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FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff-Appellee,* v. RICHARD MARSCHALL, *Defendant-Appellant.*	No. 22-30048 D.C. No. 3:20-cr-05270-BHS-1 OPINION

Appeal from the United States District Court
for the Western District of Washington
Benjamin H. Settle, District Judge, Presiding

Argued and Submitted November 8, 2022
Seattle, Washington

Filed September 20, 2023

Before: Sandra S. Ikuta and Daniel P. Collins, Circuit Judges, and Sidney A. Fitzwater,* District Judge.

Opinion by Judge Collins

* The Honorable Sidney A. Fitzwater, United States District Judge for the Northern District of Texas, sitting by designation.

SUMMARY*

Criminal Law

The panel affirmed Richard Marschall's conviction under the Federal Food, Drug, and Cosmetic Act ("FDCA") for shipping misbranded drugs in interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

Marschall contended that the district court erred in concluding that the charged offense did not require proof that Marschall knew that the drugs he shipped were misbranded.

The panel first held that the text of the various provisions of the FDCA at issue does not contain any language that imposes a scienter requirement of the sort that Marschall advocates.

The panel then addressed whether there are convincing reasons to depart from the presumption that Congress intended to require a defendant to possess a culpable mental state regarding each of the statutory elements that criminalize otherwise innocent conduct, even when Congress does not specify any scienter in the statutory text. The panel concluded that such convincing reasons are present here. The panel wrote that this is the unusual case in which a public welfare offense lacks a scienter element even though it is a felony with moderately severe potential penalties, given the confluence of circumstances: (1) Congress augmented, into a felony, a predicate misdemeanor offense that

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

concededly lacks a scienter requirement; (2) it did so by adding, not a scienter requirement, but a prior conviction requirement; (3) this action contrasts with Congress's explicit addition of a scienter requirement in the *other* clause of § 333(a)(2); and (4) the prior conviction requirement, as a functional matter, largely serves the same purposes as an express scienter requirement.

The panel rejected Marschall's other challenges to his conviction in an accompanying unpublished memorandum disposition.

COUNSEL

Mohammad Ali Hamoudi (argued) and Gregory Geist, Assistant Federal Public Defenders, Federal Public Defender's Office, Seattle, Washington, for Defendant-Appellant.

Jonas B. Lerman (argued), Tania M. Culbertson, Michelle Jensen, Nicholas A. Manheim, Teal L. Miller, and Brian Werner, Assistant United States Attorneys; Nicholas W. Brown, United States Attorney; United States Attorney's Office, Western District of Washington, United States Department of Justice, Seattle, Washington; for Plaintiff-Appellee.

OPINION

COLLINS, Circuit Judge:

Defendant-Appellant Richard Marschall appeals from his conviction under the Federal Food, Drug, and Cosmetic Act ("FDCA") for shipping misbranded drugs in interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). Marschall raises a number of challenges to his conviction, most of which we address and reject in an accompanying unpublished memorandum disposition. In this opinion, we address only Marschall's contention that the district court erred in concluding that the charged offense did not require proof that Marschall knew that the drugs he shipped were misbranded. Noting that the indictment did not allege any such scienter, Marschall moved to dismiss the indictment on this ground before trial, and the district court denied that motion. We conclude that the district court did not err, and we therefore affirm its judgment.

I

A

Marschall was first licensed as a naturopathic physician in Washington State in August 1986. As described at trial, a naturopathic physician, also known as a "naturopathic doctor" or "N.D.," is a licensed professional who works with patients "to support the body's ability to resist and recover from illnesses and different conditions through the use of mainly natural means." According to a stipulation read to the jury in this case, Marschall was convicted on October 20, 2017 of "Introduction of Misbranded Drugs into Interstate Commerce under 21 U.S.C. §§ 331 and 333," and that conviction became final

"before March 1, 2020."[1] After his 2017 conviction, Marschall's license as an N.D. was suspended. After he continued to engage in the unlicensed practice of naturopathic medicine during the time that his license was suspended, the Washington State Department of Health permanently revoked Marschall's license in 2018. That revocation was embodied in a state court order that "permanently enjoined" Marschall from the unlicensed practice of medicine as well as from "advertising naturopathic medical services and representing himself to be a naturopath, including but not limited to advertising services on his personal website and physical business locations, and from using the title 'Doctor', 'ND', 'naturopath', or any other similar title" unless and until he obtained the necessary license.

In early March 2020, Marschall published a series of posts on his Facebook page claiming that two products—"Allimed" and "IAG"—could prevent and treat "viral, bacterial, fungal and parasitic infections," that they could "crush[] 30 different viral infections including those in the Corona family like in China, 40 different bacterial infections, 25 different fungal infections and 20 different parasitic infections." He referred to these two products as the "Dynamic Duo," and his posts contained lengthy explanations as to how these products would prevent and treat such illnesses. On March 15, 2020, Marschall posted a further statement on his Facebook page suggesting that Allimed, which he described as an "empirically proven anti-viral," would help in proactively protecting against "the Corona COVID-19 virus."

[1] Marschall also had a prior conviction in 2011 for violating §§ 331 and 333, but it does not appear that the jury was informed of that earlier conviction.

This post provided Marschall's phone number and invited anyone who was interested in "being proactive" in this way to call him.

Marschall's posts attracted the attention of the FDA, and on March 30, 2020, FDA special agent Julie Ryer, posing as "Julie Richardson," reached out to Marschall at the number listed on his March 15 Facebook post. She first tried unsuccessfully to call him, and she then sent him the following text message:

> Hi, trying to reach Rick Marschall. I called this phone number earlier today. I'm just hoping to get info about something my friend saw and thought I would be interested in. Dynamic Duo I think she called it. Definitely scared about the corona virus so I would like to hear about this product and maybe order it. Do you sell this still? Is there a good way to reach you? Thanks!

Marschall called her back that same day, and Agent Ryer recorded the call. Marschall introduced himself as "Dr. Rick Marschall." Marschall stated that he was "semi . . . retired" and that he "no longer ha[s] a license in the state that I live in, in Washington state." But he said that he could still "sell plant-based medicines," because they did not require prescriptions, and he said that "that's legal in our state and across the country." In describing the "Dynamic Duo," Marschall said that the first product—which at one point he referred to as "Allimed"—contained "allicin," which he said was a "biochemical" extracted from garlic that "kills the

viruses, bacteria, parasites and fungus on contact." He said, however, that allicin "doesn't boost the immune system" but "just kills the virus." Marschall instead explained that the second product provided such a boost. It contained a "starch" from the "larch tree" that contained "fucose." The fucose, he said, sends "a message to the bone marrow to make more stem cells," which would lead to "more reticulocytes," which in turn would lead to more "white blood cells" to "attack viruses and cancer." He then volunteered, "I'm not making claims that, you know, that the FDA is—you know, the FDA says you know, this is all mumbo jumbo. They don't believe in any of this." He nonetheless said that, while he was not "trying to make claims" for the Dynamic Duo, "we do have evidence for it, that it's directly antiviral, antibacterial, antifungal, anti-yeast." He stated that, while the Dynamic Duo was "pretty amazing," it was "pricey," and that "it costs $140 to get the kit." They then talked briefly about the Covid pandemic, and Marschall ultimately said that, "because everybody wants this stuff," he could put her on a waiting list. Then, when he had the product in hand, he could text her on her cell phone.

The next day, March 31, Marschall called back Agent Ryer, and she again recorded the call. He again introduced himself as "Dr. Rick Marschall," and he said that he had the Dynamic Duo in stock, and he asked her for her credit card information and her shipping address. After Agent Ryer provided that information, Marschall explained that he would include, in the shipment, instructions on how to take the Dynamic Duo. He asked how old her children were, and after she explained that they were nine and eleven and that one of them weighed only 70 pounds,

Marschall told her to "cut the dose in half for these guys."

Agent Ryer received the package from Marschall a few days later. The package contained one bottle of "Allimax Pro" and one bottle of "IAG," along with specially printed instructions prepared by Marschall describing when and how to take them. Affixed to the instructions was a yellow post-it note with the following handwritten comment: "note: Allimed and Allimax Pro are the exact same product, manufactured by the same corporation." Marschall's printed instructions differed from the preprinted labeling on the bottles, and his instructions stated that the products should be used "For Treatment Only." Marschall's instructions stated that "10 capsules" of the Allimed should be taken "at the VERY FIRST SIGN OF flu or cold like symptoms" and that, "[a]t the SAME time," one should also take one tablespoon of the IAG "in water, juice, or EmergenC." The instruction sheet claimed that "[m]ost people will experience no other symptoms after one dose," and it listed his name at the bottom as "Rick Marschall N.D." The package received by Agent Ryer also included two other informational sheets that were shown as having been authored by "Rick Marschall," with one of them adding the title "N.D." after his name. The content of these sheets largely tracked the wording of Marschall's early March 2020 Facebook posts touting the benefits of the Dynamic Duo.

Chemical analysis of the two substances revealed that they "did not contain active pharmaceutical ingredients" or "controlled substances." The Allimax product was found to contain, *inter alia*, citrate, an unspecified sugar, and two garlic-related

components. A search of the FDA's "Electronic Drug Registration and Listing System," which contains a list of drugs for sale in the United States by registered manufacturers, did not reveal any listings for the Allimax or IAG products.

FDA agents also obtained business records indicating that, in March 2020, Marschall had sold the same Dynamic Duo products to other customers in Arizona, Washington, California, and Texas. The FDA's investigation did not uncover evidence of any person who had been harmed by taking the products.

B

In August 2020, Marschall was indicted for one count of introducing misbranded drugs into interstate commerce after a prior conviction under 21 U.S.C. §§ 331 and 333(a) had become final. Specifically, the indictment alleged that on or about March 31, 2020, "after a conviction of him under 21 U.S.C. §§ 331 and 333 had become final," Marschall "introduced, delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, from Port Angeles, Washington, to Oakland, California, via the U.S. Postal service, drugs . . . which were misbranded." The indictment alleged that the "drugs" in question were the "Dynamic Duo" of Allimax Pro and IAG. The indictment further alleged that these drugs were "misbranded" in that, *inter alia*, (1) their "labeling was false and misleading" by suggesting that Marschall "was a naturopathic doctor by listing him as 'Rick Marschall N.D.'"; and (2) "the drugs were not included in any list of drugs manufactured, prepared, propagated, compounded, and processed in a registered establishment," which listing is required by the drug

producer registration requirements of the FDCA. *See* 21 U.S.C. § 360(b), (c), (j); *see also id*. § 352(*o*) (defining as "misbranded" any drug "not included in a list required by section 360(j) of this title").

Before trial, Marschall filed several motions to dismiss the indictment. One of those motions alleged that the indictment failed to allege an essential element of the crime charged and was therefore subject to dismissal for failure to state a claim under Federal Rule of Criminal Procedure 12(b)(3)(B)(v). Specifically, Marschall asserted that the indictment omitted the requisite scienter, inasmuch as it failed to allege that "Marschall *intentionally* and *knowingly* introduced, delivered, and caused" to be introduced and delivered, into interstate commerce, misbranded drugs. The district court denied this motion, as well as Marschall's additional motions to dismiss the indictment on other grounds.

The jury returned a verdict of guilty on the sole count, specifically finding that the drugs were misbranded in that (1) "[t]he labeling of the drugs was false or misleading"; and (2) "[t]he drugs were not included in any list of drugs manufactured, prepared, propagated, compounded, or processed in a registered establishment." Marschall was sentenced to eight months' imprisonment to be followed by one year of supervised release.

Marschall timely appealed, and we have jurisdiction under 28 U.S.C. § 1291.

II

On appeal, Marschall renews his contention that the indictment was defective because, in his view, it failed to allege the requisite scienter. According to Marschall, "the indictment should have alleged that

[he] *knew* that the labeling of the 'Dynamic Duo' was false and misleading" or that he "was at least *reckless* with respect to the alleged mislabeling." In the context of the recidivism-based charge at issue here, we reject this contention.

A

We begin by examining the text of the relevant provisions to determine whether the language of the statute contains the scienter requirement that Marschall advocates. It does not.

The FDCA is generally classified to Chapter 9 of the unenacted title 21 of the United States Code. *See* 21 U.S.C. §§ 301 *et seq*. Several provisions of the FDCA are relevant here, and we will refer to each of them by their assigned section numbers in title 21, as the parties have done throughout these proceedings. Section 333(a) imposes criminal penalties on any person "who violates a provision of section 331" of title 21, and it prescribes enhanced penalties for § 331 violations involving specified aggravating circumstances. *Id*. § 333(a)(1), (2). The underlying substantive prohibition in § 331 that Marschall is alleged to have violated is contained in subsection (a), which prohibits, in relevant part, "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded." 21 U.S.C. § 331(a). Section 321 defines a "drug" as, *inter alia*, any "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." *Id*. § 321(g)(1)(B). Section 352, in turn, specifies that a drug "shall be deemed to be misbranded" if, *inter alia*, "its labeling is false or misleading in any particular." *Id*. § 352(a)(1). "Labeling," for purposes of the FDCA, "means all labels and other

written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). Section 352(*o*) alternatively provides that a drug is "misbranded" "if it was not included in a list required by" the FDCA's drug producer registration requirements. Taking these provisions together in the context of this case, Marschall was charged with having introduced into interstate commerce an article that was "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and that was (1) "accompan[ied]" by "written" or "printed" matter that was "false or misleading in any particular" and (2) not included on a list of drugs required by the FDCA's registration requirements.

Looking first just at the language of the various provisions describing this underlying prohibition, we conclude that none of them contains language imposing a scienter requirement. By its terms, § 331 flatly prohibits the "act[]" of "[t]he introduction or delivery for introduction into interstate commerce" of a "drug" that "*is* . . . misbranded," and says nothing about whether the person introducing it into commerce *knows* that it is misbranded. 21 U.S.C. § 331(a) (emphasis added). Likewise, the drug is "misbranded" if "its labeling *is* false or misleading," without any requirement that the person know that it is false or misleading. *Id.* § 352(a)(1) (emphasis added). Similarly, the drug is alternatively "misbranded" if it is "not included in a list required by" the drug producer registration requirements, without any requirement to show the defendant's knowledge of any such lack of listing. *Id.* § 352(*o*). The omission of any scienter requirement from the language of these various provisions is hardly surprising, given that these underlying prohibitions

are also enforced through *civil* proceedings for injunctive relief or seizure of misbranded drugs. *Id.* § 332(a) (giving the district courts jurisdiction "to restrain violations of section 331"); *id.* § 334(a) (authorizing *in rem* seizure proceedings against, *inter alia*, any drug "that is adulterated or misbranded"). These critical civil provisions would be unable to accomplish their goal of promptly removing misbranded drugs from commerce if they only authorized such measures in cases in which the distributor *knew* that the drugs they were distributing were misbranded.

To be sure, the definition of "drug" that is at issue in this case uses language that arguably *could* "be understood to refer to the state of mind of the defendant," *Posters 'N' Things, Ltd. v. United States*, 511 U.S. 513, 518 (1994), because it refers to an "article[] *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," 21 U.S.C. § 321(g)(1)(B) (emphasis added). But that reading is wrong, as *Posters 'N' Things* makes clear. There, the Court construed the comparable language in what is now 21 U.S.C. § 863(d), which defines "drug paraphernalia" as meaning anything "which is primarily intended or designed for use" with illegal drugs.[2] The Court held that the phrase "primarily intended . . . for use" must "be understood objectively" as "refer[ring] generally to an item's likely use," and the phrase therefore does not "serv[e] as the basis for a subjective scienter requirement." 511 U.S. at 521–22. Similarly here, the question whether an article is "intended for use"

[2] At the time that *Posters 'N' Things* was decided, this definition was contained in former 21 U.S.C. § 857(d).

in diagnosing, curing, mitigating, treating, or preventing disease turns solely on an *objective* inquiry into the article's likely use in light of its features and any accompanying labeling. Indeed, a contrary, subjective, reading of this definition of "drug" could substantially hinder the ability to remove such drugs from the channels of commerce under the previously discussed civil measures—a result Congress surely did not intend.

Having concluded that the provisions describing the underlying prohibition do not contain any language imposing a scienter requirement, we next consider whether the relevant criminal penalties provision, 21 U.S.C. § 333(a), contains language imposing such a requirement. The text of § 333(a) is as follows:

> (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

21 U.S.C. § 333(a). Marschall was charged under the *first* clause of § 333(a)(2), which subjects a

defendant to up to three years in prison if he "commits such a violation after a conviction of him under this section has become final." *Id*. § 333(a)(2). On their face, neither § 333(a)(1) nor the *relevant* clause of § 333(a)(2) makes any explicit reference to scienter. Section 333(a)(1) merely requires proof that a person has "violate[d] a provision of section 331," and the first clause of § 333(a)(2) only requires proof that the person committed a violation of § 331 "after a conviction of him under this section has become final." Nothing in the relevant language of these provisions says anything about scienter.

Accordingly, the text of the various provisions of the FDCA at issue here does not contain any language that imposes a scienter requirement of the sort that Marschall advocates.

B

As Marschall correctly notes, however, the absence of such affirmative scienter language, by itself, is *not* sufficient to establish that no such *mens rea* is required. It is well settled that, "even when Congress does not specify any scienter in the statutory text," we must "start from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state regarding 'each of the statutory elements that criminalize otherwise innocent conduct.'" *Rehaif v. United States*, 139 S. Ct. 2191, 2195 (2019) (citation omitted). But this presumption is rebuttable, and it will not be applied if there are "convincing reason[s] to depart" from it. *Id*. We conclude that such convincing reasons are present here.

1

In particular, two aspects of the relevant statutory text work together to strongly confirm that the aggravated version of the offense that applies to recidivists under the first clause of § 333(a)(2) does not require proof of scienter as to the misbranded nature of the drugs.

First, it is important to note that § 333(a)(2) defines the recidivist version of the aggravated offense by reference to a base offense that, under controlling precedent, does *not* require scienter. The first clause of § 333(a)(2) states that, "[n]otwithstanding the provisions of paragraph (1) of this section, if any person commits *such* a violation after a conviction of him under this section has become final," the person is guilty of a felony punishable by up to three years in prison. 21 U.S.C. § 333(a)(2) (emphasis added). The referent of the phrase "such a violation" is unmistakably the violation defined in "paragraph (1) of this section." *Id*. Thus, the offense defined by the relevant clause in § 333(a)(2) simply takes the *existing* offense in § 333(a)(1) and then adds, as an additional element, the requirement that the defendant be shown to have previously been convicted of violating "this section," *i.e.*, § 333. Under well-settled law, the referenced base offense in § 333(a)(1) does not require proof of scienter.

The Supreme Court addressed the question of scienter for a prosecution under § 333(a)(1) in *United States v. Dotterweich*, 320 U.S. 277 (1943). Dotterweich, the president and general manager of a pharmaceutical company, was convicted of three violations of § 333(a)(1), two involving "misbranded drugs," and one involving "an adulterated drug." *Id*.

at 278. In the course of addressing a separate issue about the scope of the statute, the Court stated that the "prosecution to which Dotterweich was subjected is based on a now familiar type of legislation" that "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing." *Id*. at 280–81. That is, because the subject of the FDCA affects "the lives and health of people" in ways that "are largely beyond self-protection," the FDCA "puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." *Id*. The Court acknowledged that "[h]ardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting." *Id*. at 284. But given the stakes involved with distribution of regulated drugs, the Court stated that Congress determined to place the onus "upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless." *Id*. at 285.

As the Supreme Court has acknowledged, *Dotterweich* reflects that there is a "limited" category of "public welfare offenses"—"involv[ing] statutes that regulate potentially harmful or injurious items"—as to which Congress has dispensed with the normal requirement of scienter and has instead "impose[d] a form of strict criminal liability through statutes that do not require the defendant to know the facts that make his conduct illegal." *Staples v. United States*, 511 U.S. 600, 606–07 (1994); *see also Rehaif*, 139 S. Ct. at 2197 ("[W]e have typically declined to apply the presumption in favor of scienter

in cases involving statutory provisions that form part of a 'regulatory' or 'public welfare' program and carry only minor penalties."). Section 333(a)(1), which makes it a misdemeanor to introduce misbranded or adulterated drugs into interstate commerce, is such a public welfare offense, and it does *not* require the Government to prove "knowledge that the items were misbranded or adulterated." *Staples*, 511 U.S. at 606; *see also United States v. Watkins*, 278 F.3d 961, 964 (9th Cir. 2002) ("An article may be misbranded pursuant to the misdemeanor provision 'without any conscious fraud at all,' thus creating a form of strict criminal liability." (quoting *Dotterweich*, 320 U.S. at 281)). Indeed, the parties here do not dispute that § 333(a)(1) is a strict liability misdemeanor offense.

As explained earlier, the recidivist offense described in the first clause of § 333(a)(2) begins with the offense described in § 333(a)(1)—which lacks a scienter requirement—and then adds a requirement to show that this scienter-less violation of § 333(a)(1) occurred after a final conviction for a previous violation of § 333. Nothing about that latter element suggests any intent by Congress to *add* a scienter requirement to the borrowed base offense. The additional element required by this clause to raise the misdemeanor to a felony is simply that the defendant committed the violation "after a conviction of him under this section has become final." 21 U.S.C. § 333(a)(2). Accordingly, nothing in the text of this clause of § 333(a)(2) provides any basis for inferring that a scienter requirement applies to this aggravated version of the offense.

Second, this conclusion is overwhelmingly reinforced by contrasting the language of the two

alternative clauses in § 333(a)(2). The two clauses of § 333(a)(2) define two different ways in which a violation of § 333(a)(1) can become a felony—namely, (1) by committing such a violation after a final conviction under § 333 *or* (2) by "commit[ting] such a violation *with the intent to defraud or mislead*." 21 U.S.C. § 333(a)(2) (emphasis added). The second of these two alternatives thus expressly imposes a "mens rea element that is absent from the broader-reaching misdemeanor provision." *Watkins*, 278 F.3d at 964. That fact strongly confirms that the *other* alternative—the recidivist provision at issue here—does not impose a *mens rea* requirement. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (simplified).

2

Marschall nonetheless argues that the strong presumption in favor of scienter has not been rebutted. According to Marschall, *Dotterweich* rests on an exception to that strong presumption for "public welfare" offenses, and the Supreme Court has subsequently clarified that this exception extends *only* to public welfare offenses with "minor penalties" and not to felonies such as § 333(a)(2). We agree that the severity of the penalty applicable under § 333(a)(2)—*viz.*, up to three years in prison—is a consideration that, all other things being equal, weighs in favor of imposing a scienter requirement. *See Staples*, 511 U.S. at 616 ("Historically, the penalty imposed under a statute has been a significant consideration in determining whether the

statute should be construed as dispensing with *mens rea*."). But we nonetheless conclude that this consideration is not controlling in the unique circumstances presented by the recidivist offense in § 333(a)(2).

In *Staples*, the Supreme Court confronted a similar contention that the "public welfare" exception to the presumption in favor of scienter should be limited to crimes involving modest penalties and therefore could not be applied to felonies. *See* 511 U.S. at 616–19. The question in *Staples* was whether, in a prosecution for unlawful possession of an unregistered machinegun, "the Government should have been required to prove beyond a reasonable doubt that [the defendant] knew the weapon he possessed had the characteristics that brought it within the statutory definition of a machinegun." *Id*. at 602. In the course of answering that question in the affirmative, the Court emphasized a number of considerations, one of which was "[t]he potentially harsh penalty" for such a violation, which was "up to 10 years' imprisonment." *Id*. at 616. In discussing the significance of the potentially severe penalties, the Court distinguished its prior cases involving public welfare offenses, noting that they have "almost uniformly involved statutes that provided for only light penalties such as fines or short jail sentences, not imprisonment in the state penitentiary." *Id*. Indeed, the *Staples* Court suggested that there was some force to the view—similar to what Marschall argues here—that, "absent a clear statement from Congress that *mens rea* is not required, [the courts] should not apply the public welfare offense rationale to interpret any statute defining a felony offense as dispensing with *mens rea*." *Id*. at 618. However, the

Court noted that such a rule would directly contradict its unanimous decision in *United States v. Balint*, 258 U.S. 250 (1922),[3] and *Staples* ultimately found it unnecessary to "adopt such a definitive rule of construction." 511 U.S. at 618. Instead, the Court held "only that where, as here, dispensing with *mens rea* would require the defendant to have *knowledge only of traditionally lawful conduct*, a severe penalty is a *further factor* tending to suggest that Congress did not intend to eliminate a *mens rea* requirement." *Id*. (emphasis added).

Our construction of the relevant clause of § 333(a)(2) is consistent with *Staples*' narrow

[3] *Balint* involved a prosecution under § 2 of the Narcotic Act of 1914, 38 Stat. 785, 786, which, as described by the Court, prohibited the charged conduct of "unlawfully selling to another a certain amount of a derivative of opium and a certain amount of a derivative of coca leaves, not in pursuance of any written order on a form issued in blank for that purpose by the Commissioner of Internal Revenue." 258 U.S. at 251. The Court held that, given the importance of "securing a close supervision of the business of dealing in these dangerous drugs by the taxing officers of the Government," Congress had decided, in effect, "to require every person dealing in drugs to ascertain at his peril whether that which he sells comes within the inhibition of the statute, and if he sells the inhibited drug in ignorance of its character, to penalize him." *Id*. at 254. The Court therefore concluded that Congress had permissibly determined, "in order to stimulate proper care, [to] require the punishment of the negligent person though he be ignorant of the noxious character of what he sells." *Id*. at 253. As described in *Staples*, the holding of *Balint* was that the statute "required proof only that the defendant knew that he was selling drugs, not that he knew the specific items he had sold were 'narcotics' within the ambit of the statute." 511 U.S. at 606. Notably, *Balint* held that this form of scienter was not required, even though the offense involved was a felony punishable by up to five years in prison. *See* Narcotic Act of 1914, § 9, 38 Stat. at 789.

description of the public welfare exception. Unlike in *Staples*, we are *not* presented with a situation in which "dispensing with *mens rea* would require the defendant to have knowledge only of traditionally lawful conduct." 511 U.S. at 618. On the contrary, by requiring proof that the defendant violated § 333(a)(1) *after* having been finally convicted of an earlier violation of § 333, the first clause of § 333(a)(2) ensures that this prohibition will be applied *only* to those who are directly familiar with the requirements of the FDCA. That is, having previously been made *personally* aware of the strictures of § 333, a defendant covered by the first clause of § 333(a)(2) is plainly *not* someone who, when he later engages in delivery of misbranded drugs, was merely engaging in what would reasonably be thought to be "traditionally lawful conduct." In this way, a prior criminal conviction under § 333 effectively serves as a functional substitute for a scienter requirement: although the Government need not show that the defendant knew that the *current* drugs at issue were "misbranded," the defendant's prior conviction puts him amply on notice that he is operating in a heavily regulated area that involves potentially dangerous substances and as to which he must proactively exercise care. Such recidivists are, in other words, the paradigmatic example of the sorts of persons who may be expected to "inform[] themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce." *Dotterweich*, 320 U.S. at 285; *see also Posters 'N' Things*, 511 U.S. at 522 (stating that the public welfare exception to the presumption in favor of scienter generally applies only where there is "proof that the defendant had knowledge of sufficient facts to alert him to the

probability of regulation of his potentially dangerous conduct").

3

Marschall argues that, at the very least, a scienter requirement must be read into the recidivist provision of § 333(a)(2) in order to avoid a serious concern that the statute would violate the constitutional guarantee of due process. We reject this contention.

Even assuming that the Due Process Clause imposes an outer limit on Congress's power to define strict liability offenses, *compare United States v. Wulff*, 758 F.2d 1121, 1125 (6th Cir. 1985) (holding that it would violate due process to subject "a person acting with a completely innocent state of mind . . . to a severe penalty and grave damage to his reputation") *with United States v. Engler*, 806 F.2d 425, 433 (3d Cir. 1986) ("We are persuaded that the Sixth Circuit in *Wulff* . . . ignored a formidable line of cases imposing strict liability in felony cases without proof of scienter."), the recidivist clause of § 333(a)(2) is well within any such constitutional limits. As the Supreme Court explained in *United States v. International Minerals & Chemical Corp,*, 402 U.S. 558 (1971), there may be certain "type[s] of products" where imposing criminal penalties on those dealing in them "might raise substantial due process questions if Congress did not require . . . '*mens rea*' as to each ingredient of the offense." *Id.* at 564–65. But such due process notice concerns are inapplicable where, as here, the statute permits a conviction *only* upon a showing that the defendant committed a second violation of § 333 after having already been finally convicted of a prior violation of that same statute. Such a defendant has personally

received ample notice "of sufficient facts to alert him to the probability of regulation of his potentially dangerous conduct." *Posters 'N' Things*, 511 U.S. at 522. Put another way, a person such as Marschall cannot be heard to complain that he was not given notice that he was engaging in something other than "traditionally lawful conduct." *Staples*, 511 U.S. at 618.[4]

* * *

In view of these considerations, and the strong textual evidence noted earlier, we conclude that this is the unusual case in which a public welfare offense lacks a scienter element even though it is a felony with moderately severe potential penalties. In short, (1) Congress augmented, into a felony, a predicate misdemeanor offense that concededly lacks a scienter requirement; (2) it did so by adding, not a scienter requirement, but a prior conviction requirement; (3) this action contrasts with Congress's explicit addition of a scienter requirement in the *other* clause of § 333(a)(2); and (4) the prior conviction requirement, as a functional matter, largely serves the same purposes as an express scienter requirement. Under this confluence of circumstances, we conclude that the first clause of § 333(a)(2) does not require the Government to prove that the defendant knew that the drugs were

[4] We reject Marschall's argument that the requisite notice has been afforded only if the *same* drugs are at issue in each successive prosecution under § 333. A prior prosecution and conviction under § 333 provides more than enough notice of the scope of the regulatory regime that is enforced by § 333 and to alert the defendant of the need "to ascertain at his peril" whether another drug that he thereafter "sells comes within the inhibition of the statute." *United States v. Freed*, 401 U.S. 601, 609 (1971) (quoting *Balint*, 258 U.S. at 254).

misbranded. Accordingly, the indictment here did not need to allege that Marschall *knew* that the labeling of the "Dynamic Duo" rendered those products misbranded in the respects described in the indictment. The district court therefore properly denied Marschall's motion to dismiss the indictment.

AFFIRMED.

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. RICHARD MARSCHALL, Defendant-Appellant.	No. 22-30048 D.C. No. 3:20-cr-05270-BHS-1 Western District of Washington, Tacoma ORDER

Before: IKUTA and COLLINS, Circuit Judges, and FITZWATER,* District Judge.

Judge Ikuta and Judge Collins have voted to deny the petition for rehearing en banc, and Judge Fitzwater so recommends. The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. *See* FED. R. APP. P. 35. The petition for rehearing en banc (Dkt. 60) is denied.

* The Honorable Sidney A. Fitzwater, United States District Judge for the Northern District of Texas, sitting by designation.