

United States Court of Appeals For the First Circuit

Nos. 16-2402
16-2403
16-2404

UNITED STATES OF AMERICA,

Appellant,

v.

ALLA V. STEPANETS; KATHY S. CHIN; MICHELLE L. THOMAS,

Defendants, Appellees.

APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Richard G. Stearns, U.S. District Judge]

Before

TorrueLLa, Thompson, and Kayatta,
Circuit Judges.

Daniel Tenny, Attorney, Appellate Staff, Civil Division, U.S. Department of Justice, with whom Chad A. Readler, Acting Assistant Attorney General, William D. Weinreb, Acting United States Attorney, Amanda P.M. Strachan, Assistant United States Attorney, George P. Varghese, Assistant United States Attorney, Douglas N. Letter, Attorney, Appellate Staff, and Scott R. McIntosh, Attorney, Appellate Staff, were on brief, for appellant.

John H. Cunha Jr., with whom Cunha & Holcomb, P.C. was on brief, for appellee Stepanets. Michael C. Bourbeau, with whom Bourbeau & Bonilla, LLP was on brief, for appellee Thomas.
Joan M. Griffin for appellee Chin.

January 12, 2018

THOMPSON, Circuit Judge.

Preface

The government appeals from orders dismissing counts in an indictment that charged Alla Stepanets, Kathy Chin, and Michelle Thomas with "dispens[ing]" misbranded drugs in violation of the Federal Food, Drug, and Cosmetic Act, see 21 U.S.C. §§ 353(b)(1), 331(a), and 333(a)(2) – a statute that often goes by the unpronounceable initialism "FFDCA." Reviewing the matter *de novo*, see United States v. Guerrier, 669 F.3d 1, 3 (1st Cir. 2011), we think dismissal was not called for. And so we reverse and remand for further proceedings.

FFDCA Primer

Here is what you need to know about the FFDCA (we simplify a bit). Enacted many decades ago "to protect consumers from dangerous products," see United States v. Sullivan, 332 U.S. 689, 696 (1948), the FFDCA bans "[t]he introduction or delivery for introduction into interstate commerce of any . . . misbranded" prescription drug, see 21 U.S.C. § 331(a). A prescription drug is "misbranded" if it is "dispensed" without "a written prescription of a practitioner licensed by law to administer such drug." Id. § 353(b)(1). "Dispensed" is an undefined FFDCA term, however. Anyhow, anyone who violates this law "with the intent to defraud

or mislead" commits a crime punishable with up to three years in prison. See id. § 333(a)(2).

Case Background

Shifting from the general to the specific, we believe a simple sketch of the key events suffices to put things in perspective. A quick heads up, though: because the judge dismissed the charges before trial, we describe the facts as though the government had proved what the indictment alleged, see United States v. Councilman, 418 F.3d 67, 71-72 (1st Cir. 2005) (en banc) – which of course is not the case.

The Defendants

Stepanets, Chin, and Thomas were Massachusetts-licensed pharmacists. That meant they could (among other things) dispense drugs, but only through "valid prescriptions from a medical practitioner."¹ The trio worked as pharmacists for New England Compounding Center ("NECC" for short), a now-defunct Massachusetts-licensed pharmacy that specialized in "high-risk compounding" – a process that involves "using non-sterile ingredients to create sterile drugs." Assigned to NECC's "packing area," they "check[ed]" drug "orders" before "shipment to NECC's customers."

¹ All quotations in this section come from the indictment unless otherwise noted.

The Indictment

Eventually, Stepanets, Chin, and Thomas got swept up in a 131-count indictment that included 11 other persons with NECC ties. The gargantuan document catalogs an array of felonious conduct – for example, it alleges that NECC failed to follow proper sterilization procedures, opted to use expired or expiring ingredients, and neglected to run proper tests. As relevant for our purposes, the indictment alleges that our defendants dispensed drugs in violation of the FFDCA, specifically by causing misbranded drugs to be introduced into interstate commerce with the intent to defraud or mislead. And the indictment charges them both as principals and as aiders and abettors. See 18 U.S.C. § 2 (making aiders and abettors punishable as principals for the offenses they aided and abetted).

The indictment is quite detailed – as a for-instance, the indictment identifies particular drug shipments to particular places on particular dates based on prescriptions for fake patients, and it specifies the laws the defendants allegedly broke. By way of illustration, just consider the following allegations pulled from the indictment:

- on February 18, 2010, Stepanets caused 60 vials of "betamethasone repository" to be delivered to Lincoln,

Nebraska, based on prescriptions for "Wonder Woman" and "Fat Albert," among others;²

- similarly, on March 8, 2012, Chin caused 60 vials of "betamethasone repository" to be delivered to Lincoln, Nebraska, based on prescriptions for "Flash Gordon," "Tony Tiger," and "Chester Cheeto," among others;
- and on March 20, 2012, Thomas and Stepanets caused 12 vials of "betamethasone repository" to be delivered to Elkhart, Indiana, based on prescriptions for "L.L. Bean," "Coco Puff," and "Filet O'fish," among others.³

² Betamethasone is a steroid medication "with anti-inflammatory and immunosuppressive properties." See Baldwin v. White, No. 3:12CV210, 2013 WL 3893997, at *5 n.17 (E.D. Va. July 26, 2013).

³ For anyone not up on pop culture: Wonder Woman is a made-up superhero of comic book, television, and movie fame. *Wonder Woman*, Wikipedia, https://en.wikipedia.org/wiki/Wonder_Woman (last visited Jan. 3, 2018). So is Flash Gordon. *Flash Gordon*, https://en.wikipedia.org/wiki/Flash_Gordon (last visited Jan. 3, 2018). Fat Albert is a cartoon character created by Bill Cosby. *Fat Albert and the Cosby Kids*, https://en.wikipedia.org/wiki/Fat_Albert_and_the_Cosby_Kids (last visited Jan. 3, 2018). Tony Tiger – a/k/a "Tony the Tiger" – is a cartoon spokesperson for Kellogg's Frosted Flakes cereal. *Tony the Tiger*, https://en.wikipedia.org/wiki/Tony_the_Tiger (last visited Jan. 3, 2018). Chester Cheeto – a/k/a "Chester Cheetah" – is a cartoon spokesperson for Frito Lay's Cheetos snacks. *Chester Cheeto*, https://en.wikipedia.org/wiki/Chester_Cheetah (last visited Jan. 3, 2018). L.L. Bean is a Maine-based outdoor clothing and equipment retailer. *L.L. Bean*, <https://en.wikipedia.org/wiki/L.L.Bean> (last visited Jan. 3, 2018). Coco Puff – a variant spelling of "Cocoa Puffs" – is a chocolate-flavored cereal made by General Mills. *Cocoa Puffs*, https://en.wikipedia.org/wiki/Cocoa_Puffs (last visited Jan. 3,

Also, the indictment notes the statutory bases for the charges – 21 U.S.C. §§ 353(b)(1), 331(a), and 333(a)(2), and 18 U.S.C. § 2 – and mimics their language in key respects.

The Dismissal Battles

Responding to the indictment, Stepanets, Chin, and Thomas moved to dismiss the FFDCA charges against them – Stepanets filed her own motion, and Chin and Thomas filed a joint motion. Stepanets argued that she was not sufficiently involved in NECC's process to have "dispensed" the drugs and that the pertinent FFDCA provisions are unconstitutionally vague as applied to her. Chin and Thomas argued that the FFDCA does not require prescriptions to be "valid" for licensed pharmacists to fill them; that as a factual matter they were not personally responsible for taking the steps they deemed necessary for them to have "dispensed" the drugs; and that the parts of the FFDCA covering their conduct are impermissibly vague as applied to them. The government responded that the FFDCA does not allow licensed pharmacists to fill obviously fraudulent prescriptions; that the indictment's allegations – which must be taken as true – support the charges;

2018). And Filet O'fish – a variant spelling of "Filet-O-Fish" – is a fish sandwich sold by McDonald's, a fast-food restaurant chain. *Filet-O-Fish*, <https://en.wikipedia.org/wiki/Filet-O-Fish> (last visited Jan. 3, 2018).

and that the FFDCA is sufficiently clear to withstand the defendants' vagueness challenges.

Acting on the parties' submissions, the judge dismissed the FFDCA counts against the defendants. Stripped to essentials, the judge's reasoning went something like this: The indictment's allegations, the judge wrote, show that the defendants "knew or should have known that at least some of the shipping labels were made out in the names of fictitious patients." But, the judge added, that conclusion helped the government only so much. Relying on a medical dictionary's definition of "dispense," the judge ruled that "a pharmacist dispenses a drug when she acts in her role as a licensed professional to fill (put together) a medical prescription for delivery to a patient." From there, the judge said that the FFDCA "as written clearly punishes pharmacists who fill or take part in the filling of invalid prescriptions placed into interstate commerce with the intent to defraud or mislead the government." But he still thought the indictment did not provide "fair notice." Explaining why, the judge wrote that "conduct incidental to the distribution of prescribed drugs" – like "checking a package" – falls outside the FFDCA's reach, and he expressed his concern that "a reasonable pharmacist" would not know "from the indictment that by matching orders to packages prior to their being shipped, she was criminally liable for participating

in the filling of a prescription that she had never approved (or is even alleged to have seen)."

Sticking to his views, the judge later denied the government's motion to reconsider. Two things about that ruling stand out. First, the judge read the indictment as simply accusing our defendants of committing a "clerical task" – a task, the judge added, that does not rise to the level of dispensing under the FFDCA. Second, responding to the government's argument that his earlier order did not address aiding-and-abetting liability, the judge said the indictment's allegations portrayed each defendant as "mere[ly] presen[t]" at the scene of the crime – and mere presence does not an aider and abettor make, the judge wrote, "even when coupled with knowledge that a crime is being committed by others."

The Appeal Taken

That brings us to today, with the government trying to torpedo the judge's rulings and the defendants trying to save them. Our jurisdiction secure thanks to 18 U.S.C. § 3731, we now offer our *de novo* take on the case.

Analysis

Guiding Legal Principles

We begin with a few basics. The Constitution says that a criminal defendant cannot "be held to answer for a capital, or

otherwise infamous crime, unless on a presentment or indictment of a Grand Jury," U.S. Const. amend. V, and that she has "the right . . . to be informed of the nature and cause of the accusation," U.S. Const. amend. VI. Consistent with these commands, Federal Rule of Criminal Procedure 7(c)(1) says that an indictment must contain "a plain, concise, and definite written statement of the essential facts constituting the offense charged" – though an indictment's "count[s] may allege that the means by which the defendant committed the offense are unknown." An indictment need not say much to satisfy these requirements – it need only outline "the elements of the crime and the nature of the charge so that the defendant can prepare a defense and plead double jeopardy in any future prosecution for the same offense." See Guerrier, 669 F.3d at 3. This means that an indictment that tracks a statute's terms is legally sufficient if the indictment itself gives the defendant adequate notice of the charges she must meet. See, e.g., Hamling v. United States, 418 U.S. 87, 117 (1974); United States v. Savarese, 686 F.3d 1, 6 (1st Cir. 2012); United States v. Troy, 618 F.3d 27, 34 (1st Cir. 2010).

As you read on, keep in mind as well that "[t]he government need not recite all of its evidence in the indictment." See United States v. Innamorati, 996 F.2d 456, 477 (1st Cir. 1993). Also keep in mind that courts must not inquire into the sufficiency

of the evidence underlying the indictment – for when "a defendant seeks dismissal of the indictment, the question is not whether the government has presented enough evidence to support the charge, but solely whether the allegations in the indictment are sufficient to apprise the defendant of the charged offense." See Savarese, 686 F.3d at 7; see also Guerrier, 669 F.3d at 4 (noting that courts "routinely rebuff efforts to use a motion to dismiss as a way to test the sufficiency of the evidence behind an indictment's allegations"). Keep in mind too that in seeing whether an indictment is up to snuff, a court must reject arguments that embrace technical niceties at the expense of common sense. See United States v. Mubayyid, 658 F.3d 35, 69-70 (1st Cir. 2011); 1 Charles Alan Wright & Andrew D. Leipold, Federal Practice and Procedure § 123 at 522-23 (4th ed. 2008). And definitely keep in mind that a court must deny a motion to dismiss if the motion relies on disputed facts. See, e.g., United States v. Covington, 395 U.S. 57, 60 (1969) (holding that a court can resolve a pretrial motion to dismiss the indictment only when "trial of the facts surrounding the commission of the alleged offense would be of no assistance in determining the validity of the defense"); Fed. R. Crim. P. 12(b)(3) (noting that a motion to dismiss for failure to state a crime "must be raised by pretrial motion if the basis for

the motion is then reasonably available and the motion *can be determined without a trial on the merits*" (emphasis added)).

A Sufficient Indictment

Measured against these modest standards, the indictment here easily passes muster – just as the government argues. After all, and again: The indictment notes the statutory bases for the counts, listing the crimes' key elements. The indictment also provides the relevant factual backdrop, alleging for example that each defendant-pharmacist approved specified drug shipments, on specified dates, to specified locations, based on obviously invalid prescriptions for specified fake patients (*e.g.*, "Wonder Woman" and "Coco Puff"). And the indictment connects the elements and the facts. So the indictment gives the defendants enough info to prepare a defense and to invoke double-jeopardy protections to forestall a later trial on the same charges. The law requires no more.⁴ See, e.g., Savarese, 686 F.3d at 6; Troy, 618 F.3d at 35.

⁴ The defendants scold the government for "[f]inding comfort in [the indictment's] tracking the language of the [FFDCA]." But we see nothing wrong with the government's approach, particularly since we have long held that "the statutory language may be used in the indictment to describe the offense," provided the indictment lets the defendant know the "general factual scenario on which the charges rest," see Troy, 618 F.3d at 34, 35 – a standard this indictment meets, for reasons already explained.

No Persuasive Counterarguments

The reason why the judge's analysis veered off-track is because he made some out-of-place fact-assumptions – assumptions that devastate his conclusion about how the indictment insufficiently charges principal or aider-and-abettor liability. Unfazed, the defendants invite us to follow the judge's lead, advancing a number of counterarguments aimed at defending the judge's rulings. We decline the invitation – though before explaining why, we must first recap some things we said earlier.

Recall that after focusing on the word "dispense" in the FFDCa, the judge ruled that the statute "punishes pharmacists who fill or take part in the filling of invalid prescriptions placed in interstate commerce."⁵ Moving on, the judge then read the

⁵ We take a quick timeout to straighten something out. Taking their cue from the judge below, the defendants say that Commonwealth v. Brown, 925 N.E.2d 845 (Mass. 2010), is – to quote their brief – "instructive in how to define 'dispense'" under the FFDCa. Dealing with Massachusetts's controlled-substances act – not with the FFDCa – Brown noted that the term "dispense" in the state statute is defined and limited to "deliver[y]" to the "ultimate user," and "ultimate user" is defined as someone who "lawfully possesses a controlled substance for his own use or the use of a member of his household." Id. at 855 (emphasis removed) (quoting Mass. Gen. Laws ch. 94C, § 1). So according to Brown, a drug is not "dispensed" under that statute if a person receives it because of "an invalid prescription" – though in that situation, because she "has devolved into a 'pusher,'" the physician can be prosecuted for "the crime of 'distribution.'" Id. at 857-58. Importantly for us, the FFDCa provisions in play here have no lawful-possession requirement. And given this big-time difference between the two statutes, there is no need to rely on Brown.

indictment as alleging that the defendants simply performed a "clerical task," like checking the address on a drug package's mailing label. And having done this, the judge concluded that the defendants could not have understood from the indictment that their conduct – helping fill prescriptions they never approved, much less saw – infringed the FFDCA. More, the judge also read the indictment as alleging that the defendants were merely present when the crimes occurred, which as he saw it sinks any aiding-and-abetting theory.

Recall too that the defendants – echoing the judge's analysis – claim as a *factual matter* that they acted not as NECC pharmacists but as NECC shipping clerks, performing "rotely clerical" tasks, like checking addresses on packages. They also insist that they did not "understand" from the FFDCA's language that they could be criminally liable for helping fill prescriptions they never signed off on, let alone caught sight of. And last but not least, they too assert that the indictment's allegations show only their mere presence at a crime scene, which in their telling means the document inadequately alleges aiding-and-abetting liability.

Taking first things first, we consider the indictment's allegations that the defendants participated as principals in the FFDCA crimes:

We agree with the government that the major flaw in the judge's and the defendants' analyses is that the indictment says nothing – *zippo* – about the defendants' having simply checked addresses or worked as clerks. Rather, the indictments says that each of them (1) was "a pharmacist licensed . . . to dispense drugs pursuant to a valid prescription from a valid medical practitioner," (2) "was employed as a pharmacist at NECC," and (3) had caused misbranded drugs to be delivered into interstate commerce – allegations that hardly suggest that they labored at NECC as mere shipping clerks. Nor does the indictment say anything about how a non-pharmacist could do the jobs each defendant-pharmacist did at NECC.

Undaunted, the defendants note that the indictment alleges that each of them worked "in the packing area checking orders." And they insist – emphasis theirs – that "[i]t is *undisputed* that [their] role checking orders in the shipping department was limited to confirming that the correct drugs were being sent to the correct facility and did not include checking the prescriptions or patient names or any other aspect of the dispensing process." But the government *does* dispute that

contention, arguing for example that the "worked in the packing area checking orders" allegations – viewed in context and with common sense – connote the kind of checking that pharmacists regularly do when filling prescriptions, *i.e.*, confirming that legit prescriptions triggered the drug shipments. Anyway, the defendants cite nothing in the indictment to support their theory that they did not check patient names or prescriptions.⁶ So at best for the defendants, we have disputes of fact – disputes that must be resolved at trial rather than on pretrial motions to dismiss. See Covington, 395 U.S. at 60; Guerrier, 669 F.3d at 3-4.

And what we have just said undermines the judge's and the defendants' no-fair-notice analyses as well. Even putting to

⁶ Interestingly, the defendants later admit that they did do more than check addresses, conceding in a footnote that NECC "use[d] a pharmacist . . . to check that the name and dosage of the drug on the shipping label [was] the same as the name and dosage on the order form." No big deal, they say, because NECC's use of a pharmacist was "a surfeit" and "hardly means that a non-pharmacist could not easily have performed the task." To their minds, "a pharmacist would only be *required*" – again, emphasis theirs – "if some sort of testing was performed," which "was not done, or alleged." This line of argument is full of holes, the most notable ones being: The defendants do not explain why they think NECC's use of a pharmacist was a surfeit (surfeit is basically a fancy word for excessive) – perhaps because the indictment does not allege non-pharmacists could have done what the defendants did. Also and critically, the indictment nowhere says that NECC needed pharmacists only when "some sort of testing" was required.

the side that no one cites a case – and we know of none – holding any key FFDCA provision void for vagueness,⁷ the no-fair-notice thesis depends on fact-assumptions about how the defendants did not know that they could be on the hook criminally for taking part in filling prescriptions they neither approved nor saw. But as the government notes, the indictment says nothing about the defendants' not approving or seeing the prescriptions. Properly understood then, the no-fair-notice theory depends on contested "facts surrounding the commission of the alleged offense" – facts no court may consider before trial. See Covington, 395 U.S. at 60; see also Guerrier, 669 F.3d at 3.

Turning then to the indictment's allegations that the defendants acted as aiders and abettors in the FFDCA crimes:⁸

Generally speaking, an aider and abettor is one who knowingly helps another commit a crime. See United States v. Urciuoli, 513 F.3d 290, 299 (1st Cir. 2008) (explaining that an

⁷ See generally United States v. Girod, No. 5:15-87-S-DCR, 2017 WL 760742, at *1 (E.D. Ky. Feb 2, 2017) (stressing that "the courts have repeatedly upheld the constitutionality of the [FFDCA's] misbranding provisions . . . in the face of vagueness challenges").

⁸ We should first say that the defendants imply that the government cannot go the aiding-and-abetting route because it debuted that theory in a motion for reconsideration. But the judge did not reject the issue on lateness grounds, opting instead to address the issue head-on. So we consider the issue preserved for appellate review. See Trenkler v. United States, 536 F.3d 85, 96 (1st Cir. 2008).

aider and abettor is one who "associate[s] himself with the venture, . . . participate[s] in it as in something that he wishes to bring about," and "seek[s] by his action to make it succeed" (quoting United States v. Peoni, 100 F.2d 401, 402 (2d Cir. 1938))). In outlawing "aiding and abetting, Congress used language that 'comprehends all assistance rendered by words, acts, encouragement, support, or presence.'" Rosemond v. United States, 134 S. Ct. 1240, 1246 (2014) (quoting Reves v. Ernst & Young, 507 U.S. 170, 178 (1993)).

As the government notes, the indictment specifically cites to the aiding-and-abetting statute, even though such a cite is not automatically required for the government to proceed on an aiding-and-abetting theory. See United States v. Sanchez, 917 F.2d 607, 611 (1st Cir. 1990) (holding that "the government may rely on an 'aiding and abetting' theory, although the indictment neither alleges nor adverts to it, except on a showing of unfair surprise"). And despite what the judge thought and the defendants think, we believe a common-sense reading of the indictment's allegations suggests that each defendant-pharmacist performed NECC-assigned tasks that caused misbranded drugs to be introduced into interstate commerce – allegations that indicate that the defendants were not merely present, but were culpably present. See Urciuoli, 513 F.3d at 299. So once again, the defendants,

tracking the judge's line of reasoning, rely here on disputed facts that they want found in their favor – a situation that calls for a trial, not a dismissal on pretrial motions.⁹ See Covington, 395 U.S. at 60; Guerrier, 669 F.3d at 3-4.

Wrap Up

Our work over, we **reverse** the judge's dismissal of the FFDA charges against the defendants.

⁹ Two loose ends dangle. Focusing on the scienter element for aiding-and-abetting liability, the defendants suggest that the indictment does not allege that they knew the names on the prescriptions were phony. Even the judge below did not buy that argument, as he accepted for purposes of deciding the dismissal motions that the defendants had the requisite knowledge. And the defendants offer no persuasive basis for second-guessing the judge's reasoning.

Without citing any authority, the defendants also suggest that we should affirm the judge's aiding-and-abetting ruling because the indictment (in their minds) fails to specifically identify who the principals were (if not these defendants, that is) – a ground not relied on by the judge. The suggestion is waived, however – they neglected to make it below; and if that were not enough, they neglected to adequately brief it here. See, e.g., Ayala-Sepúlveda v. Municipality of San Germán, 671 F.3d 24, 30 n.4 (1st Cir. 2012); Muñiz v. Rovira, 373 F.3d 1, 8 (1st Cir. 2004).