MRCT Center
14 Story Street
Cambridge, MA 02138 USA

Submitted Via Fax 010 -88,330,728 and Electronically to zhanglc@cfda.gov.cn

China Food and Drug Administration Division General Office
Xuanwumen West Street, Xicheng District, Beijing, China
Zip Code: 100 053

August 11, 2015

Dear China Food and Drug Administration

The MRCT Center of Harvard University and Brigham and Women's Hospital writes to comment on the China Food and Drug Administration (CFDA) proposed draft circular No. 140 "Circular Regarding Several Draft Policy Opinions to Accelerate the Resolution of the Backlog of Drug Applications Issued by the CFDA" which is designed to bring innovative drugs to patients in China more safely and efficiently.[i]

The MRCT Center has three primary goals: (1) to improve the design, conduct, and oversight of multi-regional clinical trials, especially trials sited in or involving the emerging economies; (2) to simplify research through the use of best practices; and (3) to foster respect for research participants, efficacy, safety and fairness in transnational, trans-cultural human subjects research. The MRCT Center does not fund, plan, conduct, or monitor clinical trials, but rather studies their regulatory, practical and ethical aspects, in order to improve design, conduct and oversight of clinical trials.

In this capacity, the MRCT Center commends CFDA for its efforts and regulatory reforms intended to facilitate clinical research in China and to improve its planning, conduct, and oversight. In particular the proposed CFDA reforms to accelerate the approval process for drugs with high clinical need and those that have been or are being submitted simultaneously in the EU and US FDA through a fast-track approval will address the most vital clinical needs quickly. The development of a separate review channel for pediatric medicines is also a critical need that will hasten the availability of necessary medicines to this underserved population.

While we support the proposed draft circular, we respectfully submit the following comments for your consideration.

1. **Considerably increased penalties for those responsible for clinical data fraud**: CFDA has proposed the banning of sponsors from filing submissions for three years if someone in their organization participates in fraud and requiring CROs and sites to requalify in order to submit filings. This proposal would also disqualify the person with direct responsibility for data forgery, for a ten year period, from making regulatory submissions. While the MRCT Center understands the historical backdrop against which this regulation was crafted and fully shares the value of assuring research data integrity, we caution against potential unintended consequences of this measure. For example, this banning of a sponsor for a

three year period from making new drug applications could prevent the Chinese population from access to cutting edge treatments, based on the unscrupulous actions of only one individual employee. It would be more targeted and effective, as a regulatory mechanism, if penalties were focused on individuals who falsify clinical trials data and on requiring industry and academia to implement remedial measures, such as stepped-up data monitoring.

2. **Increased number of reviewers at the CFDA**:

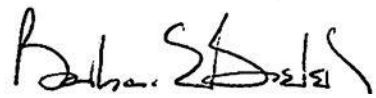
We believe that the CFDA's intent to change the submission of bioequivalence testing from the approval to the filing stage is laudatory; further, the decision to allow sponsors to proceed with testing if they do not hear from the CFDA within 30 days will increase efficiency. In addition, we recommend increasing the number of qualified reviewers at the CFDA to expedite regulatory review. An increased number of reviewers employed by the CFDA would decrease any perception of conflict of interest, and qualified reviewers would be able to identify applications that do not meet quality standards efficiently, returning them to sponsors with requests for revision or rejection in a timely manner.

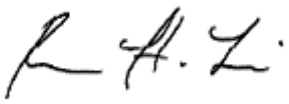
3. **Increased transparency of CFDA review process:**

Resolving the backlog of applications is a worthy goal for CFDA and for China. We encourage CFDA to increase the transparency of this process by periodically posting on the CFDA website metrics on the backlog and how quickly this backlog is being resolved such that progress can be tracked and commended.

The MRCT Center thanks the CFDA for the opportunity to provide comments. We hope the agency finds these comments helpful as you finalize these important regulatory measures.

Respectfully submitted,





Mark Barnes
JD, LLM, Co-Chair, MRCT

Barbara E. Bierer
MD, Co-Chair, MRCT

Rebecca H. Li
PhD, Executive Director, MRCT

[i] The views expressed in this letter represent the opinions of the MRCT Center and do not represent the views of the President or Fellows of Harvard University or of the Brigham and Women's Hospital.