7-20-2023

USA v. Murty Vepuri

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 22-1562

UNITED STATES OF AMERICA,
Appellant

v.

MURTY VEPURI, ASHVIN PANCHAL, KVK-TECH, INC.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Criminal No. 2:21-cr-00132)
District Judge: Honorable Harvey Bartle, III

Argued: February 7, 2023

Before: CHAGARES, Chief Judge, SCIRICA and
RENDELL, Circuit Judges

(Opinion filed: July 20, 2023)

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OPINION OF THE COURT

CHAGARES, Chief Judge.

Murty Vepuri is the de facto director of KVK-Tech, Inc. ("KVK-Tech"), a generic drug manufacturer. He employed

Ashvin Panchal as the director of quality assurance at the company. KVK-Tech manufactured and sold Hydroxyzine, a prescription generic drug used to treat anxiety and tension. The Government alleges that Vepuri, Panchal, and KVK-Tech sourced active ingredient for the Hydroxyzine from a facility that was not included in the approvals that they obtained from the Food and Drug Administration ("FDA") and that they misled the FDA about their practices. As a result of the alleged conduct, the Government brought criminal charges against them. The operative indictment charges all three defendants with conspiracy to defraud and to commit offenses against the United States, and it charges KVK-Tech with an additional count of mail fraud. At issue in this appeal is the portion of the conspiracy charge that alleges that the three defendants conspired to violate provisions of the Food, Drug, and Cosmetic Act ("FDCA"), which prohibits introducing a "new drug" into interstate commerce unless an FDA approval "is effective with respect to such drug." 21 U.S.C. § 355(a). The District Court dismissed that portion of the indictment, holding that the allegations set forth in the indictment do not state the offense. Because we agree, we will affirm the District Court's order and remand the case for continued proceedings on the remaining charges.

I.

Vepuri, Panchal, and KVK-Tech manufactured and sold generic drugs.[1] Vepuri was the de facto director of KVK-Tech;

[1] We recite the relevant facts based on the Government's allegations in the superseding indictment, which we accept as true for this appeal. See United States v. Huet, 665 F.3d 588,

despite referring to himself as an adviser or consultant, he made all key business decisions for the company and placed its ownership in private trusts with his children as the named beneficiaries. Vepuri recruited Panchal for the position of director of quality assurance.

KVK-Tech manufactured Hydroxyzine, a generic prescription drug. The FDCA requires drug manufacturers to obtain approval from the FDA before certain drugs may be manufactured and distributed. Applications for approvals of non-generic drugs are called New Drug Applications ("NDAs"), and applications for approvals of generic drugs are called Abbreviated New Drug Applications ("ANDAs"). See 21 U.S.C. § 355(b) (NDAs); 21 U.S.C. § 355(j) (ANDAs). Panchal filed and received approval of three ANDAs for Hydroxyzine in 2006, with each ANDA corresponding to a different dose of the drug. The ANDAs stated that the active ingredient would be sourced from a UCB Pharma, S.A. ("UCB") facility in Belgium. Two years later, Panchal filed a supplement with the FDA and obtained approval to source active ingredient from a Cosma, S.p.A facility in Italy.

Vepuri authorized the purchase of active ingredient for the Hydroxyzine from a Dr. Reddy's Laboratories ("DRL") facility in Mexico in October 2010. That facility was not listed in the ANDAs or otherwise approved by the FDA. Soon thereafter, KVK-Tech received three shipments of active ingredient from DRL. The shipments were logged at KVK-Tech as having been manufactured in Belgium. Vepuri authorized another purchase of active ingredient from DRL in

595–96 (3d Cir. 2012), abrogated on other grounds by United States v. De Castro, 49 F.4th 836, 845 (3d Cir. 2022).

May 2013. On June 3, 2013, 19 drums of active ingredient en route to KVK-Tech from DRL were refused import and were detained at the airport in Philadelphia. The FDA detained the drugs based on KVK-Tech's lack of approval to import active ingredient from DRL.

About two weeks after the FDA detained the shipment of active ingredient, Panchal filed a Change Being Effected in 30 Days Notice form with the FDA stating that UCB had changed its manufacturing site to Mexico. That form may be used only to inform the FDA of prospective changes, and Panchal did not disclose that KVK-Tech had been distributing drugs manufactured with active ingredient sourced from DRL since 2011. The FDA then inspected KVK-Tech's manufacturing facilities. Panchal misled the inspectors during the inspection, including by telling them that KVK-Tech had not received prior shipments of active ingredient from DRL. After he was confronted with photographs of drums stamped "Made in Mexico," Panchal told the inspectors that he was unaware that UCB had shipped active ingredient from Mexico. Appendix ("App.") 44. He then changed his story, telling inspectors that KVK-Tech had disclosed in its annual report that it was sourcing active ingredient from a new site in Mexico. That claim contradicted Panchal's prior statements that he was unaware of shipments from Mexico, and it was itself false because KVK-Tech had not mentioned the alleged change in its annual report.

In correspondence following the inspection, Vepuri and Panchal falsely blamed the use of active ingredient from DRL on "an inappropriate regulatory evaluation" by a former employee. Id. They reiterated their false claim that a former employee was responsible for sourcing active ingredient from DRL at a meeting with the FDA in June 2014. The FDA then

conducted a second inspection of KVK-Tech. In December 2014, Panchal sent the FDA a final report, detailing KVK-Tech's internal investigation and concluding that it was "not clear" why UCB had shipped active ingredient from Mexico. App. 45–46. The FDA released a report on its investigation into KVK-Tech in March 2015; that report incorporated false information from KVK-Tech's internal investigation. Vepuri, Panchal, and KVK-Tech did not notify the FDA that it had included false information in its report. The Government alleges that, as a result of its misconduct, KVK-Tech delivered to its customers more than 368,000 bottles of Hydroxyzine made with active ingredient sourced from the DRL facility.

Vepuri, Panchal, and KVK-Tech were charged in a two-count superseding indictment on June 10, 2021. The superseding indictment charges all the defendants with one count of conspiracy to defraud and to commit offenses against the United States under 18 U.S.C. § 371 and charges KVK-Tech with one count of mail fraud under 18 U.S.C. § 1341. The conspiracy charge involves three objects: (1) defrauding the United States by impeding the lawful function of the FDA; (2) with intent to defraud and mislead, introducing or delivering for introduction "unapproved new drugs" in violation of 21 U.S.C. §§ 331(d) and 355(a); and (3) making false statements to the FDA in violation of 18 U.S.C. § 1001. App. 38.

The defendants moved to dismiss the indictment on a variety of grounds. The District Court granted the motions in part, dismissing the portion of the indictment that the defendants conspired to violate 21 U.S.C. §§ 331(d) and

355(a).[2] The Government timely appealed the District Court's partial dismissal of the superseding indictment.

II.

The District Court had jurisdiction under 18 U.S.C. § 3231, and we have appellate jurisdiction under 18 U.S.C. § 3731. When reviewing a district court's decision on a motion to dismiss an indictment, we exercise plenary review over a district court's legal conclusions and review its factual findings for clear error. United States v. Stock, 728 F.3d 287, 291 (3d Cir. 2013).

III.

The District Court dismissed the portion of the conspiracy charge that alleged that Vepuri, Panchal, and KVK-Tech conspired to:

> [C]ommit an offense against the United States, by . . . with the intent to defraud and mislead, introducing or delivering for introduction, and causing the introduction or delivery for introduction, into interstate commerce of

[2] The defendants did not appeal the District Court's decision denying their motions to dismiss (1) the conspiracy charge against all three defendants to defraud the United States by impeding the lawful function of the FDA and to commit an offense against the United States by making false statements to the FDA and (2) the mail fraud charge against KVK-Tech. This appeal accordingly has no effect on those remaining charges.

> unapproved new drugs in violation of Title 21 United States Code, Sections 331(d) and 355(a)[.]

App. 38. Section 331(d) prohibits, among other things, the introduction or delivery for introduction into interstate commerce of any article that does not comply with the requirements of 21 U.S.C. § 355. See 21 U.S.C. § 331(d).[3]

Section 355(a) provides:

> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

21 U.S.C. § 355(a). Section 355(b), in turn, sets forth the procedure by which the FDA evaluates and approves NDAs for non-generic drugs, and § 355(j) sets forth the procedure by

[3] Section 331(d) prohibits the introduction into interstate commerce of any article in violation of 21 U.S.C. §§ 344, 350d, 355, or 360bbb-3. See 21 U.S.C. § 331(d). Notably absent from that list is 21 U.S.C. § 356a. Section 356a outlines what holders of NDAs and ANDAs must do in the event of manufacturing changes, such as those at issue here. Despite its apparent relevancy, § 356a is not referenced in the superseding indictment, and at oral argument, the Government clarified that although the provision supports its position, it was not relying upon § 356a to establish that the defendants conspired to violate § 355(a). We accordingly decline to discuss § 356a further.

which the FDA evaluates and approves ANDAs for generic drugs.

The term "new drug," as employed in § 355(a), is defined in the FDCA by what it is not: it is any drug that is not (1) "generally recognized, among experts . . . as safe and effective" or (2) grandfathered in, meaning that as of 1938, it was subject to the 1906 Food and Drugs Act. See 21 U.S.C. § 321(p). The parties agree that Hydroxyzine, the drug at issue here, is a "new drug" under the statute.

The dismissed portion of the superseding indictment charges Vepuri, Panchal, and KVK-Tech with conspiracy to violate the FDCA's prohibition on the introduction or delivery into interstate commerce of any "new drug," unless an approval of an NDA or ANDA is effective with respect to such drug. The Government repeatedly states in the superseding indictment and throughout its briefs that the defendants violated this prohibition by distributing the Hydroxyzine at issue because it was an "unapproved" new drug. For example, in outlining the objects of the conspiracy charge, the superseding indictment refers to "unapproved new drugs." See App. 38 (alleging that the defendants conspired to "commit an offense against the United States, by . . . with the intent to defraud and mislead, introducing or delivering for introduction, and causing the introduction or delivery for introduction, into interstate commerce of unapproved new drugs in violation of Title 21 United States Code, Sections 331(d) and 355(a)." (emphasis added)); see also Reply Br. 3 ("The only question is . . . whether 'an approval of an application . . . [was] effective with respect to' the hydroxyzine that the defendants marketed. The answer to that question is no, the hydroxyzine was an unapproved new drug." (quoting

21 U.S.C. § 355(a) (emphasis added))); id. at 9 (describing "the dispute in this case" as "whether a particular 'new drug' is approved or unapproved for distribution" (emphases added)).

But the relevant statutory provisions do not prohibit the introduction of "unapproved" new drugs. They instead prohibit the introduction of any "new drug, unless an approval of an [NDA or ANDA] is effective with respect to such drug." 21 U.S.C. § 355(a). We have held that the provision "requires only that a new drug approval be in effect before a new drug is marketed," see United States v. Kaybel, Inc., 430 F.2d 1346, 1347 (3d Cir. 1970) (emphasis added); our jurisprudence does not recognize the Government's premise that distributing "unapproved" drugs violates § 355(a).[4] Thus, alleging that the

[4] We observe that the Courts of Appeals for the Seventh and Eighth Circuits have suggested that § 355(a) has been violated when drugs are "unapproved." In United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007), the defendant admitted that it had violated the NDA for the drug at issue. The defendant argued that it was not liable under an exemption to the FDCA, and most of the court's decision addressed that argument. Id. at 961. After holding that the exemption was inapplicable, the court stated that given the admitted violations of the NDA, the drug at issue was "unapproved," which constituted a violation of § 355(a). Id. at 962, 965. Neither party contested the assumption that § 355(a) is violated when an NDA is not followed, and the court did not reference the language of the statute looking to whether the approval of an NDA or ANDA is "effective with respect to such drug." 21 U.S.C. § 355(a). See also In re Canadian Imp. Antitrust Litig., 470 F.3d 785, 789 (8th Cir. 2006) (noting in an antitrust case that the importation of drugs from Canada violates federal law

drugs are "unapproved" — without demonstrating how that violates § 355(a) — is therefore not enough on its own to state the offense of conspiracy to violate § 355(a).

We analyze the Government's arguments in terms of the text of the relevant statute, 21 U.S.C. § 355(a). See Sebelius v. Cloer, 569 U.S. 369, 376 (2013) ("As in any statutory construction case, '[w]e start, of course, with the statutory text' . . . ." (quoting BP Am. Production Co. v. Burton, 549 U.S. 84, 91 (2006))). The defendants were charged with conspiracy to violate § 355(a), which prohibits delivering "any new drug" into interstate commerce "unless an approval of an [NDA or ANDA] is effective with respect to such drug." 21 U.S.C. § 355(a). By claiming the drug is "unapproved," the Government appears to be relying upon either (1) the "with respect to such drug" portion of the provision or (2) the "is effective" portion of the provision. Under the first framing — focusing on the "with respect to such drug" language — the Government's theory of liability is that, given that the new drug's active ingredient was sourced from a facility not listed in the ANDAs, the Hydroxyzine KVK-Tech distributed was not the same "new drug" as the one with an effective approval. And because KVK-Tech had not procured approval for the Hydroxyzine manufactured with active ingredient from DRL, the argument goes, introduction of that new drug violated the

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because violations of labeling requirements make the drugs "unapproved," which violates 21 U.S.C. § 355). Because those two courts accepted the Government's premise and did not discuss the text of the statute, we follow our precedent in Kaybel and decline to adopt the apparent assumption that deviations from an NDA or ANDA make the drug "unapproved," which in turn violates § 355(a).

provision. Put into the language of the statute, the Government is arguing that the use of a manufacturing facility not listed in the ANDAs for KVK-Tech's Hydroxyzine means that the existing approval of the ANDAs is not effective "with respect to such drug," because the distributed "new drug" is not the "such drug" that has an effective approval. And under the second framing — focusing on the "is effective" language — the Government's theory of liability suggests that because the Hydroxyzine's active ingredient was manufactured at a facility not included in the ANDAs, the approval of the ANDAs for KVK-Tech's Hydroxyzine stopped being "effective" with respect to that drug.

We will accordingly consider whether the superseding indictment states a conspiracy offense under either theory of liability.

A.

To state an offense for conspiracy to violate § 355(a) under the "effective with respect to such drug" theory of liability, an unapproved change in manufacturing facility must mean that the drug introduced into interstate commerce is no longer the "such drug" with an effective approval.[5] The statute

[5] At oral argument, the Government primarily advanced this theory. See, e.g., Oral Argument at 02:55 – 03:20 ("The question ultimately is whether an approval is effective with respect to the particular product that was being introduced into interstate commerce and that product was a tablet or a group of tablets of Hydroxyzine that were manufactured at a particular facility. And as to that drug product, there is no effective approval because the only thing that was approved was

prohibits the introduction of "any new drug" into interstate commerce, unless an approval of an ANDA or NDA is effective "with respect to such drug." 21 U.S.C. § 355(a). Under a plain reading of the provision, the "such drug" in the second clause of the statute is referring to the "new drug" in the first clause of the statute. As discussed above, "new drug" is defined in 21 U.S.C. § 321(p) by what it is not: it is "any drug . . . the composition of which is such that such drug is *not*" either (1) generally recognized among experts as safe and effective for the use "suggested in the labeling thereof" or (2) grandfathered in, meaning that as of 1938, it was subject to the 1906 Food and Drugs Act, and at such time its "labeling contained the same representations[.]" 21 U.S.C. § 321(p)(1) (emphases added); see also 21 U.S.C. § 321(p)(2) (defining "new drug" as "any drug . . . the composition of which is such that such drug" is not the ones listed in § 321(p)(1) (emphasis added)). The text of § 321(p), therefore, defines a "new drug" in terms of its composition and labeling. Put another way, for a "new drug" to no longer be the "such drug" with the effective approval of an NDA or ANDA, it must have a different composition or labeling than the "new drug" with the effective approval.

The superseding indictment in this case does not include any allegations that the KVK-Tech Hydroxyzine manufactured with active ingredient from DRL had a different composition or labeling than the KVK-Tech Hydroxyzine with the effective approval. In the language of the statute, the "new drugs" at

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manufacturing Hydroxyzine at other facilities."). The Government also framed its theory in this manner in the superseding indictment and in its briefing before the District Court. See App. 36, 142.

issue here are the "such drugs" that have an effective approval. The Government, therefore, cannot state an offense under this theory of liability.

As the defendants highlight, this interpretation of the statute keeps the FDCA statutory scheme coherent.[6] See Food

[6] This is not the defendants' main argument. They principally argue that we have rejected the Government's theory in United States v. Kaybel, Inc., 430 F.2d 1346 (3d Cir. 1970), a decision the parties discuss at length. In Kaybel, the defendant, Kaybel, Inc., re-packaged a drug that Searle & Co. manufactured in compliance with its NDA. Id. at 1347. There, the Government argued that "the defendants violated § 355(a) by repackaging those tablets without securing a separate new drug approval in their own name." Id. We held that the provision "requires only that a new drug approval be in effect before a new drug is marketed," and that "[i]t would require an unwarranted distortion of the normally understood meaning of this rather simple language . . . to characterize the product marketed by the appellants as a drug different from the 'new drug' for which approval already had been obtained . . . ." Id. We concluded, therefore, that the defendants were entitled to acquittal as a matter of law. In other words, we rejected the Government's theory as to re-packagers distributing a "new drug" that fully complied with the manufacturer's NDA or ANDA.

In Kaybel, we did reject the Government's overall theory that alleging a drug is "unapproved" states an offense under the statute. Id. But we said nothing about whether § 355(a) is violated when manufacturers themselves deviate from their own approved NDA or ANDA, despite that the drugs at issue maintained the same composition and labeling as that listed in

& Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme. A court must therefore interpret the statute as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into an harmonious whole." (quotation marks and citations omitted)). Another provision of the FDCA, 21 U.S.C. § 355(k), also refers to drugs for which an approval of an NDA or ANDA is in effect. That section provides in relevant part:

> In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall . . . make such reports to the Secretary, . . . as the Secretary may by general regulation, . . . prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine . . . whether there is or may be ground for invoking subsection (e).

21 U.S.C. § 355(k)(1). In other words, § 355(k) requires applicants with "any drug" for which an approval of an NDA or ANDA is "in effect" to make reports to the FDA as required by FDA regulations, so that the FDA can determine whether it

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the approval. We need not decide whether Kaybel treated the re-packagers as manufacturers or whether our holding in Kaybel is limited to cases in which the drugs at issue have the same composition and labeling as the drugs with the effective approval. We instead reject the Government's theory under well-settled principles of statutory interpretation.

should withdraw or suspend the approval of the NDA or ANDA under 21 U.S.C. § 355(e).

The defendants point out — and the Government does not dispute — that the superseding indictment alleges that the defendants violated one such FDA regulation, 21 C.F.R. § 314.18, when Vepuri and Panchal "failed to make the required notification to the FDA that defendant KVK-TECH had distributed Hydroxyzine containing the [active ingredient,] which the FDA considered adulterated." App. 41. For that provision to apply to the defendants, the drug at issue must have had an approval of an ANDA "in effect." Under the Government's theory, the Hydroxyzine manufactured with active ingredient sourced from DRL is not the same drug that had an approved ANDA in effect for purposes of § 355(a), but it is the same drug for purposes of § 355(k). Both cannot simultaneously be true. The better reading of the statute is that in the event of manufacturing changes, the FDCA may require reporting without necessarily triggering criminal liability.

The Government also argues that the definition of "new drug" in 21 U.S.C § 321(p) should not be imputed into 21 U.S.C. § 355(a) because "the two sections serve entirely different purposes," with § 355(a) "intended to protect the public from the risks associated with unapproved new drugs." Gov. Br. 38. We disagree. When defining a statute's terms, we are required to look first to the definitions in the statute itself. See Burton, 549 U.S. at 91. And while we recognize the important Government interest in protecting public health by keeping drugs that deviate from their approvals off the market, the Government cannot rely upon a textually implausible legal theory to pursue that goal in this case. The Government discusses § 355(a) as if it exists in isolation and is the only

means to avoid adverse public health outcomes. But the FDCA includes several civil enforcement provisions that could have been invoked to address the conduct alleged in the superseding indictment. For example, the FDA could have withdrawn or suspended the approval of the defendants' ANDA under 21 U.S.C. § 355(e) or imposed civil penalties under 21 U.S.C. § 335b. And, as was done here, the Government can criminally prosecute the defendants under 18 U.S.C. § 1001 for their alleged misrepresentations to the FDA about their use of an unauthorized manufacturing facility.[7] Accordingly, relying upon the composition and labeling of a "new drug" — as the term is defined in 21 U.S.C. § 321(p) — to interpret the meaning of 21 U.S.C. § 355(a) is textually appropriate and does not threaten the Government's ability to protect the public by enforcing the FDCA.

[7] Regulating the place of manufacture undoubtedly is a critical function of the FDA. The FDA has the power to inspect and approve manufacturing facilities, see 21 U.S.C. § 374, and it can bring criminal charges against those responsible for adulterated or misbranded drugs, see 21 U.S.C. §§ 331(a), 351, 352. And when "new drugs" are distributed without an approved NDA or ANDA that is effective — because one was never obtained at all, because the existing approval was withdrawn or suspended, or because the "new drugs" that were distributed differed in composition or labeling than the ones with the effective approval — the Government may rely upon § 355(a). Moreover, to the extent that our decision has identified a gap in the FDA's ability to regulate the drugs that are introduced into interstate commerce, Congress has the tools necessary to fill it.

Because the Hydroxyzine at issue has the same composition[8] and labeling as the Hydroxyzine for which an approval of an ANDA is effective, the Government cannot rely in this case upon the premise that the two drugs are different. The Government's first theory of liability — that the Hydroxyzine that was introduced into interstate commerce is not the same Hydroxyzine with an effective approval — accordingly does not state the offense of conspiracy to violate § 355(a).

B.

The Government's second theory of liability is that the superseding indictment states an offense of conspiracy to violate § 355(a) because the fact that the "new drug" was manufactured at a facility not included in the approved ANDA means that the approved ANDA stopped being "effective" with respect to that drug. But that very theory has been rejected by the Supreme Court, and we are bound by that decision. See

[8] The FDCA does not define the word "composition." But the FDA has long interpreted the term to refer only to a drug's chemical makeup — the "name and amount of each active and inactive ingredient." FDA, Guideline for the Format and Content of the Summary for New Drug and Antibiotic Applications 7 (Feb. 1987), https://www.fda.gov/media/71139/download. And a drug's "composition" does not include the location or identity of the manufacturer of those ingredients. See 21 U.S.C. § 355(b)(1)(A) (distinguishing between the "composition of such drug" and the methods, facilities, and controls used to make the drug).

Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 633 (1973).

In Weinberger, the Supreme Court considered the 1962 amendments to the FDCA, which required that "new drugs" receive affirmative FDA approval. The drug manufacturer argued that its drug, Lutrexin, qualified for an exemption to this requirement. Qualification for the exemption "turn[ed] solely on whether Lutrexin was 'covered' by an effective NDA immediately prior to the adoption of the 1962 amendments." Id. at 632 (citing section 107(c)(4) of the 1962 amendments). The manufacturer argued that when Lutrexin became generally recognized as safe, it was no longer a "new drug" under 21 U.S.C. § 321(p), and so its NDA stopped being effective. Id. The Supreme Court rejected that argument, holding:

> That argument draws no statutory support. The 1938 Act [referring to the FDCA] did not provide any mechanism other than the Commissioner's suspension authority under [21 U.S.C. § 355(e)[9]], whereby an NDA once effective could cease to be effective. Indeed, [§ 355(e)] leads to the conclusion that an NDA remains effective unless it is suspended. That section empowers FDA to withdraw approval of an NDA whenever new evidence comes to light suggesting that the drug has become unsafe, whether or not the drug was generally recognized as safe in the interim.

[9] While the original text cites section 505 of the 1962 Amendments, that section was codified at 21 U.S.C. § 355(e).

Id. at 633. Under that holding, an NDA or ANDA only stops being effective when the procedures for suspension or withdrawal in § 355(e) are followed.

The parties in this case agree that the existing approval of the ANDAs for KVK-Tech's Hydroxyzine were not suspended or withdrawn under § 355(e). The approval of the ANDAs accordingly remains effective, so this theory of liability fails, and the Government has not stated the offense of conspiracy to violate § 355(a).

In sum, the second theory of criminal liability — that a deviation from the approved NDA or ANDA means that the approval is no longer effective — fails because the approval of an NDA or ANDA ceases being effective only when it has been withdrawn or suspended. Because the existing ANDAs here are still effective, the Government cannot rely upon this theory to state the offense of conspiracy to violate § 355(a).

IV.

For the foregoing reasons, we will affirm the order of the District Court and remand the case for proceedings on the remaining charges.