

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CRIMINAL ACTION NO. 14-10363-RGS

UNITED STATES OF AMERICA

v.

BARRY J. CADDEN, et al.

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTIONS TO DISMISS
COUNTS 1-2 AND 4-94 OF THE INDICTMENT
BASED ON THE USE OF A PRIVATE INDUSTRY CODE
AS A STANDARD OF CRIMINAL CONDUCT

May 3, 2016

STEARNS, D.J.

The defendants listed below seek to dismiss the Racketeer Influenced and Corrupt Organizations Act (RICO) Counts 1-2, and Counts 4-94 of the indictment, and more specifically, the 78 incorporated alleged racketeering acts, of which 25 involve second-degree murder.¹ In brief, the indictment

¹ This motion is filed by defendants Barry Cadden, Glenn Chin, Gene Svirskiy, Christopher Leary, Joseph Evanosky, Scott Connolly, Sharon Carter, and Alla Stepanets. Only Cadden and Chin are named in the murder predicate acts. Robert Ronzio and Michelle Thomas join the motion, but neither is named in the challenged counts. Defendants have filed a second motion (Dkt. #404) challenging the RICO counts principally on sufficiency grounds. The court will address the second motion, to the extent that it does

involves the now defunct New England Compounding Pharmacy, Inc. (NECC), and the allegedly contaminated drugs that it compounded and shipped nationwide. Charged in the indictment are twenty-five patient deaths in Michigan, Indiana, Tennessee, Maryland, Virginia, and North Carolina. These twenty-five patients died after being administered NECC-compounded doses of non-sterile methylprednisolone acetate (MPA), a steroid used to treat pain from swollen joints. More than 800 additional patients are alleged to have suffered complications of varying degrees of severity after taking the same drug. Defendant Barry Cadden, a licensed pharmacist, served as NECC's President. Defendant Glenn Chinn, also a licensed pharmacist, oversaw NECC's "Clean Rooms." Defendants Gene Svirskiy, Christopher Leary, and Joseph Evanovsky were licensed pharmacists who worked in the Clean Rooms. Defendant Alla Stepanets was employed as a pharmacist who, among other jobs, worked in the packing area checking orders prior to shipment. Defendant Sharon Carter served as NECC's Director of Operations, while defendant Scott Connolly performed

not overlap with the instant motion, by way of a separate memorandum and order.

the duties of a pharmacy technician.² Medical Sales Management, Inc. (MSM), a corporate alter-ego of NECC, served as NECC's sales arm.

An indictment meets the test of legal sufficiency if it is handed up by a properly constituted grand jury and if it adequately "sketches out the elements of the crime and the nature of the charge so that the defendant can prepare a defense and plead double jeopardy in any future prosecution for the same offense." *United States v. Guerrier*, 669 F.3d 1, 3 (1st Cir. 2011). To successfully plead a RICO violation, an indictment must allege the "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 496 (1985).³ An enterprise may be a legal entity (for example, a corporation, as is the case here) or a group of individuals associated in fact. *United States v. Turkette*, 452 U.S. 576, 580-581 (1981). An often overlooked aspect of RICO is the requirement that "the 'person' alleged to be engaged in racketeering activity . . . must be [an entity] distinct from the 'enterprise.'" *Odishelidze v. Aetna Life & Cas. Co.*, 853 F.2d 21, 23 (1st Cir. 1988) (per curiam). Engaging in the

² Connolly had been licensed as a pharmacist, but lost his license as the result of an earlier disciplinary action.

³ The substantive law underlying criminal and civil RICO violations is identical (except as to the penalties). *United States v. Shifman*, 124 F.3d 31, 35 n.1 (1st Cir. 1997).

enterprise's affairs requires "participat[ion] in the operation or management of the enterprise itself." *Reeves v. Ernst. & Young*, 507 U.S. 170, 185 (1993). Although the word "participate" makes clear that liability is not limited to those with primary responsibility for the enterprise's affairs, "some part in directing those affairs" is required. *United States v. Cummings*, 395 F.3d 392, 397 (7th Cir. 2005), quoting *Reeves*, 507 U.S. at 179. It should also be noted that "one may 'take part in' the conduct of an enterprise by knowingly implementing decisions, as well as by making them." *United States v. Oreto*, 37 F.3d 739, 750 (1st Cir. 1994).

A "pattern of racketeering activity" is defined as the commission of "at least two" related racketeering acts over a span of time.⁴ *See Schultz v. Rhode Island Hosp. Trust Nat'l Bank, N.A.*, 94 F.3d 721, 731 (1st Cir. 1996).⁵ To demonstrate relatedness, the predicate acts must "have the same or similar purposes, results, participants, victims, or methods of commission, or

⁴ Predicate acts (as listed in the statute) must be pled with particularity, *Ahmed v. Rosenblatt*, 118 F.3d 886, 889 (1st Cir. 1997), and must be more than a "cause in fact" of a plaintiff's injury; they must be the proximate cause. *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 266 n.12 (1992).

⁵ To prove a RICO conspiracy, the government need not prove the commission of two predicate offenses, only an agreement that the offenses be committed. *Shifman*, 124 F.3d at 38 ("The fourth element of the RICO conspiracy is met if the defendant agrees to commit or actually commits two or more acts of racketeering activity.").

otherwise be interrelated by distinguishing characteristics and not be isolated events.” *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 44 (1st Cir. 1991). There must also be evidence of “continuity” sufficient to show that the predicate acts constituted a “pattern” – “a closed period of repeated conduct” – amounting to a threat of continued criminal activity or one that is “a regular way of conducting . . . the RICO enterprise.” *H.J., Inc. v. N.W. Bell Tel. Co.*, 492 U.S. 229, 243 (1989).

In essence, Counts 1-2 of the indictment (the RICO counts) allege that defendants Cadden, Chin, Svirskiy, Leary, Evanovsky, and Connolly conducted the affairs of NECC and MSM through a pattern of racketeering activity to obtain money and property by fraudulent pretenses, namely by falsely representing NECC’s compounded drugs to be in compliance with the United States Pharmacopeia (USP) standards for sterile compounding. It is on this allegation that the instant issue is joined. Citing the “pervasive role” of the USP in the indictment, defendants contend that Congress has in effect “criminalized” the USP, and in so doing, has improperly delegated an essential legislative function to a private trade association. Defs.’ Mem., Dkt. #402 at 4.

A bit of background is necessary. The USP standards are formulated and published by a Council of Experts chosen by the United States

Pharmacopeia Convention (USPC), a nonprofit organization that owns the copyright to the USP compendium of drug information. The USPC was founded in 1820 by doctors “who recognized an essential need for a national lexicon of drug names and formulas in the United States.” <http://www.usp.org/about-usp> (last visited 4/29/2016). The Convention is composed of volunteer members. A Board of Trustees oversees the staff of employees and volunteers who assemble and publish the USP and related materials. Pharmacy Compounding Chapter 797 of the USP (on which the indictment principally draws) was promulgated by the USPC in its official version in 2008. Defs.’ Mem., Dkt. #402 at 4 n.6.

The specific “delegations” to which defendants object appear in the federal Food, Drug, and Cosmetic Act (FDCA), principally in 21 U.S.C. §§ 351, 352. The FDCA in its Definitions preamble, at § 321(j), states that “[t]he term ‘official compendium’ means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.” In § 351(b), Congress defined a drug as adulterated

[i]f it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever

tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

In FDCA § 352, Congress prohibited the misbranding of drugs. To effectuate the prohibition, Congress required that drugs be marketed under an “established” name (or designated ingredient). *Id.* at (e)(1).

(3) As used in subparagraph (1), the term “established name”, with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 358 of this title, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States

Pharmacopeia and in the Homœopathic Pharmacopœia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homœopathic drug, in which case the official title used in the Homœopathic Pharmacopœia shall apply.

Id. at (e)(3).

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States, it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States, and not those of the United States Pharmacopœia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.⁶

Id. at (g).

Doctrinally, defendants' improper delegation argument rests on *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). *Schechter* was decided at the apex of President Franklin Roosevelt's struggle with the Supreme Court over the powers of the agencies created to implement the New Deal, particularly the National Recovery Administration (NRA) and the

⁶ Defendants also point to § 321(g)(1), which defines the term "drugs" to mean those listed in the USP; and § 358, which directs the Secretary to refer to the USP in determining the official names of drugs.

Agricultural Adjustment Administration (AAA). The battle was first joined in *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), a case involving a Presidential prohibition of trade in petroleum goods in quantities in excess of state quotas imposed under the National Industrial Recovery Act of 1933 (NIRA). Chief Justice Hughes, writing for a majority of the Court, held that Congress had unconstitutionally (and outrageously, in the eyes of the court) empowered the President to issue decrees without any “criterion to govern the President’s course. . . . So far as this section [of the NIRA] is concerned, it gives to the President an unlimited authority to determine the policy and to lay down the prohibition, or not to lay it down, as he may see fit.” *Panama Refining*, 293 U.S. at 415.

In the wake of *Panama*, “[t]he stage was now set for an even more direct confrontation [in *Schechter*] over separation of powers.” Peter C. Hoffer, William James H. Hoffer & N.E.H. Hulle, *The Federal Courts: An Essential History* 293 (2016). Ostensibly a dispute over the prosecution of two brothers accused of the intrastate sale of “sickly” kosher chickens, the stakes in *Schechter* were much higher, as they implicated the NIRA “fair competition” codes formulated by private trade and industrial groups.⁷ A

⁷ As Hoffer, et al. observe, in implementing the NIRA, “[t]he code makers used the Depression crisis as an opportunity to impose administratively what the Fuller, White, and Taft Courts had knocked down:

now unanimous Court, again led by Chief Justice Hughes, gutted the NIRA by annulling the power that Congress had granted the President to give the codes the force of law.

Responding to the government's argument that the codes simply established "rules of competition deemed fair for each industry . . . by the persons most vitally concerned and most familiar with its problems," the Chief Justice acknowledged that it might be acceptable for Congress to look to the assistance of a private group in determining local customs or defining matters of a technical nature such as "the standard height of drawbars." *Schechter*, 295 U.S. 537.

But would it be seriously contended that Congress could delegate its legislative authority to trade or industrial associations or groups so as to empower them to enact the laws they deem wise and beneficent for the rehabilitation and expansion of their trade or industries? . . . The answer is obvious. Such a delegation of legislative power is unknown to our law, and is utterly inconsistent with the constitutional prerogatives and duties of Congress. The question, then, turns upon the authority which section 3 of the Recovery Act vests in the President to approve or prescribe. If the codes have standing as penal statutes, this must be due to the effect of the executive action. But Congress cannot delegate legislative power to the President to exercise an unfettered discretion to make whatever laws he thinks may be needed or advisable for the rehabilitation and expansion of trade or industry.

minimum wage, maximum hours, no child labor, no yellow-dog contracts, and guaranteed collective bargaining." *The Federal Courts, supra* at 293.

Id. at 537-538. Chief Justice Hughes held that this blank-check delegation of legislative authority to the President violated the separation of powers. Justices Cardozo and Stone in a concurring opinion went further (at least rhetorically) by describing the role given by the NIRA to private associations to recommend codes of fair conduct to the President as “delegation running riot.” *Id.* at 553.⁸

While lauding *Schechter* for “[striking] down a similar code [to the USP] drafted by a private industry association,” Defs.’ Mem., Dkt. #402 at 7,

⁸ Ultimately, the case turned on a since abandoned binary distinction between direct effects on interstate commerce (which Congress could regulate) and indirect effects (which it could not), leading the Court to base *Schechter’s* constitutional underpinning on the Tenth Amendment with its reservation of undelegated powers to the States. Unspoken, but in the background, was the abdication of the Reichstag in transferring its powers to Adolph Hitler and the menacing dictatorship that formed in its wake. *Schechter* presaged a series of decisions striking down one New Deal project after another on Tenth Amendment grounds ranging from the Agricultural Adjustment Act to the Municipal Bankruptcy Act. Pushback, however, came. After Roosevelt’s runaway reelection in 1936, he took on the Supreme Court, proposing among other measures, to name a new Justice for every sitting Justice over age seventy who refused to retire. In *West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937), the Court beat a tactical retreat. In a 5-4 decision authored by Chief Justice Hughes, the Court upheld a Washington State minimum wage law, signaling a cease fire in the struggle over executive powers and paving the way to the Court’s approval of the National Labor Relations Act and the Social Security tax, among other of Roosevelt’s reformation projects.

defendants concede (as they must) that “Supreme Court precedent finding unlawful delegation is rare.” *Id.* at 8. This is, if anything, an understatement – since the *Schechter* era, there is no Supreme Court case that annuls legislation under the invalid delegation doctrine. Nonetheless, as one legal compendium observes, “[t]he concept of invalid delegation of legislative power is phoenixlike in its appearance in American judicial history, burning fiercely from time to time, turning to ash, then reviving.” *The Oxford Companion to the Supreme Court of the United States* 257 (Kermit L. Hall ed. 2005).

Having thought to be dead after *Yakus v. United States*, 321 U.S. 414 (1944) (which permitted the Office of Price Administration, under the direction of a Price Administrator appointed by the President, to set a comprehensive scheme of regulations fixing maximum prices of commodities and rents to effectuate the Emergency Price Control Act), the invalid delegation doctrine reemerged in *Morrison v. Olson*, 487 U.S. 654 (1988), in a challenge to the appointment of a special prosecutor in the Iran-Contra affair. It rose up again in *Mistretta v. United States*, 488 U.S. 361 (1989), a seminal case involving the constitutionality of the creation of the United States Sentencing Commission. In *Mistretta*, the Court acknowledged that

[t]he nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of Government. The Constitution provides that “[a]ll legislative Powers herein granted shall be vested in a Congress of the United States,” U.S. Const., Art. I, § I, and we long have insisted that “the integrity and maintenance of the system of government ordained by the Constitution” mandate that Congress generally cannot delegate its legislative power to another Branch.

Id. at 371-372, quoting *Field v. Clark*, 143 U.S. 649, 692 (1892). It then reached back to a passage in a 1928 decision of Chief Justice Taft that is “now enshrined in our jurisprudence”:

“In determining what [Congress] may do in seeking assistance from another branch, the extent and character of that assistance must be fixed according to common sense and the inherent necessities of the government co-ordination.” *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406 (1928). So long as Congress “shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power.” *Id.* at 409.

Mistretta, 488 U.S. at 372. In upholding Congress’s action, the Court made the apt observation “that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power *under broad general directives.*” *Id.* (emphasis added).

This is a theme that Justice Scalia echoed in *Whitman v. American Trucking Assocs., Inc.*, 531 U.S. 457 (2001).

In the history of the Court we have found the requisite “intelligible principle” lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring “fair competition.” See *Panama Refining Co. v. Ryan*, 293 U. S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U. S. 495 (1935). We have, on the other hand, upheld the validity of § 11(b)(2) of the Public Utility Holding Company Act of 1935, 49 Stat. 821, which gave the Securities and Exchange Commission authority to modify the structure of holding company systems so as to ensure that they are not “unduly or unnecessarily complicate[d]” and do not “unfairly or inequitably distribute voting power among security holders.” *American Power & Light Co. v. SEC*, 329 U. S. 90, 104 (1946). We have approved the wartime conferral of agency power to fix the prices of commodities at a level that “will be generally fair and equitable and will effectuate the [in some respects conflicting] purposes of th[e] Act.” *Yakus v. United States*, 321 U. S. 414, 420, 423-426 (1944). And we have found an “intelligible principle” in various statutes authorizing regulation in the “public interest.” See, e. g., *National Broadcasting Co. v. United States*, 319 U. S. 190, 225-226 (1943) (Federal Communications Commission’s power to regulate airwaves); *New York Central Securities Corp. v. United States*, 287 U. S. 12, 24-25 (1932) (Interstate Commerce Commission’s power to approve railroad consolidations). In short, we have “almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or apply the law.”

Id. at 474-475 (citation omitted).

Recognizing the quagginess of the ground on which they have staked their position, defendants offer an appropriately couched and narrow argument. The argument has two components. The first relies on the fact that while in *Schechter*, the impermissible delegation of legislative power

was to the President, the Court focused its concern on the power the NIRA bestowed on private trade associations to formulate and enforce national economic policy. The second component is one of the defendants' own invention, although equally worthy of consideration. Namely, defendants posit a proposed rule that when Congress goes beyond a delegation of authority to a federal agency by allowing a private organization to define prohibited conduct, "it must be balanced by [an adequate degree of] government oversight . . . [Here] [t]he government has strayed beyond the confines of Article I in seeking to criminalize the copyrighted standards of a private organization with no government direction or control." Defs.' Mem., Dkt. #402 at 8.

Refining the argument, defendants note that in the instances where Congress has delegated legislative authority in a criminal context, it has done so only after laying out directives, as in *Mistretta* to the United States Sentencing Commission, or in *Touby v. United States*, 500 U.S. 160 (1991), to the Attorney General in granting her the authority to temporarily designate scheduled substances under the Controlled Substances Act.⁹ The

⁹ It might also be argued that the "intelligible principle" has more bite in instances involving the delegation of the power to promulgate standards enforced by penal sanctions. See Laurence H. Tribe, *American Constitutional Law* 984 n.22 (3d ed. 2000) (citing *Touby*).

Court's reasoning in *Touby* merits repeating at length as it appears to have the most bearing on this case.

Petitioners suggest, however, that something more than an “intelligible principle” is required when Congress authorizes another Branch to promulgate regulations that contemplate criminal sanctions. They contend that regulations of this sort pose a heightened risk to individual liberty and that Congress must therefore provide more specific guidance. Our cases are not entirely clear as to whether more specific guidance is in fact required. . . . We need not resolve the issue today. We conclude that § 201(h) passes muster even if greater congressional specificity is required in the criminal context.

Although it features fewer procedural requirements than the permanent scheduling statute, § 201(h) meaningfully constrains the Attorney General's discretion to define criminal conduct. To schedule a drug temporarily, the Attorney General must find that doing so is “necessary to avoid an imminent hazard to the public safety.” § 201(h)(1). In making this determination, he is “required to consider” three factors: the drug's “history and current pattern of abuse”; “[t]he scope, duration, and significance of abuse”; and “[w]hat, if any, risk there is to the public health.” §§ 201(c)(4)-(6), 201(h)(3). Included within these factors are three other factors on which the statute places a special emphasis: “actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.” § 201(h)(3). The Attorney General also must publish 30-day notice of the proposed scheduling in the Federal Register, transmit notice to the Secretary of HHS, and “take into consideration any comments submitted by the Secretary in response.” §§ 201(h)(1), 201(h)(4).

In addition to satisfying the numerous requirements of § 201(h), the Attorney General must satisfy the requirements of § 202(b).

This section identifies the criteria for adding a substance to each of the five schedules.

...

It is clear that in §§ 201(h) and 202(b) Congress has placed multiple specific restrictions on the Attorney General's discretion to define criminal conduct. These restrictions satisfy the constitutional requirements of the nondelegation doctrine.

Id. at 165-167.

By contrast with the tight restrictions placed on the Attorney General's exercise of penal discretion in *Touby*, defendants point out (accurately) that the references to the USP in the FDCA are "patchy" and unsystematic, that no guidance is provided directly by Congress (or indirectly through the Food and Drug Administration (FDA)) to the USP's Expert Committees, that the FDA has no discretion to accept or reject the revisions made in the USP by the USPC, and that the FDA has no oversight authority over the USPC, only permission from Congress to "cooperate" with it in the making of revisions to the USP. *See* 21 U.S.C. § 377. *Compare* *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381 (1940). In sum, defendants insist that the virtual absence of an "intelligible principle" renders any attempt by the government

to deploy the USP as defining sanctionable conduct under the criminal laws unavailing.¹⁰

¹⁰ The court agrees with much of defendants' reasoning to this point. It gives less weight or credence to the three additional arguments defendants advance. Briefly, defendants argue that because the FDA has sent out confusing signals as to its authority to regulate compounding pharmacies, and until at least 1992, left regulatory matters "entirely" to the States, they were deprived of notice that their conduct might result in a federal prosecution. See Defs.' Mem., Dkt. #402 at 18. In a similar vein, they argue that because the Chapter 797 UPS standards are "expansive, confusing, and often [internally] conflicting," they had no fair notice of their potential penal application, and are therefore entitled to the benefit of the "rule of lenity." *Id.* at 18-19, 21. Defendants' third argument conflates principles of arbitrary prosecution and selective prosecution. An arbitrary prosecution is one based on an exercise of personal discretion without reference to rules or standards, usually made in bad faith. Selective prosecution occurs when the enforcement of a criminal law is targeted at a particular class of persons for discriminatory reasons. See *United States v. Armstrong*, 517 U.S. 456, 464-465 (1966). Defendants claim on the one hand that they are the victims of the government's "plucking" of criminal charges from a vague and shapeless private industry standard. Defs.' Mem., Dkt. #402 at 22. On the other, they present themselves as the victims of a "rush to judgment" fueled by public criticism leveled at the very state and federal regulators who have now teamed up to prosecute them (as opposed to any of those responsible for at least eleven other poisonings caused by contaminated compounded drugs). *Id.* at 23. As to the first argument, the court is aware of no constitutional right to be prosecuted by a state as opposed to the federal government. The second argument and the arbitrary prosecution claim are rendered irrelevant by the court's agreement that the government cannot prosecute violations of USP Chapter 797 as crimes per se. Finally, "[if] the selection is not otherwise discriminatory, it would be appropriate for the [authorities] to pick out the major violator of a law to make an example 'in the expectation that general compliance will follow and that further prosecutions will be unnecessary.'" *Commonwealth v. Franklin Fruit Co.*, 388 Mass. 228, 233 (1983). See also *Oyler v. Boles*, 368 U.S. 448, 456 (1962).

To the extent that defendants contend that the government should be estopped from making any argument to the jury that the USP has the force of law, or that violations of its standards constitute criminal offenses, the court agrees. The government for its part forswears any intent to advance either argument. See Gov't.'s Mem., Dkt. #457 at 7-8 (“[T]he defendants are not charged with violating the USP (or Massachusetts pharmacy regulations), but rather are charged with perpetrating a scheme to defraud customers based on misrepresenting NECC’s compliance with the USP”). So understood, I agree with the government that the indictment passes muster. As the government aptly notes, “fraud schemes involving misrepresentations of compliance with state laws or regulations are not novel or uncommon.” *Id.* at 6.¹¹ Nor, as best as the court can determine, is there any constitutional prohibition against Congress doing what it did here by looking to best practices in the compounding industry (as distilled in the USP) for assistance in “defining matters of a technical nature,” as Chief Justice Hughes suggested in *Shechter*. This is not the only area in which Congress has looked to a private entity for outside help. As one example, many of the regulations enforced under the Occupational Safety and Health

¹¹ The cases cited by the government fully support this proposition, in particular *United States v. Paccione*, 949 F.2d 1183, 1188-1190 (2d Cir. 1991).

Act (OSH Act), 29 U.S.C. § 651 et seq., are based on industry-formulated standards. *See Associated Builders and Contractors Florida E. Coast Chapter v. Miami-Dade Cty.*, 594 F.3d 1321, 1325 (11th Cir. 2010) (upholding against an improper delegation challenge the directive in OSH Act § 655(a), that the Secretary of Labor adopt workplace safety standards that are in accordance with the “national consensus standard”). As the Eleventh Circuit observed in *Associated Builders*, “the physical impossibility of requiring OSHA independently to set safety standards for every industry job classification and industrial substance in the country adequately explains and justifies Congress’s decision to allow the Secretary to adopt the fruits of private efforts as governmental standards.” *Id.* at 1325, quoting *Towne Constr. Co. v. Occupational Safety & Health Review Comm’n*, 847 F.2d 1187, 1189 (6th Cir. 1988). *See also Associated Builders & Contractors, Inc. v. Brock*, 862 F.2d 63, 68-69 (3d Cir. 1988) (upholding against an improper delegation challenge OSHA’s reliance on chemical hazard standards formulated by the American Conference of Governmental Industry Hygienists).

There remains a practical problem, which is not insurmountable, namely, that the indictment can be read (as defendants maintain) to imply the contrary. As the indictment is structured, the USP plays a dominant role.

The standards merit their own chapter in the indictment and their description consumes sixteen numbered paragraphs. To a lay reader, the elaboration of the USP standards in the indictment strongly suggests that the criminal acts of which the defendants are accused are their multiple alleged failures to comply with the USP. For example, in paragraphs 20 and 21, the reader is warned that the USP standards “were meant to prevent harm, including death, to patients that could result from non-sterility of drugs” and that “[h]igh-risk compounding pose[s] the greatest threat to patients” The contents of the relevant USP-797 standards (set out in paragraphs 22 through 32), are realleged and incorporated into Counts 1-2 and Counts 4-94. In paragraph 36 it is alleged that “NECC’s production of purportedly sterile drugs by the pharmacists and technicians in Clean Rooms 1 and 2 failed to comply with the standards of the USP [and the related state regulations] in several ways” Each of the alleged departures from the USP is then set out in sub-paragraphs lettered from (a) to (g), in several instances incorporating the penal charging term, “in violation of USP-797. This pattern is repeated in paragraph 37, which details NECC’s substandard cleaning and disinfecting practices, alleging that defendants ignored thirty-seven “action-level sampling hits” without conducting a re-evaluation of their practices and procedures, or undertaking an investigation into the

cause of the contamination, or consulting with experts regarding the source of mold in Clean Room 1, all “as required by USP-797.”¹²

As I indicated, the potential for prejudice inherent in the structure of indictment with its heavy focus on the USP is not insurmountable. The court’s solution is twofold. First, as is its practice in the case of “speaking” indictments, the court will not have the indictment read to the jurors, nor will the jury be given a copy for its perusal during their deliberations. Second, the court will instruct the jury in emphatic terms that the USP and the associated state regulations do not define crimes or their elements. Rather, the failure (if proven) of defendants to comply with the USP may only be considered (with appropriate and admissible expert guidance) on the issues of intentional misrepresentation, causation, and recklessness (insofar as the allegations of second degree murder are concerned).¹³

ORDER

¹² References to the USP-797 requirements also appear in the description of the racketeering acts set out in paragraphs 42, 43, 45, 47, 49, 51, 53, 64, 67, and 68, in the description of the manner and means of the alleged RICO conspiracy in paragraph 74, and in the description of the mail fraud scheme in paragraph 111.

¹³ The element of malice aforethought necessary for the proof of second degree murder may be shown by proof of an act undertaken with callous and wanton disregard for human life.

The motion is DENIED as to its substance. The court will, however, instruct the jury and deal with other jury issues in the manner explained in this decision.

SO ORDERED.

s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE