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FEDERAL JUDGE REVERSES CONVICTIONS FINDING FDA AUTHORITY UNCLEAR

by Gregory A. Brower

In a bold defense of fundamental fairness in the context of a criminal prosecution, a federal district court judge in Massachusetts recently granted a motion to vacate the convictions of two defendants who argued that the Food and Drug Administration's ("FDA") regulatory authority over compounding pharmacies was not clearly established, and thus their convictions for conspiring to defraud the FDA were legally impossible and violated basic norms of due process.

In *United States v. Gregory Conigliaro and Sharon Carter*,¹ the defendants were among 14 former owners and employees of the New England Compounding Center ("NECC"), a now-defunct company in the "compounding pharmacy" business, who were indicted on federal criminal charges following a deadly outbreak of fungal meningitis attributed to contaminated batches of injectable methylprednisolone acetate ("MPA"). The gravamen of the 131-count indictment was that the defendants entered into a corrupt agreement to defraud the FDA by conspiring to hold out NECC as a conventional pharmacy regulated under Massachusetts law, when, in reality, NECC was operating as a drug manufacturer subject to federal regulation by the FDA.

The defendants charged with the so-called *Klein*² conspiracy first moved to dismiss the indictment under Fed.R.Crim.P. 12(b)(3), arguing that the relevant court failed to give adequate notice of the nature of the offense and that the federal conspiracy statute, 18 U.S.C. § 371, as applied, was therefore void for vagueness. That motion was denied.

Later, following a separate trial of a co-defendant, the defendants filed a renewed motion to dismiss the *Klein* conspiracy arguing that the evidence presented at the just-completed trial of the co-defendant established that there was "no discernible federal law defining any clear distinction between a compounding pharmacy and a drug manufacturer," and it was thus "legally impossible for the FDA to be defrauded in the manner the government alleged." The court also denied that motion. The defendants' third and fourth tries were also unsuccessful as their motions to dismiss during their own trial, first after the government's opening statement and again after the government rested, were also denied. After the jury returned a guilty verdict, yet another motion was made, this one for acquittal pursuant to Fed.R.Crim.P. 29. As it turned out, the sixth time was a charm.

After first acknowledging that the doctrine of impossibility as applied to inchoate crimes like attempt and conspiracy remains a "murky area of the law," the court endeavored to make it less murky

¹ *United States v. Gregory Conigliaro and Sharon Carter*, No. 14-10363 (D. Mass.).

² See *United States v. Klein*, 247 F.2d 908, 916 (2d Cir. 1957).

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by offering a detailed discussion of the difference between factual impossibility and legal impossibility. It explained that in the case of legal impossibility, while a defendant may appear worthy of punishment because he possesses the requisite *mens rea*, “the right of the state to impose punishment is constrained by the principle of legality, fundamental fairness, and just limits on the state’s deployment of the coercive instruments at its disposal.” The court went on to observe that the doctrine of legal impossibility “allows for a perfect defense in cases where suspect or even contemptible thoughts are unaccompanied by positive steps towards the achievement of an end that society has seen fit to criminalize.”

Turning to the case at bar, the court zeroed in on the fact that for the first 50 years or so after the enactment of the Federal Drug Control Act, the FDA generally left regulation of compounding to the states. This was true even though compounded drugs would often appear to fit within the FDA’s definition of a “new” drug. The FDA’s practice, developed over decades, was to leave regulation of “traditional pharmacy compounding” to state boards of pharmacies, while exclusively asserting its own regulatory authority over large-scale drug manufacturers. Indeed, at trial, a senior FDA official testified that “FDA has authority over all drugs in the United States; however, we didn’t have any specific regulatory scheme for this traditional pharmacy compounding. That was under the practice of pharmacy and under the state boards of pharmacies.” Moreover, the court found that internal FDA memoranda and testimony by senior FDA officials before various congressional committees, introduced as evidence at the defendants’ trial, all revealed the image of an agency “struggling to make sense of a statutory regime that Congress had not updated since 1938 and that had been overwhelmed by the rapidity of the advances in modern medicine and pharma.”

Overall, the court found that the evidence at trial “reinforced the notion that entities like NECC did not fit neatly into the compounding-manufacturing dichotomy that had historically influenced the FDA’s enforcement strategy.” The court further found that these ambiguities extended to the FDA’s direct dealings with NECC itself. In pre-outbreak inspections of NECC, the FDA labeled the company as either a “pharmacy” or “compounding pharmacy,” but never as a drug manufacturer. Moreover, the FDA also consistently took the position that regulatory jurisdiction over NECC fell to the Massachusetts pharmacy board.

In light of that complicated regulatory history, the court found that the evidence plainly showed that “during the life of the charged conspiracy, the FDA was not, and did not believe that it should be, in the business of regulating companies like NECC.” Thus, the bottom line for the court was this: “during the critical times, these defendants (and NECC) could not have defrauded the FDA by interfering with the relevant regulatory functions because there were none to speak of.” The court went on to observe that “the basic principle that a criminal sanction must follow a clear and positive legal prohibition, so that defendants are not punished for violating an unknowable something ... has been applied by the Supreme Court before in the context of determining the scope of an alleged Klein conspiracy ... and is simply too well-established and too important to ignore here. This is all the truer when bad things have happened and the thirst for accountability is most acutely felt.”

Thus, this is the rare case in which the vague nature of a federal regulatory scheme combined with the traditional rule of lenity was enough for a court to reverse convictions. Whether in the FDA context or any other, confusing statutes and regulations leave both regulators and prosecutors, as well as those subject to such laws and regulations guessing about their true meaning and proper application. Such confusion cannot fairly lead to criminal charges, regulatory enforcement efforts, or even civil lawsuits, without implicating serious due process issues. The court in this case recognized this fact, perhaps a little late, only after expensive litigation, repeated motions to dismiss, and convictions at trial. But, as Justice Felix Frankfurter astutely observed, “wisdom too often never comes, and so one ought not to reject it merely because it comes late.”