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April 13, 2009

(sent via email)

Dear Honorable Commission Members:

I am expressing my views as someone who has had long experience and extensive involvement in the issue of clinical therapeutics for mental disorders and research on the effectiveness of interventions and treatments. I have been a psychiatrist, active clinically taking care of patients, conducting research on treatment development and evaluating their effectiveness and as an administrator overseeing the development of clinical services for patients with mental illness. In addition, I have been an investigator funded by the NIH over the 25 year course of my career and was the principal investigator of the NIMH-CATIE trial.

It has been clear to me for some time and particularly in the wake of the NIMH initiative to conduct effectiveness trials, including the CATIE project with which I was involved, that phase IV comparative effectiveness research funded by an independent sponsor was essential to enable healthcare policy makers, administrators, and clinicians to make effective decisions about treatment selection and resource allocation in mental health care. Historically and currently, there has been no agency, organization or means mandated to finance trials examining the effectiveness of marketed treatments to determine how they compared with each other and their cost effectiveness. The NIH has some responsibility for this but does not view treatment research as their major focus and also views treatment research as so costly that it can only afford to allocate a small portion of its budget for this form of research. No other agency in the federal government sees it as part of its mandate, including CMS and SAMSHA or the FDA. Consequently, this work has been left to the private sector and currently 90 percent of all phase IV treatment research is sponsored by the pharmaceutical industry. These studies are designed in a way that do not rigorously or appropriately address issues of public health and scientific importance. Rather, they principally address clinical and marketing goals.

There are several ways in which this could be remedied. First, an agency can be mandated and incrementally funded to conduct phase IV effectiveness research. Clearly CMS has the largest stake in this, given the budget and the amount of funds spent through Medicaid and Medicare for treatment. However, the expertise for this kind of research currently resides in the greatest concentration within the NIH. Thus I would argue, the NIH is probably the best home for this. I would also suggest consideration be given to have the FDA require effectiveness research to be carried out either at the time of NDA review and approval or post-marketing by the company. This could be required to be funded by the company but carried out under the auspices of the

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Written Statement | Federal Coordinating Council for Comparative Effectiveness

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NIH. This would solve the problem of the NIH's budget not bearing the burden of carrying out this research and leverage resources from the companies that stand to benefit from the success of their product.

The priorities currently are for comparative effectiveness studies of marketed treatments for depression, schizophrenia and bipolar disorder compared to each other, combinations of medications and in combination with psychosocial interventions.

All in all, I believe given the rising cost of healthcare, percentage of the GDP consumed by healthcare costs and the wake-up call we have received in light of the series of effectiveness studies that have revealed "the emperor's new clothes" about the superiority and value of higher priced, newer drugs, that creation of a mandate for effectiveness research is warranted. I would be happy to provide further information or respond to any questions about this important topic.

Thank you for the opportunity to express my views.

Sincerely yours,

A handwritten signature in cursive script that reads "Jeffrey Lieberman M.D." with a horizontal line extending from the end of the signature.

Jeffrey A. Lieberman, M.D.