Brief Summary of the Joint Advisory Committee Meeting of the Microbiology Medical Devices Panel and the Blood Products Advisory Panel March 22, 2018

Introduction

The Microbiology Devices Panel of the Medical Devices Advisory Committee and the Blood Products Advisory Committee met on March 22, 2018 to discuss and make recommendations for the reclassification of HCV Antibody Tests and HCV Nucleic Acid Based Tests Used as aids in the Diagnosis of HCV Infection and/or aids in the management of patients infected with HCV. These tests are currently regulated as Class III, premarket approval (PMA) devices and are under consideration for reclassification into Class II (special controls) for which a premarket notification (510(k)) would be required. FDA was seeking recommendations from panel members and the public on whether sufficient information exists to allow the development of special controls.

FDA Question: HCV

Do Panel members believe that the risks associated with the following HCV tests can be mitigated through special controls:

1) Anti-HCV tests
2) Quantitative and Qualitative HCV RNA tests, and/or
3) HCV Genotyping tests?

Please include in your deliberations a discussion of whether the panel believes that certain modifications to the design of a device (e.g., stability and final release criteria) would be likely to significantly affect the performance of the device and, as a result, its safety and effectiveness.

Panel Deliberations

All panelists recommended down classification of HCV Antibody tests and Nucleic Acid Based Tests to Class II, and agreed with the development of special controls as presented by the FDA.

In addition, many panelists encouraged sponsors to consider gathering more data from pediatric populations and other subpopulations during clinical studies of devices. The panel agreed with the FDA proposed performance criteria to mitigate the risks associated with these diagnostic

devices; however, the panel felt that future technologies with respect to rapid point of care tests may require modified performance criteria. FDA agreed that performing benefit risk analysis for new devices based on a device's specific intended use may allow flexibility for different performance criteria with devices significantly different than those currently marketed. .

Panelists expressed concern about post market data, since annual reporting is not required for Class II devices. Drs. Gitterman and Schlottmann noted that FDA has carefully reviewed the medical device reports and there have been very few adverse events associated with these devices since marketing. It was also mentioned that FDA could require Annual Reporting in the special controls if felt necessary to assure safe and effective use. In addition, some panelists would like to see that the special controls address possible use of a lower performing predicate device and, accordingly, the 'slippery slope' of performance. Panelists unanimously recommended down classification, and expressed the opinion that no current devices should be removed from the market if they did not meet higher performance criteria that might be included in special controls for new devices.

Public Speakers

One speaker representing Roche Molecular, Inc. presented to the panel members and audience.

Guest Speakers

Dr. Arthur Kim, M.D. presented on Testing for Hepatitis C Virus: A Clinician's Persepctive and;
Dr. Saleem Kamili, Ph.D. presented on Laboratory Diagnostics of Hepatitis C

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