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11 **IN THE UNITED STATES DISTRICT COURT**  
12 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

13 BIOTECHNOLOGY INNOVATION  
14 ORGANIZATION, et al.,

15 Plaintiffs,

16 v.

17 ALEX M. AZAR II, et al.,

18 Defendants.

Case No. 3:20-CV-8603 VC

**BRIEF OF THE CHAMBER OF  
COMMERCE OF THE UNITED  
STATES OF AMERICA AND THE  
NATIONAL ASSOCIATION OF  
MANUFACTURERS AS *AMICI  
CURIAE* IN SUPPORT OF  
PLAINTIFFS**

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## INTRODUCTION AND INTEREST OF THE *AMICI CURIAE*

In their motion for preliminary injunction, Plaintiffs lay out a compelling case that the Most-Favored Nation (MFN) Rule challenged in this case is procedurally deficient, substantively unlawful, and likely to cause serious and irreparable harms. *See generally* Dkt. 26. *Amici curiae* the Chamber of Commerce of the United States of America (U.S. Chamber) and the National Association of Manufacturers (NAM) agree with Plaintiffs entirely, and respectfully submit this brief to highlight and provide context to just one of the striking features of this case: The MFN Rule is another fatally flawed attempt to use COVID-19 as the basis for an end-run around the APA's notice-and-comment procedures. In a case brought by *amici*, another court in this district recently rejected that effort with respect to two other interim final rules. *See Chamber of Commerce of U.S. v. DHS*, 2020 WL 7043877 (N.D. Cal. Dec. 1, 2020) (White, J.). This Court should do the same.

\* \* \*

The U.S. Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the U.S. Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the U.S. Chamber regularly files *amicus curiae* briefs in cases that raise issues of concern to the nation's business community.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes roughly \$2.05 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for nearly two-thirds of private-sector research and development in the Nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

Collectively, *amici* represent huge swaths of the American economy, including many firms with interests in the critically important Medicare program. More broadly, *amici* have a vital institutional interest in ensuring that the federal government is held to the procedural safeguards provided in the Administrative Procedure Act. Here, because the Department of Health and Human Services (HHS) attempts to discard those essential protections, *amici* respectfully submit this brief in support of Plaintiffs’ motion for preliminary injunction.

## ARGUMENT

### A. Notice-and-comment rulemaking is an essential democratic check on the power of unelected agencies.

In promulgating the MFN Rule, HHS purports to invoke the APA’s “good cause” exception to notice-and-comment rulemaking. At the outset, it is essential to appreciate the critical role that this notice-and-comment procedure plays in the formulation of rules that ultimately have the “force and effect of law.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-303 (1979).

The APA requires federal agencies to publish notice of proposed rules in the Federal Register and then allow “interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.” 5 U.S.C. § 553(c). The “agency must consider and respond to significant comments received during the period for public comment.” *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 96 (2015).

As the Supreme Court has long explained, “[i]n enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment.” *Chrysler Corp.*, 441 U.S. at 316. These provisions of the APA, resulting in “a full-dress regulation,” are “designed to assure due deliberation” (*Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 741 (1996)) and they “foster the fairness and deliberation that should underlie a pronouncement of such force” (*United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)).

1 Notice-and-comment rulemaking achieves these goals by “ensur[ing] that agency  
 2 regulations are tested via exposure to diverse public comment” and, further, “giv[ing] affected  
 3 parties an opportunity to develop evidence in the record to support their objections to the rule and  
 4 thereby enhance the quality of judicial review.” *Envtl. Integrity Project v. E.P.A.*, 425 F.3d 992,  
 5 996 (D.C. Cir. 2005) (quoting *International Union, United Mine Workers of America v. Mine  
 6 Safety & Health Administration*, 407 F.3d 1250, 1259 (D.C. Cir. 2005)). That is all to say, the  
 7 APA’s notice-and-comment requirement is no “empty formality”; rather, it serves “to reintroduce  
 8 public participation and fairness to affected parties after governmental authority has been  
 9 delegated to unrepresentative agencies.” *E. Bay Sanctuary Covenant v. Trump*, 349 F. Supp. 3d  
 10 838, 860 (N.D. Cal. 2018) (quoting *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980));  
 11 accord, e.g., *E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 775 (9th Cir. 2018) (*East Bay  
 12 I*).

13 In light of the critical importance of notice-and-comment rulemaking, the good-cause  
 14 exception—which “is essentially an emergency procedure” (*United States v. Valverde*, 628 F.3d  
 15 1159, 1165 (9th Cir. 2010) (quoting *Buschmann v. Schweiker*, 676 F.2d 352, 357 (9th Cir.  
 16 1982)))—is disfavored. Indeed, as the Ninth Circuit has repeatedly explained, “[i]t is antithetical  
 17 to the structure and purpose of the APA for an agency to implement a rule first, and then seek  
 18 comment later.” *California v. Azar*, 911 F.3d 558, 575 (9th Cir. 2018) (quoting *Paulsen v.  
 19 Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005)). In other words, because it operates contrary to the  
 20 essential democratic values safeguarded by the APA’s procedural protections, the good-cause  
 21 exception “is to be ‘narrowly construed and only reluctantly countenanced.’” *Id.* (quoting *Alcaraz  
 22 v. Block*, 746 F.2d 593, 612 (9th Cir. 1984)); see also *id.* (“As such, the good cause exception is  
 23 usually invoked in emergencies, and an agency must ‘overcome a high bar’ to do so.”) (quoting  
 24 *Valverde*, 628 F.3d at 1164-1165); *Nat’l Venture Capital Ass’n v. Duke*, 291 F. Supp. 3d 5, 16  
 25 (D.D.C. 2017) (“Any agency faces an uphill battle to meet that burden.”)

**B. Recent attempts to invoke the good-cause exception on similar grounds have been rejected.**

As described in Plaintiffs’ motion, HHS has invoked the APA’s good-cause exception—citing a supposedly “particularly acute need” for action that does not permit for normal notice-and-comment procedures (85 Fed. Reg. 76,180, 76,249 (Nov. 27, 2020) (MFN Rule))—at the very end of a presidential term, all in order to enact a policy that the administration has pursued for years. *See* Mot. 4-5 (citing presidential statements going back to January 2018, and an HHS advance notice of proposed rulemaking identifying a potential “‘international price index’ model” for Part B drugs in October 2018). As it turns out, this is not a unique occurrence. The administration has already tried—and failed—to use the good-cause exception, on the purported basis of the COVID-19 pandemic, to bypass the APA’s fundamental requirements.

First, the Department of Homeland Security (DHS) issued an interim final rule on October 8, 2020, which would have fundamentally reshaped the H-1B visa program for high-skilled foreign workers. *See Strengthening the H-1B Nonimmigrant Visa Classification Program*, 85 Fed. Reg. 63,918 (Oct. 8, 2020) (DHS Rule). That visa is available to highly educated workers in “specialty occupation[s]” for a term of up to six years. 8 U.S.C. §§ 1101(a)(15)(H)(i)(b); 1184(g)(4). American businesses employ over 580,000 noncitizens on H-1B visas, largely in highly technical positions that drive innovation and foster this country’s position at the forefront of the information economy. DHS Rule, 85 Fed. Reg. at 63,921 (total H-1B population of 583,420); *see also, e.g.,* Alex Nowrasteh, *Don’t Ban H-1B Workers: They Are Worth Their Weight in Innovation*, Cato at Liberty (May 14, 2020) (summarizing academic research demonstrating that “H-1B workers have an especially big impact on American innovation” and “directly increase the production of knowledge through patents, innovation, and entrepreneurship”), [perma.cc/SMW4-UUJT](https://perma.cc/SMW4-UUJT). Yet the DHS Rule would have amended the regulatory definition of “specialty occupation” in an attempt to render up to a third of currently available positions ineligible. DHS Rule, 85 Fed. Reg. at 63,924-63-926 (amending definition); *see* Michelle Hackman, *Trump Administration Announces Overhaul of H-1B Visa Program*, Wall Street J. (Oct. 6, 2020), <https://perma.cc/PD23-RH5D>.



1 The administration attempted to circumvent notice-and-comment rulemaking for the DHS  
 2 Rule through the good-cause exception, asserting (in October 2020) that COVID-19 related  
 3 domestic unemployment required DHS to “respond . . . immediately” by preventing American  
 4 businesses from hiring skilled foreign workers. DHS Rule, 85 Fed. Reg. at 63,938. Yet, as in this  
 5 case, the DHS Rule actually implemented a policy change that had been a goal of the  
 6 administration for years, as the very same rule had appeared on DHS’s Statement of Regulatory  
 7 Priorities as early as 2017. *See* DHS, *Fall 2017 Statement of Regulatory Priorities* 3 (Fall 2017),  
 8 <https://perma.cc/RP75-RZYM>.

9 Similarly, the Department of Labor (DOL) issued another rule aimed at undermining the  
 10 H-1B and related visa programs, likewise asserting that COVID-19 unemployment provided good  
 11 cause to circumvent the APA’s notice-and-comment procedures. *See Strengthening Wage*  
 12 *Protections for the Temporary and Permanent Employment of Certain Aliens in the United States*,  
 13 85 Fed. Reg. 63,872 (Oct. 8, 2020) (DOL Rule). The DOL Rule would have altered the formulas  
 14 for calculating the “prevailing wage” that must be paid to H-1B and other work-based visa-  
 15 holders, increasing the wage to such a massive extent that, according to commentators, the rule  
 16 “should be understood as an attempt to price many H-1B professionals out of the U.S. labor  
 17 market.” Stuart Anderson, *Trump Administration Issues Two New Rules To Restrict H-1B Visas*,  
 18 *Forbes* (Oct. 7, 2020), <https://perma.cc/E5QV-8JWT>. As the DOL admitted, this would have been  
 19 one of the most economically burdensome regulations in history, costing American businesses  
 20 nearly \$200 billion over the coming decade. DOL Rule, 85 Fed. Reg. at 63,908.

21 And as with the DHS Rule and the MFN Rule challenged here, the DOL Rule attempted  
 22 to rely on the good-cause exception even though the administration had long been contemplating  
 23 the same regulatory changes. Indeed, the DOL Rule itself stated that the changes it made to the  
 24 prevailing wage scale “should have been undertaken years ago.” DOL Rule, 85 Fed. Reg. at  
 25 63,900.

26 Because of the staggering burdens imposed on American businesses by these surprise  
 27 regulatory changes, *amici* led a coalition of business groups and universities in suing to set aside  
 28 the DHS Rule and DOL Rule for noncompliance with notice and comment. *See generally*

1 *Chamber of Commerce of U.S. v. DHS*, 2020 WL 7043877 (N.D. Cal. Dec. 1, 2020) (White, J.).  
 2 As we describe below, the MFN Rule fails for all of the same reasons that Judge White recently  
 3 set aside the DHS and DOL H-1B Rules.

4 **C. There is no good cause to dispense with notice-and-comment rulemaking.**

5 In *Chamber of Commerce*, Judge White held that the DHS Rule and DOL Rule failed to  
 6 satisfy the APA’s good-cause exception. That court’s reasoning is equally applicable here, and  
 7 this Court should therefore set aside the MFN Rule.

8 1. First, agency delay counsels heavily against the invocation of the good-cause exception  
 9 here. The governing rule is unassailable: “Good cause cannot arise as a result of the agency’s own  
 10 delay,” because “[o]therwise, an agency unwilling to provide notice or an opportunity to  
 11 comment could simply wait until the eve of a statutory, judicial, or administrative deadline, then  
 12 raise up the ‘good cause’ banner and promulgate rules without following APA procedures.”  
 13 *Chamber of Commerce*, 2020 WL 7043877, at \*7 (quoting *Nat’l Educ. Ass’n v. DeVos*, 379 F.  
 14 Supp. 3d 1001, 1020-1021 (N.D. Cal. 2019), and *Nat. Res. Def. Council v. Nat’l Highway Traffic*  
 15 *Safety Admin.*, 894 F.3d 95, 114-115 (2d Cir. 2018)). Courts therefore “have repeatedly rejected  
 16 good cause when the agency delays implementing its decision.” *Nat’l Venture Capital Ass’n*, 291  
 17 F. Supp. 3d at 16 (collecting cases).<sup>1</sup>

18  
 19  
 20 <sup>1</sup> See, e.g., *Air Transp. Ass’n of Am. v. Dep’t of Transp.*, 900 F.2d 369, 379 (D.C. Cir. 1990)  
 21 (holding that “the FAA is foreclosed from relying on the good cause exception by its own delay  
 22 in promulgating the [challenged] Rules,” where “[t]he agency waited almost nine months before  
 23 taking action” and therefore “could have realized [its] objective short of disregarding its  
 24 obligations under the APA” by “using expedited notice and comment procedures if necessary”),  
 25 *vacated on other grounds*, 498 U.S. 1077 (1991); *Nat’l Ass’n of Farmworkers Orgs. v. Marshall*,  
 26 628 F.2d 604, 622 (D.C. Cir. 1980) (“[W]e cannot sustain the suspension of notice and comment  
 27 to the general public” where “[t]he Department waited nearly seven months” and therefore “found  
 28 it quite possible to consult with the interested parties it selected.”); *Env’tl Def. Fund v. EPA*, 716  
 F.2d 915, 921 (D.C. Cir. 1983) (rejecting as “baseless” the argument that “outside time pressures  
 forced the agency to dispense with APA notice and comment procedures” where agency waited  
 eight months before invoking good cause); cf. *United States v. Valverde*, 628 F.3d 1159, 1164-  
 1167 (9th Cir. 2010) (good cause not available where “[t]he Attorney General had already let  
 seven months go by after SORNA’s enactment before he issued the interim rule”); *Azar*, 911 F.3d  
 at 577 (same, where agencies “let nine months go by”); *Wash. Alliance of Tech. Workers*, 202 F.  
 Supp. 3d at 27 (D.D.C. 2016) (“It was . . . unreasonable for DHS to argue, after four years of  
 inaction, that an ongoing labor shortage entitled it to proceed with an emergency rulemaking.”).

As to the DHS Rule and the DOL Rule, Judge White highlighted that the policy changes embodied in the rules had long been under consideration within the administration: “[S]ome semblance of the DHS Rule has been on DHS’s regulatory agenda since 2017,” and adjustments to the H-1B wage scale had been touted by administration officials for at least as long. *Chamber of Commerce*, 2020 WL 7043877, at \*8. Thus, the court noted, “even if the problems Defendants purport to solve with the Rules may have been exacerbated by the COVID-19 pandemic, Defendants do not suggest they are new problems.” *Id.*

Moreover, even ignoring the longstanding nature of the policy goals for which the administration claimed good cause, “both agencies cited to ‘skyrocketing’ and ‘widespread’ unemployment rates [caused by COVID-19] as a basis to find ‘immediate’ action was necessary” but failed to act “for over six months” once the gravity of the pandemic had become apparent in March and April of 2020. *Chamber of Commerce*, 2020 WL 7043877, at \*8. In other words, “[t]he COVID-19 pandemic is an event beyond Defendants’ control, yet it was within Defendants’ control to take action earlier than they did.” *Id.* at \*9.

Yet more recently, a district court in the District of Columbia likewise set aside the same DOL H-1B Rule, employing similar reasoning. *See Purdue University v. Scalia*, 2020 WL 7340156 (D.D.C. Dec. 14, 2020). The court there explained that agency delay precludes reliance on the good-cause exception even if the agency does not technically “wait until the eve of a statutory, judicial, or administrative deadline to act.” *Id.* at \*7 (quotation marks omitted). Rather, the six-month gap between when the supposed need for action crystalized and when DOL promulgated the rule was sufficient on its own to render invocation of the good-cause exception impermissible. *Id.* at \*7-8. *See Air Transp. Ass’n*, 900 F.2d at 379 (concluding that the agency was “foreclosed from relying on the good cause exception by its own delay”) (emphasis added).<sup>2</sup>

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<sup>2</sup> In *Chamber of Commerce*, Judge White concluded that agency delay was a factor to be considered “as part of th[e] calculus” evaluating “the ‘totality of the factors at play.’” *Chamber of Commerce*, 2020 WL 7043877, at \*9 (quoting *Valverde*, 628 F.3d at 1165). Although amici submit that the better approach is to view delay as itself a sufficient basis to find that an agency has forfeited reliance on the good-cause exception (*see Air Transp. Ass’n*, 900 F.2d at 379), Plaintiffs prevail in this case regardless whether delay is considered an independent bar to invocation of the good-cause exception or simply part of a multi-factor, totality-of-the-circumstances analysis.

Second, while accepting as “beyond question” that “the COVID-19 pandemic is unprecedented in its scope and its impact, and qualifies as an emergency,” the court rejected the government’s invitation to focus the good-cause analysis on “the emergent nature of the COVID-19 pandemic writ large.” *Chamber of Commerce*, 2020 WL 7043877, at \*1. Rather, the court evaluated in granular detail the extent to which pandemic-related unemployment constituted “a dire . . . emergency” in the specific field affected by the regulatory measures in question, such that immediate effectiveness of the rules was truly indispensable. *Id.* at \*10; *see generally id.* at \*9-11 (scrutinizing the government’s good-cause arguments in detail). Viewing the government’s justifications through that lens, the court could not find that good cause had been satisfied, given the “significant mismatch of facts regarding the unemployment caused by the proliferation of the pandemic and the classes’ of workers impacted by the Rules.” *Id.* at \*10 (quoting *Nat’l Ass’n of Mfrs. v. DHS*, 2020 WL 5847503, at \*13 (N.D. Cal. Oct. 1, 2020)). As the court explained, this exacting “focus” was the “appropriate” form of review in light of the fact that “[t]he good cause exception is to be narrowly construed.” *Id.* at \*9.

2. Under these same two principles—that delay deeply undermines an agency’s invocation of good cause, and that COVID-related good-cause justifications must be scrutinized in their specifics, rather than simply crediting the pandemic emergency “writ large”—HHS has not demonstrated that good cause exists to dispense with notice and comment with respect to the MFN Rule. *See, e.g., E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1278 (9th Cir. 2020) (*East Bay II*) (“The government must make a sufficient showing that ‘delay would do real harm to life, property, or public safety,’ or that ‘some exigency’ interferes with its ability to carry out its mission.”) (citations omitted); *see also id.* (rejecting good-cause argument because government had not “demonstrate[d] that the delay caused by notice-and-comment or the grace period might do harm to life, property, or public safety.”).

In recognition of its substantial delay, HHS cites general concerns about increasing drug prices “between 2009 and 2017” (MFN Rule, 85 Fed. Reg. at 76,249)—but the agency gives no indication that this gradual, decade-long increase has given way to a sudden spike that now requires action so immediate that the procedures mandated by the APA must be laid aside. As for

1 HHS’s coronavirus arguments, just as in *Chamber of Commerce*, “[t]he COVID-19 pandemic is  
 2 an event beyond Defendants’ control, yet it was within Defendants’ control to take action earlier  
 3 than they did,” given that the pandemic and all its economic repercussions began in earnest some  
 4 nine months ago. *Chamber of Commerce*, 2020 WL 7043877, at \*9. HHS’s invocation of  
 5 COVID-19 as justification for rushing a rule into effect without notice and comment in the  
 6 twilight of this administration must—at the least—be viewed skeptically, in light of the  
 7 administration’s longstanding commitment to the policies finally enacted by the MFN Rule, as  
 8 well as the many months that have elapsed between the onset of the pandemic and the agency’s  
 9 belated action. *See id.* at \*7-9.

10 Similarly, the substance of the agency’s COVID-19 arguments fails under the close  
 11 scrutiny required in this context. *Chamber of Commerce*, 2020 WL 7043877, at \*9. For example,  
 12 HHS cites to “historic levels of unemployment in the U.S.” due to the pandemic, but does not  
 13 attempt to make the required connection between unemployment and the Medicare Part B  
 14 population, which by definition consists primarily of “America’s seniors” and persons with  
 15 disabilities that prevent them from working. MFN Rule, 85 Fed. Reg. at 76,249. As Plaintiffs  
 16 point out, HHS’s reasoning is riddled with other, similar logical deficiencies, not least that a  
 17 measure justified on the basis of an urgent need to lower prices for indispensable drugs “may  
 18 cause nearly 10% of Medicare beneficiaries to *lose* access to their Medicare Part B drugs” and  
 19 incur “increased expenditures in other areas of healthcare spending, such as hospitalizations.”  
 20 Mot. 12 (citing MFN Rule, 85 Fed. Reg. at 76,237). The “narrowly construed” and “reluctantly  
 21 countenanced” good-cause exception demands much more than such surface-level analysis. *Azar*,  
 22 911 F.3d at 575; *Chamber of Commerce*, 2020 WL 7043877, at \*8-10; *cf., e.g., Mingo Logan*  
 23 *Coal Co. v. EPA*, 829 F.3d 710, 732 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) (“[R]easoned  
 24 decisionmaking requires assessing whether a proposed action would do more good than harm.”)  
 25 (collecting authorities).

26 As Judge White rightly recognized in *Chamber of Commerce*, this kind of exacting  
 27 scrutiny—under which courts must closely interrogate the logical connection between the claimed  
 28 emergency and the actual measure sought to be enacted—follows directly from the nature of the

1 good-cause exception itself. *See Chamber of Commerce*, 2020 WL 7043877, at \*1, 9. Because  
 2 the APA’s notice-and-comment requirement is no “empty formality” (*E. Bay Sanctuary*  
 3 *Covenant*, 349 F. Supp. 3d at 860), the showing required from the government “is a ‘high bar’”  
 4 due to the importance of the interests that are thus subordinated to the need for immediate action.  
 5 *East Bay II*, 950 F.3d at 1278 (quoting *Valverde*, 628 F.3d at 1164). That is, “the good-cause  
 6 inquiry is meticulous and demanding,” and no “[d]eference” should be afforded “to an agency’s  
 7 invocation of good cause.” *Sorenson Commc’ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014)  
 8 (quotation marks omitted). As the *Chamber of Commerce* case demonstrates, judicial skepticism  
 9 is particularly warranted when an agency seeks to use good cause to avoid the gauntlet of notice-  
 10 and-comment rulemaking for a policy that has long been on the government’s regulatory wish  
 11 list. *Chamber of Commerce*, 2020 WL 7043877, at \*8; *see also Wash. Alliance of Tech. Workers*  
 12 *v. DHS*, 202 F. Supp. 3d 20, 27 (D.D.C. 2016) (“long planned” agency action ineligible for good  
 13 cause).

14 Altogether, the Court should not “countenance – reluctantly or otherwise –” the current  
 15 administration’s attempt bypass the essential public safeguards of notice and comment via the  
 16 good-cause exception, enshrining into law at the eleventh hour policies the administration has  
 17 pursued unsuccessfully for years. *Chamber of Commerce*, 2020 WL 7043877, at \*11. Good cause  
 18 is not satisfied here.

19 3. Finally, Defendants’ decision to unlawfully forgo notice and comment is prejudicial.  
 20 *See* 5 U.S.C. § 706 (“[D]ue account shall be taken of the rule of prejudicial error.”). In this  
 21 context, prejudicial error is readily found. As the Ninth Circuit has repeatedly explained, courts  
 22 “must exercise great caution in applying the harmless error rule in the administrative rulemaking  
 23 context,” and “[t]he failure to provide notice and comment is harmless *only* where the agency’s  
 24 mistake *clearly* had no bearing on the procedure used or the substance of decision reached.” *Azar*,  
 25 911 F.3d at 580 (quoting *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th Cir.  
 26 1992)) (emphasis added); *accord, e.g., United States v. Ross*, 848 F.3d 1129, 1133 (D.C. Cir.  
 27 2017) (“[F]ailure to comply with notice and comment . . . cannot be considered harmless if there  
 28 is any uncertainty at all as to the effect of that failure.”) (quotation marks omitted). Indeed,

1 “[t]here is no . . . requirement” that plaintiffs even “identify any specific comment that they  
2 would have submitted.” *Azar*, 911 F.3d at 580.

3 Here, “the [agencies’] mistake clearly had a bearing on the procedure used”—precluding a  
4 finding of harmless error—because the agencies “failed to provide the required notice-and-  
5 comment period . . . thereby precluding public participation in the rulemaking.” *Paulsen*, 413  
6 F.3d at 1006. That is all that is required. *See id.* at 1007 (“[T]he difference between a procedural  
7 violation of the APA that is harmless and one that is not” is whether “interested parties received  
8 some notice that sufficiently enabled them to participate in the rulemaking process before the  
9 relevant agency adopted the rule [or] were given no such opportunity.”); *see also Azar*, 911 F.3d  
10 at 580. This conclusion is unaffected by the fact that Plaintiffs now have “an opportunity to  
11 comment on the IFRs post-issuance,” because “an opportunity to protest an already-effective rule  
12 does not render an APA violation harmless.” *Azar*, 911 F.3d at 580-581 (quoting *Paulsen*, 413  
13 F.3d at 1007) (emphasis omitted).

### 14 CONCLUSION

15 The Court should grant Plaintiffs’ motion for a preliminary injunction.  
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