Appendix G – Statement from Commissioners

LETTER FROM JOSEPH FINS, M.D. AND TIERAONA LOW DOG, M.D.

March 10, 2002

The Honorable Tommy G. Thompson
Secretary, Health and Human Services
Washington, DC 20201

Dear Mr. Secretary:

We would like to thank the American public for allowing us to serve on the White House Commission on Complementary and Alternative Medicine Policy. The Commission struggled with many complex issues and the final report reflects the enormous effort and hard work of the Commissioners and staff. We support many of the Commission's recommendations and appreciate the efforts to accommodate a diversity of views and achieve a consensus. Nonetheless, we feel it necessary to write this additional statement to provide clarification as these recommendations are considered for implementation. These are views we have stated consistently throughout the Commission's twenty months of deliberations.

The Executive Order 13147 directed that The White House Commission on Complementary and Alternative Medicine (CAM) Policy "shall provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine."

While many of the Commission's recommendations will help maximize the benefits of proven safe and effective approaches, practices and products, they do not appropriately acknowledge the limitations of unproven and unvalidated "CAM" interventions or adequately address the minimization of risk.

In this statement we will seek to be specific in our critique about these risk/benefit questions. In this effort we hope to give voice to the healthy skepticism that exists in many sectors of American public life with regard to complementary and alternative medicine, a perspective that may not have been adequately represented in the constitution of the Commission or in the testimony that we heard.

1. Acknowledging the Limitations of Unproven CAM Interventions While the

Report acknowledges that much of what is considered "CAM" has not been

shown to be safe and effective, a presumption exists that complementary and alternative medicine will be found to be beneficial. This advocacy tone persists in the Report despite great efforts to achieve editorial balance. Despite qualifying statements added to the Introduction of the Report -- which we endorse -- the body of the document continues to give voice to a perspective that suggests that most "CAM" interventions will be proven to be safe and effective through scientific research. Last minute revisions to the Introduction do not mitigate more global statements that permeate the Report. There continues to be language suggesting that "CAM" will lead us into a new paradigm of health care that will provide answers for those with chronic disease, as well as our aging and under-served populations. We will discuss these concerns in the context of research priorities, access and the underserved, the provision of primary care services and medical education.

1.1 Research Priorities

We strongly endorse the need for more research; however, we recognize that research dollars are finite. The Commission's lack of a prioritization strategy for research initiatives, given the many areas that "CAM" encompasses, makes a general endorsement of research of limited value. Promising areas of research should be investigated because they potentially have something to offer to the health of the American people or because they advance our scientific understanding of illness and healing. Asking for more research money to investigate an approach, practice or product simply because it is "CAM" is an ideological, not evidence-based approach to science. Recommendations for research on "frontier areas of science" without a strategy for building this research on scientific foundations may result in spending precious health care research dollars on areas that are unlikely to yield any beneficial data such as "iridology", "psychic healing" et. al. While dogmatic disbelief of everything that is not currently explainable is foolish, and indeed unscientific, it seems equally foolish to ask the taxpayer to bear the enormous expense of sorting out those areas that are plausible from those that are improbable.

With sound research priorities in mind, we feel it is important to point out that many of the recommendations made in the research and access sections of the Report are already being undertaken by NCCAM, a Center within the National Institutes of Health. NCCAM has established fifteen specialty research centers that cover "CAM" approaches for many areas of major public health need. These centers are focused on studying the underlying mechanisms of "CAM" modalities, cancer treatments, "CAM" for end-of-life care, botanicals, the use of "CAM" therapies to reduce health disparities and integrative medicine.[i] Given the concentration of expertise and existing infrastructure at NCCAM, recommendations for a wide sweeping "CAM" research agenda to be implemented across a large number of federal agencies does not appear to be a cost-effective or logical way to make progress.

1.2 Access and the Underserved

When the Commission sought to be inclusive by expanding access to "CAM" products, providers and modalities to underserved populations through demonstration projects or other programs it did not adequately appreciate that these recommendations were being made for populations which have limited or no access to conventional medical care. In this context, the provision of "CAM" becomes neither a complementary nor integrative intervention, but rather a less validated alternative to conventional care. The Commission heard testimony that many underserved populations utilize folkloric or "CAM" interventions because they cannot afford access to conventional care.[ii] It is worth considering whether these individuals would prefer a drug benefit over access to unproven supplements or if they would seek out "CAM" providers if they had the resources to receive care from primary care practitioners. Given the state of the science, most "CAM" interventions can only be said to add to and not replace conventional interventions. A consideration of "CAM" entitlements or an expansion of insurance benefit packages is one thing in the context of preexisting access to conventional medical care. It is ethically quite another in the absence of such coverage.

While there is room for diversity in the health care system, we should not be a party to creating a separate but unequal care system. It is our strong belief that we should provide basic health care to every American before expanding benefits to include treatments or approaches that have not been shown through rigorous research to treat or prevent disease. We must never foster a second-tier of medical care for those who are economically disadvantaged.

1.3 Primary Care Practitioners

The Commission debated at great length whether or not we would recommend that "CAM" practitioners be included in loan-forgiveness and scholarship programs, especially as it relates to their possible inclusion in the National Health Service Corps. The Report carefully delineates the eligibility requirements for inclusion in this program and why Title VII of the Public Health Services Act does not recognize "CAM" practitioners as primary care providers eligible for inclusion in this program. While we endorse demonstration projects that seek to identify what, if any, value "CAM" providers add to established primary care teams, we want to go on record noting that we do not believe that CAM providers are fungible with the primary care providers enumerated in Title VII. This concern does not mean that some CAM practitioners do not have the potential to add to the public health or meaningfully affect the lives of patients. It is simply that they are not positioned for equivalency with conventional primary care providers. Efforts to equate their degree of training, or the scientific basis of their practice, with that of the designated primary care specialties puts the public at risk of receiving unvalidated and non-evidence based primary care.

1.4 Education and Training of Conventional Practitioners

Conventionally trained health care practitioners must be able to dialogue with their patients about a wide variety of topics including sexuality, domestic violence, substance abuse, spirituality, death and dying, pain, emotional health and non-conventional therapies. We strongly support the need for health care providers to be able to critically assess the evidence for approaches, practices and products that their patients may be using, however, most medical schools (approximately 72%) already teach courses on what is considered "CAM". If the critique is that conventional medical curricula are lacking in areas such as nutrition, self-care instruction or preventive medicine, the appropriate response is to improve the teaching of this subject matter. Furthermore, as medical educators we believe that recommendations for curricular reform will be better received if they are not cast in language that implies a mandate. Whatever is included in the medical curriculum must remain true to scientific integrity, avoid ideological indoctrination and guard against teaching unproven treatments to the next generation of health care providers.

2. The Minimization of Risk

To fully meet the spirit of the Executive Order, the Report would need to do more than identify the benefits to be maximized. It would also need to avoid the assumption of avoidable risk, especially when the benefits are uncertain and the risks are clear. We will now comment on how the Report's lack of definitional clarity limits appropriate risk management, address public preferences regarding regulation and consider the special concerns of vulnerable populations.

2.1 Lack of Definitional Clarity

Addressing the risks or benefits associated with "CAM" interventions is difficult because the recommendations suffer from a lack of specificity. Generic recommendations neither serve the public interest nor protect the public health because they fail to distinguish between approaches, practices and products for which there is some scientific evidence and those that either stretch the realm of logic or are demonstrably unsafe. The Report's inability to discriminate amongst "CAM" practices, products and practitioners leaves its recommendations open to interpretation. This limits their applicability as public policy.

The Report's lack of definitional clarity undermines the legitimacy of safe and effective non-conventional approaches by failing to distinguish them from treatments that are improbable or fraudulent. For instance, there is strong evidence that relaxation therapies help reduce chronic pain in patients with a variety of medical conditions.[iii] Glucosamine sulfate has been found superior to placebo for the treatment of osteoarthritis.[iv] However, chelation therapy has not been shown to be beneficial for the treatment of ischemic heart disease,[v] though is still promoted as a treatment. Alternative diets, coffee enemas, ozone therapy,

and shark cartilage offer little for cancer patients, however, acupuncture, aromatherapy, and meditation may be useful for nausea/vomiting, mild relaxation, and pain/anxiety, respectively.[vi]

The Report's inclusion of all "CAM" practices, without appropriate nuance, fails to adequately appreciate the heterogeneity of these practices. This omission undermines those areas within CAM that have already demonstrated safety and efficacy and may be ready for integration into the healthcare system.

Wellness and Health Promotion

"Promoting wellness", "health promotion" and "prevention practices" are phrases that recur throughout the Report and are cited as being the focus of many "CAM" approaches. It is unclear what these terms actually mean, as no clear examples are provided in the document. If it means that one can enhance his or her sense of well being through a healthy diet, regular exercise and other lifestyle modifications, there is little debate. There is a large body of evidence for the beneficial role of nutrition, exercise and stress management in the scientific literature. The Commissioners debated the inclusion of these lifestyle approaches under "CAM" and the final Report acknowledges that these approaches are found in both "CAM" and conventional medicine, but claims that there is a "greater emphasis" placed upon them in "CAM." One has only to visit the local book store to find the numerous "fad" diet books that fall under "CAM" nutrition; high fat - high protein diets, eat according to your blood type diets and fruitarian diets, to name a few. There is no single "CAM" nutritional approach. In addition, if one were to accept that there actually is a greater "emphasis" on sound, scientific nutrition and exercise amongst "CAM" practitioners, there is no documented evidence that they are any more successful than conventional practitioners in motivating their patients to make lifestyle changes.

The Report fails to point out that "CAM" "health promotion" and "prevention practices" also include preventing disease by "balancing qi", "eliminating parasites and toxins," "cleansing the liver" and/or by "cleansing the blood" via a multitude of supplements and questionable practices. Our uncritical acceptance of "CAM" wellness and health promotion can be interpreted as an endorsement of these claims. It is absolutely unclear what role, if any, "CAM" practices play in preventing disease and to what extent patients are burdened with useless treatments and products in their pursuit of "wellness".

The Contributions of Public Health and Medicine to Wellness

Registered dietitians, clinical nutritionists, conventionally trained scientists, physicians and public health professionals have done the bulk of the research in the area of nutrition. It is important not to overlook the contributions of the pioneering Framingham study that documented the epidemiology of obesity, smoking and heart disease, which led to heart healthy diets, smoking cessation,

and a greater emphasis on exercise. Through rigorous science we now have a much better understanding of the role foods, nutrients and exercise play in health and disease. The notion that only "CAM" supports healthy nutrition is neither accurate nor fair.

Furthermore, the suggestion that conventional medicine is primarily focused on disease, while "CAM" is primarily focused on health promotion and prevention was a point of contention on the Commission. This perspective fails to adequately acknowledge public health initiatives that have been an integral part of medicine for decades, efforts that have dramatically improved the health of the Nation.

Cooptation of Spirituality

The most troubling of these conflations is the inclusion of spirituality under the rubric of "CAM." There is no question that many Americans find comfort in prayer, religion and/or spiritual practices and that more attention should be paid to the role of spirituality in health care. Nonetheless, it is disconcerting that the Report often categorizes spirituality as a "CAM" modality. The Report cites papers that assert that when a patient is diagnosed with cancer and turns to prayer for comfort - he or she is considered to be using "CAM." When spirituality is so designated, "CAM" prevalence grows dramatically. The truth is that spirituality transcends any arbitrary designation of conventional and non-conventional medicine and cannot be claimed by any particular group. Furthermore, the conflation of spirituality and/or religion with CAM could lead to an abridgement of the free exercise of religion by subjugating its practice to a regulated modality.

In sum, generic pronouncements about "CAM" neither serve the public interest nor protect the public health. It is essential to separate the effective from the ineffective, the safe from the unsafe and to contextualize these practices against conventional modalities before any of them can be recommended for incorporation into the Nation's healthcare system. While recognizing that research will eventually answer many of these questions, the Commission's inability to distinguish and critically evaluate broad categories of practitioners and modalities in a meaningful way, limits the applicability of many worthy recommendations.

2.2 Public Preferences and the Regulation of Supplements

The access section of the Report is predicated upon the premise that, "The public has expressed interest in maintaining easy access to CAM practitioners." Notwithstanding the selection bias of those who presented public testimony to the Commission, the data does not support that this is the view of a majority of Americans. In fact, if we consider the regulation of dietary supplements as a well-studied case in point, the literature indicates that the use of dietary supplements

has decreased and that the majority of Americans support increased regulation of supplements, including requiring the Food and Drug Administration to review the safety of new dietary supplements prior to their sale.[vii] This support for increased regulation and safer products is likely a consequence of publicity surrounding St. John's Wort and drug-interactions, the potential liver toxicity of Kava,[viii] the presence of the anti-coagulant warfarin in PC-SPES, an herbal product used for prostate cancer[ix] and the presence of heavy metals in a number of Asian herbal preparations.[x] We strongly support a number of recommendations made in the Report regarding the quality, safety and advertising of dietary supplements and the full implementation of the Dietary Supplement Health and Education Act (DSHEA). However, it remains to be seen if the full implementation of DSHEA will provide the public with the right combination of access and safety that national surveys indicate it desires. For this reason, we strongly endorse the recommendation that Congress re-evaluate DSHEA following full implementation.

2.3 Vulnerable Populations

Patients will often resort to "CAM" practices, modalities and practitioners upon the diagnosis of a debilitating, chronic or terminal condition. Recent Senate hearings have documented the special vulnerability of the elderly on fixed-incomes to these phenomena.[xi] The Report's contention that medicine lacks adequate treatment for pain and symptom management could contribute to the mistaken notion that conventional medicine has nothing to offer patients who chronically ill or in the process of dying. It is important that the public be aware of the fine work done in hospices around the country and the emergence of palliative care as an important evidence-based clinical discipline able to ameliorate patient and family distress.

3. Closing Statement

We hope that the American public is well served by the Commission's work. The Commission made enormous progress during its deliberations and we support many of its recommendations. We believe that some of aspects of "CAM," when appropriately defined, have the potential to benefit the health of the American public. However, the Commission's inability to appropriately acknowledge the limitations of unproven and unvalidated "CAM" interventions or adequately address the minimization of risk necessitates this statement.
We remain optimistic that the work of the Commission and the many people who presented testimony before it will make a contribution to the public's understanding of this complex issue. We hope that the diversity of views on this topic does not engender divisiveness. Where medical care is concerned, the common good calls for ideology and advocacy to yield to scientifically sound evidence of safety and efficacy. We are confident that this can be accomplished

with respect and compassion for all Americans.

We appreciate the honor of serving with our fellow Commissioners and thank you for your consideration.
Respectfully Submitted,

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Tieraona Low Dog, M.D.	Joseph J. Fins, M.D., F.A.C.P.

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