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# Report To
# The Mississippi Legislature


**A Review of the Mississippi Board of Animal Health's Veterinary Diagnostic Laboratory**

**May 12, 1998**

**The Board of Animal Health's Veterinary Diagnostic Laboratory is responsible for rendering quick and accurate diagnoses of diseases in the state's animals and livestock. The state's animal health interests are placed at risk if the laboratory fails to ensure quality in its diagnostic testing. PEER verified several cases in which serious lab errors have occurred. Because the lab has not established a comprehensive system for ensuring the accuracy of its test results, particularly in the facility's chemistry and microbiology labs, errors are less likely to be detected and corrected than would be the case if a full system of controls were in place. The lab's recent involvement in testing related to the quality of food for human consumption substantially increased the risk associated with errors and problems in judgment.**

**The PEER Committee**

## PEER: The Mississippi Legislature's Oversight Agency

**The Mississippi Legislature created the Joint Legislative Committee on Performance Evaluation and Expenditure Review (PEER Committee) by statute in 1973. A standing joint committee, the PEER Committee is composed of five members of the House of Representatives appointed by the Speaker and five members of the Senate appointed by the Lieutenant Governor. Appointments are made for four-year terms with one Senator and one Representative appointed from each of the U. S. Congressional Districts. Committee officers are elected by the membership with officers alternating annually between the two houses. All Committee actions by statute require a majority vote of three Representatives and three Senators voting in the affirmative.**

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**The Committee assigns top priority to written requests from individual legislators and legislative committees. The Committee also considers PEER staff proposals and written requests from state officials and others.**

# A Review of the Mississippi Board of Animal Health's Veterinary Diagnostic Laboratory

**May 12, 1998**

**The PEER Committee**

**Mississippi Legislature**

The Mississippi Legislature

**Joint Committee on Performance Evaluation and Expenditure Review**

PEER Committee

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**May 12, 1998**

**Honorable Kirk Fordice, Governor**
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**Honorable Tim Ford, Speaker of the House**
**Members of the Mississippi State Legislature**

**On May 12, 1998, the PEER Committee authorized release of the report entitled A Review of the Mississippi Board of Animal Health's Veterinary Diagnostic Laboratory.**

**Senator Ezell Lee, Chairman**

# This report does not recommend increased funding or additional staff.

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## *List of Exhibits*

# A Review of the Mississippi Board of Animal Health's Veterinary Diagnostic Laboratory

**May 12, 1998**

*Executive Summary*

## Introduction

**The PEER Committee approved a preliminary investigation into operations of the Board of Animal Health's Veterinary Diagnostic Laboratory after receiving correspondence from a legislator expressing concern, based upon specific allegations of laboratory errors, that lab services have deteriorated to unacceptable levels. After determining the validity of these allegations, PEER sought to determine if quality assurance controls were adequate to ensure clinical laboratory operations which would reduce the chance of such errors occurring.**

**MISS. CODE ANN. Section 69-15-11 (1972) requires the Board of Animal Health to "maintain a complete and adequate diagnostic clinic at Jackson capable of rendering quick and accurate diagnoses of disease conditions of animals and livestock, including but not limited to cattle, horses, sheep, swine, poultry and pets."**

## Overview

**The state's animal health interests include meeting farmers' economic need for healthy livestock, flocks, and ponds, as well as addressing animal health concerns of veterinarians and the animal owners they serve. These animal health interests are placed at risk if the Board of Animal Health or its Veterinary Diagnostic Laboratory fails to ensure quality in the lab's diagnostic testing.**

**In reviewing a series of allegations about problems at the Veterinary Diagnostic Laboratory, PEER verified several cases in which serious laboratory errors had occurred. Further review revealed that the lab has not established the systems needed to ensure proper testing and to check the accuracy of its results, particularly in the facility's chemistry and microbiology laboratories. This lack of quality assurance controls has compromised the Board of Animal Health's ability to address the state's animal health interests.**

**The work of a diagnostic laboratory entails exercise of professional judgment in selection of tests to be run, testing agents to be used, and interpretation of results. To ensure that rigorous science is taking place, a lab must establish systems to address those scientific concerns. A lab's technical personnel should develop policies specifying conditions under which control tests should be run, if samples should be split to obtain second opinions, if further testing should be conducted, and if the advice of other diagnosticians should be sought. Because the Veterinary Diagnostic Laboratory has not established a comprehensive system for ensuring the accuracy of its results, errors are less likely to be detected and corrected than would be the case if a full system of controls were in place.**

**The lab's recent involvement in testing related to the quality of food for human consumption has substantially increased the risk associated with errors and problems in judgment. The lab has no specific authority to conduct food-related tests and has not developed the strict quality assurance systems needed to ensure accuracy in food-related testing. Several of the errors PEER confirmed during this review occurred in the lab's food-related testing programs. Legislation enacted during the 1998 session specifically prohibits the lab from conducting food-related tests in the future. The same legislation places the lab under a newly created Veterinary Diagnostic Laboratory Board composed of individuals with technical expertise in clinical operations.**

**The Veterinary Diagnostic Laboratory is accredited by the American Association of Veterinary Diagnostic Laboratories and it employs many highly qualified professionals, but in order to remain an important resource for farmers and veterinarians, the Veterinary Diagnostic Laboratory must consistently provide accurate, well-documented results. The seriousness of the lab's quality control deficiencies calls for immediate intervention by its newly created board to establish systems for preventing and detecting errors that could negatively impact animal health.**

## Errors Identified in Allegations and Confirmed by PEER

**PEER identified errors in the Veterinary Diagnostic Laboratory's work affecting animal health, as well as errors with implications for the quality of food for human consumption.**

**Prior to initiating fieldwork for this review, PEER received several allegations involving falsified test results, misdiagnoses, and improper testing procedures at the laboratory. Subsequent fieldwork substantiated these allegations. Such errors indicate that the Veterinary Diagnostic Laboratory cannot ensure proper clinical operations which would fulfill the laboratory's statutory mission of rendering quick and accurate diagnoses of disease conditions of animals.**

- ***PEER noted laboratory errors that were potentially costly to farmers and misleading to veterinarians.***

**In order to render "quick and accurate diagnoses of disease conditions," laboratory personnel are charged with running the appropriate tests on samples and analyzing results to provide diagnoses to local veterinarians, county agents, or livestock owners.**

**As exemplified by the cases below, lab operations currently do not ensure accuracy. PEER found cases of falsified test results, misdiagnoses, and improper testing procedures, including the following.**

-- **A lab chemist failed to run a test needed to evaluate the health status of a dog and entered into the record the results of a test that he had conducted several days earlier on a different dog.**

-- **Although other Veterinary Diagnostic Laboratory tests strongly suggested copper toxicity in a lamb, a chemist conducting a copper analysis of tissues from the same animal did not question his test's negative results nor did he check his results to resolve the apparent contradiction.**

- ***PEER noted laboratory errors with human-health implications.***

**The Board of Animal Health exceeded its statutory mission by assuming food-related testing operations when it began conducting antibiotic residue and E. coli testing in the spring of 1997 for the Department of Agriculture and Commerce's Meat Inspection Program. The board's staff assumed these operations without developing operating procedures to govern such, which contributed to the errors noted below.**

-- **The lab's chief microbiologist directed laboratory staff to utilize the wrong size control disc in antibiotic residue testing, which caused test results to be inconclusive.**

-- **The lab's chief microbiologist required lab personnel to conduct E. coli testing on samples believed to be adulterated with chlorine, which invalidated the E. coli test results, violated federal Food Safety and Inspection Services principles, and could have created a public health risk.**

-- **The Board of Animal Health's Lab Director required a veterinarian to sign poultry health certificates without conducting the appropriate poultry examinations for such certificates, which violates American Veterinary Medical Association policies.**

## Major Quality Control Problems in Animal-Health-Related Testing and in Food-Related Testing

**By failing to establish control systems needed to ensure the technical quality of its testing, the lab has jeopardized the board's effectiveness in accomplishing its animal health mission, as well as the effectiveness of the state and federal governments in promoting human health.**

**PEER's preliminary fieldwork substantiated lab employees' allegations of falsified test results, misdiagnosis, and improper testing procedures. PEER**

**reviewed the lab's quality assurance procedures and controls to determine whether they were adequate to ensure clinical operations which would prevent and detect errors such as those PEER verified. The absence of such controls demonstrates the potential for other errors to occur without detection.**

- ***The chemistry lab has failed to implement experimental controls which would help ensure the accuracy and integrity of chemistry testing.***

**Lab personnel should run a control standard to verify or regulate a scientific experiment by conducting a parallel experiment or by comparing with some other standard. The Veterinary Diagnostic Laboratory did not establish a policy in its chemistry lab that controls be run on all tests until January 1998.**

- ***The risks associated with the Veterinary Diagnostic Laboratory's failure to establish an effective quality control system were heightened in June 1997 when the microbiology lab began conducting food-related tests. However, the microbiology lab did not establish quality control procedures to ensure the accuracy and integrity of new testing associated with the processing of food for human consumption.***

**When the microbiology lab assumed food-related testing in 1997 for the Meat Inspection Program, the lab's managers did not develop standard operating procedures and quality control procedures for antibiotic residue testing, not did they develop quality control procedures for E. coli testing.**

## Recommendations

1. **The Lab Director of the Veterinary Diagnostic Laboratory should implement the American Association of Veterinary Laboratory Diagnosticians' recommendation that the lab appoint a quality control coordinator. The Lab Director should also establish a quality control committee, to be chaired by this quality control coordinator, comprised of one representative from each of the seven specialty labs, to develop, implement, and annually review quality assurance and control procedures of the Veterinary Diagnostic Laboratory. Such control procedures should be approved by the Lab Director and by the Veterinary Diagnostic Laboratory Board, which was established by House Bill 1584.**

2. **The Board of Animal Health should comply with MISS. CODE ANN. Section 5-11-1 et seq. (1972) in its transfer of resources to the Veterinary Diagnostic Laboratory Board on July 1, 1998, as provided for in House Bill 1584, 1998 Regular Session. MISS. CODE ANN. Section 5-11-1 et seq. (1972) provides for a transition authority to develop plans to facilitate the transfer of an agency's duties and responsibilities to another agency.**

3. **The Veterinary Diagnostic Laboratory Board, Lab Director, and Quality Control Committee should adopt proper quality assurance controls before the Veterinary Diagnostic Laboratory initiates any new testing procedures. Further, the Lab Director should insure the proper training of Veterinary Diagnostic Laboratory personnel in new clinical procedures prior to the lab offering such procedures to its clients.**

4. **The Lab Director should not require any Veterinary Diagnostic Laboratory personnel to certify the clinical health of any animal which has not been examined by that person. The Lab Director should propose revisions in "Mississippi's Disease Reporting Procedures" relevant to flock health certificates to the United States Department of Agriculture's Area Veterinarian in Charge.**

5. **The Veterinary Diagnostic Lab, as well as any other clinical lab in the state, should not conduct testing on samples believed to be adulterated. Rather, the lab should require the submission of other samples from the submitting authority.**

6. **In compliance with House Bill 1584, the Veterinary Diagnostic Laboratory should not conduct any regulatory testing for food purposes.**

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# A Review of the Mississippi Board of Animal Health's Veterinary Diagnostic Laboratory

## *Introduction*

### Authority

**The PEER Committee reviewed the Mississippi Board of Animal Health's Veterinary Diagnostic Laboratory pursuant to the authority granted by MISS. CODE ANN. Section 5-3-57 et seq. (1972).**

### Scope and Purpose

**The PEER Committee approved a preliminary investigation into operations of the Board of Animal Health's Veterinary Diagnostic Laboratory after receiving correspondence from a legislator expressing concern, based upon specific allegations of laboratory errors, that lab services had deteriorated to unacceptable levels. After confirming the validity of these allegations, PEER sought to determine whether quality assurance controls were adequate to ensure proper clinical laboratory operations.**

### Method

**In conducting this review, PEER:**

- **reviewed standard operating policies and procedures of the Veterinary Diagnostic Laboratory;**
- **analyzed the laboratory's quality assurance procedures and controls;**
- **reviewed official case files of laboratory accessions;**
- **interviewed laboratory personnel with the Board of Animal Health's Veterinary Diagnostic Laboratory, the College of Veterinary Medicine at Mississippi State University, and the U. S. Department of Agriculture (USDA); and,**
- **reviewed USDA policies and directives.**

### Overview

**The state's animal health interests include meeting farmers' economic need for healthy livestock, flocks, and ponds, as well as addressing animal health**

**concerns of veterinarians and the animal owners they serve. These animal health interests are placed at risk if the Board of Animal Health or the Veterinary Diagnostic Laboratory fails to ensure quality in the lab's diagnostic testing.**

**In reviewing a series of allegations about problems at the Veterinary Diagnostic Laboratory, PEER verified several cases in which serious laboratory errors had occurred. Further review revealed that the lab has not established the systems needed to ensure proper testing and to check the accuracy of its results, particularly in the facility's chemistry and microbiology laboratories. This lack of quality assurance controls has compromised the Board of Animal Health's ability to address the state's animal health interests.**

**The work of a diagnostic laboratory entails the exercise of professional judgment in selection of tests to be run, testing agents to be used, and interpretation of results. To ensure that rigorous science is taking place, a lab must establish systems to address those scientific concerns. A lab's technical personnel should develop policies specifying conditions under which control tests should be run, if samples should be split to obtain second opinions, if further testing should be conducted, and if the advice of other diagnosticians should be sought. Because the Veterinary Diagnostic Laboratory has not established a comprehensive system for ensuring the accuracy of its results, errors are less likely to be detected and corrected than would be the case if a full system of controls were in place.**

**The lab's recent involvement in testing related to the quality of food for human consumption has substantially increased the risk associated with errors and problems in judgment. The lab has no specific authority to conduct food-related tests and has not developed the strict quality assurance systems needed to ensure accuracy in food-related testing. Several of the errors PEER confirmed during this review occurred in the lab's food-related testing programs. Legislation enacted during the 1998 session specifically prohibits the lab from conducting food-related tests in the future. The same legislation places the lab under a newly created Veterinary Diagnostic Laboratory Board composed of individuals with technical expertise in clinical operations.**

**The Veterinary Diagnostic Laboratory is accredited by the American Association of Veterinary Diagnostic Laboratories and it employs many highly qualified professionals, but in order to remain an important resource for farmers and veterinarians, the lab must consistently provide accurate, well-documented results. The seriousness of the lab's quality control deficiencies calls for immediate intervention by its newly created board to establish systems for preventing and detecting errors that could negatively impact animal health.**

# *Background*

## History and Description of the Board of Animal Health's Veterinary Diagnostic Laboratory

**The Legislature established the Livestock Sanitary Board in 1908. The five-member board consisted of the Commissioner of Agriculture and Commerce, two professors from the Agricultural and Mechanical College, and two members appointed by the Governor to represent livestock breeders. The Legislature changed the name of the Livestock Sanitary Board to the Mississippi Board of Animal Health in 1968 and also increased commodities' representation on the board (e.g., Mississippi Cattlemen's Association, Mississippi Pork Producers' Association). The fifteen-member board is now comprised of the Commissioner of Agriculture and Commerce, ten commodity groups' representatives, one veterinarian, and three clinical representatives, those being the Dean of the College of Veterinary Medicine and the heads of the Animal and Dairy Science and Poultry Science departments at Mississippi State University.**

**MISS. CODE ANN. Section 69-15-9 (1972) provides the board with full power to "deal with all contagious and infectious diseases of animals." The statutes give the board full power to make, promulgate, and enforce such rules and regulations as may be necessary to control, eradicate, and prevent animal disease. The Veterinary Diagnostic Laboratory supports the board's regulatory activities. MISS. CODE ANN. Section 69-15-11 (1972) requires the Board of Animal Health to "maintain a complete and adequate diagnostic clinic at Jackson capable of rendering quick and accurate diagnoses of disease conditions of animals and livestock, including but not limited to cattle, horses, sheep, swine, poultry and pets." The statute does not provide for food-related testing or regulatory responsibilities.**

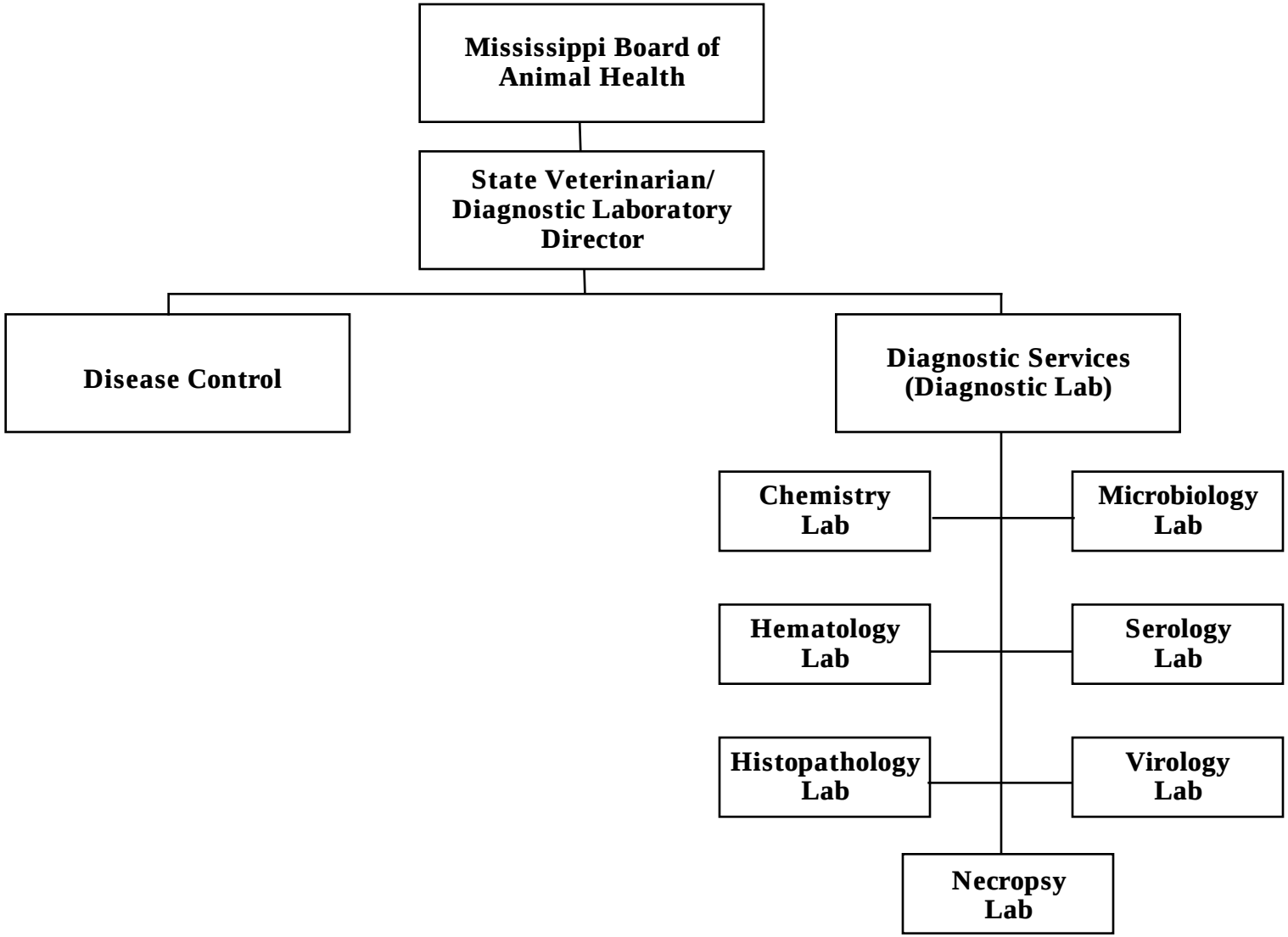
**As depicted in the organization chart in Exhibit 1, page 4, the Board of Animal Health is divided into two programmatic areas, Disease Control and Diagnostic Services, with forty-nine positions in FY 1998, to accomplish its statutory responsibilities.**

### *Disease Control*

**The Board of Animal Health's Disease Control program utilizes twenty-six positions to enforce the rules and regulations passed by the Board of Animal Health to control, eradicate, and prevent animal diseases. Board of Animal Health livestock inspectors work throughout the state. Major program activities of these inspectors include brucellosis eradication, administering the Equine Infectious Anemia program, poultry inspections, and the swine testing program. The State Veterinarian oversees the activities of the Disease Control program.**

**Exhibit 1**

**Mississippi Board of Animal Health Veterinary Diagnostic Laboratory**
**Organization Chart as of May 1, 1998**




**SOURCE: PEER analysis.**

### *Diagnostic Services*

**The Board of Animal Health's Diagnostic Services program utilizes twenty-three positions to operate the Veterinary Diagnostic Laboratory in Jackson. The laboratory receives serum and tissue samples, referred to as accessions, as well as live and dead animals, from veterinarians and animal owners. Receiving clerks route the accessions to the appropriate laboratory when they are received or laboratory personnel may take samples during gross necropsies (animal autopsies) conducted at the laboratory and then route them to the appropriate laboratory department.**

**The Diagnostic Laboratory is organized into seven departmental laboratories: virology, serology, hematology, microbiology, histopathology, necropsy, and chemistry/toxicology. Personnel in these labs run the appropriate tests on samples and then analyze results to diagnose disease conditions for the board's regulatory staff, local veterinarians, county agents, livestock, or other animal owners. The lab provides a written report of laboratory testing in response to each accession received by the lab.**

## Food-Related Testing

**The Board of Animal Health exceeded its statutory mission by assuming food-related testing operations when it began conducting antibiotic residue and E. coli testing in the spring of 1997 for the Department of Agriculture and Commerce's Meat Inspection Program. The board assumed this human food-related testing although the composition of the board does not provide for human-health related expertise.**

**Laboratories conduct antibiotic residue testing in order to insure that owners of animals to be slaughtered have met the withdrawal time on all drugs administered to the animal prior to that animal's slaughter. All antibiotics labeled for food-animal use have specified withdrawal times. Withdrawal times insure that only residue-free animal products reach marketing channels and the public.**

**The Veterinary Diagnostic Lab conducted E. coli testing in meat samples submitted by meat processing plants as required under the federal Pathogen Reduction/Hazard Analysis and Critical Control Points (HACCP) Regulation. In accordance with this regulation, all meat processing plants were to submit samples on a weekly basis for a thirteen-week period beginning the first week of June 1997 and concluding the last week of August. The purpose of the testing was to help processors and regulators identify points in processing at which contamination might be occurring. In an agreement with the Department of Agriculture and Commerce's Meat Inspection Division, the lab agreed to conduct this E. coli testing for a fee of $15 per sample, billed to the processing plant.**

**After being alerted to testing discrepancies, the Commissioner of Agriculture and Commerce temporarily suspended all antibiotic residue and E.**

**coli testing at the Veterinary Diagnostic Laboratory effective July 30, 1997. The Director of the Department of Agriculture and Commerce's Meat Inspection Program notified processing plant owners and meat inspectors of this suspension in correspondence dated July 24, 1997.**

## State Veterinarian/Lab Director

**The State Veterinarian oversees the enforcement of the Board of Animal Health's rules and regulations to control, eradicate, and prevent animal diseases. The Lab Director is the board's chief clinician and should have a strong clinical, rather than regulatory, background. The Lab Director's position should play a support role to the regulatory function and a service role to producers and veterinarians. However, currently the State Veterinarian also serves as Lab Director, although the statutory requirements for the State Veterinarian do not include the clinical expertise needed to ensure proper quality assurance of the lab's clinical operations. One person is serving two roles with different functions which should require two different backgrounds.**

**Prior to 1971, two separate positions existed for State Veterinarian and Director of the Board of Animal Health's Veterinary Diagnostic Laboratory. Dr. Fred McCrory was serving as Lab Director when he was appointed State Veterinarian in 1971 and continued to fill both positions until his resignation in 1990. Prior to being appointed State Veterinarian and Lab Director in May of 1990, Dr. Frank Rogers, who filled both of these positions during PEER's fieldwork for this review, served as Assistant Lab Director, a position which was not filled with a replacement following his appointment. Thus, with Dr. Rogers's appointment, one person fills three positions.**

## *Errors Identified in Allegations and Confirmed by PEER*

**PEERidentifiederrorsin laboratory work affecting animal health, as well as errors with implications for the quality of food for human consumption.**

**Prior to initiating fieldwork for this review, PEER received several allegations of falsified test results, misdiagnoses, and improper testing procedures at the laboratory. Subsequent fieldwork substantiated these allegations. Such errors indicate that the Veterinary Diagnostic Laboratory cannot ensure proper clinical operations which would fulfill the laboratory's statutory mission of rendering quick and accurate diagnoses of disease conditions in animals.**

### Errors in Animal-Health-Related Testing Identified in Allegations and Confirmed by PEER

- ***PEER noted laboratory errors that were potentially costly to farmers and misleading to veterinarians.***

**In fulfilling the laboratory's statutory mission of rendering quick and accurate diagnoses of disease conditions of animals and livestock, Veterinary Diagnostic Laboratory personnel are charged with running the appropriate tests on samples and interpreting results to provide diagnoses of disease conditions to local veterinarians, county agents, livestock, or other animal owners.**

**As exemplified by the cases below, lab operations currently do not ensure accuracy. PEER found cases of falsified test results, misdiagnoses, and improper testing procedures.**

- ***A lab chemist failed to run a test needed to evaluate the health status of a dog and entered into the record the results of a test that he had conducted several days earlier on a different dog.***

**A veterinarian submitted blood and serum samples from a fifteen-year-old Husky on January 29, 1996, and requested that the chemistry lab run a "Small Animal Chemistry Panel-14" and that the hematology lab run a complete blood count. The veterinarian wanted to determine if the lab work would be consistent with his diagnosis of a complicated case of heartworm disease and ongoing liver damage after examining the dog and running his own diagnostic tests.**

**The lab forwarded the submitting veterinarian a report on January 30, 1996, showing that the chemist ran a chemistry panel on January 30 which showed that twelve of the fifteen panel readings fell within the normal range. These readings were inconsistent with the veterinarian's diagnosis. These chemistry panel results were identical, in thirteen of the fifteen categories, to a chemistry panel run on January 24, 1996, on another dog. A review on January**

**30 of the computerized records tape in the chemistry panel machine by one of the lab's veterinarians showed that the chemist had not run a chemistry panel on January 30 on this case as requested by the submitting veterinarian.**

**Based upon his own accurate diagnosis, the veterinarian euthanized this dog on January 30, although the lab's original chemistry panels did not indicate abnormal readings. The lab sent an addended report to the veterinarian on January 31, showing chemistry panel results run January 30 with results different from those contained in the lab's original final report dated January 30. These second chemistry panel results from the blood and serum indicated that nine of the fifteen panel readings exceeded the normal range for these readings, with four of the nine readings far exceeding the referenced scale.**

**Although the chemistry lab's second chemistry panels supported the veterinarian's decision, the lab should have initially provided the veterinarian with accurate results to consider in making this decision. Veterinarians should be able to rely on the accuracy of Veterinary Diagnostic Laboratory results for which they have paid.**

- ***Although other Veterinary Diagnostic Laboratory tests strongly suggested copper toxicity in a lamb, a chemist conducting a copper analysis of tissues from the same animal did not question his test's negative results nor did he check his results to resolve the apparent contradiction.***

**The lab received the carcass of a lamb on December 8, 1997. The owner of the lamb requested that the lab determine the cause of death by conducting a necropsy.**

**A necropsy of the lamb, conducted by lab personnel on December 16, suggested chronic copper toxicity with resultant renal (kidney) failure, as indicated by an icteric (jaundiced) liver and the carcass having a strong uremic aroma. Because the lamb's symptoms included wine-colored urine, as well as kidney and liver lesions, which can be seen with both leptospirosis and copper toxicity, the veterinarian who conducted the necropsy requested that the serology lab run lepto serology, that the virology lab run a lepto fluorescent antibody test, and that the chemistry lab run a copper analysis liver tissue. Leptospirosis is a bacterial disease which can occur in all farm animal species and can cause septicemia, abortion, and other abnormalities.**

**The serology lab ran the lepto serology and the virology lab ran the lepto fluorescent antibody test, both with negative results, ruling out lepto as a possible cause of death and supporting copper toxicity as the cause of death. However, the lab's senior chemist conducted a copper analysis of fresh liver tissues from the lamb on the same day and reported results which did not suggest copper toxicity. The chemist did not question these results, although all other lab tests suggested possible copper toxicity and ruled out other potential causes of death.**

**Because the chemistry lab results conflicted with these other observations, lab personnel forwarded liver samples to the Texas Veterinary Medical Diagnostic Lab for diagnosis. The Texas lab's results confirmed copper poisoning in the liver and kidney tissues. The final report provided to the lamb's owner contained both the Texas and Mississippi laboratories' copper analyses, reflecting that the case had been referred to Texas due to questionable results at the Mississippi Veterinary Diagnostic Laboratory.**

**The Mississippi diagnostic lab's inaccurate results could have misled the lamb's owner, who needed accurate information to prevent or treat similar problems that might occur in other sheep. It also indicates that Mississippi Veterinary Diagnostic Laboratory veterinarians have not been able to depend on the validity of test procedures performed by their own chemistry lab.**

## Errors in Food-Related Testing Identified in Allegations and Confirmed by PEER

- ***PEER noted laboratory errors with human-health implications.***

**The Board of Animal Health's staff assumed food-related testing operations without developing operating procedures to govern such, which contributed to the errors noted below.**

- ***The lab's chief microbiologist directed laboratory staff to utilize the wrong size control disc in antibiotic residue testing, which caused test results to be inconclusive.***

**The Department of Agriculture and Commerce's Meat Inspection Program submitted a sample to the microbiology lab on July 16, 1997, of kidney for antibiotic residue testing from meat samples taken at a slaughterhouse in Biloxi. This meat-testing program involves the microbiology lab testing meat carcasses for the presence of antibiotic residues using a commercial kit called a STOP (Swab Test on Premises) test. The test is based on the principle that if the tissue contains an antibiotic residue (i.e., the carcass has been treated for disease), fluid from the tissue will inhibit the growth of a sensitive organism on a bacterial culture plate.**

**The lab's chief microbiologist directed laboratory staff to utilize the wrong size control disc in this antibiotic residue testing. According to USDA antibiotic residue testing procedures, the STOP requires a 5 mcg control disc, but the chief microbiologist authorized procedures utilizing a 30 mcg control disc.**

**Larry Dillard, Microbiologist in Charge at the USDA, Food Safety and Inspection Service, Office of Public Health and Science's Eastern Lab in Athens, Georgia, confirmed that a 5 mcg Neomycin disc should be used. He informed PEER that a disc of standard potency (5 mcg) is used because it produces a zone of inhibition of 18-20 mm. Mr. Dillard said that a using a 30 mcg disc for this test could result in very large inhibition zones, which would not give an adequate**

**assessment of the plate's sensitivity if the plate has sparse growth of the seeded bacteria.**

**Utilizing a 30 mcg disc as the control disc interfered with sampling testing, which is to indicate if the carcass has met the withdrawal time for antibiotics used in treatment of disease. Reporting negative results may have prevented residues from being detected and could have allowed meat products which might not be fit for human consumption to reach public markets.**

- ***The lab's chief microbiologist required lab personnel to conduct E. coli testing on samples believed to be adulterated with chlorine, which invalidated the E. coli test results, violated federal Food Safety and Inspection Services principles, and could have created a public health risk.***

**The lab received samples for E. coli testing on June 25, June 26, and July 10, 1997, taken from slaughterhouse carcasses which had a strong smell of bleach and tobacco. Such smells are indicative of an adulterated sample or a sample that might have been treated to kill the bacteria that the test is designed to detect. Lab technicians brought these samples to the attention of the lab's chief microbiologist, who instructed the technicians to run the E. coli testing on the samples and to make a notation in the computer as to the smell. The final report for the first two samples did not contain the notation as to the smell of chlorine and reported that E. coli was not present. The final report on the third sample contained the lab technician's notation as to the smell of chlorine. It also contained a statement from the chief microbiologist: "For microbiological purposes the sample was adulterated."**

**When questioned by PEER as to the testing of these samples believed to be adulterated, the lab's chief microbiologist stated that, in this situation, the lab was acting as a private lab and did not have the regulatory authority to elect not to run the samples believed to be adulterated. The meat processing plants were paying to have the tests run and the lab had a responsibility to run the tests. He stated that if he had been in a regulatory position, he would have had the authority to reject the samples, but that the Director of the Department of Agriculture and Commerce's Meat Inspection Program, who instructed him to run the E. coli testing, had such regulatory authority in this situation. He stated that he had fulfilled his responsibility by notifying the Director of the Meat Inspection Program of the samples. He also stated that if the lab had been in a regulatory authority position when the samples arrived, he would not have instructed the staff to run the E. coli testing.**

**When contacted by PEER, Larry Dillard stated, "No sample should be analyzed when tampering is suspected. In our regulatory environment, we would contact the inspector's superiors and advise them. A replacement sample could then be ordered." He also said that samples believed to be tampered with should not be handled differently in a fee-based lab as opposed to a regulatory lab. Mr. Dillard stated that "the standards for judging suitability for analysis should**

**not depend upon who is paying for the analysis. Samples analyzed for fee by a private laboratory may very well come under USDA scrutiny as part of our regulatory function in that plant."**

**PEER also contacted Dr. William Leese, Director of Federal/State Relations for the USDA, who stated that running tests on samples believed to be adulterated would not represent the intent of the HACCP program. He said that the validity of the sample, due to a smell of chlorine or tobacco not being a component of the processing procedure, would be inhibited. Dr. Leese stated that the sample should be identified as abnormal and should certainly not be included as one of the plant's thirteen consecutive samples.**

**The Board of Animal Health's Veterinary Diagnostic Laboratory created a public health risk by reporting no presence of E. coli on these samples. Reporting results of tests on adulterated samples defeated the purpose of the sampling, which is to indicate if an establishment may not be maintaining process controls sufficient to prevent fecal contamination of meat. Reporting no E. coli on these samples may have interfered with the detection of process control weaknesses that threaten the safety of meat processing and, ultimately, the quality of meat products placed on the market for human consumption.**

- ***The Board of Animal Health's Lab Director required a veterinarian to sign poultry health certificates without conducting the appropriate poultry examinations for such certificates, which violates American Veterinary Medical Association policies.***

**One of the countries to which Mississippi exports poultry is Russia. February 1996 negotiations established new requirements in order for states to export poultry to Russia which require USDA-accredited veterinarians to sign health certificates on all flocks which may be processed and exported to Russia.**

**Mississippi's "Disease Reporting Procedures" provide for every flock destined for Russia to be examined by a poultry company's technical service representative (a poultry company employee not required to be an accredited veterinarian) within seven days of slaughter. This employee must complete a flock "health certificate" for each flock certifying the clinical health of the flock. From these certificates, the company forwards a "Flock Health Certification Summary" of all flocks to be processed to Dr. Danny Magee, a certified federally accredited veterinarian employed by Mississippi State University's College of Veterinary Medicine. (The USDA established the veterinary accreditation program in 1921 to allow private practitioners to assist federal veterinarians working to control animal diseases.) Dr. Magee signs a statement that "all of the flocks listed above have been inspected and found to be clinically healthy." He then forwards this summary to the processing plant prior to slaughter of the flocks listed on the summary and the flock health certification is attached to the export certificates for the poultry's exportation to Russia.**

**Mississippi's "Disease Reporting Procedures" required a Veterinary Diagnostic Laboratory veterinarian to certify the flocks' health in the absence of Dr. Magee. This veterinarian notified Dr. Frank Rogers, State Veterinarian/Lab Director, on October 24, 1996, of her concern over attesting to the clinical health of these flocks which she had not inspected, when such inspections were being conducted by technical service representatives who were not required to be accredited veterinarians. The Veterinary Diagnostic Lab veterinarian was concerned with the risk this posed to her professional accreditation. Dr. Rogers continued to require the veterinarian to sign such certificates.**

**The Lab Director's directive for the Veterinary Diagnostic Laboratory veterinarian to certify the flocks' health without conducting an inspection does not comply with accepted veterinary practice. The American Veterinary Medical Association's "Position on Animal Health Certificates" states that "The accredited veterinarian is responsible for the accuracy of health certificates that he or she issues, and it behooves the individual veterinarian to conduct appropriate examinations before any health certificate is issued." The association adopted its "Position on Presigned Health Certificates" in 1974, which states that "The AVMA believes that any veterinarian found guilty of presigning or otherwise misusing intra- or inter-state or export health certificates should have his or her accreditation immediately removed, and all pertinent information should be transmitted to the state board of veterinary medical examiners for a proper hearing leading to suspension of his or her license to practice veterinary medicine. The AVMA feels that the chief animal health official of each state should exercise strict control over the issuing and control of all health certificates."**

**A procedure that does not provide the accredited veterinarian an opportunity to examine animals before issuing health certificates cannot effectively accomplish the purpose of the procedures, which is to protect the health of consumers and to prevent the spreading of disease. By requiring a procedure which jeopardizes a veterinarian's accreditation and licensure, the Lab Director could endanger the Veterinary Diagnostic Laboratory's capacity to recruit and retain qualified veterinarians needed to maintain clinical expertise.**

## *Major Quality Control Problems in Animal-Health-Related Testing and in Food-Related Testing*

**By failing to establish control systems needed to ensure the technical quality of its testing, the Veterinary Diagnostic Laboratory has jeopardized the board's effectiveness in accomplishing its animal health mission, as well as the effectiveness of the state and federal governments in promoting human health.**

**PEER's preliminary fieldwork substantiated lab employees' allegations of falsified test results, misdiagnosis, and improper testing procedures. PEER reviewed the lab's quality assurance procedures and controls to determine whether they were adequate to ensure clinical operations which would reduce the chance of and detect errors such as those verified. PEER found that the chemistry lab had not implemented proper controls and the microbiology lab had assumed new testing without establishing policies and procedures or quality assurance controls for food-related testing.**

**Board of Animal Health personnel have argued that the cases reviewed by PEER are only a few of the thousands handled by the laboratory. Although the allegations reviewed by PEER concerning these two labs, which proved to be true, made up a small proportion of the lab's caseload, the absence of controls to prevent and detect errors in these labs demonstrates the potential for other errors to occur without detection.**

**The lab's accrediting organization, the American Association of Veterinary Laboratory Diagnosticians, recommended in its February 1997 review of the lab that the lab appoint a quality control coordinator. At the time of PEER's fieldwork for this review in February 1998, the Lab Director had not appointed this coordinator.**

### Major Quality Control Problems in Animal-Health-Related Testing

- ***The chemistry lab has failed to implement experimental controls which would help ensure the accuracy and integrity of chemistry testing.***

**A diagnostic veterinarian is charged with assessing diverse information about the case submission, including the case history, necropsy findings, and the individual test results provided by departmental laboratories, in order to render a most probable diagnosis. The veterinarian's correct diagnosis depends on the validity of test procedures performed by departmental laboratories. Thus, it is critical that departmental laboratories, such as the chemistry lab, implement quality assurance standards to ensure such validity.**

**Lab personnel should run a control standard to verify or regulate a scientific experiment by conducting a parallel experiment or by comparing with**

**some other standard. The Veterinary Diagnostic Laboratory did not establish a policy in its chemistry lab that controls be run on all tests until January 1998. In an office memo dated January 6, 1998, Dr. Frank Rogers, State Veterinarian and Lab Director, stated that "this is to establish a policy in the Chemistry department that controls be run on all heavy metals as well as other tests as indicated unless it is established in writing in advance that the control is not indicated." In the case of the Veterinary Diagnostic Laboratory, the absence of controls could be compounded by the fact that the laboratory does not have maintenance and service agreements on its lab equipment, which means that this equipment may not consistently remain in proper calibration.**

**This lack of controls in chemical laboratory testing contributed to the laboratory errors discussed in earlier in this report on pages 7 through 9. Had the lab's senior chemist run the proper positive control in his copper analysis on fresh lamb tissues, the control should have indicated copper toxicity. Since the chemist did not run this control, he did not question his results, which did not support copper toxicity.**

**In addition to establishing conditions under which laboratory personnel should run controls, proper quality assurance standards require documentation of test results in order to verify the accuracy of such results. Subsequent to the incident of the chemist failing to run the appropriate test on the dog serum and concerns of senior veterinarians at the laboratory, the chemistry lab began attaching machine tapes from the tests it runs to accession reports.**

## Major Quality Control Problems in Food-Related Testing

- ***The risks associated with the Veterinary Diagnostic Laboratory's failure to establish an effective quality control system were heightened in June 1997 when the microbiology lab began conducting food-related tests. However, the microbiology lab did not establish quality control procedures to ensure the accuracy and integrity of new testing associated with the processing of food for human consumption.***

**The fifteen-member Board of Animal Health is comprised of the Commissioner of Agriculture and Commerce, ten commodity producers' representatives, one veterinarian, and three clinical representatives. The composition of the Board of Animal Health provides for a market focus to protect the health of animals in the state. The composition of the board does not provide for human-health-related expertise. However, the board assumed a human-health focus when the microbiology lab began antibiotic residue and E. coli meat testing in 1997. The board assumed these human-health-related functions without sufficient board oversight, via proper board composition with human-health expertise, or clinical oversight, via a highly qualified clinical lab director, needed to avoid the risks associated with food-related work. Further, the board**

**assumed these human-health-related duties without establishing quality control procedures to govern such activities.**

**When the Veterinary Diagnostic Laboratory assumed these food-related testing responsibilities, it should have established procedures for ensuring the integrity of samples and prescribing the proper disposition of cases in which the lab received samples of questionable quality. The lab did not develop such procedures, nor did the Lab Director obtain approval from the Board of Animal Health prior to the lab conducting this testing. This lack of procedures resulted in the microbiology lab's using improper equipment for antibiotic residue testing and mishandling of adulterated samples for E. coli testing.**

° ***The microbiology lab did not develop standard operating procedures and quality control procedures for its antibiotic residue testing.***

**As discussed on page 9, the Veterinary Diagnostic Laboratory's chief microbiologist directed microbiology lab personnel to use a 30 mcg control disc, rather than a 5 mcg control disc, in antibiotic residue testing procedures. Proper operating procedures for the antibiotic residue testing would require the use of 5 mcg control discs. Proper quality assurance procedures would have identified and detected inappropriate utilization of 30 mcg discs.**

**The Board of Animal Health's Veterinary Diagnostic Laboratory created a public health risk by concluding that antibiotic residue tests were negative, when test results were actually inconclusive due to the use of the improper size of neomycin control disc. Reporting negative results may have prevented antibiotic treatment from being detected and could have allowed contaminated meats into markets for human consumption.**

° ***The microbiology lab did not develop quality control procedures over its E. coli testing.***

**As discussed on page 10, the microbiology lab received three meat samples in June and July 1997 which had a strong smell of bleach and tobacco, indicative of an adulterated or "treated" sample. The Veterinary Diagnostic Laboratory's chief microbiologist instructed microbiology lab technicians to run the E. coli testing on the samples. The final report for the first two samples did not contain the notation as to the smell of chlorine and reported no presence of E. coli.**

**Proper disposition of the samples believed to be adulterated should have been for the microbiology lab to require replacement samples from the processing plants. Microbiology lab technicians should not have analyzed the samples suspected of adulteration.**

**Although the Veterinary Diagnostic Laboratory's chief microbiologist stated that he ran the samples at the direction of the Department of Agriculture and Commerce's Meat Inspection Division director, standard policies and**

**procedures governing the microbiology lab's E. coli testing would have established uniform protocol for the testing and the handling of samples. Such uniformity was not present in the three samples believed to be adulterated as evidenced by the note on the third sample only that "for microbiological purposes the sample was adulterated" and the requirement of another sample only for this sample.**

**The Veterinary Diagnostic Laboratory placed human health at risk by assuming new testing responsibilities related to the quality of food for human consumption without first establishing standard procedures for assessing the quality of samples, for selecting and using testing materials, and for ensuring the accuracy of test results. As discussed in the Appendix, page 19, the Legislature has now specifically prohibited the Veterinary Diagnostic Laboratory from conducting any regulatory testing for food purposes.**

## *Legislative Action*

### House Bill 1584, 1998 Regular Session

**During the course of fieldwork for this review, the Legislature adopted the Conference Report on House Bill 1584, which separated the regulatory and clinical operations of the Board of Animal Health. PEER staff worked with the conference committee by describing deficiencies noted by PEER staff at the Veterinary Diagnostic Laboratory. The Appendix, page 19, provides an overview of the major problems PEER identified and the corrective action the Legislature took in response to each. The Governor signed House Bill 1584 into law on April 17, 1998.**

## *Recommendations*

**Many of these recommendations address changes in law made by House Bill 1584, 1998 Regular Session, effective July 1, 1998.**

1. **The Lab Director of the Veterinary Diagnostic Laboratory should implement the American Association of Veterinary Laboratory Diagnosticians' recommendation that the Veterinary Diagnostic Laboratory appoint a quality control coordinator. The Lab Director should also establish a quality control committee, to be chaired by this quality control coordinator, comprised of one representative from each of the seven specialty labs, to develop, implement, and annually review quality assurance and control procedures of the Veterinary Diagnostic Laboratory. Such control procedures should be approved by the Lab Director and by the Veterinary Diagnostic Laboratory Board, which was established by House Bill 1584.**

2. **The Board of Animal Health should comply with MISS. CODE ANN. Section 5-11-1 et seq. (1972) in its transfer of resources to the Veterinary Diagnostic Laboratory Board on July 1, 1998, as provided for in House Bill 1584, 1998 Regular Session. CODE Section 5-11-1 et seq. (1972) provides for a transition authority to develop plans to facilitate the transfer of an agency's duties and responsibilities to another agency.**

3. **The Veterinary Diagnostic Laboratory Board, Lab Director, and Quality Control Committee should adopt proper quality assurance controls before the Veterinary Diagnostic Laboratory initiates any new testing procedures. Further, the Lab Director should insure the proper training of Veterinary Diagnostic Laboratory personnel in new clinical procedures prior to the lab offering such procedures to its clients.**

4. **The Lab Director should not require any Veterinary Diagnostic Laboratory personnel to certify the clinical health of any animal which has not been examined by that person. The Lab Director should propose revisions in "Mississippi's Disease Reporting Procedures" relevant to flock health certificates to the USDA's Area Veterinarian in Charge.**

5. **The Veterinary Diagnostic Lab, as well as any other clinical lab in the state, should not conduct testing on samples believed to be adulterated. Rather, the lab should require the submission of other samples from the submitting authority.**

6. **In compliance with House Bill 1584, the Veterinary Diagnostic Laboratory should not conduct any regulatory testing for food purposes.**

# *Appendix*

## *Summary of Concerns Regarding Veterinary Diagnostic Laboratory Operations and Legislative Action to Correct Such Problems*

**The focal concerns in the operation of the Veterinary Diagnostic Laboratory relate to inadequate quality assurance procedures, lax or poorly focused board oversight, and board composition and authority which does not reflect stakeholder needs. Presented below are provisions of House Bill 1584, 1998 Regular Session, which address these primary concerns. House Bill 1584 is to take effect and be in force from and after July 1, 1998, with a July 1, 1999, repealer.**

**Problem 1: The lab's failure to ensure quality in its clinical operations**

**House Bill 1584:**

**A. provides for the Veterinary Diagnostic Laboratory Board's appointment of an executive director of the diagnostic laboratory with the following qualifications: a degree of veterinary medicine from a recognized college or university; board certification in one of the following diagnostic disciplines: toxicology, pathology, microbiology, virology, or clinical pathology; and, ten years' experience in veterinary clinical diagnosis, with at least five of these ten in a supervisory capacity. The executive director is to be responsible for the daily operations of the laboratory.**

**B. creates the Veterinary Diagnostic Laboratory Board, which will assume all diagnostic functions of the current Board of Animal Health, including the maintenance of a complete and adequate veterinary diagnostic lab in Jackson. The board is to be comprised of the following seven members: the Chairman of the Board of Animal Health, the Commissioner of Agriculture and Commerce, the Dean of Mississippi State University's College of Veterinary Medicine, a person appointed by the President of Alcorn State University from its land grant staff, a licensed and practicing veterinarian appointed by the President of the Mississippi State Veterinary Medical Association who is not a member of the Board of Animal Health, the State Veterinarian, and the State Chemist.**

**The Dean of Mississippi State University's College of Veterinary Medicine will serve as chairman of this new board, which will meet monthly. The legislation created an advisory council to the Veterinary Diagnostic Laboratory Board consisting of the chairmen of the House and Senate Agriculture committees, an appointee of the Speaker of the House, and an appointee of the Lieutenant Governor.**

**Problem 2: The lab's assumption of food-related testing responsibilities**

**House Bill 1584:**

**A. creates an advisory board to the Board of Animal Health consisting of the chairmen of the House and Senate Agriculture committees, an appointee of the Speaker of the House, and an appointee of the Lieutenant Governor**

**B. prohibits the diagnostic laboratory from conducting any regulatory testing for food purposes**

**Problem 3: Potential interference with or perversion of the board's regulatory responsibilities.**

**House Bill 1584:**

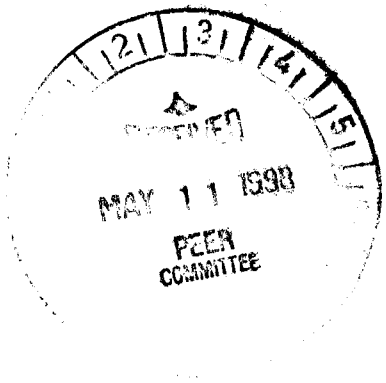
**A. increases the number of ex officio board members representing clinical expertise via the appointment by the President of Alcorn State University from its land grant staff**

**B. creates an advisory board to the Board of Animal Health consisting of the chairmen of the House and Senate Agriculture committees, an appointee of the Speaker of the House, and an appointee of the Lieutenant Governor**

MISSISSIPPI BOARD OF ANIMAL HEALTH
AND
VETERINARY DIAGNOSTIC LABORATORY

**Lester Spell, Jr. DVM**
Commissioner of Agriculture and
Commerce, Chairman

**Dr. Frank Y. Rogers**
State Veterinarian
and Director




May 11, 1998

PEER Committee
P. O. Box 1204
Jackson, MS 39215-1204

Gentlemen:

In response to the allegations of the PEER Committee regarding the Chemistry department of the Mississippi Board of Animal Health, Veterinary Diagnostic Laboratory:

The statement "falsification of records" would imply a willful misrepresentation of results. This has not occurred. Any results entered in error, was an error and nothing more. One would challenge anyone who claims that they have never made an error to back up that statement.

The case cited for copper was neither an error nor a misrepresentation. The Chemistry department received just enough samples to run the test one time and results were submitted as found. In the absence of any written chain of possession or witnesses to the sampling of the tissue by a former employee (who had a grudge against the technician who he was checking up on) would have to be highly suspect.

The statement that no policy was in effect for quality control before January, 1998, is also in error. The investigator for the PEER Committee has in her possession control reports dating back to at least February, 1996. Ask her for these!

The investigator for the PEER Committee (who on several occasions admitted that she knew nothing about chemistry or general laboratory procedures) had three sessions with the Chemistry department. The first consisted of about one hour in which the major subject of discussion was the computer program that we are using. The second consisted of getting an explanation of two cases, which were obviously fed to the investigator by someone, and an explanation was given; which, by the way, was never mentioned. The third session consisted of approximately thirty minutes in which she very briefly looked at our quality control procedures and was shown these.

One fails to understand how in approximately one hour the PEER Committee could come to the

conclusion that our quality control was lacking unless a preset agenda was being fueled by some disgruntled present and former employees. Especially when the AAVLD accreditation committee (two people who are recognized experts in chemistry and toxicology) who spent two days here looking over our procedures, determined that "what we do, we do well."

The Chemistry department handles approximately four thousand cases a year and we were cited on two cases. This is about 0.05% of the total cases that we handled. One could possibly feel that a 99.95% no complaint record is a very good record.

In response to recommendation number four, the person making the complaint called the Federal Area Veterinarian in Charge who in turn called APHIS in Washington, D.C. The person in Washington, D.C. told the Area Veterinarian in Charge there was no problem with the way the procedure was being done and no accreditation of license violation had occurred. You may talk to Dr. Debra Brennan, the Federal Veterinary in Charge of Mississippi and verify my statement. Phone number 965-4307.

There were between 15 and 20 cases pulled to be looked at by PEER. The time period involved some 60,000 cases that went through this laboratory. If this laboratory only mishandled 20 cases out of 60,000, I consider that a good sign that this laboratory is not doing bad work as the report implies.

To the best of my knowledge, samples sent out of this laboratory to checkup on technicians without the laboratory director's approval have had no established chain of custody. This means that only one individual has selected and packaged up the samples and sent it by himself without any witnesses.....we have no paper trail or chain of custody that can legally establish that the sample sent is actually the one that matches the paper work sent. For example, how do we know that sample "A" isn't sent out with sample "B" paper work to invent an error? Of course, the results that come back appear to be incorrect and an error is claimed, when the samples were perhaps switched. It is possible, of course that an unintentional error could be involved. However, any laboratory results that are claimed to be wrong because another laboratory comes up with a different result has to be viewed with suspicion if there is no established chain of custody or paper trail.

See enclosed information concerning E Coli testing.

Sincerely,

Frank Y. Rogers, BS, DVM
State Veterinarian

## I) ERRORS IDENTIFIED IN ALLEGATIONS AND CONFIRMED BY PEER

1) PEER noted laboratory errors with human-health implications.

1.1) ... The board's staff assumed these operations (antibiotic residue and E. coli testing) without developing operating procedures to govern such, which contributed to the errors noted below:

a) The lab's chief microbiologist directed laboratory staff to utilize the wrong size control disc in antibiotic residue testing, which caused test results to be inconclusive.

ANSWER: The statement made by the PEER on item 1.1 is totally unfounded and inaccurate. The lab's chief microbiologist indeed used the proper control disc as supplied by the company that manufactures the test kit. Furthermore, "ALL" control discs for antibiotic residue testing (clinical, food, etc) are from the same size, so industry can standardize its commercial production. In other words, there is NO other type of control disc available anywhere in the market. Attached is a FAX sent to the lab's chief microbiologist by the EDITEK company which describes in details the components of the test kit used. Furthermore, the same kit was being used before by the technicians of the extinct Meat Inspection Laboratory of the MDAC. Copies of the manual detailing all the operating procedures for the antibiotic testing residue was provided by EDITEK and also given to the staff of the bacteriology laboratory (see a copy attached). The technicians were then trained several times by running preliminary tests in-house in preparation for the actual samples. Ms. Laura Killebrew, former Meat Inspection Lab technician, also gave us some practical demonstration on how to run this test since she had been the person in charge of running them for a long time. Therefore, the staff of the bacteriology lab received all the information necessary to run the antibiotic residue testing in meats. Finally, the rationale of the PEER investigation regarding the issue of antibiotic residue testing cannot be understood at this time. The PEER made an allegation in which a "wrong size control disc" was used for antibiotic residue testing in meats, but failed to identify what actually was done in terms of testing. In addition, the PEER failed to check with the lab's chief microbiologist the details of this allegation, otherwise the above explanation and information would have been supplied to the investigator.

It should be mentioned that only two kidney tissue samples (cases number 11059-97 and 625-98) were forwarded to the MBAH for antibiotic residue testing. See attached print-out of a MBAH Vetlims computer search/query.

Finally, the zone size used and referent to the control discs reflect those currently recommended in the Food and Drug Administration, HHS 21 Code of Federal Regulations, Chapter 21 (4-1-8 Edition), Section 460.1.

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## FAX COVER PAGE

**DATE:** 6-26-97

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Dr. Sergio Feijoo

Vet Diagnostic Lab

**AT TELECOPIER NUMBER:** 601-354-6097

**FROM:** Nancy

**RE:** Pricing Info on Stop Kits, Plates, & Spores

**ADDITIONAL MESSAGE:**

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| 500151 | STOP Plates | $ 2.10/plate |
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**Total Number Of Pages, Including This Cover Page:** 2

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| 625-98 | 07-16-97 | RESID | 1 |
| Counts: | | | 2 |

## II) MAJOR QUALITY CONTROL PROBLEMS IN ANIMAL-HEALTH-RELATED TESTING AND IN FOOD-RELATED TESTING

1) The risks associated with the VDL's failure to establish an effective quality control system were heightened in June 1997 when the microbiology lab began conducting food-related tests. However, the microbiology lab did not establish quality control procedures to ensure the accuracy and integrity of new testing associated with the processing of food for human consumption.

1.1) When the microbiology lab assumed food-related testing in 1997 for the Meat Inspection Program, the lab's managers did not develop standard operating procedures and quality control procedures for antibiotic residue testing, nor did they develop quality control procedures for E. coli testing.

ANSWER: The microbiology lab staff started to work on the E. coli project as soon as official information was out. Dr. Feijoo met with Ms. Blackwell and Ms. Love to design a strategy to accomplish that task. Investigation was made in order to get the price of all individual materials to be used for the E. coli analyses in order to figure out the cost of the test, which was obtained. Upon arrival of the components in our unit, test kits were set up and made available to the meat processing companies, along with a short manual prepared by Dr. Feijoo explaining to the meat processing companies how to use the kit.

The Petri film procedure to run the E. coli analyses was chosen in common agreement by both Dr. Feijoo and Ms. Blackwell due to the nationally recognition of the 3M Company. Therefore, the Petri film procedure was elected.

Dr. Feijoo explained in as much details as possible to both Ms. Blackwell and Ms. Love how the analyses should be done. Furthermore, 3M Company supplied color brochures containing graphical information on how to prepare the samples, to run the analyses, and to interpret the results, which were also passed onto to both technicians.

In order to get familiarized with the test procedure itself, several preliminary tests were conducted in-house by the technicians under Dr. Feijoo's supervision, so they would be prepared and trained for the actual samples. Therefore, the staff of the microbiology laboratory knew perfectly the kind of work related to the generic E. coli testing that they would be doing.

Just after beginning of the actual testing, Dr. Feijoo started receiving several verbal complaints from both technicians about how time consuming these tests were. Also, Dr. Feijoo noticed that the results (bacterial colonies) recorded by both technicians did not correspond to what was demonstrated on the operating procedures manual supplied by the 3M Company. Thus, Dr. Feijoo had to read all microbial plates again and re-enter the appropriate results. By doing this, Dr. Feijoo was interpreted as falsifying the results, which was obviously NOT the case.

Due to the increased time consuming to run the E. coli analyses, the level of

insatisfaction and insubordination grew stronger in the lab on part of both technicians.

The situation had an unprecedented twist when a sample potentially containing chloride came to the lab. Dr. Feijoo immediately called the owner and informed him of the fact. The owner vehemently, on the phone, denied any intentional adulteration. In addition, he insured about his honesty and professional integrity. He had been in business for so many years and never was involved in such incidents. Furthermore, the sample had been collected under the supervision of a State meat inspector. Following, Dr. Feijoo called Dr. Robert West, Head of the Meat Inspection Division of the Mississippi Department of Agriculture and Commerce, and informed him of the situation and let him know the name of the company, the day the sample was collected, and what animal species was. Dr. Feijoo asked for guidance on how to handle that situation since the MBAH does not have statutory power to rule on matters like that. After a brief discussion, Dr. West told Dr. Feijoo to go ahead on the testing and inform him about the result. Later, Dr. Feijoo also sought advice from Sillikers Laboratory, a nationwide recognized food testing lab, on how to handle such situation. Dr. Feijoo was told that since the MBAH was involved in the E. coli testing program as a private lab, due to lack of statutory power, and not as an official one (example: MDAC, FSIS) a possibility would be running the sample and reporting the results to both the company and the State regulatory agency, in this case the Meat Inspection Division of the MDAC. Therefore, in order to protect the MBAH of any potential law suit, Dr. Feijoo decided to follow this possibility and a copy of the results were sent to both the company and to Dr. West at the MDAC, so the Meat Inspection Division could decide the appropriateness of taking any action.

Subsequent potentially adulterated samples were handled the same way. Thus, the MDAC had plenty of knowledge about this situation.

In the mean time, Dr. Lester Spell came twice to the MBAH to talk to Ms. Blackwell and Ms. Love, and on Thursday of the following week a letter was released by Dr. West to all meat processing plants in the State shutting down the E. coli analyses at the MBAH. During that week, Dr. Rogers was in Reno, NV, attending a scientific conference. Neither Dr. Rogers nor Dr. Feijoo were previously informed about Dr. Spell's decision in stopping the E. coli program at the MBAH.

This fact was originated from the meetings that took place between Dr. King, Ms. Blackwell, Ms. Love, and Dr. Spell at his office at the MDAC. Dr. Spell acted solely on the information passed onto him by the above mentioned employees. Dr. Feijoo's opinion and/or explanation was never requested by Dr. Spell nor anybody else within the State structure. Dr. Feijoo managed to meet with Dr. Spell on August/97 to try to explain his reasons and his decisions on how he handled the E. coli testing situation. Thus, Dr. Spell was presented with a technical description of the test, the operating procedures related to the test as well as all the supporting materials related to the results interpretation.

Dr. Spell was wrongly informed that the MBAH was "poisoning" the population of the State of Mississippi and that this State could become the new

"Jack-in-the-Box" statistics. In other words, Ms. Blackwell and other members of the group intentionally informed Dr. Spell that test results positive for pathogenic E. coli (strain O157:H7) bacteria were being "falsified" by Dr. Feijoo and that reports from these analyses were being released to the companies containing a "negative" result. This is absolutely not true.

It should be mentioned that ALL THE RECORDS pertaining to the E. coli testing program were destroyed by Ms. Blackwell while Dr. Feijoo was on leave from the lab during the month of August/97 to visit with his ill mother in Europe.

These same unfounded accusations against Dr. Feijoo were brought again, this time publicly, during the quarterly meeting of the MBAH-Board members that took place on 10/10/97, which demonstrated a great level of insubordination from the staff of the microbiology staff to Dr. Feijoo.

On the MBAH Board meeting which took place on 12/17/97, Dr. Wallace Morgan, Head of the Poultry Science Department at Mississippi State University, defended the actions of Dr. Feijoo under a technical and scientific manner. Furthermore, on the MBAH Board meeting of 1/5/98, Dr. Robert Rogers, a Professor of Meat Science at Mississippi State University was invited to speak to the Board members about the legal aspects of E. coli testing. Dr. Robert Rogers did not disagree with Dr. Feijoo's handling of the E. coli testing situation.

At this point, it needs to be understood "what" was being tested in this E. coli program. The bacterium generic E. coli belongs to Enterobacteriaceae family of bacteria, which has as natural habitat the gastro-intestinal tract of warm-blooded and higher animals (included humans). Within this family there is a special group of bacteria known as "coliformes", which include most of the generic group of non-pathogenic E. coli. Also, the pathogenic E. coli bacteria are subdivided into different groups, such as: Enteropathogenic E. coli, Enteroinvasive E. coli, Enterotoxigenic E. coli, and Enterohemorragic E. coli (which harbors strain O157:H7).

The E. coli program was designed to test for NON-PATHOGENIC generic E. coli bacteria and the procedure used to detect this group of microorganisms is totally different from the procedure designed to test for pathogenic E. coli. Therefore, we were dealing all along with a non-pathogenic microorganism. In addition, differences between procedures to detect pathogenic versus non-pathogenic strains of E. coli are also demonstrated in the attached brochures from the 3M Company.

Finally, it is totally untrue the PEER's affirmative that no standard operating procedures and quality control measures were NOT developed for the E. coli testing program. They are contained in the following OFFICIAL REFERENCES, which are and were always available in the lab and which are and were of total knowledge of Ms. Blackwell and Ms. Love:

a) Generic E. coli testing.
AOAC Official Method 991.14
Official Methods of Analysis of AOAC International
Volume I, 16th Edition, 1997

ISBN 0-935584-54-4

b) Compendium of Methods for the Microbiologic Examination of Foods
American Public Health Association
Washington, DC
APHA Ed., 1997

c) Standard Methods for the Examination of Dairy Products
American Public Health Association
Washington, DC
APHA Ed., 1996

d) Petrifilm - Coliform and E. coli Count Plates
3M Company
3M Center Bldg. 275-4E-01
St. Paul, MN 55144-1000

STATE OF MISSISSIPPI
DEPARTMENT OF AGRICULTURE AND COMMERCE
LESTER SPELL, JR., D.V.M.
COMMISSIONER

May 12, 1998

Dr. Max Arinder
Executive Director
PEER Committee
222 N. President St.
Jackson, MS 39201

Dear Dr. Arinder:

Last Tuesday, May 5, I had the opportunity to review the preliminary PEER report on the Mississippi Board of Animal Health (MBAH) at the PEER's office. Since the MBAH was scheduled to meet in Jackson the next day, Wednesday, May 6, your staff suggested that I tell the board members that they were welcome to come to the PEER office and review the preliminary report while they were in Jackson for the meeting. At the MBAH meeting the next morning, I relayed your staff's invitation to the board members and gave them the address and phone number of the PEER office.

I understand that as the agency head of the MBAH, Dr. Frank Rogers was allowed to respond in writing to the preliminary PEER report before it was presented to the full PEER Committee for final action. I read Dr. Rogers' responses to the report today for the first time. Dr. Rogers' personal replies **DO NOT** represent the MBAH regarding the preliminary report.

It is my opinion that the PEER preliminary report appears to be a very well documented and accurate analysis of the findings at the MBAH. I appreciate the courteous and professional attitude of both you and your staff in this matter.

If I or any member of my staff can be of further assistance, please call on me.

Sincerely,

Lester Spell, Jr., D.V.M.
Commissioner of Agriculture & Commerce

LS,Jr/nn




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## *Rebuttal of the State Veterinarian's Response to PEER's Report*

**In his May 11, 1998, response to this report, the State Veterinarian and Veterinary Diagnostic Laboratory Director, Dr. Frank Rogers, states that the report contains several errors and "unfounded and inaccurate" information, and alleges that PEER staff knew nothing of laboratory operations but conducted field work according to a preset agenda. Dr. Rogers's response makes false and misleading statements, none of which he supports with documentation or reference to any authority. In contrast, extensive documentary evidence and records of the PEER staff's consultation with veterinary experts support the PEER Committee's statements in its report. PEER reaffirms its report, with the conclusion that mismanagement at the laboratory has caused actual risks to human as well as animal health.**

**Statements from the State Veterinarian's written response appear below with the numbers of the pages on which they appear in this report, followed by PEER's basis for each corresponding conclusion.**

**• • •**

> ***The statement "falsification of records" would imply a willful misrepresentation of results. This has not occurred. Any results entered in error, was an error and nothing more.*** **[p. 21]**

**<u>Basis for PEER's Conclusion</u>: In attesting to the accuracy of official lab files, the lab's records clerk attested to the authenticity of all records requested by PEER staff, except for the record in question. She informed PEER staff that test results for the lab accession discussed on page 7 of PEER's report had been changed in the chemistry lab.**

**Lab personnel, in separate and individual interviews with PEER staff, brought this incident to the attention of PEER and expressed concern at the falsification of records. Computerized records tape in the chemistry panel machine did not reflect that a chemistry panel had been run on January 30 on this case as reported by the chemist.**

**When questioned by PEER staff as to factors which necessitated his revising the chemistry panel results for this dog, the lab's senior chemist responded that the different panels were run on two separate samples which were taken a day apart due to one sample being hemolyzed. This explanation is not reflected in the official lab record for this dog. Both the final and addended reports reflect chemistry panels being run at 10:24 a.m. on January 30, 1996.**

> ***The case cited for copper was neither an error nor a misrepresentation. The Chemistry department received just enough samples to run the test one time and results were submitted as found. In the absence of any written chain of possession or witnesses to the sampling of the tissue by a former employee (who had a grudge against the technician who he was checking up on) would have to be highly suspect.*** **[p. 21]**

**Basis for PEER's Conclusion:** **Three other Mississippi Veterinary Diagnostic Laboratory labs' results indicated copper toxicity. The official lab record for this lamb documents that a necropsy of the lamb suggested chronic copper toxicity with resultant renal (kidney) failure. The serology lab's lepto serology test and the virology lab's lepto fluorescent antibody test, both with negative results, ruled out lepto as a possible cause of death and supported copper toxicity as the cause of death.**

**While PEER cannot certify or document the chain of custody of the sample sent to Texas, the fact that the Texas Veterinary Medical Diagnostic Lab concurred with three other Mississippi Veterinary Diagnostic Laboratory labs does not suggest the need to question the integrity of the sample. When consulted by PEER on this case, Mississippi State University, College of Veterinary Medicine, Diagnostic Services personnel reported that a few points difference in measurement between two tests could be expected, but this difference (the chemistry lab reported copper results of 32 ppm in the liver tissue, while Texas reported copper results of 370 ppm) far exceeds the referenced scale.**

**When questioned by PEER staff as to the difference between his and Texas's copper toxicity test results, the lab's senior chemist stated that he felt that lab personnel had forwarded liver samples from a second animal to Texas for diagnosis. He also stated that he has made mistakes, but he knows that this case was not a mistake. The senior chemist's attestation as to his correct findings conflicts with the lab's record of the final report for this animal, which contains the copper analysis readings from Texas, in addition to his readings.**

> ***The statement that no policy was in effect for quality control before January, 1998, is also in error. The investigator for the PEER Committee has in her possession control reports dating back to at least February, 1996. Ask her for these!*** **[p. 21]**

**Basis for PEER's Conclusion:** **A laboratory memo from Dr. Frank Rogers to Dr. Sergio Feijoo, Supervisor of the Chemistry Lab, dated January 6, 1998, states: "This is to establish a policy in the Chemistry department that controls be run on all heavy metals as well as other tests as indicated unless it is established in writing in advance that the control is not indicated."**

**PEER staff requested the earliest record of the calibration of the Ciba Corning Express 550, the serum chemistry analyzer on which chemistry panels are run, from John Bowen, the lab's senior chemist, and he provided a tape from February 1996. However, the calibration of machines is not a comprehensive quality control system. Further, this piece of equipment is not used in all chemistry testing and it is not the only piece of equipment used.**

**The lab's accrediting organization, the American Association of Veterinary Laboratory Diagnosticians, stated in its February 1997 review of the lab that ". . .all positions are filled by individuals with adequate experience. Only the analytical chemistry position is filled with an individual with less than the recommended minimal qualifications." The need for a comprehensive and effective quality assurance system is increased when a laboratory is staffed with personnel with less than the recommended minimum qualifications.**

> ***The investigator for the PEER Committee (who on several occasions admitted that she knew nothing about chemistry or general laboratory procedures) had three sessions with the Chemistry department.*** **[p. 21]**

**<u>Basis for PEER's Conclusion:</u> This statement is a misrepresentation of the methodology and procedures used by PEER to develop an understanding of laboratory operations during the course of fieldwork. PEER staff requested a "layman's" explanation of all laboratory operations or records in order to understand the scientific principles involved so that relevant information and assistance might be sought, analyzed, and factually reported.**

**PEER staff received approximately eleven allegations at the onset of this review. PEER did not include those which it could not document or verify. PEER adhered to its own quality assurance system in documenting the report, and consulted with the following sources for expertise and information during the course of fieldwork for this review:**

**Dr. Harvey McCrory, Executive Secretary to the MS Board of Veterinary Medicine**
**Dr. Mariano Loret de Mola, Executive Director, United States Department of Agriculture (USDA), Food Safety and Inspection Services District 90 (AL, MS, TN)**
**Dr. Mary Currier, Epidemiologist, State Department of Health**
**USDA, Animal and Plant Health Inspection Service, Jackson, MS personnel**
**Dr. William Leese, USDA, Director of Federal/State Relations**
**Larry Dillard, Microbiologist in Charge, USDA, Food Safety and Inspection Service, Office of Public Health and Science's Eastern Lab in Athens, Georgia**

**Dr. Roger Easley, Director of Productive Medicine and Diagnostic Services, MSU College of Veterinary Medicine**
**American Association of Veterinary Laboratory Diagnosticians**

> ***One fails to understand how in approximately one hour the PEER Committee could come to the conclusion that our quality control was lacking unless a preset agenda was being fueled by some disgruntled present and former employees. Especially when the AAVLD accreditation committee (two people who are recognized experts in chemistry and toxicology) who spent two days here looking over our procedures, determined that "what we do, we do well."*** **[pp. 21-22]**

**<u>Basis for PEER's Conclusion:</u> PEER reasserts that the lab had inadequate procedures in place to address quality assurance or quality control issues. The lab's accrediting organization, the American Association of Veterinary Laboratory Diagnosticians (AAVLD), recommended in its February 1997 review of the lab that the lab appoint a quality control coordinator. The AAVLD's recommendation stated, "It would be desirable to designate a quality control coordinator for the laboratory to periodically review the standard operating procedures manuals and review AAVLD requirements in QA/QC." At the time of PEER's fieldwork for this review in February 1998, the Lab Director had not appointed this coordinator.**

> ***The Chemistry department handles approximately four thousand cases a year and we were cited on two cases. This is about 0.05% of the total cases that we handled. One could possibly feel that a 99.95% no complaint record is a very good record.*** **[p. 22]**

**<u>Basis for PEER's Conclusion:</u> Dr. Rogers has argued that the cases reviewed by PEER were only a few of the thousands handled by the laboratory. Due to time constraints, PEER could only investigate the initial allegations and then, upon determining the validity of those allegations, review the lab's quality assurance system which should have prevented such errors from occurring or at least detected such errors. PEER staff took a purposeful sample of the records involved in the allegations, but did not attempt to establish an error rate. Thus, PEER did not extrapolate a correct rate or "no complaint" record.**

**Although the allegations reviewed by PEER, which proved to be true, made up a small proportion of the lab's caseload, the absence of critical controls to prevent and detect errors demonstrates the potential for other errors to occur without detection.**

***In response to recommendation number four, the person making the complaint called the Federal Area Veterinarian in Charge who in turn called APHIS in Washington, D.C. The person in Washington, D.C. told the Area Veterinarian in Charge there was no problem with the way the procedure was being done and no accreditation of license violation had occurred.*** **[p. 22]**

**Basis for PEER's Conclusion:** **PEER staff spoke to USDA, Animal and Plant Health Inspection Service (APHIS) personnel in the Jackson office on February 24, 1998, to determine if APHIS policy allowed for a poultry company employee to inspect the flocks. Personnel reported that the policy was worded this way, but that when this was brought to the attention of Dr. Deborah Brennan, Federal Area Veterinarian in Charge, she sent a certified letter to each poultry company notifying them that they must obtain a veterinarian of record. PEER workpapers contain a copy of such letter, which states, "A notarized statement and signature is now required from the veterinarian supervising your flocks stating that your flocks are currently under his/her veterinary supervision and have been during the preceding six months."**

**Although the USDA policy originally allowed non-veterinarians to inspect the flocks, this policy violated the American Veterinary Medical Association's positions discussed on page 12 of this report.**

***To the best of my knowledge, samples sent out of this laboratory to checkup on technicians without the laboratory director's approval have had no established chain of custody. . . However, any laboratory results that are claimed to be wrong because another laboratory comes up with a different result has to be viewed with suspicion if there is no established chain of custody or paper trail.*** **[p. 22]**

**Basis for PEER's Conclusion:** **Dr. Rogers makes a valid point concerning the integrity of samples due to a questionable chain of custody. While PEER cannot certify or document the chain of custody of the sample sent to Texas, the fact that the Texas Veterinary Medical Diagnostic Lab concurred with three other Mississippi Veterinary Diagnostic Laboratory labs (necropsy, serology, and virology) gives PEER no reason to question the integrity of the sample.**

***I - Errors Identified in Allegations and Confirmed by PEER***
**[pp. 23-26]**

**Basis for PEER's Conclusion:** **As discussed on page 9 of PEER's report, the lab's official record documents that microbiology lab personnel used a 30**

**mcg control disc in this case. Larry Dillard, Microbiologist in Charge at the United States Department of Agriculture, Food Safety and Inspection Service, Office of Public Health and Science's Eastern Lab in Athens, Georgia, confirmed that a 5 mcg Neomycin disc should be used. According to correspondence from Mr. Dillard, "The purpose is to evaluate the STOP plate's sensitivity. Obviously the use of a disc of standard potency is required. The 5 mcg disc should produce a zone of inhibition of 18-20 mm. A 30 mcg disc should produce a significantly large zone. If a STOP plate has sparse growth of the seeded bacteria, the 30 mcg disc could result in very large zones which would not give an adequate assessment of the plate's sensitivity."**

**Dr. Rogers states, "Attached is a FAX sent to the lab's chief microbiologist by the EDITEK company which describes in details the components of the test kit used." The referenced document does not provide detail as to the size of the disc; rather, it is simply a price list.**

**Dr. Rogers states, "the PEER [sic] made an allegation in which a 'wrong size control disc' was used for antibiotic residue testing in meats, but failed to identify what was done in terms of testing." PEER states on page 9 of its report that the lab's official record documents that microbiology lab personnel used a 30 mcg control disc, rather than a 5 mcg control disc.**

***II - Major Quality Control Problems in Animal-Health-Related Testing and in Food-Related Testing***
**[pp. 27-30]**

**This information is unrelated to PEER's conclusions, which stated that the microbiology lab did not develop written procedures to govern E. coli testing. This response discusses analysis and interpretation of 3M petri films which are used in E. coli testing. PEER did not criticize such analysis and interpretation in the report.**

**Dr. Rogers refers to four documents at the bottom of page 29 as "the following OFFICIAL REFERENCES." PEER agrees with Dr. Rogers that these are official references, to be used in the compilation of policies and procedures, but they do not constitute internal written standards. The Veterinary Diagnostic Laboratory did not develop internal written standard operating procedures or quality control procedures to govern the E. coli testing. These references do not constitute a procedure.**

# PEER Staff

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