

MONOGRAPH, Consumer Protection Branch

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This monograph introduces the Consumer Protection Branch (CPB) and describes its role in U.S. consumer protection statute enforcement. While it discusses cases that illustrate CPB's work and identifies certain legal issues that CPB frequently addresses, it is not designed as a comprehensive litigation support guide. Assistant United States Attorneys handling cases under the statutes discussed in this monograph should consult USABook, § 4-8.000, *et seq.*, for litigation guidance, and should contact the Consumer Protection Branch for assistance.

I. Case Referrals Generally

When a client agency refers a case to the Department of Justice ("the Department," or "DOJ"), CPB generally receives the referral. CPB will either retain it or request that an appropriate United States Attorney's Office (USAO) handle the case. Frequently, CPB and the USAO work jointly on these matters. CPB serves several valuable functions in these joint representations. First, CPB obtains the necessary Assistant Attorney General approval to file cases under the consumer protection statutes. Second, CPB contributes expertise in unique policy or factual concerns that frequently affect litigation under consumer protection statutes. Third, CPB ensures that neither party has to "reinvent the wheel" in conducting litigation, as CPB possesses a deep store of relevant documentation and procedural experience.

Litigation under the consumer protection statutes has important public health implications, which in turn renders many CPB cases of significant public interest. Further, consumer protection litigation tends to involve a mix of scientific and medical information not present in most fraud cases, the interpretation of which is in sharp conflict by opposing parties. The Consumer Protection Branch's expertise and experience therefore plays a vital role in these difficult cases. These are cases in which, for example, the Government may have brought suit under the Federal Food, Drug, and Cosmetic Act for fraudulent distribution of an unapproved cancer treatment to a terminal cancer patient driven to desperation to find a life-sustaining cure. In these troubling cases CPB seeks to enforce the law and protect the public from fraudulent medical practices.

II. Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (FDCA) protects the public health and safety in a variety of ways. It forbids the manufacture or distribution of foods, drugs, medical devices, and cosmetics that are adulterated or misbranded. In general, the FDCA requires that drugs and devices be safe and effective for their intended uses, and that foods, drugs, and devices be accurately labeled and handled in ways that prevent them from becoming contaminated.

A. The FDCA Case Referral Process

The Food and Drug Administration (FDA) uses multiple routes for case referrals. In the first route, certain cases are developed through FDA's network of field offices, reviewed by FDA headquarters, and then sent, pursuant to longstanding DOJ policy, to CPB. CPB reviews the referral and determines whether to pursue civil or criminal remedies. If the referral is accepted, CPB usually attempts to enlist the assistance of the USAO in the district in which the case will be brought.

Another case referral method applies to condemnation of adulterated or misbranded food, drugs, or devices. The FDA refers these cases directly to USAOs for filing, concurrently notifying

CPB. Increasingly, these actions lead to litigation of complex issues under the FDCA when the owner of the item contests the validity of the condemnation. USAOs work closely with CPB on such cases, as they frequently raise legal and factual questions familiar to CPB.

A third avenue of case referrals has opened in recent years. FDA created an Office of Criminal Investigations in the early 1990s. That Office investigates only criminal cases, as its name implies. It has brought some cases directly to USAOs. These matters can be initiated by an agent seeking a search warrant, a grand jury subpoena, or a prosecution. The Office of Criminal Investigations relies on DOJ to coordinate with USAOs where similar cases are pending.

As a procedural matter, any criminal prosecution and any civil penalty or injunctive proceeding under the statutes for which CPB is responsible must be approved by the Assistant Attorney General for the Civil Division. That approval can be most readily obtained when CPB has been consulted and involved in the case early in the process. CPB involvement also helps ensure uniform nationwide implementation of the Federal consumer protection laws.

B. Criminal Prosecutions Under the FDCA — Felonies and Misdemeanors

The FDCA lists prohibited acts in 21 U.S.C. § 331. Violations include adulterating or misbranding a food, drug, or device, and putting an adulterated or misbranded food, drug, or device into interstate commerce. Any person who commits a prohibited act violates the FDCA. A person committing a prohibited act "with the intent to defraud or mislead" is guilty of a felony punishable by three years imprisonment. 21 U.S.C. § 333(a)(2). The intent to defraud or mislead required to establish a felony exists where the object of the fraud is either the ultimate consumer of the product, or a governmental authority such as the FDA. That is, a person whose fraudulent conduct is directed at the FDA rather than at consumers is guilty of felony behavior, and can be prosecuted on that basis.

CPB attempts wherever possible to bring felony charges to deal with fraudulent behavior. Nevertheless, misdemeanor liability can attach to behavior that, due to lack of proof of intent or other considerations, may not merit felony prosecution.

1. Felony Behavior: Fraud on Consumers

The most obvious application of the felony provision of the FDCA is to situations in which a supplier does not provide customers or consumers the product purportedly sold. Such activity constitutes monetary fraud under any definition and has traditionally satisfied the "intent to defraud" requirement for felony behavior. *See, e.g.*, the cases involving the substitution of cheap undeclared ingredients in food discussed below.

2. Felonious Behavior: Fraud on the FDA

CPB has prosecuted a variety of cases on the theory that non-monetary frauds against FDA satisfy the felony requirement of the FDCA. Generally, there are two kinds of fraud against FDA. One involves black market operations in which defendants attempt to hide their entire business operation from FDA. The other involves firms actively regulated by FDA, but which engage in fraudulent behavior by, for example, submitting fraudulent data to FDA.

a. Felonious Behavior in the Black Market Context

A variety of black markets exist in which defendants sell products regulated by FDA, but attempt to evade that regulation. Where individuals take steps to hide from FDA activities that by law should be regulated, the courts have not hesitated to find that they are defrauding FDA of its regulatory authority, and therefore satisfy the "intent to defraud" requirement of a felony FDCA violation. *United States v. Arlen*, 947 F.2d 139, 143 (5th Cir. 1991) (defendant attempting to hide black market steroid distribution activities from FDA acted with "intent to defraud"), *cert. denied*, 112 S. Ct. 1480 (1992); *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988) (black market steroid dealer acting with intent to defraud state or Federal law enforcement agency satisfies "intent to defraud" element), *cert. denied*, 488 U.S. 924 (1988).

Similarly, courts have viewed intent of this nature as meriting sentencing under the sentencing guideline that governs fraud. E.g., *United States v. Andersen*, 45 F.3d 217, 220 (7th Cir. 1995) (black market in animal drugs – failure to register animal drug manufacturing facility with FDA so drugs could be made without FDA's knowledge leads to sentencing based on amount of fraud); *United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991) (counterfeit steroid dealer trying to hide activities from FDA sentenced on basis of fraud).

b. Felonious Behavior by Regulated Firms

CPB has prosecuted numerous cases in which regulated entities defrauded FDA by submitting bogus data to the agency. In *United States v. Marcus*, 82 F.3d 606 (4th Cir. 1996), for example, the president of a generic drug manufacturing firm did not report to FDA a change his firm made in a drug formula. The change was hidden from FDA to avoid additional testing the defendant feared FDA would have required, satisfying the fraud requirement for a felony.

3. FDCA Misdemeanors

A misdemeanor conviction under the FDCA, unlike a felony conviction, does not require proof of fraudulent intent, or even of knowing or willful conduct. Rather, a person may be convicted if he or she held a position of responsibility or authority in a firm such that the person could have prevented the violation. *United States v. Park*, 421 U.S. 658, 674-77 (1975), *United States v. Dotterweich*, 320 U.S. 277, 280-81 (1943).

However, a person committing any violation of the FDCA, if previously convicted, is guilty of a felony and subject to three years in prison. 21 U.S.C. § 333(a)(2).

B. Criminal Prosecutions Under the FDCA – Individuals as Defendants

Individuals who are responsible for criminal behavior are normally named as defendants along with corporate entities through which crimes are committed. A corporate defendant's willingness to enter a plea of guilty is accordingly not a basis for dismissal of charges against an individual.

Individual defendants are generally the highest ranking officials in a firm who made decisions that violated the law, along with others who actively participated in fraudulent activity. Thus, presidents of corporations and managers of facilities where violations take place are often appropriate defendants. E.g., *United States v. Marcus*, 82 F.3d 606 (4th Cir. 1996) (President/CEO of generic drug manufacturing firm prosecuted for altering heart medication formula without adequate testing or FDA approval); *United States v. James V. Mays*, 77 F.3d

906 (6th Cir. 1996), and *United States v. Samuel and Patsy Mays*, 69 F.3d 116 (6th Cir. 1995), *cert. denied*, 116 S. Ct. 2504 (1996) (President, Secretary/Treasurer, and Operations Manager of

juice concentrate company prosecuted for secretly adding 20,000,000 pounds of sugar to product sold as pure 100% orange concentrate); *United States v. Azeem*, 983 F.2d 1057 (4th Cir. 1993) (table), 1993 U.S. App. LEXIS 9009; 1993 WL 5902 (Vice President in charge of Technical Service, and responsible technician at generic drug company prosecuted for fabricating drug testing data); *United States v. Beech-Nut Nutrition Corp. et al.*, 871 F.2d 1181 (2d Cir.), cert. denied, 493 U.S. 933 (1989), subsequent opinion, 925 F.2d 604 (2d Cir. 1991) (President/CEO and Vice President in Charge of Operations prosecuted for selling phony apple juice); *United States v. Hiland*, 909 F.2d 1114 (8th Cir. 1990) (president of generic drug maker, and president and executive vice-president of distributor, prosecuted for manufacturing and distributing injectable drug that caused deaths of premature infants).

C. Criminal Prosecutions Under the FDCA – Sentencing Goals

The goals of criminal prosecutions include deterrence and punishment. 18 U.S.C. § 3553. Imprisonment provides both punishment for and a strong deterrent against white collar crime. Accordingly, in all prosecutions of fraudulent activity, CPB seeks a prison sentence that reflects the serious injury to the public caused by the defendants. This is true both in cases where consumers are the victims and where FDA is the defrauded party.

Under guidelines that govern Federal sentencing, the dollar amount of loss defendants cause through fraud has a direct relationship to the length of sentence imposed. United States Sentencing Guidelines, § 2F1.1. This guideline controls sentencing of felony FDCA violations pursuant to Guidelines § 2N2.1(b)(1).

Many probation offices and courts have employed realistic loss estimates that CPB recommended, estimates reflecting the large losses frequently caused by FDCA violations. *E.g.*, *United States v. Shulman* 107 F.3d 868 (4th Cir. 1997) (table) (over \$80,000,000 in gross sales of drug proper measure of loss where FDA approval of drug based on fraudulent data and resulting drug was of unknown safety and efficacy – resulting in 5 year sentence, which the Fourth Circuit affirmed; *United States v. Marcus*, 82 F.3d 606, 608-10 (4th Cir. 1996) (over \$10,000,000 in gross sales of drug that varied from FDA approved formula appropriate measure of loss – resulting in 41 month sentence); and *United States v. Kohlbach*, 38 F.3d 832, 840-42 (6th Cir. 1994) (affirming consumer loss finding of \$10.3 million based on comparative price of ingredient declared in 37,000,000 gallons of orange juice products sold versus what was actually provided, to wit, sugar); *United States v. Jekot*, 47 F.3d 1176 (9th Cir. 1995) (table) (district court found doctor who sold steroids and human growth hormone outside his medical practice caused over \$200,000 in loss, and imposed a five year sentence, which the Ninth Circuit affirmed in an unpublished opinion.

D. Civil Cases

CPB conducts both affirmative and defensive civil litigation under the FDCA. Affirmatively, CPB handles suits seeking various remedies for FDCA violations. These include suits for injunction, product condemnation, and civil penalties. Defensively, CPB represents FDA and its officers in litigation challenging agency action or inaction.

1. Injunctions

Courts may enter injunctions to restrain conduct that violates the FDCA. 21 U.S.C. § 332. CPB has sought injunctions under the FDCA in a wide variety of contexts. Injunctions have been obtained to enforce compliance with FDA's good manufacturing practice regulations, e.g.,

United States v. Richlyn Laboratories, Inc., 822 F. Supp. 268 (E.D. Pa. 1993); to enjoin the distribution of unapproved drugs or devices, *e.g.*, *United States v. Vital Health Products, Ltd.*, 786 F. Supp. 761 (E.D. Wis. 1992), *aff'd*, 985 F.2d 563 (7th Cir. 1993); to ensure proper sanitation in food-processing facilities, *e.g.*, *United States v. Union Cheese Co.*, 902 F. Supp. 778 (N.D. Ohio 1995); and to control drug residues in food-producing animals, *e.g.*, *United States v. Tuentes Livestock*, 888 F. Supp. 1416 (S.D. Ohio 1995).

Injunctions can have far-reaching effects in an industry. For example, CPB negotiated a consent decree of injunction against the American Red Cross. That decree, negotiated after the AIDS virus threatened America's blood supply, established procedures to ensure the proper handling of blood products at Red Cross facilities across the country to ensure the blood's safety. The decree also established what became industry standards for ensuring the safety of the U.S. blood supply.

CPB frequently files a motion for preliminary injunction along with a complaint for injunction. Temporary restraining orders are less frequently requested, but may be necessary in certain cases to protect the consumer. The standards for preliminary injunctive relief under the FDCA differ from the standards applied in private cases. Once a violation of the FDCA has been proven, a preliminary injunction may issue without proof of irreparable harm. This is because harm is presumed where an FDCA violation exists. *See, e.g.*, *United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 175 (9th Cir. 1987); *United States v. Diapulse Corp.*, 457 F.2d 25, 28 (2d Cir. 1972).

If a defendant violates an injunction, CPB can seek criminal or civil remedies for contempt of court. *E.g.*, *United States v. 22 Rectangular or Cylindrical Finished Devices*, 941 F. Supp. 1086 (D. Utah 1996) (criminal contempt where defendant shipped medical device in violation of court order).

2. Condemnation Actions

Foods, drugs, or devices which are misbranded or adulterated, or which have not received required FDA approval, may be condemned pursuant to 21 U.S.C. § 334. For example, the United States filed a seizure complaint against approximately 15,000,000 pounds of cocoa beans that were stored in unsanitary conditions in Norfolk, Virginia warehouses. This inventory constituted a significant portion of the world's supply of cocoa beans at the time. *U.S. v. 155/137 Pound Burlap Bags, et al.*, No. 2:93cv63 (E.D. Va., filed January 27, 1993).

Thirteen parties filed claims to these beans, requiring a trial of whether the beans were adulterated. After the trial, the court concluded that approximately 90 percent of the beans were adulterated because they had been stored in unsanitary conditions and ordered them condemned. Ultimately, FDA approved a plan for "reconditioning" the beans, which made them safe for use as food.

a. Case Referrals

Unlike requests for criminal prosecution or for injunction, which are referred to CPB, FDA's requests for condemnation are referred simultaneously to CPB and to the appropriate U.S.

Attorney's Office. Simultaneous referral helps expedite the seizure of violative product to prevent distribution to consumers.

Many condemnation actions are routine matters (involving, for example, contaminated or decomposed food) that can be quickly resolved by default or consent decree.

Sometimes, a condemnation action raises significant issues under the FDCA. Medical device cases in particular often present complex questions concerning the reach of FDA's regulatory authority. For example, CPB has prevailed in litigation against specimen collection cups and silicone-filled bags used in breast self-examinations, overcoming contentions that these articles were not "devices" under the FDCA. *See United States v. Undetermined No. of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994) (collection cups); *United States v. 25 Cases, More or Less*, 942 F.2d 1179 (7th Cir. 1991) (Sensor Pads).

b. Proceedings

A condemnation action is an *in rem* proceeding against a violative article. The action is commenced under admiralty rules with the filing of a verified complaint and a request for a civil seizure warrant. The seizure warrant is issued by the clerk of court, rather than by a judge or magistrate judge, and requires no showing of probable cause beyond the allegations in the verified complaint. *See* Rule C(3), Supplemental Rules for Certain Admiralty and Maritime Claims, Federal Rules of Civil Procedure; *United States v. Argent Chemical Laboratories*, 93 F.3d 572 (9th Cir. 1996), *cert. denied*, 117 S. Ct. 1244 (1997). Notice of the action must be made by publication. Rule C(4), Supplemental Rules.

Condemnation renders the violative articles subject to disposal or destruction by the Government. However, the court may release condemned goods for reconditioning, or for re-export in the case of imported goods, if certain conditions are satisfied. 21 U.S.C. § 334(d). Court costs and storage fees may be assessed against any claimant who intervenes in the action. 21 U.S.C. § 334(e).

3. Civil Penalties

Monetary penalties may be awarded for violations of the FDCA involving medical devices, 21 U.S.C. § 333(f), and for certain prohibited acts relating to radiation-emitting electronic products, 21 U.S.C. § 360pp (discussed under a separate heading, below).

4. Defensive Litigation On Behalf Of FDA

Suits are often filed challenging FDA action or inaction. Generally, these suits seek declaratory or injunctive relief. In some cases monetary damages are also requested. Plaintiffs might challenge an agency policy or regulation, *e.g.*, *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592 (5th Cir. 1995); a decision to approve (or not to approve) a drug or device for marketing, *e.g.*, *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484 (D.C. Cir. 1995); or a response to a petition requesting that the agency take (or refrain from taking) certain action, *e.g.*, *Heckler v. Chaney*, 470 U.S. 821 (1985).

Frequently, a plaintiff seeks to enjoin FDA from regulating a product, for example, cigarettes. *See Coyne Beahm, Inc., et al., v. FDA*, 966 F. Supp. 1374 (M.D. N.C. 1997), *rev'd sub nom.*, *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 153 F.3d 155 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000). When FDA has manifested its intention to regulate the product through

rulemaking or other final agency action, CPB defends the agency's action under the FDCA. Plaintiffs do not always await final agency action before bringing suit, however. In those circumstances, CPB has often successfully won dismissals by invoking the doctrines of ripeness and exhaustion of remedies. *E.g.*, *Dietary Supplement Coalition, Inc. v. Sullivan*, 978 F.2d 560 (9th Cir. 1992), *cert. denied*, 508 U.S. 906 (1993). Another defense is that Federal courts lack jurisdiction to enjoin FDA from taking enforcement action. *See Ewing v. Mytinger &*

Casselberry, Inc., 339 U.S. 594 (1950); *United States v. Alcon Laboratories*, 636 F.2d 876, 882 (1st Cir.), *cert. denied*, 451 U.S. 1017 (1981).

E. FDA Inspection Warrants

Administrative inspections under the FDCA are conducted pursuant to 21 U.S.C. § 374. Section 374 provides authority for, and defines the limits of, nonconsensual warrantless inspections of factories, warehouses, and establishments that are subject to the requirements of the FDCA.

1. Referral

FDA generally refers requests for inspection warrants to CPB. In emergencies, FDA will refer warrant requests directly to USAOs. Coordination and cooperation among FDA, the USAO, and CPB is of great importance in these cases. Requests for inspection warrants frequently raise sensitive policy issues for both the agency seeking to inspect and the DOJ.

2. Initial Refusal to Permit Inspection

An establishment which has refused to allow inspection under the FDCA is subject to criminal penalties under 21 U.S.C. §§ 331(f) and 333. However, because a prosecution does not lead to an immediate inspection, the agency should apply to a court for an administrative inspection warrant when it encounters resistance.

Occasionally an establishment will allow an inspection to begin but balk at some aspect of the inspection, such as the taking of photographs. Photographs can provide persuasive evidence of violations. *See, e.g., United States v. Union Cheese Co.*, 902 F. Supp 778, 780, 782 (N.D. Ohio 1995). Photography during an inspection is recognized by courts as appropriate agency activity. *United States v. Gel Spice Co., Inc.*, 601 F. Supp. 1214, 1220-22 (E.D.N.Y. 1985); *United States v. ACRI Wholesale Grocery Co.*, 409 F. Supp. 529, 532-33 (S.D. Iowa 1976). Accordingly, a refusal to allow photographs is considered a partial refusal to permit inspection, and may also result in a request for an administrative warrant.

3. Application for a Warrant

The application for the warrant is *ex parte* and in writing before a United States Magistrate Judge. The application should be made by a representative of FDA, and should be entitled, *e.g.*, In Re Establishment Inspection of [name of establishment]. The application is generally signed by an FDA compliance officer or investigator before the Magistrate. The officer should be accompanied by an Assistant United States Attorney or CPB attorney when the application is made.

The application proceeding should not become a contested hearing. The application need not demonstrate "probable cause" under the standards of a criminal search warrant. Because FDA is authorized to inspect without a warrant, the application need not demonstrate modified

"probable cause" under standards frequently applied in the administrative warrant arena pursuant to *Marshall v. Barlow's Inc.*, 436 U.S. 307 (1978). However, to facilitate the issuance of the warrant, the application should be drafted to meet this modified probable cause standard. Because administrative warrants are seldom needed unless there has been a prior refusal, modified probable cause almost always exists.

4. Failure to Allow Inspection Pursuant to a Warrant

Because FDA agents do not claim the right to enter a business' premises by employing physical force, a Deputy United States Marshal may accompany an FDA investigator pursuant to a warrant, and can use force to compel the inspection authorized by the judicial officer. *See* 18 U.S.C. § 3109; *Marshall v. Shellcast Corp.*, 592 F.2d 1369, 1372 n.7 (5th Cir. 1979). Thus, where resistance to honoring the terms of a warrant is anticipated, and where the enforcement power is available, a Marshal can accompany the FDA investigator when the warrant is served.

If an establishment refuses to comply with an administrative warrant, CPB should be contacted immediately before further action is taken by a United States Attorney's Office.

III. Other Acts Administered by FDA

E. Electronic Product Radiation Control

In 1990, the Radiation Control for Health and Safety Act, 42 U.S.C. §§ 263c-263n, was renamed Electronic Product Radiation Control and recodified as Subchapter C of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 360hh-360ss ("Radiation Control Program"). The Radiation Control Program applies to products such as X-ray units, suntanning bulbs, sonography equipment, microwaves, lasers, and televisions, 21 U.S.C. §§ 360hh(1), (2), and to persons who import, assemble, sell and manufacture electronic products. 21 U.S.C. § 360hh(3).

The Secretary of Health and Human Services implements and enforces the Radiation Control Program, 21 U.S.C. § 360ii, and has delegated those functions to FDA. 21 C.F.R. § 5.10(a)(3). The statute authorizes FDA to issue performance standards for electronic products. 21 U.S.C. § 360kk. FDA's regulations, 21 C.F.R. Subchapter J, include performance standards for products such as X-ray units, CT scan equipment, microwave emitting products, lasers, sonic, and ultrasonic products. 21 C.F.R. Part 1010 - 1050.

The Radiation Control Program establishes record keeping requirements for manufacturers and importers of regulated products. It also mandates that assemblers and installers file reports with FDA. Manufacturers must also repair, replace, or refund the cost of defective products. 21 U.S.C. § 360ll(f).

The Radiation Control Program prohibits regulated persons from failing to: 1) keep required records, 2) furnish required reports, or, 3) repair, replace, or refund the cost of a defective electronic product. 21 U.S.C. § 360oo. Section 360pp specifically authorizes the United States to file actions in Federal district court for civil penalties and for injunctive relief. For each violation of 21 U.S.C. § 360oo, each named defendant is subject to a civil penalty of up to \$1,000. (Civil penalty maximums for all statutes have been adjusted upward, generally by 10 percent, to account for inflation. Regular upward adjustments will be made in the future pursuant to the Civil Monetary Penalties Provision of the Debt Collection Improvement Act of 1996.) Thus, if both a corporation and an individual are named as defendants, each may be held separately

liable for civil penalties. *United States v. Hodges X-Ray*, 759 F.2d 557 (6th Cir. 1985); *United States v. DeHaven & Associates, et al.*, No. 95-1177(F) (E.D. La., February 9, 1996) (holding both corporation and its president liable for civil penalties on summary judgment).

Although under *Tull v. United States*, 481 U.S. 412 (1987), liability for civil penalties is a fact issue to be decided by a jury, the amount of civil penalties to be assessed is determined by the court without a jury. *Tull*, 481 U.S. at 426. The amount of civil penalties may be determined on the

briefs and without an evidentiary hearing. *Hodges*, 759 F.2d at 564-65; *DeHaven*. Unlike the Federal Trade Commission Act, 15 U.S.C. § 45(m)(1), Section 360pp of the FDCA does not specify the factors that a court must consider in determining the amount of a civil penalty. However, it is likely that a court, in its discretion, would consider those factors, which include ability to pay, degree of culpability and history of prior violations.

The procedure for referring and handling cases under the Electronic Product Radiation Control provisions is the same as that for other FDA cases.

F. The Fair Packaging and Labeling Program

The Fair Packaging and Labeling Program, 15 U.S.C. §§ 1451-1461, enacted in 1966 and substantially amended in 1992, prohibits any person who packages or labels consumer commodities, as defined, from distributing commodities that are not packaged and labeled as required by this program and its implementing regulations. 15 U.S.C. § 1452. The law is designed to ensure that consumers receive accurate and usable information about consumer commodities from the labeling on their packages.

Consumer commodities include any food, drug, device or cosmetic, as defined by FDA, and any other article, product or commodity customarily produced or distributed through retail sales agencies for use or consumption by individuals. 15 U.S.C. § 1459(a). Meat, poultry, tobacco products, and specified beverages, drugs, and agricultural products regulated under other statutes and programs are excluded from the definition of consumer commodity. 15 U.S.C. § 1459(a)(1)-(5).

The law specifies the kind of information that must be provided to consumers. Required items include the net quantity of contents and an identification of the manufacturer. Such information be conspicuously displayed. 15 U.S.C. § 1453.

"Secret ingredients" which FDA recognizes as trade secrets do not need to be separately identified on the package. In cases in which FDA denied trade secret status, manufacturers sometimes challenge FDA's administrative procedures for making such determinations. *Zotos International, Inc. v. Young*, 830 F.2d 350 (D.C. Cir. 1987); *Carson Products Co. v. Califano*, 594 F.2d 453 (5th Cir. 1979); *Del Laboratories, Inc. v. United States*, 86 F.R.D. 676 (D.D.C. 1980).

FDA is authorized to issue regulations relating to the packaging and labeling of foods, drugs, medical devices, and cosmetics. 15 U.S.C. §§ 1453, 1454. FDA labeling requirements under the FDCA may be found at 21 C.F.R. Part 1, Subpart B (general), Part 101 (food), Part 201 (drugs), and Part 801 (devices). Labeling requirements issued under this Act for cosmetics are codified at 21 C.F.R. Part 701. The FTC is authorized to issue similar regulations for all other consumer commodities, 15 U.S.C. §§ 1453, 1454, and those regulations have been codified at 16 C.F.R. Subchapter E (Parts 500-503). In 1992 the Act was amended to authorize the regulating agency to issue additional packaging and labeling standards upon determining those measures are

required to prevent deception of consumers or to facilitate value comparisons. 15 U.S.C. § 1454(c).

The Fair Packaging and Labeling Act contains a savings provision that makes clear that it shall not be deemed to repeal the FTC Act, any antitrust law, the FDCA, or the Federal Hazardous Substances Labeling Act. 15 U.S.C. § 1460. There is also a preemption provision setting forth Congress' intent to supersede less stringent State laws. 15 U.S.C. § 1461. After passage of the Act,

the issue of whether particular State laws were preempted by the Fair Packaging and Labeling Act was litigated, and these State laws were determined preempted by the Federal law. *See, e.g., Jones v. Rath Packing Co.*, 430 U.S. 519 (1977), *reh'g. denied*, 431 U.S. 925 (1977) (California law preempted); *L & L Started Pullets, Inc. v Gourdine*, 762 F.2d 1 (2d Cir. 1985) (New York law not preempted).

Foods, drugs, medical devices, or cosmetics introduced into commerce with packaging or labeling that does not conform to law are misbranded. 15 U.S.C. § 1456(a). Distribution of such articles may be enjoined or the articles may be seized pursuant to 21 U.S.C. § 334. Violations of the Act which involve other consumer commodities constitute unfair or deceptive practices under 15 U.S.C. § 45(a), and are subject to enforcement under 15 U.S.C. § 45(b). 15 U.S.C. § 1456(b). The United States Customs Service is authorized to enforce the Act with respect to violative consumer commodities imported into the United States. Enforcement procedures are the same as for FDCA cases and FTC cases.

G. The Public Health Service Act

The Public Health Service Act, 42 U.S.C. §§ 262, 264, regulates certain biologic products such as blood, tissues, vaccines, and genetically engineered products. The law is designed to protect both donors and recipients from communicable diseases and other illness. The Public Health Services Act provides for the licensing of biological products and clinical laboratories. Both the establishments and the products for which the license is desired must meet regulatory standards designed to insure the continued safety, purity, and potency of the products. The products may only be licensed upon a showing that they meet such standards.¹

Violations are punishable by a civil penalty of up to \$100,000 per day of violation, or by criminal prosecution. 42 U.S.C. § 262(d), (f). *See United States v. Blood Systems, Inc. and J. Daniel Connor*, Civil No. 96-0967 (D. Ariz., April 22, 1996)(consent decree requiring the second largest blood bank in United States and its President/CEO to take measures to insure safety and integrity of blood and blood products); *United States v. American Red Cross*, 1993 WL 186094, Civil No. 93-0949 (D.D.C., May 12, 1993)(consent decree against Red Cross for violations of PHSA); *United States v. Steinschreiber*, 219 F. Supp. 373 (S.D.N.Y. 1963), *aff'd*, 326 F.2d 759

¹ FDA has promulgated regulations governing the licensing of biologics for commercial use. 21 C.F.R. Subchapter F (Parts 600 - 680), 21 C.F.R. Part 1270 (human tissue transplants). Biologics are not "new drugs" under the FDCA, but biologics have a secondary regulatory status as either drugs or devices which governs the clinical investigation procedures that must be followed prior to licensing a product. *See, for example*, 21 C.F.R. Part 312 (requirements for investigational new drug applications). In addition, manufacturers of biologics must comply with certain requirements as a pre-condition to obtaining an establishment license. 21 C.F.R. Part 601, Subpart B. In *Berlex Laboratories v. FDA*, 942 F. Supp. 19 (D.D.C. 1996), the Court rejected a challenge, based in part on the PHSA, to FDA's approval of a competitor's biologic product.

(2d Cir. 1964), *cert. denied*, 376 U.S. 962 (1964) (criminal); *United States v. Calise*, 217 F. Supp. 705 (S.D.N.Y. 1962) (criminal).

The Act authorizes the issuance of regulations to control communicable diseases. 42 U.S.C. § 264. Violations of any regulation issued under this provision may be prosecuted criminally. 42 U.S.C. § 271(a). FDA refers cases for enforcement of the PHSA through the same procedures applicable to referrals under the FDCA.

IV. The Federal Trade Commission Act

CPB is responsible for civil and criminal actions brought under the Federal Trade Commission Act, 15 U.S.C. §§ 41-58 ("FTC Act"). These cases generally fall into three categories: 1) enforcement actions for civil penalties and injunctive relief based on violations of final orders issued by the FTC; 2) enforcement actions for civil penalties and injunctive relief based on violations of FTC trade regulation rules; and 3) prosecutions for criminal violations of the FTC Act, and for violations of district court orders obtained under the FTC Act.

E. Case Referral

In general, under the FTC Act, the FTC must notify the Attorney General of its intention to commence, defend, or intervene in any civil penalty action under the FTC Act. 15 U.S.C. § 56(a)(1). The Department of Justice then has 45 days from the date of the receipt of notification by the Attorney General in which to commence, defend, or intervene in the suit. *Id.* If the Department does not act within the 45-day period, the FTC may file the case in its own name, using its own attorneys. *Id.*

However, the Department may commence, defend, or intervene in the suit even after the 45-day period expires, during which time the Department and the FTC have concurrent authority. *United States v. Restland Funeral Home, Inc.*, 51 F.3d 56 (5th Cir. 1995), *cert. denied*, 116 S. Ct. 772 (1996).

Notification under 15 U.S.C. § 56 is made directly to the Attorney General, and transmitted to CPB for review. The FTC frequently asks the DOJ to decline to handle, and thus permit the FTC to file in its own name, cases alleging violations of antitrust orders. The Department acquiesces in these requests if the facts of the case do not suggest that CPB's participation necessary, such as a potential for criminal violations.

Other than the cases discussed above, the Department generally files all cases that are referred. After CPB reviews the case, the appropriate pleadings are transmitted to the United States Attorney's Office for final review and filing. In general, CPB personally handles these FTC cases.

F. Actions for Civil Penalties and Injunctive Relief for Violations of Final Orders Issued by the FTC

Actions for civil penalties and injunctive relief for violations of final orders issues by the FTC are primarily brought under two sections of the FTC Act: (1) Section 45(l) for violations of orders previously entered by the FTC against the defendant under the FTC Act; and (2) Section

In recent criminal contempt actions, CPB has obtained sentences of four to five years imprisonment for violations of final judgments in FTC cases. This has resulted from analysis under the Sentencing Guidelines which takes into account the amount of fraudulent behavior the defendant engaged in that violated the Order.

V. Other Acts Administered by the FTC

E. Consumer Credit Protection Act

The Consumer Credit Protection Act, 15 U.S.C. §§ 1601-1667, includes the Truth in Lending Act and establishes disclosure and other requirements when credit is extended, advertised, and billed to consumers. The Act also deals with disclosures and other requirements for consumer leases. The FTC is responsible for enforcing those requirements imposed under this Act that are not committed to another agency. *See* 15 U.S.C. § 1607(c).

A violation of any requirement under the Consumer Credit Protection Act is deemed a violation of a requirement imposed under the FTC Act. *Id.* All the functions and powers of the FTC under the FTC Act are thus available to the FTC in enforcing compliance with the Consumer Credit Protection Act. Regulations M (consumer leases, amended in 1996 specifically to include a focus on auto leasing) and Z (truth in lending), 12 C.F.R. §§ 213 *et seq.* and 226 *et seq.*, respectively, set forth regulations issued by the Federal Reserve Board under the Act, and include sample forms and disclosures.

CPB's enforcement responsibilities include criminal cases under 15 U.S.C. § 1611 and civil penalty cases based on orders and trade regulation rules issued by the FTC.

1. Civil Penalty Cases

Civil penalty actions are referred to CPB and handled in the same way as other civil penalty actions under the FTC Act.

2. Criminal Cases

Knowing and willful violations of the Consumer Credit Protection Act are misdemeanors, as provided in 15 U.S.C. § 1611.

F. The Fair Credit Reporting Act

The Fair Credit Reporting Act ("FCRA"), 15 U.S.C. § 1681, requires consumer reporting agencies to adopt certain procedures relating to consumer credit, personnel, insurance, and other information to ensure the confidentiality, accuracy, reliability and proper verification of the information in accordance with the Act. The FTC is responsible for administrative enforcement of compliance with the FCRA, except to the extent that enforcement responsibility is specifically committed to another agency under 15 U.S.C. § 1681s(a). A violation of any requirement or prohibition imposed under the FCRA is treated as a violation of the FTC Act. *Id.* The FTC may thus use all of the procedural, investigative, and enforcement powers available to it under the FTC Act as if they were part of the Fair Credit Reporting Act.

Some significant recoveries under the FCRA and other Acts include *United States v. Tower Loan of Mississippi, Inc.*, Civ. No. J90-0447(L) (S.D. Miss.) (\$175,000 civil penalty and over \$1.3 million in consumer redress for violations of ECOA and FCRA, with additional \$100,000 civil penalty and \$240,000 consumer redress in 1997 action related to order violations); *United States v. Academic International, Inc.*, No. 1-91-CV-02738 (N.D. Ga., November 26, 1991) (\$150,000 civil penalty for violations of ECOA, FDCPA and FCRA).

Criminal cases under the Fair Credit Reporting Act can be brought when a person knowingly and willfully obtains information on a consumer from a consumer reporting agency under false pretenses. 15 U.S.C. § 1681q. In 1998, CPB obtained the conviction of an individual in Colorado who had fraudulently obtained a credit report to use in a political campaign. Criminal charges also lie where a consumer reporting agency knowingly and willfully provides information concerning an individual to a person not authorized to receive that information. 15 U.S.C. § 1681r. The criminal provisions of the FCRA are only enforced by the Department of Justice.

G. The Credit Repair Organizations Act

The Credit Repair Organizations Act (“CROA”), 15 U.S.C. § 1679-1679j, regulates those offering "credit repair" services, especially "credit repair organizations." These organizations are defined to include any person, including an attorney, who uses interstate commerce or the mails to sell or provide services for the express or implied purpose of improving any consumer's credit history. 15 U.S.C. § 1679a(3). Violations of CROA are treated as a violation of the FTC Act, making all of the enforcement powers of the FTC available. 15 U.S.C. § 1679h(b). The statute became effective in 1997. In 1998, CPB brought a series of cases that led to injunctive relief against several firms for CROA violations involving misleading practices and other violations.

Commonly, credit repair organizations promise to "repair" consumers' credit by employing the FCRA's verification provisions. The FCRA requires that if a credit reporting agency cannot verify a challenged item on a credit report, the credit reporting agency must delete the item. 15 U.S.C. § 1681i(a). CROA prohibits misrepresentations of the services a credit repair organization can provide. 15 U.S.C. § 1679b(a)(3). Common misrepresentations include claims that such organizations can remove negative items from credit reports due to alleged difficulties in the verification process. However, verification is usually automated, and most debts may remain on a consumer's report for seven years, 15 U.S.C. § 1681c (a) (2) - (6), and bankruptcies for ten years, 15 U.S.C. § 1681c (a) (1). Thus, claims that most consumers can get such items removed from credit reports frequently violate CROA.

CROA also prohibits requiring advance payments for promised services. 15 U.S.C. § 1679b(b). Thus, credit repair organizations cannot lawfully promise to "repair credit" and collect money for their services before accomplishing that goal.

CROA also prohibits "file segregation" schemes, which are advertised as a way of creating a new credit identity. File segregation operators advise the consumer to apply to the Internal Revenue Service (“IRS”) for an Employer Identification Number (“EIN”). Consumers are told to use the EIN in lieu of their Social Security Number when applying for credit in order to create a completely new credit file in which the old debts will not appear. The scheme essentially involves an attempt to hide one's identity from creditors by getting credit with the EIN and a name and address that differ slightly from accurate identifiers.

Both the person selling such a scheme and consumers who follow the scheme are violating the law. CROA bars any person from making or counseling any consumer to make any untrue or

misleading statement the intended effect of which is to alter the consumer's identification in an effort to hide accurate credit information. 15 U.S.C. § 1679b(a)(2). Consumers following such advice may be committing felonies. *See* 42 U.S.C. § 408(a)(7)(B) (falsely representing a number to be the social security account number); 18 U.S.C. § 1014 (false statement on credit application). In 1999, CPB brought a series of cases seeking injunctions and civil penalties against businesses that offered "file segregation" schemes.

H. Equal Credit Opportunity Act

The Equal Credit Opportunity Act (“ECOA”), 15 U.S.C. § 1691, also part of the Consumer Credit Protection Act discussed above, requires that financial institutions and other firms engaged in the extension of credit make that credit equally available to all credit-worthy customers. The Federal Trade Commission is responsible for administrative enforcement of compliance with the ECOA, except to the extent that enforcement responsibility is specifically committed to another agency under 15 U.S.C. § 1691c(c). A violation of any requirement of the ECOA is treated as a violation of the FTC Act, and enforced in the same manner as if the violation had been a violation of an FTC trade regulation rule. *Id.*

CPB's enforcement responsibility includes civil penalty cases, *e.g.*, *J.C. Penney Company, Inc.* (E.D. N.Y. 1996) (civil penalty of \$225,000), and *Barclays America Corporation* (W.D. N.C. 1991) (penalty of \$265,000). The Civil Rights Division also has authority under 15 U.S.C. § 1691e(h) to bring a civil action seeking injunctive relief when it has reason to believe that the defendant is engaged in a "pattern or practice" in violation of this Act. Regulation B, 12 C.F.R. § 202 *et seq.*, contains the regulations issued by the Federal Reserve Board under the Act, and includes sample forms and disclosures.

I. Fair Debt Collection Practices Act

The Fair Debt Collection Practices Act ("FDCPA") prohibits the use of abusive and harassing debt collection practices by debt collectors. The term "debt collector" generally does not cover creditors collecting their own debts. *See* 15 U.S.C. § 1692a(6). The United States Supreme Court has held that the term does cover attorneys regularly engaged in consumer debt collection litigation on behalf of a creditor client. *Heintz v. Jenkins*, 115 S. Ct. 1489 (1995).

The FTC is responsible for administrative enforcement of compliance with the FDCPA, except to the extent that enforcement responsibility is specifically committed to another agency under 15 U.S.C. § 16921. A violation of the FDCPA is treated as an unfair or deceptive act or practice in violation of the FTC Act. Civil penalty cases can be brought pursuant to 15 U.S.C. § 16921(a). That section provides that the FTC may use all of its functions and powers under the FTC Act, including the power to enforce the FDCPA in the same manner as if the violation had been a violation of an FTC trade regulation rule.

CPB's enforcement responsibility includes civil penalty and injunction cases. Civil penalties and FDCPA injunctions were obtained against major debt collection companies in *United States v. National Financial Services*, 98 F.3d 131 (4th Cir. 1996) (affirming trial court's decision on summary judgment, which found that defendants had — in millions of computer-generated collection notices that made both false threats to sue debtors and failed to comply with the Act's validation notice requirements — violated the FDCPA repeatedly and deliberately; the court assessed a civil penalty of \$500,000 against National Financial Services and its president, and \$50,000 against an attorney); *United States v. Payco American* (E.D. WI. 1995) (consent decree for injunctive relief — barring violations of FDCPA by harassing consumers in collecting money on behalf of creditors, and requiring Payco to advise consumers and Payco's employees of consumers' rights under the FDCPA — and to pay civil penalties of \$500,000); and *United States v. Trans Continental Affiliates, et al.*, 1997 WL 26297 (N.D. Cal. 1997) (granting partial summary judgment and imposing injunction against further violations by officers who had authority to control violative acts).

J. Wool Products Labeling Act, Fur Products Labeling Act, and Textile Fiber Products Identification Act

Three statutes, the Wool Products Labeling Act, Fur Products Labeling Act, and Textile Fiber Products Identification Act (15 U.S.C. §§ 68-70) establish Federal requirements for the labeling of wool, fur, and textile products. Such labeling, under the statutes and implementing regulations, must include information regarding the country of origin and a breakdown of the fiber content of the products. The FTC is responsible for administrative enforcement of the Acts. A violation of these Acts is considered a violation of the FTC Act.

The Department of Justice has enforcement authority that includes seizures (15 U.S.C. § 68e and § 69g), injunctions (15 U.S.C. § 68e, § 69g and § 70f), civil penalty cases and criminal actions (15

U.S.C. § 68h, § 69i and § 70i). CPB has brought several actions on behalf of the FTC against companies violating these statutes. For example, under the Textile Fiber Products Identification Act, 15 U.S.C. § 70, CPB obtained a \$100,000 criminal fine against a firm that misrepresented the correct fiber content of carpets it sold. *Diamond Rug*, Cr. No. 1-95-CR-539 (N.D. Ga., February 29, 1996). CPB also obtained civil penalties of \$130,000 from K-Mart in connection with misrepresentations of the cotton content of shirts. *K-Mart Corporation (Wishbone Trading Co.)*, Civ. No. 91-2223 (C.D. Ca., April 30, 1991).

K. Magnuson-Moss Warranty Act

The Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301-2312, requires that persons who sell products with written warranties must "fully and conspicuously disclose in simple and readily understood language the terms and conditions of such warranty." 15 U.S.C. § 2302. The FTC has promulgated a rule concerning the specific items that must be included in a written warranty. 16 C.F.R. Part 700. The FTC and the Attorney General both have the authority to bring actions under Magnuson-Moss. Such actions may be brought to restrain a warrantor from making a deceptive warranty or to restrain any person from violating either the sections or a rule promulgated under them. There is also specific provision for the issuance of a temporary restraining order or preliminary injunction. 15 U.S.C. § 2310(c). There are no criminal penalties for violations. The Magnuson-Moss Warranty Act does, however, provide for private remedies. 15 U.S.C. § 2310(d).

L. Telephone Disclosure and Dispute Resolution Act, Telemarketing and Consumer Fraud and Abuse Prevention Act

The Telephone Disclosure and Dispute Resolution Act, and the Telemarketing and consumer Fraud and Abuse Prevention Act (15 U.S.C. §§ 5701 and 6101) deal with the conduct of business by telephone, and each statute authorizes both FTC and State attorney general enforcement actions. First, to deal with abuses arising from the proliferation of pay-per-call (900 number) services, Congress enacted the Telephone Disclosure and Dispute Resolution Act, and provided that the FTC was to issue regulations of the industry's advertising practices, pay-per-call service standards, and billing and collection practices. Violations of these FTC rules (16 C.F.R. § 308 *et seq.*) are treated as if they were violations of the FTC Act, and the Commission has all the same functions, powers and penalties as are available under the FTC Act. The first 900 number case resulted in a negotiated civil penalty of \$500,000, along with a \$2 million consumer redress fund. *United States v. American TelNet*, No. 94-2551-Civ (S.D. Fl., decree entered December 12, 1994).

Second, to address abusive telemarketing practices, Congress enacted the Telemarketing and Consumer Fraud and Abuse Prevention Act, and directed the FTC to prescribe rules to prohibit these practices. Violations of those FTC rules (16 C.F.R. § 310 *et seq.*) are similarly treated as if they were violations of the FTC Act. The FTC has all the same functions, powers, and penalties that are available under the FTC Act.

In addition, the Telemarketing Act encourages criminal contempt actions for violations of orders for injunctive relief that the FTC has obtained in district court pursuant to 15 U.S.C. § 53(b). In order to bring such actions, the FTC is authorized to request that the Attorney General appoint an FTC attorney to be a Special Assistant United States Attorney to prosecute the case, and the Attorney General must act on that request within 45 days of receipt. *See* 15 U.S.C. § 6107.

These requests for special appointment are made to the Attorney General and reviewed within CPB. If CPB believes the request to be warranted, it will contact the appropriate United States Attorney's Office and help arrange for the appointment. For a discussion of factors to be considered in determining whether such a request is appropriate, see *F.T.C. v. American National Cellular*, 868 F.2d 315 (9th Cir. 1989). CPB attorneys will normally handle these cases personally, in conjunction with the FTC attorney appointed as a Special Assistant.

VI. The Consumer Product Safety Commission

CPB is responsible for civil and criminal affirmative litigation, and defensive civil litigation, under statutes administered by the United States Consumer Product Safety Commission (the "CPSC"). Affirmatively, CPB may assist the CPSC in its enforcement work by invoking a variety of statutory remedies for violations. CPB may also support the CPSC's enforcement work by seeking court intervention when necessary to overcome resistance to administrative proceedings. Defensively, CPB represents CPSC in Federal court challenges to its actions.

E. Statutes Administered by the CPSC

The Consumer Product Safety Act, 15 U.S.C. §§ 2051 *et seq.* ("CPSA"), confers on the CPSC broad authority to protect the public against unreasonable risks of injury from consumer products. However, Congress has directed that the CPSC should, absent an express finding of need, rely on alternative, more targeted authority to address risks presented by defined categories of consumer products. 15 U.S.C. § 2079(d).

The alternative authority is conferred by the Flammable Fabrics Act, 15 U.S.C. §§ 1191 *et seq.* (the "FFA"), the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261 *et seq.* (the "FHSA"), and the Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471 *et seq.* (the "PPPA"). In addition, the CPSC administers the Refrigerator Safety Act, 15 U.S.C. § 1211 *et seq.* ("RSA"). The scope of each of these statutes is outlined below. These outlines, however, are not an exhaustive treatment of enforcement remedies and tools available to the CPSC.

1. The Consumer Product Safety Act

Regulatory jurisdiction under the CPSA extends fairly broadly across the range of consumer products.² The CPSC has authority under the CPSA to promulgate binding labeling or performance standards, or rely expressly on non-governmental standards, to protect the public from unreasonable risks of injury from consumer products. 15 U.S.C. § 2056. In addition, the CPSA provides for mandatory reporting (by manufacturers, distributors, and retailers) of known failures of consumer products to meet applicable standards, of information suggesting a product defect that could create a substantial risk of injury, and of information suggesting an inherent unreasonable risk of serious injury or death. 15 U.S.C. § 2064(b).³

On the basis of information reported in compliance with § 2064(b) or obtained through other means,⁴ the CPSC is broadly empowered, through administrative processes, to order appropriate corrective action as to hazardous consumer products. The CPSC can, for instance, require product recalls or a halt to distribution. 15 U.S.C. § 2064(c) and (d). The CPSA authorizes the CPSC to conduct on-site inspections of regulated firms for enforcement purposes. 15 U.S.C. § 2065.

2. The Flammable Fabrics Act

The FFA authorizes the CPSC to issue binding flammability and related labeling standards to protect the public against unreasonable risks of fire that could lead to death, personal injury, or significant property damage. 15 U.S.C. § 1193. Jurisdiction under the FFA extends essentially to clothing and to interior furnishings composed of fabric and related materials. 15 U.S.C. § 1191. One distinctive feature of the FFA is that it deems any violation to be unlawful conduct under the Federal Trade Commission Act and equips the CPSC with authority to take enforcement action according to the remedies and procedures provided for by that Act. 15 U.S.C. §§ 1192, 1194(a) - (c).

3. The Federal Hazardous Substances Act

The FHSA confers jurisdiction over defined categories of potentially injurious consumer goods presenting hazards such as toxicity, combustion, radioactivity, or unreasonable risks to children of electric shock, choking, burns to the skin, or other physical harm. *See generally* 15 U.S.C. § 1261 (definitions).⁵ To address unreasonable risks of injury within the scope of the FHSA, the CPSC may by rule impose binding labeling requirements, performance standards, or, if need be, outright product bans. In addition, the FHSA generally subjects all hazardous substances to certain baseline labeling requirements. 15 U.S.C. §§ 1261(p), 1262.

² Certain categories of products — including tobacco, pesticides, motor vehicles, and products subject to FDA jurisdiction — are expressly exempt from regulation under the CPSA. *See* 15 U.S.C. § 2052(a)(1).

³ By regulation, the CPSC has made the finding necessary to confirm that the reporting requirements of 15 U.S.C. § 2064(b) apply to products within the ambit of the FFA, the FHSA, and the PPPA. 16 C.F.R. § 1115.2(d).

⁴ The CPSC might otherwise gather such information through independent investigation, or pursuant to 15 U.S.C. § 2084, which requires the manufacturer of a consumer product to report information about products liability litigation in defined circumstances.

⁵ As does the CPSA, the FHSA expressly exempts certain categories of goods from regulation. 15 U.S.C. § 1261(f)(2) and (f)(3).

As does the CPSA, the FHSA broadly empowers the CPSC, through administrative processes, to order appropriate corrective action to guard against unreasonable risks, including product recalls and a halt to distribution. 15 U.S.C. § 1274(a), (b), and (c). Like the CPSA, the FHSA authorizes the CPSC to conduct on-site inspections of regulated firms for purposes of enforcement. 15 U.S.C. § 1270.

4. The Poison Prevention Packaging Act of 1970

The PPPA applies to household substances within both CPSC and FDA jurisdiction. It authorizes the CPSC, by rule, to set standards for labeling and packaging so as to protect children from potential serious harm. If it is within the CPSC's jurisdiction, a household product that is subject to a PPPA standard, and that fails to meet it, is deemed to be improperly labeled under the FHSA. 15 U.S.C. § 1261(p). By dint of that cross-reference, any CPSC enforcement action founded upon a PPPA standard would proceed under authority conferred by the FHSA.

5. The Refrigerator Safety Act 38

The RSA requires that household refrigerators be equipped with a mechanism allowing the door to be opened from the inside, in accordance with standards prescribed by the CPSC. 15 U.S.C. §§ 1211, 1213.

F. CPB Litigation in Conjunction with the CPSC

The enforcement remedies and tools available under statutes that the CPSC administers are largely parallel, as are the types of litigation that CPB conducts under those statutes. Each major type is discussed below, with reference to illustrative cases and underlying statutory authority. These statutes share a design feature in how they prohibit specified behavior and provide remedies. Each statute enumerates in one section the "unlawful" or "prohibited" acts. *See* 15 U.S.C. § 2068 (CPSA), 15 U.S.C. § 1192 (FFA), 15 U.S.C. § 1263 (FHSA), 15 U.S.C. § 1211 (RSA).

Sanctions (either civil or criminal) and injunctive relief are available upon an adequate showing of "unlawful" or "prohibited" conduct. Most commonly, CPB's enforcement litigation focuses upon conduct such as the unlawful interstate distribution of goods that fail to comply with pertinent performance or labeling requirements, the failure to make required product hazard reports, or the failure to permit a statutorily-authorized facility inspection.

1. Criminal Prosecution

The CPSC-administered statutes all provide for the remedy of criminal prosecution. 15 U.S.C. § 2070 (CPSA), 15 U.S.C. § 1196 (FFA), 15 U.S.C. § 1264 (FHSA), 15 U.S.C. § 1212 (RSA). Although the *mens rea* ("guilty mind," referring to the mental elements of criminal conduct) required for conviction differs from statute to statute (as do some other particulars), the maximum term of incarceration for a conviction under any of the pertinent provisions does not exceed one year. Thus, these are misdemeanor provisions. Nevertheless, where appropriate, CPB can utilize other criminal statutes, including felony provisions, to prosecute conspiracy, fraud, obstruction of justice, false statements, and other related Federal offenses that may emerge in the context of CPSC regulation.

In one Colorado prosecution, the defendant pled guilty to 15 misdemeanor violations of the FHSA and PPPA. The defendant sold poisonous chemicals used in solar power systems. He distributed them in recycled food containers lacking child-resistant closures and required warning labels. This led to one death, and thereafter the defendant continued shipping products in unlawful packaging. He was sentenced in 1998 to over 23 months' incarceration for these misdemeanor violations. In another case, CPB prosecuted a manufacturer of unsafe baby pacifiers and rattles. The case led to a plea agreement providing for the maximum possible criminal fines under the FHSA. *See United States of America v. Luv N' Care International, Inc. et al.*, 897 F. Supp. 941 (W.D. La. 1995) (relating to the disposition of pretrial motions).

2. Suit for Civil Penalties

Knowing violations of CPSC-administered statutes may also be sanctioned through the assessment of civil penalties. 15 U.S.C. § 2069 (CPSA), 15 U.S.C. § 1194(e) (FFA), 15 U.S.C. § 1264(c) (FHSA). Determination of appropriate penalty amounts is guided by criteria specified in the statutes. The statutes also impose limits on the amounts recoverable for individual violations and for related series of violations. The ceilings allow for assessment of penalties for a related series of violations in excess of \$1 million, depending on the number of violative products involved.

In 1996, after extensive civil discovery, CPB settled companion suits against a major manufacturer of juvenile products by accepting a civil penalty of \$725,000. *United States v. Cosco, Inc.*, Nos. IP-95-1648 and IP-95-1649 (S.D. Ind., filed December 11, 1995). In the suits, CPB contended that Cosco, Inc., the manufacturer, had knowingly failed to comply with product

hazard reporting requirements by withholding from the agency dozens of consumer complaints about entrapment of the head or neck of children in toddler beds and accessory guardrails.

3. Suit for Injunction

Federal district courts are expressly authorized under the leading CPSC-administered statutes to restrain violations of the statute or of CPSC orders. 15 U.S.C. § 2071(a) (CPSA), 15 U.S.C. § 1267 (FHSA). Courts also have authority to grant interim injunctive relief pending the completion of administrative proceedings. 15 U.S.C. § 2064(g) (CPSA), 15 U.S.C. § 1195(a) (FFA). CPB may seek orders of injunction either as part of a civil suit also seeking civil penalties, or independently. *United States v. Focht*, 882 F.2d 55 (3d Cir. 1989), is an example of the type of involved litigation that may ensue if the CPSC encounters resistance in trying to obtain injunctive relief.

4. Inrem Seizure Actions

CPSC-administered statutes also provide for the removal of violative goods from the market through *in rem* seizure actions. 15 U.S.C. § 2071(b) (CPSA), 15 U.S.C. § 1195(b) (FFA), 15 U.S.C. § 1265 (FHSA).

5. Enforcement Assistance

Resort to the courts may occasionally be necessary to vindicate the CPSC's statutory authority to conduct inspections, issue administrative subpoenas, and the like. *In re Establishment Inspection of Skil Corporation*, 846 F.2d 1127 (7th Cir. 1988), illustrates the kind of court intervention that CPB may pursue on the CPSC's behalf.

6. Defensive Litigation

CPB represents the CPSC in Federal court when aggrieved parties seek to invalidate its actions, or to compel action contrary to the CPSC's intended course. Most commonly, challenges are raised to labeling or performance requirements that the CPSC may promulgate under the statutes it administers. *O'Keefe's, Inc. v. U.S. Consumer Product Safety Comm'n.*, 92 F.3d 940 (9th Cir. 1996), is representative of CPB's defense of the CPSC in such a context.

VII. The Federal Odometer Tampering Statutes

Altering the mileage reading on a motor vehicle is a felony. Effective July 5, 1994, the odometer tampering statutes were recodified from Title 15, U.S.C., to Title 49. The change was not substantive, though the statutes were reworded. Some of the old and new statutes are:

- Tampering prohibition: moved from 15 U.S.C. § 1984 to 49 U.S.C. § 32703(2).
- False odometer statement prohibition: moved from 15 U.S.C. § 1988 to 49 U.S.C. § 32705(a)(2).
- Odometer fraud conspiracy prohibition: moved from 15 U.S.C. § 1986 to 49 U.S.C. § 32703(4).
- Criminal penalty provision: moved from 15 U.S.C. § 1990c to 49 U.S.C. § 32709(b).

E. The Nature of Odometer Fraud

Odometer fraud is a pernicious crime that robs thousands of dollars from each victim it touches. See, e.g., *United States v. Whitlow*, 979 F.2d 1008, 1012 (5th Cir. 1992) (under sentencing

guidelines, court affirmed estimate that consumers lost \$4,000 per vehicle). The television news magazine *60 Minutes* once characterized odometer as the largest consumer fraud in America. Odometer-tampering involves several interrelated activities. Late-model, high-mileage vehicles are purchased at a low price. The vehicles are "reconditioned" or "detailed" to remove many outward appearances of prolonged use. Finally, odometers are reset, typically removing more than 40,000 miles.

In addition to the cosmetic "reconditioning" of the car, the odometer tamperer "reconditions" paperwork. Automobile titles include a declaration of mileage statement to be completed when ownership is transferred. To hide the actual mileage that is declared on the title when the car is sold to an odometer tamperer, the tamperer must take steps to conceal this information. These steps vary from simple alteration of mileage figures to creating fictitious transfers to "straw" dealerships to make it unclear who was responsible for the odometer rollback and title alteration. Alternatively, the odometer tamperers frequently destroy original title documents indicating high-mileage, and obtain duplicate certificates of title from state motor vehicle departments, upon which the false, lower mileage figures are entered.

Whatever method is used, the result is the same: the odometer tamperer possesses an altered, forged, or replacement title document (which is a security under Federal law) containing a false low-mileage reading. This title is used to sell the car, for several thousand dollars above its actual value, to a purchaser who is deceived regarding the vehicle's remaining useful life by the altered odometer, by the vehicle's outward appearance, and by the counterfeit, low-mileage title and odometer statement.

F. Nature of CPB's Criminal Prosecutions

A variety of people practice odometer fraud, including:

- Organizations that roll back (or "clock") the odometers on thousands of cars, wholesaling them to dealers who resell them to the public.
- Groups of individuals (commonly called "curbstoners") who buy cars, clock them, and sell them through the classifieds, passing them off as cars of a friend or relative ("I'm selling Aunt Sally's Buick for her.").
- Individuals who only clock their own car to defeat a lease provision or cheat on a warranty.

Thus, odometer fraud is a pervasive problem in the used car industry. Indeed, the Department of Transportation, National Highway Traffic Safety Administration (NHTSA), has estimated annual consumer loss from this fraud as exceeding \$1 billion.

CPB works with the Odometer Fraud Staff of NHTSA, the FBI, the United States Postal Inspection Service, the IRS, and numerous State agencies in prosecuting odometer fraud. NHTSA's small Odometer Fraud Staff serves both as the lead investigator in many of these cases, and as a partner with other investigative agencies. The cases that CPB prosecutes typically involve rings that purchase and sell hundreds, and often thousands, of used cars annually. Major defendants in large odometer fraud prosecutions have received prison terms of up to seven years under current Sentencing Guidelines, which do not permit parole. Sentences in the 18-month to three-year range are common.

Odometer fraud and motor vehicle titling fraud investigations generally require coordination—both on a multi-jurisdiction level and on a Federal-State level. Rarely do such crimes occur within only one Federal jurisdiction. Where a target has operated only locally, or only been

involved in a small number of vehicles, prosecution by State or local bodies is the common response.

G. Contact and Resource Sharing

Many States have law enforcement agents or department of motor vehicle investigators who investigate odometer fraud activities. Early contact and coordination with these agents in investigations not only can provide new investigatory leads, but also can prevent confusion at the State/Federal level. CPB and NHTSA both have extensive contacts in the odometer fraud investigative community that can assist this process.

AUSAs can consult USABook § 4-8.300, *et seq.*, for assistance in odometer fraud prosecutions. Discussion of odometer fraud as well as model indictments, briefs, sentencing materials, and other useful litigation and investigative information is part of USABook. After consultation with NHTSA's Odometer Fraud Staff, CPB developed a series of forms and form letters that are used in conducting an odometer fraud/altered securities investigation. These forms, essential to tracking down the "paper side" of an odometer fraud/altered securities investigation, have been gathered in an "Investigatory Resources" manual. Individuals who would like to access the Investigatory Resource Manual are invited to contact the Consumer Protection Branch to request access.

H. Other Offenses Commonly Charged

As the above description of the steps involved in odometer tampering might suggest, tampering rings also violate several additional Federal criminal statutes. Charges in odometer tampering cases, therefore, often include allegations that these additional statutes have also been violated. Such charges more accurately depict the totality of the illegal conduct than odometer tampering charges standing alone.

The general conspiracy statute is commonly used in tampering cases. In addition, it is almost always possible to charge mail or wire fraud (18 U.S.C. §§ 1341, 1343). This is because odometer rollback schemes typically involve various types of mailings or wire communications that further the illegal activity. For example, virtually every State mails new titles to the ultimate purchasers of vehicles. The United States Supreme Court has held that such mailings satisfy the mail fraud statute's requirement that mailings be in furtherance of the scheme. *See Schmuck v. United States*, 489 U.S. 705 (1989).

Several cases have held that the foreseeability requirement for mail fraud was satisfied by mailings of this nature. *United States v. Hubbard*, 96 F.3d 1223, 1229-30 (9th Cir. 1996); *United States v. Shryock*, 537 F.2d 207, 209 (5th Cir. 1976), *cert. denied*, 429 U.S. 1100 (1977); *United States v. Locklear*, 829 F.2d 1314, 1318 (4th Cir. 1987); *United States v. Galloway*, 664 F.2d 161, 163-65 and n.6 (7th Cir. 1981), *cert. denied*, 456 U.S. 1006 (1982); *United States v. Waldrop*, 786 F. Supp. 1194, 1202 (M.D. Pa. 1991), *aff'd* 983 F.2d 1054 (3d Cir. 1992), *cert. denied*, 508 U.S. 950 (1993).

Title alteration and replacement practices also violate various Federal statutes. Possessing, uttering, or making a forged, altered, falsely made or counterfeited title violates 18 U.S.C. § 513. Transporting such a title in interstate commerce violates 18 U.S.C. § 2314. Motor vehicle titles are "securities" within the meaning of these statutes. *See* 18 U.S.C. §§ 513(c)(3), 2311. A title is "falsely made" even if it is genuine, but contains false information or has been fraudulently procured. *See Moskal v. United States*, 498 U.S. 103 (1990).

In addition to these violations, money laundering violations are sometimes appropriate. It is not uncommon for odometer tamperers to use checking accounts maintained in bogus names to carry on their businesses. Of course, money laundering charges require a more detailed financial investigation than may otherwise be necessary. Thus, such charges and their attendant forfeitures are generally employed only where there are significant assets of the illegal venture that can be forfeited to the United States. The proceeds of the forfeiture will generally be used for victim restitution.

I. Restitution and Notice to Victims

Congress has encouraged communications between prosecuting offices and victims of crime, as well as victim restitution. *See, e.g.*, 42 U.S.C. § 10607; U.S.S.G. § 5E1.1(a); 18 U.S.C. §§ 3663-64. Accordingly, investigating agencies generally provide notice to the victims of odometer fraud that their vehicles have been subjected to tampering. This enables victims to take appropriate steps to maintain their vehicles, given their actual mileage.

Notice also allows many victims to obtain compensation from dealers which sold cars with altered odometers, regardless of who was responsible for the alteration. For business and legal reasons, dealers frequently compensate consumers who purchased vehicles with altered odometers. Federal law permits consumers to obtain treble damages, or \$1,500, whichever is

greater, when they are victims of odometer fraud. 49 U.S.C. § 32710. The courts have been liberal in protecting consumers in lawsuits against dealers.

J. Administrative Warrants, Civil Penalties, Injunction Actions

Car dealers are subject to administrative inspection for compliance with the odometer tampering and record-keeping provisions of the odometer tampering laws. 49 U.S.C. § 32707. Section 32707 requires "probable cause" for issuance of a warrant. It defines "probable cause" as a valid public interest in effective enforcement of the law sufficient to justify inspection or impoundment. CPB should be contacted for guidance when administrative inspections are sought.

While criminal sanctions are usually appropriate for fraudulent behavior of the sort involved in odometer fraud, civil remedies are also available in appropriate cases. Civil penalties of up to \$100,000 for a related series of violations are authorized. The Secretary of Transportation can impose the penalties, which are collected by the Department of Justice. 49 U.S.C. § 32709(a).

The Attorney General can also seek injunctive relief to restrain violations. 49 U.S.C. § 32709(c). State attorneys general may also bring such actions. 49 U.S.C. § 32709(d). Such civil actions to restrain record-keeping violations are often appropriate.

VIII. Automobile Information Disclosure

The Automobile Information Disclosure Act ("AIDA"), 15 U.S.C. §§ 1231-1233, is more commonly known as the Monroney Act (Senator Mike Monroney was the chief sponsor of the Act) or Price Sticker Act. This Act requires retail price sticker (often called a "Monroney label") to be affixed the windshield or side window of new automobiles indicating the Manufacturer's Suggested Retail Price ("MSRP"), that is, the "sticker price." Additional

information, such as a list of any optional equipment offered or transportation charges, is also required.

The Federal Trade Commission publishes a fact sheet entitled [Buying a New Car](#), that contains additional information.

The AIDA was amended in 2005 in an effort to improve the dissemination of New Car Assessment Program ratings. The United States Department of Transportation (DOT) issued a Final Rule, 49 C.F.R. 375.301, that has a September 1, 2007, compliance date, that requires new car crash safety information, known as “Stars on Cars,” to be on the Monroney label. Gold stars appear on the Monroney label, ranging from 1-5, with more stars being better, to help consumers evaluate a car’s crash worthiness. See [DOT’s website](#) for more information. Automobiles, by definition, include passenger vehicles and station wagons, and by extension passenger vans and similar vehicles, such as Sport Utility Vehicles (SUVs). Not included, as explained in the legislative history, are pick-up trucks.

AIDA prohibits the sticker from being removed or altered prior to sale to a consumer. Criminal prosecution is possible under 15 U.S.C. § 1233, for willful label removal of a label, and the removal is punishable as a Class A misdemeanor permitting a fine (\$100,000 per violation for an individual and \$200,000 per violation for an organization under 18 U.S.C. § 3571) as well as imprisonment for not more than one year, or both.

Under a related statute, 49 U.S.C. § 32908, manufacturers and importers of new automobiles, including each category of vehicle identified above and pick-up trucks, are required to affix a label to such vehicles with an EPA (Environmental Protection Agency) label containing fuel economy information. See [EPA website](#). Normally, the price sticker label and EPA label are combined as one large label. Failure to maintain the EPA label on the vehicle is considered a violation of AIDA. There are no private remedies under either AIDA or Section 32908.

CPB enforces AIDA, most commonly, by sending warning letters to dealerships alleged to have violated the Act. CPB also advises consumers of alternative avenues of redress where allegations have been made that a price sticker or EPA label is missing or altered.

IX. Federal Cigarette Labeling and Advertising Act

The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341, prohibits cigarette advertising on any medium of electronic communication subject to the jurisdiction of the FCC. 15 U.S.C. § 1335. It also requires conspicuous “Surgeon General’s Warnings” to be placed on all packages of cigarettes and on all cigarette advertisements and billboards. 15 U.S.C. § 1333. The Act provides for both criminal penalties, 15 U.S.C. § 1338, and injunctive relief, 15 U.S.C. § 1339.

CPB enforces this Act, and obtained consent decrees that forced the removal of tobacco-related signs from various sports facilities. One decree required Madison Square Garden to remove a prominent Marlboro sign from its strategic courtside location (across the face of the scorers’ table) at televised New York Knicks’ games. *United States v. Madison Square Garden, L.P.*, No. 95-2228 (S.D.N.Y. filed April 4, 1995). Another decree required Philip Morris Incorporated to remove comparably prominent Marlboro billboards from professional baseball, football, basketball, and hockey stadiums, and arenas around the country. *United States v. Phillip Morris, Inc.*, No. 95-1077 (D.D.C. filed June 6, 1995). In addition, CPB occasionally provides informal, non-binding advice to advertisers and event promoters who seek to conform their conduct to the requirements of the Cigarette Labeling and Advertising Act.

To ensure that the DOJ responds consistently to requests for guidance and to violations of the Act, nationwide investigation and enforcement responsibility have been vested in CPB. CPB forwards investigative results and cases to appropriate USAOs.