

United States Court of Appeals
for the Fifth Circuit

United States Court of Appeals
Fifth Circuit

FILED

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Lyle W. Cayce
Clerk

No. 25-60200

TEXAS TOBACCO BARN, L.L.C., *doing business as* TXVAPEBARN,

Petitioner,

versus

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*; FOOD & DRUG ADMINISTRATION; CENTER FOR TOBACCO PRODUCTS; MARTIN A. MAKARY, *FDA Commissioner,*

Respondents.

Petition for Review from an Order of the
Department of Health & Human Services
Agency No. A-25-15

Before JONES, DUNCAN, and DOUGLAS, *Circuit Judges.*

STUART KYLE DUNCAN, *Circuit Judge:*

Texas Tobacco Barn (TTB) petitions for review of a \$19,192 civil penalty for allegedly selling unauthorized vape products. The penalty was levied by the Department of Health & Human Services (HHS) following an agency proceeding that lacked a jury. We conclude that this process denied TTB its rights under the Seventh Amendment. Accordingly, we GRANT the petition and VACATE the agency's decision.

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I

We begin by surveying the regulatory landscape for vape products and then describe how this case came before us.

A

Congress passed the Food, Drug, and Cosmetic Act (FDCA) in 1938 to stop the sale of “any food, drug, device, or cosmetic that is adulterated or misbranded.” Federal Food, Drug, and Cosmetic Act, ch. 675, sec. 301(a), 52 Stat. 1040, 1042 (1938). The law requires the Food and Drug Administration (FDA) to authorize new drugs before they can be sold in interstate commerce. *See FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 549 (2025).

In 2000, the Supreme Court held that the FDCA did not authorize regulating tobacco. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000). Congress responded by enacting the Family Smoking Prevention and Tobacco Control Act (TCA), which empowers FDA to regulate “tobacco products” in two ways. *See* Pub. L. No. 111-31, 123 Stat. 1776 (2009); *White Lion Invs.*, 604 U.S. at 551. First, FDA can regulate “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.” 21 U.S.C. § 387a(b). Second, it can regulate other things the agency “deems” a “tobacco product[.]” *Ibid.*¹ (We refer to this as the “deeming provision.”)

In 2016, FDA issued “a rule deeming e-cigarettes and e-liquids to be ‘tobacco products.’” *White Lion Invs.*, 604 U.S. at 555 (quoting 81 Fed. Reg. 28974, 29028 (May 10, 2016)). Unlike conventional tobacco products,

¹ A “tobacco product” is defined as “any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product.” 21 U.S.C. § 321(rr)(1).

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e-cigarettes (or “vapes”) do not burn tobacco but instead use a heating element to turn liquid nicotine “into a nicotine-infused vapor.” *Id.* at 553. As a result, any new vape product now needs FDA approval to be sold. 21 U.S.C. § 387j(a)(1)–(2). To apply for authorization, vape manufacturers detail their products’ components and additives, manufacturing method, proposed labeling, and health risks. *See id.* § 387j(b)(1). FDA must deny authorization if the manufacturer fails to show a product “would be appropriate for the protection of the public health,” among other reasons. *Id.* § 387j(c)(2)(A)–(D). If sold without FDA authorization, tobacco products are considered “adulterated” and “misbranded.” *Id.* §§ 387b(6)(A), 387c(a)(6), 331(a).

FDA enforces this prohibition in two ways: (1) by filing suit in federal district court to enjoin sales, *id.* § 332, or (2) by bringing an HHS proceeding to exact civil penalties, *id.* § 333(f)(5)(A), (f)(9). HHS proceedings lack juries. *See id.* § 333(f)(5)(A); 21 C.F.R. 17.1–17.47 (2025). If an alleged violator loses before HHS, it may seek review in the D.C. Circuit or any circuit where the seller resides or conducts business. 21 U.S.C. § 333(f)(6); *see also FDA v. R.J. Reynolds Vapor Co.*, 606 U.S. 226, 230–31 (2025). Civil penalties may reach up to \$15,000 per violation and, if the seller had intent, may be enhanced up to \$250,000 per 30-day period, capped at \$10,000,000. 21 U.S.C. § 333(f)(9)(A), (f)(9)(B)(i). HHS considers factors akin to culpability, deterrence, and recidivism when it sets penalties, which are paid to the United States Treasury. *See id.* § 333(f)(5)(B); 21 C.F.R. § 17.54 (2025).

B

TTB runs a laboratory and adjoining retail space in Lubbock, Texas, where it makes and sells e-liquids and other vape products. In September 2020, TTB applied for authorization to sell more than 2,200 different vape

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products. Several were e-liquids TTB called “Barn Brewed Beetle Juice.” FDA denied authorization, warned TTB the products were “adulterated” and “misbranded,” and threatened enforcement if TTB sold them.

Sixteen months later, FDA wrote TTB that it had discovered TTB was making and selling a variant of unapproved Barn Brewed Beetle Juice. TTB responded it would stop making it. But in May 2023, FDA inspected TTB and discovered it was selling the unauthorized e-liquid anyway.

Three months later, FDA brought an HHS proceeding alleging TTB made and sold adulterated and misbranded e-liquid products. It sought a civil penalty of \$19,192.

TTB admitted FDA had not authorized Barn Brewed Beetle Juice. But it denied the FDA inspector saw that e-liquid for sale. TTB also challenged FDA’s authority by arguing that Congress improperly delegated authority to FDA to regulate vapes and that the HHS proceeding violated its Seventh Amendment jury-trial right as explained in *SEC v. Jarkesy*, 603 U.S. 109 (2024).

At a hearing before an HHS administrative law judge (ALJ), FDA presented exhibits, including photos from the May 2023 inspection, and the FDA inspector’s testimony. TTB presented no evidence. FDA’s photos depicted e-liquid products, including Barn Brewed Beetle Juice variants, for sale in TTB’s retail area. An FDA witness confirmed TTB used its laboratory and manufacturing space to make the products it sold in its adjoining retail space.

Nevertheless, TTB contended that FDA failed to show it used out-of-state ingredients in its unauthorized e-liquid. The ALJ rejected that argument and concluded FDA demonstrated, by a preponderance of the evidence, that TTB sold unauthorized Barn Brewed Beetle Juice containing out-of-state ingredients. The ALJ also explained she lacked jurisdiction to

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decide TTB's nondelegation and Seventh Amendment defenses. She imposed the requested penalty of \$19,192 because TTB received a letter warning of its potential violations yet sold the unauthorized product anyway.

TTB appealed to HHS's Departmental Appeals Board. It reasserted its nondelegation and Seventh Amendment defenses and argued again that FDA failed to establish out-of-state ingredients were in its product. The Appeals Board issued a final decision affirming the ALJ's decision. Despite agreeing the ALJ lacked jurisdiction to decide TTB's nondelegation and Seventh Amendment defenses, the Appeals Board offered its view on *Jarkesy* and advised that the public-rights exception may apply.

TTB filed this timely petition for review under 21 U.S.C. § 333(f)(6).

II

We review final agency decisions under the Administrative Procedure Act. We may “set aside” a decision if it exceeds statutory authority or is arbitrary or capricious, an abuse of discretion, contrary to constitutional right, unsupported by substantial evidence, or otherwise not in accord with law. 5 U.S.C. § 706(2)(A)–(C), (E). TTB bears the burden to show the decision was invalid. *See Tex. Clinical Labs, Inc. v. Sebelius*, 612 F.3d 771, 775 (5th Cir. 2010). We review all questions of law *de novo*. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412–13 (2024).

III

TTB challenges the final decision on three grounds. First, it argues the deeming provision unconstitutionally delegated to FDA the authority to deem vape products as “tobacco products.” Second, it argues the HHS proceeding violated its Seventh Amendment jury right. Third, it argues the final decision was not supported by substantial evidence.

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TTB's first argument fails, but its second argument succeeds. We therefore need not consider its third argument.

IV

We first consider TTB's contention that the deeming provision represents an unconstitutional delegation of authority. The nondelegation doctrine bars Congress from transferring legislative authority to an agency unless it includes some "intelligible principle" to guide the agency's decisionmaking. *See Mistretta v. United States*, 488 U.S. 361, 372 (1989); *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). Our precedent forecloses this claim.

In *Big Times Vapes, Inc. v. FDA*, 963 F.3d 436 (5th Cir. 2020), our court rejected a nondelegation challenge to the same deeming provision. *See id.* at 441–47. We concluded that "the TCA's delegation" "falls comfortably within the outer boundaries demarcated by the Supreme Court" in *Mistretta*. *Id.* at 444. Congress, we explained, had properly limited the agency's deeming authority by setting a "general policy" and defining "tobacco product." *Id.* at 444, 445. "[T]he TCA's delegation to [FDA] is circumscribed, and Congress provided far more signposts to direct the exercise of the authority it delegated." *Id.* at 446.

TTB seeks to avoid *Big Time Vapes* by relabeling its challenge as one under the "major questions doctrine." That does not work, as we recently explained in rejecting an identical challenge to the same deeming provision. *See VDX Distro, Inc. v. FDA*, No. 24-60537, 2026 WL 1811451, at *3–4 (5th Cir. Jun. 24, 2026) ("Despite [TTB's] characterization, [its] argument in substance invokes not the major questions doctrine but the nondelegation doctrine."). The major-questions doctrine bars agencies from exploiting ambiguous statutes to grant themselves broad new powers. *See West Virginia v. EPA*, 597 U.S. 697, 723 (2022); *see also Learning Res., Inc. v. Trump*, 146 S.

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Ct. 628, 639 (2026) (opinion of ROBERTS, C.J.) (major questions resists executive claims to “broad, expansive power on an uncertain statutory basis”). The doctrine does not apply here because Congress expressly granted FDA the power to “deem” items “tobacco products.” *See White Lion Invs.*, 604 U.S. at 551 (explaining the provision confers on FDA “explicit[]” deeming authority); *see also* 21 U.S.C. § 387a(b).

TTB’s challenge can only be understood as falling under the nondelegation doctrine, a challenge our precedent has already rejected. *See VDX Distro*, 2026 WL 1811451, at *4 (“[TTB’s] argument is on all fours with *Big Time Vapes*, so it is foreclosed, in whatever wrapping it is packaged.”).²

V

We turn to the Seventh Amendment. TTB contends the agency adjudication of its alleged FDCA violations denied its right to a jury. We agree.

The Seventh Amendment provides: “In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved.” U.S. CONST. amend. VII. This jury-trial guarantee applies to both common-law and statutory claims that are “legal in nature.” *Jarkesy*, 603 U.S. at 122 (quoting *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 53 (1989)). But even when a claim implicates the Seventh Amendment, Congress may assign its adjudication to an agency if the so-called “public rights” exception applies. *Id.* at 127.

² TTB separately argues the FDCA lacks an intelligible principle to guide the FDA in choosing between an Article III suit or an agency adjudication to enforce the FDCA. Because we resolve this appeal on TTB’s Seventh Amendment challenge, *see infra*, we need not address this issue.

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HHS wisely concedes that its adjudication of TTB’s alleged FDCA violations implicates the Seventh Amendment. It contends, however, that the public-rights exception allowed the matter to be adjudged by a juryless agency.

HHS’s concession notwithstanding, we first briefly explain why the Seventh Amendment is implicated by the agency proceeding here. We then consider whether the public-rights exception applies.

A

To determine whether an agency enforcement proceeding implicates the Seventh Amendment, courts consider “the cause of action and the remedy it provides.” *Id.* at 122–23. Because the remedy is the “‘more important’ consideration,” we address it first. *Id.* at 123 (quoting *Tull v. United States*, 481 U.S. 412, 421 (1987)).

1

The civil monetary penalty imposed on TTB is “the prototypical common law remedy.” *Id.* at 123. It seeks to “punish or deter the wrongdoer,” rather than “serve a remedial purpose” or “return any money to victims.” *Id.* at 123–24. When HHS sets the penalty amount, it considers factors bearing on culpability—such as the “gravity of the violation,” “any history of prior such violations,” and “the degree of culpability.” 21 U.S.C. § 333(f)(5)(B).³ Indeed, penalties may be enhanced if the violation was intentional. *See id.* § 333(f)(9)(B). And penalties are paid to the Treasury, not to victims. 21 C.F.R. § 17.54 (2025).

³ Agency regulations reinforce this by directing the adjudicator to “evaluate any circumstances that mitigate or aggravate the violation.” 21 C.F.R. § 17.34(a) (2025).

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Accordingly, just as in *Jarkesy*, the penalty here is “a type of remedy at common law that could only be enforced in courts of law.” 603 U.S. at 125 (quoting *Tull*, 481 U.S. at 422). That is “all but dispositive” of the Seventh Amendment issue. *Id.* at 123; *see also Tull*, 481 U.S. at 418–19 (“Actions by the Government to recover civil penalties under statutory provisions therefore historically have been viewed as one type of action . . . requiring trial by jury.”). HHS concedes all this.

2

Moreover, the cause of action here is analogous to various common law actions, something that “confirms” the applicability of the Seventh Amendment. *Jarkesy*, 603 U.S. at 125.

For example, the common law action for trespass-on-the-case lay against the “unwholesome practices” of selling “bad provisions or wine.” 3 WILLIAM BLACKSTONE, COMMENTARIES (“BLACKSTONE”) *122. Juries hearing such cases could levy fines. *Ibid.*⁴ Similarly, the common law cheat action afforded damages to those “defraud[ed]” by false affirmations that something was of “superior Quantity or Quality than it [was].” 2 EDWARD HYDE EAST, A TREATISE OF THE PLEAS OF THE CROWN 813 (London, J. Butterworth & J. Cooke 1803). Such cases concerned, for example, a brewer delivering 16 gallons of beer instead of the 18 gallons the buyer purchased, *id.* at 818 (discussing *Rex v. Wheatly* (1761) 97 Eng. Rep.

⁴ *See also* 4 BLACKSTONE *162 (discussing English statutes providing similar actions for, *e.g.*, “selling of unwholesome provisions” like “corrupted wine, [or] contagious or unwholesome flesh”); *see also* William Renwick Riddell, *The Food and Drink of an Englishman—By Statute*, 18 J. CRIM. L. & CRIMINOLOGY 527, 527–28 (1928).

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746 (KB)), or a trader representing wine to be from Portugal when in fact it was not “drinkable or wholesome,” *id.* at 823–24.⁵

Such common law actions bear a “close relationship” to the FDCA violations at issue here. *Jarkesy*, 603 U.S. at 125. Just as the common law went after those selling unwholesome or adulterated products, today FDA decides whether vape products are adulterated, misbranded, or otherwise threaten public health. 21 U.S.C. §§ 387b, 387c, 387j(c)(2). Indeed, the FDCA’s definition of “adulterated” echoes the common law understanding of “unwholesome” products.⁶ And, like the common law cheat action, the FDCA deems a tobacco product misbranded if its label is “false or misleading,” does not include required disclosures, or was not approved for sale. *See* 21 U.S.C. § 387c(a), (a)(6); *cf.* *EAST*, *supra*, at 813.

While these common law actions are not “identical” to the FDCA, they confronted the “same basic conduct” as the modern statute: selling adulterated or misbranded consumables. *Jarkesy*, 603 U.S. at 125–26. These analogues confirm that the Seventh Amendment is implicated by the agency proceeding (again, something HHS concedes).⁷

⁵ *See also* 2 WILLIAM OLDNALL RUSSELL, RUSSELL ON CRIME: A TREATISE ON FELONIES AND MISDEMEANORS 1074 (9th ed. 1936) (explaining that cheat actions might also confront those “selling . . . unwholesome provisions” or “victuals”).

⁶ *Compare* 21 U.S.C. § 387b(1)–(8) (defining tobacco products as “adulterated” if they contain “filthy, putrid, or decomposed substance,” were prepared under unsanitary conditions, or have not been authorized for sale), *with* *EAST*, *supra*, at 821 (describing a case in which a brewer provided bread baked “in an unwholesome and insufficient manner . . . containing dirt, filth, and other pernicious and unwholesome materials and ingredients not fit to be eaten by man”); *cf.* *Jarkesy*, 603 U.S. at 125.

⁷ Shortly before we issued this opinion, the Supreme Court held in *FCC v. AT&T* that FCC’s adjudicatory process does not violate the Seventh Amendment. *See* 146 S. Ct. 1418 (2026). In supplemental briefs addressing *FCC*, both sides agree the decision has no impact on this case. That is correct. *FCC* turned on the fact that the statute at issue

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B

To avoid the Seventh Amendment, HHS puts all its chips on the public-rights exception.

1

Suits at common law presumptively concern “private rights” and must be adjudicated by Article III courts. *Jarkesy*, 603 U.S. at 127 (citing *Stern v. Marshall*, 564 U.S. 462, 484 (2011)). “The Constitution prohibits Congress from ‘withdraw[ing] [such matters] from judicial cognizance.’” *Ibid.* (first alteration in original) (quoting *Murray’s Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1856)). “Public rights” cases, however, may be channeled to agencies instead of courts. *Ibid.*

This narrow exception to Article III applies only to matters that “historically could have been determined exclusively by [the executive and legislative] branches.” *Id.* at 128 (alteration in original) (quoting *Stern*, 564 U.S. at 493). While the Supreme Court has not “definitively explained” what divides public from private rights, it has pointed to “historic categories of adjudications” occurring outside Article III. *Id.* at 131, 130. Examples include revenue collection, foreign commerce, immigration, tariffs, tribal relations, public lands, public benefits, and patents. *Id.* at 128–30.⁸ That said,

provided AT&T “a trial de novo” if the Department of Justice sued it for not paying the penalty. *Id.* at 1426 (quoting 47 U.S.C. § 504(a)). By contrast, if TTB fails to pay and DOJ sues, the “validity, amount, and appropriateness” of the penalty “shall not be subject to review” in district court. 21 U.S.C. § 333(f)(7). The lack of any possibility of a trial *de novo* plainly distinguishes the statutory scheme here from the one in *FCC*.

⁸ See *Murray’s Lessee*, 59 U.S. (18 How.) at 281, 285 (action to compel federal customs collector to pay public funds into Treasury); *Oceanic Steam Navigation Co. v. Stranahan*, 214 U.S. 320, 329–35 (1909) (action to enforce fine on steamship company for disobeying federal prohibition on allowing immigration by aliens with contagious diseases); *Ex parte Bakelite Corp.*, 279 U.S. 438, 446, 458 (1929) (assessment of President’s tariffs on goods imported by “unfair methods of competition”); *United States v. Jicarilla Apache*

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the exception must be handled “with care.” *Id.* at 131. “[E]ven with respect to matters that arguably fall within the scope of the ‘public rights’ doctrine, the presumption is in favor of Article III courts.” *Id.* at 132 (quoting *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 69 n.23 (1982)).

2

HHS fails to show that agency adjudications of FDCA violations fall within the public-rights exception.

To start, HHS does not demonstrate that adjudicating violations of public-health regulations “historically could have been determined exclusively by [the executive and legislative] branches.” *Jarkesy*, 603 U.S. at 128 (alteration in original) (quoting *Stern*, 564 U.S. at 493); *see also id.* at 153 (GORSUCH, J., concurring) (explaining there must be a “serious and unbroken historical pedigree” for the public-rights exception to apply). That alone is fatal because courts may not expand the public-rights exception beyond its historical limits. Instead, they must pay “close attention to the basis for each asserted application of the doctrine.” *Intuit, Inc. v. FTC*, 170 F.4th 411, 417 (5th Cir. 2026) (quoting *Jarkesy*, 603 U.S. at 131). “[T]he kind of civil-penalty suit” at issue here has a “history [that] points in the opposite direction, suggesting actions of this sort belong before an independent judge, a jury, and decided in a trial that accords with traditional judicial procedures.” *Jarkesy*, 603 U.S. at 154 (GORSUCH, J., concurring).

Undeterred, HHS claims Congress could assign it authority to adjudicate FDCA violations because the FDCA is a valid exercise of “congressional power to regulate public health.” But *Jarkesy* rejected that

Nation, 564 U.S. 162, 174 (2011) (relations with Indian tribes); *Crowell v. Benson*, 285 U.S. 22, 51 & n.13 (1932) (administration of public lands); *ibid.* (public benefits such as veterans benefits and pensions); *United States v. Duell*, 172 U.S. 576, 582–83 (1899) (patent rights).

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very claim. The Court explained that “where Congress has assigned” an issue’s adjudication does “not” matter. *Id.* at 134. The brute fact that the FDCA is within congressional power does not mean Congress can “siphon” FDCA adjudications from Article III courts to Article I tribunals. *Id.* at 135. Accepting that argument would create an “automatic[]” public-rights exception “whenever Congress assigns a matter to an agency for adjudication.” *Id.* at 139–40. That is not the law.

The cases HHS relies on also fail to support its public-rights argument. HHS emphasizes that *Crowell v. Benson* included “public health” in a long list of matters sometimes assigned to agencies. 285 U.S. at 51 (also listing “interstate and foreign commerce, taxation, immigration, [and] the public lands,” among others). But this passing reference to “public health” was dicta the Court did not elaborate. *See ibid.* *Crowell* itself concerned “federal courts’ admiralty jurisdiction,” which “long heard certain matters falling within the public rights exception.” *Intuit*, 170 F.4th at 423–24 (quotation omitted). Thus, it “did not purport to recognize public health as a distinct category of public rights.” *Vaping Dragon LLC v. FDA*, No. 1:25-CV-081, 2026 WL 266277, at *17 (N.D. Tex. Feb. 2, 2026).

Since *Crowell*, the Court has never suggested that, merely by invoking “public health,” or for that matter “interstate . . . commerce,” *Crowell*, 285 U.S. at 51, Congress may sweep away Seventh Amendment rights—particularly with respect to civil monetary penalties that fall in the heartland of Article III. *See supra* V.A. To do so would blow a hole in what is meant to be a narrow exception to presumptive Article III jurisdiction. *See Jarkesy*, 603 U.S. at 132 (citation omitted).

HHS’s reliance on *Houston v. St. Louis Independent Packing Co.*, 249 U.S. 479 (1919), fares no better. *Houston* concerned a sausage manufacturer’s challenge to the Secretary of Agriculture’s authority to make fact findings to

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enforce the Meat Inspection Act’s labeling requirements. *Id.* at 479, 483. *Houston* appeared in *Crowell*’s 11-case unelaborated string cite to support including “public health” as one matter agencies sometimes adjudicate. *Crowell*, 285 U.S. at 51 n.13. But *Houston* “said nothing about Article III adjudication, the Seventh Amendment, or public rights.” *Vaping Dragon*, 2026 WL 266277, at *17. And tellingly, *Jarkesy* did not recognize “public health” as a distinct public-rights category. 603 U.S. at 130.

Finally, HHS emphasizes that the FDCA and TCA together “establish[] a novel and comprehensive scheme for the regulation of tobacco products.” It therefore contends the regime was “unknown to the common law.” Once again, *Jarkesy* rejected such reasoning. It confirmed that “the Seventh Amendment *does apply* to novel statutory regimes.” *Id.* at 139 (emphasis added). Merely because an action “‘originate[s] in a newly fashioned regulatory scheme’” does not mean “Congress [can] siphon this action away from an Article III court.” *Id.* at 134–35 (quoting *Granfinanciera*, 492 U.S. at 52). Again, what matters “is the substance of the action, not where Congress has assigned it.” *Id.* at 134.

In sum, the public rights exception does not apply here. TTB is therefore entitled “to a jury trial in an Article III court” for allegedly selling vape products that violate the FDCA. *Id.* at 140.⁹

VI

The petition is GRANTED and the agency’s decision is VACATED.

⁹ Accordingly, we do not address TTB’s third argument that the final decision was not supported by substantial evidence.

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DANA M. DOUGLAS, *Circuit Judge*, dissenting:

I agree with the majority’s analysis of the nondelegation issue, but part ways on the Seventh Amendment issue. I write briefly to explain why I would hold that the public rights exception applies to the violation of the FDCA pre-sale authorization requirements at issue here. I agree that this action implicates the Seventh Amendment. That alone, however, does not end the inquiry. Although *SEC v. Jarkesy*, 603 U.S. 109 (2024) counsels that virtually all actions seeking civil monetary penalties implicate the Seventh Amendment, it also recognizes that public rights “historically could have been determined exclusively by the executive and legislative branches, even when they were presented in such form that the judicial power was capable of acting,” on such rights. *Id.* at 128 (citation modified). Here, the public rights exception applies because TTBB points to no common law cause of action sufficiently analogous to this enforcement action. As is relevant to both issues, I disagree with the majority’s treatment of whether the enforcement action here has a “close relationship” with the common law causes of action TTBB points to, or whether the “substance” of the enforcement action is the same as a common law suit. Neither TTBB nor the majority identifies a common law cause of action that is analogous to the offering of unauthorized tobacco products for sale like those at issue here. Although *Jarkesy* clarified that enforcement actions need not be precisely the same as common law causes of action to implicate private rights, it retained the general rule that Congress may create government enforcement actions and assign them for initial adjudication outside of Article III, unless they at least resemble a common law suit. Because no such resemblance exists, I respectfully dissent.

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I

First, it is important to define the scope of the public rights exception HHS argues should apply. The majority suggests that HHS proposes a broad “public health” exception—while also referring to interstate commerce—and concludes that any such exception would “blow a hole” in “what is meant to be a narrow exception to presumptive Article III jurisdiction.” *Ante* at 14. This is not what HHS proposes. In its brief, HHS argues that the Supreme Court’s “precedents have long recognized that the Executive may adjudicate ‘public health’ matters *related to the human consumption of food and drugs involved in interstate commerce.*” It further describes the proposed exception in terms of “comprehensive regulatory schemes related to ‘public health,’ . . . including schemes directing executive officials to determine which products are appropriate for protecting public health and *to require that such products be properly labeled* to be transported in interstate commerce.” In its brief and at oral argument, HHS further specified that the public rights exception applies because the challenged action involves a “novel premarket authorization process” that protects the public health by regulating the sale of “hazardous” food and drug products that Congress could otherwise completely prohibit from interstate commerce.

The Supreme Court has recognized that at least some public health and interstate commerce-based laws fall within the public rights exception. HHS cites *Crowell v. Benson*, 285 U.S. 22 (1932), which listed “public health” and “interstate commerce” as among a “class” of “matters” that “[f]amiliar illustrations of administrative agencies” have been created to determine outside of Article III, because cases involving them may “arise between the government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments,” and thus involve public rights. *Id.* at 50–51.

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Among the examples cited in *Crowell*, HHS places particular reliance on *Houston v. St. Louis Independent Packing Co.*, 249 U.S. 479 (1919), which recognized the Secretary of Agriculture’s authority to make fact findings to enforce the Meat Inspection Act’s labeling requirements. *Id.* at 483–84. HHS also cites *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985), which upheld an arbitration requirement in the Federal Insecticide, Fungicide, and Rodenticide Act’s pesticide registration scheme serving “a public purpose as an integral part of a program safeguarding the public health.” *Id.* at 589.

The majority dismisses the Supreme Court’s statement in *Crowell* that public rights include matters affecting the “public health” and “interstate commerce” as “dicta the Court did not elaborate [on].” *Ante* at 13. Likewise, it dismisses HHS’s reliance on *Houston* on the grounds that the Court “said nothing about Article III adjudication, the Seventh Amendment, or public rights.” *Id.* at 14 (quoting *Vaping Dragon LLC v. FDA*, No. 1:25-CV-081, 2026 WL 266277, at *17 (N.D. Tex. Feb. 2, 2026)).

I would not so lightly dismiss Supreme Court dicta. *See United States v. Hernandez*, 159 F.4th 425, 427 n.1 (5th Cir. 2025) (“[W]e are bound by the [Supreme] Court’s explications of law, whether dicta or not.”). By citing *Houston*, the Court in *Crowell* clearly indicated that it considered Department of Agriculture factfinding of the kind done there as an example of a matter involving public rights. Thus, in the case at the headwaters of modern public rights doctrine, *see Jarkey*, 603 U.S. at 154–55 (GORSUCH, J., concurring), *Crowell* expressed the Supreme Court’s clear recognition that *Houston* was what we would now call a public rights case.¹ If any further indication that a

¹ Notably, *Houston* described the rule of deference it applied as a “rule most frequently applied in Land Department cases,” and described the typical deference afforded to the Secretary of the Interior’s factfinding impacting the public lands. 249 U.S.

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category of public health and interstate commerce-based public rights exists were needed, *Thomas* provided it. 473 U.S. at 589–90 (“The near disaster of the [statute’s] amendments and the danger to public health of further delay in pesticide registration led Congress to select arbitration as the appropriate method of dispute resolution. Given the nature of the right at issue and the concerns motivating the Legislature, we do not think this system threatens the independent role of the Judiciary in our constitutional scheme.”).

That leaves the question of whether the action here falls within the public rights exception for matters involving public health and interstate commerce. This is a more difficult issue than the majority opinion acknowledges. Civil monetary penalties in themselves do not automatically render an action a matter of private right. *Jarkesy* discussed, without calling into question, *Oceanic Steam Navigation Co. v. Stranahan*, 214 U.S. 320 (1909), which involved the levying of monetary penalties in the context of Congress’s exercising its foreign commerce and immigration powers, and expressly declined to overrule *Atlas Roofing Co. v. Occupational Safety and Health Review Commission*, 430 U.S. 442 (1977), which involved the imposition of monetary penalties in the context of laws promoting safe working conditions. *Jarkesy*, 603 U.S. at 129, 136–40. And, although *Jarkesy* stated that “[e]ven with respect to matters that arguably fall within the scope of the ‘public rights’ doctrine, the presumption is in favor of Article III courts,’” it did so in the context of describing the broader rule that Congress cannot withdraw matters that are in their nature suits at law, in equity, or admiralty from the courts. 603 U.S. at 132 (quoting *Northern Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 69 n.23 (1982) (plurality opinion)). Thus, the question remains whether this action is in the nature of a suit at

at 484–85. *Jarkesy* lists “the administration of the public lands” among the categories of recognized public rights adjudications. 603 U.S. at 130.

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common law. As one of our sister circuits has observed, “[t]his inquiry . . . is a matter of ascertaining whether an action *more closely resembles* the essentially common law action in *Granfinanciera*[, *S.A. v. Nordberg*, 492 U.S. 33, 53 (1989)] . . . or, instead, the action in *Atlas Roofing*.” *Axalta*, 144 F.4th at 475 (emphasis added); *see also id.* at 483–84 (BIBAS, J., concurring) (noting that *Atlas Roofing* “presumes” a public right is involved “any time Congress creates a cause of action enforced by the government,” and that, although *Jarkesy* extended *Granfinanciera* to causes of action that merely “resemble[]” common law claims, it “never flipped the presumption back in favor of public rights”).²

Keeping this general framework in mind, I turn to the specific guardrails provided by *Jarkesy*. As we recently described in *Intuit, Inc. v. FTC*, 170 F.4th 411 (5th Cir. 2026), *Jarkesy* “concluded that an Article III adjudication was necessary” for securities fraud enforcement actions “because the securities-fraud laws ‘borrow[ed] [their] cause of action from the common law’ *and* were distinguishable from claims that involve public rights.” *Id.* at 417 (alterations in original) (emphasis added) (quoting *Jarkesy*, 603 U.S. at 136).³ To make that determination, we explained, “[s]everal facts

² *Granfinanciera* held that a statutory action for fraudulent conveyance under the Bankruptcy Code required a jury because the “substance of the suit” was the same as fraudulent conveyance actions known to the common law. *See Jarkesy*, 603 U.S. at 133–34. *Atlas Roofing* held that the public rights exception applied to, and so no jury was required for, claims adjudicating violations of the Occupational Safety and Health Act of 1970’s safety regulations, because the regulations were novel safety and health standards that did not trace their ancestry to the common law. *See id.* at 136–38.

³ *Intuit* analyzed a claim based in Article III, not the Seventh Amendment. 170 F.4th at 417 n.5. Its analysis of *Jarkesy* is applicable here, however, because it goes to the question of whether the claim at issue implicates private or public rights, and, “if Congress may assign the adjudication of a statutory cause of action to a non-Article III tribunal, then the Seventh Amendment poses no independent bar to the adjudication of that action by a nonjury factfinder.” *Granfinanciera*, 492 U.S. at 53–54 (citations omitted).

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were identified by the Court as particularly important: (1) securities fraud claims ‘target[ed] the *same basic conduct* as common law fraud’; (2) securities fraud laws ‘employed the *same terms of art*’ as common law fraud; (3) securities fraud actions ‘operate[d] pursuant to *similar legal principles*’ as common law fraud; and (4) civil penalties are a remedy that was traditionally available in the courts of law.” *Id.* (quoting *Jarkesy*, 603 U.S. at 134).⁴

The majority opinion does not closely analyze the factors delineated in *Jarkesy* and *Intuit*. Conducting an analysis under the factors identified there, I conclude that the “failure-to-prepare” action at issue here does not resemble the common law trespass-on-the-case and adulteration causes of action identified by the majority, but instead more closely resembles the novel, technical requirements at issue in *Atlas Roofing* and other public rights cases like *Houston*. Because the action at issue here was thus “unknown to the common law,” I would hold that the public rights exception applies. *Jarkesy*, 603 U.S. at 138 (quoting *Atlas Roofing*, 430 U.S. at 461).

First, there is no dispute that the action at issue here involves civil penalties of the kind typically available in courts of law. Thus, I turn to the first, second, and third factors of *Jarkesy* and *Intuit*.

The majority conducts a “same basic conduct” analysis as part of its discussion of whether the Seventh Amendment is implicated. *Ante* at 9–10. According to the majority, “the cause of action here is analogous to various

⁴ There are other factors the Supreme Court has considered relevant to the public rights analysis in its landmark cases. See *Stern v. Marshall*, 564 U.S. 462, 504 (2011) (SCALIA, J., concurring) (identifying “at least seven different reasons” given by the *Stern* majority opinion for requiring Article III adjudication); *id.* at 511–12 (BREYER, J., dissenting) (identifying five factors referred to in *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833 (1985)). While acknowledging this complexity, I assume for purposes of this discussion that *Jarkesy*’s form of analysis is meant to govern the kind of claim we are faced with here.

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common law actions,” including trespass on the case for selling unwholesome provisions or wine and the common law cheat action for representing that provisions were of a higher quantity or quality than they were. *Id.* at 9–11. The majority points out that “the FDCA’s definition of ‘adulterated’ echoes the common law understanding of ‘unwholesome’ products,” and that “the FDCA deems a tobacco product misbranded if its label is ‘false or misleading,’ does not include the required disclosures, or was not approved for sale.” *Id.* at 10 (first quoting 21 U.S.C. § 387b; and then quoting *id.* § 387c(a)(1)). It concludes that, “[w]hile these common law actions are not ‘identical’ to the FDCA, they confronted the ‘same basic conduct’ as the modern statute: selling adulterated or misbranded consumables.” *Id.* (quoting *Jarkesy*, 603 U.S. at 125–26).

The problem with the majority’s analysis is that TTB was not accused of selling an unwholesome product or misrepresenting anything about the product.⁵ This mismatch between statutory and common law actions is apparent in the looseness with which the majority applies *Jarkesy*: *Jarkesy* did not ask whether “various” common law actions were “analogous” to the action at issue, but instead confirmed that the securities fraud enforcement action targeted the same basic conduct as the specific common law cause of action for fraud, that is, “misrepresenting or concealing material facts.” 603 U.S. at 125. Tellingly, the majority opinion refers to conduct not at issue here in describing its proffered common law analogues of selling unwholesome provisions and misrepresenting those provisions’ quality or quantity. *Ante* at

⁵ As to potential applications of the statute to conduct other than TTB’s, such as selling actually injurious provisions or misleadingly labeled goods, “[t]he traditional rule is that a person to whom a statute may constitutionally be applied may not challenge that statute on the ground that it may conceivably be applied unconstitutionally to others in situations not before the [c]ourt.” *New York v. Ferber*, 458 U.S. 747, 767 (1982). Thus, these applications are strictly irrelevant to the issue before us.

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10. The *conduct* here—failure to include required disclosures or to approve a product for sale—cannot be said to be addressed by these actions. In essence, the majority culls together multiple common law causes of action and concludes that, because actions penalizing the sale of unwholesome food products or misrepresentations regarding the same also aimed (in part) to keep harmful food or drink from being sold, they are close enough to a statutory action for selling unauthorized food products.⁶

For its conclusion that the cited common law causes of action target the same basic conduct as the action at issue here, the majority really needs another, unstated premise: the idea that wherever the same basic *harm* is *ultimately* targeted by a contemporary statute and by a common law cause of action, the former triggers the Seventh Amendment’s jury trial requirement. But that is not the rule set out in *Jarkesy*, and it is hardly a rule at all: all statutes target harms in some sense, and ultimate harms of the kind the majority alludes to—harms to the public health from food, cheating—are perennial. At this level of generality, it is no surprise that the majority can identify “various” common law actions that are “analogous” to the one at issue here: bad food has been a problem since before the common law, and any legal regime whatsoever is likely to have laws that target it, whether directly or indirectly. That does not mean any two laws involving potential harms from food products therefore target the same basic conduct.

When closely examined, the conduct actually targeted by the action at issue here is far afield from any of the cited common law precedent. HHS

⁶ The majority’s conclusion that the enforcement action at issue targets the same basic conduct as common law adulteration or trespass on the case because it targets “selling adulterated or misbranded consumables” is circular. *Ante* at 11. The question is what basic conduct this specific adulteration and misbranding action targets. The answer is that it targets selling tobacco products without authorization from the FDA.

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does not accuse TTB of selling unwholesome provisions or of misrepresenting the quantity or quality of those provisions, but instead, of offering a tobacco product for sale *without the required premarket review*. See 21 U.S.C. § 387b(6)(A); *id.* § 387c(a)(6). Under *Jarkesy*, whether the FDCA *ultimately* targets harmful food, or dishonest sales practices, is not the question. The question, again, is whether the action at issue targets the “same basic conduct” as a specific common law cause of action. It does not. TTB points to nothing akin to a pre-sale authorization regime at common law, nor any authority for its leap from targeting unwholesome food products and deceit in food sales to targeting a failure to pre-authorize.⁷

Indeed, the Supreme Court has described the FDCA’s premarket approval regime as its “most substantial innovation,” *Wyeth v. Levine*, 555 U.S. 555, 566 (2009), and as “one of the . . . major innovations” in a statute that “vastly expanded the FDA’s regulatory authority,” *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 549 (2025). The enforcement action applying this novel requirement is thus similar to the “self-consciously novel” statutory regime analyzed in *Atlas Roofing*, “the purpose of” which “was not to enable the Federal Government to bring or adjudicate claims that traced their ancestry to the common law.” *Jarkesy*, 603 U.S. at 137. It therefore brings “no common law soil with” it. *Id.* Unlike the majority, then, I conclude that factor (1) weighs against finding that private rights are implicated by the FDCA failure-to-preauthorize action brought against TTB.

⁷ TTB’s principal historical source supports the proposition that common law adulteration targeted the sale of actually unwholesome food, and the cheat action targeted intentional misrepresentations about the quality or quantity of that food. See Peter Barton Hutt, *Criminal Prosecution for Adulteration and Misbranding of Food at Common Law*, 15 FOOD DRUG COSM. L. J. 382, 387–95 (1960).

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As to the second factor, I would give some weight to the FDCA’s recycling of the common law term “adulteration.”⁸ I would balance this consideration, however, with the fact that it does not appear that common law adulteration “operated pursuant to *similar legal principles*” as the action at issue here. *Intuit*, 170 F.4th at 417 (citation modified). TTB points to no evidence that “[o]ur precedents . . . consider” the principles of the common law trespass-on-the-case or cheat actions “when interpreting” claims that the FDCA’s premarket review requirements have been violated. *Jarkesy*, 603 U.S. at 126. Thus, although the use of the term “adulteration” suggests some relationship between the action at issue and the common law, it does not show the “enduring link” between present action and “common law ‘ancestor’” *Jarkesy* attributed to “Congress’s decision to draw upon common law fraud” in shaping federal securities fraud. *Id.* at 125 (quoting *Foster v. Wilson*, 504 F.3d 1046, 1050 (9th Cir. 2007)).⁹ Rather, as HHS argues, the Tobacco Control Act (“TCA”), by adding the pre-authorization requirement to the FDCA, “established a novel and comprehensive scheme for the regulation of tobacco products,” which, like the labeling regulation at issue in *Houston* and the building code-like regulations in *Atlas Roofing*, was “unknown to the common law.”¹⁰

⁸ “The term ‘misbranding’ was unknown to the common law.” Hutt, *supra*, at 382.

⁹ As the majority notes, the FDCA’s adulteration provisions do target unwholesome food products, and its misbranding provisions target misrepresentations; but, again, the provisions that do so are not the statutory provisions at issue here, where TTB was accused only of offering unauthorized products for sale. *See supra* note 5.

¹⁰ The majority responds to HHS’s “novel and comprehensive scheme” argument by claiming that “*Jarkesy* rejected such reasoning” when it confirmed “that ‘the Seventh Amendment *does apply* to novel statutory regimes.” *Ante* at 14–15 (quoting *Jarkesy*, 603 U.S. at 139). But *Jarkesy* stated that “the Seventh Amendment does apply to novel statutory regimes, *so long as the claims are akin to common law claims.*” 603 U.S. at 139 (emphasis added). The majority omits the limiting clause. HHS sets out the history of the

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Given that *Intuit*'s factors (2) and (3) give little guidance, and factor (1) weighs in favor of HHS but factor (4) against, I find the factors inconclusive as to whether this action "resembles a traditional legal claim." *Jarkesy*, 603 U.S. at 135.

Two considerations lead me to further conclude that it does not. First, as noted above, *Jarkesy* declined to overrule *Atlas Roofing* or "flip[] the presumption back in favor of private rights," *Axalta*, 144 F.4th at 484 (BIBAS, J., concurring), so *Atlas Roofing*'s assumption that "new statutory obligations" involving "civil penalties" may be "committed exclusively to an administrative agency" still applies, 430 U.S. at 450. Second, although *Jarkesy* discussed the use of "common law terms of art" when deciding whether there was a "close relationship" between common law fraud and federal securities fraud, it did so in the context of determining that federal

FDCA's enactment to provide a system of premarket authorization for new drugs, and Congress's specific focus on tobacco's health effects on children when passing the TCA out of a recognition that its past efforts had not adequately addressed this problem. In passing the TCA, Congress made specific statutory findings that "past efforts to restrict advertising and marketing of tobacco products ha[d] failed adequately to curb tobacco use by adolescents," and that "Federal and State governments ha[d] lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products." TCA, Pub. L. No. 111-31, § 2(6)-(7), 123 Stat. 1776, 1777 (2009). In other words, the TCA was enacted to fill in a significant blank in the law, including the common law, much like the laws enacted to develop "innovative methods, techniques, and approaches for dealing with occupational safety and health problems" at issue in *Atlas Roofing*. *Jarkesy*, 603 U.S. at 137 (citation modified). Likewise, like the FDCA's premarket authorization regime, *Houston* involved a novel labeling regime requiring that sausage products containing more than 2% cereal or more than 3% water should be labeled as such, and refusing to label sausage products as "Inspected and passed" when they contained these amounts of cereal or water. 249 U.S. at 480-81. A major industry manufacturer objected that its sausage products containing these amounts of cereal or water were entirely wholesome and sued to enjoin the Secretary of Agriculture from refusing to label such products as sausage, but the Supreme Court upheld the Secretary of Agriculture's finding that the sale of such food products as sausage was false and deceptive, applying deferential substantial evidence review. *Id.* at 480-87.

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securities fraud and its common law analogue “target the same basic conduct,” which the “deliberate[] use” of common law terms merely confirmed was “no accident.” 603 U.S. at 125. Thus, the issue of whether the same basic conduct is targeted receives special weight in the analysis, because “what matters is the substance of the suit, not where it is brought, who brings it, or how it is labeled.” *Id.* at 135 (citation omitted). As discussed above, TTBB identifies no common law cause of action targeting the failure to pre-authorize a product with state authorities. Although “the statutory action need not be ‘identical’ to a common law analogue,” I find no “close relationship” or resemblance between failure-to-preauthorize actions under the FDCA and common law trespass on the case or cheating. *Id.* (quoting *Jarkesy*, 603 U.S. at 126). Thus, faced with a novel statutory scheme and an enforcement action with no common law analogue, I would hold that the public rights exception applies.¹¹

¹¹ As a final consideration, HHS’s argument that premarket authorization regimes for the sale of hazardous food and drink in interstate commerce constitute public rights plausibly suggests that, if Congress could *completely* outlaw a practice—such as tobacco product sales—it may a fortiori condition participating in that practice on receiving prior approval, and remove adjudications concerning failure to seek approval from the purview of Article III factfinding. See *Wulferic, LLC v. U.S. FDA*, 793 F. Supp. 3d 830, 847 (N.D. Tex. 2025) (“In essence, the FDA’s cause of action is a licensing requirement.”); *id.* at 850 n.46 (noting that “[s]ome scholars propose that the public rights exception contemplates a licensing regime”); Will Baude, *The Seventh Amendment, Private Rights, and Administrative Penalties*, THE VOLOKH CONSPIRACY (Dec. 8, 2023), <https://reason.com/volokh/2023/12/08/the-seventh-amendment-private-rights-and-administrative-penalties/> (“It seems to me that the best defense of [administrative penalty proceedings] would be to argue something like this: Congress has the power to completely ban the interstate trade in [tobacco products]. Therefore, Congress has the power to completely ban the interstate trade except for those who have obtained a license from the federal government. And perhaps this license could be seen as a public right, and perhaps one could condition this license on willingness to accept various kinds of administrative penalties[.]” (citing John Harrison, *Public Rights, Private Privileges, and Article III*, 54 Ga. L. Rev. 143 (2019))). Thus, actions to enforce the FDCA’s preauthorization regime not only fit within the public health and interstate commerce exception recognized in prior

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II

Because I would hold that the public rights exception applies, I respectfully dissent.¹²

cases, but also the possible exception for licensing regimes, which share some features of the public benefits and patent rights cases endorsed in *Jarkesy*. See Harrison, *supra*, at 182–85 (discussing *Oceanic Steam*’s endorsement of monetary penalties for failure to comply with health regulations required for port clearance and *Thomas*’s endorsement of an arbitration requirement in a registration regime protecting the public health); *id.* at 196–99 (discussing licensing regimes in general).

¹² I do not address the substantial evidence question we would reach if the public rights exception applied, except to note that TTB acknowledges its claim in this respect is “a bit wonky,” and to observe that the question TTB insists much go before a jury is whether the ingredients of its Barn Brewed Beetle Juice, which it does not contest it offered for sale, moved in interstate commerce. TTB acknowledges that the product in question contained ingredients that matched the bulk ingredients at its facility, that these bulk ingredients moved in interstate commerce, and that it manufactures tobacco products at the identified facility with the identified ingredients—but argues that the specimen product examined by the FDA was not exactly the same as the product with the same name whose ingredient list it filed when it attempted premarket authorization. This is a good example of the Supreme Court’s repeated warning not to “defeat the obvious purpose of . . . legislation to provide a prompt, continuous, expert and inexpensive method for dealing with a class of questions of fact which are peculiarly suited for examination and determination by an administrative agency specially assigned to the task.” *Thomas*, 473 U.S. at 590 (quoting *Crowell*, 285 U.S. at 46).