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STATEMENT OF
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BEFORE THE
SUBCOMMITTEE ON COMMERCE, CONSUMER,
AND MONETARY AFFAIRS
OF THE
HOUSE COMMITTEE ON GOVERNMENT OPERATIONS
ON

FEDERAL ACTIONS IN DEALING WITH CONTAMINATED IMPORTED WINES

Mr. Chairman and members of the Subcommittee:

We are pleased to be here today to discuss our recent report[1] on federal agency actions in dealing with imported wines contaminated with the industrial chemical diethylene glycol (DEG). DEG is a highly toxic substance used in a number of industrial applications including uses as a component and solvent in antifreeze and automotive brake fluids. Last October Congressman Frank Horton expressed concern over the contamination of imported wines and asked us to review the manner and extent of actions taken by the Department of Health and Human Services' Food and Drug Administration (FDA) and the Department of Treasury's Bureau of Alcohol, Tobacco, and Firearms (Bureau) to identify and halt the sale of wines contaminated with DEG.

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[1] Imported Wines: Identifying and Removing Wines Contaminated With Diethylene Glycol, (GAO/RCED-86-112, March 4, 1986).

Wines containing DEG came to the attention of U.S. authorities through an article in The Washington Post on July 12, 1985, describing West Germany's detection of contaminated Austrian wines. Within a week the Canadian Food and Drug Administration notified the Bureau that it had tested and found some contaminated Austrian wines. The Austrian government was initially unable to determine if contaminated wines had been exported to the United States. On July 18, 1985, the Bureau initiated a testing program to try to identify which contaminated wines had entered the U.S. market. Subsequently, the Bureau received information from the governments of West Germany, the United Kingdom, and Canada that DEG was also found in some West German and Italian wines. As a result the Bureau began testing these wines for DEG in August 1985.

WHAT IS DEG?

As I mentioned, DEG is a highly toxic substance used in a number of industrial applications. In 1937 a pharmaceutical preparation (elixir) containing 72 percent DEG caused more than 100 deaths across the United States.

DEG is illegal in wine and food products at any level. It is a colorless liquid having a sweet taste. DEG has reportedly been used by Austrian winemakers as a sweetening agent since as early as 1979, allowing producers to bypass the more expensive and time-consuming natural fermentation process. How DEG got into Italian and West German wines is uncertain.

EXTENT TO WHICH THE BUREAU AND FDA TEST WINES FOR CONTAMINANTS

Neither the Bureau nor FDA routinely test wine for the presence of contaminants. FDA is responsible for preventing the importation of adulterated food and beverages. Although FDA tests samples of domestic and imported food products for adulteration, FDA does not usually test imported alcoholic beverages for contaminants, such as DEG. The Bureau normally samples alcoholic beverages to determine ingredient levels and to verify the accuracy of the labeling under its authority over mislabeled imported alcoholic beverages. These tests cannot determine the presence of contaminants, such as DEG, since its detection requires a specific test that the Bureau normally does not use. Since the discovery of DEG in Austrian wines, the Bureau started testing for the presence of DEG as part of its regular wine sampling program.

BUREAU ACTIONS

The Bureau began testing Austrian wines for DEG's presence on July 18, 1985, and West German and Italian wines in August 1985. Through December 3, 1985, Bureau testing found 81 different brands of contaminated wines and our report focused on these 81. Subsequently, the Bureau has reported 14 additional contaminated wines.

The Bureau initiated a DEG testing effort because it decided that it could conduct the testing more quickly than FDA. The Bureau informed FDA officials that it had developed a testing strategy for detecting Austrian wines contaminated with DEG. According to FDA officials, FDA concurred with the Bureau's

decision and deferred to the Bureau on the testing of wines for DEG.

Identifying contaminated Austrian wines

There are about 1,800 different Austrian wines approved by the Bureau for importation into the United States, and Bureau officials estimate that about one-half of these (about 900) are still actively being imported. The Bureau adopted a dual approach for addressing the problem of contaminated Austrian wines in the U.S. market. First, the Bureau asked the U.S. Customs Service to hold all shipments of Austrian wine entering after July 18, 1985, until testing conducted at Bureau laboratories could determine if the samples were free of DEG. If the Bureau found that the wine contained DEG, Customs was directed to refuse entry. Secondly, the Bureau requested that wholesalers and importers of Austrian wine have private laboratories test samples of all Austrian wine that they imported prior to July 18, 1985, and that were still under their control, to determine if they were free of DEG.

Importer and wholesaler testing of Austrian wines

Bureau officials told us that importers and wholesalers were notified of the need to test their Austrian wines for DEG. The Bureau estimated that there may be more than 500 different importers that have Bureau approval to import Austrian wines. In addition, Bureau officials indicated that an unknown number of wholesalers (believed to be many more than the number of importers) handle Austrian wines. Bureau officials informed us that they had received results on private laboratory testing from

26 different importers or wholesalers covering 330 wine samples (not necessarily 330 different wines because the same wine may be sampled by different importers and wholesalers.)

By requiring importers and wholesalers to have samples of all Austrian wines under their control tested for DEG by private laboratories and by conducting its own tests of all Austrian wines entering the United States after July 18, 1985, the Bureau made an effort to have all Austrian wines tested for DEG that are currently being marketed in the United States. The extent to which the Bureau was successful in getting all Austrian wines tested for DEG is unknown because the Bureau did not identify which importers and wholesalers sold and distributed Austrian wines, nor did it identify which Austrian wines were currently being marketed in the United States. As a result, the Bureau lacked the information necessary to (1) effectively monitor and review the actions of the importers and wholesalers in complying with the testing requirement and (2) determine the extent to which Austrian wines currently marketed in the United States were in fact tested.

Bureau testing of Austrian wines

In addition to testing by importers and wholesalers, the Bureau tested samples of Austrian wines in its laboratories located in San Francisco, California, and Rockville, Maryland. The samples tested by the Bureau included wines detained by Customs, samples of wine collected from retail outlets by Bureau personnel, and samples of wines sent to the Bureau by wine dealers and consumers. The wines selected for testing by Bureau personnel

included suspected brands and others judgmentally selected by Bureau personnel. Suspected brands included brand names similar to those previously found to be contaminated as well as other brands imported from these producers.

The Bureau tested 364 samples of Austrian wine through December 3, 1985. However, the number of Austrian wines represented by these samples could be considerably less because duplicate samples of some wines were tested. The Bureau found that 86 of the Austrian wine samples contained DEG and that these 86 samples represented 54 different wines indicating a duplication rate of about 37 percent (32 out of 86).

Identifying contaminated German and Italian wines

The Bureau's approach for the West German and Italian wines was different from its approach for identifying contaminated Austrian wines. Unlike the Austrian wines, the West German and Italian wines were not stopped at ports of entry by the U.S. Customs Service nor tested for DEG by the Bureau prior to Customs' release. In addition, the Bureau did not request importers and wholesalers of West German and Italian wines to have private laboratories test their wines.

According to Bureau officials, the testing of West German and Italian wines was limited because of the effort that would be required to test the large volumes of these wines. In 1984 the United States imported 174,000 gallons of still (nonsparkling) wines from Austria; 16 million gallons from West Germany; and 63 million gallons from Italy. Another factor influencing this

decision was the information from the British, Canadian, and West German governments indicating that the DEG levels found in these wines were significantly lower than that found in Austrian wines.

Testing of West German and Italian wines was limited to the testing of selected brands by the Bureau and samples sent to the Bureau by outside sources such as wine dealers and consumers. The selected brands included some suspected brands and others judgmentally selected by Bureau personnel. The suspected Italian brands included those identified by the British and Canadian governments. Suspected West German brands included those wines from the same producers or regions of Germany where wines were found to contain DEG by the West German government.

RESULTS OF THE BUREAU TESTING FOR DEG IN WINES

Mr. Chairman, we have prepared Chart A (app. I) to show you the results of Bureau testing. Bureau laboratory documents indicate that 1,167 foreign wine samples were tested for DEG through December 3, 1985. In addition, the Bureau tested 224 samples of domestic wines. DEG was found only in Austrian, West German, and Italian wines.

Because some wines were tested more than once by the Bureau, the number of wines tested is less than the number of samples tested. The Bureau did not keep track of the actual number of different wines that were tested. Bureau testing found DEG in 127 of the wine samples it tested and determined that, because of duplicate testing of some brands, the contaminated samples

represented 81 different imported wines. These 81 wines consisted of 54 Austrian, 20 Italian, and 7 German.

Chart B (app. II) presents the ranges of DEG found by Bureau testing. The DEG found in Austrian wines ranged from 0.1 to 19.66 grams per liter. (Note: a gram is about 0.035 ounces.) The contaminated West German and Italian wine samples had much lower DEG levels. The seven contaminated German wines contain DEG levels ranging from 0.005 to 0.1 grams per liter. The 20 contaminated Italian wines contain DEG levels ranging from 0.009 to 0.06 grams per liter. The chart also shows the DEG ranges as parts per million.

Let me now discuss the toxicity and health risk associated with these DEG levels. On the basis of the 1937 elixir episode, researchers have concluded that the toxic effects of DEG in humans varies with the age, weight, and especially the health of an individual. Various toxicology evaluations have addressed the DEG doses that may be fatal to humans and the range of DEG doses that may have cumulative effects. These evaluations indicate that consuming DEG could pose harmful effects to humans either as a single dose or by repeated doses over a period of time.

Chart C (app. III) presents summary information on the 81 contaminated wines and the amount of the DEG found, with references to associated toxicity. The chart shows that about two-thirds of the Austrian wines had DEG levels over 1 gram per liter.

Our chart shows that five of the contaminated Austrian wines contain DEG levels that research has shown could cause adverse

health effects. A July 1985 FDA Division of Toxicology DEG evaluation determined that crystals and stones may begin to form in the kidneys through ingesting from 6 to 12 grams (about 0.2 to 0.4 ounces) of DEG per day. According to the author of this evaluation, a person in poor health could develop these symptoms after several days of ingesting DEG at these doses.

Various toxicology studies address the fatal doses of DEG. The July 1985 FDA evaluation based on the elixir episode states that some fatalities were observed with DEG levels as low as about 24 grams. In addition, press articles have reported that the Austrian Ministry of Health has stated that the consumption of 14 grams could be lethal to someone in poor health. Two of the Austrian wines contain more than 14 grams.

BUREAU ACTIONS TO GET CONTAMINATED WINES REMOVED FROM THE MARKET

The Bureau relied on the importers and wholesalers to remove all contaminated wines from the market but it did not routinely observe or review importers and wholesalers' action in doing so. Consequently, the Bureau does not know the extent to which wines contaminated with DEG were removed from the market.

The Bureau did not generally observe the actions of the importer or subsequently review importers' actions to verify that the contaminated wine had been removed from the market. And the Bureau did not require the importer to report to the Bureau on its actions to remove the contaminated wines. For the most part, Bureau officials told us that their follow-up is limited to having

its inspectors spot-check the wines on the retailers' shelves to see if any of the contaminated wines are still being sold.

GAO FOLLOW-UP

The preceding discussion summarizes the major findings of our report. Subsequent to the issuance of our report you asked us to obtain more information on four areas mentioned in our report. Let me summarize the main points of each; Appendix IV of my prepared statement provides more detailed responses.

First, you asked us to discuss the Bureau's failure to identify Austrian wine importers. We concluded that it would have been reasonable for the Bureau to have identified the importers of Austrian wines to help focus its notification and follow-up efforts. Our analysis of a Bureau computer list of Austrian wine labels approved for importation found only 174 different importers and it took one staff person less than 3 hours to complete this analysis.

Second, you asked us to address the lack of a master list of contaminated wines. The Bureau did not maintain and disseminate a current master list of all contaminated wines. Instead the Bureau relied on press releases issued periodically to communicate the names of the latest wines it found to be contaminated. The Bureau did not compile a master list of all contaminated wines until December 1985.

Third, you asked us to discuss problems with the Bureau's recordkeeping. We noted gaps and inconsistencies in Bureau recordkeeping that in our opinion may have hampered the Bureau's ability to (1) ensure that all contaminated wines were identified and (2) effectively monitor the actions of importers in removing these wines from the market.

Finally you asked us to contact importers of highly contaminated Austrian wines regarding Bureau actions. At your request we telephoned the four importers of the most highly contaminated Austrian wines and found that Bureau actions to ensure that these importers removed contaminated wines from the market were limited.

CONCLUSIONS AND RECOMMENDATIONS

Based on our review we concluded that the Bureau's efforts to verify importers' actions in testing and removing contaminated wines from the market were limited. The extent to which all wines were tested and all contaminated wines were removed from the market cannot be determined.

In addition, we believe that government efforts to find and remove DEG contaminated wines need to provide an appropriate degree of assurance that wines with DEG in amounts representing a significant risk to health are identified and removed from the market. The Bureau did not conduct a risk assessment or seek an assessment from FDA to determine what amount of DEG in wine would represent a significant risk to health. In the absence of such a health assessment, we concluded that Bureau actions do not provide a high degree of assurance that wines contaminated with DEG in amounts posing a significant risk to health were identified and removed from the market.

We recommended that the Bureau consult with FDA to determine whether the actions taken by the Bureau in sampling, testing, and having wines contaminated with the DEG removed from the marketplace were adequate to protect the public health and safety

and to take whatever action is warranted as a result of these consultations. We further recommended that the results of such consultation be used to develop appropriate policies and procedures for working with FDA regarding any future contamination of alcoholic beverages.

In addition, we recommended that the Director of the Bureau report to the appropriate oversight committees as well as to the House Government Operations Committee on the results of these consultations and any actions taken.

Mr. Chairman, this concludes my prepared statement. We would be glad to respond to your questions.

APPENDIX I

Chart A

Bureau Testing of Wines
(through December 3, 1985)

	Number of samples tested	Number of contaminated samples	Number of different brands found to be contaminated
Foreign			
Austrian	364	86	54
West German	438	9	7
Italian	298	32	20
Other countries	67	0	0
subtotal	1,167	127	81
Domestic	224	0	0
Total	1,391	127	81

APPENDIX II

Chart B

DEG Ranges in Contaminated Wines
(through December 3, 1985)

	DEG ranges (grams per liter)	DEG ranges (parts per million)
Austrian	0.1 to 19.66	100 to 19,660
West German	0.005 to 0.1	5 to 100
Italian	0.009 to 0.06	9 to 60

Note: a gram is about 0.035 ounces.

APPENDIX III

Chart C

DEG Levels in Contaminated Wines

DEG ranges per liter of wine	Number of contaminated wines		
	Austrian	German	Italian
Less than 1 gram	17	7	20
1 gram to 6 grams	30	0	0
6 grams to 12 gramsa	3	0	0
Over 12 gramsb	2	0	0
DEG levels not specifiedc	2	0	0
Total	54	7	20

aA July 1985 FDA Division of Toxicology DEG evaluation determined that crystals and stones may begin to form in the kidneys through the repeated ingestion of 6 to 12 grams per day.

bA July 1985 FDA Division of Toxicology DEG evaluation based on the elixir episode states that some fatalities were observed with DEG levels as low as about 24 grams. In addition, press articles have reported that the Austrian Ministry of Health has stated that the consumption of 14 grams could be lethal to someone in poor health.

cDEG levels for 2 of the 54 Austrian wines were not identified in the records provided to us.

This section provides detailed responses to the four additional areas which were requested subsequent to the issuance of our report.

1. Bureau failure to identify Austrian wine importers

We reported that the Bureau did not identify which importers and wholesalers sold and distributed Austrian wines, nor did it identify which Austrian wines were currently being marketed in the United States. Bureau officials said they did not do so because extensive time and effort would have been required. The Bureau provided us with a computer list of Austrian wine labels it approved from 1979 through 1985 indicating vendor (or importer) code numbers. We analyzed this list and found that it contains 1,786 different Austrian wines approved for importation by 174 different importers. It took one staff person less than 3 hours to analyze the list. We believe that such an analysis by the Bureau would have helped it focus its notification and follow-up efforts.

Bureau officials informed us that they had received results on private laboratory testing from 26 different importers or wholesalers--the equivalent of about 15 percent of approved importers of Austrian wines. Because the Bureau did not determine those importers actively importing Austrian wines they could not assess compliance with the testing and reporting requirement. It would seem to have been reasonable for the Bureau to have identified the importers of Austrian wines and to follow-up with

them to ensure that all such wines under their control were tested and the results sent to the Bureau.

2. Lack of a master list of contaminated wines

The Bureau issued 14 press releases to notify its field offices and the public of the wines its testing found to be contaminated. The press releases did not provide an updated listing of all contaminated wines; instead they only listed the contaminated wines found since the previous press release. As a result it was necessary to have all 14 press releases in order to compile a complete list of all contaminated wines. Although we did not verify statements by Bureau regional officials, they indicated that they were not sure if they received all press releases. The Bureau did not compile a master list of all contaminated wines until December 1985. This list contains several gaps such as missing DEG levels for two wines and missing code numbers or vintage years for others.

3. Problems with Bureau recordkeeping

Bureau documentation was inadequate to verify the actions and results claimed by the Bureau officials. Its contacts with regional offices and importers were often by telephone with no summary records maintained. Regional directors who we contacted were not sure of the number of contaminated wines reported to them by headquarters nor the number of importers actually contacted by their staff.

In addition to the lack of documentation, Bureau documents contain numerous gaps and inconsistencies. For example, we were not able to confirm either the number or descriptions of the 81 contaminated wines because of discrepancies among Bureau documents. Also, we were not able to confirm either the total number of samples tested or the number of different brands represented by these samples. Because of these recordkeeping problems we frequently had to rely on the Bureau's best estimate and statements by Bureau officials describing their operations.

Better recordkeeping would have enhanced the Bureau's ability to effectively monitor and review the actions of importers in removing contaminated wines from the market. Improved recordkeeping would have also aided the Bureau in its attempts to identify those wines contaminated with DEG.

4. GAO contacts with importers of highly contaminated Austrian wines

The 54 contaminated wines were imported by 12 different importers. Four importers handled 37 (or 69 percent) of the 54 contaminated wines and handled the 5 wines with the highest levels of DEG. At your request we telephoned these four importers to obtain their description of the identification and removal of contaminated wines and their involvement with the Bureau.

The four importers recalled being contacted by the Bureau about the DEG issue by telephone and/or memorandum. Two of the

importers contacted said that state authorities directed them to remove contaminated wines from the market. These states closely monitored their actions; for example, one state required the firm to destroy contaminated wines in their presence. (Our review of the contamination issue centered on the Bureau's and FDA's involvement as agreed with the requester.) The four importers said they had removed all identified contaminated wine from the shelves that were under their control.

One importer was required by state authorities to remove all Austrian wines from retail outlets until the Bureau's testing indicated the wine was free of DEG. One importer had only recently been notified about a brand of contaminated wine that was found by Bureau testing in August 1985 to contain DEG. Another importer stated that the Bureau would often contact his firm to inform them that a wine had been found to be contaminated with DEG, but the firm was already aware of this since state authorities had contacted his firm very promptly about wines identified through the Bureau's testing. An importer who Bureau records indicate carried five contaminated brands claimed that his firm carries only one of the five brands; one of these four brands was the highest contaminated wine.

Although the importers contacted by us handle the brands with the highest levels of DEG, Bureau actions to ensure that these importers had indeed removed contaminated wines were limited. Although the importers recalled getting a few telephone calls from

APPENDIX IV

the Bureau, only one importer recalled Bureau staff visiting warehouses to verify that they were not selling any contaminated wines.