# **United States Court of Appeals**For the First Circuit

No. 24-1283

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 for 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.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

[Hon. John D. Levy, <u>U.S. District Judge</u>]

Before

Barron, <u>Chief Judge</u>, Lynch and Howard, Circuit Judges.

<u>Kimberly L. Patwardhan</u>, Assistant Attorney General, Office of the Maine Attorney General, with whom <u>Aaron M. Frey</u>, Attorney General, and <u>Thomas A. Knowlton</u>, Deputy Attorney General, Chief, Litigation Division, Office of the Maine Attorney General, were on brief, for appellees.

January 17, 2025

This appeal challenges the LYNCH, Circuit Judge. district court's February 23, 2024 dismissal on mootness grounds of appellants' constitutional challenge to Maine's COVID-19 vaccine mandate for certain healthcare workers, which was originally promulgated by emergency rule on August 12, 2021, no longer enforced as of July 12, 2023, and repealed by amendment of the regulation, effective on September 5, 2023. See 10-144-264 Me. Code R. § 2 (amended Sept. 5, 2023) (requiring designated healthcare facilities to "require for all employees who do not exclusively work remotely a Certificate of Immunization, or Proof Immunity" against COVID-19). The appellants are Maine healthcare workers who do not exclusively work remotely and who were terminated from their employment at covered healthcare facilities after they refused to comply with the COVID-19 vaccine mandate based on their religious beliefs.

In 2021, the appellants filed suit in the United States District Court for the District of Maine against their former employers and various Maine government officials, asserting that the failure of the mandate to provide for religious exemptions violated, inter alia, the First and Fourteenth Amendments of the United States Constitution. On the same day, they filed a motion for a temporary restraining order and a preliminary injunction, which were denied. The appellants appealed the denial of

preliminary injunctive relief.<sup>1</sup> On October 19, 2021, this court affirmed the district court's denial of a preliminary injunction, Does 1-6 v. Mills, 16 F.4th 20, 37 (1st Cir. 2021), and the Supreme Court denied the appellants' subsequent application for emergency injunctive relief, Does 1-3 v. Mills, 142 S. Ct. 17, 17 (2021).

On February 14, 2022, the defendants moved to dismiss the complaint for failure to state a claim, which was granted on August 18, 2022. In May 2023, this court affirmed in part and reversed in part, reversing the dismissal of the First Amendment Free Exercise and Fourteenth Amendment Equal Protection Clause claims for declaratory and injunctive relief against the Commissioner of the Maine Department of Health and Human Services ("MDHHS") and the Director of the Maine Center for Disease Control and Prevention ("MCDC"). Lowe v. Mills, 68 F.4th 706, 709, 725 (1st Cir. 2023).

Following the September 2023 repeal of the challenged regulation, the defendants moved to dismiss these remaining claims as moot, and their motion was granted. The district court also denied the appellants leave to amend the complaint. This timely appeal followed.

<sup>&</sup>lt;sup>1</sup> They also sought an emergency injunction pending appeal in this court, which was denied the following day. The appellants appealed to the Supreme Court, which also denied their emergency application for injunctive relief. See Does 1-3 v. Mills, No. 21A83, 2021 WL 11710854 (U.S. Oct. 19, 2021).

On de novo review, we affirm the district court's determinations that the defendant state health officials have met their burden to show the challenge is moot and that no exceptions to mootness apply. See Bos. Bit Labs, Inc. v. Baker, 11 F.4th 3, 8-12 (1st Cir. 2021); Corrigan v. Bos. Univ., 98 F.4th 346, 353-54 (1st Cir. 2024); Harris v. Univ. of Mass. Lowell, 43 F.4th 187, 194-95 (1st Cir. 2022). We also affirm the denial of appellants' request to amend their complaint. See Palmer v. Champion Mortg., 465 F.3d 24, 30 (1st Cir. 2006).

I.

We have previously recounted the background facts and procedural history of this matter, including the genesis of the Maine covered healthcare workers COVID-19 vaccine mandate, see Lowe, 68 F.4th at 709-13; Does 1-6, 16 F.4th at 24-28. We focus here on the facts bearing on the repeal of the Maine mandate and the mootness issue.

On January 30, 2023, the Biden administration announced its intent to extend the COVID-19 health emergency to May 11, 2023, and then to end it on that date. On May 1, 2023, the federal Centers for Medicare and Medicaid Services ("CMS") announced that it would soon end the requirement that covered healthcare providers require staff vaccination against COVID-19. The federal public health emergency ended on May 11, 2023, as planned. Because the Maine public health emergency was designed to be in effect through

the duration of the federal public health emergency, it too ended on May 11, 2023. This court published its opinion on May 25, 2023, reinstating the claims discussed. Lowe, 68 F.4th at 706. CMS formally withdrew its COVID-19 vaccination requirement on June 5, 2023. See Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements, 88 Fed. Reg. 36,485 (June 5, 2023) (codified at 42 C.F.R. pts. 416, 418, 441, 460, 482-86, 491, 494).

On July 11, 2023, MDHHS announced that it was proposing to end the requirement that employees be vaccinated against COVID-19 and that it would not enforce the requirement during the pendency of the procedural requirements to repeal the regulation. In the announcement, MDHHS explained:

While COVID-19 vaccination remains important tool to protect public health, the vaccination requirement for health care workers achieved the intended benefits of saving lives, protecting health care capacity, and limiting the spread of the virus in Maine during the height of the pandemic. Despite having the oldest population in the nation, Maine consistently rated among the top states in the country on vaccination and among the lowest on COVID-19 deaths. Maine currently ranks third on bivalent booster vaccination overall and first for those age 65 and older. Additionally, Maine health professionals' strong culture of patient safety has limited risk of severe COVID-19 being spread among staff and patients.

The Department filed the proposed rule change with the Secretary of State today based on available clinical and epidemiological data

about COVID-19, increased population immunity resulting from vaccination and prior infections, decreasing disease severity, improved treatments, and declining infection and death rates. This follows [CMS's] withdrawal of its requirement for COVID-19 vaccination of health care workers on June 6, 2023. Maine is among four remaining states with some type of COVID-19 vaccine requirement.

Per Maine law, the amendment of the regulation went through public notice and comment. The Rulemaking Fact Sheet stated, in part:

This proposed change is based on available clinical and epidemiological data about COVID-19, increased population immunity resulting from vaccination and prior infections, decreasing disease severity, improved treatments, and declining infection and death rates. In addition, [CMS] in June 2023 withdrew the COVID-19 vaccine requirement for healthcare employees, following the May 11, 2023 end of the federal Public Health Emergency for COVID-19.

The proposal entailed removing COVID-19 from the list of specified infectious diseases against which immunizations are required and other changes reflecting that removal. The changed MDHHS regulation became effective on September 5, 2023.

In support of its post-repeal motion to dismiss and in addition to the public records described above, the Deputy Director of the MCDC, an office within MDHHS, submitted a declaration. The MDHHS Declaration stated that since November of 2021, MDHHS and MCDC had continued to monitor the COVID-19 public health situation in Maine, and that MDHHS began planning for the end of the public

health emergency in early 2023, by "identifying programs and services that would be ending or transitioning back to pre-COVID standards." "Around the end of May 2023 and beginning of June 2023," MDHHS and MCDC also conducted a review of available scientific data and research regarding COVID-19 risks healthcare settings as part of an evaluation of state rules and policies, including the state's COVID-19 vaccine requirement for healthcare workers. "This review was triggered by the end of the federal public health emergency, the announcement that CMS would be rescinding its COVID-19 vaccine requirement, and changed circumstances regarding COVID-19 variants, vaccination[] rates, and disease prevalence." The MDHHS Declaration contained detailed information and data supporting the repeal, including, inter alia, changes and developments as to new COVID-19 variants, antiviral treatments, antigen tests, further vaccine developments, vaccination rates, and hospitalization rates. It stated that, on the basis of that information, MDHHS "concluded that it would no longer be necessary to require that [designated healthcare facilities] ensure their employees are vaccinated against COVID-19." The MDHHS Declaration contained two pages of exhibits: a graph of COVID-19 hospitalization data between late 2021 and late

2023, and a graph of daily COVID-19 deaths from January 2022 to September  $2023.^2$ 

The appellants opposed dismissal but did not put in any evidence and chose not to depose any state officials. They do not contest the accuracy of the defendants' data but strenuously argue the data does not support mootness.

In holding that the challenges were moot, the district court rejected the appellants' argument that they had mounted a facial attack on the statute authorizing the challenged regulation and setting forth exemptions. See Me. Rev. Stat. Ann. tit. 22, § 802. The district court concluded that the appellants had mounted "an as-applied challenge to the tandem operation of the pre-repeal regulation and statute, but no more." Lowe v. Mills, 718 F. Supp. 3d 69, 75 (D. Me. 2024). The statute merely

<sup>&</sup>lt;sup>2</sup> The MDHHS Declaration also stated that MDHHS

has no plans to include COVID-19 again among diseases against which [designated healthcare facilities] must ensure their employees are vaccinated against in the healthcare worker vaccination rule. . . . [B]ased 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 [MDHHS] will seek to impose COVID-19 vaccination requirements on [designated healthcare facilities] in the future.

<sup>&</sup>lt;sup>3</sup> The district court concluded that the appellants treated

authorizes MDHHS to promulgate by regulation requirements, but it does not specify the diseases or itself mention COVID-19, and it authorizes only certain exemptions. See Me. Rev. Stat. Ann. tit. 22, § 802(4-B).

The district court then held the repeal of the COVID-19 vaccine regulation mooted the case because the court "[could not] provide any relief to the Plaintiffs that would redress injuries that arise from an actual case or controversy." Lowe, 718 F. Supp. 3d at 79. The district court further held that neither the "voluntary cessation" nor the "capable of repetition yet evading review" exceptions to the mootness doctrine applied. Id. at 79-82.

In holding that the defendants had met their burden to show the voluntary cessation exception did not apply, the court rejected the appellants' argument that the defendants "engaged in a bad faith litigation tactic" in repealing the mandate soon after our May 25, 2023 opinion. <u>Id.</u> at 80-81. The court held that argument "[did] not account[] for obviously relevant Federal and

the governor's August 21, 2021 announcement as the challenged mandate, which referred to the state regulation. Lowe v. Mills, 718 F. Supp. 3d 69, 75 (D. Me. 2024). Moreover, the district court noted that the regulation rather than the statute imposed the challenged COVID-19 vaccination requirement, and the statute's "exemptions only take effect in this context when the regulation is enforced." Id. at 76. The district court further concluded that no facial challenge existed because the appellants challenged only the statute's application to COVID-19 vaccinations, and not the other vaccines required under the regulation. Id. at 76-77.

State governmental actions, [and] is based on a substantially incomplete and, therefore, misleading narrative of the relevant events." Id. at 81. The court also noted that the appellants had "not supported their position with declarations under oath or exhibits, nor ha[d] they requested permission to perform discovery on the issue." Id.

The exception for conduct capable of repetition but evading review likewise did not apply because the appellants had "fail[ed] to present any positive, non-speculative evidence to support a reasonable expectation that they will be subject to the challenged COVID-19 vaccination requirement -- or one substantially similar to it -- again." Id.

The court denied appellants' request for leave to amend the complaint, made in their opposition. <u>Id.</u> at 77. The district court held that "justice does not require permitting the Plaintiffs to further amend the Amended Complaint to drastically broaden the scope of their claims to challenge all possible applications of the [designated healthcare facilities] worker immunization rule and the Department's authorizing statute." <u>Id.</u> Moreover, the appellants "ha[d] not identified any post-filing transactions, occurrences, or events that would justify additional amendments" under Federal Rule of Civil Procedure 15(d). <u>Id.</u>

II.

We review the mootness determination de novo. Bos. Bit Labs, 11 F.4th at 8.

### A. Appellants have not mounted a facial challenge to the statute

district court correctly concluded that the appellants' complaint did not present a facial challenge to the statute, Me. Rev. Stat. Ann. tit. 22, § 802. Appellants' challenge was only to that portion of the regulation, 10-144-264 Me. Code R. § 2(A), concerning COVID-19 vaccinations which was in existence from August 12, 2021 to September 5, 2023. The statute itself says nothing about a COVID-19 mandate and merely authorizes MDHHS to promulgate vaccination requirements with certain exceptions. See Me. Rev. Stat. Ann. tit. 22, § 802(4-B). Indeed, in their amended complaint, the appellants describe the target of their challenge as "the Governor's COVID-19 Vaccine Mandate," the very term that they use elsewhere in the amended complaint to identify the emergency rule -- but not the enabling statute -- that added COVID-19 to the list of required vaccinations in Chapter 264. Further, the appellants have not challenged the regulation's still-existing vaccination requirements for measles, mumps, rubella, varicella, hepatitis B, and influenza. See 10-144-264 Me. Code R. § 2(A); Lowe, 718 F. Supp. 3d at 76-77. The appellants have only ever challenged the COVID-19 vaccination requirement, a fact that they do not dispute on appeal. Appellants may not on appeal recharacterize their challenge as a facial attack on the statute.

#### B. Appellants' claims are moot

"The 'heavy' burden of showing mootness is on the party raising the issue." Bos. Bit Labs, 11 F.4th at 8 (quoting Connectu LLC v. Zuckerberg, 522 F.3d 82, 88 (1st Cir. 2008)). The state officials have met their burden to show that the appellants' claims for relief are moot. "Article III limits federal court jurisdiction to 'cases' and 'controversies.'" O'Neil v. Canton Police Dep't, 116 F.4th 25, 30 (1st Cir. 2024) (quoting U.S. Const. art. III, § 2). "The doctrine of mootness enforces the mandate 'that an actual controversy must be extant at all stages of the review, not merely at the time the complaint is filed.'" Mangual v. Rotger-Sabat, 317 F.3d 45, 60 (1st Cir. 2003) (quoting Steffel v. Thompson, 415 U.S. 452, 459 n.10 (1974)). "[A] case is moot when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome . . . . [or] 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) (first alteration in original) (quoting Town of Portsmouth v. Lewis, 813 F.3d 54, 58 (1st Cir. 2016)); see also ACLU of Mass. v. U.S. Conf. of Cath. Bishops, 705 F.3d 44, 52-53 (1st Cir. 2013) (dismissal is required where "events have transpired to render a court opinion merely advisory" (quoting Mangual, 317 F.3d at 60)).

The appellants sought "a permanent injunction . . . restraining and enjoining [state] Defendants . . . from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the Governor's COVID-19 Vaccine Mandate." Because the COVID-19 vaccine mandate has been repealed by way of COVID-19's removal from Chapter 264, and it has not been reinstated, there is simply "no ongoing conduct to enjoin," and the claim for injunctive relief is accordingly moot. Bos. Bit Labs, 11 F.4th at 9 (quoting Lewis, 813 F.3d at 58) (claim for injunctive relief was moot where executive order imposing challenged COVID-19 restriction was no longer in effect).

In order for appellants' request "[f]or declaratory relief to withstand a mootness challenge, the facts alleged must 'show that there is a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" ACLU of Mass., 705 F.3d at 53-54 (emphasis omitted) (second alteration in original) (quoting Preiser v. Newkirk, 422 U.S. 395, 402 (1975)). Because the COVID-19 vaccination mandate no longer exists and is "no longer in controversy," this request for relief "is at this point neither immediate nor real." Bos. Bit Labs, 11 F.4th at 9 (second quoting Lewis, 813 F.3d at 58). Our sister circuits have also held that challenges to COVID-19

vaccination requirements become moot when those requirements are See, e.g., Donovan v. Vance, 70 F.4th 1167, 1172 (9th Cir. 2023) (holding that case including claims for declaratory and injunctive relief was moot after challenged executive orders creating COVID-19 vaccine mandate no longer existed); Marciano v. Adams, No. 22-570-CV, 2023 WL 3477119, at \*1 (2d Cir. May 16, 2023) (claims for declaratory and injunctive relief were moot because COVID-19 vaccine mandate had been repealed 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) (unpublished) (dismissing as moot relief after COVID-19 vaccine mandate had been rescinded); Regalado v. Dir., Ctr. for Disease Control, No. 22-12265, 2023 WL 239989, at \*1-2 (11th Cir. Jan. 18, 2023) (case was moot where challenged COVID-19 vaccination mandate was withdrawn).

#### C. Exceptions to mootness do not apply

A primary focus of the appellants' argument to us is their contention that the exceptions to mootness apply. We disagree. The state defendants have met their burden of showing that the voluntary cessation doctrine does not apply. See Bos. Bit Labs, 11 F.4th at 10. The appellants bear the burden of showing that the exception for conduct capable of repetition yet

evading review applies, <u>Gulf of Me. Fishermen's All.</u> v. <u>Daley</u>, 292 F.3d 84, 89 (1st Cir. 2002), and have not met that burden.

The voluntary cessation doctrine creates an exception to mootness where two tests are met: "'a defendant voluntar[ily] ceases the challenged practice in order to moot the plaintiff's case and there exists a reasonable expectation that the challenged conduct will be repeated' after the suit's 'dismissal.'" Bos. Bit Labs, 11 F.4th at 9 (alteration in original) (emphasis added) (quoting Lewis, 813 F.3d at 59). Under the first test, the exception does not apply to changes in conduct that are "unrelated to the litigation," given that the exception "exists to stop a scheming defendant from trying to 'immuniz[e] itself from suit indefinitely' by unilaterally changing 'its behavior long enough to secure a dismissal' and then backsliding when the judge is out of the picture." Id. at 10 (alteration in original) (quoting Lewis, 813 F.3d at 59).

We begin our analysis with the second test: whether "it is 'absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" Calvary Chapel of Bangor v. Mills, 52 F.4th 40, 47 (1st Cir. 2022) (quoting Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167, 189 (2000)).

## i. The challenged conduct is not reasonably expected to recur

The defendant state health officials have met their burden to show that the challenged conduct "[can]not reasonably be expected to recur." Id. (quoting Friends of the Earth, 528 U.S. at 189). The MDHHS Declaration states that MDHHS "has no plans to include COVID-19 again among the diseases against which [designated healthcare facilities] must ensure their employees are vaccinated against in the healthcare worker vaccination rule." The COVID-19 vaccine mandate also has not been reinstated in the nineteen months since its enforcement ended and in the seventeen plus months since its repeal. See id. at 49 (voluntary cessation exception did not apply in part because state had not attempted to "reinstate" or "impose anything like the complained-about restrictions" in intervening months).

On this record, it is extremely unlikely that the risks presented by any future variation in the SARS-CoV-2 virus would require the reinstatement of the same or an equivalent vaccine mandate. See Bos. Bit Labs, 11 F.4th at 11 (the conclusion that the Governor would again declare a COVID-19 emergency and reinstitute previous policies was "unrealistically speculative"); Corrigan, 98 F.4th at 353 (Because "there are no signs that the pandemic will worsen, it is not reasonable to expect that BU again

will impose a similar testing program.").<sup>4</sup> The regulation was geared to the risks from the SARS-CoV-2 virus as it existed at the time the regulation was in force, and the developments since regarding vaccination rates (including vaccination rates for healthcare workers), circulating variants, disease prevalence, and available tests, treatments, and new vaccines have all reduced those risks. As to vaccination rates, as of October 31, 2021, COVID-19 vaccination rates for healthcare workers in Maine in various workplaces ranged from 92.6 percent to 98.1 percent. Between May 28, 2023 and June 30, 2023, 93.3 percent of all

This case is easily distinguishable from Bayley's Campground, in which this court determined that the challenge there to a COVID-19 restriction was not moot because the state defendants had not met their burden of showing that the allegedly wrongful behavior could not reasonably be expected to recur. See 985 F.3d 153, 157-58 (1st Cir. 2021). In Bayley's Campground, the challenged COVID-19 restriction had not been rescinded entirely, as here, but merely replaced with a less strict version, and indeed, without the check of a rulemaking process like that required of MDHHS under Me. Rev. Stat. Ann. tit. 5, § 8052, the state could have unilaterally done so as the "dynamic" public health conditions evolved. See id. at 156-57; Me. Rev. Stat. Ann. tit. 37-B, § 742. Moreover, the time that elapsed between the challenged restriction's implementation and removal was about two months; in contrast, the repeal of the regulation at issue here reflects enduring changes in the COVID-19 pandemic over the course of nearly two years. See id. at 155-56. The Bayley's Campground court also observed that the state defendant "has not denied that a spike in the spread of the virus in Maine could lead her to impose a self-quarantine requirement just as strict as [the challenged measure]." Id. at 157. Here, the state defendants have declared that "it is highly unlikely that [MDHHS] will seek impose COVID-19 vaccination requirements on [designated healthcare facilities] in the future," a prediction corroborated by lasting trends in disease prevalence, vaccine availability and acceptance, and treatment efficacy.

essential healthcare workers in Maine had completed the primary series of COVID-19 vaccinations, with 99.8 percent having received at least one dose. Data from July 31, 2023 indicated that, at that time, 91.9 percent of adults in Maine had completed a primary series of COVID-19 vaccinations and 31.2 percent had received at least one additional dose of a bivalent vaccine, which targeted more variants of the virus.

The data on which MDHHS relied showed that, as to changes in circulating variants, the SARS-CoV-2 virus has mutated a number of times. Since the regulation was implemented, the Omicron variant became the predominant variant in the United States, and the Omicron variant caused fewer deaths and hospitalizations per year on a population level than had the Delta variant of 2021 or the variants circulating in 2020.

The data on which MDHHS relied showed that prevalence of the COVID-19 disease had also diminished. Data regarding hospitalization rates in 2023 relative to 2022 showed an overall decrease. For example, in June of 2023, the average number of hospitalized COVID-19 patients per day in Maine had been thirty-seven, compared with 137 in June 2022. COVID-19 deaths likewise declined between 2022 and 2023. In June of 2023, there were ten COVID-19 deaths in Maine, compared with fifty-seven in June 2022.

The data also showed new and effective treatments had been developed: three antiviral treatments for COVID-19 including

Paxlovid and Lagrevio. COVID-19 antigen tests have also become widely available since 2021, when Maine experienced a shortage. Bivalent formulations and booster doses of vaccines were approved, and in late 2021 and 2022, the FDA expanded authorizations for children of certain ages to receive different vaccines. In August 2022, the FDA issued an Emergency Use Authorization for the Novavax COVID-19 vaccine for people who are unable or unwilling to receive an mRNA vaccine. All of these data support MDHHS' conclusion that it was "highly unlikely" they would ever promulgate an equivalent COVID-19 vaccine mandate regulation.

Nor does the fact that the defendant state health officials have the authority to promulgate regulations as to future events negate mootness. As held in <u>Bos. Bit Labs</u>, "[t]hat 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." 11 F.4th at 10; <u>see Calvary Chapel</u>, 52 F.4th at 49 (rejecting argument that voluntary cessation exception applied because appellant "face[d] a constant threat that [the Governor] will use [her] power to restore [COVID-19] restrictions that (allegedly) discriminate against religious services").

ii. Repeal of the mandate was not done to moot the litigation

Although, strictly speaking, the voluntary cessation

doctrine does not apply if the party seeking mootness can show

either that the challenged conduct cannot reasonably be expected to recur or that it was ceased for a non-litigation reason, the defendant state officials have independently demonstrated that the "voluntary" repeal of the COVID-19 regulatory vaccine mandate was not done in order to moot the case. The evidence of record demonstrates that when MDHHS instituted the regulation, it did so in response to its own assessment of the risks posed by the Delta variant circulating at the time and the risk posed by the circulating COVID-19 variants to its citizens and its healthcare workers. The repeal of the regulation followed the same characteristic behavior.

After imposing the vaccine mandate, MDHHS and MCDC continued to monitor the COVID-19 public health situation in Maine. In early 2023, when the federal government announced that the public health emergency would end on May 11, MDHHS began planning for the end of Maine's public health emergency, which was set to terminate on the same date. In early May, CMS announced that it planned to rescind the federal vaccine requirement, which it did on June 5, 2023. Following these events, and in recognition of "changed circumstances regarding COVID-19 variants, vaccination rates, and disease prevalence," around the end of May and the beginning of June, MDHHS began a review of the available science and research undergirding its vaccine requirement. It concluded, based on the changed COVID-19 risk in Maine, that the mandate was

no longer necessary. Accordingly, after conducting this evidence-based review, MDHHS announced on July 11, 2023 that it would be repealing the mandate. This approach -- sensitive to changes in the COVID-19 virus and informed by scientific research -- is the same approach that Maine has taken regarding other COVID-19 policies. See, e.g., Calvary Chapel, 52 F.4th at 48 (determining that Governor Mills rescinded COVID-19 policies based on "expert advice" and evolving information about case counts, positivity rates, and vaccination rates).

The appellants argue that the timing shows that it was this court's reinstatement of their claims and remand which motivated the Maine health officials to revoke the regulation. They support this contention by pointing to evidence showing that "the number of hospitalizations and deaths were increasing dramatically at the exact time of Defendants' repeal." The appellants point only to two months of data, but the complete set of data that the state reviewed showed an overall decline in hospitalizations and deaths since the vaccine mandate was issued. The increases that appellants point to also represent small numeric shifts, not "dramatic" increases: three deaths in July 2023 relative to eight deaths in August 2023, and thirty-one

hospitalized COVID-19 patients per day in July 2023 relative to forty-four in August 2023.

In light of contemporaneous events and documented changes in the COVID-19 pandemic that reasonably explain defendants' decision to review and repeal the vaccine mandate, and the "presumption of regularity" typically accorded governmental decision-making in this context, Health Freedom Def. Fund, Inc. v. Carvalho, 104 F.4th 715 (9th Cir. 2024), the mere fact of an overlap with this court's opinion does not plausibly suggest the conclusion that the repeal of the regulation was motivated by an effort to moot out the case. Coincidence is not causation.

## iii. Capable of repetition yet evading review exception does not apply

Appellants have not met their burden to show that the final exception to mootness for conduct capable of repetition yet evading review applies. "[T]he capable-of-repetition doctrine

The appellants argue that an out-of-circuit case, <u>Health Freedom Def. Fund</u>, <u>Inc. v. Carvalho</u>, 104 F.4th 715 (9th Cir. 2024), supports their argument. Not so. In that case, the defendants had "withdraw[n] and reinstat[ed]" their COVID-19 vaccination policies directly following litigation events multiple times without a clear public health rationale. <u>Id.</u> at 719-22. And, in denying the defendants a "presumption of regularity" to which they would otherwise have been entitled, the court relied on specific comments made by defendants that "confirm[ed] that [the] policy rescission aimed to avoid litigation." <u>Id.</u> at 723. There was also no evidence that the decision to repeal the mandate tracked with any change in federal regulations or guidance regarding COVID-19, as there is here. <u>See id.</u> at 721 n.2 (policy withdrawal occurred in September 2023).

applies only in exceptional situations." <u>ACLU of Mass.</u>, 705 F.3d at 57 (alteration in original) (quoting <u>City of Los Angeles</u> v. <u>Lyons</u>, 461 U.S. 95, 109 (1983)); <u>see also Kingdomware Techs.</u>, <u>Inc. v. United States</u>, 579 U.S. 162, 170 (2016). To prove the exception, an appellant "must show that '(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.'" <u>Daley</u>, 292 F.3d at 89 (quoting <u>Weinstein</u> v. Bradford, 423 U.S. 147, 149 (1975) (per curiam)).

The appellants have not met their burden as to either prong. As to the first prong, appellants "must show that 'the generic types of claims that they seek to pursue are likely to evade review.'" Harris, 43 F.4th at 194 (quoting Cruz v. Farquharson, 252 F.3d 530, 535 (1st Cir. 2001)). Here, the factual circumstances -- a disease outbreak and corresponding vaccination regulation -- are not, per se, of the "inherently transitory" nature that always evades review. See, e.g., ACLU of Mass., 705 F.3d at 57 (collecting cases); Moore v. Ogilvie, 394 U.S. 814, 816 (1969) (some challenges to elections are capable of repetition yet evading review because "while the 1968 election is over, [the challenged burden] remains and controls future elections, as long as [the state defendant] maintains her present system as she has done since 1935"); Roe v. Wade, 410 U.S. 113, 125 (1973) ("[W]hen

. . . pregnancy is a significant fact in the litigation, the normal 266-day human gestation period is so short that the pregnancy will come to term before the usual appellate process is complete."), overruled on other grounds by Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022); Neb. Press Ass'n v. Stuart, 427 U.S. 539, 546-47 (1976) (temporary restraining orders were capable of repetition yet evading review because "these orders are by nature short-lived"). Nor were they "'in [their] duration too short to be fully litigated' through the . . . courts (and arrive [at the Supreme Court]) prior to its 'expiration.'" Turner v. Rogers, 564 U.S. 431, 440 (2011) (quoting First Nat'l Bank of Bos. v. Bellotti, 435 U.S. 765, 774 (1978)); see also Harris, 43 F.4th at 194 (holding that plaintiffs must show "a realistic threat [exists] that no trial court ever will have enough time to decide the underlying issue[]" (quoting Cruz, 252 F.3d at 535)). The claims here are not like those that the Supreme Court has recognized as "inherently transitory": the vaccine mandate could have been in effect for much longer or even permanently had the public health situation evolved differently. It was not "by nature short-lived" along the lines of elections, pregnancy, or temporary restraining Neb. Press Ass'n, 427 U.S. at 547. Indeed, we have orders.6

<sup>&</sup>lt;sup>6</sup> Appellants argue that the mandate was inherently transitory because the state defendants admitted in the MDHHS declaration "that the public health emergency upon which the Vaccine Mandate was purportedly based, and their consideration of compulsory

similarly held that challenges to a university's COVID-19 vaccination requirements were "not among or closely analogous to" types of claims recognized as "inherently transitory." Corrigan, 98 F.4th at 353 (quoting Harris, 43 F.4th at 194). The appellants have also not shown that "a realistic threat" exists that there would be insufficient time to obtain a judgment on the merits before the repeal of the mandate. See id. at 353 (quoting Cruz, 252 F.3d at 535).

The duration of the vaccine mandate here was similar to durations in other cases holding that the exception does not apply.

See Corrigan, 98 F.4th at 353 (holding that, with regard to a COVID-19 vaccination requirement, "[i]t is struthious at best to suggest that a resource-intensive effort continuously spanning almost two years is so fleeting that a court could never have time to pass on its legality"); Robert v. Austin, 72 F.4th 1160, 1165 (10th Cir. 2023) (holding that duration of COVID-19 vaccine mandate, which was in effect for about a year and a half, was not too short to be fully litigated such that "capable of repetition but evading review" exception did not apply); see also Fund for Animals, Inc. v. Hogan, 428 F.3d 1059, 1064 (D.C. Cir. 2005) ("As

vaccination programs, were transitory and subject to change." This argument fails. The MDHHS declaration merely describes reviewing COVID-19 policies in light of evolving data and federal guidance and does not establish that the vaccine mandate was definitionally temporary.

a general rule, two years is enough time for a dispute to be litigated.").

As to the second prong, for the reasons we have already pointed out, the appellants have simply not shown that they will be subject to the same regulation again. See Corrigan, 98 F.4th at 354; see also Resurrection Sch. v. Hertel, 35 F.4th 524, 530 (6th Cir. 2022) (en banc) (capable-of-repetition-yet-evading-review exception was "inapposite for largely the same reasons" as voluntary cessation because "the challenged mandate was a product of the pandemic's early stages, and . . . . [w]e are unlikely to see this mandate in a similar form again").

#### III.

We review the district court's denial of the appellants' request for leave to amend the complaint for abuse of discretion.

See, e.g., Palmer, 465 F.3d at 30. The district court's decision will be affirmed "so long as the record evinces an adequate reason for the denial," such as "undue delay, bad faith, futility, [or] the absence of due diligence on the movant's part." Id. at 30 (first quoting Aponte-Torres v. Univ. of P.R., 445 F.3d 50, 58 (1st Cir. 2006)). The district court did not abuse its discretion in holding that "justice does not require permitting the Plaintiffs to further amend the Amended Complaint to drastically broaden the scope of their claims" by creating a previously-nonexistent facial challenge to the statute.

The district court also did not abuse its discretion in denying the appellants leave to file supplemental pleadings under Federal Rule of Civil Procedure 15(d). The motion sought to amend to change the attack to one on all aspects of the regulation and to bring a facial attack on the statute. The statute and the regulation preexisted the filing of the suit. Rule 15(d) permits courts to allow supplemental pleadings to add transactions, occurrences, or events that happened after the date of the pleading. See Fed. R. Civ. P. 15(d). The appellants filed the amended complaint on July 11, 2022, never filed a separate motion for leave to amend, and never identified any relevant subsequent transactions, occurrences, or events that would prevent mootness.

We  $\underline{\textbf{affirm}}$  the district court's dismissal of this suit as moot and the denial of the motion to amend.