The Constitution limits the jurisdiction of federal courts to hearing “Cases” or “Controversies.”

The Supreme Court has interpreted this requirement to mean that a plaintiff wishing to sue in federal court must show an injury in fact that has been caused by the behavior complained of and that is likely redressable by a judgment in favor of the plaintiff. The Court has also instituted a number of “prudential” limits, such as the rule barring generalized grievances more appropriate for resolution through the political process. In light of standing’s role as a jurisdictional bar, the plaintiff bears the burden of establishing standing, and courts must raise Article III standing concerns sua sponte if the parties fail to do so. Recently, in *Center for Food Safety v. Hamburg*, the United States District Court for the Northern District of California allowed suit for declaratory and injunctive relief by the Center for Food Safety (CFS), a public interest group, against the Food and Drug Administration (FDA) for failure to promulgate a number of food safety rules by a congressionally mandated deadline. In an opinion granting the requested relief and ordering the FDA and CFS to agree to a new judicially acceptable deadline, the court never engaged in a standing analysis, implicitly accepting CFS’s reliance on probabilistic harms to establish a concrete injury. While the FDA did not challenge CFS’s standing in its motions, the district court’s failure to analyze standing sua sponte led the court to ignore problematic questions of causation, redressability, and generalized harms, and to tacitly accept a view of probabilistic harms as injury in fact, which appears to contravene the Supreme Court’s stance, as clarified recently in *Clapper v. Amnesty International USA*.

---

3. See *Lujan*, 504 U.S. at 576–77. While the bar on considering generalized harms is called prudential — that is, not part of the three “irreducible constitutional minim[a] of standing,” id. at 560 — the Court has noted that generalized harms may also fail to satisfy Article III requirements, insofar as a claim does not represent “a ‘particularized’ interest sufficient to create a case or controversy.” *Hollingsworth v. Perry*, 133 S. Ct. 2652, 2663 (2013) (quoting *Lujan*, 504 U.S. at 560 & n.1).
4. See *Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 110 (2001) (per curiam) (holding that the Supreme Court is “obliged to examine standing sua sponte where standing has erroneously been assumed below”); *Lujan*, 504 U.S. at 561 (setting burdens of proof).
6. Id. at *7.
In 2011, Congress passed the FDA Food Safety Modernization Act\(^8\) (FSMA) to modernize the nation’s food safety laws by “mandating science-based standards and controls,” by giving the FDA greater prophylactic “inspection and enforcement powers” to prevent food safety hazards, and by “improving coordination among federal, state, and foreign food safety agencies.”\(^9\) To ensure the rapid realization of this goal, Congress required the FDA to publish seven new food safety regulations within eighteen months of the FSMA’s effective date.\(^10\)

Because of the complexity and novelty of the regulations — requiring the FDA both to create a new international regulatory system and to coordinate this new system with other federal, state, and foreign officials, all while continuing to oversee over $400 billion worth of food and hundreds of thousands of facilities — the FDA found Congress’s “aggressive timeline[\(^{11}\)]” to be “unachievable.”\(^11\) Finding it impossible to simultaneously develop and promulgate seven distinct rules, the FDA prioritized by first developing four “foundational” rules with the greatest public health benefits, to be followed later by the remaining three rules.\(^12\) At the time of the suit, the first four rules were undergoing review by the Office of Management and Budget, while the latter three rules were at different stages of development within the FDA.\(^13\)

In August 2012, just over eighteen months after the FSMA was enacted, CFS filed suit under the Administrative Procedure Act\(^14\) (APA), alleging that the FDA had failed to promulgate the rules by their statutorily mandated deadline.\(^15\) CFS sought a declaratory judgment that the FDA violated the FSMA and the APA by failing to issue the rules, as well as an injunction ordering the FDA to issue the regulations as soon as possible.\(^16\) CFS alleged that the FDA’s delay injured CFS and its members by increasing the risk that they might contract a foodborne illness.\(^17\) To demonstrate the concreteness of the injury complained of, numerous CFS members filed declarations alleging person-
al harms as a result of the FDA's inaction. 18 Both the FDA and CFS moved for summary judgment. 19

Judge Phyllis J. Hamilton granted CFS’s motion and denied the FDA’s motion. 20 Judge Hamilton began by reviewing the legal standards that control a federal court’s jurisdiction over agency action. She explained that suits under the APA afford federal question jurisdiction under 28 U.S.C. § 1331, 21 but noted that the Supreme Court in Norton v. Southern Utah Wilderness Alliance 22 had narrowed jurisdiction over agencies’ “failure to act” to cases where the agency fails to take “a discrete action” like issuing a rule by a deadline. 23 In such a situation, the court’s only remedy is to “compel agency action.” 24 Because the FSMA set out specific statutory deadlines, Judge Hamilton reasoned that failure to meet those deadlines constituted a per se “failure to act” under the APA, such that — despite the FDA’s pleas — no balancing test was permitted and so declaratory relief was proper. 25

Judge Hamilton found the question of injunctive relief to be more difficult because, as the FDA argued, Congress’s purpose of protecting food safety would not be fulfilled by court-mandated promulgation of ill-considered rules. 26 However, Judge Hamilton concluded that an injunction was in order because “by setting deadlines, Congress signaled its intention that the process be closed-ended.” 27 In recognition of the fact that any court-created time line by which the FDA must promulgate the rules would be arbitrary, Judge Hamilton ordered the FDA and CFS to agree upon a new deadline, which the court would then enforce. 28 Ultimately, the FDA and CFS failed to reach an agreed-upon schedule, and so Judge Hamilton herself ordered the FDA to “publish all proposed regulations by November 30, 2013.” 29

18 See, e.g., Declaration of Norval Bhendra in Support of Plaintiff’s Motion for Summary Judgment and Opposition to Defendants’ Motion for Summary Judgment, Ctr. for Food Safety, 2013 WL 1741816 (No. C 12-4529 PJH) [hereinafter Bhendra Declaration] (one of seventeen such declarations).
19 Id. Ctr. for Food Safety, 2013 WL 1741816, at *2.
20 Id. at *7.
21 Id. at *2.
23 Id. Ctr. for Food Safety, 2013 WL 1741816, at *3 (quoting Norton, 542 U.S. at 63 (emphasis omitted)).
24 Id. (quoting 5 U.S.C. § 706(1) (2012)) (internal quotation mark omitted).
25 Id. at *5.
26 Id. at *6.
27 Id.
28 Id. at *6–7.
One need not conclude that standing was granted incorrectly to realize that the issue was at the very least improperly ignored. Standing doctrine is highly complex and interminably unsettled, but there are at least four distinct challenges to CFS’s standing (injury in fact, causation, redressability, and the bar on generalized harms) that the court was obligated to consider given the Supreme Court’s clarification in Clapper only months before. The district court’s failure to grapple with these issues, and its implicit acceptance of the disputed view that probabilistic harms suffice as injury in fact, allowed the court to find that an injunction was proper, and thus to issue a new deadline.

The Supreme Court articulated Article III’s standing requirements most clearly in Lujan v. Defenders of Wildlife.30 First, a plaintiff must establish an injury in fact, which “requires more than an injury to a cognizable interest[; it] requires that the party seeking review be himself among the injured,”31 and that the injury be “concrete and particularized”32 as well as “actual or imminent, not ‘conjectural’ or ‘hypothetical.’”33 Second, the causation prong requires that the injury be “fairly . . . trace[able] to the challenged action of the defendant.”34 Third, it must be likely that a favorable decision will redress the injury.35 Finally, the allegation of “a generally available grievance about government” does not suffice to confer standing.36

In response to Lujan’s apparent bar against citizens as such suing the government for failure to comply with its responsibilities, some scholars argued that a party might still attain standing by claiming that the injury caused by an agency action is not the harm itself (which may or may not occur), but the increased risk of suffering such harm.37 These probabilistic harms — representing a concrete (even if

31 Id. at 563 (quoting Sierra Club v. Morton, 405 U.S. 727, 734–35 (1972)) (internal quotation mark omitted).
32 Id.
33 Id. at 560 (quoting Whitmore v. Arkansas, 495 U.S. 149, 155 (1990)) (internal quotation marks omitted).
35 Id. at 561.
36 Id. at 573–74. The rationale for this limitation is that “[v]indicating the public interest (including the public interest in Government observance of the Constitution and laws) is the function of Congress and the Chief Executive,” and so allowing these issues into the courts is a violation of the separation of powers. Id. at 576; see also Antonin Scalia, The Doctrine of Standing as an Essential Element of the Separation of Powers, 17 SUFFOLK U. L. REV. 881 (1983).
small) increased risk of injury — could be sufficiently particularized and immediate to satisfy the injury in fact requirement. 38

While this “increased-risk” approach met with mixed results at the circuit level, 39 the Supreme Court’s recent ruling in Clapper largely rejected such a view. 40 Even the Ninth Circuit, which had previously accepted a credible increased risk as an injury in fact, had primarily limited that acceptance to environmental cases. 41 The Supreme Court had never formally accepted probabilistic harm as satisfying injury in fact, and in Clapper held that, while plaintiffs need not be “literally certain that the harms they identify will come about,” 42 they must show that harms either are “certainly impending” 43 or at least have a “substantial risk” of occurring. 44 No longer does a “credible” 45 threat of harm suffice for Article III standing. After Clapper, and in the context of food safety, CFS seems to fall short of standing.

Injury in fact proves the most difficult hurdle, especially given the discussion in Clapper. CFS claimed that roughly 128,000 people are hospitalized and 3,000 die annually as a result of foodborne diseases. 46 Given that on the day CFS filed its complaint, the U.S. population was well over 314 million, 47 the annual risk to an individual of hospitalization or death, respectively, was at most 0.041% and 0.00096% — and shrinking. 48 For an individual to fall ill due to the FDA’s failure to

---

38 For an account of “probabilistic standing,” arguing that an injury exists whenever harm has a “positive expected value” (calculated by multiplying the magnitude of the harm by its probability), see Jonathan Remy Nash, Standing’s Expected Value, 111 MICH. L. REV. 1283 (2013).

39 See id. at 1298–99; see also, e.g., Cent. Delta Water Agency v. United States, 306 F.3d 938, 950 (9th Cir. 2002) (“A credible threat of harm is sufficient to constitute actual injury for standing purposes . . . .”).


41 For instance, the Ninth Circuit has explained its acceptance of increased risk as injury in fact by arguing that “to require actual evidence of environmental harm, rather than an increased risk . . . misunderstands the nature of environmental harm.” Ecological Rights Found. v. Pac. Lumber Co., 230 F.3d 1141, 1151 (9th Cir. 2000) (emphasis added). Perhaps the unique risk of environmental harm — damage that may be irreversible — compels the courts to allow standing before a plaintiff’s “lake becomes barren and sterile.” Id. (quoting Friends of the Earth, Inc. v. Gaston Copper Recycling Corp., 204 F.3d 140, 160 (4th Cir. 2000) (en banc). But see Krottner v. Starbucks Corp., 628 F.3d 1139, 1142 (9th Cir. 2010) (extending, on a case of first impression, the circuit’s increased-risk rule from “the context of environmental claims” to an identity theft case).

42 Clapper, 133 S. Ct. at 1150 n.5.

43 Id. at 1150.

44 Id. at 1150 n.5. Though holding that harms must be “certainly impending,” the majority noted that the Court has in the past required “substantial risk,” but left open to what extent the two standards differ. Id.

45 Baur v. Veneman, 352 F.3d 625, 637 (9th Cir. 2003).

46 CFS Complaint, supra note 17, at 2.


48 Even these calculations are vastly exaggerated: they are simply the risk of injury, not the risk due to the failure to regulate. Even in the unlikely event that the FDA could reduce the risk
regulate “relies on a highly attenuated chain of possibilities,” which
“does not satisfy the requirement that threatened injury must be cer-
tainly impending.” It is unlikely, given Clapper and the speculative
nature of CFS’s injury, that a court that undertook the standing analy-
sis would have found that CFS or its members faced a “certain” or
“substantial” risk sufficient to attain Article III standing.

Though CFS only discussed harms resulting from increased risk in
its motions, its members’ declarations included allegations of present
physical and emotional injuries, and claims that members changed
their habits due to the failure to regulate. Given that it was not
briefed, it is unlikely that the court relied on these claims to grant
standing; in any event, it would have been incorrect to do so. First,
the alleged emotional injury and changed behavior are derived from —
and thus dependent upon a finding of — increased risk. Clapper
sets a categorical prohibition on these second-order harms:
“[R]espondents cannot manufacture standing merely by inflicting
harm on themselves based on their fears of hypothetical future harm
that is not certainly impending.” Second, the physical injury (food
poisoning) allegedly occurred in August or September 2012, the
two months after the congressionally imposed deadline. Even if the
claim sufficed as injury in fact, it would still fail the causation prong.
At best, Congress required promulgation of rules by July 2012; newly
finalized rules would not affect food already in or soon to enter the
supply chain.

Causation proves troublesome for the probabilistic harms, too. In
some environmental cases, for example, causation is easy: because
there is a fixed geographical area at risk, a plaintiff who can show
contact with the harmed resource is likely to be injured. In food-safety
cases, however, the question is more difficult. Supposing that the FDA
did issue the rules, it is unclear how those regulations would rectify any
injury. The likelihood that an injury will occur is very low. And because
some illness will continue despite the most rigorous enforcement —
and because it is impossible to know which pieces of food were contami-

49 Clapper, 133 S. Ct. at 1148.
50 See, e.g., Bhendra Declaration, supra note 18.
51 Clapper, 133 S. Ct. at 1151.
52 See U.S. FOOD & DRUG ADMIN., THE FOOD SAFETY LAW AND THE RULEMAKING
/Food/GuidanceRegulation/UCM277713.pdf (“Even when a final rule is published, it may have
an effective or compliance date in the future . . . . [I]t may be six months from publication of the
final rule, or it may be a year from publication . . . .”).
53 See Diana R. H. Winters, Not Sick Yet: Food-Safety-Impact Litigation and Barriers to
Justiciability, 77 BROOK. L. REV. 905, 921 (2012); see also Massachusetts v. EPA, 549 U.S. 497,
522 (2007) (granting standing to Massachusetts in its “capacity as a landowner” of coastal prop-
erty — that is, based on its proximity to the sea, which may rise as a result of global warming).
ed because of, rather than despite, the regulations — it is also more difficult to show that a given failure to regulate caused a specific injury. As Clapper noted, would-be plaintiffs do not avail themselves of standing if they “can only speculate as to whether any (asserted)” injury arises under the challenged regulation or from another source.54

For the same reason — that is, the imperfect nature of food-safety controls — it is unclear whether those harms would be redressed by court-ordered FDA rulemaking. Complex schemes like food safety involve many regulated entities that may comply at different levels of precision.55 Food safety is just the sort of system that “depends on the unfettered choices made by independent actors not before the courts,” which cannot be redressed by compelling agency action alone.56

Finally, even if federal courts should recognize a small (if not “certain”) risk of injury as an injury in fact, the lower the probability of risk, the more generalized the injury becomes. Although the injury would not be speculative (the percentage risk to each individual is known), it may not be sufficiently particularized, because all face this same less-than-substantial risk.57 In such a case, the Court’s concern that the political process is the place for such a “generally available grievance about government” might foreclose granting standing.58

In light of Judge Hamilton’s order imposing a new deadline on the FDA, the failure to address these standing issues is particularly problematic. A major concern underlying standing relates to separation of powers, ensuring federal courts do not intrude in areas of governance reserved for their coequal branches.59 Though the APA clearly grants courts the authority to compel delayed agency action, this authority assumes that the action at issue is fairly before the courts — that there is a “case” or “controversy” to be heard. Standing doctrine is what tells courts whether such an individualized injury exists, thereby shifting from an undifferentiated political right — best addressed by the political branches — to a private right requiring judicial intervention.

Although a flouted congressional deadline might seem like precisely the case where the political process has failed and judicial involvement is appropriate, considering the reasons for the FDA’s failure and the

54 Clapper, 133 S. Ct. at 1149.
55 Cf. Sunstein, supra note 37, at 229 (describing industry choices after agency regulation).
57 See Sunstein, supra note 37, at 228.
58 Lujan, 504 U.S. at 573. But see FEC v. Akins, 524 U.S. 11, 25 (1998) (holding that, where an injury “is sufficiently concrete and specific[,] . . . the fact that it is widely shared” does not preclude Article III standing). However, this holding may be limited to informational harms where Congress granted standing to all citizens. See Cass R. Sunstein, Informational Regulation and Informational Standing: Akins and Beyond, 147 U. PA. L. REV. 613, 616–17 (1999).
59 See Lujan, 504 U.S. at 559-60; Scalia, supra note 36, at 892-93.
lack of cognizable injury from the FDA’s inaction, judicial restraint is more appropriate. While deadlines shorten the rulemaking process, speedy agency response may ultimately harm consumers more than they are benefited.60 Such was the explicit argument of the FDA, largely accepted by the district court.61 Indeed, in an article presaging *Lujan*, then-Judge Scalia asserted that a central aspect of separation of powers involves courts’ allowing Congress to let rules get “lost or misdirected” inside agencies, so long as such neglect does not injure anyone.62 On this view, a principal role of standing is to permit agencies to ignore duly enacted laws when doing so is beneficial, thus allowing Congress to evolve and respond63 to the effects of its actions, rather than having the courts do it instead.64

By eschewing a formal standing analysis, the district court here intruded upon Congress’s and the FDA’s functions. Where meeting a deadline would force an agency to make a rule that might hurt the intended beneficiaries, thus conflicting with the very purpose of the statute, and failure to meet the deadline has not injured the intended beneficiaries, federal courts should reasonably defer to Congress in deciding whether to enforce the deadline. Today’s standing doctrine, which the Supreme Court has now clearly held cannot be satisfied by anything less than a significant probability of harm, was designed to serve — and likely would have served — just that purpose.


62 Scalia, supra note 36, at 897 (quoting Calvert Cliffs’ Coordinating Comm., Inc. v. U.S. Atomic Energy Comm’n, 449 F.2d 1109, 1111 (1971)).

63 Such responses could run from ex ante self-executing “hammers,” see M. Elizabeth Magill, *Congressional Control over Agency Rulemaking: The Nutrition Labeling and Education Act’s Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 154–55 (1995) (describing an applicable hammer as “transform[ing] proposed regulations . . . authored by the agency into final regulations” should they miss the deadline, id. at 155), to ex post nonintervention (allowing the deadline to lapse) or budgetary consequences such as appropriations riders directing agency spending toward Congress’s desired policy outcome, see Frederick M. Kaiser, *Congressional Control of Executive Actions in the Aftermath of the Chadha Decision*, 36 ADMIN. L. REV. 239, 258–59 (1984).

64 To the extent that this approach would make statutory deadlines — absent an injury — essentially unenforceable, this is a favorable outcome. Congress should not get credit for “trying” to force agency action via a deadline it has no intention to enforce, and then get to blame the agency when it fails to meet the deadline. If standing blocks judicial enforcement of such deadlines absent a showing of harm, then Congress may be forced to be accountable for its policy decisions: it can either create meaningful consequences or not attempt to influence agency rulemaking at all.