

# United States Court of Appeals For the First Circuit

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No. 18-1514

COMMONWEALTH OF MASSACHUSETTS,

Plaintiff, Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;  
ALEX MICHAEL AZAR II, in his official capacity as Secretary of  
Health and Human Services; UNITED STATES DEPARTMENT OF THE  
TREASURY; STEVEN T. MNUCHIN, in his official capacity as  
Secretary of the Treasury; UNITED STATES DEPARTMENT OF LABOR;  
R. ALEXANDER ACOSTA, in his official capacity as  
Secretary of Labor,

Defendants, Appellees.

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

[Hon. Nathaniel M. Gorton, U.S. District Judge]

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Before

Torruella, Lynch, and Thompson,  
Circuit Judges.

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Julia E. Kobick, Assistant Attorney General, with whom Maura Healey, Attorney General of Massachusetts, Jon Burke, Assistant Attorney General, Jonathan B. Miller, Assistant Attorney General, and Elizabeth Carnes Flynn, Special Assistant Attorney General, were on brief, for appellant.

Allan J. Arffa, Crystal Johnson, Elizabeth J. Grossman, Melina M. Meneguini Layerenza, and Paul, Weiss, Rifkind, Wharton & Garrison LLP on brief for amici curiae Planned Parenthood Federation of America, National Health Law Program, and National Family Planning and Reproductive Health Association.

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Karen Schoen, Attorney, Appellate Staff, Civil Division, U.S. Department of Justice, with whom Joseph H. Hunt, Assistant Attorney General, Andrew E. Lelling, United States Attorney, Hashim M. Mooppan, Deputy Assistant Attorney General, and Sharon Swingle, Attorney, Appellate Staff, were on brief, for appellees.

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May 2, 2019

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**TORRUELLA, Circuit Judge.**<sup>1</sup> The Commonwealth of Massachusetts brought suit on October 6, 2017, to enjoin the enforcement of two federal Interim Final Rules (together, the "IFRs") promulgated by the United States Departments of Health and Human Services ("HHS"), Labor, and the Treasury (the "Departments"), which were to become effective that day. See Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017).

The IFRs permitted employers with religious or moral objections to contraception to obtain exemptions from providing health insurance coverage to employees and their dependents for Food and Drug Administration ("FDA")-approved contraceptive care. Such coverage would otherwise be required by guidelines issued pursuant to a provision in the Affordable Care Act, subject to the limitations imposed by the Supreme Court in Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014).

These IFRs were superseded by final rules (the "Final Rules"), promulgated on November 15, 2018, with an effective date of January 14, 2019. Religious Exemptions and Accommodations for

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<sup>1</sup> I am particularly appreciative of my panel colleagues' contributions to this opinion.

Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018).

After both sides here moved for summary judgment, the district court determined that Massachusetts lacked standing to challenge the IFRs. Massachusetts v. U. S. Dep't of Health & Human Servs., 301 F. Supp. 3d 248, 266 (D. Mass. 2018). And so, it did not reach the merits of the Commonwealth's challenges or its prayer for injunctive relief. The Commonwealth appealed.<sup>2</sup>

The issue on appeal is narrow: whether the Commonwealth has Article III standing to challenge the rules. We hold that it does. Specifically, we conclude that: (1) in agreement with the position of the United States, the Commonwealth's substantive challenges have not been mooted by the promulgation of the Final Rules, but the Commonwealth's procedural challenge to the IFRs has been mooted; and (2) the Commonwealth has established Article III standing to challenge the substance of the rules by demonstrating a sufficiently imminent fiscal injury under a traditional standing analysis (and so we do not reach the Commonwealth's alternative parens patriae standing argument).

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<sup>2</sup> We appreciate the numerous amici who submitted briefs to this court.

I.

A. Factual Background

1. **The Affordable Care Act and the Contraceptive Care Requirement**

The Affordable Care Act requires employer-sponsored health plans to provide coverage for a range of preventive care and related medical services at no cost to the covered employee. See 42 U.S.C. § 300gg-13(a).<sup>3</sup> A provision commonly known as the Women's Health Amendment requires coverage for, "with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration."<sup>4</sup> Id. § 300gg-13(a)(4).

While the Women's Health Amendment did not indicate the additional preventive care services that must be covered, it instructed the Health Resources and Services Administration ("HRSA"), part of HHS, to determine the specifics of such required

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<sup>3</sup> Employers who provide health plans that existed before March 23, 2010, and who have not made specified changes after that date to their health plans, are not subject to this requirement. 42 U.S.C. §§ 18011(a), (e).

<sup>4</sup> The IFRs and the statutory provision at issue -- the Women's Health Amendment -- discuss only women. The Commonwealth's complaint similarly focuses on women. The denial of coverage for contraceptive care and services may directly affect some transgender men and gender non-conforming people, as well as indirectly affect some men (for example, men who have dependents, whether children or partners, who rely on the man's employer-sponsored health insurance coverage for contraceptive care and services).

care and services. See 155 Cong. Rec. 511, 987 (daily ed. Nov. 30, 2009) (Senate Amendment 2791).

In August 2011, HRSA accepted the recommendations of the Institute of Medicine ("IOM") and issued guidelines requiring insurance coverage, at no cost to users, of all "Food and Drug Administration . . . approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012) (quoting HRSA Guidelines, <http://www.hrsa.gov/womens-guidelines>). In its report, the IOM made extensive factual findings about contraceptive care and public health outcomes. See Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps (2011). Plans within the guidelines' ambit had to provide such contraceptive coverage for plan years starting on or after August 1, 2012.<sup>5</sup> See 77 Fed. Reg. at 8,725-26.

**2. The Departments' Regulations and Related Litigation from 2010 to 2016**

Concurrently, the Departments promulgated regulations, which became final in February 2012, that provided an exemption

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<sup>5</sup> The Departments estimated in 2017 that about "46.6 million women aged 15 to 64 received the [contraceptive and related] coverage through employer sponsored private insurance plans," 82 Fed. Reg.

from the requirement to provide contraceptive coverage to "churches, their integrated auxiliaries, and conventions or associations of churches" with religious objections to contraception. 76 Fed. Reg. at 46,623; see also 77 Fed. Reg. at 8,725.

Later regulations also created what the Departments termed an "accommodation" process. Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (July 2, 2013). This process allowed nonprofit organizations, including colleges and universities, to submit a form to their health insurance issuers asserting their religious objections to contraception. See id. at 39,874-77. The insurance issuer was then required to remove contraceptive coverage from the objecting organization's plan, but still had to provide contraceptive coverage to members of the plan (without directly involving the objecting organization) (the "Accommodation"). Id. at 39,875-80.

On June 30, 2014, the Supreme Court held in Hobby Lobby that the contraceptive regulatory requirement as applied to closely held corporations violated the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. § 2000bb-1 et seq. 573 U.S.

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at 47,821, and cited studies showing "that application of HRSA Guidelines had applied preventive services coverage to 55.6 million women and had led to a 70 percent decrease in out-of-pocket expenses for contraceptive services among commercially insured women," id. at 47,805.



at 736. That was because the regulations "clearly impose[d] a substantial burden" on closely held employers who had religious objections to contraception, and the regulations were not the least restrictive means of furthering a compelling government interest (assuming *arguendo* that one existed). Id. at 726, 730-32. The Supreme Court noted that the Accommodation already available to nonprofit organizations with religious objections was less restrictive than "requiring employers to fund contraceptive methods that violate their religious beliefs." Id. at 730.

After Hobby Lobby, the Departments issued a new rule in 2015 which allowed "Closely Held for-Profit Entit[ies]" who had religious objections to providing contraceptive coverage to use the Accommodation process described above. Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318, 41,323 (July 14, 2015).

Nevertheless, numerous religious nonprofit organizations sued to obtain an exemption similar to that provided to churches rather than the more limited Accommodation process (which still allowed for contraceptive coverage for employees of the objecting organizations). Nine circuits considered the issue from late 2014 to early 2016. Eight circuits held that the Accommodation did not substantially burden religious exercise; one

held that it did.<sup>6</sup> The Supreme Court granted certiorari in some of these cases (from the Third, Fifth, Tenth, and D.C. Circuits). In a per curiam opinion, it vacated and remanded, instructing that the parties "be afforded an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." Zubik v. Burwell, 136 S. Ct. 1557, 1560 (2016) (per curiam) (internal quotation marks omitted).

After Zubik, the Departments sought comment in July 2016 through a request for information, seeking alternative ways in which the contraceptive coverage mandate and employers' religious beliefs could coexist. Coverage for Contraceptive Services, 81

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<sup>6</sup> Specifically, the Second, Third, Fifth, Sixth, Seventh, Tenth, Eleventh, and D.C. Circuits held that the Accommodation did not substantially burden religious exercise. Eternal Word Television Network, Inc. v. Sec'y of U.S. Dep't of Health & Human Servs., 818 F.3d 1122, 1151 (11th Cir. 2016); Mich. Catholic Conf. & Catholic Family Servs. v. Burwell, 807 F.3d 738, 752 (6th Cir. 2015); Catholic Health Care Sys. v. Burwell, 796 F.3d 207, 226 (2d Cir. 2015); Little Sisters of the Poor Home for the Aged, Denver, Colo. v. Burwell, 794 F.3d 1151, 1195 (10th Cir. 2015); E. Tex. Baptist Univ. v. Burwell, 793 F.3d 449, 463 (5th Cir. 2015); Univ. of Notre Dame v. Burwell, 786 F.3d 606, 619 (7th Cir. 2015); Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs., 778 F.3d 422, 442 (3d Cir. 2015); Priests for Life v. U.S. Dep't of Health & Human Servs., 772 F.3d 229, 252 (D.C. Cir. 2014). The Eighth Circuit held that the Accommodation process substantially burdened religion and faltered under strict scrutiny. Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs., 801 F.3d 927, 945-46 (8th Cir. 2015). All were vacated as a result of or in light of Zubik v. Burwell, 136 S. Ct. 1557 (2016) (per curiam).

Fed. Reg. 47,741, 47,741 (July 22, 2016). The Departments ultimately stated that, though they received 54,000 public comments after this request, "includ[ing] [from] the plaintiffs in Zubik, . . . consumer advocacy groups, women's organizations [and] health insurance issuers," by September 20, 2016, "no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage." United States Department of Labor, FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).

**3. President's Executive Order and Interim Final Rules on Exemptions**

On May 4, 2017, the President issued an Executive Order "Promoting Free Speech and Religious Liberty." Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 4, 2017). This Order directed the Departments to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [42 U.S.C. §] 300gg-13(a)(4)." Id.

Several months later, the Departments issued two IFRs: a religious exemption IFR and a separate moral exemption IFR, both effective immediately on publication, on October 6, 2017. See 82 Fed. Reg. at 47,792; 82 Fed. Reg. 47,838. The IFRs included a

request for further comments before final rulemaking. 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838. The Departments did not go through the notice and comment process before issuing the IFRs, asserting first that these procedures did not apply, and second, that if the Administrative Procedure Act ("APA") procedures applied, the "good cause" exception to notice and comment allowed for the Departments' chosen approach, see 5 U.S.C. § 553 (b)(1)(B),(d); 82 Fed. Reg. at 47,813-15; 82 Fed. Reg. at 47,854-56.

The religious exemption IFR expanded the previous exemption (which had covered only churches and related entities, see 76 Fed. Reg. at 46,623) to include nonprofit organizations, corporations, institutions of higher education, and health insurance issuers that object to "establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs." 82 Fed. Reg. at 47,835.

The moral exemption IFR created a similar exemption but based on "sincerely held moral convictions" as opposed to "sincerely held religious beliefs." 82 Fed. Reg. at 47,853-54. This second IFR did not define the term "moral conviction." Unlike the religious exemption, this exemption did not apply to publicly traded corporations; it did apply to privately held corporations.

See id. at 47,849-52. Both IFRs allowed an objecting organization to use either the expanded exemptions (which would then leave their employees and/or students without direct coverage for contraceptive care and service), or the Accommodation (under which employees and/or students would continue to receive contraceptive care and services paid for and managed by the issuer, not by the employer or school). See 82 Fed. Reg. at 47,812-13; 82 Fed. Reg. at 47,854.

The Departments included a regulatory impact analysis in the IFRs (the "Regulatory Impact Analysis"), see 82 Fed. Reg. at 47,815-28; 82 Fed. Reg. at 47,856-59, as required by law, see Regulatory Planning and Review, Executive Order 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993). In their Regulatory Impact Analysis, the Departments estimated that, nationwide, between about 31,700 and 120,000 women would be affected by the expanded exemptions. See 82 Fed. Reg. at 47,821-23.<sup>7</sup> In so doing, they accounted for various factors that could skew the estimates. For example, they excluded publicly traded corporations from the estimates, as the Departments stated that "although publicly traded entities could make use of exempt status under these interim final rules, the

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<sup>7</sup> The Commonwealth and several amici challenge these estimates as too low, arguing, for example, that they rely on data about women using a contraceptive method at a point-in-time rather than over time, and that the estimates do not adequately consider the impact of the untested moral exemption.

Departments do not expect that very many will do so." 82 Fed. Reg. at 47,817. This was based primarily on the fact that, at that point, "[n]o publicly traded for-profit entities ha[d] filed lawsuits challenging the Mandate." Id.

The Departments based their lower bound estimate of 31,700 women partially on the number of employers that had previously challenged the contraceptive coverage requirement in litigation, and partially on an estimate of the number of employers using the Accommodation. See 82 Fed. Reg. 47815-21. The Departments acknowledged that they had "not received complete data on the number of entities actually using the accommodation, because the accommodation does not require many accommodated entities to submit information to us." Id. at 47,817.

To calculate an "upper bound" of 120,000 women likely to lose contraceptive coverage because of the IFRs, the Departments started from the number of women that used FDA-approved contraceptives but were employed by entities that did not cover such care before the Affordable Care Act was enacted, relying on a survey from the Kaiser Family Foundation. Id. at 47,822. This estimate did not consider employees of the "31 percent of survey respondents that did not know about contraceptive coverage." Id. at n.88. After reducing the extrapolated numbers to account for already exempt church plans and the assumption that publicly-traded employers would not make use of the expanded exceptions,

the Departments reached an amount of 362,100 women. From there, the Departments calculated their final "upper bound" estimate of 120,000 women based on the view that a "reasonable estimate is that no more than approximately one third of the persons covered by relevant entities . . . would likely be subject to potential transfer impacts." Id. at 47,823. The Departments based this "one third" estimate on several factors, including employers potentially objecting to only certain contraceptive methods and a "prominent poll" purporting to "show[] that 89 percent of Americans say they believe in God, while 11 percent say they do not or are agnostic." Id.

The Departments then estimated an "average annual expenditure on contraceptive products and services of \$584 per user," so a "transfer effect[]" attributable to the IFRs of between about \$18.5 and \$63.8 million annually nationwide. Id. at 47,823-24. In a footnote, the Departments also noted the "noteworthy potential impact[]" of "increased expenditures on pregnancy-related medical services," but did not provide a numerical estimate of such expenditures (or of how many women might face unintended pregnancies due to the IFRs). Id. at 47,828 n.113.

In their Regulatory Impact Report, the Departments also included spreadsheets listing either litigating employers or employers currently using the Accommodation that the Departments flagged could switch to the expanded exemption. Three

Massachusetts employers were listed.

**4. Relevant Commonwealth Laws and Public Health Structure**

The Commonwealth legislature has enacted two laws that are relevant to this case and factor into the Commonwealth's claims of injury. In 2002, the legislature passed "An Act Providing Equitable Coverage of Services Under Health Plans," see 2002 Mass. Acts ch. 49, §§ 1-4, which required employer-sponsored health plans to cover contraceptive care and services at the same level that the plans covered other outpatient care and services, see Mass. Gen. Laws ch. 175, § 47W; id. Mass. Gen. Laws ch. 176A, § 8W; id. Mass. Gen. Laws ch. 176B, § 4W; id. Mass Gen. Laws ch. 176G, § 40. Under this Act, people using contraceptive care and services pursuant to insurance plans could be required to pay cost-sharing fees such as deductibles and copays for the care and services. Moreover, in November 2017, the Commonwealth legislature passed "An Act Relative to Advancing Contraceptive Coverage and Economic Security in Our State" (the "ACCESS Act"), which barred employer-sponsored health plans from collecting cost-sharing fees for contraceptive care and services. 2017 Mass. Acts ch. 120, § 4(e)(1). The ACCESS Act did not provide any moral exemption for employers, but did provide an exemption for churches and "qualified church-controlled organization[s]." Id. § 3.

Importantly, Massachusetts healthcare laws -- including the ACCESS Act and the earlier Equitable Coverage law -- do not



apply to self-insured plans, because such plans come under the Employee Retirement Income Security Act of 1974 ("ERISA") (which preempts state regulation). 29 U.S.C. §§ 1144(a) & (b)(2)(A). A study submitted by the Commonwealth shows that, as of March 2017, fifty-six percent of Commonwealth residents who have private commercial health insurance had such insurance from ERISA plans. Center for Health Information and Analysis, Enrollment Trends: August 2017 Edition, Ctr. For Health Info. And Analysis 3 (2017). Thus, to the extent the ACCESS Act and the Equitable Coverage law mitigate any injury done by the IFRs, that mitigation does not apply to fifty-six percent of the Commonwealth's residents who have private ERISA-covered insurance.

The Commonwealth also provides health services to about two million Commonwealth residents through its Medicaid program, the MassHealth Program. Massachusetts, 301 F. Supp. 3d at 255-56. This program provides access to contraceptives. See 130 Mass. Code Regs. 450.105 ("The following services are covered for MassHealth Standard members . . . [:] family planning services."). MassHealth also serves as a "secondary payer" for about 150,000 residents. This means that qualifying residents with employer-sponsored plans who lose contraceptive coverage would then be covered by MassHealth, and the Commonwealth would owe ten percent of the cost of contraceptive coverage paid by MassHealth (and so ten percent of the cost for loss of coverage occasioned by the

IFRs). See 42 U.S.C. § 1396b(a)(5); Robert Seifert & Stephanie Anthony, The Basics of MassHealth, Mass. Medicaid Policy Inst. 3 (Feb. 2011).

In addition to the MassHealth program, the Sexual and Reproductive Health Program ("SRHP") of the Commonwealth's Department of Public Health reimburses groups and clinics that are providing contraceptive care and services in the Commonwealth. Services funded by the SRHP are available to Massachusetts residents that either (1) do not have insurance and make less than 300% of the poverty level; (2) need confidential care; or (3) make less than 300% of the poverty level and have insurance that does not cover all contraception methods and services. See 101 Mass. Code Regs. 312.00. The Commonwealth provides about three-quarters of SRHP's total funding. Massachusetts, 301 F. Supp. 3d at 256.

**B. Procedural History of This Litigation**

The Commonwealth filed suit to enjoin the IFRs in October 2017. The Commonwealth included, with its amended complaint filed in November 2017, various declarations from medical professionals, state officials, the CEO of a partially Commonwealth-funded nonprofit organization specializing in "sexual and reproductive health," and an investigator, all in support of its assertion that the Commonwealth would be harmed by the IFRs. These declarations are discussed further below where relevant.

Both sides moved for summary judgment. In its memorandum in opposition to defendants' cross-motion to dismiss or for summary judgment, the Commonwealth asserted standing based on a procedural injury, financial harm, and harm to the Commonwealth's quasi-sovereign interests. The Departments asserted that the Commonwealth's projections of injury were too speculative to support standing.

This case is in an unusual posture for the following reasons. When filed, it was brought as a pre-enforcement suit. Before the district court ruled on the cross motions for summary judgment, two federal district courts issued nationwide injunctions blocking the IFRs, after finding that the plaintiff states had standing. See California v. Health & Human Servs. ("California I"), 281 F. Supp. 3d 806, 832 (N.D. Cal. 2017); Pennsylvania v. Trump ("Pennsylvania I"), 281 F. Supp. 3d 553, 585 (E.D. Pa. 2017). The former injunction, out of California, was modified to include only the plaintiff states. See California v. Azar ("California II"), 911 F.3d 558, 585 (9th Cir. 2018). The IFRs were only effective in the Commonwealth, then, for about two months. There is no suggestion in the record that, during those two months, it was possible to measure any injury to the Commonwealth's interests, much less to measure projected future injury from this period. Indeed, under the religious exemption IFR, "[i]f contraceptive coverage is currently being offered by an

issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation," or alternatively sixty days after notice is provided. 82 Fed. Reg. at 47,831. The moral exemption IFR does not have a similar rule, likely because no Accommodation process existed for organizations with moral objections to contraception prior to this IFR.

On March 12, 2018, the district court granted the Departments' motion for summary judgment. Massachusetts, 301 F. Supp. 3d at 266. The district court held that the Commonwealth failed to establish standing because the Commonwealth had not "set forth specific facts establishing that it will likely suffer future injury from the defendants' conduct." Id. at 250. It rejected the Commonwealth's proportional argument, based on the Departments' own estimates of women affected, as too "tenuous," id. at 259, and faulted the Commonwealth for failing to "identify any particular woman who is likely to lose contraceptive coverage because of the IFRs" or "any Massachusetts employer that is likely to avail itself of the expanded exemptions," id. at 265. The district court similarly rejected the Commonwealth's alternative procedural injury and quasi-sovereign harm theories. Id. at 265-66.

The Commonwealth appealed. After the Commonwealth filed its opening brief, the Departments issued Final Rules superseding the IFRs in November 2018, effective in January 2019. 83 Fed. Reg. at 57,536; 83 Fed. Reg. at 57,592. In December 2018, this court directed the parties to address, in the remaining briefing, whether the appeal was moot. Order, Commonwealth of Mass. v. Dep't of Health & Human Servs., et al. (18-1514) (Dec. 21, 2018), ECF No. 117. The parties did so in their response brief and reply brief, respectively, and agreed that the Commonwealth's substantive arguments as to the IFRs also apply to the Final Rules and so that aspect of the case is not moot and should proceed.

During the briefing of this case, California and another group of states, which did not include the Commonwealth, obtained an injunction against the Final Rules for the plaintiff states in January 2019, see California v. Health & Human Servs. ("California III", 351 F. Supp. 3d 1267, 1301 (N.D. Cal. 2019)); this decision has been appealed. Pennsylvania and New Jersey, together as plaintiffs, obtained a nationwide injunction in January 2019 against the Final Rules, see Pennsylvania v. Trump ("Pennsylvania II"), 351 F. Supp. 3d 791, 835 (E.D. Pa 2019); this decision has also been appealed. In both district court cases, the courts found Article III standing for the plaintiff states. The net effect of these cases is that the Final Rules are currently enjoined nationwide.

## II.

### A. Mootness

We first consider whether the Commonwealth's challenges to the rules are moot because the Departments have promulgated superseding Final Rules. A case is moot where it is "impossible for a court to grant any effectual relief whatever to the prevailing party." Chafin v. Chafin, 568 U.S. 165, 172 (2013) (quoting Knox v. Serv. Employees Int'l Union, Local 1000, 567 U.S. 298, 307 (2012)). The mootness review is grounded in "[t]he case or controversy requirement [and] ensures that courts do not render advisory opinions." Overseas Military Sales Corp. v. Giralt-Armada, 503 F.3d 12, 16-17 (1st Cir. 2007). "But as long as the parties have a concrete interest, however small, in the outcome of the litigation, the case is not moot." Ellis v. Bhd. of Ry., Airline & S.S. Clerks, Freight Handlers, Express & Station Emps., 466 U.S. 435, 442 (1984).

#### 1. **Mootness of the Substantive Challenges**

Both parties agree that the Commonwealth's substantive challenges to the rules have not been mooted by the promulgation of the Final Rules. We still must independently review the issue. The parties' view accords with our view, based on Supreme Court

and First Circuit caselaw, that this aspect of the case is not moot.

The challenged portions of the Final Rules are sufficiently similar to the IFRs that the case is not moot as to the Commonwealth's substantive challenges. See Ne. Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville, 508 U.S. 656, 662 & n.3 (1993) (holding that the case was not moot where the statute challenged had been replaced by a different but sufficiently similar statute that "disadvantage[d] [plaintiffs] in the same fundamental way"); Conservation Law Found. v. Evans, 360 F.3d 21, 25-30 (1st Cir. 2004) (holding that the case was not moot where the framework then in place was "largely an extension" of the originally challenged framework). The Final Rules have not excised the features of the IFRs that Massachusetts challenges; instead, if they were to harm Massachusetts, they would do so in the "same fundamental way" as the IFRs. City of Jacksonville, 508 U.S. at 662. And the Final Rules are not based on "entirely new analysis." Gulf of Me. Fishermen's All. v. Daley, 292 F.3d 84, 90 (1st Cir. 2002). Here, the "challenged regulation[s]" are "only superficially altered by [the] subsequent regulation[s]." Evans, 360 F.3d at 26. The Departments correctly recognize that the "changes are immaterial to the scope of the challenge." Therefore, the Commonwealth's substantive challenges to the federal regulations are not moot.

**2. Mootness of the Procedural Challenge to the IFRs**

Nevertheless, we find that the Commonwealth's APA procedural challenge to the IFRs is moot. Although the IFRs did not go through notice and comment rulemaking, the Final Rules superseded the IFRs. 83 Fed. Reg. 57592 (Nov. 2018).

The Final Rules would have become effective as planned on January 14, 2019, if not enjoined before that date. Past that date, it would be "impossible for a court to grant any effectual relief whatever to the prevailing party" as to the IFRs. Chafin, 568 U.S. at 172 (quoting Knox, 567 U.S. at 307). As the Ninth Circuit has stated, there is "no justiciable controversy regarding the procedural defects of IFRs that no longer exist." California II, 911 F.3d at 569; see Daley, 292 F.3d at 88 ("[P]romulgation of new regulations and amendment of old regulations are among such intervening events as can moot a challenge to the regulation in its original form."); Nat. Res. Def. Council v. U.S. Nuclear Regulatory Comm'n, 680 F.2d 810, 814-15 (D.C. Cir. 1982) (holding that a procedural challenge to a regulation promulgated in alleged violation of notice and comment requirements became moot due to re-promulgation of the rule with notice and comment).

Levesque, which the Commonwealth relies upon to argue that its procedural challenge to the IFRs has not been mooted, is distinguishable. Levesque v. Block, 723 F.2d 175 (1st Cir. 1983). In that case, the district court had found the interim rule to be



void for "procedural omissions" while it was still in effect. Id. at 177. Here, any determination by us as to the validity of the IFRs would be made for the first time after they have ceased to exist. We see no point in that. Moreover, in Levesque, the court also considered whether the existing final rule was valid, which is not the issue here. Id. at 187.

**B. Article III Standing for Substantive Challenges**

We turn to whether the Commonwealth has established Article III standing for its substantive challenges to the federal regulations. "[N]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 341 (2006). As one aspect of the case-or-controversy requirement, plaintiffs must "establish that they have standing to sue." Raines v. Byrd, 521 U.S. 811, 818 (1997); see also Arizonans for Official English v. Arizona, 520 U.S. 43, 64 (1997). "[T]he standing inquiry [is] focused on whether the party invoking jurisdiction had the requisite stake in the outcome when the suit was filed." Davis v. Fed. Election Comm'n, 554 U.S. 724, 734 (2008).

"The existence of standing is a legal question, which we review de novo." Kerin v. Titeflex Corp., 770 F.3d 978, 981 (1st Cir. 2014). "The party invoking federal jurisdiction bears the

burden of establishing" that it has standing. Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992). There are three requirements for Article III standing. A plaintiff must demonstrate (1) an injury in fact which is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical," (2) that the injury is "fairly traceable to the challenged action," and (3) that it is "likely . . . that the injury will be redressed by a favorable decision." Id. at 560 (internal quotation marks and alterations omitted). "In response to a summary judgment motion," the "specific facts" set forth by a plaintiff "will be taken as true." Id. at 561.

The Commonwealth's primary argument for standing is based on a fiscal injury to itself. In this circuit, "[i]t is a bedrock proposition that 'a relatively small economic loss -- even an identifiable trifle -- is enough to confer standing.'" Katz v. Pershing, LLC, 672 F.3d 64, 76 (1st Cir. 2012) (quoting Adams v. Watson, 10 F.3d 915, 924 (1st Cir. 1993)); see also United States v. Students Challenging Regulatory Agency Procedures (SCRAP), 412 U.S. 669, 690 n.14 (1973) ("We have allowed important interests to be vindicated by plaintiffs with no more at stake in the outcome of an action than a fraction of a vote[,], a \$5 fine and costs[,], and a \$1.50 poll tax." (internal citations omitted)).

We hold that the Commonwealth has demonstrated Article III standing for its substantive claim based on an imminent fiscal

injury that is fairly traceable to the federal regulations and redressable by a favorable decision. We do not afford the Commonwealth "special solicitude in [the] standing analysis," Massachusetts v. EPA, 549 U.S. 497, 520 (2007), in light of its demonstration of fiscal injury. As the Commonwealth has established standing under a traditional Article III analysis, we need not consider the Commonwealth's self-described "alternative basis" of parens patriae standing based on an alleged "injury to the Commonwealth's legally protected quasi-sovereign interests." See, e.g., Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez, 458 U.S. 592, 600-02, 607 (1982).

**1. Imminent Fiscal Injury to the Commonwealth**

The heart of the Departments' standing challenge is that the Commonwealth has not demonstrated an imminent injury. That requires us to decide whether the Commonwealth has adequately demonstrated that a fiscal injury is imminent due to the challenged federal regulations. Of course, the Commonwealth need not wait for an actual injury to occur before filing suit. See Adams, 10 F.3d at 921 ("[I]t could hardly be thought that administrative action likely to cause harm cannot be challenged until it is too late." (quoting Rental Hous. Ass'n of Greater Lynn v. Hills, 548 F.2d 388, 389 (1st Cir. 1977))).

The imminence requirement is met "if the threatened injury is 'certainly impending' or there is a 'substantial risk'

that the harm will occur." Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) (quoting Clapper v. Amnesty Int'l, USA, 568 U.S. 398, 409, 414 n.5 (2013)). Either a certainly impending harm or substantial risk of harm suffices. See Reddy v. Foster, 845 F.3d 493, 500 (1st Cir. 2017). We have considered risk of harm for Article III standing in a range of cases asserting different forms of injury, from allegations of future environmental harm, see Me. People's Alliance v. Mallinckrodt, Inc., 471 F.3d 277, 283 (1st Cir. 2006), to future harm stemming from a store's policy of a "refusal to sell alcoholic beverages to a disabled person whose symptoms mimic the traits of intoxication," Dudley v. Hannaford Bros. Co., 333 F.3d 299, 301 (1st Cir. 2003). The "imminence concept, while . . . far reaching, is bounded by its Article III purpose: 'to ensure that the alleged injury is not too speculative.'" Berner v. Delahanty, 129 F.3d 20, 24 (1st Cir. 1997) (quoting Lujan, 504 U.S. at 564 n.2).

The Commonwealth's argument that it faces an imminent fiscal injury proceeds in steps: First, it argues that it established a substantial risk that the rules will cause women in the Commonwealth to lose their contraceptive coverage. Second, it argues that it established a substantial likelihood that some of these women will then obtain state-funded contraceptive services or prenatal and postnatal care for unintended pregnancies, and thus that the Commonwealth will incur costs as a result. As for

those women who go forward with pregnancies because of the loss of contraceptive services or the loss of the most effective contraceptive devices, the Commonwealth states it "will incur costs providing pre- and post-natal care to some of the women who lose contraceptive coverage and consequently experience an unintended pregnancy."

The Departments counter that the Commonwealth (1) has failed to show that employers therein "will use the expanded exemption under the challenged rules to deprive employees of contraceptive coverage they previously had"; (2) has not identified any particular women who would be affected by employers' use of the exemptions; and, (3) "[e]ven assuming that some Massachusetts women will lose coverage of their chosen contraceptive method," the Commonwealth has "fail[ed] to demonstrate economic injury as a result."

In our view, the Commonwealth has demonstrated that there is a substantial risk of fiscal injury to itself. It has made "rational economic assumptions," Adams, 10 F.3d at 923, and presented "concrete evidence." Clapper, 568 U.S. at 420.<sup>8</sup> We explain.

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<sup>8</sup> Unlike in Clapper, the issue here is not whether a plaintiff would ever be subject to the challenged government policy (there, surveillance under the Foreign Intelligence Surveillance Act). See 568 U.S. at 411-14. No one disputes that, barring injunctions, employers in the Commonwealth would have been subject to the IFRs.

**a. The Commonwealth Has Shown There Are Employers Likely to Use the Exemptions**

First, the Commonwealth established that there is a substantial risk that some women in Massachusetts will lose coverage due to the regulations. It pointed to the Departments' Regulatory Impact Analysis, which estimated that between 31,715 and 120,000 women would lose coverage. From there, Massachusetts set forth that based on its 2.1 percent of the national population "and [a]djusting these figures to exclude women in fully-insured plans covered by Massachusetts' contraceptive coverage laws, between 373 and 1,414 Massachusetts women in self-insured plans will lose coverage because of the IFRs." The district court rejected what it deemed Massachusetts' "proportional theory," relying in part on Summers v. Earth Island Inst., 555 U.S. 488 (2009). Massachusetts, 301 F. Supp. 3d at 259. Yet unlike Summers, this is not a case resting on unsupported "statistical probability" for organizational standing. See Summers, 555 U.S. at 497-98. Summers rejected as insufficient "self-descriptions" the plaintiff organization's assertions, as the Supreme Court characterized them, that "some (unidentified) members have planned to visit some (unidentified) small parcels affected by the Forest Service's procedures and will suffer (unidentified) concrete harm as a result." Id.

Moreover, the Commonwealth has demonstrated that it is highly likely that at least three employers in the Commonwealth with self-insured health plans (that is, exempt from state regulation due to ERISA) will use the expanded exemptions, based in part on their past litigating positions or their past objections to providing contraceptive coverage. The three are Autocam Medical Devices, LLC ("Autocam"), Hobby Lobby Stores, Inc. ("Hobby Lobby"), and Cummins-Allison Corporation ("Cummins-Allison"), all identified in the Departments' administrative record.<sup>9</sup> In a spreadsheet listing litigating entities likely to use the expanded exemptions, the Departments included both Autocam and Hobby Lobby, both employers in Massachusetts. Additionally, the Departments included Cummins-Allison in a list of employers using the Accommodation that had notified the Departments of their religious

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<sup>9</sup> Before the district court, the Commonwealth also listed Little Sisters of the Poor as a litigating entity operating in the Commonwealth. Massachusetts, 301 F. Supp. 3d at 261. Though this is technically correct, the Little Sisters of the Poor likely denied contraceptive coverage even before the IFRs. As the Departments correctly point out, the Little Sisters of the Poor provided healthcare coverage through a self-insured church plan, which allowed them to effectively avoid the obligation to provide contraceptive care prior to the implementation of the IFRs. See Little Sisters of the Poor Home for the Aged, 794 F.3d at 1166-67.

objections to providing contraceptive coverage.<sup>10</sup> See 82 Fed. Reg. 47,817-18.

The Commonwealth refers to data, which the Departments do not contest, stating that as of September 2018, Autocam employed over one hundred people in the Commonwealth, and Hobby Lobby operated four stores with employees in the Commonwealth.<sup>11</sup> See Brief for Nat'l Women's Law Ctr. et al., as Amici Curiae in Support of Plaintiff-Appellant and in Favor of Reversal, at 7 nn.14, 15 (2019).

The Departments' record further supports standing in two respects. First, the Departments acknowledge that for purposes of the Regulatory Impact Analysis, they assumed that the litigating entities, excluding previously exempt ones, would use the expanded exemption under the interim rules. 82 Fed. Reg. 47,817-18. Moreover, the Departments estimated that "just over half of the [estimated 209 previously accommodated entities] will use the expanded exemption."<sup>12</sup> 82 Fed. Reg. at 47,818. Hence, the

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<sup>10</sup> Cummins Allison had used the Accommodation process under the prior rules, but had not litigated against the Accommodation process.

<sup>11</sup> In Column H of the spreadsheets of "litigating entities" used for the Departments' Regulatory Impact Analysis, the Departments list the "number of [employees] counted towards final total." Both Autocam and Hobby Lobby have a positive number listed in Column H -- 183 for Autocam, 13,250 for Hobby Lobby -- and both have employees in the Commonwealth.

<sup>12</sup> The estimate of 209 employers using the accommodation process was made by HHS in 2014. See 82 Fed. Reg. at 47,817-18. The



Departments have done much of the legwork in establishing that there is a substantial risk (as opposed to a certainty) that at least Hobby Lobby, Autocam, and Cummins-Allison would choose to use the expanded exemptions. See Davis, 554 U.S. at 735 (finding standing based on third party's likely behavior, and crediting evidence in the record that "most candidates who had the opportunity to receive expanded contributions had done so").

We turn to the argument that because the Commonwealth "cannot point to a single woman who will lose coverage she would otherwise want," the Commonwealth lacks standing. First, a plaintiff need not "demonstrate that it is literally certain that the harms they identify will come about." Clapper, 568 U.S. at 414 n.5. The Departments' brief fails to cite the "substantial risk" standard drawn from Clapper and Susan B. Anthony List. Its effort to recast the imminence requirement as one of near certainty does not comport with the law. Moreover, plaintiffs need not point to a specific person who will be harmed in order to establish

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Departments acknowledge a paucity of data concerning how many employers used the accommodation process, since employers were not required to inform the Departments that they were using that process. Id. at 47,817. A reasonable inference would be that more employers would have used the Accommodation process over time. Even if women employed by organizations who would use the exemption are not scattered proportionally by state, it is improbable based on the evidence that no women in the Commonwealth would lose contraceptive coverage. See California II, 911 F.3d at 572 ("Evidence supports that, with reasonable probability, some women residing in the plaintiff states will lose coverage due to the IFRs." (emphasis added)).

standing in situations like this.<sup>13</sup> See Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 153-55 (2015) (holding that plaintiffs, alfalfa farmers, had standing based on a causal chain, though plaintiffs did not identify particular alfalfa plants that had been, or would necessarily be, pollinated by bees who carried the genetically engineered gene at issue). Hence, we agree with the statement of the Ninth Circuit that, though "[a]ppellants fault the [plaintiff] states for failing to identify a specific woman likely to lose coverage," "[s]uch identification is not necessary to establish standing." California II, 911 F.3d at 572.<sup>14</sup>

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<sup>13</sup> In Massachusetts v. EPA, the Commonwealth's declarations did not identify particular coastal land that had been lost or would necessarily be lost based on rising sea levels, but the Supreme Court found standing, stating that "the likelihood that Massachusetts' coastline will recede has nothing to do with whether [Massachusetts] ha[s] determined the precise metes and bounds of [its] soon-to-be-flooded land." 549 U.S. at 523 n.21. Similarly, the likelihood of a fiscal injury to the Commonwealth does not turn on the identification of specific women, and such identification is not required for standing here.

<sup>14</sup> Here, as the Commonwealth discusses in its reply brief, it is not clear how it could reasonably be expected to point to particular women affected by the IFRs, even if the IFRs or Final Rules were in effect and employers in the Commonwealth had used the exemptions. Like the IFRs, the Final Rules do not require employers to notify the Commonwealth that they are using the exemptions, see 83 Fed. Reg. at 57,558; 83 Fed. Reg. at 57,614, nor do women have to tell the Commonwealth when they are seeking contraceptive care and services from a state-funded program. Indeed, medical privacy concerns cut against any such formal notification by women to the Commonwealth.

**b. The Commonwealth Has Shown Its Costs Will Most Likely Rise with Increased Numbers of Women Using State-Funded Contraceptive Care**

The Commonwealth's evidence has also established a substantial risk that a portion of the women who would lose contraceptive coverage would then obtain state-funded contraceptive care or state-funded prenatal care for unintended pregnancies, and thus cause the Commonwealth to incur costs. The evidence establishes the following: (1) the Commonwealth provides at least partially state-funded contraceptive services through MassHealth, which has about two million enrolled members, through the Massachusetts Department of Public Health, and through the University of Massachusetts Boston; (2) women with incomes up to 300 percent of the federal poverty line usually can receive contraceptive care through programs funded by the Commonwealth's Department of Public Health; and (3) on average, about twenty-five percent of women in the Commonwealth who currently have employer-sponsored coverage could qualify for these state-funded programs because they (a) have "employer or union provided health insurance and . . . [b] have household insurance unit income[s] less than or equal to 300% of the [Federal Poverty Level]," adding up to 365,762 between the ages of 15 and 45 who have employer or union provided

health insurance and are in household insurance units with income less than or equal to 300% of the federal poverty level.

Applying the state's calculation that at least twenty-five percent of women who currently have employer-sponsored coverage will be eligible for state-funded care, and adjusting the upper and lower bound estimates of the Departments' Regulatory Impact Analysis to the Commonwealth's percentage of the national population, the Commonwealth set forth that 99 to 354 women that will likely lose coverage as a result of the regulations will qualify for state funded programs. Considering that, based on the Departments' Regulatory Impact Analysis, the annual cost of contraceptive coverage averages around \$584 a year per woman, 82 Fed. Reg. 47,821, the state estimated it will likely be liable for about \$54,312 to \$206,736 a year for contraceptive care.

None of these statements have been seriously contested by the Departments (and besides, at the summary judgment stage, the "specific facts" "'set forth' [by a plaintiff] by affidavit or other evidence . . . will be taken as true," Lujan, 504 U.S. at 561). The Commonwealth has indeed produced specific facts regarding the imminent injury, and they go well beyond the proportional theory on which the district court focused on. The Departments' attack on the accuracy of the numbers provided by the Commonwealth misses the point: the Commonwealth need not be exactly correct in its numerical estimates in order to demonstrate an

imminent fiscal harm. Indeed, the Departments have assumed in their own regulatory impact analysis that "state and local governments will bear additional economic costs," California II, 911 F.3d at 572, and the Commonwealth's evidence fleshes this out.

The Departments' own estimate is based on average costs across the nation rather than what might be higher costs in the Commonwealth. Even so, the average cost to the Commonwealth of a single woman relying fully on state-funded contraceptive care for one year would be \$584 (if no portion was covered by other sources), based on the national estimate. 82 Fed. Reg. at 47,823. Whether costs to the Commonwealth are above or below this average, they are not zero. The declaration submitted by the General Counsel of the Massachusetts Department of Public Health states that, based on the General Counsel's personal knowledge and review of relevant information, "[a]n increase in the prevalence of employer-sponsored insurance that does not provide coverage for comprehensive family planning services would likely result in an increase in the number of Massachusetts residents eligible for and receiving services funded" by the Commonwealth.

And a birth resulting from the denial of contraceptive access will likely have significant costs to the Commonwealth as well. A 2010 analysis found that the average cost to the Commonwealth of an unplanned birth was \$15,109 in maternity care and other healthcare in the first year of the child's life alone.

See Adam Sonfield & Kathryn Kost, Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010, Guttmacher Inst., p.8 (Feb. 2015), [https://www.guttmacher.org/sites/default/files/report\\_pdf/public-costs-of-up-2010.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf).

The Departments theorize about a hypothetical woman who loses coverage but is "able to pay out of pocket for contraceptive services" or "ha[s] access to such coverage through a spouse's (or parent's) plan." Such a hypothetical woman may exist, but the number of women with incomes that make them eligible for state-assisted contraceptive coverage but who still fit in that category would, logically, be very small. The argument is largely irrelevant to the Commonwealth's claims of injury.

**c. The Commonwealth Has Shown a Likely Chain of Events for Standing**

The Commonwealth's "cause and effect [chain is] predicated on . . . probable market behavior." Adams, 10 F.3d at 923. That the asserted imminent fiscal injury relies on a prospective chain of events does not defeat standing. Indeed, the Supreme Court has found standing in cases involving causal chains more attenuated than this one. In Monsanto, standing was found where the claim of injury was based on a causal chain of at least four steps: (1) "genetically engineered alfalfa seed fields [we]re . . . being planted in all the major alfalfa seed production

areas"; (2) "bees that pollinate alfalfa have a range of at least two to ten miles"; (3) the alfalfa seed farms at issue were in an area within the bees' range, due to the "compact geographic area of the prime alfalfa seed producing areas"; all of which, taken together, meant that (4) growers would incur injury by taking, for example, "certain measures to minimize the likelihood of potential contamination and to ensure an adequate supply of non-genetically-engineered alfalfa." 561 U.S. at 153 n.4 & 154-55 (internal quotation marks omitted); accord Clapper, 568 U.S. at 420. The Commonwealth has set forth predictions of injury, supported by evidence, that are even more likely than those in Monsanto, and thus they are not merely a "highly attenuated chain of possibilities." Clapper, 568 U.S. at 410.

## **2. The Alleged Injury is Concrete and Particularized**

The next question is whether the imminent injury alleged is concrete and particularized. See Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1548 (2016). The Departments do not claim that the Commonwealth's alleged fiscal injury would not be both concrete and particularized.

Concreteness requires something "real, and not abstract." Id. (internal quotation marks omitted). An imminent fiscal injury, supported by evidence, as here, is a concrete injury. A sufficiently particularized injury "affect[s] the plaintiff in a personal and individual way." Id. (quoting Lujan,

504 U.S. at 560 n.1). The imminent financial harm alleged would impact the Commonwealth in an "individual" way. So, the Commonwealth's asserted imminent financial injury is concrete and particularized.

**3. The Commonwealth Has Shown Causation and Redressability**

Causation and redressability are the final two requirements for Article III standing. Lujan, 504 U.S. at 561-62. The Departments do not contest that the alleged injury would be caused by the federal regulations and would be redressable by an injunction. As to causation, the asserted imminent fiscal injury is clearly "fairly traceable to the challenged action," Monsanto, 561 U.S. at 149, as we have described earlier. As to redressability, an injunction preventing the application of these exemptions would stop the alleged fiscal injury from occurring, making it not only "likely," Spokeo, 136 S. Ct. at 1547, but certain that this injury would not occur for as long as the exemptions are enjoined.

**III.**

In sum, the Commonwealth's substantive challenges to the Departments' federal regulations are not moot. Its procedural challenge to the IFRs, however, has been mooted by the promulgation of the Final Rules, but this does not preclude the Commonwealth from asserting any procedural challenges to the Final Rules. Finally, the Commonwealth has Article III standing to challenge



the Departments' actions. We vacate and remand for proceedings consistent with this opinion.

**VACATED AND REMANDED.**