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April 7, 2004

Dr. Mark Helfand, MPH  
Director  
Oregon Evidence-based Practice Center  
8317 S.W. 35<sup>th</sup> Street  
Portland, Oregon 97219

Dr. John Santa  
Assistant Director for Health Projects  
The Center for Evidence-based Policy  
Oregon Health Sciences University  
2611 SW 3<sup>rd</sup> Avenue  
MQ280  
Portland, Oregon 97201-4950

Mr. Mark Gibson  
Program Officer  
Milbank Memorial Fund  
12501 Fishback Road  
Monmouth, OR 97361

Dear Dr. Helfand, Dr. Santa and Mr. Gibson:

On behalf of the American Psychiatric Association (APA), the National Alliance of the Mentally Ill (NAMI), and the National Mental Health Association (NMHA), we are writing to share with you some of our concerns about the Drug Effectiveness Review Project undertaken by the Center for Evidence-based Policy and to identify some key areas in which consumers and advocates need to have a crucial role.

Our organizations are well aware that in the health and mental health fields, there is an increasing focus on research that when appropriately applied can provide a more refined understanding of the effectiveness of different interventions across populations and treatment settings. This focus holds the promise of better integration of scientific knowledge with the best

practices for individual care across a spectrum of services. However, terms such as “evidence-based medicine” can also serve as cover for decision makers who want to justify arbitrary cost cutting and suppress consumer choice. Unfortunately, we are concerned that many states seeking to participate in your initiative have this latter approach as their primary goal.

As representatives of mental health consumers, family members, providers and other advocates, we have identified several areas we wish to address with you through ongoing dialogue. Our initial review and dialogue leads us to the following concerns:

1. **Public Input is Lacking.** Analysis and review of medications in any given class are not required to be subject to public comment or input from consumer groups who would be affected by those decisions. Despite your organization’s encouragement that participating states gather public input prior to implementation of any recommendations, we know from experience that state commitment to meaningful dialogue with advocates is rare.
2. **An Inconclusive Result on Efficacy Does Not Yield Open Access.** There is no mechanism for ensuring open access to all therapies within a class if a) existing evidence is not conclusive as to which medication is “best”; b) if there is insufficient evidence base to make such a determination or c) if the evidence is disputed (due to questions about study methodology, for example). In fact, as we understand it, if such findings are inconclusive, the recommendation immediately defaults to cost (i.e., cheapest therapies will be preferred therapies). Given the evolving field of research and clinical practice knowledge in the realm of mental health medications, we are alarmed that this is a chief underpinning of your organization’s review of the evidence. Moreover, it is unclear how your work will be reviewed and applied by states when there are other efforts, such as the CATIE study, whose findings are more strongly grounded in scientific analysis and yet not available until well after policy decisions have been made and individuals harmed.
3. **The Quality and Scope of Research Questions Determine the Quality of the Review.** We understand that the Center’s evidence-based review of the classes of medications is based on predetermined questions that the consortium states will help to develop. Though your literature notes that participating organizations will have time to gather input from other stakeholders, there is no requirement nor is any mechanism or timeframe spelled out. Thus, real concern exists that meaningful inclusion and participation by consumers, family members and other advocates will be limited and at the whim of the particular participating state. Furthermore, we believe that the lack of public input will skew the research questions and the resulting analyses will be unlikely to take into consideration all issues relating to interchangeability (e.g., racial and ethnic considerations, co-morbidities etc.). Moreover, how participating states and evaluators define “effectiveness” is crucial to the ultimate recommendations – if the definition is focused on symptom management as opposed to other outcome measures that are more oriented toward achieving recovery, the resulting conclusions about which is a “best” therapy will be different. Our organizations strongly support the position of the President’s New Freedom Commission on Mental Health that “care must focus on increasing consumers’ ability to successfully cope with life’s challenges, on facilitating recovery, and on building resilience, not just on managing symptoms.”<sup>1</sup>
4. **Selectivity of Research to be Reviewed Won’t Yield Thorough Review.** In addition to defining what questions are asked, we understand that the participating states may also determine what the “admissible” forms of evidence for review are (e.g., types of studies, age of studies, publications to review etc.). This selectivity can yield results that are not based on all available evidence. Moreover, there is significant controversy surrounding recent analyses of mental health medications, which may or may not be taken into consideration in the Center’s review.
5. **Center Recommendations Don’t Address Implementation Issues.** Though the Center process expects to yield evidence-based guidance about what can be considered “best” for inclusion on a PDL, states are free

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<sup>1</sup> New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report*, p. 5. U.S. Department of Health and Human Services. Rockville, MD: 2003.

to make local decisions about the ultimate design of a PDL and its implementation. This can (and does) occur without any discussion of necessary consumer protections, exemptions for certain classes and/or population subgroups, or alternative measures to contain cost growth without restricting access. As an example, this Center grew up in Oregon, which has a voluntary PDL (physicians may prescribe any medication they deem medically necessary, without prior authorization, by designating “dispense as written” on the script) and which exempts mental health, HIV/AIDS and cancer medications. This is not pointed out in the literature, nor is the design of a PDL discussed with regard to these two features.

6. **Cultural Competence Is Not Adequately Addressed.** Although one of the Center’s standard research questions addresses the differential impact of medications within a class on subpopulations, a major concern is the shortage of research into the effects of various mental health interventions, including medications, on different racial, cultural and ethnic groups. Such a lack of adequate research for review means that any recommendations from the Center are likely to inadequately address the implications for culturally competent PDL design and implementation.

As we strive to educate our respective memberships about the Center and the activities of states participating in the project, we are encouraging state and local advocates to initiate and maintain dialogue with Medicaid and Mental Health agency officials about their goals for involvement in such an initiative, to seek advisory roles for input on review questions and implementation issues, and to define parameters of local implementation issues, especially in the areas of preferred drug list design and process implementation, consumer protection and evaluation and review.

We hope you consider the points in this letter in the spirit of collaboration and concern for a balanced approach to utilization management of pharmaceuticals for individuals with mental illnesses. Such an approach is predicated on quality of care as a driving factor in decision-making. Evidence-based knowledge from the science community is one component of that formula that must be balanced with knowledge of clinical practice, real world experience of patients, and ongoing and thorough evaluation of the impact of policy choices.

Sincerely,



James H. Scully, Jr., M.D.  
Medical Director  
American Psychiatric Association



Michael J. Fitzpatrick, M.S.W.  
Acting Executive Director  
National Alliance for the Mentally Ill



Michael M. Faenza, M.S.S.W.  
President and CEO  
National Mental Health Association