

ENFORCEMENT CORNER



Vindicated on Appeal— It Does Happen

by John R. Fleder

How often do we hear after a criminal indictment: “My client welcomes a trial so that he will have his good name restored.” How often do we hear after a conviction: “The judge and jury made fatal errors in this case, and we intend to vigorously appeal this conviction so that justice can be served by dismissal of all charges.” How often are these words successful in Food and Drug Administration (FDA) cases?

Well, the latter recently occurred in *United States v. Farinella*, where the United States Court of Appeals for the Seventh Circuit in Chicago reversed a conviction, and ordered the case dismissed against Mr. Farinella.¹ The panel which decided the case was noteworthy for the highly respected status of its members: Seventh Circuit Judges Posner, Kanne and Wood. The Court’s Opinion highlights serious missteps by the prosecutors. The decision shows what can happen when, as the Court concluded, a prosecutor relies on bad facts, and combines those facts with no favorable controlling law, a government witness who is asked to testify about irrelevant matters and highly questionable courtroom conduct by the prosecutor. All of these circumstances resulted in an Opinion that makes a broadside attack on the entire prosecution case.

Bad Decisions Make for a Bad Prosecution

On July 11, 2006, Charles Farinella was charged with three counts of wire fraud (18 U.S.C. § 1343), one count of misbranding (21 U.S.C. § 331(a) and § 333(a)(2)), and one count of consumer product tampering (18 U.S.C. § 1365(a)). Farinella proceeded to trial in July 2007, and was found guilty of two counts of wire fraud, and the Food, Drug and Cosmetic Act (FDCA) misbranding count.

The conviction was not surprising in light of the facts outlined in the government’s appellate brief. Farinella bought approximately 1.6 million bottles of Henri’s Salad Dressing from ACH Foods. The “best when purchased by” dates on the bottles of dressing ranged from January through June, 2003.

ACH Foods faxed Farinella a letter which noted the “best when purchased by” dates on the salad dressing, and warned that ACH Foods would only guarantee the product’s freshness up to 180 days past the date on the label. Farinella arranged for new date labels to be applied to the bottles to cover up the old labels. The new labels stated a “best when purchased by” date of 2004. Starting in the fall of 2003, ACH began to receive complaints about the alleged poor quality of Henri’s dressing and the apparent alteration of the date on the bottles.

ACH received from a retailer a copy of a letter ACH had earlier provided to Farinella’s company, but with the last sentence changed. The original letter stated: “the product should not turn rancid for up to 180 days after the purchase by date.” The altered letter stated: “the product can be labeled for a May 25, 2004 expiration which is after the original best when purchased date.” ACH had not authorized the relabeling of the salad dressing or the alteration of the letter. Nevertheless, when Farinella was asked if it was legal to relabel the dressing, he stated that he had permission from the manufacturer to do so. An employee of Farinella also rented a post office box falsely bearing the name of ACH, and listed its sales address and phone number on the rental application.

Several months after ACH sold the dressing, it received a complaint from a wholesaler that Farinella was selling the dressing with “bogus” dates on the labels. ACH called Farinella, who falsely assured ACH that he knew nothing about the relabeling. ACH nevertheless sent Farinella a “cease and desist letter.” The next day, ACH had a telephone conversation with Farinella where he acknowledged the relabeling, but falsely represented to ACH that he had checked with FDA and that the bottles had been relabeled.

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in accord with FDA's requirements. Farinella also falsely stated that he had not been contacted with any complaints concerning the letter or the relabeling of the products. A codefendant instructed his assistant to leave a recorded greeting purporting to be a representative of ACH attesting to the freshness of the salad dressing.

These alleged facts, if true, have all the makings of a classic fraud case, although probably not for misbranding. Clearly, something happened on appeal to color the Court of Appeals' decision.

The Court concluded that a shelf-stable product, such as salad dressing, is edible for years after it has been manufactured. It further concluded that without any evidence, the prosecutor implied that the product was deteriorated and tasted "foul [and] rancid" after the "best when purchased by" date. The prosecution presented no evidence that consumers were misled by the change of the "best when purchased by" date or that there was a uniform food industry understanding of the meaning of "best when purchased by" date. The Court criticized the fact that without any citation to a law or regulation or some written document, FDA's expert witness offered testimony implying that a change of the "best by date" required FDA approval. As the Court of Appeals pointed out, "to prove a person guilty of having made a fraudulent representation, a jury must be given evidence about the meaning ... of the representation claimed to be fraudulent." The appellate court found that there had been no such evidence.²

The Court's decision suggests that it was terribly troubled by two sets of events. First, it concluded that the government had misapplied the misbranding provisions of the FDCA. Second, the Court was troubled by the closing arguments of government counsel (who was identified by name in the Opinion) such that the Court suggested that some sanction needed to be assessed against that prosecutor. This combination seemed to trump the apparent fraud committed by Farinella if the testimony discussed in the government's appellate brief was indeed an accurate reflection of the evidence presented.

The Court of Appeals unmistakably concluded that the government had misapplied the FDCA by charging that Farinella had violated the FDCA misbranding provisions. The indictment had alleged that Farinella had misbranded food products because the labels he had caused to be put on the salad dressing were false or misleading pursuant to 21 U.S.C. § 343(a) because they contained "false or

misleading expiration dates." Throughout the District Court proceedings, and the subsequent appeal, the government consistently referred to "best when purchased by" as an "expiration" date, a practice roundly criticized by the Seventh Circuit.

The Court concluded that: 1) no FDA or Federal Trade Commission regulation defines the term "best when purchased by;" 2) no law forbids a wholesaler or retailer from changing a date on a label; 3) the government had introduced no evidence concerning consumers' understanding of the significance of "best when purchased by"; 4) the phrase had no uniform meaning in the food industry.³ As a result, the Court found that there was no way to determine if the "redating" was misleading, a necessary element of a conviction for an alleged violation of 21 U.S.C. § 343(a).

The government did assert in its appellate brief that a "sell by" label represents quality, flavor, freshness and an assumption of responsibility by the manufacturer. It claimed that a false and misleading "sell by" label tended to influence the wholesalers and retailers who bought the dressing directly from the defendants as well as the general public which in turn bought it. The government did not back up these assertions with citation to any part of the trial record.

In a rare showing of contempt for the government's arguments in an FDCA case, the Seventh Circuit called the government's references to the labels as "expiration" statements to be itself "false and misleading, and is part of a pattern of improper argumentation in this litigation that does no credit to the Justice Department."⁴ The Court concluded that the two terms are unrelated, in that an expiration date (but not a "best when purchased by" date) refers to the date after which a consumer should not eat the product.⁵

The Court's concern about this mistake was caused in part by testimony that the Court concluded should never have been given. The prosecutors called an FDA Director of Compliance to testify. He acknowledged that FDA does not mandate or regulate the application of "sell-by" labels in the first instance; however, he testified that FDA *does* require supporting data before approving a request to change a sell-by label by extending the date on the label. What made this testimony troubling is that the government cited no statutory provision or regulation to support the proposition that Farinella had any duty to notify FDA before altering the

“best when purchased by” date that appeared on the products’ labels. The Court of Appeals concluded that his testimony “was not just improper and inadmissible but incoherent.”⁶

In words that can undoubtedly be cited against FDA in a multitude of situations, the Court of Appeals ruled that “[i]t is a denial of due process of law to convict a person of a crime because he violated some bureaucrat’s secret understanding of the law.”⁷ FDA frequently commences criminal prosecutions when there is no regulation that publicly explains what are often general prohibitions in the FDCA itself. The Court’s language could well be a valuable tool for defendants in future FDCA prosecutions.

In fact, prior to trial, Farinella filed a motion *in limine* stating that there were no federal statutes or FDA regulations governing the “dating of ordinary food products such as salad dressing or changes thereto.” The government’s response was simple: “The government has no intention of introducing evidence of a federal regulation where no such regulation exists; therefore, it does not oppose defendant’s motion as it pertains to the absence of FDA regulations regarding dating of food products.” The district court ruled that the defendants’ motion was granted, although it would allow testimony to show that “relabeling was a material act designed to influence the customers of” Farinella.

The Assistant United States Attorney, however, claimed that once a manufacturer elects to put a label on salad dressing, FDA’s regulatory authorities step in, and while there is no requirement that the open date be placed on a package to begin with, if it is on it and changed, that is a violation of the FDCA. The Court of Appeals obviously disagreed.

The Court’s Opinion is also noteworthy for the emphasis it placed on the absence of evidence that Farinella’s practices endangered human health: “There is no evidence that any buyer of any of the 1.6 million bottles sold by the defendant has ever complained about the taste.”⁸ FDA often argues that products are misbranded whether or not the agency has any evidence that the alleged misbranding endangers human health. Yet again, this language may assist defendants in future FDCA prosecutions.

The second area that clearly troubled the Court of Appeals was the prosecutor’s closing arguments, where she made the following statements, among others: 1) “Ladies and Gentlemen, don’t let the defendant and his high-paid lawyer buy his way out of this;” 2) “Black and White in our system of justice, ladies and gentlemen. You have to earn justice. You can’t buy it;” 3) although Farinella “isn’t charged with

poisoning people,” the prosecutor did not “see them opening any of these bottles and taking a whiff;” and 4) “(I)f what Chuck Farinella did was business as usual in the food industry, I suggest that we all stop going to the store right now and start growing our own food.” The government conceded that the remarks were improper, because they cast defendant’s exercise of his constitutional right to counsel in a negative light.

Putting aside the Court’s dismissal of the misbranding charges, that dismissal still left the two wire fraud counts for which Farinella was convicted. Those counts alleged a transfer of money by Farinella that was part of a scheme that included the alleged facts discussed earlier in this article that included false statements by him. Indeed, the Court of Appeals concluded that defendants had made false statements, but that those false statements were not the basis of the misbranding charge because the statements did not appear on the labels.⁹ Then why did the Seventh Circuit not affirm the wire fraud convictions?

The Court of Appeals noted (correctly) that the government’s appellate brief did not contain a separate discussion of the wire fraud charges, and thus the government conceded that the wire fraud charges should fall if the misbranding charge fell. The government made no such explicit concession because the defense did not address the point. Thus, one is left with the unmistakable conclusion that the Court of Appeals sought to teach the government a lesson for the mistakes it made at the trial court level and on appeal.

Conclusion

Our Constitution imposes a heavy burden on the government when it initiates criminal charges, whether under the FDCA or other federal statutes. Given the wide range of enticements that the government can offer to people to plead guilty, it is often the wise person who cuts his losses and attempts to strike the best deal with the government he can. However, this case teaches two fundamental points. First, courts can punish the government when the court believes that the prosecution has overstepped the bounds of vigorously representing the interests of the people. Second, while often risky, going to trial can lead to government mistakes that will result in a defendant walking away from a prosecution a free person. ▲

1 558 F.3d 695 (7th Cir. 2009).

2 *Id.* at 700.

3 *Id.* at 698.

4 *Id.* at 697.

5 *Id.*

6 *Id.* at 700.

7 *Id.* at 699.

8 *Id.* at 698.

9 *Id.* at 697.