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September 20, 2016

Lori D. White, Ph.D., PMP
NTP Designated Federal Officer
NIEHS/NIH
P.O. Box 12233, MD K2-03
Research Triangle Park, NC 27709

Sent via email to whiteld@niehs.nih.gov

Re: Public Comments for the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) annual meeting

Dear Dr. White:

Thank you for the opportunity to submit comments regarding development of a strategy for implementing the vision for Toxicity Testing in the 21st Century. I hereby endorse the remarks submitted by the Center for Responsible science, specifically, section 1.A. Regulation: Advancing Innovation and use of Human-Relevant Test Methods through ICCVAM Member Agency Regulation Updates.

A substantial roadblock to advancement of modern test methods is that scientific progress is outpacing changes in regulatory standards.[1] The FDA states it has flexibility to accept non-animal test methods (NATMs), such as in vitro studies or prior experience with the drug or biological product in humans.[2] However, current regulations do not reflect this flexibility, and de facto require animal testing, discouraging the use of non-animal tests which may be more predictive of human response.

A simple first step would be to amend current FDA regulations to reflect stated policy. NIH Director, Francis Collins, said in a hearing on the FY2017 National Institutes of Health Budget Request, that animal testing for assessing toxicity of pharmaceuticals will largely be replaced by human tissue chips and induced pluripotent

[1] SACATM Background Document: A Strategy for Implementing the Vision for Toxicity Testing in the 21st Century. http://ntp.niehs.nih.gov/ntp/about_ntp/sacatm/2016/september/vision20160927_508.pdf

[2] Letter from David H. Dorsey, Acting Deputy Commissioner for Policy, Planning and Budget, Food and Drugs to Katherine Meyer, Meyer Glitzenstein & Crystal 3-4 (May 20, 2010), available at http://www.regulations.gov/#!documentDetail;D=FDA-2007-P-0109-0012

stem cells (iPS) within ten years[3]. Dr. Collins also testified that using these methods would provide more accurate results at lower cost[4].

Regulatory language needs to be modified to encourage sponsor use of modern test methods, to broaden testing options for sponsors, and to spark innovation of more predictive methods.

Sincerely,

[Signature Redacted]

Gerry R. Boss, M.D.
Professor of Medicine

[3] United States Senate Appropriations Committee Hearing on FY2017 National Institutes of Health Budget Request, April 7, 2016
http://www.appropriations.senate.gov/hearings/hearing-on-fy2017-national-institutes-of-health-budget-request

[4] *Id.*