DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 13, 1990

MEMORANDUM

TO: The Secretary

THROUGH: US _____
COS _____
ES _____
ASH _____

FROM: Acting Commissioner,
Food and Drug Administration

SUBJECT: FDA'S Successful Use of Criminal Prosecutions -- Information

INTRODUCTION

Recently, concerns have been expressed about FDA's ability and willingness to enforce the Federal Food, Drug and Cosmetic Act, particularly its criminal provisions. The concerns stem from last summer's generic drug episode and surrounding events, including the delegation of certain FDA criminal enforcement authorities to the Office of Inspector General and the eventual rescission of that delegation.

This Enforcement Report describes the historical growth and present scope of FDA's responsibilities, FDA's range of options to enforce the law, including criminal prosecutions, and the agency's enforcement policy. An Appendix attached to the report summarizes the criminal cases that FDA has investigated and successfully prosecuted during the years 1985-1989.

OVERVIEW/EXECUTIVE SUMMARY

FDA has been responsible for safeguarding the public health since 1906, when Congress enacted the first federal food and drug legislation. Today, as a result of amendments to the initial legislation and the passage of other laws, the scope of FDA's responsibilities is staggering. The products under FDA's jurisdiction, which account for approximately one-fourth of the consumer dollar and which are made or distributed by 90,000 establishments, include all foods

(except meat, eggs, and poultry), human and veterinary drugs, cosmetics, medical devices, vaccines, blood and blood components, pesticides, medicated animal feeds, and food and color additives.

FDA's surveillance activities disclose numerous instances in which industry has violated the law. The violations range from inadvertent, minor infractions of FDA regulations to complex frauds involving fabrication of scientific data and drug counterfeiting.

While many of these violations could be prosecuted as criminal matters, it is neither practical nor responsible to do so in every case. The nature of the violation, its public health and economic consequences, the history and attitude of the violator, the persuasiveness of the evidence available to prove the violation, the use of other remedies to correct the problem, the deterrent effect of the case, and governmental resources (FDA, the Department of Justice, and the courts) are some of the factors that FDA evaluates when deciding whether to proceed criminally.

FDA's first concern is to protect the public health. A criminal prosecution provides small consolation to a patient who has received an ineffective or unsafe drug or medical device.

Because of the foregoing considerations, FDA uses a system of incremental measures to promote compliance with and enforce the law. In order of increasing severity, these measures include the list of observations that the FDA investigator gives to a company upon completing an inspection, warning correspondence describing a violation and demanding correction within a specific period of time, publicity, product recalls, withdrawal of a product license, civil seizure of a violative article, injunction, and criminal prosecution. If necessary in a particular case, FDA can and will use all of these remedies to effect compliance with the law.

The incremental system should not be construed to mean that FDA uses criminal sanctions only as a measure of last resort. Where the conduct reflects a disregard for public health, criminal intent, or flagrant or repeated violations, criminal charges will be filed, even when none of the other measures have been used and regardless of the resources that must be employed to prosecute the case successfully.

FDA has been investigating and developing criminal cases independently and in cooperation with other state and federal law enforcement agencies for more than 80 years. During the years 1985-1989, FDA referred to the Department of Justice 90

recommendations for criminal prosecution. (This number does not include cases still under investigation.) These cases, which are summarized in the Appendix to this report, range in complexity from food sanitation cases (which require no proof of intent to violate the law) to complex felony prosecutions involving drug counterfeiting, smuggling, and fraudulent scientific testing. The cases have been brought against individuals and companies, including the largest companies in the food and drug industry (e.g., Beechnut Foods and Eli Lilly & Co.), and have resulted in million dollar fines and terms of imprisonment up to 24 years.

ENFORCEMENT REPORT

1. FDA's Mandate

The 1906 Federal Food and Drugs Act was limited in scope: It regulated only food and drugs; was concerned exclusively with the misbranding and adulteration, narrowly defined; and authorized only seizure and criminal prosecution.

In 1938, Congress expanded FDA's regulatory authority to include medical devices, cosmetics, and pre-market approval of new drugs for safety; broadened the definitions of adulteration and misbranding; and added injunctions to FDA's enforcement arsenal. Since 1938, Congress has expanded FDA's responsibilities under the Federal Food, Drug and Cosmetic Act (the Act) even further to include pesticides, food additives, and color additives; ensuring the effectiveness of new drugs; setting standards of identity for foods; and greatly increasing the controls over medical devices.

FDA has also been charged with enforcing provisions of the Public Health Service Act governing biological products, such as vaccines, blood, and blood components; X-ray machines, microwave ovens, and ultrasound equipment; and sanitation in interstate carriers. More recently, The Federal Anti-Tampering Act, insofar as it relates to foods, drugs, devices, and cosmetics, and the Prescription Drug Marketing Act (PDMA), aimed at preventing the illegal diversion of drugs, have also been added to FDA's growing list of diverse responsibilities.

Each of the foregoing provisions (and the list is by no means complete) presents a potential for criminal and civil liability that may require FDA to select which of its enforcement tools will be brought to bear. To understand how and why FDA selects one remedy over another, one must not

only compare the magnitude of these industries with the resources available to the FDA, but also understand the factors that must be considered when selecting a particular remedy.

2. How FDA Promotes Compliance With And Enforces The Law

The articles under FDA's jurisdiction, which account for about one-quarter of the consumer dollar, are produced and distributed by some 89,400 establishments, including 48,000 companies that handle food, 15,400 medical device companies, 13,600 companies that distribute human drug products, and 5,800 companies that make animal drugs and medicated feeds.

During the course of an average year, FDA investigators inspect 20,000 domestic and 400 foreign companies, review approximately 1,500,000 import entries, and conduct 100,000 wharf examinations; FDA laboratory personnel analyze approximately 75,000 samples. While some inspections may only require a part of one day, it is not unusual for an investigator to spend a month conducting a more complex inspection of a single facility. A sample analysis may be a simple label review or a difficult scientific procedure requiring many days of set-up and bench time. A great deal of investigator and analyst time must also be devoted to careful documentation of observations so that decisions can be made regarding appropriate follow-up.

Based on these surveillance activities, FDA will issue approximately 8,000 lists of inspectional findings (Form FD-483s) and 3,000 formal warning letters (Regulatory Letters, Notices of Adverse Findings). The agency will also effect approximately 3,700 voluntary corrections, 2,000 product recalls, 25,000 import detentions, 200 in rem seizures, 20 injunctions, and 20 criminal prosecutions.

During the years 1985-1989, FDA referred to the Department of Justice 90 recommendations for criminal prosecution; most referrals named an organization and several individuals to be charged or further investigated.[1] These recommendations involved prosecutions for misbranding or adulterating foods, drugs, veterinary drugs, medical devices and biologics, as well as a range of related criminal violations including conspiracy, money laundering, false

---

1/ This number does not include over 100 steroid-related convictions in which FDA investigators and compliance officers participated, but which, once the legal precedents for such prosecutions were established, were not referred though FDA headquarters units.

statements to the government, mail fraud, wire fraud, drug counterfeiting, and obstruction of justice.

Because the preparation and successful prosecution of an injunction, seizure, or criminal action through the judicial system require a considerable amount of time and energy, the agency has historically chosen its enforcement actions with care and proceeded with those cases that would have the most significant deterrent effect. This is particularly true for criminal actions, which frequently require intensive investigation, meticulous review of thousands of documents, witness interviews, and gathering of physical evidence. While litigated seizures and injunctions may also require a great deal of investigative resources, usually they are less resource-intensive than criminal cases.

Balancing deterrence and punishment against resources is critical for another reason: Investigators who are gathering evidence and preparing to testify in a criminal case cannot be performing duties that affect immediate public health concerns. While FDA is not hesitant to seek punitive sanctions in appropriate cases, as a regulatory law enforcement agency, FDA's primary purpose in seeking such sanctions has always been to motivate members of the regulated industry to conform their conduct to the requirements of the law. Where sanctions other than criminal prosecution are not appropriate or effective in changing behavior, as they are not in counterfeiting and drug diversion, FDA has always pursued criminal sanctions.

3. Regulatory Framework

The Act now includes more than 20 specific "prohibited acts" which are misdemeanor crimes, ranging from the adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce to the introduction into interstate commerce of unapproved new drugs.[2] If any of these acts is committed by a person already convicted of such violations, or is committed with the intent to defraud or mislead, the violation is a felony, and individual violators are subject to longer imprisonment, and fines up to $250,000.

2/ Misdemeanors are crimes punishable by fines and imprisonment not exceeding 1 year. Violations of the Act (if committed by first offenders without the intent to defraud or mislead) are misdemeanors, and are subject to fines up to $100,000 (or $250,000 for a misdemeanor resulting in a death) under new federal fines enhancement statutes. 18 U.S.C. §3571. The applicable maximum fines are twice as high for organizations.

Organizations which do or cause felony violations of the Act may be fined up to $500,000 per count.

In substance, the Act defines the articles and practices it regulates, defines what causes articles to be deemed adulterated, misbranded, or otherwise illegal; and makes it a crime to engage in interstate trafficking of them or to manufacture such articles. The Act also requires regulated firms to allow FDA inspections and to produce and allow copying of certain documents, and provides that it is an offense to refuse inspection. The Act likewise makes it a crime to do anything which results in the adulteration or misbranding of a regulated article (food, drug, animal drug, biologic, device, or cosmetic) which has crossed any state line. Those who cause violations are as culpable as those who accomplish them. Thus, decision makers are subject to the same prosecutions and penalties as those who carry out the orders which result in violations of the Act.

4. FDA's Investigative and Case Development System

FDA investigators are the front-line officers in the agency's enforcement programs. They may first observe such violations during the routine inspections which FDA makes of every regulated establishment, through consumer or trade complaints, from occasional anonymous tips of disgruntled or conscientious employees of the regulated firm, and they frequently learn of them in the process of pursuing leads from other FDA investigations.

FDA investigators record their observations, collect documentary evidence as well as physical samples of potentially violative regulated articles, following procedures to preserve both the evidence itself and the chain of custody that is necessary to rely on the evidence in court. The evidence is sent to the FDA District Office for analysis and review.

FDA laboratories perform tests to determine whether the sample is violative, and sometimes to prove or confirm other significant characteristics of the sample.[3]

3/ In one case involving a death caused by a poisoned OTC drug, the Seattle District FDA laboratory confirmed the presence of traces of an algicide as well as the poison which was in the sample of the drug. The presence of the algicide helped the State to win its murder case as it helped to confirm that the accused had mixed the poison in the bucket she used to mix her aquarium water with the algicide. The

(continued...)

Of course, FDA engages in investigations beyond those relying on inspectional observations at a particular regulated facility. FDA investigators make undercover buys, engage in various forms of surveillance, participate in consensual monitoring of conversations, interview former employees and current employees of regulated industry off-site, and debrief cooperating defendants who are cooperating as a part of their plea bargains. FDA investigators assist in the preparation and execution of inspection warrants and criminal search warrants. Pursuant to 21 U.S.C § 702(e), specially designated and authorized FDA employees may also effect seizures of counterfeit drugs and drug counterfeiting equipment without a warrant.

FDA investigational evidence and laboratory conclusions are evaluated by District Compliance Officers, and, if the facts justify it, these officers prepare a recommendation for a criminal case.[4] After FDA field approval, a proposed criminal case is reviewed for policy and scientific uniformity at headquarters, and forwarded to the Food and Drug Division of the Department's Office of the General Counsel.

FDA generally refers its criminal cases to the Department of Justice through (and after review by) the Office of the General Counsel. Staff of FDA and the Office of the General Counsel assemble each case and often prepare an Information or an Indictment for the Department of Justice's consideration when the case is referred. An attorney from the Food and Drug Division who is familiar with the issues is assigned to each referral. Division attorneys actively participate with Department of Justice attorneys in preparing and presenting FDA cases.

For other cases in which the FDA investigation has not identified all suspected targets or all apparently illegal conduct and the power of a grand jury is needed, FDA usually forwards a recommendation for a grand jury inquiry through

---

3/(...continued)
FDA laboratory was able to confirm that the algicide found in tiny amounts in the accused's bucket was the same as that found in the victim's pills. More typically, FDA laboratories find and confirm trace amounts (in amounts as low as parts per billion) of illegal or carcinogenic drug residues in animal feed or edible tissue.

4/ In many cases, the FDA provides a proposed defendant an opportunity to argue against criminal referral. 21 U.S.C. §335.

the Office of the General Counsel. In these cases, the Assistant United States Attorney and the FDA Office of the General Counsel attorneys depend on FDA investigators to analyze and interpret the documents and testimony gained through the grand jury.

5. FDA Enforcement Philosophy

One of the ways FDA protects the public health is through law enforcement. FDA assumes that most regulated persons are law-abiding and expects and encourages compliance with regulatory requirements. But FDA's experience and observations of the damage done by violators also make clear that compliance must be encouraged among the honest majority of regulated industry by vigorous enforcement against detected violators.

While many violations of the Act are criminally punishable, at least as misdemeanors, for the reasons stated previously FDA uses a system of incremental enforcement sanctions to ensure compliance with the law. Violations that do not present a danger to public health, are inadvertent, and are likely to be corrected upon request by FDA, may be addressed by warning correspondence demanding correction within a specified period of time. More intractable problems may be addressed by product recalls, publicity, or license withdrawal, as well as by seizure or injunction in appropriate cases. Where conduct reflects a disregard for public health, or where there are violations involving fraud, intentional violations, and gross or repeated misconduct, FDA is most likely to employ a criminal sanction. Not infrequently, FDA uses a criminal sanction after it has taken whatever steps are necessary to remove dangerous products from interstate commerce.

Where non-judicial remedies would not be as effective in protecting the public health and ensuring compliance with legal requirements, FDA may choose to act by obtaining an injunction, preliminary injunction or a Temporary Restraining Order (TRO). These remedies can be obtained much more rapidly than a criminal conviction. Injunctive relief may be sought either because criminal sanctions are not deemed necessary, or because the public's protection will be advanced immediately with a civil injunction, even though a prosecution may also ultimately be necessary. Given the choice between prompt public protection and a later successful prosecution, FDA will choose to protect first, and prosecute later if possible. In one case, FDA was able to obtain a TRO within 24 hours of documenting that an individual was supplying an inert gas to hospitals, misbranded as oxygen. The TRO prevented additional deaths

promptly; a criminal prosecution was justified and later accomplished.

6. Results: The Cases FDA Brings

FDA criminal prosecutions range in size from four-count "dirty warehouse" misdemeanor cases, involving rodent or insect defilement of stored foods, to hundreds of felony counts against a major baby-food company and its chief executive officers involving adulteration and misbranding of juice for infants. In complexity, FDA prosecutions in the late 80's ranged from prosecutions for interstate shipment of crab meat picked and packed in filthy conditions to cases based on the analyses of pacemaker failures caused by the swelling of tiny printed circuit boards in the sealed environments of pacers implanted for years in cardiac patients.

Congress intended, and experience has confirmed, that both misdemeanor and felony prosecutions are needed to apply criminal sanctions to food and drug violators effectively. Although recent years have seen an increasing share of FDA prosecutions and prosecutorial effort devoted to felonies, the deterrent power of misdemeanor strict liability violations should not be underestimated. Because of the nature of the wholesale food distribution business in the United States, firms of modest size handle and store immense quantities of food in facilities remote from and invisible to the consumer. It is easy for sanitation of such facilities to lapse between infrequent inspections. The strict criminal liability available only in misdemeanor cases under the Act means that the occasional prosecution in such situations can be brought economically, with a high enough likelihood of success that holders of food conclude that proper sanitation will cost less than a criminal defense. If felony cases were the only criminal option, the necessary preparation time, presentation expense and litigation risk would increase to the point where FDA might not be able to afford to inspire the necessary concern for sanitation in smaller firms.

Charges for felony violations are essential for adequate punishment of violators who have acted with evil intent-- those who fabricate safety data, falsify laboratory studies on drugs and people, and those who counterfeit valuable effective drugs, sometimes substituting different (and ineffective) ingredients. Although such cases are more resource-intensive of both investigative and legal resources, they are needed to punish and deter the worst violators of the Act.

7. Effects of FDA's Criminal Prosecutions ... on the Public

FDA criminal referrals in recent years have resulted in the indictments and convictions of some of the most well recognized national and international names in food and pharmaceutical industries-- Eli Lilly, SmithKline Beckman, Wyeth Laboratories, Beechnut Foods, and Cordis Corporation.

Although the convictions obtained in these cases are unsettling to the public, they are at the same time reassuring, demonstrating that FDA is vigilant and is willing, when necessary, to prosecute even the largest, most trusted firms if they violate the law. Such cases also serve to remind the public of the need to remain alert and concerned about the products from whatever source. This involves the public in its own protection, and increases the likelihood that unusual or defective regulated products are brought to the FDA's attention by consumers.

... on Regulated Industry

Columnists, corporate counsel, and industry representatives seem unanimous that nothing gets the industry's attention as well as a prosecution. Although this "attention" may express itself first in strident calls to weaken FDA's statutory criminal provisions, it ultimately creates an industry that is concerned about its level of compliance with the law, concern that motivates the industry to find and correct its own problems before the FDA finds them. This concern magnifies the effect of FDA's limited investigative forces, and concentrates industrial compliance improvements in areas where the firm knows improvements are most needed.

... on Industry Employees

FDA prosecutions provide both positive and negative incentives for executive-level and managerial employees, as well as operating-level employees. On the positive side, FDA prosecutions serve to prompt employees in regulated industry to speak within the company as a continuing corporate conscience to remind the company that it is best served by adherence to the law. On the more direct, negative side, would-be violators can observe the fate of the first co-conspirator to cooperate with the government. Because such defendants usually end up with lesser charges and sentences, even persons who are unresponsive to the threat of possible prosecution must worry about the loyalty of their

work mates and potential co-conspirators. The net effect of these factors in preventing violations is impossible to measure, but probably exceeds the effect that prosecutions have on the immediate targets of the prosecution.

... on Corporate Managers

The prophylactic effect of FDA's criminal enforcement cases has an especially powerful effect on responsible officials in even the largest companies because of one of the most unique aspects of the Federal Food, Drug and Cosmetic Act: "strict liability" for misdemeanor criminal conduct. In United States v. Dotterweich, 320 U.S. 277 (1943), the Supreme Court held an individual responsible for violations at the Buffalo Pharmacal Corp. The lengthy quote from the court's decision highlights this special standard:

> The offense is committed, ... by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

Thirty years later, the Court reiterated and emphasized that holding of special responsibility in United States v. Park, 421 U.S. 658 (1975). In Park, the United States Court of Appeals for the Fourth Circuit had reversed the conviction of a corporate president who had been convicted, pursuant to the Dotterweich standard, although he had not been personally present at, nor participated in, nor been specifically aware of, the conditions for which his company and he were convicted. The Supreme Court's language again shows the special responsibility the courts have imposed on officials of FDA's regulated industries:

> The rationale of the interpretation given the Act in Dotterweich, as holding criminally accountable the persons whose failure to exercise the authority and supervisory responsibility

reposed in them by the business organization resulted in the violation complained of, has been confirmed in our subsequent cases. Thus, the Court has reaffirmed the proposition that "the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors." ...Similarly, in cases decided after Dotterweich, the Courts of Appeals have recognized that those corporate agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act bear a "responsible relationship" to, or have a "responsible share" in, violations.

Thus Dotterweich and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission -- and this is by no means necessarily confined to a single corporate agent or employee -- the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

This demanding judicial standard, together with FDA's persistence and investigative thoroughness, inspires a greater concern for compliance in industry officials than would otherwise be possible. FDA's reliance in "voluntary compliance", and the public's protection afforded by it, are at bottom dependent on industry's appreciation of the alternatives to voluntary compliance, and on the FDA's continued willingness to use them. The following case descriptions demonstrate that willingness.

James S. Benson

Attachment

APPENDIX

The Appendix summarizes the FDA-investigated and referred criminal prosecutions which became public in the years 1985-1989.[1]

Although the cases have been assigned to topics, such assignment necessarily fails to reveal the interconnections of individual cases, which often include several elements. Conspiracy, inspectional refusals and false statements were often included within cases indexed under the subject-matter topics. For example, although bogus fruit juices could be considered "counterfeits" or "ingredient substitution fraud" they are indexed here under "food, adulteration".

Table of FDA Criminal Case Notes 1985-1990

1/ These cases will not be the same as those forwarded to the Justice Department during the period because some recent referrals have not become public, and because many cases concluded within the period were forwarded much earlier.

Biologics, Plasma

FDA enforces not only the Federal Food Drug and Cosmetic Act, but at least parts of over 10 other statutes, including the portions of the Public Health Service Act pertaining to Biological, Radiation Control, and food equipment and service on vehicles and vessels in interstate commerce. Biological include blood and blood-derived products, such as plasma, the straw-colored fluid left when the red cells are centrifuged out of fresh whole blood. FDA regulates plasmapheresis centers, including those where paid donors allow two successive units of red cells to be removed, centrifuged, the plasma removed, and the red cells reinfused, each donation day, frequently twice a week. Some plasma centers save money by not screening their donors carefully, others save by not fully testing the donors' blood or the extracted plasma before shipping the plasma, and some centers routinely falsify donor medical records, whole blood weight logs (to understate the quantity of blood drawn from a given donor), and testing documents.

United States v. Lighte

In FDA's regulation of biologics, a Miami financier of plasma programs was convicted in Buffalo, New York in January 1985 of perjury to a grand jury during an investigation of plasma program violations (he lied to conceal an account set up to bribe an official of a plasma buyer, using his dead mother's social security number to avoid having the interest on the bribery fund account taxed to his number). The conviction was reversed in February 1986 because the Court of Appeals held that the jury verdict did not make it clear whether the conviction was based on one of the false responses to the grand jury or to a merely indirect answer. United States v. Lighte, 782 F.2d 367 (2nd Cir. 1986). Before the retrial began, the defendant pled to two misdemeanor contempt violations (including false testimony on six different grand jury questions) and to two violations of the Food and Drug Act. In that case, FDA investigators and compliance officers had reviewed and analyzed subpoenaed bank records of the defendant's and the plasma program's accounts to trace proceeds to demonstrate the defendant's control over the account. FDA investigators located the eyewitness to the defendant's opening of the account, years earlier, and experts to refute the defendant's loss-of-memory defense.

United States v. Colorado Plasma Co.

In January, 1988 another plasma center corporation and two individuals each pled guilty to two misdemeanor violations of the Act at a plasmapheresis facility in Colorado Springs, Colorado. The firm's manager and assistant manager pled to two refusals to permit the FDA inspection, which is a separate specific violation set out at 21 U.S.C. §331(f). (They had made or directed false entries in records required to be kept for FDA's inspection, thereby preventing FDA from completing an investigation.) Their false entries in the whole blood log had initially concealed from FDA investigators that too much blood had been drawn from donors, and that plasma was taken from donors who should have been deferred. The corporation pled to one count of inspection refusal and one count of misbranding of plasma. The corporation was fined $1,200, and the individuals were sentenced to 180 and 120 hours, respectively, of community service. Neither individual was fined, but both were put under supervised probation for three years.

United States v. Pioneer Blood Services, Inc.

Another New York plasma firm (and blood test lab), Pioneer Blood Services Inc, was convicted (after a plea) in July, 1988 of five misdemeanor violations involving adulteration and misbranding of plasma, and refusal to permit inspection. The plasma manager also was convicted (after a plea) of two misdemeanor violations involving misbranding of plasma and refusal to permit inspection. The plasma was adulterated in that it had not been prepared as required under good manufacturing practices, including failure to conduct proper hepatitis testing. The violations included the failure to determine the health status of donors of the plasma. This plasma center, also, had made false entries in donor record files and in plasma production records.

Cancer Fraud

United States v. M. T. Products, Ltd.

An Oklahoma promoter of a cancer cure allegedly derived from Easter lilies was prosecuted in United States v. M. T. Products, Ltd. After violating a 1980 injunction FDA had obtained under the Act prohibiting such distribution, the owner and the company were found in criminal contempt of the injunction after a three day trial in April, 1985 and sentenced in July. The individual was sentenced to three years probation (and received a warning that further violations would risk a jail sentence) and the corporation

was fined $50,000. By March of 1987, FDA had documented. further violations including promotion and distribution of the drug. The defendant was sentenced to 39 months, six to be served in jail, and 33 on probation. The District Court's judgment of contempt and the revocation of probation was affirmed by the Court of Appeals.

Counterfeiting of Drugs

United States v. Naghdi (Naprosyn Counterfeiting)

FDA learned of the possible counterfeiting of Naprosyn, a widely used anti-inflammatory drug, from Syntex, the manufacturer of the drug, on March 20, 1987. Through surveillance, use of search and seizure warrants, and thorough investigating, Mr. Naghdi was apprehended on March 28, 1987. The drugs he shipped were tracked down and seized. The manufacturing site, a metalworking plant, was located and documented. The maker of the labeling for Naghdi was identified. Mr. Naghdi and three associates were charged with conspiracy, trafficking in counterfeit goods, counterfeiting trademark plates, making and selling counterfeit drugs, and misbranding drugs. Mr. Naghdi pled guilty to four felony charges of counterfeiting and conspiracy. On the day he was to be sentenced, however, he went to the airport instead of the courthouse, and fled the country under a different name. Naghdi was later apprehended and extradited from England. He attended the rescheduled sentencing under custody and is serving five years in prison on these charges.

Scheme to sell 8 million bottles of Counterfeit Drugs. Naghdi II

In late 1987, FDA learned of a scheme to sell 8 million bottles of three prescription drugs. Such a large single transaction was unheard of, and the two manufacturers whose products were being offered assured the agency they could not be authentic product. The FDA borrowed the services of an expert undercover agent from the United States Customs Service to assist in tracking down the source of the offer. Working with the FDA National Steroid Coordinator and an Assistant United States Attorney in San Diego, California, the agent traced the offer back to Javid Naghdi, who was then residing as a fugitive in London, England. He evidently took steps to execute this second scheme within days of his guilty plea for his first counterfeiting violation. Grand Jury subpoenas were obtained for a variety of records. Face-to-face meetings were held with Mr. Naghdi in England, and a contract signed for one million bottles of

Tagamet, the biggest selling ulcer drug in the world. The selling price of $28 million was covered by an authentic Letter of Credit negotiated and backed by Smithkline Beckman, the manufacturer of Tagamet. A drug wholesaler, Owens and Minor, assisted in the case by establishing the undercover agent as their west coast representative. Scotland Yard was involved in surveillance and the arrest of Mr. Naghdi in August 1988. On the same day, search and seizure warrants were served on four locations in the United States in a coordinated strike to obtain records of the scheme. Mr. Naghdi was extradited to the United States, sentenced for the first counterfeiting case as described above, and was subsequently tried and convicted on 9 counts in this second case, the scheme to sell counterfeit prescription drugs. On May 2, 1990, he was sentenced to 14 years in prison.

Counterfeit Ovulen-21

In October 1984, FDA learned that counterfeit Ovulen-21 (oral contraceptive tablets marketed by G.D. Searle and Company, Chicago, Illinois) was being distributed in the United States. FDA made thirteen seizures across the country of approximately 70,952 cycles of the counterfeit Ovulen-21. Comparison of the counterfeit tablets and labeling revealed two separate products, with different lot numbers - 441 and 489. Lot 441 actually contained the two active ingredients used in the genuine product, but failed content uniformity, and was in packaging and labeling that was easily discernible from the genuine package because the counterfeit packaging was of poor quality. The tablets were embossed with the number "401" on both sides. Lot 489 contained a different active ingredient from the authentic tablet, was subpotent, and was contained in packaging and labeling that was difficult to distinguish from the authentic product. FDA's investigation included a search warrant at Lantor Corporation, Miami, Florida, use of Grand Jury subpoenas, and numerous interviews across the nation. At times, FDA utilized other Federal agencies and Interpol in conducting this investigation. Identity was finally made of the two pharmaceutical manufacturers of the counterfeit tablets, one in Barcelona, Spain (lot 441), and the other in Guatemala City, Guatemala, Central America (lot 489). The six individuals responsible for getting the tablets into the country (which included smuggling) and the use of the counterfeit labeling were identified and located in Miami, Florida. A 29-count indictment was filed in February 1987, charging:

> Fermin Alfonso (21 counts), Jacque Behar (6 counts), Sheldon Harwin (5 counts), Edward J. Peterson (9 counts), Beatriz Villalon (21 counts),

and Gilberto Yurubi (6 counts), with conspiracy (18 U.S.C. §271), wire fraud (18 U.S.C. §1341) drug counterfeiting (21 U.S.C. §331(i)) and distribution of counterfeit drugs.

A seventh individual, Robert Pollack, waived indictment and pled guilty to a one-count felony of knowingly distributing counterfeit Ovulen-21.

Court sentences were as follows:

Name		Sentence
Alfonso:	Bench trial - guilty 21 counts	Prison - 24 years
Behar:	Plea - 1 count (conspiracy)	Prison - 10 months
Harwin:	Jury trial - guilty 5 counts	Prison - 11 years
Peterson:	Plea - 2 counts (conspiracy and distribution of counterfeit Ovulen-21)	Prison - 5 years
Pollack:	Plea - 1 count counterfeiting Fine - $7,500	Probation - 3 years
Villalon:	Bench trial - guilty - 21 counts	Prison - 24 years
Yurubi:	Plea - 1 count (conspiracy)	Prison - 10 months

United States v. Smith (Counterfeit Growth Hormone)

When FDA learned of the appearance on the black market of large quantities of "counterfeit" Genentech Human Growth Hormone, it again enlisted the support of a fellow investigative agency to assist in finding the persons responsible. This investigation was particularly critical because the drug was found to be contaminated with viable bacteria and fungus. Because the drug's intended use on the legitimate market is only in children, the distribution of this drug into the legitimate market might have had devastating effects. FDA, directed an investigation which eventually led to the source of this drug and numerous other clandestinely manufactured counterfeit steroids which had been found on the black market. With additional help from the Drug Enforcement Administration, the person responsible has been apprehended, the label printer identified, and the source of these dangerous drugs to the black market stopped.

The individual responsible for this operation, Dennis Smith, has now pled guilty and is presently awaiting sentencing.

Devices

United States v. Cordis Corporation (Pacemakers)

FDA regulates medical devices, from tongue depressors to computed axial tomography (CAT) scanning machines. Among the devices regulated are implanted cardiac pacemakers. FDA investigators confirmed anonymous tips that a Florida pacemaker manufacturer had made tens of thousands of defective cardiac pacemakers, later discovered that they had manufacturing defects, and continued to sell the few thousand defective pacemakers still in inventory, even in the expectation that a small portion of them were likely to have a "sudden no-output failure". After a long grand jury investigation, FDA investigators documented a number of crimes by the company, and identified the individuals who seemed to have been responsible.

The company, Cordis Corporation, of Miami, Florida eventually pled guilty to 12 felony counts and 13 misdemeanors, including shipping of defective pacers and misbranded pacers, each with the intent to defraud and mislead the government and the pacer recipients; shipment of pacer programmers[2] prior to required FDA approval; and false statements in submissions to FDA seeking permission to market new or revised pacers. In April, 1989, the company was fined $623,000, and ordered to pay $141,000 of FDA's investigational costs. In a related action, Cordis agreed to pay $5,000,000 in a civil settlement of the United States' claims against Cordis for defective pacers and programmers Cordis had either sold to the United States, or for which the United States had reimbursed purchasers. The four former Cordis officials charged were acquitted after a jury trial in Miami in the Fall of 1989.

2/ Pacer programmers are devices used to change the operating characteristics of a pacer without surgery to actually reach in to the pacer. Some of Cordis's programmers would cause some of Cordis' pacers to "lock up" at an undesirable setting. This converted some routine pacer setting appointments to emergency pacer replacement surgery.

Intraocular Lenses

United States v. Geising

FDA's investigators also documented false statements submitted to the agency regarding the testing of intraocular lenses for ethylene oxide residues (remaining after sterilization of the lenses with the ethylene oxide). FDA investigators found that some tests were certified as having been conducted, when in fact they had not been conducted, leaving the possibility that lenses with this toxic substance would be released for implantation in patients' eyes. On February 26, 1985 the defendant (who had pled guilty to two of the thirteen counts charged) was sentenced to six months in prison for his false test report, to be followed by three years of probation, to include 100 hours of community service during each year of probation.

Drugs, Adulteration

Contempt for Failure to Comply with Grand Jury Subpoena

After an FDA investigation had disclosed apparent violations of the Act, a Baltimore grand jury subpoenaed documents concerning the manufacture of prescription drugs. The respondent refused to comply. The district court judge ordered compliance, and held the respondent in contempt when it failed to comply. The respondent appealed to the Fourth Circuit, which declined to disturb the district court's decision, thus upholding the contempt order. Matter of Grand Jury Subpoena of June 12, 1988, 831 F.2d. 290 (4th Cir. 1988). cert. denied John D. Copanos & Sons, Inc. v. United States 484 U.S. 1062 (1988). In June, 1988, the district court ordered the respondent drug firm to pay over $20,000 in attorney fees, along with other costs, and gave permission for the government to seek additional damages to cover the costs of re-interviewing grand jury witnesses and additional grand jury proceedings necessitated by the earlier failure to produce the subpoenaed documents. Matter of Grand Jury Subpoena of June 12, 1988, 690 F. Supp. 1451 (D. Md. 1988).

United States v. Copanos

In April, 1988, a grand jury returned a 22 count indictment against two drug companies, the president-owner of both and three employees, based on an FDA and grand jury investigation. The charges included conspiracy to violate the Act, false statements, obstruction (of FDA investigation), conspiracy to defraud the FDA, concealing test records concerning contaminated lots of penicillin,

false records which masked contamination of other lots, and the sale of penicillin with an unapproved ingredient. The case followed multiple seizures, an injunction against shipment of drugs from plants with defective manufacturing conditions, and the revocation of the all of the company's New Drug Approvals. The case reached trial in November, 1989. After eight days of trial the lead individual defendant, John Copanos, and his two companies pled guilty to two felony violations of adulteration and misbranding of prescription drugs. One of the company employees pled guilty to a misdemeanor violation, admitting that he caused drug production records to be changed. Mr. Copanos was sentenced to a year and a day in prison, 1600 hours of community service (to be served at the rate of eight hours a week for 200 weeks) and a fine of $260,000. Each of his companies was fined $185,000. His motion for a modification of his sentence to allow him to manage the possible sale of the company was denied.

United States v. General Nutrition

One of the larger "health food store" chains and three of its officers and two managers were indicted in June of 1986 in the Western District of New York in a 7-count indictment alleging conspiracy to defraud the FDA and drug misbranding. The FDA investigation had documented the company's pattern of training employees to make oral representations of drug effects for items labeled as foods or food additives; and the pattern of having labeling which made drug claims near, but not on the container of the "food" products, thus attracting customers with claims which had not passed FDA scrutiny, but maintaining the pretense that the items were sold as foods. By January, 1987, the corporation (General Nutrition) pled to four counts of misbranding drugs, and the former president and a then-current vice president pled guilty to one count of misbranding in the promotion and sale of primrose oil. The former corporate president was fined $1,000. The corporation also paid $10,000 toward the costs of the prosecution, but was not fined.

Drugs, Generics

United States v. Generix (Obstruction of Inspection)

An FDA investigation revealed that employees had been instructed to hide drugs in process and in inventory from FDA inspectors, in part by quickly loading them onto trucks and driving around while the FDA inspectors were in the plant, returning to unload after the inspection. FDA assisted the United States Attorney in obtaining a seven count indictment

against Generix Drugs Corporation of Hollywood, Florida and four of its officers for conspiracy, obstruction of agency proceeding (the inspection), and false statements. On February 2, 1986 the company's president and executive vice president each pled guilty to one felony violation of the Act for refusing to permit inspections, and the corporation pled guilty to four felony counts. Other counts and other defendants were dismissed. The court levied the then-maximum fines (see footnote 2) of $40,000 against the corporation, and $10,000 each against the individuals. The corporation also paid $10,000 toward the costs of the prosecution.

Drugs, Misbranded

United States v. Dixie Welding Supply Co.

Misbranding of drugs may sometimes sound less threatening than adulteration, but in United States v. Dixie Welding Supply Co., the drug was argon, misbranded as oxygen, and packaged for use as life-sustaining oxygen for use in a hospital's medical oxygen system. In May, 1983 three people died at an Alabama hospital because of the mislabeling. In March, 1986, the corporation, its president and vice president each pled guilty to misdemeanor violations of the Act, of repacking oxygen outside of the requisite good manufacturing practices (GMP's) for medical gases; and to a count of misbranding the argon by labeling it as oxygen. Each defendant received the maximum fine of $1,000 per count.[3]

Failure to Report Adverse Reactions

During this period, FDA investigations revealed that two of the major drug companies in the United States had failed to make required reports of significant adverse reactions suffered by persons taking drugs that were widely used.

3/ The maximum fines have since been raised, for violations committed after 1984. Presently, the fines can be up to $250,000 per misdemeanor count, and have been raised from the $10,000 maximum per felony count to a maximum of $500,000 in some cases.

United States v. SmithKline Beckman

In the first of these cases, SmithKline Beckman Corporation pled guilty in March of 1985 to 34 misdemeanor counts; 20 of them for causing the introduction into interstate commerce of misbranded Selacryn, and 14 for failure to report adverse reactions. The company had failed to report promptly to FDA hepatic adverse reactions associated with Selacryn, an antihypertensive prescription drug. The corporation was sentenced to pay a fine, which was then suspended, and the individuals received suspended fines and five years' probation and were ordered to perform 200 hours of community service.

United States v. Eli Lilly and Company

On August 21, 1985, Eli Lilly and Company pled guilty in the Southern District of Indiana to ten counts of failing to report to FDA adverse reactions occurring overseas associated with the arthritis drug Oraflex, and 15 counts of misbranding resulting from the failure of the drug's label to reflect the possibility of such adverse reactions. Another defendant, a former vice president and chief medical officer of the corporations's research subsidiary, pled no contest to ten counts of failing to report and five counts of misbranding. On the same date, a District Court judge imposed the maximum fine of $25,000 on the corporation and $15,000 on the individual ($1,000 for each count). The drug was withdrawn from the market in 1982.

False Statements, by Clinical Investigators

United States v. Sherwin

A physician (psychiatrist) was the subject of a criminal information in United States v. Sherwin in April of 1985 for three counts of violations of mail fraud and false statements he made concerning a clinical investigation (a drug experiment on humans). After an initial agreement to plead guilty, the Doctor reneged on the agreement (attempting instead to enter a nolo contendere plea) and it was necessary to seek an indictment. In August of that year, the doctor pled to five felonies (involving the falsified data) of the 36 felonies on which he was indicted. He was sentenced to a $5,000 fine, required to make restitution to the sponsor of the drug study, and to 5 years' probation.

United States v. Baratta

In May of 1985, another physician pled guilty in the Eastern District of New York to perjury to a grand jury (18 U.S.C. §1623) concerning a drug study he conducted for Squibb (he altered a patient medical file he used before the grand jury to conform to the case report form for that patient that he had submitted to Squibb, the sponsor of the drug study). This same defendant had been convicted after a jury trial of mail fraud and submitting false documents to the government. He was sentenced for all three crimes the same day; fined $10,000 for the perjury, $7,500 for each of the two false reports, and $1,000 for mail fraud. He was also sentenced to a three-year suspended sentence, three years probation and 250 hours of community service.

United States v. Cullen

During an FDA administrative hearing on a drug, FDA personnel and the Food and Drug Division attorney presenting the Center's case became suspicious that a study cited by the drug's proponent was falsified. After an FDA investigation revealed false statements, falsified patient record cards, fabricated data on case report forms and forged patient signatures on "informed consent" forms, the physician, Dr. Cullen, and his assistant (his wife) were indicted by a Grand Jury in the Southern District of Texas in August 1987 on one count of mail fraud and three counts of making false or fraudulent statements within the jurisdiction of the FDA. After a jury trial in April of 1988, the defendants were found guilty as charged. The doctor was sentenced to three years (all but two months suspended) in prison, and his assistant/wife received a one year sentence to a halfway house (all but one month suspended).

United States v. Fogari

The investigation of Dr. Robert Fogari began on June 1983 when FDA conducted a "for cause" inspection[4] of the doctor's studies. The drugs involved were non steroidal anti-inflammatory drugs for the treatment of arthritis. The ensuing grand jury investigation revealed that Dr. Fogari had

---

4/ FDA's Center for Drug Evaluation and Research makes or directs FDA districts to make routine inspections of clinical investigators, and also a smaller number of "for cause" inspections where there is agency suspicion that a particular study (or study physician) is not in compliance with the applicable law and regulations.

conducted at least 18 clinical studies for nine drug companies from 1977 to 1985, for which he had been paid close to $2 million.

Over 50,000 documents were obtained pursuant to subpoena and the FDA Investigator and Compliance Officer conducted over 200 interviews of patients, study assistants and drug company representatives. The investigation was hampered and prolonged by Dr. Fogari's obstruction of FDA's investigation and subornation of perjury before the grand jury.

The evidence was presented to a grand jury sitting in the District of New Jersey and resulted in a 20 count indictment in February 1988. The indictment charged Dr. Fogari with one count of conspiracy, 15 counts of submission of false documents, 1 count of submitting a false affidavit to the FDA during an informal hearing before the agency and three counts of obstruction.

Dr. Fogari pled not guilty to the 20 counts. However, after seven days of trial testimony in September, 1988, Dr. Fogari changed his plea to guilty on four counts; count 1, conspiracy, counts 9 and 11, false statements and count 17, submitting a false affidavit to the FDA.

Dr. Fogari was sentenced in February 1989 to 3 years in prison, a $2 million fine, and to make restitution of $1,866,656 for the conspiracy count; three years, to run concurrently with the conspiracy count for the nine false statements; 1 year to run consecutive to the conspiracy count for the false affidavit, and 5 years probation to commence after the custodial sentence for the count 11 false statement.

In March 1989, the New Jersey Board of Medical Examiners voted unanimously to revoke Dr. Fogari's medical license effective 3/17/89. Dr. Fogari was incarcerated at the Federal prison in Allenwood, Pa.

United States v. Kostas

In July, 1988, Constantine I. Kostas pled guilty to one count of making a false statement and to one count of mail fraud. He had confessed to the drug company sponsoring the investigation that only 15 of the 85 subjects listed in the study had actually received the experimental drug. In addition, he had included in the study patients who did not meet the medical criteria of the research protocol, and he had faked results of nonexistent laboratory tests and office examinations. In October, 1988 he was sentenced in Boston to

a one year (suspended) prison term, a $30,000 fine, and 400 hours of community service.

United States v. Wallens

Dr. Wallens, a clinical investigator, was charged with violations of Title 18 (mail fraud and false documents), and violations of 21 U.S.C. §331(e) and 355 (i). He pled guilty in the Western District of New York to failing to establish and maintain adequate and accurate records in connection with investigational new drugs. Dr. Wallens pled guilty to a five-count information, and agreed to repay $7,125 to the Cancer and Leukemia Group for improper reporting and $12,875 to the FDA for the costs of the investigation. He was sentenced to 122 days in prison, (suspended) and placed on five years probation.

United States v. Jerome Weiss, M.D.

From October 1983 through January 1984, FDA inspected Dr. Weiss' conduct of clinical studies performed for Smith, Kline and French Laboratories. Dr. Weiss fabricated data, using the names of some of his patients as participants in the studies, did not in fact treat them with the study medications, and falsified data to make it look as if these patients had been eligible study participants.
Dr. Weiss was charged with the failure to establish or maintain records or reports of clinical studies required to be maintained under the Act, with the intent to defraud. In February 1987 Dr. Weiss pled guilty to one felony count of falsification of medical records with intent to defraud in violation of 21 USC §331(e) and 18 U.S.C. §2. He was sentenced to two years probation with special conditions, including 200 hours of community service, and a fine of $10,000.

False Statements By Non-Clinical Investigators and Laboratories

United States v. Keplinger (Industrial Bio-Test)

In November, 1985 the Seventh Circuit Court of Appeals affirmed the convictions of three officials of IBT on mail fraud, wire fraud, making false statements involving animal studies of TCC, an ingredient of deodorant soap, and of the non-steroidal anti-inflammatory drug Naproxyn. United States v. Keplinger, 776 F.2d 678 (7th Cir. 1985). The case had resulted from a major FDA investigation of the animal studies conducted at IBT, in which it was revealed that there was

systematic false reporting of animal toxicity data, and animal health status. (Some particular mice or rats were reported to have "died" several times during long-term studies in the raw notes of animal caretakers.) Final study reports did not reveal that a few of the mice had led two (or three) lives. In actual practice, the company had its employees replace dead or dying animals if their premature demise would threaten an expensive or deadline study. One of the firm's animal colony rooms was fitted with an "automatic watering device" which frequently overflowed the animals' water dishes, causing the employees to call that area "the swamp" and causing so much mortality to the study animals that the firm's employees resorted to innovative accounting and reporting to conceal the excess deaths, which might otherwise have ruined the study and lost a customer for IBT. The toxicity reports which resulted from these laboratories were later filed by product sponsors in support of their FDA applications. After a six month trial in Chicago, one defendant was sentenced to a year in prison and four years probation, and two others were sentenced to six months in jail and two years probation.

False Statements, Other

United States v. Miller

In May 1987 Mildred Miller, owner of the Degenerative Disease Medical Center, Las Vegas, Nevada was indicted along with five co-defendants for her role in a scheme involving intravenous use of dimethylsulfoxide (DMSO), Laetrile, and other unapproved drugs. The 72-count indictment charged the defendants with conspiring to defraud the United States and insurance companies, making false claims and obstructing justice. The case focused primarily upon the defendants' defrauding the United States through the Medicare program. Drug GMP violations and new drug violations were included as overt acts in the conspiracy count. FDA investigators assisted postal inspectors and agents of the HHS Inspector General's office, and FDA compliance officers assisted the prosecutors. Mildred Miller was found guilty, after a three week trial, of one count of conspiracy, 14 counts of mail fraud, 14 false statements, seven counts of obstruction of justice. She was sentenced to prison.

United States v. Michigan Pharmacal Corporation

On June 2, 1987, as part of a preindictment plea agreement in the Eastern District of Michigan, Michigan Pharmacal Corporation (MPC) pled guilty to a felony violation of 18 U.S.C. §1001 for making false statements to an FDA

investigator. Through its employees, MPC falsely represented to FDA that it had last received a bulk shipment of B-15 on a particular date and had destroyed all stocks of B-15, when in fact, it had received another shipment that was concealed from FDA. MPC also continued to distribute the substance to retailers. B-15, also known as calcium pangamate or pangamic acid, contains an unapproved food additive. B-15 is sold in health food stores and promoted (without FDA approval) for self-treatment of a variety of medical conditions. As part of the plea agreement, MPC was fined $10,000 and ordered to pay $90,000 as reimbursement to the government for costs of investigation. As part of the same plea agreement, the president of the corporation pled guilty to a misdemeanor conspiracy count under 21 U.S.C. §374 for refusing to permit FDA inspection of a quantity of B-15, its containers, and labeling. The firm's president was fined $1,000.

Sunny Suzy Company

In an unusual false document case, Sunny Suzy Company's president pled guilty in December, 1987 to creating a false document which purported to be an FDA detention notice. Instead of falsely stating that bad food was good, Sunny Suzy falsely claimed that good food was detained as adulterated. (Not on a whim; Sunny Suzy then sold the food, which was actually acceptable, and billed the foreign shipper for the "adulterated and detained" shipment, claimed to be worth $18,000.) The president of Sunny Suzy pled to one count of income tax violation, and one count of felony mail fraud; the corporation pled to the mail fraud. The individual was fined $5,000 and sentenced to a year and a day in jail; the corporation was fined $1,000.

Food, Adulteration

United States v. Khan

After a series of deaths of infants in Lima, Peru were traced to lethal amounts of excess potassium in the special-purpose foods which are used to "re-hydrate" victims of severe diarrhea, the FDA helped to obtain evidence for what became the 32 count indictment (including manslaughter and fraud) against Mohammed Khan. The allegations were based on his causing violations of the food adulteration and misbranding provisions of the Act. The defendant pled guilty to wire fraud in August 1987, and was sentenced in October, 1987 to three years in jail, to be followed by two years probation. He was fined $1,000, and ordered to pay

restitution of $266,000[5] to the United States for the value of the Agency for International Development contract under which the rehydration salts had been provided.

Beechnut Apple Juice

Because Beechnut was uncooperative in the investigation of allegations that one of Beechnut's suppliers was selling fake apple juice concentrate, a grand jury subpoena was issued for all of the firm's records concerning apple juice. The records produced were reviewed by FDA investigators and showed that Beechnut had been aware for several years that it was substituting colored water for apple juice. FDA conducted extensive interviews of employees and others to determine the extent of the substitution. The information resulted in a 470 count indictment of the corporation, its President, Niels Hoyvald, the Vice-President for Operations, John Lavery, and five others for conspiracy, mail fraud, and felony FD&C Act violations of adulterating and misbranding apple juice. The indictment charged the company with intentionally shipping adulterated and mislabeled products made from artificially flavored sugar water instead of apple juice concentrate with the intent to defraud and mislead, and with mail fraud.

Three days before the trial was to begin, the corporation pled guilty to 215 felony violations of the FD&C Act, and was sentenced to pay fines and costs totaling $2,180,000. All five entities charged with supplying the phony apple juice pled guilty. South Orange Express was fined $32,000. Nina Williamson pled to 20 misdemeanor FD&C Act counts and was placed on five years probation and fined $2,000. Danny Shaeffer also pled to 20 misdemeanor counts and received 5 years probation and was fined $5,000. Raymond Wells pled to ten felony counts, including one conspiracy, one mail fraud, and eight FD&C counts. He was placed on probation for five years, fined $10,000, and 1500 hours of community service. Zev Kaplansky received a $285,000 fine, five years probation, and 300 hours of community service.

5/Kahn fired his attorney and appealed his conviction to the Second Circuit Court of Appeals, based on the trial court's failure to inform him during the plea allocution of the possibility of a restitution requirement as a part of the sentence. The Appeals court first agreed with Kahn, United States v. Khan, 857 F.2d 85 (2nd Cir. 1988); then reversed itself on rehearing and remanded the case to the District Court to allow correction of the sentence. United States v. Khan, 869 F.2d 661 (2nd Cir. 1989).

The two principal Beechnut officers, Hoyvald and Lavery, were tried and convicted. The Court of Appeals reversed the conviction of Hoyvald, but let stand 19 felony convictions against Lavery. Lavery was sentenced to a year and a day in prison and to pay $100,000 fine. After a second trial resulted in a mistrial against him, Niels Hoyvald subsequently pled guilty to 10 felony violations and was fined $100,000, and sentenced to six consecutive months of full-time community service, and to five years probation.

United States v. Boden (Bodine's Orange Juice)

This case involved a conspiracy to adulterate and misbrand orange juice products by the substitution of cheaper, inferior ingredients and by the false labeling the product as orange juice. FDA investigators reviewed and analyzed Bodine's records from January 1983 to May 1985. They determined that the firm sold 28 million more pounds of orange juice concentrate than they purchased and also that the firm purchased 35 million pounds of beet sugar more than what would be needed for the fruit drink products that were sold during that period. FDA was also able to demonstrate some of the financial benefits this illegal substitution caused, based on the lesser costs of the non-genuine "concentrate" used.

Edward Boden, Sr., Bodine's CEO, was charged in a 19 count indictment with conspiracy and violations of the Act. Edward Boden, Jr., President, and Roger Walsh, Jr., Vice President, were charged in the same indictment with violations of the Act. Edward Boden, Sr., pleaded guilty to three felony counts and was sentenced to two years imprisonment, a $250,000 fine, 1,000 hours of community service and a five year probation. Edward Boden, Jr., pleaded guilty to three misdemeanor counts and was sentenced to a $200,000 fine and 200 hours of community service and two years probation. Roger Walsh, Jr., plead guilty to three misdemeanor counts and was sentenced to 200 hours of community service and two years probation.

United States v. Anthony Syrup Company

This criminal case was filed in 1984 in Mississippi against the manufacturer, Anthony Syrup Company, and two individuals, Oliver Anthony and Dewey Clark. Mr. Anthony manufactured various syrup and honey products which he sold directly and through Mr. Clark as a business partner.

Mr. Anthony was well aware of the standards required for his products, but intentionally substituted cheaper ingredients such as corn syrup for the valuable constituents - maple, sorghum, and honey. Until the development of analytical methods for detection of such adulteration, FDA was not able to prove the adulteration. The carbon isotope and sugar profile analytical methods, developed by FDA, provided the necessary tools to bring this case. FDA also had difficulty locating consignees since Anthony and Clark would not voluntarily provide that information. Through extensive contacts with state regulatory officials, FDA investigators located consignees and obtained samples to bring the case.

Anthony and Clark were charged by a grand jury with conspiracy; the company and the individuals were charged with 13 felony adulteration and misbranding charges. After a plea agreement, Mr. Anthony was fined $20,000 and placed on four years' probation. Mr. Clark was fined $10,000 and also placed on four years' probation. The terms of their probation were that they would not violate the Food, Drug, and Cosmetic Act.

Almost immediately FDA began to receive complaints that Mr. Anthony was continuing to sell adulterated syrup and honey products. Within about eighteen months FDA had gathered sufficient evidence, through sample analysis and other investigative procedures, to bring a contempt charge against Mr. Anthony for violation of his probation. Following a trial, Mr. Anthony's probation was revoked and he was sent to a federal penitentiary in July 1986. He served six months of his sentence before being released.

United States v. Pilgrim Syrup

In October 1989, a grand jury in the Southern District of Mississippi returned a 12-count indictment against the sole proprietor of a syrup producer, based on an extensive FDA investigation of the producer's products, manufacturing processes, and marketing. Although the defendant went to considerable lengths to conceal his substitution of cheaper sweeteners for genuine honey and sorghum molasses (including using his own vehicles for raw materials pick-up to avoid the documentation which might accompany a commercial hauler's trip and reliance on cash transactions without paperwork for his raw materials purchases), FDA was able to demonstrate through sugar analysis "profiles" that whatever the ingredients were, they could not be the ones on some of his labels. He pled guilty in April, 1990 to four felony misbranding counts and on June 13, 1990, was sentenced to

$25,000 fines on each count, required to pay $30,000 for investigative costs, and placed on three years probation.

United States v. Gel Spice Co., Inc.

In February 1985, the Gel Spice corporation and its president were found guilty of 10 misdemeanor food adulteration charges for causing the adulteration of stored food by subjecting it to insanitary conditions. The individual was sentenced to two years probation and a $10,000 fine. The corporation was ordered to pay a $10,000 fine and $6,000 in costs. The conviction was affirmed in United States v. Gel Spice Co., Inc., 773 F 2d 427 (2d Cir. 1985), cert. denied 474 U.S. 1060. The appellate decision explicitly rejected the claimed defense of objective impossibility (claiming that one should not be convicted for failing to do the impossible, eliminating pests a food warehouse). The court noted evidence that the same facility had passed prior FDA inspections proved that it could be done.

Crabmeat Processors

United States v. Seafood, Incorporated of Henderson

Seafood Incorporated of Henderson (Louisiana) pled guilty in May, 1986 to two second-offense[6] felonies involving the interstate shipment of adulterated crabmeat, and its president pled to one count. He received a three year suspended sentence, with three years probation, and the corporation was fined $10,000.

United States v. Pearson

Another crabmeat processor pled guilty in March 1989 to two misdemeanor counts of a six count information for interstate shipments of adulterated food. The defendant received a two year suspended sentence, three years probation and a $2,000 fine.

6/ The criminal violations of the Food, Drug and Cosmetic Act set out at 21 U.S.C. §331 are misdemeanors unless they are committed with the intent to defraud or mislead, or unless they follow prior convictions of the same defendant under section 331. 21 U.S.C. §333(a)(2).

Food Warehouses

United States v. Bueno Foods

In March 1986, Bueno Foods Old Mexico Brand, Inc. was tried in the Western District of Texas. The court found the corporate and individual defendants guilty of six misdemeanor counts of causing the adulteration of food held under insanitary conditions, and in April, sentenced each to pay a $6,000 fine, and additionally sentenced the individual to a one year (suspended) sentence, three years' probation, and 300 hours of community service.

United States v. Mascot Candy Co.

The Mascot Candy Company and its president pled guilty in April 1989 to one count of food adulteration, in a facility infested with insects (roaches in chocolate tanks) and rodents, which had caused the contamination of candy. Each received a $1,000 fine and was placed on two years probation.

United States v. Capitol Fish Co.

In July 1985 Capitol Fish Co. of the Northern District of Georgia pled to a four count information for adulteration of food by storage under insanitary conditions. In August, the individual defendant was sentenced to a $4,000 fine and to one year's probation. The firm was also fined $4,000.

United States v. Chitty & Co.

In February 1988, Chitty & Co., Inc. of Jacksonville, Florida, pled guilty (along with its vice president, its secretary-treasurer and warehouse manager) to two misdemeanor counts of causing the adulteration of stored food. The vice president was fined $5,000, sentenced to 6 months in prison, the Secretary-treasurer was fined $5,000 and sentenced to 30 days in prison, and the warehouse manager was sentenced to two years probation and to perform 120 hours community service. The corporation was fined $20,000. The corporation also paid a $25,000 fine to the Florida State Department of Agriculture for distributing food which the state had embargoed after an FDA inspection of the warehouse.

United States v. Hot An Cold, Inc.

A seven count Information was filed against the Hot An Cold corporation and Fred A. Alexy, its president and Vernon L. Brown (warehouse manager) in October, 1985 in the Northern District of New York. The Information charged adulteration and contamination of food products while held for sale after shipment in interstate commerce. All three defendants pled guilty and the corporation and its president were sentenced to a fine of $1,000 each. The warehouse manager was fined $250.

United States v. Tally-Ann Bakery

In February, 1985, Tally-Ann Bakery, of Philadelphia, and Dominic Mastrangelo, its president, were prosecuted and charged with eight counts of manufacturing bakery products in an insect and rodent infested bakery and with shipping the products in interstate commerce. This followed a course of 16 violative inspections (out of 17) over a nine-year period. The defendants pled guilty to all counts, and the company was fined $8,000, and its president received a suspended sentence and three years probation. After another set of violative inspections, Mr. Mastrangelo's probation was extended and the court ordered regular inspections of the bakery by a court-appointed consultant.

United States v. Forrest City Grocery Co.

Also in April 1986, the individual and corporate defendants in United States v. Forrest City Grocery Co. pled guilty to two felony counts each of causing adulteration of foods. The corporation was sentenced to pay a $10,000 fine on each count and the individual fined $5,000 on each count.

United States v. S.N. Long, Inc.

In February, 1985, S.N. Long Inc. pled to all seven counts, and its president and vice president pled to two food adulteration charges each. The individuals were sentenced to fourteen days in jail, two years probation, and 200 hours' community service. The corporation was fined $3,500.

Contempt of Seizure Order

United States v. Ciales Cash and Carry Inc.

Most FDA food seizures are settled by a consent decree in which the claimant of the seized food admits that the food is adulterated, and then posts a bond while the claimant attempts to recondition the food to remove the offending adulteration or misbranding, or at least to salvage any good food still left within the seized lots of food. The bond is required to reduce the likelihood of diversion of the foods under seizure.

In Ciales Cash and Carry Inc., in the District of Puerto Rico, FDA investigators noticed that some of the seized food had been removed between seizure and reconditioning, and developed evidence that the firm's owner had sold the food prior to any reconditioning approved by FDA. In August 1987, Ciales and its owner pled guilty to criminal contempt for violation of the court's seizure order after the food had been seized by the United States Marshal. Luis A. Colon, the owner, was fined $5,000 and received a sentence of 6 months probation. The court also found that the firm was in civil contempt and would be fined $10,000 per day for any future violations, and awarded $1500 in costs to the federal government.

United States v. Wong

A noodle firm's proprietor's son converted himself from spectator to a defendant in Norfolk, Virginia by offering to bribe the FDA investigator who was checking on whether the warehouse was fit to undertake reconditioning of food seized earlier at the warehouse. The FDA investigator contacted his supervisors pursuant to FDA's standing instructions for employees offered bribes. With his supervisor's help the FDA investigator was fitted with an FBI transmitting microphone. When the proprietor's son consummated the transaction ($200 for a favorable inspection report) in the firm's parking lot, the FBI monitored the conversation, and confronted the aspiring briber. Plea negotiations ensued promptly, and after a guilty plea, the defendant was sentenced to two months in a treatment facility, probation for one year and a $2,000 fine. Additionally, the firm forfeited the $10,000 bond it had posted in the original seizure.

United States v. Sun Shine Trading and Transportation, Inc.

In January 1990, the Sun Shine Trading and Transportation Inc. of the Eastern District of Virginia and Richard Lu, its Vice President were sentenced after pleading guilty to a misdemeanor count of causing the adulteration of food by holding it under insanitary conditions. The Corporation was fined $4,000 and the individual $1,000 and sentenced to 18 months probation.

United States v. Tulkoff's Horseradish Co.

An FDA inspection in November, 1984 of a horseradish manufacturer in Baltimore, Maryland, revealed that the firm was substituting, in part, potatoes for horseradish. This substitution resulted in significant economic gain by the firm. Company officials went to great lengths to cover up this practice, but FDA found large quantities of potatoes hidden at the firm, some in a secret compartment. Analysis of samples collected at the firm and around the country revealed the presence of potato starch in the samples, using a new method developed by FDA. Multiple seizures were accomplished on the lots found to be adulterated and a criminal information was filed against the company and three responsible individuals. Two individuals pled guilty to four misdemeanor counts each in June 1986, and the company pled to all ten counts. The company was fined $9,900, plus a $100 assessment, and each of the convicted individuals was fined $800.

Infant Formula

E-Ferol Related Deaths

E-Ferol was a high potency, single ingredient, vitamin E intravenous injection manufactured by Carter Glogau Laboratories, Glendale, Arizona, exclusively for O'Neal, Jones and Feldman (OJF), Maryland Heights, Missouri. Neither firm did any studies to demonstrate the drug's safety and effectiveness and the firm did not seek or obtain a New Drug Approval regarding E-Ferol. The drug was promoted to neonatologists and neonatal intensive care units. While on the market E-Ferol was associated with adverse reactions in approximately 100 premature infants, resulting in 40 deaths. FDA initiated inspections of O'Neal, Jones and Feldman, Inc., and Carter-Glogau Laboratories. These direct inspections produced little information, because both firms refused to provide information on the development of the drug. FDA subsequently learned of several civil lawsuits which had been filed against the companies. FDA was able to obtain

depositions and documents from the civil cases including some records regarding the development of E-Ferol that had been refused during the FDA inspections.

In January 1986 the matter was brought before a grand jury. FDA compliance officers served as the case agents for the grand jury investigation and assisted in drafting subpoenas, questioning witnesses, reviewing documents and drafting the indictment. FDA's compliance officer also served as custodian of grand jury subpoenaed documents. In July 1987 both firms and their presidents and one vice president were indicted on twenty-five felony counts, including conspiracy, mail fraud, wire fraud, misbranded drug charges and new drug charges. Prior to the trial, O'Neal, Jones and Feldman entered into a plea agreement. During the trial James Madison pled guilty to three felonies. At the conclusion of the trial, Larry Hiland, President of OJF, was convicted of 18 felonies and Carter Glogau and its President, Ronald Carter were each convicted of 13 felonies. James Madison was fined $12,000 and sentenced to 8 years (all but 6 months dismissed). Larry Hiland and Ronald Carter were each fined $130,000 and sentenced to 9 years (all but 6 months dismissed). Carter-Glogau Laboratory was fined $135,000 and ordered to pay $100,000 toward the cost of the government investigation. O'Neal, Jones and Feldman Company was fined $125,000 and ordered to pay $115,000 penalty toward the cost of the government investigation.

United States v. Wyeth Laboratories, Inc.

On May 31, 1985, Wyeth Laboratories, Inc. pled guilty in the Western District of Michigan to 12 misdemeanor violations of the Act. The prosecution was the result of a mishap in which vitamin B-1 was substituted for vitamin B-6 in several lots of infant formula. Continued consumption of a formula deficient in vitamin B-6 can have serious, permanent, adverse health effects on an infant. The incident, which occurred in 1982, was caused by human error in handling raw materials. The incident was widely reported, resulted in the recall of two million cans of formula and was the focus of a congressional hearing. The company was fined $12,000. No corporate officials were involved in the pleas. This was the first criminal case to be brought under the Infant Formula Act of 1980.

United States v. Eden Foods

On November 30, 1988 Eden Foods and its president pled guilty in the Eastern District of Michigan, to misdemeanor violations involving the shipment of a soy milk beverage that

was promoted as a good substitute for mother's milk, but did not contain some necessary nutrients for infant formula. The corporation pled guilty to 12 violations occurring between 1983 and 1985 and was fined the maximum of $111,000. The president pled guilty to one violation that occurred in 1985 and was sentenced to one year in prison, with all but 30 days suspended, and a $25,000 fine. He was the first individual convicted of violating the Infant Formula Act of 1980.

The guilty pleas in Eden Foods were made after the District Court ruled on October 20, 1988 that the product's uses for adults did not allow it to escape FDA regulation as an infant formula when it was promoted as a breast milk substitute.

Steroids

Anabolic steroid drugs are widely misused by body-builders, powerlifters, and athletes (even adolescent ones) anxious to build bulk and strength rapidly. There is a substantial black market in these drugs (and, consequently in diverted, counterfeit and illegally made steroids, as well). Although there have been a number of world-famous cases and disqualifications of prominent steroid users, use of these drugs, even among young people, continues. Because they are not (so far, at least) recognized as drugs subject to regulation by the DEA under the Controlled Substances Act, they are regulated through the adulteration, misbranding, counterfeiting and new drug provisions of the Food, Drug, and Cosmetic Act. Since 1985, FDA has investigated or referred over 150 individuals, and the cases have resulted in over 15 persons being indicted and over 100 convictions. Sentences in these cases are usually tougher than sentences in the mor traditional FDA prosecutions. These cases tend to involve more dangerous defendants than most FDA cases, and the defendants seem increasingly like the more traditional illegal drug-dealing organizations than most of our cases. FDA cooperates extensively with the Department of Justice on them, with the FBI, with Customs, and with state regulators. The following cases are illustrative of the breadth and complexity of these cases.

United States v. Fitton (S.D. Cal.)

In February 1985, an individual pled guilty to three counts charging him with conspiracy to import steroids and with importing steroids into the United States. In Novembe 1985, the defendant pled guilty to additional charges arisi

from his fleeing the United States to avoid sentencing. He was sentenced to four and one half years in prison.

United States v. Shields (D. N.J.)

In June 1985, an individual pled guilty to two counts of dispensing prescription drugs without a prescription. In September 1985, the defendant was sentenced to pay a fine of $7,500, placed on probation for five years, and ordered to perform 150 hours of community service.

United States v. Glascow (W.D. Ark.)

In December 1985, an individual pled guilty to five counts charging him with dispensing prescription drugs without a prescription. The defendant was sentenced in February 1986 to pay a fine of $1,075.

United States v. Harrison (S.D. Ill.)

In April 1986, a licensed pharmacist and a corporation pled guilty to dispensing prescription drugs without a prescription. The individual was fined $2,000 and the corporation was fined $8,000. The State of Illinois Department of Registration and Education suspended the individual's license to practice pharmacy for one year and permanently revoked the pharmacy license of the corporation.

United States v. Krusinski (E.D. Michigan)

In March 1986, an individual offered his plea of guilty to charges of three felony counts of dispensing prescription drugs without a prescription. In September of that year, he was sentenced to 18 months in prison and fined $6,000.

United States v. Kennedy (W.D. Texas)

One defendant was convicted of conspiracy to violate the Act and felony dispensing of prescription drugs without prescription; the second defendant was convicted of conspiracy to defraud FDA and of three misdemeanor counts of introducing a misbranded drug into interstate commerce. In August 1986, defendant Kennedy was fined $20,000, sentenced to five years probation and to forfeit $180,000 in profits, and to surrender his pharmacist's license, and to perform 300 hours community service during each year of probation. Co-defendant Haga was sentenced to 90 days in jail and 5

years probation, fined $9,000, and required to forfeit $2,000 in profits. Hagas's conspiracy conviction was reversed on a charging defect in 1987, but the Court of Appeals affirmed his misdemeanor conviction based on introducing the misbranded drug into interstate commerce.

United States v. Bradshaw (S. D. Fla.)

In October 1986, a trial jury convicted Bradshaw of 21 felony counts of dispensing steroids without a prescription with the intent to defraud and mislead. In December, the defendant was sentenced to six years in prison, three years probation and a fine of $210,000. In April 1988, the Eleventh Circuit affirmed the conviction, and confirmed that the "intent to defraud or mislead" may be the intent to defraud the government, even when there was no intent to defraud the purchaser, as when a dealer in counterfeit drugs sells to another dealer who knows the drugs are counterfeit. United States v. Bradshaw, 840 F.2d 871 (2nd Cir. 1986).

United States v. Lodi (C.D. Cal.)

In June 1987 the defendant pled guilty to eight felony counts under the Act of selling a prescription drug without a prescription, a customs smuggling violation and conspiracy. This defendant had sent over $1,200,000 to one foreign supplier for steroid drugs to be smuggled into the United States. Mr. Lodi was sentenced to four years in prison, five years probation, and a $300,000 fine. In addition, his wife was sentenced to five years probation and a $100,000 fine. his associated, Artino, was sentenced to six months in prison, three years probation, and a $10,000 fine.

United States v. Pacifico (S.D. Cal.)

In June 1987 the defendant, a nationally-known powerlifter, pled guilty to two felony violations of the Act and to customs violations in connection with smuggling steroids. Mr. Pacifico was sentenced to three months in prison.

United States v. Dixon (C.D. Cal.)

In August 1987 the defendant pled to two felony counts involved in the distribution of steroids without a prescription. Mr. Dixon was sentenced to three years probation and a $10,000 fine.

United States v. Golini (C.D. Cal.)

In September 1987, Golini was indicted for three counts of perjury to a grand jury investigating black market steroids. He was convicted in May 1988 on all three counts after a jury trial, and sentenced in September to two years in prison.

Clandestine Steroid Manufacturing Plant

The National Steroid Coordinator became aware of an alleged clandestine drug manufacturing lab reportedly operating in Georgia and South Carolina. FDA investigators visited a number of large brokers who were known to import large amounts of bulk steroid raw materials into the United States. Using distribution records obtained from these firms, FDA was able to identify the actual site of the illicit drug lab. The subsequent investigation resulted in the closure of the firm, prosecution of individuals (Danny Rogers and his wife) involved in this conspiracy in South Carolina, the owner of the pharmaceutical company in Georgia, and the first prosecution of a label printing operation under the Act.

United States v. Rogers (D. S.C.)

In December 1988 a grand jury returned a 44 count indictment against a drug wholesaler, manufacturer and six individuals, charging illegal manufacturing and distribution of steroids, interfering with a grand jury investigation, conspiracy, wire fraud, drug misbranding, obstructing justice, and perjury. In January 1989, the wholesaler pled to ten felonies in connection with the conspiracy to manufacture and distribute steroids and to obstruct justice. In December 1989 he was sentenced to five years in prison and fined $3,000. His wife pled to lesser charges and was sentenced to five years' probation and 300 hours community service. The corporation was sentenced to a fine of $350.

United States v. Tirado (N.D. Cal.)

In September 1989 Tirado pled guilty to conspiracy, money laundering, and counterfeiting of steroids, all felonies. Carol Stasi (Tirado's sister) pled guilty to a felony conspiracy count and Eric Swanholt pled guilty to three FDA misdemeanors. This case resulted from a joint IRS/FDA investigation, and is the first application of the money laundering statute in an FDA prosecution. In December

1989, Tirado was sentenced to four years in prison; Carol Stasi was sentenced to three years imprisonment (all suspended) and 180 hours of community service; and Eric Swanholt was sentenced to three years probation and 300 hours of community service.

Mexican (Jenkins) Steroid Smuggling Ring

In the fall of 1986, while working with the FBI on the execution of a criminal search warrant in Los Angeles, California, the National Steroid Coordinator recognized the importance of the discovery of loose prescription drug labels found at the home of a steroid trafficker. Upon checking with the manufacturer listed on the label, he learned that these drugs were counterfeit. This was the first notice to FDA of the existence of a clandestine or counterfeit drug manufacturing problem on the steroid black market. Using leads supplied by a local police department in Phoenix, Arizona in an extortion and robbery case, FDA documented the probability that these drugs were being manufactured in Mexico and smuggled into the United States through San Diego, California.

At the request of FDA, United States Customs provided up to 30 agents at a time to assist in this investigation. The result was the 1987 indictment of the owner of a multimillion - dollar pharmaceutical firm in Mexico, and the smuggling ring of individuals throughout the United States including a British Olympian, who were involved with the Mexican pharmaceutical operation in smuggling millions of dollars worth of prescription drugs into this country. With the exception of the Mexican citizens who could not be apprehended, all of the 30 individuals charged pled guilty and have been sentenced to as much as 7 years in jail. Some of the individual sentences were ultimately reduced after the sentences were partially served.

Veterinary products

FDA's regulation (and investigations) of the animal-health industry are too little appreciated as protective of human health. Because so much of our diet is animal-derived, and because so many of our food-producing animals are dosed or fed drugs or animal feed products with toxic potential, these products affect the public much more than the public realizes. The public's lack of appreciation of the extent of this protection is a recognition of the effectiveness, so far, of that protection.

United States v. J.E.W., Inc.

(Heptachlor-treated Seed Caused Contaminated Milk)

J.E.W., Inc. (for Jack E. White), Van Buren, Arkansas, was a Gasohol plant that purchased distressed and salvaged grains, treated seed and discarded seed grains for the manufacturing of alcohol for use as fuel. The wet mash resulting from the alcohol production was marketed by a wholly-owned subsidiary, Valley Feeds, Inc., as animal feed.

An inspection conducted in January and February 1986 documented the firm's use of high-moisture grain and seeds treated with heptachlor, a pesticide toxic to humans. FDA analysis of feed from this firm and of milk from dairy farms that were using the feed revealed heptachlor levels 1,000 times the allowable level in feeds and more than 120 times the FDA action level for heptachlor in milk. Eleven firms initiated recalls of milk or dairy products that were found to be contaminated with heptachlor.

FDA coordinated the investigation of the firm's activities concerning the knowledge and intent of the individuals to violate various laws. In addition to FDA, FBI USDA, EPA, and the Arkansas State Health Department were involved. On March 12, 1986, an injunction was obtained against J.E.W., Inc. and Valley Feed to cease production and sale of animal feed.

A federal grand jury indicted four individuals; Jack E. White, Henry R. White, Brownie C. McBride and Jerry L. Finley, on 52 counts, including one RICO (racketeering) count, eight mail fraud counts, 13 fraud counts, five transportation of money acquired by fraud counts, 17 FDA felony counts of contamination of feeds with heptachlor and aflatoxin, and 7 EPA counts.

A jury rendered a guilty verdict on May 22, 1987. Jack E. White, Henry R. White and Brownie C. McBride were sentenced to prison terms ranging from three years to one year and a day, with fines up to $7,500 for selling pesticide-contaminated feed and for polluting Arkansas waterways. A fourth defendant, Jerry L. Finley was fined $5,000 and placed on three years probation.

United States v. Vermedahl

In January, 1985 in United States v. Vermedahl (N.D. Tex.) the manager of two large cattle feedlots pled guilty to six misdemeanor violations arising from his authorization of

the use of diethylstilbestrol (DES) in cattle in feedlots he managed after he knew that the drug's FDA approval for such use had been withdrawn. FDA had withdrawn DES approvals in 1979 because of findings that the drug had not been shown to be safe for use in food-producing animals. An FDA administrative hearing on a record had established that DES was a carcinogen, and that its use left residues in the edible tissues of beef cattle; residues that were of carcinogenic concern. Vermedahl's feedlot had concealed the use of DES by misdescribing its use in the feedlot's internal computer system.

A cowboy at one of the lots, disappointed at not being selected for a new position at the feedlot, had threatened to go to the FDA and did go to the parent corporation with reports of the illegal use. The parent firm, fearing the employee was on his way to FDA with the story, admitted to FDA that the use of DES had continued after the legal deadline. As FDA followed the trail of illegal sale and use of DES after the withdrawal, it eventually identified over 200 feeders who illegally used the drug, and hundreds of thousands of cattle which were illegally implanted with the carcinogenic DES implants after the legal deadline. At least seven criminal prosecutions were assembled by FDA investigators and compliance officers and brought against DES sellers and users because of these illegal transactions.

Vermedahl was sentenced in February 1985 to three years probation.

United States v. Walco International, Inc.

In November 1979, FDA put into effect the total ban on the distribution and use of the animal growth hormone diethylstilbestrol (DES). By Spring, 1980, reports began to surface that the banned drug was continuing to be sold for use in food producing animals. FDA investigators identified Walco International, Inc., Porterville, California as a major source of the illegal drug. The firm is a wholesale veterinary drug distributor with 45 divisional sales outlets throughout the United States and Canada. After a lengthy investigation by FDA and the Department of Justice, the grand jury for the Eastern District of California at Fresno indicted Walco International, Inc., and its President. The indictment charged the defendants with causing 18 separate shipments of the banned drug in interstate commerce in Arizona, California, Colorado, Kansas, Oklahoma and Texas. This grand jury indictment was particularly difficult because it involved gathering evidence from uncooperative and hostile food animal producers and veterinarians still upset over the ban of DES. On November 18, 1985, after a brief trial, USDC

Judge Robert Coyle found Walco International guilty on all eighteen counts and assessed a total fine of $9,000. The individual defendant was found not guilty.

United States v. Henriquez
United States v. Damon Corp.

Another illegal DES transaction sparked United States v. Henriquez. In this case, an employee of a DES manufacturer arranged to covertly "buy back" DES from a customer after the sale of the drug for animal use became illegal. FDA investigators pieced together a triangular transaction in which a struggling international freight forwarder in Miami picked up over $45,000 in cash from a Miami bank which had allegedly been wired from Brazil, then transferred the cash in a briefcase to two employees of the drug company in a hotel bar near the Ft. Lauderdale airport. The cash was carried to a Boston suburb, where $31,000 of it was converted to treasurer's checks deleting the usual identification of the purchaser's name (all "off the books" of the animal drug company, to avoid the revelation that the company was trafficking in DES well after the legal deadline). The cashier's checks were mailed to a Childress, Texas veterinary supply dealer, who used the money to pay back the drug company ("on the books" for the earlier shipment of the drugs when they could still be legally sold) and sent the DES implants to the Miami freight forwarder. The Miami freight forwarder swore that he then sent the DES to the Brazilian customer, identifying the shipment on the customs declaration as "machinery parts" to avoid Brazilian authorities' questions about drug shipments and import duties.

In the process of documenting this transaction, FDA investigators and compliance officers in the Dallas, Miami, Newark and Boston Districts sorted thousands of transaction slips, bank records and a few significant notes from tens of thousands of useless documents to discern the pattern.

The Damon Corporation, Needham, Massachusetts and the individual defendant pled guilty, the corporation in 1984 to a misdemeanor and the individual to a felony count, causing the interstate shipment of a unapproved new animal drug, with the intent to defraud and mislead. The corporation had been fined $500 in 1984, and the individual was fined $7,500 in January, 1985. The individual was additionally sentenced to community service one day each week (to be designated by the Probation Officer, not the defendant) for one of his two years of probation.

United States v. Utica Veal

After an investigation by FDA with a number of other enforcement agencies, the Buffalo, New York, United States Attorney and Department of Justice Strike Force at Syracuse convened a Grand Jury utilizing FDA and FBI case agents which resulted in judgments in August 1985 against Utica Veal Company, Mariano J. Broccoli, President, and Celia D. Soelner, Secretary, for introducing adulterated veal into commerce with the individuals each fined $1000.

The investigation began in February 1982, when an eighteen year old informant phoned FDA's Buffalo District Office reporting an individual identified as "Gus", noted to be wearing a Utica Veal (slaughter facility) jacket, medicated veal calves with an unknown milky white substance at the Ronald Thurber farm. The substance was promoted by Gus to dramatically increase the weight of the veal calves. The District believed the substance was Diethylstilbestrol (DES). Inspection of Utica Veal at the time the Thurber animals were sent for slaughter confirmed some of the reported information including Utica Veal's knowledge of Gus. However, screening analyses of tissues from the Thurber calves did not identify the presence of DES. Thurber filed a tort claim against the government for monetary losses incurred as the result of the hold placed on the carcasses of veal calves offered for slaughter.

Buffalo District FDA persisted with the assistance of other agencies. FBI agents identified the name and Canadian address of Gus from the files at Utica Veal Co. in August 1982. U.S. Customs officials were notified and in August 1982. Customs seized two bottles of the undeclared substance when Gus entered the United States at Alexandria Bay, New York. FDA's Denver Laboratory confirmed the substance to be DES with penicillin. New York State Police, Bureau of Criminal Investigations, followed Gus to several farms that he visited on subsequent entries several times per month. The Royal Canadian Mounted Police and Ontario Provincial Police petitioned their government for and secured telephone toll records concerning calls from Gus' residence enabling Buffalo FDA to put together pieces of the informant's story with New York State Police reports to identify potential users of DES. New York State Department of Agriculture & Markets, Animal Industry Division investigators conducted surveillance at suspect farms. USDA veterinarians were notified to sample veal calves offered for slaughter by suspects farms. FDA's Denver laboratory confirmed the presence of DES in the tissues of calves offered by Edward Conhaim, d/b/a Tomahara Farms; Edward Nelbach Farm; Martin Horeth farm; and the James Varga farm. Analyses found DES in the parts per billion range. Inspections were made at each

veal farm and subsequent analyses confirmed the presence of DES in the feces of veal calves. New York State quarantined all the affected animals. The four producers were enjoined (Temporary Restraining Orders were obtained) in March 1983. As a result of a hearing in the Tomahara Farms injunction, United States Magistrate Edward Conan issued an Opinion and Order finding for the government. Consent Decrees of Permanent Injunction were obtained and entered against the four farms.

FDA's Denver laboratory analyzed reserve samples taken from the original Thurber veal calves offered for slaughter and confirmed the presence of DES in the animal tissues at the more sensitive parts per billion range. The tort claim against the government by Thurber was dismissed by a federal judge at Rochester.

Plea agreements resulted from indictments filed against Edward Conhaim (Tomahara Farms), Edward Nelbach, and James Varga for introducing adulterated veal into commerce with each fined $500. The charges against Utica Veal and seven employees were part of several other Title 18 charges including conspiracy, mail fraud, falsification of records, and shipment of stolen cattle resulting in a total fine of $38,500 and orders to make restitution to farmers in the amount of $292,000.

United States v. Argent Chemical Laboratories, Inc. (E.D. Wash)

Argent Chemical was convicted in the Eastern District of Washington of shipping unapproved new animal drugs and unapproved pesticides; the corporation was fined $70,000, the individuals fined $20,000 and $10,000. The president of the corporation was sentenced to a one year prison term with all but 60 days suspended. The sentence was served in a work-release program.

United States v. Jacobs

Unusual persistence was required in United States v. Jacobs (E.D. Cal.) after the district court had dismissed the indictment of two veterinarians because of alleged misconduct at trial by the Department of Justice prosecutor. The 'misconduct" involved a suposedly inaccurate copy of a record, which in fact was accurate. In August of 1988 the Ninth Circuit reversed the trial court's dismissal, United States v. Jacobs, 855 F.2d 652 (9th Cir. 1988), and granted the government's request for transfer to a different district court judge for trial. The defendants then pled guilty to

adulterating and misbranding chloramphenicol, a prescription-only drug used in humans and animals. The defendants were fined the (then) maximum $1,000 per count, and sentenced to 300 hours community service each, and placed on probation for a period of three years.

United States v. Western Serum Company, Inc.

In July 1986, pursuant to a plea agreement, Western Serum Company, Inc. of Tempe, Arizona, and its president pled guilty to two counts of an eight count information charging criminal contempt for violating an October 1980 civil injunction which had permanently restrained defendants from introducing into interstate commerce 11 specified new animal drugs and other similarly labeled drugs, and from violating FDA's good manufacturing practice regulations. In September 1986, the individual and the corporation were each fined $50,000. The individual's five year probation was conditioned on his engaging in no business relating to drugs. The corporations' fine was suspended because the corporate charter had been revoked.

United States v. Chittick
and
United States v. Sturtz (N.D. Iowa)

In June, 1987 in United States v. Chittick and United States v. Sturtz (N.D. Iowa) five veterinarians pled guilty; each to one count of misbranding chloramphenicol in connection with their sales of the drug without a prescription to an FDA undercover buyer. Chloramphenicol is a prescription-only drug. Each of the veterinarians was fined $500.

Bulk Veterinary Drugs

In January 1987 the Agency forwarded to the Office of Consumer Litigation/Department of Justice a request to initiate grand jury investigations into the illegal distribution of "bulk" veterinary drugs. This referral was a result of nearly three years of investigational activity by several FDA District offices including Kansas City, Minneapolis, Chicago, Atlanta, and New York. The evidence indicated nation-wide illegal importation and smuggling of high potency bulk animal drugs and subsequent distribution in the United States by individuals who did not hold new animal drug approvals for the drugs.

Utilizing grand juries, targets were identified in 15 states, (10 FDA District offices). Additionally, information has been obtained which indicates ties to several foreign countries including West Germany, the Netherlands, Canada and the Grand Cayman Islands.

Smuggling, conspiracy, adulteration and misbranding of animal drugs are among the charges that have resulted from these investigations.

More than 30 tons of adulterated and misbranded animal drugs with a wholesale value of more the $600,000 have been seized in Illinois and Nebraska in connections with the case. Additionally, 5,000 pounds of smuggled drugs was seized in December 1988, by United States Customs. These drugs had a wholesale value of $200,000.

Custom Feed Blenders and its president and general manager, Jeffrey A. Engel, made and distributed drugs for sale to veterinarians, farm supply outlets and farmers throughout the nation. Jeffrey A. Engel is one of 12 individuals who have been charged with conspiring to violate customs laws and the Federal Food, Drug, and Cosmetic Act. Those charged worked to import, distribute, manufacture or sell high potency bulk animal drugs for which neither they nor their customers possessed the requisite New Animal Drug applications (NADA). The charges included making false statements and using illegal practices to import and merchandise the drugs, and for failing to register as a drug manufacturing facility. Engel pled guilty to three of the felony charges. In August 1989, Jeffrey Engel was sentenced to a jail term of 3 years, with 2 1/2 years suspended, a $10,000 fine, and to 1500 hours of community service.

These and all the bulk animal related cases were a direct result of extensive criminal investigations by FDA Investigators, working independently and with United States Customs agents. Investigative tools used in these cases have included undercover surveillance, monitoring of consensual phone calls and in one case, a concealed recording or transmitting device on an FDA investigator.

Bulk Animal Drug Smuggling

In another case developed as part of the bulk animal drug investigation, Gary Van Dusen, Mississauga, Ontario, Canada, was involved in smuggling the drugs into the United States from Canada. One of his primary customers was Ardean Veldkamp. Van Dusen came into the country to receive payment for one of his shipments and was arrested. Van Dusen pled guilty to one felony count of smuggling and was sentenced to

30 days in jail. Veldkamp received a one year suspended sentence and was fined $25,000.

Twenty-eight individuals and four firms have been sentenced in the bulk animal drug cases. Three of the individuals have entered guilty pleas and are awaiting sentencing.

Clack and Dall Bulk Animal Drugs

In a case developed as part of the bulk animal drug investigation, in November, 1988 a grand jury in Cedar Rapids, Iowa indicted Heinz G. Dall, of Ossining, New York, and Robert M. Clack, D.V.M., of Pittsfield, Illinois for not having approved new animal drug applications required prior to making and marketing animal drugs and conspiring to illegally import the drugs. They pled not guilty. Shortly before trial was to begin, Dall pled guilty to two felony counts of conspiracy to commit offenses against the United States government and to smuggling chloramphenicol into the United States. He was sentenced in November, 1989 to 24 months imprisonment, three years probation, and $40,000 fine. Clack pled guilty to use of a false document and to a conspiracy to commit offenses against the United States and was sentenced to 21 months imprisonment, three years supervised release, and fined $44,000.