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Testimony of David A. Eisenberg, Chairman, Anresco, Inc. (1943) commercial analytical laboratory before the House Energy & Commerce Committee 26 February 2008.

Thank you for inviting my testimony. My name is David Eisenberg I have an MBA in Finance from the Wharton School of the University of Pennsylvania. I am Chairman and CEO of Anresco, Inc., a commercial analytical laboratory founded by my father Dr. Sylvan Eisenberg in 1943. I have been with the company for 34 years.

Anresco has performed sampling and analytical work for importers to meet FDA requirements since 1981. Such work represents approximately 40% of our total business. We employ 30 people. We are one of 3 or 4 private laboratories that together perform possibly 80% of the sampling and analyses required by importers to meet FDA requirements nationally. The range of analyses we perform is very broad, including testing for filth (microscopy), pesticide residues, drug residues, heavy metals, illegal colors and sweeteners, decomposition and microbiological contamination. Private laboratories in total employ possibly 50 people to service this very small but highly specialized market.

Anresco's sampling and analytical work is equivalent to that performed by the FDA's of

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own laboratories and our work meets FDA's "fit for use" documentary requirements. Our cost performing this work is lower than the FDA's and we generally report results more quickly. For ten years- from 1996 to 2006- I was Chairman of the San Francisco Bay Area Section of the FDA-PICSC Committee (Pacific Import Community Steering Committee). This group was organized as a result of former Vice President Gore's Initiative on Re-Inventing Government. The group consisted of Sections based in Los Angeles, San Francisco and Seattle each consisting of members from the import community- importers, customs brokers, cold storage operators, ports, private laboratories and FDA staff. The purpose of the PICSC was to provide a conduit for information from the FDA to the regulated import community and from that community back to the FDA- in the public interest to assure and improve the FDA's regulation of imports. The 3 Sections would meet 3 times each year by televideo conference. The FDA ended its involvement/sponsorship of the PICSC in early 2006.

The FDA regulates food and related imports by reviewing import entries, releasing imports it considers low risk and sampling and analyzing at its own laboratories a percentage of imports it believes may be unsafe or otherwise violate US food standards. This work is performed under its "Surveillance" Program.

The FDA sets "Defect Action Levels" for filth, methyl mercury, pesticide residues and other contaminants. These are the criteria the FDA generally uses to release or reject given imports. Many "Defect Action Levels" are available to the public. Some are not.
The percentage of import shipments the FDA samples and analyzes pursuant to its Surveillance Program has dropped from 8% in 1992 to 1.3% in 2007. This reduction has occurred because

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the volume of FDA regulated imports has grown and FDA import staff has been constant or reduced.

When the FDA finds an imported product violates its standards, it will deny entry of the shipment into commerce and will require that the importer either re-export the product, destroy it or recondition it (correct the defect). It may- at its discretion then place the product on Detention Without Physical Examination (DWPE) where the FDA considers the product violative until the importer proves it meets FDA standards. The importer does so by retaining a private laboratory such as Anresco to sample and analyze the product and to submit such results to the FDA.

Only a very small proportion of FDA regulated imports are subject to DWPE- possibly 1%.

Private laboratories may also sample and analyze shipments the FDA has found violative under its Surveillance Program as when a shipment can be segmented by lot number, size or other criteria. This does not occur very often.

With this as background, I am pleased to offer comments and suggestions to improve the efficacy of FDA's regulation of imports.

Relating to the FDA's Surveillance Program

1. The FDA should provide an organized forum either via the PICSC or other venue where industry can provide advice/input into what imports the FDA should select for sampling and for what "Defect Action Levels" are appropriate. The FDA should review these on

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an ongoing basis. The import industry can provide the FDA important and useful advice (i.e., that melamine was being added to wheat gluten meal in China).

2. The FDA should re-allocate its import staff so enforcement of its regulations is uniform among its 15 Districts. For years, the FDA has been understaffed in New York and in Los Angeles and overstaffed at smaller ports. At least until 1998, the likelihood of FDA stopping an import was 3 to 5 times greater in the San Francisco District than in the Los Angeles District. This caused importers to "port shop" making the inequities even greater as freight diverted to understaffed ports.
3. The FDA should again- as it did until about 2003, post at its website information on all Import Detentions- whether the detention was from its Surveillance Program or the DWPE Program. This allowed the import industry to know if FDA enforcement was consistent between its Districts. The suspicion of unequal enforcement is enough to cause "port shopping".
4. The FDA should allow importers to use "approved" private laboratories to sample and analyze samples under its "Surveillance Program". This would expedite the release of shipments and allow the FDA to significantly increase the number of shipments sampled and analyzed. The FDA should assume private laboratory submissions meet its requirements if the FDA has approved that laboratory in advance of the shipment. The FDA should then eliminate its current line by line review of private laboratory submissions that wastes a great deal of FDA staff time and delays shipments.

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5. The FDA must have the legal authority to assure itself private laboratories provide FDA equivalent sampling and analytical work. The FDA itself must Certify, Accredit or otherwise approve private laboratories. The FDA must: a) have the right to physically visit/audit private laboratories at any time- to assure itself of the adequacy of the laboratory facilities, instrumentation and staff, b) run a "check sample" program where samples it prepares with known contaminants are sent to and analyzed by the private laboratories with results reported back to the FDA- as a means of verifying the competence of the laboratories, c) approve the financial responsibility and the integrity/honesty of laboratory management and d) provide approved laboratories ready access to its technical and compliance requirements and "due process" when the FDA finds deficiencies in private laboratory work. The FDA should disqualify a private laboratory only as a last resort.
6. The incentive for importers to use private laboratories and pay for such use for Surveillance sampling and analysis is that such laboratories will perform the work more quickly than the FDA's own laboratory and the shipment can be released into commerce more quickly.
7. Private laboratories would be willing to pay a fee for FDA Certification, Accreditation or approval as this will provide them additional work.
8. ISO 17025 Accreditation is NOT an adequate basis for assuring private laboratories are technically and administratively competent to perform work meeting FDA's standards. Private laboratories such as Anresco perform a broad variety of highly specialized

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analyses for submission to FDA. FDA's requirements are generally for "legal quality" work and it requires a team skilled in FDA's technical and administrative requirements to fairly evaluate the private laboratory. Only the FDA has the resources to do this.

9. By utilizing private laboratories in the FDA's Surveillance Program, the Agency could substantially increase the percentage of import shipments sampled and analyzed at no added cost to the taxpayer. The use of private laboratories could also free up FDA compliance personnel to make more cargo and warehouse inspections and its technical personnel to develop new methods for contaminants not now considered. If the FDA has more time to investigate potential problems, it will find them. In 1997, Operation "Bad Apple" found 40% of import shipments were not available at importers warehouses after FDA found them violative and 21.4% of import shipment documentation did not correctly identify of cargo.

Relating to the FDA's Detention without Physical Examination (DWPE) Program

While this Program is excellent in concept and works well in practice for most imports, it is greatly weakened by inadequate or non-caring FDA implementation.

The FDA Southwest Import District - SWID based in Dallas, Texas has in place procedures that assure the honesty of the DWPE Program. These procedures should be adopted nationwide. They include:

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1. A requirement that DWPE shipments be sampled by the private laboratory. The New York District still allows importers to take their own samples. This is akin to the wolf guarding the sheep. If independent samplers take samples and provide these to a private laboratory and the results are wrong, it is usually impossible to determine who was at fault. The laboratory must be the responsible party.
2. Analytical results must be submitted to the FDA directly by the private laboratory (this procedure now may apply generally). Some years ago, Anresco encountered two situations where importers deleted information from reports that evidenced FDA violations and then submitted the corrupted Reports to the FDA.
3. The importer must advise the FDA in advance what private laboratory they intend to use for a given import. In the other FDA Districts, this is not required. Except in SWID, when Anresco finds a violative import the importer usually advises us not to submit the result. The importer may then find another private laboratory to take new samples and to re-analyze the product to get the shipment released.

Non-Caring FDA implementation of its rules/regulations:

1. In June 2006, Dr. Robert Brackett then Director of the FDA Center for Food Safety and Applied Nutrition at the Institute of Food Technologists Meeting at Orlando, Florida advised FDA did not consider pesticide residues in foods a serious matter and it would no longer monitor them. This sent a message to fruit and vegetable growers, shippers and

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importers and to private laboratories there was no need to comply with EPA/FDA regulations. Anresco chose not to cheat and we lost our business in South Florida. If the FDA considers its regulations governing pesticide residues in foods unnecessary, then it should request Congress to change the law not ignore it.

2. Twice during 2005, I met with senior FDA staff the second time with Margaret Glavin, Associate Commissioner for Regulatory Affairs to complain the FDA was not adequately enforcing its pesticide residue requirements on snowpeas imported from Guatemala. I presented data for 25 samples Anresco had taken at retail in the greater Miami area during 2004 and had analyzed with 13 being violative of FDA standards. I pleaded for FDA to take more Surveillance Samples and to then place violative shippers on DWPE status as it had done in prior years. Even though FDA had found a high percentage of violations itself, the result of my pleading was FDA reduced by 50% the number of Surveillance samples analyzed. I was flabbergasted when I saw President George Bush on television talking from a Guatemalan farm last year praising that country for developing an export industry for produce when his appointees knew a high percentage of the product violated US food standards and they had facilitated its importation.

Two more suggestions:

1. FDA should allow electronic submission of all private laboratory Reports relating to food imports- especially perishables. Anresco has pioneered this with the FDA Southeast

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Regional Laboratory in Atlanta and with the FDA Miami Compliance Office. With electronic review, Anresco can sample an import on a Tuesday in Miami, analyze it Wednesday at San Francisco and the FDA can release it Thursday morning.

2. With a fast turnaround of results, importers can comply with applicable FDA rules and regulations. The FDA should not allow the importers to place their products in commerce before having a release.

Thank you for considering my comments and suggestions.

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