S. 149, 162–66 (1990).

Did the Court follow this approach when allowing associations to sue for their members? Far from it. Its trail of case citations suggests that this standing arose more from historical accident than practice. When adopting the associational-standing test in *Hunt*, the Court cited *Warth*, not any common-law analog. 432 U.S. at 342–43. But *Warth*, too, included no justification rooted in tradition. It instead cited *National Motor Freight Traffic Association v. United States*, 372 U.S. 246 (1963) (per curiam). *Warth*, 422 U.S. at 511. There, a lower court had held that motor-carrier associations could not challenge an agency order harming their members because they lacked standalone injuries. *Nat'l Motor Freight Traffic Ass'n v. United States*, 205 F. Supp. 592, 593–94 (D.D.C. 1962) (Burger, J.). The Supreme Court disagreed in a one-paragraph opinion, finding that the associations were "proper representatives" of their members. 372 U.S. at 247. For a third time, the Court identified no historical support. It merely cited *NAACP v. Alabama ex rel. Patterson*, 357 U.S. 449 (1958), and *FCC v. Sanders Brothers Radio Station*, 309 U.S. 470 (1940).

But these two cases did not address when an entity that has sustained no injury may sue on behalf of those who have. In *Patterson*, the NAACP was sued in state court by state officials who sought its membership list. 357 U.S. at 452–54. The Court held that the NAACP could invoke the constitutional rights of its members in defense against producing this list. *Id.* at 458–60. These facts show that *Patterson* concerned third-party standing, not associational

standing. Third-party standing sometimes allows one party to rely on the rights of others. *See Powers v. Ohio*, 499 U.S. 400, 410–11 (1991). Critically, though, this standing (unlike associational standing) requires the plaintiff to suffer its own injury. *See Hollingsworth*, 570 U.S. at 707–09. *Patterson* even recognized that the NAACP would likely incur a standalone injury (“diminished financial support and membership”) if it were forced to disclose its list of members. 357 U.S. at 459–60.

Sanders Brothers is equally irrelevant. A radio station challenged the FCC’s grant of a license to a competitor because the competition would cause the station economic loss. 309 U.S. at 471–72. The Court held that this financial harm made the station an aggrieved party under a statute. *Id.* at 476–77; *see Sierra Club*, 405 U.S. at 737. Thus, neither *Patterson* nor *Sanders Brothers* jettisoned the usual rule that the plaintiff before the court must have suffered an injury.

Perhaps an unidentified common-law practice could nevertheless justify the cursory conclusion from *National Motor Freight Traffic Association* that an association may assert its members’ injuries? The law of equity’s “bill of peace” (the precursor to the modern class action) might help fill in the logical void. *See* Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev. 417, 426–27 (2017); 7A Charles Alan Wright et al., *Federal Practice & Procedure* § 1751 (3d ed. 2005); Joseph Story, *Commentaries on Equity Pleadings* §§ 107–19 (1838). Yet that analogy would raise distinct questions. The Constitution, for example, permits class members to represent a class only if they suffer their *own* injury. *Frank v. Gaos*, 139 S. Ct. 1041, 1046 (2019) (per curiam). If class actions require the named plaintiffs to identify their own injury, how can associational standing throw this requirement overboard?

More fundamentally, federal courts have yet to justify associational standing with this (or any other) historical practice—as the Supreme Court’s recent cases suggest they must. Instead, the Court’s foundation for allowing an uninjured association to sue is a paragraph-long opinion citing cases on different subjects. Similarly, early lower-court cases do not rely on any historical analogy when permitting associational standing. They instead describe associational standing as part of the then-ongoing “revision of judicial thinking on the standing question” that had “deprived [standing] of meaningful vitality.” *Nat’l Automatic Laundry & Cleaning Council v.*

Shultz, 443 F.2d 689, 693 (D.C. Cir. 1971). The Supreme Court has since overturned this judicial thinking—epitomized by cases like *Flast v. Cohen*, 392 U.S. 83 (1968)—and reinvigorated standing as a core part of the separation of powers. *Lewis v. Casey*, 518 U.S. 343, 353 n.3 (1996). Associational standing thus may be nothing more than an outdated relic from *Flast*'s short-lived age.

Reason Two: The “irreducible constitutional minimum” of standing also requires a plaintiff’s requested relief to redress the plaintiff’s injury. *Lujan*, 504 U.S. at 560–61. How can any relief in this case satisfy this element if the Association has not been injured by the FDA’s Authorization and if its allegedly injured members are not parties? The Supreme Court has said that this redressability element will not impede an organization’s standing if the organization requests injunctive relief against the law or agency order that it challenges (as the Association has done in this case). *Warth*, 422 U.S. at 515. The Court reasoned that one can “suppose[.]” that such an injunction “will inure to the benefit of those members of the association actually injured.” *Id.* It thus simply assumed that injunctions will regularly prevent the defendant from enforcing a law or agency order not just against the associational *plaintiff* but also against *nonparties*.

This broad view of the remedies permitted by Article III also clashes with the Court’s more recent guidance. The Court has held that a valid Article III remedy must “operate with respect to specific parties,” not with respect to a law or regulation “in the abstract.” *California v. Texas*, 141 S. Ct. 2104, 2115 (2021) (quoting *Murphy v. Nat’l Collegiate Athletic Ass’n*, 138 S. Ct. 1461, 1486 (2018) (Thomas, J., concurring)). This party-focused rule means that a “remedy must be ‘limited to the inadequacy that produced [a plaintiff’s] injury in fact.’” *Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018) (quoting *Lewis*, 518 U.S. at 357). The plaintiff must show that each requested remedy will redress some portion of the plaintiff’s injury. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352–53 (2006). Conversely, the plaintiff cannot seek a remedy that has no ameliorative effects on that injury. *See California*, 141 S. Ct. at 2116. While, for example, a completed injury may give a plaintiff the right to seek damages, it does not alone give the plaintiff the right to seek an injunction. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983). Likewise, a plaintiff cannot “combin[e] a request for injunctive relief for

which he *has* standing with a request for injunctive relief for which he *lacks* standing.” *Salazar v. Buono*, 559 U.S. 700, 731 (2010) (Scalia, J., concurring in the judgment); *see Lewis*, 518 U.S. at 357.

Associational standing is in tension with these Article III redressability rules because it creates an inherent mismatch between the plaintiff and the remedy. An injunction that bars a defendant from enforcing a law or regulation against the “specific” party before the court—the *associational plaintiff*—will not satisfy Article III because it will not redress an injury. *See California*, 141 S. Ct. at 2115. The association, by definition, has not suffered the injury. Its members have. To satisfy Article III’s redressability requirement, then, the injunctive relief in an associational-standing case must benefit (and ameliorate an injury to) the association’s *members*. That fact generates an alternative problem. Article III requires the remedy to be “limited” to the plaintiff’s injury. *Lewis*, 518 U.S. at 357. Yet, unlike with a certified class action in which the unnamed class members “are considered parties to the litigation in many important respects,” *United States v. Sanchez-Gomez*, 138 S. Ct. 1532, 1538 (2018), the Supreme Court has not characterized an association’s members as “parties” to the suit. So relief to these nonparties might also exceed constitutional bounds. *Cf. Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975).

Even if the association may constitutionally seek remedies for its nonparty members, that relief raises other procedural questions. Consider the injunction’s proper scope. *See* Michael T. Morley, *Disaggregating Nationwide Injunctions*, 71 Ala. L. Rev. 1, 25–27 (2019). Should an injunction cover only the members that an organization identified as having standing? Or should it cover all members? If the latter, should it apply only to existing members on the date of the judgment? Or should it cover future members—seemingly allowing an organization to advertise the injunction in its marketing materials? Next consider the litigation’s proper procedure. Federal Rule of Civil Procedure 23(b)(2) sets forth the ground rules for a party who seeks an injunction for a class. *See Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 360–63 (2011). Must an association follow Rule 23 before obtaining relief for its members or did the Court create an implied exception to the rule? *Cf. Morley, supra*, at 27. Lastly consider the judgment’s proper scope. If members may rely on the injunction if an organization wins, should they be bound by

the judgment if it loses? Would that satisfy due process? *See Taylor v. Sturgell*, 553 U.S. 880, 892–95 (2008).

The Court's associational-standing cases have not squarely confronted these questions. *Cf. Brown Grp.*, 517 U.S. at 556 n.6. The timing of associational standing might explain why. The doctrine's emergence in the 1960s overlaps with the emergence of another remedial phenomenon that the Court has yet to squarely confront—the “universal” or “nationwide” injunction. *See Bray, supra*, at 437–45. That type of defendant-focused injunction “transcends” the case by barring a defendant from enforcing a challenged law or regulation against *anyone*—not just the *plaintiff*. *See Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring in the grant of stay).

Associational standing appears more workable in a world with universal injunctions. Some courts have used this standing as a “backdoor” way to grant a universal injunction and avoid the difficult task of crafting member-limited relief. *Morley, supra*, at 25. Take *Hunt*, which involved a North Carolina law that barred apple sellers from listing state-specific grades on their apple containers. 432 U.S. at 337. The Washington State Apple Advertising Commission challenged this law on behalf of in-state growers. *See id.* at 335–39. After finding the law unconstitutional, a district court did not grant an injunction to the Commission or identify the nonparties entitled to one. *Wash. State Apple Advert. Comm'n v. Holshouser*, 408 F. Supp. 857, 858, 861–62 (E.D.N.C. 1976). Rather, it seemed to broadly “enjoin” the law's “enforcement as applied to state grade markings on closed containers.” *Id.* at 858. But Justices (and commentators) have started to question the constitutionality of these types of broad defendant-focused injunctions. *See New York*, 140 S. Ct. at 600–01 (Gorsuch, J., concurring in the grant of stay); *Trump v. Hawaii*, 138 S. Ct. 2392, 2425–29 (2018) (Thomas, J., concurring); *see also Bray, supra*, at 469–72; *Morley, supra*, at 28–29, 31. If the Court decides to rein them in, it may need to reassess associational standing along with them.

Reason Three: The Supreme Court at one time regularly followed “prudential standing” rules that arose from what it viewed as the judiciary's discretionary case-management power rather than from any mandatory constitutional command. *See Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 11–12 (2004). The Court recently called this line of precedent into doubt

on the ground that prudential standing sits uncomfortably next to the courts' "virtually unflagging" duty to decide cases within their jurisdiction. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126 (2014) (citation omitted). *Lexmark* recharacterized one of these prudential doctrines—that a plaintiff must fall within the "zone of interests" of a statute to sue under it—as being about something else. *See id.* at 126–28. Rather than raise a standing question implicating the court's discretion to refuse to consider a claim, this doctrine raises a statutory question about whether a court should interpret the statute's cause of action to cover the plaintiff. *See id.*

Lexmark might also necessitate reexamination of the Court's associational-standing test. The Court's second associational-standing requirement asks whether the interests that an association's suit seeks to vindicate are "germane" to its purpose. *Hunt*, 432 U.S. at 343. Although the Court has said (in potential dicta) that this element is rooted in Article III, it has described the element as ensuring that an association has enough "adversarial vigor" to litigate the legal issues well. *Brown Grp.*, 517 U.S. at 555–56. And the Court has elsewhere described concerns about whether a party will provide a proper "adversarial presentation" as prudential (not constitutional). *United States v. Windsor*, 570 U.S. 744, 759–60 (2013); *see Sec'y of State of Md. v. Joseph H. Munson Co.*, 467 U.S. 947, 956 (1984). The Court has similarly described the third associational-standing requirement—that neither the claim nor the relief necessitates a member's participation—as prudential only. *See Brown Grp.*, 517 U.S. at 556–57.

If Article III otherwise permits associations to seek redress for their members' injuries, what legal source gives a court the power to decline jurisdiction on the ground that an association lacks sufficient "vigor"? *Cf. Island Creek Coal Co. v. Bryan*, 937 F.3d 738, 747–49 (6th Cir. 2019). And why should the "administrative convenience" that arises from having the association's members participate in a suit trump an association's right to bring it if their participation is not necessary to make out a case or controversy? *Brown Grp.*, 517 U.S. at 557. *Lexmark's* skepticism of prudential standing suggests that the Court should reexamine all of the doctrines that have grown out of it—which would include part of the associational-standing test. *Cf. June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2144 (2020) (Thomas, J., dissenting).

* * *

In sum, it is hard to see how the Supreme Court's more recent caselaw on standing has not undercut its associational-standing test. In these circumstances, though, the Court has told lower courts that they must stick to its directly on-point precedent even if the logic from other cases has called that precedent into doubt. *See State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997); *Agostini v. Felton*, 521 U.S. 203, 237 (1997). We thus must apply that associational-standing test here.

2

Still, the Court's more recent guidance on the "irreducible constitutional minimum" of standing clarifies what an organization must plead to establish the first element of associational standing—that its members have Article III standing in their own right. *Lujan*, 504 U.S. at 560–61; *see Shelby Advocs. for Valid Elections v. Hargett*, 947 F.3d 977, 982 (6th Cir. 2020) (per curiam). To satisfy this element, an organization must do more than identify a likelihood that the defendant's conduct will harm an unknown member in light of the organization's extensive size or membership base. *See Summers*, 555 U.S. at 498–99. The organization must instead identify a member who has suffered (or is about to suffer) a concrete and particularized injury from the defendant's conduct. *See id.* And the organization must show that its requested relief will redress this injury. *See Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 257–58 (6th Cir. 2018); *Friends of Tims Ford v. Tenn. Valley Auth.*, 585 F.3d 955, 970–71 (6th Cir. 2009).

The Association's complaint in this case includes allegations with respect to two physician members. It alleges that the FDA's Authorization has harmed a "Dr. John Doe" who practices in Michigan. Compl., R.1, PageID 19. Dr. Doe, and another unidentified physician who practices in an unidentified state, allegedly want to prescribe hydroxychloroquine for patients who do not have COVID-19 or who have just been diagnosed with it. *Id.* But the Authorization has allegedly prevented them from doing so. *Id.* Why? The Association offers two theories—one direct, the other indirect. The Association initially argues that the Authorization directly restricts its physician members from prescribing the drug in their preferred

fashion. It alternatively argues that the Authorization could indirectly cause the members to face state-level sanctions for prescribing the drug in this fashion. Neither theory pleads the physician members' standing.

Before reaching these theories, we must identify the legal standards for assessing whether a complaint's standing allegations suffice. The FDA brought what is known as a "facial" (as opposed to "factual") challenge to the Association's standing and the district court's jurisdiction under Federal Rule of Civil Procedure 12(b)(1). See *Gentek Bldg. Prods., Inc. v. Sherwin-Williams Co.*, 491 F.3d 320, 330 (6th Cir. 2007). A party raising a facial challenge argues that a complaint does not adequately plead standing even accepting its facts as true. See *Mosley v. Kohl's Dep't Stores, Inc.*, 942 F.3d 752, 756 (6th Cir. 2019). Under the old pleading test from *Conley v. Gibson*, 355 U.S. 41 (1957), a court considering such a challenge assumed that the complaint's "general allegations embrace[d] those specific facts that [were] necessary to support the claim." *Shelby Advocs.*, 947 F.3d at 982 (quoting *Lujan*, 504 U.S. at 561). In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), however, the Court retired this lenient test in favor of a "plausibility" test—at least in the context of a motion to dismiss on the merits under Rule 12(b)(6). *Id.* at 560–61.

Should *Twombly*'s plausibility test apply to a motion to dismiss on standing grounds too? We think so. The Supreme Court has held that standing's elements "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof," which indicates that the same rules apply at this pleading stage. *Lujan*, 504 U.S. at 561. The Court has also made clear that a complaint must "clearly . . . allege facts demonstrating" standing. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citation omitted). And many other circuit courts have extended *Twombly*'s plausibility test to this standing context. See *Silha v. ACT, Inc.*, 807 F.3d 169, 174 (7th Cir. 2015) (citing cases); see also, e.g., *Hawse v. Page*, 7 F.4th 685, 688–89, 689 n.6 (8th Cir. 2021); *Kareem v. Haspel*, 986 F.3d 859, 865–66 (D.C. Cir. 2021); *Dantzler, Inc. v. Empresas Berríos Inventory & Operations, Inc.*, 958 F.3d 38, 46–47 (1st Cir. 2020); *Ctr. for Biological Diversity v. Bernhardt*, 946 F.3d 553, 560 (9th Cir. 2019). We will do the same. Accepting as true the complaint's factual allegations (as opposed to its legal conclusions), we

must ask whether either of the Association's two theories asserts a "plausible claim" that one of its members has standing. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

Did the Association plead a direct harm to its members? The Association first argues that the Authorization barred its physician members from prescribing hydroxychloroquine for their patients in the prophylactic manner that they would like. That is allegedly because the Authorization restricted use of hydroxychloroquine only for hospitalized COVID-19 patients, not for patients who have yet to be hospitalized or get COVID-19. This theory failed to plausibly plead an Article III injury because it rests on a misinterpretation of the Authorization.

If the Authorization noted that the FDA would punish doctors for prescribing hydroxychloroquine outside its narrow guidelines, that type of punishment might well create an Article III injury—assuming that enforcement of the policy against the Association's members was sufficiently imminent. *See Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158–59 (2014). But the Authorization said no such thing. It nowhere barred physicians from prescribing hydroxychloroquine to non-hospitalized patients. Indeed, it did not regulate doctor prescribing habits at all. Rather, it governed distribution of the hydroxychloroquine *specifically* in the federal stockpile, not of hydroxychloroquine *generally*. Auth., R.8-8, PageID 259, 262–65. The Authorization thus did not limit the ability of the Association's members to prescribe the drug to their patients, who could seek to fill those prescriptions through nongovernmental channels.

This reading of the Authorization comports with the background understanding of the Federal Food, Drug, and Cosmetic Act. The Act regulates drug distribution; it does not bar doctors from prescribing an approved drug (like hydroxychloroquine) for an off-label use (like COVID-19). *See Caronia*, 703 F.3d at 153. The Association's complaint thus alleges that the Act permits off-label prescriptions. Compl., R.1, PageID 5–6. And the FDA even acknowledged this narrow reading of the Authorization's scope on appeal. Appellees' Br. 21; *cf. Driehaus*, 573 U.S. at 165.

The Association responds that the Authorization's restrictions made hydroxychloroquine practically (if not legally) unavailable to its members' patients. That is so, the Association claims on appeal, because the federal government has a monopoly on the drug. It is unclear why

this argument would show that the Association's physician members have suffered any type of injury. Without a threat of punishment for prescribing the drug, the Association has not identified a harm to *physicians* merely because the drug may not be available to *patients*. Cf. *California*, 141 S. Ct. at 2114–16. Ultimately, though, we need not decide the point. The Association's complaint did not factually allege that hydroxychloroquine was unavailable outside the federal stockpile. To the contrary, it alleged that a “plentiful supply” exists of the “easy-to-manufacture” drug. Compl., R.1, PageID 15. The complaint added that “it is feasible for manufacturers to produce a million new doses of [hydroxychloroquine] daily.” *Id.*, PageID 17–18. Because we assess the Association's standing based on the complaint's allegations on this appeal, see *Mosley*, 942 F.3d at 756, the allegations about the drug's wide availability doom this argument.

Did the Association plead an indirect harm to its members? The Association alternatively argues that the Authorization could cause its physician members to face discipline in a distinct way if they prescribe hydroxychloroquine in the broad fashion that they would like. How? According to the complaint, state medical boards have allegedly relied on the Authorization in their regulation of doctors. Compl., R.1, PageID 18. The Association's members thus allegedly fear prescribing hydroxychloroquine due to the threat of “retaliation” from these state boards. *Id.*, PageID 19. This theory failed to plausibly plead standing's injury and causation elements.

Start with the injury. A state medical board's threatened disciplinary action against a doctor may well qualify as a valid Article III injury to the doctor. See, e.g., *Driehaus*, 573 U.S. at 158–59; *McKay v. Federspiel*, 823 F.3d 862, 867–70 (6th Cir. 2016). But a yet-to-happen “injury must be *certainly impending* to constitute injury in fact”; the mere possibility that the injury will arise in the future does not suffice. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quoting *Whitmore*, 495 U.S. at 158). And a plaintiff claiming that a government agency might bring an enforcement action against the plaintiff usually must show a “credible threat of prosecution” under the challenged law or regulation to establish that this type of enforcement action is certainly impending. *McKay*, 823 F.3d at 867 (quoting *Driehaus*, 573 U.S. at 159).

Here, however, the Association's complaint identifies nothing but speculation that a state medical board might pursue discipline against one of its physician members for prescribing hydroxychloroquine to treat COVID-19. The Association alleged details for only one physician member—the Dr. Doe who practices in Michigan. Yet its complaint did not make a single allegation that the state medical board in Michigan has made statements or taken actions against the use of hydroxychloroquine to treat COVID-19. The complaint, for example, did not allege any prior enforcement actions against Michigan doctors. *Cf. Driehaus*, 573 U.S. at 164. Nor did it allege that the Michigan board had circulated warning letters critical of the prescriptions that the Association's members would like to write. *Cf. Berry v. Schmitt*, 688 F.3d 290, 296 (6th Cir. 2012). And unlike when a plaintiff alleges that a challenged law or regulation bars the conduct in which the plaintiff would like to engage, the complaint did not even tell us the Michigan law, regulation, or common-law standard that the physician members' prescribing habits would allegedly infringe. *See Glenn v. Holder*, 690 F.3d 417, 421–24 (6th Cir. 2012). In sum, the complaint's conclusory allegations that an unknown state medical board might bring disciplinary charges against an unknown physician member for conduct violating an unknown standard did not suffice to plausibly allege the required credible threat of prosecution. *See McKay*, 823 F.3d at 869.

Turn to causation. Even if an unknown state medical board would discipline an unknown physician member for prescribing hydroxychloroquine to treat COVID-19, the Association did not sue a state board (the entity that would cause this harm). It sued the FDA. Yet the Supreme Court has “been reluctant to endorse standing theories that require guesswork as to how independent decisionmakers” (like the state medical board in this case) would “exercise their judgment.” *Clapper*, 568 U.S. at 413; *see Warth*, 422 U.S. at 505. Many cases thus hold that a plaintiff failed to establish that an injury was traceable to a defendant when the injury would arise only if some third party decided to take the action triggering the injury. *See Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–43 (1976); *Binno v. Am. Bar Ass'n*, 826 F.3d 338, 344–45 (6th Cir. 2016); *Ammex, Inc. v. United States*, 367 F.3d 530, 533–34 (6th Cir. 2004).

The Association's alternative standing theory requires this sort of guesswork. Its complaint conclusorily alleged that unknown state medical boards had “imitated or relied upon

the unjustified FDA” Authorization. Compl., R.1, PageID 18. Yet the complaint did not allege that these state boards were somehow bound by the Authorization or that they would fail to exercise “independent” judgment about the propriety of their physicians’ prescribing practices. *Simon*, 426 U.S. at 42. Indeed, the complaint did not even identify any state medical board that had cited the Authorization in its own guidance to regulated physicians. Nor did it plausibly allege that a state medical board would have adopted a different regulatory approach if the Authorization had not existed. The Association instead relies on rank speculation to suggest that the Authorization might have influenced the actions of state medical boards. But this “speculation about ‘the unfettered choices made by independent actors not before the court’” does not suffice to plead the Association’s standing. *Clapper*, 568 U.S. at 414 n.5 (quoting *Lujan*, 504 U.S. at 562).

In response, the Association argues that it has shown a credible threat of prosecution based on a press release from the Federation of State Medical Boards. The press release identified the Authorization’s permitted uses of the federal hydroxychloroquine stockpile and reminded doctors that “deviating from the standard of care could put their license at risk.” Compl., R.1, PageID 18. This statement does the Association no good. For one thing, it did not criticize prescribing hydroxychloroquine to treat COVID-19. Rather, it highlighted reports of physicians “inappropriately prescribing” hydroxychloroquine “to prevent or treat COVID-19 for themselves or their family members” rather than for patients who might need the drug. Statement, R.8-13, PageID 281. Nothing in the statement warned against prescribing hydroxychloroquine for COVID-19 (as compared to prescribing it to favored family members). For another thing, the Federation of State Medical Boards is an advocacy organization for state medical boards; it is not a sovereign regulatory body. So the Association’s reliance on this separate entity’s press release confirms the central problem with its standing theory: The theory rests on pure guesswork about the decisions of parties not before the court. *See Clapper*, 568 U.S. at 413.

The Association also cites *Association of American Physicians & Surgeons, Inc. v. Texas Medical Board*, 627 F.3d 547 (5th Cir. 2010). In that case, the Association sued the Texas Medical Board on behalf of its physician members because the board had allegedly been

disciplining physicians in illegal ways. *See id.* at 549–50. Because this discipline qualified as an injury and because the board would have undoubtedly caused it, the board did not even dispute that the Association’s members had standing. *Id.* at 550 & n.2. Here, by contrast, the Association sued the FDA for harm that would be caused by other entities—the unknown state medical boards. This theory of indirect harm is nothing like the theory of direct harm in *Texas Medical Board*.

B. Third-Party Standing

The Association lastly seeks to invoke third-party standing to sue for injuries allegedly incurred by its physician members’ patients. Third-party standing permits a plaintiff to assert the constitutional or statutory rights of parties not before the court if the plaintiff has a close relationship to those parties and if they are hindered in protecting their own rights. *See Kowalski v. Tesmer*, 543 U.S. 125, 129–30 (2004). The Supreme Court held, for example, that a merchant could invoke the equal-protection rights of her male customers who were under the age of 21 when she challenged a law that barred her from selling beer to these customers. *See Craig v. Boren*, 429 U.S. 190, 195–97 (1976). As noted, however, this theory (unlike associational standing) does not relieve plaintiffs of the need to independently establish their *own* Article III standing. *See Hollingsworth*, 570 U.S. at 708; *Powers*, 499 U.S. at 411. The merchant in *Craig*, for example, had suffered (and sought a remedy for) her own “economic injury” from the law barring beer sales to male customers under 21. *See* 429 U.S. at 194.

The Association cannot rely on third-party standing in this case because it has forfeited any argument that it has suffered its own Article III injury. To be sure, some cases suggest that the Association might have been able to “borrow” its physician members’ third-party standing to assert the separate rights of their patients. 13A Charles Alan Wright et al., *Federal Practice & Procedure* § 3531.9.5, at 890–92 (3d ed. 2008); *cf. New York State Club Ass’n, Inc. v. City of New York*, 487 U.S. 1, 9–10 (1988); *Pa. Psychiatric Soc’y v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 291–93 (3d Cir. 2002); *Ohio Ass’n of Indep. Schs. v. Goff*, 92 F.3d 419, 421–22 (6th Cir. 1996). But we need not decide in this case whether we would have allowed this double “stacking” of the standing exceptions to the general rule that a party must assert its own rights. *Pa. Psychiatric Soc’y*, 280 F.3d at 295–96 (Nygaard, J., dissenting). As already explained,

the Association's complaint failed to allege that any of its physician members had Article III standing. Without their own injuries, these members likewise could not rely on third-party standing to invoke the rights of their patients.

We affirm.

CONCURRENCE

SILER, Circuit Judge, concurring. I concur with the majority opinion, but I decline to join the discussion of associational standing in Part III.A.1, as I believe it is unnecessary to the resolution of the case.