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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

'Legal Impossibility' Lets Convicted Ex-NECC Execs Off Hook

By **Chris Villani**

Law360, Boston (June 7, 2019, 8:43 PM EDT) -- A Massachusetts federal judge overturned the convictions of a pair of former New England Compounding Center executives Friday, agreeing that their guilt was "legally impossible" even as he acknowledged not being aware of the defense ever having worked before.

U.S. District Judge Richard G. Stearns allowed acquittal motions for former co-owner Gregory Conigliaro and operations director Sharon Carter after a jury convicted them of conspiring to defraud the U.S. Food and Drug Administration. Judge Stearns found that the two could not have tricked the FDA as to whether NECC was a drug manufacturer or a compounding center because the law never made a distinction between the two. He also found that whether the FDA had any regulatory authority at all over NECC was murky at best.

"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," Judge Stearns wrote in a 51-page order. "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."

NECC found itself in the government's crosshairs after contaminated drugs shipped from the now-defunct Framingham, Massachusetts, lab caused a fungal meningitis outbreak, leading to 64 deaths nationwide and sickening about 800 more people.

Conigliaro and Carter were among five defendants found guilty in December in the third of four trials connected to the lab. Despite Carter being acquitted of the top charge, a Racketeer Influenced and Corrupt Organizations Act count, each still faced up to five years in prison.

The defendants' attorneys extolled Judge Stearns for Friday's ruling.

"Today's decision validates what we have said all along: that there was no legal distinction between a drug manufacturer and a compounding pharmacy and that therefore it was legally impossible to try and deceive the FDA as to whether NECC was a compounder," said Daniel M. Rabinovitz of Murphy & King PC, counsel for Conigliaro. "We are thrilled that the court recognized that so clearly."

"We are pleased with the decision and grateful to the court for the time and care it took in writing its opinion," said Michael J. Pineault of Clements & Pineault LLP, an attorney for Carter.

In a brief statement, Andrew Lelling, the U.S. Attorney for the District of Massachusetts, said his office was "reviewing the decision and, if appropriate, will seek to appeal Judge Stearns' decision."

During a hearing on the acquittal motion, Pineault said the government had failed to meet its burden of proof on a required element of the crime, namely that the FDA was actually performing the "government functions" the alleged conspirators tried to upend. In penning his decision, Judge Stearns said he found that argument to be compelling.

"While I am unaware of any precedential case in which such a defense has proven effective, I can think of no reason why, on facts like those here, it could not succeed," Judge Stearns wrote.

Some of the issues were raised during the trial, including testimony provided by Dr. Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research. Clips of Woodcock's 2013 testimony before Congress were played and she told lawmakers the FDA has struggled for years to create "a coherent scheme" distinguishing drug manufacturers from pharmacies based on the volume of drugs they produce. The FDA, she said, needed "clarity" on that from Congress.

In Friday's ruling, Judge Stearns made it clear he did not blame the FDA for what happened at NECC, saying testimony at trial and before lawmakers showed 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."

Exercising more control over the industry in the face of an ambiguous law could have slowed the flow of needed drugs to hospitals, the judge pointed out.

"The FDA admirably admitted in the aftermath of the outbreak that it could have done more, but it did not believe that Congress had given it the appropriate statutory tools to do so," Judge Stearns wrote.

Judge Stearns laid out his rationale behind the ruling in great detail, ticking off several hypotheticals to clarify what constitutes legal impossibility.

"Examples of pure legal impossibility might include smoking marijuana in Massachusetts in the mistaken belief that the recreational use of marijuana was illegal in the Commonwealth, or shooting at a stuffed deer outside of deer hunting season, when in fact only real deer were protected and hunting was allowed year round," he wrote.

In addition to Conigliaro and Carter, clean room pharmacist Gene Svirskiy **was convicted** by the same jury of racketeering and racketeering conspiracy, and he and fellow pharmacist Christopher Leary were found guilty of multiple felony counts of mail fraud and shipping out misbranded drugs with the intent to defraud.

The jury also said pharmacist Alla Stepanets introduced misbranded drugs into interstate commerce, but did not find she had acted with an intent to defraud, reducing her crimes to misdemeanors.

Svirskiy and Leary were recently sentenced by Judge Stearns, with Svirskiy receiving **30 months in prison** and Leary **two years probation**. NECC founder Barry Cadden and head pharmacist Glenn Chin were the first two convicted and are serving prison terms of **nine** and **eight** years, respectively.

A total of 13 former NECC employees have either pled guilty or been convicted since the meningitis outbreak. Most recently, on May 2, a Boston federal jury found two former verification pharmacists, Kathy Chin and Michelle Thomas, **guilty** of approving prescription orders with fake patient names.

The government is represented by George P. Varghese and Amanda P. Strachan of the U.S. Attorney's Office for the District of Massachusetts.

Conigliaro is represented by Daniel M. Rabinovitz and Shawn Lu of Murphy & King PC.

Carter is represented by Michael J. Pineault of Clements & Pineault LLP.

The case is U.S. v. Cadden et al., case number 1:14-cr-10363, in the U.S. District Court for the District of Massachusetts.

--Additional reporting by Aaron Leibowitz. Editing by Alanna Weissman.