MASSACHUSETTS LAWYERS WEEKLY
FIRST INDEMNITY INSURANCE GROUP
Your defense is our focus.
Your direct source for lawyers professional liability.
800.982.1151

Judge: no clear FDA authority to regulate compounding pharmacy

'Klein' conspiracy verdict vs. NECC employees tossed on 'legal impossibility' grounds

By: Eric T. Berkman June 20, 2019

Two former employees of a Framingham compounding pharmacy that was responsible for a deadly fungal meningitis outbreak should not have been found guilty of conspiracy to defraud the Food & Drug Administration, a federal judge has ruled.

Counsel for defendants

New England Compounding Center made and sold drugs in an unsafe manner, using contaminated and expired ingredients in filthy conditions in an apparent effort to cut corners and boost profits. As a result, nearly 20,000 vials of tainted steroid medications were shipped all over the country, killing at least 60 people in nine states and sickening at least 700 more.

According to the government, NECC also fraudulently maintained the appearance of being a pharmacy dispensing valid prescriptions when, in fact, it routinely dispensed drugs in bulk utilizing fake prescriptions.

Eleven former NECC owners, executives and employees were ultimately convicted on charges including racketeering, conspiracy, mail fraud, and introduction of adulterated or misbranded drugs into interstate commerce.

Among the defendants were NECC's former co-owner, defendant Gregory Conigliaro, and its former director of operations, Sharon Carter, both of whom were found guilty of a "Klein conspiracy" to defraud the FDA in violation of 18 U.S.C. §371 by frustrating its regulatory oversight.

After the verdict, Conigliaro and Carter moved for acquittal, arguing that because the FDA did not have clearly established regulatory authority over compounding pharmacies, their conspiracy convictions were "legally impossible" and thus violated their due process rights.

U.S. District Court Judge Richard G. Stearns agreed, ordering that Conigliaro and Carter both be acquitted under Rule 29 of the Federal Rules of Civil Procedure.

"[W]hatever the efforts that were … undertaken to fix federal law as applied to compounding, the evidence plainly shows 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 that were engaged in anticipatory pharmacy compounding," Stearns wrote. "Thus, the bottom line: 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 51-page decision is *United States v. Conigliaro, et al.*, Lawyers Weekly No. 02-299-19. The full text of the ruling can be found here.

No regulatory authority

A spokesperson for the U.S. Attorney's Office said the ruling was being reviewed, and, if appropriate, an appeal would be filed.

Conigliaro's attorney, Daniel M. Rabinovitz of Boston, said it was gratifying that Stearns "clearly recognized that there was no legal distinction between a drug manufacturer and a compounding pharmacy, and thus it was legally impossible to conspire to impede the FDA in that manner."

Boston attorney Michael K. Loucks, who led the health care fraud group at the U.S. Attorney's Office for more than a

decade, said the government has long used the charge of conspiracy to defraud an agency in instances in which defendants engaged in trickery, fraud and deceit to defeat a legitimate agency purpose or goal.

"But its effort to do so in the compounding prosecution was a case of putting a square peg in a round hole," said Loucks, who also served as acting U.S. attorney before entering private practice. "Judge Stearns' opinion makes clear that such charges may only be brought where the agency has been clear and consistent in its stated purpose or goal."

And where an agency has "flip-flopped" over time or has expressed doubts about its ability to pursue a particular purpose or goal, then the criminal charge may not and should not be brought, Loucks said.

Loucks added that that is true even where the law may be clear.

"Indeed, the Department of Justice argued that the Food, Drug and Cosmetic Act plainly applied to compounding," Loucks said. "But the contrary and inconsistent views by the core agency — the FDA — regarding its ability to regulate compounding fatally undermined the [DOJ's] assertion that there was a 'clear and positive legal prohibition' that the defendants had violated."

Vikas S. Dhar, a federal criminal defense attorney in Charlestown, said Stearns suggested that the legal impossibility defense could be raised in circumstances in which the act is illegal according to statute but the government fails to introduce the necessary evidence at trial.

"The case also demonstrates that the defense of legal impossibility can operate in cases of Klein conspiracies," he said.

In practice, however, cases of pure legal impossibility will be rare, Dhar said.

"The impossibility will often be mixed with factual impossibility, which does not often provide a defense, and whether a defense arises will largely depend on the factual matrix of the case, semantics and construction," Dhar said.

"This decision should motivate defense counsel to do archaeological digs into the breadth of a federal administrative agency's powers before conceding that such charges as conspiracy to defraud a federal agency relate to matters that are properly being regulated by the agency in question."

— Martin G. Weinberg, Boston

Martin G. Weinberg of Boston, who represented the defendant before the 1st U.S. Circuit Court of Appeals in *U.S. v. Fernandez*, a 2013 case in which the panel reversed a conviction on legal impossibility grounds, said *Conigliaro* is a reminder for attorneys not simply to rest on prior experience to guide their defense decisions.

"This decision should motivate defense counsel to do archaeological digs into the breadth of a federal administrative agency's powers before conceding that such charges as conspiracy to defraud a federal agency relate to matters that are properly being regulated by the agency in question," he said.

Tainted batches

In December 2014, a federal grand jury indicted 14 former owners and employees of NECC on a total of 131 separate criminal counts stemming from the pharmacy's distribution of contaminated batches of the steroid medication methylprednisolone acetate, which triggered a national outbreak of fungal meningitis.

The indictment was broadly based on the government's allegation that NECC was operating as a criminal enterprise under federal racketeering law, willfully disregarding safety standards in pursuit of profits.

The government alleged specifically that Conigliaro and Carter were involved in an effort to hold out NECC as a conventional pharmacy subject to state regulation when in reality it was operating as drug manufacturer producing compounded medicine in bulk quantities with no valid prescription.

According to the indictment, Conigliaro allegedly furthered the conspiracy by describing NECC as a "small-scale, family-run compounding-only pharmacy" in a 2004 letter to the FDA, while Carter allegedly knew NECC was using fictitious names and names of celebrities to facilitate the bulk shipment of the medication to hospitals and clinics.

Before trial, the U.S. District Court denied the defendants' motions to have the indictments dismissed, and a jury found both defendants guilty of a Klein conspiracy.

After trial, the defendants moved for acquittal under Rule 29.

Legal impossibility

Stearns granted the motions, noting the lack of clear FDA regulatory authority over entities such as NECC.

"Because the FDA did not believe it had the statutory authority to regulate these new forms of pharmacy compounders, people 'of common intelligence' in the industry were left to guess as to the FDA's future enforcement policies," said Stearns, who noted that there was a circuit split over the issue of federal oversight and that FDA officials, in testimony before Congress, had acknowledged the lack of a specific regulatory scheme for compounding pharmacies.

"Previous judicial decisions had not 'fairly disclosed' to the industry that the FDA was poised to insert itself as a hands-on overseer of compounding pharmacies; to the contrary, the few cases that had been decided mostly pointed in the opposite direction," Stearns continued.

Finally, even if the FDA had never affirmatively renounced its authority to regulate compounders, "the contradictory nature of the public pronouncements it did make on the subject would justify application of the tie-breaking rule of lenity," the judge said, pointing out that an ambiguous law must be applied in the manner most favorable to the defendant.

United States v. Conigliaro, et al.

THE ISSUE: Should two former employees of a Framingham compounding pharmacy that was responsible for a deadly fungal meningitis outbreak have been found guilty of charges of conspiracy to defraud the Food & Drug Administration?

DECISION: No (U.S. District Court)

LAWYERS: John W.M. Claud of the U.S. Department of Justice, Washington, D.C.; Amanda P. Strachan and George P. Varghese, of the U.S. Attorney's Office, Boston (government)

Michael J. Pineault of Clements & Pineault, Boston; Daniel M. Rabinovitz of Murphy & King, Boston (defense)

June 27, 2019