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SUMMARY MINUTES

OF THE
MICROBIOLOGY DEVICES PANEL MEETING

OPEN SESSION

July 27-28, 2000

**Gaithersburg Holiday Inn
Whetstone Room
Gaithersburg, MD**

July 27, 2000

Microbiology Devices Panel

Michael L. Wilson, M.D., Panel Chair
Denver Health Medical Center

Margaret R. Hammerschlag, M.D.
State University of NY Health Science Center

Valerie L. Ng, Ph.D., M.D.
San Francisco General Hospital

Carmelita U. Tuazon, M.D.
George Washington University Hospital

Melvin P. Weinstein, M.D.
Robert Wood Johnson Medical School

David T. Durack, M.D., Ph.D., Industry Representative
Becton Dickinson Microbiology Systems

Stanley M. Reynolds, Consumer Representative
Pennsylvania Department of Health

Microbiology Devices Panel Consultants

Ellen Jo Baron, Ph.D.
Stanford Health Services

Douglas M. Hawkins, Ph.D.
University of Minnesota

Frederick S. Nolte, Ph.D.
Emory University School of Medicine

L. Barth Reller, M.D.
Duke University Medical Center

Margot A. Smith, M.D.
Washington Hospital Center

Steven C. Specter, Ph.D.
University of South Florida College of Medicine

John A. Stewart, M.D.
National Center for Infectious Diseases, CDC

Panel Discussants

Col. Erik A. Henchal, Ph.D.
U.S. Army Medical Research Institute of Infectious Diseases

Richard F. Meyer, Ph.D.
National Center for Infectious Diseases

Guest Speaker

Joseph L. Curtis, Ph.D.
SVERDUP Technology, Quantico, VA

FDA Personnel

Freddie Poole
Panel Executive Secretary

Steven I. Gutman, M.D.
Director, Division of Clinical and Laboratory Devices (DCLD)

OPEN SESSION—JULY 27, 2000

Panel Chair **Michael L. Wilson** called the meeting of the Microbiology Devices Panel to order at 10:05 a.m. and asked the panel members to introduce themselves. The Executive Secretary **Freddie Poole** read the conflict of interest statement, noting that limited waivers had been granted to all the panel members and consultants for today's issues meeting. She also noted that the employers of **Col. Erik Henschal, Ph.D.** and **Richard Meyer, Ph.D.**, the panel discussants, have interests in the topic to be discussed. **Dr. Wilson** then stated that the panel's task was to discuss the appropriate types of important, relevant, and reasonable data and information required to assess safety and effectiveness of diagnostic tests intended to identify the presence of biothreat agents, when used on different specimen types, and under different conditions, for evidence of exposure to biothreat agents.

Opening Statement

Elizabeth D. Jacobson, Ph.D., Senior Advisor for Science in the Office of the Commissioner, Food and Drug Administration, stressed that the focus of the day's session was on science and on the types of general scientific evidence needed for characterizing safety and efficacy of assays used to identify organisms used in bioterrorist attacks. These assays include diagnostic reagents and kits that could be used in laboratories on different specimen types to provide evidence of exposure to biological agents. She acknowledged the participation of experts from the Centers for Disease Control (CDC) and the U.S. military, thanking **Col. Erik Henschal, Ph.D.**, from the U.S.

Army Medical Research Institute of Infectious Diseases (USAMRIID) and **Richard Meyer, Ph.D.** of the CDC, and guest speaker **Joseph L. Curtis, Ph.D.** of the SVERDUP Technology, Inc. for their help. She concluded by stressing the need for cooperation on this topic among the military, the scientific community, the regulatory agencies, and law enforcement groups.

Overview of Issues

Steven I. Gutman, M.D., M.B.A., Director of the Division of Clinical Laboratory Devices emphasized that the objective of today's meeting was to have a scientific review of the general types of evidence needed to support premarket safety and effectiveness decisions for reagents and test kits used to identify biothreat agents. Dr. Gutman said that the focus of the day's session was on *in vitro* products used to test cultures from human specimens, and emphasized the critical role of laboratories in bioterrorism preparedness.

Dr. Gutman explained the various types of intended uses for these assays, such as direct detection from human samples, detection in human specimens prior to culture, identification of isolates recovered from cultured specimens, and serologic identification of human host response as an indication of infection or exposure. He also presented some challenges in detecting these agents, the safety requirements involved in handling biothreat agents, the limitations that exist with using banked specimens, and the difficulties in culturing certain agents. Dr. Gutman concluded by presenting three questions for panel consideration.

Colonel Erik Henschal, Ph.D. of USAMRIID provided information on the Department of Defense (DOD) research program on medical diagnostics. He presented an overview of the chemical/biological defense doctrine and listed more than 50 possible infectious and biological diseases. Col. Henschal provided information on an analysis of clinical specimens in three different patient scenarios: early, acute, and late exposure, and described the use of an integrated process for identification of agents in clinical specimens.

Col. Henschal explained the laboratory response network for bioterrorism, with different levels of capability for detection, which was developed to fulfill a requirement for a comprehensive system for global response. He described the 520th Theater Army Medical Laboratory and its responsibilities, particularly in regards to special pathogens sample testing, and development of tools for rapid specimen preparation and portable gene amplification detection. He stated that avoiding technological surprise by broadening reagents to detect infection early through use of biomarkers is critical. He suggested that evaluation studies should include analytical specificity, sensitivity, detection limits, precision, and reproducibility—all of which must be evaluated for each specific agent. Evaluation trials have been conducted in the lab, on animals, in the field, and in hospitals, using a standardized nucleic acid panel. He concluded with a description of proposed model systems for biothreat and infection which use a bacterial reference collection and a specimen hierarchy.

Richard Meyer, Ph.D. of the Bioterrorism Rapid Response and Advanced Technology Laboratory, NCID, CDC, described the joint CDC/DOE effort to develop and validate tailored assays for the user community. The objective of this effort, he

stated, is to develop and provide assays to public health organizations for detection and identification of possible biothreat agents. The two main assay formats are molecular, which identifies unique target specific sequence signatures, and antigen detection, which identifies highly specific antibodies to each agent. Dr. Meyer defined the terms used in assay development process, as well as the steps in that process. Assay in-house evaluation is based on specificity, sensitivity, and the clinical matrix used. Assay validation is based on a multi-center, collaborative study, involving five to ten public health labs, military labs, and other participants using a specific preparation. Performance analysis, such as accuracy and reproducibility, determines if assays are ready for dissemination through the CDC National Public Health Network of tiered laboratories.

OPEN PUBLIC HEARING

There were no requests to address the panel.

Guest speaker **Joseph Curtis, Ph.D. of SVERDUP Technology, Inc.** presented the Advanced Concept Technology Demonstration involving a Chem–Bio Individual Sampler that detects exposure of the individual war fighter and measures sub-clinical exposure to chemical-biological agents. The analyzer unit uses light to detect upconverting phosphor reporter (UCR)-technology-labeled antibodies in a lateral flow immunoassay. This system detects and measures individual exposure at sub-clinical levels from environmental samples.

OPEN COMMITTEE DISCUSSION

Dr. Wilson opened the Committee discussion by asking if there were any other questions of the speakers or issues that could be addressed. There being none, Dr. Wilson suggested that the panel address FDA's questions:

Question # 1: What types of data and information would be considered appropriate to evaluate safety and effectiveness when these assays are used to: a) identify culture isolates from human specimens, b) to detect the agents directly, and c) to determine exposure in clinical labs or at point of care?

The panel recommended that sensitivity of the assays should be close to 100% when used for 'rule-out' type assays in level A laboratories in the civilian sector because an effective response to unannounced events would be dependent on accurate laboratory information.

The panel also acknowledged the importance of specificity for mass exposure and the announced event.

Question # 2: To determine or infer effectiveness for these devices, can specimens from naturally or experimentally infected animals be used when appropriate specimens from humans cannot be obtained?

The panel suggested that spiked samples were valuable for analytical studies, but would have limited use for predicting performance with clinical specimens. They suggested that while no animal model appears appropriate as a surrogate for humans, animal models could be useful for estimating exposure variables and providing a source of infected specimens (vs. spiked specimens) to study matrix effects. They cautioned that animal testing should not be expected to duplicate performance with human specimens. They

recommended that animal testing should be limited to those types of studies that could get relevant performance information, that preliminary animal testing be done with the lowest level animal possible, and that specimens from infected animals could also be used for comparing different tests.

Question # 3: Are there issues not addressed in above questions, that would impact on reliability of using these assays for evidence of human exposure or infection?

The panel responded that specimen handling and storage conditions were very critical to detection of agents. They recommended that specimen handling and storage conditions should be evaluated. Studies to assess specificity of the assay should include testing of a substantial number of specimens from normal individuals and also a broad range of potential conflicting agents. Validation is critical for each instrument and each reagent. Additionally, the rationale for why testing was conducted on certain agents should be provided.

The panel noted that there is such a wide array of biothreat agents and samples that no one size test or specification fits all needs. Because such tests are to be used infrequently, there should be studies done to evaluate proficiency testing, stability data on controls, inter-user variability, and shelf life limitation. Risks to users should be noted. CLIA regulations and requirements on performance in the hands of untrained users should be stressed.

OPEN PUBLIC HEARING

Jack Sewiki of Geomet Technologies suggested that the FDA spur development

of commercial kits by providing specific guidance for industry to follow. Mr. Sewiki also asked the panel and FDA to consider how environmental testing could be validated to help First Responders, many of whom are now purchasing unregulated kits. He suggested that the FDA address regulation of such kits, which may or may not have been validated using a standardized format. He noted that many government agencies provide grants for preparedness, which are used to purchase such devices, the end result of which is more widespread use of unvalidated detectors.

Final Panel Recommendations

The panel recommended that the standards for tests used to identify biothreat agents become progressively more challenging. The panel suggested that appropriate cross-reactivity studies are important, and interference and inter-observer variability should be determined adequately. Both sensitivity and specificity are very important. It is key to specify the rationale for use of spiked specimens, choice of appropriate matrix, and method of specimen collection. Because animal studies can be a problem with some isolates, animal studies should not be a requirement for investigational studies. Commonly, while no animal model appears appropriate as a surrogate for humans, animal studies can provide some useful information on particular agents. It was recommended that preliminary animal testing be done with the lowest level animal possible.

Dr. Gutman thanked the panel and presenters and invited them to submit any further comments. **Dr. Wilson** also thanked the panel discussants, the guest speaker, and

the panel members and consultants for their participation, and then adjourned the session for the day at 3:30 p.m.

July 28, 2000

Microbiology Devices Panel

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Baylor University, College of Medicine

Steven C. Specter, Ph.D., Temporary Voting Member
University of South Florida College of Medicine

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Steven I. Gutman, M.D.
Director, Division of Clinical and Laboratory Devices (DCLD)

John R. Ticehurst, M.D.
Medical Officer, Microbiology Branch

OPEN SESSION—JULY 28, 2000

Panel Chair **Michael Wilson, M.D.** called the meeting to order at 9:05 a.m. and asked the panel members and consultants to introduce themselves. The Panel Executive Secretary **Freddie Poole** announced that Dr. Wilson's appointment as Panel Chair was confirmed. She then read the conflict of interest statement, noting that a limited waiver had been granted allowing Dr. Baron to participate, but not vote, and that matters concerning Drs. Hammerschlag and Hollinger had been considered and their full participation was allowed.

New Business:

Jean Toth-Allen, Ph.D., from the Office of Compliance, Division of Bioresearch Monitoring, presented information on IVD device development, component, and feasibility testing on human tissue samples, and the regulations concerning institutional review boards (IRBs). She stated that an IRB must review all studies supporting submissions using human subjects and /or specimens, and the review cannot be waived by anyone other than the FDA. It may be exempted if the risk to subjects is minimal.

For repository collections, research samples, and identification of subjects, she explained that the FDA is adopting the same terminology as the National Bioethics Advisory Commission (NBAC). The NBAC August 1999 Report on research involving human biological materials cited the concern for the safety and welfare of study subjects. Informed consent is now recommended for IRB-approved prospective studies and "repository" sample collections, and documentation for banked samples because of issues

such as consent information and privacy laws and other legal considerations. Dr. Toth-Allen noted that there were state and local government differences on legal questions involving privacy and health insurance. She concluded by providing web sites for IVD guidance on clinical trials and information on human subject protection.

Panel members asked Dr. Toth-Allen about the effect of the IRB requirement in “gutting” research efforts and about the need for informed consent even for repository or banked sample specimens. She replied that there are more legal issues involved in protection of privacy and that this was an educational effort to raise panel awareness of this issue. A question was raised on use of banked specimens, to which Dr. Toth-Allen urged consultation with whichever division/branch responsible for the device in question. In answer to a panel question on whether she was suggesting general IRB consent for all microbiology studies, she replied that this was the advice currently provided by NBAC.

Clara A. Sliva, Acting CLIA Coordinator in the Division of Clinical Laboratory Device, presented new information on the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and reported on CLIA categorization at the FDA. She stated that since January 2000 the FDA was responsible for the categorization of commercially marketed test systems, and the CDC was responsible for the categorization of laboratory procedures.

Ms. Sliva outlined the history of regulatory provisions for waiving CLIA provisions. She noted that a CLIA waiver workshop was planned for August 14-15, 2000, for interested parties such as consumers, the medical community, and industry, and

that this workshop will revisit the criteria for CLIA waivers. Ms. Sliva concluded that it is unclear whether the waived test list will be expanded or limited in the future.

There being no further questions of the FDA presenters, Dr. Wilson closed the Business section and began the Open Discussions of the PMA.

PRESENTATION OF THE PREMARKET APPROVAL APPLICATIONS

Dr. Wilson reminded the panel that their today was to consider two premarket approval applications (PMAs) from Roche Molecular Systems (RMS). The devices are nucleic acid amplification in vitro diagnostic qualitative devices to detect hepatitis C virus (HCV) ribonucleic acid (RNA). They are the AMPLICOR HCV test v. 2.0 and the semi-automated version COBAS AMPLICOR HCV Test v. 2.0, neither of which is intended for blood donor screening.

Sponsor Presentation

Mr. David B. Thomas, Vice President for Clinical and Regulatory Affairs for RMS, presented a brief summary of the devices. He stated that because 1) this product was the first to seek approval as a direct test for HCV RNA; 2) of the limitations of the available quantification methodologies to characterize HCV; and 3) there is no independent gold standard for assessing clinical HCV infection, he would focus his discussion on the specifics of the devices and the product labeling.

Karen Gutekunst, Ph.D., Director of Product Development for RMS, provided an overview of the nonclinical performance data. She presented a description of the technology of the assays, a brief background of HCV and the structure of the HCV virion RNA, and described how the new assay differed from the Roche version 1.0 assay. She also explained the kit format and test procedure. Dr. Gutekunst provided an overview of the nonclinical studies performed and explained how preliminary cutoff determinations were conducted. She discussed the WHO International Standard for HCV RNA assays 96/790, and the National Institute of Biological Standards and Controls (NIBSC) working reagent. She presented results of the anti-HCV seroconversion panels. Dr. Gutekunst stated that the specificity studies showed no cross-reactivity to other microorganisms or viruses and no interference by endogenous and exogenous substances and co-infections. She explained the design of the reproducibility study and concluded by stating that the assay performance on serum and plasma demonstrated comparable detection of HCV in serum, ACD plasma, and EDTA plasma. Studies conducted to evaluate genotype detection provided evidence of detection, and produced comparable detection of known genotypes of HCV.

Michael Fried, M.D., Consultant to RMS and Principal Investigator for the Clinical trials, presented information on the use of PCR assays for detection of HCV viremia. He summarized the principles of patient evaluation, the risk factors for hepatitis C, and he compared the available screening methods for HCV. Dr. Fried concluded that diagnosis of chronic hepatitis C involves multiple modalities, including history, exam, lab tests, and liver biopsy. Supplemental assays, such as RIBA, are most useful in the low-risk patient population. HCV RNA testing is required to determine the presence of active

viremia and is the second-line test of choice for patients with suspected chronic hepatitis C infection. Genotypic differences are unlikely to affect diagnosis of hepatitis C, given the high levels of HCV RNA in untreated patient populations.

Alison Murray, M.D. Director of Clinical Affairs at RMS, discussed the clinical performance of the devices. She stated the objectives of the clinical study and described the four study sites. She described the reference methods used to evaluate the performance of the two devices; i.e., anti-HCV enzyme immune assay (EIA 3.0), anti-HCV recombinant immune blot (RIBA 2.0), alanine transaminase, and liver biopsy histology reports, if available. She described the patient groups evaluated and the demography of those subjects. She stated that the analysis of the performance of the devices, when compared to anti-HCV serology and to ALT and liver histology, demonstrated that the assays performed consistently across matrices, patient groups, and sites. The majority of the assay results were supported by serologic testing. When serologic testing was not available, the results were supported by the ALT level, the histology data, the clinical history, and/or alternate PCR assays. There was a very high percentage of agreement with serology, ALT levels, and liver histology for those patients with histology data.

Dr. Murray concluded that these data support the clinical utility of the devices for testing patients with liver disease and antibodies to HCV. Both tests performed consistently and were specific and sensitive at the 50 IU/mL limit and demonstrated comparable detection of all genotypes listed in the consensus classification of HCV. The assays produced comparable detection of HCV in serum, ACD plasma, and EDTA

plasma in nonclinical and clinical studies. The Cobas Amplicor and the Amplicor HCV results were supported by serologic data and clinical evidence of infection.

Dr. Wilson then invited the panel to ask questions of the sponsor.

The Panel questioned the rationale for specimen selection for sensitivity and cross-reactivity studies, the lack of Flaviviruses and inhibitory samples in the selected specimens, interfering endogenous samples, amplicon contamination in specificity studies, and reproducibility study results.

OPEN PUBLIC HEARING

There were no responses from the public to address the panel.

FDA Presentation

John R. Ticehurst, M.D., Medical Officer for the Microbiology Branch, provided a brief background to HCV RNA assays and the challenges involved in appropriately reviewing an HCV RNA assay. He discussed the PMA claims for equivalent detection of HCV genotypes and stated that the FDA would ask the panel to consider the appropriate threshold for determining performance for detecting HCV genotypes, as well as appropriate use of the WHO genotype 1 standard and its international unit quantifier.

Dr. Ticehurst explained that the submission was granted expedited review status because of the public health significance, and that it underwent collaborative review among various FDA divisions and branches, as well as between FDA and the manufacturer. Dr. Ticehurst then discussed the relevance of genotypes and subtypes and presented FDA's

analysis of the RMS studies. He described the clinical studies for a diagnostic indication and the lack of data that could demonstrate anti-HCV seroconversion. He stated that no data was submitted for monitoring of chronic infection. He discussed the Indications for Use and the warning statements presented by the sponsor in the package inserts and closed by presenting the FDA questions to the panel.

Dr. Wilson then invited the panel to ask questions of the sponsor or the FDA. The questions were all directed to the sponsor concerning the false positive results in the specificity study, the reactivity of a patient with primary biliary cirrhosis, and HCV genotypes.

OPEN COMMITTEE DISCUSSION

Dr. Wilson invited the panel to begin the committee discussion by first addressing the FDA's questions.

Question # 1: Is the proposed indications for use appropriate? "The Amplicor HCV test is indicated for patients who have liver disease and antibodies to HCV that were detected by enzyme immunoassay and immunoblot assay, and who are suspected to have active HCV infection. Detection of HCV RNA is evidence of active HCV infection but does not distinguish between acute and chronic infection."

The panel suggested revising the proposed indication for use to remove the phrase "that were detected by enzyme immunoassay and by immunoblot assay." The Warning statements should be revised as follows: Bullet #1 should read "Performance has not been

demonstrated for diagnosis of individuals who were not tested for antibodies to HCV.”

Bullet # 2 should be revised to include that “Performance has not been demonstrated for monitoring of progress of disease.” Bullet # 3 should be revised by deleting the last clause of the statement to read “Although a wide range of HCV genotypes can be detected, analytical sensitivity and other performance characteristics have not been determined for all HCV genotypes.”

Question # 2: Based on data submitted to support the proposed indications for use, are the data from patients who were treated with antiviral agents or who had received a liver transplant, appropriate for evaluating the diagnostic indications for use? Were the data appropriately analyzed? Are data sufficient for determining specificity in appropriate populations? Should additional instructions be provided for interpreting an ‘HCV RNA not detected’ result? Do the data support the proposed indication?

The panel suggested that the data on the 31 patients treated with antiviral agents or who had received a liver transplant could be included in the package insert for information only and no claims should be made for testing these type of patients. The panel had no comment on whether clinical data were appropriately analyzed. The panel members thought the data were not sufficient for determining specificity in appropriate populations but provided useful information. As to whether additional instructions should be provided to laboratories and primary care clinicians for interpreting a result of “HCV RNA not detected,” the panel suggested use of an algorithm. A statement should be added about not diluting the test specimen for further testing if results were unclear; a new specimen should be used. The data on interference from heparin were clear and

should be included in information provided by sponsors. Data on dialysis patients were limited.

Question # 3: Based on data submitted for detecting HCV genotypes and subtypes; and to verify performance to the WHO Standard for genotype 1 RNA, are the proposed warnings and limitations appropriate, and should additional genotype studies or other approaches be done?

The panel suggested that if there were specific claims made for specific genotype detection then the studies should confirm this. The panel did not suggest any other confirmatory methods other than PCR.

Question # 4: Concerning standard reference materials, how should quantitative data such as limits of detection be expressed with reference to the WHO Genotype 1 Standard?

The panel recommended that the device package inserts should state that the limits of detection of the test could be described as genome equivalents in terms of IU, which correlates to the WHO Genotype 1 standard. The panel commented that most HIV PCR assays and other HCV assays saw differences between plasma and serum, but Amplicor exhibited no differences. The sponsor noted that there were no reproducible differences between various matrices probably because this was a qualitative assay and they deliberately over-sampled in order to have adequate sample.

There were additional discussions on the package insert, the position of the controls in the run, a clear explanation of the manual separation technique, and training

and certification for the technologists. The panel noted that the package insert should clearly state that if the internal control is invalid, the entire run is invalidated.

OPEN PUBLIC HEARING

There were no requests to address the panel.

FDA Closing Comments

The FDA made no additional remarks.

Sponsor Closing Comments

The sponsor thanked the panel for their useful and interesting comments.

FINAL RECOMMENDATIONS AND VOTE

Freddie Poole read the voting options and instructions, and identified the voting and temporary voting members.

The Panel voted separately on each PMA. It was moved and seconded that the Amplicor HCV (version 2) NAT test PMA be approvable with conditions as follows:

- 1) A phrase should be deleted from the indication for use so that it reads as follows: "The AMPLICOR HCV Test is indicated for patients who have liver disease and antibodies to HCV and who are suspected to have active HCV infection. Detection of HCV RNA is evidence of active HCV infection but

does not distinguish between acute and chronic states of infection.” (This motion carried unanimously.)

- 2) The third bulleted warning should be amended as follows: “A negative AMPLICOR HCV test result does not exclude active HCV infection. Although a wide range of HCV genotypes can be detected, analytical sensitivity and other performance characteristics have not been determined for all HCV genotypes.” The panel recommended that a statement, to be worked out by the company and the FDA, be included that lists any genotype or subtype numbers. (This motion carried unanimously.)
- 3) A warning should be added about the use of heparin interfering with the test. (This motion carried unanimously.)
- 4) An HCV RNA test with an indeterminate result should not be diluted to retest the same assay specimen, but rather a new specimen should be collected. (This motion passed unanimously.)
- 5) The second warning bullet should be revised to state: “Performance has not been demonstrated for monitoring of disease progression in HCV-infected patients or of response to treatment.” (This motion passed unanimously.)
- 6) Whenever quantitative data is noted in the package insert, it should be noted that the standard was based on the WHO 1 Standard IU/mL of the international standard for HCV genotype 1.” (This motion passed unanimously.)

(A motion to state that HCV RNA had not been detected in hemodialysis patients was withdrawn, as was a motion to add to the second bullet that further serologic testing may be indicated to elaborate the result of "HCV RNA not detected.")

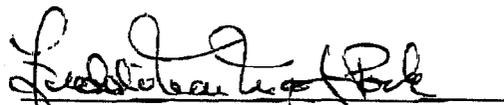
The Panel also recommended that the AMPLICOR placement of controls in the microwell plate be addressed in the labeling and that the sponsor submit reproducibility data to the FDA.

The motion to recommend the PMA as approvable subject to the above conditions was unanimously passed. The panel members stated that they voted for Approvable with Conditions because they thought the device was a safe and effective test for measuring HCV RNA, but the application required some revisions to the labeling and the FDA's satisfactory analysis of the reproducibility data.

The Panel agreed that the AMPLICOR COBAS HCV NAT Test was essentially the same as the AMPLICOR HCV test and that the same conditions apply. It was moved, seconded, and unanimously agreed to recommend the AMPLICOR COBAS as Approvable with conditions, the conditions being identical to those above.

Dr. Wilson thanked the panel members and consultants, and the FDA for their participation. He commended the sponsor for a very well presented application. The meeting was adjourned at 4:00 p.m.

I certify that I attended
the Meeting of the Microbiology
Devices Panel on July 27-28, 2000,
and that this summary accurately
reflects what transpired.



Freddie Mae Moody Poole
Executive Secretary,
Microbiology Devices Panel

I approve the minutes of this meeting
as recorded in this summary.



Michael L. Wilson, M.D.
Panel Chair

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