Chapter 7 – Court Decisions

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Court Decisions

United States v. Genendo, (S. Ct.). On November 26, 2007, the United States (U.S.) Supreme Court denied Genendo Pharmaceutical's petition for a writ of certiorari. Genendo, a drug importer located in Curacao, Netherlands Antilles, sought review of the Seventh Circuit's May 10, 2008, decision that affirmed the District Court's 2005 order of permanent injunction.

The Food and Drug Administration (FDA) initiated the case in 2003 to seize adulterated, misbranded, and unapproved new drugs from Phil & Kathy's, Inc., a drug repackager doing business under the name Local Repack. The U.S. amended the complaint to seize additional drugs and to add Genendo as a defendant. Phil & Kathy's, Inc., and its owner, Phil Giannino, entered a consent decree of condemnation and injunction with the U.S. in 2004. The remaining case against Genendo went to trial in 2005, and the U.S. prevailed.

Consistent with the 2005 order, the Seventh Circuit's decision held that Genendo violated the Federal Food, Drug, and Cosmetic Act (FDCA) when it imported name-brand drugs that were not intended for domestic distribution, and which did not fully comply with FDA-approved new drug applications (NDAs). In rejecting Genendo's arguments, the Seventh Circuit recognized that foreign versions of FDA-approved drugs that are not fully compliant with FDA-approved NDAs are unapproved new drugs under the FDCA. The Seventh Circuit also rejected Genendo's argument that under a limited provision in the FDCA, the imported drugs were exempt from all labeling and packaging requirements in the FDCA, including NDA requirements, because they were sent to a drug repackager before distribution to consumers.

Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, (S. Ct.). On January 14, 2008, the U.S. Supreme Court denied the petition for a writ of certiorari filed by Abigail Alliance for Better Access to Developmental Drugs and Washington Legal Foundation (the petitioners). The petitioners brought this action in 2003 to challenge FDA regulations and policy that limit patient access to unapproved drugs on the ground that limited access violates the constitutional rights of terminally ill patients. The district court dismissed the case on the ground that there is no fundamental right of access to unapproved

drugs. On May 2, 2006, a three-judge panel of the D.C. Circuit (by a 2-1 vote) reversed the district court's decision and recognized a new fundamental right of access to investigational drugs for terminally ill individuals. The majority panel of the D.C. Circuit found a fundamental right based on a long-standing traditional right of self-preservation. The government petitioned for rehearing before the entire court *(en banc)*, which the D.C. Circuit granted. After oral argument on March 1, 2007, the *en banc* court (by an 8-2 vote) issued an opinion on August 7, 2007, finding that there is no Constitutional right of access to experimental drugs for terminally ill patients. The majority opinion concluded that there is no deeply rooted right to procure and use experimental drugs in our nation's history and traditions. Because there was no fundamental right implicated, the court evaluated and upheld the constitutionality of FDA's regulatory scheme under the rational basis standard. The Supreme Court's denial of the petitioners' writ of certiorari left the *en banc* decision intact and put an end to the case.

United States v. Brownwood Acres Foods, Inc., (W.D. Mich.). On February 19, 2008, a U.S. District Judge entered a consent decree of permanent injunction against Brownwood Acres Foods, Inc., and company officials Stephen C. de Tar and Robert L. Underwood (the defendants). The defendants agreed to stop manufacturing and distributing any product with claims to cure, treat, mitigate, prevent, or reduce the risk of disease in its labeling until the product is either approved by FDA as a new drug, is exempt from approval as an investigational new drug, or has permissible health claims or acceptable qualified health claims. The defendants manufacture and distribute various products including juice concentrates, soft fruit gel capsules, fruit bars, dried fruits, liquid glucosamine, and salmon oil capsules. They have a history of including unapproved drug claims on their product labels, brochures, and Websites. Most recently, the companies' Websites referred customers to a second Website which contained similar statements regarding the unproven benefits of its products. This second Website was under the control of Brownwood's president. Under the terms of the decree, the defendants must remove drug and unauthorized health claims from their labels, brochures, and Websites, as well as references to other Websites that contain such claims. The decree also requires the defendants to retain an independent expert to review the claims for their products, and provides that FDA may require the defendants to cease manufacture and distribution of any product in the event of future violations. If the defendants fail to comply with the

terms of the decree, the companies must pay liquidated damages to the U.S. in the amount of $1,000 per violation per day.

United States v. Scientific Laboratories, Inc., (D. Md.). On May 8, 2008, a U.S. District Judge entered a consent decree of permanent injunction against Scientific Laboratories, Inc.; its President, Rajeshwari Patel; and its Chief Executive Officer (CEO), Amit Roy (the defendants), that prohibits the defendants from manufacturing, processing, packing, labeling, holding, or distributing any drug, other than under FDA regulations that establish conditions which certain over-the-counter (OTC) drugs may legally be marketed without FDA premarket approval (referred to as OTC monographs). Further, it requires the defendants to remedy their Current Good Manufacturing Practice (CGMP) violations. The decree allows FDA to order the defendants to shut down in the event of future violations, and requires the defendants to recall and destroy all of the unapproved drugs they have produced since January 1, 2007. In addition, the decree provides for liquidated damages in the amount of $5,000 per day and $5,000 per violation, up to a maximum limit of $1 million per year if the defendants fail to comply.

United States v. Frank Abrano, (D. Mass.). On May 28, 2008, Frank Abrano pled guilty before a U.S. District Judge to one count of mail fraud in connection with the distribution of unapproved and non-sterile drugs. Abrano was the president of Bryan Corporation, a Massachusetts company that sold drugs and medical devices. Between March 1997 and September 2000, Bryan Corporation sold more that $3.7 million worth of an unapproved new drug called "Sterile Bulk Talc" or "Sterile Talc Powder" for the treatment of pneumothorax and malignant pleural effusion. Abrano admitted that Bryan Corporation did not inform its customers that the drug lacked FDA approval. In addition, Abrano admitted that Bryan Corporation distributed quantities of the drug even after receiving laboratory test results that indicated that the drug had tested non-sterile. Abrano faces up to five years imprisonment, followed by up to three years of supervised release, and a maximum fine of more than $7.5 million. Bryan Corporation previously pled guilty to related charges, was sentenced to pay a criminal fine of more than $4.5 million, and agreed to pay $485,000 plus interest pursuant to a civil agreement to resolve allegations that it violated the False Claims Act.

United States v. An Undetermined Quantity of ½ Ounce Bottles … NC Solution, (E.D. Mo.). On May 29, 2008, a U.S. District Judge issued an order and decree of condemnation and destruction with respect to more than $200,000 worth of adulterated drugs, dietary supplements, and their components. The articles were seized from General Therapeutic Corporation of St. Louis, Missouri, on October 31, 2007, after an inspection revealed, among other things, grossly insanitary conditions and a failure to follow CGMP regulations. Although General Therapeutic initially filed a claim with respect to the articles, it subsequently sought to abandon its claim. Pursuant to the judge's order, the claimed articles are condemned and forfeited to the U.S., and General Therapeutic is required to reimburse the U.S. for its costs and expenses. The claimed articles represent approximately one-half of the articles seized from General Therapeutic. The remaining, unclaimed, seized articles were the subject of a default judgment of forfeiture issued by the judge on March 13, 2008.

United States v. Leiner Health Products, LLC, (D. S.C.). On June 13, 2008, Leiner Health Products, LLC, (Leiner) pled guilty to mail fraud and agreed to forfeit $10 million to the government in connection with its manufacture of adulterated OTC drugs at its facility in Fort Mill, South Carolina. Leiner, a contract manufacturer of various store brand OTC drugs for national chain pharmacies and retailers, admitted that it falsified stability test data used to assess whether drug products met the required specifications for identity, strength, quality, and purity during the time of possible use by the consumer. FDA investigators discovered that, from 2004 to 2007, Leiner's quality control personnel falsified test data from at least seven different product lines and approximately 1,275 batches. Leiner, which has since filed for bankruptcy, received authorization from the U.S. Bankruptcy Court to set aside the necessary funds to pay its obligations to the government.

United States v. Faust, (W.D. Wash.). On June 13, 2008, a U.S. District Judge sentenced Marilou P. Faust, following her guilty plea to misbranding a drug and aiding and abetting that offense. The charges stemmed from her role in operating an unlicensed cosmetic surgery center from her home. Faust acknowledged that she permitted two women, who claimed to be physicians, to use her home for the procedures, while she scheduled appointments and collected the money. In early

2007, the Washington State Department of Health received complaints from individuals who had received cosmetic surgical procedures at Faust's home. The procedures involved the injection of non-sterile silicon-like fillers that FDA had not approved. Complainants reported that they had contracted serious infections and permanent scarring and disfigurement as a result of these procedures. Rejecting a recommendation of probation by the U.S. Probation Department, and citing the significant public health risks created by Faust's actions, the court sentenced her to 90 days imprisonment to be followed by five years of supervised release, a $5,000 fine, and 100 hours of community service. The other two women fled the U.S. and are currently fugitives.

United States v. Cephalon, Inc., (E.D. Pa.). On September 29, 2008, the government filed a criminal injunction against, and a civil settlement with, Cephalon, stemming from the off-label marketing of three of its drugs (Provigil, Gabitril, and Actiq) for indications that were not approved by FDA. FDA approved Actiq, a powerful and highly addictive fentanyl product manufactured as a lollipop, for use only in opioid-tolerant cancer patients. Cephalon promoted the drug for non-cancer patients to treat migraines and sickle-cell crises among other indications. FDA approved Gabitril for use as an anti-epilepsy drug in the treatment of partial seizures. Cephalon promoted Gabitril as a remedy for anxiety, insomnia, and pain. FDA approved Provigil to treat excessive daytime sleepiness associated with narcolepsy, and then expanded the label to include treatment of excessive sleepiness associated with sleep apnea and shift work sleep disorder. Cephalon promoted Provigil as a non-stimulant drug for the treatment of sleepiness, tiredness, decreased energy, and fatigue. In the plea agreement with the U.S., Cephalon agreed to pay $50 million to resolve the criminal case and $375 million to resolve False Claims Act charges. As part of the resolution, the U.S. Department of Health and Human Services' Office of Inspector General and Cephalon have entered into a five-year corporate integrity agreement.

United States v. 5 Unlabeled Boxes ... Lipodrene, (W.D. Pa.). On October 15, 2007, a U.S. District Judge granted the government's motion for summary judgment and denied the motions of claimant and third-party plaintiff, Hi-Tech Pharmaceuticals, finding that Hi-Tech's dietary supplements containing

ephedrine alkaloids were adulterated under the Federal Food, Drug and Cosmetic Act (the Act), because they present a "significant or unreasonable risk of illness or injury" under labeled or ordinary conditions of use. After the seizure, Hi-Tech, the same company that in August lost a nearly identical seizure in the Northern District of Georgia filed a claim and alleged affirmative defenses, arguing that the rule banning the use of ephedra in dietary supplements did not follow notice and comment procedures and was arbitrary and capricious on the substantive adulteration issue. Hi-Tech also claimed that under the Act, FDA could not rely on the final rule as substantive evidence of adulteration but would have to prove its case with experts and discovery. The court adopted the decision of the Georgia court in the other Hi-Tech seizure, as well as decisions by the Tenth and Third Circuit, which affirmed the final rule in the face of direct (non-enforcement) challenges under the Administrative Procedures Act (APA). The court found that FDA could use the rule to establish adulteration and need not start anew, that FDA's scientific findings were not arbitrary and capricious, and that the articles were adulterated for the reasons articulated in the final rule. The court also found that FDA was not required to follow the APA's notice and comment requirements with respect to its interpretation of "unreasonable risk" because that reading was only an interpretative rather than substantive rule.

People of New York v. Mastromino, et al., (N.Y. S. Ct). On June 27, 2008, Michael Mastromarino was sentenced to serve 18 to 54 years in prison, and on June 18, 2008, Christopher Aldorasi was sentenced to serve 9 to 27 years in prison. Both were convicted on April 28 in a multi-million dollar human tissue theft conspiracy. Mastromarino, Aldorasi and two codefendants were charged with orchestrating a large-scale criminal enterprise centered in Biomedical Tissue Services (BTS), owned by one of the defendants. On September 2, 2008, Louis and Gerald Garzone pled guilty in state court in Philadelphia to charges of conspiracy, theft, and the abuse of a corpse. The Garzones admitted to selling corpses in the scheme to Mastromarino's operation. Many of the defendants have pled guilty to similar charges in state court in Philadelphia.

The defendants and their employees conspired with various funeral homes to harvest tissues from cadavers without having obtained the consent of the deceased person before their death, or their families after death; they also harvested tissues from cadavers whose age, medical conditions or risk factors would have excluded them from donating tissue under federal law. The firm failed to keep, and affirmatively falsified records in order to conceal the source of

tissues or the medical issues which made the donors ineligible. The illegally harvested tissues were sold to medical companies for use in transplantation or grafting. Some of the tissues are believed to have been harvested from persons who had communicable diseases. It is believed that more than 1,000 cadavers were subjected to the illegal tissue harvesting. In October 2005, FDA ordered a recall of all unused tissues originating from BTS; according to the Centers for Disease Control, approximately 25,000 body parts from BTS had been distributed for medical uses in all fifty states, as well as in other countries. Two of the remaining three defendants have pled guilty and await sentencing. The case against the third was pending at publication. FDA assisted the state investigation and prosecution.

United States v. 448 cases ... Extra Virgin Olive Oil, (E.D.N.Y.). On December 11, 2007, a U.S. District Judge entered a consent decree of condemnation and destruction between the U.S. and Krinos Foods, Inc., which provides for the disposition of over 50,000 gallons of adulterated and misbranded olive oil that was seized by the U.S. on May 22. The seized oil, which was packaged in 3-liter tins and 750 mL bottles, was packaged in violation of the Act because the labeling identifies the oil as extra virgin olive oil or olive pomace oil, but the bottles and tins actually consist primarily of soybean oil. Under the consent decree, the seized oil is condemned and subject to destruction at Krinos' expense. After executing a $500,000 penal bond in the form of an irrevocable letter of credit, Krinos will be permitted to propose to FDA a plan whereby the oil will be sold as biodiesel fuel, a use that ensures that it will not be consumed as food. The consent decree also gives FDA representatives authority to make inspections and take any other measures deemed necessary to monitor and ensure compliance with the decree. Krinos is required to reimburse the U.S. for the costs of such supervision.

United States v. Thomas L. Crofut and Judith H. Crofut, (W.D. Tex.). On May 6, 2008, a U.S. District Judge entered a consent decree of permanent injunction against the owners of Good Flow Honey and Juice Company, a Texas firm that manufactures a variety of fresh-squeezed juices and juice blends. Pursuant to the consent decree, Good Flow is required to implement necessary corrective steps to ensure that its juice production is conducted in compliance with FDA's juice

Hazard Analysis and Critical Control Point (HACCP) regulation. FDA inspections since 2003 have cited the firm for failing to implement control measures in its HACCP plans. HACCP control measures are intended to consistently produce an acceptable reduction in the microorganisms of public health significance. The firm must also hire a HACCP expert to develop HACCP plans that are acceptable to FDA. After implementation of the plans, FDA is authorized to order the company to take a variety of actions if it fails to comply with the consent decree or the Act, including the cessation of production or the recall of affected products.

On September 5, 2008, the judge found the defendants in contempt of court for violating the terms of the consent decree and also found that, notwithstanding the requirements of the consent decree, the defendants had continued to operate after entry of the consent decree and thereafter refused to comply with a letter from FDA that ordered them to cease operations. In addition to finding the defendants in contempt of court, the judge fined them $10,000 and ordered them to pay $2,500 for the government's attorney's fees.

United States v. Lifeway Foods, Inc., et. al., (N.D. Ill.). On May 15, a U.S. District Judge entered a consent decree of permanent injunction against Lifeway Foods, Inc.; its subsidiary LFI Enterprises, Inc.; and two company officials, Julie Smolyansky, President and CEO of Lifeway and President of LFI, and Edward Smolyansky, Chief Financial Officer (CFO) of Lifeway and CFO and treasurer of LFI. The defendants, based in Morton Grove, Illinois, manufactured over 30 different varieties of cream cheeses and cream cheese spreads as well as several ready-to-eat seafood products at facilities in Skokie, Illinois and Philadelphia, Pennsylvania. The defendants: (1) labeled and distributed cream cheese products with inadequate labels, including labels that did not disclose major food allergens, trans fat levels, and complete ingredient lists; (2) processed and distributed products with seafood, including whitefish salad, ground nova salmon, and lox cream cheese and lox cream cheese spreads, without adequate HACCP plans to ensure the safe and sanitary processing of seafood containing products; and (3) failed to document that they monitored sanitation conditions to keep food contact surfaces clean, to prevent cross-contamination from unsanitary objects, and to maintain hand washing, hand sanitizing, and toilet facilities. The decree requires defendants to cease cream cheese and seafood production and distribution until they come into compliance with the Act and obtain approval from FDA after hiring labeling and HACCP experts and submitting their reports

to FDA. The decree also allows FDA to require immediate shutdown, recall, and other remedies in the event of future violations.

United States v. Michael E. and Anita C. Puckett, (W.D. Wash.). On June 18, 2008, Michael E. Puckett and Anita C. Puckett, owners and operators of Dee Creek Farm, a dairy that markets raw milk directly to consumers, pled guilty to causing the introduction of adulterated food into interstate commerce. In December 2005, an outbreak of *E. coli* illness was traced to raw milk purchased from Dee Creek Farm. Three of the victims were children diagnosed with total renal failure, who underwent blood transfusions and experienced extended hospitalization; some may have suffered permanent kidney damage. The Pucketts originally argued that they were not selling raw milk, but had sold "shares" of various cows to people. Those "owners" then paid the Pucketts to care for and milk the cow in which they owned a "share," and arranged for the Pucketts to ship them the milk they purportedly already owned. Since no milk was being sold, they argued, the dairy did not need a state raw milk license, nor did the FDCA or Public Health Services Act (PHSA) apply. The Pucketts ultimately abandoned this defense and pleaded guilty to a misdemeanor violation of the FDCA for causing the introduction into interstate commerce of adulterated food (food prepared or held in unsanitary conditions) in lieu of facing indictment for felony FDCA violations.

United States v. Berkeley Premium Nutraceuticals, (S.D. Ohio). On August 29, 2008, a U.S. District Judge sentenced the last of eleven Berkeley Premium Nutraceutical executives who were convicted for their roles in a multi-million dollar fraud scheme involving dietary supplements. The scheme involved the misbranding of dietary supplements and defrauding customers using a variety of fraudulent practices. The judge sentenced Berkeley's in-house attorney, Paul Kellogg to a term of one year and one day of imprisonment, followed by three years of supervised release. A jury convicted Kellogg on February 22, 2008, of six counts of conspiracy, including conspiracy to obstruct proceedings before the FDA. Company president and owner, Steven E. Warshak was previously sentenced to a term of 25 years imprisonment, followed by five years of supervised release, with a fine of $93,000. In February, the jury also convicted Warshak of five counts of conspiracy to commit money laundering and various

types of fraud, conspiracy to obstruct agency proceedings, mail fraud, bank fraud and money laundering. Warshak's mother, Harriet Warshak, was sentenced to 24 months imprisonment, followed by three years supervised release for her part in the scheme. The Warshaks, Berkeley Premium Nutraceuticals, and Kellogg were ordered to forfeit approximately $500 million to the U.S. Other defendants received sentences of imprisonment that ranged from one month to one year and a day, and included the warehouse manager, the accountant, and the vice president of sales. The warehouse manager, Steven P. Pugh, was convicted only of conspiracy to obstruct proceedings of the FDA, and received a sentence of a year plus a day imprisonment. The company was sentenced to five years probation and a fine of $15 million.

United States v. Caputo, (7th Cir.). On February 27, 2008, the U.S. Court of Appeals for the Seventh Circuit upheld the convictions of Ross A. Caputo and Robert M. Riley. The award of restitution that the defendants owe to each of their former customers was remanded to the U.S. District Court for the Northern District of Illinois for recalculation.

These two executives of AbTox, Inc. were convicted on April 13, 2006, of fraudulently selling uncleared sterilizers that led to loss of sight or other eye injuries for 18 patients. Caputo was the President and CEO and Riley was the Vice President of Regulatory Affairs when the company received permission to market a small, gas plasma sterilizer only for use in sterilizing solid, stainless steel surgical instruments without tubes or hinges. The defendants instead, marketed a larger, unauthorized version of the sterilizer and promoted its use for a wide array of non-stainless steel instruments.

AbTox showed the hospitals that purchased the larger, unauthorized units the clearance letter for the smaller, authorized unit. Because of the way AbTox marketed them, these larger units were used in an unauthorized manner to sterilize complex instruments, including cataract instruments which have small tubes that are used to put solution into a patient's eye. One unauthorized use was to sterilize ophthalmic instruments that had brass joints which reacted to the sterilizing agent (peracetic acid) and created a toxic residue. AbTox knew of the reaction, but did not advise users or implement corrective action. The blindness was caused by a harmful copper acetate residue that remained in the tube of the instrument after it was sterilized in the machine.

Of the unauthorized units sold, 168 were sold to hospitals nationwide, including U.S. Department of Veterans Affairs hospitals and other government agencies, with sales totaling more than $18 million. Hospitals reported to AbTox that their sterilizer was suspected of causing injuries to several patients, but the company failed to notify FDA about these reports as required.

Caputo and Riley were convicted of three counts of wire fraud, four counts of mail fraud, seven counts of selling an unapproved, (adulterated or misbranded) human medical device, and conspiracy to defraud the FDA. Riley was also convicted of one count of making a false statement to the FDA. Two other defendants, Mark E. Schmitt, former Director of Marketing, and Marilyn M. Lynch, former Director of Clinical Services, previously pleaded guilty in the case.

On September 13, 2006, Caputo and Riley were sentenced to 10 years and 6 years in federal prison, respectively. Additionally, the defendants were ordered to pay more than $17 million in restitution. This amount represents AbTox's gross proceeds from sales of the sterilizers.