No. 24-1283

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

ALICIA LOWE; DEBRA CHALMERS; JENNIFER BARBALIAS; GARTH BERENYI; NICOLE GIROUX; ADAM JONES; NATALIE SALAVARRIA,

Plaintiffs - Appellants,

v.

SARA GAGNÉ-HOLMES, in her official capacity as Acting Commissioner of the Maine Department of Health and Human Services; DR. PUTHIERY VA, Director of the Maine Center for Disease Control and Prevention,

Defendants - Appellees,

JANET T. MILLS, in her official capacity as Governor of the State of Maine; NANCY BEARDSLEY, in her official capacity as Acting Director of the Maine Center for Disease Control and Prevention; MAINEHEALTH; GENESIS HEALTHCARE OF MAINE, LLC; GENESIS HEALTHCARE LLC; MAINEGENERAL HEALTH; NORTHERN LIGHT EASTERN MAINE MEDICAL CENTER,

Defendants.

On Appeal from the United States District Court for the District of Maine

STATE DEFENDANTS'-APPELLEES' PRINCIPAL BRIEF

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II. Whether the District Court correctly determined that the repeal of Maine's COVID-19 vaccine requirement for certain healthcare workers mooted the remaining claims in Appellants' Amended Complaint.

III. Whether the District Court properly exercised its discretion by not permitting Appellants to further amend their Amended Complaint.

STATEMENT OF THE CASE

For more than 30 years, the State of Maine has mandated that certain healthcare facilities require their employees to be vaccinated against several highly communicable diseases. *See* 1989 Me. Laws, ch. 487, § 11 (requiring employees of hospitals to be vaccinated against measles and rubella). Under Maine's current framework, the diseases that designated healthcare facilities (DHCFs) must ensure their employees are immunized against are specified in state regulations adopted by the Maine Department of Health and Human Services (Department) and the Maine Center for Disease Control and Prevention (Maine CDC): Immunization Requirements for Healthcare Workers, 10-144-264 Me. Code R. [hereinafter,

"Rule"]. The exemptions to these vaccination requirements are provided in state statute. 22 M.R.S.A. § 802(4-B) (Supp. 2024) [hereinafter, "Statute"]. This sensible bifurcation vests medical experts and public health officials with the authority and responsibility to determine what diseases healthcare workers must be immunized against, but leaves the Maine Legislature and the political process to determine what exemptions are available. Since April of 2020, the only available exemption in the Statute to any vaccine required by the Rule has been a medical exemption. *Id.*

This Court is familiar with the facts and procedure of this case, *see Lowe v. Mills*, 68 F.4th 706 (1st Cir. 2023); *Does 1-3 v. Mills*, 39 F.4th 20 (1st Cir. 2022); and *Does 1-6 v. Mills*, 16 F.4th 20 (1st Cir. 2021), which State Defendants do not recount here. Suffice to say, much has changed since August 12, 2021, when the Department and Maine CDC revised the Rule on an emergency basis to add COVID-19 to the list of vaccinations that DHCFs must require for their employees. *See* 10-144-264 Me. Code R. §§ 1(F)(7), 2(A)(7) (2021) (as amended Aug. 2021). Only the changes that are most pertinent to this appeal are recited here.

On January 30, 2023, the Biden administration announced its intent to extend the COVID-19 public health emergency until May 11, 2023, and then end the emergency on that date. Appendix [hereinafter, "A."] 124. The end of the federal COVID-19 public health emergency would trigger the end of the State public health emergency that had been in effect since July 1, 2021. A. 124. Accordingly, the

Department began planning for the end of the Department-declared health emergency. A. 124-25. This work began in early 2023 and included identifying program and services that would be ending or transitioning back to pre-COVID standards as a result of the termination of the health emergency and working to ensure a smooth transition back to those standards. A. 124-25.

In May and June of 2023, a series of rapid regulatory changes occurred. On May 1, 2023, in light of the impending end of the federal public health emergency, the United States Center for Medicare and Medicaid Services (CMS) announced that it would soon end the requirement that covered providers establish policies requiring staff vaccination against COVID-19. *See* 86 Fed. Reg. 61,555 (proposed Nov. 5, 2021) (codified at 42 C.F.R. pts. 416, 418, 441, 460, 482-86, 491 & 494) [hereinafter, "CMS Rule"]. A. 125. On May 11, 2023, the federal public health emergency for COVID-19 ended. A. 125. On May 11, 2023, the health emergency declared under state law also ended. A. 125. On May 25, 2023, this Court issued its prior decision in this matter. *See Lowe*, 68 F.4th 706. On June 5, 2023, CMS withdrew the COVID-19 health care staff vaccination requirements that were part of the CMS Rule.[1] A. 125.

[1] While the CMS Rule was in effect, the Division of Licensing and Certification (Maine DLC) within the Department was the regulatory authority responsible for ensuring covered facilities were complying with the CMS Rule. A. 125. Maine DLC is the CMS-designated state agency for CMS survey and certification oversight in Maine. A. 125. Maine DLC evaluated heath care facilities and health care

Contemporaneously, i.e., during the latter part of May 2023 and the beginning of June 2023, the Department and Maine CDC reviewed the available science and research on the then current risks of COVID-19 in healthcare settings to ensure their rules and policies were consistent with that science and research. A. 126. This review was triggered by the end of the federal and state public health emergencies, the announcement that CMS would be rescinding its COVID-19 vaccine requirement, and changed circumstances regarding COVID-19 variants, vaccinations rates, and disease prevalence. A. 126. That work included reviewing the evidence base for the COVID-19 vaccination requirement in the Rule.[2] A. 126.

Generally accepted indicators of disease severity with respect to COVID-19 are the numbers of hospitalizations and deaths caused by that disease. A. 133. By mid-2023, the variants of SARS-CoV-2 that were circulating in the United States, including Maine, caused fewer deaths and hospitalizations per year on a population level than the previous variants. A. 126, 133. The rates of hospitalizations and deaths from COVID-19 in Maine declined significantly between January 2022 and

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agencies' compliance with the CMS Rule at every federal complaint and recertification survey conducted during the public health emergency consistent with CMS-issued requirements and guidance. A. 125. Maine DLC was also responsible for investigating DHCFs' compliance with the Maine Rule. A. 125.

[2] Throughout the pandemic, the Department and Maine CDC monitored COVID-19 variants, treatments, testing capacity, and available vaccines, along with vaccination rates, cases, outbreaks, hospitalizations, and deaths across the State. A. 126.

August 2023. A. 131-35, 137-38. At the same time, the rate of vaccination against COVID-19 in the State of Maine climbed. A. 131. As of July 31, 2023, 91.9% of adults in Maine had completed a primary series of COVID-19 vaccinations and 31.2% had received at least one additional dose of a bivalent vaccine. A. 131. New treatments for COVID-19, such as Paxlovid and Lagrevio, had become widely available. A. 126-27. These treatments, when taken as indicated, are effective at reducing the severity of symptoms resulting from COVID-19 infections and had contributed to declining hospitalization and death rates from 2022 and into 2023. A. 126-27, 135. Moreover, there were significantly fewer outbreaks of COVID-19 in Maine hospitals and nursing homes amongst their patients, residents, and staff in 2023 than in 2022. A. 133.

As a result of the Department's consideration of this and other available information, the Department concluded that, while vaccination against COVID-19 remains an important tool to protect public health, *see* A. 135-36, it would no longer be necessary to require that DHCFs ensure their employees are vaccinated against COVID-19. A. 132, 135.

On July 11, 2023, the Department announced that it was proposing to end the requirement that DHCFs require their employees to be vaccinated against COVID-19. A. 132. The Department also announced it would not be enforcing that requirement effective July 11, 2023, and during the pendency of the rulemaking

proposing the change. A. 87-89, 132. The necessary rulemaking was completed August 31, 2023, and the repeal of requirement that DHCFs ensure their employees are vaccinated against COVID-19 became effective September 5, 2023. A. 133.

Because of the reduction in outbreaks of COVID-19 in healthcare facilities, the decreased disease severity from the variants now circulating, and the decline in hospitalizations and deaths from COVID-19 since January of 2022, the Department has no plans to include COVID-19 among the diseases against which DHCFs must ensure their employees are vaccinated against in the future. A. 133-35. Moreover, available data indicated that as of August of 2023, approximately 96% of the population of the United States had some immunity against COVID-19 from vaccination, prior COVID-19 infection, or both. A. 135. In sum, based on the available clinical and epidemiological data about COVID-19, increased population immunity resulting from vaccination and prior infections, decreasing disease severity, improved treatments, and declining hospitalization and death rates, it is highly unlikely that the Department will seek to impose COVID-19 vaccination requirements on DHCFs in the future. A. 135.

On September 8, 2023, State Defendants moved to dismiss the remaining claims in the Amended Complaint as moot. A. 29. The District Court held oral argument on the motion on December 4, 2023, and granted State Defendants' motion on February 23, 2024. A. 31.

The District Court concluded that the repeal of the COVID-19 vaccination requirement for healthcare workers in Maine mooted the remaining claims in the Amended Complaint. Addendum [hereinafter, "Add."] 14. Notwithstanding Appellants' belated claims that they were making a facial challenge to the Statute, generally, the District Court concluded the Amended Complaint alleged only an as-applied challenge to the tandem operation of the Statute and Rule with respect to COVID-19. Add. 6 The District Court analyzed whether any exception to mootness applied and concluded that none did. Add. 14-21. The District Court also declined to permit Appellants to further amend their Amended Complaint. Add. 11.

This timely appeal followed. A. 32.

SUMMARY OF THE ARGUMENT

After this Court's decision in *Lowe*, 68 F.4th 706, the only remaining claims against the remaining State Defendants in the Amended Complaint are their First Amendment Free Exercise and Fourteenth Amendment Equal Protection challenges to the unavailability of a religious exemption in the Statute to the COVID-19 vaccination requirement in the Rule. The Amended Complaint does not seek any relief from a vaccination requirement for any disease other than COVID-19, and the District Court correctly determined that Appellants' claims were so limited.

Because the requirement to be vaccinated against COVID-19 has been repealed, however, Appellants' remaining claims are now moot. The Court can no

longer provide Appellants with any effectual relief. The repeal of the COVID-19 vaccination requirement was precipitated by changed circumstances of the pandemic and other events wholly outside State Defendants' control—not by this litigation. Moreover, sworn testimony demonstrates that there is no reasonable likelihood that State Defendants will seek to reimpose the COVID-19 vaccine requirement in the future—and State Defendants have not done so in the year since its repeal. This case no longer presents a live controversy, and the District Court correctly dismissed the Amended Complaint, without permitting unnecessary and unwarranted further amendment.

STANDARD OF REVIEW

This Court's review of a dismissal on the grounds of mootness is de novo. *Me. Sch. Admin. Dist. No. 35 v. Mr. R.*, 321 F.3d 9, 17 (1st Cir. 2003). A district court's resolution of disputed facts "under Rule 12(b)(1) . . . will be set aside only if clearly erroneous." *Valentin v. Hosp. Bella Vista*, 254 F.3d 358, 365 (1st Cir. 2001). The Court "review[s] the denial of a motion to amend under Rule 15(a) for an abuse of discretion." *Steir v. Girl Scouts of the USA*, 383 F.3d 7, 12 (1st Cir. 2004).

ARGUMENT

I. The District Court correctly determined the scope of Appellants' remaining claims in the Amended Complaint.

The District Court determined that the scope of remaining claims in Appellants' Amended Complaint was a challenge to the tandem operation of the

Statute and the now-repealed COVID-19 vaccination requirement in the Rule, but no more. Add. 5-10. Appellants claim that the District Court erred in its construction of the Amended Complaint, and that this error requires reversal. They argue that their Amended Complaint includes a facial challenge, generally, to the Statute which is still in effect and precludes a finding of mootness. Br. 19-24.

Contrary to Appellants' arguments, there was no reversible error in the District Court's analysis. The District Court analyzed the scope of Appellants' remaining claims to determine whether the Amended Complaint could be read fairly to include challenges to any vaccine requirement, other than COVID-19. Add. 6-10. This is the essence of a facial challenge to a statute: whether a plaintiff has alleged facts to demonstrate that it is unconstitutional in every instance. *See Dutil v. Murphy*, 550 F.3d 154, 160 (1st Cir. 2008) (explaining a plaintiff "must establish that no set of circumstances exists under which the [statute] would be valid" to be successful in facial constitutional challenge (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987))).

The District Court, correctly, concluded that the Amended Complaint raised no such dispute because Appellants' challenge was limited to COVID-19. The Amended Complaint made no reference to any other vaccine requirement, Appellants' objections to any other vaccine requirement, or whether Appellants were seeking a religious exemption to any other vaccine requirement. Add. 9-10. The

District Court's conclusion is also entirely consistent with Appellants' counsel's representation to this Court last year, when Appellants expressly disclaimed their intent to challenge any other required vaccine in the Rule.[3] In the remaining claims in their Amended Complaint, Appellants no less than 50 times identify the State law they are challenging as the "Governor's COVID-19 Vaccine Mandate." A. 39-42, 44-45, 53-58, 60-64, 66-68, 75-77. Put another way, Appellants' Amended Complaint failed to allege facts showing that they had standing to challenge the Statute with respect to anything other than COVID-19. As such, the remaining claims in the Amended Complaint raised only challenges to the now-repealed COVID-19 vaccination requirement.

The District Court did characterize Appellants' remaining claims as solely as-applied challenges, Add. 7, but this is a distinction without a difference in this circumstance. The gravamen of the District Court's analysis was whether the Amended Complaint raised constitutional challenges to the tandem operation of the Statute and Rule outside of the COVID-19 context. Appellants' arguments on this point are flawed, because they focus on the substance of facial challenges to a statute

[3] When asked to confirm that "the only aspect of the vaccine mandate that [they] are challenging is the COVID vaccine mandate, and [they're] not challenging any of the other vaccines that the State wants healthcare workers to have," Appellants' counsel responded: "That's correct." Oral argument at 1:36-2:02, *Lowe v. Mills*, 68 F.4th 706 (1st Cir. 2023) (No. 22 1710), https://www.ca1.uscourts.gov/sites/ca1/files/oralargs/22-1710_20230504.mp3.

under the First Amendment Free Exercise Clause, and not the nature of a facial challenge itself. Whether the Amended Complaint labeled its challenges as "facial" or "as applied" makes little difference to the issue of whether any claims remained after the repeal of the COVID-19 vaccination requirement. *Cf. Showtime Ent., LLC v. Town of Mendon*, 769 F.3d 61, 71 (1st Cir. 2014).

Appellants' "facial vs. as-applied" argument may have been more persuasive if the District Court had dismissed the Amended Complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) by analyzing Appellants' First Amendment and Equal Protection claims only as as-applied claims (and stating that they had not asserted any facial claims). But that is not what the trial court did. The District Court analyzed the Amended Complaint to determine whether there were any remaining claims (as-applied or facial) or relief after the COVID-19 vaccination requirement was repealed. The Amended Complaint challenges only the application of the Statute to the now-repealed COVID-19 requirement, as the District Court correctly held. Add. 6-10.

II. The District Court properly dismissed Appellants' Amended Complaint as moot.

A. Because the COVID-19 vaccination requirement was repealed in September of 2023, Appellants' remaining claims are moot.

Article III of the United States Constitution confines the jurisdiction of federal courts "to those claims that involve actual 'cases' or 'controversies.'" *Redfern v.*

Napolitano, 727 F.3d 77, 83 (1st Cir. 2013) (quoting U.S. Const. art. III, § 2, cl. 1). "Federal courts are not in the business of pronouncing that past actions which have no demonstrable continuing effect were right or wrong." *ACLU of Mass. v. U.S. Conf. of Cath. Bishops*, 705 F.3d 44, 53 (1st Cir. 2013) (cleaned up); *see also Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90 (2013) ("In our system of government, courts have no business deciding legal disputes or expounding on law in the absence of such a case or controversy." (quotation marks omitted)). For a case to qualify as one "fit for federal-court adjudication, an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) (cleaned up). "If events have transpired to render a court opinion advisory, Article III considerations require dismissal of the case." *Mangual v. Rotger-Sabat*, 317 F.3d 45, 60 (1st Cir. 2003).

Thus, a case is considered "moot when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome. Another way of putting this is that a case is moot when the court cannot give any effectual relief to the potentially prevailing party." *Bayley's Campground, Inc. v. Mills*, 985 F.3d 153, 157 (1st Cir. 2021) (quotation marks omitted). State Defendants have the burden to show mootness. *Calvary Chapel of Bangor v. Mills*, 52 F.4th 40, 47 (1st Cir. 2022).

Appellants' challenge to the repealed COVID-19 vaccination requirement is moot. They brought suit in August 2021, A. 12, claiming they faced termination

from their jobs and would suffer a loss of their constitutionally protected rights based on their refusal to be vaccinated against COVID-19 due to their sincerely held religious beliefs, A. 33-85. They sought a permanent injunction "restraining [State] Defendants . . . from enforcingm threatening to enforce, attempting to enforce, or otherwise requiring compliance with the Governor's COVID-19 Vaccine Mandate" and requiring State Defendants to "grant Plaintiffs' requests for religious exemption an accommodation from the Governor's COVID-19 Vaccine Mandate." A. 75-76. Appellants also sought "a declaratory judgment that the Governor's COVID-19 Vaccine Mandate, both on its face and as applied by Defendants is illegal and unlawful" by "imposing a mandatory COVID-19 vaccine without any provision for exemption or accommodation for sincerely held religious beliefs" that violates the First Amendment and the Equal Protection Clause. A. 76-77.

But now, the requirement that DHCFs ensure their employees are vaccinated against COVID-19 was repealed over a year ago and has not been reinstated. There is no longer any Maine (or federal) law that requires any of Appellants to be vaccinated against COVID-19. Because of this repeal, the Court cannot "grant any effectual relief whatever" to Appellants. *Chafin v. Chafin*, 568 U.S. 165, 172 (2013) (quotation marks omitted). "No matter how vehemently [Appellants] continue to dispute the lawfulness of the conduct that precipitated the lawsuit," their case "is no longer embedded in any actual controversy about [their] particular legal rights."

Already, LLC, 568 U.S. at 91 (quotation marks omitted).

Accordingly, because there is "no ongoing conduct to enjoin," Appellants' "injunctive-relief claims" are moot. *Boston Bit Labs, Inc. v. Baker*, 11 F.4th 3, 9 (1st Cir. 2021) (cleaned up). The same is true for Appellants' claims for declaratory relief. Federal courts cannot issue the declarations that Appellants seek because the COVID-19 vaccination requirement is "no longer in controversy" and "the dispute is at this point neither immediate nor real." *Id.* (cleaned up). In sum, there is "nothing harming" Appellants "and nothing left for [the Court] to do that would make a difference to [their] legal interests." *Id.* It follows that Appellants' claims are now moot and the federal courts lacks jurisdiction over the case. *See Berge v. Sch. Comm. of Gloucester*, 107 F.4th 33, 45 (1st Cir. 2024) (noting events outside the courtroom can overtake the litigation and afford plaintiffs all relief they sought to win).

Consistent with these principles, numerous courts have concluded that cases challenging government mandated COVID-19 vaccination requirements became moot when the challenged authority and associated requirements were rescinded. *See, e.g.*, *Donovan v. Vance*, 70 F.4th 1167, 1172 (9th Cir. 2023) (explaining that because the challenged COVID-19 vaccine mandate exemption processes were based on executive orders that no longer exist, no relief is available); *Marciano v. Adams*, No. 22-570-CV, 2023 WL 3477119, at *1 (2d Cir. May 16, 2023) ("But the

Defendants have repealed th[e COVID-19 vaccine] mandate, and we 'cannot enjoin what no longer exists.'" (quoting *Exxon Mobil Corp. v. Healey*, 28 F.4th 383, 393 (2d Cir. 2022)); *Navy SEAL 1 v. Austin*, No. 22-5114, 2023 WL 2482927, at *1 (D.C. Cir. Mar. 10, 2023), *rehr'g en banc denied*, 2023 WL 2795667 (D.C. Cir. Apr. 4, 2023) (dismissing as moot an appeal challenging military COVID-19 vaccination requirement following rescission of that mandate); *Regalado v. Dir., Ctr. for Disease Control*, No. 22-12265, 2023 WL 239989, at *1-2 (11th Cir. Jan. 18, 2023) (upholding dismissal for mootness where the challenged COVID-19 vaccination mandate-applicable to private employers with at least 100 employees "was withdrawn and [the plaintiff s] claims stemmed from th[at] mandate"). The District Court correctly determined the same. Add. 11-14.

Appellants resist this conclusion, claiming that the continued existence of the Statute means their case is not moot. Br. at 24-26. Appellants argue that their challenge "involves the complete prohibition on requesting or receiving religious accommodations for compulsory vaccination," but this belated argument is wholly unsupported by the Amended Complaint. Br. 25. The Amended Complaint challenges only the unavailability of a religious exemption to the now repealed COVID-19 vaccine requirement. *See* A. 39-42, 44-45, 53-58, 60-64, 66-68, 75-77. The Amended Complaint does not seek any relief from State Defendants with respect to anything other than COVID-19, include objections to any other vaccine,

or allege any adverse consequences to Appellants from anything other than their refusal to be vaccinated against COVID-19. *See id.* Other than their verified Amended Complaint, Appellants presented no evidence demonstrating how their rights are or were affected solely from the application of the Statute. The causal link between (A) the conduct challenged in Appellants' Amended Complaint and their claims for relief and (B) the facts that gave rise to those claims has been severed by the repeal of the COVID-19 vaccine requirement in the Rule.

Further, the Statute is not self-executing—its applicability is limited to diseases identified in the Rule. The Statute provides, in pertinent part, that "[e]mployees [of DHCFs] are exempt from immunization otherwise required by this subchapter or by rules adopted by the department pursuant to this section under the following circumstances." 22 M.R.S.A. § 802(4-B). The Statute does not require vaccination. Appellants' theory, that they can continue to challenge the Statute without having shown or even alleged how it is or likely will be applied to them in practice (i.e., through the Rule), is at odds with this Court's precedent. *Bos. Bit Labs*, 11 F.4th at 9 ("there is nothing harming [plaintiffs] and thus nothing left for us to do that would make a difference to [their] legal interests").

B. The voluntary cessation exception to mootness does not apply.

A claim may not be moot if a defendant, in an attempt to avoid judicial review, voluntarily ceases the conduct at issue. The "voluntary cessation" exception is

intended to prevent a "manipulative litigant" from "immunizing itself from suit indefinitely, [by] altering its behavior long enough to secure a dismissal and then reinstating it immediately after." *ACLU of Mass.*, 705 F.3d at 54-55; *see also Bos. Bit Labs,* 11 F.4th at 10 (the purpose of the exception is to stop a "scheming defendant" from ceasing its conduct to obtain a dismissal and "then backsliding when the judge is out of the picture"). Consistent with the limited purpose of this exception, "[t]he voluntary cessation doctrine does not apply when the voluntary cessation of the challenged activity occurs because of reasons unrelated to the litigation." *ACLU of Mass.*, 705 F.3d at 55 (quoting M. Redish, *Moore's Fed. Practice,* § 101.99[2]).

Even if a party changes its conduct in response to litigation, "the voluntary cessation exception can be triggered only when there is a reasonable expectation that the challenged conduct will be repeated following dismissal of the case." *Id.* at 56; *cf. City of Mesquite v. Aladdin's Castle, Inc*., 455 U.S. 283, 289 & n.11 (1982). In that case, "a defendant's voluntary change in conduct moots a case only if it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Calvary Chapel*, 52 F.4th at 47 (quotation marks omitted). State Defendants have the burden to show that the voluntary cessation exception does not apply. *Id.*

The record establishes that State Defendants repealed the COVID-19

vaccination requirement based on changed circumstances of the COVID-19 pandemic, not on this litigation. As shown above, the Department and Maine CDC began reviewing all its policies in early 2023 in preparation for the end of the federal public health emergency and the state health emergency. A. 124-25. The end of the federal public health emergency and CMS's announcement that it would be ending its COVID-19 vaccination requirements triggered a review by the Department and Maine CDC of the available science and research on the then current risks of COVID-19 in healthcare settings to ensure the State's rules and policies were consistent with that science and research. A. 126.

That review included an examination of the evidentiary underpinnings of Maine's COVID-19 vaccination requirement for healthcare workers, and showed that circumstances had changed since of November of 2021. A. 126. *See Clark v. Governor of New Jersey*, 53 F.4th 769, 778 (3d Cir. 2022) ("Our knowledge of the virus and its vectors of transmission, the rollout of vaccines, and the availability of therapeutic responses to infection have totally changed the nature of the disease itself, our understanding of it, and our response to it."), *cert. denied sub nom. Clark v. Murphy*, 143 S. Ct. 2436 (2023). Since November of 2021, new treatments for COVID-19 were approved and became widely available, and new vaccines and new vaccine formulations were approved. A. 126-130. Critically, hospitalizations and deaths from COVID-19 in Maine declined significantly in 2022 and 2023 and then

leveled off in the spring of 2023. A. 137-38. There were fewer outbreaks of COVID-19 in Maine healthcare facilities in 2023 than in 2022, and approximately 96% of the country's population now has some immunity against COVID-19 from vaccination, prior COVID-19 infection, or both. A. 133, 135. The Department's review of this and other evidence resulted in its repeal of the COVID-19 vaccination requirement for healthcare workers. A. 126-132, 134-35.

This approach was consistent with Maine's evolving response to the COVID-19 pandemic over time. *See, e.g.*, *Calvary Chapel*, 52 F.4th at 48 (explaining changes in Maine's COVID-19 related gather restrictions premised upon "expert advice" on the "best available science"); *Bayley's Campground*, 985 F.3d at 157, 162 (noting changed circumstances accounted for the rescission of a self-quarantine executive order issued by Governor Mills); *Gray v. Mills*, No. 1:21-CV-00071-LEW, 2021 WL 5166157, at *5 (D. Me. Nov. 5, 2021) ("the evidence suggests that Defendants' abandonment of the challenged measures constituted a series of good-faith policy changes in response to an evolving public health crisis, rather than an attempt to evade litigation").

The available evidence led to the repeal of the COVID vaccination requirement for healthcare workers two years after it was implemented. A. 133-35. Accordingly, because the record shows that circumstances wholly unrelated to this litigation led to the repeal of the portion of the Rule challenged by Appellants, the

voluntary cessation exception to mootness does not apply. *Calvary Chapel*, 52 F.4th at 47; *Bos. Bit Labs*, 11 F.4th at 10; *cf. Town of Portsmouth, R.I. v. Lewis*, 813 F.3d 54, 59 (1st Cir. 2016) (voluntary cessation "can apply when a defendant voluntar[ily] ceases the challenged practice in order to moot the plaintiff's case" (emphasis added) (quotation marks omitted)).

Appellants nevertheless claim that State Defendants' repeal of the COVID-19 vaccination requirement was "a litigation tactic, not a genuine change of heart." Br. 28; *see also id.* at 37-40 (claiming State Defendants' defense of this action weighs against mootness). Appellants' claim is misplaced and not supported by the record.

As an initial matter, State Defendants are not required to renounce the legality of the Rule or Statute as Appellants suggest. "No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute is no longer embedded in any actual controversy about the plaintiffs' particular legal rights." *Already, LLC*, 568 U.S. at 91 (quotation marks omitted) (emphasis added); *see also Health Freedom Def. Fund v. President of United States*, 71 F.4th 888, 892 (11th Cir. 2023) ("And while we recognize that the government continues to defend the legality of the Mandate, that fact has little, if anything to do with the voluntary-cessation analysis." (cleaned up)); *Harris v. Univ. of Mass. Lowell*, 43 F.4th 187, 191-92 (1st Cir. 2022).

Appellants also present to this Court, Br. 26-30, what the District Court

described as a "misleading narrative of the relevant events." Add. 17. According to Appellants, the issuance of this Court's opinion on May 25, 2023, and a slight uptick in COVID-19 hospitalizations and deaths between July and August of 2023, renders all other factors immaterial. Appellants' myopic focus ignores the full context of relevant events. Comparing hospitalizations and deaths between July 2023 to August 2023 ignores that hospitalizations and deaths from COVID-19 in Maine declined significantly in 2022 and 2023 and then leveled off in the spring of 2023. A. 137-38. Further, on May 1, 2023, CMS announced it would soon end its COVID-19 vaccine requirement. A. 125. The federal and state public health emergencies ended on May 11, 2023. A. 125. Then, on June 5, 2023, CMS withdrew its COVID-19 healthcare staff vaccination requirements, but left other COVID-19 requirements in place. A. 125.

This Court's decision happened to coincide with this timeline of regulatory changes and responses, and is one factor among many the District Court considered. But the record establishes that the aforementioned changes triggered the Department's review of the evidentiary underpinnings of the Rule at the end of May and beginning of June 2023. A. 126. The subsequent repeal of the COVID-19 requirement was not a "litigation tactic."

Similarly, Appellants' reliance on the Ninth Circuit's recent decision in *Health Freedom Defense Fund, Inc. v. Carvalho*, 104 F.4th 715 (9th Cir. 2024), is

misplaced. In that case, the Ninth Circuit determined that the Los Angeles Unified School District (LAUSD) had engaged in manipulative litigation tactics. In a prior suit, the same plaintiff challenged what it asserted was a mandatory COVID-19 vaccination policy imposed on LAUSD employees, but which LAUSD said was vaccinate or test policy, despite having described it a mandatory vaccination requirement with no exceptions. *Id.* at 718-19. The trial court dismissed the case, concluding that LAUSD employees had not been injured, any future injury was speculative, and there was no threat of future injury. *Id.* at 719.

Two weeks after obtaining that dismissal, LAUSD adopted a mandatory vaccination policy—which was the subject of the *Carvalho* matter. *Id.* at 719-20. LAUSD obtained a second dismissal, *id.* at 720, only to abandon its COVID-19 vaccination requirement on appeal, twelve days after oral argument before the Ninth Circuit and after the case was discussed at a public meeting of LAUSD's Board, *id.* at 721. During oral argument, LAUSD's counsel argued the requirement was still necessary because of COVID-19 spikes, but immediately after the argument suggested (correctly) to opposing counsel that its repeal was imminent. *Id.* at 721. These tactics led the Ninth Circuit to conclude that LAUSD was gaming the litigation process. *Id.* at 722-24.

These facts bear no resemblance to facts before the District Court regarding State Defendants repeal of the COVID-19 portion of the Rule. The Department and

Maine CDC amended the Rule to add the COVID-19 vaccination requirement in response to the then-existing circumstances of the pandemic. When those circumstances changed, as described above, the Department and Maine CDC amended the Rule again to repeal the COVID-19 vaccination requirement. As the District Court supportably found, State Defendants "met their burden of demonstrating that the Department initiated its review and ultimately decided to repeal the COVID-19 vaccination requirement for substantial reasons unrelated to this litigation, and not out of bad faith." Add. 18. *See Corrigan v. Bos. Univ.*, 98 F.4th 346, 353 (1st Cir. 2024) ("After almost two years in place, BU retired the program not in response to Corrigan's lawsuit, but rather because of more favorable trends in regard to COVID-related illnesses and hospitalizations." (quotation marks omitted)).

Appellants next argue that the voluntary cessation exception to mootness applies because State Defendants retain the "authority to reinstate a compulsory COVID-19 vaccination requirement." Br. 31-33. This argument "is essentially a rehash of an argument rejected" by this Court in both in *Boston Bit Labs* and *Bayley's Campground*: "That the Governor has the power to issue executive orders cannot itself be enough to skirt mootness, because then no suit against the government would ever be moot. And we know some are." *Calvary Chapel*, 52 F.4th at 49

(quoting *Bos. Bit Labs*, 11 F.4th at 10). The mere retention of authority to do (or not do) something in the future is insufficient to defeat mootness.

Further, contrary to Appellants' claims, the District Court did not shift the burden of proof on voluntary cessation from State Defendants to Appellants. Br. 34-35. State Defendants provided a declaration under oath with supporting exhibits to support their motion. A. 123-38. In response, Appellants made legal arguments as to why this evidence was insufficient, but they provided no countervailing evidence, nor did they seek discovery on the issue of mootness.[4] Add. 17. Rather than shifting the burden, the District Court simply noted the lack of any other evidence.

Finally, State Defendants have made it absolutely clear that the challenged conduct cannot reasonably be expected to reoccur. Br. 36-37. State Defendants stopped enforcement of the COVID-19 vaccination requirement in July 2023, formally repealed the requirement in September of 2023, and have not sought to reinstate it. A. 132-33. *See Calvary Chapel*, 52 F.4th at 49 (reasoning that voluntary cessation does not apply in part because Maine's Governor had not sought to "reinstate" or "impose anything like the complained-about restrictions" in the intervening 16 months). Because of the changed circumstances, neither the

[4] Appellants assert they have not received a single page of discovery, Br. 43, but all parties made the required initial disclosures and the case was dismissed before any other responses to discovery requests were due.

Department nor Maine CDC have any plans to include COVID-19 again among the diseases against which DHCFs must ensure their employees are vaccinated against in the Rule. A. 133. *Corrigan*, 98 F.4th at 353 ("Because it is absolutely clear that BU ended its mandatory testing program in response to encouraging public health data and there are no signs that the pandemic will worsen, it is not reasonable to expect that BU again will impose a similar testing program."). It is therefore highly unlikely that the Department will seek to impose COVID-19 vaccination requirements on DHCFs in the future. A. 135. Any suggestion to the contrary by Appellants rests solely on speculation. *See Bos. Bit Labs*, 11 F.4th at 11.

C. The "capable of repetition yet evading review" exception to mootness does not apply.

The "capable of repetition yet evading review" exception to mootness is "limited to the situation" where "(1) the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there was a reasonable expectation that the same complaining party would be subjected to the same action again." *Weinstein v. Bradford*, 423 U.S. 147, 149 (1975) (emphasis added); *see also Gulf of Me. Fishermen's Alliance v. Daley*, 292 F.3d 84, 89 (1st Cir. 2002). Therefore, for this exception to apply, there must be a reasonable expectation or demonstrated probability that Appellants will be subject to same action in the future. *See ACLU of Mass.*, 705 F.3d at 57. The Supreme Court has cautioned that this exception "applies only in "exceptional situations." *See, e.g.*, *City of Los*

Angeles v. Lyons, 461 U.S. 95, 109 (1983). Appellants bear the burden of making a "reasonable showing" that it will again be subject to the challenged restrictions. *Id.* The District Court properly held that Appellants did not make such a showing.

First, the requirement challenged by Appellants was in effect for nearly two years. A law or regulation in place for that length of time is not so short as to foreclose complete judicial review prior to its cessation or expiration.

Second, and regardless, Appellants have not shown that they will be subject to a state-imposed COVID-19 vaccination requirement on healthcare workers in the future. To the contrary, Nancy Beardsley, Deputy Director of the Maine CDC, explained under oath that because of the changed circumstances of the COVID-19 pandemic, "it is highly unlikely that the Department will seek to impose COVID-19 vaccination requirements on DHCFs in the future." A. 135. Because the record establishes that there is no reasonable expectation or demonstrated probability that Appellants will be subject to the same action in the future, this exception does not apply. *See ACLU of Mass.*, 705 F.3d at 57.

III. The District Court correctly exercised its discretion by not permitting Appellants to further amend their Amended Complaint.

In opposing State Defendants' motion to dismiss below, Appellants argued that their Amended Complaint sufficiently pled a challenge to the Statute, despite the repeal of the COVID-19 vaccination requirement. ECF No. 195 at 4-5. In the alternative, they claimed that "the appropriate remedy would not be dismissal, but

permitting [them] to file an amended complaint to more specifically state such related claims over which this Court would doubtlessly have jurisdiction," citing Fed. R. Civ. P. 15(a) and (d) as grounds for their request. *Id*. at 4, 5.

A request to file a second amended complaint requires leave of court, which should be "freely" given "when justice so requires." Fed. R. Civ. P. 15(a)(2). "Under Rule 15(d), the filing of a supplemental pleading is not available to the pleader as a matter of right but, rather, is subject to the court's discretion." *United States. ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 6 (1st Cir. 2015). "[A] trial court [need not] mindlessly grant every request for leave to amend. When a proffered amendment comes too late, would be an exercise in futility, or otherwise would serve no useful purpose, the district court need not allow it." *Aponte-Torres v. Univ. of Puerto Rico*, 445 F.3d 50, 58 (1st Cir. 2006). The denial of a motion to amend "will be upheld so long as the record evinces an arguably adequate basis for the court's decision." *Hatch v. Dep't for Child., Youth & Their Fams.*, 274 F.3d 12, 19 (1st Cir. 2001).

Here, there was ample basis for the District Court's dismissal without allowing leave to further amend. As an initial matter, Appellants neither moved to amend their Amended Complaint nor filed a further amended complaint for the District Court's review. Instead, they simply asked for "leave to amend their [Amended] Complaint to address any pleading concerns." ECF No. 195 at 5.

In similar circumstances, this Court has indicated that a request for leave to amend can be denied on that basis alone. In *Aponte-Torres v. University of Puerto Rico*, 445 F.3d 50, the plaintiffs, as Appellants did below, made a "bare request" for leave to amend in opposition to a dispositive motion. *Id.* at 58; *cf.* ECF No. 195 at 5. Further, like the Appellants here, "the plaintiffs made no attempt to supplement their" request, "nor did they preview what additional facts or legal claims might be included in a second amended complaint (should one be allowed)." *Aponte-Torres*, 445 F.3d at 58; *cf.* ECF No. 195 at 5. This Court ruled that the "absence of supporting information may, in and of itself, be a sufficient reason for the denial of leave to amend." *Aponte-Torres*, 445 F.3d at 58.

Further, the District Court properly determined that justice did not require further amendment of the Appellants' Amended Complaint because, in the District Court's view, it would have broadened, drastically, the scope of the case from just COVID-19 to all other diseases in the Rule. Add. 11. Such an amendment would not have been "merely clerical or corrective. It would have established an entirely new factual basis for [Appellants'] claims" and required the parties to rework their strategies and proof to address new diseases and vaccinations. *Little v. Liquid Air Corp.*, 952 F.2d 841, 846 (5th Cir. 1992), *on reh'g en banc*, 37 F.3d 1069 (5th Cir. 1994). The District Court did not abuse its discretion by denying Appellants the opportunity to transform this case into a brand-new matter.

Appellants nevertheless claim that they should have been allowed to further amend their Amended Complaint in order to "clarify any ambiguity in their claims" that they were challenging the Statute and cure any pleading deficiency. Br. at 52-53. There was no "ambiguity" in their claims. Moreover, State Defendants and this Court have treated Appellants' claims as challenging both the Rule and the Statute throughout this litigation. Add. 5-10. *See Lowe*, 68 F.4th at 711; *Does 1-6 v. Mills*, 16 F.4th 20 *passim*. Put another way, the deficiency with Appellants' Amended Complaint was not the clarity of their claims; the deficiency was their failure to allege and show how the Statute continued to apply to them post-repeal of the COVID-19 vaccination requirement.

Finally, for similar reasons, the District Court did not abuse its discretion in dismissing the Amended Complaint without permitting a supplemental pleading. Add. 11. Rule 15(d) serves to permit a supplemental pleading to address events that have occurred after the relevant pleading. Fed. R. Civ. P. 15(d). Appellants' "clarification" related to events that had all occurred before August of 2021, Add. 11, and amendment under Rule 15(d) was unwarranted.

CONCLUSION

For the reasons set forth above, State Defendants request that the Court affirm the District Court's dismissal of Appellants' Amended Complaint.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6). I further certify that all text in this opposition brief is in proportionally spaced Times New Roman Font and is 14 points in size. I further certify that, according to the word count function of the word-processing software used to prepare this opposition brief (Microsoft Word 365), this brief contains 6,967 words.

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CERTIFICATE OF SERVICE

I, Kimberly L. Patwardhan, hereby certify that on September 16, 2024, I electronically filed the State Defendants'-Appellees' Principal Brief with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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