Chapter 7 - Court Decisions

Contents

Court Decisions

Gannon v. United States, (E.D. Pa.). On July 17, 2007, a U.S. District Judge granted the United States' Motion for Judgment on Partial Findings as to causation in a tort case filed against the United States under the Federal Tort Claims Act. The complaint alleged that Mr. Gannon developed cancer after receiving an oral polio vaccine ("OPV") that was contaminated with SV40, a monkey virus present in the original strain material developed by Dr. Albert Sabin, which was later used to manufacture the OPV administered to millions of people. The complaint also asserted that the Division of Biologic Standards (CBER's predecessor) was negligent in its review of manufacturing and licensing documents received from OPV manufacturers, and improperly approved the release vaccine lots that were allegedly contaminated with SV40. After hearing trial testimony from both parties' causation experts, and following extensive post-trial briefing, the Judge found that the Plaintiffs failed to demonstrate by a preponderance of the evidence that SV40 causes cancer in humans, much less Mr. Gannon's cancer.

United States v. 18 cases, more or less, and Hi-Tech Pharmaceuticals v. von Eschenbach, et al., (N.D. Ga.). On August 15, 2007, United States District Judge G. Ernest Tidwell granted summary judgment for the government in these two consolidated cases challenging the validity and enforcement of FDA's Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated (Final Rule). Hi-Tech Pharmaceuticals, Inc. (Hi-Tech) filed a case to prevent FDA from enforcing the Final Rule. In February, 2006, the government filed a complaint for forfeiture *in rem* against Hi-Tech's Ephedras's Dietary Supplements (EDS) and raw materials, which resulted in the seizure of over $3 million worth of product. Hi-Tech sued the agency to challenge the Final Rule and filed a motion for preliminary injunction seeking return of the seized articles, which the Court denied. The Court consolidated the cases.

In his Order, Judge Tidwell held that: 1) FDA complied with the requirements of the Administrative Procedures Act (APA) by providing sufficient notice that it intended to regulate EDS and the Final Rule was a logical outgrowth of the proposed rule; 2) Congress unambiguously required the use of a risk-benefit analysis under Dietary Supplement Health Ephedrine Adulterated Alkaloids. (DSHEA) to determine whether a dietary supplement presented an "unreasonable risk" of illness or injury; 3) FDA's interpretation of "unreasonable risk" in DSHEA was not a substantive rule for which FDA was required to provide notice and comment; 4) the evidence in the Final Rule was sufficient to

show by a preponderance of the evidence that dietary supplements containing *any* dosage of ephedrine alkaloids present an unreasonable risk of illness or injury; 5) FDA was not arbitrary and capricious manner in enacting the Final Rule; and 6) in a forfeiture action alleging that a dietary supplement is adulterated, the *de novo* language in the Act is properly read to require the court to defer to an agency's valid regulation declaring the dietary supplement in question adulterated.

Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, (D.C. Cir.). On August 7, 2007, the D.C. Circuit Court, sitting *en banc*, issued an opinion finding that there is no Constitutional right of access to experimental drugs for terminally ill patients. Abigail Alliance for Better Access to Developmental Drugs and the Washington Legal Foundation brought this action to challenge, on substantive due process grounds, FDA regulations and policy that limit patient access to unapproved drugs. 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 panel of the D.C. Circuit, by a 2-1 vote, reversed the district court 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 dissenting judge argued that the majority impermissibly concocted this right without any evidence that it met the Supreme Court's test for a fundamental right. The government petitioned for rehearing *en banc*. Although the D.C. Circuit grants such petitions infrequently, the court granted the petition, vacated the May 2006 panel decision, and held oral argument on March 1, 2007. The August 7, 2007 *en banc* decision was written by Judge Griffith, the dissenter on the original panel. The Court 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, FDA's regulatory scheme would be subject to the rational basis standard, which it satisfies.

Americans for Safe Access v. HHS and FDA, (N.D. Cal.). On July 24, 2007, a U.S. District Judge granted the United States' Motion to Dismiss Plaintiff's Complaint. The Plaintiff, an organization dedicated to ensuring access to marijuana for therapeutic uses and research, brought suit to force HHS to

"correct" its 2001 statement to the Drug Enforcement Agency that marijuana has no currently accepted medical use in the United States. The Plaintiff specifically alleged that the correction was required under the Information Quality Act (IQA), which requires each federal agency to establish an administrative mechanism through which affected persons can seek correction of information maintained and disseminated by the agency. In dismissing Plaintiff's case, the Judge found that the IQA does not permit judicial review of information disseminated by agencies. Noting that the Department of Health and Human Services had not yet ruled on Plaintiff's 2004 IQA petition, however, the Judge Alsup gave Plaintiff until August 17th, to amend the Complaint to raise the issue of whether the Defendants violated a legal duty by not making a substantive response to the Plaintiff's 2004 IQA petition.

United States v. Genendo, (7th Cir.). On May 10, the U.S. Court of Appeals for the Seventh Circuit affirmed U.S. District Judge James F. Holderman's 2005 order of permanent injunction against Genendo Pharmaceutical N.V., a drug importer located in Curacao, Netherlands Antilles. The Seventh Circuit 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 the FDA-approved new drug application (NDA). In rejecting Genendo's arguments, the court recognized that foreign versions of FDA-approved drugs that are not fully-compliant with FDA-approved NDAs are unapproved new drugs under the FDCA.

In addition to being enjoined from further importation of unapproved new drugs, the Seventh Circuit affirmed Judge Holderman's condemnation of a shipment of Lipitor that the United States seized in 2003 after it was imported by Genendo. At trial, the government established that the seized Lipitor was not fully compliant with the approved NDA because it was packaged in a Brazilian facility that was not identified in the NDA and was labeled in Portuguese (the approved NDA for Lipitor does not encompass Portuguese labeling). The Seventh Circuit also rejected Genendo's argument that, under a limited provision in the Federal Food, Drug, and Cosmetic Act's (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.

Nutraceutical Corporation and Solaray, Inc. v. von Eschenbach, (D. Utah). On March 16, 2007, U.S. District Judge Paul G. Cassell held that FDA's final rule declaring dietary supplements containing ephedrine alkaloids (EDS) to be adulterated, complied with the notice-and-comment requirements of the Administrative Procedure Act (APA). The court found that FDA provided the public with "generous notice" under the APA that the agency planned to regulate EDS under the Federal Food, Drug, and Cosmetic Act's (FDCA) "unreasonable risk" adulteration provision.

The court rejected Nutraceutical's argument that FDA failed to give the public notice and opportunity to comment on the agency's supposed departure from an alternative standard, because the court found that FDA never expressed an intent to rely on such a standard. In addition, the court held that FDA acted consistently with the FDCA by excluding non-dietary supplement products containing ephedrine alkaloids from the reach of the final rule.

Previously, in April 2005, the Utah district court (U.S. District Judge Tena Campbell) ruled that FDA applied the wrong standard in its evaluation of ephedrine alkaloids' safety in dietary supplements and had failed to prove that supplements with low doses of ephedrine alkaloids (< 10 mg) presented an unreasonable risk of illness or injury. FDA appealed and, in August 2006, the U.S. Court of Appeals for the Tenth Circuit unanimously reversed, holding that: (1) Congress unambiguously required FDA to conduct a risk-benefit analysis to determine whether the dietary supplement products pose an unreasonable risk of illness or injury; and (2) FDA had demonstrated that these products pose an unreasonable risk of illness or injury at any dose level and the agency was justified in banning them completely.

The case was sent back to the district court, which, in November 2006, granted summary judgment for the government on those two issues. Counsel for plaintiffs has stated publicly that his clients will appeal the March 16th decision. In addition, plaintiffs' January 2007 Petition for a Writ of Certiorari, which seeks review by the U.S. Supreme Court of the Tenth Circuit's decision, is still pending.

United States v. All articles of food … stored on the premises at Happy Valley Food, Inc., (D.D.C.). On March 22, 2007, Happy Valley Food, Inc. ("Happy Valley"), and its successor corporation, SBC Food, Inc. ("SBC"), paid liquidated damages totaling $7,000, assessed by FDA pursuant to a Consent Decree of Condemnation and Injunction (the "Decree"). Under the terms of the Decree, the adulterated food, which was seized at Happy Valley on

February 17, 2006, was condemned, and Happy Valley agreed, among other things, to pay liquidated damages if it violated the terms of the Decree. Inspections conducted by FDA revealed that Happy Valley and SBC violated the Decree in several ways: 1) Happy Valley operated before receiving authorization from FDA; 2) the company failed to notify FDA at least ten days prior to SBC taking over operations; 3) pest control continued to be inadequate and the company failed to maintain the physical plant and grounds in a condition that would protect against contamination of food; 4) it failed to have a written sanitation control program; and 5) it did not submit a timely independent audit report.

United States v. Niaja Kane, (E.D. Pa.). On January 22, 2007, United District Court Judge Timothy Savage sentenced Niaja Kane to 32 months in federal prison for distributing counterfeit drugs. Judge Savage ordered Kane to serve two years probation following her incarceration and to pay a $300 special assessment. Kane contracted with a manufacturer in China to produce counterfeit prescription drugs, including Viagra®, Cialis®, Xanax®, and Percocet®. Kane sent the manufacturer photographs of the drugs she wanted, and the unlabeled drugs were then mailed to her home. At the time of her arrest, Kane possessed over 12,000 counterfeit prescription tablets, with an estimated street value of close to $50,000.

Allen v. FDA, (N.D. Cal.). On January 24, 2007, United States District Judge Saundra Brown Armstrong denied plaintiff Brian Allen's motion for temporary restraining order ("TRO") to enjoin the continued distribution (including post-approval clinical trials) of Natrecor, a drug manufactured by Scios, Inc. ("Scios") to treat heart failure. Plaintiff, a former chemist at Scios, alleged that the Natrecor's manufacturing process produces a toxic by-product that causes the drug to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA") and that the warnings on the drug's labeling are inadequate. Accordingly, he asked the court to order FDA and Scios to take action to remove the drug from the market and FDA to withdraw the drug's approval.

In denying the motion for TRO, the court found that plaintiff had failed to established a likelihood of success on the merits because (1) he had not demonstrated that he has standing; (2) there is no private right to enforce the FDCA; (3) he had not alleged that FDA waived sovereign immunity; and (4) there was no final agency action to review. In addition, the court sustained

numerous objections to the evidence offered by plaintiff because had failed to establish his qualifications as an expert and lacked personal knowledge with respect to particular allegations. Although the court denied plaintiff's initial request for relief, it did set a further briefing schedule. Oral argument, if necessary, will occur in late March, 2007.

United States v. DeMarco and Lerner, (D.N.J.). On December 7, a jury convicted defendants Charlene C. DeMarco, a doctor of osteopathy, and Elizabeth Lerner, of 11 charges, including three counts of mail fraud, six counts of wire fraud, one count of conspiracy to commit mail and wire fraud, and one count of money laundering. The jury found that from October 2002 until November 2004, the defendants defrauded patients seeking treatment for amyotrophic lateral sclerosis (ALS), also known as "Lou Gehrig's disease," by falsely claiming FDA approval for an unapproved stem cell therapy. Defendants attempted to defraud the victims and their families of more than $140,000, and successfully obtained at least $40,000, in exchange for promises of treatments that defendants could never have performed despite DeMarco's numerous false statements to the victims that she had received FDA approval to treat ALS using stem cells. In fact, FDA had denied her Investigational New Drug Applications for such use.

Each count carries a potential fine of $250,000 in addition to a maximum sentence of 20 years per count for the mail and wire fraud charges, and 10 and five years in prison for the money laundering and conspiracy charges, respectively.

International Center for Technology Assessment v. Leavitt, (D.D.C.). On January 8, 2007, a United States District Judge denied plaintiffs' motion for relief from judgment. Plaintiffs' suit challenged FDA's decision not to regulate a genetically engineered ornamental fish ("GloFish") as a new animal drug. The court granted the government's motion to dismiss the case on March 30, 2005, concluding that FDA's decision not to regulate GloFish was committed to agency discretion and, therefore, not subject to judicial review. Thereafter, plaintiffs filed a motion to alter or amend the judgment, which the court denied on March 8, 2006. Plaintiffs filed their motion for relief from judgment on April 14, 2006, claiming to have newly discovered evidence that would undermine the court's previous decisions.

The court held, however, that "[b]ecause the plaintiffs lacked diligence in

presenting the newly discovered evidence to the court, because some of the evidence is merely cumulative and impeaching, and because the newly discovered evidence is not of such a material and controlling nature that it will probably change the court's decision to dismiss the case, the court denies [plaintiffs'] motion."

RxUSA Wholesale, Inc. v. Department of Health and Human Services, (E.D.N.Y.). On December 4, 2006, U. S. District Judge Joanna Seybert heard oral arguments and issued a bench ruling enjoining FDA from enforcing the regulation requiring a "pedigree" for prescription drugs. The regulation implements a provision of the Prescription Drug Marketing Act of 1987 ("PDMA") that requires each person engaged in the wholesale distribution of a prescription drug, who is not the drug's manufacturer or "an authorized distributor of record ("ADR")," to provide to the recipient of such drug a statement ("pedigree") identifying each prior sale, purchase, or trade of the drug.

The plaintiffs, nine wholesale distributors of prescription drugs, filed a complaint in the United States District Court for the Eastern District of New York on September 20th, challenging this implementing regulation, which became effective on December 1st. The regulation provides, among other things, that pedigrees must include each prior transaction involving the drug, starting with the manufacturer.

On November 22nd, plaintiffs moved for a preliminary injunction to stay the effective date of the regulation, claiming that it erroneously interprets the PDMA, is unconstitutional and arbitrary and capricious. They further argued that, even if FDA's regulation correctly interprets and implements the PDMA, the statutory pedigree requirement is unconstitutional**.**

On November 30th, U. S. Magistrate Judge A. Kathleen Tomlinson issued a Report and Recommendation in which she recommended that plaintiffs' motion for preliminary injunction be granted. The Magistrate Judge found that plaintiffs had demonstrated that they would be irreparably harmed by implementation of regulation. She further found that, although plaintiffs were not likely to succeed on their challenge to the regulation, they had demonstrated a substantial likelihood of success on the merits of their claim that the pedigree provision of the PDMA was unconstitutional when read in conjunction with the regulation. At the December 4th hearings, the District Judge said that she has adopted this Report and Recommendation in part.

The district court announced its intention to issue an opinion and order no later than Friday, December 8th, that would state the basis for the injunction and the scope of the preliminary relief.