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Request for Comments on the Science and Technology Report

We appreciate the fact that Commissioner von Eschenbach solicited this report from the Science Board to the FDA, and that the agency has provided the opportunity to comment. We support many of the ideas presented by the Science Board, and we hope that the FDA will heed this urgent call for change.

We have voiced many of the same concerns in the Mandatory Alternatives Petition (MAP), submitted to the FDA on November 14th, 2007 on behalf of the MAP Coalition. The MAP requests several steps by the FDA to improve preclinical drug testing, standardize FDA review practices, and enhance international harmonization regarding validation and implementation of non-animal drug testing methods.

Our greatest concern is the FDA's inability to keep pace with advances in science and technology and how this deficiency impacts its regulatory responsibilities. The Science Board report finds that the agency's lack of scientific expertise, suboptimal review processes, and information technology (IT) deficiencies render it incapable of evaluating new drug candidates using best practices. Inability to incorporate advances in sciences such as bioinformatics, systems biology, and -omics technologies means the FDA is unable to support, promote, or even implement innovation in drug development.

The Science Board report traces these deficiencies to several factors: evaluation methods that have remained largely unchanged over the last 50 years; reviewers with inadequate training making slow, poor, and/or inconsistent regulatory decisions; a weak IT infrastructure and resultant inability to protect, access, integrate, and analyze data. Through their reliance on outmoded scientific and performance approaches, the agency and its reviewers serve as impediments to innovation, improved preclinical drug testing, and therefore public health and safety.

The Science Board report offers several suggestions for moving the FDA toward the adoption of modern evaluation methods that are more predictive of human outcomes, leading to the development of safer and more efficacious drugs. Chief among them is the need for regular interdisciplinary training sessions for scientific staff and reviewers in areas of emerging science. Also of paramount importance is the need for FDA to take an active role in developing and validating new methods and standards to assess emerging science and technology. In order to access the expertise necessary to close the multitude of scientific and technological gaps highlighted, the report sensibly suggests the formation of extensive internal and external collaborations with academia, industry and other government agencies.

The Science Board report specifically highlights the need for integration of mechanistic and pharmacogenomic knowledge into pre- and post-market safety assessments and surveillance activities. We suggest that mechanistic and genomics knowledge and methods should also be integrated into preclinical testing requirements and FDA reviewer practices as well.

We hope the FDA will accept and implement the Science Board's thoughtful and practical recommendations, and in doing so will not neglect to require the most scientifically sound drug testing methods to be included in New Drug Application submissions, specifically the rapidly expanding population of human-based and non-animal methods.

Sincerely,



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