

## **RICO Indictment of NECC Executives for Acts of Second-Degree Murder**

January 26, 2015

### An Unprecedented Approach to Regulatory Violations

In December 2014, the United States Attorney for the District of Massachusetts obtained a sweeping indictment that charges business executives of the New England Compounding Center (“NECC”) with 25 acts of second-degree murder as predicate offenses under the Racketeer Influenced and Corrupt Organizations (“RICO”) Act.<sup>1</sup> The Government’s decision to pursue a RICO indictment for deaths allegedly resulting from regulatory violations is a marked departure from past practice. Query whether this case is a stark anomaly or a new approach in cases where regulatory violations allegedly resulted in death or extreme patient injury.

### 131-Count Indictment Charges Second-Degree Murder Based on NECC’s Allegedly Unsafe, Unsanitary and Unlawful Production Practices

In September 2012, the U.S. Centers for Disease Control and the Food and Drug Administration began to investigate a nationwide outbreak of fungal meningitis.<sup>2</sup> The agencies traced the outbreak to contaminated vials of preservative-free methylprednisolone acetate (MPA) manufactured by NECC, a compounding pharmacy located in Framingham, Massachusetts.<sup>3</sup> According to the CDC, 751 individuals in 20 different states suffered from fungal infections after receiving injections of NECC’s MPA.<sup>4</sup> Those injections allegedly caused the death of 64 patients in 9 states.<sup>5</sup>

A little more than two years later, on December 17, 2014, a federal grand jury in the District of Massachusetts charged 14 individuals associated with NECC with a host of crimes related to the outbreak, including racketeering, conspiracy to defraud the Government, mail and wire fraud, criminal contempt, and violations of the Food, Drug and Cosmetics Act, such as introduction of adulterated and misbranded drugs into interstate commerce.<sup>6</sup> Most seriously, the indictment charges NECC’s owner and head pharmacist, Barry J. Cadden, as well as the company’s supervisory pharmacist, Glenn A. Chin, with 25 predicate acts of second-degree murder under RICO.<sup>7</sup> These charges stem from the deaths of patients in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee and Virginia.<sup>8</sup>

In its 131-count indictment, the Government alleges that from at least 2006 until approximately October 2012, the defendants knowingly made and sold numerous drugs in an unsafe manner and under unsanitary conditions while simultaneously promoting and selling their products without disclosing these issues and concealing their wrongdoing from regulators.<sup>9</sup>

According to the Government, the defendants used expired ingredients, employed improper sterilization practices, and mislabeled drugs.<sup>10</sup> Surface and air-sampling reports allegedly produced “alert level and action-level results” showing that mold and bacteria were growing in NECC’s “clean” facilities.<sup>11</sup> Chin allegedly instructed technicians “to prioritize production over cleaning and disinfecting” and to fraudulently complete cleaning logs.<sup>12</sup> Meanwhile, Cadden allegedly told sales representatives to say that NECC “was providing the highest quality compounded medications” with a “strictly enforced environmental monitoring program and a comprehensive end-product testing program for its drugs.”<sup>13</sup> To avoid oversight, the defendants allegedly misled regulators by claiming that they only produced drugs pursuant to valid, patient-specific prescriptions, when in fact they produced drugs in bulk.<sup>14</sup> The indictment alleges that these acts constituted a wanton and reckless indifference to human life in violation of seven states’ second-degree murder statutes.<sup>15</sup> Thus, the indictment takes allegations that are the norm in healthcare fraud cases, and claims that these same allegations establish second degree murder.

The Government’s use of the RICO statute to charge business executives with murder premised upon what is typically considered white collar fraud is a dramatic move. The few instances in which pharmaceutical providers have faced criminal charges under RICO bear little resemblance to the facts here. *See, e.g., United States v. Cooper*, 880 F.2d 415 (6th Cir. 1989) (affirming RICO conviction based on evidence that defendant was part of a wide-ranging, decade-long conspiracy to engage in fraudulent insurance company billing, controlled

substance violations and mail fraud by more than 20 pharmacies). In the First Circuit, federal prosecutors have traditionally used RICO to target gangs or crime families involved in classic racketeering such as bribery, extortion or dealing controlled substances. *See, e.g., Cianci*, 378 F.3d at 86-87 (affirming RICO conspiracy convictions for three city officials for acts of public corruption including several coordinated bribery schemes); *United States v. Patrick*, 248 F.3d 11, 19 (1st Cir. 2001) (affirming RICO convictions of members of Intervale Posse gang including predicate acts of murder and drug dealing); *United States v. London*, 66 F.3d 1227, 1245 (1st Cir. 1995) (affirming RICO conviction for predicate acts including illegal gambling and money laundering).

## A Potential Stumbling Block: The Enterprise Requirement

Whether the Government will be able to sustain its burden of proof remains an open question. To prove a substantive RICO violation, “the Government must prove beyond a reasonable doubt that (1) the enterprise affected interstate or foreign commerce, (2) that the defendant under consideration associated with the enterprise, (3) that [the] defendant participated in the conduct of the enterprise’s affairs, and (4) that the defendant’s participation was through a pattern of racketeering activity.” *United States v. Shifman*, 124 F.3d 31, 35 (1st Cir. 1997) (internal quotation marks omitted).<sup>16</sup>

One hurdle the Government will face in the NECC case is establishing the enterprise requirement. The Government claims that the defendants constituted a criminal enterprise “associated in fact” under RICO. “An association-in-fact enterprise is a group of persons associated together for a common purpose of engaging in a course of conduct.” *Boyle v. United States*, 556 U.S. 938, 938 (2009). Significantly, “the enterprise must be distinct from the pattern of racketeering activity[.]” *United States v. Nascimento*, 491 F.3d 25, 32 (citing *United States v. Turkette*, 452 U.S. 576, 583 (1981)). In the First Circuit, “[a]n enterprise is chiefly distinguished from the pattern of racketeering activity by the fact that it possesses some goal or purpose more pervasive and more enduring than the instant gratification that can accrue from the successful completion of each particular criminal act.” *Nascimento*, 491 F.3d at 32. The organization must “function as an ongoing unit and constitute an ‘ongoing organization.’” *United States v. Cianci*, 378 F.3d 71, 82 (2004). Although the First Circuit has declined to require that a criminal enterprise have an “ascertainable structure,” *id.*, it has considered several non-dispositive factors to determine whether an association-in-fact exists, including:

(1) whether the associates have a common purpose; (2) whether there is systematic linkage, such as overlapping leadership, structured or financial ties or continuing coordination; (3) whether there is a common communication network for sharing information on a regular basis; (5) whether the associates hold meetings and sessions where important discussions take place; (6) whether the associates wear common colors, signs or insignia to make the group identifiable; and (7) whether the group conducted common training and instruction. *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 182 (D. Mass. 2003) (internal citations omitted).<sup>17</sup>

In this case, the Government seeks to meet its burden of proof on the enterprise element with allegations that the defendants (1) made misrepresentations to customers about NECC’s production practices; (2) produced drugs in a manner that did not comply with applicable regulations; and (3) failed to properly clean and disinfect NECC’s facilities, all for the common purpose of “obtaining money and property.”<sup>18</sup> These allegations, if proven, would show some coordination and communication between the defendants. It is not clear, however, what ongoing objective or characteristics this association possessed that make it distinct from the charged predicate acts. *Compare United States v. Connolly*, 341 F.3d 16, 26 (1st Cir. 2003) (affirming RICO conviction where Government introduced “significant evidence of the existence of the enterprise apart from the specified racketeering acts.”); *Libertad v. Welch*, 53 F.3d 428, 442 (1st Cir. 1995) (“As a matter of law, it is not sufficient that several organized, ongoing groups come together for one concerted action, unless those groups can also be shown to constitute a larger unit, over and above their separate structures and operations.”).

## From Reckless Disregard for Regulatory Standards to an Extreme Indifference to Human Life: Can the Government Bridge the Gap?

Demonstrating that Cadden and Chin had the necessary mental state to support convictions for second degree murder may also be a significant hurdle. The indictment charges second-degree murder as defined by the statutes of seven different states, each with its own wrinkle on the defendants’ required state of mind at the time of the offense.<sup>19</sup> North Carolina, for instance, defines second degree murder as “acting in a manner inherently dangerous to human life so recklessly and wantonly as to manifest a mind utterly without regard for human life and social duty and deliberately bent on mischief,”<sup>20</sup> whereas Indiana requires that defendants acted only with “an awareness of a high probability that their conduct would result in death.”<sup>21</sup> The Government alleges the defendants’ conduct showed “an extreme and appalling indifference to human life.”<sup>22</sup> The indictment, however, on its face suggests some contrary facts. For example, the defendants did routinely autoclave drugs to sterilize them, even if they allegedly did so for an insufficiently long period of time.<sup>23</sup> Similarly, at least some drug samples were allegedly sent for sterility testing.<sup>24</sup> And discovery and investigation may very well reveal other acts that

will preclude the Government from meeting its burden of proof.

This not the first time that mislabeled or tainted pharmaceuticals produced by compounding pharmacies have resulted in death or serious injury. According to one review of the data, “more than two dozen deaths since 2001 have been linked to contaminated or mismeasured doses of medications produced by compounding pharmacies.”<sup>25</sup> Criminal charges in these circumstances are rare; a charge of second-degree murder has never been brought. For example, in March 2007, in the Apothécure case, three patients from the Pacific Northwest died after receiving super-potent doses of colchicine injectable solution, a drug used for the treatment and prevention of gout.<sup>26</sup> The drugs were hundreds of times stronger than was declared on their label and had been misbranded by a Texas-based compounding pharmacy.<sup>27</sup> The pharmacy and its owner were charged with two misdemeanor violations of violations of the Food, Drug and Cosmetics Act.<sup>28</sup> The owner was sentenced to one year of probation and a \$100,000 fine.<sup>29</sup> Similarly, in 2011, in the Main Street Family Pharmacy case, a Tennessee compounding pharmacy and its owner pled guilty to a misdemeanor criminal violation for selling contaminated MPA—the same drug produced by NECC.<sup>30</sup> The owner was sentenced to one year of probation and a \$25,000 fine.<sup>31</sup> In stark contrast, if they are convicted, Cadden and Chin face maximum sentences of life in prison.<sup>32</sup>

The Government’s use of the RICO statute in *United States v. Cadden* to charge 25 acts of second-degree murder as predicate offenses reflects an unprecedented approach to pharmaceutical regulatory violations that allegedly resulted in patient deaths. It remains to be seen whether this approach will be embraced by other jurisdictions.

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1. See Indictment, *United States v. Cadden et al.*, 1:14-cr-10363 (D. Mass.) (“Indictment”); Press Release, U.S. Attorney’s Office, District of Massachusetts, *14 Indicted in Connection with New England Compounding Center and Nationwide Fungal Meningitis Outbreak* at 1 (Dec. 17, 2014) (hereafter “NECC Press Release”).<sup>↔</sup>

2. U.S. Centers for Disease Control, *Multistate Outbreak of Fungal Meningitis and Other Infections*, available here (last visited Jan. 11, 2015) (“CDC Report”). A compounding pharmacy produces drugs that are tailor-made to a physician’s specifications to suit a particular patient. See T. R. Goldman, *Health Policy Brief: Regulating Compounding Pharmacies*, 33 HEALTH AFFAIRS 1 (May 1, 2014). Between 1 and 3 percent of all pharmaceuticals are compounded. *Id.*<sup>↔</sup>

3. NECC Press Release at 1.<sup>↔</sup>

4. See *id.*; see also CDC Report at 1.<sup>↔</sup>

5. See NECC Press Release at 1; CDC Report at 1.<sup>↔</sup>

6. See generally Indictment.<sup>↔</sup>

7. NECC Press Release at 1.<sup>↔</sup>

8. *Id.*<sup>↔</sup>

9. *Id.* at 3.<sup>↔</sup>

10. See *id.*; see also Indictment ¶ 74.<sup>↔</sup>

11. Indictment ¶ 37(d).<sup>↔</sup>

12. *Id.* at ¶ 37(b).<sup>↔</sup>

13. *Id.* at ¶ 35.<sup>↔</sup>

14. See NECC Press Release at 3; see also Indictment ¶¶ 76-108.<sup>↔</sup>

15. NECC Press Release at 1.<sup>↔</sup>

16. The Government also charged NECC executives with a racketeering conspiracy under 18 U.S.C. 1962(d). See Indictment ¶¶ 72-75. The elements of this charge are closely aligned with those of the substantive RICO count. “For a defendant to be found guilty of conspiring to violate RICO, the government must prove (1) the existence of an enterprise affecting interstate commerce, (2) that the defendant knowingly joined the conspiracy to participate in the conduct of the affairs of the enterprise, (3) that the defendant participated in the conduct of the affairs of the enterprise, and (4) that the defendant did so through a pattern of racketeering activity by agreeing to commit, or in fact committing, two or more predicate offenses.” *Shifman*, 124 F.3d at 35 (internal quotation marks omitted)<sup>↔</sup>

17. “[I]t is appropriate to rely on civil RICO precedent when analyzing criminal RICO liability. The standard is the same for both criminal and civil RICO violations.” *Shifman*, 124 F.3d at 35 n.1.↔

18. See Indictment ¶¶ 34-37 (sections titled “The Enterprise” and “Manner and Means of the Enterprise”).↔

19. See Indictment ¶¶ 58-62.↔

20. *Id.* at ¶ 62.↔

21. *Id.* at ¶ 58.↔

22. See NECC Press release at 1.↔

23. See Indictment ¶ 36(c).↔

24. See *id.* at ¶ 36(e).↔

25. See Peter Eisler, *Deaths, infections tied to ‘compounding’ drugs*, USA TODAY (Mar. 6, 2013), available here.↔

26. See Press Release, Department of Justice, Office of Public Affairs, *U.S. Files Criminal Charges Against Dallas Company in Connection with Misbranded Drug Shipment That Led to Three Deaths* (Feb. 10, 2012) (“Apothecure Release”); see also *United States v. Gary D. Osborn and Apothecure Inc.*, 3:12-CR-047-M (N.D. Tx. Feb. 10, 2012). ↔

27. See Apothecure Release.↔

28. See *id.*↔

29. See *U.S. v. Osborn*, Dkt. # 58.↔

30. See Press Release, U.S. Attorney’s Office, Western District of Tennessee, *Main Street Pharmacy Co-Owner Pleads Guilty To Criminal Violation Of The Federal Food, Drug, And Cosmetic Act* (Dec. 11, 2011), available here.↔

31. See *id.*↔

32. See NECC Press Release at 3.↔

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