## United States Court of Appeals For the First Circuit

Nos. 05-2059 08-1147

UNITED STATES,

Appellee,

v.

CARLOS ORREGO-MARTINEZ,

Defendant, Appellant.

APPEALS FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF PUERTO RICO

[Hon. Daniel R. Domínguez, <u>U.S. District Judge</u>]

Before

Lynch, <u>Chief Judge</u>, Torruella and Boudin, <u>Circuit Judges</u>.

Carlos Orrego-Martinez on brief pro se.

<u>Nelson Pérez-Sosa</u>, Assistant U.S. Attorney, <u>Thomas F. Klumper</u>, Assistant U.S. Attorney, and <u>Rosa Emilia Rodríguez-Vélez</u>, on brief for appellee.

July 30, 2009

**Per Curiam**. Defendant Carlos Orrego-Martinez helped to operate a business that injected clients with liquid silicone and other substances for wrinkle reduction and related cosmetic purposes. The business was fostered by misrepresentations about such matters as the nature of the substances being injected and the attendant health risks. A jury convicted defendant of eight offenses involving the introduction of adulterated devices and nonapproved new drugs into interstate commerce with intent to defraud and mislead. 21 U.S.C. §§ 331(a) & (d), 333(a)(2).

The district court imposed a 58-month prison term. Defendant then filed a direct appeal, which we held in abeyance pending a district court ruling on defendant's motion for new trial. The denial of that motion prompted a second appeal. Having scrutinized defendant's various arguments, we affirm in all respects. The pertinent facts are stated in the light most favorable to the government insofar as the defendant attacks the adequacy of the evidence to support a conviction.

From June 2001 until March 2002, defendant and a collaborator named Sergio Lopez operated a business in Puerto Rico called Esthetics International, Inc. ("EI"), which was devoted to nonsurgical cosmetic improvements. The primary treatment consisted of injecting liquid silicone into the face and other areas of the body for purposes of wrinkle reduction. Defendant and Lopez ran EI on the premises of a beauty salon owned by an individual named

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Evelyn Valentin. They visited the salon approximately one week per month, often arriving from the Dominican Republic where they conducted a similar operation. Lopez performed the promotional and administrative work and interviewed prospective clients, while defendant purchased and transported all materials and administered the injections.

The scheme involved four separate products. Most frequently used was the liquid silicone, which defendant purchased under the brand name "Silicex" from a Venezuelan company. He injected some clients with an alternative substance known as "Karthy Swed," which he purchased from a Guatemalan company. Defendant also used two drugs: Lignocaine Injection BP 2% and Kenacort-A. The former was an anaesthetic; the latter was used to treat granulomas, which are nodules of hard tissue that can result from silicone injections. Defendant carried these substances with him in a handbag to and from the salon.

Misrepresentations were made to prospective clients. Chief among these were false assurances that defendant and Lopez were doctors and that the substances had been approved by the Food and Drug Administration ("FDA") and had negligible side-effects.<sup>1</sup> EI occasionally retained a physician to evaluate prospective

<sup>&</sup>lt;sup>1</sup>In fact, injection of liquid silicone can have serious sideeffects. In addition to causing granulomas, for example, it can cause inflammation of surrounding tissue, and the silicone can move to and remain indefinitely in other parts of the body.

clients. But the physician did not supervise defendant when the injections were administered. The silicone was not described as silicone but as a "biopolymer," said to be a natural product derived from minerals. The Karthy Swed was said to be shark cartilage; in fact, it was petroleum jelly.

Lopez, in charge of recruiting new customers, was the source of most such comments, but defendant also contributed to the deception; several witnesses described specific instances where he claimed to be a doctor or denied that silicone was involved. Nearly 400 persons ended up being evaluated for possible treatment; approximately 200 ended up being injected. Between June 2001 and March 2002, EI collected payments of almost \$200,000, often by way of credit cards.

Misrepresentations were also made to the government. After encountering problems getting the substances through U.S. Customs and Border Protection ("U.S. Customs") at the airport, defendant decided that false papers were needed to facilitate that process. At his request, the Venezuelan company in its shipment papers stopped describing the silicone as an implant and instead referred to the contents as "various capular treatments." Also at his request, the Guatemalan company created an "information sheet"

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that falsely described the Karthy Swed as a "relaxing facial mask for topical use" containing cartilage.<sup>2</sup>

In 2002, defendant was indicted along with Lopez and Valentin for wire fraud. Specifically, the three were charged with causing wire communications to be transmitted in interstate commerce as part of a scheme to obtain money by false pretenses. The indictment listed seven instances in which five EI clients (identified by their initials) made charges to American Express credit cards; each of the seven counts, in other words, concerned a specific act of wire fraud perpetrated against a specific individual on a specific date.

Lopez and Valentin pled guilty, while defendant went to trial. In September 2002, after discharging a hung jury, the court granted defendant's motion under Fed. R. Crim. P. 29(c) for judgment of acquittal. By way of explanation, it stated that "the Government has not proven beyond a reasonable doubt the specific intent to defraud in this case."

Less than three months later, defendant was indicted on the current charges. The statute in question, the Federal Food, Drug and Cosmetic Act, bars the introduction into interstate

<sup>&</sup>lt;sup>2</sup>The implants went through U.S. Customs when mailed to defendant in Miami or Puerto Rico by way of DHL mail carrier. Defendant also personally carried the implants through U.S. Customs when he traveled from the Dominican Republic to Puerto Rico.

commerce of any "adulterated device" or non-approved new drug.<sup>3</sup> <u>See</u> 21 U.S.C. § 331(a), (d). Any such violation is a felony if committed "with the intent to defraud or mislead," <u>id.</u> § 333(a)(2); otherwise, it is a misdemeanor. The nine-count indictment charged a conspiracy covering the same time period as the wire-fraud indictment.<sup>4</sup>

The indictment also charged eight substantive violations, five involving the silicone and three involving the other three substances respectively; one of the silicone charges was later dismissed. These counts listed the dates on which, and the countries from which, the substances were introduced (either from the Dominican Republic or Venezuela). Although the indictment included the "intent to defraud or mislead" element in each count, it did not identify the victim(s).

Before trial, defendant moved to bar the government from relitigating the issue of intent to defraud. Pointing to his earlier acquittal, and citing the doctrine of issue preclusion (also known as collateral estoppel), he contended that all evidence

<sup>&</sup>lt;sup>3</sup>Liquid silicone and Karthy Swed are considered adulterated devices when used as an implant for cosmetic purposes. Liquid collagen is the only injectable substance approved for the purpose of wrinkle reduction. The injection of silicone is authorized only for treatment of a rare eye condition. Whether Lignocaine BP 2% and Kenacort-A are nonapproved new drugs is an issue on appeal.

<sup>&</sup>lt;sup>4</sup>Both indictments alleged that the scheme operated from June 2001 to March 2002. However, the seven specific acts of wire fraud charged in the earlier indictment occurred over a two-month period (between November 2001 and January 2002).

pertaining to the fraud issue should be excluded and all counts accordingly reduced to misdemeanors. The government filed an opposition that was perhaps ambiguous: it could be read to say that the fraud evidence would be limited to showing defendant's efforts to defraud or mislead government agencies but it also suggested that issue preclusion would only bar evidence of fraud pertaining to the five clients listed in the earlier wire-fraud indictment.

The magistrate judge appears to have construed this opposition to mean that defendant was being charged with intent to defraud or mislead only government agencies and officials, not EI's clients. Largely for this reason, he issued a report and recommendation ("R&R") proposing that the motion be denied. But the district judge, in adopting that recommendation, voiced a different interpretation. Applying plain-error review because of defendant's failure to object to the R&R, he stated (emphasis added):

Though no intent to defraud was [earlier] found under the wire fraud statute as to particular end users [clients], the government is entitled to prove under 21 U.S.C. § 331 that Defendant had [the] intent to defraud other end users and/or government agencies.

Defendant voiced no objection to this declaration.

During the 12-day trial, the government offered a smattering of evidence concerning the efforts to mislead U.S. Customs, but it focused overwhelmingly on the false statements made

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to the clients (other than the five clients listed in the wirefraud indictment)-- $\underline{e.g.}$ , the same type of misrepresentations concerning the identity and safety of the implants and defendant's status as a physician that were presented at the first trial. The government did the same during closing argument, making only a passing reference to the U.S. Customs matter.

Defendant filed no contemporaneous objection to the evidence of fraud on other clients (except in one minor respect not pertinent here), stating that he "d[id]n't have a problem with that." Such evidence was received, <u>inter alia</u>, through the testimony of Lopez (the main government witness), Valentin (the salon owner who was also a client), and four other clients. The jury returned a verdict of guilty on all counts. Thereafter, a Rule 29 motion for judgment of acquittal was denied after extensive hearings.

The court held eight days of sentencing hearings. The government there put Lopez and various EI clients on the stand to establish, <u>inter alia</u>, the number of victims and amount of loss; defendant, acting pro se, was allowed to cross-examine Lopez for five days. After filing a direct appeal, defendant submitted a Rule 33 motion for new trial based on newly discovered evidence which, when ultimately denied, prompted a second appeal, which has been consolidated with the first.

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## Issues Involving Evidence of Defrauding Clients.

Defendant's main complaint on appeal is that the government impermissibly altered its theory of the case in midstream. According to defendant, the government told the grand jury and the magistrate judge that the issue was not how the clients were fooled but, rather, how government agencies were defrauded or misled in order to get the products into the country. At trial, however, the government allegedly shifted its focus to the issue of fraud on the clients, the subject of the first trial. This new tack is said to have violated issue preclusion and other constitutional protections.

Issue preclusion--now deemed to implicate double jeopardy protection in criminal cases--provides that "when an issue of ultimate fact has once been determined by a valid and final judgment, that issue cannot again be litigated between the same parties in any future lawsuit."<sup>5</sup> <u>Ashe</u> v. <u>Swenson</u>, 397 U.S. 436, 443 (1970); <u>accord</u>, <u>e.q.</u>, <u>Bobby</u> v. <u>Bies</u>, 129 S. Ct. 2145, 2152 (2009) ("Issue preclusion bars successive litigation of an issue of fact or law that is actually litigated and determined by a valid and final judgment, and ... is essential to the judgment.") (internal quotation marks omitted). An acquittal will thus bar

<sup>&</sup>lt;sup>5</sup>The "more descriptive term 'issue preclusion,'" although a more recent coinage, is generally used now "in lieu of 'collateral estoppel.'" <u>Yeager</u> v. <u>United States</u>, 129 S. Ct. 2360, 2367 n.4 (2009).

prosecution on new charges if a fact necessarily determined in the prior proceeding is an essential element of those charges. <u>See</u>, <u>e.g.</u>, <u>United States</u> v. <u>Dray</u>, 901 F.2d 1132, 1136 (1<sup>st</sup> Cir. 1990).

While it is often hard to tell whether an issue of ultimate fact was resolved in a defendant's favor in an earlier proceeding, no such problem exists here; as already noted, the district judge in the wire-fraud trial specifically found that intent to defraud the five listed clients had not been proven. According to defendant, this ruling establishes as a fact that he did not intend to defraud any of the approximately 195 other clients who were injected.<sup>6</sup>

We do not agree that issue preclusion barred the government's evidence but, at the outset, put to one side a different government response to the claim. It is true, as the government points out, that the evidence of defendant's intent to deceive U.S. Customs provides an adequate foundation for invoking § 333(a)(2)'s felony provision. Various courts have held, and defendant does not dispute, that the government can satisfy § 333(a)(2) by establishing an intent to defraud or mislead a government enforcement agency. <u>See, e.q.</u>, <u>United States</u> v. <u>Arlen</u>,

<sup>&</sup>lt;sup>6</sup>The government contends that defendant forfeited this argument by not objecting to the R&R. Yet it was the district judge, not the magistrate judge, who permitted evidence of fraud involving "other end users." And while defendant failed to object to this ruling, either when it was issued or when such evidence was introduced, curiously the government has not relied on those omissions in arguing default and we too bypass that issue.

947 F.2d 139, 141-45 (5<sup>th</sup> Cir. 1991); <u>United States</u> v. <u>Bradshaw</u>, 840 F.2d 871, 873-75 (11<sup>th</sup> Cir. 1988).

Here, the government presented evidence of defendant's efforts to deceive U.S. Customs regarding the nature of the substances being brought into the country. Defendant challenges the sufficiency of such evidence but that is a different matter and in any event the evidence was sufficient. Nevertheless, that was slight compared to the evidence showing that customers were misled and was lightly touched upon in the government's closing argument.

Further, if issue preclusion barred the evidence of defrauding of customers, its introduction could have been unduly prejudicial in a case that was based on defrauding only of government officials. And, to top the matter off, the sentence appears to have been driven importantly by evidence that the customers were defrauded. So, while the government's reliance on defrauding of the government officials might still pass muster, we think the stronger answer is that issue preclusion did not bar evidence that defrauding of customers occurred (other than the five customers already mentioned).

EI's clients were recruited and injected individually or in small groups. That defendant did not intend to defraud five of them over a two-month span does not necessarily mean that he lacked such intent with respect to all of the others who were recruited and injected over a nine-month span. <u>Cf. United States</u> v. <u>Brown</u>,

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983 F.2d 201, 202-05 (11<sup>th</sup> Cir. 1993) (holding that, after acquittal of fraud charges involving sale of one condo, collateral estoppel did not bar subsequent fraud prosecution for similar financing scheme involving contemporaneous sale of second condo in same complex).<sup>7</sup>

A crime involving multiple victims could in principle be successively prosecuted in one case after another and, even where collateral estoppel did not apply, successive bites at the apple might, in extreme circumstances, raise concerns about abuse implicating the courts' authority under the common law or even constitutional doctrine. <u>But cf. United States</u> v. <u>Dixon</u>, 509 U.S. 688, 711 n.15 (1993). In any event, the circumstances here do not appear abusive and defendant is relying upon issue preclusion and not some independent doctrine based solely on due process.

Besides his issue-preclusion claim, defendant makes a couple of related arguments. First, he says that the government's alleged shift as to the victims violated his right to an

<sup>&</sup>lt;sup>7</sup>The government also asserts that evidence of defendant's intent to mislead--as opposed to defraud--EI's clients would likewise suffice to defeat any issue-preclusion challenge. In theory, this is so. As the terms were defined by the district court, one theoretically could intend to mislead ("deceive as to a material fact") without also intending to defraud ("cause injury or loss by deceit as to a material fact"). And intent to mislead is not an element of wire fraud. Yet under the evidence here, it is not immediately clear how defendant could have intended the one without the other. The misrepresentations, after all, were designed to recruit clients in order to make money--i.e., to cause the clients loss. In the end, we need not decide the point.

independent grand jury, produced an indictment that did not adequately notify him of the charges, and amounted to a constructive amendment or prejudicial variance. Yet, each of these arguments mistakenly assumes that the indictment needed to identify the defrauded or misled victim(s).

> The elements of a [§ 333(a)(2)] violation are (1) a violation of § 331, (2) committed by ... someone "with the intent to defraud or mislead." The prosecution must prove beyond a reasonable doubt that a defendant intended to defraud or mislead someone, but the indictment need not specify the intended victim; the focus is on defendant's intent, not the victim's identity.

<u>Arlen</u>, 947 F.2d at 145; <u>see also</u> <u>id.</u> at 144 (rejecting similar argument that fatal variance had occurred); <u>id.</u> at 145 n.7 (noting that motion for bill of particulars could always be used to gain specifics).

Defendant also complains of unfair surprise. Given that the district court's ruling on the magistrate judge's report specifically allowed evidence of fraud on EI's clients, and given that defense counsel stated he "d[id]n't have a problem with that," this claim falls short. Defendant may have been unhappy with the trial evidence but it could hardly have come as surprise.

<u>Rule 29 Motion for Judgment of Acquittal</u>. In challenging the denial of his motion under Fed. R. Crim. P. 29(c) for judgment of acquittal, defendant makes two preliminary mistakes. First, he relies on new evidence--mainly, the testimony provided by Lopez at

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sentencing--but review of sufficiency challenges is confined to "evidence presented at trial." <u>United States</u> v. <u>Combs</u>, 555 F.3d 60, 65 (1<sup>st</sup> Cir.), <u>cert. denied</u>, 129 S. Ct. 2814 (2009); <u>United</u> States v. Torres, 2007 WL 30848, at \*5 (5<sup>th</sup> Cir. 2007).

Second, because of the "numerous issues presented" and the "legal limitations of the brief," he seeks to incorporate by reference the arguments made in his Rule 33 motion for new trial based on newly discovered evidence (again, Lopez's testimony at sentencing). Such a practice has been "consistently and roundly condemned", <u>Gilday</u> v. <u>Callahan</u>, 59 F.3d 257, 273 n.23 (1<sup>st</sup> Cir. 1995) (internal quotation marks omitted), and any incorporated argument is ordinarily deemed forfeited, <u>see</u>, <u>e.q.</u>, <u>Sleeper Farms</u> v. <u>Agway, Inc.</u>, 506 F.3d 98, 104-05 (1<sup>st</sup> Cir. 2007), even when advanced by a pro se litigant, <u>see</u>, <u>e.q.</u>, <u>Cofield</u> v. <u>First Wis.</u> <u>Trust Co.</u>, 1996 WL 521199, at \*1 (1<sup>st</sup> Cir. 1996) (per curiam).

Once the new evidence and the incorporated arguments are set aside, little remains. Defendant does properly present one argument: that Lopez's ignorance of the nature of the substances being used--in particular, his unawareness that the Silicex consisted of silicone--meant that the conspiracy as charged in the indictment never existed. Yet Lopez testified that he did know from the outset that it was illegal to use the products as implants in the United States. And the government need not show "that the

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conspirators knew all the details of the conspiracy." <u>United</u> <u>States</u> v. <u>Soto-Beniquez</u>, 356 F.3d 1, 19 (1<sup>st</sup> Cir. 2003).

Beyond this, defendant in his brief refers in skeletal fashion to a trio of other Rule 29 contentions. Each of these assignments of error can be deemed waived for lack of sustained argument. <u>See</u>, <u>e.g.</u>, <u>United States</u> v. <u>Zannino</u>, 895 F.2d 1, 17 (1<sup>st</sup> Cir. 1990). Each improperly relies in part on Lopez's testimony at sentencing. And based on the evidence at trial, each proves meritless. One example will suffice since they are not properly presented and the government's brief deals sufficiently with them all.

As to counts 3 & 4 (involving the introduction of silicone from Venezuela), he contends that "not even one piece of material evidence was seized in Puerto Rico, and nobody testified that [the] product would ... ever [be] used to inject anybody in Puerto Rico." Yet Lopez testified directly that the silicone used in Puerto Rico was obtained by defendant from the Venezuelan company. Shipping documents reveal that the company sent a shipment of Silicex to Valentin's salon addressed to defendant as "contact person." And vials of liquid injectable silicone were seized at the salon on the day defendant was arrested.

**Challenges to Lopez's Testimony**. Defendant accuses Lopez of false testimony. He first points to alleged discrepancies between his testimony before the grand jury and that at trial. Yet

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the inconsistencies either vanish on closer inspection or prove insignificant. "All but the most serious errors before the grand jury are rendered harmless by a conviction at trial." <u>United States v. Reyes-Echevarria</u>, 345 F.3d 1, 4 (1<sup>st</sup> Cir. 2003). And "[s]imply because there exist[] inconsistencies between [a witness's] grand jury and trial testimony does not warrant the inference that the government knowingly introduced perjurious testimony." <u>United States</u> v. <u>Hemmer</u>, 729 F.2d 10, 17 (1<sup>st</sup> Cir. 1984).

Defendant also complains of alleged discrepancies between Lopez's testimony at trial and that at sentencing. Yet once again, he improperly seeks to incorporate by reference various arguments made in his Rule 33 motion and elsewhere. In his brief, he only mentions three alleged inconsistencies: involving whether he ever traveled with the false descriptions of the implants; whether Silicex was actually used; and whether a physician was present during the treatments. Neither alone nor in combination are these matters so problematic as to warrant a new trial.

Jury Instructions. Defendant next presents two unavailing challenges to the jury instructions. First, he complains that the instruction describing the conspiracy under 18 U.S.C. § 371 did not identify the victim. Yet there was no need to do so. He was charged under the "commit any offense" prong of § 371, which "does not refer to a particular victim of a particular

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crime." <u>United States</u> v. <u>Brandon</u>, 17 F.3d 409, 422 (1<sup>st</sup> Cir. 1994).

Second, defendant objects that the court improperly changed the definition of interstate commerce between its preliminary and final instructions. Yet the two descriptions were quite close. Whatever argument he might have about the phrasing of the preliminary instruction, and it is not a strong one, the final instruction mirrored the definition set forth in 21 U.S.C. § 321(b).

Sentencing. Defendant next complains, mostly in generalized fashion, that the sentence he received was based on improper factors and was otherwise unreasonable. The district court calculated a base offense level of 6 and then imposed six separate enhancements to reach a total offense level of 28.<sup>8</sup> With a criminal history category of I, the ensuing sentencing range was 78-97 months, which exceeded the statutory maximum for both the conspiracy offense (60 months) and the substantive offenses (36 months). The court ended up imposing a 58-month prison term for the former and 36-month concurrent terms for the latter.

Defendant asserts that <u>Apprendi</u> v. <u>New Jersey</u>, 530 U.S. 466 (2000), was somehow violated. Yet "an <u>Apprendi</u> error cannot

<sup>&</sup>lt;sup>8</sup>The court added 12 points for loss exceeding \$200,000 (U.S.S.G. § 2B1.1(b)(1)); 2 points because mass marketing was used (§ 2B1.1(b)(2)); 2 points because the offense was committed from outside the U.S. (§ 2B1.1(b)(8)); 2 points for role as organizer or manager (§ 3B1.1(c)); 2 points for abuse of position of trust or use of special skill (§ 3B1.3); and 2 points for obstruction of justice (§ 3C1.1).

occur unless the sentence actually imposed is greater than the otherwise applicable statutory maximum." <u>United States</u> v. <u>Eirby</u>, 515 F.3d 31, 36 (1<sup>st</sup> Cir.), <u>cert. denied</u>, 129 S. Ct. 72 (2008). That is not the case here.

Defendant also alleges that the court relied on vindictive prosecutorial comments seeking to punish him for his decision to go to trial. Yet the cited remarks--<u>e.g.</u>, a reference to his refusal to stipulate to certain evidence--do not stray outside the bounds of acceptable advocacy. And there is no evidence that the court had any such improper consideration in mind.

Nor has defendant cited any other reason to regard the sentence as unreasonable. The court rejected two other enhancements proposed by probation, as well as the government's request for a 60-month sentence on the conspiracy charge. And in general, the court afforded defendant extraordinary latitude during the sentencing proceedings--allowing him, for example, to crossexamine Lopez at length.

Rule 33 Motion for New Trial. Defendant's request for a new trial, although receiving considerable attention below, has largely fizzled out on appeal. In a lengthy Rule 33 motion, defendant separately challenged each count of conviction. On appeal, however, he confines his attention to counts 8 and 9, which charged him with introducing non-approved new drugs--Lignocaine

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Injection BP 2% and Kenacort-A--into interstate commerce. Defendant points to so-called new evidence allegedly showing that both drugs were approved years ago by the FDA.

At trial, an FDA official (Syzmanski) testified that neither drug was approved for use in the United States. He explained that, after conducting searches based on drug name, active ingredient, and manufacturer, he had found no approval for either drug in the form provided to him--i.e., based on the labeling.

In his Rule 33 motion, filed almost one year after sentencing, defendant disputed this conclusion. Relying on information from the internet, he asserted that Lignocaine was another name for Lidocaine and Xylocaine, both of which had been approved. And relying on information from the FDA website, he asserted that Kenacort-A was one of several brand names for a drug called Triamcinolone Acetonide, which similarly had been approved. In response, the court allowed the parties to submit written questions to Syzmanski and another FDA official and receive written answers.

A defendant seeking a new trial based on newly discovered evidence must satisfy a four-part test. He must show that (1) the evidence was unknown or unavailable at the time of trial; (2) the failure to learn of the evidence was not due to lack of diligence; (3) the evidence is material, not merely cumulative or impeaching;

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and (4) it will probably result in an acquittal upon retrial. <u>See</u>, <u>e.g.</u>, <u>United States</u> v. <u>Wright</u>, 625 F.2d 1017, 1019 (1<sup>st</sup> Cir. 1980). We review the denial of a Rule 33 motion for "manifest abuse of discretion." <u>United States</u> v. <u>Falu-Gonzalez</u>, 205 F.3d 436, 442 (1<sup>st</sup> Cir. 2000).

The district court properly denied the motion. First, as the district court found, the evidence could have been reasonably discovered prior to trial and, second, Szymanski's written answers explained that "[w]hen [the] FDA approves drugs to be sold, part of the approval is specific plant manufacturing location." The seized bottle labels showed that the Lignocaine was manufactured in Germany and the Kenacort-A in Equador. And Szymanski stated that Lignocaine Injection BP 2% (Germany) and Kenacort-A (Equador) had not been approved by the FDA.

The convictions and sentences are <u>affirmed.</u>