



Criminal Prosecutions Initiated for the FDA

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Introduction

Is FDA operating in its old traditional ways. Hardly. FDA goes to people's homes, going through trash, obtaining grand jury subpoenas and search warrants for telephone and business records not available to FDA under the Act, including many computer records. In 1991, the FDA formed an Office of Criminal Investigations. That office and agents from other federal agencies are playing a dramatically increasing role in the federal government's regulation of food, drug and medical device companies.

Value of Criminal Prosecutions to the Government

- A. Deterrence - often from publicity generated
 - B. Money maker for government
 - C. Improves relations with Congress
 - D. Could define meaning of ambiguous provision of law
 - E. Punishes wrongdoers
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Problems with Criminal Prosecutions for the Government

- A. Costly to government
 - B. Risks to the government from losing case
 - C. Interference with lives of FDA personnel and witnesses
 - D. Hard feelings that develop with industry
 - E. Assuring uniformity of prosecution
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Overview of Criminal Prosecutions under the FDC Act

- A. 21 U.S.C. § 331 sets out prohibited acts for most cases initiated under the Federal Food, Drug, and Cosmetic Act (FDC Act).

 - B. Previously, FDA referred all cases to the Office of Consumer Litigation, Civil Division, U.S. Department of Justice. Presently, however, FDA's Office of Criminal Investigations is making referrals of cases directly to the United States Attorneys. The Department of Justice can initiate a prosecution without a referral from FDA.
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Misdemeanor Prosecutions - 21 U.S.C. § 333(a)(1): Criminal intent not required

- 1) United States v. Dotterweich, 320 U.S. 277 (1943).

The Supreme Court concluded that the FDC Act "is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct awareness of some wrongdoing."

Misdemeanor Prosecutions - 21 U.S.C. § 333(a)(1): Criminal intent not required (cont.)

2) United States v. Park, 421 U.S. 658 (1975).

The rationale of the Court's decision upholding the conviction was the premise that people who manage food businesses have an affirmative duty to insure that the food they sell is safe. Accordingly, a corporate officer, who is in a responsible relationship to some activity within the company that violates the food laws can be criminally prosecuted even though that officer did not personally engage in that activity.

Misdemeanor Prosecutions - 21 U.S.C. § 333(a)(1): Criminal intent not required (cont.)

- 3) United States v. General Nutrition, 638 F. Supp. 556 (W.D.N.Y. 1986) (criminal prosecution permitted under the FDC Act against a manager/store clerk and an assistant manager).
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Misdemeanor Prosecutions - 21 U.S.C. § 333(a)(1): Criminal intent not required (cont.)

- 4) In 1998, Odwalla pleaded guilty to sixteen misdemeanors, and paid \$1.5 million including \$250,000 that was to go to a food safety organization, all for selling tainted apple juice. No individual was charged. The recipients (companies Odwalla sold to) were not identified in criminal information-just the city where the product went.
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Misdemeanor Prosecutions - 21 U.S.C. § 333(a)(1): Criminal intent not required (cont.)

5) In 1999, National Medical was fined \$3.8 million for releasing adulterated components of kidney dialysis systems.

Felonies under the FDC Act

- 1) Commission of a prohibited act under 21 U.S.C. § 331 with the intent to defraud or mislead, 21 U.S.C. § 333(a)(2).
 - (a) U.S. v. Bradshaw, 840 F.2d 871 (11th Cir. 1988). Conduct that defrauds federal or state agencies is a felony violation.
 - (b) United States v. Hiland, 909 F.2d 1114 (8th Cir. 1990). Distribution of unapproved new drugs is a felony violation.
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Felonies under the FDC Act

- (c) United States v. Beech-Nut Nutrition Corp, 871 F.2d 1181 (2d Cir. 1989). The corporation and its top two executives were convicted of selling adulterated and misbranded apple juice, and the company agreed to pay a two million dollar fine. The Court held that the government could properly charge the company and its suppliers in a conspiracy even though the suppliers sought to cheat Beech-Nut.
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Felonies under the FDC Act

(d) Several years ago, Genentech agreed to pay a \$30,000,000 fine and \$20,000,000 in civil penalties regarding selling Protropin for unapproved uses.

Felonies under the FDC Act

- 2) Prosecution for activity committed after defendant has already been convicted of another misdemeanor, 21 U.S.C. § 333(a)(2).
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Felonies under the FDC Act

3) Prosecution under the Prescription Drug Marketing Act (PDMA), 21 U.S.C. § 333(b).

(a) United States v. Acosta, 17 F.3d 538 (2d Cir. 1994). Conviction affirmed based on FBI investigation into drug diversion business.

4) Prosecution for distribution of human growth hormones, 21 U.S.C. § 333(e).

Felonies under Title 18 of the United States Code

- 1) In October 1993, C.R. Bard pleaded guilty to 391 felonies and agreed to pay 61 million dollars in criminal fines and civil penalties/damages. In addition, a federal grand jury indicted six current or former Bard officials for a variety of federal offenses, including "racketeering" charges under the "RICO" statute. The subsequent conviction of two of these officials was recently reversed by the Court of Appeals because of defective jury instructions. In November 1987, the highest fine ever in an FDA criminal case was \$300,000. As a result of the C.R. Bard criminal case the amount of the largest fine multiplied over 100 fold in less than six years.

Statutes often used in FDA cases

- (a) Criminal Conspiracy statute, 18 U.S.C. § 371-
Covers situations when two or more persons agree to
and violate any federal law, such as the FDC Act,
and situations where two or more persons seek to
defraud federal agencies such as FDA. Most
FDA felony prosecutions include this charge.
- (b) Mail Fraud Act, 18 U.S.C. § 1341- Prohibits devising
a scheme to defraud and using or causing the mail
to be used in order to execute the scheme. Use of
the mail need not be an essential part of the
scheme.

Statutes often used in FDA cases

- (c) Wire Fraud Act, 18 U.S.C. § 1343- Is worded much like the mail fraud statute except there must be an interstate element and only applies to frauds involving use of the wire, such as telephone, television, or radio.

 - (d) Customs violations, 18 U.S.C. § 542- Prohibits introducing imported merchandise (such as drugs and devices) by means of false declarations and statements such as what was in the package or to whom it was going.
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Statutes often used in FDA cases

- (e) False Statement, 18 U.S.C. 1001- Prohibits any person, in a matter within the jurisdiction of any agency of the government, from knowingly and willfully falsifying or concealing by any scheme a material fact or making any false or fraudulent statement or using any false

 - (f) Obstruction of proceedings before Agencies, 18 U.S.C. § 1505- Prohibits corrupt or threatening conduct that obstructs or impedes the law in a pending agency proceeding.
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Criminal prosecution can follow, precede
or be accompanied by civil remedies

United States v. Kordel, 397 U.S. 1 (1970)

Criminal Case Development by FDA

- A. "Consumer" complaints
 - B. Inspections by FDA
 - C. Referrals from Congress
 - D. Competitors' complaints
 - E. Hospitals
 - F. Interviews
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Criminal Case Development by FDA

G. Grand jury subpoenas - documents

In re Doe, 801 F.2d 1164 (9th Cir. 1986)- Physician and co-conspirators allegedly sold steroids illegally. According to the court, the doctor had no Fifth Amendment right for "required" records, no physician/patient privilege, and it was irrelevant what the FDA could inspect under FDC Act.

Criminal Case Development by FDA

H. Grand jury subpoenas - testimony

1) Immunity

2) Target letter

I. Must defendant have received a "warning" from FDA before being prosecuted?

Criminal Case Development by FDA

J. Must FDA hold a "hearing" under 21 U.S.C. § 335?

Kent v. Benson, 945 F.2d 372 (11th Cir. 1991) (court reaffirmed that § 335 hearing is not a prerequisite to a criminal prosecution).

Criminal Case Development by FDA

K. Search warrants

L. Sting operations

M. Wiretaps

N. Informants

O. Coordination with other agencies such as the Postal Service, the FBI, Customs, DEA, IRS, and the HHS OIG.

Punishment in an FDA Criminal Prosecution

A. Misdemeanor prosecutions -

Punishable by a maximum of one year incarceration and a fine of

\$100,000 for an individual and

\$200,000 for corporations. 21

U.S.C. § 333(a) and 18 U.S.C. § 3571.

Punishment in an FDA Criminal Prosecution

B. Felony prosecutions under 21 U.S.C. § 333(a)(2) - The maximum punishment is three years imprisonment and a fine of \$250,000 for individuals and \$500,000 for corporations. 21 U.S.C. § 333(a) and 18 U.S.C. § 3571. Alternatively, a defendant can be required to pay twice the pecuniary gain derived from or loss caused by the violative conduct. 18 U.S.C. § 3571(d).

Punishment in an FDA Criminal Prosecution

C. Felony prosecutions under other statutes - Usually more severe sentence than when sentence is imposed under the FDC Act.

Punishment in an FDA Criminal Prosecution

- D. The Federal Sentencing Guidelines - The Sentencing Reform Act of 1984 provided for the development of guidelines. Pursuant to that law, the Sentencing Commission created categories of offense behavior and offender characteristics to insure consistent sentencing. Section 2N2.1 is the Sentencing Guideline applicable to misdemeanor violations of statutes and regulations relating to foods, drugs, biological products, devices, cosmetics, and agricultural products. Section 2F1.1 is the guideline usually used in FDA fraud prosecutions of individuals. For corporations, Chapter Eight is the application chapter.
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Food and Drug Cases Under the Sentencing Guidelines

- 1) United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995)(court reversed the sentence of person who had been one of the Quad cofounders. The Court reversed the sentence because of inappropriate calculation of fraud. Court said there was no record of actual loss attributable to Chatterji's conduct, and this was not a case where consumers were harmed. The court found that when a drug possesses FDA approval, poses no threat to the health and well-being of the consumer and meets all of the goals of FDA requirements for safety and efficacy, there can be no monetary loss attributable to the regulatory fraud by which FDA approval was obtained. Economic gain to the manufacturer is not the appropriate measure of loss.

Food and Drug Cases Under the Sentencing Guidelines

- 2) United States v. Roggy, 76 F.3d 189 (8th Cir. 1996). Loss under 2F1.1 calculated by looking at loss suffered by customer which included its consequential damages-here the amount of tainted oats and cereal General Mills was left with as a result of criminal violations.
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