

pharmacogenomics and toxicogenomics; however, next-generation sequencing technologies promise to provide some unique advantages in DNA and RNA analyses and are expected to be adopted by the pharmaceutical and medical industries for advancing personalized nutrition and medicine.

Starting in 2005, FDA initiated an open project, MicroArray Quality Control (MAQC), which has gone through three phases. MAQC-I focused on the technical aspects of microarray-based gene expression measurements, the MAQC-II focused on validation of microarray-based predictive models, and MAQC-III, which is also called the Sequencing Quality Control (SEQC), focused on assessing the performance of whole transcriptome sequencing (RNA-seq).

The Sequencing Quality Control Phase 2 (SEQC-II) is a natural extension of the SEQC project with emphasis on DNA-Seq for various applications. The SEQC-II project, with broad participation from scientists and reviewers within FDA and collaborators across the public, academic, and private sectors, is expected to help prepare FDA for the next wave of submission of genomic data generated from the next-generation sequencing technologies.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by August 31, 2016. FDA will email a confirmation to those who have registered. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. No registration on the day of the public workshop will be provided.

If you need special accommodations due to a disability, please contact Weida Tong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on July 21 and July 22, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 1116, 10903 New Hampshire Ave., Silver Spring, MD 20993; patricio.garcia@fda.hhs.gov; 301-796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On July 21, 2016, the committee will discuss, make recommendations, and vote on information regarding a premarket approval application (PMA) panel-track supplement for a proposed change in intended use of Dexcom, Inc.'s, Dexcom G5® Mobile Continuous Glucose Monitoring System (CGM) device so that, in addition to tracking and trending interstitial fluid glucose concentrations, patients can use the device as a replacement for their blood glucose meters and make treatment

decisions based on the interstitial fluid glucose concentration reported by the CGM.

On July 22, 2016, the committee will discuss and make recommendations on information regarding a premarket notification (510(k)) submission for the Alere Afinion™ HbA1c Dx point-of-care test system, sponsored by Alere Technologies AS. The proposed intended use, as stated by the sponsor:

Alere Afinion HbA1c Dx is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in human whole blood. This test is to be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus. For use in clinical laboratories and point of care laboratory settings.

Current clinical guidelines contraindicate the use of point-of-care hemoglobin A1c (HbA1c) tests to diagnose diabetes. FDA is seeking feedback from the clinical community to determine significant, scientific and practical, reservations or support for using this point-of-care HbA1c test as an aid in the diagnosis of diabetes and pre-diabetes.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 15, 2016. Oral presentations from the public will be scheduled on July 21 and 22, 2016, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 7, 2016. Time allotted for each presentation may be limited. If the

number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 8, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams, at Annmarie.Williams@fda.hhs.gov, or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 24, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Ricky Malhotra, Ph.D., University of Michigan and University of Chicago: Based on the Respondent's admission to committing research misconduct at the University of Michigan (UM) and subsequently at the University of Chicago (UC), the reports of separate investigations conducted by UM and UC, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Ricky Malhotra, former Research Assistant Professor, Department of Internal Medicine, UM,

from 2005–2006, and Research Assistant Professor, Department of Surgery, UC, from 2007–2011, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants K08 HL081472 and R01 HL107949.

ORI found that falsified and/or fabricated data were included in the following three (3) NIH grant applications, one (1) NIH grant progress report, one (1) publication, seven (7) presentations, and one (1) image file:

- R03 AG029508–01
- R21 AG030361–01
- R01 HL102405–01
- K08 HL081472–05 Progress Report
- *J Biol Chem.* 285(18):13748–60, 2010 Apr 30 (hereafter referred to as “*JBC 2010*”)
- Presentation: Autophagy Pathway.ppt, MKK4 expression after UV.ppt, Oct Ppt.ppt, RicDec.ppt, Ricky Presentation 06.ppt, Ricky STC.ppt, and RM.ppt
- Image file: Final LC 3.jpg

ORI found that Respondent reused and falsely relabeled Western blot gel images, falsified the related densitometry measurements based on the falsified Western blots, and falsified and/or fabricated data for experiments that were not performed. Respondent continued this falsification at UC, after the UM research misconduct investigation was completed. Specifically:

- While at UM, Respondent falsified and/or fabricated images in R03 AG029508–01 and three (3) presentations, where:
 - R03 AG029508–01, Figure 2, represented Western blots for phosphorylated p53 (Ser15) and β -actin expression in normal and Snell dwarf mice fibroblasts (mN/SF) treated with the DNA alkylating agent methyl methanesulfonate (MMS), when the same images were duplicated to represent different proteins and treatments in the presentations Autophagy Pathway.ppt and RM.ppt.
 - R03 AG029508–01, Figure 3, represented Western blots for p16^{Ink4a} and β -actin expression in mN/SF, when the same images were duplicated to represent different proteins and treatments in the presentations Autophagy Pathways.ppt, RicDec.ppt, and RM.ppt.
 - While at UM, Respondent fabricated data in R21 AG030361–01 and supporting data for the grant application in the research record, where:
 - R21 AG030361–01, Figure 2, represented a Western blot for

phosphorylated c-Jun-N-terminal kinase (JNK) expression in mN/SF exposed to cadmium, when the experiment was not performed.

- The research record contained ninety (90) Western blot images and ninety (90) densitometry measurement files for 45 experiments that examined phosphorylated JNK or Mitogen-activated protein kinase 4 (MMK4) expression in mN/SF exposed to UV light, H₂O₂, cadmium, or anisomycin, when the experiments were not performed.

- The research record contained densitometric analyses for an additional twenty-eight (28) experiments that examined phosphorylated JNK or MMK4 expression in mN/SF exposed to UV light, H₂O₂, cadmium, or anisomycin, when the quantifications were based on experiments that were not performed.

- While at UM, Respondent falsified and/or fabricated Western blots for phosphorylated and total Rac1/cdc42 expression in mN/SF, total JNK expression in mN/SF treated with anisomycin, phosphorylated JNK expression in Snell dwarf mice fibroblasts treated with cadmium, β -actin expression in mN/SF, β -actin expression in Snell dwarf mice fibroblasts treated with or without MMS, β -actin expression in normal mice fibroblasts treated with cadmium, and β -actin expression in mN/SF treated with H₂O₂ in the presentations Autophagy Pathway.ppt, Oct Ppt.ppt, RicDec.ppt, Ricky Presentation 06.ppt, Ricky STC.ppt, and RM.ppt, and the image file Final LC 3.jpg, when the images were duplicated and falsely relabeled Western blots of unrelated experiments.

- While at UM, Respondent falsified twenty-four (24) Western blots for phosphorylated JNK or MMK4 expression in mN/SF exposed to UV light, H₂O₂, cadmium, or anisomycin in the seven (7) presentations and twenty-six (26) data files in the research record, when the images were duplicated and falsely relabeled Western blots of unrelated experiments.

- While at UC, Respondent falsified and/or fabricated Western blots by using images from unrelated experiments and the related densitometric analyses that were based on falsified Western blots in the following:

- R01 HL102405–01 for:
 - Figure 1A for phosphorylated Rhodopsin (Rho) expression in neonatal rat ventricular cardiac myocytes (NRVCM) subjected to stimulation with Angiotension II (Ang II)