United States Court of Appeals
For the First Circuit

No. 19-1644

UNITED STATES OF AMERICA,

Appellant,

v.

SHARON P. CARTER,

Defendant, Appellee.

No. 19-1645

UNITED STATES OF AMERICA,

Appellant,

v.

GREGORY CONIGLIARO,

Defendant, Appellee.

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

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

Before

Lynch, Lipez, and Barron,
Circuit Judges.

Ross B. Goldman, Criminal Division, Appellate Section, United States Department of Justice, with whom Andrew E. Lelling, United

States Attorney, Amanda P.M. Strachan, Assistant United States Attorney, Donald C. Lockhart, Assistant United States Attorney, Brian A. Benczkowski, Assistant Attorney General, and John P. Cronan, Principal Deputy Assistant Attorney General, were on brief, for appellant.

Michael J. Pineault, with whom Clements & Pineault, LLP was on brief, for appellee Sharon P. Carter.

Daniel M. Rabinovitz, with whom Shawn Lu and Murphy & King, P.C. were on brief, for appellee Gregory Conigliaro.

September 27, 2021

BARRON, Circuit Judge. These consolidated appeals are the latest to reach us in connection with the federal criminal investigation that ensued after patients across the country became seriously ill or died in the fall of 2012 after having been injected with a contaminated medication traced to the New England Compounding Center ("NECC"). NECC was a licensed pharmacy based in Framingham, Massachusetts. It combined drugs with other substances to create specialized medications -- a practice known as compounding.

Unlike in the other appeals that we have considered in connection with the federal criminal investigation into NECC's operations, see United States v. Stepanets, 989 F.3d 88 (1st Cir. 2021); United States v. Cadden, 965 F.3d 1 (1st Cir. 2020); United States v. Chin (Chin I), 965 F.3d 41 (1st Cir. 2020), the appellant here is the government. It challenges the post-verdict judgments of acquittal that the District Court entered in favor of Sharon Carter and Gregory Conigliaro, who were, respectively, NECC's former Director of Operations and NECC's former Vice President, Secretary, Treasurer, and General Manager.

Carter and Conigliaro were named along with twelve others in a 131-count indictment that a grand jury in the District of Massachusetts handed up in December 2014. Neither Carter nor Conigliaro was charged with playing any direct role in the physical compounding of the contaminated medication that was linked to

patient illnesses and deaths. Instead, each was charged only with counts that pertained to their roles in connection with other aspects of NECC's operations. Among those charges was one that alleged that each had, while working at NECC, conspired to defraud the United States in violation of 18 U.S.C. § 371 "by interfering with and obstructing" the ability of the United States Food and Drug Administration ("FDA") to oversee the practices of NECC.

A jury found both Carter and Conigliaro guilty of violating § 371 following their joint trial. Carter and Conigliaro then each moved pursuant to Federal Rule of Criminal Procedure 29 for a post-verdict judgment of acquittal on the § 371 count for which each had been found guilty.[1] The District Court granted the motions. The government now appeals the resulting judgments of acquittal. We reverse.

I.

We describe the facts concerning the defendants' alleged conduct as they are pertinent to our analysis. To set the stage for that analysis, though, it is useful first to recount both the involved procedural history that has brought us to this point and some of the basic legal background that bears on the issues present in these appeals.

[1] Before and during the trial, both defendants had already filed multiple motions challenging the § 371 conspiracy charge against them, each of which the District Court had denied.

A.

The indictment charged that between 1998 and approximately October 2012, Carter, Conigliaro,[2] and three of their codefendants who also were employees of NECC at the time -- Barry Cadden, Robert Ronzio, and Alla Stepanets[3] -- had engaged in a conspiracy to violate 18 U.S.C. § 371. That statute criminalizes the "conspir[acy]" by "two or more persons . . . to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose" as long as "one or more of such persons do any act to effect the object of the conspiracy." Id. We have interpreted the "defraud" clause of § 371 to encompass conspiracies that seek to "interfere with government functions." United States v. Goldberg, 105 F.3d 770, 773 (1st Cir. 1997); see also United States v. Morosco, 822 F.3d 1, 6 (1st Cir. 2016) (explaining that § 371 criminalizes conspiracies to "obstruct[] the operation of any government agency by any 'deceit, craft or trickery, or at least by means that are

[2] Conigliaro began working at NECC in 2004 and was charged with joining the conspiracy then.

[3] Ronzio was NECC's National Sales Manager. He ended up entering into a cooperation agreement with the government and pleading guilty to the § 371 conspiracy count that he faced. Stepanets was a pharmacist who worked in NECC's packing area. See Stepanets, 989 F.3d at 96. Cadden was NECC's founder and president. Stepanets and Cadden were both acquitted of the § 371 conspiracy count by their respective juries but found guilty of other counts that each faced. See id. at 93; Cadden, 965 F.3d at 8.

dishonest'" (quoting Hammerschmidt v. United States, 265 U.S. 182, 188 (1924))); United States v. Barker Steel Co., 985 F.2d 1123, 1128 (1st Cir. 1993) ("The objective of the agreement is unlawful if it is 'for the purpose of impairing, obstructing or defeating the lawful function of any department of [g]overnment.'" (quoting United States v. Hurley, 957 F.2d 1, 4 (1st Cir. 1992))).

In detailing the alleged § 371 conspiracy, the indictment charged the defendants with "interfering with and obstructing the lawful governmental functions of the FDA." In support of this contention, the indictment alleged that Carter, Conigliaro, and their co-conspirators had agreed to enter into a conspiracy defraud the FDA by "purport[ing] to be operating NECC as a state-regulated pharmacy, dispensing drugs pursuant to valid, patient-specific prescriptions as required by Massachusetts law, rather than as a drug manufacturer distributing drugs in bulk to customers without prescriptions and thereby subject to heightened regulatory oversight by the FDA" pursuant to its authority under the Food, Drug, and Cosmetic Act ("FDCA").

Passed in 1938, the FDCA gave the FDA authority to regulate "any new drug." Act of June 25, 1938, Pub. L. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. § 301 et seq.); FDCA § 505(a) (codified at 21 U.S.C. § 355(a)). During the time of the alleged conspiracy, the FDCA defined "new drug" as "[a]ny drug . . . not generally recognized . . . as safe and effective for use under the

conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p). It further provided that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the FDA] is effective with respect to such drug." Id. § 355(a). In addition, it provided that any "new drug" must be made in accordance with "current good manufacturing practice" ("GMP") -- a set of regulations that the FDA subsequently promulgated to impose strict safety controls on manufacturers of new drugs. Id. § 351(a)(2)(B); see also 21 U.S.C. § 371(a) ("The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the [Commissioner of the FDA].").

Compounded drugs would appear to fit within the FDCA's definition of a "new drug." After all, "[d]rug compounding is a process [that] combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient . . . that [is typically] not commercially available." Thompson v. Western States Med. Cntr., 535 U.S. 357, 360-61 (2002). Nevertheless, for the first fifty years after the FDCA's enactment, "the FDA generally left regulation of compounding to the States." Id. at 362.

"[E]ventually," however, the FDA "became concerned . . . that some pharmacists were manufacturing and selling drugs under

the guise of compounding, thereby avoiding the FDCA's new drug requirements." Id. It then began to take a more proactive role in the oversight of compounders -- at least those compounders that the FDA concluded behaved as manufacturers. Id. at 362-63.

The indictment here centered on the role that the alleged conspirators supposedly played in defrauding the FDA. In particular, the indictment claimed that the defendants conspired to prevent the FDA from being able to determine whether NECC was a manufacturer or a pharmacy by intentionally misrepresenting the nature of the company's operations. The indictment explained in that respect that, as a "manufacturer," NECC would have been subject to heightened regulatory oversight by the FDA pursuant to its authority under the FDCA, while, as a "pharmacy," NECC would have been primarily regulated by state pharmacy boards. By conspiring to misrepresent to the FDA that NECC was operating only as a pharmacy and not as a manufacturer, the indictment alleged, the defendants conspired to interfere with the FDA's oversight function with respect to NECC and thereby conspired to defraud the United States in violation of § 371, given that such regulatory oversight by FDA is a "government function."

The indictment also alleged how the defendants carried out the alleged conspiracy to misrepresent the company's operations. Specifically, it alleged that the defendants agreed to participate in a conspiracy by which NECC would regularly

misrepresent to the FDA that it was shipping its compounded medications to customers (which were hospitals and medical facilities rather than patients in their own right) pursuant to valid, patient-specific prescriptions. Yet, in fact, the indictment alleged, the company was processing the customers' orders for those medications without there being any such prescriptions. It then described three methods by which NECC allegedly disguised the fact that it was shipping compounded drugs in this manner before turning to the roles that that conspirators allegedly each played in carrying out the deception.

One such alleged method involved "backfilling." Here, NECC allegedly allowed customers to place their first order for medications without supplying any prescriptions or patient names. NECC then collected from customers the roster of patient names to whom these customers ended up prescribing and administering the medications on site. Thereafter, NECC allegedly attached such a roster either retrospectively to that first order or used it to process a subsequent order by the same customer -- thereby making it look as if NECC had filled the orders only after it had received valid, patient-specific prescriptions from a customer.

A second alleged method involved NECC's processing of orders using prescriptions for fictitious patients. Sometimes, according to the indictment, NECC processed orders using the names of celebrities or fantasy characters that customers had supplied,

such as "Michael Jackson" and "Wonder Woman." At other times, the indictment alleged, NECC used the names of customers' staff members or those of previous patients that customers had supplied. At still other times, NECC allegedly fabricated the prescriptions rather than relying on its customers to do so. And, finally, according to the indictment, NECC sometimes used a given patient name for multiple medications and for multiple units of the same medication in a single order, applying a ratio that would look plausible to regulators rather than filling a valid multidose prescription.

Pursuant to yet a third alleged method of shipping the drugs without a valid patient-specific prescription, according to the indictment, NECC processed some customers' orders using just the names of those institutional customers. NECC allegedly did so even though the customer was a hospital or medical facility that would then itself later dispense the drug to a patient and thus was not itself a patient for whom a prescription had been issued. Under this method, then, the drug was shipped by NECC to its customers without there being any patient identified who had been issued a prescription for it.

The indictment alleged that the defendants helped NECC deploy these methods despite knowing that the company was representing to the FDA that it was a compounding pharmacy that dispensed drugs only pursuant to valid prescriptions for

individual patients and therefore was not subject to the FDA's GMP regulations that govern drug manufacturers. In setting forth this allegation, the indictment highlighted several statements allegedly made by the defendants that purportedly showed their awareness of both the alleged scheme and the regulatory background in which NECC's scheme was taking place.

The indictment included, for example, Conigliaro's alleged statements to the FDA that NECC was a "compounding-only pharmacy, not a manufacturer" and thus "not subject to GMP." Also cited in the indictment was an email Carter shared with NECC's order-processing staff, instructing them that "the MAX total number of units . . . per patient must make sense," that "all names must resemble 'real' names," and not to use "obviously fake names [] (Mikey Mouse)" because she "must be able to logically explain to a regulator why [NECC] processed x# of units per patient" (emphasis added).

B.

The § 371 case against Carter and Conigliaro eventually went to trial. They were tried along with the four other defendants who were also charged with committing the § 371 offense.

At trial, the government presented documentary evidence alongside testimony from twenty-nine witnesses, many of whom were from the FDA or were former NECC employees. We summarize the record presented at trial as it is relevant to the motions for

judgments of acquittal by Carter and Conigliaro that are before us in these appeals.

Many of the documents that the government introduced at trial were the product of two search warrants executed against NECC and its sales-affiliate, Medical Sales Management. The evidence introduced included order forms that NECC had filled for its customers under various "patient" names, such as "Ted Bundy" and "Barney Fife." The evidence also included an employee manual that Carter signed that detailed the "FDA Modernization Act of 1997-Pharmacy Compounding Provisions" and "[h]ow to handle an FDA inspection" (as well as many of the emails described in the indictment).

In addition, the government introduced testimony from several former employees who testified to Carter's and Conigliaro's understanding of the importance to NECC of the company being considered a pharmacy and not a manufacturer in the eyes of regulators. Ken Boneau, for example, one such former sales representative, testified that during his training as a new employee, it was explained to him that "if the FDA regulated [NECC], there would be a lot of limitations" and that it was "important that the FDA not regulate NECC." Beth Reynolds, an NECC licensing coordinator, further testified to conversations that she had with Conigliaro and others about NECC needing to comply with state laws requiring the compounder to meet state

manufacturing guidance. As to Carter, the government introduced testimony from former employees, including Boneau and Mario Giamei, Jr., about emails that they had received from Carter about what to do in the event that NECC's customers did not provide patient names with orders. And, finally, FDA Agent Michael Mangiacotti testified that during the search of NECC's offices, he found signs posted in the sales staff's cubicles with instructions from Carter warning NECC employees about the need to give "regulators" the impression that NECC was compounding drugs after receipt of real patient names.

c.

The jury was instructed with respect to the § 371 counts that Carter, Conigliaro, and their co-defendants had been "charged with conspiring to defraud the FDA by impeding its ability to perform its regulatory function by misleading it into believing that NECC was a Massachusetts regulated compounding pharmacy and not operating as a drug manufacturer subject to FDA regulation and oversight." The jury was further instructed that "[a] conspiracy is an agreement between or among two or more persons to accomplish an unlawful purpose," and that, "[t]o prove a defendant guilty of a crime of conspiracy, the government must prove three essential elements beyond a reasonable doubt": (1) "that the conspiratorial agreement alleged in the indictment and not some other agreement or agreements existed at or about the time specified"; (2) "that

a defendant knowingly and willfully joined in that agreement with the purpose of seeing it succeed in accomplishing its unlawful goals"; and (3) "that one of the conspirators committed an overt act, that is, took an affirmative step to further the purposes of the conspiracy at some time during its existence."

The jury acquitted all the defendants of the § 371 counts at issue other than Carter and Conigliaro, who were each found guilty. Carter and Conigliaro each then then filed a motion for a post-verdict judgment of acquittal supported by a memorandum. The memoranda advanced three arguments for entering the judgments of acquittal.

First, the memoranda argued that it was legally impossible for either Carter or Conigliaro to have been part of the alleged conspiracy due to what the record assertedly showed about the FDA's authority, during the life of the alleged conspiracy, to conduct the regulatory oversight of NECC with which they were alleged to have interfered. Second, the memoranda contended that Carter and Conigliaro could be convicted on the counts of which the jury had found them guilty only by adopting an overbroad and vague construction of § 371's "defraud" clause that would deprive them of fair notice and thus violate their right to due process under the Fifth Amendment of the United States

Constitution.[4] Third, and finally, the memoranda contended that the evidence presented at trial was insufficient to support their convictions under § 371, even assuming the defenses to those convictions that we have just described failed.

At the same time that Carter and Conigliaro moved for judgments of acquittal on the § 371 counts under Rule 29, they also moved in the alternative pursuant to Federal Rule of Criminal Procedure 33 for a new trial on those counts. Conigliaro argued in support of his motion for a new trial that the District Court had failed to sever his trial from that of four other defendants named in the indictment with whom he and Carter were jointly tried and that the District Court had also committed several prejudicial evidentiary errors. Carter contended in her new trial motion that the jury's verdict finding her guilty of violating § 371 was contrary to the substantial weight of the evidence and that her trial, too, was tainted in various ways by prejudicial evidence.

D.

The District Court held a hearing on the motions for entering a post-verdict judgment of acquittal on the one § 371

[4] Insofar as the defendants meant to argue not only that the construction of § 371's "defraud" clause on which their convictions are premised deprived them of fair notice in violation of the Due Process Clause, but also -- separately -- that § 371 is void for vagueness in violation of the Due Process Clause, the District Court rejected that argument and neither defendant renews it on appeal.

count that Carter and Conigliaro each faced. The District Court granted those motions in a written decision on June 7, 2019. It thus did not rule on the then-still-pending Rule 33 motions for a new trial on those same counts that were also brought by these codefendants. The District Court determined that its ruling in their favor on the motions to enter judgments of acquittal on their § 371 counts rendered their new trial motions moot.

The District Court issued a lengthy opinion setting forth its reasoning for ruling as it did on the Rule 29 motions. See United States v. Conigliaro, 384 F. Supp. 3d 145 (D. Mass. 2019). That opinion included a substantial discussion of the legal impossibility and due process defenses that Carter and Conigliaro advanced. In granting the motions, the District Court did not reach the contention that, even if those defenses were unavailing, the Rule 29 motions still would have to be granted based on the independent contentions Carter and Conigliaro both made that the evidence was insufficient to support their conviction of the charges.

Because the District Court's analysis of these defenses engages in a detailed manner with the state of regulatory play during the alleged conspiracy, it is useful to provide a relatively fulsome description of some of the key regulatory milestones before describing the District Court's analysis further. After providing this historical background, we then turn to a review of the

District Court's reasoning in its opinion, starting with its discussion of the defense of legal impossibility.

1.

As we explained above, the FDCA authorizes the FDA to regulate "any new drug," FDCA § 505(a) (codified at 21 U.S.C. § 355(a)), which was defined in the relevant period as "[a]ny drug . . . not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p). And, as we also explained above, although compounded drugs would seem to fit within that definition, for the first fifty years after the FDCA's enactment, the FDA generally left regulation of compounding to state pharmacy boards. Western States, 535 U.S. at 360-61. Over time, however, as we have noted, the FDA grew concerned that some pharmacists were manufacturing and selling large quantities of drugs under the guise of compounding in an effort to evade the FDA's "new drug" requirements. Id.

The FDA responded to the concerns about compounding by issuing a Compliance Policy Guide in 1992. FDA Compliance Policy Guide (CPG) Sec. 7132.16 (1992) (the "1992 CPG"). It explained "that while retail pharmacies . . . are exempted from certain requirements of the [FDCA], they are not the subject of any general exemption from the [FDCA's] new drug, adulteration, or misbranding

provisions." Western States, 535 U.S. at 360-61 (quoting the 1992 CPG).

The Guide announced that the FDA "may, in the exercise of its enforcement discretion, initiate federal enforcement actions . . . when the scope and nature of a pharmacy's activities raise[] the kinds of concerns normally associated with a manufacturer and . . . result[] in significant violations of the new drug, adulteration, or misbranding provisions of the Act." Id. (quoting the 1992 CPG). But, the Guide also announced that the FDA otherwise would continue to exercise discretionary abstention from the policing of prescription-based compounding pharmacies as well as pharmacies that compounded drugs without prescriptions in "very limited quantities" for buyers with whom they could demonstrate an "established professional practitioner-patient-pharmacy relationship." Id. at 363 (quoting the 1992 CPG).

Congress codified parts of the FDA's 1992 Guide concerning compounding a number of years later in the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). See Pub. L. 105-115, 111 Stat. 2296, § 127 (codified at 21 U.S.C. § 503A (1997)). In particular, as the District Court noted:

> [The FDAMA] created a safe harbor for compounded drugs, exempting them from the FDCA's "new drug" requirements provided that certain criteria were met, most pertinently, that they be compounded in response to a valid prescription or only in limited non-prescription quantities where an established

> relationship existed between the specific pharmacist, patient, and prescribing physician.

Conigliaro, 384 F. Supp. 3d at 160 (citing 21 U.S.C. § 353a(a)).

The next major development of note occurred in 2002. That was when the Supreme Court of the United States struck down adjacent provisions of the FDAMA in Thompson v. Western States on the ground that they violated the First Amendment. See Western States, 535 U.S. at 377. The Court did not reach the question of severability in that decision. See id. at 360. But, thereafter, a circuit split ensued as to what, if anything, remained of the FDAMA and its provisions regulating compounders.

The Ninth Circuit held that the FDAMA as a whole was invalid. See Western States Med. Ctr. v. Shalala, 238 F.3d 1090 (9th Cir. 2001). The Fifth Circuit held, in contrast, that the FDAMA stripped of those unconstitutional provisions remained viable after Western States. See Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383 (5th Cir. 2008). Our circuit did not weigh in on the issue.

The FDA reacted to Western States in 2002 by issuing a new CPG. See FDA Compliance Policy Guide Sec. 460.200 Pharmacy Compounding (2002) (the "2002 CPG"). The 2002 CPG sought to head off any uncertainty that might result from the Supreme Court's decision in Western States with respect to the FDA's continued

enforcement approach by, as the District Court explained, "essentially reembrac[ing] the FDA's 1992 guidance." Conigliaro, 384 F. Supp. at 160.

The 2002 CPG reiterated that, for enforcement purposes, the FDA would continue to draw a line between, on the one hand, compounders that operated like traditional retail pharmacies in that they produced and sold drugs "upon receipt of a valid prescription for an individually identified patient from a licensed practitioner," and, on the other hand, compounders that operated like manufacturers in that they, for instance, "receive[d] and use[d] large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription for them." The FDA assured compounders of the first kind, which operated as retail pharmacies, that it would abstain from enforcement actions, but warned compounders of the second kind, which operated as manufacturers, that it would "seriously consider enforcement action" against them. The FDA, moreover, specified that one of the factors it would consider in determining whether a compounder fell into this latter category of manufacturers was whether it "compound[ed] . . . drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid

prescriptions." This 2002 CPG, while not legally binding, remained in effect through the end of the alleged conspiracy in 2012.

2.

Carter and Conigliaro drew on this regulatory history in making their legal impossibility and due process arguments to the District Court. They claimed that, during the relevant period, there was "no discernible federal law" or regulation that "defin[ed] any clear distinction between a compounding pharmacy and a drug manufacturer." As a result, the defendants argued, it was legally impossible to conspire to interfere with the FDA's "government functions" overseeing compounders. Moreover, the defendants argued that, in light of this history, it would violate notions of fair warning embedded in the Due Process Clause of the Fifth Amendment to find them criminally liable under § 371.

The District Court began its opinion assessing the defendants' defenses with the defense of legal impossibility. It then took up their due process-based contentions. We describe each portion of the District Court's analysis in turn.

a.

A "pure legal impossibility" defense applies "when no statute proscribe[s] the result that the defendant expected, desired, and intended to achieve." United States v. Fernandez, 722 F.3d 1, 31 (1st Cir. 2013) (citation omitted). "Pure legal impossibility is always a defense" -- including where, as here,

the defendants were charged and convicted of the inchoate crime of conspiracy. Id.

As the District Court explained, however, legal impossibility is distinct from factual impossibility. Factual impossibility "arises when an attempt is frustrated by a physical circumstance of which the actor is unaware." Conigliaro, 384 F. Supp. 3d at 153 (citing People v. Fiegelman, 33 Cal. App. 2d 100 (1939)). And, as the District Court also noted, "we long have held that factual impossibility is not a defense to . . . liability . . . for inchoate offenses such as conspiracy or attempt." Id. at 153 (citing United States v. Dixon, 449 F.3d 194, 202 (1st Cir. 2006)).

Against this legal backdrop, the District Court explained that, in its view, "if the FDA, even if mistakenly, disavowed a legal right to regulate compounding pharmacies like NECC, and if the evidence at trial showed that the FDA abstained from regulating NECC as a result of its internal determination of its own jurisdiction, a legal impossibility defense would plainly be available." Id. at 158 (emphasis added). The District Court added that it did not mean "to fault the FDA" insofar as it wrongly disavowed legal authority that it possessed, as the court "recognize[d] . . . that the dividing line between pharmaceutical compounding and drug manufacturing had (prior to the NECC disaster) never been drawn with any clarity by Congress," which, "in turn,

created a regulatory lacuna in the borderland in which NECC progressively came to operate." Id.

The District Court then noted that "another way to frame a legal impossibility defense" in this case would be to base it "on the proposition that the government failed to meet its burden of proof on a required element of the crime -- namely, that the 'government functions' with which the conspirators sought to interfere were in fact being exercised by the FDA." Id. at 159. It explained that in identifying this framing of the legal impossibility defense it was "influenced by basic principles of lenity and due process," which "require that it be 'reasonably clear at the relevant time that the defendant's conduct was criminal.'" Id. (quoting United States v. Lanier, 520 U.S. 259, 267 (1997)).

The District Court at that point undertook an extensive analysis of the federal statutory, precedential, and regulatory regime that governed compounding pharmacies during the time of the alleged conspiracy -- reviewing much of the history discussed above as well as additional statements made by FDA officials. The District Court found that "the FDA itself" had "rejected" the position that it had the authority to regulate compounding pharmacies during those years. Id. at 162. The District Court also found that the FDA in that time period repeatedly failed "to

articulate a clear line between compounding and drug manufacturing." Id.

According to the District Court, the FDA recognized over that span of time that its "authority over compounding [was] limited, unclear, and contested." Id. at 165 (citing Testimony Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Nov. 14, 2012). And, the District Court further noted, "the evidence [at trial] plainly show[ed] that during the life of the charged conspiracy, the FDA was not, and did not believe that it should be, in the business of regulating companies like NECC that were engaged in anticipatory pharmacy compounding." Id. at 165. "[T]he bottom line," the District Court then concluded, was that "during the critical times, these defendants (and NECC) could not have defrauded the FDA by interfering with the relevant regulatory functions because there were none to speak of." Id.

b.

The District Court next considered the defendants' due process-based defenses. The District Court had stated in the introductory section of its opinion that the entry of judgments of conviction of the defendants on the § 371 count that each faced would "violate[]" their "rights to fair notice and due process." Id. at 148. In the course of its due process analysis, though, the District Court appeared to rely less on a conclusion based on

the Fifth Amendment's Due Process Clause than on the related concerns about "fair warning" rooted in the rule of lenity that it had invoked in connection with its second framing of the legal impossibility defense described above.

In that regard, the District Court explained that a narrow construction of the "government functions" element of the § 371 offense might be appropriate based on such concerns. It then stated that because the record showed that the FDA's regulatory authority was uncertain in this area and that the agency had not in fact exercised it, the "tie-breaking rule of lenity" applied to § 371. See id. at 168.

The District Court elaborated on these conclusions regarding due process and lenity as follows. It explained that if the defendants' convictions were based on "the hypothetical jurisdiction that the FDA might have asserted over 'new' drugs, based on a 1938 statute, standing alone -- and irrespective of the contrary positions since taken by the FDA itself -- . . . [they] raise[d] legitimate concerns of constitutional due process and fair notice." Id. at 168. The District Court then closed by emphasizing that "[b]ecause the FDA did not believe it had the statutory authority to regulate . . . new forms of pharmacy compounders" like NECC, "people 'of common intelligence' in the industry were left to guess as to the FDA's future enforcement policies." Id. at 167. It also noted that "[p]revious judicial

decisions had not 'fairly disclosed' to the industry that the FDA was poised to insert itself as a hands-on overseer of compounding pharmacies; to the contrary, the few cases that had been decided mostly pointed in the opposite direction." Id. And, it finally noted that "even if the argument could be made that the FDA had never affirmatively and publicly renounced its residual authority to regulate compounders, the contradictory nature of the public pronouncements it did make on the subject would justify application of the tie-breaking rule of lenity." Id.

The District Court did not specify to what provision of law the "tie-breaking" rule of lenity that it invoked would apply. It appeared to be concluding, however, at least given its earlier statements, that the rule of lenity would apply to the "government functions" element of the § 371 offense at issue.

In consequence of the narrow construction of that element that it was thus required to adopt, the District Court appeared to conclude, a juror could not find beyond a reasonable doubt that the "government functions" with which the defendants had been charged with conspiring to interfere existed. Here, it seemed to suggest that such a finding would be precluded by the lack of clarity in the record as to whether the FDA had the regulatory authority with which the defendants allegedly conspired to interfere in the years during which the conspiracy was alleged to have been ongoing.

Notably, though, the District Court did not appear to be concluding at any point in its analysis that the rule of lenity would apply to the FDCA itself, as opposed to the "government functions" element impliedly incorporated into § 371 in a case involving an alleged fraud of the sort at issue here. Thus, the District Court did not appear to be holding that, due to the rule of lenity, the term "new drug" in 21 U.S.C. § 321(p) would have to be construed narrowly during the life of the conspiracy to exclude either the practice of compounding altogether or, at the least, that practice in the form in which NECC was alleged to have engaged in it. In other words, the District Court at no point held that the FDA would have been legally barred during the relevant period of time from treating NECC as a "manufacturer" under that statute, even for purposes of exercising its civil regulatory enforcement powers and even if the agency had chosen to assert such authority only after having provided due notice to regulatory parties of its intention to do so.

E.

The District Court entered the post-verdict judgments of acquittal four days after issuing its written decision granting the motions for such judgments. The United States then timely appealed.

II.

We begin our analysis with the government's contention that neither a legal impossibility defense (in either of the formulations articulated by the District Court that we have just described) nor a due process defense (including the variant of it that appears to be premised on the rule of lenity that, as we have just explained, the District Court seems to have embraced rather than a variant premised on the Fifth Amendment itself) justifies an affirmance of the District Court's post-verdict judgments of acquittal in this case. We review a District Court's post-verdict judgment of acquittal de novo. See United States v. Mubayyid, 658 F.3d 35, 47 (1st Cir. 2011).

In undertaking this review, we consider preserved arguments putting forward the defense of legal impossibility de novo. See Fernandez, 722 F.3d at 8. But, insofar as the District Court's judgments of acquittal rested on factual determinations, we "may uphold [them] only if the evidence, viewed in the light most favorable to the government, could not have persuaded any trier of fact of the defendants' guilt beyond a reasonable doubt." Mubayyid, 658 F.3d at 47. Similarly, in considering the government's challenge to the District Court's due process ground for acquittal, our review is again de novo. See United States v. Silva, 794 F.3d 173, 177 (1st Cir. 2015).

Because we agree with the government's contention that the District Court's grounds for granting the Rule 29 motions were mistaken, we will also consider Carter's contention that we may nonetheless affirm the District Court's judgment as to her because the evidence was insufficient to support her conviction of the charged offense. As we will explain, we find that contention unavailing as well.

Here, as before, our review is de novo. United States v. Velazquez-Fontanez, 6 F. 4th 205, 212 (1st Cir. 2021). The central inquiry is "whether 'any rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt.'" Id. (quoting United States v. Bailey, 405 F.3d 102, 111 (1st Cir. 2005)). We engage in it by viewing the record "in the light most favorable to the verdict and draw[ing] all reasonable inferences in the verdict's favor." Id. (citing United States v. Meléndez-González, 892 F.3d 9, 17 (1st Cir. 2018)).

Before explaining our reasons for agreeing with the government's challenges to the District Court's ruling on the defendants' Rule 29 motions, however, it is important to clarify up front a critical point about the discussion of the defenses just described that will follow. We thus start our analysis with that clarification.

A.

Questions implicating the FDA's authority to regulate compounders as "manufacturers" under the FDCA in the relevant period are of central import to the defenses at issue. We thus emphasize up front that the analysis of those defenses that follows adopts -- as we have explained above we understand the District Court itself to have also adopted -- the premise (for which no preserved challenge has been made) that, during the life of the conspiracy, the FDA possessed the statutory authority under the FDCA to regulate NECC as a "manufacturer" because a compounded drug was a "new drug" within the meaning of the FDCA, see 21 U.S.C. § 321(p), whatever the FDA's own view (even if "mistaken") may have been as to whether it possessed that authority.[5]

It is important to be clear about this premise for the following reason. We do not dispute that, if the FDCA itself were properly construed to be limited in a way that precluded the FDA from exercising such regulatory power over NECC during the period of the alleged conspiracy, even if the FDA sought to exercise such authority after making known in advance its intention to do so, a legal impossibility defense would be available to the defendants

[5] We also note that no party has made the argument that NECC was an "outsourcing facility" as defined by 21 U.S.C. §§ 331(a), 333(a), and 353(b)(1) and thus eligible to be exempt from certain provisions of the FDCA if it satisfied several requirements, including registration with the FDA as such a facility and compliance with the current GMP.

on that basis. Thus, in rejecting the defense of legal impossibility here, we do not mean to suggest otherwise.

Moreover, we are aware that the defendants do attempt on appeal to advance a defense of legal impossibility grounded in that understanding of the legal limits on the FDA's regulatory authority in the relevant time period -- due to the limited manner in which they contend that the FDCA must itself be construed -- as an alternative basis for affirming the District Court's rulings on their Rule 29 motions. But, neither defendant developed that argument below.

Indeed, consistent with that finding of forfeiture, there is no indication that the District Court understood any such contention to have been advanced. The opinion of the District Court not only did not address such a contention but also appeared to premise its own analysis on the understanding that the FDCA conferred such regulatory authority on the FDA. See, e.g., id. at 159. Thus, we, like the government, do not understand the District Court, with respect to either variant of the legal impossibility defense that it laid out, to have held that such a legal limit on the FDA's authority was then in place. The result is that any defense to the charges at issue before us on appeal that is premised on the contention that the scope of the FDCA itself did not reach pharmacies engaged in compounding during the life of the alleged conspiracy -- because the term "new drug" in

the FDCA did not encompass compounded drugs -- would have to satisfy the demanding plain error standard to succeed. See United States v. Pinkham, 896 F.3d 133, 136 (1st Cir. 2018). But, the defendants cannot meet that standard, at least given the contrary circuit case law regarding the meaning of the FDCA during that time frame. See Med. Ctr. Pharmacy, 536 F.3d 383, 395, 400; see also United States v. Rivera-Morales, 961 F.3d 1, 13 (1st Cir. 2020) ("[A] criminal defendant generally cannot show that a legal error is clear or obvious in the absence of controlling precedent resolving the disputed issue in his favor." (citing United States v. Delgado-Sánchez, 849 F.3d 1, 10-11 (1st Cir. 2017); United States v. Amaro-Santiago, 824 F.3d 154, 163 (1st Cir. 2016))).

For these reasons, our discussion of the legal impossibility and due process defenses that will follow adopts as its sole focus the focus of the District Court, the government, and the defendants in their preserved arguments to us on appeal. It thus considers only how the FDA's own understanding of its regulatory authority -- as reflected in part in its own public and internal statements regarding it -- bears on Carter's and Conigliaro's criminal liability under § 371 on the understanding that the FDCA is best construed to have authorized the FDA to treat a compounded drug as a "new drug" and thus a compounding pharmacy as a "manufacturer" under the FDCA during the years in question.

B.

With that background in place, we are -- at last -- well positioned to take up the government's argument that, given the state of regulatory play during the life of the conspiracy, neither variant of the legal impossibility defense that the District Court described as being available to the defendants was available. The government further contends that any fair-warning-based defense (whether rooted in the Fifth Amendment's Due Process Clause or the application of the rule of lenity to the "government functions" element of § 371) is also -- given the relevant regulatory history -- unavailing. We agree with the government in both respects.

1.

We start with the government's arguments as to the District Court's first way of framing the legal impossibility defense. Here, the government appears to treat the District Court as having held that the defendants made out a viable legal impossibility defense because, even if the FDCA would have authorized the FDA to have asserted regulatory authority over NECC as a manufacturer during the alleged conspiracy, the record established that the agency had disavowed any authority to do so during the relevant time frame and thereby had barred itself from doing so. On this understanding, then, the District Court held that, due to what the record showed regarding the FDA's own understanding of its own regulatory power, mistaken though it may

have been, there were no "government functions" with which the defendants could conspire to interfere and hence the charged crime was one that it was legally impossible for the defendants to commit.

It is not entirely clear to us that the District Court did in fact embrace the holding regarding the defense of legal impossibility that the government attributes to it. The District Court stated that a disavowal-based variant of that defense would "plainly be available" if the record showed that the agency had made such a disavowal. Conigliaro, 384 F. Supp. 3d at 158. But, it is not evident to us that the District Court then actually held that judgments of acquittal must be entered on the basis of the variant of the legal impossibility defense that it described that was predicated on the record showing that the agency had in fact made such a disavowal of its legal authority. The District Court appeared instead to hinge its ruling vis-a-vis legal impossibility on the second variant of that defense that it described, and which we next address.

Nevertheless, the defendants, like the government, appear to treat the District Court as having relied on the first variant of the legal impossibility defense and not solely the second, and, in any event, they urge us to embrace it ourselves. We thus proceed on the understanding that the District Court did

so hold, and we conclude that, insofar as it did, it erred, just as the government contends.

As a threshold matter, we are dubious that, even if the FDA had disavowed its legal authority during the life of the conspiracy, it would follow that the offense charged here was legally impossible to commit. And that is so because the offense charged here was conspiracy to defraud the FDA by means of deceptive practices that were designed to prevent the agency from determining that the company was operating as a manufacturer.

An agency's "mistaken" disavowal of authority is not written in stone. See FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009); Massachusetts v. EPA, 549 U.S. 497, 532 (2007). Thus, the FDA would appear to have been entitled at any time to reverse course and assert the authority that (for purposes of evaluating the existence of this variant of the legal impossibility defense) we understand the FDCA itself would have entitled it to assert vis-a-vis compounders like NECC, at least so long as the FDA in reversing course did so on a going-forward basis and after providing due notice. Indeed, it is hard for a disavowal of authority to be "mistaken" -- as the District Court plainly indicated it was assuming any disavowal here might have been -- if the authority in fact does not exist. See Conigliaro, 384 F. Supp. 3d at 158.

Thus, even if there had been a mistaken disavowal of authority by the FDCA vis-a-vis its power to treat compounders like NECC as manufacturers, we do not see why such a mistaken disavowal would provide the basis for a legal impossibility defense that would bar a finding that Carter and Conigliaro violated § 371. Regulated parties who conspire to trick an agency into thinking they are conducting themselves other than they are -- and in a manner that would be material to an agency's decision about whether it may wish to assert regulatory authority that it had previously disavowed but legally might be capable of asserting upon rethinking the disavowal -- may easily be understood to have defrauded the United States, notwithstanding that during the period that the conspiracy was ongoing the agency had wrongly construed its power too narrowly. The deception by the alleged conspirators could be found to have prevented the agency from rethinking its authority in light of how regulated parties were in fact operating and thereby lulled the agency into not determining that it needed to reverse course and, on a prospective basis after providing due notice, assert the regulatory authority that it had previously disclaimed.

There is, however, also a more record-specific reason in this case for rejecting this disavowal-based ground for crediting a defense of legal impossibility to the charges at issue. The

record fails to support a finding that the claimed disavowal occurred.

The District Court offered a lengthy account of its understanding of what the record showed about the extent of FDA authority over compounders during the period of the alleged conspiracy. In the course of that account, the District Court addressed the government's contention that the complex regulatory history revealed that, during the life of the conspiracy, "compounding pharmacies would be subject to the drug approval, manufacturing, and inspection provisions of the FDCA" and that "NECC was making new drugs, as defined in the FDCA, and was subject to the jurisdiction of the FDA." Conigliaro, 384 F. Supp. 3d at 161 (quoting the government).

The District Court explained that "[t]he difficulty with" the government's contention was that, in its view, "the most significant actor rejected it: the FDA itself." Id. The District Court indicated that it was relying for that critical finding on "internal memoranda, testimony by senior FDA officials before various House and Senate committees as part of Congress's investigation into the fungal meningitis outbreak, in-court testimony and exhibits offered at the trial" it oversaw. Id. (footnote omitted).

But, the materials that the District Court identified as support for its findings do not support a finding that the alleged

disavowal occurred. It is true that, from that collection of evidence, as the District Court found, "the picture emerge[d] of an agency struggling to make sense of a statutory regime that Congress had not updated since 1938 and that had been overwhelmed by the rapidity of the advances in modern medicine and pharma." Id. at 162. The District Court also supportably found that the FDA was "under considerable pressure" due to developments in the pharmaceutical industry itself that had resulted in a "demand vacuum" for generics and specialty drugs that "compounding pharmacies like NECC stepped in to fill." Id. Nor do we disagree with the District Court that the record shows "the FDA recognized that an overly robust enforcement posture on its part towards compounders could jeopardize hospitals' and clinics' supplies of potentially life-saving medications." Id.

But, the District Court did not identify any statement in which the FDA during the time period in question publicly or internally disavowed that it possessed regulatory power to treat a compounding pharmacy as a manufacturer, including even one engaged in practices not unlike those in which the government asserts the record suffices to show that NECC was then engaged. The District Court did note statements in which FDA officials expressed concerns about the fit between the existing regulatory structure and compounding. Id. It noted as well expressions of concern within the FDA about whether it did have the authority to

treat compounders as manufacturers and the circumstances in which it could do so. Id. at 163. But none of those statements support the conclusion that the FDA in fact disavowed its legal authority to so treat them.

Moreover, the guidance documents that the FDA issued during the relevant time period concerning its authority to treat compounded drugs as "new drugs" under the FDCA affirmed rather than disclaimed the FDA's legal authority over compounders under that statute's "new drug" authority. See Western States, 535 U.S. at 362 ("[W]hile retail pharmacies . . . are exempted from certain requirements of the [FDCA], they are not the subject of any general exemption from the [FDCA's] new drug, adulteration, or misbranding provisions." (quoting 1992 CPG). To be sure, in 2002, the FDA issued guidance that stated that "section 503A" -- the section of the FDAMA that codified the FDA's 1992 CPG to compounders -- "is now invalid" in light of the Supreme Court's decision in Western States and the Ninth Circuit's determination that § 503A was not severable. See Shalala, 238 F.3d 1090. But, that statement -- at least in context -- cannot be read to be a disavowal of authority over compounders. In that same guidance, the FDA explained that "when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the [FDCA], [the] FDA has determined

that it should seriously consider enforcement action" under the FDCA.

The FDA did also define a safe harbor from its regulatory oversight over compounding pharmacies in the guidance it publicly supplied. But, it defined that safe harbor as encompassing compounding pharmacies that produced and sold drugs "upon receipt of a valid prescription for an individually identified patient from a licensed practitioner."

Indeed, in another case pending before this Court also stemming from the NECC disaster, United States v. Chin (Chin II), No. 20-1050 (1st Cir. ___), the government has made clear that the safe harbor defined in the 2002 CPG extended to only "the compounding of drugs prior to the receipt of valid, patient-specific prescriptions under specified circumstances, not shipping them before the receipt of a valid prescription." Therefore, even if NECC's compounding practices were in compliance with the safe harbor, its delivery practices were not. The announcement of the safe harbor is thus at odds with the notion that the FDA disavowed authority to regulate compounders outright or even to regulate compounders alleged to have engaged in the practices that NECC was alleged to have engaged in here.

At most, then, the record supports a finding that the FDA publicly rejected the notion that its regulatory authority to treat compounders as manufacturers was clear or without caveats.

But, that is not a finding of an actual disavowal by the FDA of its authority to treat NECC as a manufacturer under the FDCA, insofar as that company was engaging in practices that did not entitle it to claim the protection of the safe harbor that the agency had publicly identified in the 2002 guidance. Thus, while the District Court did state that "the bottom line" was that "during the critical times, these defendants (and NECC) could not have defrauded the FDA by interfering with the relevant regulatory functions because there were none to speak of," Conigliaro, 384 F. Supp. 3d at 166, we cannot agree that the record supports such a finding.

This conclusion is not undermined by the support in the record for the District Court's finding that "the evidence plainly show[ed] that during the life of the charged conspiracy, the FDA was not, and did not believe that it should be, in the business of regulating companies like NECC that were engaged in anticipatory pharmacy compounding." Id. at 165. That finding does not establish that the FDA understood itself to lack the power under the FDCA to treat a compounding pharmacy like NECC as a manufacturer. It establishes only that, at that time, the FDA was of the view that a certain type of dispensing by compounding pharmacies -- because of the bounded way in which it was undertaken -- was not something that the FDA "should" be in the "business" of policing. That is not itself evidence of a disavowal of authority,

let alone a disavowal of authority to regulate the practices in which NECC was engaged.

The defendants nevertheless insist that the District Court was correct in finding that the FDA had disavowed its authority over compounders like NECC by the time the alleged conspiracy took place. In support, they point to the testimony of Samia Nasr, who led FDA's Center for Drug Evaluation and Research Compounding Team from 2011 to 2016. Nasr testified at trial that the FDA put all inspections of compounding pharmacies on hold from 2009 to 2012.

With respect to NECC, the defendants contend, this hold became manifest in the FDA's 2011 and 2012 correspondence with the Colorado Board of Pharmacy that the defendants introduced into evidence. There, the Colorado regulators notified the FDA that NECC was shipping drugs in bulk quantities across state lines and the FDA, in response, referred the Colorado regulators to the Massachusetts Board of Pharmacy rather than investigating the allegation. According to the defendants, the "national moratorium" on inspections compels the conclusion that the FDA "affirmatively disclaimed its authority" to regulate compounders.

The evidence to which the defendants point, however, shows at most that the FDA made an internal policy decision not to exercise its authority over compounders -- a decision that lacked legally binding force that would preclude the FDA from reversing

course (after giving proper notice) on even a prospective basis. Cf. Fox Television Stations, 556 U.S. at 515. The defendants thus fail to show that the evidence compelled a reasonable jury to conclude that the FDA disavowed its legal right to regulate compounders, such that it understood itself to be as powerless legally during the period of the alleged conspiracy as if the FDCA had been amended during that period of time to strip the FDA of exercising the power it was not exercising. And, for that reason, the first ground on which the District Court based its conclusion of legal impossibility -- or, at least, the first ground the parties treat the District Court as having based that conclusion on -- does not hold up.

2.

The government also challenges the District Court's other formulation of the legal impossibility defense. In that formulation, the District Court focused on the FDA having abstained from exercising its regulatory authority over compounders as a result of its uncertainty about its own authority, even assuming that the agency did not in doing so actually disavow the existence of such regulatory authority. The District Court reasoned as follows in justifying its decision to grant the Rule 29 motions based on a defense of this kind.

The District Court began this aspect of its analysis by finding, on the basis of the FDA's conflicting public statements

about its authority to regulate compounders as well as its inability to clearly distinguish compounding manufactures from compounding pharmacies, that "the FDA's 'authority over compounding [was] limited, unclear and contested.'" Conigliaro, 384 F. Supp. 3d at 165 (quoting congressional testimony). In particular, the District Court noted that "the FDA was unable under [c]ongressional questioning to articulate a clear line between compounding and drug manufacturing." Id. at 162. The District Court pointed to testimony by Dr. Janet Woodcock, an FDA official, before Congress, that described the FDA's understanding of "how much product . . . a drug compounder [could] make without being designated a manufacturer" as "blurry" and that there "[was] no bright line in the statute that says when you cross that line and become a manufacturer." Id. at 163 (quoting congressional testimony).

Next, the District Court addressed the import of that finding. It explained that the ambiguity in these statements was such that, even if the FDA had authority under the FDCA to treat compounders like NECC as manufacturers during the years of the alleged conspiracy, the "contrary position[] . . . taken by the FDA itself [at that time] . . . raises legitimate concerns of

constitutional due process and fair notice."[6] Id. at 166. It then appeared to hold, based on that conclusion, that those due process and lenity concerns warranted a narrow construction of the "government functions" element of the § 371 offense with which the defendants were charged. Finally, the District Court appeared to wrap up its analysis by holding that this narrow construction precluded the "government functions" element of § 371 from encompassing regulatory authority of the uncertain type that the District Court had found that the FDA possessed.

Here, too, we agree with the government that this chain of reasoning is mistaken. As an initial matter, we do not find persuasive the notion that it was legally impossible for the defendants to have conspired to interfere with a government function just because it was unclear during the life of the conspiracy whether the government had that function or understood itself to have it. That it is unclear to alleged conspirators whether the government will assert a regulatory function because it is convinced that the government is uncertain of its authority

[6] The District Court noted as well that a federal district court in the Eleventh Circuit had found that "though [the FDA] certainly has the statutory authority to do so, the FDA has chosen not to draw the line between manufacturing and traditional compounding with formal regulations. Nor has it sought to distinguish traditional pharmacy compounding from pharmacists who are manufacturing under the guise of compounding." United States v. Franck's Lab, 816 F. Supp. 2d 1209, 1248 (M.D. Fla. Sept. 12, 2011) (vacated pursuant to the parties' join motion).

to assert it provides no basis for concluding that such a function does not exist. Thus, if the government function was one that the government had the legal authority to exercise -- and we have no reason not to assume that was the case, at least with respect to prospective exercise after the provision of due notice -- then we do not see how it would be legally impossible for the defendants to conspire to trick the government into wrongly concluding through misrepresentations about NECC's means of operating that it could not be regulated pursuant to that function.

That is not to say the lack of clarity about the existence of that function -- especially if fostered by the government's indications of its own doubts about the existence of that function -- would have no bearing on whether the evidence in a given case suffices to prove the elements under § 371 beyond a reasonable doubt. It is only to say that the lack of clarity about the existence of a government function does not equate to its non-existence.

Thus, such lack of clarity cannot in and of itself make it legally impossible for the defendants to have conspired to interfere with a government function, insofar as the function's existence is not disputed as a matter of law and there is no basis for concluding that the function could not be asserted after the provision of due notice prospectively. For, if that is the case, then so long as the evidence is otherwise sufficient the fact that

the FDA's authority was less than clear during the alleged conspiracy -- and that the FDA itself understood it to be unclear during that time frame -- is of no moment for purposes of assessing the availability of the defense of legal impossibility to the § 371 charges at issue. After all, those charges concern an alleged conspiracy to trick the FDA into thinking that a company subject to its regulatory authority was operating differently than it was in order to conceal the fact that its actual manner of operating would make it subject to more intensive regulatory oversight.

Nor is there force to the contention that the defendants' legal impossibility defense to their § 371 charges has merit because -- due to concerns about fair warning -- the high degree of uncertainty about which compounders were subject to FDA's regulations pertaining to drug manufacturers during the period of time at issue itself precluded the FDA from lawfully exercising regulatory authority over NECC as if it were a manufacturer even if the FDA otherwise would have had such authority under the FDCA. The defendants were not charged with violating the FDCA based on evidence showing that NECC was operating as a manufacturer. They were charged with violating § 371 for conspiring to interfere with the FDA's ability to determine whether to regulate NECC as such by misleading the FDA about practices of the company that could bear on just that determination.

Thus, absent the FDA lacking the legal power to do so even on a going forward basis -- and after having given the requisite degree of fair warning of its intention to do so -- we see no basis for concluding that the ambiguity about the FDA's authority that the District Court identified precluded it from being "reasonably clear at the relevant time that the defendant's conduct was criminal." Lanier, 520 U.S. at 267. We appreciate the District Court's concern with the "worrisome position that, in this context, what is not affirmatively permitted by the law is criminally prohibited." Conigliaro, 384 F. Supp. 3d at 166. But, because the defendants were charged with conspiring to defraud the FDA by impeding its ability to determine NECC's status through misrepresentations about the company's operations, we do not find that "worrisome position" implicated here. As we have explained above, the precise contours of the "government functions" implicated in a § 371 conspiracy -- assuming the agency has the authority to engage in those functions in the first place -- do not have to be defined before defendants can formulate the requisite agreement to interfere with those functions. The defendants here could have been mistaken as to whether NECC's compounding practices would have run afoul of the FDA's regulations under the FDCA while still conspiring to interfere with the FDA's ability to draw such a conclusion. After all, a conspiracy does not need to be successful in order to be illegal.

In support of the District Court's finding of legal impossibility, the defendants make the related argument that it was legally impossible for them to obstruct the FDA in deeming NECC to be a manufacturer because the FDA did not actively make such determinations concerning compounding manufacturers in the indictment period. The defendants point to testimony suggesting that the agency was, at the very least, hesitant to enforce its regulations concerning drug manufacturers against compounders and that it even abstained from conducting inspections of compounders for a period.

But, for purposes of a defense of legal impossibility, the FDA's actual exercise of its legal authority over compounders in general and over NECC specifically is irrelevant. That is so because the FDA's exercise of its legal authority can at most show the factual impossibility of actually interfering with the FDA's oversight function during the time of the alleged conspiracy. The defendants, however, were convicted of conspiring to defraud the United States by interfering with the FDA's oversight function, not of actually interfering with its oversight function. And, because, as the District Court correctly stated, "factual impossibility is not a defense to . . . liability . . . for inchoate offenses such as conspiracy or attempt," the literal inability of the defendants to actually interfere with the FDA's enforcement actions cannot be a defense. Conigliaro, 384 F. Supp.

3d at 153 (quoting Dixon, 449 F.3d at 202). Or, to put it differently, if a juror could find the defendants guilty of conspiring to interfere with the FDA's oversight function regardless of whether they succeeded in interfering with it, then that juror could also find them guilty of doing so even if the FDA did not actually engage in oversight over compounders during that time. See United States v. Jimenez Recio, 537 U.S. 270, 274 (2003).

Conigliaro raises one final argument in support of the District Court's finding of legal impossibility: he contends that it was legally impossible for him to have violated § 371 because § 371 only criminalizes conspiracies to defraud the federal government and that here the object of the conspiracy was a state agency. See Tanner v. United States, 483 U.S. 107, 130 (1987). Conigliaro is correct that a conspiracy to defraud a state agency, such as a state pharmacy board, would not violate § 371. But, the question of whether the object of the conspiracy charged here was the federal government is a factual one for the jury. At its root then, his argument is that there was insufficient evidence for a juror to have concluded that he conspired with others to defraud the FDA. As Conigliaro has not brought such a challenge, we do not consider whether the evidence is sufficient to support his conviction under § 371. To the extent that this argument is raised

by Carter, we consider its merits in the course of our evaluation below of the sufficiency of the evidence supporting her conviction.

3.

We come, then, to the government's challenge to the District Court's due process ground for acquittal. In determining whether the defendants' convictions comported with the due process requirement of fair notice, "the touchstone is whether the [relevant] statute, either standing alone or as construed, made it reasonably clear at the relevant time that the defendant's conduct was criminal." Lanier, 520 U.S. at 267. The defendants contend, and the District Court agreed, that such clarity was absent in this case. In support, the defendants reassert:

- That the FDA's statutory authority to regulate compounding pharmacies as manufacturers under the FDCA was at best "contested" and "unclear" -- especially in the wake of Western States;
- That the FDA disclaimed whatever authority it had, thus again depriving the defendants of fair notice;
- That because the FDA did not exercise whatever authority it had over compounders, the defendants were not on notice that there were "government functions" with which their activities could "interfere," Goldberg, 105 F.3d at 773;
- That because neither the FDCA nor the FDA's construal of that statute drew a clear line in the relevant respect, it was

unclear that NECC's compounding activities constituted manufacturing and, thus, for that reason, too, the defendants lacked fair notice that their alleged conspiracy to cover up those activities would make them guilty of conspiring to interfere with the FDA's "government functions" in violation of 18 U.S.C. § 371.

For much the same reasons that we have already given in explaining why the legal impossibility defenses are not available here, we also conclude that there is no due process-based bar to the defendants being convicted under § 371.

We do not dispute the District Court's finding that the FDA did not in fact exercise its legal authority over compounders that operated as manufacturers during the time of the alleged conspiracy. But, the defendants fail to show that this fact is relevant to the defendants' due process right of fair notice (or even to an application of the rule of lenity).

The defendants' contention in this respect appears to be that, due to notice concerns rooted in the guarantee of due process, we must construe the meaning of "government functions" for purposes of the "defraud clause" of § 371 narrowly to refer to functions that the government is actually carrying out rather than those that it merely has the legal authority to carry out. And that is so, the defendants appear to contend further, because this court noted in United States v. Goldberg, 105 F.3d 770 (1st Cir.

1997), that the "defraud clause" has "a special capacity for abuse because of the vagueness of the concept of interfering with a proper government function." 105 F.3d at 775.

But, neither Goldberg nor our other due process precedents supports this construction of the "defraud" clause. "[T]he touchstone" for determining whether a conviction comported with the due process requirements of fair notice and lenity, as we noted, "is whether the [relevant] statute, either standing alone or as construed, made it reasonably clear at the relevant time that the defendant's conduct was criminal." Lanier, 520 U.S. at 267. If the defendants had been charged and convicted of interfering with the FDA's oversight function over compounders that operated as manufacturers, we may assume that it would matter for due process purposes whether it was reasonably clear that the FDA possessed the function to regulate NECC's activities as a legal matter. But, here, as we noted in our discussion of legal versus factual impossibility, the defendants were not so charged. They were charged with the distinct offense of conspiring to interfere with the FDA's oversight function over compounders that operated as manufacturers. And, with respect to that offense, the uncertainty that the District Court described regarding FDA authority does not preclude it from being reasonably clear that a conspiracy to pass off NECC as a kind of compounding pharmacy that it was not -- through the stratagems detailed in the indictment -

-- was one prohibited by § 371. Or, at least, that uncertainty does not do so if we find -- as we must, given the arguments made to us -- that the FDA remained free throughout the life of the conspiracy to choose to regulate compounders as manufacturers under the FDCA in accord with the 2002 CPG insofar as it gave notice of its intention to do so.

In other words, the defendants could have reasonably understood that agreeing to make material misrepresentations to the FDA about how NECC operated so as to shield it from being deemed a manufacturer under the FDCA could have impeded the FDA's ability to make a determination regarding NECC's status as a manufacturer under that same statute. And, as the making of that determination is itself an oversight function of the FDA -- and as there is no preserved argument to us supporting the conclusion that the FDA was legally barred from exercising that function even prospectively and after giving notice of its intent to exercise it during the conspiracy -- the defendants were on notice that the conspiracy's alleged stratagems could interfere with the FDA's exercise of that function. We consequently agree with the government that the District Court erred in finding that the fair notice concerns -- whether rooted in the Due Process Clause or precedent concerning when the rule of lenity applies -- precluded the defendants' convictions.

c.

Having found no merit to the defendants' legal impossibility and due process arguments, we have left only the separate ground on which Carter asks us to affirm her post-verdict judgment of acquittal. Here, she contends that the record does not contain sufficient evidence to permit a reasonable juror to find beyond a reasonable doubt that she knowingly and willfully joined the alleged conspiracy.[7]

Carter asks us to remand this issue to the District Court, which did not previously reach her sufficiency challenge. But, we routinely resolve such challenges on appeal and see no reason to deviate from that practice in this case. See, e.g., Stepanets, 989 F.3d at 97, 101, 112. Reviewing de novo and construing the evidence in the light most favorable to the verdict, see id. at 95, we find that a reasonable jury could have found beyond a reasonable doubt that Carter conspired to violate § 371. We therefore conclude that Carter's sufficiency argument has no merit.

[7] Conigliaro made a similar sufficiency argument below, but does not renew it on appeal. Insofar as Conigliaro does mean to renew his insufficiency of the evidence challenge when he contends in his surreply brief that "there is no evidence in the Record that [he] ever misrepresented anything to the FDA about prescriptions or anything else," he has failed to adequately develop that challenge. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990).

At trial, the government introduced an email into evidence that Cadden sent Carter on May 21, 2012, and that Carter forwarded on that same day to other NECC employees with the words: "New confirming guidelines in regards to patient names. (please see Barry's e-mail below). When an order is received that does not have the correct number or format of patient names, then we need to show Barry the order. At that time, he will determine how to proceed." Cadden's email below those words instructed NECC employees who processed orders for medications that "[t]he MAX total number of units (vials, syringes, etc.) per patient must make sense. I must be able to logically explain to a regulator why we processed x# of units per patient. . . . All names must resemble 'real' names . . . no obviously false names! (Mickey Mouse[])]." (emphases added).

On the basis of this email thread, a juror could find that Carter was familiar with NECC's practice of pretending to process drugs pursuant to valid, patient-specific prescriptions and also familiar with the target of that pretense: "regulator[s]." The jury could likewise find that Carter took deliberate actions to promote that pretense -- in this case, by forwarding Cadden's instructions to other staff.

Moreover, the record includes internal emails in which Carter admitted that she and her colleagues had processed orders without valid prescriptions and instead used patient names from

previous orders -- admissions that again support the finding that she knowingly and willfully joined the § 371 conspiracy. In September 2011, for instance, Carter notified an NECC sales representative that "[w]e processed [the order of a customer] using old p[atient] names." And in June 2012, Carter similarly emailed her alleged co-conspirator Ronzio that she had "used the old names in the file that we had not used previously," and that "[w]e are still processing the order for today so [the customer] will not need to send in more names."

Carter seeks to resist the weight of this evidence by arguing that even if the evidence was sufficient to support a finding that she knowingly and willingly helped to process orders without valid prescriptions and also that she knowingly and willingly helped to cover up that practice, the evidence did not suffice to support the further finding that she did so to interfere with the regulatory function of the FDA. That further finding, as she rightly contends, is necessary because for a conspiracy conviction to stand, "the evidence must establish that the defendant . . . intended to effectuate the objects of the conspiracy." United States v. Burgos, 703 F.3d 1, 11 (1st Cir. 2012) (internal quotations and citation omitted). However, there was in fact sufficient evidence to support that further finding in this case.

At trial, a law enforcement agent testified that he had found a folder entitled "Tech Manual" at Carter's workstation. That folder included a document labeled "compounding legally." The jury could thus reasonably infer that Carter was aware of the FDA's regulatory authority and enforcement approach and therefore also aware that NECC, given its practice of compounding large quantities of drugs without valid prescriptions, was subject to that authority and enforcement, and that covering up that practice by, for instance, using fictitious patient names, would interfere with the FDA's ability to exercise its oversight over NECC.

Other circumstantial evidence added support to this inference by showing that some of Carter's closest colleagues made that awareness explicit. The jury, for instance, heard testimony by Ronzio that Cadden had considered and rejected the possibility of officially registering NECC as a manufacturer with the FDA in internal conversations because he worried that NECC was "very far from . . . current Good Manufacturing Practices, which the FDA required." The record also contained communications between NECC and its regulators -- both at the FDA and at the state level -- in which Carter's colleagues represented that NECC was a pharmacy that produced drugs only pursuant to valid prescriptions and was therefore not subject to the FDA's stricter regulations for manufacturers.

For example, Conigliaro claimed in a faxed letter to the Missouri State Board of Pharmacy on March 23, 2009, that "[a]ll of [NECC's] compounding activities are carried out in compliance with applicable local, state and federal rules and regulations as well as . . . the FDA's Compliance Policy Guide Sec. 460.200 Pharmacy Compounding," which is the FDA's 2002 CPG (emphases added). A few years earlier, on October 1, 2004, he claimed in an email to the FDA that NECC "compounds numerous different sterile and non-sterile preparations to fill patient specific, physician prescriptions," that it "always compound[s] only the amount [it] anticipate[s] will be required based on prescribing physician's historical prescribing patterns," and, finally, that it is a "small-scale, family-run, compounding-only pharmacy, not a manufacturer. As such we are not subject to GMP [current good manufacturing practice]."

Similarly, Cadden wrote to the FDA on January 5, 2007, to deny allegations that the FDA had made in its warning letter to NECC -- namely, that NECC "told physicians that [it] would fill prescriptions written in the name of a staff member rather than in the name of an actual patient." Cadden assured the FDA that this alleged practice "contradicts all of [NECC's] standard operating procedures." He claimed that "NECC dispenses compounded medications upon the receipt of valid prescriptions. We are

engaged in the practice of pharmacy and comply with the Massachusetts Board of Registration in Pharmacy's laws and rules."

Based on this evidence as a whole, a reasonable juror could find that Carter, who occupied a supervisory role within NECC and worked closely with Cadden and Conigliaro, shared her alleged co-conspirators' intention of interfering with the regulatory functions of the FDA. See United States v. McDonough, 727 F.3d 143, 156 (1st Cir. 2013) ("[A]n agreement to join a conspiracy may . . . be proved by direct or circumstantial evidence." (internal citations and quotation marks omitted)); see also Mubayyid, 658 F.3d at 57 ("[A] conspiracy may be based on a tacit agreement shown from an implicit working relationship." (citations and quotation marks omitted)); United States v. Serrano, 870 F.2d 1, 7 (1st Cir. 1989) (concluding that evidence of fraudulent intent was sufficient in part because of the defendant's "supervisory responsibilities"). Finding sufficient evidence in the record to support Carter's conviction, we reject Carter's argument that the District Court's judgment of acquittal can be affirmed on these alternative grounds and reverse.

III.

Because, as we have concluded, the District Court's post-verdict judgments of acquittal must be reversed, there remains to address the alternative request that Carter and Conigliaro both made for a new trial. Deeming this request moot,

the District Court did not rule on it below, even though Federal Rule of Criminal Procedure 29(d)(1) provides that "[i]f the court enters a judgment of acquittal after a guilty verdict, the court must also conditionally determine whether any motion for a new trial should be granted if the judgment of acquittal is later vacated or reversed." Because we review a district court's new-trial ruling for an abuse of discretion, see, e.g., United States v. Gonzalez, 949 F.3d 30, 34 (1st Cir. 2020), and because we do not have full briefing on the defendants' arguments in support of their request for a new trial, we remand this request to the District Court, in accord with the requests of the parties.

IV.

We thus **reverse** the District Court's post-verdict judgments of acquittal, reinstate the jury's convictions, and **remand** to the District Court for further proceedings consistent with this opinion.