UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES v. MICHAEL L. BABICH et al., Defendants.	Criminal No. 16-CR-10343-ADB LEAVE TO FILE GRANTED ON MAY 18, 2018 (DKT. NO. 310) ORAL ARGUMENT REQUESTED

DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF MOTION TO DISMISS INDICTMENT

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INTRODUCTION

This case is an unprecedented, and unfounded, attempt to prosecute employees of an established pharmaceutical company—marketing an FDA-approved medication to licensed healthcare providers—with operating a criminal drug-dealing enterprise. It rests on a wildly over-expansive application of the federal RICO statute and equally defective and novel contortions of the Controlled Substances Act and honest-services-fraud statute. These inflammatory charges may be effective in grabbing media attention. But they cannot be squared with indisputable facts, which the Indictment itself acknowledges, or with the law, which firmly forecloses the prosecutorial overreach that pervades this case. The Court should dismiss the Indictment in its entirety.

The medication at issue is Subsys, an FDA-approved opioid pain therapy. Subsys was brought to the market by Insys Therapeutics, Inc., following nearly a decade of research, development, and clinical testing. It was approved by the FDA in 2012, following extensive regulatory review. And it remains, to this day, a lawful medication that healthcare providers can, and do, prescribe to treat various pain conditions, including but not limited to the "breakthrough" pain that afflicts many cancer patients.

Like various other opioid pain medications, the active ingredient in Subsys is fentanyl. Fentanyl has been used by doctors and approved by the FDA to relieve serious pain for decades—in the form of dozens of therapies that treat pain in a variety of cancer and non-cancer conditions. The innovation that Subsys offers is its method of delivery. A "sublingual spray" that rapidly enters the blood stream, Subsys provides targeted, fast-acting relief for sudden, severe bouts of pain that other medications are often unable to address.

As with all opioid medications, use of Subsys comes with certain risks, including the risk of misuse, abuse, and potential addiction. Those risks are prominently described in the FDA-

approved warnings that accompany every Subsys prescription. And they are further addressed by FDA and DEA regulatory programs that monitor and control the manufacture, distribution, and prescription of all opioid medications. Another critical safeguard against the improper use of opioids—and indeed any prescription medication—comes from the healthcare providers who prescribe it. After all, it is only a physician or other licensed medical professional who can decide, and who has the duty to decide, whether a medication is a safe and appropriate treatment for his or her patient. Neither the law, nor common sense, suggests that pharmaceutical companies or their employees can or should supplant a physician's role and responsibility in making that important medical judgment.

Notwithstanding the foregoing facts, which the Indictment acknowledges, the government seeks to prosecute the founder and several former employees of Insys for peddling Subsys as if it were an illegal street drug. In an extended press release announcing its charges, the government accuses these employees as being "no better than street-level drug dealers," responsible for "fuel[ing] the opioid epidemic" by conspiring to push an "extremely dangerous" medication on people "who did not need it."[1] The Indictment itself—in an obvious appeal to the public's anxiety about illegal opioids—refers to Subsys as "fentanyl" no fewer than 200 times, only once using its proper name. Relying on ugly insinuation about lawful business practices, the charging document accuses Defendants of operating a criminal organization designed to "divert[] [Subsys] from legitimate medical distribution to illicit commercial drug distribution."

Given the novel and incendiary nature of these accusations, one would have expected the government to carefully delineate how exactly marketing a lawful medication to licensed

[1] Press Release, United States Attorney's Office for the District of Massachusetts, Oct. 26, 2017, *available at* https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

healthcare providers, who make individual prescribing decisions for their patients, could amount to an "illicit" scheme to deal drugs. But the government does no such thing. Though long on accusatory rhetoric and ploys to stoke public prejudice, the actual charges provide none of the specificity the Constitution demands to initiate a criminal case and do not come close to properly pleading the criminal charges the government seeks to prosecute.

Nowhere are these deficiencies more obvious than in Count 1, the government's RICO conspiracy charge. The Indictment's most obvious effort to push a drug-dealer theory, Count 1 accuses Defendants of scheming with healthcare providers, pharmacists, and others "known and unknown to the grand jury" to violate the Controlled Substances Act ("CSA"), deprive patients of the honest services of their doctors, and commit various other federal and state crimes. The charge is sweeping in scope and falls apart at multiple levels.

Perhaps most fundamentally, Count 1 utterly fails to plead an "enterprise," the critical element in any RICO charge. It asserts that Defendants and their alleged co-conspirators constituted an "association-in-fact," but does nothing to specify what the association was—what common purpose its members sought to achieve, what relationships its associates purportedly shared, or how they manifested any ongoing organization. As the Supreme Court has made clear, a RICO association-in-fact must, at a minimum, possess each of those elements. The government's RICO count does not allege a single one.

Outside Count 1, perhaps in an effort to allege "common purpose," the Indictment does assert that Defendants and their alleged co-conspirators sought to promote the "illicit distribution of [Subsys]." But that assertion does not cure Count 1's enterprise pleading deficiency. For one thing, there is no allegation that all of the various doctors and pharmacists with whom Defendants purportedly conspired coordinated their efforts to achieve that (or any other) alleged purpose.

Instead, the Indictment describes relationships and activity between certain Defendants and *individual* doctors and pharmacists. As courts have repeatedly held, that kind of "hub-and-spoke" structure, with no "rim" linking the various spokes, does not a RICO enterprise make.

Even if that structural defect could be ignored (and it cannot), another fatal deficiency remains: the absence of any alleged *facts* to support the government's accusation of illicit Subsys distribution by anyone. Yes, the Indictment claims that Insys salespeople encouraged doctors specializing in pain management to transition patients from their existing opioid therapies to Subsys, with its newly available clinical benefits. But that is a common and entirely lawful marketing practice for any pharmaceutical company. The Indictment also contends that salespeople urged doctors to "titrate" their Subsys patients to higher doses of the medication. But Subsys's FDA-approved label recommends *exactly the same process* to ensure the medication provides its intended benefits. Also pervasive are claims that Insys salespeople promoted the use of Subsys for pain conditions not specifically indicated in the medicine's labeling. But "off-label" promotion is not tantamount to "illicit" distribution. As the government well knows, doctors can and often do exercise their professional judgment to prescribe medications, including opioid medications, for appropriate, *non*-illicit purposes.

In sum, *none* of that alleged conduct, even if it occurred, would amount to the "illicit" distribution of Subsys. Nor would it constitute criminal drug distribution under the CSA or deprivation of a physician's honest services. Where an FDA-approved medication is involved, those crimes cannot occur unless (among other things) the medication is prescribed without regard to patient need and contrary to a physician's duty to exercise reasonable medical judgment. Here, there is nothing beyond bald accusation that any Defendant ever agreed or intended Subsys should be prescribed to patients in a medically unnecessary way.

Nor does the Indictment explain in what other possible way Defendants could be held criminally liable for individual prescribing decisions made by licensed medical professionals—particularly since none of the Defendants had any alleged interaction with Subsys patients and little or no contact with Subsys prescribers. As far as our (extensive) research reveals, no court has ever interpreted the CSA or the honest-services-fraud statute as imposing liability based on the kind of allegations made in this case. The rule of lenity, void-for-vagueness doctrine, and principle of constitutional avoidance all strongly counsel against permitting such novel and expansive interpretations here.

A closer call would be whether the facts alleged might constitute improper off-label promotion potentially chargeable as misbranding under the federal Food, Drug, and Cosmetic Act. But the government chose *not* to seek such a charge in the Indictment (which would have created its own constitutional difficulties). Having made that decision, the government should not now be permitted to prosecute conduct that amounts (at most) to misbranding—an offense the Congress has not authorized as a RICO predicate act—under the guise of illicit drug distribution or honest-services fraud.

If the foregoing were not enough to bring down the government's drug-dealing enterprise theory, there is more. Count 1 also identifies money-or-property fraud as part of Defendants' purported "pattern of racketeering activity." But the charge fails to explain how that supposed fraud—described as a scheme to trick insurance companies into covering patients' off-label Subsys prescriptions—relates to any shared objective the government has woven throughout its RICO count: *illicit* drug dealing. Count 1 also cites the commercial-bribery laws of various states to try to support its racketeering allegations. RICO, however, requires any alleged predicate acts based on state statutes actually to be "chargeable under state law." And the bribery statutes Count 1

invokes are rarely (and in some cases *never*) charged in state court prosecutions. The little authority that does exist regarding these statutes provides no support for how the government is attempting to charge them here.

The defects in the government's Indictment are not limited to Count 1. For example, Count 2 and Count 3 each purport to plead a single conspiracy to commit mail and wire fraud. But, in fact, each count alleges two *distinct* conspiracies: one to commit an honest-services fraud (alleged bribes to doctors) and another to commit a money or property fraud (alleged deception of insurers). This plainly violates Rule 12's prohibition on duplicitous indictments and is, by itself, grounds for dismissal.

Count 4 suffers similar infirmities in charging a conspiracy to violate the Anti-Kickback Statute ("AKS"). It fails to allege (beyond bare accusation) that the seven Defendants agreed to make payments to doctors that they *knew* would break the law—as opposed to agreeing that Insys should pursue various marketing strategies common in the pharmaceutical industry and specifically protected under the Statute's various "safe harbors."

For all of these reasons, and those described below, the Indictment fails scrutiny under the Federal Rules and deprives Defendants of critical Constitutional protections. The Court should dismiss it.

BACKGROUND

I. The Research, Development, And Federal Regulation Of Subsys

Insys Therapeutics, Inc. ("Insys") was founded by Dr. John Kapoor in 2002 to research and develop a platform of medications intended to treat the side effects of cancer and chemotherapy. One of the company's earliest drug candidates was Dronabinol, now known as Syndros, which helps to relieve chemo-induced nausea and vomiting. Dr. Kapoor conceived of this and other

concepts for new medicines based on his education and expertise as a medical chemist and—in the case of the cancer drugs—his personal experience watching his wife battle and ultimately succumb to metastatic breast cancer.

Shortly after its founding, Insys began efforts to develop an opioid medication that could provide unique clinical benefits in treating the breakthrough pain that many cancer patients experience on top of the persistent pain caused by their disease. Sudden and severe, this pain "breaks through" a patient's regular pain therapy to cause acute suffering. At the time Subsys was under development, there were already several FDA-approved opioid medications available to treat acute pain of this type—all fast-acting fentanyl compounds absorbed through the mouth's mucous membrane and collectively known as "TIRFs" (transmucosal immediate-release fentanyls).[2] Administered through a sublingual spray, Subsys was developed to provide more rapid and complete absorption of the drug into the bloodstream, and therefore more rapid and targeted relief from severe, rapid onset pain, than existing TIRF medicines. Indictment ¶¶ 19, 20, 23, 27.

On March 4, 2011, following nearly ten years of research and development, Insys sought regulatory approval for Subsys, submitting to the FDA a New Drug Application ("NDA") that detailed the results of the clinical testing for the drug. *See id.* ¶ 22. The FDA scrutinized the extensive information and data the NDA provided and, on January 4, 2012, approved Subsys as

[2] *See* Indictment ¶ 10 (noting that the market was "crowded with competitor drugs"); ¶ 23 (noting that Subsys was in the TIRF "category of drugs"); ¶ 34 (noting that "[p]ractitioners willing to write prescriptions for the Fentanyl Spray had a large number of TIRF medications to choose from"). Dozens of other non-TIRF, fentanyl-containing therapies were also already approved by the FDA and available to doctors, including medications to treat breakthrough cancer pain, post-operative pain in a hospital setting, and acute pain in pediatric populations; transdermal patches to treat chronic pain in adults; and epidural analgesia to relieve pain during labor.

safe and effective to treat breakthrough pain in "opioid-tolerant" cancer patients—that is, patients already receiving "around-the-clock" opioid therapy for their persistent pain. *See id*. ¶¶ 22–23.

As part of its review, the FDA also considered the labeling that Insys proposed to accompany Subsys. That label details the risks and potential side effects of the drug.[3] It also guides doctors in determining the appropriate dose for their patients, based on the results of the clinical studies. As the label sets forth, those results demonstrate that only four percent of patients experienced pain relief when prescribed the lowest dose of the medication, whereas more than a third of patients needed one of the two highest approved doses to obtain pain relief.[4] Accordingly, the label advises the healthcare provider to begin by prescribing a low dose of Subsys and then to consult with their patient to determine whether "a dosage adjustment"—also known as "titration"—is appropriate.[5]

The Subsys label also explains that the FDA approved the medication to treat the particular condition of breakthrough cancer pain. *See id.* ¶ 22. As with any FDA-approved medication, that approved "indication" does not constrain how licensed healthcare practitioners may exercise their medical judgment to treat their patients. Rather, as the Indictment acknowledges, practitioners "acting in the usual course of professional practice possess[] the authority" to prescribe

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[3] *See id.* ¶ 22 (noting that "[t]he label for the Fentanyl Spray warned that the drug posed risks of misuse, abuse, addiction, overdose, and serious complications due to medical errors"); *see also* Subsys Label (Jan. 2012) at 3 (Blackbox Warning), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202788s000lbl.pdf. The Court may take judicial notice of the Subsys label in deciding this motion. *See, e.g.*, *United States v. Lewis*, 732 F.3d 6, 10 (1st Cir. 2013) (taking judicial notice in reviewing challenge to indictment); *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1023–24 (C.D. Cal. 2008) (taking judicial notice of drug labels taken from FDA's website).

[4] *See* Subsys Label (Jan. 2012) at 22 (§ 14: Clinical Studies).

[5] *See* Indictment ¶¶ 82–83 (noting that the label specifically discusses the need for dose titration when using Subsys); Subsys Label (Jan. 2012) at 4–5 (§ 2.2: Dose Titration).

medications, including Subsys, for other indications as long as they do so for "a legitimate medical purpose." *Id.* ¶ 107. The "prescribing practitioner," as the professional providing the prescription, is responsible for ensuring that any "off-label" prescription he or she writes is medically appropriate and "proper." *Id.* ¶ 41.

Notwithstanding prescribing practitioners' well-recognized rights and responsibilities, both the FDA and the DEA monitor and control the distribution of Subsys through various programs and regulations.[6] Under these programs, every doctor who prescribes Subsys, and every pharmacy that dispenses it, must register with the DEA and record and report every prescription and sale of the medication that occurs. *See id.* ¶¶ 8, 9, 11, 32, 35, 41. Doctors and pharmacists, as well as Subsys patients themselves, must also participate in a nationwide Risk Evaluation and Mitigation Strategy (REMS) program.[7] Administered by the FDA for all TIRF medications, this program is designed "to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines."[8] The rules of the program block Subsys from being prescribed to any patient unless and until the doctor, the pharmacy, and the patient all certify that they have participated in an educational process mandated by the REMS program and that they understand the risks and potential side effects associated with the medication. *See id.* ¶¶ 23–25. The Indictment does not allege that Insys or any of its employees ever violated any of the foregoing rules or requirements.

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[6] *See* Indictment ¶¶ 23–24 (detailing the TIRF REMS Access Program); ¶¶ 29–30 (detailing the "restrictions imposed on all schedule II substances").

[7] *Id.* ¶¶ 23–25 (detailing the requirements of the program).

[8] *TIRF REMS Access Program*, https://www.tirfremsaccess.com/TirfUI/rems/home.action.

II. The First Indictment

On December 6, 2013, the Office of Inspector General (OIG) of the Department of Health and Human Services issued a subpoena for materials concerning certain Insys sales practices. Three years later, the government charged six current and former Insys employees with conspiring to engage in RICO violations, honest-services-mail fraud, wire fraud, and violations of the AKS. *See* Dkt. No. 1 ("First Indictment"). The First Indictment did not charge Dr. Kapoor, who was Chairman of the Insys Board of Directors during the charged conspiracy.

III. The Superseding Indictment

In October 2017, nearly a year after the First Indictment was returned, the government obtained a Superseding Indictment (the "Indictment") and stretched its theory of prosecution even further. Though the government devoted an additional year to investigating the matter, it adds very few additional alleged *facts* to the charging document. Instead, the new Indictment contains a new, overarching *accusation*—that Defendants, together with an unspecified number of physicians, healthcare practitioners, pharmacies, and other "persons and entities both known and unknown to the Grand Jury," purportedly "conspired with one another to profit from the illicit distribution of the Fentanyl Spray[] . . . ." Indictment ¶ 47. In service of this accusation, the government vaguely alleges a new RICO predicate act—"multiple offenses involving the distribution of controlled substances," *id.* ¶ 246; sprinkles the word "illicit" into various paragraphs, *see, e.g.*, *id.* ¶¶ 13, 16–18, 22, 47, 76, 78, 120; appends a section discussing dosage titration, *id.* ¶¶ 82–91; and inserts a reference to the DEA's suspicious order monitoring regulations, *id.* ¶¶ 18, 92.

The Indictment also adds Dr. Kapoor as a seventh defendant, *see id.* ¶ 1, though like most allegations as to the other Defendants, includes largely non-specific references to his purported

participation in the charged conspiracy. And it also adds all seven named defendants to each of the counts. Finally, whereas the First Indictment charged the alleged scheme to defraud patients of honest services and the alleged scheme to defraud insurers and pharmacy benefits managers in separate counts—Counts 2 and 3, respectively—the Indictment merges these distinct conspiracies into both counts. *Compare* First Indictment ¶¶ 198–199 (Count 2 – Scheme to Defraud Patients of Honest Services), and ¶¶ (Count 3 – Scheme to Defraud Insurers and Pharmacy Benefits Managers), *with* Indictment ¶¶ 249, 251 (alleging in both the Mail Fraud Conspiracy—Count 2—and Wire Fraud Conspiracy—Count 3—counts the intent to "devise a scheme and artifice to defraud patients of honest services and to obtain money and property by means of materially false and fraudulent pretenses, representations and promises, for the purpose of executing such scheme and artifice to defraud . . . .").

ARGUMENT

The desire of the government in this case is clear: to prosecute Defendants based on headline-grabbing accusations of organized criminal drug distribution. What the Indictment does *not* make clear is how the conduct of Defendants—marketing a lawful medicine to licensed health care practitioners who are each responsible for their own prescribing decisions—could amount to illicit drug dealing.

Instead, the Indictment rests on (1) four threadbare Counts that are little more—and sometimes *less*—than a cut-and-paste of the criminal statutes Defendants purportedly violated; and (2) a narrative "Introduction" that does present certain factual allegations (and plenty of innuendo), but still fails to properly plead the crimes the government is attempting to prosecute. This deficient charging document cannot pass muster under Federal Rule of Criminal Procedure 7(c), which requires the government to begin every prosecution with "a plain, concise and definite

written statement of the essential facts constituting the offense charged." Fed. R. Crim. P. 7(c).[9] Nor does it satisfy Federal Rule of Criminal Procedure 12. Fed. R. Crim. P. 12(b)(3)(B)(v). Even taking into account all of the allegations scattered throughout the document, it fails to state an offense under any of the criminal statutes the government attempts to invoke. *See, e.g.*, *United States v. Pirro*, 212 F.3d 86, 95 (2d Cir. 2000).

I. Count 1 Must Be Dismissed

The core of the government's effort to equate Defendants with a drug cartel and Subsys with an illegal street drug is Count 1, which charges an unsupported RICO conspiracy. RICO is a powerful statute with "draconian penalties" designed to combat organized crime, like loan-sharking, illegal gambling, and illicit drug smuggling. It is also quite broadly drafted, rendering it potentially susceptible to a "wide range of applications, not all of which were foreseen or intended by the Congress that enacted it." Gerard E. Lynch, RICO: The Crime of Being a Criminal, Parts I & II, 87 Columbia L. Rev. 661, 661 (1987). Given these features of the federal racketeering law, courts have made clear that the government bears a substantial and difficult burden in pleading a RICO offense and policing against misapplication and overextension of the statute. *See, e.g.*, *United States v. Davidoff*, 845 F.2d 1151, 1154 (2d Cir. 1988).

That vigilance is clearly called for in this case. The allegations contained in Count 1 itself are largely inscrutable, raising serious questions about what theory of criminal liability the grand jury passed on when it returned this serious charge. But the Indictment as a whole, together with the government's media statements, reveal the theory the prosecution would like to pursue—and

[9] This fatal lack of specificity, as well as the other legal defects described herein, require dismissal of the Indictment. In the event the Court does not agree, Defendants have simultaneously moved for a bill of particulars (though a bill could not cure the lack of particulars in the Indictment itself). *Russell v. United States*, 369 U.S. 749, 770 (1962).

that theory finds no support in alleged facts or in clearly established law. Much as the government might like, an array of individuals and entities scattered all over the country sharing no alleged common purpose, or even ongoing relationship, does not quality as a RICO enterprise. Nor do off-label marketing or the purported payment of kickbacks to doctors qualify as predicate RICO offenses. Recognizing as much, the government tries to charge this alleged conduct as criminal drug distribution under the CSA, 21 U.S.C. §§ 841, 846, and honest-services fraud, 18 U.S.C. § 1346. But doing so stretches those federal statutes beyond recognition and only compounds the overreach that the entire RICO charge represents. For these and other reasons, Count I fails legal scrutiny and the entire charge must be dismissed.

A. Count 1 Lacks The Specificity The Constitution Requires

As countless cases make clear, under Federal Rule of Criminal Procedure 7(c), an indictment "'must do more than simply repeat the language of the criminal statute.'" *United States v. Murphy*, 762 F.2d 1151, 1154 (1st Cir. 1985) (quoting *Russell v. United States*, 369 U.S. 749, 764 (1962)). It must set forth "the essential facts constituting the offense charged," and "sufficiently apprise[] the defendant of what he must be prepared to meet." *Murphy*, 762 F.2d at 1154 (quoting Fed. R. Crim. P. 7(c) and *Russell*, 369 U.S. at 764). That critical requirement enforces the Sixth Amendment's guarantee that anyone accused of a crime be sufficiently informed of the nature and cause of the accusation, which in turn permits an individual to prepare a meaningful defense. *See United States v. Tomasetta*, 429 F.2d 978, 979 (1st Cir. 1970). It also safeguards the Fifth Amendment's promise that a defendant will be prosecuted *only* on the specific theory of culpability that the grand jury approved, rather than some other "charges that are not made in the indictment against him." *See United States v. Santa-Manzano*, 842 F.2d 1, 2 (1st Cir. 1988) (quoting *Stirone v. United States*, 361 U.S. 212, 217 (1960)). Only the specificity that Rule

7(c) demands can ensure that the government does not constructively amend, and thereby impermissibly vary, the charges the *grand jury* approved in passing on the Indictment. *See Stirone*, 361 U.S. at 215–17.[10]

That critical specificity is absent here. Spanning two cursory pages, Count 1 does little more than recite the elements of a RICO conspiracy charge. Tracking the statutory language, it asserts that Defendants, together with "co-conspirator" physicians, pharmacies, and other unspecified "persons and entities," knowingly "associated in fact" to form a conspiracy that conducted its "affairs" by engaging in a "pattern of racketeering activity," consisting of "multiple acts" indictable under various statutory provisions. *See* Indictment ¶¶ 242–47. Those generalized assertions fail to apprise Defendants "with reasonable certainty[] of the nature of the accusation" against them. *Russell*, 369 U.S. at 765 (quoting *United States v. Simmons*, 96 U.S. 360, 362 (1877)); *see also United States v. Yefsky*, 994 F.2d 885, 893 (1st Cir. 1993) (an indictment's "statement of the facts and circumstances" must "inform the accused of the specific offense, coming under the general description, with which he is charged") (quoting *Hamling v. United States*, 418 U.S. 87, 117–18 (1974)). They also provide no indication of what particular conduct "the *grand jury* has deemed adequate to support" the government's accusation against each Defendant. *Tomasetta*, 429 F.2d at 979 (emphasis added).

Defendants could attempt to divine the charges the government would like to prosecute at trial, including from the prosecutor's media statements. But guesswork is no way to prepare an effective defense. And it provides no assurance that the charges Defendants will face match what

[10] *See United States v. Dellosantos*, 649 F.3d 109, 125 (1st Cir. 2011) (vacating defendants' convictions because "the variance between the conspiracy specified in the indictment and the evidence at trial was unfairly prejudicial"); *United States v. Glenn*, 828 F.2d 855, 859 (1st Cir. 1987) (reversing convictions because "the variance between the single conspiracy charged and the conspiracy that the evidence proved significantly prejudiced [the defendant]").

the grand jury had in mind when it returned the Indictment. *See Santa-Manzano*, 842 F.2d at 2 ("[T]he Fifth Amendment assures the defendant that the government will try him on the charges that the grand jury voted . . . ."). The only thing that could provide *that* guaranteed assurance is the Indictment's specification of what alleged conduct the grand jury deemed adequate to constitute each of the elements of the offense. That specification is not provided in Count 1 itself. Nor can it be discerned from the rambling narrative "Introduction" that precedes the Indictment's actual criminal charges. Based on that defect alone, the government's RICO conspiracy charge should be dismissed.

B. The Indictment Does Not Plead A RICO Enterprise

"[F]or a defendant to be found guilty of conspiring to violate RICO," the government must establish, among other things, "the existence of an enterprise affecting interstate [or foreign] commerce." *United States v. Ramirez-Rivera*, 800 F.3d 1, 18 (1st Cir. 2015) (second alternation in original) (quoting *United States v. Shifman*, 124 F.3d 31, 35 (1st Cir. 1997)). If the alleged enterprise is an established legal entity, such as a corporation or partnership, the fact that the entity has a legal existence easily satisfies the enterprise element. *See* 18 U.S.C. § 1961(4). An "association-in-fact" enterprise is different. *See id.* While it need not exhibit any particular form or organization, an association-in-fact must be "an entity separate and apart from the pattern of activity in which it engages . . . ." *United States v. Turkette*, 452 U.S. 576, 583 (1981). And that means "at least three structural features" must be present: "a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit those associated to pursue the enterprise's purpose." *Boyle v. United States*, 556 U.S. 938, 946 (2009).

Count 1 does not plead any of these structural features. *See* Indictment ¶ 243. It identifies the alleged associates by category only and then states, in circular fashion, that the purpose of their

purported "association-in-fact" enterprise was to "achiev[e] the objectives of the enterprise." *See id.* It contains no description at all of what relationships the alleged associates shared or how their activities were coordinated over time to permit them to achieve their (unspecified) purpose.

1. The Indictment Describes, At Most, A "Hub-And-Spoke" Structure

Even if Defendants could fairly be forced to piece together the government's enterprise theory from the rest of the Indictment, it would still fail. The government's introductory allegations describe no relationship joining all the alleged associates, nor any coordinated activity among them, towards an alleged common purpose. Instead, the allegations *at most* set forth a "hub-and-spoke" structure—with Defendants occupying the hub and various doctors and pharmacies the spokes—with no common rim linking the individual spokes together. *See In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 327 (3d Cir. 2010) (the "critical issue" in a hub-and-spoke conspiracy "is how the spokes are connected to each other") (quoting *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 436 (6th Cir. 2008)); *see also id.* at 374–75.[11]

Courts have repeatedly held that a "rimless" hub-and-spoke structure does not amount to a RICO association-in-fact. *See, e.g.*, *Gov't Emps. Ins. Co. v. Analgesic Healthcare* ("*GEICO*"), 2017 WL 1164496, at *2 (D. Mass. Mar. 28, 2017).[12] And for good reason. As the law makes clear, an enterprise cannot exist under RICO unless some "system[ic] linkage" or "continuing

[11] The First Circuit has held that precedent in civil RICO cases is applicable to criminal RICO cases. *See Shifman,* 124 F.3d at 35 n.1 (1st Cir.1997) ("[I]t is appropriate to rely on civil RICO precedent when analyzing criminal RICO liability" because "[t]he standard is the same for both criminal and civil RICO violations.") (citing 18 U.S.C. § 1962).

[12] *See also In re Trilegiant Corp., Inc.*, 11 F. Supp. 3d 82, 98 (D. Conn. 2014) ("Hub-and-spoke enterprises have long been held by courts in this circuit to be insufficient as a matter of law to constitute the requisite enterprise for a RICO violation." (citing *N.Y.C. v. Chavez*, 944 F. Supp. 2d 260, 269–76 (S.D.N.Y. 2013)).

coordination" joins *all* of a purported enterprise's members into one continuing unit. *See Ezell v. Lexington Ins. Co.*, 286 F. Supp. 3d 292, 298–99 (D. Mass. 2017) (quoting *Libertad v. Welch*, 53 F.3d 428, 443 (1st Cir. 1995)). Thus, "[t]he parallel conduct of a number of 'spokes,' even through a central 'hub,' is not a RICO enterprise without more—that is, without a 'rim' that connects the spokes." *Abbott Labs. v. Adelphia Supply USA*, 2017 WL 57802, at *5 (E.D.N.Y. Jan 4, 2017).

In re Lupron Marketing & Sales Practices Litigation, 295 F. Supp. 2d 148 (D. Mass. 2003), is illustrative. There, the plaintiffs alleged an "enterprise" consisting of a pharmaceutical company plus all of the practitioners who had dispensed a certain drug to patients. *Id.* at 173–74. But there were "no allegations . . . that [the practitioners] were associated together in a meaningful sense, or were even aware of each other's existence . . . ." *Id.* at 173. Instead, the plaintiffs' alleged enterprise was essentially a loose collection of people sharing "a common occupation" and "a similar motive." *Id.* at 174. The court dismissed the RICO claim. *Id.* at 184; *see also GEICO*, 2017 WL 1164496, at *2–4 (dismissing RICO claim where alleged enterprise consisted of company offering kickbacks to health care practitioners in return for prescriptions, with no "unifying rim").

Ezell is similar. There, the plaintiffs alleged an "enterprise" consisting of several insurance companies plus "the brokers participating in [one of the defendant's] 'Approved Broker' program." 286 F. Supp. 3d at 298. But the complaint failed to "state how the *brokers* collaborated with *each other* or if the brokers were even aware of each other's participation in the alleged scheme." *Id.* (emphases added). Absent any allegation that the brokers—the spokes—"associated together for a common illegal purpose, as opposed to merely conducting their business in parallel," the RICO claim failed. *Id.* at 298–99.

The same pleading deficiencies are present here. *See supra* at 15–16. The Indictment may allege "bilateral agreements" between certain Defendants and certain practitioners and pharmacies. *GEICO*, 2017 WL 1164496, at *2. But a "series of distinct, albeit similar . . . relationships" does not suffice to form a RICO enterprise. *McDonough v. First Am. Title Ins. Co.*, 2011 WL 285685, at *6 (D.N.H. Jan. 28, 2011) (no RICO enterprise between "hub" mortgage company and unrelated title-agent "spokes" who sold insurance at allegedly fraudulently inflated rate). The reason is simple. "RICO . . . is *not* a conspiracy statute. Its draconian penalties are not triggered just by proving conspiracy." *Fitzgerald v. Chrysler Corp.*, 116 F.3d 225, 228 (7th Cir. 1997) (Posner, J.) (emphasis added). The term "'[e]nterprise' . . . connotes more." *Id.* And that "more" is nowhere to be found in this Indictment.

2. The Indictment's "Illicit Distribution" Allegations Fail

To be clear, the Indictment appears to ascribe a similar scheme to Defendants and their alleged co-conspirators: namely, the "diver[sion]" of Subsys "from legitimate medical distribution to illicit, commercial drug distribution." *See* Indictment ¶ 76. These allegations fail to plead a RICO enterprise for two reasons.

First, even if various alleged co-conspirators *separately* possessed and pursued that similar objective, that would not be sufficient. "[C]ommonality of motive" or "[s]imilarity of goals and methods does not suffice to show that an enterprise exists . . . ." *GEICO*, 2017 WL 1164496, at *3 (quoting *Lupron*, 295 F. Supp. 2d at 173–74); *see also Ezell*, 286 F. Supp. 3d at 299 (citing *Libertad*, 53 F.3d at 443). Rather, "common purpose" means "coordinated activity in pursuit of a common objective" by *all* members of an association-in-fact. *GEICO*, 2017 WL 1164496, at *3 (quoting *Lupron*, 295 F. Supp. 2d at 173–74). "Were the rule otherwise, competitors who independently engaged in similar types of transactions with the same firm could be considered associates in a common enterprise." *Ins. Brokerage Antitrust Litig.*, 618 F.3d at 375; *see also*

Lupron, 295 F. Supp. 2d at 174 ("Without [these limitations] any group of persons sharing a common occupation, *e.g.*, urologists and lawyers, and a similar motive, *e.g.*, greed, could be held to constitute a RICO enterprise.").

Here, as already previewed above, there are no allegations that the members of the alleged enterprise coordinated their efforts to achieve any commonly shared purpose—including the "illicit" distribution of Subsys.

Second, while the Indictment accuses Defendants and their alleged co-conspirators of engaging in the illicit distribution of Subsys, the actual conduct the Indictment alleges is anything but. Instead, the document describes situations in which Defendants purportedly "tr[ied] to cause" healthcare practitioners "to issue new prescriptions" of Subsys or to "increase[] . . . the dosage, and volume, of existing prescriptions." *See* Indictment ¶ 14.[13] New prescriptions of a newly launched medication offering new clinical benefits are not illicit, *see id.* ¶¶ 10, 34—especially where those prescriptions were written by doctors who were already using similar medications to provide pain relief to their patients and made a decision to try an alternative therapy. *See id.* ¶¶ 57, 59, 68, 133, 157, 191, 222. Nor is a doctor's decision to increase the dose or volume of a prescription for pain medication normally lacking in medical purpose. In fact, the clinical study data for Subsys demonstrated—and the FDA-approved label advised—that, for the vast majority

[13] *See also* Indictment ¶¶ 67 (new prescriptions), ¶ 71 (new prescriptions), ¶ 72 (new prescriptions), ¶ 88 (dosage), ¶ 89 (dosage), ¶ 91 (dosage), ¶ 93 (new prescriptions), ¶ 122 (new prescriptions), 127 (new prescriptions), ¶ 130 (new prescriptions), ¶ 145 (new prescriptions), ¶ 149 (new prescriptions), ¶ 169 (new prescriptions), ¶ 177 (new prescriptions), ¶ 181 (new prescriptions), ¶ 182 (new prescriptions), ¶ 185 (new prescriptions), ¶ 193 (new prescriptions), ¶ 195 (new prescriptions), ¶ 202 (new prescriptions), ¶ 214 (new prescriptions), ¶ 218 (new prescriptions), ¶ 223 (new prescriptions), ¶ 226 (new prescriptions), ¶ 228 (new prescriptions), ¶ 234 (new prescriptions), ¶ 236 (new prescriptions), ¶ 238 (new prescriptions), ¶ 239 (new prescriptions).

of patients, "titrating" to a higher dose was medically *necessary* to ensure the patient experienced effective pain relief. *See* Subsys Label (Jan. 2012) at 4–5 (§ 2.2: Dose Titration).[14]

The Indictment also refers in various places to Insys salespeople urging doctors to prescribe Subsys for "off-label" use. But prescribing an FDA-approved drug for an off-label indication is not outside the legitimate practice of medicine. Quite the opposite. As the Indictment acknowledges, doctors can, and often do, decide in their professional judgment to prescribe a medicine to treat conditions not specifically indicated in the drug's label. *See* Indictment at ¶ 107; *see also United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012) (noting that "courts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use") (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("[Off-label use is] "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.")); *Weaver v. Reagen*, 886 F.2d 194, 198–99 (8th Cir. 1989) ("FDA[-]approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient.")). As the Indictment also concedes, it is only the prescribing physician who can—and must—determine, in his or her medical judgment, the propriety of the prescriptions he or she writes, including those that are off-label. *See id.* at ¶ 41. Nowhere does the Indictment allege any facts demonstrating that Defendants supplanted any prescribing physician's role and responsibility in making that medical judgment or otherwise conspired with prescribers to surrender that judgment and give Subsys to patients for improper purposes.

[14] *See also* Indictment ¶ 28 ("Practitioners had to follow the patient closely, increasing the strength of the prescription until the patient reached the adequate dosage strength."); *id.* ¶¶ 82–83 (explaining that dose titration will be required for many patients).

C. The Indictment Does Not Plead A Pattern Of Racketeering Activity

Count 1's RICO charge fails for a separate reason as well: the Indictment does not properly plead a "pattern of racketeering activity." 18 U.S.C. § 1962(c).

Count 1 asserts that such a "pattern" existed because Defendants conspired "with others" to commit various federal and state crimes. Indictment ¶ 246. The "fundamental characteristic of a conspiracy is a joint commitment to an 'endeavor which, if completed, would satisfy all of the elements of [the underlying substantive] criminal offense.'" *Ocasio v. United States*, 136 S. Ct. 1423, 1429 (2016) (citation omitted). Thus, to plead a conspiracy to commit a particular crime, the government must allege that "*each* conspirator . . . specifically intended that *some conspirator* commit *each* element" of the crime in question. *Id.* (emphasis added). Here, Count 1 identifies statutes that Defendants and their alleged co-conspirators purportedly agreed to violate. In no case does the Indictment plead an agreement to commit each of the elements of the alleged offense.

1. The Indictment Does Not Plead An Agreement To Violate The Controlled Substances Act

As noted above, Count 1 invokes Sections 841 and 846 of the CSA as part of Defendants' alleged "pattern of racketeering." Indictment ¶ 246. Remarkably, the Indictment does not describe the most basic elements of a Section 841 or 846 offense, or what alleged conduct satisfied each of those elements, or even which of the seven Defendants were purportedly involved in the offenses. Specificity concerning RICO's racketeering element is critical because "[u]nder the [RICO] statutory scheme the predicate acts are not only important 'elements of the crime' but they are also, by definition, distinct offenses," which may be subject to increased penalties. *United States*

v. Neapolitan, 791 F.2d 489, 501 (7th Cir. 1986).[15] That specificity is clearly lacking as to the government's CSA charge.

Inscrutable as the Indictment may be, the law is very clear: Where an FDA-approved medication is involved, the CSA is violated if, and only if, a healthcare provider "intentionally prescribes" the medication for some reason "other than 'a legitimate medical purpose in the usual course of professional practice.'" *United States v. Zolot*, 968 F. Supp. 2d 411, 428 (D. Mass. 2013); *see also United States v. Hooker*, 541 F.2d 300, 305 (1st Cir. 1976).[16] Nor does a crime occur where a doctor is negligent or commits malpractice in prescribing a drug. *See United States v. Sabean*, 885 F.3d 27, 45 (1st Cir. 2018) ("[M]edical negligence alone [is] insufficient to ground a conviction [under the CSA]."); *United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006) ("A practitioner becomes a criminal not when he is a *bad* or *negligent* physician, but when he

[15] The base offense level for a RICO violation is either the offense level applicable to the "underlying racketeering activity," or 19, whichever is greater. U.S.S.G. § 2E1.1; *see also United States v. Butt*, 955 F.2d 77, 88–89 (1st Cir. 1992). "Where there is more than one underlying offense" or predicate violation, the Sentencing Guidelines "treat each underlying offense as if contained in a separate count of conviction for the purposes of" the offense level calculation. U.S.S.G. § 2E1.1 cmt. 1 (2016). Violation of the CSA predicate, for example, would—even on its own—likely result in a base offense level greater than 19, depending on the amount of fentanyl. *See id.* § 2D1.1(c (showing offense levels for CSA violation in drug quantity table).

[16] Courts across the country agree on this principle. *See United States v. Azmat*, 805 F.3d 1018, 1035 (11th Cir. 2015) ("In order to secure a conviction for unlawful dispensation under [the CSA], the government must prove that the defendant dispensed controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally.") (citation omitted); *United States v. Elder*, 682 F.3d 1065, 1071 (8th Cir. 2012); *United States v. Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994); *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986); *United States v. Stump*, 735 F.2d 273, 276 (7th Cir. 1984); *United States v. Voorhies*, 663 F.2d 30, 33 (6th Cir. 1981); *United States v. Bartee*, 479 F.2d 484, 489 (10th Cir. 1973). *See also* 21 C.F.R. § 1306.04 ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."); *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 831–32 (11th Cir. 2018). No "corresponding responsibility" is applied to a manufacturer.

ceases to be a physician *at all*."); *United States v. Solomon*, 2016 WL 10894663, at *4 (E.D. Ky. June 23, 2016) (recognizing the distinction between a "malpractice case" and a "criminal case" under the CSA).

Rather, to establish criminal distribution of an FDA-approved medication, the government must allege, and prove, that when prescribing the drug, the healthcare provider intended "to act as a [drug] pusher rather than a medical professional." *Feingold*, 454 F.3d at 1008; *see also United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005) (noting that the question is whether the practitioner was "acting as a healer" or as a "seller of wares"). In doing so, the government cannot just state that there is a "pattern" of purportedly problematic prescriptions. *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1141 (4th Cir. 1994). Instead, it must demonstrate that a particular prescription to a particular patient was lacking in "legitimate medical purpose[]." *See id.* (overturning counts in a § 841 conviction that were based on a pattern, as opposed to an individual analysis of each prescription).

Here, the Indictment insinuates that Subsys was distributed in violation of the CSA. Indictment ¶ 76. But it does not identify any particular prescription that was purportedly written without regard to medical need. More to the point, the Indictment does not allege that any *Defendant* knew about any improper prescription of Subsys or that any Defendant agreed Subsys should be prescribed for improper purposes to particular patients (or even as a general matter). *See Shifman*, 124 F.3d at 35 ("For a defendant to be found guilty of *conspiring* to violate RICO, the government must prove . . . that the defendant . . . [agreed] to commit, or in fact [committed], two or more predicate offenses.").

As various cases make clear, where a non-practitioner is charged with distributing, or conspiring to distribute, medication in violation of the CSA, the government must show that the

defendant either forged prescriptions themselves for medically unnecessary purposes, or "directed or caused" the licensed practitioners to issue prescriptions that had no legitimate purpose. *See United States v. Boccone*, 556 F. App'x 215, 230, 235 (4th Cir. 2014) (affirming conviction of non-practitioner defendant, an owner of a pain clinic, stating that his "culpability rests on his conduct in directing or causing the charged prescriptions" by "conduct[ing] the patient visits" and "direct[ing] prescriptions" for patients by entering directions to prescribe medication to them in their medical files); *see also United States v. Orta-Rosario*, 469 F. App'x 140, 144 (4th Cir. 2012) (affirming conviction of non-practitioner owner of online prescription service, noting factors relevant to guilt, including "permitting non-medical personnel to write prescriptions with pre-signed blank prescription forms"); *United States v. Mahar*, 801 F.2d 1477, 1487 (6th Cir. 1986) ("[T]hat patients were regularly sold controlled substances . . . selected by non-physician lay employees of the Clinic would further support a finding that controlled substances were issued outside the usual course of medical practice and for no legitimate medical purpose.").

Establishing that a defendant who is not the prescribing doctor "directed or caused" licensed practitioners to issue prescriptions without any legitimate medical purpose may be possible where the defendant owns a pain clinic or online prescription service, or has some other reason to have knowledge of illegitimate prescriptions. *See, e.g.*, *United States v. Johnson*, 831 F.2d 124, 128 (6th Cir. 1987) (finding liable a non-practitioner owner of a medical center and a doctor's wife who sold fake prescriptions to be used to obtain controlled substances); *Mahar*, 801 F.2d at 1487–88 (6th Cir. 1986) (finding liable a president of a medical clinic who was "present at the Clinic nearly every day, usually putting in long hours" and "supervis[ing] and direct[ing] the activities of the Clinic's employees"). But in this case the Defendants are executives of a pharmaceutical company, with no control over the individual doctors to whom they, as well as

competing pharmaceutical companies, market their medications. It is thus not surprising that the Indictment does not allege that Defendants exerted any authority or control over licensed practitioners in such a way that they could ever direct or cause doctors to prescribe Subsys to patients outside of their valid medical practices.[17]

The Indictment does present a section entitled, "Intending the Illicit Distribution of Fentanyl." Indictment ¶¶ 76–92. But most of what that section describes is Defendants' supposed "target[ing]" of healthcare providers who might prescribe Subsys for conditions other than breakthrough cancer pain. *Id.* ¶ 77. Here, and throughout the Indictment, the government appears to take issue with what it views as improper efforts by Insys salespeople to market Subsys for off-label uses. *See, e.g.*, *id.* ¶¶ 77–81 (targeting pain clinics beyond breakthrough cancer pain), ¶¶ 107–110 (using "the spiel" to obtain insurance authorization for patients Insys employees allegedly knew did not have breakthrough cancer pain), ¶¶ 111–117 (deceiving insurers through including fake or inaccurate diagnosis codes, including "dysphagia," regardless of whether the patient was experiencing that condition), ¶ 118 (asserting a cancer diagnosis if the patient had ever had one, regardless of whether the patient still had cancer or whether cancer was the condition for which the patient had been prescribed Subsys), ¶ 119 (falsely confirming to insurers and pharmacy benefit managers that a patient had tried and failed other medications). As far as we are aware (based on extensive research), the CSA has never been used to prosecute that kind of marketing practice. And understandably so. As the caselaw above makes abundantly clear, the CSA applies

[17] The only allegations that even touch on this subject are (1) a reference to *one* doctor whom *one* Insys employee suggested, ostensibly after *one* interaction with the doctor, might be running a "pill mill," *see* Indictment ¶ 191, and (2) a conclusory allegation that a subset of Defendants "sought to" cause another doctor to prescribe "outside the usual course of professional practice and without regard to medical necessity," *see id.* ¶ 162. These stray allegations do not come close to pleading that Defendants directed or caused particular patients to be prescribed Subsys for illegitimate reasons.

only to particular prescriptions written to particular patients for no valid medical reason. *See supra* at 22–23. As the government itself acknowledges, doctors can, and often do, have very good medical reasons for prescribing opioids like Subsys to treat pain conditions not specifically indicated on the medication's label. Of course, the government could have attempted to bring an off-label-marketing prosecution under federal misbranding laws. It chose not to do so, perhaps because of the First Amendment concerns cases of this type necessarily trigger,[18] or perhaps because violations of the misbranding laws through alleged off-label marketing cannot be prosecuted under RICO. Whatever the reason, the government made its choice and should not be permitted to back-door an off-label prosecution theory through an unprecedented and improper application of the CSA.

The Indictment also alleges in its paragraphs claiming "Illicit Distribution of Fentanyl," Indictment ¶¶ 76–92, that salespeople encouraged prescribers to titrate patients to higher doses of the medication, *id.* ¶¶ 84–85; and that Insys modified its distribution channel to avoid DEA scrutiny, *id.* ¶ 92. That conduct also has nothing to do with the CSA. Increasing a patient's Subsys dose to ensure the medication is effective is "not outside the usual practice of medicine"—in fact, the FDA-approved label advises doctors to titrate patients in this way. *See* Subsys Label (Jan. 2012) at 4–5 (§ 2.2: Dose Titration). And the distribution methods the government criticizes are common and perfectly lawful practice in the pharmaceutical industry. They certainly do not

[18] *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 576 (2011) (holding that [s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by . . . the First Amendment."); *Caronia*, 703 F.3d at 169 (holding that "the government cannot prosecute pharmaceutical manufacturers and their representatives . . . for speech promoting the lawful, off-label use of an FDA-approved drug"); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015) (holding that "under *Caronia*, the FDA may not bring such an action based on truthful promotional speech alone, consistent with the First Amendment").

establish that Defendants agreed among themselves or with others that particular patients should be prescribed Subsys without regard to medical need, or that the distribution channel caused a doctor to issue any particular prescription.[19]

2. The Indictment Does Not Plead An Agreement To Commit Honest-Services Fraud

The government's pattern of overcharging and adopting overbroad interpretations of criminal statutes is further exhibited in its pleading of honest-services fraud as a RICO predicate act.

The honest-services-fraud statute, 18 U.S.C. § 1346, requires the prosecution to prove that the defendant participated in a scheme to "deprive another of the intangible right of honest services." Although it can apply to private sector conduct, the honest-services-fraud statute has been used mainly to prosecute schemes involving the corruption of public officials. *See Skilling v. United States*, 561 U.S. 358, 399–402 (2010) (detailing the history of the statute); *United States v. Martin*, 228 F.3d 1, 17 (1st Cir. 2000) ("[T]he honest services doctrine has mainly been used to punish fraud against the citizenry perpetrated by government officials."). "[A]s one moves beyond core misconduct covered by the statute (*e.g.*, taking a bribe for a legislative vote)," serious constitutional concerns arise. *United States v. Urciuoli*, 513 F.3d 290, 294 (1st Cir. 2008). So that

[19] Specifically, the Indictment asserts that modifying Insys's distribution channel also allowed Defendants to "subvert reporting requirements of the DEA" and "escape the DEA's scrutiny of suspicious orders." ¶¶ 17, 92. But all the Indictment alleges, in terms of facts, is that Insys chose to replace one distributor for another that was "willing . . . to distribute a larger quantity" of Subsys—glossing over the fact that DEA regulations not only permit but *require* every distributor to design *its own* system for monitoring and reporting suspicious orders to the DEA. *Id.* ¶ 92; *see also* 21 C.F.R. § 1301.74(b) ("The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances."). The Indictment does not allege that Insys or any of its distributors lacked suspicious order monitoring systems, nor does it allege that any of those systems were somehow deficient or failed to report a suspicious order. In fact, the Indictment does not identify a single report or other piece of data that Insys or any of its distributors failed to provide to the DEA or any other way in which any DEA regulation was ever violated.

the statute provides the fair notice that the Constitution requires, application of the statute outside its "core" must be "cabin[ed] . . . lest it embrace every kind of legal or ethical abuse." *Id.*

It is well established under First Circuit law that, to plead an honest-services-fraud scheme, an indictment must do more than allege that the defendant offered or received an unlawful bribe or kickback. The indictment must also allege that the scheme's purpose involved a breach of fiduciary duty, *see United States v. Czubinski*, 106 F.3d 1069, 1077 (1st Cir. 1997), which was to be accomplished through materially deceptive acts, *see United States v. Sawyer*, 85 F.3d 713, 732 n.16 (1st Cir. 1996). Even accepting as true the Indictment's allegations that Defendants conspired to provide physicians benefits that violated the AKS, this is not sufficient to transform that conduct into an honest-services-fraud scheme. Because the Indictment fails to plead facts establishing that Defendants agreed that physicians should breach the fiduciary duties owed to their patients through material deception, the honest-services fraud RICO predicate is defective as a matter of law and should be dismissed.

a) The Indictment Fails To Allege That Defendants Agreed That Physicians Should Violate A Cognizable Fiduciary Duty Owed To Their Patients

For a scheme to violate the honest-services-fraud statute, the prosecution must prove that the scheme's purpose involved a fiduciary's violation of the duties owed to his principal. *United States v. Milovanovic*, 678 F.3d 713, 722 (9th Cir. 2012) (en banc) (holding that breach of fiduciary duty is "an element of honest services fraud"); *see also United States v. Urciuoli*, 613 F.3d 11, 17–18 (1st Cir. 2010) (recognizing that some "fiduciary" needs to violate his or her duty for an honest-services conviction to stand); *Czubinski*, 106 F.3d at 1077 (agreeing that there "must be a breach of a fiduciary duty" to sustain an honest-services-fraud prosecution); *United States v. Scanlon*, 753 F. Supp. 2d 23, 25 (D.D.C. 2010) (holding that, under *Skilling*, the charged scheme "must involve a breach of fiduciary duty"); *cf. Sawyer*, 85 F.3d at 725 (holding that not all "reprehensible

misconduct" constitutes a breach of fiduciary duty sufficient to establish honest-services fraud). Thus, even assuming that § 1346 can reach a private-sector relationship between a pharmaceutical company and a physician—an issue that the First Circuit has never addressed, either before or after *Skilling*—the government here is required to prove, and therefore is required to plead in the Indictment, that Defendants agreed that physicians, in exchange for bribes and kickbacks, should violate the fiduciary duties owed to their patients. The government has failed to do so.

The government describes its fiduciary duty theory in paragraph 8 of the Indictment, stating that practitioners "owe a fiduciary duty to their patients to refrain from accepting or agreeing to accept bribes and kickbacks in exchange for prescribing any drug." The Indictment does not cite any specific source for this alleged fiduciary duty, but the government's theory seems to be that the source is the AKS. Under this theory, the government could convict a pharmaceutical company employee of an honest-services-fraud conspiracy even without having any *evidence* that the employee agreed or intended that the physician should provide the patient with medically unnecessary or substandard care—such as where the employee offered the impermissible remuneration merely to influence the physician's preference between two drugs that the FDA considers therapeutically equivalent. Indeed, a pharmaceutical company employee could be convicted of conspiring to deprive a patient of his or her intangible rights even if he fully expected and intended that the physician would exercise "the degree of care and skill of the average qualified practitioner." *Palandjian v. Foster*, 446 Mass. 100, 104 (2006).

If the government's theory were right, it would be able, with a mere stroke of the pen, to convert essentially any violation of the federal AKS (which carries a ten-year statutory maximum) into a violation of § 1346 (which carries a 20-year statutory maximum and can be a RICO predicate). That cannot be the law. The AKS does not purport to create a fiduciary duty that a

physician owes to a patient, let alone a fiduciary duty that is breached any time the physician accepts "remuneration" that the statute prohibits. The government may believe that such a fiduciary duty exists in the penumbra of the statute, but the common thread that runs through the entire patchwork of case law addressing § 1346 is that the Constitution requires far more clarity than that. As the Supreme Court held in *Skilling*, the rule that "ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity . . . is especially appropriate in construing [§ 1346]." 561 U.S. at 410–11 (second alteration in original; internal quotation marks omitted). To ensure a meaningful distinction between a scheme that violates the AKS and one that constitutes honest-services fraud, the Court should hold that an agreement to bribe a physician implicates § 1346 only if the parties intend for the physician to sacrifice the quality of the patient's medical care in favor of the bribe. This would ensure the clarity and fair notice that the Constitution and the Supreme Court's case law requires, because it would limit § 1346 to agreements that the physician should violate his Hippocratic Oath, which is a "uniform national standard" of care that every physician owes to every patient. *Id.* at 411.

The Eighth Circuit's decision in *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996), is instructive. In *Jain*, the government alleged that the defendant, a psychologist, entered into a secret agreement with a hospital, whereby he would refer patients to the hospital in return for kickbacks received through an improper referral-fee arrangement. *Id.* at 441. There was no evidence that, in making these referrals, the psychologist failed to provide "quality psychological services" to his patients, that the hospital to which he referred patients was sub-standard, or that any patient was hospitalized unnecessarily. *Id.* Nor was there any evidence that the fee arrangement was part of an effort to defraud the defendant's patients, as § 1346 requires. *Id.* at 442. "True," the court held, the defendant "did not disclose the referral fees" to his patients. *Id.* But, the court explained, "a

fiduciary's nondisclosure must be material to constitute a criminal scheme to defraud." *Id.* The court explained further that an objective patient would not have considered the defendant's receipt of the referral fee material *unless* it "affect[ed] the quality or cost of his services . . . ." Because there was no evidence that it did, the court reversed the defendant's honest-services-fraud conviction as a matter of law.[20] *Id.*

The Indictment here does not come close to satisfying *Jain*. It does not allege that Defendants intended or agreed to deprive patients of quality medical care, or favor the bribe at the expense of the patient. *Hawkes v. Lackey*, 207 Mass. 424, 432 (1911) (defining a fiduciary breach as one in which "influence is exerted to obtain an advantage at the expense of the confiding party"). To the contrary, the Indictment acknowledges that Defendants received reports from the field that healthcare practitioners were "very pleased" and "impressed" with the pain relief Subsys provided their patients.[21] Absent allegations that Defendants agreed and intended to induce physicians to prescribe Subsys even where medically unnecessary, the government's attempt to convert a scheme that is *at most* a violation of the AKS into an honest-services-fraud conspiracy and RICO predicate cannot stand.[22]

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[20] The Seventh Circuit, in *United States v. Nayak*, 769 F.3d 978 (7th Cir. 2014), expressed disagreement with *Jain*. The *Nayak* panel, however, misunderstood *Jain*'s holding. It construed *Jain* as holding that the prosecution must prove "tangible harm," in addition to a scheme to deprive patients' of their intangible right to their physician's honest services. *Id.* at 981–82. That is neither *Jain*'s holding nor the point Defendants are making here. Rather, *Jain* stands for the proposition that a patient has not been deprived of her intangible rights at all where the alleged *quid pro quo* does not intend for the physician to compromise the quality of the patient's care.

[21] *See* Indictment ¶ 165 (quoting Email from Casey Hanoch to Michael Babich (Oct. 8, 2012, 1:56:43 a.m.). That same email also reported the complimentary comments from practitioners.

[22] As discussed, *infra*, the Indictment does not adequately allege an AKS violation either. *See infra* at 42–48.

b) The Indictment Fails To Allege That Defendants Agreed That Physicians Should Materially Deceive Their Patients

Even assuming that the AKS creates a fiduciary duty of physicians to their patients (and does so with the requisite constitutional clarity), and even assuming the Indictment pleads a conspiracy between Defendants and physicians to violate the AKS, the case law is clear that the government must also prove, and therefore plead in the Indictment, that Defendants agreed that the physicians should engage in deception of their patients. *See Sawyer*, 85 F.3d at 732 n.16 (1st Cir. 1996) (stating that "deceit . . . is inherent in the term 'fraud'"); *see also United States v. McDonough*, 727 F.3d 143, 163 (1st Cir. 2013) (holding that, on a charge of honest-services fraud, the government had the "burden of proving that the putative scheme to defraud involved a material falsehood"); *United States v. DeFries*, 129 F.3d 1293, 1306 (D.C. Cir. 1997) ("To constitute a deprivation of 'honest services,' the breach of fiduciary duty must have some element of dishonesty"). The government has failed on this score as well.

In *Sawyer*, the First Circuit rejected the government's theory that a deprivation of honest services "necessarily includes the deceit factor." 85 F.3d at 732 n.16. In other words, even if the government has proven a bribe or kickback in breach of a fiduciary duty, it must go further and prove that the defendant engaged in deception. Here, the Indictment does not allege that the Defendants agreed that their alleged physician co-conspirators should deceive or misrepresent to patients their financial relationship with Insys. To the contrary, and as the government presumably well knows, Insys affirmatively disclosed, through CMS's public, fully searchable "Open Payments" website, the speakers bureau fees and the in-kind benefits that it provided to physicians. Critically, there is no allegation in the Indictment that Defendants agreed to violate CMS's disclosure regulations; and there is no allegation that one of the conspiracy's elements was for physicians to lie to their patients about whether they had a financial relationship with Insys. *Cf.*

United States v. DeMizio, 2012 WL 1020045, at *14 (E.D.N.Y. March 26, 2012) (Gleeson, J.) (agreeing that a kickback scheme does not violate § 1346 if the putative victim was "aware of the [alleged] kickbacks"). This pleading deficiency is fatal to the honest-services-fraud predicate.

3. The Indictment Does Not Plead An Agreement To Commit Mail And Wire Fraud

In addition to its honest-services-fraud reference, Count 1 also lists simple mail and wire fraud as part of Defendants' alleged racketeering. But neither Count 1 nor the paragraphs that precede it clarify the scope of the fraud the members of the alleged RICO enterprise supposedly conspired to commit—giving rise to yet *another* impermissible failure of notice in the Indictment. *See supra* at 13–15. A defendant cannot "be expected to defend himself from a charge of conspiring to join a conspiracy to perpetrate a fraud if the indictment [does] not identify the *fraud* that was the ultimate underlying offense." *Yefsky*, 994 F.2d at 893 (emphasis added).

It *appears* that the alleged fraud concerns misstatements allegedly made to insurance companies through the Insys Reimbursement Center ("IRC"). *See, e.g.*, Indictment ¶¶ 18, 114, 116, 118, 119**.** If that is the case, it creates another pleading problem for the government, as the Indictment fails to explain how those alleged misstatements furthered the schemes the government seeks to ascribe to the alleged RICO enterprise: the "illicit" distribution of Subsys. The charging document contains no allegation that any employee of Insys misrepresented or omitted facts to obtain "preauthorization" for an *illegitimate* prescription lacking any medical purpose. Instead, all of the alleged misstatements appear to relate to instances in which a doctor had prescribed Subsys for an off-label indication. *See id.* ¶¶ 109, 111, 115, 118, 119. As explained above, off-label prescriptions cannot be equated to *illicit distribution*, and the decision of an insurer to deny coverage for an off-label prescription is not evidence, let alone proof, that the prescription was medically inappropriate.

The Indictment's failure to link the (apparent) alleged fraud to any common purpose is fatal. A criminal offense, even if properly pled, cannot qualify as part of the "pattern of racketeering activity" unless that offense relates to the *other* alleged predicate acts and to the purpose of the enterprise itself. That relatedness requirement mandates that *all* of an enterprise's purported predicate acts "have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise [be] interrelated by distinguishing characteristics and are not isolated events." *United States v. Cianci*, 378 F.3d 71, 88 (1st Cir. 2004) (quoting *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 240 (1989); *United States v. Marino*, 277 F.3d 11, 27 (1st Cir. 2002) ("It is clear that . . . Congress intended some connection between the defendant's predicate acts and the enterprise.")

Here, the Indictment does not even clarify what the supposed fraudulent scheme was. And it certainly does not explain how that supposed scheme fit within the larger pattern of alleged racketeering activity or related to the common purpose the government seeks to ascribe to the alleged enterprise.

4. The Indictment Does Not Plead An Agreement To Commit Commercial Bribery

The government strains the credibility of its RICO theory even further in Count 1 by citing a series of state commercial-bribery statutes as part of its racketeering allegations.[23] These laws—from Florida, Connecticut, New Hampshire, and Texas—cannot sustain the government's RICO charge either.

[23] With respect to the New Hampshire and Texas statutes, the charge fails even to specify which provision of the state's laws it intends to invoke. *See* Indictment ¶ 246. Fair notice certainly requires at least that much.

Research reveals that the states that enacted these commercial-bribery laws rarely (if ever) invoke them in their own courts. If a state has largely declined to bring prosecutions under one of its criminal laws, it is hardly the federal government's place to break new prosecutorial ground. As the court observed in *United States v. Ferber*, 966 F. Supp. 90, 105 (D. Mass. 1997), "the fact that the [state] has not charged anyone situated as was [the defendant] with a criminal gratuity violation suggests that the [state], at least at this point in time, does not view such conduct as a prosecutorial priority." Here, for two of the states in question—New Hampshire and Connecticut—we have been unable to identify *any* use of the states' commercial-bribery statutes in *any* criminal prosecution. And Texas and Florida have made only scant use of their analogous statutes. As *Ferber* observed, "[i]t is state, not federal, prosecutors who are charged with deciding the manner in which state criminal laws are to be enforced." *Id.* at 106. The government should not be permitted to use the federal RICO law to subvert that basic principle.[24]

That need for charging restraint is doubly true where it is uncertain whether the state law at issue even applies to the case being prosecuted. As *Ferber* explained, federal prosecutors "should avoid relying on obscure or strained interpretations of state law in order to commence a federal prosecution." *Id.* Similarly, in *United States v. Genova*, 333 F.3d 750, 759 (7th Cir. 2003), the court reversed a RICO conviction on the ground that no *state* decision existed to support the prosecution's interpretation of a state bribery statute, concluding that "it would deprive [the defendant] of fair warning to put that statute to such a novel use in order to secure his conviction for violating RICO."

[24] To the contrary, the United States Attorneys' Manual instructs that "RICO should be used to prosecute what are essentially violations of state law only if there is a *compelling reason* to do so." USAM 9-110.310 (emphasis added). No such reason exists here.

In this case, the uncertainty and ambiguity regarding the government's use of the various state laws is considerable. No authority indicates that these commercial-bribery laws were intended to apply to benefits conferred upon a *healthcare practitioner* providing medical care to a patient. To the contrary, in Connecticut, the pattern jury instructions indicate that its statute applies only to "any employee, agent or fiduciary" who owes a *financial* duty to another, such as a trustee or executor. *See* Conn. Gen. Stat. Ann. § 53a-160.[25] And we are unaware of any instance in which New Hampshire's statute—which likewise applies to "any employee, agent or fiduciary"—has been applied to a healthcare practitioner. N.H. Rev. Stat § 638:7(I).[26]

As for Florida, it is doubtful that its commercial-bribery statute may be constitutionally applied at all. In 1995, the Florida Supreme Court struck down, on vagueness and fair-notice grounds, a related statute that made it a crime for certain persons, including physicians, to *accept* a commercial bribe. *See Roque v. State*, 664 So. 2d 928, 929 (Fla. 1995) (striking down F.S.A. § 838.15). More specifically, *Roque* held that the phrase "common law duty" was far too vague a term to give fair notice in a criminal statute. Here, the government is invoking the defunct provision's sister statute, which instead criminalizes *offering* a bribe. Moreover, unlike the invalid text of Section 838.15, the statute that the government cites *does not even apply to physicians*. F.S.A. § 838.16(1). Yet in defining commercial bribery, the statute relied on by the government in this case explicitly incorporates by reference the very language from Section 838.15 that *Roque*

[25] *See also* Conn. Criminal Jury Instructions 4.1-5 (Rev. Dec 1, 2007), *also available at* https://jud.ct.gov/JI/Criminal/Criminal.pdf at 235.

[26] As noted, the Indictment fails to specify which of two subsections of the New Hampshire statute is alleged as the predicate. *See* Indictment ¶ 246. Subsection II applies to "person[s]" who "hold[] [themselves] out to the public as being engaged in the business of making disinterested selection, appraisal or criticism of goods [or] services"—a description that does not fairly encompass doctors providing medical care to patients. Again, we are aware of no case applying the statute to such a circumstance.

deemed constitutionally deficient. *See* F.S.A. § 838.16(1) (defining commercial bribery as "knowing that another is subject to a *duty described in s. 838.15(1)* and with intent to influence the other person to violate *that duty*" conferring, offering to confer, or agreeing to confer a benefit on the other) (emphasis added). Thus, it is "hard to see how section 838.16(1) could be considered constitutional if the language that it refers to was found deficient in *Roque*."[27]

Although the Texas statute *does* apply to physicians, *see* Tex. Penal Code § 32.43(a)(2)(C), it forbids only those benefits solicited or accepted "on agreement or understanding that the benefit will influence the conduct of the fiduciary in relation to the affairs of his beneficiary." *See id.* § 32.43(b). In this case, there is no allegation that Defendants conspired to pay bribes to "influence" doctors' conduct towards their patients in any negative way, to act contrary to their patients' best interests, or (more to the point) to prescribe them a medication they did not need. The Texas statute, like the others the government invokes, would appear to require that specific showing given its language and purpose. *See* N.H. Rev. Stat § 638:7 (applies to benefits "contrary to the best interests of the employer or principal"); Conn. Gen. Stat. Ann. § 53a-160 (similar).[28] As explained previously, the Indictment does not sufficiently allege particularized facts that any patient's medical care was substandard, deficient, or medically unnecessary.

If the state statutes were *not* so constrained, their provisions could theoretically extend to marketing and business-development practices common throughout the pharmaceutical industry

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[27] *See* Mark M. Dobson, *Criminal Law: 1996 Survey of Florida Law*, 21 Nova L. Rev. 101, 135 (1996 *see also* 2010 Nineteenth Statewide Grand Jury Report on Public Corruption, *available at* http://myfloridalegal.com/webfiles.nsf/WF/JFAO-8CLT9A/$file/19thSWGJInterimReport.pdf, at 34 ("In *Roque v. State*, the Florida Supreme Court held that Florida's commercial bribe receiving law under F.S. 838.15 was unconstitutionally vague. *Since commercial bribery under F.S. 838.16 refers to F.S. 838.15, it is most certainly unconstitutionally vague as well*.") (emphasis added).

[28] The Florida statute, even if it could withstand the holding in *Roque* (which it cannot), applies only where the defendant intended the person receiving the benefit to violate a legally defined duty. F.S.A. § 838.16(1).

and the economy as a whole. And that elastic interpretation, in turn, would raise serious questions about whether the statutes provide "ordinary people [with] fair notice of the conduct [they] punish[]" or are "so standardless that [they] invite[] arbitrary enforcement." *Johnson v. United States*, 135 S. Ct. 2551, 2556 (2015). Courts should "shun [a statutory] interpretation . . . that raises [such] serious constitutional doubts" where the language of the provision so naturally permits a more limited and reasonable interpretation. *Jennings v. Rodriguez*, 138 S. Ct. 830, 836 (2018).[29] That reluctance is particularly appropriate where federal prosecutors are pressing a novel interpretation of a state statute that has never been advanced by the state's own prosecutors or tested by its own courts.

5. The Indictment Does Not Plead An Agreement To Violate The Travel Act

Count 1's final attempt to force a square peg into the round hole of a RICO predicate act is pleading a "pattern of racketeering activity" by passing reference to the Travel Act. The Travel Act prohibits: "(1) interstate travel or the use of an interstate facility; (2) with the intent to promote, manage, establish, carry on, or facilitate an unlawful activity . . . and (3) performance or attempted performance of acts in furtherance of the unlawful activity." *United States v. Nishnianidze*, 342 F.3d 6, 15 (1st Cir. 2003) (internal quotation marks omitted). The government's single passing reference to the Travel Act is a tail-chasing tautology: it alleges that defendants "agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise," through

[29] A potentially vague statute provides even less notice where there is neither any recognizable pattern of enforcement nor any judicial decisions interpreting the state laws, as is the case here. *See United States v. Morosco*, 822 F.3d 1, 5 (1st Cir. 2016), cert. denied, 137 S. Ct. 251 (2016) (noting that in cases of vague drafting, "requisite fair warning can come from judicial decisions construing the law.").

"multiple acts" including under "Title 18, United States Code, § 1952 (interstate and foreign travel or transportation in aid of racketeering)." *See* Indictment ¶ 246(c).

"[V]ague allusions" to the Travel Act are not "sufficient to meet RICO's racketeering activity requirement." *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 n.8 (1st Cir. 1991); *see also United States v. Werme*, 939 F.2d 108, 112 n.1 (3d Cir. 1991) ("Absent further detail [beyond passing mention of the Travel Act] . . . an indictment . . . would not indicate which 'unlawful' activity the defendant conspired to promote through interstate activity."). And here Count 1 does not even identify the "unlawful activity" that purportedly serves as the basis for the Travel Act charge. Indictment ¶ 246; *see Nishnianidze*, 342 F.3d at 15 (Travel Act violation requires an intent to "promote, manage, establish, carry on, or facilitate an *unlawful activity*" and "performance or attempted performance of acts in furtherance of the *unlawful activity*"); *Bernstein v. Misk*, 948 F. Supp. 228, 236 n.2 (E.D.N.Y. 1997) (purported Travel Act violation could not serve as RICO predicate because no "unlawful activity" was identified to give defendants "adequate notice").

To the extent the government intended the *other* predicate offenses asserted in Count 1 to constitute the necessary "unlawful activity," that does not suffice because none of those offenses is adequately pled either. *See supra* at 21–38. Further, the government cannot double dip by charging the same conduct as one predicate offense *and* as a Travel Act violation in an attempt to establish a "pattern." *See Misk*, 948 F. Supp. at 236 n.2 (where a purported "unlawful activity" under the Travel Act is "repetitive of" a separate wire fraud predicate, it "should not be counted again to create a pattern"); *Mylan Laboratories, Inc. v. Akzo, N.V.*, 770 F. Supp. 1053, 1078 (D. Md. 1991) (holding that a single payment cannot constitute both a bribe and a Travel Act violation to form a "pattern").

II. Counts 2 And 3 Must Be Dismissed

Counts 2 and 3, which charge conspiracies to engage in Mail Fraud and Wire Fraud, respectively, also must be dismissed.[30]

Like Count 1, these charges provide none of the specificity that Rule 7(c) and the Constitution demand. *See supra* at 13–15. Unsupported by any particularized factual allegations, these counts do not permit "exact identification of what is being charged" as the alleged fraud. *See Neapolitan*, 791 F.2d at 501; *Yefsky*, 994 F.2d at 893. Nor do they allow the defense (or the Court) to discern what alleged conduct the grand jury had in mind when it passed on these fraud charges. *See Russell v. United States*, 369 U.S. 749, 770 (1962) ("To allow the prosecutor, or the court, to make a subsequent guess as to what was in the minds of the grand jury at the time they returned the indictment would deprive the defendant of a basic protection which the guaranty of the intervention of a grand jury was designed to secure. For a defendant could then be convicted on the basis of facts not found by, and perhaps not even presented to, the grand jury which indicted him."). Again, Counts 2 and 3 do incorporate by reference the Indictment's "Introduction." But that portion of the charging document does not sufficiently resolve these questions; quite the opposite, the lengthy Introduction, chock-full of speculation, bare assertions, and generalized opinions, indicates yet another fundamental flaw in these counts.

As noted above, the Introduction appears to allege two distinct fraud schemes: one that purportedly used bribes to deprive patients of the honest services of their physicians, and another that allegedly relied on misrepresentations to defraud insurance companies. From what we can

[30] In addition, to the extent that Counts 2 and 3 accuse defendants of "defraud[ing] patients of honest services," *see* Indictment ¶¶ 249, 251, Defendants also ask these counts be dismissed for the same reasons that the government failed to plead honest-services-fraud as a predicate act under RICO. *See supra* at 27–33.

tell, Counts 2 and 3 are attempting to "join[] in a single count" these two "distinct and separate offenses." *United States v. Newell*, 658 F.3d 1, 23 (1st Cir. 2011) (quoting *United States v. Canas*, 595 F.2d 73, 78 (1st Cir. 1979)). That is impermissible. Under the law, "[a] single agreement to commit several crimes constitutes one conspiracy," and "multiple agreements to commit separate crimes constitute multiple conspiracies." *United States v. Broce*, 488 U.S. 563, 570–71 (1989). Multiple conspiracies must be charged as separate crimes or else suffer dismissal.[31] *See* Fed. R. Crim. P. 12(b)(3)(B)(i).

The government could have attempted to charge *one* dual-purpose conspiracy—a single unlawful agreement to defraud both patients *and* insurers. *See, e.g.*, *Braverman v. United States*, 317 U.S. 49, 54 (1942). But to do so, it would have needed to allege that *all seven* Defendants (and the unnamed conspirators) agreed to use bribes to defraud patients *and* to make material misstatements to defraud insurers. The Indictment makes no such claim. To the contrary, the Introduction alleges, at most, that certain Defendants agreed to the supposed bribery scheme and a *separate* set of Defendants agreed to the alleged insurance-fraud scheme. *Compare* Indictment ¶¶ 15; 103–119 (alleging that a subset of Defendants perpetrated the insurance fraud scheme), *with* ¶¶ 121–241 (alleging that various combinations of Defendants sought to provide bribes for Subsys prescriptions). Aside from the conclusory charges in the Counts themselves, none of the

[31] The improper joining of distinct and separate offenses in a single count is known as "duplicity." *See United States v. Rigas*, 605 F.3d 194, 210 (3d Cir. 2010) (en banc) (stating that "'[d]uplicitous counts may conceal the specific charges, prevent the jury from deciding guilt or innocence with respect to a particular offense, exploit the risk of prejudicial evidentiary rulings, or endanger fair sentencing'") (quoting *United States v. Haddy*, 134 F.3d 542, 548 (3d Cir. 1998). As the court explained in *United States v. Newell*, "[t]he risks of serious unfairness presented by a duplicitous indictment are apparent. In conditions where jurors disagree among themselves as to just which offenses the evidence supports, the defendant may nevertheless wind up convicted because the jurors agree that the evidence showed that he committed *an* offense, even if it was ambiguous as to which one." 658 F.3d 1, 27 (1st Cir. 2011); *see also United States v. Valerio*, 48 F.3d 58, 63 (1st Cir. 1995); *United States v. Verrecchia*, 196 F.3d 294, 297 (1st Cir. 1999).

allegations even insinuate—much less allege—that *all seven* Defendants consummated a single agreement to commit the bribe and fraud schemes charged in Counts 2 and 3. *See Broce*, 488 U.S. at 570–71. And the Indictment certainly does not provide any confidence that the grand jury was properly instructed on (or actually approved) a pair of dual-purpose conspiracies.

III. Count 4 Must Be Dismissed

Count 4 attempts to plead a conspiracy to violate the AKS, 42 U.S.C. § 1320a–7b(b)(2), pursuant to 18 U.S.C. § 371. *See* Indictment ¶¶ 252–253. It fails to do so for a number of reasons.

A. Count 4's Overt Act Allegations Are Deficient

Like the charges that come before it, Count 4 does not contain the specificity Defendants require to prepare their defense or to make clear what conduct "the grand jury deemed adequate to support" the government's accusations. *See Tomasetta*, 429 F.2d at 979; *supra* at 13–15. Instead, in two cursory paragraphs, Count 4 simply recites certain portions of the relevant criminal statutes (without providing any supporting particulars) and fails altogether to mention one of § 371's core elements: the commission of an overt act in furtherance of the alleged conspiracy, let alone one that occurred in Massachusetts.

As with the other charges, the deficiencies of Count 4 cannot be cured by reference to other portions of the Indictment. *See supra* at 15, 40. The document's narrative Introduction nowhere specifies what alleged conduct the government presented, the grand jury endorsed, or the prosecution would seek to prove, as an overt act sufficient to satisfy § 371. *See United States v. Santa-Manzano*, 842 F.2d 1, 2 (1st Cir. 1988) (noting that the Fifth Amendment "assures the defendant that the government will try him on the charges *that the grand jury voted* [upon]") (emphasis added). Further, the charging document does not point to *any* offensive conduct that purportedly occurred in Massachusetts—something the government must prove to obtain a

conviction under § 371, or any other statute, in this Court. *See* Fed. R. Crim. P. 18; *United States v. Lanoue*, 137 F.3d 656, 661 (1st Cir. 1998) ("A defendant in a criminal case has a constitutional right to be tried in a proper venue."). That critical omission casts doubt on whether any conduct was passed on by the grand jury. It also seriously hampers Defendants' ability to respond to what will necessarily be a critical aspect of the government's case at trial—namely, proving venue in Massachusetts.

The Indictment does assert that unspecified "Sham Speaker Program events occurred at restaurants within the District of Massachusetts and elsewhere, and functioned as bribes in the form of free dinners with friends." *See* Indictment ¶ 65.b. But that vague description fails to identify the specific "events" paragraph 65.b purports to describe—leaving the defense at a loss to respond to the accusation that the alleged events were in fact "shams," that they involved "bribe[ry]," or that they occurred at all. The Indictment's other references to Massachusetts and "this district" are even more nebulous. *See, e.g.*, *id.* ¶ 245 (alleging that Defendants conspired to commit racketeering "within the District of Massachusetts and elsewhere"); *id.* ¶ 251 (alleging that Defendants conspired to commit wire fraud "within the District of Massachusetts and elsewhere"); *id.* ¶ 253 (alleging that Defendants conspired to violate the AKS "within the District of Massachusetts and elsewhere").

The Indictment's lack of specificity on this critical element seriously hampers Defendants' ability to litigate a critical issue at trial: whether proper venue exists in this District. It also casts serious doubt on whether any Massachusetts-based conduct was even passed on by the grand jury. This deficiency is by itself a reason for dismissal, at least absent a bill of particulars alleging facts

sufficient to establish constitutionally required venue.[32] *See United States v. Trie*, 21 F. Supp. 2d 7, 17 (D.D.C. 1998) (holding that if "failure to adequately allege the basis for venue" in an indictment is not addressed by a bill of particulars, a "trial court may dismiss an indictment for improper venue").

B. Count 4 Does Not Adequately Allege That Defendants Knowingly And Willfully Entered A Conspiracy To Violate The Anti-Kickback Statute

Count 4 also does not allege any fact sufficient to show an agreement to violate the AKS. The AKS is a specific-intent statute, 42 U.S.C. § 1320a–7b(b)—one that makes criminal only those violations that are "knowing and willful." *See United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989) (defining "willfully" to mean "to do something purposely, with the intent to violate the law, to do something purposely that the law forbids"); *see also* Jury Instructions, *United States v. W. Carl Reichel*, 15-CR-10324-DPW, Dkt. No. 244 at 6 (D. Mass. June 17, 2016); *Bryan v. United States*, 524 U.S. 184, 191–92 (1998). Thus, to properly plead a conspiracy to violate the statute, the government needed to allege that Defendants agreed to provide benefits that they *knew* the law forbade. The government has failed to carry this burden.

[32] Pleading specific facts sufficient to establish venue is not necessary to avoid dismissal. *See, e.g.*, *United States v. Honneus*, 508 F.2d 566, 570 (1st Cir. 1974); *see generally Wright & Miller* § 125 However, doing so is an important practice, *see* U.S. Attorneys' Manual 231 (citing *Hemphill v. United States*, 392 F.2d 45, 48 (8th Cir. 1968)), including because it may avoid the need for a bill of particulars. *See United States v. Hallock*, 941 F.2d 36, 40 (1st Cir. 1991) (noting that a bill of particulars may be granted "to give the accused details concerning the charges against him" and thereby "enable[e] him to prepare a defense" and "avoid surprise at trial."); *see generally* Wright & Miller § 130. Defendants have separately moved for a bill seeking those particulars in the event the Indictment survives this Motion. It should be noted, however, that "it is a settled rule that a bill of particulars cannot save an invalid indictment." *Russell v. United States*, 369 U.S. 749, 770 (1962). And Defendants reserve the right to seek dismissal should the government fail to provide particulars sufficient to show proper venue. *See, e.g.*, *United States v. King*, 259 F. Supp. 3d 1267, 1269 (W.D. Okla. 2014) (noting that the right to be tried in a proper venue "must be upheld prior to trial if it is to be enjoyed at all" (quoting *United States v. MacDonald*, 435 U.S. 850, 861 (1978)).

Take, for example, the Insys speakers bureau program. The Indictment asserts that this program was used to funnel improper payments to doctors in violation of the AKS. *See* Indictment ¶¶ 48–49, 65 (describing "Speaker Honoraria"). But, as the government knows, speakers bureaus are routinely employed by pharmaceutical companies to have expert practitioners disseminate information about medications to the healthcare community, particularly when a medication is new to the market. The AKS, together with its implementing regulations, make clear that running such programs, and paying the doctors who speak at them with honoraria, are inherently lawful activities. *See* 42 U.S.C. § 1320a–7b(b)(3)(E) (allowing for regulations to specify "payment practice[s]" to which the AKS "shall not apply"); 42 C.F.R. § 1001.952(d) (regulations defining "personal services . . . contracts" as one of the permissible "payment practice[s]").[33]

Recognizing these principles, in one recent case, a District of Massachusetts court granted summary judgment to defendants who were accused of conducting a sham speaker program in violation of the AKS. *U.S. ex rel. Booker v. Pfizer*, 188 F. Supp. 3d 122, 134 (D. Mass. 2016). There, Judge Woodlock cited the personal services exception to the AKS and then noted that the defendants executed their speaker programs under written contracts; engaged consultants to establish fair market value for honoraria; trained speakers on AKS compliance; and "otherwise established systems that purportedly protect against the speaker series turning into a kickback scheme." *Id.* The Court also considered it "unremarkable" and "expected" that a for-profit company calculated its return on investment from paying physicians affiliated with the programs. *Id.* Given that legal landscape, charging a conspiracy to violate the AKS by running a speakers bureau program requires the government to allege *not just* that Defendants agreed to compensate

[33] *United States v. Neufeld*, 908 F. Supp. 491, 498 (S.D. Ohio 1995 ("[S]afe harbor regulations [under the AKS] specify[] payment practices that would not be subject to either criminal or civil penalties.") (internal quotation omitted).

doctors for serving as speakers (something the law permits), or even that, as it turned out, certain improper payments occurred. Rather, the government must allege that Defendants *agreed* doctors should receive payments under circumstances that each Defendant *knew* would be illegal because, for example, those payments would fall outside the AKS "safe harbors".[34] *See United States v. Monserrate-Valentín*, 729 F.3d 31, 43 (1st Cir. 2013). "[T]he gist of the conspiracy offense remains the *agreement*, and it is therefore essential to examine what kind of agreement or understanding existed as to each defendant." *Id.* (quoting *United States v. Glenn*, 828 F.2d 855, 857 (1st Cir. 1987)) (emphasis added).

What is more, a defendant's "agreement" to join a conspiracy is "'not supplied by mere knowledge of an illegal activity, let alone by mere association with other conspirators or mere presence at the scene of the conspiratorial deeds.'" *Monserrate-Valentín*, 729 F.3d at 41 (quoting *United States v. Dellosantos*, 649 F.3d 109, 115 (1st Cir. 2011)). Here, the Indictment alleges that benefits were provided in violation of the AKS, with certain Defendants being (at most) aware that some of those benefits were provided. *See, e.g.*, Indictment ¶¶ 150, 185, 197. But the government has not adequately alleged which Defendants possessed the specific intent necessary to establish participation in the conspiracy or how that intent manifested in particularized facts connecting particular alleged bribes to particular healthcare practitioners and pharmacists. As a result, the allegations in the Indictment cannot sustain Count 4's conspiracy charge as to each Defendant.

[34] Remuneration merely to cultivate a business relationship does not violate the AKS. As Judge Woodlock explained in his jury instructions in *Reichel*, the AKS requires an intent to engage in a "quid pro quo ('this for that') transaction . . . in which a person pays for meals or gives speaker payments (the 'this') in exchange for the order or prescribing of [drugs] (the 'that')." *Reichel*, No. 1:15-cr-10324-DPW, Dkt. No. 244 at 5. Judge Woodlock specifically instructed the jury in that matter that a violation of the AKS does not occur "merely because [a company] sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more unspecified purchase or order decisions." *Id*.

C. The Indictment's Theory Of "Administrative Support As Bribes And Kickbacks" Fails

In addition to speaker program honoraria, the Indictment also relies on novel theories of remuneration, unsupported by either the text of the AKS or the caselaw construing it. For example, the government has alleged that the Defendants used "Area Business Liaisons" ("ABLs") and "Business Relations Manager" ("BRMs") to provide "administrative support . . . [as] bribe[s] and kickback[s]" by "assist[ing] the office staff of co-conspirator practitioners with filling out and faxing prior authorization paperwork and other documentation." Indictment ¶¶ 72, 154.[35] But no existing legal authority supports the proposition that assisting in the processing of paperwork related to the sale of Subsys could constitute improper remuneration under the AKS.

To the contrary, the government itself "consistently has distinguished between free items and services that are integrally related to the offering provider or supplier's services and those that are not." OIG Advisory Opinion 11-07 at 7 (citing 56 Fed. Reg. 35952, 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulation)); *see also U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 68 (D. Mass. 2011) (citing approvingly 56 Fed. Reg. 35978 for the proposition that a product or service that "is part of a package of services" does not implicate the AKS). Thus, as the government explained in a recent advisory opinion, a laboratory does not run afoul of the AKS when it provides a free computer to a physician, so long as the computer cannot be used for

[35] The government's deficient theory of the AKS is also evident in its allegation that the hiring of family and friends "compensated" practitioners for writing prescriptions. Indictment ¶ 71. The Indictment does not allege that any of these were not bona fide employment relationships or that any monetary compensation flowed to the practitioners. Since the AKS explicitly exempts bona fide employment relationships, 42 U.S.C. § 1320a-7b(b)(3)(B), it is not clear what "compensation" the government alleges was provided to the practitioners.

any purpose other than printing out test results or conducting other services integral to the laboratory's services. OIG Advisory Opinion 11-07 at 7.[36]

We acknowledge that the web of guidance documents and advisory opinions that exist in this field is complex and sometimes unclear. We also acknowledge that federal courts typically give no deference to agency interpretations of criminal statutes. *See United States v. Apel*, 134 S. Ct. 1144, 1151 (2014). But where, as in this case, on-point guidance does exist and that guidance is *contrary* to the theory under which the government seeks to bring a *criminal* prosecution, the government cannot credibly claim a defendant could (or even *should*) have known that conduct consistent with the guidance was "something . . . that law forbids." *See Bay State Ambulance*, 874 F.2d at 33.[37]

CONCLUSION

For the foregoing reasons, Counts 1 through 4 of the Indictment must be dismissed, pursuant to the Fifth and Sixth Amendments to the Constitution and Rules 7(c) and 12, for lack of specificity and failure to state an offense.

[36] *See also* OIG Advisory Opinion 00-10 at 7 ("Drug manufacturers often offer free assistance to physicians and other providers by serving as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products. Since these services have no independent value to providers apart from the products, they are properly considered part of the products purchased and their cost is already included in the products' price. *Therefore, standing alone, these services have no substantial independent value and do not implicate the Federal anti-kickback statute*.") (emphasis added).

[37] To the extent that the AKS is ambiguous as to whether it encompasses the provision of goods or services integral to the product being offered, as previously described, the rule of lenity would also apply. *See Rewis v. United States*, 401 U.S. 808, 812 (1971) ("[A]mbiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.").

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document will be served on counsel for the Government through the ECF system.

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