A Year in Litigation: Overview of Legal Challenges to 2017 Federal Executive Actions and Legislation

Speaker:
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Overview of Legal Challenges to
Federal Executive Actions and Legislation in Health Care

NYSBA, Health Law Section
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Legal Challenges on the Affordable Care Act's Cost-Sharing Reduction Payments

Issue Outline:

- The ACA's Cost Sharing Reduction (CSR) payments were intended to offset the cost of copay and deductible waivers that health plans are required to provide to low-income individuals under the ACA. CSR payments are also referenced in the ACA's payment methodology for its Basic Health Plan (BHP), which two states—New York and Minnesota—have enacted to cover individuals between 138-200% of the Federal Poverty Limit.
- In 2014, the US House of Representatives sued the Obama Administration over the payment of CSRs, on the grounds that Congress had not specifically appropriated the funding (*House v. Burwell.*) A DC district court ruled in favor of the House, ordered that the payments be stopped, then stayed the order. The payments continued.
- On October 12, 2017, President Trump announced a halt to the payment of CSRs, citing the district court's ruling, among other reasons.
- In December 2017, the parties in what had become *House v. Hargan*, announced a conditional settlement, as there was no longer any controversy on the merits between the House and the Executive.
- In the meantime, several state attorneys general, including New York's, took action, first intervening in *House v. Hargan*, then, in October 2017, commencing a new action in the Northern District of California. In that case, the AGs allege the Administration's cessation of the payments violated the Administrative Procedure Act and US Constitution.
- The district court in *California, et al, v. Trump* denied the plaintiffs' motion for a preliminary injunction. The case is continuing.
- New York State stands to lose approximately $870m in Federal funding for its Basic Health Plan, known in NYS as the Essential Plan, in addition to any impacts on health plan market participation and premium increases. The Essential Plan covers approximately 700,000 New Yorkers.

Attachments:

- Proposed Settlement Agreement in *House v. Hargan,* dated December 15, 2017
- Order Denying Motion for Preliminary Injunction in *California, et al v. Trump,* by Judge Chhabria, dated October 25, 2017

SETTLEMENT AGREEMENT

This Settlement Agreement (the "Agreement") is entered into by and between (a) the United States House of Representatives (the "House"); (b) the United States Department of Health and Human Services, the United States Department of the Treasury, and their respective Secretaries (the "Agencies"); and (c) the States of California, New York, Connecticut, Delaware, Hawaii, Illinois, Iowa, Kentucky, Maryland, Massachusetts, Minnesota, New Mexico, North Carolina, Pennsylvania, Vermont, Virginia, and Washington, and the District of Columbia (the "States").

1. In light of changed circumstances, the House, the Agencies, and the States have determined to resolve the dispute that is pending before the U.S. Court of Appeals for the D.C. Circuit ("Court of Appeals") in *United States House of Representatives v. Hargan, et. al*, No. 16-5202 (D.C. Cir.).

2. By no later than two business days after execution of this Agreement, the House and the Agencies (collectively, "the Parties") will submit to the district court a request that the district court issue an indicative ruling pursuant to Rule 62.1 of the Federal Rules of Civil Procedure stating that, if the case is remanded by the court of appeals, the district court will vacate the portion of its final order providing that "reimbursements paid to issuers of qualified health plans for the cost-sharing reductions mandated by Section 1402 of the Affordable Care Act, Pub. L. 111-148, are ENJOINED pending an appropriation for such payments." ECF No. 74, *United States House of Representatives v. Burwell, et al.*, No. 1:14-cv-01967-RMC (D.D.C.). If the district court grants that motion, the Parties and the States will file a motion that asks the court of appeals to remand the case to allow the district court to grant the motion as provided in its indicative ruling.

3. The Parties recognize that the Executive Branch of the United States Government ("Executive Branch") continues to disagree with the district court's non-merits holdings, including its conclusion that the House had standing and a cause of action to bring this suit. The Parties agree that because subsequent developments have obviated the need to resolve those issues in an appeal in this case, the district court's holdings on those issues should not in any way control the resolution of the same or similar issues should they arise in other litigation between the House and the Executive Branch. The Parties also recognize that the States continue to disagree with the district court's merits holding. Accordingly, if the court of appeals grants the Joint Motion, the Parties agree that the district court's holding on the merits should not in any way control the resolution of the same or similar issues should they arise in other litigation, and hereby waive any right to argue that the judgment of the district court or any of the district court's orders or opinions in this case have any preclusive effect in any other litigation.

4. If the district court grants the motion described in paragraph 2 above and, following remand from the D.C. Circuit, the district court vacates its injunction in accordance with its indicative ruling, the Parties and the States agree that this litigation will have been resolved. The Parties and the States will bear their own fees and costs.

5. If the district court declines to grant the motion described in paragraph 2 above, or indicates that it would enter other relief not jointly supported by the Parties, this Agreement shall be of no force and effect and the Parties and the States shall be returned to their respective positions prior to execution of this Agreement.

6. FULL AUTHORITY TO SIGN. Each person signing this Agreement represents and warrants that he or she has full authority to execute the Agreement on behalf of himself or herself, or on behalf of the party or entity on whose behalf he or she signs this Agreement.

7. EXECUTION IN COUNTERPARTS AND ELECTRONIC SIGNATURES. This Agreement may be executed and delivered in counterparts, and may be executed by electronic signature, and if so, shall be considered an original. Each counterpart, when executed, shall be considered one and the same instrument, which shall comprise the Agreement, which takes effect on the date of execution by all parties to the Agreement.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, et al.,

Plaintiffs,

v.

DONALD J. TRUMP, et al.,

Defendants.

Case No. 17-cv-05895-VC

ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION

The Affordable Care Act requires health insurance companies to subsidize the cost of co-payments and deductibles for lower-income people. In turn, the Act requires the federal government to make advance payments to the companies to cover the cost of this subsidy. The legal problem in this case is that while the Act requires the insurance companies to be paid, it's unclear whether the Act actually appropriated money for these payments. If Congress doesn't appropriate money for a program, the Constitution prohibits the executive branch from spending money on that program – even if Congress previously enacted a statute requiring the expenditure.

The Obama Administration took the position that the Affordable Care Act indeed appropriated money for the payments, so it drew funds from the U.S. Treasury every month to make them. The Trump Administration initially continued this practice, but has now concluded that the Act did not actually make the necessary appropriation. So the Trump Administration has terminated the payments, at least until Congress decides to appropriate the money.

In response, the State of California, along with 17 other states and the District of Columbia, filed this lawsuit, contending the Obama Administration was right. They seek an

emergency ruling requiring the Trump Administration to continue making the payments while the lawsuit is pending. This request is denied. First, although the case is at an early stage, and although it's a close question, it appears initially that the Trump Administration has the stronger legal argument. Second, and more importantly, the emergency relief sought by the states would be counterproductive. State regulators have been working for months to prepare for the termination of these payments. And although you wouldn't know it from reading the states' papers in this lawsuit, the truth is that most state regulators have devised responses that give millions of lower-income people better health coverage options than they would otherwise have had. This is true in almost all the states joining this lawsuit. Including California, whose regulators issued a press release just days before the suit explaining how so many lower-income people will benefit.

I.

The central purpose of the Affordable Care Act is to provide health coverage for the millions of people who don't get it through their jobs. Six years after its enactment in 2010, the Act is well on its way to achieving that purpose: almost half of the previously uninsured people in the United States now have coverage.[1] Some people have coverage because the Act expanded Medicaid eligibility.[2] Many others have purchased insurance, usually on new insurance "exchanges" where people can shop for coverage. Three key policies acting in concert have enabled the Act's success: (1) the Act bars insurance companies from denying coverage to people or charging them more based on their health status; (2) the Act requires people to buy insurance; and (3) the Act provides significant subsidies to help lower-income people buy insurance on the exchanges. It cannot reasonably be disputed that, for the Affordable Care Act to achieve its

[1] *See* Robin A. Cohen et al., National Center for Health Statistics, *Health Insurance Coverage: Early Release of Estimates from the National Health Interview Survey, 2016* at 2 (May 2017), https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201705.pdf [https://perma.cc/W2TP-L9RK].

[2] Around 15 million people were covered by the expansion of Medicaid in 2016. *Medicaid Expansion Enrollment, Timeframe: FY 2016*, Kaiser Family Foundation, https://www.kff.org/health-reform/state-indicator/medicaid-expansion-enrollment [https://perma.cc/EWQ4-MUZ5].

goals, all three of these pillars must remain standing. *See King v. Burwell*, 135 S. Ct. 2480, 2485, 2487 (2015).

Lower-income people have access to two forms of subsidies to help them afford insurance sold on the exchanges. The most significant subsidy is a tax credit to help offset the cost of monthly insurance premiums: people whose income puts them between 100% and 400% of the federal poverty level receive significant tax credits to alleviate the cost of buying insurance. (The federal poverty level for a single person is a mere $12,060 per year.)[3] To use an example of how the tax credit works on the exchanges, in San Francisco, a 60-year-old making around $45,000 in 2017 could purchase a fairly typical plan for around $360 per month – even though the actual premiums would be $940 per month absent the tax credits.[4] A large majority of people who purchase health care on the exchanges rely on these tax credits.[5]

The premium tax credit is structured so you get it in advance, when you are actually paying your insurance premiums. Although normally with tax credits you have to wait for the benefits until your tax returns are filed the following year, the Affordable Care Act established a system through which your tax credit is estimated and paid in advance to the insurance companies, so they can reduce your premiums by a corresponding amount. If, after the year is over, there is a discrepancy between the discount you received and the amount of your premium tax credit, it is reconciled through your tax returns. 26 U.S.C. § 36B(f). In fact, when you're shopping for insurance on the exchange – at least in California – you are not even told the amount of monthly premium before the tax credit. You're simply told the amount you're required to pay.[6]

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[3] Annual Update of the HHS Poverty Guidelines, 82 Fed. Reg. 8831, 8832 (Jan. 31, 2017).
[4] App. B at 2, 5; 2017 QHP Individual Rates, Covered California, http://hbex.coveredca.com/data-research/library/2017_QHP_Individual_Rates_File_for_Posting_100716.xlsx [https://perma.cc/2MT6-EH3D]; *see also* 26 U.S.C. § 36B(b)(2)(B).
[5] In March 2016, 84.7% of people who purchased health care on the exchanges received the tax credit. March 31, 2016 Effectuated Enrollment Snapshot, Centers for Medicare & Medicaid Services, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-30.html [https://perma.cc/3ESH-M44Z].
[6] *See, e.g.*, App. B at 4-6, 9-11.

The other subsidy – the one that's the subject of this dispute – reduces the amount that lower-income people have to pay out-of-pocket when they use their insurance to get care. When you have insurance, you typically make "co-payments" when you visit the doctor or pick up medications from the pharmacy. Sometimes you also have a "deductible," which means that you must pay the full cost of your health-care expenses until you reach the deductible amount, at which point your insurance kicks in and covers the rest. You also might be required to pay "co-insurance." Co-insurance is triggered after you've reached your annual deductible and requires you to pay a percentage, say 20%, of your doctor's bill or the price of your medications; the insurance company pays the remaining share.

The Affordable Care Act refers to these payments as "cost-sharing" payments, because you are sharing the cost of your treatment with your insurance company. The subsidy provided by the Act is called a "cost-sharing reduction," because the insurance companies are forced to reduce your cost-sharing payments. Specifically, the Act requires insurance companies to offer plans to lower-income people with reduced cost-sharing payments. People whose income puts them between 100% and 250% of the federal poverty level can buy plans of this type.

In turn, the Act requires the federal government to compensate the insurance companies for those reductions. Typically, people refer to the payments by the federal government to the insurance companies as "cost-sharing reduction payments," or "CSR payments." Throughout this opinion, the phrase "CSR payments" references these payments that the federal government is required to make to the insurance companies.

As with the tax credits, the Act provides that the federal government will pay for these subsidies in advance. Specifically, the federal government estimates in advance the amount of subsidy to which you are entitled and makes a CSR payment in that amount to your insurance company. As a result, the insurer can reduce your cost sharing by a corresponding amount throughout the year on the federal government's dime. If, after the year is over, you ended up using less money from the subsidy than what the federal government gave the insurance company, the insurance company must return the excess to the federal government. *See* 45

C.F.R. § 156.430(e)(2).

The premium tax credits and the cost-sharing reductions work together: the tax credits help people obtain insurance, and the cost-sharing reductions help people get treatment once they have insurance. In 2016, the federal government spent $32 billion on premium tax credits, and these credits helped around 10 million people purchase insurance on the exchanges. For the same year, it spent $7 billion on CSR payments to insurance companies, which helped 7 million people pay for doctor's visits, medications, and other treatment. [7]

Following passage of the Affordable Care Act, and once the exchanges were ready to get up and running, an issue about the statutory language arose. For the premium tax credits, the language of the Act was clear: it required the tax credits to be paid, and made a "permanent appropriation" for those tax credits, meaning the money would automatically be available each year for the executive branch to fulfill its duty to make the payments. But for the cost-sharing subsidies, the language of the Act was different. It required the insurance companies to give people the reductions, and it required the federal government to pay the insurance companies in advance for these reductions, but it did not explicitly make a permanent appropriation for the CSR payments to the insurance companies. Absent a permanent appropriation, the responsibility would be on Congress to help fulfill the federal government's obligation to make the CSR payments by providing money through the annual appropriations process.

In 2013, the Obama Administration concluded that the Act could be interpreted as implicitly making a permanent appropriation for CSR payments, meaning that no annual appropriations were required. So, beginning in January 2014, the Administration began drawing money from the U.S. Treasury to make those payments on a monthly basis, just as it did for the

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[7] Congressional Budget Office, *Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2016 to 2026* 31, tbl. 2 (2016), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51385-healthinsurancebaselineonecol.pdf [https://perma.cc/M3S7-8X53]; 2017 Marketplace Plan Selections with Financial Assistance, Kaiser Family Foundation, https://www.kff.org/health-reform/state-indicator/2017-marketplace-plan-selections-by-financial-assistance-status [https://perma.cc/VX6G-Q47Z].

premium tax credits. In contrast, the House of Representatives took the position that the Act contained no permanent appropriation for CSR payments. Because Congress was not making annual appropriations, the House believed the Administration was violating the Constitution by making payments to the insurance companies for which money had not been appropriated. *See* U.S. Const. art. I, § 9, cl. 7 ("No money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . . .").

Accordingly, in November 2014, the House filed a federal lawsuit against the Obama Administration in Washington, D.C., to stop the allegedly unconstitutional payments. In May 2016, United States District Judge Rosemary Collyer ruled in favor of the House, concluding the Act had made no permanent appropriation for the federal government to make CSR payments. As a result, Judge Collyer concluded, the Administration could not (absent annual appropriations or an amendment to the Affordable Care Act providing for a permanent appropriation) continue to make the CSR payments. *U.S. House of Representatives v. Burwell*, 185 F. Supp. 3d 165, 168 (D.D.C. 2016). However, Judge Collyer stayed her ruling so the federal government could continue making the payments while the Obama Administration pursued an appeal of her ruling in the D.C. Circuit. *Id.* The Obama Administration therefore continued making payments.

Then the election happened. Shortly afterward, on November 21, 2016, the House asked the D.C. Circuit to stay the appeal. Appellee's Motion to Hold Briefing in Abeyance, *U.S. House of Representatives v. Burwell*, No. 16-5202 (D.C. Cir. Nov. 21, 2016). The House explained that, in light of public statements by members of the incoming Trump Administration, it believed that the executive branch might reconsider its legal position on the validity of the payments. Given that, the House asserted that it might be a waste of time to keep moving forward on an appeal the new Administration might eventually drop. *Id.* at 3-4. The D.C. Circuit granted the motion in December 2016 and stayed the case. Order Granting Motion to Hold in Abeyance, *U.S. House of Representatives v. Burwell*, No. 16-5202 (D.C. Cir. Dec. 5, 2016).

In spring 2017, 17 states (including most of those bringing the current lawsuit) and the District of Columbia sought to intervene in the D.C. Circuit appeal. Their argument for

intervention was that: (i) they believed the Affordable Care Act had made a permanent appropriation for CSR payments; (ii) it appeared the Trump Administration was prepared to renounce that position, leaving nobody in the case to argue it; and (iii) the states would be harmed if the payments stopped. In August 2017, the D.C. Circuit granted the states' motion. It concluded that the states had standing to intervene because they would be injured by any decision to terminate the payments, and that the states' participation in the appeal was needed to ensure that someone would continue to argue the position previously taken by the Obama Administration in the case. Order Granting Motion to Intervene, *U.S. House of Representatives v. Price*, No. 16-5202 (D.C. Cir. Aug. 1, 2017). But the D.C. Circuit kept the stay in place, apparently awaiting the Trump Administration's decision about whether it would change its position in the case.

Meanwhile, seeing the writing on the wall, states throughout the country began working with insurance companies early in 2017 to prepare for the likelihood that the Trump Administration would switch positions and stop making the CSR payments. The problem was that even if the payments to the insurance companies stopped, the Affordable Care Act would still require the companies to provide the cost-sharing reductions to patients enrolled in certain plans. To offset this cost increase, insurance companies would want to raise premiums for 2018 insurance coverage. And if the companies did not believe they'd be able to offset the costs through premium increases, they might withdraw from the exchanges for 2018. Withdrawal by an insurance company would be especially harmful if it was the only company offering plans on an exchange for a given region: although people can buy insurance "off-exchange," they are only eligible for premium tax credits or cost-sharing reductions if they purchase insurance on an exchange. *See* 42 U.S.C. § 18071(b)(1); 26 C.F.R. § 1.36B-2(a)(1). So most states went to work with the insurance companies to try to figure out a way the companies could increase premiums to make up for the expected termination of the CSR payments. Their efforts are described more fully in Section IV below.

On October 11, 2017, the anticipated termination of the CSR payments became a reality.

The Attorney General sent a letter to the Treasury Department and the Department of Health and Human Services, explaining his view that the Affordable Care Act had not made a permanent appropriation for the CSR payments, and that the agencies therefore were precluded from making them. Notice at 6, *U.S. House of Representatives v. Hargan*, No. 16-5202 (D.C. Cir. Oct. 13, 2017). The next day, the White House announced this decision to the media. The day after that, October 13, the Justice Department filed a notification with the D.C. Circuit, informing it of the decision. *Id.*

Also on October 13, the State of California, along with 17 other states and the District of Columbia, filed this lawsuit in San Francisco. They allege the federal government is required under the Affordable Care Act to make the CSR payments to the insurance companies, that the Act permanently appropriated the money to make these payments, and that the Administration is therefore violating the law by refusing to make them. On October 18, the states filed a request for a temporary restraining order that would force the Administration to make the payments. The states sought a ruling by 4 p.m. on October 19, because the insurance companies had been anticipating the next round of payments on October 20. During a telephonic conference with the parties, the Court declined to issue a ruling on such a tight time frame and without receiving a response from the Administration. Instead, the Court scheduled a hearing for October 23. Since then, both sides have agreed that the TRO application should be converted to a motion for a preliminary injunction. Therefore, the question presented by this motion is whether the Court should issue a preliminary injunction requiring the Administration to make the CSR payments to the insurance companies while this case is pending, rather than wait until the case is fully adjudicated before deciding what relief (if any) is appropriate.

II.

The Administration believes that two procedural defects in the states' lawsuit prevent the Court from even inquiring whether to issue a preliminary injunction. The current record reveals no such defects.

First, the Administration contends the states lack standing under Article III of the

Constitution to bring this case in federal court, because they have failed to allege any direct injury from the decision to terminate the CSR payments. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-62 (1992). But the states allege – among other harms – that they have incurred and will continue to incur administrative costs because of the disruption to the exchanges caused by the federal government's decision to stop CSR payments. And the states have presented evidence to back up those allegations. These costs are enough to satisfy the standing requirement. *See West Virginia v. EPA*, 362 F.3d 861, 868 (D.C. Cir. 2004); *see also Texas v. United States*, 787 F.3d 733, 748-41 (5th Cir. 2015); *Ass'n of Private Sector Colleges & Univs. v. Duncan*, 681 F.3d 427, 458 (D.C. Cir. 2012); Order Granting Motion to Intervene at 1-2, *U.S. House of Representatives v. Price*, No. 16-5202 (D.C. Cir. Aug. 1, 2017) (holding the states have standing based on their allegations of harm to their citizens from the termination of CSR payments and the resulting costs likely to be borne by the states in response to the harm).

Second, the Administration contends that even if the states have standing to sue in federal court, they haven't sued in the proper federal court. Since most of the plaintiffs in this case have intervened in the D.C. Circuit appeal, the Administration contends it is not appropriate for the states to pursue a separate action in this Court. While it's true that the usual rule is for federal district courts to refuse to adjudicate matters where a case with significant overlap is already being adjudicated in another federal court, that rule is subject to many exceptions. Whether to allow the second suit to proceed is a matter of judicial discretion, particularly in extraordinary cases. *See Church of Scientology of California v. U.S. Dep't of Army*, 611 F.2d 738, 749-50 (9th Cir. 1980), *overruled on other grounds, Animal Legal Defense Fund v. U.S. Food & Drug Admin.*, 836 F.3d 987 (9th Cir. 2016) (en banc); *see also Alltrade, Inc. v. Uniweld Products, Inc.*, 946 F.2d 622, 628 (9th Cir. 1991); *EEOC v. Univ. of Pennsylvania*, 850 F.2d 969, 977 (3d Cir. 1988). This is not a situation where a plaintiff sued in one court, didn't like how it was going, and then tried to sue in another court. *See, e.g., Padilla v. Willner*, No. 15-cv-04866-JST, 2016 WL 860948, at *5 (N.D. Cal. Mar. 7, 2016). Nor is it a situation where a plaintiff sued in one court only to see the defendant respond by suing in a different forum that the defendant found

more attractive. *See, e.g., Intersearch Worldwide, Ltd. v. Intersearch Grp., Inc.*, 544 F. Supp. 2d 949, 955-64 (N.D. Cal. 2008). The states were not parties to the D.C. litigation until they moved to intervene in the appeal to protect their interests.

Moreover, given the states' alleged need for emergency relief, it was not merely justifiable to seek that relief in a different forum; it was prudent. The D.C. case is on appeal, and currently stayed, so it's not clear how quickly the states could get their request for emergency relief heard in D.C. What's more, there are serious questions about whether the D.C. Circuit has jurisdiction in the appeal. The Obama Administration argued, and the Trump Administration continues to argue, that the House of Representatives never had standing to bring the lawsuit challenging the CSR payments in the first place. Brief for Appellants at 19-38, *U.S. House of Representatives v. Burwell*, No. 16-5202 (D.C. Cir. Oct. 24, 2016); Defs.' Opp'n at 8 n.5, Dkt. No. 35. If that's correct (and could it really be wrong if both Administrations agree on it?), it means Judge Collyer lacked jurisdiction to issue the ruling against the Obama Administration. This, in turn, likely means the D.C. Circuit lacks jurisdiction to do anything other than dismiss the appeal (or remand to the district court with instructions to dismiss the case for lack of standing). *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998); *see also, e.g., Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 539-49 (1986); *Ervine v. Desert View Regional Medical Center Holdings, LLC*, 753 F.3d 862, 866-71 (9th Cir. 2014).

III.

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). A court may grant a preliminary injunction even if a plaintiff only shows that there are "serious questions going to the merits"—a lesser showing than likelihood of success on the merits, if the balance of hardships "tips sharply in the plaintiff's favor," the plaintiff is likely to suffer irreparable harm, and the injunction is in the public interest. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135

(9th Cir. 2011). When the government is a party, the public interest and balance of hardships analyses often merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014).

A.

First the merits. On the legal question presented – whether Congress has appropriated money for the CSR payments – both sides have reasonable arguments. However, with the important caveats that the Court has only been given a few days to study this complex matter and the states may not have fully developed all arguments, it initially appears the Administration has the stronger legal position.[8]

To understand both sides' arguments, it's important to know how laws get put on the books. When statutory provisions from new laws like the Affordable Care Act are incorporated into the U.S. Code (the official compilation of all federal laws), they are considered "codified." The U.S. Code is divided into different parts based on subject area, such as the Internal Revenue Code and the Public Health and Welfare Code. The numbering of the sections of bills when they are first passed by Congress do not match the numbering of the sections of the U.S. Code where they are ultimately codified. In other words, when Congress votes on a bill, that bill has many sections. But language from different sections of the bill is often inserted into different parts of the U.S. Code, based on what the particular section seeks to accomplish.

The Affordable Care Act contains clear language making a permanent appropriation for the premium tax credits. Section 1401 of the Act established the premium tax credits, and the language of section 1401 was codified in the Internal Revenue Code – specifically, in 26 U.S.C. § 36B. Section 36B provides that lower-income people buying insurance on an exchange "shall"

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[8] The states raise claims under the Administrative Procedure Act, the Take Care Clause of the U.S. Constitution, and the Declaratory Judgment Act. Complaint at 22-23. Success on any of these claims almost certainly depends on whether Congress appropriated money to fund the CSR payments, because the Court can only award the relief the states seek if money was appropriated for this purpose. *See, e.g., Office of Personnel Management v. Richmond*, 496 U.S. 414, 424-25 (1990); *Reeside v. Walker*, 52 U.S. (11 How.) 272, 291 (1850); *Rochester Pure Waters Dist. v. EPA*, 960 F.2d 180, 184 (D.C. Cir. 1992).

receive the "premium assistance credit." *Id.* That is how, to use federal budgeting parlance, the tax credits were "authorized." But this language does not appropriate the money for the credits. The Affordable Care Act accomplished the appropriation by amending a different statute, namely 31 U.S.C. § 1324. This statute is contained in the portion of the U.S. Code titled "Money and Finance," and section 1324 is in fact titled "refund of internal revenue collections." Subsection 1324(a) makes a permanent appropriation for tax refunds, stating that "[n]ecessary amounts are appropriated to the Secretary of the Treasury for refunding internal revenue collections as provided by law." Then, subsection 1324(b) imposes limits on the tax refunds for which the permanent appropriation is made. It states that the executive branch may "only" make disbursements under section 1324 for: (1) individual tax refunds; and (2) "refunds due from" various provisions of the Internal Revenue Code, including (after passage of the Affordable Care Act) section 36B. Therefore, section 1324 clearly contains a permanent appropriation for the premium tax credit program codified at 26 U.S.C. § 36B.

This clarity is in contrast to the language in the Act involving cost-sharing reductions. As mentioned in the preceding paragraph, section 1401 of the Affordable Care Act created the tax credits and was codified at 26 U.S.C. § 36B – which is part of the Internal Revenue Code. Section 1402 of the Affordable Care Act created the cost-sharing reduction program. Unlike section 1401's premium tax credits, section 1402's cost-sharing reduction program is not codified in section 36B of the Internal Revenue Code; rather it is codified in the Public Health and Welfare Code, at 42 U.S.C. § 18071. The cost-sharing reduction program requires the insurance companies to lower the amount consumers must pay out of pocket, and in turn requires the federal government to pay the companies for the reductions. 42 U.S.C. § 18071(c)(3)(A) (federal government "*shall* make periodic and timely payments to the [insurance company] equal to the value of the reductions" (emphasis added)). This is how the Affordable Care Act "authorized" the cost-sharing reduction program and the CSR payments to the insurers. But there is no explicit language regarding appropriations. While the Act added section 36B of the Internal Revenue Code to the permanent appropriations statute for tax refunds (namely, 31

U.S.C. § 1324) the Act did not add section 18071 of the Public Health and Welfare Code to that same appropriations statute for tax refunds. Nor does the Act appear to have included any other explicit language making a permanent appropriation for the CSR payments to insurers. This may suggest that Congress needed to make annual appropriations before the executive branch could make the CSR payments, and that the Obama Administration (along with the Trump Administration for the first half of 2017) acted unconstitutionally by making the payments every month since 2014. *See* U.S. Const. art. I, § 9, cl. 7 ("No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . . ."); *see also U.S. House of Representatives*, 185 F. Supp. 3d at 185.

The response by the states is that the language of 31 U.S.C. § 1324, which makes a permanent appropriation for the premium tax credits established in 26 U.S.C. § 36B, impliedly includes a permanent appropriation for the CSR payments established by 42 U.S.C. § 18071. Specifically, the states argue that: (i) 31 U.S.C. § 1324 appropriates money for "refunds due from" 26 U.S.C. § 36B; (ii) the cost-sharing reductions from 42 U.S.C. § 18071 are closely coordinated with the premium tax credits throughout the statute; (iii) a person cannot receive the cost-sharing reductions unless she also gets the tax credits; and therefore (iv) the cost-sharing reductions from 42 U.S.C. § 18071 should be considered "refunds due from" section 36B within the meaning of section 1324.

This argument is based on the Supreme Court's ruling in *King v. Burwell*, which also involved the Affordable Care Act. There, the Court considered language providing that tax credits would go to people who purchased insurance through "an Exchange established by the State." *King*, 135 S. Ct. at 2487. This language seemed unambiguous when read in isolation: premium tax credits were available for lower-income people who purchased insurance through an exchange established by a state, but not for people who purchased insurance through an exchange established by the federal government. But the Court held that the Act did, in fact, provide premium tax credits for lower-income people who bought insurance through federal exchanges. *Id.* at 2495-96.

There were two steps in the Court's analysis. First, the Court determined that although the pertinent language seemed unambiguous when read in isolation, it became ambiguous upon reading other parts of the Act. Among other things, the Act required all exchanges (state and federal) to complete certain tasks relating to the premium tax credits. "If tax credits were not available on Federal Exchanges," the Court explained, "these provisions would make little sense." *Id.* at 2492.

Second, after concluding that the phrase "an Exchange established by the State" was ambiguous in light of the surrounding statutory language, the Court set out to resolve the ambiguity by examining the purposes of the Affordable Care Act. That part was easy, because as discussed at the outset of this ruling, there are three pillars to the Act: preventing insurers from refusing coverage or charging more based on a person's health status, requiring people to get insurance, and making it affordable to purchase insurance on the exchanges. The failure to provide tax credits to lower-income people in places with federal exchanges would have removed one of those pillars, causing the whole health care reform project designed by Congress to come crumbling down. *Id.* at 2495-96. Thus, the Court resolved the ambiguity in the pertinent language by interpreting it to provide tax credits for insurance purchased on all exchanges, state and federal.

In this case, the states present some good arguments relating to the second part of the *King v. Burwell* analysis. To be sure, the absence of money for CSR payments does not seem to be causing health care reform to come crumbling down, as discussed in the next section. Nonetheless, the absence of a permanent appropriation for these payments may be in significant tension with congressional purpose. For example, as argued most persuasively by the amicus brief from America's Health Insurance Plans, the absence of a permanent appropriation seems odd from a timing standpoint. Insurance companies must work with the states to set their rates for the coming year well in advance (for example, insurers were expected to set their 2018 rates early in 2017). If CSR payments are subject to the vagaries of the annual appropriations process (which Congress often does not complete until late in the year), insurance companies cannot

reasonably predict how much it will cost to provide insurance on the exchanges. This uncertainty could make insurance companies less likely to offer coverage on the exchanges, leaving consumers with fewer options (or, far worse, no options) in a given geographic region.[9]

In addition, the two subsidies that form one pillar of health care reform – the tax credits and the cost-sharing reductions – fit hand in glove: the tax credits allow lower-income people to buy health coverage, and the cost-sharing reductions allow people to actually use this coverage. It's not clear why Congress would have intended more certainty for one type of expenditure than the other. This is particularly true where the Act establishes the same basic procedure for processing the subsidies. The federal government estimates the amount of tax credits and cost-sharing reductions to which a person is entitled and provides that amount in advance to the insurance company, allowing the insurance company to provide cheaper coverage to lower-income people who get insurance on the exchanges.[10] *See* 42 U.S.C. § 18082.

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[9] On the other hand, perhaps one response is that this is not the first time Congress has imposed mandatory spending requirements – important ones – on the executive branch, while leaving appropriations for those spending requirements to the annual appropriations process. *See, e.g.*, 42 U.S.C. § 1396-1 (authorizing annual appropriations for Medicaid grants to states pursuant to Title XIX of the Social Security Act); Defs.' Opp'n at 22-23, Dkt. No. 35 (listing other mandatory spending programs funded by annual appropriations); *see also U.S. House of Representatives*, 185 F. Supp. 3d at 185.

[10] But perhaps the response here is that the tax credits are far more central to the Act's health care reform project, so Congress took extra care to protect funding for those. After all, as discussed earlier, the tax credits represent a much larger investment of money by the federal government – $32 billion in 2016 compared to $7 billion for the cost-sharing reductions. Congressional Budget Office, *Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2016 to 2026* at 31, tbl. 2 (2016), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51385-healthinsurancebaselineonecol.pdf [https://perma.cc/M3S7-8X53]. They benefit more people, as well as a wider range of the population (for the tax credits, people whose incomes put them between 100% and 400% of the federal poverty level, and for the cost-sharing reductions, people whose incomes put them between 100% and 250% of the federal poverty level). 2017 Marketplace Plan Selections with Financial Assistance, Kaiser Family Foundation, https://www.kff.org/health-reform/state-indicator/2017-marketplace-plan-selections-by-financial-assistance-status [https://perma.cc/VX6G-Q47Z]. It also bears recalling that the absence of funding for CSR payments does not prevent lower-income people from receiving that subsidy. It means only that the insurance companies pay for it, rather than the federal government. And as discussed in the next section, the states have devised a way for insurance companies to recoup those costs, apparently while also avoiding harm to (and instead

But recall that the Court in *King v. Burwell*, before resolving a statutory ambiguity by looking to the purpose of the Affordable Care Act, first had to conclude that a provision which seemed clear in isolation was actually ambiguous in light of other language in the Act. It's this first part of the analysis that gives the states a tougher challenge.

Although the states emphasize that the premium tax credits and cost-sharing reductions are mentioned together no fewer than 45 times in the Affordable Care Act, it's not clear that this feature of the statute supports their proposed reading of it. Repeatedly referring to the two programs by their separate names suggests Congress considered them distinct, if undoubtedly related. And the statute often recites not just the names of these two programs, but the different statutory provisions that created them. For instance, in the advance payment provision, which is central to the states' argument, the statute refers to "the premium tax credit allowable under section 36B of Title 26 and the cost-sharing reductions under section 18071 of this title." 42 U.S.C. § 18082(a)(1); *see also, e.g.*, *id.* § 300gg-4(l)(3)(A)(ii) ("credits under section 36B of Title 26 or cost-sharing assistance under section 18071 of this title"); *id.* § 18031(i)(3)(B) ("premium tax credits under section 36B of Title 26 and cost-sharing reductions under section 18071 of this title"). That Congress so often identified each reform by its location in one title of the U.S. Code or the other suggests that Congress was cognizant of the different way in which each reform fit into the statutory scheme. In other words, the language relied on by the states may further suggest that Congress did not intend the reference to section 36B in the permanent appropriation provision to encompass the CSR payments codified in an altogether different place.

The states also point to language prohibiting the use of either premium tax credits or CSR payments for abortion services. *See id.* § 18023(b)(2)(A). This language achieves the same purpose as the Hyde Amendment, which is the amendment routinely enacted as part of annual appropriations legislation that likewise bars the use of federal funds for abortion services. *See*

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benefitting) lower-income people who buy insurance on the exchange.

Dalton v. Little Rock Family Planning Services, 516 U.S. 474, 475 n.1 (1996) (per curiam). Including a similar restriction in the Affordable Care Act, the states contend, would be redundant unless the CSR payments were exempted from the annual appropriations process. Perhaps that's right. On the other hand, there appears to be no requirement that Congress incorporate the Hyde Amendment into its appropriations legislation every year. So perhaps there is an argument that Congress, by including a similar restriction in the Affordable Care Act, simply intended to ensure that the federal money associated with either reform not be used to pay for abortion services regardless of whether Congress chose to enact the Hyde Amendment in any given year. *See id.* at 477-78 (acknowledging "the changeable nature of spending bills in general, and the Hyde Amendment in particular" (citation omitted)).

The states also argue that, had Congress intended for the CSR payments to be funded through annual appropriations, it would have included a provision saying so. For instance, Congress could have included an "authorization of appropriations" provision when it set up the cost-sharing program, as it did in several other provisions of the Affordable Care Act. *See, e.g.*, Pub. L. No. 111-148, § 3511, 124 Stat. 119, 538 (2010); *id.* § 4003(a)(7), 124 Stat. at 543; *id.* § 5306(a), 124 Stat. at 626-67. In other words, in the states' view, because the Act included language authorizing annual appropriations for other programs implementing health care reform, the omission of such language in the CSR payment provisions suggests that Congress funded the CSR payments through the permanent appropriation in 31 U.S.C. § 1324(b). That might be right, but it's not a necessary conclusion. At oral argument, counsel for the states referred to other, unspecified programs created by the Affordable Care Act that didn't include specific authorization language but for which there may also be no permanent appropriation. Moreover, apparently such language is not needed to authorize an annual appropriation, and annual appropriations appear to be the default way in which Congress provides funds. *See* U.S. Government Accounting Office, GAO-04-261SP, Principles of Federal Appropriations Law (Vol. 1) 2-13, 2-41 (3d ed. 2004); *Civil Rights Commission*, 71 Comp. Gen. 378 (1992).

Looming over this whole discussion is the fact that the parties are disputing the meaning

of an appropriations statute, not just any statute. Congress has established certain rules regarding appropriations, including that "[a] law may be construed to make an appropriation out of the Treasury . . . only if the law specifically states that an appropriation is made . . . ." 31 U.S.C. § 1301(d). Perhaps the clear-statement rule announced in this provision is of limited relevance here, since it is undisputed that the appropriations provision at issue, 31 U.S.C. § 1324, makes a permanent appropriation, meaning that the disagreement concerns the scope of that appropriation, not its existence. Counsel for the Administration appeared to concede this point at oral argument. But even putting section 1301 aside, the role of the Appropriations Clause in enforcing the constitutional separation of powers provides reason for caution in adopting a reading of an appropriations statute broader than the one most obviously provided by the text. *See, e.g.*, *U.S. Dep't of Navy v. Federal Labor Relations Authority*, 665 F.3d 1339, 1347 (D.C. Cir. 2012).[11]

In sum, the Affordable Care Act requires the federal government to pay insurance companies to cover the cost-sharing reductions. The federal government is failing to meet that obligation. If there was no permanent appropriation in the Act, Congress is to blame for the

[11] There are a couple of arguments the states and their allies do not make. Perhaps there is good reason for this, so the Court mentions them only as an indication of the extent to which further briefing and research would be helpful before a definitive ruling on the merits. First, although the states contend Congress affirmatively intended to make a permanent appropriation through section 36B while the Administration contends Congress affirmatively intended to leave CSR payments to the annual appropriations process, it's conceivable that Congress simply forgot to include permanent appropriations language for the payments. Certainly if CSR payments are as integral to the statutory scheme as the states claim (and as the Obama Administration argued) then the omission of any appropriations-related language may have been unintentional. *Cf. Lamie v. U.S. Trustee*, 540 U.S. 526, 538 (2004); *Heppner v. Alyeska Pipeline Serv. Co.*, 665 F.2d 868, 872 (9th Cir. 1981). There are, after all, numerous apparent errors in the statutory text. *See, e.g.*, *King*, 135 S. Ct. at 2942 (noting that the Affordable Care Act created "three separate Section 1563s"). The parties have not discussed what the legal implications would be if Congress had intended, but simply forgotten, to make the appropriation. Nor do the states explore, as an alternative argument, the possibility that funds for CSR payments could be drawn from a general programmatic appropriation or other source. *Cf.* Department of Health and Human Services – Risk Corridors Program, B-325630, 2014 WL 4825237 (Comp. Gen. Sept. 30, 2014).

failure, because it has not been making annual appropriations for CSR payments. The Administration cannot fix Congress's error, because the Constitution prevents the Administration from making payments on its own. In contrast, if the Act created a permanent appropriation, the Administration is legally at fault for the federal government's failure to meet its obligation under the Act to make CSR payments. On the merits, it's a close and complicated question, even if the Administration may seem to have the better argument at this stage.

B.

The remaining three preliminary injunction inquiries (irreparable harm to the plaintiffs, the balance of hardships, and the public interest) overlap significantly, so they are discussed together in this section. On the issue of harm to the plaintiffs themselves (namely, the states), the Administration's decision to terminate the CSR payments certainly will cause some degree of direct and irreparable injury. As already discussed in Section II, the states are incurring significant administrative costs in responding to the termination of the payments, and there likely is no way to remedy that when the case is over. But in a case like this, where so much of the harm is alleged to be inflicted on society, and particularly on lower-income residents who need health coverage, the crucial question is whether the absence of a preliminary injunction would harm the public and impede the objectives of health care reform. The Affordable Care Act is the law of the land, and its goal is to provide meaningful and affordable health coverage to people who don't get it through their jobs. Any significant interference with that goal not clearly permitted by law is a major harm that would justify an injunction.

But it bears repeating that the only question presented by this motion is whether the Court should require the Administration to make the CSR payments for a few months – that is, until this Court can reach a final decision on the case, likely in early 2018. Therefore, allegations by the states about harms that loom further on the horizon – say, in 2019 or beyond – are not particularly relevant at the moment, because those harms can likely be addressed at the end of the case, if the states are indeed able to prevail on the merits. What matters for this motion is how people will be affected in 2017 and 2018 without a preliminary injunction.

In that regard, it appears that because of the measures taken by the states in anticipation of a decision by the Administration to terminate CSR payments, the large majority of people who purchase insurance on exchanges throughout the country will either benefit or be unharmed. In particular, many lower-income people stand to benefit. To explain this requires a somewhat detailed discussion of how things work on the exchanges.

There are four basic levels of health insurance plans available on the exchanges: bronze plans, silver plans, gold plans, and platinum plans. As the names imply, the levels vary in quality, with the bronze plans estimated to cover 60% of a person's health care costs, the silver plans 70%, the gold plans 80%, and the platinum plans 90%. *See* 42 U.S.C. § 18022(d).

If you meet the income requirements (that is, if your income puts you between 100% and 400% of the federal poverty level) you qualify for the premium tax credits, and you can use those tax credits to help purchase insurance on the exchanges. As mentioned earlier, you don't need to front the full premium payments and wait for a tax credit the following year. Under the Affordable Care Act, the federal government estimates your tax credit for next year and gives the insurance company the money, so that you get an upfront discount on premiums based on your tax credit. *See* 42 U.S.C. § 18082(c)(2)(A). .

The calculation of the tax credit is complicated, but for this discussion what's important is that the amount is based on the cost of the second-cheapest silver plan available on the exchange in your geographic area, and then adjusted based on your income (that is, based on where you fall on the spectrum between 100% and 400% of the federal poverty level). So, if premiums for the second-cheapest silver plan in your area go up, the amount of your tax credit will go up by a corresponding amount. *See* 26 U.S.C. § 36B.

With respect to cost-sharing subsidies, the Affordable Care Act only requires insurers to offer them for silver plans. 42 U.S.C. § 18071(b)(1). This often makes silver plans the most attractive for lower-income people who qualify for both tax credits and cost-sharing subsidies (people who earn between 100% and 250% of the poverty level). The monthly premiums of the silver plans are relatively low and covered in part by tax credits, and the cost of actually going to

the doctor is low because of the Act's cost-sharing reductions.[12]

With this background, let's rewind to early 2017. Anticipating that the Administration would terminate CSR payments, most states began working with the insurance companies to develop a plan for how to respond. Because the Affordable Care Act requires insurance companies to offer plans with cost-sharing reductions to customers, the federal government's failure to meet its CSR payment obligations meant the insurance companies would be losing that money. So most of the states set out to find ways for the insurance companies to increase premiums for 2018 (with open enrollment beginning in November 2017) in a fashion that would avoid harm to consumers. And the states came up with an idea: allow the insurers to make up the deficiency through premium increases for *silver plans only*. In other words, allow a relatively large premium increase for silver plans, but no increase for bronze, gold, or platinum plans.[13]

As a result, in these states, for everyone between 100% and 400% of the federal poverty level who wishes to purchase insurance on the exchanges, the available tax credits rise substantially. Not just for people who purchase the silver plans, but for people who purchase other plans too.

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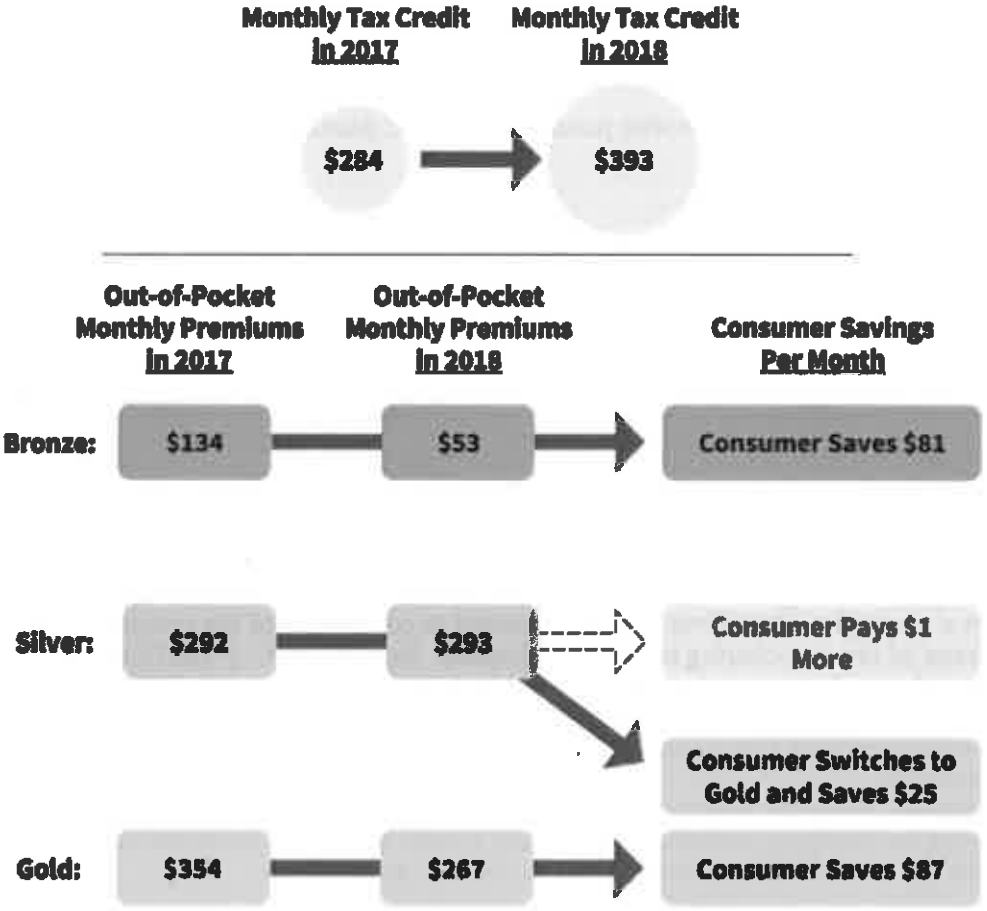
[12] For example, when a person earning between 100% and 150% percent of the federal poverty level buys a silver plan, that silver plan is estimated to cover 94% of the person's health care costs because of the cost-sharing reduction subsidies. *See* 42 U.S.C. § 18071(c)(2)(A). Recall that a silver plan without cost-sharing subsidies is designed to cover only 70% of a person's health care costs. By covering 94% of her costs, the silver plan with cost-sharing subsidies provides more insurance than even a platinum plan, which is designed to cover 90% of a person's health care costs.

[13] To be precise, premium increases for those other plans were permitted for other reasons, such as to account for changing medical costs and the overall health of plan members, but not to account for the loss of CSR payments from the federal government.

As an example, take a 50-year-old single person at 300% of the poverty level who lives in Santa Clara County (specifically, San Jose). The chart below shows the effect for her, in 2018, of California's response to the Administration's termination of the CSR payments. For 2017, her available tax credit was $284. In 2018, because of the silver plan premium increases, her tax credit will be $393. As a result, the area's most popular bronze plan would have cost her $134 per month in 2017, but the same bronze plan, with her increased tax credit, will cost her $53 per month in 2018. The area's most popular silver plan would have cost her $292 per month in 2017, while the same plan will cost her only a dollar more per month in 2018. And take a look at the gold plan. The area's most popular gold plan would have cost her $354 per month in 2017, but it will cost her just $267 per month in 2018. This means that if she had the silver plan in 2017, she can switch to the gold plan in 2018, paying $25 less per month for higher quality care.



These figures were taken directly from the website for Covered California, the state entity that operates the exchanges and is largely responsible for administering the Affordable Care Act exchanges in the state. The chart is reproduced at Appendix A to this opinion, backed up by the screenshots from the queries made on the Covered California website. Incidentally, in these screenshots the consumer is not told what the premium price would be absent the tax credit, so there's nothing to scare the customer away – nothing to mislead her into thinking the premiums are higher than they actually will be for her. Appendices B through E contain charts and screenshots for people in other California cities and with different income levels. Although results vary somewhat from place to place, the pattern is largely similar: for lower-income people who purchase insurance on the exchange, the elimination of the CSR payments will not increase premiums for the silver plans, but it will cause premiums for the other plans to go down. No wonder that back in January 2017, economists hired by the State of California estimated that the state's response to the anticipated termination of CSR payments would result in 20,000 more people buying health care in California in 2018.[14]

Even before the Administration announced its decision, 38 states accounted for the possible termination of CSR payments in setting their 2018 premium rates.[15] And now that the

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[14] Wesley Yin & Richard Domurat, Covered California, Evaluating the Potential Consequences of Terminating Direct Federal Cost-Sharing Reduction (CSR) Funding (2017), https://www.coveredca.com/news/pdfs/CoveredCA_Consequences_of_Terminating_CSR.pdf [https://perma.cc/ZB9D-XVVL].

[15] *See* Decl. of Jeff Wu at 5, Dkt. No. 35-5; *see also, e.g.*, *Part II Rate Increase Justification*, Mountain Health CO-OP, https://doi.idaho.gov/DisplayPDF?Cat=consumer&ID=2018_MHC_Indiv&Type=pdf [https://perma.cc/T6MN-PC4Z]; *Insurance Shopping A Challenge for Connecticut Consumers*, New Haven Register (Oct. 20, 2017), http://www.nhregister.com/news/article/Insurance-shopping-a-challenge-for-Connecticut-12293891.php [https://perma.cc/VH65-BYWD]; Steve Sinovic, *Subsidy Cut Already Priced Into Premiums*, Albuquerque Journal (Oct. 19, 2017), https://www.abqjournal.com/1080093/subsidy-cut-already-priced-into-premiums.html [https://perma.cc/9HKF-KP26]; Margot Sanger-Katz, *Trump's Attack on Insurer 'Gravy Train' Could Actually Help a Lot of Consumers*, New York Times (Oct. 18, 2017), https://www.nytimes.com/2017/10/18/upshot/trumps-attack-on-insurer-gravy-train-could-actually-help-a-lot-of-consumers.html; Kristen Schorsch, *How Team Rauner Hustled To Protect Obamacare from Trump*, Crain's Chicago Business (Oct. 17, 2017), http://www.chicagobusiness.com/article/20171017/NEWS03/171019869/how-team-rauner-hustled-to-protect-obamacare-from-trump [https://perma.cc/26GG-P9X4]; Louise Norris, Nevada's Health Insurance Marketplace: History and News of the State's Exchange,

announcement has been made, even more states are adopting a strategy like California's, including states that are plaintiffs in this lawsuit but had not already put a plan in place.[16] Recall that roughly 85% of people who purchase insurance on exchanges throughout the country qualify for tax credits, and recall that roughly 12 million people purchase insurance on exchanges, so the improvements described above have the potential to benefit millions of lower-income people.

What about a person who does not qualify for tax credits? This question is more complicated. In the states that responded to the Administration's decision by permitting premium increases for only silver plans, this higher-income person can buy a bronze, gold, or platinum plan for the same price they'd otherwise have been required to pay.[17] And in at least a

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HealthInsurance.org (Oct. 5, 2017), https://www.healthinsurance.org/nevada-state-health-insurance-exchange/#CSR [https://perma.cc/W4E3-XUST].

[16] *See* Decl. of Jeff Wu at 5-6, Dkt. No. 35-5; Meredith Cohn, *Maryland Officials Consider Higher Obamacare Rates After Federal Subsidies Cut*, Baltimore Sun (Oct. 23, 2017), http://www.baltimoresun.com/health/bs-hs-new-obamacare-rates-20171023-story.html; Holly K. Michels, *Health Insurance Companies Able To Raise Rates, Continue Selling on Exchange*, Independent Record (Oct. 19, 2017), http://helenair.com/news/politics/state/health-insurance-companies-able-to-raise-rates-continue-selling-on/article_f2e30986-d61e-5b15-8fdc-73e8448ee1e4.html [https://perma.cc/C278-9RNA]; Press Release, Pennsylvania Pressroom, Acting Insurance Commissioner Announces Approved 2018 Individual and Small Group Rates, Highlights Opportunities To Lessen Impact of Trump Administration Actions on Pennsylvania Consumers (Oct. 16, 2017), http://www.media.pa.gov/Pages/Insurance-Details.aspx?newsid=278 [https://perma.cc/HZ8P-2VLE]; Letter from Mike Kreidler, Insurance Commissioner, State of Washington, to Plan Year 2018 Individual Market Health Plan Issuers (Oct. 16, 2017), https://www.insurance.wa.gov/sites/default/files/documents/Kreidler-letter-to-issuers-CSR-101617.pdf [https://perma.cc/Q5W9-SBG9]; Press Release, Oregon Division of Financial Regulation, State Announcement Regarding Trump Administration Discontinuation of Cost-Sharing Reduction Payments, Oregon Division of Financial Regulation (Oct. 13, 2017), http://dfr.oregon.gov/news/Pages/20171013-trump-payment-reduction.aspx [https://perma.cc/3HTP-RU58]; Liz Ruskin, *Premera To Bump Up Premium To Cover Trump Cut*, Alaska Public Media (Oct. 13, 2017), http://www.alaskapublic.org/2017/10/13/premera-to-bump-up-premium-to-cover-trump-cut [https://perma.cc/T4G8-TNCF].

[17] *See* Decl. of Jeff Wu at 7-8, Dkt. No. 35-5; *see also, e.g.*, Press Release, Oregon Division of Financial Regulation, State Announcement Regarding Trump Administration Discontinuation of Cost-Sharing Reduction Payments (Oct. 13, 2017), http://dfr.oregon.gov/news/Pages/20171013-trump-payment-reduction.aspx [https://perma.cc/3HTP-RU58]; Press Release, Pennsylvania Pressroom, Acting Insurance Commissioner Announces Approved 2018 Individual and Small Group Rates, Highlights Opportunities To Lessen Impact of Trump Administration Actions on Pennsylvania Consumers (Oct. 16, 2017), http://www.media.pa.gov/Pages/Insurance-Details.aspx?newsid=278 [https://perma.cc/HZ8P-2VLE]; Press Release, Covered California, Covered California Keeps Premiums Stable by Adding Cost-Sharing Reduction Surcharge Only to Silver Plans to Limit Consumer Impact 2 (Oct. 11, 2017), https://www.calhospital.org/sites/main/files/file-attachments/10-11-17_-_coveredca_-_csr_surcharge.pdf [https://perma.cc/4P73-BPCU].

subset of the states described above, including California, this person can also buy a silver plan without paying more. Although the monthly premiums for silver plans sold *on* the exchange will increase, insurers and regulators in some states have also developed a set of comparable plans available *off* the exchange. The monthly premiums for these "off-exchange silver" plans will not increase in response to the CSR increases, because unlike on-exchange silver plans, these plans will not provide cost-sharing reductions.[18] So someone with a higher income who wants to purchase a silver plan need not lose money, but to do so he will have to purchase that policy from outside the exchange.

For all these reasons, Covered California issued a press release the day before the Administration publicly announced its decision to terminate CSR payments. In the press release, Covered California proclaimed: "because the surcharge [that is, the increase attributable to the Administration's decision] will only be applied to Silver-tier plans, nearly four out of five consumers will see their premiums stay the same or decrease, since the amount of financial help they receive will also rise." The press release later says: "In addition, Covered California consumers with Silver plans *who do not receive financial help* to pay their premium can also avoid paying the surcharge by switching to a different metal tier or buying near-identical Silver coverage directly from a health insurance company."[19]

But apparently, even in California, one out of five consumers will see premiums increase because of the termination of CSR payments. Though the states certainly haven't offered a concrete explanation for why some people might see increased premiums, here are some possibilities. Some people whose income is not low enough to receive tax credits will likely enroll or re-enroll in silver plans sold on the exchange because they do not know they can purchase a comparable but more affordable plan outside the exchange. Others may see their

[18] *See supra* note 17.
[19] Press Release, Covered California, Covered California Keeps Premiums Stable by Adding Cost-Sharing Reduction Surcharge Only to Silver Plans to Limit Consumer Impact 1-2 (Oct. 11, 2017), https://www.calhospital.org/sites/main/files/file-attachments/10-11-17_-_coveredca_-_csr_surcharge.pdf [https://perma.cc/4P73-BPCU].

rates increase because the price of the silver plan they purchased increased by more than the price of the second cheapest silver plan in their region (the plan that matters for purposes of measuring tax credits). In any event, the Covered California press release says that about half those people "will see increases of less than $25 per month."[20]

Presumably, if the payments were restored, premiums for the silver plans would need to be reduced, because the insurance companies would no longer need to increase them to recover the value of the lost CSR payments. But as the above discussion shows, such a remedy would likely cause millions of lower-income people across the country who purchase insurance on the exchanges to be worse off than if today's status quo is preserved. Their tax credits would go down, the bottom-line cost of purchasing bronze and gold plans would go up, and the bottom-line cost of purchasing silver plans wouldn't go down.

When counsel for the State of California was confronted at oral argument with the fact that the relief sought by the states could cause this harm, he responded by suggesting that perhaps the Court could order the Administration to resume the CSR payments even while the states continue to allow the insurance companies to charge higher premiums on the exchanges, with the idea that the numbers would reconciled later, through some unexplained process. In other words, allow the insurance companies to collect double payments in 2018. This argument does not even merit a response.

But it does raise the question: why, in light of this discussion, have all these Attorneys General rushed to court seeking an emergency ruling against President Trump?

The primary reason offered by the states, and one they repeat over and over, is that premiums will go up for millions of people. But as already discussed, they are only able to make that argument sound compelling by omitting the fact that the premium increases in almost every state will cause tax credits to increase in a corresponding amount, leaving so many people (especially lower-income people) better off or unharmed. To be sure, in the few states that have

[20] *Id.* at 2.

not responded as most states have, the harm may be greater. But it may not be too late for those states to change course; for example, just two days ago, Maryland apparently finalized its decision to take the California approach.[21]

The states also assert that insurance companies will withdraw from the exchanges for 2018 because of the Administration's decision to terminate the CSR payments. But for the most part insurance companies seem to have chosen to work with the states to anticipate the termination rather than withdrawing. And the states don't identify a single company that has withdrawn since the Administration announced its decision 13 days ago, even though open enrollment for 2018 begins just 7 days from now. It's true, as the states note, that Anthem withdrew from some exchanges earlier this year, primarily citing the anticipated termination of CSR payments. But the fact that more insurance companies have not done so suggests perhaps Anthem did not understand that states would devise a way for insurance companies to recoup their costs while avoiding harm to most people and in fact benefitting many.[22]

The states repeatedly cite a report from the Congressional Budget Office from August 2017 that predicted that termination of CSR payments would cause the ranks of the uninsured in the United States to increase by 1 million. Two things about that. First, this prediction was based on the assumption that many insurance companies would respond by fleeing the exchanges – something that hasn't happened (at least not for 2018). Second, the Congressional Budget Office report predicts that, starting in 2020, the CSR payment termination will cause the ranks of

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[21] Morgan Eichensehr, *Maryland Seeks To Minimize Higher Obamacare Premiums Following Subsidy Cut*, Baltimore Business Journal (Oct. 23, 2017), https://www.bizjournals.com/baltimore/news/2017/10/23/maryland-seeks-to-minimize-higher-obamacare.html [https://perma.cc/23GM-VNBN]; *see also* Decl. of Jeff Wu at 5-6, Dkt. No. 35-5.

[22] There may be one very real harm to the insurance companies: although they are recouping the lost CSR payments through 2018 premium increases, it appears those increases don't compensate for the missed payments in October, November, and December of 2017. But financial harm is almost never irreparable harm. *Idaho v. Coeur d'Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015). The insurance companies could presumably recover that money once this case is over, if not through a judgment by this Court then through lawsuits brought under the Tucker Act, 28 U.S.C. § 1491(a)(1). *See Greenlee County. v. United States*, 487 F.3d 871, 877 (Fed. Cir. 2007); *Moda Health Plan, Inc. v. United States*, 130 Fed. Cl. 436, 441, 450 (2017); *see also United States v. Mitchell*, 463 U.S. 206, 215-16 (1983).

the uninsured to *decrease* by roughly 1 million people.[23]

Speaking of which, another harm the states discuss is that the termination of CSR payments will end up costing the federal government more money. They note, correctly, that the widespread increase in silver plan premiums will qualify many people for higher tax credits, and that the increased federal expenditure for tax credits will be far more significant than the decreased federal expenditure for CSR payments. In other words, in their effort to get emergency relief, the states complain that the federal government will be spending more money on health coverage for poor people.

The United States suffers from immense inequality of wealth and opportunity. Courts (and in fact, all branches of government) should be reluctant to balance harms or apply laws in ways that exacerbate these inequalities.[24] That's especially true when the statute involved – the Affordable Care Act – reflects a policy judgment that it's unacceptable to allow tens of millions of people (mostly lower-income people) to go uninsured. As the Ninth Circuit has explained in an analogous context, when the tradeoff is between saving money and allowing lower-income people to obtain meaningful health coverage, the balance tips sharply in favor of health coverage. *Golden Gate Restaurant Ass'n v. City & County of San Francisco*, 512 F.3d 1112, 1125-26 (9th Cir. 2008). Therefore, to the extent the states are truly arguing that it's harmful to bolster health coverage for lower-income people through the use of the progressive tax system, that argument is not well-taken.

Finally, the states express concern that the termination of CSR payments will cause confusion among people who shop on the exchanges. In particular, the states argue, the fear of increased premiums may scare consumers from the exchanges. There is likely some truth to that. The Affordable Care Act is complicated, the endeavor of buying insurance on the exchanges is

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[23] Congressional Budget Office, *The Effects of Terminating Payments for Cost-Sharing Reductions* 7 (2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53009-costsharingreductions.pdf [https://perma.cc/RF6V-TY3C].

[24] *See* Joseph Fishkin & William E. Forbath, *Wealth, Commonwealth, & the Constitution of Opportunity: A Story of Two Traditions*, NOMOS (forthcoming), http://ssrn.com/abstract=2620920 [https://perma.cc/RZ2R-4N28].

confusing enough as it is, and the consumers who shop there are not universally sophisticated. *See* Brief of Amicus Curiae Families USA et al. at 12-19, Dkt. No. 51-2. But if the Administration's decision to terminate the CSR payments added to the confusion, would a court order requiring their resumption alleviate it? Moreover, the states may be overstating their "confusion" argument. As the Appendices illustrate, if you benefit from tax credits and you go shopping for insurance on the Covered California website, you may never even realize that premiums went up. You are only informed of what *you* have to pay for insurance. And as already discussed, if you're eligible for tax credits, it's highly likely you'll pay the same or less.

One last point on the issue of confusion. If the states are so concerned that people will be scared away from the exchanges by the thought of higher premiums, perhaps they should stop yelling about higher premiums. With open enrollment just days away, perhaps the states should focus instead on communicating the message that they have devised a response to the CSR payment termination that will prevent harm to the large majority of people while in fact allowing millions of lower-income people to get a better deal on health insurance in 2018.

IV.

The motion for a preliminary injunction is denied. A telephonic case management conference will take place on November 21, 2017, at 2:30 p.m. for the purpose of setting a schedule for the full adjudication of the case.

IT IS SO ORDERED.

Dated: October 25, 2017

VINCE CHHABRIA
United States District Judge

Legal Challenge to Reimbursement Cut for Certain Outpatient Drugs Covered under the 340B Drug Discount Program

Issue Outline:

- The 340B program, enacted in 1992, requires pharmaceutical manufacturers to provide discounts on certain outpatient drugs to certain hospitals and Federal grantees as a condition of participating in the Medicaid program. The purpose is to assist safety net and other providers in supporting health care access to low income patients.
- The 340B program has grown significantly since its inception, both in terms of affected patients, but also covered entities and discount savings. The pharmaceutical industry, legislators and others, such as MedPac have called for reform of the program.
- Legislators and regulators have been working on studies and reform recommendations. Guidance is pending from the Health Resources and Services Administration, the primary overseer of the 340B program.
- Late last year, the Centers for Medicare and Medicaid Services issued its annual Outpatient Prospective Payment System final rule, containing a significant (~30%) cut to the payment rates for certain outpatient drugs covered under the 340B program. The goal is to reduce the margin that 340B covered entities achieve on such drugs by virtue of the program.
- The American Hospital Association, along with two other national trade associations and three hospital systems filed suit in DC district court in December, arguing that the Secretary of the Department of Health and Human Services exceeded his authority in adjusting the payment rates. They also argued that the final rule, in general, is an attempt to undermine the 340B statute.
- On December 29, 2017, the district court dismissed *AHA v. Hargan*, finding that it lacked subject matter jurisdiction because the plaintiffs had failed to meet a statutory predicate to filing suit, that a claim be presented to the government for payment. The plaintiffs have filed a notice of appeal.

Attachment:

- Memorandum Opinion by Judge Contreras, denying plaintiffs' motion for a preliminary injunction, dated December 29, 2017

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	:	
Plaintiffs,	:	Civil Action No.: 17-2447 (RC)
v.	:	Re Document Nos.: 2, 17, 19
ERIC D. HARGAN, Acting Secretary, Department of Health and Human Services, *et al.*	:	
Defendants.	:	

MEMORANDUM OPINION

GRANTING DEFENDANTS' MOTION TO DISMISS; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION; AND DENYING MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

I. INTRODUCTION

This case represents a dispute between certain public and not-for-profit hospitals and the Department of Health and Human Services ("HHS") over the rates at which Medicare will begin reimbursing them for pharmaceuticals that they acquire through a federal program known as the 340B Program. Although the 340B Program has enabled eligible hospitals to purchase pharmaceuticals from manufacturers at discounts, Medicare has historically reimbursed those hospitals at rates that were significantly higher than acquisition costs. Healthcare providers, including Plaintiffs, claim that they have used this surplus to provide additional healthcare services to communities with vulnerable populations. But in 2017, the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS, issued a regulation which was designed to begin closing the gap between what hospitals were paying for drugs and the rates at which Medicare reimbursed those hospitals.

Plaintiffs in this action, three hospital associations and three of their member hospitals, contend that the Medicare reimbursement rate for 340B drugs is set by statute and that the Secretary exceeded his authority when he "adjusted" that statutory rate downward by nearly 30%. Compl. ¶¶ 47–49, ECF No. 1. In order to preserve the *status quo*, Plaintiffs now seek a preliminary injunction directing HHS and the Acting Secretary not to implement these provisions pending the resolution of this lawsuit and any appeal. Pls.' Mot. Prelim. Inj., ECF No. 2. In response, Defendants, HHS and the Acting Secretary, have opposed this motion and have themselves moved to dismiss the action pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted. *See* Defs.' Mot. Dismiss, ECF No. 17. For the reasons stated below, the Court concludes that it lacks subject matter jurisdiction because Plaintiffs have failed to present any claim to the Secretary for final decision as required by 42 U.S.C. § 405(g). Accordingly, the Court grants Defendants' motion to dismiss and denies Plaintiffs' motion for preliminary injunction as moot.

II. BACKGROUND

A. The 340B Program

In 1992, Congress established what is now commonly referred to as the "340B Program." Pub. L. 102-585. This program was intended to enable certain hospitals and clinics "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384(II), at 12 (1992). To do this, it allowed participating hospitals and other health care providers to purchase certain "covered outpatient drugs" at discounted prices from manufacturers. *See* 42 U.S.C. § 256b. Under this program, participating drug manufacturers agree to offer certain covered outpatient drugs to "covered

entities" at or below a "maximum" or "ceiling" price, which is calculated pursuant to a statutory formula. *See* 42 U.S.C. § 256b(a)(1)–(2).

B. Setting Medicare Reimbursement Rates for 340B Drugs

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. §§ 1395 *et seq.* Part A of Medicare provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* at § 1395c. Part B, provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* at §§ 1395j, 1395k.

One component of Medicare Part B is the Outpatient Prospective Payment System ("OPPS"), which pays hospitals directly to provide outpatient services to beneficiaries. *See id.* at § 1395*l*(t). Under this system, hospitals are paid prospectively for their services for each upcoming year. As part of the annual determination of OPPS rates, CMS must also determine how much Medicare will pay for "specified covered outpatient drugs" ("SCODs"). *See id.* at § 1395*l*(t)(14). Importantly, some of these SCODs include outpatient drugs that hospitals purchase pursuant to the 340B Program.

Under the statutory scheme applicable here, Congress has authorized two potential methods of setting SCOD rates. First, if available, the payment rates must be set using "the average acquisition cost for the drug for that year." *Id.* at § 1395*l*(t)(14)(iii)(I). If that data is not available, however, then the payment rates must be set equal to "the average price for the drug in the year established under [certain other statutory provisions] . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* at § 1395*l*(t)(14)(iii)(II). For 2018, the applicable provision was 42 U.S.C. § 1395w-3a, which specified that the payment rate should be the "average sales price" for the drug plus six percent ("ASP + 6%"). *See id.* at § 1395w-3a(b).

C. The 2018 OPPS Rule

On July 13, 2017, CMS issued a proposed rule for OPPS rates for the Calendar Year 2018. *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 33,558 (Jul. 20, 2017). In addition to updating the OPPS rates for 2018, CMS also proposed changing the way Medicare would pay hospitals for SCODs acquired through the 340B Program. *See id.* at 33,634. In its proposed rule, CMS noted that several studies in recent years had shown that the difference between the price that hospitals paid to acquire 340B drugs and the amount that Medicare reimbursed hospitals for those drugs was significant. *See id.* at 33,632–33. For example, in 2015, the Medicare Payment Advisory Commission ("MedPAC") estimated that, on average, "hospitals in the 340B program 'receive[d] a minimum discount of 22.5 percent of the [average sales price] for drugs paid under the [OPPS]," yet hospitals were being reimbursed at a rate of ASP + 6%. *Id.* at 33,632 (second alteration in original). The MedPAC report also observed drug spending increases correlated with hospitals' participation in the 340B Program. *Id.* Moreover, the number of hospitals participating in the 340B Program was only going higher. *Id.* at 33,633.

"Given the growth in the number of providers participating in the 340B program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, [CMS] believe[d] it [was] timely to reexamine the appropriateness of continuing to pay the current OPPS methodology of ASP + 6 percent to hospitals that have acquired those drugs under the 340B program at significantly discounted rates." *Id.* CMS also expressed concern "about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of

the Medicare payment rate for these drugs." *Id.* Specifically, CMS was "concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs." *Id.*

Accordingly, CMS proposed lowering the Medicare payment rate for 340B Program drugs. CMS's goal was "to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals to stretch scarce resources while continuing to provide access to care." *Id.* CMS, however, did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug[s]." *Id.* at 33,634. For that reason, CMS believed it was appropriate to essentially estimate hospitals' acquisition costs based on hospitals' average discount under 340B. *See id.* Specifically, CMS proposed applying the average discount that MedPAC had estimated—22.5 percent of the average sales price. *See id.* CMS believed that MedPAC's estimate was appropriate and, in fact, conservative because the "actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent." *Id.*

CMS also stated its purported statutory basis for altering payment rates for 340B drugs. Specifically, CMS believed that this proposed change was within its authority "under section 1833(t)(14)(A)(iii)(II) [of] the Act [(codified at 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II))], which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug . . . as calculated and adjusted by the Secretary as necessary. *Id.* CMS conceded that it did not "have hospital acquisition cost data for 340B drugs" and, therefore, it was proposing to continue paying for the drugs under its authority at § 1395*l*(t)(14)(A)(iii)(II). *Id.* CMS proposed "exercise[ing] the Secretary's authority to adjust

applicable payment rate as necessary and, for separately payable drugs and biologicals . . . acquired under the 340B program, . . . adjust[ing] the rate to ASP minus 22.5 percent which [CMS] believe[d] better represents the average acquisition cost for these drugs and biologicals." *Id.*

The proposed rule, of course, solicited comment from the public and Plaintiffs in this case responded. Plaintiffs argued, among other things, that CMS, for various reasons, did not in fact, have the legal authority to change the 340B payment rates in the manner that CMS proposed and that adopting the nearly 30% reduction would severely impact covered entities' ability to provide critical healthcare programs to their communities, including underserved patients. *See* AHA Comments at 1–9, ECF No. 2-6; AAMC Comments at 3–6, ECF No. 2-7; AEH Comments at 3–13, ECF No. 2-8; EHMS Comments at 2–3, ECF No. 2-9; Henry Ford Comments at 1–3, ECF No. 2-10.

Nevertheless, on November 13, 2017, CMS adopted the payment reduction for 340B drugs that it had originally proposed. *See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 52,356, at 52,362 (Nov. 13, 2017). CMS did, however, respond to Plaintiffs' arguments about its authority to change Medicare reimbursement rates for 340B drugs. *See id.* at 52,499. CMS argued that the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gave the Secretary broad discretion to adjust payments for drugs, which it believed included an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount. *Id.* CMS also disagreed with commenters that the authority to "calculate and adjust" drug rates as necessary is limited to "minor changes" and it saw "no evidence in the statute to

support that position." *Id.* at 52,500. Accordingly, CMS saw fit to use its purported authority "to apply a downward adjustment that is necessary to better reflect acquisition costs of [340B] drugs." *Id.* Under this final rule, the change to 340B reimbursement rates is scheduled to go into effect on January 1, 2018. *Id.* at 52,356.

D. The Present Action

On November 13, 2017, Plaintiffs brought suit in this Court challenging the 340B provisions of the 2018 OPPS Rule under the Administrative Procedure Act ("APA"). *See* Compl., ECF No. 1. Plaintiffs allege, as they did in their comments, that the Secretary's nearly 30% reduction in the Medicare reimbursement rate for 340B drugs was "in excess of [his] authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)" and that it, therefore, violated the APA. Compl. ¶¶ 47–49. That same day, Plaintiffs also moved for a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure. *See* Pls.' Mot. Prelim. Inj. Plaintiffs specifically requested that this Court enjoin Defendants from implementing the new 340B provisions until this case has been fully adjudicated. *See* Pls.' Mot. Prelim. Inj. Defendants opposed Plaintiffs' motion and filed their own motion to dismiss pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.[1] *See* Defs.' Mot. Dismiss. On December 21, 2017, the Court heard oral argument from the parties on both motions.

[1] On December 8, 2017, thirty-two not-for-profit state and regional hospital associations filed a consent motion for leave to submit a brief as *amici curiae* in support of Plaintiffs' motion for preliminary injunction and in opposition to Defendants' motion to dismiss. ECF No. 19. Because the Court does not reach the merits of Plaintiffs' claim, the Court finds it unnecessary to consider the amicus brief. Accordingly, the Court will deny the motion for leave.

III. ANALYSIS

The Court's analysis in this matter necessarily begins and ends with an inquiry into its own subject matter jurisdiction. On a motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, it is the plaintiff's burden to establish that the court has subject matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). When considering whether it has jurisdiction, a court must accept "the allegations of the complaint as true." *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1129 (D.C. Cir. 2015) (citing *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992)). However, a court may also "consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Id.* (quoting *Herbert*, 974 F.2d at 197).

In this case, there is only one potential source of subject matter jurisdiction—42 U.S.C. § 405(g). "The Medicare Act places strict limits on the jurisdiction of federal courts to decide 'any claims arising under' the Act." *Am. Orthotic & Prosthetic Ass'n, Inc. v. Sebelius*, 62 F. Supp. 3d 114, 122 (D.D.C. 2014) (citing 42 U.S.C. § 405(h)). Indeed, any such claim must be brought pursuant to 42 U.S.C. § 405(g) of the Social Security Act (which is made applicable to the Medicare Act by virtue of 42 U.S.C. § 1395ii) even if the claim has been framed as a challenge under other laws or the Constitution. *See* 42 U.S.C. § 405(h); *Heckler v. Ringer*, 466 U.S. 602, 615–16 (1984) ("§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act") (alterations in original); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 2 (D.C. Cir. 2009) ("Parties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or

regulatory challenge.") (per curiam). A claim arises under the Medicare Act when its provisions provide "both the standing and the substantive basis" for the complaint. *Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975). Because Plaintiffs' sole claim is substantively based on the Medicare Act, judicial review may occur only if § 405(g)'s jurisdictional requirements are satisfied. *See Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 122 ("As all of [plaintiff]'s claims are substantively based in the Medicare Act, satisfaction of the Act's conditions regarding judicial review is required.")

Section 405(g) permits judicial review only "after [a] final decision of the [Secretary] made after a hearing to which he was a party." 42 U.S.C. § 405(g); *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976). Thus, § 405(g) speaks in terms of both "ripeness" and "exhaustion." And while these are familiar concepts in the administrative law context, the Supreme Court has been clear that the requirements under § 405(g) represent an even more exacting standard. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. at 12 ("the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'. . . ."). Indeed, while ordinary administrative law doctrines might permit judicial review under various exceptions, the Medicare Act "demands the 'channeling' of virtually all legal attacks through the agency." *Id.*

The Supreme Court has defined two elements that a plaintiff must establish in order to satisfy § 405(g). First, there is a non-waivable, jurisdictional "requirement that a claim for benefits shall have been presented to the Secretary." *Eldridge*, 424 U.S. at 328. "Absent such a claim there can be no 'decision' of any type," which "is clearly required by the statute." *Id.* Thus, the D.C. Circuit has previously described the presentment requirement as an "absolute prerequisite" to review and has found jurisdiction to be lacking where a plaintiff "proceeded

directly to district court, seeking a preliminary injunction barring HHS . . . from implementing [a] new rate reduction." *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1129–30 (D.C. Cir. 1992). The second element is a waivable "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Eldridge*, 424 U.S. at 328. Unlike the first element, however, a plaintiff may be excused from this obligation when, for example, exhaustion would be futile. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992); *Nat'l Ass'n. for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015) ("Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with the other factors . . . ."). Together, § 405(g)'s two elements serve the practical purpose of "preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Salfi*, 422 U.S. at 765; *see also Ill. Council on Long Term Care, Inc.*, 529 U.S. at 13 (§ 405(g)'s requirements "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts . . . ."). In this case, Plaintiffs argue that they have satisfied the presentment requirement and that they should be excused from the exhaustion requirement. *See* Pls.' Reply at 14–17, ECF No. 20.

The Plaintiffs' problem, however, is that they have not yet presented any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision. Indeed, the Rule that sets the reimbursement rates at issue and which might form the basis of reimbursement claims that they might submit someday in the future has not yet gone into effect. The Supreme Court addressed similar circumstances in *Heckler v. Ringer*, 466 U.S. 602 (1984).

In *Ringer*, the plaintiff had not presented an actual claim, but was instead "seeking to establish a right to future payments" on a potential future claim. *Id.* at 621. The Court held that allowing an anticipatory challenge to the Secretary's policy choice in the absence of a specific claim "would be inviting [claimants] to bypass the exhaustion requirements of the Medicare Act by simply bringing declaratory judgment actions in federal court." *Id.* Thus, "[b]ecause [the plaintiff] ha[d] not given the Secretary an opportunity to rule on *a concrete claim for reimbursement*, he ha[d] not satisfied the nonwaivable exhaustion requirement of § 405(g)." *Heckler v. Ringer*, 466 U.S. 602, 622 (1984) (emphasis added); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 2 (D.C. Cir. 2009) ("anticipatory challenges to the lawfulness of a provision that might later bar recovery of benefits must proceed 'through the special review channel that the Medicare statutes create.'" (quoting *Ill. Council*, 529 U.S. at 5)).

Plaintiffs argue, however, that they have met the presentment requirement because they "submitt[ed] detailed comments during the notice-and-comment process for the 340B Provisions of the OPPS Rule." Pls.' Reply at 14. But comments submitted in a rulemaking are not individualized, "concrete claim[s] for reimbursement," as courts routinely require to satisfy presentment. *Ringer*, 466 U.S. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary."). Not surprisingly then, the few Courts that have specifically considered arguments like those espoused by Plaintiffs have generally found that the submission of letters and comments that are divorced from discrete claims for reimbursement are insufficient for purposes of § 405(g). For example, in *National Association for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103 (D.D.C. 2015), another court in this District held that the presentment requirement was not satisfied when the

plaintiffs "submit[ed] comments to the agency and [] me[t] with agency officials to voice disagreement with [a particular] rule" because "an association may not challenge the constitutionality of Medicare regulations in the abstract on the basis that its members are likely to confront those regulations in the future." *Id.* at 109 n.1 (citing *Ill. Council*, 529 U.S. at 5); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x at 3 (holding that plaintiff's "letter to the PRRB requesting a jurisdictional ruling" did not satisfy the presentment requirement because "[t]he Medicare Act [] requires that parties present all such challenges to the agency in the context of a fiscal year reimbursement claim"); *Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 ("Because [plaintiff's letters] were not tied to any concrete claims, [plaintiffs]'s self-described 'detailed critiques of the [agency action] . . . [were] insufficient to establish presentment.").

Plaintiffs do not cite any authority in this Circuit or elsewhere in which a court has found the submission of comments in response to an agency's request for notice and comment on a proposed regulation satisfies 405(g)'s presentment requirement. *See* Hr'g Tr. at 21:22–22:4 (Dec. 21, 2017) (admitting that Plaintiffs have not seen any "circuit case that specifically finds that commenting in a notice-and-comment period satisfies the presentment requirement"). Nevertheless, Plaintiffs attempt to bolster their argument with two cases that they claim support their position. First, Plaintiffs point to *Mathews v. Eldridge*, 424 U.S. 319 (1976), where the Supreme Court held that the plaintiff's failure to "raise with the Secretary his constitutional claim" was "not controlling." *Id.* at 329. But in that case, even though the plaintiff had not presented his precise constitutional argument to the Secretary, there had been a "'final decision' by the Secretary with respect to the [plaintiff's] claim of entitlement to benefits." *Id.* Indeed, the Court found that the named plaintiff, "[t]hrough his answers to the state agency questionnaire,

and his letter in response to the tentative determination that his disability had ceased, had specifically presented the claim that his benefits should not be terminated because he was still disabled." *Id.* Moreover, "[t]his claim was denied by the state agency and its decision was accepted by the [Social Security Administration]." *Id.* Thus, despite not presenting a particular constitutional argument to the Secretary, the plaintiff in *Eldridge*—unlike the Plaintiffs here—*had* submitted a claim for definite benefits, which the Secretary had denied. Thus, *Eldridge* does not lend support to Plaintiffs' position that comments made during the rulemaking process alone may satisfy § 405(g)'s presentment requirement.

Plaintiffs also place heavy reliance on *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009), but it too offers limited support to Plaintiffs' position. In that case, two organizations and one recipient of Medicare benefits sought to challenge the Secretary's decision to recover refunds that HHS had erroneously issued to Medicare beneficiaries. After filing their complaint, plaintiffs sought, and were granted, a preliminary injunction. *See Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 854 (D.C. Cir. 2007). The Secretary challenged that injunction in several respects on appeal, but he did not contest subject matter jurisdiction until the D.C. Circuit itself raised the issue *sua sponte* and requested supplemental briefing. *See id.* at 856. Ultimately, the Circuit held that the district court did not have jurisdiction to consider plaintiffs' claims or to issue the preliminary injunction because the plaintiffs had not adequately presented their claims to the Secretary for a final determination. *See id.* It then remanded the case to the district court. *Id.* at 861.

Following the D.C. Circuit's opinion, the plaintiffs sent letters to the agency setting forth their various legal arguments and requesting that it accord the affected Medicare beneficiaries with certain relief. *Action All. of Senior Citizens*, 607 F. Supp. 2d at 37–38; *see also* Joint

Appendix at A-130, *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010) (No. 09-5191). The agency responded by denying the plaintiffs' requests and explaining its rationale. *See Action All. of Senior Citizens*, 607 F. Supp. 2d at 37–40. On remand, the Secretary argued that the two association plaintiffs did not satisfy the presentment requirement because the letters were from the associations rather than their members. *See id.* at 38–39. The Secretary did not argue, however, that presentment must be accomplished, if at all, through a formal submission of a concrete claim. *See* Defs.' Mot. Dismiss at 21–23, *Action All. of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009) (No. 06-1607), ECF No. 49. And the district court did not address this issue on its own. Rather, the district court held that associations may present claims on behalf of their members and concluded, without explanation, that the organizations' letters satisfied § 405(g)'s presentment requirement. *See Action All. of Senior Citizens*, 607 F. Supp. 2d at 40. The district court then proceeded to consider the merits of plaintiffs' claims, but ultimately sided with the Secretary and granted his motion to dismiss. *See id.* at 42.

Plaintiffs then appealed the district court's decision. The Secretary did not cross-appeal on the jurisdictional issue and, in fact, conceded that the Circuit "ha[d] jurisdiction to address the issues presented in th[e] appeal." *See* Appellee's Brief at 11 n.2, *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010) (No. 09-5191). And while the Secretary did present an abbreviated version of the argument made to the trial court, the Secretary still did not argue that the generalized nature of the letters in anyway made them deficient. *See id.* After reviewing the case, the D.C. Circuit affirmed the judgment of the district court and observed in a footnote that, while presentment had at one time precluded judicial review of their claims, "[p]laintiffs ha[d] since cured the jurisdictional defect." *See Action All. of Senior Citizens v. Sebelius*, 607 F.3d

860, 862 n.2 (D.C. Cir. 2010). But like the district court, the Court of Appeals did not offer any explanation as to why generalized letters satisfied the presentment requirement. *See id.* at 862.

Given the lack of any substantive discussion on the issue of whether generalized letters may suffice for purposes of presentment by either the defendant Secretary, the district court, or the Court of Appeals, at least one court has questioned the precedential value of *Action Alliance* in that regard. *See Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 ("The lack of explanation in both cases is likely because the precise question presented here—whether generalized grievance letters rather than discrete claims are sufficient to satisfy presentment—was not raised by the parties in Action Alliance, and the Court therefore questions the precedential value of those opinions."); *see also Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 144 (2011) ("When a potential jurisdictional defect is neither noted nor discussed in a federal decision, the decision does not stand for the proposition that no defect existed."); *Ticor Title Ins. Co. v. FTC*, 814 F.2d 731, 749 (D.C. Cir. 1987) ("[I]t is well settled that cases in which jurisdiction is assumed *sub silentio* are not binding authority for the proposition that jurisdiction exists." (citing *Pennhurst State Sch. & Hospital v. Halderman*, 465 U.S. 89, 119 (1984))). This Court too believes that *Action Alliance*'s value on this underdeveloped issue is doubtful. In any event, there is a meaningful difference between the letters at issue in *Action Alliance* and the comments that Plaintiffs submitted in this case. Indeed, in *Action Alliance,* the associations' letters concerned specific claims that *had already accrued to individuals* and thus "were closer to the 'concrete claim for reimbursement' that the Supreme Court has held is required for proper presentment." *Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 (quoting *Ringer*, 466 U.S. at 622). By contrast, even though Plaintiffs' comments in this case criticized the proposed 2018 OPPS Rule, they were not advancing any specific, concrete claims for reimbursement.

Thus, they cannot satisfy the presentment requirement of § 405(g). *See id.* ("Because [plaintiff's letters] were not tied to any concrete claims, [plaintiff]'s self-described 'detailed critiques of the [agency action]' . . . [were] insufficient to establish presentment."); *Ringer*, 466 U.S. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary.").

In conclusion, Plaintiffs' failure to present any concrete claim for reimbursement to the Secretary for a final decision is a fundamental jurisdictional impediment to judicial review under 42 U.S.C. § 405(g). As a result, the Court must necessarily dismiss Plaintiffs' action for want of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss (ECF No. 17) is **GRANTED**; Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**; and the Motion for Leave to File Brief as *Amici Curiae* (ECF No. 19) is **DENIED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: December 29, 2017

RUDOLPH CONTRERAS
United States District Judge

Legal Challenges to "Travel Ban" Executive Orders

Issue Outline:

- On January 27, 2017, President Trump issued the first "travel ban" executive order, *Protecting the Nation from Foreign Terrorist Entry into the United States.*
- On March 6, a second version was issued, clarifying and narrowing its terms.
- On September 24, a third version was issued, *Enhancing Vetting Capabilities and Processes for Detecting Attempted Entry Into the United States by Terrorists or Other Public-Safety Threats,* further clarifying certain terms and applying restrictions more tailored to each of eight countries, based on a review by Department of Homeland Security.
- Multiple lawsuits challenging the lawfulness and constitutionality of each of the versions have been commenced. Currently, the main cases are pending in the Fourth and Ninth Circuit Courts of Appeals.
- The Supreme Court has ruled that the September travel ban may take effect while the appeals are pending.
- The challenges have focused on alleged violations of the Immigration and Nationality Act and the Establishment Clause of the US Constitution, among other provisions.
- The primary concern for the hospital community has been the travel ban's impact on the recruitment of international medical graduates (IMGs) as workforce members and trainees. IMGs disproportionately serve in safety net hospitals and medically underserved areas and are thought to be key to addressing physician shortages in a number of specialties over coming years.

Attachment:

- *Per Curiam* Opinion by Ninth Circuit, in *Hawaii v. Trump*, affirming in part and vacating in part Hawaii district court's preliminary injunction, dated December 22, 2017

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

DEC 22 2017

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

STATE OF HAWAII; ISMAIL ELSHIKH; JOHN DOES, 1 & 2; MUSLIM ASSOCIATION OF HAWAII, INC.,

Plaintiffs-Appellees,

v.

DONALD J. TRUMP, in his official capacity as President of the United States; U.S. DEPARTMENT OF HOMELAND SECURITY; KIRSTJEN M. NIELSEN, in her official capacity as Secretary of Homeland Security; U.S. DEPARTMENT OF STATE; REX W. TILLERSON, in his official capacity as Secretary of State; UNITED STATES OF AMERICA,

Defendants-Appellants.

No. 17-17168

D.C. No.
1:17-cv-00050-DKW-KSC
District of Hawaii,
Honolulu

ORDER

Before: HAWKINS, GOULD, and PAEZ, Circuit Judges.

The opinion disposition filed on December 22, 2017, is withdrawn and a new opinion disposition is filed concurrently with this order.

FOR PUBLICATION

FILED

DEC 22 2017

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

STATE OF HAWAII; ISMAIL ELSHIKH; JOHN DOES, 1 & 2; MUSLIM ASSOCIATION OF HAWAII, INC., Plaintiffs-Appellees, v. DONALD J. TRUMP, in his official capacity as President of the United States; U.S. DEPARTMENT OF HOMELAND SECURITY; KIRSTJEN M. NIELSEN, in her official capacity as Secretary of Homeland Security; U.S. DEPARTMENT OF STATE; REX W. TILLERSON, in his official capacity as Secretary of State; UNITED STATES OF AMERICA, Defendants-Appellants.	No. 17-17168 D.C. No. 1:17-cv-00050-DKW-KSC OPINION

Appeal from the United States District Court
for the District of Hawaii
Derrick Kahala Watson, District Judge, Presiding

Argued and Submitted December 6, 2017
Seattle, Washington

Before: Michael Daly Hawkins, Ronald M. Gould, and Richard A. Paez, Circuit Judges.

PER CURIAM:

For the third time, we are called upon to assess the legality of the President's efforts to bar over 150 million nationals of six designated countries[1] from entering the United States or being issued immigrant visas that they would ordinarily be qualified to receive. To do so, we must consider the statutory and constitutional limits of the President's power to curtail entry of foreign nationals in this appeal of the district court's order preliminarily enjoining portions of § 2 of Proclamation 9645 entitled "Enhancing Vetting Capabilities and Processes for Detecting Attempted Entry Into the United States by Terrorists or Other Public-Safety Threats" (the "Proclamation").

The Proclamation, like its predecessor executive orders, relies on the premise that the Immigration and Nationality Act ("INA"), 8 U.S.C. § 1101 et seq., vests the President with broad powers to regulate the entry of aliens. Those powers, however, are not without limit. We conclude that the President's issuance of the Proclamation once again exceeds the scope of his delegated authority. The Government's interpretation of 8 U.S.C. § 1182(f) not only upends the carefully crafted immigration scheme Congress has enacted through the INA, but it deviates from the text of the statute, legislative history, and prior executive practice as well.

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[1] Although Proclamation 9645 imposes varying restrictions on nationals of eight countries—Chad, Iran, Libya, Somalia, Syria, Yemen, North Korea, and Venezuela—Plaintiffs challenge only the restrictions imposed on the nationals of six Muslim-majority countries.

Further, the President did not satisfy the critical prerequisite Congress attached to his suspension authority: before blocking entry, he must first make a legally sufficient finding that the entry of the specified individuals would be "detrimental to the interests of the United States." 8 U.S.C. § 1182(f). The Proclamation once again conflicts with the INA's prohibition on nationality-based discrimination in the issuance of immigrant visas. Lastly, the President is without a separate source of constitutional authority to issue the Proclamation.

On these statutory bases, we affirm the district court's order enjoining enforcement of the Proclamation's §§ 2(a), (b), (c), (e), (g), and (h). We limit the scope of the preliminary injunction, however, to foreign nationals who have a bona fide relationship with a person or entity in the United States.

I. Background[2]

A. Prior Executive Orders and Initial Litigation

On January 27, 2017, one week after his inauguration, President Donald J. Trump signed an Executive Order entitled "Protecting the Nation From Foreign Terrorist Entry into the United States." Exec. Order 13,769, 82 Fed. Reg. 8977 (Jan. 27, 2017) ("EO-1"). EO-1's stated purpose was to "protect the American people from terrorist attacks by foreign nationals admitted to the United States."

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[2] Portions of the background section have been drawn from the district court's order below. *See Hawai'i v. Trump*, No. CV 17-00050 DKW-KSC, 2017 WL 4639560, at *1–4 (D. Haw. Oct. 17, 2017) ("*Hawai'i TRO*").

Id. EO-1 took effect immediately and was challenged in several venues shortly after it was issued. On February 3, 2017, a federal district court in the State of Washington enjoined the enforcement of EO-1. *See Washington v. Trump*, No. C17-0141JLR, 2017 WL 462040 (W.D. Wash. Feb. 3, 2017). The Government filed an emergency motion seeking a stay of the injunction, which we denied. *See Washington v. Trump*, 847 F.3d 1151, 1161–64 (9th Cir. 2017) (per curiam), *reh'g en banc denied*, 853 F.3d 933 (9th Cir. 2017). The Government later voluntarily dismissed its appeal of the EO-1 injunction.

On March 6, 2017, the President issued Executive Order 13,780, which was given the same title as EO-1 and was set to take effect on March 16, 2017. 82 Fed. Reg. 13,209 (Mar. 6, 2017) ("EO-2"). EO-2 directed the Secretary of Homeland Security to conduct a global review to determine whether foreign governments were providing adequate information about their nationals seeking entry into the United States. *See* EO-2 § 2(a). EO-2 also directed the Secretary of Homeland Security to report those findings to the President; following the Secretary's report, nations identified as providing inadequate information were to be given an opportunity to alter their practices before the Secretary would recommend entry restrictions for nationals of noncompliant countries. *Id.* §§ 2(b), (d)–(f).

During this global review, EO-2 imposed a 90-day suspension on the entry of certain foreign nationals from six Muslim-majority countries: Iran, Libya,

Somalia, Sudan, Syria, and Yemen. *Id.* § 2(c). That 90-day suspension was challenged in multiple courts and was preliminarily enjoined by federal district courts in Hawai'i and Maryland. *See Hawai'i v. Trump*, 245 F. Supp. 3d 1227 (D. Haw. 2017); *Int'l Refugee Assistance Project* ("*IRAP*") *v. Trump*, 241 F. Supp. 3d 539 (D. Md. 2017). Those injunctions were affirmed by the Ninth and Fourth Circuits, respectively. *See Hawai'i v. Trump* (*Hawai'i I*), 859 F.3d 741 (9th Cir. 2017) (per curiam); *IRAP v. Trump*, 857 F.3d 554 (4th Cir. 2017) (en banc), *as amended* (May 31, 2017). The Supreme Court granted a writ of *certiorari* in both cases and left the injunctions in place pending its review, except as to foreign nationals who lacked a "credible claim of a bona fide relationship with a person or entity in the United States." *Trump v. IRAP*, 137 S. Ct. 2080, 2088 (2017).

On September 24, 2017, the President issued the Proclamation, which indefinitely suspends immigration by nationals of seven countries and imposes restrictions on the issuance of certain nonimmigrant visas for nationals of eight countries. 82 Fed. Reg. 45,161, 45,164–67 (Sept. 24, 2017). The entry restrictions were immediately effective for foreign nationals who 1) were subject to EO-2's restrictions, and 2) lack a credible claim of a bona fide relationship with a person or entity in the United States. *Id.* at 45,171. For all other affected persons, the Proclamation was slated to take effect on October 18, 2017. *Id.* On October 10, 2017, the Supreme Court vacated the Fourth Circuit's opinion in *IRAP v. Trump* as

moot. *See Trump v. IRAP*, No. 16-1436, — S. Ct. —, 2017 WL 4518553 (U.S. Oct. 10, 2017). On October 24, 2017, the Supreme Court vacated our opinion in *Hawai'i I* on the same grounds. *See Trump v. Hawai'i*, No. 16-1540, — S. Ct. —, 2017 WL 4782860 (U.S. Oct. 24, 2017). In vacating our prior decision as moot, the Supreme Court explicitly noted that it expressed no view on the merits of the case. *See id.*

B. Plaintiffs' Third Amended Complaint

On October 10, 2017, Plaintiffs sought to amend their complaint to include allegations related to the Proclamation. The third amended complaint includes statutory claims for violations of the INA, the Religious Freedom Restoration Act, and the Administrative Procedure Act, as well as constitutional claims for violations of the Establishment and Free Exercise Clauses of the First Amendment and the equal protection guarantees of the Fifth Amendment's Due Process Clause. Plaintiffs also moved for a temporary restraining order; after expedited briefing, the district court granted the motion on October 17, 2017. *Hawai'i TRO*, 2017 WL 4639560, at *1. Relying on our now-vacated opinion in *Hawai'i I*, the district court found that the Proclamation suffered from the same deficiencies as EO-2. *Id.* at *1, *9–13. At the parties' request, the district court converted the temporary restraining order into a preliminary injunction on October 20, 2017, rendering it an

appealable order. *Hawai'i v. Trump*, No. CV 17-00050 DKW-KSC (D. Haw. Oct. 20, 2017), ECF No. 390 (order entering preliminary injunction).

The Government timely appealed. During the pendency of this appeal, we partially stayed the district court's preliminary injunction "except as to foreign nationals who have a credible claim of a bona fide relationship with a person or entity in the United States." *Hawai'i v. Trump*, No. 17-17168, 2017 WL 5343014 (9th Cir. Nov. 13, 2017). On December 4, 2017, the Supreme Court granted the Government's request for a complete stay pending review of the district court's preliminary injunction. *Trump v. Hawai'i*, No. 17A550, — S. Ct. — (Dec. 4, 2017).

C. The Proclamation

The Proclamation derives its purpose from the President's belief that he "must act to protect the security and interests of the United States." 82 Fed. Reg. at 45,161. In furtherance of this goal, the Proclamation imposes indefinite and significant restrictions and limitations on entry of nationals from eight countries whose information-sharing and identity-management protocols have been deemed "inadequate." *Id.* at 45,162–67. The Proclamation notes that screening and vetting protocols and procedures play a critical role in preventing terrorist attacks and other public safety threats by enhancing the Government's ability to "detect foreign nationals who may commit, aid, or support acts of terrorism." *Id.* at

45,162. Thus, the Proclamation concludes, "absent the measures set forth in th[e] proclamation, the immigrant and nonimmigrant entry into the United States of persons described in section 2 of th[e] proclamation [will] be detrimental to the interests of the United States." *Id.* at 45,161–62.

The President selected eight countries for inclusion in the Proclamation based on a "worldwide review" conducted under the orders of EO-2. *Id.* at 45,161, 45,163–64. As part of that review, the Secretary of the Department of Homeland Security established global requirements for information sharing "in support of immigration screening and vetting" that included a comprehensive set of criteria on the information-sharing practices, policies, and capabilities of foreign governments. *Id.* at 45,161–63. The Secretary of State then "engaged with the countries reviewed in an effort to address deficiencies and achieve improvements." *Id.* at 45,161. The Secretary of Homeland Security, after consultation with the Secretary of State and the Attorney General, ultimately identified 16 countries as "inadequate" based on "an analysis of their identity-management protocols, information-sharing practices, and risk factors." *Id.* at 45,163. An additional 31 countries were deemed "at risk" of becoming "inadequate." *Id.*

Countries were classified as "inadequate" based on whether they met the "baseline" developed by the Secretary of Homeland Security, in consultation with the Secretary of State and the Director of National Intelligence. *Id.* at 45,162. The

baseline incorporated three categories of criteria: 1) identity-management information; 2) national security and public-safety information; and 3) national security and public-safety risk assessment. *Id.* Identity-management information ensures that foreign nationals seeking to enter the United States are who they claim to be. *Id.* This category "focuses on the integrity of documents required for travel to the United States," including whether the country issues passports with embedded data to confirm identity, reports lost and stolen passports, and provides additional identity-related information when requested. *Id.* National security and public-safety information includes whether the country "makes available, directly or indirectly, known or suspected terrorist and criminal-history information upon request," whether it provides identity document exemplars, and whether the country "impedes the United States Government's receipt of information about passengers and crew traveling to the United States." *Id.* Finally, national security and public-safety risk assessment focuses on whether the country is "a known or potential terrorist safe haven," whether the country participates in the Visa Waiver Program, and whether the country "regularly fails to receive its nationals" following their removal from the United States. *Id.* at 45,162–63.

After a "50-day engagement period to encourage all foreign governments . . . to improve their performance," the Secretary of Homeland Security ultimately determined that Chad, Iran, Libya, North Korea, Syria,

Venezuela, and Yemen continued to be "inadequate" based on their identity-management protocols, information-sharing practices, and risk factors.[3] *Id.* at 45,163. The Secretary of Homeland Security also determined that Iraq did not meet the baseline requirements, but concluded that entry restrictions and limitations were not warranted because of the "close cooperative relationship between the United States and the democratically elected government of Iraq, the strong United States diplomatic presence in Iraq, the significant presence of United States forces in Iraq, and Iraq's commitment to combating the Islamic State of Iraq and Syria (ISIS)." *Id.*

On September 15, 2017, the Secretary of Homeland Security submitted a report to the President recommending entry restrictions for nationals from seven countries "determined to be 'inadequate' in providing such [requested] information and in light of the other factors discussed in the report." *Id.* After consultation with "appropriate Assistants to the President and members of the Cabinet, including the Secretaries of State, Defense, and Homeland Security, and the Attorney General" and "accounting for the foreign policy, national security, and

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[3] The Proclamation does not include the other thirty-nine countries deemed either "inadequate" or "at risk" of becoming "inadequate." *See* 82 Fed. Reg. at 45,163. As the district court noted, "the explanation for how the Administration settled on the list of eight countries is obscured." *Hawai'i TRO*, 2017 WL 4639560, at *11 n.16. This is due, in large part, to the fact that no court has been able to consider—or even view—the DHS report in question.

counterterrorism objectives of the United States," the President decided to "restrict and limit the entry of nationals of 7 countries found to be 'inadequate'": Chad, Iran, Libya, North Korea, Syria, Venezuela, and Yemen. *Id.* at 45,164. And although Somalia "generally satisfies" the information-sharing requirements of the baseline, the President also imposed entry restrictions and limitations on Somalia nationals because of "its government's inability to effectively and consistently cooperate, combined with the terrorist threat that emanates from its territory." *Id.* The President restricted entry of all immigrants from seven of the eight countries, and adopted "a more tailored approach" to the entry of nonimmigrants. *Id.* at 45,164–65.

Section 2's challenged country restrictions and proffered rationales are as follows:

Chadian nationals may not enter as immigrants or nonimmigrants on business, tourist, or business/tourist visas because, although Chad is "an important and valuable counterterrorism partner of the United States, and . . . . has shown a clear willingness to improve," it "does not adequately share public-safety and terrorism-related information," and several terrorist groups are active within Chad or the surrounding region. *Id.* at 45,165.

Iranian nationals may not enter as immigrants or nonimmigrants except under valid student and exchange visitor visas, and such visas are subject to

"enhanced screening and vetting." *Id.* The Proclamation notes that "Iran regularly fails to cooperate with the United States Government in identifying security risks, fails to satisfy at least one key risk criterion, is the source of significant terrorist threats, and fails to receive its nationals" following final orders of removal from the United States. *Id.*

The entry of Libyan nationals as immigrants and as nonimmigrants on business, tourist, or business/tourist visas is suspended because, although Libya "is an important and valuable counterterrorism partner," it "faces significant challenges in sharing several types of information, including public-safety and terrorism-related information," "has significant deficiencies in its identity-management protocols," does not "satisfy at least one key risk criterion," has not been "fully cooperative" in receiving its nationals after their removal from the United States, and has a "substantial terrorist presence" within its territory. *Id.* at 45,165–66.

The entry of all Syrian nationals—on immigrant and non-immigrant visas alike—is suspended because "Syria regularly fails to cooperate with the United States Government in identifying security risks, is the source of significant terrorist threats, and has been designated by the Department of State as a state sponsor of terrorism." *Id.* at 45,166. Syria also has "significant inadequacies in identity-

management protocols, fails to share public-safety and terrorism information, and fails to satisfy at least one key risk criterion." *Id.*

Yemeni nationals may not enter the United States as immigrants or nonimmigrants on business, tourist, or business/tourist visas because despite being "an important and valuable counterterrorism partner," Yemen "faces significant identity-management challenges, which are amplified by the notable terrorist presence within its territory." *Id.* at 45,166–67.

Somali nationals may not enter the United States as immigrants, and all nonimmigrant visa adjudications and entry decisions for Somali nationals are subject to "additional scrutiny." *Id.* at 45,167. Although Somalia satisfies information-sharing requirements, it "has significant identity-management deficiencies" and a "persistent terrorist threat also emanates from Somalia's territory." *Id.*

These restrictions apply to foreign nationals of the affected countries outside the United States who do not hold valid visas as of the effective date and who do not qualify for a visa under § 6(d)[4] of the Proclamation. *Id.* Suspension of entry does not apply to lawful permanent residents of the United States; foreign nationals

[4] Section 6(d) of the Proclamation permits individuals whose visas were marked revoked or canceled as a result of EO-1 to obtain "a travel document confirming that the individual is permitted to travel to the United States and seek entry under the terms" of the revoked or canceled visa. 82 Fed. Reg. at 45,171.

who are admitted, paroled, or have a non-visa document permitting them to travel to the United States and seek entry valid or issued on or after the effective date of the Proclamation; any dual national traveling on a passport issued by a non-designated country; any foreign national on a diplomatic visa; any refugee already admitted to the United States; or any individual granted asylum, withholding of removal, advance parole, or Convention Against Torture protection. *Id.* at 45,167–68. Further, a consular officer, the Commissioner of U.S. Customs and Border Protection, or the Commissioner's designee "may, in their discretion, grant waivers on a case-by-case basis to permit the entry of foreign nationals for whom entry is otherwise suspended or limited if such foreign nationals demonstrate that waivers would be appropriate and consistent" with certain specified guidelines. *Id.* at 45,168.

II. Justiciability

We first address several of the same justiciability arguments that we found unpersuasive in *Washington v. Trump* and *Hawai'i I*. Once more, we reject the Government's contentions. The Proclamation cannot properly evade judicial review.

A. Ripeness

The Government argues that Plaintiffs' claims are speculative and not ripe for adjudication until a specific applicant is denied a visa.[5] We reject this argument. We conclude that the issues in this case are "fit for review," and that significant hardship to Plaintiffs would result from "withholding court consideration" at this point. *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808, 812 (2003).

"Ripeness is peculiarly a question of timing, designed to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements." *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1122 (9th Cir. 2009) (alteration and internal quotation marks omitted) (quoting *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000)). This case does not concern mere abstract disagreements. Instead, Plaintiffs challenge the Proclamation as implemented by the Department of State and the Department of Homeland Security. That is permissible. Under the traditional "pragmatic" approach to finality, an order may be immediately reviewable even if no "particular action [has been] brought against a particular [entity]." *U.S. Army*

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[5] The Government does not challenge Plaintiffs' Article III standing on appeal. Nonetheless, we "have an obligation to consider Article III standing independently, as we lack jurisdiction when there is no standing." *Day v. Apoliona*, 496 F.3d 1027, 1029 n.2 (9th Cir. 2007). For the reasons set forth in the district court's order, we conclude that Plaintiffs have Article III standing. *See Hawai'i TRO*, 2017 WL 4639560, at *4–7.

Corps of Eng'rs v. Hawkes Co., 136 S. Ct. 1807, 1815 (2016) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 150 (1967)).

Moreover, contrary to the Government's position, the Proclamation's waiver provisions are not a "sufficient safety valve" and do not mitigate the substantial hardships Plaintiffs have already suffered and will continue to suffer due to the Proclamation. *Washington*, 847 F.3d at 1168–69. Plaintiff Muslim Association of Hawaii, for example, has already lost members as a result of the Proclamation and its predecessors, and expects to lose more. The mere possibility of a discretionary waiver does not render Plaintiffs' injuries "contingent [on] future events that may not occur." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks omitted) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580–81 (1985)). "[W]ithholding court consideration" at this juncture would undoubtedly result in further hardship to Plaintiffs. *See Nat'l Park Hosp. Ass'n*, 538 U.S. at 808. We therefore conclude that Plaintiffs' claims are ripe for review.

B. Doctrine of Consular Nonreviewability

As in the litigation over EO-1 and EO-2, the Government contends that we are precluded from reviewing the Proclamation by the consular nonreviewability doctrine. Under that doctrine, "the consular official's decision to issue or withhold a visa is not subject either to administrative or judicial review." *Li Hing of Hong Kong, Inc. v. Levin*, 800 F.2d 970, 971 (9th Cir. 1986). In other words, "it is not

within the province of any court, unless expressly authorized by law, to review the determination of the political branch of the Government to exclude a *given* alien." *U.S. ex rel. Knauff v. Shaughnessy*, 338 U.S. 537, 543 (1950) (emphasis added). Although the political branches' power to exclude aliens is "largely immune from judicial control," it is not *entirely* immune; such decisions are still subject to "narrow judicial review." *Fiallo v. Bell*, 430 U.S. 787, 792 (1977) (citations omitted). Moreover, this case is not about individual visa denials, but instead concerns "the President's *promulgation* of sweeping immigration policy." *Washington*, 847 F.3d at 1162. Reviewing the latter "is a familiar judicial exercise," *Zivotofsky ex rel. Zivotofsky v. Clinton*, 566 U.S. 189, 196 (2012); courts do not hesitate to reach "challenges to the substance and implementation of immigration policy." *Washington*, 847 F.3d at 1163. Although "[t]he Executive has broad discretion over the admission and exclusion of aliens, [] that discretion is not boundless. It extends only as far as the statutory authority conferred by Congress and may not transgress constitutional limitations. It is the duty of the courts, in cases properly before them, to say where those statutory and constitutional boundaries lie." *Abourezk v. Reagan*, 785 F.2d 1043, 1061 (D.C. Cir. 1986), *aff'd by an equally divided court*, 484 U.S. 1 (1987).

The Government's arguments to the contrary are foreclosed by *Sale v. Haitian Ctrs. Council, Inc.*, 509 U.S. 155, 187–88 (1993). In *Sale*, the Supreme

Court reviewed on the merits whether the President had violated the INA and the United States' treaty obligations by invoking his authority under 8 U.S.C. § 1182(f) to "suspend[] the entry of undocumented aliens from the high seas." *Id.* at 160. By reaching the merits, *Sale* necessarily first decided that the Court had jurisdiction to review whether the President's orders under the color of § 1182(f) were *ultra vires*. *See id.* at 187–88. As in *Sale*, here we determine whether the Proclamation goes beyond the limits of the President's power to restrict alien entry.

Because *Sale* did not address the Court's jurisdiction explicitly, the Government speculates that the Supreme Court "could have decided it was unnecessary to" reach this issue, "given that the Court agreed with the government on the merits." We disagree. Instead, the argument "that a court may decide [questions on the merits] before resolving Article III jurisdiction" is "readily refuted." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 95 (1998). "Without jurisdiction the court cannot proceed at all in any cause." *Id.* at 94 (quoting *Ex parte McCardle*, 7 Wall. 506, 514 (1868)). "On every writ of error or appeal, the first and fundamental question is that of jurisdiction . . . ." *Id.* (quoting *Great S. Fire Proof Hotel Co. v. Jones*, 177 U.S. 449, 453 (1900)). While it is true that "drive-by jurisdictional rulings . . . have no precedential effect," *Sale* was not a case where jurisdiction "had been assumed by the parties" and so went unaddressed. *Id.* at 91. To the contrary, as the Government concedes, the parties

in *Sale* thoroughly briefed and debated this issue. *See* U.S. Br. 13–18 (No. 92-344); Resp. Br. 50–58 (No. 92-344); Reply Br. 1–4 (No. 92-344).

Judicial review of the legality of the Proclamation respects our constitutional structure and the limits on presidential power. The consular nonreviewability doctrine arose to honor Congress's choices in setting immigration policy—not the President's. *See Sing v. United States*, 158 U.S. 538, 547 (1895). This doctrine shields from judicial review only the enforcement "through executive officers" of Congress's "declared [immigration] policy," *id.*, not the President's rival attempt to set policy. The notion that the Proclamation is unreviewable "runs contrary to the fundamental structure of our constitutional democracy."[6] *Washington*, 847 F.3d at 1161. We have jurisdiction to review such an action, and we do so here.

C. Cause of Action and Statutory Standing

[6] The Government argues that the President, at any time and under any circumstances, could bar entry of all aliens from any country, and intensifies the consequences of its position by saying that no federal court—not a federal district court, nor our court of appeals, nor even the Supreme Court itself—would have Article III jurisdiction to review that matter because of the consular nonreviewability doctrine. United States Court of Appeals for the Ninth Circuit, *17-17168 State of Hawaii v. Donald Trump*, YouTube (Dec. 7, 2017) at 13:01–17:33, https://www.youtube.com/watch?v=9Q0p_B40Pa8. Particularly in the absence of an explicit jurisdiction-stripping provision, we doubt whether the Government's position could be adopted without running roughshod over the principles of separation of powers enshrined in our Constitution.

The Government also contends that Plaintiffs' statutory claims are unreviewable for lack of a cause of action and lack of statutory standing. We disagree.

1. APA Cause of Action

We begin first by examining whether Plaintiffs' claims are reviewable under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq. Although the President's actions fall outside the scope of direct review, *see Franklin v. Massachusetts*, 505 U.S. 788, 800–01 (1992), "[r]eview of the legality of Presidential action can ordinarily be obtained in a suit seeking to enjoin the officers who attempt to enforce the President's directive," *id.* at 828 (Scalia, J., concurring); *see also Chamber of Commerce v. Reich*, 74 F.3d 1322, 1324, 1328 (D.C. Cir. 1996) (holding that the court could review whether an executive order conflicted with a federal statute where plaintiffs had sought to enjoin executive branch officials implementing the order). Here, Plaintiffs bring suit not just against the President, but also against the entities charged with carrying out his instructions: the Department of State and the Department of Homeland Security. Further, because these agencies have "consummat[ed]" their implementation of the Proclamation, from which "legal consequences will flow," their actions are "final"

and therefore reviewable under the APA.[7] *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citation and internal quotation marks omitted).

Finally, the Government argues that the APA precludes review of actions committed to "agency discretion by law," 5 U.S.C. § 701(a)(2), and that the Proclamation is such an action. Plaintiffs counter that the Proclamation is not an unreviewable discretionary action, but rather is cabined by discernible constitutional and statutory limits. We are not persuaded by the Government's characterization of the Proclamation as an action committed to the Executive's discretion. This exception to the presumption of judicial review is "very narrow," applying only where "statutes are drawn in such broad terms that . . . there is no law to apply." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985) (quoting *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 410 (1971)). It does not apply where, as here, a court is tasked with reviewing whether an executive action has exceeded statutory authority. *See Assiniboine & Sioux Tribes v. Bd. of Oil & Gas Conservation*, 792 F.2d 782, 791–92 (9th Cir. 1986) (collecting cases).

2. Zone of Interests

The Government additionally argues that even if an APA cause of action exists, Plaintiffs cannot avail themselves of it because they do not fall within the

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[7] The Government contends that there is no "final" agency action here because Plaintiffs' claims are unripe. For the reasons discussed previously, we reject this argument.

INA's zone of interests. Once again, we are tasked with determining whether Plaintiffs' interests "fall within the zone of interests protected by the law invoked." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1388 (2014) (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)).

We conclude that Dr. Elshikh's challenge to the Proclamation falls within the INA's zone of interests. He asserts that the Proclamation prevents his brothers-in-law from reuniting with his family. *See Legal Assistance for Vietnamese Asylum Seekers v. Dep't of State*, 45 F.3d 469, 471–72 (D.C. Cir. 1995) ("The INA authorizes the immigration of family members of United States citizens and permanent resident aliens. In originally enacting the INA, Congress implemented the underlying intention of our immigration laws regarding the preservation of the family unit. Given the nature and purpose of the statute, the resident appellants fall well within the zone of interest Congress intended to protect." (internal citations and alterations omitted)), *vacated on other grounds*, 519 U.S. 1 (1996). John Does 1 and 2 fall within the same zone of interest, alleging that they will be separated from family members—a son-in-law and a mother, respectively.

The Government maintains that these interests are inadequate because a relative of an alien seeking admission has no right to participate in visa proceedings. Yet the Supreme Court has reviewed the merits of cases brought by U.S. residents with a specific interest in the entry of a foreigner, as have we. *See,*

e.g., *Kerry v. Din*, 135 S. Ct. 2128, 2131 (2015) (involving a challenge by U.S. citizen to denial of her husband's visa); *Kleindienst v. Mandel*, 408 U.S. 753, 756–60 (1972) (arising from a challenge by American professors to denial of visa to journalist invited to speak at academic events); *Cardenas v. United States*, 826 F.3d 1164, 1167 (9th Cir. 2016) (addressing a U.S. citizen's challenge to denial of husband's visa). In a case similar to the one before us, *Legal Assistance for Vietnamese Asylum Seekers v. Department of State*, the D.C. Circuit found that visa sponsors had standing to sue when they alleged that the State Department's refusal to process visa applications resulted in an injury to the sponsors. 45 F.3d at 471–73.

Likewise, Hawai'i's "efforts to enroll students and hire faculty members who are nationals from the six designated countries fall within the zone of interests of the INA." *Hawai'i I*, 859 F.3d at 766. The INA clearly provides for the admission of nonimmigrant students into the United States. *See* 8 U.S.C. § 1101(a)(15)(F) (identifying students qualified to pursue a full course of study); 8 C.F.R. § 214.2(f) (providing the requirements for nonimmigrant students, including those in colleges and universities). The INA also provides that nonimmigrant scholars and teachers may be admitted into the United States. *See, e.g.*, 8 U.S.C. § 1101(a)(15)(J) (identifying students, scholars, trainees, and professors in fields of specialized knowledge or skill, among others); *id.* §

1101(a)(15)(H) (identifying aliens working in specialty occupations); *id.* § 1101(a)(15)(O) (identifying aliens with extraordinary abilities in the sciences, arts, education, business, or athletics). As we have said before, "[t]he INA leaves no doubt" that Hawai'i's interests in "student- and employment-based visa petitions for its students and faculty are related to the basic purposes of the INA." *Hawai'i I*, 859 F.3d at 766.

Further, the Muslim Association of Hawai'i (the "Association") alleges that its members will suffer harms such as separation from their families, and that the Association itself will suffer the loss of its members if it is not granted a preliminary injunction.

Once again, we conclude that "Plaintiffs' claims of injury as a result of the alleged statutory violations are, at the least, '*arguably* within the zone of interests' that the INA protects" and therefore judicially reviewable. *Id.* at 767 (quoting *Bank of Am. Corp. v. City of Miami*, — U.S. —, 137 S. Ct. 1296, 1303 (2017) (citation omitted) (emphasis added).

3. Equitable Cause of Action

Even if there were no "final agency action" review under the APA, courts have also permitted judicial review of presidential orders implemented through the

actions of other federal officials.[8] This cause of action, which exists outside of the APA, allows courts to review *ultra vires* actions by the President that go beyond the scope of the President's statutory authority. *See Reich*, 74 F.3d at 1327–28 (citing *Am. Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108, 110 (1902) and *Leedom v. Kyne*, 358 U.S. 184, 188–89 (1958)) (permitting challenge to an Executive Order promulgated by the president and implemented by the Secretary of Labor, despite the lack of a final agency action under the APA); *see also Duncan v. Muzyn*, 833 F.3d 567, 577–79 (6th Cir. 2016); *R.I. Dep't Envtl. Mgmt. v. United States*, 304 F.3d 31, 40–43 (1st Cir. 2002); *cf. Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1384 (2015) (citing *McAnnulty* for the proposition that federal courts may enjoin "violations of federal law by federal officials"). When, as here, Plaintiffs challenge the President's statutory authority to issue the Proclamation, we are provided with an additional avenue by which to review these claims.

Having concluded that Plaintiffs' claims are justiciable, we now turn to the district court's preliminary injunction.

III. The Preliminary Injunction

[8] The Supreme Court has decided the merits of such claims, including the specific claim that an action exceeded the authority granted under § 1182(f). *See Sale*, 509 U.S. at 187–88; *see also Dames & Moore v. Regan*, 453 U.S. 654 (1981).

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* at 20. We may affirm the district court's entry of the preliminary injunction "on any ground supported by the record." *Enyart v. Nat'l Conference of Bar Exam'rs, Inc.*, 630 F.3d 1153, 1159 (9th Cir. 2011).

A. Likelihood of Success on the Merits

We consider first whether Plaintiffs are likely to succeed on the merits. In so doing, we consider four arguments[9] advanced by Plaintiffs: (1) the President has exceeded his congressionally delegated authority under 8 U.S.C. § 1182(f); (2) the President has failed to satisfy § 1182(f)'s requirement that prior to suspending entry, the President must find that entry of the affected aliens would be detrimental to the interests of the United States; (3) the Proclamation's ban on immigration from the designated countries violates 8 U.S.C. § 1152(a)(1)(A)'s prohibition on nationality-based discrimination; and (4) the President lacks the authority to issue

[9] As we explain below, we decline to reach Plaintiffs' arguments other than those listed here.

the Proclamation in the absence of a statutory grant. We address each in turn.

1. Scope of Authority under § 1182(f)

In determining whether the President has the statutory authority to issue the Proclamation under 8 U.S.C. § 1182(f), we begin with the text. *See Sale*, 509 U.S. at 171; *Haig v. Agee*, 453 U.S. 280, 289–90 (1981). But our inquiry does not end there. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132–33 (2000); *see also United States* v. *Witkovich*, 353 U.S. 194, 199 (1957) (declining to "read in isolation and literally" an immigration statute that "appear[ed] to confer upon the Attorney General unbounded authority"). In *Brown & Williamson*, the Court looked beyond the "particular statutory provision in isolation," and interpreted the statute to create a "symmetrical and coherent regulatory scheme." 529 U.S. at 132–33. The Court thus undertook a holistic review, which entailed examining the statute's legislative history, *see id.* at 146–47, "congressional policy," *id.* at 139, and "common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude," *id.* at 133.

Taking guidance from the Court's instructions in *Brown & Williamson* to look beyond the challenged "provision in isolation," *id.* at 132, we conclude that the Proclamation is inconsistent not just with the text of § 1182(f), but with the statutory framework as a whole, legislative history, and prior executive practice.

Although no single factor may be dispositive, these four factors taken together strongly suggest that Plaintiffs are likely to succeed on their claim that the President has exceeded his delegated authority under section 1182(f). We discuss each factor in greater detail below.

a. Statutory Text

We turn first to the text of § 1182(f). The INA grants the President the power to "*suspend* the entry of . . . any class of aliens" "for *such period* as he shall deem *necessary*." 8 U.S.C. § 1182(f) (emphasis added). We note at the outset that broad though the provision may be, the text does not grant the President an unlimited exclusion power.

Congress's choice of words is suggestive, at least, of its hesitation in permitting the President to impose entry suspensions of unlimited and indefinite duration. "The word 'suspend' connotes a temporary deferral." *Hoffman ex rel. N.L.R.B. v. Beer Drivers & Salesmen's Local Union No. 888*, 536 F.2d 1268, 1277 (9th Cir. 1976) (citing Webster's Third New International Dictionary (1966) and Bouvier's Law Dictionary (3d ed. 1914)). "[T]he word 'period,'" in turn, "connotes a stated interval of time commonly thought of in terms of years, months, and days." *United States v. Updike*, 281 U.S. 489, 495 (1930). This construction

of the term "period" is reinforced by the requirement that it be "necessary." [10] § 1182(f).

At argument, the Government contended that the indefinite duration of the Proclamation's entry restrictions is consistent with the text of § 1182(f). United States Court of Appeals for the Ninth Circuit, *17-17168 State of Hawaii v. Donald Trump*, YouTube (Dec. 7, 2017) at 22:45–23:15. Citing to § 4 of the Proclamation, which provides for a review of the restrictions every 180 days, the Government argued that because the suspensions will be "revisited" twice a year, the Proclamation is less indefinite than President Reagan's and President Carter's orders regarding Cubans and Iranians,[11] respectively. *Id.* at 23:04–23:14. This argument is unpersuasive.

The Government has repeatedly emphasized that the travel restrictions are necessary to incentivize and pressure foreign governments into improving their information-sharing and identity-management practices. This creates a peculiar situation where the restrictions may persist ad infinitum. To paraphrase a well-

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[10] As we discuss later, although prior executive orders or proclamations invoking § 1182(f) did not provide for a set end date, they were noticeably narrower in scope than the Proclamation. At the very least, Congress in adopting § 1182(f) likely did not contemplate that an executive order of the Proclamation's sweeping breadth would last for an indefinite duration.

[11] Proclamation 5517, 51 Fed. Reg. 30,470 (Aug. 22, 1986) (Cuba order); Exec. Order 12172, 44 Fed. Reg. 67,947 (Nov. 26, 1979) (Iran order), *amended by* Exec. Order 12206, 45 Fed. Reg. 24,101 (Apr. 7, 1980).

known adage, the Proclamation's review process mandates that the restrictions will continue until practices improve. The Proclamation's duration can be considered definite only to the extent one presumes that the restrictions will, indeed, incentivize countries to improve their practices. Where, as here, there is little evidence to support such an assumption, the Proclamation risks producing a virtually perpetual restriction—a result that the plain text of § 1182(f) heavily disfavors for such a far-reaching order.[12]

b. Statutory Framework

We next examine the statutory framework of the INA. *Brown & Williamson*, 529 U.S. at 133. We first note that the Constitution gives Congress the primary, if not exclusive, authority to set immigration policy. *See Arizona v. United States*, 567 U.S. 387, 409 (2012) (citing *Galvan v. Press*, 347 U.S. 522, 531 (1954)); *see also Fiallo*, 430 U.S. at 792 ("[O]ver no conceivable subject is the legislative power of Congress more complete than it is over the admission of

[12] Because issuing indefinite entry restrictions under these circumstances violates § 1182(f), we further view § 1182(f) as prohibiting a series of temporary bans when it appears such serial bans are issued to circumvent the bar on indefinite entry restrictions. *See also* Brief of T.A., a U.S. Resident of Yemeni Descent, as Amicus Curiae, Dkt. No. 41 at 7–8 (arguing that § 1182(f)'s use of the singular as it relates to "proclamation" and "period" is meaningful and precludes the use of serial bans to bypass the bar on indefinite suspensions, and noting that other provisions in § 1182 specifically use plural nouns to authorize multiple actions by the executive branch).

aliens." (citation and internal quotation marks omitted)); *Oceanic Steam Nav. Co. v. Stranahan*, 214 U.S. 320, 340 (1909) ("[T]he authority of Congress over the right to bring aliens into the United States embraces every conceivable aspect of that subject . . . ."). Congress has delegated substantial power in this area to the Executive Branch, but the Executive may not exercise that power in a manner that conflicts with the INA's finely reticulated regulatory scheme governing the admission of foreign nationals.

In line with this principle, the D.C. Circuit has held that the Executive cannot use general exclusionary powers conferred by Congress to circumvent a specific INA provision without showing a threat to public interest, welfare, safety or security that was independent of the specific provision. *Abourezk*, 785 F.2d at 1057–58. The *Abourezk* court reasoned that the Executive's use of the general exclusionary provision to deny entry to members of groups proscribed in the specific provision would "rob [the general provision] of its independent scope and meaning," render the specific provision superfluous, and conflict with limits that Congress imposed on the use of the specific provision. *Id.* at 1057. We agree with the D.C. Circuit's approach and apply it to § 1182(f).

We conclude that the Proclamation conflicts with the statutory framework of the INA by indefinitely nullifying Congress's considered judgments on matters of immigration. The Proclamation's stated purposes are to prevent entry of terrorists

and persons posing a threat to public safety, as well as to enhance vetting capabilities and processes to achieve that goal. *See* 82 Fed. Reg. at 45,161. Yet Congress has already acted to effectuate these purposes.

As for the prevention of entry of terrorists and persons likely to pose public-safety threats, Congress has considered these concerns, and enacted legislation to restrict entry of persons on those specific grounds. Under 8 U.S.C. § 1182(a)(3)(B), any alien who has "engaged in a terrorist activity" is inadmissible,[13] unless the Secretary of State determines in his unreviewable discretion that the alien qualifies for a waiver. *See id.* § 1182(d)(3)(B). With regard to public safety, Congress has created numerous inadmissibility grounds, including an array of crime-related grounds. *See, e.g., id.* § 1182(a)(2)(A) (crime of moral turpitude or drug offense); § 1182(a)(2)(B) (two or more offenses for which the aggregate sentences were five years or more); § 1182(a)(2)(C) (drug trafficking or benefitting from a relative who recently trafficked drugs); § 1182(a)(2)(D) (prostitution or "commercialized vice"); § 1182(a)(2)(H) (human trafficking); § 1182(a)(2)(I) (money laundering); § 1182(a)(3) ("Security and related grounds").

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[13] The term "engaged in a terrorist activity" is comprehensive. For example, "terrorist activity" includes any unlawful use of a weapon or dangerous device "other than for mere personal monetary gain," and "[e]ngag[ing] in terrorist activity" includes providing "material support" for any "terrorist activity" or terrorist organization. *See* 8 U.S.C. § 1182(a)(3)(B)(iii)(V)(bb), (a)(3)(B)(iv).

With respect to the enhancement of vetting capabilities and processes, we likewise conclude that Congress has considered the reality that foreign countries vary with respect to information-sharing and identity-management practices, as well as terrorism risk. In fact, Congress addressed those concerns in a neighboring section, 8 U.S.C. § 1187 (the Visa Waiver Program or "VWP"), which was amended as recently as 2015 to address the heightened risk of terrorism in certain countries. *See* Visa Waiver Program Improvement and Terrorist Travel Prevention Act of 2015, Pub. L. No. 114-113, § 203, 129 Stat. 2242, 2989–91. Significantly, many of the criteria used to determine whether a foreign national's country of origin qualifies for VWP treatment are replicated in the Proclamation's list of baseline criteria. This includes that the countries use electronic passports, § 1187(a)(3)(B), report lost or stolen passports, § 1187(c)(2)(D), and not provide safe haven for terrorists, § 1187(a)(12)(D)(iii). *See* 82 Fed. Reg. 45,162. The Proclamation even makes participation in the Visa Waiver Program part of its criteria for evaluating countries. *Id.* at 45,162–63.

The Government argues that the Visa Waiver Program is irrelevant because its "specific purpose" is the "facilitation of travel," and therefore it does not foreclose the President from addressing the "separate issue of what to do about a country that fails so many criteria that its information-sharing practices and other risk factors are collectively inadequate." This argument falls short. The Visa

Waiver Program's travel facilitation purpose is notable, but not for the reason advanced by the Government. As we explained above, the Visa Waiver Program utilizes many of the same criteria relied upon by the Proclamation. Congress thus expressly considered the reality that countries vary with respect to information-sharing and identity-management practices, as well as terrorism risk. In response to that reality, Congress could have enacted measures restricting travel from countries with inadequate risk factors, taken no action, or enacted provisions facilitating travel from low-risk countries. In creating the Visa Waiver Program, Congress chose the third approach. In so doing, Congress necessarily determined that the interests of the United States would be better served by facilitating *more* travel, not less. By heavily restricting travel from the affected countries, the Proclamation thus conflicts with the purpose of the Visa Waiver Program.

More broadly, the Government contends that Plaintiffs' reliance on the statutory framework is misplaced because § 1182(f) empowers the President to issue "*supplemental*" admission restrictions when he finds that the national interest so warrants. Although true, this merely begs the question of whether the restrictions at issue here are "supplemental." We conclude that the indefinite suspension of entry of all nationals from multiple countries, absent wartime or exigent circumstances, nullifies rather than "supplement[s]" the existing statutory scheme. The President is not foreclosed from acting to enhance vetting capabilities

and other practices in order to strengthen existing immigration law, but must do so in a manner consistent with Congress's intent. Put another way, the President cannot effectively abrogate existing immigration law while purporting to merely strengthen it; the cure cannot be worse than the disease. Here, the President has used his § 1182(f) and § 1185(a) powers to nullify numerous specific provisions of the INA indefinitely with regard to all nationals of six countries, and has overridden Congress's legislative responses to the same concerns the Proclamation aims to address. The Executive cannot without assent of Congress supplant its statutory scheme with one stroke of a presidential pen.

c. Legislative History

The legislative history suggests further limitations on § 1182(f)'s broad grant of authority. Prior to passing the INA, which included § 1182(f), the House of Representatives debated an amendment that would have continued to restrict the President's authority to suspend immigration only "[w]hen the United States is at war or during the existence of a national emergency proclaimed by the President." 98 Cong. Rec. 4423 (statement of Rep. Multer).[14] Speaking in opposition to the

[14] Section 1182(f)'s 1941 predecessor limited the president's authority to suspend entry of aliens only to times of war or national emergency. *See* Act of June 21, 1941, 55 Stat. 252, 252–53. In anticipation of future immigration reform, the Senate Committee on the Judiciary published a comprehensive report in 1950 on the state of immigration laws in the country. *See* S. Rep. No. 81-1515, at 1–2 (1950). Although the report states that the committee was considering a provision that would "permit the President to suspend any and all immigration whenever he

ultimately unsuccessful amendment, the sponsor of the bill urged that § 1182(f)'s broad language was "absolutely essential," because

> [W]hen there is an outbreak of an epidemic in some country, whence these people are coming, it is *impossible* for Congress to act. People might conceivably in large numbers come to the United States and bring all sorts of communicable diseases with them. More than that, suppose we have a period of great unemployment? In the judgment of the committee, it is advisable at such times to permit the President to say that for a certain time we are not going to aggravate that situation.

Id. (statement of Rep. Walter) (emphasis added).

Although Representative Walter and the bill's supporters did not "intend[] [their] list of examples to be exhaustive," *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 649 (1990), "it is significant that the example[s] Congress did give" all share the common trait of exigency. *Moran v. London Records, Ltd.*, 827 F.2d 180, 183 (7th Cir. 1987). Proponents of § 1182(f) deliberately pinned the provision to examples where it would be difficult, if not impossible, for Congress to react in a timely manner, thus necessitating swift presidential action.[15] The

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finds such action to be desirable in the best interests of the country," it is unclear whether the report's brief statement was in reference to what would eventually become § 1182(f) two years later. *Id.* at 381. More importantly, as Plaintiffs point out, none of the bill's supporters affirmatively voiced such a broad interpretation of § 1182(f) when pressed on the matter by members of the opposition.

[15] We note that hearings in 1970 and 1977 produced testimony from the Department of State that § 1182(f) (or § 212(f) of the INA) could be traced to "health prohibitions" even though the text does not explicitly limit executive use to exigencies, health or otherwise. *See, e.g.*, *United States-South African Relations: South Africa's Visa Policy: Hearing Before the Subcomm. on Africa & Int'l Org. of*

legislative history, then, suggests that despite § 1182(f)'s facially broad grant of power,[16] the Proclamation—which cites to no exigencies, national or otherwise, and does not respond to a situation Congress would be ill-equipped to address—falls outside of the boundaries Congress set.

d. Prior Executive Practice

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the Comm. on Int'l Relations H. Rep., 95th Cong. 10–11 (1977) (statement of Hon. Barbara M. Watson, Administrator, Bureau of Security and Consular Affairs, Dep't of State). Considering the strength of legislative history supporting use of § 1182(f) to restrict entry during epidemics, it is noteworthy that a 2014 Congressional Research Service report cautioned that the provision could only "potentially" be used to prevent entry of "foreign nationals traveling from a particular country or region from which there has been an Ebola outbreak." *See* Sarah A. Lister, *Preventing the Introduction and Spread of Ebola in the United States: Frequently Asked Questions*, Cong. Res. Serv. 3 (Dec. 5, 2014). The report noted that § 1182(f) had "never been employed so broadly" before. *Id.*

[16] Several congressmen did express concerns prior to enactment that § 1182(f) would give the President "an untrammeled right, an uninhibited right to suspend immigration entirely." 98 Cong. Rec. 4423 (statement of Rep. Celler). Their "fears and doubts," however, "are no authoritative guide to the construction of legislation[,] [because] [i]n their zeal to defeat a bill, [opponents to a bill] understandably tend to overstate its reach." *Bryan v. United States*, 524 U.S. 184, 196 (1998) (internal citations and quotation marks omitted).

Moreover, there is some evidence that supporters of § 1182(f) and its predecessor provision believed the opposition's concerns unreasonably presumed executive abuse of power. *See* 87 Cong. Rec. 5049 (1941) (statement of Rep. Bloom) (dismissing a representative's concerns because "the gentleman is figuring on something that the President would not do"); *see also* 98 Cong. Rec. 4424 (statement of Rep. Halleck) ("I take it that the gentleman would not be concerned [about section 1182(f)] if he were sure he would always have a President that could not do any wrong").

Notwithstanding the aforementioned factors, the Government argues that "[h]istorical practice confirms the breadth of, and deference owed to, the President's exercise of authority under Sections 1182(f) and 1185(a)(1)." We pass no judgment on the legality or appropriateness of the Executive's past practice, but we consider such practice to the extent it bears on congressional acquiescence. *See Abourezk*, 785 F.2d at 1055 ("[E]vidence of congressional acquiescence (or the lack thereof) in an administrative construction of the statutory language during the thirty-four years since the current act was passed could be telling."); *see also Zemel v. Rusk*, 381 U.S. 1, 17–18 (1965) ("We have held . . . and reaffirm today, that the 1926 [Passport] Act must take its content from history: it authorizes only those passport refusals and restrictions 'which it could fairly be argued were adopted by Congress in light of prior administrative practice.'" (quoting *Kent v. Dulles*, 357 U.S. 116, 128 (1958))).

The Government is correct that presidents have suspended the entry of foreign nationals in various foreign policy and national security settings, but we nevertheless conclude that the Proclamation and its immediate predecessors, EO-1 and EO-2, stand apart in crucial respects. First, out of the forty-three proclamations or orders issued under § 1182(f) prior to EO-1, forty-two targeted only government officials or aliens who engaged in specific conduct and their associates or relatives. *See* Kate M. Manuel, Cong. Research Serv., R44743,

Executive Authority to Exclude Aliens: In Brief 6–10, (2017) (listing prior § 1182(f) proclamations and orders).

Only one § 1182(f) proclamation suspended entry of all nationals of a foreign country. Proclamation 5517, issued in 1986, suspended entry of Cuban nationals as immigrants in response to the Cuba government's own suspension of "all types of procedures regarding the execution" of an immigration agreement between the United States and Cuba. 51 Fed. Reg. 30,470 (Aug. 22, 1986). In addition, President Carter delegated authority under § 1185(a) to the Secretary of State and the Attorney General to prescribe limitations governing the entry of Iranian nationals, but did not ban Iranian immigrants outright. *See* Exec. Order 12172, 44 Fed. Reg. 67,947 (Nov. 26, 1979), *amended by* Exec. Order 12206, 45 Fed. Reg. 24,101 (Apr. 7, 1980). These isolated instances, which applied to a single country each and were never passed on by a court, cannot sustain the weight placed on them by the Government. *See Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 169 (2001) ("Although we have recognized congressional acquiescence to administrative interpretations of a statute in some situations, we have done so with extreme care.").

Moreover, unlike the Proclamation, the Cuba and Iran orders were intended to address specific foreign policy concerns distinct from general immigration concerns already addressed by Congress. The same holds true for the vast majority

of prior § 1182(f) suspensions. *See, e.g.*, Executive Order 13606, 77 Fed. Reg. 24,571 (Apr. 22, 2012) (suspending entry of persons who facilitated cyber-attacks and human rights abuses by the Syrian or Iranian governments); Proclamation 6925, 61 Fed. Reg. 52,233 (Oct. 3, 1996) (suspending entry of persons "who formulate, implement, or benefit from policies that impede Burma's transition to democracy, and the immediate family members of such persons"); Proclamation 6569, 58 Fed. Reg. 31,897 (June 3, 1993) (suspending entry of persons "who formulate, implement, or benefit from policies that impede the progress of the negotiations designed to restore constitutional government to Haiti, and the immediate family members of such persons").

The only prior entry suspension lacking a foreign policy or national security purpose distinct from general immigration concerns is found in President Reagan's High Seas Interdiction Proclamation and its implementing executive orders. That Proclamation suspended "entry of undocumented aliens from the high seas" and ordered that such entry "be prevented by the interdiction of certain vessels carrying such aliens." Proclamation 4865, 46 Fed. Reg. 48,107 (Sep. 29, 1981). Consequently, Proclamation 4865 and its implementing executive orders, unlike the present Proclamation, applied by their terms almost entirely to aliens who were

already statutorily inadmissible.[17] *See id.*; Exec. Order 12324, 46 Fed. Reg. 48,109 (Sep. 29, 1981); Exec. Order 12807, 57 Fed. Reg. 23,133 (May 24, 1992).

We recognize that presidents ordinarily may use—and have used—§ 1182(f) to suspend the entry of aliens who might otherwise be admissible under the INA. But when, as here, a presidential proclamation addresses only matters of immigration already passed upon by Congress, the President's § 1182(f) authority is at its nadir.

The High Seas Interdiction suspensions are consistent with this principle because they apply predominantly to otherwise inadmissible aliens. In contrast, by suspending entry of a class of 150 million potentially admissible aliens, the Proclamation sweeps broader than any past entry suspension and indefinitely nullifies existing immigration law as to multiple countries. The Proclamation does so in the name of addressing general public-safety and terrorism threats, and what it deems to be foreign countries' inadequate immigration-related practices—concerns that Congress has already addressed.

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[17] Under 8 U.S.C. § 1182(a)(7)(A)(i)(I), an alien who does not possess "a valid unexpired immigrant visa, reentry permit, border crossing identification card, or other valid entry document" is inadmissible. The High Seas Interdiction suspensions did, however, affect some aliens who could have become admissible insofar as the suspensions prevented refugees fleeing persecution from reaching United States territorial waters. *See Sale*, 509 U.S. at 187–88 (holding that barring the entry of refugees outside the territorial waters of the United States did not violate the INA or the United Nations Convention Relating to the Status of Refugees).

We conclude that the Executive's past practice does not support the Government's position. Instead, such practice merely confirms that the Proclamation, like EO-2, "is unprecedented in its scope, purpose, and breadth." *Hawai'i I*, 859 F.3d at 779.

e. Constitutional Avoidance and Separation of Powers

Principles of separation of powers further compel our conclusion that the Proclamation exceeds the scope of authority delegated to the President under § 1182(f). It is a bedrock principle of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988); *see also INS v. St. Cyr*, 553 U.S. 289, 300 (2001) ("[W]e are obligated to construe the statute to avoid [serious constitutional] problems."). Here, a conclusion that the Proclamation does not exceed the President's delegated authority under § 1182(f) would raise "serious constitutional problems" and should thus be avoided. *See DeBartolo*, 485 U.S. at 575. Reading § 1182(f) to permit the Proclamation's sweeping exercise of authority would effectively render the statute void of a requisite "intelligible principle" delineating the "general policy" to be applied and "the boundaries of th[e] delegated authority," *Mistretta v. United*

States, 488 U.S. 361, 372–73 (1989). Without any meaningful limiting principles,[18] the statute would constitute an invalid delegation of Congress's "exclusive[]" authority, *Galvan*, 347 U.S. at 531, to formulate policies regarding the entry of aliens.

As discussed above, the Proclamation functions as an executive override of broad swaths of immigration laws that Congress has used its considered judgment to enact. If the Proclamation is—as the Government contends—authorized under § 1182(f), then § 1182(f) upends the normal functioning of separation of powers. Even Congress is prohibited from enabling "unilateral Presidential action that either repeals or amends parts of duly enacted statutes." *Clinton v. City of New York*, 524 U.S. 417, 439 (1998). This is true even when the executive actions respond to issues of "first importance," issues that potentially place the country's "Constitution and its survival in peril." *Id.* at 449 (Kennedy, J., concurring). In addressing such critical issues, the political branches still do not "have a somewhat free hand to reallocate their own authority," as the "Constitution's structure requires a stability which transcends the convenience of the moment" and was crafted in recognition that "[c]oncentration of power in the hands of a single branch is a threat to liberty." *Id.* at 449–50.

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[18] These limiting principles are primarily found in the text of the statute, but also include the surrounding statutory framework, the legislative history, and prior executive practice.

And the Proclamation's sweeping assertion of authority is fundamentally legislative in nature. Where an action "ha[s] the purpose and effect of altering the legal rights, duties and relations of persons, including the Attorney General, Executive Branch officials and [an alien], all outside the legislative branch," the Supreme Court has held that the action is "essentially legislative in purpose and effect" and thus cannot bypass the "single, finely wrought and exhaustively considered, procedure" for enacting legislation.[19] *INS v. Chadha*, 462 U.S. 919, 951–52 (1983). Here, the Proclamation does not merely alter the "legal rights, duties and relations" of a single alien, *id.* at 952, but rather affects the rights, duties and relations of countless American citizens and lawful permanent residents whose ability to be reunified with, and receive visits from, their family members is inhibited by the Proclamation; the Proclamation also significantly affects numerous officials within the Department of Homeland Security and Department of State. Whereas the House's action in *Chadha* "operated . . . to overrule the Attorney General," *id.*, here the Proclamation would operate to overrule Congress's "extensive and complex" scheme of immigration laws, *Arizona*, 567 U.S. at 395, as

[19] Although the Government has not explained why the President has thus far failed to ask Congress to enact the Proclamation's policies by legislation, potential congressional inaction cannot sustain the President's authority to issue the Proclamation, as "[f]ailure of political will does not justify unconstitutional remedies" like violating the Constitution's separation of powers. *Clinton v. City of New York*, 524 U.S. at 499 (Kennedy, J., concurring).

they pertain to the eight affected countries and the over 150 million affected individuals.

Decades of Supreme Court precedent support reading meaningful limitations into § 1182(f) in order to avoid striking down the statute itself as an unconstitutional delegation. For example, in *Zemel v. Rusk*, the Court opted to read in limiting principles despite statutory language that, on its face, appeared to grant the Executive complete discretion: "The Secretary of State may grant and issue passports under such rules as the President shall designate and prescribe for and on behalf of the United States." 381 U.S. at 7–8, 17. By so doing, the Court saved the statute from constituting "an invalid delegation." *Id.* at 18. The Court noted that principles of separation of powers still apply even in the field of foreign relations, holding that "simply because a statute deals with foreign relations" does not mean that the statute "can grant the Executive totally unrestricted freedom of choice." *Id.* at 17. Similarly, in *United States v. Witkovich*, the Court—faced with statutory language that "if read in isolation and literally, appears to confer upon the Attorney General unbounded authority"—nonetheless adopted a more "restrictive meaning" in order to avoid the "constitutional doubts" implicated by a "broader meaning." 353 U.S. at 199.

To avoid the inescapable constitutional concerns raised by the broad interpretation the Government urges us to adopt, we interpret § 1182(f) as

containing meaningful limitations—limitations that the Proclamation, in effectively rewriting the immigration laws as they pertain to the affected countries, exceeds. After all, "whether the realm is foreign or domestic, it is still the Legislative Branch, not the Executive Branch, that makes the law." *Zivotofsky ex rel. Zivotofsky v. Kerry,* 135 S. Ct. 2076, 2090 (2015).

2. Compliance with § 1182(f)

We next turn to whether, even assuming the President did not exceed the scope of his delegated authority under § 1182(f), the Proclamation meets § 1182(f)'s requirement that the President find that the entry of certain persons "would be detrimental to the interests of the United States" prior to suspending their entry. 8 U.S.C. § 1182(f).

Although we considered this question in *Hawai'i I* and ultimately answered it in the negative, 859 F.3d at 770–74, the Proclamation differs from EO-2 in several ways. As we discussed above, the Proclamation's suspensions of entry apply indefinitely, rather than for only 90 days. Unlike EO-2, the Proclamation developed as a result of a multi-agency review. The justifications for the Proclamation are different, too. The Proclamation puts forth a national security interest in information sharing between other countries and the United States, explains that it imposes its restrictions as an incentive for other countries to meet the United States' information-sharing protocols, and identifies "tailored"

restrictions for each designated country. And the list of affected countries differs from EO-2's: the Proclamation adds Chad, removes Sudan, and includes two non-majority Muslim countries, North Korea and Venezuela.

Although there are some differences between EO-2 and the Proclamation, these differences do not mitigate the need for the President to satisfy § 1182(f)'s findings requirement. Despite our clear command in *Hawai'i I*, the Proclamation—like EO-2—fails to "provide a rationale explaining why permitting entry of nationals from the six designated countries under current protocols would be detrimental to the interests of the United States." *Id.* at 773. In assessing the scope of the President's statutory authority, we begin with the text. The relevant portion of § 1182(f) states:

> Whenever the President finds that the entry of any aliens or of any class of aliens into the United States would be detrimental to the interests of the United States, he may by proclamation, and for such period as he shall deem necessary, suspend the entry of all aliens or any class of aliens as immigrants or nonimmigrants, or impose on the entry of aliens any restrictions he may deem to be appropriate.

8 U.S.C. § 1182(f).

While § 1182(f) gives the President broad authority to suspend or place restrictions on the entry of aliens or classes of aliens, this authority is not unlimited. Section 1182(f) expressly requires that the President *find* that the entry of a class of aliens would be *detrimental* to the interests of the United States before the aliens in a class are excluded. The use of the word "find" was deliberate.

Congress used "find" rather than "deem" in the immediate predecessor to § 1182(f) so that the President would be required to "base his [decision] on some fact," not on mere "opinion" or "guesses." 87 Cong. Rec. 5051 (1941) (statements of Rep. Jonkman and Rep. Jenkins).

By contrast, the Proclamation summarily concludes: "[A]bsent the measures set forth in this proclamation, the immigrant and nonimmigrant entry into the United States of persons described in section 2 of this proclamation would be detrimental to the interests of the United States." 82 Fed. Reg. 45,161–62. The Proclamation points out that screening and vetting protocols enhance the Government's ability to "detect foreign nationals who may commit, aid, or support acts of terrorism and other public-safety threats." *Id.* at 45,162. It then asserts that the travel restrictions will encourage the targeted foreign governments to improve their information-sharing and identity-management protocols and practices. The degree of desired improvement is left unstated; there is no finding that the present vetting procedures are inadequate or that there will be harm to our national interests absent the Proclamation's issuance.

In assessing the merits of Plaintiffs' motion for a preliminary injunction, the district court considered whether the Government had made the requisite findings for the President to suspend the entry of aliens under § 1182(f). Relying on our decision in *Hawai'i I*, the district court concluded that the Government had not.

Hawai'i TRO, 2017 WL 4639560, at *9–10. Although our prior decision in *Hawai'i I* has since been vacated as moot, the Supreme Court "express[ed] no view on the merits" in ordering vacatur. *Trump*, 2017 WL 4782860, at *1. We therefore adopt once more the position we articulated in *Hawai'i I* that § 1182(f) requires entry suspensions to be predicated on a finding of detriment to the United States. 859 F.3d at 773.

The Government argues that the "detailed findings" in the Proclamation satisfy the standard we set forth in *Hawai'i I*. Plaintiffs respond that the findings were inadequate because § 1182(f) expressly requires (1) "'find[ings]' that support the conclusion that admission of the excluded aliens would be 'detrimental,'" and (2) "the harm the President identifies must amount to a 'detriment to the interests of the United States.'" We agree with Plaintiffs.

The Proclamation makes no finding whatsoever that foreign nationals' nationality alone renders entry of this broad class of individuals a heightened security risk to the United States.[20] Nor does it contain a finding that the nationality of the covered individuals alone renders their entry into the United States on certain forms of visas detrimental to the interests of the United States. As such, there is no stated connection between the scope of the restriction imposed

[20] Rather, a declaration from former national security advisors—quoting a study from the Department of Homeland Security—states: "country of citizenship is unlikely to be a reliable indicator of potential terrorist activity."

and a finding of detriment that the Government seeks to alleviate. While the district court may have imprecisely stated that the Proclamation was "unsupported by verifiable evidence," *Hawai'i TRO*, 2017 WL 4639560, at *11, it was correct in concluding that the stated findings do not satisfy § 1182(f)'s prerequisites.

To be sure, the Proclamation does attempt to rectify EO-2's lack of a meaningful connection between listed countries and terrorist organizations. For instance, it cites to the fact that "several terrorist groups are active" in Chad. 82 Fed. Reg. at 45,165. But the Proclamation does not tie the nationals of the designated countries to terrorist organizations. For the second time, the Proclamation makes no finding that nationality alone renders entry of this broad class of individuals a heightened security risk or that current screening processes are inadequate.[21]

National security is not a "talismanic incantation" that, once invoked, can support any and all exercise of executive power under § 1182(f). *United States v. Robel*, 389 U.S. 258, 263–64 (1967). Section 1182(f) requires that the President make a finding that the entry of an alien or class of aliens *would be* detrimental to the interests of the United States. That requirement has not been met.

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[21] As the statistics provided by the Cato Institute demonstrate, no national from any of the countries selected has caused any of the terrorism-related deaths in the United States since 1975. *See* Brief of the Cato Institute as Amicus Curiae, Dkt. No. 84 at 26–28.

The Government argues that the district court erred by imposing a higher standard than that set forth in *Hawai'i I* by objecting to the President's stated reasons for the ban, by identifying internal inconsistencies, and by requiring verifiable evidence. We need not address the Government's argument because, as discussed above, the Proclamation has failed to make the critical finding that § 1182(f) requires. We therefore hold that Plaintiffs have shown a likelihood of success on the merits of their § 1182(f) claim that the President has failed to make an adequate finding of detriment.

3. Section 1185(a)

In addition to relying on § 1182(f), the Proclamation also grounds its authority in 8 U.S.C. § 1185(a), which states:

> Unless otherwise ordered by the President, it shall be unlawful [] for any alien to depart from or enter or attempt to depart from or enter the United States except under such reasonable rules, regulations, and orders, and subject to such limitations and exceptions as the President may prescribe.

8 U.S.C. § 1185(a)(1).

The Government does not argue that § 1185(a) provides an independent basis to suspend entry. Instead, the Government contends that § 1185(a) permits the President to skirt the requirements of § 1182(f) because § 1185(a) does not require a predicate finding before the President prescribes reasonable rules, regulations, and orders governing alien entry and departure. The Government also

argues that there is no meaningful standard for review because these matters are committed to the President's judgment and discretion. Plaintiffs respond that the Government cannot use the general authority in § 1185(a) to avoid the preconditions of § 1182(f).

We conclude that the Government cannot justify the Proclamation under § 1182(f) by using § 1185(a) as a backdoor. General grants in a statute are limited by more specific statutory provisions, and § 1182(f) has a specific requirement that there be a finding of detriment before entry may be suspended or otherwise restricted. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) ("It is a commonplace of statutory construction that the specific governs the general." (internal quotation marks and alterations omitted)). Section 1185(a) does not serve as a ground for reversal of the district court's conclusion on Plaintiffs' likelihood of success.

4. Section 1152(a)(1)(A)'s Prohibition on National Origin Discrimination

Next, we consider the impact of 8 U.S.C. § 1152(a)(1)(A) on the President's authority to issue the Proclamation. Section 1152(a) states:

> [N]o person shall receive any preference or priority or be discriminated against in the issuance of an immigrant visa because of the person's race, sex, *nationality*, place of birth, or place of residence.

8 U.S.C. § 1152(a)(1)(A) (emphasis added).

The Government argues that the district court erred by reading § 1152(a)(1)(A) to limit the President's authority under § 1182(f), and that § 1152(a)(1)(A) has never been used as a constraint on the President's authority under § 1182(f). In making this argument, the Government once again urges us to conclude that § 1152(a)(1)(A) operates in a separate sphere from § 1182(f). This we decline to do.

Congress enacted § 1152(a)(1)(A) of the INA contemporaneously with the Civil Rights Act of 1964 and the Voting Rights Act of 1965 to eliminate the "national origins system as the basis for the selection of immigrants to the United States." H.R. Rep. No. 89-745, at 8 (1965). In so doing, Congress manifested its intent to repudiate a history of nationality and race-based discrimination in United States immigration policy.[22] *See* 110 Cong. Rec. 1057 (1964) (statement of Sen.

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[22] The discriminatory roots of the national origins system may be traced back to 1875, when xenophobia towards Chinese immigrants produced Congress's first race-based immigration laws. *See* Brief of the National Asian Pacific American Bar Association as Amicus Curiae, Dkt. No. 126, at 5. The Page Law, passed in 1875, banned immigration of women—primarily Asian women—who were presumed, simply by virtue of their ethnicity and nationality, to be prostitutes. *Id.* at 5. The Page Law was followed in quick succession by the Chinese Exclusion Act in 1882 and the Scott Act in 1888. *Id.* at 6. These laws were justified on security grounds. *See Chae Chan Ping v. United States*, 130 U.S. 581, 606 (1889) (declining to overturn the Scott Act because "the government of the United States, through its legislative department, considers the presence of foreigners of a different race in this country, who will not assimilate with us, to be dangerous to its peace and security."). This underlying xenophobia eventually produced the national origins system, which clearly signaled that "people of some nations [were]

Hart) ("[A]n immigration policy with different standards of admissibility for different racial and ethnic groups, in short, a policy with build-in bias, is contrary to our moral and ethical policy."). Recognizing that "[a]rbitrary ethnic and racial barriers [had become] the basis of American immigration policy," Senator Hart, the bill's sponsor, declared that § 1152(a)(1)(A) was necessary "[t]o restore equality and fairplay in our selecting of immigrants." *Id.*

The Government argues that § 1152(a)(1)(A)'s prohibition of discrimination in the issuance of visas does not cabin the President's authority to regulate entry under § 1182(f). We disagree. As the Government concedes, the Proclamation restricts the entry of affected aliens *by precluding consular officers from issuing visas* to nationals from the designated countries. *See* 82 Fed. Reg. at 45,168. Put another way, the Proclamation effectuates its restrictions by withholding immigrant visas on the basis of nationality. This directly contravenes Congress's "unambiguous[] direct[ions] that no nationality-based discrimination . . . occur." *Legal Assistance for Vietnamese Asylum Seekers*, 45 F.3d at 473.

We are bound to give effect to "all parts of a statute, if at all possible." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 633 (1973). The Government's position that § 1152(a)(1)(A) and § 1182(f) operate in different

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more welcome to America than others," and created "token quotas" based on "implications of race superiority." 110 Cong. Rec. 1057 (statement of Sen. Hart).

spheres—the former in issuance of immigrant visas, the latter in entry—would strip § 1152(a)(1)(A) of much of its power. It is difficult to imagine that Congress would have celebrated the passing of the bill as "one of the most important measures treated by the Senate . . . [for its] restate[ment] [of] this country's devotion to equality and freedom" had it thought the President could simply use § 1182(f) to bar Asian immigrants with valid immigrant visas from entering the country. 111 Cong. Rec. 24785 (1965) (statement of Sen. Mansfield); *see also* Lyndon B. Johnson, *Remarks at the Signing of the Immigration Bill, Liberty Island, New York*, The Am. Presidency Project (Oct. 3, 1965), http://www.presidency.ucsb.edu/ws/index.php?pid=27292 (concluding that the discriminatory national origins quota system "will never again shadow the gate to the American Nation with the twin barriers of prejudice and privilege").

We do not think Congress intended § 1152(a)(1)(A) to be so easily circumvented. We therefore read § 1152(a)(1)(A) as prohibiting discrimination on the basis of nationality *throughout* the immigration visa process, including visa issuance and entry.[23]

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[23] Even if we assume for the sake of argument that Congress intended § 1182(f) and § 1152(a)(1)(A) to operate in entirely separate spheres, as is argued by the Government, the result would be the same. This is so because both at oral argument and in the Proclamation's text, the Government has conceded that if its entry ban were upheld, all embassy actions in issuing visas for nationals of the precluded countries would cease. 82 Fed. Reg. at 45,168 (noting that waiver by consular officers will be effective "both for *the issuance of a visa and for any*

To the extent that § 1152(a)(1)(A) conflicts with the broader grant of authority in § 1182(f) and § 1185(a), the Government asks us to give the latter two provisions superseding effect. The Government argues that as the more recently amended and "more specific" provision, § 1185(a) ought to control over § 1152(a)(1)(A). We are unpersuaded by this argument for several reasons.

First, when two statutory provisions are in irreconcilable conflict, a later-enacted, more specific provision is treated as an exception to an earlier-enacted, general provision. *See, e.g.*, *Perez-Guzman v. Lynch*, 835 F.3d 1066, 1075 (9th Cir. 2016); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts*, 183–87 (2012). Section 1152(a)(1)(A) was enacted over a decade after § 1182(f). Section 1152(a)(1)(A) also operates at a greater level of specificity than either § 1182(f) or § 1185(a)—it eliminates nationality-based discrimination for the issuance of immigrant visas. Because the "specific provision is construed as an exception to the general one," we agree with Plaintiffs that § 1152(a)(1)(A) provides a specific anti-discrimination bar to the President's general § 1182(f) powers. *RadLAX*, 566 U.S. at 645.

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subsequent entry on that visa" (emphasis added)); United States Court of Appeals for the Ninth Circuit, *17-17168 State of Hawaii v. Donald Trump*, YouTube (Dec. 7, 2017) at 9:55–11:33; 11:59–12:12. Enforcement of the entry ban under § 1182(f) would inescapably violate § 1152(a)(1)(A)'s prohibition on nationality-based discrimination in the issuance of immigrant visas, because the Proclamation effectively bars nationals of the designated countries from receiving immigrant visas.

Second, § 1152(a)(1)(A) clearly provides for exceptions in a number of circumstances. *See* 8 U.S.C. §§ 1101(a)(27), 1151(b)(2)(A)(i), and 1153. Neither § 1182(f) nor § 1185(a) is included in the list of enumerated exceptions. We presume that Congress's inclusion of specified items and exclusion of others is intentional. *See United States v. Vance Crooked Arm*, 788 F.3d 1065, 1075 (9th Cir. 2015) ("Under the longstanding canon *expressio unius est exclusio alterius*, we presume that the exclusion of . . . phrases" by Congress was intentional). The conspicuous absence of § 1182(f) and § 1185(a) from the listed exceptions vitiates the Government's position that both provisions fall outside § 1152(a)(1)(A)'s purview.

Lastly, the Government's reliance on prior Executive practice is misplaced. The Government again points to President Reagan's Proclamation 5517 suspending immigration from Cuba in response to Cuba's own suspension of immigration practices, and President Carter's Executive Order 12172 and the accompanying visa issuance regulations as to Iranian nationals during the Iran hostage crisis. As we explained above, *supra* at § III.A.1.d, those restrictions were never challenged in court and we do not pass on their legality now. Moreover, both orders are outliers among the forty-plus presidential executive orders restricting entry, and therefore cannot support a showing of congressional acquiescence. *See Solid Waste Agency*, 531 U.S. at 169. Finally, we need not

decide whether a President may, under special circumstances and for a limited time, suspend entry of all nationals from a foreign country. *See IRAP v. Trump*, No. TDC-17-0361, 2017 WL 4674314, at *21 (D. Md. Oct. 17, 2017). Such circumstances, if they exist, have not been argued here.

For the reasons stated above, the Proclamation's indefinite entry suspensions constitute nationality discrimination in the issuance of immigrant visas. We therefore conclude that Plaintiffs have shown a likelihood of success on the merits of their claim that the Proclamation runs afoul of § 1152(a)(1)(A)'s prohibition on nationality-based discrimination.

5. Alternative Authority

Having concluded that the Proclamation violates the INA and exceeds the scope of the President's delegated authority under § 1182(f), we view the Proclamation as falling into Justice Jackson's third category from *Youngstown Sheet & Tube Co. v. Sawyer*: "[w]hen the President [has] take[n] measures incompatible with the expressed or implied will of Congress." 343 U.S. 579, 637 (1952) (Jackson, J., concurring). Under *Youngstown*'s tripartite framework, presidential actions that are contrary to congressional will leave the President's "power [] at its lowest ebb, for then he can rely only upon his own constitutional powers minus any constitutional powers of Congress over the matter." *Id.* We therefore must determine whether the President has constitutional authority to issue

the Proclamation, independent of any statutory grant—for if he has such power, it may be immaterial that the Proclamation violates the INA. But when a President's action falls into "this third category, the President's asserted power must be both 'exclusive' and 'conclusive' on the issue" in order to succeed. *Zivotofsky ex rel. Zivotofsky*, 135 S. Ct. at 2084.

We conclude that the President lacks independent constitutional authority to issue the Proclamation, as control over the entry of aliens is a power within the exclusive province of Congress.[24] *See Galvan*, 347 U.S. at 531 ("[T]he formulation of these [immigration] policies is entrusted exclusively to Congress"); *see also Arizona*, 567 U.S. at 407 (citing *Galvan*, 347 U.S. at 531). While the Supreme Court's earlier jurisprudence contained some ambiguities on the division of power between Congress and the Executive on immigration,[25] the Court has

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[24] In *Hawai'i I*, we opted not to decide the question of "whether and in what circumstances the President may suspend entry under his inherent powers as commander-in-chief or in a time of national emergency." 859 F.3d 741, 782 n.21 (9th Cir. 2017). In holding today that the President lacked independent constitutional authority to issue the Proclamation, we again need not, and do not, decide whether the President may be able to suspend entry pursuant to his constitutional authority under *any* circumstances (such as in times of war or national emergency), as the Proclamation was issued under no such exceptional circumstances.

[25] *See* Adam B. Cox & Cristina M. Rodriguez, *The President and Immigration Law*, 119 Yale L.J. 458, 467–482 (2009) (examining the Supreme Court's shift from viewing authority over immigration as ambiguously belonging to the political branches—without specifying the allocation of power between the two—to increasingly identifying control over immigration as the province of Congress).

more recently repeatedly recognized congressional control over immigration policies. *See, e.g.*, *Chadha*, 462 U.S. at 940 ("The plenary authority of Congress over aliens under Art. I, § 8, cl. 4 is not open to question"); *Fiallo*, 430 U.S. at 793 (recognizing "the need for special judicial deference to congressional policy choices in the immigration context"); *Galvan*, 347 U.S. at 531–32 ("[T]hat the formulation of these policies is entrusted exclusively to Congress has become about as firmly imbedded in the legislative and judicial tissues of our body politic as any aspect of our government . . . . [we] must therefore under our constitutional system recognize congressional power in dealing with aliens.").

Exclusive congressional authority over immigration policy also finds support in the Declaration of Independence itself, which listed "obstructing the Laws for Naturalization of Foreigners" and "refusing to pass [laws] to encourage their migrations hither" as among the acts of "absolute Tyranny" of "the present King of Great Britain." The Declaration of Independence para. 2 (U.S. 1776). As Justice Jackson noted in *Youngstown*, "The example of such unlimited executive power that must have most impressed the forefathers was the prerogative exercised by George III, and the description of its evils in the Declaration of Independence leads me to doubt that they were creating their new Executive in his image." 343 U.S. at 641 (Jackson, J., concurring). This is perhaps why the Constitution vested Congress with the power to "establish an uniform Rule of Naturalization": the

Framers knew of the evils that could result when the Executive exerts authority over the entry of aliens, and so sought to avoid those same evils by granting such powers to the legislative branch instead. *See* U.S. Const. art. I, § 8, cl. 4.

B. Remaining Preliminary Injunction Factors

The three remaining preliminary injunction factors also lead us to affirm the preliminary injunction. Plaintiffs have successfully shown that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that the preliminary injunction is in the public interest. *Winter*, 555 U.S. at 20.

1. Irreparable Harm

The Government argues that Plaintiffs will suffer "no cognizable harm" absent the injunction because the Proclamation may only "delay" their relatives, students and faculty, and members from entering the United States. Indefinite delay, however, can rise to the level of irreparable harm. *See, e.g.*, *CBS, Inc. v. Davis*, 510 U.S. 1315, 1318 (1994) (Blackmun, J., in chambers) (granting emergency stay from preliminary injunction because the "indefinite delay" of a broadcast would cause "irreparable harm to the news media"). This is one such instance.

Plaintiffs have presented evidence that the Proclamation will result in "prolonged separation from family members, constraints to recruiting and retaining

students and faculty members to foster diversity and quality within the University community, and the diminished membership of the Association," the last of which "impacts the vibrancy of [the Association's] religious practices and instills fear among its members." *Hawai'i TRO*, 2017 WL 4639560, at *13. As we have said before, "[m]any of these harms are not compensable with monetary damages and therefore weigh in favor of finding irreparable harm." *Hawai'i I*, 859 F.3d at 782–83; *see also Washington*, 847 F.3d at 1168–69 ("[T]he States contend that the travel prohibitions harmed the States' university employees and students, separated families, and stranded the States' residents abroad."); *Hernandez v. Sessions*, 872 F.3d 976, 995 (9th Cir. 2017) (characterizing the "collateral harms to children of detainees whose parents are detained" as an irreparable harm); *Regents of Univ. of Cal. v. Am. Broad. Cos., Inc.*, 747 F.2d 511, 520 (9th Cir. 1984) (crediting intangible harms such as the "impairment of their ongoing recruitment programs [and] the dissipation of alumni and community goodwill and support garnered over the years"); *cf. Moore v. East Cleveland*, 431 U.S. 494, 503–04 (1977) (explaining that "the Constitution protects the sanctity of the family precisely because the institution of the family is deeply rooted in this Nation's history and tradition").

We therefore conclude that Plaintiffs are likely to suffer irreparable harm in the absence of the preliminary injunction.

2. Balance of Equities

We next conclude that the district court correctly balanced the equities in this case. When considering the equities of a preliminary injunction, we must weigh the "competing claims of injury" and "consider the effect on each party of the granting or withholding of the requested relief." *Winter*, 555 U.S. at 24 (citation omitted). In contrast to Plaintiffs' concrete allegations of harm, the Government cites to general national security concerns.[26] National security is undoubtedly a paramount public interest, *see Haig*, 453 U.S. at 307 ("[N]o governmental interest is more compelling than the security of the Nation."), but it cannot be used as a "talisman . . . to ward off inconvenient claims." *Ziglar v. Abbasi*, 137 S. Ct. 1843, 1862 (2017); *cf. New York Times Co. v. United States*, 403 U.S. 713, 719 (1971) (Black, J., concurring) (describing "security" as a "broad, vague generality whose contours should not be invoked to abrogate" the law). When, as here, the President has failed to make sufficient findings that the "entry of certain classes of aliens would be detrimental to the national interest," "we cannot conclude that national security interests outweigh the harms to Plaintiffs." *Hawai'i I*, 859 F.3d at 783.

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[26] The Government additionally argues that "[t]he injunction . . . causes irreparable injury by invalidating an action taken at the height of the President's authority." Not so. For the reasons discussed earlier, by acting in a manner incompatible with Congress's will, the President's power here is "at its lowest ebb." *Youngstown*, 343 U.S. at 638 (Jackson, J., concurring).

The injunction here would only preserve the status quo as it existed prior to the Proclamation while the merits of the case are being decided. We think it significant that the Government has been able to successfully screen and vet foreign nationals from the countries designated in the Proclamation under current law for years. *See* Brief of the Cato Institute as Amicus Curiae, Dkt. No. 84 at 26–27 (explaining that, from 1975 through 2017, "no one has been killed in a terrorist attack on U.S. soil by nationals from any of the eight Designated Countries"); *id.* at 29 (showing that the U.S. incarceration rate for persons born in the designated countries is lower than the U.S. incarceration rates for persons born in the U.S. or other non-U.S. countries). Accordingly, the balance of equities tips in Plaintiffs' favor.

3. Public Interest

Lastly, we consider whether Plaintiffs have successfully shown that "an injunction is in the public interest." *Winter*, 555 U.S. at 20. We conclude that they have.

It is axiomatic that the President must exercise his executive powers lawfully. When there are serious concerns that the President has not done so, the public interest is best served by "curtailing unlawful executive action." *Texas v. United States*, 809 F.3d 134, 187 (5th Cir. 2015), *aff'd by an equally divided court* 136 S. Ct. 2271 (2016). Amici provide further insight into the public interests that

would be served by sustaining the district court's injunction. They have furnished us with a plethora of examples, of which we highlight a few.

Amici persuasively cite to increased violence directed at persons of the Muslim faith as one of the Proclamation's consequences. *See* Brief of Civil Rights Organizations as Amici Curiae, Dkt. No. 52 at 19–23; Brief of Members of the Clergy et al. as Amici Curiae, Dkt. No. 97 at 29–32. Amici also explain that by singling out nationals from primarily Muslim-majority nations, the Proclamation has caused Muslims across the country to suffer from psychological harm and distress, including growing anxiety, fear, and terror. Brief of Muslim Justice League et al. as Amici Curiae, Dkt. No. 68 at 21–23.

In assessing the public interest, we are reminded of Justice Murphy's wise words: "All residents of this nation are kin in some way by blood or culture to a foreign land." *Korematsu v. United States*, 323 U.S. 214, 242 (Murphy, J., dissenting). It cannot be in the public interest that a portion of this country be made to live in fear.

We note, too, that the cited harms are extensive and extend beyond the community. As Amici point out, the Proclamation, like its predecessors, "continues to disrupt the provision of medical care" and inhibits "the free exchange of information, ideas, and talent between the designated countries and [various] [s]tates, causing long-term economic and reputational damage." Brief of New

York et al. as Amici Curiae, Dkt. No. 71 at 4. Moreover, because the Proclamation bans the entry of potential entrepreneurs, inventers, and innovators, the public's interest in innovation is thwarted at both the state and corporate levels. *See* Brief of Technology Companies as Amici Curiae, Dkt. No. 99 at 5–7. The Proclamation further limits technology companies' abilities to hire to full capacity by barring nationals of the designed countries from filling vacant positions. *See* Brief of Massachusetts Technology Leadership Council as Amicus Curiae, Dkt. No. 120 at 8–16 (explaining that "the technology industry is growing too rapidly to be staffed through domestic labor alone").

The Proclamation also risks denying lesbian, gay, bisexual, transgender, and queer ("LGBTQ") individuals in the United States the opportunity to reunite with their partners from the affected nations. *See* Brief of Immigration Equality et al. as Amici Curiae, Dkt. No. 101 at 17–20. The Proclamation allows that it "may be appropriate" to grant waivers to foreign nationals seeking to reside with close family members in the United States. 82 Fed. Reg. at 45,168–69. But many of the affected nations criminalize homosexual conduct, and LGBTQ aliens will face heightened danger should they choose to apply for a visa from local consular officials on the basis of their same-sex relationships. Brief of Immigration Equality at 4. The public interest is not served by denying LGBTQ persons in the United States the ability to safely bring their partners home to them.

* * *

For the foregoing reasons, we conclude that the district court did not abuse its discretion in granting an injunction.

C. Scope of the Preliminary Injunction

The Government argues that the injunction is overbroad because it is not limited to redressing the Plaintiffs' "own cognizable injuries." Plaintiffs argue that the nationwide scope of the injunction is appropriate particularly in the immigration context because piecemeal relief would fragment immigration policy. Plaintiffs further argue that it would be impracticable or impossible for them to name all those who would apply to the University of Hawai'i or the Association, but who have been chilled or prevented by the Proclamation from doing so.

We review the scope of a preliminary injunction for abuse of discretion. *McCormack v. Hiedeman*, 694 F.3d 1004, 1010 (9th Cir. 2012). Although the district court has "considerable discretion in fashioning suitable relief and defining the terms of an injunction," *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 941 F.2d 970, 974 (9th Cir. 1991), there are limitations on this discretion. Injunctive relief must be "tailored to remedy the specific harm[s]" shown by the plaintiffs. *Id.*

Because this case implicates immigration policy, a nationwide injunction was necessary to give Plaintiffs a full expression of their rights. *See Bresgal v. Brock*, 843 F.2d 1163, 1170–71 (9th Cir. 1987) ("[A]n injunction is not necessarily

made over-broad by extending benefit or protection to persons other than prevailing parties in the lawsuit—even if it is not a class action—*if such breadth is necessary to give prevailing parties the relief to which they are entitled.*"). "[T]he Constitution requires 'an *uniform* Rule of Naturalization'; Congress has instructed that 'the immigration laws of the United States should be enforced vigorously and *uniformly*'; and the Supreme Court has described immigration policy as 'a comprehensive and *unified* system.'" *Texas*, 809 F.3d at 187–88 (citations omitted). Any application of § 2 of the Proclamation would exceed the scope of § 1182(f), violate § 1152(a)(1)(A), and harm Plaintiffs' interests. Accordingly, the district court did not abuse its discretion by granting a nationwide injunction.

Although a nationwide injunction is permissible, a worldwide injunction as to all nationals of the affected countries extends too broadly. As the Supreme Court observed in *IRAP*: "The equities relied on by the lower courts do not balance the same way in that context." 137 S. Ct. at 2088. "[W]hatever burdens may result from enforcement of § 2(c) against a foreign national who lacks any connection to this country, they are, at a minimum, a good deal less concrete than the hardships identified [previously]." *Id.* "At the same time, the Government's interest in enforcing § 2(c), and the Executive's authority to do so, are undoubtedly at their peak when there is no tie between the foreign national and the United States." *Id.*

We therefore narrow the scope of the preliminary injunction, as we did in our November 13, 2017 order on the Government's motion for emergency stay. *See Hawai'i v. Trump*, 2017 WL 5343014, at *1. We then wrote:

> The preliminary injunction is stayed except as to "foreign nationals who have a credible claim of a bona fide relationship with a person or entity in the United States," as set out below.
>
> The injunction remains in force as to foreign nationals who have a "close familial relationship" with a person in the United States. Such persons include grandparents, grandchildren, brothers-in-law, sisters-in-law, aunts, uncles, nieces, nephews, and cousins. "As for entities, the relationship must be formal, documented, and formed in the ordinary course, rather than for the purpose of evading [Proclamation 9645]."

Id. (internal citations omitted).

We again limit the scope of the district court's injunction to those persons who have a credible bona fide relationship with a person or entity in the United States. The injunction remains in force as to foreign nationals who have a "close familial relationship" with a person in the United States, including grandparents, grandchildren, brothers-in-law, sisters-in-law, aunts, uncles, nieces, nephews, and cousins. As for entities, the relationship must be formal, documented, and formed in the ordinary course of business, rather than for the purpose of evading the Proclamation.

IV. Establishment Clause Claim

Plaintiffs argue that the Proclamation also violates the Establishment Clause of the United States Constitution. They urge us to adopt the view taken by the *en banc* Fourth Circuit in its review of EO-2 that "the reasonable observer would likely conclude that EO-2's primary purpose [was] to exclude persons from the United States on the basis of their religious beliefs." *IRAP*, 857 F.3d at 601.

Because we conclude that the district court did not abuse its discretion in granting the preliminary injunction relying on Plaintiffs' statutory claims, we need not and do not consider this alternate constitutional ground. *See Am. Foreign Serv. Ass'n v. Garfinkel*, 490 U.S. 153, 161 (1989) ("Particularly where, as here, a case implicates the fundamental relationship between the Branches, courts should be extremely careful not to issue unnecessary constitutional rulings.").

V. Conclusion

For all of these reasons, we affirm in part and vacate in part the district court's preliminary injunction order. We narrow the scope of the injunction to give relief only to those with a credible bona fide relationship with the United States, pursuant to the Supreme Court's decision in *IRAP*, 137 S. Ct. at 2088. In light of the Supreme Court's order staying this injunction pending "disposition of the Government's petition for a writ of certiorari, if such writ is sought," we stay our decision today pending Supreme Court review. *Trump v. Hawai'i*, No. 17A550, — S. Ct. —, 2017 WL 5987406 (Dec. 4, 2017). Because we conclude

that Plaintiffs have shown a likelihood of success on their statutory claims, we need not reach their constitutional claims.

AFFIRMED IN PART, VACATED IN PART.

Legal Challenge to "2-for-1" Regulatory Streamlining Executive Order

Issue Outline:

- On January 30, 2017, President Trump issued an Executive Order, *Reducing Regulation and Controlling Regulatory Costs*, as part of the Administration's de-regulation efforts.
- On February 8, 2017, Public Citizen, along with three other organizations, filed suit against the Executive Order, seeking declaratory and injunctive relief.
- The plaintiffs argued that the Executive Order violates the Take Care Clause of the US Constitution, exceeds the President's authority by directing the executive agencies to take action that would be contrary to the laws enacted by Congress, and violates the statutory bar against arbitrary and capricious decision making, among other arguments.
- Cross-motions for dismissal and summary judgment are pending. The case is ongoing.
- The first year of the Trump Administration has seen very little regulatory activity in health care, with some notable exceptions for modifications to the Affordable Care Act and Obama-era regulations that were revisited, such as the rulemaking on bundled payment models.
- In the meantime, the agencies are still conducting reviews of regulations, considering where to streamline provisions.

Attachment:

- September 6, 2017 GNYHA comment letter to HHS's Office for Civil Rights urging the revision or rescission of several provisions of the Health Insurance Portability and Accountability Act (HIPAA)

GREATER NEW YORK HOSPITAL ASSOCIATION

• (21 262-6350 • KENNETH

September
Six
2017

Via Electronic Mail
US Department of Health and Human Services
Office for Civil Rights
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201

Attention: Deven McGraw

Re: Regulatory Streamlining

Dear Ms. McGraw:

On behalf of the 160 hospital members of the Greater New York Hospital Association (GNYHA), I am writing to provide input into the Office for Civil Rights' (OCR) ongoing effort to consider streamlining amendments to certain regulatory provisions of the Health Insurance Portability and Accountability Act (HIPAA). In our view, various HIPAA regulations impose significant burdens on covered entities (CEs) without generating much benefit, often requiring a substantial amount of paperwork in the form of documentation and policies. These activities divert time and resources from other pressing endeavors such as developing meaningful training programs and shoring up defenses against cyberattacks. We offer the following detailed comments for your consideration.

Notice of Privacy Practices (45 CFR 164.520)

Providing patients with adequate notice of how their protected health information (PHI) may be used and disclosed is important, but the provision of the notice of privacy practices (NPP) has become a burdensome, *pro forma* exercise that supplants meaningful notice and understanding on the part of patients. Part of the problem is the extremely detailed implementation specifications for the content and provision of the notice, especially the onerous requirement that CEs obtain written acknowledgement that the NPP was received. This exercise diverts CEs' time and resources from more productive activities that could enhance patient understanding, and patients get little to no benefit from it. The NPP requirement is also particularly challenging in the context of telemedicine, where transmitting the document and obtaining acknowledgement in accordance with the rules is impracticable.

With respect to the content of the notice, the US Department of Health and Human Services (HHS) model NPP was a significant step in the right direction. But recent OCR desk audit findings raise questions about use of the model NPP, since audits indicated that OCR requires content (such as a description of how protected health information [PHI] may be forwarded to a third party) that is not found in the model NPP.

The regulations at 45 CFR 164.520(b) should be replaced with the requirement for a standardized notice that OCR should develop (to which CEs may add, if they wish). This may include a safe harbor for use of the HHS model NPP. The regulations at 45 CFR 164.520(c) should be streamlined in favor of a requirement that CEs post the standardized notice at their premises and on their website, with rescission of the requirement for a signed acknowledgement.

Security Incidents 45 CFR 164.304, 164.314, and 164.308(a)(6)

Security incidents are currently defined as attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system. In this era of cyberattacks, "attempts" are made on a constant basis. It is impracticable at best to document each and every security incident that is attempted.

The regulations should be updated to reflect today's security challenges. Security incidents that are "attempted" should be removed from the definition of "security incident" at 45 CFR 164.304.

"Minimum Necessary" Rule (45 CFR 164.514(d))

The "minimum necessary" rule requires CEs to determine the categories of PHI that each person or class of persons in their workforce needs access to, and to make reasonable efforts to limit such access accordingly. The regulations also require CEs to have policies and procedures in place to limit PHI disclosed on a regular and recurring basis, as well as on an individual basis, to the minimum necessary to achieve the purpose of the disclosure. Similar requirements apply to CEs' requests for PHI. These regulations have always been somewhat unrealistic, but they have become increasingly cumbersome as electronic health records have become more prevalent and care delivery has become more integrated.

The concept of "minimum necessary" should be revisited in light of the prevalence of electronic health records and exchange and integrated delivery systems. The requirement to identify the categories of PHI that persons or classes of persons in the workforce need access to (45 CFR 164.514(d)(2)) should be rescinded. The requirements at 45 CFR 164.514(d)(3) and (4) should be streamlined to impose a general requirement that access, disclosures, and requests for PHI be tailored to the purpose of the use or disclosure, subject to a reasonableness standard or professional judgment. If it is determined that a more

detailed regulatory requirement for a minimum necessary standard is indicated, the burden should be on the requester of the PHI, not the discloser.

Policies and Procedures (45 CFR 164.316, 45 CFR 164.530(i))

The HIPAA regulations on policies and procedures, as interpreted by OCR, are so expansive that to comply a CE must reiterate the regulatory language in voluminous policies and procedures. For example, OCR's published audit protocol has over 400 references to "policies and procedures," effectively dictating that CEs have hundreds of pages of privacy and security policies. In recent desk audits, it was not enough for CEs to perform risk analyses and implement risk management plans; OCR made clear that they must have extremely detailed policies and procedures governing these processes. This is counterproductive to compliance, as it requires CEs of all sizes to retain counsel or consultants to draft and update policies that few, if any, CE staff can even understand. These sorts of policies hamper, rather than support, training.

The standard for policies and procedures at 45 CFR 164.316 and .530(i) should be revised, as should the audit protocols. OCR should focus on whether CEs are complying with the Privacy, Security, and Breach Notification Rules, rather than focusing on policies and procedures.

"Addressable" Security Rule Specifications (45 CFR 164.306(d)(3))

The Security Rule implementation specifications that are "addressable" require an unreasonable amount of documentation, which diverts resources from the actual work of assessing and addressing security risks. If a CE concludes an addressable implementation specification is not reasonable and appropriate, the CE must document why not and implement an equivalent, alternative measure. While these requirements sound simple, they are in fact quite onerous in today's complex cybersecurity environment. Further, the concept of an "equivalent" measure is unclear in many cases (as an example, it is unclear what an equivalent measure is with respect to encryption in transit).

As health care entities have become major targets of cyberattacks, CEs are struggling to stretch scarce resources to address myriad threats. It is not the best use of those resources to create and maintain all of the documentation required in connection with addressable implementation specifications. The regulations at 45 CFR 164.306(d)(3) should be rescinded. The requirements for conducting and documenting a risk analysis ensure that CEs would continue to be held to a reasonable standard that entails identification, ranking, and addressing security risks.

Conclusion

We believe the above, relatively non-controversial suggestions would reduce the amount of regulatory burden facing CEs. Other aspects of the HIPAA regulations merit study and possible streamlining on a longer-term basis. For example, many of the purposes of business associate

agreements may be achieved through the use of a basic notice, with more complicated, unique terms placed in a written agreement (an approach that is similar to that of the cloud computing guidance). Another potential area for streamlining is the accounting of disclosures requirement.

Thank you for the opportunity to provide this informal comment. We look forward to working with you in the future to ensure HIPAA compliance among our membership.

Sincerely,

Kenneth E. Raske
President

OVERVIEW OF LEGAL CHALLENGES TO FEDERAL EXECUTIVE ACTIONS AND LEGISLATION IN HEALTHCARE

NYSBA Health Law Section
January 24, 2018

Laura M. Alfredo

GREATER NEW YORK HOSPITAL ASSOCIATION
Over 100 years of helping hospitals deliver the finest patient care in the most cost-effective way.

Overview

- ACA
- 340B
- Regulatory Streamlining
- Immigration

ACA

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Where We Are

December 2017: Individual Mandate Repealed

Executive Action Stopping Cost Sharing Reduction Payments

Cost-Sharing Reduction (CSR) Payments

Subsidized health plan waivers of deductible and copay amounts for low-income people, as required under ACA

Referenced in payment methodology for ACA Basic Health Plans *a.k.a.* NYS Essential Plan -- $870 million, covering approximately 700,000 New Yorkers (138% - 200% FPL)

ACA appropriation language at issue

House v. Burwell … Price … Hargan

- Action commenced in DC District Court in 2014 arguing Obama Administration making CSR payments without authorization
- DC District Court ordered payments be stopped but stayed order
- State AGs, including NYS, successfully intervened in August 2017; GNYHA Amicus
- Case conditionally settled December 2017 in three-way agreement

December 2017 Conditional Settlement of *House v. Hargan*

Executive's Interests	House's Interests	State-Intervenors' Interests
• Agreed with merits holding that CSRs not authorized • Disagreed with non-merits holding that House had standing and a cause of action • **Result**: Vacate district court's language ordering Executive to stop the payments	• Agreed with both non-merits and merits holdings • Given October 2017 Executive action stopping payments, willing to forego risk of adverse appellate ruling on standing	• Disagreed with merits holding • Wished to avoid preclusive effect on other litigation • **Result**: Parties agree not to cite district court decision on merits

California, et al v. Trump

Action commenced in ND Ca October 2017 by California, New York and 17 other states; GNYHA Amicus

Violations of APA, “Take Care Clause” alleged

Seeking DJ, injunctive relief

Motion for preliminary injunction denied October 2017

340B

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340B Basics

1992 program under Public Health Service Act

Requires pharmaceutical companies to discount OP drugs to certain hospitals and Federal grantees as a condition of participating in Medicaid

Technical requirements on patient, provider, and drug eligibility, and “duplicate discounts”

Program growth since 1992 in patients, savings

340B Environmental Scan

HRSA "Mega-Guidance" (under review)

- Wide-ranging proposals -- eligible patient, determination of outpatient status, contract pharmacy arrangements

Energy & Commerce Committee

- Oversight Committee Report issued January 10, 2018
- Recommends more rigorous oversight, expanded audits, Congressional clarification of intent

GAO Report (Under Development)

- Anticipated focus on contract pharmacies, fee arrangements, benefits to uninsured patients

OPPS Cut

Medicare Outpatient PPS 340B Cut

Final rule effective Jan. 1, 2018

Cuts separately payable drugs (defined as >$120/day) from ASP + 6% to ASP -22.5%

With budget neutrality adjustment, NYS impact ~$51m/year, net

AHA, et al v. Hargan

- Action commenced in DC December 2017 seeking to bar OPPS cut based on HHS's exceeding authority in adjusting payment rates and undermining 340B statute
- GNYHA amicus with several other hospital associations, showing real-world impact
- District Court dismissed case for lack of subject matter jurisdiction (presentment) December 29, 2017
- Plaintiffs appealing and pursuing administrative process in connection with claims

REGULATORY STREAMLINING

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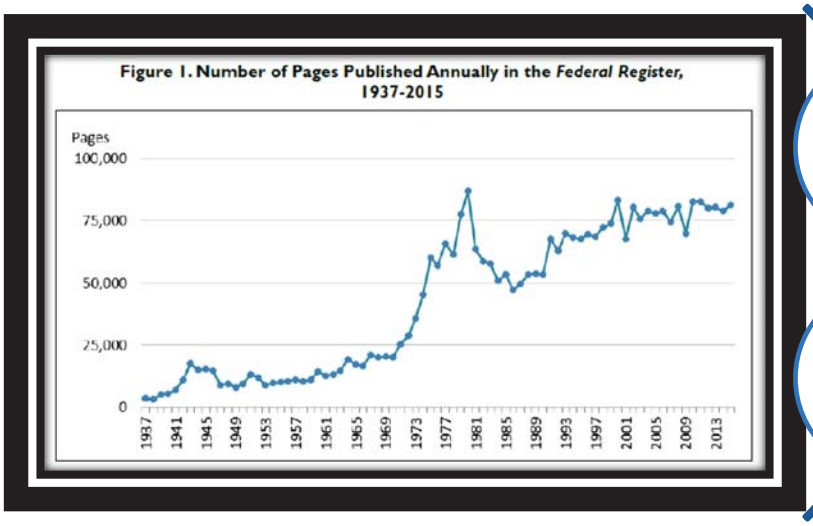
Re-cap; Regulatory Freeze

Directed agencies to hold or withdraw regulations not effective as of January 20, 2017, pending review, further rulemaking

Key rules impacted:

- Bundled Payment Models (CJR/SHFFT)
- Substance use disorder confidentiality rule
- Human subjects research (common rule)
- 340B Mega Guidance

January 30, 2017 Executive Order, *Reducing Regulation and Controlling Regulatory Costs*, ("2-for-1")

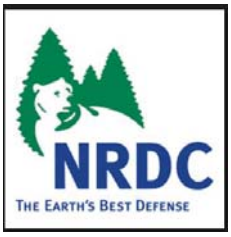


- For each "significant regulatory action," two regulations must be repealed
- Net zero growth in incremental costs 2017; future years TBD

Public Citizen v. Trump

Action commenced in February 2017, by Public Citizen, National Resources Defense Council, Communication Workers of America seeking declaratory and injunctive relief, citing APA, Constitutional grounds

Cross-motions pending



Speaking of Regulatory Streamlining … A Word on HIPAA

Notice of Privacy Practices

- NPPs burdensome, ineffectual
- Written acknowledgement of receipt especially onerous
- **GNYHA**: Replace with standardized notice as a safe harbor, drop written acknowledgement.

Security Incidents

- Attempted or successful unauthorized access, use, disclosure, … interference
- Impracticable in this era to document attempts
- **GNYHA**: Redefine security incidents to exclude attempts.

"Minimum Necessary" Rule

- Must determine the categories of PHI to which each person or class of persons in their workforce needs access, make reasonable efforts to limit this access accordingly, and implement certain policies and procedures
- Always unrealistic, more so now with EHR
- **GNYHA**: Replace with a general requirement that disclosures be tailored to the purpose of the use or disclosure, subject to a reasonableness standard or professional judgment.

Policies and Procedures

- Expansively interpreted; extreme, hyper-technical detail required
- Boon for counsel and consultants
- **GNYHA**: Revise the regulations and focus on substantive compliance, not paperwork.

IMMIGRATION

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Impacts on Health Care

Patient issues	Workforce issues
ICE enforcement concerns	Travel ban
DOJ memo on prosecuting immigration violations, other announcements	Extreme vetting for visa applicants
BUT, “Sensitive Locations” policy remains in effect	Actions to limit H1-B visas

Timeline of Travel Ban Executive Orders

January 27, 2017

Protecting the Nation from Foreign Terrorist Entry into the United States

- EO -1

March, 6, 2017

Second EO, revising and narrowing the first

- *EO-2*

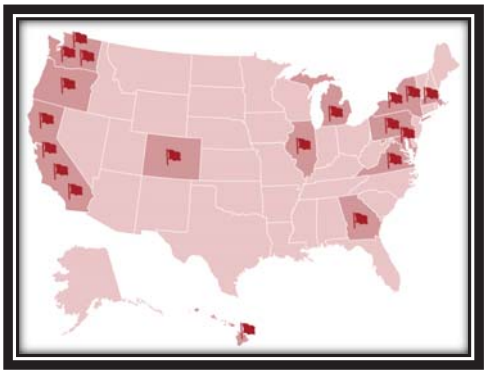
September 24, 2017,

Enhancing Vetting Capabilities and Processes for Detecting Attempted Entry Into the United States by Terrorists or Other Public-Safety Threats

- *EO-3*

EO-1 and its Legal Challenges

Basics	Initial Reaction from the Courts, Litigants	**GNYHA Advocacy**
• 7 nations, 90 days -- can be expanded in time and scope as screening procedures are reviewed • Applies to current and prospective visa holders	• Nationwide temporary stay upheld by 9th Circuit; government seeking further review • Preliminary injunction issued by VA court; no appeal yet • 20+ cases	•GNYHA to Secretaries of State, DHS: •"*We urge you to issue a clear, specific waiver or other notice of your intention to exercise this discretion [granted in EO] in the case of foreign nationals currently under consideration for residency slots in U.S. physician training programs.*" •GNYHA amicus in two actions



GNYHA January 2017 Member Survey on Visa Usage

	All Countries	7 Countries
Total visas	5,649	121
Total trainees	2,058	79
Trainees with H1-B	843	18
Trainees with other visas	1,215	61
Other workers	3,591	42
Other workers with H1-B	1,339	17
Other workers with other visas	2,252	25

Data from 37 respondents representing 91 hospitals

15/37 respondents (57 hospitals) had interviewed or planned to interview candidates from one of the seven countries during current match process

Current State: EO-3

Indefinite travel restrictions for 8 countries, tailored based on DHS review of each country's internal procedures and ability/ willingness to cooperate with US screening

B visas -- business visitors and tourists – used for meetings and conferences, including interviews, exams

H1-B and J-1 visas used for professionals and students/trainees

Exceptions and waiver authority clarified, expanded, compared to prior EOs

Country	H1-B Permitted?	J-1 Permitted?
Iran	No	Yes
Syria	No	No
North Korea	No	No
Libya	Yes	Yes
Chad	Yes	Yes
Venezuela	Yes	Yes
Yemen	Yes	Yes
Somalia	Yes	Yes

Current State: Legal Challenges

On December 4, the Supreme Court ruled EO-3 could take effect pending Government appeals to 4th and 9th Circuits

On December 8, 4th Circuit heard arguments on appeal of MD decision granting injunction on statutory (Immigration and Nationality Act) and Constitutional grounds

On December 22, 9th Circuit upheld ruling issued by district court in HI, finding EO-3 violated INA

GNYHA amicus in prior iteration of 4th Circuit case

Thank You

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GNYHA