

FOOD AND DRUG LAW INSTITUTE

Top Food and Drug Cases
2015
& Cases to Watch
2016

EDITED BY GREGORY J. WARTMAN



UNITED STATES V. QUALITY EGG, LLC, NO. 14-CR-3024, (N.D. IOWA)

by Jennifer M. Thomas and Anne K. Walsh

WHY IT MADE THE LIST

For years, the government has threatened to increase the number of criminal charges it brings against executives of companies that have violated the Federal Food, Drug, and Cosmetic Act (“FDC Act”), even in the absence of intent or even knowledge of the company’s wrongdoing. The “responsible corporate officer” doctrine operates on the principle that these officers are in positions of responsibility and authority over regulatory compliance, and thus can be held strictly liable for violations committed by their companies. Courts have approved criminal prosecution of corporate officers and imposition of criminal penalties under the FDC Act based on a determination that such individuals have an affirmative obligation to be aware of and to prevent FDC Act violations. *See, e.g., United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (public health legislation “puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger”); *United States v. Park*, 421 U.S. 658, 673-74 (1975) (food and drug laws are designed to punish neglect where the law requires care, or inaction where it imposes at duty).

Although *Quality Egg* predates the September 2015 memorandum authored by Deputy Attorney General Sally Quillian Yates (the “Yates Memo”), the DOJ memo is worth mention here because it further supports DOJ’s intent to hold individuals responsible for corporate negligence and misconduct. *See* Memorandum from Sally Quillian Yates, Deputy Attorney General, to all DOJ Attorneys (Sept. 9, 2015), <http://www.justice.gov/dag/file/769036/download>.¹ Although it does not speak directly to strict liability under the responsible corporate officer doctrine, the Yates Memo emphasizes DOJ’s goal to “deter[] future illegal activity, [and to] incentivize[] changes in corporate behavior” through prosecution of individuals. Yates Memo at 1.

United States v. Quality Egg made the list this year because not only does it evidence the government’s trend toward prosecuting more individuals, it also serves as a high-water mark for a criminal sentence imposed on

these individuals. Given the significant consequences of a conviction – up to \$250,000 in penalties per violation, in addition to possible imprisonment (should the *Quality Egg* precedent stand), and disbarment from employment in the healthcare industry – the implications are frightening.

WHAT HAPPENED: FACTS, HOLDING, AND RATIONALE

In August 2010, there was a major outbreak of *salmonella enteritidis* poisoning in the United States that sickened thousands of consumers. The U.S. Food and Drug Administration (“FDA”) and Centers for Disease Control and Prevention traced the outbreak to an Iowa-based company, Quality Egg, LLC (“Quality Egg”). Quality Egg also went by the names Wright County Egg, Environ, and Lund/Wright Company, and was helmed by a father-son duo, Austin DeCoster (owner and father) and Peter DeCoster (chief operating officer and son). As a result of the outbreak, and faced with epidemiologic evidence tying that outbreak to the company’s products, Quality Egg voluntarily recalled hundreds of millions of eggs.

After a lengthy investigation, the government brought charges against Quality Egg, Austin DeCoster, and Peter DeCoster in May 2014. The government alleged that the company (1) bribed a public official, (2) introduced misbranded food into interstate commerce with the intent to defraud or mislead, and (3) introduced adulterated food into interstate commerce. The company ultimately pleaded guilty to each of these crimes, and was sentenced to pay a fine of



Jennifer M. Thomas is an associate at Hyman, Phelps & McNamara, P.C. with a practice focused on assisting drug, medical device, food, dietary supplement, and cosmetic companies with managing responses to warning letters, subpoenas, civil investigative demands, and proposed consent decrees.



Anne K. Walsh is a director at Hyman, Phelps & McNamara, P.C. where she counsels clients on compliance and enforcement issues, including FDA inspections, seizure and injunction actions, warning letters, and recalls.

\$6.79 million and placed on probation for three years. Quality Egg also agreed to forfeit \$10,000 in ill-gotten gains from its illegal activity.

The Quality Egg plea agreement reveals serious wrongdoing by the company's employees. Quality Egg admitted that in 2010, company employees acting in their official capacity bribed a U.S. Department of Agriculture ("USDA") inspector to release pallets of Quality Egg eggs that had been tagged as failing to meet USDA standards. From January 2006 until approximately August 2010, Quality Egg employees shipped eggs to wholesale customers with deliberately mislabeled processing dates and expiration dates. The eggs were actually older than indicated by the dates on their cases. Some eggs were shipped with no labeling, so that inaccurate processing and expiration dates could be sent to wholesalers and added to the egg cases at a later time. By mislabeling or failing to label the eggs, Quality Egg personnel "intended to mislead, at least, state regulators and retail egg customers regarding the age of the eggs . . . [and did mislead] state regulators and retail egg customers regarding the age of these eggs." Mem. Op. and Order at 17, *United States v. Quality Egg, LLC*, No. C 14-3024 (N.D. Iowa Apr. 14, 2015), ECF No. 116 [hereinafter "Mem. Op. and Order"]. The company also admitted to selling adulterated eggs that were contaminated with *salmonella enteritidis*, although the plea agreement states that "the government's investigation has not identified any personnel employed by or associated with defendant who had knowledge, during the time frame from January 2010 through August 12, 2010, that [Quality Egg] eggs sold by defendant were, in fact, contaminated" Plea Agreement at 7, *United States v. Quality Egg, LLC*, 14-CR-3024 (N.D. Iowa June 2, 2015), ECF No. 15-1.

The charges against the individuals, Austin and Peter DeCoster, and the ultimate plea agreement appear to have been entered into based on their positions as "responsible corporate officers" of the company. Both DeCosters pleaded guilty to a misdemeanor violation of "selling adulterated food as a responsible corporate officer" of the company. According to Austin DeCoster's plea agreement, he "exercised substantial control over the operations of Quality Egg and related entities and assets in Iowa." See Mem. Op. and Order at 7. Peter DeCoster also "exercised some control over the

//////////////////////////////////////
**[T]he government argues strenuously that . . .
 sentencing was based on a determination that the
 DeCosters did have "culpable knowledge" of, and
 "culpable participation" in, the subject offense . . .**
 //////////////////////////////////////

production and distribution of shell eggs by Quality Egg and related entities and assets in Iowa." *Id.* The government agreed that Austin and Peter DeCoster lacked "knowledge, during the time frame . . . that eggs sold by Quality Egg were, in fact, contaminated with *Salmonella Enteritidis* [sic]." *Id.* at 9.

Prior to their sentencing hearing, the DeCosters filed a motion seeking to preclude as unconstitutional any sentence of incarceration or confinement. Specifically, the DeCosters argued that sentencing an individual to prison for a strict-liability offense violated the Due Process Clause of the Fifth Amendment to the U.S. Constitution. The DeCosters argued in the alternative that a prison sentence would violate the Eighth Amendment's prohibition on "cruel and unusual punishment." U.S. Const. amend. VIII. Specifically, the DeCosters argued that imprisonment was "grossly disproportionate" to their crime, and thus, cruel and unusual. They asserted that a "strict vicarious liability crime, is the most minor offense known to the law." See Mem. Op. and Order at 33.

The U.S. District Court for the Northern District of Iowa disagreed with the DeCosters, and on April 14, 2015, the court sentenced them both to three months incarceration. See *id.* at 68. The court found the Fifth Amendment argument unpersuasive because the DeCosters were not contesting the imposition of a criminal penalty, but merely the nature of that penalty. The court noted that "[i]n general, the Supreme Court has permitted the punishment of persons for violating strict liability offenses," including criminal punishment. *Id.* at 66. Further, "the Supreme Court has not invalidated the [FDC Act], or ruled that the penalties authorized by [that Act] for the strict liability misdemeanor offense . . . are unconstitutional on due process grounds." *Id.* at 67. Thus, the court concluded that criminal sanctions authorized by the FDC Act, including up to one year imprisonment for certain crimes, did not violate the Due Process Clause.

With respect to the Eighth Amendment argument, the court determined that “even a sentence of the statutory maximum of one year in prison” would not run afoul of the Eighth Amendment. *Id.* at 36. Indeed, such a sentence would not be grossly disproportionate, in light of the harm caused to thousands of consumers by the DeCosters’ neglect of their duties. *Id.* at 37-38. According to the court, a sentence falling within the sentencing guideline range of zero to six months based on the sentencing factors established by 18 U.S.C. § 3553(a) was manifestly appropriate.

WHAT HAPPENS NEXT

The DeCosters timely appealed their prison sentence to the U.S. Court of Appeals for the Eighth Circuit. *See* Appellants’ Opening Br., *United States v. DeCoster*, Nos. 15-1890, 15-1891 (8th Cir. July 21, 2015). Appellants’ opening brief emphasizes that historically, strict liability crimes “have been punished with light fines, amid substantial doubt whether ‘imprisonment [is] compatible with the reduced culpability required for such regulatory offenses.’” *Id.* at i (quoting *Staples v. United States*, 511 U.S. 600, 617 (1994)). The brief repeats the DeCosters’ arguments under the Fifth Amendment’s Due Process Clause and the Eighth Amendment, and asserts procedural and substantive error on the part of the district court. *Id.* at 1-2. Amici curiae, comprised of the Washington Legal Foundation, the Chamber of Commerce of the United States, and the Pharmaceutical Research and Manufacturers of America (“PhRMA”), filed separate briefs in support of the DeCosters.

In response to the DeCosters’ arguments, and those of the amici curiae, the government’s brief notably does *not* focus on defending imprisonment as an appropriate penalty for strict liability offenses under the FDC Act. Rather, the government argues strenuously that the district court’s sentencing was based on a determination that the DeCosters *did* have “culpable knowledge” of, and “culpable participation” in, the

subject offense, although knowledge and intent did not form the basis for their guilty pleas. Specifically, the government details a long history of non-compliance at Quality Egg, and even measures taken by Quality Egg employees (potentially at the behest of the DeCosters or with their knowledge) to evade or frustrate quality audits and government inspections. *See* Gov’t Br. at 7-18, *United States v. DeCoster*, Nos. 15-1890, 15-1891 (8th Cir. Sept. 22, 2015). In light of this sordid history, the government asserts, “[t]he DeCosters are not being held ‘vicariously’ liable for the conduct of their employees; they are being held accountable for their own acts and omissions in causing a massive, nationwide outbreak of food-borne illness.” *Id.* at 25.

At the time of this writing, all appellate briefs have been filed in the DeCoster’s Eighth Circuit appeal, but the oral argument has not yet been scheduled. We may very well be discussing the appellate decision in next year’s top cases publication.

CONCLUSIONS

Pending the results of the DeCosters’ appeal, corporate officers have reason to be cautiously optimistic that the government has chosen to focus its appellate briefing on the degree to which the DeCosters *did* have culpable knowledge and intent, rather than on defending the imposition of a prison sentence in the complete absence of such knowledge and intent. This suggests that government prosecutors themselves may view incarceration as appropriate only when the facts of a case suggest willful ignorance or outright negligence on the part of responsible corporate officers.

ENDNOTES

- 1 The policies set forth in the Yates Memo have since been codified in the United States Attorneys Manual. *See* DOJ, U.S. Attorneys’ Manual, Pursuit of Claims Against Individuals § 4-3.100; DOJ, U.S. Attorneys’ Manual, Principles of Federal Prosecution of Business Organizations: Focus on Individual Wrongdoers § 9-28.210.