Cong. Ref. No. 90-3981X
Filed: November 26, 1997

BANFI PRODUCTS CORPORATION,	*	
Plaintiff,	*	
v.	*	**Congressional Reference; Legal Claim; Equitable Claim; Gratuity; Negligence.**
UNITED STATES,	*	
Defendant.	*	

Edward Wood Dunham, Wiggin & Dana, New Haven, Connecticut, attorney of record for plaintiff.

Dominique Kirchner, Commercial Litigation Branch, Civil Division, United States Department of Justice, Washington, D.C., with whom were **Donna C. Maizel**, **David M. Cohen**, **Director**, and the **Assistant Attorney General**, attorneys of record for the defendant.

R E P O R T

HORN, Hearing Officer.

In this congressional reference case, the United States House of Representatives, in H.R. Res. 308, 101st Cong. (1990), referred a private "Bill for the relief of Banfi Products Corporation," H.R. 5148, 101st Cong. (1990), to the United States Court of Federal Claims.[(1)] Under the congressional reference procedure, 28 U.S.C. § 1492 (1994), either house of Congress may refer a bill, except a bill for pension, to the Chief Judge of the United States Court of Federal Claims. Once the reference is made, the case is handled in accordance with 28 U.S.C. § 2509 (1994). Upon reference by the House of Representatives of the instant claim to the Chief Judge, this hearing officer was designated from among the Judges of the United States Court of Federal Claims.

Following referral from the House of Representatives, the plaintiff, Banfi Products Corporation (Banfi), filed a complaint in this court seeking legal or equitable compensation to recover damages allegedly

suffered as the result of a 1985-1986 nationwide voluntary recall of approximately 1.3 million cases of imported Riunite wine, requested by the defendant, acting through the Bureau of Alcohol, Tobacco and Firearms (ATF). The plaintiff alleges that the United States, acting through ATF and the Food and Drug Administration (FDA), was "negligent, unreasonable, and/or reckless in its response to the presence of" the chemical diethylene glycol (DEG) "in certain Riunite" wines. Specifically, the plaintiff claims that ATF and FDA mistakenly determined that all wines containing DEG were a health hazard, and that the government ignored evidence the plaintiff presented which allegedly showed that the amounts of DEG in Riunite wines posed no health risk to the public. As a result of defendant's alleged negligent, unreasonable, and/or reckless conduct, the plaintiff claims that it suffered damages in excess of $34 million.

After discovery was completed by the parties, the liability portion of the case was tried before the hearing officer in the United States Court of Federal Claims over the course of numerous difficult and intensely adversarial weeks. Following trial, the parties submitted extensive post-trial briefings and supplemental filings.[(2)]

FACTS

The plaintiff, Banfi, a New York corporation with its principal place of business in Brookville, New York, imports wine into the United States from Europe, South America, and Australia. In 1985, Banfi was the exclusive American importer of Riunite wines pursuant to a 1977 sales contract with Cantine Cooperative Riunite (Cantine), the Italian agricultural cooperative that produces Riunite wines. Neither Banfi nor its principals have ever held an ownership interest in Cantine, or any role in the production or quality control of Riunite wines.[(3)]

Banfi is a closely held corporation, founded by John Mariani, Sr. in 1919, and in 1985-1986 run by his sons John F. and Harry F. Mariani. At all times relevant to this action, John F. Mariani served as chairman of the board and chief executive officer, and Harry F. Mariani served as president and a member of the board of directors. Banfi distributed its wines through a nationwide network of approximately 320 wholesalers, which in turn sold Banfi products to tens of thousands of retailers across the country. According to Banfi, in 1984, the last full year before the Riunite recall, sales were close to 10 million cases of wine and the company generated revenues in excess of $200 million. Also, according to the plaintiff, by the early 1980s, Riunite was one of the country's best-selling imported wines. This high volume of sales reflected the enormous popularity of Riunite, which Banfi began to import into the United States in 1967.

The Department of the Treasury derives its regulatory authority over domestic and imported alcoholic beverages from the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. §§ 201-211 (1982 & Supp. IV 1986), and the Internal Revenue Code (IRC), 26 U.S.C. §§ 5001-5691, 7301-7302 (1982 & Supp. IV 1986). The FAA Act regulates interstate and foreign commerce in distilled spirits, wines, and malt beverages, including the labeling and advertising of both domestic and imported alcoholic beverages. Pursuant to 27 U.S.C. § 205(e), the Department of the Treasury has the authority to promulgate regulations to ensure that the labeling of alcoholic beverages is not deceptive and provides consumers with adequate information concerning the identity and quality of such products. With respect to domestic and imported wines, the authority to administer and enforce the FAA Act and the provisions of the IRC that pertain to alcoholic beverages has been delegated by the Secretary of the Treasury to the Director of ATF. ATF issues regulations to specify materials which are "consistent with good commercial practice" and authorized for the treatment of wines, wine juice, and distilling material used in wine. 27 C.F.R. §§ 240.1051, 240.1051a (1985).[(4)] Therefore, only materials which are acceptable for human consumption and approved by ATF as being consistent with good commercial practice may be

used in wine.

Importers, wholesalers, and certain producers of alcoholic beverages must obtain a basic ATF permit to engage in business. 27 U.S.C. § 203. These permits are conditioned upon compliance with the requirements of 27 U.S.C. § 205 and all other federal laws relating to distilled spirits, wine, and malt beverages. 27 U.S.C. § 204(d). If an industry member violates the laws and regulations enforced by ATF, the agency has authority to suspend or revoke the industry member's basic permit, after notice and a hearing, upon a finding that the permittee willfully conducted transactions in alcoholic beverages in violation of the labeling provisions of the FAA Act or other laws upon which basic permits are conditioned. 27 U.S.C. § 204(e). ATF also may seek an injunction against a permittee to prevent the introduction into interstate commerce of alcoholic beverages which are mislabeled in violation of the FAA Act. 27 U.S.C. § 207. Furthermore, ATF has authority to detain and to seize and cause forfeiture of a product under 27 U.S.C. § 205 and 26 U.S.C. §§ 5311, 7301-7302.

In written responses to questions posed by the House of Representatives Committee on Government Operations on May 28, 1986, which were included in the joint exhibits submitted in the above-captioned case, William Drake, then Deputy Director of ATF and an Associate Director for Compliance Operations, wrote the following regarding ATF's authority:

2. ATF has the authority, pursuant to 27 C.F.R. § 4.38(h), to require that importers test wine products to ensure that the wine is not mislabeled both prior to and after a determination that a suspect wine is contaminated. Section 4.38(h) states that "upon the request of the Director, there shall be submitted a full and accurate statement of the contents of the containers to which labels are to be or have been affixed." Willful failure by the importer to test wines pursuant to ATF's request could result in revocation or suspension of their basic permit or result in a misdemeanor penalty under section 7 of the FAA Act.

Wholesalers, as well as importers, may be required to test imported wines pursuant to 27 U.S.C. § 202 (d), which authorizes the Director to require "such reports as are necessary to carry out [his] powers and duties" under the FAA Act. Willful failure to test wines could result in a revocation or suspension of the wholesaler's and importer's basic permit.

3. ATF has no authority under the IRC or FAA Act to require that importers and wholesalers (i) obtain wine samples or (ii) remove suspect wines from retail premises either prior to or after a determination of contamination. ATF has no recall authority under either the IRC or the FAA Act. ATF would rely on the voluntary compliance of importers and wholesalers to conduct such sampling and removal procedures.

4. ATF has no jurisdiction under the IRC or FAA Act with respect to requiring retailers to test suspect wines either prior to or after a determination of contamination.

5. Under the authority described in subparagraph (2), ATF may require importers and wholesalers to submit reports of wine testing to ATF both prior to and after a determination of contamination. Willful failure of an importer to comply could result in a revocation or suspension of the basic permit or in a misdemeanor penalty. A wholesaler's willful failure to submit test results could result in a revocation or suspension of the basic permit. ATF has no authority to require that retailers submit such reports as stated in subparagraph (4). As stated in subparagraphs (3) and (4), ATF has no authority to require importers, wholesalers, or retailers to submit reports on removals of wine from the retail level.

At the time of the events at issue, ATF directive (ATF O 1200.7, dated November 25, 1975) set forth policy on the public disclosure of ATF actions. The policy provided that the agency would issue a press

release concerning regulatory actions that involved a health hazard, significant consumer deception, large quantities of a deficient alcoholic product, or problems of similar magnitude. The directive also indicated that "[a]ny determination made as to the existence of a health hazard will be made by ATF in conjunction with the Food & Drug Administration."

According to the joint stipulations, wines that contain a chemical substance not authorized to be in wine and which pose a risk to consumers' health, do not meet the standard of identity for wines pursuant to 27 C.F.R. § 4.21 and, thus, may not lawfully be labeled as "wine." ATF would not issue or allow the use of a certificate of label approval for such products and no labeling change would cure this particular violation. Further, according to the joint stipulations, because ATF does not have the authority or expertise to determine what ingredients are safe for use in alcoholic beverages, it consults with FDA to determine if a particular substance found in an alcoholic beverage poses a risk to consumers' health.

FDA derives its authority from the Federal Food, Drug and Cosmetic Act (FDCA), codified in 21 U.S.C. §§ 301-920 (1982 & Supp. IV 1986). In 1985-1986, FDA's Center for Food Safety and Applied Nutrition (CFSAN) was responsible for ensuring that foods complied with the FDCA. At the times relevant to the instant case, the CFSAN consisted of the Office of Compliance, Office of Toxicological Sciences, Office of Physical Sciences, and Office of Nutrition and Food Sciences. The Office of Toxological Sciences had two primary functions. It conducted research in toxological sciences and provided support to the regulatory responsibilities of CFSAN.

The FDCA prohibits the shipment in interstate commerce of "adulterated" food. 21 U.S.C. § 331. A food is generally deemed to be "adulterated" when an added poisonous or deleterious substance is present if the added substance "may render it injurious to health" or "bears or contains any food additive which is unsafe within the meaning of § 348 of this title." 21 U.S.C. § 342(a). According to 21 U.S.C. § 321(f), the term "food" is defined as "articles used for food or drink for man or other animals" and "articles used for components of any such article." In 1985-1986, DEG was not authorized as an additive to any foods or beverages under the FDCA.[(5)]

FDA's regulations governing the agency's enforcement actions pursuant to the FDCA and other laws administered by FDA set forth policies and procedures for product recalls. 21 C.F.R. § 7.40. According to the language of the final rule, the regulations were intended as "guidelines." 43 Fed. Reg. 26202 et seq. (June 16, 1978). These regulations provided that an FDA recall could be undertaken voluntarily, at any time by manufacturers and distributors or at the request of FDA. 21 C.F.R. § 7.40(b). However, "a request by FDA that a firm recall a product was reserved for urgent situations, i.e., those violative distributed products that pose a hazard or significant deception to the consumer."[(6)] 43 Fed. Reg. 26208 (June 16, 1978); see also 21 C.F.R. § 7.45(a).

FDA's regulations also provided for an evaluation of the health hazard by an ad hoc committee of FDA scientists of a product being recalled by FDA.[(7)] 21 C.F.R. § 7.41(a). At the time relevant to this case, the ad hoc committee consisted of scientists working at CFSAN, was known as the Health Hazard Evaluation Board (HHEB), and its reports were called Health Hazard Evaluations (HHE). In cases of contamination, when unauthorized ingredients were found to be present in food or drink, the HHEB could be convened to assess the potential health risks of exposure to such contaminants and to aid FDA compliance officials in determining a response to the problem. FDA compliance officials also used the HHE to aid in classifying a recall, to indicate the relative degree of health hazard caused by a product already being recalled, or to assist in deciding on an appropriate level of effort for following up on the recall. See 21 C.F.R. 7.41(b). In 1985-1986, when another agency requested information concerning the toxicity of a chemical substance, there was no established FDA policy or procedure requiring that an HHE be completed. Instead, FDA made a case-by-case determination concerning whether the request

would be sent to a toxicologist, to another subject matter expert with expertise in the relevant subject matter, or to the HHEB for consideration.

The procedure followed in cases of contamination and for recalls differed from that followed when determining whether to authorize substances as intentional ingredients or "additives" in foods and beverages. In 1985, parties wishing to use a substance as a food additive had to petition FDA for approval and had the burden of establishing, by laboratory animal studies that satisfied set criteria on the duration and number of subjects, that lifetime exposure to the substance in the amounts contemplated by the particular use would not pose a hazard to health. As part of this process, FDA typically calculated an acceptable daily intake (ADI) for the substance. An ADI is the level of a substance, measured in milligrams per kilograms of body weight, that FDA determines is safe for lifetime exposure by an individual. In contrast, when the health risks of a contaminant are assessed by the HHEB, or by an FDA toxicologist, the focus is on acute and short-term exposure because the product containing the contaminant is unlikely to remain on the market for an extended period of time.

The events that form the basis of plaintiff's claim began on or before July 11, 1985, when Dr. Sanford Miller, Director of CFSAN, was advised that certain Austrian wines had been found to contain DEG and was requested to provide information on the toxicity of the substance to Professor A.G. Hildebrandt, an official of the German Government. Dr. Miller passed this request on to Dr. Herbert Blumenthal, Director of CFSAN's Division of Toxicology. On July 11, 1985, Dr. Blumenthal instructed one of his subordinates, Dr. Charles Kokoski, the Chief of the Food Additives Evaluation Branch in the Division of Toxicology, to prepare a response for Dr. Miller on DEG toxicity. Dr. Kokoski expeditiously completed his review of information on the toxicity of DEG and conveyed it to Dr. Miller in a memorandum dated July 12, 1985. An HHE, as defined in 21 C.F.R. § 7.41(a), is conducted by a committee of FDA scientists, but was not conducted at the time relevant to the instant case. When Dr. Kokoski conducted his review on DEG, he had no particular understanding of what Dr. Miller would do with the memorandum that he was preparing, although he believed that it would be used to respond to the German Government's inquiry.

DEG is a colorless, nonvolatile, sweet tasting liquid that is commercially available for various industrial applications. DEG is not, and was not in 1985-1986, authorized or approved for use as an additive to foods or beverages in the United States under the FDCA, nor was it approved in Europe and other countries, in accordance with European Economic Commission wine laws and regulations, or the wine laws and regulations of Austria, Germany, Italy, Canada and Japan.

ATF and FDA were alerted to the possibility that wines containing DEG might be present in the United States when, on July 12, 1985, the Washington Post reported the discovery of Austrian wines containing DEG in West Germany. It soon became evident that some Austrian wine producers intentionally had added DEG as a sweetener to wine in order to short-cut the expensive and time-consuming fermentation process. In July 1985, the State Department sent a telegram to FDA and sent a cable, from the American Embassy in Vienna, Austria, to the Department of Treasury, ATF, and FDA, reporting that the DEG contamination had been intentional. Immediately after reading the news article, members of ATF's Industry Compliance Division contacted the Austrian Embassy, the Austrian Trade Commission, and the German Embassy in order to ascertain the identities of the producers, bottlers, and shippers involved in the production of the wines identified in Europe as contaminated with DEG.

ATF relies upon FDA for determinations concerning the toxicity of substances found in alcoholic beverages. After an importer informed ATF that it had tested and discovered DEG contamination in some Austrian wines in the United States, ATF conveyed this information to FDA. Subsequently, ATF requested that FDA provide information about DEG. ATF did not in 1985-1986, and does not now, possess the authority or expertise to make an independent determination concerning the toxicity of DEG

in wine. Although in 1985 ATF was aware of FDA's expertise in making determinations concerning the toxicity of ingredients found in alcoholic beverages, ATF officials responsible for supervising activities concerning the presence of DEG in wine were not aware of the existence of FDA's HHEB. Thus, ATF did not specifically request that an HHE be conducted by a committee of FDA scientists, as defined in 21 C.F.R. § 7.41.

On or about July 18, 1985, ATF indicated and John Taylor, the Director of the Office of Compliance of FDA's CFSAN, agreed that ATF would take the lead in handling the problems concerning DEG in wines, including implementing a program to test wines for the presence of DEG, requesting that industry members recall wines found to contain DEG, and issuing press releases concerning those wines. Mr. Taylor discussed this decision with his superior, Dr. Sanford Miller, who did not disagree. This decision was based upon various factors, including Mr. Taylor's understanding of FDA's priorities and resources, FDA's authority versus ATF's authority over the alcoholic beverage industry, and ATF's ability to handle the problem. At the time Mr. Taylor made that decision, he knew that ATF had no regulations concerning recalls, and was not aware of ATF's degree of experience with product recalls.

According to the joint stipulations, in July 1985 FDA believed that DEG in wine was a serious public health emergency. The initial determination that FDA communicated to ATF was that wines contaminated with DEG were not safe for human consumption, and included information about potential health problems associated with the consumption of DEG, including nausea, kidney dysfunction, or death, depending upon the quantities consumed. At that time, wines imported into the United States generally were not tested to determine whether they contained DEG.

Less than one week after learning of the DEG contamination in certain wines and following the receipt of information about DEG from FDA, William Drake, Deputy Director of ATF, and an Associate Director for Compliance Operations, decided that ATF would request the recall of all wines tainted with DEG. On July 17, 1985, ATF first began to take action concerning DEG contaminated wines pursuant to its existing authority, policies, and procedures. Initially, ATF requested that the United States Customs Service (Customs) detain all Austrian wines imported into the United States, and Customs complied. After receiving information about the particular Austrian wines contaminated with DEG from the Austrian and German Embassies, ATF conducted searches in its certificate of label approval data base to determine if the same or similar brands were present in the United States. On or about July 18, 1985, ATF began collecting and testing samples of all Austrian wines that were being imported into the United States.

On July 18, 1985, ATF issued its first press release to the wire services concerning the contamination of certain Austrian wines. The press release warned people not to drink such wines and cautioned that "diethylene glycol may cause nausea, kidney dysfunction, or death when ingested in certain quantities." On July 19, 1985, ATF also issued an industry memorandum in the form of a Product Alert to wine importers and wholesalers concerning "a potentially poisonous substance," DEG, in Austrian wines. The Product Alert described DEG as a chemical substance which is used in antifreeze. In addition to containing a health advisory, the Product Alert indicated that ATF was working with Customs to ensure that the shipments of Austrian wine entering the United States did not contain DEG, that laboratory analysis was being required for all Austrian wines prior to their release from the custody of Customs, and that wholesalers and importers were being requested to withhold Austrian wines from sale pending verification by independent testing that the wines did not contain DEG. ATF's Product Alert also advised industry members that wine found to contain DEG was considered mislabeled and, therefore, was not eligible for sale in the United States. The Product Alert further instructed that industry members conducting transactions in wines found to contain DEG without having such wines satisfactorily tested on or after the date of the industry memorandum would be deemed in willful violation of the terms of their basic permit, and that such actions could result in suspension or revocation of their basic permit.

Another press release, issued several days after the first, contained much of the same information that had been included in the Product Alert.

In July 1985, the ATF National Laboratory Center confirmed that DEG was present in varying amounts in twelve brands of Austrian wines that it had tested, including the three brands identified in ATF's July 18, 1985 press release. On July 31, 1985, ATF issued another press release which identified the twelve brands of Austrian wine found to contain DEG. In August 1985, after Germany had advised that German authorities had found DEG in two German wines, and Great Britain and Japan had reported that certain Italian wines similarly were contaminated, ATF began testing German and Italian wines for DEG. ATF's testing of wines for DEG lasted from approximately July 1985 through April 1986.(8)

Following a determination by ATF laboratories that some imported wines were contaminated with DEG, ATF contacted importers who held certificate of label approvals for these wines to request that the wines be recalled from the market. ATF inspectors conducted on-site inspections of wholesalers and retailers to verify that the imported wines found to contain DEG were not being sold. Press releases were issued listing all Austrian, German, and Italian wines found to contain DEG. In addition, ATF provided FDA with information over the telephone concerning the levels of DEG found in wine by ATF laboratories and also provided FDA with copies of the press releases about those wines.

As indicated above, on July 12, 1985, Dr. Kokoski completed his review on the toxicity of DEG and conveyed his conclusions in writing to Dr. Miller. Dr. Kokoski's cover memorandum stated "[h]ere is the information you requested on the toxicity of diethylene glycol. It's brief and to the point. Hope this will be useful." Dr. Kokoski testified that he had reviewed materials on DEG that were readily available to him, including a file that was in his office, a file concerning a petition by British Cellophane, Ltd. to receive approval for DEG as a food additive in 1979, and several standard toxicology texts. He did not, however, conduct a literature search to update any of the information in the 1979 file. His memorandum contains information from two animal studies, "Studies of the Toxicity of Diethylene Glycol in Rats" (Research Report No. 5/1976), by Gaunt, et al. and "Comparison of the Chronic Toxicity of Triethylene Glycol with that of Diethylene Glycol," 28 J. Indus. Hygiene Toxicology 40, by Fitzhugh and Nelson, and from one study of human exposure to DEG, "The Toxicity for Human Beings of Diethylene Glycol with Sulfanilamide," 32 S. Med. J. 1105, by Calvery and Klumpp. It appears that Dr. Kokoski, however, did not have a copy of or even read the Calvery and Klumpp study prior to issuing his July 12, 1985 memorandum.

Dr. Kokoski identified various adverse effects resulting from consumption of DEG, including the presence of oxalate crystals and increased oxalate excretion in the urine, stones and tumors in the bladder, and fatalities. He concluded that the maximum ADI of DEG for a 60 kg person is about 6 mg, based upon the evidence that DEG is toxic to humans at 6 gm of DEG per day.

Dr. Miller reviewed Dr. Kokoski's memorandum on the toxicity of DEG. Before approving it, he directed Dr. Kokoski to add a statement that imported foods containing DEG are illegal. Thus, Dr. Kokoski's July 12, 1985 final memorandum includes the following statement:

Diethylene Glycol is not allowed as a direct food additive in 21 CFR Food Additive Regulations. It may occur as a contaminant limited to low levels in some ethylene oxide condensates (e.g. polyethylene glycol) used as food additives. However, any purposefully added DEG to food is not authorized by the regulations and any such imported food would be considered illegal.

On or about August 2, 1985, Sonia Delgado, a compliance officer in FDA's Division of Regulatory Guidance, requested that the Division of Toxicology assemble information about DEG. On August 6, 1985, Dr. Kokoski sent a cover memorandum to Ms. Delgado, attaching documents that he understood would be forwarded to ATF: Working Paper "A," dated February 16, 1979, by John D. Walker, Ph.D., of FDA's Division of Toxicology; a list of references on DEG; his July 12, 1985 memorandum; and a copy of the Gaunt study.

Two days later, on August 8, 1985, Dr. Kokoski wrote a second memorandum on DEG, titled "Additional Information on Diethylene Glycol - Wines (your IAR-8/2/85)," in response to an inquiry from Ms. Delgado. The Austrian Embassy in the United States had asked FDA certain questions about DEG toxicity, and Dr. Kokoski understood that his second memorandum would be transmitted to the Austrian Government. In his August 8, 1995 memorandum, Dr. Kokoski addressed the following questions raised by the Austrian Government:

"4. Are there tolerance levels and [sic] thresholds regarding chronic or acute consumption of DG in humans?"

There are no tolerances. DEG is not allowed for direct addition to food. Where it may be a contaminant in a food additive, e.g. Polyethylene Glycol, the Food Chemicals Codex[(9)] sets a specification maximum limit of not more than 0.25% ethylene glycol and diethylene glycol, individually or combined. At the use levels of Polyethylene Glycols, the exposure to DEG would be very low.

"5. Has intoxication with DG ever occurred in the US?"

Yes! In the 1938 [sic] sulfanilamide elixir episode, a number of deaths and injuries occurred as a result of patients consuming the elixir which used DEG as the solvent and vehicle. The DEG caused oxalate crystals in the kidneys and severe kidney damage. 25 ml DEG or above was fatal in humans in about 30% of the cases of injury.

"5.[sic]Are data available of toxicological animal tests with DG?"

Yes. Studies done in rats show oxalate crystals in urine at .4% & 2% DEG in the diet for 225 days, oxalate excretion in urine at 0.17% of diet, and a no-effect level at only 0.085 of the diet (about 50 mg DEG per kg b.w. of rats). Another study in rats for 2 years showed bladders stones at 1% and bladder tumors and stones at 2% and 4% DEG in the diet.

Direct extrapolation with no margins of safety or safety factor applied would mean a minimum toxic effect (increased oxalate excretion) may be seen at 6 gm DEG/day, and oxalate crystals in kidney may be seen at 12 gm DEG/day. However, the human may be more susceptible to toxicity to DEG than other species based on the fatalities seen at 25 ml DEG or above and pathological findings from the 1938 [sic] sulfanilamide elixir episode.

The maximum acceptable daily intake (ADI) based on a no-effect level of 0.085% in rats, applying a 500-fold safety factor (because only a 225 day study and one species), would be about 6 mg DEG for a 60 kg person.

FDA also considered the metabolism of DEG in humans and whether the presence of ethanol in wine would provide a protective effect against DEG's toxicity. Dr. Kokoski's view was that it would not, based in part on an August 20, 1985 memorandum, prepared by Dr. Michael Wade, a toxicologist, who reported to Dr. Kokoski. The report was entitled "Metabolism of Glycols and Potential Protection Effect

of Ethanol against Glycol Toxicity," and summarized information concerning the metabolism of DEG and the treatment of DEG poisoning with ethanol. Dr. Wade concluded that "[t]here is insufficient data currently available to us to determine if the potential toxicity of diethylene glycol in adulterated wine would be ameliorated by the wine's ethanol content."

In July and August 1985, Ms. Delgado provided both of Dr. Kokoski's memorandums and Dr. Walker's February 16, 1979 Working Paper "A" to Norris Alford, Chief of ATF's Product Compliance Branch, which is responsible for the labeling and advertising of alcoholic beverages. Mr. Alford discussed the information that he had received with Dr. Kokoski in a telephone call on or about August 28, 1985. Mr. Alford informed Dr. Kokoski that ATF had found high levels of DEG in wine (i.e., 0.6 to 16 grams/liter, which is equivalent to 600 to 16,000 milligrams/liter or 600 to 16,000 ppm). Dr. Kokoski advised Mr. Alford that a person who consumed one liter of wine a day that contained those DEG levels would likely suffer an adverse effect.

In mid-October 1985, ATF laboratories initially determined that certain brands of Riunite wine were contaminated with DEG, as follows:

Wine Tested DEG Content[(10)]

Riunite Bianco .009 g/liter (9 ppm)

Riunite Rosato .009 g/liter (9 ppm)

Riunite Lambrusco .009 g/liter (9 ppm)

dell' Emilia

Riunite Spumante .011 g/liter (11 ppm)

ATF determined that Banfi held certificate of label approvals for the four Riunite wines found to contain DEG. Therefore, consistent with its position that DEG was not an approved additive to wine and that all wines found to contain DEG posed a risk to health, ATF initiated steps to request that Banfi recall the Riunite wines contaminated with DEG.

On or about October 18, 1985, Robert Maxwell, ATF's Deputy Associate Director for Compliance Operations, telephoned Banfi's outside counsel, Wiggin & Dana, and informed them that ATF had detected DEG in samples of Riunite wine. The Riunite wines contaminated with DEG came from two of Cantine's facilities and the majority of the wine came from Cantine's Campagnola bottling facility in the Reggio Emilia province of Italy. ATF never received any information which demonstrated that Cantine was deliberately adding DEG to Riunite wines.

On October 23, 1985, a meeting between representatives of Banfi, Cantine, and ATF officials took place at ATF headquarters in Washington, D.C. The participants for Banfi were: John F. Mariani, Chairman of Banfi, and John Troiano, General Counsel of Banfi; Shaun Sullivan and Edward Dunham of Wiggin & Dana; Walter Sacchetti, President of Cantine, Antonio Maccieri, an oenologist from Cantine; and Lucio Sorre of Banfi, who served as a translator for Mr. Sacchetti and Mr. Maccieri. For ATF, the meeting representatives were Robert Maxwell; Bruce Weininger, Chief, Industry Compliance; and Norris Alford, Chief, Product Compliance Branch. During the meeting, Mr. Maxwell gave the Banfi participants a copy of the ATF laboratory test results which indicated the level of DEG contamination in certain types of Riunite wine. The Banfi and Cantine officials questioned whether DEG was actually present in Riunite

wines and whether the wines tested were actually Riunite wines.[(11)] As a result, ATF officials authorized Banfi and Cantine representatives to visit the ATF National Laboratory Center in Rockville, Maryland to satisfy their concerns as to whether the testing methods used were reliable and to confirm that the tested wines were actually Riunite.

Sometime after the October 23, 1985 meeting, Banfi contacted several experts for assistance, including Dr. Andrew Patterson, a Yale University chemistry professor, and Dr. Steven Taylor, a food scientist at the University of Wisconsin, who had previously given Banfi technical advice about sulfites in wine. Banfi requested Dr. Taylor's advice about whether the DEG found in Riunite represented any risk to the consuming public. Dr. Taylor performed a quick analysis, which included a review of leading toxicology texts and other literature, and reported to Banfi's counsel, perhaps as early as October 25, 1985, that he found no evidence that low levels of DEG in wine were in any way hazardous to health. [(12)]

On October 24, 1985, Mr. Maccieri, Mr. Sorre, Mr. Dunham, and Dr. Patterson visited ATF's National Laboratory Center in Rockville, Maryland, and observed and discussed with ATF chemists their testing procedures and equipment. The visit confirmed for the Banfi and Cantine representatives that the lab's testing methods were appropriate, that the Riunite tested was genuine, and that, as ATF chemists had concluded, DEG was identifiable and present in certain types of Riunite.

Representatives of Banfi again met with ATF officials at ATF headquarters in Washington, D.C. on October 28, 1985. The participants were: John F. Mariani; John Troiano; Carmel Tintle, Banfi's Vice President for Public Relations; Mr. Sullivan; Mr. Dunham; Mr. Maxwell; Mr. Alford; and possibly other ATF officials. At all the October 1985 meetings, ATF advised Banfi that ATF expected the Riunite wines tainted with DEG to be recalled from the market, and that Riunite wine should not be imported into the United States without prior testing of the wines to confirm that the products being imported did not contain DEG.

At the October 28, 1985 meeting, Banfi stated that it had consulted with experts who said that the Riunite wines contaminated with DEG were safe for consumption by humans. Mr. Maxwell, however, informed Banfi that all wines containing DEG, including the Riunite wines containing DEG, were mislabeled and should be recalled. Furthermore, Mr. Maxwell reviewed various regulatory actions ATF could take in the event that Banfi did not conduct a recall. By the end of the October 28, 1985 meeting, ATF understood that Banfi would cooperate by recalling the Riunite wines that contained DEG.

ATF officials advised Banfi that ATF would issue a press release about the Riunite wines found to contain DEG. In addition, ATF offered Banfi an opportunity to review the press release and request changes before it was issued by ATF, but would not allow Banfi to have editorial rights. On October 31, 1985, ATF and Banfi exchanged drafts of their respective press releases announcing that Banfi was recalling all Riunite which bore the same bottling codes as the wines found to contain DEG.[(13)] After receiving Banfi's draft press release, ATF added language to its draft press release which addressed the health effects of DEG:

According to [Stephen E.] Higgins, diethylene glycol is a chemical commonly used for industrial purposes, and is not approved for use in food and beverages. Diethylene glycol has both short-term and cumulative effects depending on the amount ingested.

On October 31, 1985, pursuant to agency policy stated in ATF Directive O 1200.7, ATF issued press release number FY-86-09, identifying the four brands of Riunite wines contaminated with DEG and the size of the bottles. At that time, ATF believed that DEG present in any amount was unsafe for human

consumption and, therefore, that Riunite wines found to contain DEG were not safe. ATF furnished Banfi with a copy of the final press release on October 31, 1985, as well as a list of the print and broadcast media that had received the press release on Riunite. The announcement resulted in nationwide publicity. ATF Headquarters Division and Staff Chiefs and all Regional Directors received ATF's press release that concerned the Riunite wines that were contaminated with DEG on October 31, 1985. ATF Regional Directors received instructions to provide the information contained in the press release to state liquor control agencies in their respective regions. ATF also provided FDA with a copy of its press release that concerned DEG tainted Riunite wines.

Also, on October 31, 1985, Banfi issued its own press release to inform the public of the status of the Riunite wines containing DEG. Banfi announced that it was initiating a "voluntary recall" of the Riunite wines containing DEG, that Riunite was conducting an extensive investigation to determine how the DEG got into the wine, and that Riunite would not use the wine facilities involved until the source of the DEG was eliminated. Banfi also sent a letter, dated October 31, 1985, to its Riunite distributors advising them of the specific Riunite wines that were contaminated and were being recalled.

The Riunite wines contaminated with DEG were being sold in retail outlets nationwide. The recall process involved Banfi's coordinating the recall activities in the chain of distribution, reimbursing distributors, and arranging for and paying for the costs of shipping, handling, storage, and destruction. In October 1985, ATF understood that the nationwide recall of the tainted Riunite wines was a substantial project that could not be accomplished immediately and Banfi would conduct the recall as expeditiously as possible. ATF itself had never before dealt with a recall involving as much product as the nationwide Riunite wine recall.

Deputy Associate Director for Compliance Maxwell, by memorandum dated December 24, 1985, directed ATF Regional Directors, among other directives, to conduct retail-level spot checks of Riunite wines. Following this memorandum, ATF monitored Banfi's recall of the Riunite wines and conducted field inspections to ensure that the Riunite wines containing DEG were being removed from the market. When those inspections revealed that some wines contaminated with DEG had not yet been pulled off the shelves, ATF obtained affidavits from retailers and, in some cases, from distributors. ATF also notified Banfi that some Riunite wines containing DEG remained on the market and indicated that those wines should be removed.

Beginning on or about October 21, 1985, Banfi had samples of Riunite wines analyzed for DEG by Hazleton Laboratories, Madison, Wisconsin. The levels of DEG found in Riunite wine by the lab ranged as high as 27.5 ppm. ATF continued to test samples of Riunite wines obtained from the marketplace. In late 1985 and early 1986, ATF determined that DEG was present in Riunite Rosato and Riunite Lambrusco wines in bottle sizes that differed from bottle sizes identified in ATF's October 31, 1985 press release concerning Riunite wines. The amounts of DEG found in these wines varied from 21 to 29 ppm. ATF relayed this information to Banfi and requested that the company take steps to ensure that these wines were also removed from the market. Banfi advised ATF that it was recalling all Rosato and Lambrusco wines containing 1124 and 332 BR codes; therefore, ATF determined that it did not have to issue a new press release.

In late October 1987, Banfi filed an administrative tort claim against ATF under the Federal Tort Claims Act (FTCA), 28 U.S.C. §§ 2671-2680 (1982 & Supp. IV 1986). ATF denied Banfi's administrative tort claim on May 3, 1988 on the grounds that the FTCA bars claims against the government for performance of discretionary functions, and for libel and slander, and in the event that the claim was not excluded by the FTCA, that the actions of ATF officers were not negligent or wrongful. Banfi did not seek judicial review of ATF's denial of its FTCA claim in a United States District Court within the allowed six-month statutory period. 28 U.S.C. § 2401(b).

DISCUSSION

A. The Congressional Reference

The congressional reference procedure, once set in motion by Congress, allows a party to seek relief for a claim against the United States through a private bill passed by either the House of Representatives or the Senate. Martin v. United States, 37 Fed. Cl. 86, 90 (1996) (citing Paul v. United States, 20 Cl. Ct. 236, 266, aff'd, 21 Cl. Ct. 758 (1990)); see 28 U.S.C. § 1492 (1994). This mechanism, as stated by our predecessor court, grants a party a forum in which to have its case assessed:

Congressional [Reference] cases, of which this case is one, are peculiar to the jurisdiction of this court alone and have their origin in those acts which authorize either house . . . of Congress to refer certain bills for a judicial investigation upon which findings are to be made and reported to the body transmitting the resolution. They are a separate class of cases designed to supply information so full and exact as to leave to the legislative body nothing to do but determine the justice of the complaint . . . as a legal or equitable demand against the United States; or, as one resting upon no law but depending upon moral considerations of such character as may or may not fairly appeal to the *bounty* of the Government.

Alleman v. United States, 43 Ct. Cl. 144, 150-51 (1908) (citations omitted) (emphasis in original). The current reference is derivative of a private bill, introduced by Congressman Robert Mrazek and referred to the House Committee on the Judiciary, which states in pertinent part:

SECTION 1. SATISFACTION OF CLAIM AGAINST THE UNITED STATES.

(a) IN GENERAL. -- (1) The Secretary of the Treasury shall pay, out of any money in the Treasury not otherwise appropriated, to Banfi Products Corporation, a New York corporation with an office at Old Brookville, New York, a sum of money in compensation for amounts expended by Banfi Products Corporation as a result of the recall in 1985 and 1986 of certain cases of imported Riunite wine based upon the negligent identification by the United States Government of such wine as a health hazard.

(2)(A) Amounts expended by Banfi Products Corporation for which compensation under paragraph (1) is made shall include, but not be limited to, amounts expended as --

(i) refunds to distributors of the purchase price of the recalled wine;

(ii) costs, credits, and refunds for recalled wine owned by Banfi and held in inventory at the time of the recall;

(iii) reimbursements to distributors for their transportation, storage, and handling costs associated with the recall; and

(iv) other costs incurred for transportation, destruction, brokerage and custom fees, demurrage, printing, and postage.

(B) Compensation under paragraph (1) shall not be made for loss of anticipated profits or legal fees associate with the recall of the wine described in that paragraph.

(b) CONDITION OF PAYMENT. -- The payment of the sum set forth in subsection (a)(1) shall be in full satisfaction of all claims of Banfi Products Corporation against the United States in connection with

the recall described in subsection (a)(1).

SEC. 2. LIMITATION ON ATTORNEY'S AND AGENT'S FEES.

(a) IN GENERAL. -- No more than 10 percent of the sum appropriated by section 1 shall be paid to or received by any agent or attorney for services rendered in connection with the claim described in such section.

(b) ENFORCEMENT. -- Any person violating the provision of this section shall be fined not more than $1,000.

H.R. 5148, 101st Cong. (1990). On October 2, 1990, the House of Representatives specifically referred the above-quoted private bill to this court by passing a resolution that states:

Resolved, That the bill (H.R. 5148) entitled, "A bill for the relief of Banfi Products Corporation", now pending in the House of Representatives, together with all accompanying papers, is referred to the chief judge of the United States Claims Court pursuant to section 1492 of title 28, United States Code, for proceedings in accordance with section 2509 of such title.

H.R. Res 308, 101st Cong. (1990).[(14)]

The parameter of this court's authority in a congressional reference case is defined in 28 U.S.C. § 2509, which for the purposes of investigating the merits of a claim states in pertinent part:

The hearing officer to whom a congressional reference is assigned by the chief judge shall proceed in accordance with the applicable rules to determine the facts, including facts relating to delay or laches, facts bearing upon the question whether the bar of any statute of limitations should be removed, or facts claimed to excuse the claimant for not having resorted to any established legal remedy. [The hearing officer] shall append to his findings of fact conclusions sufficient to inform Congress of whether the demand is a legal or equitable claim or a gratuity, and the amount, if any, legally or equitable [sic] due from the United States to the claimant.

28 U.S.C. § 2509(c); see also Paul v. United States, 20 Cl. Ct. 236, 264, aff'd, 21 Cl. Ct. 758 (1990). "The statute does not require information as to any amount of compensation to be reported for a gratuity." Paul v. United States, 20 Cl. Ct. at 264 (footnote omitted).

The fact that a case is lodged in this court as a result of a congressional reference, in accordance with 28 U.S.C. § 2509, does not change the inherent focus of this court's intellectual framework. Once a congressional reference case has been referred to the court, the hearing officer must determine whether the claim is a legal claim or an equitable claim. The definition of a "legal claim" is not altered in a congressional reference case:

the words "legal claim" as used in the congressional reference statute imply no special meaning beyond the conventional understanding of that term: a claim based in the invasion of a legal right, that is "one of property, one arising out of contract, one protected against tortious invasion, or one founded on a statute which confers a privilege."

Spalding & Son, Inc. v. United States, 28 Fed. Cl. 242, 247 (1993) (review panel) (quoting Tennessee Elec. Power Co. v. Tennessee Valley Authority, 306 U.S. 118, 137-38 (1939)). See, e.g., INSLAW v. United States, 35 Fed. Cl. 295, 302 (1996); Land v. United States, 29 Fed. Cl. 744, 751 (1993). "A legal

claim arises when there is a violation of substantive law." Martin v. United States, 37 Fed. Cl. at 90.

The meaning of the words "equitable claim," as used in the congressional reference statute, has evolved in the jurisprudence of this court:

In congressional reference actions decided by our predecessor institution, the United States Court of Claims, the view was occasionally expressed that an equitable claim was one that rested on considerations of moral responsibility -- "what the Government ought to do as a matter of good conscience." B. Amusement Co. v. United States, 148 Ct. Cl. 337, 342, 180 F. Supp 386, 390 (1960); Burkhardt v. United States, 113 Ct. Cl. 658, 667, 84 F. Supp. 553, 559 (1949). That view no longer finds favor. The rule now uniformly applied is stated in California Canners & Growers Ass'n v. United States, 9 Cl. Ct. 774, 785 (1986) "'An equitable claim on a Congressional reference must rest on some unjustified governmental act that caused damage to the claimants. Absent a finding of negligence [or wrongdoing] on the part of governmental employees, any award . . . would be a gratuity.'"

Spalding & Son, Inc. v. United States, 28 Fed. Cl. at 250 (alteration in original) (citations omitted). At times, however, a claim in "equity" has been interpreted more expansively. Martin v. United States, 37 Fed. Cl. at 90 ("An equitable claim arises when the plaintiff has a broad moral right to recover based on some unjustified governmental act that caused him harm."); INSLAW v. United States, 35 Fed. Cl. at 302 ("An 'equitable claim,' in the context of a congressional reference, does not mean a claim in equity in the technical sense, but rather a broad moral right to recover based upon general equitable considerations."). This court favors the assessment made by a previous congressional reference review panel member who wrote "this court no longer interprets the term 'equitable claim' in 28 U.S.C. § 2509 as synonymous with 'moral claim.'" Spalding & Son, Inc. v. United States, 28 Fed. Cl. at 251 (Andewelt, J. concurring).

Thus, an equitable claim, in comparison to a gratuity, must be grounded in positive law rather than in conscience, ethics or morals. See Menominee Indian Tribe of Wisconsin v. United States, Cong. Ref. No. 93-649X, slip op. at 25-26 (Fed. Cl. Oct. 30, 1997). In the Menominee case, the hearing officer wrote that "for the plaintiff to have an equitable claim against the Government, the Government must have had a duty to the plaintiff and must have breached that duty by committing a wrongful or negligent act that caused . . . damage." Id. at 26; see Spalding & Son, Inc. v. United States, 28 Fed. Cl. at 250, 251 (finding by review panel and concurring hearing officer that there is a viable "equitable claim only upon a demonstration of 'some unjustified governmental action that caused damage to the claimants.'" In the event that there is no basis for legal or equitable relief to the plaintiff, the other option available to the hearing officer in a congressional reference case is to recommend a gratuity. California Canners & Growers Ass'n v. United States, 9 Cl. Ct. 774, 785 (1986) (review panel).

B. Legal Claim

Had the above-captioned congressional reference case been brought through more common channels of litigation after denial of an administrative claim, Count I of plaintiff's complaint would have been subject to the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706 (1994). Count II of plaintiff's complaint would have been reviewed pursuant to the Federal Tort Claims Act (FTCA), 28 U.S.C. §§ 1346(b), 2671-2680 (1994). As discussed above, the framework for assessing a legal claim in a congressional reference case is consistent with that normally followed, except that the party seeking relief is granted a forum by Congress which otherwise might not be available. Kanehl v. United States, 38 Fed. Cl. 89, 98 (1997) ("Even if the plaintiff in a congressional reference might otherwise have a valid claim to legal recovery on the merits that legal claim may nonetheless be barred by some technical or procedural impediment . . ."). Thus, this hearing officer must examine the plaintiff's claim in light of the applicable statutes that frame both procedural and substantive law.

The APA, in 5 U.S.C. § 701, "provides that the action of 'each authority of the Government of the United States,'" which includes ATF and FDA, "is subject to judicial review except where there is a statutory prohibition on review or where 'agency action is committed to agency discretion by law.'" Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 410 (1971). In turn, the FTCA "waive[s] sovereign immunity from suit for certain specified torts of federal employees . . . [but does] not assure injured persons damages for all injuries caused by such employees." Dalehite v. United States, 346 U.S. 15, 17 (1953).

The APA applies if the plaintiff alleges that it has been "adversely affected or aggrieved" by agency action, 5 U.S.C. § 702, and would be "entitled to 'judicial review thereof,' as long as the action is a 'final agency action for which there is no other adequate remedy in a court,' see § 704." Heckler v. Chaney, 470 U.S. 821, 828 (1985). However, the FTCA applies if the allegations are grounded in tort. See, e.g., United States v. Gaubert, 499 U.S. 315, 318 (1991); Dalehite v. United States, 346 U.S. at 17-18. For example, the APA applied in a case in which the plaintiffs sued the Commissioner of FDA alleging that the agency had relied upon an invalid study in certifying the safety of a food additive. Simpson v. Young, 854 F.2d 1429, 1431 (D.C. Cir. 1988). In contrast, the FTCA applied in a case in which the plaintiffs alleged that FDA "had acted wrongfully in approving release to the public of the particular lot of vaccine containing [the plaintiff's] dose." Berkovitz v. United States, 486 U.S. 531, 533 (1988). Thus, whether a plaintiff's claim falls under the APA or the FTCA depends largely upon the theory on which a plaintiff bases the case filed. In the instant case, the plaintiff's complaint alleges in the first count that ATF and FDA acted improperly and in the second count alleges negligence on the part of the government.[(15)]

When evaluating claims that the government has violated either the APA or the FTCA, great deference is afforded to the government agency. In the instant case, the plaintiff's first count must be analyzed under the APA which entitles "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. Government actions are reviewable by courts if those actions are made reviewable by statute or if the action is a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. The scope of review undertaken by a court in reviewing the action of a government agency is outlined in 5 U.S.C. § 706, as follows:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record of those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

5 U.S.C. § 706. The standard for review must be determined because, while generally the "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" standard applies, the statute allows for two exceptions. "In certain narrow, specifically limited situations, the agency action is to be set aside if the action was not supported by 'substantial evidence.' And in other equally narrow circumstances the reviewing court is to engage in a de novo review of the action and set it aside if it was 'unwarranted by the facts.'" Citizens to Preserve Overton Park v. Volpe, 401 U.S. at 414 (citing 5 U.S.C. §§ 706 (2)(E),(F) (1964 Supp. V)). Neither of these exceptions, however, is applicable here. "Review under the substantial-evidence test is authorized only when the agency action is taken pursuant to a rulemaking provision of the Administrative Procedure Act itself, 5 U.S.C. § 553 (1964 ed., Supp. V), or when the agency action is based on a public adjudicatory hearing." Id. FDA's determination that DEG was hazardous was clearly not part of a rulemaking function and ATF's actions did not involve rulemaking; both agencies actions were inherently decision making in scope.

Regarding the APA, the Supreme Court has written:

De novo review of whether the Secretary's decision was 'unwarranted by the facts' is authorized by § 706 (2)(F) in only two circumstances. First, such de novo review is authorized when the action is adjudicatory in nature and the agency factfinding procedures are inadequate. And, there may be independent judicial factfinding when issues that were not before the agency are raised in a proceeding to enforce nonadjudicatory action.

Id. at 415 (citing H.R. Rep. No. 1980, 79th Cong. (1946)). Neither of these situations exists in the case at bar.

The first count in the plaintiff's complaint is subject to the "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" standard applicable under 5 U.S.C. § 706. Consequently, the court must determine whether the agency acted within the scope of its authority. Id. at 416. In this case, there is no question that FDA is vested with the authority to determine whether a food additive is hazardous to humans. ATF is vested with the authority to request that a corporation recall harmful or mislabeled products, to stop the importation of those products, to seize those products pursuant to an injunction if the corporation does not comply with the Bureau's request, and to revoke basic permits after a hearing and due notice for failure to comply with proper labeling requirements and recall requests. "Scrutiny of the facts does not end, however, with the determination that the [agency] has acted within the scope of [its] statutory authority." Id. at 416. Section 706 (2)(A) requires the court then to determine whether the actual choice made by the agency was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.

Id. (citations omitted). Review of the government action "is therefore governed by the traditional arbitrary and capricious standard set forth in APA, 5 U.S.C. at § 706(2)(A). This review is highly

deferential; we must presume the validity of agency action." Kisser v. Cisneros, 14 F.3d 615, 618 (D.C. Cir. 1994).

The court must determine if a rational connection exists between the facts and the decisions made by the agency. Id. at 619. In this case, the errors alleged by the plaintiff are that ATF erred in its assessment that there was cause to request a recall, FDA erred when it determined that DEG found in low levels in wine was harmful to health, and FDA failed because it did not make more formal findings prior to transmitting its conclusions to ATF. If the agency decision demonstrates that it has carefully considered the evidence on both sides of the issues presented, the court is not required to re-weigh the evidence presented to ATF and FDA; in fact, such a re-weighing might not only be inappropriate as a matter of law, but also would not be practical. See Simpson v. Young, 854 F.2d at 1434. The court must consider whether ATF and FDA "ignored highly relevant evidence or formed a conclusion for which record support is absent or clearly inadequate to the commonsense observer." Id. (citing Citizens to Preserve Overton Park v. Volpe, 401 U.S. at 416). Moreover, ATF and FDA did not have to address each argument advanced by the plaintiff as the APA does not require "separate, specific rulings on each exception to a decision." Id. (emphasis in original). "The agency need only state the main reasons for its decision and indicate that it has considered the most important objections." Id. (citations omitted). In addition, "the absence of formal findings [by the agency] does not necessarily require that the case be remanded" to the agency. Citizens to Preserve Overton Park v. Volpe, 401 U.S. at 417. While formal findings may be required in some cases, it is rare that such findings are required in the absence of a statutory directive. Id.

Although FDA's review in the above-captioned case may not have been as thoroughly arrived at as the plaintiff would have preferred, the decision was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706 (2)(A). FDA acted in accordance with the statutory authority provided to it by 21 U.S.C. § 348, which grants FDA the power to determine whether a food additive is unsafe. The decision making authority vested in the FDA along with the trial testimony that indicated that FDA officials did not act arbitrarily, capriciously, abusively, or otherwise not according to law result in the conclusion that pursuant to the APA, the FDA acted in an appropriate manner.

Likewise, ATF's decision to request that the plaintiff recall its wine was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Banfi attempts to argue that it was coerced into undertaking the recall, by suggesting the ATF "was prepared to use all the power at its disposal to ensure that Riunite containing DEG came off the market" without a dialogue. Specifically, Banfi contends that the threat of permit suspension or revocation was utilized by ATF in an effort to request the recall by Banfi. It is apparent to this hearing officer that Banfi was not stonewalled by ATF during the evaluation process that led to the recall, as evidenced by the fact that when Banfi questioned the sampling and scientific testing that ascertained the DEG contamination in Riunite wine, Banfi representatives were allowed to visit and inspect the wine and the laboratories where the testing occurred. In addition, Banfi maintained a continuous dialogue with ATF, as demonstrated by the numerous meeting with officials from both parties, a point highlighted by the fact that ATF allowed Banfi to review ATF's press release about the Riunite contamination and recall prior to publication. Moreover, it is inescapable that Banfi could have elected not to recall its product if it so desired, and face the consequences, if any, at a formal permit hearing, which would have occurred with due notice prior to any wholesaler/importer permit suspension or revocation. Banfi now apparently argues that the presentation of this stark reality by ATF is coercion that led to the recall. This hearing officer notes that Banfi's voluntary election not to proceed to a permit hearing apparently was considered by Banfi as its best course of action because the Riunite wine did contain a contaminant that was not an approved food additive and, thus, was mislabeled and misidentified in direct violation of the labeling requirements and permit obligations enforced by ATF. In other words, ATF did not order the recall and Banfi had other

options, however unpleasant, that stemmed from the indisputable contamination. Banfi chose the option of voluntarily recalling a tainted product.

ATF consulted with FDA to obtain information regarding whether DEG in an alcoholic beverage posed a risk to consumers' health. There is no dispute that ATF took into account the expertise of FDA, which had determined that DEG was hazardous to consumers, and that ATF had no basis for questioning the determination made by FDA. The request for a recall, however, was appropriate due to the mislabeling and misidentification even if DEG in wine posed no health hazard. Thus, based on the APA as it applies to Count I of the plaintiff's complaint, the request for recall of plaintiff's wines by ATF, even if it was based in part on the advice received from FDA that low levels of DEG are a potential health hazard, was proper.

Count II in the plaintiff's complaint alleges negligence on the part of the government and, therefore, is subject to the requirements of the FTCA. The plaintiff's legal claim is barred by the discretionary function exception to the FTCA which covers agency regulatory decisions. This exception provides that the FTCA's waiver of sovereign immunity shall not apply to:

Any claim based upon an act or omission of an employee of the Government, . . . based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

28 U.S.C. § 2680(a). An agency decision to request a recall of hazardous products from the market is grounded in agency policy and falls within the discretionary function exception. Fisher Bros. Sales, Inc. v. United States, 46 F.3d 279, 285 (3d Cir.), cert. denied, 116 S. Ct. 49 (1995). Notably, the exception under the FTCA specifically covers acts that are discretionary in nature and involve judgment or choice. United States v. Gaubert, 499 U.S. 315, 322 (1991). Any legal claim for relief which Banfi could advance would be based upon ATF's decision to request the recall of Riunite wines and FDA's assessment of the health impact of DEG as a contaminant. See id. at 285-86. As such, the discretionary function exception bars plaintiff's legal claim. See Innocent Victims of the Occupation of Wounded Knee, South Dakota v. United States, 229 Ct. Cl. 465-66 (1981); Webb v. United States, 192 Ct. Cl. 925, 932 (1970). In fact, the plaintiff's attorney testified before Congress that Banfi "has no remedy under the FTCA." Hearing on Private Claims Bills Before the Subcomm. on Administrative Law and Governmental Relations of the House Comm. on the Judiciary 24 (1990). In sum, the actions taken in the instant case by the government fall within the discretionary authority granted to the agencies. As such, under the FTCA, the plaintiff's claim would not result in liability by the government for requesting the recall of contaminated Riunite wines or for considering information that the DEG found in imported wines presented a potential health hazard.

In addition to the bar to plaintiff's claim under the discretionary function doctrine, Banfi also has no legal claim to relief because any tort claim it may have urged is barred by the statute of limitations under the FTCA. See Land v. United States, 29 Fed. Cl. 744, 751 (1993); see also Innocent Victims of the Occupation of Wounded Knee, South Dakota v. United States, 229 Ct. Cl. 465-66 (1981). The FTCA is the only mechanism whereby the United States has waived its sovereign immunity for tort claims, and, thus, provides the exclusive legal remedy for tort claims arising from the actions of government agencies or employees. See Lance Indus., Inc. v. United States, 3 Cl. Ct. 762, 777 (1983). The statute of limitations provision of the FTCA states in pertinent part:

A tort claim against the United States shall be forever barred unless it is presented in writing to the appropriate Federal agency within two years after such claim accrues or unless action is begun within six months after the date of mailing, by certified or registered mail, or notice of final denial of the claim

by the agency to which it was presented.

28 U.S.C. § 2401(b). Although pursuant to the FTCA, the plaintiff, by letter, submitted an administrative claim to ATF seeking to recover damages from the recall of Riunite wines, the plaintiff did not file suit within the six-month statutory period following the denial of its administrative claim. Prior determinations in this court have reiterated that the consequences of dilatory legal efforts in appealing administrative decisions are unforgiving:

In the context of a congressional reference, failure to meet a statute of limitations bars legal recovery. See, e.g., Clark v. United States, 167 Ct. Cl. 197, 198 (1964); Erie R.R. Co. v. United States, 140 Ct. Cl. 398, 399, 156 F. Supp. 908, 909 (1957); Ann Arbor Constr. Co. v. United States, 130 Ct. Cl. 244, 253, 126 F. Supp. 161, 166 (1954); Land, 29 Fed. Cl. at 751; Spalding & Son, 28 Fed. Cl. at 250. Failure to seek review of the contracting officer's decision rendered it final; "once the decision of the contracting officer becomes final . . . the merits of that decision cannot be judicially challenged." Seaboard Lumber Co. v. United States, 903 F.2d 1560, 1562 (Fed. Cir. 1990), cert. denied, 499 U.S. 919, 111 S. Ct. 1308, 113 L. Ed. 2d 243 (1991); . . .

INSLAW, Inc. v. United States, 35 Fed. Cl. at 306. The statute of limitations is a hurdle "attached by Congress as a condition of the government's waiver of sovereign immunity" that "must be strictly construed." Bear Claw Tribe, Inc. v. United States, 36 Fed. Cl. 181, 187 (1996). "Thus, even assuming plaintiff's argument supports an equitable claim, plaintiff's failure to satisfy the statute of limitations bars recovery on a legal claim in a congressional reference case." Id. Moreover, plaintiff's election not to pursue its legal claim upon rejection by ATF of Banfi's administrative claim, and plaintiff's decision to allow the statute of limitations to expire, is not sufficient to remove the statute of limitations bar, or to excuse the claimant for having failed to resort to a legal remedy. See 28 U.S.C. § 2509(c). Under 28 U.S.C. § 2401(b), plaintiff's legal claim which is defined in Count II of the complaint and sounds in tort is barred.

C. Equitable Claim

In the case at bar, the plaintiff attempts to rely primarily on a theory of equitable relief to obtain recovery from the government. The congressional reference directs that "the Secretary of the Treasury shall pay to Banfi Products Corporation . . . a sum of money in compensation for amounts expended by Banfi Products Corporation as a result of the recall in 1985 and 1986 of certain cases of Riunite wine based upon the negligent identification by the United States Government of such wine as a health hazard." The key questions posed by the plaintiff to this court therefore include: (1) whether the recall by ATF was improper; (2) whether the identification by the government of certain Riunite wines as a health hazard was negligent; and (3) whether the recall request of certain Riunite wines by ATF was improperly the result of a negligent identification of DEG as a health hazard.

As a result of the way in which the congressional reference was framed, there has been much discussion about the propriety of the actions taken by ATF and FDA. The difficulty with the language of the congressional reference is that the words in the reference direct that Banfi shall be entitled to "a sum of money . . . as a result of the recall . . . based upon the negligent identification by the United States Government of such wines as a health hazard." Although in 1985 and 1986, ATF was of the opinion that any DEG in wine posed a health hazard, ATF was entitled to take the actions they took regardless of any perceived health hazard. Banfi was not entitled to import and distribute the Riunite wines containing DEG which were mislabeled. Consequently, whether or not ATF officials were willing to entertain entreaties from Banfi regarding their belief that the Riunite wines containing DEG in quantities plaintiff alleges were not harmful is not dispositive of whether or not ATF acted properly. It is correct that ATF relied on FDA to offer advice on the toxicity of DEG and that it was, at least in part, as a result of the

advice ATF received from FDA that ATF believed that any quantity of DEG in wine posed a health hazard, however, the request for recall cannot be said to be solely "based" on the FDA's actions. FDA did not request, nor did it have the power to require, the recall of Riunite wines.

In its filings, the plaintiff attempts to craft a link between FDA's determination of DEG as a health hazard and the request for recall by ATF. Moreover, the damages requested and delineated by plaintiff are a consequence of the recall, and are not related to the act of determining whether the quantity of DEG in Riunite was a health hazard. The plaintiff is only entitled to equitable damages if it successfully can prove that the recall, in and of itself, was not justified, and, thus, was a wrongful or negligent act. Consequently, if this hearing officer finds that ATF was authorized to request a recall, order seizure, and to publish its conclusions regarding the contaminated Riunite wine, regardless of their identification as a hazard to health, then plaintiff is without a viable equitable claim.

This court has previously written the following regarding equitable claims in congressional reference cases:

"'An equitable claim in a Congressional reference must rest on some unjustified governmental act that caused damage to the claimants. Absent a finding of negligence [or wrong doing] on the part of governmental employees, any award herein would be a gratuity.'" Shane v. United States, 3 Cl. Ct. 294, 304 (1983)(quoting Wong v. United States, Cong. Ref. No. 3-74, slip op. at 12-13 (Ct. Cl. November 23, 1977). Therefore, plaintiffs must show: (1) that defendant committed a negligent or wrongful act; and (2) that this act caused damage to the plaintiffs. California Canners & Growers Ass'n v. United States, 9 Cl. Ct. 774, 785 (1986).

Sneeden v. United States, 31 Fed. Cl. 671, 675 (1994); reconsid. denied, 33 Fed. Cl. 303 (1995); see also Lance Indus., Inc. v. United States, 3 Cl. Ct. at 779 (1983).

As stated, the key determination for the court is not whether the government committed a wrongful or negligent act in identifying the DEG found in plaintiff's wine to be a health hazard, because the government's determination of the DEG in Riunite wines as a health hazard did not, on its own, cause or grant authority to ATF to request the recall of the wine. Instead, the hearing officer must examine upon what authority ATF based its request for recall. DEG, in the quantities identified, regardless of its determination by FDA as hazardous, was not an authorized ingredient pursuant to the applicable regulation which states in relevant part:

"grape wine" is wine produced by the normal alcoholic fermentation of the juice of sound, ripe grapes (including restored or unrestored pure condensed grape must), with or without the addition, after fermentation, of pure condensed grape must, and with or without other addition or abstraction except as may occur in cellar treatment.

27 C.F.R. § 4.21(a)(1). Based on the above-quoted regulation and the testimony of Stephen Higgins, who was the Director of ATF from 1983 to 1993, it is clear that DEG was not an approved additive or ingredient in the making or manufacturing of wine. Furthermore, the parties have stipulated that:

DEG is not, and was not in 1985-1986, authorized as an additive to any foods or beverages under the Federal Food, Drug, and Cosmetics Act. DEG is not, and was not in 1985-1986, an approved additive in accordance with European Economic Commission (EEC) wine laws or regulations or in accordance with the wine laws and regulations of Austria, Germany, Italy, Canada, or Japan. DEG is not naturally present in wine.

Only ingredients acceptable to FDA and approved by ATF as being consistent with good commercial practice may be used in wines. 27 C.F.R. §§ 240.1051, 1051a. DEG was not included in the ingredients identified to ATF for approval during the formal labeling process in any of the brands of Riunite wines in which DEG was found to be an ingredient. The applicable regulations require that all wines be properly labeled. 27 C.F.R. § 4.21. ATF would not issue or allow the use of a certificate of label approval for products which contain a chemical substance that is not authorized to be in wine and no labeling change could cure such a violation. According to Higgins, ATF routinely treats alcohol which contains an unapproved ingredient as mislabeled. Selling mislabeled alcohol violates the FAA Act. 27 U.S.C. §§ 205(e), 207. In this case, the presence of any DEG, whether reaching hazardous levels or not, caused the wine to be mislabeled. ATF, while not having the power to require that a manufacturer recall a product, may request that a manufacturer recall a product when it is mislabeled. Moreover, ATF has the authority to detain any container of alcoholic beverages, domestic or imported that is deemed to be in violation of law and to seize mislabeled alcoholic beverages. 26 U.S.C. §§ 5311, 7302.

Consequently, in the instant case, ATF did not act improperly when it requested that the plaintiff recall its mislabeled wine. The parties have stipulated that in July 1985, prior to ATF's finding DEG in the plaintiff's wine, FDA believed that DEG in wines was a serious public health emergency, in part because it did not know the extent of the contamination problem. The parties have further stipulated that ATF relied upon information provided by FDA concerning the health risks posed by wines containing the contaminant DEG. However, when ATF determined that it would request the recall of all wines found to contain any amount of DEG, ATF had the authority to do so independent of any perceived health issues based on its regulations concerning the proper labeling of wine. ATF's Product Alert in July 1985 placed all industry members, including Banfi, on notice not only that products contaminated with DEG were potentially hazardous to health, but also that these products were considered mislabeled, were not eligible for sale in the United States, and that any transactions of such wine would be a violation of their basic permits and could result in suspension or revocation of their basic permit. Thus, whether or not the FDA was negligent when it identified the Riunite wine as hazardous to health did not alter that ATF was authorized to request the recall based upon violations of law and regulation, and cannot form the basis of an equitable claim for damages.

Lance Indus., Inc. v. United States, 3 Cl. Ct. 762 (1983), is an example of a congressional reference case in which there was some evidence that the government had acted improperly, but in which a claimant did not sustain an equitable claim. Lance involved a review of the government's publication of a warning, generated by rumor, concerning a product known as "Lance," which happened to have the same name as the plaintiff's safe product. Id. at 763. The plaintiff alleged that the United States breached its standard of due care because it failed to verify the rumor before it was republished. In evaluating the government's actions under a negligence standard, the court found that the government had a two-fold duty: to protect the public against unreasonable risk and to not unreasonably jeopardize the interests of the product's manufacturer. Id. at 779. In concluding that the government had exercised due care under the circumstances in republishing the "Lance" warning, the court clearly considered the government's duty to the public and heavily weighed that duty into the balance. Id. Similarly, this hearing officer finds that, in the instant case, ATF's and FDA's duty to the public should be heavily weighed in balancing the ultimate decision by ATF to request a recall. Therefore, the ATF actions leading to the request for the recall were proper and authorized. Plaintiff's equitable claim must be denied.

D. Determination of Negligence by FDA in Identifying Riunite as a Health Hazard

Regardless of the plaintiff's claims under legal or equitable theories of entitlement, the congressional reference suggests an additional task to this court. The exact words of the reference direct that "[t]he Secretary of the Treasury shall pay, out of any money in the Treasury not otherwise appropriated, to Banfi Products Corporation . . . a sum of money in compensation for amounts expended by Banfi

Products Corporation as a result of the recall in 1985 and 1986 of certain cases of imported Riunite wine based upon negligent identification by the United States Government of such wine as a health hazard." Congress, thus, appears to have directed this court also to review, outside of any legal or equitable claim, whether or not the identification by government officials, either ATF or FDA, of the wine as a health hazard was negligent, regardless of whether the recall actions initiated by ATF were proper or not. The Congressional Reference Statute, 28 U.S.C. § 2509(c), recognizes an alternative form of payment to a plaintiff as a gratuity in the event that the hearing officer finds negligent identification of the wine as a health hazard on the part of government officials, even though the ATF's request for the recall was legitimate and proper.

The hearing officer must determine, based upon the language in the congressional reference, whether FDA's identification of the DEG in the plaintiff's wines as a health hazard was negligent. Therefore, in order to show that FDA was negligent in identifying certain Riunite wine as a health hazard, the plaintiff must prove the elements of negligence. See generally Lance Industries, Inc. v. United States, 3 Cl. Ct. at 779 n.6. However, prior to assessing these elements, it is necessary for the court to make a choice of law analysis.

Regarding what law should apply, it is the practice of federal district courts, which normally have jurisdiction over tort claims under the FTCA, to look to "the law of the place where the act or omission occurred." See Land v. United States, 35 Fed. Cl. at 349 (citing 28 U.S.C. § 1346(b)), Here, the defendant's actions occurred in the District of Columbia, a jurisdiction that follows the traditional formula regarding the elements necessary to state a cause of action for negligence. See, e.g., Scott v. District of Columbia, 101 F.3d 748, 757 (D.C. Cir. 1996). cert. denied, 117 S. Ct. 1824 (1997) (applying District of Columbia negligence standards); McNeil Pharmaceutical v. Hawkins, 686 A.2d 567, 577 (D.C. App. 1996), cert. denied, 118 S. Ct. 63 (1997); District of Columbia v. Watkins, 684 A.2d 395, 401 (D.C. App. 1996); see also W. Page Keeton, et al., Prosser and Keeton On the Law of Torts § 30, at 164-65 (5th ed. 1984).

Under District of Columbia law, the plaintiff in a negligence action "bears the burden of proving 'the applicable standard of care, a deviation from that standard by the defendant, and a causal relationship between that deviation and the plaintiff's injury.'" McNeil Pharmaceutical v. Hawkins, 686 A.2d at 577 (quoting Toy v. District of Columbia, 549 A.2d 1, 6 (D.C. App. 1988)); see also District of Columbia v. Watkins, 684 A.2d at 401. In negligence actions, the standard of care by which the defendant's conduct is measured is "'that degree of care which a reasonably prudent person would have exercised under the same or similar circumstances.'" Morrison v. MacNamara, 407 A.2d 555, 560 (D.C. App. 1979) (quoting Washington Hospital Center v. Butler, 384 F.2d 331, 335 (D.C. Cir. 1967)). "[T]here is but one uniform standard of conduct: that of reasonable care under the circumstances." Ray v. American Red Cross, 685 A.2d 411, 415 (D.C. App. 1996) (quotations omitted).

The terms of the congressional reference set forth the parameters of the court's negligence inquiry: to determine whether the identification of the Riunite wine as a health hazard by the United States Government was negligent. Courts have recognized that administrative powers must "be exercised reasonably, with due regard to the objectives of the statute, the practice under it and the circumstances of the case at hand." White Sands Ranchers of New Mexico v. United States, 14 Cl. Ct. 559, 568, op. adopted in part, 16 Cl. Ct. 13 (1988). Similarly, when the government acts to execute a policy, it is charged with the duty of reasonable care. Henderson v. Bluemink, 511 F.2d 399, 401-02 (D.C. Cir. 1974).

The FTCA provides a useful starting point for analyzing a claim in the congressional reference context, see E.L. Armiger Estates v. United States, 168 Ct. Cl. 379, 384, 339 F.2d 625, 628 (1964), Kochendorfer v. United States, 193 Ct. Cl. 1045, 1056 (1970), however, in this instance both the legal

and equitable claims are disposed of and the sole determination remaining is outside the parameters of the FTCA. A claim in a congressional reference, by definition, involves an inquiry into alleged government fault for which there is either no enforceable legal remedy or an existing legal remedy that is considered inadequate by the plaintiff. See White Sands Ranchers of New Mexico v. United States, 14 Cl. Ct. at 565. As explained in California Canners & Growers v. United States:

Legal claims against the Government are frequently foreclosed by the doctrine of sovereign immunity (or by a similar doctrine of governmental privilege) under circumstances where a private party would be subject to liability. The circumstances giving rise to such claim may nonetheless be examined on the merits in the context of a Congressional Reference. . . . Perhaps the best illustrations of the elements of such [foreclosed legal] claims are found in the tort area. They involve actions by the Government allegedly constituting negligence, but in which the Government might well be protected by the preservation of sovereign immunity under the terms of the Federal Tort Claims Act.

7 Cl. Ct. 69, 99 (1984). The language of the congressional reference, nonetheless, appears to direct the hearing officer to make an assessment of negligence. Specifically, the hearing officer must determine whether the defendant breached its duty of due care in stating that certain Riunite wines were a health hazard by asking what a reasonable government agency, with its knowledge and resources should have done under the circumstances. See Ray v. American Red Cross, 685 A.2d at 416; see also Lance Industries, Inc. v. United States, 3 Cl. Ct. at 779 (defining the government's duty under the circumstances as "to warn against a perceived hazard in a manner that does not unreasonably jeopardize the interests of a product's manufacturer").

Negligence is composed of the following elements: duty, breach, causation, and damages. See Scott v. District of Columbia, 101 F.3d at 757. FDA had a duty to follow standard scientific procedures of analysis in determining whether or not the DEG contained in the plaintiff's wines constituted a health hazard and to properly inform ATF of its results. FDA allegedly breached this duty by hastily making its determination without undergoing a full investigation of the consequences of the differing levels of DEG contamination in the wine and the health hazards thus posed to the public.

1. Dr. Kokoski's Analysis of DEG Toxicity in Wine

The plaintiff contends that FDA acted negligently, beginning with Dr. Kokoski's analysis of DEG toxicity in the summer of 1985. Plaintiff relied heavily on the testimony of Dr. William Flamm, and to some extent on the testimony of Dr. Sorrell Schwartz. Dr. Flamm, who holds a Ph.D. in biological chemistry, served as director of FDA's Office of Toxicological Sciences, from 1982-88, and as vice chairman of the HHEB. The hearing officer qualified Dr. Flamm as an expert in toxicology and food safety.

According to Dr. Flamm's testimony, a toxicologist assessing the toxicity of a particular substance should follow a number of basic principles. First, Dr. Flamm testified that, because toxicology is not a static science and new research is constantly being performed, it is important for the toxicologist to be sure that he or she has a thorough and up-to-date understanding of the existing literature on the substance being assessed. Further, Dr. Flamm stated that it is important for the toxicologist to identify the authoritative studies and to then review them. He asserted that the toxicologist must review the literature to determine whether there is an established "no observable adverse effect level" (NOAEL) of a contaminant.(16) Next, Dr. Flamm stated that if FDA regulations already allow the contaminant under review to be present in foods "under certain circumstances up to a designated amount," a toxicologist should then consider the existing amount of the substance to which people will be exposed and how much of the substance people are likely to consume in making this assessment.

Dr. Flamm endorsed the proposition that "[f]or toxicologists as for lawyers and people in lots of other disciplines, scientific and un [sic], it is sensible to test one's assumptions and analysis and conclusions through consultation with other people in the discipline." He further testified that toxicological practice at FDA typically requires some form of quality control or peer review. Finally, Dr. Flamm testified that it is important for the toxicologist to communicate in such a way as to avoid misunderstandings on the part of non-toxicologists who might see his or her work.

Based in part on Dr. Flamm's testimony, the plaintiff alleges that "the traces of DEG in Riunite were not a health hazard, and Dr. Kokoski's analysis of DEG was negligent in every material respect." According to the plaintiff, Dr. Kokoski's analysis of DEG in wine was negligent because: (1) by his own admission, he failed to perform a literature search; (2) he did not read the Calvery and Klumpp study that he had identified as authoritative;[(17)] (3) he failed to consider existing derivative exposure to DEG pursuant to FDA regulations which allows its presence at very low levels as a by-product of the additive polyethylene glycol, which is found in over the counter medications; (4) he identified an incorrect NOAEL; (5) he did not consider how much DEG was in wine people would be exposed to, nor how much wine consumers were likely to drink; (6) his work underwent no peer review or other quality control before it was sent to ATF; and (7) he failed to communicate his analysis and conclusions to non-toxicologists in an understandable fashion.

When, on July 11, 1985, Dr. Kokoski received from Dr. Blumenthal the assignment to perform the DEG risk assessment for Dr. Miller, Dr. Kokoski understood that Dr. Miller wanted the assessment as soon as possible and he completed a first draft of his memorandum in approximately four hours. Because he "didn't have enough time to pull perhaps everything together, . . . [he] pulled what [he] thought were the critical papers." In particular, Dr. Kokoski collected from the filing cabinet in his office articles, studies, and extracts relevant to DEG toxicity. He also looked at some standard toxicology texts and had his secretary retrieve a 1979 file on a petition by British Cellophane to have DEG approved as a food additive. He did not perform original literature research, go to the library, or make any other effort to ensure that the materials in the British Cellophane file concerning DEG toxicity were current. Although Dr. Kokoski admitted that, at the time he wrote his memoranda, there could have been numerous studies on DEG toxicology in existence which he did not review, he believed that, had a significant article on DEG been published from 1979 to 1985, he would have been aware of it from his own reading of scholarly journals.

Dr. Kokoski's July 12, 1985 memorandum summarizes two animal studies, Gaunt and Fitzhugh and Nelson, and one human study, Calvery and Klumpp. Dr. Kokoski testified that Calvery and Klumpp is "the important work" that deals with DEG toxicity in humans. However, Dr. Kokoski relied on the Gaunt study when preparing his memorandum and testified that he did not read Calvery and Klumpp when he prepared his August 1985 memorandum.

The Calvery and Klumpp article is a 1939 case study of a 1937 incident in the United States in which 353 people consumed varying amounts of an elixir of sulfanilamide, which contained a concentration of 72 percent DEG. Thereafter, over 100 of the 353 people who had consumed the DEG died. Dr. Kokoski reported the findings of the Calvery and Klumpp study as "25 ml DEG or above was fatal in humans in about 30% of the cases." In addition, Dr. Kokoski wrote: "Calvary [sic] and Klumpp stated (1930) that man may be more susceptible than other species, which may make above levels of DEG even more toxic to humans." In his report, however, Dr. Kokoski also noted that:

Diethylene Glycol is not allowed as a direct food addictive in 21 CFR Food Addictive Regulations. It may occur as a contaminant limited to low levels in some ethylene oxide condensates (e.g., polyethylene glycol) used as food additives. However, any purposefully added DEG to food is not authorized by the

regulations and any such imported food would be considered illegal.

During his testimony, Dr. Kokoski admitted that the summary of the Calvery and Klumpp article which he placed in his July 12, 1985 memorandum was based on the Gaunt study, and, therefore, was imprecise. Dr. Kokoski testified that he "lifted that statement [25 ml DEG or above was fatal] out of the Gaunt report, and at that point I assumed it was correct. And the statement is exactly what it was in the Gaunt report and it talked about total dose which I neglected to put in my quotation." Because Dr. Kokoski's memorandum did not report what percentage of DEG was consumed, counsel for the plaintiff inquired as to Dr. Kokoski's understanding of what percentage of DEG the elixir contained:

Q . . . [W]as your understanding of this Calvary [sic] and Klumpp 25 ML DEG or above was fatal that the solution that proved to be fatal was 100 percent DEG?

A No, I did not assume that the elixir was 100 percent DEG. It couldn't have been because it was sulfanilamide elixir.

Q Didn't it make a difference in the assessing the toxicity of DEG to know whether the solution that killed people was 100 percent DEG, 50 percent DEG, DEG of five percent DEG?

A I assumed from the Gaunt study that they would have considered what the amount of DEG and the elixir was when they made this statement.

* * *

The Gaunt study had a summary. It was a rat study, yes. But it had a summary of the toxicity of diethylene glycol from various other studies. And this was in the part of the summary section of the Gaunt report. And I lifted it because it seemed to put in a very brief sentence in essence what the toxicity of DEG and the over the [sic] sulfanilamide elixir was.

* * *

Q I know you lifted it, Dr. Kokoski. But what I'm trying to find out as I said before is whether you simply lifted it or whether you also thought while you were lifting. Did it ever cross your mind how much of the solution, the sulfanilamide, the elixir of sulfanilamide was DEG might have some significant effect in determining the relative toxicity of DEG?

A At that point that was not a consideration.

Although Dr. Kokoski reported that the minimum fatal dose in the elixir of sulfanilamide incident was 25 ml, in fact, the Calvery and Klumpp article reports that the minimum fatal dose for adults was 20 ml. Moreover, Dr. Kokoski admitted that, had he read the Calvery and Klumpp study, he would not have reported that 25 ml DEG was fatal in approximately 30 percent of the cases.

In his summary of the Gaunt study, in which rats consumed DEG for a period of 225 days, Dr. Kokoski reported that the minimum effect level (MEL) was 0.17 percent and that the NOAEL was 0.085 percent (about 50 mg/kg b.w.). However, the Gaunt study reported that there was a "no untoward effect" level of 0.17 percent, notwithstanding the fact that there was increased oxalate production at that level. When counsel for the plaintiffs suggested that the "no untoward effect" level substantively was the same thing as the NOAEL, Dr. Kokoski testified that the authors meant that at 0.17 percent DEG there was no "oxalate burden." Dr. Kokoski apparently viewed increased oxalate production as an adverse effect,

because he used a lower percentage -- 0.085 -- as the NOAEL. According to Dr. Kokoski, what he referred to as the minimum effect level was "the level in animals at which there was an increase in oxalate excretion in some of the animals which is an adverse effect in my opinion." The NOAEL was "that level where the test animals were comparable with the control animals. They did not have significant increase in oxalate excretion which is the endpoint that is determined." Thus, without undertaking a thorough scientific examination himself, and counter to the results of the report, Dr. Kokoski increased the impact of the Gaunt study by 50 percent.

Regarding the Fitzhugh and Nelson study, Dr. Kokoski testified as follows:

Q. As you understood it, in July of 1985, what significance did the Fitzhugh and Nelson Study, Exhibit 200, have in terms of your evaluation of diethylene glycol?

A. It showed that diethylene glycol is toxic at all test levels. And it was toxic both to the kidney and the liver. And this was in the rat two years studies. And at the high levels, there were stones, bladder stones. And there were tumors. So it caused bladder tumors. At lower levels, there were stones and crystals. And there was toxicity at all levels.

Q. And was there any significance to the statement that you just made that there was toxicity at all levels?

A. Yes, there was. Because we did not have a [NOAEL] from this study in order to determine by extrapolating using safety factors for what may be a safe level for human exposure.

Q. And why was a [NOAEL] significant in your view in 1985 when you did this work?

A. Because this is the standard procedure at FDA before determining a safe level for material. You need studies which show no adverse effects in animals in order to extrapolate to the human population.

Q. Now when you were doing your work in July of 1985, did you think that you were coming up with a safe level of diethylene glycol in wine that could be an acceptable amount for all time?

A. No. This was a theoretical or tentative ADI. And it was for the immediate situation, not for all time. Certainly not for food additive regulation purposes.

Dr. Kokoski also testified that, at the time he received his assignment on July 11, 1985, he understood that the problem of DEG contamination in wine was extensive but did not have any particular information concerning how long this problem had existed.

Following his summary of the Gaunt, Fitzhugh and Nelson, and Calvery and Klumpp studies, Dr. Kokoski included a section in his July 12, 1985 memorandum extrapolating DEG toxicity to humans, in which he calculated the maximum ADI for humans as 6 mg of DEG for a 60 kg person. Dr. Kokoski started with the NOAEL that he had identified from the Gaunt study and applied a 500-fold safety factor. According to the plaintiff's expert, Dr. Rodricks, safety factors are used "to compensate for certain uncertainties in the data, among them the applicability of animal data to people and the issue of variability in response across the human population." Like the NOAEL, the safety factor that Dr. Kokoski used differed significantly from that contemplated by the authors of the study, who suggested "application of the usual 100-fold safety factor" to their results.

Once he arrived at an ADI, Dr. Kokoski apparently did not complete any further research. His

memoranda of July 12, 1985 to Dr. Miller and of August 8, 1985 to Sonia Delgado reflect no data on how much DEG was in the wine people would be exposed to, nor any data on the quantity of wine consumers were likely to drink. Thus, the memoranda provided little, if any, guidance in formulating a regulatory response to the problems identified regarding DEG contaminated wines. While it is significant that, as the defendant suggests, further research or review of the existing literature, including reading the Calvery and Klumpp study, probably would not have altered Dr. Kokoski's conclusions, the fact remains that he failed to follow reasonable and sound principles of scientific inquiry.

It is apparent from the above, particularly from Dr. Kokoski's formulation of an ADI, that he evaluated for long-term exposure of DEG despite the immediate need to deal with a short-term toxic contaminant. His goal should not have been to determine the long-term impact of DEG because the contaminated wine was only going to be available on the consumer market for a relatively short period of time. In other words, Dr. Kokoski was treating DEG as a potential food additive in his analysis as opposed to as a temporary contaminant with short-term exposure.

Regarding the principle that a toxicologist should consider potential exposure levels to the contaminant being assessed, the defendant contends that Dr. Kokoski assumed a consumption level of one liter of wine daily in determining his safety concern level for DEG. There is no evidence in his July 12, 1985 and August 8, 1985 memoranda, however, that Dr. Kokoski utilized a specific consumption level. Both memoranda set forth an ADI for DEG of 6 mg. Milligrams (mg) specify a volume designation rather than a concentration level specified in parts per million (ppm) to indicate that a consumption level had been factored in by Dr. Kokoski. Moreover, Dr. Kokoski admitted that his memoranda did not incorporate a consumption level:

Q . . . [I]f one were going to do a comprehensive assessment of the potential health hazard of DEG in wine, it would be important to incorporate some estimate of how much wine containing DEG a typical consumer was likely to drink, right?

A Yes.

Q But you didn't do that in either [memorandum], correct?

A Correct.

Q One reason you didn't do that is because as you understood it, nobody asked you to, right?

A That's correct.

Q Another reason you didn't do it is that you understood that there were others at FDA who had responsibility for gathering consumption data?

A That's correct, generally.

On cross examination, Dr. Kokoski testified that, although his July 12, 1985 and August 8, 1985 memoranda did not provide a consumption level of wine, he "mention[ed] to various individuals, particularly in compliance, that if one were to consider one liter of wine consumption, which I felt was a reasonable amount, that this would represent six parts per million." Specifically, Dr. Kokoski stated that he spoke to Ms. Delgado and Mr. Coker regarding the consumption of one liter of wine to arrive at a 6

ppm NOAEL for DEG. In addition, the parties stipulated that Dr. Kokoski advised Mr. Alford that a person consuming one liter of wine a day which contained over 600 ppm of DEG would likely suffer adverse effects.

Dr. Kokoski's testimony, but not his memorandum, addressed the purpose of evaluating a contaminant as opposed to a food additive. For a food additive, the object at FDA is to determine whether the agency should publish a regulation allowing deliberate addition of the substance to food. According to Dr. Kokoski, DEG in wine, however, is an example of a contaminant, which is a substance or chemical that gets into a product, without FDA approval either by inadvertent contamination or intentionally. He testified that one of the aims of FDA in looking at contaminants is "to determine whether and at what level there is a health hazard so that the agency can determine the maximum tolerant level of the contaminant."(18) Dr. Kokoski offered the following testimony:

Q Dr. Kokoski, when the FDA goes about approving a food additive, unless the approval is later revoked, the substance can be in food or drink essentially forever, right?

A That's correct.

Q Whereas if you're dealing with an accidental contaminant when the Health Hazard Evaluation Board is establishing a level of concern. . . . You typically wouldn't be faced with a contaminant being around forever, right?

A Correct.

Q . . . This is an important difference between the establishment of an ADI and the approval of a food additive on the one hand and what the Health Hazard Evaluation Board does in considering a contaminant on the other hand, right?

A Correct.

* * *

Q Dr. Kokoski, we've already established that an important difference between the use of ADIs in the process of approving food additives and what the Health Hazard Evaluation Board does in considering contaminants is the difference between lifetime exposure on the on[e] hand and acute or short term exposure on the other hand, right?

A The -- let me qualify my answer yes. The ADI could be for a lifetime. It would be for purposes of regulation if in the food additive petition process. So therefore it would be a lifetime potentially.

Q Right. Whereas with a accidental contaminant when the Health Hazard Evaluation Board is establishing a level of concern, in a typical situation you would not be faced with the prospect of that contaminant being in there forever.

A I would hope so.

Q And in your mind, that represents a very material difference between the establishment of an ADI on the one hand and the Health Hazard Evaluation Board's use of levels of concern on the other.

Q Yes.

Thus, the fact that Dr. Kokoski focused on establishing an ADI for a temporary contamination incident was evidence of his flawed approach.

After he completed his analysis, Dr. Kokoski gave his July 12, 1985 memorandum directly to Dr. Miller and his August 8, 1985 memorandum to Ms. Delgado at FDA. Unlike an HHE, which is prepared or signed off on by a group of scientists, Dr. Kokoski's documents were sent to ATF without either being reviewed or formally approved by any other FDA toxicologist. Moreover, at trial, it became apparent that the non-toxicologists at ATF who relied on Dr Kokoski's work product not only received incomplete information, but also did not understand the technical analysis and conclusions submitted by Dr. Kokoski. For example, in answering the question about whether there are tolerance levels for DEG in his August 8, 1985 memorandum, Dr. Kokoski stated that "[t]here are no tolerances" for DEG. ATF interpreted this language to mean there was no safe amount of DEG in the imported wines. In contrast, Dr. Kokoski testified at trial that his response was not a comprehensive overview of the status or scientific concerns of DEG under FDA regulations. The testimony elicited indicated that Dr. Kokoski apparently meant that there were no regulations allowing the presence of DEG as a direct additive to food or drink.

Furthermore, it is evident that, prior to release to ATF of the July 12, 1985 and August 8, 1985 memoranda, Dr. Kokoski's work did not undergo formal peer review. Dr. Flamm testified, however, that the review process for toxicological work at FDA differed depending upon the standing of the toxicologist performing the work. He also stated that branch chiefs did not have to have their work reviewed by another toxicologist, although such a review occurred in special circumstances and the branch chief could request peer review if desired. At the time Dr. Kokoski prepared his July 12, 1985 memorandum, he was the Chief of the Food Additives Branch in the Division of Toxicology at the CFSAN and seemingly had the authority to provide scientific advice without review by any other toxicologist.

Moreover, Dr. Kokoski's work was apparently sent to ATF through Dr. Miller, who, although not part of the Division of Toxicology, was the Director of CFSAN, and perhaps also through Dr. Blumenthal. According to Dr. Kokoski, Dr. Miller, after reviewing a draft of the memoranda, told Dr. Kokoski that it was "what he want[ed]" except that he requested the addition of a statement that any DEG which is purposefully added to food is not authorized by the regulations and any such imported food would be considered illegal. After adding this statement, Dr. Kokoski provided a final copy of his memorandum to Dr. Miller.

2. FDA's Advice on DEG

Dr. Kokoski testified that, when he received the assignment on July 11, 1985 to provide information on the toxicity of DEG in wine, "I had no particular understanding of what [Dr. Miller] would do, but I understood it was to be transmitted back to [the German Government]." As noted above, he also understood that time was of the essence. When Dr. Kokoski prepared his second memorandum on August 8, 1985, he understood that he was answering certain questions about DEG toxicity posed by the Austrian Embassy to Dr. Flamm at FDA, and which Ms. Delgado had passed on to Dr. Kokoski. Dr. Kokoski testified as follows regarding his various responses:

Q Do you recall that you testified yesterday in response to Ms. Kirchner's [defendant's counsel] questions about a request that you got from Sonia Delgado, in compliance part of FDA, to pull together some information to provide the Bureau of Alcohol, Tobacco and Firearms?

A Yes.

Q I take it that Ms. Delgado did not at that point ask you to do any new work, right?

A Correct.

Q She didn't ask you in words or substance to prepare a memo giving BATF a comprehensive overview on the toxicity and/or regulatory status of DEG, right?

A That's correct.

Q And at the time that Ms. Delgado told you that she wanted you to pull together information for BATF, I gather it never crossed your mind to do any new work?

A I will say yes.

Q Here is my point, Doctor.

Exhibit 12 [Dr. Kokoski's Memorandum dated July 12, 1985] was something you put together on short notice, as quickly as you could in the space of about four hours, right?

A Yes.

Q Based upon no literature search and no reference to the seminal study on human toxicity, right?

A If you mean by "seminal" --

Q Calvary [sic] & Klumpp

A -- for humans. But my conclusion was based on animal studies.

Q Exhibit 35 [Dr. Kokoski's memorandum dated August 8, 1985] was just an attempt by you to give specific answers to specific questions from the Austrian Embassy to the United States?

A Correct.

Q All I am asking you -- I don't mean this to be critical, I just want to know what your thought process was. When Sonia Delgado says to you in substance, we need to give advice to BATF about the potential health consequences of DEG in wine, did it ever cross your mind that the two memos you had done previously were done quickly for limited purposes and maybe you or somebody else ought to take a somewhat more fulsome approach to answering the inquiry from BATF?

A I felt that what I had was adequate for responding to her request, to give her a package of information.

By August 2, 1985, when Ms. Delgado requested that the FDA Division of Toxicology assemble information about DEG, the contamination of wine was already in the news and FDA and ATF had met to discuss the problem. Moreover, ATF had requested both oral and written information on DEG toxicity from FDA. While ATF did not specifically request an HHE, Dr. Kokoski and others at FDA were on notice that DEG contamination of wine had become a concern and that the information FDA provided would likely be used by ATF to formulate policy. FDA's response was limited, but not identified as such. It was not responsible for Dr. Kokoski to forward responses which did not identify the limitations under which they were prepared, when he knew or should have known that he had done a

less than thorough job, and especially when he knew that the information was being forwarded to another government agency (which did not have expertise to determine health hazards), for use in formulating a response to public inquires. Furthermore, because ATF had regulatory authority regarding wine importation, it was reasonable for Dr. Kokoski to also assume that the information which he prepared and transmitted could be used to prepare a response to the presence of DEG in wine by ATF.

It is clear from the record that FDA followed no established written procedure when responding to a request from another government agency involving a potential health hazard and that referral to an HHEB was not required. However, according to Mr. Eugene Newberry, who served as Chief of the Case and Advisory Branch within the Division of Regulatory Guidance of FDA from 1980 to 1985, certain practices were generally followed. The matter would be referred to an expert within CFSAN and the written opinion from the expert "would go though all of his superiors and be signed out. The response would be developed in the form of a letter to the other agency." Mr. Newberry testified:

Q And what you would expect is any time a fellow agency in 1985 or '86 went to FDA and said in effect we're aware that there is this substance in the product, and we want to know whether there is a health hazard, that the reply coming out of FDA would start somewhere down around Curtis Coker's level, would get reviewed by various people above Mr. Coker on the organization chart, revised if necessary and then finally reviewed, approved and sent by somebody on the order of Mr. Hile, the Associate Commissioner for Regulatory Affairs, right?

A That's right.

Q That was the policy at FDA back in 1985 and 1986, correct Mr. Newberry?

A That was the working method, yes.

Q I'll take working method. That was the standard practice.

A Yes, yes.

Q That was how things happened, right?

A Yes.

The actual procedures followed by FDA in assessing the health risks from DEG contamination, however, did not follow the practices outlined by Mr. Newberry. The response FDA provided to ATF regarding DEG contamination of wine was not in the form of a letter, instead it was a compilation of papers and research notes, and underwent little, if any, review. The cover memorandum that Dr. Kokoski sent to Ms. Delgado stated simply: "[a]s requested we attach a package of summaries of toxicology data on Diethylene Glycol (DEG) as well as a list of references, and a brief outline of DEG toxicology dated July 12, 1985 which was provided earlier to Dr. Miller/HFF-1." Specifically, Dr. Kokoski attached: Working Paper "A," dated February 16, 1979, prepared by John D. Walker, Ph.D., of FDA's Division of Toxicology; a list of references on DEG; his July 12, 1985 memorandum to Dr. Miller; and the Gaunt study. However, by the time FDA documents reached the desk of ATF Director Drake, several pages were missing and FDA had elected not to provide the list of references. There is no evidence that ATF received a written letter or memorandum explaining the materials from FDA, or that anyone in FDA compliance senior to Ms. Delgado ever reviewed or approved the materials. This does not appear to follow proper procedures by the agency responsible for ensuring that all foods are safe for consumption and use.

3. ATF's Reliance Upon FDA

Although ATF did not have written recall guidelines in place in the summer and fall of 1985, its stated regulatory policy, included in the Quarterly Bulletin of the Bureau of Alcohol, Tobacco and Firearms No. 1980-3, July-Sept., required that "ATF's major regulatory emphasis is to achieve voluntary compliance. . . ." In the case of non-compliance, ATF's "actions must be prompt, objective, consistent, fair, and commensurate with the seriousness of the situation." Moreover, the industries that ATF regulates were "entitled to the same consideration, treatment, and protection as is any other business," and that every action "be based upon rational analysis of factual information. . . ."

ATF officials interpreted Dr. Kokoski's statement that "[t]here are no tolerances" for DEG to mean that any amount of DEG found in wine posed a health problem. Because Dr. Kokoski later testified that what he meant was not that all levels of DEG were unsafe, but rather that "there were no regulations allowing the presence of DEG as a direct additive to food or drink," it is clear that FDA did not adequately present and communicate what it now asserts as its scientific conclusions, specifically, that a person could safely consume 6 mg of DEG every day. Both Norris Alford, who served as Chief of the Products Compliance Branch at ATF Washington, and William Drake testified that ATF interpreted the "no tolerances" statement as indicating that any amount of DEG, no matter how small, would pose a health hazard problem. According to Mr. Drake, "[t]here was no acceptable level for diethylene glycol. Our interpretation of that [the 'no tolerances' language] was that there was, it could be none, that any amount could possibly harm a person, any amount." Mr. Drake testified that, in reading the August 8, 1985 memorandum, it never occurred to him that certain regulations expressly allowed DEG to be present in food up to a designated level, and that the presence of DEG would be considered safe under certain circumstances.[(19)]

Mr. Alford, who was ATF's liaison to FDA, testified that he was sent a copy of Dr. Kokoski's August 8, 1985 memorandum by Ms. Delgado of FDA. The written information that Mr. Alford obtained from FDA in the summer of 1985, he believed, "was what FDA regarded as necessary in order to give ATF reliable guidance on the health consequences of DEG." Moreover, Mr. Alford testified that, after he got the August 1985 transmission, FDA did not transmit any additional written information about DEG in wine at any point. Mr. Alford engaged in the following colloquy on the subject of DEG tolerances with plaintiff's counsel:

Q And you and others at ATF who you discussed this with thought the phrase, "there are no tolerances" meant that any amount of DEG, no matter how small, was a health hazard in the eyes of the FDA.

Right?

A Exactly. You know that when it said there was no tolerance, our reading of it was anything else would pose a health problem.

The defendant contends that Dr. Kokoski was not negligent in his research, analysis and communications to ATF in light of the task he was asked to perform. The defendant argues that Dr. Kokoski was asked by FDA compliance personnel to assemble information about DEG to be sent to ATF, and that he did so. This argument, however, obscures the fact that Dr. Kokoski provided two written memoranda that were not qualified, or limited in any way and were not written so that a lay person could understand the subtleties of the scientific evaluation prepared by a trained toxicologist. In fact, ATF personnel interpreted the words of the memoranda literally, and concluded that no level of DEG in wine was safe for human consumption and, thus, that any amount would pose a health hazard.

4. ATF's Use of the FDA Analysis on DEG

As a result of ATF's understanding that FDA had determined that any amount of DEG in wine was a health hazard and that the wines containing DEG were mislabeled, ATF concluded that the Riunite wines which were contaminated with DEG should be removed from the market. As a result of this conclusion, ATF would not debate whether a particular amount of DEG in a given wine was safe. As Deputy Associate Director of Compliance Maxwell explained:

Q Based upon FDA's position that, at least as ATF understood that position, that there was no safe limit for DEG, isn't it true, that ATF concluded that any amount of DEG constituted a potential health hazard?

A I think that's correct.

Q And from the time that ATF received this advice from FDA forward, you personally would not debate health issues with members of the industry.

A Absolutely not.

Q You would not debate whether a particular amount of DEG in a given wine was safe, or unsafe.

Correct?

A I would not.

Q Because that wasn't the issue.

A That's right.

Q The issue was would the industry member recall the product or not?

A Right. But because of my style of dealing with the industry, I would not just simply say we're not going to discuss it. What I would say is, if you want to debate that, go debate it with FDA. Get them to change their minds. I would not debate it with them.

The DEG, whether an actual health hazard as opposed to simply a contaminant that was a potential hazard, was clearly in the Riunite wine and not a permissible or approved additive. Therefore, the direct link between the identification of DEG as a health hazard and the damages claimed by the plaintiff as a result of the recall is not apparent.

After a thorough review of the voluminous trial transcript and exhibits and the parties' extensive post-trial briefs, and after careful consideration of the multiple issues raised by the parties, including many that were extraneous to the central question of the congressional reference, the hearing officer concludes that FDA failed to exercise a duty of care appropriate to the scientific discipline involved when, in July and August of 1985, it responded to the inquiry regarding the toxicity of DEG. FDA failed to perform a complete and thorough assessment of DEG toxicity in wine and failed to communicate clearly its findings to ATF.[(20)] Nevertheless, under its rules and regulations, ATF was entitled and authorized to request a recall and issue press releases based on mislabeling, even if the FDA analysis was incomplete and damages are not appropriate. Although FDA appears to have failed to exercise the requisite duty of care to provide a properly conducted scientific evaluation to ATF in response to ATF's request, because this hearing officer is examining negligence only regarding eligibility for a gratuity, an assessment of an

amount of damages is not within the statutory mandate. 28 U.S.C. § 2509; Paul v. United States, 20 Cl. Ct. at 264.

It is submitted, however, that any determination of damages to be granted as a gratuity by Congress should consider the duties and responsibilities assigned to ATF and FDA when they were asked to respond to questions regarding contamination in wines. Once ATF and FDA determined that tainted and potentially hazardous wines were on the shelves of retailers throughout the United States, an immediate response was required to protect the health, welfare and safety of consumers. In making this assessment, ATF and FDA, as mandated by their responsibilities to the population at large, had as their first priority the prevention of a negative, national, health impact. The irony in this congressional reference is that Banfi seeks renumeration for damages arising out of actions by these agencies which occurred while they were attempting to protect the public. Although the court is cognizant of the possible financial impact on industry and commerce of actions taken to protect the public, such impacts must be balanced against the public protection concerns to which ATF and FDA were responding. It is, therefore, ironic that the mandate to protect the public health in the instant case stemmed, in part, from a major health catastrophe that prompted the passage of the Food, Drug and Cosmetic Act of 1938, which was caused by the very contaminant at issue in this congressional reference, DEG:

The story of the 1938 [Food, Drug and Cosmetics] Act has been told before. The most important change in the law governing therapeutic drugs, premarket review for safety, was not among the reforms originally sought by the architects of the new law in 1933. That change did not surface until the eve of congressional passage almost five years later. It was a response to the infamous "Elixir Sulfanilamide" disaster, in which over one-hundred [people in the United States] were poisoned by the solvent diethylene glycol that a reckless producer incorporated in a new therapeutic potion without testing. Realizing that simply strengthening FDA's ability to act against adulterated drugs would still leave the agency responding to evidence of harm rather than attempting to prevent it, Congress invented a new legal category -- "new drugs" -- which a manufacturer could not market without first notifying FDA and allowing it time to assess their safety.

This was the beginning of the modern system of premarket approval which now covers practically all drugs -- a system in which marketing without FDA approval is unlawful without any need to prove that a product poses a hazard or may not work.

Richard A. Merrill, The Architecture of Government Regulation of Medical Products, 82 U. Va. L. Rev. 1753, 1761-62 (1996); see Senate Doc. No. 124, 75th Cong. (1938). It is evident that a primary purpose of FDA is to protect the public from consuming potentially harmful substances. ATF likewise is empowered to prevent mislabeling and potentially harmful alcoholic beverages from reaching the public. ATF and FDA must act quickly in order to protect potential consumers, although mindful not to cause unnecessary economic detriment to sellers and distributors. Safety must be a heavily weighed factor in this balance.

In the instant case, the possibility that only a few bottles of Riunite could cause severe damage to consumers was potent enough to justify ATF's request for a recall of the wine. In fact, although not directly relevant to the specific determinations made in this case, the later HHEB scientific results confirmed that some of the Riunite wines which were recalled contained concentrations of DEG that were high enough to cause harm to the purchasers of the wine. This fact underscores that, while the FDA's initial research regarding the toxicity of DEG may have been completed in a fashion which the plaintiff believes to have been unacceptable, there were legitimate health and safety concerns identified by FDA and responded to by ATF. Regardless of the levels of DEG present in Riunite wines in 1985 and 1986, neither FDA nor ATF exceeded the statutory authority which vested in those agencies the power to make decisions that affect both sellers and consumers. Specifically, the actions taken by ATF

which led to the recall were appropriate, based on the DEG contamination and the resulting mislabeling of the Riunite wines that were imported by the plaintiff under their basic permit obtained from ATF.

CONCLUSION

It is the finding of this hearing officer that the United States acting through ATF and FDA, committed no act which should entitle Banfi to compensation for a legal or equitable claim. The government did not breach its duty of care or step beyond the scope of its authority when ATF requested the voluntary recall by Banfi of certain Riunite wines containing DEG. DEG is indisputably a potentially serious health hazard in relatively small quantities and is not a permissible additive to wine. The Riunite wine at issue was mislabeled and misidentified under the applicable statutes and regulations. Nevertheless, after rejecting Banfi's legal or equitable claims, this hearing officer undertook additional efforts, as discussed above, to examine whether FDA was negligent in identifying as a health hazard the quantities of DEG contained in the Riunite wines. It bears repeating that while this hearing officer has identified negligent conduct on the part of FDA officials, such negligence did not establish an equitable or legal claim on behalf of plaintiff Banfi. Nor was there negligence by the government's decision making on safety and health issues which was sufficient to hurdle the discretionary authority doctrine, which vests authority in ATF and FDA to take action. Government agencies have an obligation to maintain their duty of care to protect the public from real and potential health hazards, and ATF acted accordingly when it issued the ATF press releases and requested plaintiff to effect a recall.

The consequence of not establishing a viable legal or equitable claim is indisputable: "[i]f relief would constitute a mere gratuity, however, the court will recommend that Congress deny relief." Kanehl v. United States, 38 Fed. Cl. at 98 (citing White Sands Ranchers v. United States, 14 Cl. Ct. 559, 565 (1988)). Based on the reasons stated, the plaintiff does not have a viable legal or equitable claim against the United States and such relief should be denied. Any award to the plaintiff would be a gratuity.[(21)]

IT IS SO ORDERED.

MARIAN BLANK HORN Judge

1. By enactment of the Court of Federal Claims Technical and Procedural Improvement Act of 1992, Pub. L. No. 102-572, 106 Stat. 4516 (1992) (codified in various sections of 28 U.S.C.), the United States Claims Court was renamed the United States Court of Federal Claims.

2. During the lengthy trial, the hearing officer heard testimony from over thirty witnesses and lengthy argument by the attorneys, which resulted in a transcript of over 5,000 pages that was accompanied by over 600 voluminous exhibits. In hindsight, and after a careful review of the transcript and exhibits, the relevant facts emerged as relatively straight forward and are summarized below. The trial was interrupted by many difficulties experienced by defendant's counsel, especially during direct questioning. Although none of these obstacles has a bearing on the final decision on the merits in this case, they made the conduct of trial and review of the record, including the transcripts, difficult, cumbersome and time consuming.

3. The defendant's initial answer to the plaintiff's complaint included a contributory negligence defense

which alleged that Banfi "allowed DEG [diethylene glycol] to be contained in its Riunite wines." Subsequently, however, the defendant withdrew this defense, with the statement that "it appears to defendant that the aforementioned defenses may not be sustained at trial."

4. Unless otherwise noted, citations to the Code of Federal Regulations are to the regulations in effect as of April 1, 1985.

5. The parties also stipulated that DEG was not an approved additive to wine in Austria, Germany, Italy, Canada or Japan in 1985-1986.

6. FDA had authority to request a recall only when, as stated in the regulations, certain determinations were made:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

21 C.F.R. § 7.45(a).

7. An evaluation for an FDA recall was to consider the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

21 C.F.R. § 7.41(a).

8. ATF advised that it would continue to test wines for the presence of DEG until "it is assured that all imported wines are free of the contaminant." As of an April 29, 1986 news release, ATF had identified DEG in 95 brands of Austrian, German and Italian wines. ATF testing revealed the following ranges of DEG in Austrian, German, and Italian wines: 0.1 grams per liter (100 ppm) to 19.66 grams per liter (19,660 ppm) in Austrian wines; 0.005 grams per liter (5 ppm) to 0.1 grams per liter (100 ppm) in German wines; and 0.003 grams per liter (3 ppm) to 0.06 grams per liter (60 ppm) in Italian wines. One

ppm is equivalent to .001 gram/liter (g/l).

9. During his testimony at trial, Dr. Kokoski defined the Food Chemicals Codex as "a compendium produced by the National Academy of Sciences which sets out . . . recommendations for specifications which the Food & Drug Administration often will refer to in the case of food chemicals."

10. Two of the wines tested, Riunite Rosato and Riunite Lambrusco dell' Emilia, were later found to contain up to 29 ppm of DEG.

11. After the Austrian wine scandal became public, Cantine arranged for testing of certain Riunite wines at the University of Bologna and other foreign laboratories. These tests did not detect the presence of DEG. Information from the University of Bologna and other foreign laboratories led Banfi to believe that levels of DEG below 10 ppm could not be detected. Contrary to the initial assertions made by Banfi representatives, the parties later agreed and have stipulated that ATF's laboratory was capable of detecting the presence of DEG in wine at levels below 10 ppm.

12. Dr. Taylor's opinion was disputed at trial during the testimony of defendant's experts, and is referenced here only to identify the type of scientific evidence that Banfi relied upon in attempting to forestall the recall of the DEG contaminated wine.

13. Banfi's draft release asserted that the levels of DEG contaminants in the Riunite wines were not injurious to health, as follows:

According to Dr. Mark Cullen, associate professor at the Yale University School of Medicine and Medical Director of the Occupational Medicine Program at Yale-New Haven Hospital, "a consumer who drank wine containing this small amount of D.E.G. would not have experienced any adverse health effects." Dr. Steven Taylor of the Food Research Institute at the University of Wisconsin, who is one of America's leading food scientists, agrees. Taylor stated that "there is no evidence that such low levels of D.E.G. are in any way injurious."

14. This hearing officer notes that the plaintiff's original private bill for relief, H.R. 3894, 101st Cong. (1990), contained a broader basis upon which damages were sought, but it appears that the first bill was never referred by the Congress to the Chief Judge of the United States Court of Federal Claims for action. This original bill stated in pertinent part:

(1) the recall of approximately 1,300,000 cases of imported Riunite wine directed by the Federal Bureau of Alcohol, Tobacco, and Firearms based upon an erroneous identification of a chemical health hazard in such wine; and

(2) the misleading public statements made between October 1985 and March 1986 by agents of the United States Government to the effect that consuming the subject wine was or could be hazardous to human health.

H.R. 3894, 101st Cong. (1990).

15. It is apparent to this hearing officer that the plaintiff may not believe that it has a viable legal claim as demonstrated by the fact that Banfi devotes a solitary footnote in its post-trial memorandum to argue that it has a meritorious legal claim. However, this hearing officer is compelled to fully evaluate the merits of plaintiff's alleged legal claim as required by the congressional reference and 28 U.S.C. § 2509.

16. NOAEL is often stated as the "no observable effect level," or "no effect level" but is more precisely the "no observable adverse effect level." It may be defined as the approximate threshold at which a study of animals or humans is unable to detect any adverse effects from exposure to the particular chemical under review.

17. Dr. Flamm, Dr. Kokoski's one-time colleague at FDA, stated that it was "inappropriate" for Dr. Kokoski not to have read a study that he himself had identified as key, whereas Dr. Schwartz stated outright that "[o]f course he should have read it."

18. For example, in the case of the 1986 HHE of DEG, the board set a level of concern for an acute and short term hazard rather than establishing an ADI.

19. ATF appears to have had difficulty interpreting what Dr. Kokoski had written because the following language indicated the exceptions as to when DEG is allowed derivatively into food:

Where it may be a contaminant in a food additive, e.g. Polyethylene Glycol, the Food Chemicals Codex sets a specification maximum limit of not more than 0.25% ethylene glycol and diethylene glycol, individually or combined. At the use levels of Polyethylene Glycols, the exposure to DEG would be very low.

Dr. Kokoski acknowledged that "Food Chemicals Codex" is a technical term with which regulators outside FDA probably would not be familiar.

20. It is important to distinguish the methodology and the communication of the scientific inquiry with the actual result of the scientific analysis. This hearing officer reviewed the scientific evidence, including the results of HHE No. 2854, which was issued on June 15, 1992. HHE No. 2854, concerning DEG in wines and corrected errors contained in an earlier HHE, No. 1488 (1986), also concerning DEG in wines. Like HHE No. 1488, HHE No. 2854 concerned only the short-term consumption of wines containing DEG. HHE No. 2854 reached the following conclusions:

Wine containing 11 ppm or less DEG would not be expected to result in a hazard to health.

Wine containing more than 11 ppm up to 110 ppm DEG would be expected to result in a potential hazard that would range up to possibly life-threatening, particularly for individuals with previously compromised kidneys.

Wine containing DEG in excess of 110 ppm up to 1,100 ppm could range up to a life-threatening hazard to health.

The hearing officer also notes, however, that two of the four recalled brands of Riunite, Rosato and Lambrusco dell' Emilia, were found to contain up to 29 ppm of DEG.

21. This court, and its predecessor, upon the rejection of all legal and equitable claims, has at times recommended an amount for a gratuity as supported by the facts presented to the hearing officer. See, e.g., Lance Indus., Inc. v. United States, 3 Cl. Ct. at 780 n.6 ("Were an award recommended, the record would support a figure of $250,000."). In the instant congressional reference case, the court conducted trial on the issue of liability and indicated in an order that if liability was found, a trial on damages could be held later. Nevertheless, the parties submitted almost seventy-five stipulations of fact on the issue of damages. Therefore, this hearing officer, despite having rejected the legal and equitable claims of the plaintiff, reviewed the material submitted regarding an award amount for a possible gratuity.

Banfi claims that it expended $33,455,569.00 as a result of the recall, of which $28,765,357.00 was for "reimbursements" (cash and/or credit) to distributors and New York City area retailers. Distributors and retailers had purchased wines at the distributor list price or the published retailer list price, respectively, from Banfi, and then, upon the recall, the distributors and retailers were fully recompensed for that purchase by Banfi. Thus, Banfi is claiming the entire amount that was reimbursed as expenditure to be recompensed in this congressional reference. This "expended" amount, however, appears to reflect not only Banfi's cost (or basis) in purchasing the wine from Cantine, but also reflects the lost profit that Banfi would have gained upon an undisturbed and finalized (i.e., non-recalled) sale by Banfi to the distributors and retailers. In addition, the fact that Banfi granted some purchasers credit instead of a cash refund does not turn this amount into an "out-of-pocket" expense; instead, this means that Banfi is claiming expenses for money that was already collected and retained, and that reflects future profit.

Significantly, the instant congressional reference specifically orders that "[c]ompensation . . . shall not be made for loss of anticipated profits . . . associated with the recall of the wine." H.R. 5148, § 1(2)(B). The basis or cost for the Riunite wine is evidenced by the payment from the Italian manufacturer, Cantine, of $233,397.00 for 33,300 cases of recalled wines shipped back by Banfi to Italy. This basis is roughly comparative to the basis in the remaining roughly 1.27 million cases, reflected in the amounts that Cantine paid in eight cash installments to Banfi, pursuant to invoices issued by Banfi to Cantine, for a total of $6,572,201.00. A logical conclusion is that Banfi, in receiving these payments after the recall, appears to have been fully recouped for the original cost or basis in the wine for its initial purchase from Cantine.

This analysis reflecting that Banfi's actual basis or cost for the recalled wine was remitted by Cantine coupled with the analysis reflecting that Banfi, in all likelihood, is claiming lost profits in its "reimbursements," demonstrates that the bulk of Banfi's claim is not supportable. Simply stated, it appears that Banfi already may have been paid for the cost of purchasing wine from Cantine and that the remainder is lost profit. After reducing the above analyses to numbers, the resulting computation appears to indicate that roughly $4.6 million remains of Banfi's original claim. In addition, according to the joint stipulations, ATF auditors questioned additional expense amounts of approximately $1.9 million on claims outside of the "reimbursements" discussed above. More significantly, the final figures claimed by Banfi do not reflect the possible tax consequences for the losses sustained because of the recall; if such a loss was taken by Banfi this would further negate the need for any award. Also, the plaintiff cannot escape the fact that two Riunite wines, Rosato and Lambrusco dell' Emilia, contained DEG in quantities that clearly are a potential health hazard. Thus, it appears that the record does not support a specific amount for an award as a gratuity. However, it is apparent that the amount would be significantly less than $4.6 million. If the Congress chooses to award a gratuity, the computation will reflect an assessment not of legal or equitable entitlement, but rather of sympathy for plaintiff's years of attempts to seek congressional resolution through two congressional references and numerous congressional hearings, for years of administrative and judicial litigation, and for possible loss of reputation in 1985 and thereafter.