No. 23-35494

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GRAND RIVER ENTERPRISES SIX NATIONS, LTD,

Appellant,

v.

AUSTIN KNUDSEN, IN HIS OFFICIAL CAPACITY, ATTORNEY GENERAL OF THE STATE OF MONTANA

Appellee.

On Appeal from the United States District Court for the
District of Montana, No. 23-cv-00048
Hon. Brian Morris, Chief District Judge

REPLACEMENT OPENING BRIEF OF APPELLANT GRAND RIVER ENTERPRISES SIX NATIONS, LTD.

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DISCLOSURE STATEMENT

Grand River Enterprises Six Nations, Ltd. is not owned by a parent company and no publicly traded corporation owns 10% or more of its stock.

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INTRODUCTION

This case concerns whether the Montana Attorney General ("AG") may ban the sale of all products manufactured by Grand River Enterprises ("GRE") based on the AG's unilateral determination that GRE violated federal law, even though GRE has not received any of the procedural protections that federal law provides before such a determination can be made.

GRE is a Canadian tobacco product manufacturer. It sells products to U.S. importers, which, in turn, sell them to downstream distributors, that ultimately resell the products to Montana retailers. In 2012, following a dispute over whether Montana had jurisdiction and authority to require GRE to make regulatory payments on account of consumer purchases of GRE's products, GRE and Montana entered into a settlement agreement known as the "Assurance of Voluntary Compliance" ("AVC"). Among other things, the AVC recites that GRE will "remain in compliance with all local, state, and federal laws."

In 2023, the Montana Attorney General ("AG") accused GRE of violating the federal Food, Drug and Cosmetic Act ("FDCA") with respect to certain now-discontinued products. GRE strongly disagrees with this accusation. The Food and Drug Administration ("FDA") has never even suggested that GRE violated federal law, much less initiated an enforcement proceeding. But without giving GRE any process at all, the AG unilaterally declared it illegal for *all* of GRE's products to be

sold statewide. He sent all in-state wholesalers notice requiring them to immediately stop selling GRE's products, and they all immediately complied to avoid severe penalties.

Neither federal law nor state law authorized this remarkable action. Instead, the AG's asserted basis for exercising this authority was the AVC's provision requiring GRE to comply with "all … federal laws." According to the AG, if he unilaterally determined that GRE violated federal law, this entitled him to inflict the corporate death penalty on GRE without any process whatsoever. The district court accepted this argument and refused to grant GRE preliminary injunctive relief.

That argument is as wrong as it sounds. First, the AG's action is preempted. The AG has no authority to enforce the FDCA—that authority resides solely in the FDA. He certainly has no authority to enforce the FDCA in a manner that strips GRE of its federal statutory protections and undermines the FDA's discretionary enforcement policies. Contrary to the AG's suggestion, the AVC does not alter the analysis and give him the power to unilaterally enforce federal law. If it did, the AVC would be unenforceable, as the FDA never agreed to permit the AG to undermine the FDA's enforcement authority. And to cap it all off, the AG is substantively wrong—GRE did not violate federal law.

Second, the AG's action violates the Due Process Clause. The AG banned the sale of GRE products in Montana without a hearing. That is a textbook due

process violation. The AVC did not and could not confer the AG with the unilateral authority to decide the fate of GRE's business in Montana.

The Court should hold that GRE is entitled to a preliminary injunction.

JURISDICTIONAL STATEMENT

The district court denied GRE's motion for a temporary restraining order on July 17, 2023. In its July 17 ruling, the district court further stated that it would defer ruling on GRE's motion for preliminary injunction pending a state court ruling. GRE filed its initial notice of appeal on July 20, 2023.

On August 3, 2023, this Court issued its decision in *Ernest Bock, LLC v. Steelman*, 76 F.4th 827 (9th Cir. 2023). GRE moved for reconsideration of the district court's July 17 order in light of *Ernest Bock*. On September 7, 2023, this Court issued an order holding this appeal in abeyance pending the district court's resolution of that motion and further stating: "To challenge the district court's ruling on the motion, appellant must file an amended notice of appeal within the time set by Federal Rule of Appellate Procedure 4." The district court denied that motion for reconsideration on September 18, 2023. GRE filed an amended notice of appeal on September 19, 2023, seeking review of both the July 17 order and the September 18 order denying reconsideration. *See* Fed. R. App. P. 4(a)(4)(B)(ii).

As explained below, *infra* at I.A.1, this Court has jurisdiction under 28 U.S.C. § 1292(a)(1) because "the circumstances render the denial tantamount to the denial

of a preliminary injunction." *Religious Tech. Ctr., Church of Scientology Int'l, Inc. v. Scott*, 869 F.2d 1306, 1308 (9th Cir. 1989). In its initial order, the district court denied a temporary restraining order and declined to rule on GRE's motion for preliminary injunction pending a state court ruling, which is tantamount to a denial of GRE's request for immediate injunctive relief. Any doubt over this Court's jurisdiction under § 1292(a)(1) was resolved by the district court's September 1, 2023 order denying a motion for injunction pending appeal and its September 18, 2023 order denying GRE's motion for reconsideration. *Infra* at I.A.2. The district court made its view clear that GRE's request for a preliminary injunction failed on the merits because GRE lacked a likelihood of success and could not show irreparable harm. Those rulings were tantamount to the denial of a preliminary injunction, conferring jurisdiction under § 1292(a)(1).

Alternatively, as explained below, *infra* at I.B, this Court has jurisdiction because the district court's initial order effectively granted a stay under *Colorado River Water Conservation District v. United States*, 424 U.S. 800 (1976). This Court has jurisdiction over appeals of *Colorado River* stays under the collateral order doctrine. *United States v. State Water Res. Control Bd.*, 988 F.3d 1194, 1201-02 (9th Cir. 2021).

STATUTORY AND REGULATORY AUTHORITIES

Pertinent statutes appear in an addendum to this brief.

ISSUES PRESENTED

1. Whether this Court has jurisdiction over this interlocutory appeal.
2. Whether the district court erred, in its July 17 order, in refusing to rule on GRE's request for a temporary restraining order and preliminary injunction because GRE was simultaneously pursuing a related case in state court raising state-law claims.
3. Whether GRE is entitled to a preliminary injunction enjoining enforcement and implementation of the Montana Attorney General's order banning sales of GRE's products in the State on the ground that the Attorney General's order is preempted by the Federal Food, Drug, and Cosmetic Act.
4. Whether GRE is entitled to a preliminary injunction enjoining enforcement and implementation of the Montana Attorney General's order banning sales of GRE's products in the State on the ground that the Attorney General's order violates the Due Process Clause.

STATEMENT OF THE CASE

I. The AVC Agreement

Under Montana law, tobacco manufacturers must submit annual certifications to the Montana Attorney General identifying, among other things, "a list of all of its

brand families" and "a list of all of its brand families that have been sold in the state at any time during the current calendar year." *See* Mont. Code Ann. § 16-11-503. The AG maintains a Directory listing all tobacco product manufacturers that have provided those certifications, as well as all brand families listed in the certifications. Mont. Code Ann. § 16-11-504(1). The AG is authorized to exclude or remove a manufacturer or its brand families from the Directory for two reasons: (1) the manufacturer fails to provide a compliant annual certification, or (2) the manufacturer fails to comply with Montana's requirement to make annual deposits into an escrow account based on the number of its cigarettes that are sold in the State. *Id.* § 16-11-504(2), (3). Brand families not on the Directory are prohibited from sale or distribution in Montana. *Id.* § 16-11-504(4).

GRE is an indigenous-owned Canadian tobacco product manufacturing business headquartered on the Six Nations of the Grand River Territory in Ontario. ER-106 ¶ 5. From 2000-2002, GRE's cigarettes were imported into the United States by American licensed importers that then sold the cigarettes to downstream distributors that resold the products in Montana. ER-72. At the start of this period, Montana adopted an escrow statute requiring certain tobacco manufacturers to deposit funds into escrow accounts based on the volume of their tobacco products sold in Montana—regardless if they were sold in the state by the manufacturer. Mont. Code Ann. § 16-11-403 (En. Sec. 3, Ch. 412, L. 1999). GRE disputed whether

Montana had jurisdiction to impose escrow requirements on GRE for direct sales made by downstream sellers, so GRE sued Montana in federal court.[1]

In 2012, GRE and Montana resolved their differences via an agreement entitled "Assurance of Voluntary Compliance" ("AVC"). ER-71-76. Without conceding that Montana had regulatory jurisdiction, GRE agreed to drop its lawsuit and pay escrow deposits. ER-73-74. In exchange, Montana agreed to list GRE and its brand families on the Directory. ER-73. The AVC states, among other things, that GRE will "remain in compliance with all local, state, and federal laws." *Id.*

II. Federal Review Of Tobacco Products

Pursuant to the FDCA, the FDA's regulation of tobacco products is comprehensive. As relevant here, sections 905(j) and 910(a) of the FDCA require the FDA to review tobacco products that tobacco manufacturers intend to introduce into interstate commerce for commercial distribution in the United States. *See* 21 U.S.C. §§ 387e(j), 387j(a). One way a tobacco product manufacturer can continue such introduction into commerce is to show that its tobacco products are "substantially equivalent to a tobacco product commercially marketed … in the United States as of February 15, 2007." 21 U.S.C. § 387j(a)(2)(A)(i)(I). The FDA

[1] During this period, other states enacted similar escrow statutes and GRE challenged those states' authority to enforce those statutes as well. *See, e.g.*, *see South Dakota v. Grand River Enterprises Six Nations, Ltd.*, 757 N.W.2d 305 (S.D. 2008) (holding that GRE is not subject to in-state jurisdiction for purposes of enforcement of escrow deposit requirements),

review process, however, often moves slowly, even when this provision is invoked. To accommodate this delay, when a tobacco manufacturer submits a "Substantial Equivalence Report" ("SE Report") for a product on the market in March 2011, the FDCA permits the tobacco manufacturer to continue to produce and introduce the product into interstate commerce while the application is pending. *Id.* § 387j(a)(2)(B).

There are two ways this process can end with a formal FDA order. Sometimes, the FDA completes review of a product and affirmatively concludes that it is *not* substantially equivalent to a pre-2007 product, resulting in an order of non-Substantial Equivalence (or "NSE Order"). Other times, the FDA issues an order of Substantial Equivalence. The FDA has also adopted an informal policy and protocol for tobacco products that are subject to a substantial equivalence report, but do not proceed to a formal order. When the FDA itself removes a product from Substantial Equivalence review, the FDA issues no order and advises the manufacturer it may continue to produce and introduce the product into commerce unless and until the FDA resumes review and issues a NSE Order. *See* FDA, *Draft Guidance for Industry: Enforcement Policy for Certain Marketed Tobacco Products* at 2 (Feb. 2019), https://www.fda.gov/media/120808/download ("[T]he FD&C Act permits a provisional tobacco product to remain on the market pending FDA's review.") When a manufacturer voluntarily removes a product from review, the FDA accepts the

withdrawal and advises the manufacturer that the product is deemed adulterated and misbranded. When a product is adulterated and misbranded, the FDCA prevents the manufacturer from introducing the product into commerce. *See* 21 U.S.C. §§ 387b(6)(A), 387c(a)(6). In all scenarios, because the FDCA permitted the tobacco manufacturer to produce and introduce the product into interstate commerce while the application is pending, the product may be on the shelves even after the conclusion or suspension of the review process. *See Draft Guidance for Industry: Enforcement Policy for Certain Marketed Tobacco Products* at 2 ("[B]ecause the [FDCA] permits a provisional tobacco product to remain on the market pending the FDA's review of the SE Report for that product, the product is likely to be available to consumers at retail locations within the United States when [the review process completes].").

Recognizing that reality, the FDA has developed policies and practices for dealing with existing stock after a product's review is concluded or suspended. When the FDA affirmatively concludes a product is not substantially equivalent to a pre-2007 product, it has chosen "not to take enforcement action against a manufacturer, importer, or distributor of the product for at least 30 calendar days from the date of the [Not Substantially Equivalent ('NSE')] order"—*i.e.*, it allows sales of remaining stock to occur, but only for a period of 30 days. *Id.* In the case of products voluntarily withdrawn from the SE process by a manufacturer, by

contrast, the FDA has opted not to establish a set deadline for selling off wholesalers' and retailers' remaining product.

III. This Dispute

As noted above, the Montana AG maintains a Directory listing all brand families identified in a tobacco manufacturer's certification. Mont. Code Ann. § 16-11-504(1). A brand family's inclusion in the Directory allows wholesalers and retailers to distribute and sell the brand styles associated with that brand family in Montana. *See id.* § 16-11-504(4).[2]

At the heart of this case are eight tobacco products for which GRE initially submitted but then, in January 2020, voluntarily withdrew SE Reports. ER-91-95. When GRE withdrew the eight products from FDA review, the FDA did not take any steps to limit third parties from selling out their existing inventories. *See id.*

Before GRE voluntarily withdrew the SE Reports for the eight tobacco products at issue, it listed the relevant brand families—Couture brand (six products) and Seneca brand (two products)—in its annual Montana certification. ER-66. This was undisputedly legal because, pursuant to the FDCA, GRE was permitted to

[2] A style is a common reference for a specific tobacco product that is sold to consumers. Consumers do not purchase a "brand family" as that term is defined under Montana law (and federal law does not recognize nor define "brand family"). Rather, consumers purchase specific styles—for example Marlboro Menthol Gold 100 Box, which is a pack of 20 cigarettes bearing that description and included within the Marlboro brand family.

produce and introduce the underlying products into interstate commerce while FDA review was pending. 21 U.S.C. § 387j(a)(2)(B). When GRE voluntarily withdrew the SE Reports, it did not alter its 2020 and 2021 certifications to remove the relevant brand styles, because the FDA did not take any steps to limit third parties from clearing their existing inventories. ER-68-69. If GRE had removed the relevant brand families from its certification, Montana wholesalers and retailers would have been forbidden from clearing their inventories, even though the FDA's only direction to GRE at the time of the removal was for GRE itself to cease production and marketing of these products. ER-92-93. Since withdrawing the SE reports, GRE has not manufactured the relevant brand styles, and wholesalers and distributors in Montana have sold only 3 cartons (600 cigarettes) of those brand styles from their existing stock. ER-67-68 ¶¶7-8.

In April 2022, GRE discontinued listing the Couture brand family on its annual certification. *See* ER-77-90.[3] On May 9, 2022, the AG sent GRE a letter stating that GRE's Couture brand would be removed from the Directory and asked why GRE had not removed the brand from the previous years' certifications. *Id.* On May 26, 2022, GRE responded by explaining that in January 2020, GRE voluntarily withdrew its SE Reports for the eight relevant tobacco products. *See* ER-91-94.

[3] GRE did not remove the Seneca brand because GRE continued to produce and introduce into interstate commerce FDA-approved brand styles that fit under that brand family.

GRE further explained that, because the FDA's letter accepting GRE's withdrawal did not request or direct GRE to take any steps to limit third parties from selling out their existing inventories of the eight withdrawn styles, GRE left its 2020 and 2021 certifications unaltered. *See id.*

On July 15, 2022, the AG updated the Directory. GRE's Seneca and Opal brand families were listed on the Directory. ER-68. The Couture brand family was removed, in accordance with GRE's voluntary withdrawal of the Couture brand from its certification. ER-71-76.

On April 27, 2023, GRE submitted its 2023 annual certification for listing on the Directory. ER-68. Because the Montana AG expressed no concerns with the 2022 certification and continued to list GRE and its Seneca and Opal brand families on the Montana directory through the end of 2022, GRE identified the same brand families (Seneca and Opal) in its 2023 certification. *Id.* Montana continued to list these brand families in the Directory during the first half of 2023. ER-68-69.

On June 14, 2023, the AG—despite accepting GRE's 2022 certification—unexpectedly changed positions. He sent GRE a letter and Notice (also sent to each Montana wholesaler), ER-102-03, stating the wholesalers are immediately banned from distributing GRE products in Montana that are shipped to such wholesalers after June 14, 2023, and that retailers are prohibited from selling GRE products received after July 14, 2023. *See id.*; ER-99-102. The letter and Notice also advised

that GRE and its brand families would be removed from the Montana Directory on July 14, 2023. ER-99-102; ER-102-03. The ban was immediate and without prior notice or opportunity for GRE to be heard. *See* ER-68-69 ¶ 11. The reason provided by the AG for imposing the ban was that GRE's listing of the Couture brand in its 2020 and 2021 certification constituted acts done "in violation of federal law." ER-103.

No Montana statute authorized the AG's action. Instead, the AG relied on the AVC. *Id.* As noted above, the AVC requires GRE to "remain in compliance with all local, state, and federal laws." ER-71-76. According to the AG, this provision authorized the AG to *unilaterally* determine that GRE violated federal law—a determination no federal official had ever made—and *unilaterally* ban GRE's products from being sold in Montana based *solely* on the AG's unilateral determination that GRE violated federal law. ER-102-03.

In response to the AG's actions, GRE filed lawsuits in state and federal court. GRE's state court suit alleged that the AG had violated its contractual obligations under the AVC. GRE moved for a temporary restraining order and preliminary injunction. Those motions remain pending in the state court.

The federal suit—this case—alleges federal preemption and federal due process violations not raised in the state court proceeding. GRE moved for a Temporary Restraining Order and Preliminary Injunction. ECF 6. On July 17, 2023,

following argument on GRE's motion, the district court denied GRE's request for a TRO. ER-4-13. It did not rule on the merits of GRE's motion; instead, the court "deem[ed] it prudent to allow the Montana state district court the opportunity to resolve the question before it." ER-12. The court explained: "GRE has not identified any unusual circumstances that would weigh in favor of the Court's intervention in an essentially parallel state court proceeding, a proceeding where the Montana state district court remains better positioned to evaluate issues involving likely significant state interests." *Id.* The court also "assume[d] that the case and motion now pending before the Montana state district court [would] provide GRE adequate opportunity to raise any constitutional or other procedural challenges to the Attorney General's actions." *Id.* The court therefore "defer[red] to the Montana state district court to address the motion and related issues first filed in that court." *Id.*

In addition to denying the motion for a temporary restraining order, the Court also stated it "reserves ruling on GRE's request for a preliminary injunction and show-cause hearing pending resolution of the motions now before the Montana state district court." ER-13.

On July 20, 2023, GRE filed a notice of interlocutory appeal of the district court's order. On July 24, 2023, GRE filed a motion for injunction pending appeal in the district court, as required by Fed. R. App. P. 8(a)(1)(C).

On August 3, 2023, this Court decided *Ernest Bock, LLC v. Steelman*, 76 F.4th 827 (9th Cir. 2023), which cast significant doubt on the district court's refusal to rule on GRE's request for a preliminary injunction. Therefore, on August 4, 2023, GRE moved the district court for reconsideration of its July 17 order. GRE filed its opening brief in this Court on August 17, 2023.

On September 1, 2023, the district court issued an order denying GRE's motion for injunction pending appeal and deferring consideration of GRE's motion for reconsideration until GRE's appeal was resolved. On September 5, 2023, GRE filed a motion in this Court for an injunction pending appeal. On September 7, 2023, this Court issued an order holding the appeal in abeyance pending the district court's resolution of the motion for reconsideration. The Court's order further stated: "To challenge the district court's ruling on the motion, appellant must file an amended notice of appeal within the time set by Federal Rule of Appellate Procedure 4."

On September 18, 2023, the district court denied the motion for reconsideration. On September 19, 2023, GRE filed an amended notice of appeal, seeking review of both the July 17 order and the September 18 denial of reconsideration. GRE now submits this replacement opening brief, which addresses both orders identified in the notice of appeal.

SUMMARY OF ARGUMENT

I. This Court has appellate jurisdiction. First, under 28 U.S.C. § 1292(a)(1), this Court has appellate jurisdiction over "[i]nterlocutory orders … refusing … injunctions." The district court: (1) denied GRE's motion for a temporary restraining order based on the pendency of GRE's state-court lawsuit raising state-law claims, and (2) stated it would not act on GRE's motion for a preliminary injunction "pending resolution of the motions now before the Montana state district court." ER-13. As such, the district court concluded that GRE is not entitled to a preliminary injunction in the current posture of the state-court case, rendering the court's order an "[i]nterlocutory order[] … refusing … [an] injunction[]." 28 U.S.C. § 1292(a)(1).

The district court's denial of GRE's motions for injunction pending appeal and for reconsideration confirms this Court's appellate jurisdiction under § 1292(a)(1). GRE's motions argued that this Court's recent decision in *Ernest Bock, LLC v. Steelman*, 76 F.4th 827 (9th Cir. 2023), establishes that the district court should not have stayed its proceedings pending the state-court case. In denying those motions, the district court made its view clear that GRE was not entitled to a preliminary injunction on the merits. This Court's precedent establishes that, in this posture, the Court has appellate jurisdiction under § 1292(a)(1).

Alternatively, the district court's initial order deferred resolution of GRE's motion for a preliminary injunction pending developments in the state court case. Although the court did not denominate its order as such, the court's order was a stay under *Colorado River Water Conservation District v. United States*, 424 U.S. 800 (1976), which authorizes district courts to stay cases pending state-court proceedings under limited circumstances. This Court has jurisdiction of appeals of *Colorado River* stays under the collateral order doctrine. *See United States v. State Water Res. Control Bd.*, 988 F.3d 1194, 1201-02 (9th Cir. 2021).

II. The district court's initial order, which refused to adjudicate GRE's motion for a preliminary injunction in view of the state-court case, was incorrect. In *Ernest Bock, LLC v. Steelman*, 76 F.4th 827 (9th Cir. 2023), this Court held that "[w]hen one possible outcome of parallel state court proceedings is continued federal litigation," a stay is unwarranted because there is "a 'substantial doubt' that the state court action will provide a 'complete and prompt resolution of the issues,' because the federal court may well have something 'further to do.'" *Id.* at *9 (citations omitted). In this case, GRE raises only state-law claims in state court. One possible outcome of the state-court case is that GRE will lose, which will require the federal court to adjudicate GRE's federal claims. Hence, under *Ernest Bock*, a *Colorado River* stay was unwarranted. In addition, even if GRE prevails in its state court case,

the parties will still need to litigate in the District Court whether GRE violated federal law – as the state court is without jurisdiction to decide that federal issue.

III. Following *Ernest Bock*, the district court switched gears and concluded that GRE was not entitled to a preliminary injunction because it lacked a likelihood of success on the merits. That holding was wrong.

GRE is likely to succeed on the merits of its federal preemption claim. Montana's AG concluded that GRE violated the FDCA, and therefore banned GRE's products from Montana's shelves. However, under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), only the United States may enforce the FDCA. Even if a state is nominally enforcing state law, the enforcement action is still preempted if it "would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1049 (9th Cir. 2022) (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010)). Here, the AG did exactly what *Buckman* and *Nexus* prohibit: bring an enforcement action premised on a violation of federal law when the FDA has not brought such an enforcement action.

Preemption is especially appropriate in this case because the AG is enforcing federal law in a manner that the FDA never could. The AG *unilaterally* banned *all* GRE products without judicial process. The FDA lacks statutory authority to do this.

Indeed, the FDA lacks statutory authority to do this even *with* judicial process. The FDA must seek permission from a federal court to obtain an injunction, and a federal court would lack authority to enjoin the sale of products unrelated to the alleged violation. Finally, the FDA could not obtain *any* injunction in this case from a federal court for a simple reason: GRE did not violate the FDCA at all.

The AG invokes a settlement agreement that GRE signed in 2012, the Assurance of Voluntary Compliance ("AVC"), which recites that "Grand River shall remain in compliance with all local, state, and federal laws." ER-73 8-1 ¶4. The AVC, by its terms, does not authorize the AG to unilaterally find a violation of the FDCA without the FDA's input. If it did, the AVC would be preempted: the FDA never agreed to allow the AG to undermine its exclusive authority to enforce the FDCA.

GRE is also likely to succeed on its due process claim. GRE has a protected property interest in being listed in Montana's directory, thereby allowing GRE's products to be sold in Montana. GRE similarly has a protected property interest in the goodwill it has created over the past eleven years for its products in Montana. By removing GRE from Montana's directory, the AG stripped GRE of those property interests without any process—a paradigmatic violation of due process. Contrary to the district court's suggestion, GRE's participation in a regulated industry does not undermine its due process claim. Even in a heavily regulated

industry, an industry participant has the right to due process when regulations governing entrance into that market are based on mandatory criteria, as is the case here.

Contrary to Montana's claim, GRE did not give up its due process rights by signing the AVC. The AVC's text rebuts that suggestion, and Montana's interpretation of the AVC would itself raise serious constitutional concerns.

GRE will suffer irreparable harm without an injunction. The AG has sovereign immunity, so GRE cannot recover the monetary damages it is incurring every day from the AG's actions. *Idaho v. Couer d'Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015). The balance of hardships and public interest tip in GRE's favor, given that GRE has not sold the purportedly misbranded products for several years.

The Court should reverse the district court's order and hold that GRE is entitled to a preliminary injunction.

STANDARD OF REVIEW

The Court reviews the denial of a preliminary injunction for abuse of discretion, but considers the underlying legal principles de novo. *Mobilize the Message, LLC v. Bonta*, 50 F.4th 928, 934 (9th Cir. 2022). The Court reviews the denial of a motion for reconsideration for abuse of discretion. *Berman v .Freedom Financial Network, LLC*, 30 F.4th 849, 855 (9th Cir. 2022). "An error of law is an

abuse of discretion." *Fowler v. Guerin*, 899 F.3d 1112, 1120 (9th Cir. 2018) (emphasis and quotation marks omitted).

ARGUMENT

I. This Court Has Appellate Jurisdiction.

This Court has appellate jurisdiction under 28 U.S.C. § 1292(a)(1) because the district court's denial of the TRO and subsequent denial of reconsideration was tantamount to the denial of a preliminary injunction. Alternatively, the Court has appellate jurisdiction under the collateral order doctrine.

A. This Court Has Appellate Jurisdiction Under 28 U.S.C. § 1292(a)(1).

This Court has appellate jurisdiction under 28 U.S.C. § 1292(a)(1) because the district court denied a preliminary injunction. The district court's July 17, 2023 order denied a TRO and held that GRE was not entitled to a preliminary injunction in light of the pending state-court proceedings. That order constituted the denial of a preliminary injunction, giving rise to appellate jurisdiction under § 1292(a)(1). Any doubt over this Court's jurisdiction under § 1292(a)(1) was resolved by the district court's September 1, 2023 denial of a motion for injunction pending appeal and September 18, 2023 denial of reconsideration, which made clear that the district court believed GRE was not entitled to a preliminary injunction.

1. The District Court's July 17 Order Denied a Preliminary Injunction, Giving Rise to Appellate Jurisdiction.

Under 28 U.S.C. § 1292(a)(1), this Court has appellate jurisdiction over "interlocutory orders … refusing … injunctions." "[The] denial of a TRO may be appealed if the circumstances render the denial tantamount to the denial of a preliminary injunction." *Religious Tech. Ctr., Church of Scientology Int'l, Inc. v. Scott*, 869 F.2d 1306, 1308 (9th Cir. 1989) (internal quotation marks omitted). The denial of a TRO is "tantamount to the denial of a preliminary injunction [when] the denial of the TRO followed a full adversary hearing and in the absence of review, the appellants would be effectively foreclosed from pursuing further interlocutory relief." *Id.* (internal quotation marks omitted).

Applying that standard, the district court's July 17, 2023 order is appealable. First, the district court held an adversary hearing on the TRO. Second, the district court made clear it would not rule on GRE's request for a preliminary injunction "pending resolution of the motions now before the Montana state district court." ER-13. By effectively issuing a stay of proceedings with no fixed end date, the district court's order has the practical effect of stripping GRE of its right to seek immediate injunctive relief in a federal forum, despite the extreme harm that GRE is experiencing by being banned from selling any products in Montana.

Although the district court's July 17 order left open the possibility of granting preliminary injunctive relief at some distant point in the future, the order foreclosed

GRE from pursuing further interlocutory relief pending further developments in the state court case. Under the plain text of Section 1292(a)(1), therefore, the district court's July 17 order qualifies as an order "refusing" an "injunction." GRE has asked for a preliminary injunction, and the district court has made a legal determination that, in the current posture of the case, GRE is not entitled to one. Until the state court rules, "[t]he futility of any further hearing [is] thus patent; there [is] nothing left to talk about." *Religious Tech. Ctr.*, 869 F.2d at 1310.

This case differs materially from cases in which this Court dismissed appeals of denials of TROs when the district court was still actively considering motions for preliminary injunctions. *See, e.g.*, *Givens v. Newsom*, 830 F. App'x 560, 561 (9th Cir. 2020) (holding denial of TRO was not appealable when district court "invited Plaintiffs to present more evidence to persuade the court of their position"). Here, the district court is not actively considering any motion for preliminary injunctive relief. Instead, in its July 17 order, it concluded that injunctive relief is not presently available. It therefore refused a preliminary injunction under 28 U.S.C. § 1292(a)(1).

2. The District Court's September 18 Order Confirms that this Court Has Appellate Jurisdiction Under § 1292(a)(1).

The district court's September 18 order effectively denies preliminary injunctive relief on the merits, thus confirming that this Court has appellate jurisdiction under § 1292(a)(1).

On August 3, 2023, two weeks after the district court's initial ruling, this Court issued its decision in *Ernest Bock*, which cast significant doubt on the district court's refusal to rule on GRE's preliminary injunction motion. GRE moved for reconsideration of the district court's ruling in light of *Ernest Bock*. In addition, in its briefing supporting its motion for injunction pending appeal, GRE cited *Ernest Bock* in support of the proposition that a stay was unwarranted.

On September 1, 2023, the district court denied GRE's motion for injunction pending appeal, but its reasoning shifted significantly from its July 17 order. Rather than stating it would defer action on GRE's request for a preliminary injunction, the court stated that GRE was not entitled to a preliminary injunction, period. The court held that "GRE has not shown that it will succeed on the merits of the case," reasoning that the AVC agreement foreclosed GRE's claims. ER-143, ER-144-45. It further concluded that "GRE has failed to demonstrate that it likely will suffer irreparable harm in the absence of preliminary relief" and that "GRE also failed to demonstrate that the balance of equities tip in its favor." ER-146. For all intents and purposes, the September 1 order was an order denying a preliminary injunction.

On September 18, 2023, the district court denied GRE's motion for reconsideration. Although the court's reasoning was sparse, the court observed that GRE "raised this same argument in its motion for injunction pending appeal," and again pointed to the AVC agreement. ER-144-45. Effectively, the September 18

order reaffirms the reasoning of the September 1 order. GRE amended its notice of appeal to challenge the September 18 order.

In light of these proceedings, this Court has appellate jurisdiction under § 1292(a)(1). In *Religious Tech*, the district court denied a TRO but was "emphatic" that Ninth Circuit case law "foreclosed any interlocutory relief." 869 F.2d at 1308. This Court held it had appellate jurisdiction because "[t]he futility of any further hearing was thus patent; there was nothing left to talk about." *Id.* at 1309. As such, the denial of a TRO was "tantamount to the denial of a preliminary injunction." *Id.* (quotation marks omitted). So too here. The district court's September 1 denial of an injunction pending appeal demonstrates that the futility of any future hearing is patent: the district court has unambiguously concluded that GRE is not entitled to a preliminary injunction. The district court's September 18 denial of reconsideration, which refers back to GRE's request for an injunction pending appeal, is to the same effect. The district court has therefore effectively denied a preliminary injunction, giving rise to appellate jurisdiction under § 1292(a)(1).

B. Alternatively, This Court Has Appellate Jurisdiction Because The District Court Effectively Issued A *Colorado River* Stay.

Even if this Court interprets the district court's order as staying, rather than denying, GRE's motion for a preliminary injunction, the Court would still have appellate jurisdiction. The stay order would effectively be a *Colorado River* stay, and this Court has jurisdiction over appeals of such stays because they are deemed

collateral orders under 28 U.S.C. § 1291. *See State Water Res. Control Bd.*, 988 F.3d at 1201-02.

Under *Colorado River Water Conservation District v. United States*, 424 U.S. 800 (1976), a district court may, under extraordinary circumstances, stay a federal suit due to the presence of a concurrent state proceeding. "Generally, as between state and federal courts, the rule is that the pendency of an action in the state court is no bar to proceedings concerning the same matter in the Federal court having jurisdiction.'" *Ernest Bock*, 76 F.4th at 835 (quoting *Colorado River*, 424 U.S. at 817 (internal quotation marks and citation omitted)). However, "in *Colorado River*, the Supreme Court recognized that in exceptional circumstances, considerations of wise judicial administration, giving regard to conservation of judicial resources and comprehensive disposition of litigation can support a stay of federal litigation in favor of parallel state proceedings." *Id.* at 836 (cleaned up).

Here, to the extent the district court's initial order is not an outright denial of preliminary injunctive relief, it is a *Colorado River* stay. The district court "deem[ed] it prudent to allow the Montana state district court the opportunity to resolve the question before it." ER-12. The court explained: "GRE has not identified any unusual circumstances that would weigh in favor of the Court's intervention in an essentially parallel state court proceeding, a proceeding where the Montana state district court remains better positioned to evaluate issues involving

likely significant state interests." *Id.* The court "assume[d] that the case and motion now pending before the Montana state district court will provide GRE adequate opportunity to raise any constitutional or other procedural challenges to the Attorney General's actions." *Id.* The court therefore "defer[red] to the Montana state district court to address the motion and related issues first filed in that court." *Id.*

Although the district court did not cite *Colorado River*, its order should nonetheless be treated as a *Colorado River* stay for a straightforward reason: no other type of stay pending parallel state court proceedings exists. In *Ernest Bock*, this Court explained that "the *Colorado River* factors control whether a stay can issue in favor of parallel state proceedings." 76 F.4th at 843. "A docket management stay may not issue in favor of parallel state proceedings if the *Colorado River* factors do not support a stay." *Id.* As a practical matter, therefore, the district court entered a *Colorado River* stay. As such, even if the Court does not characterize the district court's decision as the denial of a preliminary injunction, its decision is immediately appealable.

II. The District Court Erred In Denying Injunctive Relief Because Of The Pending State Court Case.

This Court's recent decision in *Ernest Bock* establishes that the district court's July 17 order refusing to grant preliminary relief was incorrect.

The Supreme Court has held that it would be a "serious abuse of discretion" to grant a *Colorado River* stay if there is "any substantial doubt" as to whether

"parallel state-court litigation will be an adequate vehicle for the complete and prompt resolution of the issues between the parties." *Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 28 (1983). In *Ernest Bock*, this Court clarified that "[w]hen one possible outcome of parallel state court proceedings is continued federal litigation," a stay is unwarranted because there is "a 'substantial doubt' that the state court action will provide a 'complete and prompt resolution of the issues,' because the federal court may well have something 'further to do.'" 76 F.4th at 841.

Ernest Bock is dispositive here. In state court, GRE brings solely state law claims for breach of contract. *See* Counter-Complaint, *Grand River Enterprises v. Montana*, No. ADV-2012-246 (Mont. Dist. Ct. June 15, 2023). Indeed, GRE specifically stated in its state court filings that it was *not* pursuing any federal claims before the state court. *See* GRE's Brief in Support of Motion for Temporary Restraining Order, *Grand River Enterprises v. Montana*, No. ADV-2012-246 (Mont. Dist. Ct. June 15, 2023). Therefore, "one possible outcome" of the state court litigation is indeed "continued federal litigation." *Id*. Plaintiff is not raising any federal claims in state court. If Plaintiff loses the state court case, the district court will have to consider Plaintiffs separate federal law claims that were not addressed in the state court. As such, *Ernest Bock* holds that the district court should not have issued a *Colorado River* stay but should instead have adjudicated GRE's motion for a TRO and preliminary injunction and on the merits.

The district court's order cannot be justified based on its inherent docket management powers. As noted above, *Ernest Bock* held that "[a] docket management stay may not issue in favor of parallel state proceedings if the *Colorado River* factors do not support a stay." 76 F.4th at 843. And here, as shown above, the *Colorado River* factors do not support a stay.

The district court had no basis for delaying consideration of GRE's motions for a TRO and preliminary injunction. It should instead have decided those motions on their merits.

In denying GRE's motion for reconsideration, the district court offered a different theory for deferring to the state court. The court pointed to paragraph 7 of the AVC, which provides that a Montana state court "shall retain jurisdiction over the subject matter of the AVC and over Grand River for purposes of enforcement of this AVC." ER-74 ¶7. The court seemingly viewed this provision as a kind of forum-selection clause requiring GRE to bring its federal claims in state court. ER-157. This reasoning is wrong. GRE is not filing its federal suit "for purposes of enforcement of this AVC." ER-74 ¶7. It is pursuing its *federal* rights in federal court, not its contractual rights under the AVC. Indeed, it is the AG—not GRE—who has violated paragraph 7 by unilaterally enforcing the AVC before obtaining any state-court order authorizing his actions. *See infra* at III.A.2.c. Nor are GRE's

federal claims part of the "subject matter of the AVC." ER-74 ¶7. The AVC does not govern whether the AG's actions violate federal law.

III. The Court Should Reverse The Denial Of A Preliminary Injunction.

The district court's September 1 order denying a motion for injunction pending appeal—which the district court referred back to in its September 18 order denying reconsideration—explains in detail why the district court believes GRE is not entitled to a preliminary injunction. As explained above, this Court has appellate jurisdiction to review the correctness of that ruling. That ruling is wrong.

"A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Doe v. San Diego Unified Sch. Dist.*, 19 F.4th 1173, 1176 (9th Cir. 2021). "The Ninth Circuit applies a 'sliding scale' approach to preliminary injunctions such that a preliminary injunction can issue where the likelihood of success is such that serious questions going to the merits were raised and the balance of hardships tips sharply in [plaintiff's] favor." *Id.* at 1177.

Applying this test, the district court erred in denying a preliminary injunction.

A. GRE Has a High Likelihood of Success on the Merits.

GRE is likely to succeed on both its preemption claim and its Due Process claim.

1. Federal Law Preempts Montana's Attempt To Enforce The FDCA.

GRE is likely to prevail on its claim that federal law preempts Montana's attempt to enforce the FDCA.

What happened in this case was unprecedented. Montana's AG decided that GRE violated federal law—a determination no federal official has even *hinted* at. And based solely on this determination, Montana's AG unilaterally blocked distribution of all GRE products in the state without *any* process—a power that is unavailable even to *federal* enforcement officials. The AG effectively crowned himself the single most powerful enforcer of federal tobacco law.

The AG's actions are repugnant to federal law and should be enjoined immediately. First, the AG's action is preempted because only the United States may enforce the FDCA. Second, the AG's action is preempted because the FDA instituted an extreme remedy that the FDA would never institute, both as a matter of law and as a matter of policy. Third, the AG's action is preempted because GRE did not, in fact, violate federal law.

a. Only the United States may enforce the FDCA.

Montana's purported basis for removing GRE from the directory is its determination that GRE has violated the FDCA. Congress, however, has provided that only the FDA—not state governments—may enforce the FDCA. Montana's

removal of GRE from the directory based on non-compliance with the FDCA is thus preempted by federal law.

The federal government heavily regulates tobacco products. As touched on above, Sections 905(j) and 910(a) of the FDCA require the FDA to review certain tobacco products that tobacco manufacturers intend to introduce into interstate commerce for commercial distribution in the United States. *See* 21 U.S.C. §§ 387e(j), 387j(a). For the tobacco products at issue in this case, a manufacturer may seek FDA approval by showing that they are "substantially equivalent to a tobacco product commercially marketed … in the United States as of February 15, 2007." *Id.* § 387j(a)(2)(A)(i)(I). When a manufacturer submits an SE Report for FDA review for such a product, the tobacco manufacturer may continue to produce and introduce the product into interstate commerce while the application is pending. *Id.* § 387j(a)(2)(B). A product that is not approved becomes subject to certain, delineated prohibitions. *See id.* § 331.

Congress has entrusted the FDA—and the FDA alone—with enforcing these provisions of the FDCA. Section 337 of the FDCA states that, with certain exceptions not relevant here, "all … proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court held that this provision "impliedly pre-empt[s]" state-law

"claims [that] exist[] solely by virtue of the FDCA." *Id.* at 352-53; *see also, e.g.*, *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1339 (10th Cir. 2015) (Gorsuch, J.) ("*Buckman* concluded[] [that] § 337(a) preempts any state [violation] that exists 'solely by virtue' of an FDCA violation." (quoting *Buckman*, 531 U.S. at 353)). Applying *Buckman*, this Court has been "protective of the FDA's statutory monopoly on enforcement authority," *Nexus Pharms.*, 48 F.4th at 1048, and foreclosed any state action that would "duplicate or interfere with the [FDA's] own enforcement procedures," *Gilstrap v. United Air Lines, Inc.*, 709 F.3d 995, 1010 (9th Cir. 2013). Thus, actions for violation of state law "may not be pursued when[] … the [action] would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *Nexus*, 48 F.4th at 1049 (quoting *PhotoMedex*, 601 F.3d at 924).

Montana's removal of GRE from the Montana directory runs afoul of the FDCA's "prohibition of [non-federal] enforcement." *Id.* at 1048. The basis that Montana has provided for the removal is its determination that, after GRE withdrew its SE Reports for several of its tobacco products, GRE "marketed and promoted [these] cigarettes on the Directory for sale in Montana *in violation of federal law*." ER-99 (emphasis added). Yet the FDA has not determined that merely by listing GRE's brand families in its Montana certifications, GRE "marketed and promoted" the products at issue in violation of the FDCA. And the FDA has certainly not sought

to restrain GRE from listing the products. Montana's action is thus a prototypical "[determination] of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation," and as such is preempted by the FDCA. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 601 F.3d 191, 922 (9th Cir. 2010).

b. The Montana AG is enforcing federal law in a manner that violates both federal procedural law and FDA policy.

Although state enforcement of the FDCA is always preempted, the preemption problem is particularly egregious here because the AG is enforcing federal law in a manner that the FDA never could or would. The Montana AG is accusing GRE of violating federal substantive law, while simultaneously stripping GRE of all the procedural protections that accused manufacturers obtain under federal law. Moreover, the Montana AG is usurping the FDA's enforcement discretion by instituting an enforcement action that the FDA would never institute as a matter of agency policy.

The FDA's process for enforcing the FDCA's restrictions is carefully crafted to balance multiple goals and mandates, including protecting tobacco manufacturers' due process rights and maximizing willing conformance with the law. To start, before initiating an enforcement action, FDA sends to a tobacco product manufacturer a warning letter designed to "achiev[e] prompt voluntary compliance" and to "advise" the manufacturer that "failure to comply … may result in FDA

enforcement action(s), including but not limited to, civil money penalties, no-tobacco-sale order, seizure, injunction, and/or criminal prosecution." FDA, *Enforcement Action Plan for Promotion and Advertising Restrictions* § 3.3.1 (Oct. 2010), https://www.fda.gov/media/79017/download.

By statute, the FDA has discretion to decline to bring enforcement actions. *See* 21 U.S.C. § 336 ("Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning."). When it does choose to bring an enforcement action, it has discretion on what that enforcement action should be. "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349.

In many cases, the FDA seeks only monetary penalties. In those cases, it must institute an administrative proceeding that provides a manufacturer with due process and is subject to judicial review. *See* 21 U.S.C. § 335b.

The FDA *can* choose instead to pursue injunctive relief, but only in extraordinary cases. As a matter of law, the FDA must demonstrate not just that a tobacco product manufacturer "violated the FDCA," but that "there is 'some cognizable danger of recurrent violations.'" *United States v. Zollinger*, No. C22-

0278, 2023 WL 2527178, at *5 (W.D. Wash. Mar. 15, 2023) (quoting *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)). As a matter of agency discretion, the FDA seeks an injunction only in egregious cases, such as when "a firm has a history of violations, and has promised correction in the past, but has not made the corrections." *Enforcement Plan* § 3.3.4. Finally, given the high stakes for a manufacturer, the FDA may not obtain an injunction through the administrative process. Instead, the FDA must institute a proceeding in federal court to "restrain violations of this title." 21 U.S.C. § 332.

In contrast to this well-wrought process, Montana seeks to make its AG a super enforcer of federal law with powers that far exceed that of the FDA itself. It claims its AG can act based solely on his say-so that GRE violated the FDCA. The FDA could never unilaterally issue such an order—it could not obtain an injunction against a manufacturer unless it went to federal court, a proceeding in which the manufacturer would have an opportunity to defend itself.

Even a federal court, at the FDA's request, would not be legally authorized to issue the order that the AG issued unilaterally. GRE voluntarily removed the Couture brand family from GRE's Montana certification two years ago, so there is no "cognizable danger of recurrent violations." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). Moreover, the AG's order is wildly overbroad—whereas a federal court's authority is limited to injunctions to "restrain violations of this title,"

21 U.S.C. § 332, here the AG has effectively enjoined not only the purportedly violative *marketing*, but also all *sales* of the relevant products, *and* all sales of *any other* GRE tobacco products. And the AG appears to maintain that he can impose this ban indefinitely—regardless of what GRE does going forward. There could hardly be a greater "assum[ption of] enforcement power which the statute does not allow." *Nexus*, 48 F.4th at 1049.

On top of exceeding these legal boundaries, the AG's action also usurps the FDA's enforcement *discretion*. The FDA has balanced careful considerations when deciding what actions to take regarding products that are not deemed to be "substantially equivalent" to pre-2007 products. As noted above, "because the [FDCA] permits a provisional tobacco product to remain on the market pending FDA's review of the SE Report for that product, the product is likely to be available to consumers at retail locations within the United States when" the review process completes. FDA, *Draft Guidance for Industry: Enforcement Policy for Certain Marketed Tobacco Products* at 2 (Feb. 2019), https://www.fda.gov/media/120808/download. Given that fact, the FDA has had to make choices about whether to allow retailers to sell off their existing stock and, if so, how long to allow them to do so. For instance, when the FDA *completes* review of a product and affirmatively *concludes* that it is not substantially equivalent to a pre-2007 product, it has chosen "not ... to take enforcement action against a manufacturer, importer, or distributor of

the product for at least 30 calendar days from the date of the [Not Substantially Equivalent ('NSE')] order"—*i.e.*, it allows sales of remaining stock to occur, but only for a period of 30 days. *Id.* In the case of products *voluntarily withdrawn* from the SE process, however, the FDA has opted *not* to establish a set deadline for selling off wholesalers' and retailers' remaining product, presumably because there is no FDA determination that the product qualifies as NSE or otherwise presents any increased risk of harm to consumers relative to other legally marketed tobacco products. *Cf.* FDA, *Guidance for Industry and FDA Staff: Use of "Light," "Mild," "Low" or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products* at 3-5 (June 2010), https://www.fda.gov/media/78927/download (providing that wholesalers and retailers may sell out their inventories of tobacco products with descriptors such as "light" and "mild" despite FDCA provision automatically deeming such products to be "adulterated"). As such, the FDA does not, as a matter of policy, take enforcement actions against retailers and wholesalers who are merely selling off existing inventory of products voluntarily withdrawn from the SE process, much less penalize the manufacturers up the chain of distribution who already sold the products.

Even if the FDA decided to switch gears and take enforcement action regarding such products, it certainly would not seek an injunction against the manufacturer, much less the extreme order that the AG has instituted. As noted

above, as a matter of agency discretion, the FDA seeks an injunction only in egregious cases, such as when "a firm has a history of violations, and has promised correction in the past, but has not made the corrections." *Enforcement Plan* § 3.3.4. Here there is no history of violations and no past promise of corrections. To the contrary, GRE has relied on the FDA's longstanding practices of permitting wholesalers and retailers to sell out inventory that was perfectly legal when obtained from the manufacturer.

Montana may disagree with the FDA's enforcement choices. But Section 337 prevents Montana—or anyone else—from overriding the FDA's judgment. The sell-off of existing stock after a voluntary SE Report withdrawal is "generally accepted," *Buckman*, 531 U.S. at 351, and Montana may not take from "the FDA discretion to temper enforcement or not to enforce in circumstances it deems appropriate." *Nexus*, 48 F.4th at 1048.

Finally, permitting Montana to serve as a super FDCA enforcer would "interfere with the [FDCA's] own enforcement procedures." *Gilstrap*, 709 F.3d at 1010. Tobacco manufacturers sometimes voluntarily withdraw SE Reports based on a decision that moving forward with the relevant product no longer makes business sense. Because the FDA allows wholesalers and retailers to sell out their inventory, this action does not prejudice those wholesalers and retailers who may have obtained the products in reliance on the manufacturer's application. But if state

AGs can overrule the FDA's enforcement discretion and ban all sales indefinitely when a manufacturer exercises this option, manufacturers will be forced to prosecute their SE Reports to the bitter end. The result would be a "deluge of [requests] that the Administration neither wants nor needs, resulting in additional burdens on … the FDA[]." *Buckman*, 531 U.S. at 351.

In short, under the FDCA, Montana may not "bypass the FDA" and "make a decision the FDA chose not to make." *PhotoMedex*, 601 F.3d at 929. Section 337(a) thus preempts Montana's attempt to enforce the FDCA.

c. GRE did not violate the FDCA.

Montana's action is all the more egregious because GRE has not, in fact, violated the FDCA. To start, the FDCA contains no flat prohibition on "marketing or promoting" products that do not successfully complete the SE process. Rather, it contains three prohibitions related to products deemed "adulterated or misbranded": the "introduction or delivery for introduction" of such products "into interstate commerce," 21 U.S.C. § 331(a); the "receipt" of such products "in interstate commerce" "and the delivery or proffered delivery thereof," *id.* § 331(c); and the "manufacture" of such products," *id.* § 331(g). Montana has never identified which of these prohibitions GRE purportedly violated.

Even to the extent these prohibitions encompass "marketing" and "promoting," GRE did not market or promote the product styles at issue after it voluntarily

withdrew the relevant products from SE review. The only thing GRE did was include the brand families on its Montana certification form. Including products in a statutorily required certification form is not "marketing" and "promoting" of specific product styles in violation of the FDCA.[4] *Cf. Perez v. Nidek Co.*, 711 F.3d 1109, 1119–20 (9th Cir. 2013) (stating that there was "no case where a court has allowed a plaintiff to bring suit solely for failure to disclose lack of FDA approval" (footnote omitted)).

Montana's botched reading of the FDCA underscores the preemptive effect of Section 337(a). "As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States'" separate interpretations of the FDCA would "dramatically increase the burdens facing" tobacco manufacturers—"burdens not contemplated by Congress in enacting the FDCA." *Buckman*, 531 U.S. at 350. Indeed, if Montana's interpretation of the FDCA is any guide, tobacco manufacturers could become subject to "readings" of the FDCA that have no basis in the text at all. Congress foreclosed that possibility in Section 337(a).

d. The AG is not enforcing state law.

In an effort to avoid federal preemption, Montana argued below that it is enforcing state law, not federal law. ECF 37 at 9-10. In its order denying an

[4] Moreover, the FDCA's prohibitions concern tobacco *products* and *styles*, while the listings on the Montana directory were brand *families*—a mismatch Montana never addresses.

injunction pending appeal, the district court similarly suggested that GRE "failed to provide the required certification" in violation of state law. ER-145. That is wrong. Montana's purported state-law enforcement action is premised on GRE's alleged violation of federal law. The enforcement action is therefore preempted.

To begin, the record leaves little doubt that Montana is enforcing federal law. The June 14, 2023 letter notifying GRE of its removal from the directory stated clearly and repeatedly that Montana removed GRE because it violated the Assurance of Voluntary Compliance ("AVC") by "market[ing] and promot[ing] [its] cigarettes on the Directory for sale in Montana *in violation of federal law*." ER-99 (emphasis added); *see also* ER-100 ("GRE … marketed and promoted on the Directory to the Montana public cigarettes that it knew to be adulterated and misbranded for over two years *in violation of federal law*." (emphasis added)); *id*. ("GRE continued to affirmatively put forward and market the adulterated and misbranded brands/brand styles for sale on the 2020 Directory and the 2021 Directory *in violation of federal law*…." (emphasis added)). Likewise, in the pending state court proceeding, Montana has maintained that GRE violated the AVC by failing to "compl[y] with *federal law*." TEU Response to GRE Motion for Temporary Restraining Order at 14, *Grand River Enterprises v. Montana*, No. ADV-2012-246 (Mont. Dist. Ct. June 19, 2023). (emphasis added) ("GRE's own filing undercuts its theory that it is compliant with federal law."); *id*. at 12 ("GRE clearly … promoted and marketed

the adulterated and misbranded brand/brand styles in violation of FDA's 2/21/2020 Letter to GRE."). Indeed, Montana's state court brief never even cites the provision of Montana law that Montana now claims, in federal court, is a state-law basis for GRE's removal. *Compare* ECF 37 at 9-10 (claiming that GRE violated Mont. Code Ann. § 16-11-503(4)), *with* ER-14-36 (never citing Mont. Code Ann. § 16-11-503(4)). And even Montana's response brief in the district court states that Montana acted because GRE violated federal law. ECF 37 at 2 (claiming that by listing the relevant brand families on its 2020 and 2021 certifications, GRE violated "the FDA's immediate requirement to stop sales and marketing," and that the AG removed GRE from the directory "[b]ased on this violation"); *id*. at 18 (claiming that the AG has an "interest in … protecting the public from misbranded and adulterated products").

But even accepting Montana's newfound contention that it is enforcing state law, Montana's action is still preempted. *Buckman* holds that even allegations of state-law violations are preempted when the state-law violation hinges on an underlying FDCA violation. 531 U.S. at 353. And here, it is obvious that the purported state-law violation hinges on the purported FDCA violation. Montana maintains that "[u]nder Mont. Code Ann. § 16-11-503(4), and the certification documentation … GRE is required to notify the AG of any modification to the brands listed in its certification." ECF 37 at 10. But Mont. Code Ann. § 16-11-

503(4) states merely that "[a] tobacco product manufacturer shall update its list of brand families 30 calendar days prior to any addition to or modification of its brand families by executing and delivering a supplemental certification to the attorney general and the director of the department." Similarly, the parts of the certifications that Montana points to require only that an applicant (1) "update and keep current all information provided," (2) ensure that the information is "true and correct," and (3) certify compliance with "applicable federal, state and local laws." ER-40; *see* ER-38. Nothing in these provisions gives any suggestion that GRE did anything wrong.

Why, then, does Montana claim that GRE violated these provisions? Because, according to Montana, "the FDA had modified the classification of the Eight Brand Styles to adulterated and misbranded products." ECF 37 at 10. As Montana's statement makes clear, this case is *Buckman* all over again. Montana claims that GRE's products are "adulterated and misbranded" under federal law, and because of that, GRE also violated state law. As such, the asserted FDCA violation is a "critical element," *Buckman*, 531 U.S. at 353, of Montana's case, triggering federal preemption.

e. The AVC does not alter the analysis.

In holding that GRE lacked a likelihood of success on the merits, the district court pointed to paragraph 4 of the AVC, which provides that "Grand River shall

remain in compliance with all local, state, and federal laws." ER-73 ¶4. According to the district court, "[t]he Attorney General's act instead proves more akin to a repudiation of an agreement upon a material breach of the agreement's terms." ER-145. In the district court's view, *Buckman* does not hold that "federal preemption would apply to an alleged breach of the terms of an express voluntary agreement." *Id.* The district court's reasoning is incorrect. The AVC does not and cannot transform the AG into a super-enforcer of federal law.

To begin, the AG's reading of the AVC is implausible. In agreeing to comply with federal law, GRE did not consent to the Montana AG becoming the *arbiter* of whether GRE complies with every provision of the U.S. Code. Rather, paragraph 4 is triggered when a duly authorized adjudicator—such as a federal court—determines that GRE violated federal law.

The AG's interpretation of the AVC makes even less sense when considering the AVC's purpose. The parties entered into the AVC in order to settle their dispute over whether Montana had regulatory jurisdiction over GRE under state law. Without conceding Montana had such jurisdiction, GRE agreed to voluntarily pay escrow deposits. GRE did not commit the inexplicable blunder of acquiescing to the AG's authority to unconstitutionally enforce federal law in violation of the Supremacy Clause.

Even if the AVC allowed the AG to unilaterally determine FDCA violations, Section 337(a) would preempt that aspect of the AVC. Federal preemption protects the federal government's interest in being the exclusive enforcer of the FDCA—and the federal government never agreed to the AVC. A state cannot usurp federal law enforcement authority merely by extracting "voluntary" agreements from tobacco manufacturers to submit to the AG's authority as a condition of selling tobacco products in the state.

Indeed, Montana's own practices illustrate why a state cannot circumvent Section 337(a) merely by using its coercive regulatory powers to obtain a tobacco manufacturer's "agreement" to Montana enforcing the FDCA. In recent years, the certification form that *all* tobacco manufacturers are required to submit to be listed on the Montana directory has required manufacturers to declare that they are "in full compliance with … applicable federal, state and local laws" and acknowledge that they "must remain in compliance with such laws to be listed on the Tobacco Product Directory." *E.g.*, ER-98. Taking Montana's logic to its natural conclusion, then, it can now enforce the FDCA (and any other federal law) against *any* tobacco manufacturer whose products have recently sold in Montana. The Court should reject Montana's effort to exercise authority it does not have.

2. Montana Violated Due Process.

GRE is also likely to prevail on its claim that Montana deprived GRE of its property interests without due process of law.

a. Due process required a pre-deprivation hearing.

The Fourteenth Amendment prevents Montana from "depriv[ing] any person of … property, without due process of law." U.S. Const. amend. XIV. Generally, "due process of law requires notice and an opportunity for some kind of hearing prior to the deprivation of a … property interest." *Halverson v. Skagit County*, 42 F.3d 1257, 1260 (9th Cir. 1994) (cleaned up).

Here, the failure to provide a pre-deprivation hearing is obvious. Not only did Montana provide no hearing before it removed GRE from the directory, but it acted with no warning whatsoever. Indeed, Montana waited until *two years* after GRE stopped listing the brand at issue in its Montana certification before deciding to remove GRE entirely from the directory based on that conduct. *Supra* Statement of the Case, Section III. And then when Montana did act, it did so unilaterally, without providing GRE any opportunity—a hearing or otherwise—to advocate for its right to remain listed.

The district court nonetheless concluded that GRE lacked a likelihood of success on its due process claim because "GRE's continued participation in Montana's tobacco market does not constitute a protected entitlement, but rather

exists as a privilege of Montana's licensing scheme." ER-144. The district court's reasoning is incorrect. It is true, as the district court stated, that Montana's directory operates as a licensing regime: just as a doctor or a lawyer must obtain a professional license to offer its services within a state, so must a tobacco manufacturer be listed on the directory for its products to be sold in Montana. But characterizing Montana's directory as a licensing scheme does not *close* the door to a due process claim, as the district court believed: it *opens* the door to a due process claim. Although such licenses, permits, and similar approvals are "government benefit[s]," *Thorton v. City of St. Helens*, 425 F.3d 1158, 1164 (9th Cir. 2005), "[t]he Ninth Circuit has long held that applicants have a property interest protectible under the Due Process Clause where the regulations establishing the entitlement to the benefit are … mandatory in nature," *Foss v. Nat'l Marine Fisheries Serv.*, 161 F.3d 584, 588 (9th Cir. 1998).

That is the case here. Montana's escrow statutes "direct[] that a [tobacco company shall be listed on the directory] upon compliance with certain criteria, none of which involve the exercise of discretion by [the Montana AG]," such that inclusion on the directory is a "property right." *Thornton*, 425 F.3d at 1165. They provide that "the attorney general *shall* develop and publish on the attorney general's website a directory listing all tobacco product manufacturers that have provided current and accurate certifications…, except as otherwise provided in this section." Mont. Code Ann. § 16-11-504(1) (emphasis added). "Shall" in this context "denotes

a mandatory duty." *Sierra Club v. Whitman*, 268 F.3d 898, 904 (9th Cir. 2001). The Montana AG must include a tobacco product manufacturer on the directory so long as the manufacturer has "provided current and accurate certifications." Mont. Code Ann. § 16-11-504(1). And this mandatory duty continues even after the directory is published: "The attorney general *shall* update the directory as necessary in order to correct mistakes and *to add* or remove a tobacco product manufacturer or brand family to keep the directory in conformity with the *requirements* of this part." *Id.* § 16-11-504(4) (emphases added). If the Montana AG fails to meet these obligations, a manufacturer may seek judicial review, where the Montana AG's decision must be reversed if "in violation of … statutory provisions." *Id.* § 2-4-704(2)(a)(i); *see id.* § 16-11-510 (providing for judicial review). These provisions are thus mandatory and confer on GRE a protected property interest in having its products sold within Montana. Indeed, at least three different courts have awarded preliminary due process relief based on a state's exclusion, and threat of exclusion, of a tobacco manufacturer from its directory without a hearing. *See* ER-41-64 (providing the relevant orders).

Even if GRE lacks a property interest in a license, it would still have a property interest in its goodwill. GRE's goodwill is "a property interest entitled to protection" under the Fourteenth Amendment's Due Process Clause. *Soranno's Gasco, Inc. v. Morgan*, 874 F.2d 1310, 1316 (9th Cir. 1989). By statute, Montana expressly

recognizes "the goodwill of a business" as a property interest. Mont. Code Ann. § 70-1-104(4) ("There may be ownership of[] … such products of labor or skill as … the goodwill of a business…."). And by banning the sale of GRE's products, Montana deprives GRE of its goodwill. *See* ER-69 ¶¶14-15.

b. GRE's participation in a regulated industry does not undermine its due process claim.

In dicta in its initial order denying the TRO, the district court "questioned" whether GRE possesses a protected property right given that GRE "functions as a willing participant in [a] heavily regulated industry." ER-11. Montana's regulation of tobacco products does not undermine GRE's due process claim. In a regulated industry, an industry participant possesses a property interest where, as here, the regulations governing entrance into the market are "mandatory in nature." *Foss*, 161 F.3d at 588. Even Montana has recognized that inclusion on the state directory is an entitlement. *E.g.* ER-101 (letter notifying GRE of removal from directory) (acknowledging that a tobacco manufacturer possesses an "entitlement to be on [the] Directory" if it meets its burden of proof). Indeed, there is no "discretion" that could be exercised here—the determination of whether GRE violated federal law is the type of "application of law to fact that does not entail the exercise of discretion." *Ramadan v. Gonzales*, 479 F.3d 646, 656 (9th Cir. 2007) (per curiam). GRE

therefore has a non-discretionary property interest in being included on the Directory, and has a right to due process before being stripped of that interest.

c. The AVC does not change the analysis.

The district court reasoned that the AVC "confirm[s] the fact that GRE possesses a privilege, as opposed to a protected entitlement that rises to the level of a protected property right." ER-144. It pointed to paragraph 9 of the agreement, which provides that "[f]ailure to abide by any terms of this AVC is grounds for the immediate removal of Grand River of the Montana Directory." ER-74 ¶9. But this paragraph is only triggered when a violation of the AVC occurs. Here, the alleged violation of the AVC is based on paragraph 4's requirement that GRE comply with federal law, but as explained above, no violation of paragraph 4 occurs unless a federal court or other duly authorized adjudicator of federal law concludes that GRE violated federal law. *Supra* III.A.1. So paragraph 9 has not been triggered.

Nor does paragraph 9 confer unilateral authority on the AG to remove GRE from the directory even in the event of a violation of the AVC. Paragraph 9 itself is silent on the issue of *who* may compel GRE's removal. And surrounding context demonstrates that removal from the directory pursuant to paragraph 9 requires state court action. Namely, paragraph 7 provides that the state court retains jurisdiction "for purposes of enforcement of this AVC"; paragraph 10 waives GRE's immunity from suit to allow actions for enforcement of the AVC; and paragraph 8 provides

that "[i]n the event that [GRE] violates any provision of this AVC, [GRE] shall reimburse the State for any costs the State incurs, including reasonable attorney's fees, in any proceeding to enforce the provisions of this AVC." ER-74 ¶¶7-8, 10. These provisions would be pointless if the AG could unilaterally enforce the AVC by removing GRE from the directory based solely on his unilateral decision that GRE violated the AVC's terms.

Montana nevertheless insists that under its reading, these provisions do have meaning because they apply to the pending state proceeding *initiated by GRE*. ECF 37 at 15. But an action by GRE that challenges the AG's unlawful action is not a proceeding by "the State … to enforce the provisions of this AVC." ER-74 ¶ 8. Indeed, Montana's answer does not and cannot explain the waiver of GRE's immunity, which is necessary only to ensure Montana can bring suit *against* GRE. *See* ER-74 ¶10. These provisions lay out a process where Montana must go to court before penalizing GRE for an alleged AVC violation, in conformance with GRE's due process right to a pre-deprivation hearing.

Montana's interpretation is especially baseless because the AVC *cannot*, as a matter of federal law, deprive GRE of its due process rights. Montana has stressed that "AVC was a bargained for agreement, not … a unilateral power-grab by the AG." ECF 37 at 14. But a state "may not exact as a condition of [a] corporation's engaging in business within its limits that its rights secured to it by the Constitution

of the United States may be infringed." *Hanover Fire Ins. Co. v. Carr*, 272 U.S. 494, 507-08 (1926); *see also, e.g.*, *S. Pac. Co. v. Denton*, 146 U.S. 202, 207 (1892) (same); *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 607 (2013) (citing this point). And that is so regardless of whether the exaction is purportedly bargained for, as such an exaction "is not ratified by an acceptance." *United States v. Chi., Milwaukee, St. Paul & Pac. R.R. Co.*, 282 U.S. 311, 328 (1931). At a minimum, constitutional avoidance concerns counsel against Montana's extreme reading of the AVC.

* * *

Federal law preempts Montana's attempt to enforce the FDCA, and Montana violated Due Process when it removed GRE from the directory without a hearing. For these reasons, GRE is likely to prevail on the merits.

B. GRE Will Suffer Irreparable Harm Absent An Injunction.

GRE experiences irreparable financial and reputational harm each day its products are prevented from being sold in Montana. ER-69 ¶14. Financial harm is irreparable when a plaintiff is barred from suing a defendant for monetary damages. *Idaho v. Couer d'Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015). Here, Montana's Eleventh Amendment immunity prohibits GRE from suing the AG to recover the damages it has incurred because of the AG's ultra vires decision to pull GRE

products from the Montana market. As such, GRE's financial harm is irreparable absent an injunction. *See id.*

GRE also suffers irreparable harm to its market share and goodwill each day its products remain banned from the market. ER-69 ¶ 14. "Without court intervention, GRE's products will lose wholesalers and customers in Montana, and its market share that has taken years to establish." ER-69 ¶ 15. "Evidence of threatened loss of prospective customers or goodwill certainly supports a finding of the possibility of irreparable harm." *Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 841 (9th Cir. 2001); *see also Gallagher Benefit Servs., Inc. v. De La Torre*, 283 F. App'x 543, 546 (9th Cir. 2008) (same); *Rent–A–Ctr., Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir. 1991) (same). Below, Montana has not contested—and thus has conceded—this irreparable harm. *See* ECF 37 at 16-17; *Facebook, Inc. v. Power Ventures, Inc.*, 252 F. Supp. 3d 765, 783 (N.D. Cal. 2017) (Koh, J.), *aff'd*, 749 F. App'x 557 (9th Cir. 2019).

The district court stated that allegations of "harm to potential future business relations" are too "speculative" to support an injunction. ER-146. But GRE is not merely relying on "harm to potential future business relations." *Id.* All of GRE's products are banned from sale in Montana, right now.

The district court also observed that only 600 units of the allegedly "adulterated" brand styles were sold after GRE withdrew the SE Reports. *Id.* GRE's

harm has nothing to do with those brand styles. The AG has banned GRE from selling *all products* in Montana—even brand styles that the AG *does not* allege to be "adulterated."

C. The Balance of Hardships And Public Interest Tips In Grand River's Favor.

While GRE will suffer significant harm absent an injunction, the harm to the AG and the public interest due to any injunction will be minimal. The brand styles that form the basis of the AG's revocation have not been sold in Montana for over three years. ER-67-68 ¶8. Moreover, the AG knew that GRE had requested the FDA withdraw the relevant tobacco products from SE review for over a year before it issued its notice banning sales of GRE products in Montana. *Supra* Statement of the Case, Section III. "If th[is] harm does exist ... it is not new." *Stuhlbarg Int'l Sales Co.*, 240 F.3d at 841. An injunction to return to the status quo while litigation proceeds will simply return Montana to the position it itself chose to be in for well over a year. This pales in comparison to the hardship GRE is currently suffering.

The public interest also weighs in favor of an injunction. "[I]t is clear that it would not be equitable or in the public's interest to allow the state ... to violate the requirements of federal law, especially when there are no adequate remedies available" to compensate GRE for its injury. *Arizona Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1069 (9th Cir. 2014) (quotation marks omitted).

The district court stated there was a "public interest in ensuring the safety of tobacco products in the state." ER-147. However, GRE has not produced or sold the allegedly adulterated brand products for years, and these products were removed from the Montana directory in 2022. The AG has not justified his action based on safety. Indeed, the only products that are the subject of the AG's recent ban are products FDA *has authorized to be sold*.

The court should return the parties to the status quo pending adjudication of GRE's claims. Contrary to the district court's holding, the status quo is not "GRE's removal from the Montana Directory." *Id.* The status quo is the position the parties occupied *before* the illegal removal from the Montana Directory—the position Montana itself chose to be in for well over a year. *See GoTo.com, Inc. v. Walt Disney Co.,* 202 F.3d 1199, 1210 (9th Cir. 2000) (defining the status quo for purposes of preliminary injunction analysis as "not simply to any situation before the filing of a lawsuit, but instead to the last uncontested status which preceded the pending controversy.").

CONCLUSION

The Court should reverse the district court's denial of the preliminary injunction and direct the district court to enter a preliminary injunction.

Respectfully Submitted,

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DATED this 21 day of September, 2023

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Replacement Brief, Statutory Addendum, and Excerpts from the Record

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STATUTORY ADDENDUM

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Montana Tobacco Directory Statute

16-11-504. Directory of cigarettes approved for stamping and sale. (1) Not later than July 16, 2003, the attorney general shall develop and publish on the attorney general's website a directory listing all tobacco product manufacturers that have provided current and accurate certifications conforming to the requirements of 16-11-503 and all brand families that are listed in the certifications, except as otherwise provided in this section.

(2) The attorney general may not include or retain in the directory the name or brand families of any nonparticipating manufacturer that has failed to provide the required certification or whose certification the attorney general determines is not in compliance with 16-11-503, unless the attorney general has determined that the violation has been cured to the satisfaction of the attorney general.

(3) Neither a tobacco product manufacturer nor a brand family may be included or retained in the directory if the attorney general concludes, in the case of a nonparticipating manufacturer that:

(a) an escrow payment required pursuant to 16-11-403 for any period for any brand family, whether or not listed by the nonparticipating manufacturer, has not been fully paid into a qualified escrow fund governed by a qualified escrow agreement that has been approved by the attorney general; or

(b) an outstanding final judgment, including interest on the judgment, for a violation of 16-11-403 has not been fully satisfied for the brand family or the manufacturer.

(4) The attorney general shall update the directory as necessary in order to correct mistakes and to add or remove a tobacco product manufacturer or brand family to keep the directory in conformity with the requirements of this part. The attorney general shall post in the directory and transmit by electronic mail and certified mail, return receipt requested, to each wholesaler notice of the intended removal from the directory of a tobacco product manufacturer or brand family no less than 30 days prior to the removal. During that period, cigarettes of the tobacco product manufacturer or brand family subject to the notice are contraband under 16-11-147 and the affixing of tax insignia to or the sale or possession for sale of the cigarettes is unlawful as provided in 16-11-505, except that, notwithstanding the provisions of 16-11-147 and 16-11-505:

(a) a wholesaler may affix tax insignia to, possess for sale, or sell at wholesale cigarettes of any tobacco product manufacturer or brand family subject to notice of removal under this subsection (4) if the cigarettes were shipped to the wholesaler on or before the date of issuance of the notice and if the total number of the cigarettes sold by the wholesaler following issuance of the notice of removal and prior to reinstatement of the tobacco product manufacturer or brand family in the directory does not exceed a number that is the average of the number of cigarettes of the tobacco product manufacturer or brand family sold by the wholesaler during each of the 3 months preceding the issuance of the notice; and

(b) a licensed seller at retail may possess and sell cigarettes of a tobacco product manufacturer or brand family that the attorney general has removed from the directory or that is subject to notice of removal if the cigarettes were lawfully shipped to the retailer before the issuance of the notice of removal or after the issuance of notice of removal but before the attorney general removes the tobacco product manufacturer or brand family from the directory. A contract with a tobacco product manufacturer that has been removed from the directory that purports to require, contemplate, or provide for delivery of cigarettes or tobacco products in any applicable brand family after the date of removal from the directory is not valid or enforceable.

(5) Every wholesaler shall provide and update as necessary an electronic mail address to the attorney general for the purpose of receiving any notifications required by this part.

Food Drug and Cosmetics Act (Relevant Excerpts)

§331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. . . .

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. . . .

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

§332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown [1] to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

§335b. Civil penalties

(a) In general

Any person that the Secretary finds-

(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

(6) is a person that has an approved or pending drug product application and has knowingly-

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of, a person who was debarred under section 335a of this title, or

(7) is an individual debarred under section 335a of this title and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application, shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

(b) Procedure

(1) In general

(A) Action by the Secretary

A civil penalty under subsection (a) shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) Action by the Attorney General

In lieu of a proceeding under subparagraph (A), the Attorney General may, upon request of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a). Such

an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this chapter.

(2) Amount

In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

(3) Limitation on actions

No action may be initiated under this section-

(A) with respect to any act described in subsection (a) that occurred before May 13, 1992, or

(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

(c) Judicial review

Any person that is the subject of an adverse decision under subsection (b)(1)(A) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(d) Recovery of penalties

The Attorney General may recover any civil penalty (plus interest at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

(e) Informants

The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a)) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed-

(1) $250,000, or

(2) one-half of the penalty so imposed and collected, whichever is less. The decision of the Secretary on such award shall not be reviewable.

§336. Report of minor violations

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

§337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)-

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or

formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

§387b. Adulterated tobacco products

A tobacco product shall be deemed to be adulterated if-

(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 387s of this title by the date specified in section 387s of this title or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 387g of this title unless such tobacco product is in all respects in conformity with such standard;

(6)(A) it is required by section 387j(a) of this title to have premarket review and does not have an order in effect under section 387j(c)(1)(A)(i) of this title; or

(B) it is in violation of an order under section 387j(c)(1)(A) of this title;

(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 387f(e)(1) of this title or an applicable condition prescribed by an order under section 387f(e)(2) of this title; or

(8) it is in violation of section 387k of this title.

§387c. Misbranded tobacco products

(a) In general

A tobacco product shall be deemed to be misbranded-

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing-

(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

(D) the statement required under section 387t(a) of this title, except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

(3) if any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 387e(b), 387e(c), 387e(d), or 387e(h) of this title, if it was not included in a list required by section 387e(i) of this title, if a notice or other information respecting it was not provided as required by such section or section 387e(j) of this title, or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 387e(e) of this title as the Secretary by regulation requires;

(7) if, in the case of any tobacco product distributed or offered for sale in any State-

(A) its advertising is false or misleading in any particular; or

(B) it is sold or distributed in violation of section 387f(d)(5) of this title or of regulations prescribed under section 387f(d) of this title;

(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product-

(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

(B) a brief statement of-

(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components

of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

(9) if it is a tobacco product subject to a tobacco product standard established under section 387g of this title, unless it bears such labeling as may be prescribed in such tobacco product standard; or

(10) if there was a failure or refusal-

(A) to comply with any requirement prescribed under section 387d or 387h of this title; or

(B) to furnish any material or information required under section 387i of this title.

§387e. Annual registration (Relevant Excerpts)

(j) Report preceding introduction of certain substantially equivalent products into interstate commerce

(1) In general

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)-

(A) the basis for such person's determination that-

(i) the tobacco product is substantially equivalent, within the meaning of section 387j of this title, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 387j of this title, is substantially equivalent and that is in compliance with the requirements of this chapter; or

(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this chapter, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

(B) action taken by such person to comply with the requirements under section 387g of this title that are applicable to the tobacco product.

(2) Application to certain post–February 15, 2007, products

A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009, shall be submitted to the Secretary not later than 21 months after June 22, 2009.

(3) Exemptions

(A) In general

The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 387j of this title, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that-

(i) such modification would be a minor modification of a tobacco product that can be sold under this chapter;

(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

(iii) an exemption is otherwise appropriate.

(B) Regulations

Not later than 15 months after June 22, 2009, the Secretary shall issue regulations to implement this paragraph.

§387j. Application for review of certain tobacco products (Relevant Excerpts)

(a) In general

(1) New tobacco product defined

For purposes of this section the term "new tobacco product" means-

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless-

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product-

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product-

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period, except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 387e(j) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product-

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to

the tobacco product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.