September 20, 2016

Lori D. White, Ph.D., PMP
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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. 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. 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


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\textsuperscript{3}. Dr. Collins also testified that using these methods would provide more accurate results at lower cost\textsuperscript{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

\textsuperscript{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

\textsuperscript{4} Id.