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Grollman

Divider Title: _____

Arthur P. Grollman, M.D. – Biographical Sketch

Dr. Arthur Grollman is currently the Evelyn Glick Professor of Experimental Medicine, Professor of Pharmacological Sciences at the State University of New York at Stony Brook (SUNY-SB) and Director of the Zickler Laboratory of Chemical Biology. He received a B.A. in chemistry from the University of California at Berkeley and an M.D. from the Johns Hopkins School of Medicine. Following a residency in internal medicine at Johns Hopkins, he conducted research from 1961-1963 at the National Institutes of Health and served on the faculty of the Albert Einstein College of Medicine from 1964-1974. In 1974, he became the founding Chairman of the Department of Pharmacological Sciences at SUNY-SB and continued in this role until 2000, when he relinquished his administrative responsibilities to devote full time to research. From 1970-1972 and again from 1994-1996, he served concurrently as Associate Dean for Scientific Affairs.

Dr. Grollman is internationally known for work in cancer research which currently focus on molecular and environmental carcinogenesis. He serves as Principal Investigator for two NIH-supported Program-Projects: "Exocyclic DNA Adducts and Oxidative DNA Damage" and "Molecular Toxicology of DNA Adducts", and holds a MERIT Award for "Molecular Pharmacology of Tumor and Virus Inhibitors". Under Dr. Grollman's leadership, Pharmacological Sciences at SUNY-SB consistently ranked among the top five Departments of Pharmacology in the U.S. Dr. Grollman also played a central role in establishing a Center for Structural Biology and initiated a pharmacology major in the College of Arts and Sciences—one of only two such undergraduate programs in the country.

Dr. Grollman has published more than 150 papers in the field of molecular pharmacology and toxicology, including studies on active principles derived from botanical products. He served as Attending Physician at hospitals associated with Albert Einstein and Stony Brook and as Visiting Professor at Stanford, Johns Hopkins, and the Weizmann Institute. He has served on many national scientific advisory boards and recently organized a symposium sponsored by the American Association of Medical Colleges entitled "Alternative Medicine—The Importance of Evidence in Medicine and in Medical Education".

Herbal Medicines: Danger and Opportunity (危機)[1,2]

Since the advent of the era of modern medicine, the majority of Americans have relied heavily on prescription drugs and/or over the counter medications for relief from symptomatic illness. The first effort by the federal government to protect consumers of drugs took place in 1906 with the passage of the Pure Food and Drug Act, which was prompted by journalistic exposure of false and misleading advertisements for patent medicines. The first legislation designed to ensure safety of drugs, introduced in 1938, was an amendment to this Act, following the deaths of children treated with sulfanilamide, an early antimicrobial, which had been formulated as a toxic elixir. In 1962, human tragedy again resulted in new regulations when women in Europe, given thalidomide as a sleeping medicine during the first trimester of pregnancy, subsequently gave birth to infants with phocomelia, a rare birth defect. Legislation requiring premarketing testing of new drugs for carcinogenicity and teratogenicity was promptly enacted. The responsibility for monitoring safety and efficacy of drugs has been placed on the Food and Drug Administration with funding and oversight provided by Congress (1).

Most Americans take effective FDA surveillance for granted. Relatively few are aware that a major change has occurred with respect to the regulation of what are now called dietary supplements, including herbal medicine. This category comprises products taken by more than 100 million Americans.

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[1] 危機 =Chinese characters for danger and opportunity which together translate as "crisis".
[2] Statement to be presented to WHCCAM on May 15, 2001

The Dietary Supplement Health and Education Act of 1994 (DSHEA) now allows botanical products to be marketed without prior testing for safety. Omission of such protection is considered by pharmacologists, pharmacists, physicians, consumer health advocates, regulators, and some leaders in the botanical industry to be, in the words of one eminent pharmacologist, "an accident waiting to happen" (2).

Five centuries ago, Paracelsus wrote that "all drugs are poisons—it is a question only of the dose". This wisdom from the father of modern pharmacology is applicable to this discussion of herbal medicine. Some proponents of complementary and alternative medicine (CAM) have been quoted as saying that herbs, being "nature's chemicals," are intrinsically non-toxic. Nothing could be further from the truth! Some of the world's most toxic substances, including strychnine, hemlock, poison mushrooms, and tobacco, are derived from plants. The handful of plant products whose therapeutic effectiveness is unquestioned (digoxin, morphine, quinine, etc.), exhibit exceedingly narrow therapeutic windows. In permitting botanicals to be marked as dietary supplements rather than as drugs, Congress regrettably has released manufacturers from the burden of providing "proof of safety" prior to exposing a large and potentially vulnerable population to serious adverse effects (3). In contrast, before a new drug can be marketed or even administered to patients in clinical trials, studies on experimental animals, followed by limited Phase I tests in human volunteers, are required. Phase I studies explore the potential of a new drug to produce adverse effects, including drug interactions.

Three current situations epitomize the problems inherent in permitting herbal products to be classified as dietary supplements and to circumvent the premarket safety

testing required for drugs. The dangers associated with the herb *Aristolochia fanci* will be discussed first but the story is not unique. Many other herbs are toxic (4) as reflected in numerous reports to Poison Control Centers throughout the U.S. (5).

Aristolochia—The herb *Aristolochia fanchi* (also known as birthwort) has been used since ancient times and is a component of traditional Chinese medicine. *Aristolochia* is available in capsule form in the U.S. (6). This herb was reported to be nephrotoxic as long ago as 1964; shortly thereafter, it was shown to cause cancer in experimental animals. In 1992 in Belgium, more than 100 cases of renal failure, requiring chronic dialysis and/or kidney transplantation, were reported (7). An epidemiological investigation revealed that the victims, most of them young women, had been given *Aristolochia fangchi* in the same weight reduction clinic. More than half of these women went on to develop urothelial cancer (8). Despite this report—and the banning of this herb in many European countries—*Aristolochia* remained on sale in the United States. In April, 2001, nine years after the first clinical report, the FDA belatedly wrote letters to physicians, pharmacists, consumers, and manufacturers, alerting them to the serious danger to health associated with use of this herb (8). It is instructive to contrast this sequence of events—where the ability of the FDA to take preventive action against a toxic and demonstrably carcinogenic dietary supplement is constrained by the provisions of DSHEA—with those associated with thalidomide—where the FDA acted on European reports before the drug was released in the United States, protecting the American public against exposure to a drug associated with irreversible birth deformities.

Ephedra—Many dietary supplements contain ephedra alkaloids, the active principle of a popular herb known as ma huang. Ephedra is heavily promoted for use in weight reduction programs and for energy enhancement—a so called "thermogenic" product or "pep pill". The safety and efficacy of products containing ephedra have not been established and reports of their adverse effects—including permanent injury and death—have appeared with increasing frequency since passage of DSHEA (10). Between 1993 and 2000, the FDA received over 1,100 such reports including notices of heart attacks, cardiac arrhythmias, hypertension, acute psychoses, seizures, and in a few cases, death (11). More than half of these events occurred in persons less than 40 years of age. An independent study revealed that FDA records less than 1% of the total number of adverse events resulting from dietary supplements; thus, more than 100,000 consumers may have suffered similar adverse effects over this period of time.

Why has regulatory action against ephedra not been taken? Because, under DSHEA, *there are no provisions for manufacturers to demonstrate proof of safety or effectiveness for any substance classified as a dietary supplement before it reaches the consumer!* In contrast to new drugs, manufacturers and distributors of dietary supplements are not legally required to record, investigate, or even forward to the FDA reports they may receive of injuries or illness related to the use of their products (3). Following release for public consumption, FDA assumes full responsibility for proving that a supplement is unsafe. Only then may it take action to restrict the product's use or to remove it from the marketplace. As documented in an important recent report from the Office of the Inspector General (5), Congress has failed to allocate sufficient resources to conduct necessary investigations. Making matters worse, in the case of

ephedra, FDA was blocked in 1997 from mandating labels warning of potential toxicity and setting dosage limits for reasonable use.

Phenylpropylamine—The pharmacological effects of phenylpropylamine (PPA) on the cardiovascular system are very similar to those of ephedra. It is instructive to compare the handling of these two products by the FDA. A controlled study describing hemorrhagic stroke in young women taking PPA appeared in the same issue of *The New England Journal of Medicine* as a detailed report from UCSF analyzing the adverse effects of ephedra (12). As a direct result of this study, PPA was banned by the FDA and OTC products containing the drug were voluntarily removed by pharmacies throughout the U.S. In contrast, the sale of ephedra herbs without appropriate labeling to warn consumers of their inherent risks continues unchecked.

I have cited only two examples of serious toxicities resulting from the failure to regulate dietary supplements. Toxic effects of many other herbs have been reported (4) and calls to Poison Control Centers to report adverse reactions to dietary supplements have increased sharply since 1997, reaching 17,000 last year (5).

Another important safety aspect of the marketing of herbal products relates to the lack of standardization (13). Even for commonly used herbal products the amount state on the label often differs substantially from the amount contained in the preparation (14). In addition, adulteration of herbal remedies with heavy metals and prescription drugs (including steroids) is widespread. A random analysis of herbal products sold in San Francisco, conducted by the California Department of Health, revealed that 40% of herbs tested contained these such toxic contaminants (15). To complicate matters, it is difficult and often impossible for an analytical chemist to determine whether a botanical

remedy contains the specific herb(s) named on the label. Good manufacturing processes have been promised by industry but are slow in coming as they are required by common sense but not by law. Unannounced inspections and strong penalties for violations are required to address this present threat to public health. An effective system for reporting adverse effects of dietary supplements as recommended by the OIG (5) is crucial and should promptly be put in place.

Drug Interactions—The failure to regulate herbal medicine is associated with a major risk of drug interactions. This problem can—and probably does—occur with many herbal preparations, as recently shown for St. John's Wort, a product used widely in the U.S. and in Europe for the treatment of depression. The administration of St. John's Wort concomitantly with a protease inhibitor used in the treatment of AIDS, was shown to result in a dramatic decline in the level of the inhibitor (16). This situation is life-threatening to the HIV-infected individual who requires protease inhibitors for continued viral suppression. Furthermore, patients with heart and kidney transplants receiving immunosuppressants showed signs of organ rejection after co-administration of St. John's Wort (17).

Follow-up investigations confirmed that a common family of P450 enzymes involved in metabolism of these and many other pharmaceuticals is induced by St. John's Wort. Other drugs metabolized by this pathway (designated CYP3A4) include many of those used by the millions of Americans being treated for hypertension, heart failure, asthma, certain infections, and other chronic diseases, conferring on this herbal remedy—innocuous when taken alone—the ability to inactivate life-saving drugs on which many elderly patients depend. Because the potential for drug interactions is

proportional to the number of chemical constituents present; herbals are much more likely than single drugs to be involved in drug interactions, due to the myriad of chemical principles they contain. *The scope of this problem could be significantly reduced by requiring premarketing safety testing.*

As the title of this presentation suggests, there is an "opportunity" to improve the safety of dietary supplements. Health professionals and consumers should be informed about the dangers of herbal medicines and the need for controlled studies to evaluate efficacy as well as safety. These issues recently have been addressed in editorials in leading medical journals (18-19) and in a symposium sponsored by the American Association of Medical Colleges (20). Journalists and consumer advocates have a special responsibility to convey messages regarding drug safety to the public.

RECOMMENDATIONS

What should the White House Commission on Alternative and Complementary Medicine recommend to the President to reduce the dangers associated with the use of herbal medicines? I suggest the following:

1. As a matter of the highest priority, Congress should amend DSHEA so that manufacturers of dietary supplements, including herbs and other botanicals, would be required to obtain pre-marketing approval by demonstrating to the FDA that the product does not present a significant or unreasonable risk of injury under conditions of uses recommended or suggested in the label. Additionally, manufacturers should be required to develop warning labels for consumers and to participate in good

manufacturing processes. Severe penalties would be imposed on manufacturers who avoid or neglect this public health responsibility.

2. All recommendations contained in the OIG report should be promptly implemented. These actions will ensure that the FDA receives necessary information regarding adverse reactions to herbs, botanicals, and other dietary supplements, facilitating early detection of toxicity and disclosure of this essential information to consumers. A modest (0.3%) increase in the FDA budget would be sufficient to effect the recommended changes.

3. NIH should conduct randomized double-blind, placebo-controlled clinical trials designed to test the efficacy of selected herbal medicines and, at the same time, quantify their adverse effects. This basic information has been recently obtained for St. John's Wort (21) and will help to establish the risk/benefit ratio.

4. Basic research should be conducted on the mechanism(s) of action and toxicity of commonly used herbal medicines. This approach may provide leads to new drugs and help to anticipate toxic effects.

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EXECUTIVE SUMMARY

PURPOSE

To assess the effectiveness of the Food and Drug Administration's (FDA) adverse event reporting system for dietary supplements in protecting the American consumer.

BACKGROUND

Dietary supplements are increasingly popular. Currently about 60 percent of Americans take some form of dietary supplement every day without any apparent problems. Supplements include substances such as vitamins, minerals, botanicals, and amino acids. Although many of these supplements can be beneficial, there are risks associated with some. For example, ginkgo biloba may lead to excessive bleeding, vitamin A in high dosages during pregnancy may lead to birth defects, and St. John's Wort may reduce the effectiveness of some antiviral drugs. Unlike new prescription and over-the-counter drugs, FDA does not have the authority to require supplements to undergo premarket approval for safety and efficacy. Instead, it relies mostly on its adverse event reporting system to identify safety problems.

FDA's Adverse Event Reporting System for Dietary Supplements

FDA's adverse event reporting system for dietary supplements includes (1) detecting adverse events, (2) generating signals of possible public health concerns, (3) assessing those signals, and (4) taking appropriate safety actions based on its assessment. An adverse event is an incident of illness or injury that *may* be associated with a product or ingredient. With further investigation, the association may or may not be confirmed. Reporting adverse events is entirely voluntary, and FDA receives reports from a variety of sources including consumers and health professionals.

When a signal of a possible health problem is generated from the adverse event reporting system, FDA assesses whether it is an actual public health problem warranting attention. FDA can assess these signals by reviewing scientific literature, consulting with experts, reviewing clinical data, conducting its own laboratory tests, and/or commissioning studies. If FDA confirms that a public health problem exists it can take a range of safety actions, such as issuing warnings to consumers and health professionals, issuing important alerts, requesting product recalls, or seizing products.

This Inquiry

In this report, we evaluate how well FDA's adverse event reporting system for dietary supplements functions as a consumer protection tool. We analyzed data from FDA's database; reviewed FDA laws, regulations, policies, and procedures; reviewed several adverse event reports; reviewed relevant literature; and interviewed FDA officials, industry representatives, and scientific experts. We did not evaluate the internal

operatingproceduresofthesystem.

FINDINGS

FDA'sadverseeventreportingsystemdetectsrelativelyfewadverseevents.

Adverseeventreportingsystemstypicallydetectonlyasmallproportionoftheeventsthat actuallyoccur.Thisappearstobeespeciallytrueof FDA'ssystemfordietary supplements.ArecentFDA-commissionedstudyestimatedthatFDAreceiveslessthan1 percentofalladverseeventsassociatedwithdietarysupplements.Amongthefactorsthat maycontributetounder-reportingarethatmanyconsumerspresumesupplementstobe safe,usetheseproductswithoutthesupervisionofahealthcareprofessional,andmaybe unawarethatFDAregulatesthem.FDA'slimitedoutreachconcerningthissystem contributestothisunawareness.

Ithasdifficultygeneratingsignalsofpossiblepublichealthconcerns.

FDAlacksmuchoftheinformationthatisnecessarytoeffectivelyanalyzeadverseevent reportsandtogeneratepossiblesignalsofconcern.Belowwedocumentthelackof informationbypresentingFDAdatabetween1994-1999.

Limitedmedicalinformation. FDAdidnotreceivethemedicalrecordsfor58percent (464of801)ofthereportsforwhichitrequestedthem.Only20percent(527of2,547) ofadverseeventsreportsreceivedbyFDAcamefromhealthprofessionals.

Limitedproductinformation. FDAwasunabletodeterminetheingredientsfor32 percent(1,153of3,574)oftheproductsmentionedinadverseeventreports.FDAdoes nothavetheproductlabelsfor77percent(2,752of3,574)oftheproductsmentionedin reports.FDAdoesnothaveproductsamplesfor69percent(130of188)oftheproducts forwhichitrequestedthem.Productsamplesareespeciallyhelpfulbecausedietary supplementingredientsarenotstandardized.

Limitedmanufacturerinformation. FDAreportsthatithasreceivedfewerthan10 adverseeventreportsdirectlyfrommanufacturers.FDAwasunabletodeterminethe manufacturerofdietarysupplementproductsfor32percent(1,153of3,574)ofthe productsinvolvedinreports.FDAwasunabletodeterminethecityandStatefor71 percent(644of904)ofthemanufacturers.

Limitedinformationonthedietarysupplementconsumer. FDAwasunableto follow-upwith27percent(214of801)ofthereportsittaggedforfollow-upprimarily becausethereportslackedsufficientinformationtoidentifytheallegedinjuredparty.

Limitedabilitytoanalyzetrends. FDAhasdifficultyanalyzingtrendsofadverseevent reportsbecauseitslacksanadequatecomputerdatabaseforroutineanalysisandreceives relativelyfewreports.

FDA lacks vital information to adequately assess signals of possible public health concerns generated by the adverse event reporting system.

In order to assess such signals, FDA must draw upon key information external to the system. But FDA faces obstacles in obtaining such information. For a recent case study that documents these obstacles see appendix A.

Limited clinical information. There is some clinical information available on dietary supplements and more is becoming available everyday. But, the current regulatory framework for dietary supplements permits manufacturers to market a supplement without premarket safety studies. For this and other reasons, FDA has relatively little clinical information on particular products. The law requires manufacturers of certain new dietary ingredients to notify FDA 75 days prior to market and include "relevant" safety information. However, very few dietary ingredients are subject to this requirement, and FDA has issued no guidance on the type of safety information that should be submitted.

Limited information on consumer use. FDA lacks a mechanism to track the number of consumers using a particular supplement. Such information can be helpful to determine the incidence of certain adverse events in the user population and thus, the extent of the public health problem that it poses.

As a result, FDA rarely takes safety actions related to the adverse event reporting system.

Safety actions can be of significant benefit to consumer safety. For example, based on FDA's investigation of adverse event reports, it found products containing plantain were contaminated with *Digitalis lanata*, a plant that can cause heart attacks in certain individuals. FDA issued a consumer warning against certain products containing plantain and asked supplement manufacturers to voluntarily recall their products contaminated with *Digitalis lanata*.

But, between January 1994 and June 2000, we were able to document only 32 safety actions that FDA took based on the adverse event reporting system—a period when more than 100 million people were taking supplements. With limited information to draw upon to generate and assess signals, FDA rarely reaches the point of knowing whether taking a safety action is warranted.

Public disclosure of adverse event reports can also be considered a type of safety action. FDA uses its website as its main vehicle for disclosure. However, its website has significant limitations; for example, it provides no evaluation of the reports, contains misleading information, and is rarely updated.

RECOMMENDATIONS

Our evaluation of FDA's dietary supplement adverse event reporting system leads us to conclude that without further development of the overall regulatory framework for

dietarysupplements,thepotentialofthesystemtoserveasaconsumersafeguardis inherentlylimited. Theprogramsimplycannotserveasanadequatesafetyvalveuntil othermeasuresaretakenthatwillallowFDAtogenerateandconfirmsignalsofpossible publichealthconcerns.

BelowweofferourrecommendationsasablueprintforactionsthatFDAcantakeovera reasonableperiodoftime.Ithasalreadycalledforsomeoftheminitsstrategicplanfor dietarysupplements.Werecognizethatsomeofourrecommendationswillcallfor legislativeorregulatorychanges.Wealsorecognizethatresourcesarelimitedandthat someofourrecommendationsmayrequireadditionalresources.

RECOMMENDATION1:Facilitategreaterdetectionofadverseevents.

Requiredietarysupplementmanufacturerstoreportseriousadverseeventstofda forsomeproducts. FDAshouldexaminewhattypesofproductsoringredientsshould fallunderthisrequirement.FDAalreadyrequirespharmaceuticalmanufacturerstoreport adverseeventsforallprescriptionandsomeover-the-counterdrugs.

ContractwithPoisonControlCenterstoobtaintheiradverseeventreportson dietarysupplements. Thesecentersholdinformationthatmaybeusefultofda. ReportsfromPoisonControlCentersmayprovideadditionaldatatohelpgeneratesignals ofpossiblepublichealthconcern.

Informhealthprofessionalsandconsumersabouttheadverseeventreporting systemfordietarysupplements. ThemainwayFDAcanaccomplishthisisby expandingitsoutreachtohealthprofessionalsandincludinginformationaboutthesafety actionsithastaken.Otherpossibilitiesincluderequiringmanufacturerstoprovideatoll-freenumberontheirproductlabelsorplacingFDA'stoll-freenumberonlabels.

RECOMMENDATION2:Obtainmoreinformationonadverseeventreportsin ordertogeneratestrongersignalsofpublichealthconcerns.

Educatehealthprofessionalsabouttheimportanceofincludingmedicalinformation inadverseeventreports. Withoutmedicalinformationabouttheallegedinjuredparties, FDAlackscrucialinformationfordeterminingthelikelihoodthatanadverseeventwas relatedtotheuseofadietarysupplement.WhenFDAconductsoutreachitshould encouragehealthprocessionalstoobtainpermissionfromtheirpatientstoreleasetheir medicalrecordswhenappropriate.

Requiredietarysupplementmanufacturerstoregistertheirproductswithfda.A completeproductregistrywouldallowFDAtoinstantlyaccessalistofallofthe ingredientsinaparticularproductanddeterminetheproductmanufacturer'snameassoon asitreceivesanadverseeventreport.

Requiredietarysupplementmanufacturerstoregisterwithfda. Aregistryof manufacturerswouldenableFDAtoquicklyandeasilycontactamanufacturerwhose productwasassociatedwithanadverseeventtoobtainadditionalinformation.

NotifymanufacturerswhenFDAreceivesaseriousadverseeventreport. Alerting manufacturersofadverseeventsinwhichtheirproductshavebeenmentionedwouldgive FDAtheopportunitytoobtainmoreproductinformationfromthemanufacturer.It wouldalsoallowmanufacturerstoreevaluatethesafetyprofileoftheproduct,including manufacturingprocedures,inatimelymanner.

Emphasizetohealthprofessionalsandconsumerstheimportanceofprovidingaway toidentifytheallegedinjuredparty. WithoutthisinformationFDAmaybeunableto gatheradditionalinformationexcludedfromthereport.

Developanewcomputerdatabasetotrackandanalyzeadverseeventreports. To helpidentifysignals,FDAneedsadatabasethatallowsforqueryingbyingredientsaswell asproductsandtypesofadverseevents.

RECOMMENDATION3:Obtainvitalinformationtoadequatelyassesssignals generatedbytheadverseeventreportingsystem.

Issueguidanceonthetypeofsafetyinformationthatmanufacturersshouldinclude inthe75-daypremarketnotificationrequirementforsomenewdietarysupplement ingredients. FDAshouldtakefulladvantageofitsexistingauthoritytoobtainasmuch safetyinformationaspossiblepriortomarketing.

Explorethepossibilityofamonographsystemfordietarysupplementsthatwould containsafetyinformationonparticularingredients. Monographsarepointpaperson particularingredientsthatcontainsafetyandefficacyinformation.Suchasystemwould allowFDAtohaveinasystematicfashionsafetyinformationthatitcouldrelyuponto helpmakedecisions.

CollaboratewiththeNationalInstitutesofHealthinsettingaresearchagenda addressingsafetyissues. AnotherwaythatFDAcangainclinicalinformationisby collaboratingwiththeNationalInstitutesofHealththatfundsandconductsresearch relatedtodietarysupplements.

AssistindustryandtheUnitedStatePharmacopeiainstandardizingdietary supplementingredients,particularlybotanicals. Standardizedingredientswouldallow FDAtohavetheconfidencethatintakingactionagainstunsafeproductsoringredientsit isaddressingalltheproductsposingahealthrisk.

Expeditethedevelopmentandimplementationofgoodmanufacturingpracticesfor dietarysupplementmanufacturers. Standardizedingredientsmustbecomplementedby FDAenforcingthosestandardsthroughgoodmanufacturingpractices.Theseareessential forFDAtobeassuredoftheprecisecontentsofeachbatchofsupplementsthatis manufactured.

RECOMMENDATION4:Disclosemoreusefulinformationtothepublicabout dietarysupplementadverseevents.

FDAshouldprovidemoreusefuldataonitswebsitesothatconsumerscan,tosome extent,evaluatethelikelihoodthattheadverseeventwasrelatedtothesupplement. FDAcouldupdatetheinformationonitswebsitemoreregularly.FDAcouldalso accomplishthisisbyprovidingsummarydataonthenumbersandtypesofreports receivedbyproducttypesoringredients.Overtime,asresourcesbecomeavailableit couldconsiderindicatingthelikelihoodtheeventwascausedbyaproduct.

COMMENTS

WereceivedcommentsonourdraftreportsfromtheFoodandDrugAdministration.We alsosolicitedandreceivedcommentsfromthreetradeassociations(ConsumerHealthcare ProductsAssociation,AmericanHerbalProductsAssociation,andtheCouncilfor ResponsibleNutrition)andtwopublicinterestorganizations(PublicCitizen'sHealth ResearchGroupandtheCenterforScienceinthePublicInterest.)SeeappendixCforthe commentsintheirentirety.

Onthebasisofthesecommentswemadeseveralchangesthatarereflectedinthisfinal report.Someinvolvedminortechnicalchanges,andothersinvolvedbriefelaborationsto clarifyandaddcontext.Intwoinstanceswemodifiedourrecommendationstotarget themmoreeffectivelyandtominimizeregulatoryburden.Welimitedthescopeof mandatoryreportingofadverseeventreportstoeventsthatarebothseriousinnatureand fallunderacertainsubsetofproductstobedeterminedbyFDA.Similarly,insteadof callingforFDAtonotifymanufacturersofalladverseeventreportsitreceives,wecalled forittonotifythemanufacturersofseriousreportsonly.

FoodandDrugAdministration

FDAreportedthatourfindingswereafairassessmentofthechallengesitfaces.Italso agreedwiththemajorityofourrecommendations.Aspartofitscomments,itcategorized ourrecommendationsintothreeareas:(1)tasksthatitcancurrentlyaccomplish,(2)tasks thatrequireadditionalresources,and(3)tasksthatrequirebothlegislativechangesand additionalresources.FDAdocumentedtheprogressithasmadeineachofthese categories. FDAindicatedthatthemajordifficultyitfacestoimprovingthesystemisa lackofadequateresources.

FDAismakingprogresstowardimprovingthesystemalongthelineswecallforinour report.Manyofourrecommendationsarealreadyincludedamong FDA'stoppriorities fortheyearaswellasinits10-yearstrategicplan.WealsoencourageFDAtoseekthe authorityitneedstorequiremanufacturerandproductregistrationandmandatory manufacturerreportingofadverseevents.

TradeAssociations

Thethreetradeassociationsprovidedsomesupportforourrecommendations,butforthe mostpart,theywerehighlycriticalofbothourfindingsandrecommendations.Whilewe disagreewiththethrustoftheircomments,theyhelpsharpentheissuesthatneedtobe addressedaspartofanyreform.

Oneoftheirmajorcritiqueswasthatwechosenottoevaluatetheinternaloperating proceduresofFDA'sadverseeventreportingsystem,therebyleavinguswithlittlebasis forourbroaderrecommendations.Weagreethattherecouldbevaluetoaprocedural review.FDAshouldbedoingeverythingitcantomakesurethecurrentsystemoperates aseffectivelyasitpossiblycan.However,weofferstrongevidencethatthecurrent systemisfundamentallyflawedandcannotprovideanadequateconsumersafeguard unlessFDAisgivenmoretoolstodothejob.

Anothersignificantcritiquewasthatwefailedtoviewdietarysupplementsinthecontext ofafood-relatedsystem.Thisfailure,theyclaim,ledustocallformoreextensive oversight,similartothatforprescriptiondrugs.Ourinquiryfocusedonhowthecurrent systemwasfunctioningandmadeusacutelyawareofjusthowlittleinformationFDAhas availabletodeterminewhetheradverseeventsaboutdietarysupplements(however characterized)presentdangersignsthatshouldbeaddressed.Withoutanimproved capacitytoobtainsuchinformation,FDA'sadverseeventreportingsystemwillcontinue tofallshortofitspotential.

Stillanothercritiquewasthatourreportreflectsanegativeviewofdietarysupplements andfailstorecognizetheirroleasself-careproductsthatsomanyconsumersvalue.We regretanyimplicationofsuchanegativeview.Ifthekindofrecommendationswecallfor areenacted,wesuggestthatconsumerswouldhavemoreextensiveandusefulinformation availabletothemontheseself-careproductsandcouldhavemoreconfidencethatan adverseeventreportingsystemwasprovidingthemwithavaluablemeasureofprotection.

PublicInterestOrganizations

Thetwopublicinterestorganizationsstronglysupportedourreport.Theirmaincritique wasthatwedidnotgofarenough.Onecalledforlegislativechangesthat,overtime, wouldsignificantlyenhanceFDAauthorities.TheothercalledforFDAtosupporta systematicstudyofdietarysupplementsafetyandefficacy.Whileourevidencedidnot allowustogoasfarastheseorganizationswouldlike,itdidleadustoemphasizethata comprehensivesetofchangesmustbecarriedoutiftheadverseeventreportingsystemis toprovideanadequateconsumersafetyvalve.

White House Commission on Complementary and Alternative Medicine Policy

Meeting Site: Academy for Educational Development
1825 Connecticut Avenue, N.W., Academy Hall, 8th Floor
Washington, DC

May 15-16, 2001

AGENDA II

DAY TWO: TUESDAY, MAY 15, 2001

Meeting Topic II. Complementary and Alternative Medicine: Research Challenges

12:30 p.m. **Opening Remarks**

- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

12:40 p.m. **Panel Session I: Overview of CAM Research Challenges**

20. *David Eisenberg, M.D.*
    Harvard University

- Discussion

1:25 p.m. **Panel Session II: Foundation Support for CAM Research**

21. *M. Bridget Duffy, M.D.*
    Medtronic Foundation

22. *Doriane C. Miller, M.D.*
    Robert Wood Johnson Foundation

23. *Susan Braun*
    Susan G. Komen Breast Cancer Foundation

24. *Ronald Chez, M.D.*
    Samueli Institute for Information Biology

- Discussion

2:35 – 2:50 p.m. **BREAK**

2:50 p.m. **Panel Session III: Approaches to Evaluating Research Literature**

25. *Donald A. Lindberg, M.D.*
    National Library of Medicine, NIH

26. *Douglas B. Kamerow, M.D., M.P.H.*
Agency for Healthcare Research and Quality

27. *Brian Berman, M.D.*
University of Maryland

◆ Discussion

4:10 p.m. **Panel Session IV: Concerns about CAM and CAM Research**

28. *William M. London, Ed.D., M.P.H.*
National Council Against Healthcare Fraud

29. *Simeon Margolis, M.D., Ph.D.*
Johns Hopkins University

30. *Arthur P. Grollman, M.D.*
State University of New York at Stonybrook

◆ Discussion

5:30 p.m. **ADJOURN**

DAY THREE: WEDNESDAY, MAY 16, 2001

7:30 a.m. **Registration Opens**

Meeting Topic II. Complementary and Alternative Medicine: Research Challenges (continued)

8:00 a.m. **Panel Session V: Research Methodology**

31. *John A. Chabot, M.D.*
Columbia University

32. *Marcia Angell, M.D.*
Editor-in-Chief, Emeritus, New England Journal of Medicine

33. *Jennifer Jacobs, M.D., M.P.H.*
American Institute of Homeopathy

34. *B. Alex White, D.D.S., Dr.P.H.*
Kaiser Permanente Center for Health Research

35. *Bruce Rabin, M.D., Ph.D.*
University of Pittsburgh

◆ Discussion

9:25 a.m. **Panel Session VI: Training of Conventional and CAM Investigators**

36. *Nancy Pearson, Ph.D.*
National Center for Complementary and Alternative Medicine, NIH

37. *Neal West, Ph.D.*
National Center for Complementary and Alternative Medicine, NIH

38. *Robert H. Blanks, Ph.D.*
University of California at Irvine

39. *Russell Phillips, M.D.*
Harvard University

40. *Richard Hammerschlag, Ph.D.*
Oregon College of Oriental Medicine

◆ Discussion

10:35 – 10:50 a.m. **BREAK**

10:50 a.m. **Panel Session VII: Publication of Peer-Reviewed CAM Research Results**

41. *Edward W. Campion, M.D.*
New England Journal of Medicine

42. *Jackie C. Wootton, M.Ed.*
Journal of Alternative and Complementary Medicine

43. *Phil B. Fontanarosa, M.D.*
Journal of the American Medical Association

44. *David Riley, M.D.*
Alternative Therapies in Health and Medicine

45. *Christine Laine, M.D., M.P.H.*
Annals of Internal Medicine

46. *Arnold Relman, M.D.*
Editor-in-Chief, Emeritus, New England Journal of Medicine

◆ Discussion

12:30 – 1:30 p.m. **LUNCH BREAK**

1:30 p.m. **Breakout: Small Group Discussion (CAM Research Challenges)**

2:50 p.m. **Group Reports and Discussion/Adjourn Meeting Topic II**

4:00 p.m. **BREAK**

4:15 p.m. **Public Comment Session: 3-Minute Oral Statements**

47. James Sensenig, American Association of Naturopathic Physicians
48. Candace Campbell, American Preventive Medical Association
49. Diane Davis Cole, University of Virginia Cancer Center
50. Katherine Jane Gorton, American Dietetic Association
51. Audrey Di Maria, Art Therapy Credential Board
52. Judy Simpson, American Music Therapy Association

◆ Discussion

53. Richard Goldberg, Private Practice
54. Nancy Kristine Haller, Feldenkrais Guild of North America
55. Christina Herlihy, National Certification Commission for Acupuncture and Oriental Medicine
56. Su Liang Ku, Florida Institute for Traditional Chinese Medicine
57. Sharon Stevenson, National Center for Homeopathy

◆ Discussion

58. Barbara Moquin, National Navel Medical Center
59. Matt Ward Russell, National Integrative Medicine Council
60. Carolyn Jones Sabatini, Pharmavite Corporation
61. Christina Walker, The Shenk Human Energetic Institute
62. Alan Dumoff, Private Practice

◆ Discussion

5:30 p.m. **MEETING ADJOURN**

White House Commission on Complementary and Alternative Medicine Policy

Meetings on
CAM: Understanding Coverage and Reimbursement
CAM: Research Challenges

May 14-16, 2001

Academy for Educational Development, Washington, DC

SPEAKER ROSTER

Marcia Angell, M.D.
Senior Lecturer
Department of Social Medicine
Harvard Medical School
641 Huntington Avenue
Boston, MA 02115
Telephone: (617) 576-6934
Fax: (617) 576-7926

Linda Bedell-Logan
President and CEO
Solutions in Integrative Medicine
P.O. Box 207
Saco, ME 04072
Telephone: (207) 282-5110
Fax: (207) 286-1866
E-mail: mbcm@gwi.net

Brian Berman, M.D.
Professor of Family Medicine
Director of Complementary Medicine Program
University of Maryland School of Medicine
2200 Kernan Drive
James L. Kernan Mansion
Baltimore, MD 21207
Telephone: (410) 448-6871
Fax: (410) 448-6875
E-mail:
bberman@compmed.ummc.umaryland.edu

Robert Blanks, Ph.D.
Professor, Anatomy and Neurobiology
University of California Irvine
College of Medicine
364 Med Surge II
Irvine, CA 92697-1275
Telephone: (949) 824-7991
Fax: (949) 824-8549
E-mail: rhblanks@uci.edu

Abby Block, M.A., M.S.W., M.B.A.
Assistant Director for Insurance Programs
Office of Personnel Management
1900 E Street, N.W., Suite 3400
Washington, DC 20415
Telephone: (202) 606-0770
Fax: (202) 606-4640
E-mail: alblock@opm.gov

Susan Braun
President and CEO
Susan G. Komen Breast Cancer Foundation
5005 LBJ Freeway, Suite 250
Dallas, TX 75244
Telephone: (972) 855-1611
Fax: (972) 855-1612
E-mail: sbraun@komen.org

Edward Campion, M.D.
Deputy Editor
New England Journal of Medicine
10 Shattuck Street
Boston, MA 02115
Telephone: (617) 734-9800
Fax: (617) 739-9864

John Chabot, M.D.
Associate Professor of Clinical Surgery
New York Presbyterian Hospital
161 Fort Washington Avenue
New York, NY 10032
Telephone: (212) 305-9468
Fax: (212) 305-5992
E-mail: jac4@columbia.edu

Ronald Chez, M.D.
Professor of Obstetrics and Gynecology
Professor of Community and Family Health
University of South Florida
2101 East Pacific Coast Highway, Suite 220
Corona del Mar, CA 42625-1900
Telephone: (949) 760-4417
Fax: (949) 759-5707
E-mail: rchez@siib.org

M. Bridget Duffy, M.D.
Medical Director
Medtronic USA, Inc. and
Medtronic Foundation
710 Medtronic Parkway, MS LC110
Minneapolis, MN 55432
Telephone: (763) 505-2644
Fax: (763) 505-2648
E-mail: bridget.duffy@medtronic.com

David Eisenberg, M.D.
Associate Professor of Medicine
Harvard Medical School and
Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, MA 02215
Telephone: (617) 632-7770
Fax: (617) 632-7772
E-mail: deisenbe@caregroup.harvard.edu

Phil Fontanarosa, M.D.
Executive Deputy Editor, *JAMA*
American Medical Association
515 North State Street
Chicago, IL 60610
Telephone: (312) 464-2427
Fax: (312) 464-5824
E-mail: phil_fontanarosa@ama-assn.org

Merilyn Francis, R.N., M.P.P.
Director, Quality Management and Health
Services Research
American Association of Health Plans
1129 20th Street, N.W., Suite 600
Washington, DC 20036
Telephone: (202) 778-3224
Fax: (202) 778-3287
E-mail: mfrancis@aahp.org

Derrick Gallion
Director, Complementary and
Alternative Medicine
Blue Cross and Blue Shield
of South Carolina
I-20 at Alpine Road, AF-325
Columbia, SC 29219
Telephone: (803) 788-0222, ext. 41080
Fax: (803) 419-3338
E-mail: rick.gallion@bcbssc.com

Melinna Giannini
President and CEO
Alternative Link, Inc.
1065 South Main, Building C
Las Cruces, NM 88005
Telephone: (505) 527-0636
Fax: (505) 523-4152
E-mail: mg@alternativelink.com

Arthur Grollman, M.D.
Professor
Department of Pharmacological Sciences
State University of New York at Stony Brook
BHS T8, 160
Stony Brook, NY 11794-8651
Telephone: (631) 444-3080
Fax: (631) 444-7641
E-mail: apg@pharm.sunysb.edu

Richard Hammerschlag, Ph.D.
Research Director
Oregon College of Oriental Medicine
10525 S.E. Cherry Blossom Drive
Portland, OR 97216
Telephone: (503) 253-3443, ext. 156
Fax: (503) 253-2701
E-mail: rhammerschlag@ocom.edu

Daniel Hawkins, Jr., B.S.
Vice President
National Association of Community Health Centers, Inc.
Suite 122
1330 New Hampshire Avenue, N.W.
Washington, DC 20036
Telephone: (202) 296-0131
Fax: (202) 296-3526
E-mail: dhawkins@nachc.com

Max Heirich, Ph.D.
Professor and Research Scientist Emeritus
The University of Michigan
1111 East Catherine
Ann Arbor, MI 48109
Telephone: (734) 763-1187
Fax: (734) 763-0913
E-mail: mheirich@umich.edu

Jennifer Jacobs, M.D., M.P.H.
Clinical Assistant Professor
University of Washington
23200 Edmonds Way, Suite A
Edmonds, WA 98026
Telephone: (206) 542-5595
Fax: (425) 771-4789
E-mail: jjacobs@igc.org

Joy Johnson Wilson
National Conference of State Legislators

Douglas Kamerow, M.D., M.P.H.
Director, Center for Practice and Technology Assessment
Agency for Healthcare Policy and Research
6010 Executive Boulevard, Suite 300
Rockville, MD 20852
Telephone: (301) 594-4026
Fax: (301) 594-4027
E-mail: dkamerow@ahrg.gov

John T. Kelly, M.D.
Aetna/U.S. Healthcare

Kathleen King
Vice President
Washington Business Group on Health
50 F Street, N.W., Suite 600
Washington, DC 20010
Telephone: (202) 628-9320
Fax: (202) 628-9244
E-mail: king@wbgh.org

Alan Korn, M.D.
Blue Cross and Blue Shield Association

Christine Laine, M.D., M.P.H.
Senior Deputy Editor
Annals of Internal Medicine
190 North Independence Mall West
Philadelphia, PA 19106
Telephone: (215) 351-2527
Fax: (215) 351-2644
E-mail: claine@mail.acponline.org

Donald Lindberg, M.D.
Director
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
Telephone: (301) 496-6221
Fax: (301) 496-4450
E-mail: lindberg@nlm.nih.gov

William London, Ed.D., M.P.H.
President
The National Council Against Health Fraud, Inc.
P.O. Box 141
Fort Lee, NJ 07024
Telephone: (201) 723-2955
E-mail: ncahf@worldnet.att.net

Judith MacPherson
Benefits Manager
CACI International Inc.
1100 North Glebe Road
Arlington, VA 22201
Telephone: (703) 841-7836
Fax: (703) 528-8112
E-mail: jmacpherson@caci.com

Simeon Margolis, M.D., Ph.D.
Professor of Medicine and Biological Chemistry
Johns Hopkins School of Medicine
Room 336, 1830 Building
Johns Hopkins Hospital
Baltimore, MD 21287
Telephone: (410) 955-1777
Fax: (410) 955-8172
E-mail: smargoli@jhu.edu

Doriane Miller, M.D.
Program Vice President
The Robert Wood Johnson Foundation
Route 1 and College Road East
Princeton, NJ 08543-2316
Telephone: (609) 627-5772
Fax: (609) 514-5520
E-mail: dmiller@rwjf.org

Michael O'Grady
Project Hope, Center for Health Affairs

Nancy Pearson, Ph.D.
Program Officer
National Center for Complementary and Alternative Medicine
6707 Democracy Boulevard, Room 106
Bethesda, MD 20892
Telephone: (301) 594-0519
Fax: (301) 480-3621
E-mail: pearsonn@mail.nih.gov

Russell Phillips, M.D.
Director, Harvard Fellowship Program
Complementary and Alternative Medicine
Harvard Medical School
Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, MA 02215
Telephone: (617) 667-5384
Fax: (617) 667-2751
E-mail: rphillip@caregroup.harvard.edu

Bruce Rabin, M.D., Ph.D.
Professor of Pathology
University of Pittsburgh Medical Center
200 Lothrop Street
Pittsburgh, PA 15213-2582
Telephone: (412) 647-6150
Fax: (412) 647-7741
E-mail: bsr@pitt.edu

Arnold Relman, M.D.
Professor Emeritus of Medicine and of Social Medicine
Harvard Medical School
Channing Laboratory
181 Longwood Avenue, 5th Floor
Boston, MA 02115-5804
Telephone: (617) 525-2185
Fax: (617) 525-2186

David Riley, M.D.
Editor in Chief, Alternative Therapies in Health and Medicine
University of New Mexico Medical School
P.O. Box 4310
Santa Fe, NM 87502
Telephone: (505) 983-0546
Fax: (505) 983-4196
E-mail: dsriley@integrativemed.org

Tom Sawyer, Ph.D.
William M. Mercer, Incorporated
3131 East Camelback Road, Suite 300
Phoenix, AZ 85016
Telephone: (602) 522-6560
Fax: (602) 957-9573
E-mail: tom.sawyer@us.wmmercer.com

Wayne Sickels, M.T.S., M.Div.
Massage Therapist
Virginia State C.M.T.
489 A Carlisle Drive
Herndon, VA 20170
Telephone: (703) 481-6411
E-mail: tmasters@erols.com

Nathan Stinson, Jr., M.D., Ph.D., M.P.H.
Deputy Assistant Secretary for
Minority Health
Office of Minority Health
Office of Public Health and Science, DHHS
5515 Security Lane, Suite 1000
Rockville, MD 20852
Telephone: (301) 443-5084
Fax: (301) 594-0767
E-mail: nstinson@osophs.dhhs.gov

John Weeks
Principal
Integration Strategies for Natural
Health Care
3345 59th Avenue S.W.
Seattle, WA 98116
Telephone: (206) 933-7983
Fax: (206) 933-7984
E-mail: pihcp@aol.com

Neal West, Ph.D.
Program Officer
National Center for Complementary
and Alternative Medicine
6707 Democracy Boulevard, Room 106
Bethesda, MD 20892
Telephone: (301) 402-5867
Fax: (301) 480-3621
E-mail: westn@mail.nih.gov

B. Alex White, D.D.S., Dr.P.H.
Senior Investigator and Assistant
Program Director
Kaiser Permanente Center for Health
Research
3800 North Interstate Avenue
Portland, OR 97227-1110
Telephone: (503) 335-6765
Fax: (503) 335-6311
E-mail: alex.white@kpchr.org

John Whyte
Health Care Financing Administration

Jackie Wootton, M.Ed.
Executive Editor
Journal of Alternative and Complementary
Medicine
5411 West Cedar Lane, Suite 205-A
Bethesda, MD 20814
Telephone: (301) 581-0116
Fax: (301) 581-0119
E-mail: jcw@amfoundation.org

Candace Lee Campbell, B.A.
American Preventive Medical Association
Box 458
Great Falls, VA 22066

Diane Davis Cole, M.P.H.
University of Virginia Cancer Center
P. O. Box 800334
Charlottesville, VA 22908

Audrey Di Maria, M.A., ATR-BC
Secretary of Art Therapy Credential Board
4200 Cathedral Avenue, N.W., #901
Washington, DC 20016

Alan Dumoff
Private Practice

Richard Ira Goldberg, M.S.W.
Private Practice
4330 East West Highway, Suite 306
Bethesda, MD 20814

Katherine Jane Gorton, M.S.
American Dietetic Association
1120 Connecticut Avenue, N.W., #480
Washington, DC 20036

Nancy Kristine Haller, L.M.P., B.A.
Guild Certified Feldenkrais Practitioner
Feldenkrais Guild of North America
821 South 219th, #8
Des Moines, WA 98198

Christina Herlihy, Ph.D.
National Certification Commission on Acupuncture and Oriental Medicine
11 Canal Center Plaza, Suite 300
Alexandria, VA 22314

Su Liang Ku, A.P., Professor
Florida Institute of Traditional Chinese Medicine
5335 66th Street North
St. Petersburg, FL 33702

Alice McCormick, Dipl. Ac. & C.H.
National Certification Commission on Acupuncture and Oriental Medicine
11 Canal Center Plaza, Suite 300
Alexandria, VA 22314

Barbara E. Moquin, Ph.D.(cand), R.N., M.S.N., CS-P
National Naval Medical Center
8901 Wisconsin Avenue
Bethesda, MD 20878

Matt Ward Russell
National Integrative Medicine Council
5151 E. Broadway, Suite 1095
Tucson, AZ 85711

Carolyn Jones Sabatini, B.A., M.B.A.
Pharmavite Corporation
11904 Cherokee Lane
Leawood, KS 66209

James S. Sensenig, N.D.
American Association of Naturopathic Physicians
2558 Whitney Avenue
Hamden, CT 06518

Judy Simpson, MT-BC
American Music Therapy Association
8455 Colesville Road, Suite 1000
Silver Spring, MD 20910

Sharon Stevenson
National Center for Homeopathy

Christina Walker
The Shenk Human Energetic Institute

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Recommendations

Divider Title: _____

Summary of Major Themes and Recommendations from October 5-6, 2000 Research Meeting

The following themes and recommendations drawn form the October 5-6, 2000 meeting on research have been placed under the panels in which they were discussed.

However, you will find considerable overlap of the issues and recommendations from panel to panel. Multiple panels may include references to research, research training, integrative academic centers, regulatory agencies, foundations, the private sector, and so forth.

Please keep in mind this list of themes and recommendations and the presentations and discussions from the May 15-16 research meeting when you discuss key issues and recommendations during your breakout sessions on the afternoon of May 16.

Panel I: Research Priorities and Public Input

The IOM recommendation to increase the public's voice in the NIH priority setting process can serve as a model for public input into the process of developing recommendations for CAM policy setting.

Encourage CAM practitioners to work within the current research system and aspire to the rigorous, blinded, randomized studies that are the gold standard, recognizing the ways by which reliabel, objective data on health and medicine may are obtained, such as observational data, pilot studies, case studies. **(Leon Rosenberg, Institute of Medicine, IOM)**

Encourage the NIH to expand its portfolio of clinical research with efforts that answer questions concerning modalities that are not going to be patentable and that will not have their research paid for by biotech or pharmaceutical or drug device industries. **(Leon Rosenberg, IOM)**

In addition to full support for NIH, a remarkably successful Federal research agency that has served the public so well, fund related Federal agencies, such as CDC, FDA, HRSA and others, adequately so that they may carry out their public health mandates, and include CAM-related activities as part of their mandate.

Panel II: Federally Funded CAM Research

One of the biggest hurdles facing CAM is opening up dialogue and collaboration with conventional practice and conventional clinical research. CAM practitioners interested in research must make their voices heard more strongly. Sponsor interdisciplinary workshops and conferences. Invite CAM practitioners and researchers to serve on interdisciplinary advisory groups and sit on committees.

The RCT is the preferred method of clinical study and can be applied successfully to some CAM questions. However, traditional clinical trials may not be very informative about the efficacy of many CAM treatments. CAM research questions are hard to validate. Some CAM regimens are difficult to study because they are complex, individualized, lack uniformity, and are hard to generalize. It is difficult to acquire preclinical information on many CAM patients. Survival as the endpoint may not apply to CAM treatments. Many CAM modalities are not presently reimbursed by Medicare.

NIH Institutes interested in studying CAM modalities may face a lack of validated data and reluctance of established investigators to do the research. To encourage established scientists to address CAM questions, define a measurable research question and explore ways of obtaining pre-clinical data . In developing protocols, there are methodologies other than the gold standard to employ. If necessary, the challenge exists to develop new ways of pursuing the question.

Define the types of questions that are and that are not appropriate for RCTs. Identify the

appropriate methodology for the type of (scientific) question being asked.

Develop alternative investigative methods for studies where there is concern about using a placebo as a standard part of the technique. Because of the risk of using uncertain measurement techniques to study untested CAM approaches, a grant should be announced to bring together experts with broad experience and interest in research methodology to explore, in a think tank effort, with CAM practitioners and trained researchers possible scientific approaches to various types of questions.

Many CAM practitioners are unfamiliar with research techniques and requirements. The lack of trained CAM investigators is a significant problem. Funds must be made available to train people interested in CAM. Fund and plan workshops to enhance communication and awareness in both communities, and to offer guidance on how to prepare grant applications and obtain grant funding. Promote research partnerships with CAM practitioners and researchers.

Increase funding for research, training, and infrastructure at CAM research institutions, and open doors to cross training and collaboration between conventional and CAM institutions.

Quality research leads to credibility and credibility leads to acceptance and integration of services. There needs to be a paradigm shift to respect the modality under study, and research training programs for clinicians, through academic partnerships, that allow them to stay in practice and become familiar with the clinical environment and clinical outcomes research.

Federal efforts in CAM are expanding. CAM research now has funding, better peer review, and credibility at NIH. There is still a need for research infrastructure and training at CAM centers. FDA policies and procedures also must address CAM issues.

The social sciences and behavioral sciences are receiving more recognition, and more attention is being paid to promoting health and preventing disease. CAM approaches contribute to general health and wellness. Opportunities to study these approaches to improve quality of life should be encouraged. CAM helps to envision what the future in medicine will be, especially given an aging society suffering with chronic illnesses, and a need to strengthen health maintenance in younger people.

There is overlap between CAM and conventional medicine in areas such as nutrition, analysis of plant and animal products, mind-body medicine, pain control and palliative care. Nutrition and prevention were once disregarded by conventional medicine; now they are becoming standard. Patients who suffer from chronic diseases like low back pain and arthritis often turn to CAM.

Encourage strengthened support for NCAAM and its collaborations with other NIH Institutes, the NCI best case series program, and the ODS, which is supporting such studies as the synergistic properties of blended compounds. Also support Federal funding for clinical research on nonpatentable modalities.

An important challenge is finding a way for the CAM community to work with the medical establishment. CAM needs to strengthen its reputation and reach out to people in conventional medicine who can make a contribution.

The absence of common and consistent definitions of CAM contributes to problems in communication.

Develop strategies to increase CAM cancer research needed to address the range of challenges—e.g., difficulty in establishing uniformity, complexity of individual regimens, difficulty replicating treatments in clinical settings—posed by the nature of the field. **(Jeffrey White, National Cancer Institute, NCI)**

More fully examine the potential of CAM's whole-patient approach to improve the quality and perhaps quantity of remaining life for cancer patients. **(Jeffrey White, NCI)**

Expand CAM research in ways that access the resources of the larger and more research-savvy conventional community. **(Jeffrey White, NCI)**

Provide resources to bridge the "two culture problem." Opportunities and resources are needed to foster communication and collaboration between CAM and conventional practitioners and researchers. Inherent problems in CAM clinical research, difficulty in standardizing interventions, culture problems between practitioner and research communities, general awareness about CAM, can be resolved by building appropriate interdisciplinary collaborations **(Jeffrey White, NCI)**

Use existing mechanisms of federal research support to train CAM practitioners areas in conventional research methodologies. **(Steven Hausman, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIAMS)**

Look at low back pain as a vast potential opportunity for the integration of conventional and CAM modalities. **(Steven Hausman, NIAMS)**

Study the placebo effect more rigorously. **(Steven Hausman, NIAMS)**

Discourage rules barring Medicare payments for things Medicare does not normally cover, including many complementary and alternative modalities, which pose a significant obstacle for getting elderly people on Medicare to participate in CAM trials. **(Steven Hausman, NIAMS)**

Invite the public to give their views in setting CAM research priorities. (**Steven Hausman, NIAMS**)

Encourage research into dietary supplements to be evidence-based and structured like other medical research. (**Paul Coates, Office of Dietary Supplements, ODS**)

Support dietary supplement research activities that engage partnerships between research organizations, non-profits, and private industry with common interests in the field to help merge the sometimes conflicting impressions that (a) evidence supporting traditional CAM falls outside the American medical paradigm and should be ignored and that (b) traditional products don't need to be evaluated because of their long traditions of use. (**Paul Coates, ODS**)

Increase the number of workshops and conferences that focus on interdisciplinary approaches to medical research as a way of increasing the share of the research pie that goes to CAM activities. (**Paul Coates, ODS**)

Panel III: Academic Centers and Support for CAM Research

Encourage Federally-funded universities to develop programs that bring CAM clinical research into the academic health centers working with CAM practitioners/researchers. Create interdisciplinary collaborations with CAM institutions to develop research capability.

Increase the publication of valid CAM research findings in major medical journals and increase the readership of quality CAM journals. Lack of coverage limits further study

Increase awareness of physicians regarding CAM therapies their patients are using to avoid adverse reactions.

Create a steering committee that understands CAM to advise IRB's on applications they may not fully appreciate. (**Alfred Fishman, Penn**)

Integrate complementary and alternative therapists into the educational curriculum in places where it is appropriate to consider them. (**Alfred Fishman, Penn**)

Sponsor a meeting with a critical mass of people at institutions engaged in CAM research who want to exchange ideas. (**Alfred Fishman, Penn**)

Address the issue of a fundamental lack of research orientation in CAM institutions by partnering with institutions that have a research focus. (**Alfred Fishman, Penn**)

When creating a new CAM division, engage people with real opposition to the idea in the planning panel. (**Daniel Federman, Harvard University**)

Refrain from disparaging good, well-written anecdotes. Recognize that anecdotes are appropriately the precursor to rigorous scientific research. (**Daniel Federman, Harvard University**)

Connect CAM with existing institutional strengths by granting programs cooperatively. (**Daniel Federman, Harvard University**)

Develop an interdisciplinary, multi-disciplinary, interprofessional research agenda that employs social, clinical, and basic sciences, to integrate CAM and conventional medicine. (**William Meeker, Palmer College of Chiropractic, PCC**)

Train CAM scientists. Provide programs, incentives, pre and post-doc positions and career tracks for capable and interested young people. (**William Meeker, PCC**)

Create ways to encourage interdisciplinary, multidisciplinary and inter-professional collaborations between CAM institutions and tax-supported universities. (**William Meeker, PCC**)

Apply the entire universe of research project and program funding mechanisms to initiate, encourage and support CAM research, including bricks and mortar. (**William Meeker, PCC**)

Call for interdisciplinary conferences to explore scientific states-of-the-art on CAM topics and establish rigorous research agendas. Support the agendas with targeted research funding program announcements. (**William Meeker, PCC**)

Encourage the National Library of Medicine to include CAM topics and references in its indexing systems. (**William Meeker, PCC**)

Establish academic CAM clinical centers. (**William Meeker, PCC**)

Support CAM training institutions in the broadest possible sense, like all other health professions, in order to eliminate the dependence on tuition and provide the resources to develop a more effective and consistent research culture. (**William Meeker, PCC**)

Ensure that CAM professionals are routinely appointed and otherwise included in research policy making efforts. (**William Meeker, PCC**)
Consider something similar to the Centers of Excellence program in HRSA's Bureau of Health Professions to help jumpstart the research efforts of CAM professions and their institutions. (**William Meeker, PCC**)

Develop training programs and career tracks, so that people that have a natural inclination in this direction see that they can have a job and a career doing it. That has not existed in the CAM profession so far. (**William Meeker, Palmer College of Chiropractic**)

Botanicals, which have potential beyond over-the-counter products and the DSHEA marketplace, test the law because they are manufactured like a biological under heavy process control, sold as a food or dietary supplement by Congressional fiat, and used as therapy by the public.

There should be more focus on folk medicine, which has been used widely, but does not fall within the DSHEA model. Good anecdotal information should be considered.

There should be more international outreach and access to European safety data. Better information systems would be helpful.

Because it is difficult to give exclusive rights for substances used for many centuries, natural products research has shut down and FDA has approved very few preventive medicines.

Submit comments related to new guidelines, Botanical Drug Products, designed to open the door for the study of traditional botanicals without the barriers that currently exist, which are designed for synthetic drugs. **(Janet Woodcock, FDA, Center for Drug Evaluation and Research)**

Provide input on proposed changes in combination product regulations, which were originally written for purified drugs and are being revised to help botanicals move through the approval stage more quickly. **(Janet Woodcock, CDER)**

Provide additional resources to assist small companies to get through the FDA drug review. **(Janet Woodcock, CDER).**

Encourage the FDA to promulgate additional chemistry and manufacturing standards to accommodate the reproducibility and stability and constant dose issues raised by plants.**(Janet Woodcock, CDER)**

Create a place in FDA with sufficient staffing that could work with groups at various levels to assess the appropriate classification of botanicals as treatments. **(Janet Woodcock, CDER)**

Define the safety standard for dietary supplements. As yet, the law is silent on the question of their benefits, and only speaks to their safety, though what degree of safety and confidence is still being determined. **(Joe Levitt, Food Center at FDA)**

Panel VI: Research in the Regulatory Framework

State medical boards protect the public from unqualified physicians. Some CAM practices lack scientific validation. Three areas of harm are outlay of money on ineffective treatments, delay in seeking appropriate care, and direct harm. Guidelines are being developed to educate and regulate all physicians. Regulators must have solid information about interventions and research on effectiveness. If chelation is effective, medical boards should hold doctors responsible for not using it. If not, physicians who use it should go before the state medical boards. Medical boards

do not want to create barriers to legitimate research, but their first priority is public safety. Once the Federation establishes a process, the states pick it up.

The Federation of State Medical Boards should consider a process for state medical boards to meet with CAM practitioners who want to conduct research but whose treatments are considered nonstandard or fraudulent by the state.

A practitioner who goes through an IRB, may need help in navigating the process.

Include CAM practitioners as members or consultants on state medical boards. Also, IRBs and study sections should include panelists familiar with CAM.

CAM practitioners who believe in practice-based research need an environment that allows for thinking outside of the box and the development of new methodologies. There is precedent for waiving the gold standard. FDA did it for interleukin-2 based on a pilot study. Changes need to be made so that medical boards work with and not against people trying to validate their procedures.

Lack of insurance reimbursement, fear of losing one's license, lack of time and money, and bias in the system stand in way of moving ahead with research. Most people cannot be both a clinician and researcher. Many clinicians have data on which to build, but do not want to hand it over for fear of what is going to happen to them. More needs to be learned about these problems, while preserving the goal of protecting the public.

Include in the guidelines for fraudulent and deceptive practices those guidelines standards for assessing the work of a non-institution based physician who is engaged in research. **(James Winn, Federation of State Medical Boards, FSMB)**

Include on medical boards CAM consultants to assist in their evaluation of cases and any kind of complaint that comes forward. **(James Winn, FSMB)**

Invite patent lawyers to address the issue of exclusive rights to botanical extracts. . **(Floyd Leaders, Botanical Enterprises, Inc.)**

Rather than bring foreign plants to the US for research, work in a partnership within that country. **(Floyd Leaders, Botanical Enterprises, Inc.)**

Allow the elimination of the disclaimer on a DSHEA regulated label if a certain threshold of evidence is achieved, or give it over-the-counter drug status. **(Robert McCaleb, Herb Research Foundation)**

Increase the focus on traditional medicine, recognizing that DSHEA leaves that out. **(Robert McCaleb, Herb Research Foundation)**

Develop ways to look at historical information on herbs and using this information in the evaluation of their efficacy and safety. **(Robert McCaleb, Herb Research Foundation)**

Facilitate international outreach in terms of accessing the information from European and Asian clinical practice. **(Robert McCaleb, Herb Research Foundation)**

Cut through the maze of information and try to get information, especially for consumers and practitioners that is quality evaluated, so people can trust the information and utilize in their decision-making process. **(Robert McCaleb, Herb Research Foundation)**

More funding is needed for libraries and collaboration to utilize the resources that are currently untapped. **(Robert McCaleb, Herb Research Foundation)**

Appoint a panel of experts, who are really specifically focused in this area of natural product health care, to look at the evidence on herbs and make decisions. **(Robert McCaleb, Herb Research Foundation)**

Adequately fund alternative medicine research centers so that they can collaborate with orthodox medicine. **(Anthony Rosner, Foundation for Chiropractic Education and Research, FCER)**

Address anti-chiropractic sentiments in the composition and proceedings of institutional review panels and boards. **(Anthony Rosner, FCER)**

Require an equitable number of individuals within each study section of a grant proposal, who are familiar with and sensitive to the conduct of CAM therapeutic regimes to be tested. **(Anthony Rosner, FCER)**

Place far greater emphasis on cohort studies and case series in reaching research goals rather than to assume categorically that they provide inferior guidance to the clinical decision-making than RCTs. **(Anthony Rosner, FCER)**

Panel VII: Outcomes Research Part I – Interface between CAM Research and Regulatory Agencies

The NCI best case series program is dependent on practitioners feeling comfortable giving documentation of their practices to the federal government. Changes in regulation need to be explored to change the regulations so that best case series can become more productive.

Some very excellent researchers have had difficulty getting INDs. Perhaps NIH research Institutes, such as NCI, could establish procedures to explore this concern with the FDA.

Develop a forum for alternative practitioners or scientists who believe they are being harassed unfairly.**(Nicholas Gonzalez, Private Practice)**

Use the threat of cuts in Medicare or Medicaid funding to force the states to protect new ideas.(**Nicholas Gonzalez, Private Practice**)

Use health departments to identify the top 35 public health problems in the United States and aim therapies at them, also see what is working in clinical settings and use that evidence as a starting point for understanding why. (**Ann McCombs, Private Practice**)

Explore how regulation could help the Best Case Series program become more productive since some CAM practitioners are not willing to come forward because they feel they need to practice in secret. (**Jeffrey White, National Cancer Institute, NCI**)

Learn more about problems with getting INDs for certain herbal products and the effect that is having on inhibiting some cancer research. (**Jeffrey White, NCI**)

Panel VIII: Private Sector Support for CAM Research

Develop a model for coordination of research between the Federal, private, and not-for-profit sectors.

Private industry should be encouraged to endorse coordinated research programs to transform medical science into products wanted and needed by the public. NIH should support more effective integration of Federal and private efforts. Incentives and intellectual property issues need to be resolved to allow for marketing protection, as well as appropriate regulatory pathways

Nature has been a fruitful source of new medications. The largely empirical screening methods of the natural product-derived drug discoveries have fallen into disfavor, viewed as labor-intensive and unproductive. DSHEA is allowing fresh interest in plant medicine. Impending changes in the regulation of botanical drugs could stimulate more development and research. Botanicals must be evaluated by the highest standards. The level of investment in this area needs to be comparable to that of pharmaceuticals. The return on investment is an issue; corporations need protection for their work and incentives.

A primary obstacle is the lack of recognition of the benefits of herbs. The German regulatory system recognizes the benefits and half of the herbs sold in Germany are doctor recommended or prescribed. Much of European research was done on proprietary commercial products. Some European companies are concerned about their research being "borrowed" and used unfairly by competitors.

DSHEA has been a stimulus for herbal research and there are many examples of private sector funding by the herb industry. However, incentives are needed, such as rights to exclusivity claims and market protections. Modification of the dietary supplement disclaimer allowing removal from a product that has had some clinical study review should be considered, as well as tax incentives. FDA approval of structure/function claims could promote research. The

government should consider establishing an expert review panel to evaluate the safety and appropriateness of both the structure/function claims under DSHEA and as OTC drugs. Herbs do not qualify for composition-of-matter patents. Since the passage of DSHEA, some process and use patents have been granted, but use patents may not be able to withstand public domain and traditional use challenges. Trademark protection should be available as a motivator for research investment, and there should be a way to protect small companies.

Industry should also share information from incomplete studies in order to guide other efforts, provide substances for clinical trials, assist in the preparation of appropriate placebos, and offer industry-sponsored symposia with CAM practitioners. Products with defined standards should be used in studies, and industry should form partnerships with clinicians and academia and participate on NIH advisory panels.

Pharmaceuticals, OTCs, and herbals need to provide a competitive advantage; exclusivity is a major issue. Another concern is that a single study might not be accepted as sufficient. There are many intellectual property issues. The company has the ultimate responsibility for the safety of its product. FDA guidance will facilitate getting to Phase II trials. Depending on the size of the market, a process use patent would be a solid incentive.

FDA guidelines suggest that with a minimal preclinical package, moving some of these materials directly into Phase 2 studies might be possible, and instead of taking the individual components out of the plants, one can look at how the combination is working. However, there is the question of safety moving straight to Phase II. In some cases, safety documentation from elsewhere is strong, other times it is not.

Looking at the genomes of plants will eventually allow us to see what happens with the entire plant, and this is where corporate interests lie. Even when looking at health and wellness as a unified field, the cultural aspects are not for a company to determine, but rather fall to the provider.

DSHEA requires that the product deliver what the label says. Industry is about to undertake a third-party testing program. Companies will pay a licensing fee for periodic testing in return for receiving a seal.

The Federal government should compile a primer on funding mechanisms and make funding opportunities more visible. Hold a conference on completion of relevant studies and develop a database including privately-supported study results.

To overcome barriers, meetings should be held with journal editorial boards to solicit recommendations to increase acceptance of papers submitted by industry.

Involve companies up front in developing a system of appropriate regulation. (**Randy Burkholder, Advanced Medical Technology Association, AMTA**)

Provide incentives for developing CAM related medical devices with private or public reimbursement mechanisms. (**Randy Burkholder, AMTA**)

Facilitate research collaborations with private sector research organizations, and take advantage of such mechanisms as Small Business Innovation Research grants. (**Raymond Ruddon, Johnson & Johnson, J&J**)

Provide incentives for private industry's involvement in CAM research by resolving intellectual property issues through something akin to legislative exclusivity remedies like the Ortho-Drug program. (**Raymond Ruddon, J&J**)

Provide proprietary protection around the process, extraction, production, and use of unique mixtures or combinations of agents for single herbs. (**Raymond Ruddon, J&J**)

Expand communication between traditional and conventional medical experts. (**Raymond Ruddon, J&J**)

Increase the availability of private and federal funding for CAM research. (**Raymond Ruddon, J&J**)

Develop a rigorous review process involving both academic and industry scientists to evaluate scientific-merited CAM research proposals. (**Raymond Ruddon, J&J**)

Design discovery research projects in CAM using such tools as gene expression arrays or proteolytics to identify new bioactive substances in natural products and pharmacogenomics to individualize therapies. (**Raymond Ruddon, J&J**)

Address the anti-CAM bias in subsequent editions of Goodman and Gelman's, "Textbook of Pharmacology." (**Raymond Ruddon, J&J**)
Create incentives for the private sector to invest more substantially in research and development of natural medicines like a Waxman-Hatch type data or marketing exclusivity period that would allow the investor to fully develop the medical and commercial potential of natural medicines. (**Frank Sciavolino, Pfizer**)

Allow early access to Phase II trials to help lower attrition rates for new neutraeuticals and to reduce overall development costs. (**Frank Sciavolino, Pfizer**)

Explore the CDSL recommendation that label disclaimers mandated by DSHEA could be modified or removed if a botanical product met certain requirements for research. (**Mark Blumenthal, American Botanical Council**).

Find a viable balance among free market and competitive issues, science, regulation, and the need to respect cultural heritage, and traditional use. (**Mark Blumenthal, ABC**)

Help promote research by making structure/function claims approvable by FDA, modifying the dietary supplements disclaimer following some clinical study review, allowing process and use patents for botanicals, providing tax credits for research funding. (**Mark Blumenthal, ABC**)

Establish an expert review panel similar to Commission E to evaluate the safety and appropriateness for claims for herbal products, both the structure/function claims under DSHEA and as OTC drugs. (**Mark Blumenthal, ABC**)

Encourage the CAM industry to submit its studies to peer review journals for publication and provide data from its unpublished studies to assist in selection of therapies for further study and to contribute to study design. (**Annette Dickenson, Council for Responsible Nutrition, CRN**)

Encourage the supplement industry to cosponsor symposia or conferences to provide networking opportunities between researchers and clinicians. (**Annette Dickenson, CRN**)

Convene meetings with journal editorial boards to solicit recommendations which would increase the acceptance of papers submitted by the supplement industry. (**Annette Dickenson, CRN**)

Encourage the supplement industry to generate a clinical trials guidance document outlining the standard components and proper design of study protocols. (**Annette Dickenson, CRN**)

Encourage the supplement industry to form partnerships with clinicians or academia, depending on the type of study. (**Annette Dickenson, CRN**)

Establish a special web site to facilitate communications regarding ongoing research needs and opportunities. (**Annette Dickenson, CRN**)

Develop a primer on funding mechanisms for research and conferences within government agencies that apply to industry should also be compiled to explain, for example, cooperative research and development agreements, small business grants, investor-initiated grants, and contracts. (**Annette Dickenson, CRN**)

Develop a document for industry use, explaining, how each research agency determines its research agenda. (**Annette Dickenson, CRN**)

Develop a government-industry partnership to conduct testing to confirm the safety of the product not simply in terms of lack of any knowledge of un-safety, but in terms of proactive, positive demonstration of lack of teratogenicity and for safety during pregnancy. (**Annette Dickenson, CRN**)

Give the FDA more enforcement authority to assure that products are what they are supposed to be. (**Annette Dickenson, CRN**)

Panel IX: Not-for-Profit Sector Support for CAM Research

Not-for-profit organizations can stimulate CAM research by providing seed money; supporting grants and publication of research, offering financial awards for medical school and research training; and convening conferences. The lack of awareness of existing research is a problem. The solution is publication of studies in peer reviewed journals. To increase funding and partnerships for CAM research, improve the rigor of proposed studies. Find incentives to stimulate mentors who can help develop new CAM researchers. Include studies on mechanisms of action and cost effectiveness, and fund conferences to review strengths and weaknesses of existing research and propose new, well-designed studies.

Productive partnerships should be created between Federal agencies and foundations that focus on communication and opportunities for collaboration. Each should host meetings and plan site visits to CAM research centers, where information about current research and the federal grant process is available. Agencies should seek more foundation representation on their panels, and include them on mailing lists. Foundations should stimulate CAM research by funding more small pilot studies, often a requirement for government funding, and by creating a pool of research funds among themselves to diminish risk.

Identify foundations interested in finding and supporting new, cutting-edge areas to research.

Some investigators are not affiliated with institutions, but both government and not-for-profit institutions usually do not support individuals. Should changes in not-for-profit law be recommended to permit grants to fund individuals? .

Improve funding access for CAM by improving the methodical rigor of proposed studies. **(John Templeton, Jr., John Templeton Foundation, JTF)**

Encourage new researchers in CAM therapies with mentors trained in scientific research. **(John Templeton, Jr., JTF)**

Develop better coordination between non-profit and federally supported CAM research by convening a jointly funded consensus conference to review in depth the strengths and weaknesses of existing research and propose new studies to build the science behind CAM. **(John Templeton, Jr., JTF)**

Because the scientific study of spirituality is in its infancy, and as spirituality is hard to define, I think it is important to try and pick some aspect of spirituality that a group that practices a certain type of spirituality embraces and then study their intervention. **(John Templeton, Jr., JTF)**

Promote a consensus conference to suggest ways of studying spirituality. **(John Templeton, Jr., JTF)**

Train medical students and residents to understand that it is appropriate to take a spiritual or religious history. **(John Templeton, Jr., JTF)**

Host introductory, face-to-face meetings and site visits among foundation people with representatives of existing CAM research centers currently funded by the NIH. **(Dyanne Hayes, Conrad N. Hilton Foundation)**

Be more aggressive in seeking opportunities for foundation representatives to participate on panels such as this to discuss their experiences and perceptions regarding CAM and CAM research. **(Dyanne Hayes, Hilton Foundation)**

Include foundations on mailing lists and publicize the those grants that do or have had public/private funding support. **(Dyanne Hayes, Hilton Foundation)**

Encourage foundations to be more willing to fund small pilot projects. **(Dyanne Hayes, Hilton Foundation)**

Encourage foundations interested in CAM research to create a pooled fund of monies and announce the competition for projects up to so many dollars. The collaborative would set up a scientific advisory board of reputable scientists knowledgeable in the area in which the proposals are being submitted. **(Dyanne Hayes, Hilton Foundation)**

Address the sense of separation between Eastern and Western cultures that pervades relations between the two communities. **(Dyanne Hayes, Hilton Foundation)**

Help the foundation community stay better informed on relevant symposia as well as what has been funded. **(Dyanne Hayes, Hilton Foundation)**

Conduct research on why people are drawn to CAM, what people who are drawn to it, what do they mean by what we say works, and what do they find satisfying about it that they don't find satisfying in the rest of medicine? **(Daniel Callahan, Hastings Center)**

Keep the discussion of Medicine as art and science alive. **(Daniel Callahan, Hastings Center)**

Utilize CAM as a lens to help us envision the future of medicine when an aging population with chronic ills will share the national stage with a younger population that will need to learn how to take better care of itself. **(Daniel Callahan, Hastings Center)**

Find some better ways of formalizing means of investigation other than randomized clinical trials in which one can have confidence. **(Daniel Callahan, Hastings Center)**

Develop a think tank that brings together research methodologists, not just people interested in CAM, to discuss the methodological problems of investigating CAM. **(Daniel Callahan,**

Hastings Center)

Encourage private philanthropy to fund CAM research to get things going to a point where federal funding, based on other criteria can be used. **(Daniel Federman, Harvard University)**

Develop a generally accepted definition of CAM to ensure the everyone is talking about the same thing. **(Teri Ades, American Cancer Society)**

Protect patient access to CAM, while providing oversight and accountability by governmental, public, and private entities that are needed to protect the public. **(Teri Ades, ACS)**

Support NCCAM and its stress on the importance of systematic and scientific approaches to studying various medicines, as well as the NCI's Best Case Studies program.**(Teri Ades, ACS)**

Support additional funding for mentoring programs that help those with promising therapies to collect quality data and take part in the necessary research. **(Teri Ades, ACS)**

Invest more efforts in understanding the limits of randomized clinical trials in CAM and in finding other research approaches that work better. **(Teri Ades, ACS)**

Rather than consider incentives, consider setting the expectation that all therapies must be proved to be safe and effective so the public does not have to question their therapy. **(Teri Ades, ACS)**

Have NCCAM serve as coordinator for a group of public, private, and governmental agencies convened to discuss how to better coordinate federal support for CAM research. **(Teri Ades, ACS)**

Panel X: Outcomes Research Part II – CAM Research and Experimental Design

Schools of Public Health are the ideal environment for CAM research. Many faculty are involved in CAM-related projects. Most of the schools of chiropractic health care have some course work in public health and chiropractors belong to the APHA. Their special interest section has been planning a syllabus in public health education for chiropractic colleges. A working group made up of schools of public health and chiropractic colleges will collect and analyze baseline data for developing a curriculum for future students.

Provide funding and trust-building for the Best Case Series Program. NCCAM funded centers could play a very important role in the Best Case Series Program by providing methodological support to clinicians **(Leanna Standish, Bastyr University)**

Create partnerships between CAM academic centers and CAM practitioners for developing Best Case studies, especially in the cancer area, and have that collaborative work be funded by the NCI. **(Leanna Standish, Bastyr University)**

Encourage institutional review boards to be flexible in assessing joint CAM/conventional medicine research efforts. **(Leanna Standish, Bastyr University)**

Have practitioners develop algorithms to describe the "if then" nature of CAM treatments and formalize them, to facilitate doing individualized therapy inside of a clinical study. **(Leanna Standish, Bastyr University)**

In assessing CAM, analyze a therapeutic approach that is not too refined and examine the entire system and include elements like lifestyle, exercise, plus the addition of dietary modification or we will miss the forest for the trees. **(Elaine Cramer, Center for Disease Control and Prevention, CDCP)**

Put together an integrated team of researchers from both the CAM and conventional communities who are open-minded practitioners, who are really willing to collaborate and randomize patients to CAM treatment arms as well. **(Elaine Cramer, CDCP)**

Use integrative research to study integrative medicine. The way to properly evaluate any outcomes is through a team-based approach using existing methods. **(Elaine Cramer, CDCP)**

To implement these strategies in a community setting, solicit proposals from integrated research teams which are comprised of both CAM and conventional practitioners who demonstrate the ability to collaborate on, not just the study design, but case definitions, the selection of exposures, and the designation of CAM and conventional treatment sites. **(Elaine Cramer, CDCP)**

Assign a research mentor not only to CAM practitioners who are interested in evaluating CAM therapies, but whoever needs research and who really needs some assistance with both protocol and study design development. **(Elaine Cramer, CDCP)**

Establish experienced research teams that are comprised of scientists, subject matter experts and send them out en masse to selected research sites to really expedite development and implementation of the protocols for CAM evaluation. **(Elaine Cramer, CDCP)**

Conduct clinical outcomes research on CAM to determine what is efficacious, what is effective, what is safe, and to give the patient a wider choice of treatment modalities. **(Lydia Segal, Kaiser Permanente)**

Develop research training programs for clinicians that allow them to stay in their practice, be it a mentoring program or a partnership with academic or government institutions, while bringing researchers into the clinical environment. **(Lydia Segal, Kaiser Permanente)**

Develop research designs to accommodate the patient specific nature of CAM treatments to make different treatments statistically comparable. **(Lydia Segal, Kaiser Permanente)**

Encourage collaborative research efforts between conventional and CAM academic institutions. **(Douglas Lloyd, Association of Schools of Public Health,ASPH)**

Panel XI: Federal Agency Support for CAM Research

Increase funding for other federal health agencies involved in CAM research-related activities.

In the last 10 years, the VA has funded $60 million in CAM research, while VA. investigators have participated in other CAM research projects worth $92 million in funding during that same time. Additional CAM research has been done without funding. Among the areas studied are biofeedback, acupuncture, electromagnetic therapy, and others covering the entire spectrum. The VA is doing an omnibus report of these numerous studies. Concerns are variability of training, credentials of CAM practitioners, stability of funding, and safety.

Most research is done by the VA's intramural research scientists, and they are the only ones eligible for the grants. Initiatives come from the field. Research is organized into four basic types: basic, bench, rehabilitation, and outcomes. If they opened the door to a special interest, other groups would ask for the same treatment.

The VA is the ideal place to do demonstration projects.

To the Zuni Indian Tribe, CAM is standard. Traditional healing practices vary among the 500-plus tribes. The IHS is authorized to provide health services, not research, but some community organizations have an interest in it. NIH has funded centers for health research for Native Americans. Such centers must be governed by the Indian people, not by researchers.

IHS identifies native healers as mental health technicians. It is difficult to measure practice utilization, failure, etc. The healers are willing to push the limit rather than be constrained by conventional measures. They put their attention beyond biology and disease. This is a challenge for American Indian physicians who are researchers. The great belief is in the power of the healer.

A good contact point for Native American medicine is the National Indian Health Organization, which reflects the health interests of tribal governments nationwide. Also consider contacting the National Council of Rural Indian Health.

Work with tribal governments to establish research priorities for investigating traditional practices utilized by American Indians and Alaska Natives. Priorities and policy should set by Native Americans, not by researchers. **(Craig Vanderwagen, Indian Health Service, IHS)**

Examine how CAM might reach out to tribal communities and offer them tools and techniques for examining internally the effectiveness of their providers. **(Craig Vanderwagen, IHS)**

Methodology Example (addendum)

The preferred method is the RCT because chart documentation is uneven in observational studies and data collection will be limited by the lowest common denominator available on all the charts. In addition, there are inherent differences in patients that can be factored into a study, but only a randomized study can deal with the unknown differences. If two patients receive the same treatment, one might also experience an improved quality of life, so qualitative survey instruments need to be in the study design from the outset. Finally, for experimental study design, the most important feature of a valid study is the comparison group. This requires expanding the study arena beyond one CAM practitioner. For these reasons we elected to move to an experimental study design of randomized treatment. If the study keeps in mind the modality being evaluated, there is no need for alternative methods or a redesign. The need is to be careful about what it is that is being measured and what the outcome is. The entire or aggregate system is analyzed rather than one unit of measure. If the entire system or modality shows promise, then go back and do the chemical analyses and basic science on those that work. The findings should be as valid and reproducible as possible. The problem is in over-interpreting data. There will be difficulties adjusting for all the differences. Data could be collected in standardized form. And patients could fill out an evaluation after they are seen.

A potential solution to the issue of individuality is to look into using an algorithm and doing flow charts on how the practitioner decides to do a type of therapy. It would be possible to do individual therapy inside a study and examine what makes certain practitioners effective and then teaching that.

Chang, Michele (WHCCAMP)

From: Chang, Michele (WHCCAMP)
Sent: Tuesday, August 07, 2001 2:10 PM
To: Bill Fair (E-mail); Conchita Paz (E-mail); David Bresler (E-mail); Dean Ornish (E-mail); Donald Warren (E-mail); Effie Chow (E-mail); George Bernier (E-mail); George DeVries (E-mail); Jim Gordon (E-mail); Joe Fins (E-mail); Joe Pizzorno; Julia Scott (E-mail); Linnea Larson; Tieraona Low Dog (E-mail); Tom Chappell (E-mail); Veronica Gutierrez (E-mail); Wayne Jonas (E-mail); Wayne Jonas2 (E-mail); Xiaoming Tian (E-mail)
Cc: Anne/Rita For Tieraona (E-mail); Carolyn Gillett (E-mail); Chris Wennerstrom; Joan Matthews (E-mail); Marjorie for Ornish (E-mail); Tracy Wiens (E-mail); Axelrod, Corinne (WHCCAMP); Fisher, Ken (WHCCAMP); Gerry Pollen (E-mail); Jim Swyers (E-mail); Joe Kaczmarczyk (E-mail); Kingsbury, Doris (WHCCAMP); Miller, Maureen (WHCCAMP); Steve Groft (E-mail)
Subject: WHCCAMP Work Groups

Commissioners:

Thank you for nominating the following facilitators for work groups. Where possible, co-facilitators have been selected to share and ease responsibilities of tasks.

NOTE: Meanwhile, Kate Groft continues her arduous task of scheduling our first conference call (1.5 hrs) with the 8 work groups, all of which we hope to conduct by August 17. With the overlap between work groups and differences in time zones, Kate's task is Herculean at best. Your continued flexibility and willingness to work with Kate to find mutually possible schedules is critical. You can reach her most easily through Michele at 301-435-6232, or by fax 301-480-1691.

A. Coordination of CAM Research
Staff Lead: Gerry Pollen
Co-facilitators: **Wayne Jonas, Dean Ornish**

B. Information Development and Dissemination
Staff Lead: Corinne Axelrod (Maureen Miller substitute until 8/20)
Co-facilitators: **David Bresler, Tieraona Low Dog**

C. Access to and Delivery of CAM
Staff Lead: Michele Chang
Co-facilitators: **Joe Fins, Linnea Larson**

1D. Coverage and Reimbursement
Staff Lead: Maureen Miller
Facilitator: **George DeVries**

E. Education and Training of Health Care Practitioners in CAM
Staff Lead: Joe Kaczmarczyk
Co-facilitators: **George Bernier, Joe Pizzorno**

F. Coordinating and Centralizing Federal CAM Efforts
Staff Lead: Joe Kaczmarczyk
Facilitator: **Donald Warren**

G. CAM in Wellness, Self-Care, Health Promotion and Disease Prevention
Staff Lead: Corinne Axelrod (Michele Chang substitute until 8/20)
Facilitator: **Dean Ornish**

H. Definition of CAM and Guiding Principles

Staff Lead: Jim Swyers
Co-facilitators: **Tom Chappell, Wayne Jonas**

If you have any questions concerning this list, please contact Dr. Joe at 301-435-6197, or Michele at 301-435-6232.

Thank you for your efforts!

James S. Gordon, MD
Chair

Joseph M. Kaczmarczyk, DO, MPH
Acting Executive Director

WORKING DRAFT 29 SEP 00
ACCESS, DELIVERY, AND REIMBURSEMENT

I. Current reimbursement environment
   A. Overview of conventional health care system reimbursement
   B. Overview of CAM reimbursement
   C. Overview of HCFA perspective on reimbursement

II. Reimbursement Options
   A. 3 panels:
      1. Maintain current reimbursement
      2. Adapt current reimbursement systems to include CAM
      3. Create a new reimbursement system
   B. Questions for each panel:
      1. Why are you advocating or not advocating change?
      2. What are the policy implications of what you're proposing?

III. Consumer perspective
   A. Survey data (Einsenberg, Astin, Dross & Rosenheck, etc.)
   B. Organized labor (AFL-CIO)
   C. Organizations representing "Special Populations" such as women, pregnant women, children, HIV/AIDS, cancer, old/very old, Native Americans/Alaskan Natives, Native Hawaiians, recent immigrants, Traditional populations, poor/medically underserved, persons with disabilities, ...
   D. Questions:
      1. Why do you want to use CAM practices and products?
      2. For what do you want to use CAM practices and products?
      3. When and how do you decide to use CAM practices and products?
      4. Do you need to see a practitioner to use CAM practices and products? If not, when don't you need to see a CAM practitioner? How do you decide when not to see a CAM practitioner?
      5. What are some examples of CAM practices and products that are working?
      6. Do you have access to all of the CAM practices and products you want? If not, what are the barriers [for example, financial, transportation/geographic, child/elder care, cultural, linguistic] and what can be done to remove those barriers?
      7. Who pays for the CAM practices and products you use?
      8. Do you have difficulty paying for CAM practices and products? If so, what do you think should be done about it and what policy changes should be made?

IV. Provider perspective
   A. Conventional physicians
   B. CAM practitioners
   C. Integrative physicians
   D. Questions:
      1. Why do you or why don't you want to include CAM practices and products in your practice?
      2. For what indications should CAM practices and products be used clinically?
      3. How do you decide which CAM practice or product to use or recommend?
      4. Who should provide CAM practices and products?
      5. How do you determine to which CAM practitioner to refer patients?
      6. Where and how should CAM practices and products be provided?
      7. What is the role of CAM in self-care?
      8. What barriers have you experienced in providing CAM practices and products? How have you overcome those barriers? What policy changes would you recommend to facilitate provision/delivery of CAM practices and products?

V. Payors and Purchasers
   A. Conventional health care only
   B. CAM only
   C. Integrative
   D. Benefits managers trade association
   E. Organized Labor
   F. OPM (FEHBP)
   G. AAHP
   H. George Foundation
   I. Questions:
      1. Why should you pay or why should you not pay for CAM practices and products?
      2. For which indications should you be paying for CAM practices and products? How do you decide for which CAM practices and products you will pay?
      3. For which CAM practices and products should you be paying? How do you decide for which CAM practices and products you will pay?
      4. Who should be providing CAM practices and products for which you will pay? How do you decide who should be providing CAM practices and products for which you will pay?
      5. What is the role of CAM practices and products in self-care? Should you pay for CAM practices and products for self-care? If

so, for which practices and products and which conditions should you pay? On what bases should you make those decisions?

6. What is the role of CAM practices and products in managed care?
7. Where and how should CAM practices and products be provided? How do you decide where and how CAM practices and products for which you will pay should be provided?
8. What problems or barriers have you encountered? What should be done about them? What policy changes should be made from your perspective as a payor or purchaser?

VI. Lessons learned from integrative delivery systems (Pre-conception to end-of-life)

A. Private sector

1. Academic health/medical center-based
2. Community hospital-based
3. Free-standing for-profit practice-based
4. Questions:
    a. Why and how did you decide to integrate CAM practices and products with conventional health care?
    b. For which indications do you provide CAM practices and products? Who made that decision? On what basis was that decision made?
    c. Which CAM practices and products do you provide? Who determined which CAM practices and products you provide? On what basis was that decision made?
    d. Who provides CAM practices and products in your organization? On what basis was that decision made? How are your CAM providers selected? Do you use any unlicensed CAM practitioners? If so, why and how are they used?
    e. Where and how are your CAM practices and products provided? How was that determined?
    f. Who pays for the CAM practices and products you provide?
    g. Have any of the users of your CAM practices and products experienced difficulty with access to or payment for CAM practices and products? If so, please specify the difficulty and how it was resolved or should be resolved?
    h. What have you done to make the delivery of CAM practices and products culturally and linguistically appropriate for your CAM users?
    i. Do you provide all of the CAM practices and products you would like to offer? If not, what would you like to add and why? Likewise, do you provide all of the CAM practices and products that your CAM users want? If not, why?

j. What is the role of self-care in the CAM practices and products that you provide?
k. What is the role of CAM practices and products in managed care?
l. What are the lessons that you have learned in dealing with CAM practices and products? What is the single most important lesson that you have learned?
m. From you perspective, what policy changes do you think should be made?

B. Public sector
1. Kent Natural Medicine Clinic
2. Country Doc Community Health Center
3. Winslow, AZ IHS
4. Native Hawaiian Traditional healing
5. Questions: As above

C. Federal
1. HRSA
2. VA
3. DOD
4. SAMSHA
5. IHS
6. Questions:
a. Has your Agency determined the utilization of CAM practices and products in its target populations? If so, how were the utilization data obtained and what did those data show? If not, why?
b. What CAM practices and products does your Agency provide or support? How, why, and by whom were those CAM practices and products selected?
c. Where, how, and by whom are CAM practices and products provided? Who determined this? On what basis was this decided?
d. Is the delivery of CAM practices and products to your target populations integrated with conventional health care? If so, why and to what extent? Where, how, and by whom was this accomplished?
e. What has your Agency done to make the delivery of CAM practices and products culturally and linguistically appropriate for your target populations?
f. Who pays for the CAM practices and products used by your Agency's target populations?
g. Do your target populations have access to all of the CAM practices and products they want? If not, why?
h. Does your Agency provide or support all of the CAM practices and products it would like to offer? If not, why?

i. In dealing CAM practices and products, what are the lessons that your Agency has learned? What is the single most important lesson that your Agency has learned?

VII. Quality of Services and Delivery

A. Consumer/Purchaser perspective

1. Questions:
   a. What is "quality" in terms of CAM practices and products? Should it be measure? If so, how?
   b. Who should be providing CAM practices and products and what credentials should these individuals have?
   c. Where and how should CAM practices and products be provided to assure quality?
   d. What should consumers be told about costs, safety, effectiveness, and time for effectiveness to be evident of CAM practices and products?
   e. How can quality of CAM practices and products be assured if these practices and products are used as self-care?
   f. What should be done to minimize the risks of drug-herb and herb-herb interactions?
   g. If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?
   h. What policy changes should be made to assure the quality of CAM practices and products?

B. Provider perspective

1. Conventional only
2. CAM only
3. Integrative
4. Questions:
   a. How should "quality" in terms of CAM practices and products be defined? Who should define it? How do cost, safety, and effectiveness relate to quality of CAM practices and products?
   b. Should the quality of CAM practices and products be measured? If so, how and by whom?
   c. To assure quality of CAM practices and products, who should provide CAM practices and products?
   d. What credentials should providers of CAM practices and products possess to assure quality?
   e. Where and how should CAM practices and products be provided to assure quality?

f. What should consumers be told about costs, safety, effectiveness, and time for effectiveness to be evident of CAM practices and products?
g. What should be done to minimize the risks of drug-herb and herb-herb interactions?
h. What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider/referring physician or provider?
i. If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?
j. What policy changes should be made to assure the quality of CAM practices and products?

C. Payors perspective
   1. Questions:
      a. As above

D. Malpractice implications
   1. Conventional provider
      a. Questions:
         1.) What are the malpractice implications of **not** discussing, offering, or referring a patient for CAM practices and products?
         2.) What is the liability of referring a patient to a CAM practitioner who then has an adverse outcome?
         3.) What policy changes should be made to reduce malpractice liability associated with referral for CAM practices and products?
   2. CAM practitioner
      a. Questions:
         1.) What is the liability of providing CAM practices and products?
         2.) What policy changes should be made to reduce malpractice liability associated with CAM practices and products?
   3. Integrative provider
      a. Questions:
         1.) What is the liability of integrating CAM practices and products with conventional health care?
         2.) What policy changes should be made to reduce malpractice liability associated with CAM practices and products when integrated with conventional health care?

E. Federal perspective
    1. Federal Trade Commission
        a. Questions:
            1.) What should consumers be told about the safety, effectiveness, and time necessary for effectiveness to be evident of CAM practices and products?
            2.) What should be done to minimize the risks of drug-herb and herb-herb interactions?
            3.) If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?
            4.) What policy changes should be made to assure the quality of CAM practices and products
    2. AHRQ
        a. Questions:
            1.) How should "quality" in terms of CAM practices and products be defined? Who should define it? How do cost, safety, and effectiveness fit
            2.) Should the quality of CAM practices and products be measured? If so, how and by whom?
            3.) To assure quality of CAM practices and products, who should provide CAM practices and products?
            4.) What credentials should providers of CAM practices and products possess to assure quality?
            5.) Where and how should CAM practices and products be provided to assure quality?
            6.) What should consumers be told about costs, safety, effectiveness, and time for effectiveness to be evident of CAM practices and products?
            7.) What should be done to minimize the risks of drug-herb or herb-herb interactions?
            8.) What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider/referring physician or provider?
            9.) If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?

10.) What policy changes should be made to assure the quality of CAM practices and products?

3. National Practitioners Data Bank
   a. Questions:
      1.) Should all CAM practitioners irrespective of whether or not they are physicians be included in the NPDB? Why or why not? If so, how should this accomplished?
      2.) Should entities and individuals providing CAM practices and products provided in the Federal environment be covered under Federal Torts Act (FTCA)?
      3.) What policy changes should be made to assure the quality of CAM practices and products

F. Licensure/Certification [National] considerations
   1. Unlicensed CAM practitioners
      a. Minnesota legislation
      b. Native Hawaiian and Native American Traditional healers
      c. Practitioners licensed by some but not all states such as NDs and LACs
   2. Licensed CAM practitioners
   3. Licensed health providers practicing CAM
      a. All providers other than physicians (RN, NP, CNM, PA, PT, RD, Nutritionists, RPh/PharmD, ...)
      b. Physicians (primarily MDs)
         1.) Texas guidelines for integration
         2.) Arizona State Board Homeopathy
         3.) Medical Acupuncture Board Certification
         4.) DOs, DCs, NDs need to be considered as well, especially in States with separate Boards
   3. Questions:
      a. Should there be national standards, licensure, or certification to provide CAM practices and products? If so, who should establish them?
      b. What is the role of the unlicensed CAM practitioner such as the Traditional Healer?
      c. Should there be practice condition-specific or modality-specific practice guidelines? If so, who should develop them and how should they be implemented?
      d. What policy changes should be made to assure the quality of CAM practices and products?

G. Turfism/differential rates of reimbursement
   1. Example: Acupuncture

    a. Reimbursed differently for LACs and physicians
2. Questions:
    a. How should issues of "turfism" be resolved?
    b. Should there be universal/standardized or differential reimbursement rates for a given CAM practice or product? If so, who should establish these reimbursement rates and policies?
    c. What policy changes should be made to assure the quality of CAM practices and products?

White House Commission on Complementary and Alternative Medicine Policy

Meeting Site: Academy for Educational Development
1825 Connecticut Avenue, N.W., Academy Hall, 8th Floor
Washington, DC

May 14-15, 2001

AGENDA I

DAY ONE: MONDAY, MAY 14, 2001

7:30 a.m. **Registration opens**

Meeting Topic I. Complementary and Alternative Medicine: Understanding Coverage and Reimbursement

8:15 a.m. **Opening Remarks and Introductions**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy
- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

8:30 a.m. **Panel Session I: Overview of Health Care Financing in the United States**

1. *Michael O'Grady, Ph.D.*
   Project Hope, Center for Health Affairs — 30 minutes
- Discussion — 25 minutes

9:25 a.m. **Panel Session II: Federal Purchasers**

2. *John Whyte, M.D.*
   Health Care Financing Administration — 30 minutes
3. *Abby Block, M.A., M.S.W., M.B.A.*
   U.S. Office of Personnel Management — 20 minutes

(10:15) - Discussion — 30 minutes

10:45 - 11:00 a.m. **BREAK**

11:00 a.m. **Panel Session III: State and National Perspectives**

4. *Joy Johnson Wilson*
   National Conference of State Legislatures

11:10 5. *Merilyn Francis, R.N., M.P.P.*
American Association of Health Plans

11:20 6. *Alan Korn, M.D.*
Blue Cross Blue Shield Association

11:30 ◆ Discussion 30 min

12:00 – 1:00 p.m. LUNCH BREAK

1:00 p.m. **Panel Session IV: Employer Perspectives**

7. *Tom Sawyer*
William M. Mercer, Inc.

1:10 8. *Kathleen King*
Washington Business Group on Health

1:20 9. *Judith MacPherson*
CACI International Inc

1:30 ◆ Discussion (40 min)

2:10 p.m. **Panel Session V: Health Plan Perspectives**

10. *Rick Gallion*
Blue Cross Blue Shield of South Carolina

2:20 11. *John Kelly, M.D.*
Aetna/U.S. Healthcare

2:30 12. *John Weeks*
The Integrator

2:40 ◆ Discussion (40 min)

3:10 – 3:25 p.m. BREAK

3:25 p.m. **Panel Session VI: Special Populations: Minorities, Uninsured, Underinsured**

13. *Nathan Stinson, M.D., Ph.D., M.P.H.*
Office for Minority Health, DHHS

3:35 14. *Doriane Miller, M.D.*
Robert Wood Johnson Foundation

3:45 15. *Daniel Hawkins*
National Association of Community Health Centers

3:55 ◆ Discussion (20 min)

4:15 p.m. **Breakout Groups: Access and Delivery*** (60 min)
**(Review of December 4-5, 2000 Meeting Discussion)*

5:15 p.m. **Group Reports and Discussion**

6:00 p.m. **ADJOURN**

DAY TWO: TUESDAY, MAY 15, 2001

7:30 a.m. **Registration Opens**

Meeting Topic I. Complementary and Alternative Medicine: Understanding Coverage and Reimbursement (continued)

8:00 a.m. **Opening Remarks**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy
- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

8:05 a.m. **Panel Session VII: Issues and Ideas**

16. *Melinna Gianninni* — 10 min.
    Alternative Link, Inc.
17. *Linda Bedell-Logan* — 10 min
    Solutions in Integrative Medicine
18. *Wayne Sickles, M.T.S., M.DIV.* — 10 min
    Massage Therapist

◆ Discussion — 20 min

Call up 9:00 Separately 9:10

19. *Max Heirich, Ph.D.* — 15 min.
    University of Michigan

◆ Discussion — 15 min

9:25 - 10:50 a.m. **Break/Breakout: Small Group Discussion (CAM Reimbursement)**

10:50 a.m. **Group Reports and Discussion**

11:30 a.m.-12:30 p.m. **LUNCH BREAK – ADJOURN MEETING TOPIC I**

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White House Commission on Complementary and Alternative Medicine Policy

Meetings on
CAM: Understanding Coverage and Reimbursement
CAM: Research Challenges

May 14-16, 2001

Academy for Educational Development, Washington, DC

SPEAKER ROSTER

Marcia Angell, M.D.
Senior Lecturer
Department of Social Medicine
Harvard Medical School
641 Huntington Avenue
Boston, MA 02115
Telephone: (617) 576-6934
Fax: (617) 576-7926

Linda Bedell-Logan
President and CEO
Solutions in Integrative Medicine
P.O. Box 207
Saco, ME 04072
Telephone: (207) 282-5110
Fax: (207) 286-1866
E-mail: mbcm@gwi.net

Brian Berman, M.D.
Professor of Family Medicine
Director of Complementary Medicine Program
University of Maryland School of Medicine
2200 Kernan Drive
James L. Kernan Mansion
Baltimore, MD 21207
Telephone: (410) 448-6871
Fax: (410) 448-6875
E-mail:
bberman@compmed.ummc.umaryland.edu

Robert Blanks, Ph.D.
Professor, Anatomy and Neurobiology
University of California Irvine
College of Medicine
364 Med Surge II
Irvine, CA 92697-1275
Telephone: (949) 824-7991
Fax: (949) 824-8549
E-mail: rhblanks@uci.edu

Abby Block, M.A., M.S.W., M.B.A.
Assistant Director for Insurance Programs
Office of Personnel Management
1900 E Street, N.W., Suite 3400
Washington, DC 20415
Telephone: (202) 606-0770
Fax: (202) 606-4640
E-mail: alblock@opm.gov

Susan Braun
President and CEO
Susan G. Komen Breast Cancer Foundation
5005 LBJ Freeway, Suite 250
Dallas, TX 75244
Telephone: (972) 855-1611
Fax: (972) 855-1612
E-mail: sbraun@komen.org

Edward Campion, M.D.
Deputy Editor
New England Journal of Medicine
10 Shattuck Street
Boston, MA 02115
Telephone: (617) 734-9800
Fax: (617) 739-9864

John Chabot, M.D.
Associate Professor of Clinical Surgery
New York Presbyterian Hospital
161 Fort Washington Avenue
New York, NY 10032
Telephone: (212) 305-9468
Fax: (212) 305-5992
E-mail: jac4@columbia.edu

Ronald Chez, M.D.
Professor of Obstetrics and Gynecology
Professor of Community and Family Health
University of South Florida
2101 East Pacific Coast Highway, Suite 220
Corona del Mar, CA 42625-1900
Telephone: (949) 760-4417
Fax: (949) 759-5707
E-mail: rchez@siib.org

M. Bridget Duffy, M.D.
Medical Director
Medtronic USA, Inc. and
Medtronic Foundation
710 Medtronic Parkway, MS LC110
Minneapolis, MN 55432
Telephone: (763) 505-2644
Fax: (763) 505-2648
E-mail: bridget.duffy@medtronic.com

David Eisenberg, M.D.
Associate Professor of Medicine
Harvard Medical School and
Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, MA 02215
Telephone: (617) 632-7770
Fax: (617) 632-7772
E-mail: deisenbe@caregroup.harvard.edu

Phil Fontanarosa, M.D.
Executive Deputy Editor, *JAMA*
American Medical Association
515 North State Street
Chicago, IL 60610
Telephone: (312) 464-2427
Fax: (312) 464-5824
E-mail: phil_fontanarosa@ama-assn.org

Merilyn Francis, R.N., M.P.P.
Director, Quality Management and Health
Services Research
American Association of Health Plans
1129 20th Street, N.W., Suite 600
Washington, DC 20036
Telephone: (202) 778-3224
Fax: (202) 778-3287
E-mail: mfrancis@aahp.org

Derrick Gallion
Director, Complementary and
Alternative Medicine
Blue Cross and Blue Shield
of South Carolina
I-20 at Alpine Road, AF-325
Columbia, SC 29219
Telephone: (803) 788-0222, ext. 41080
Fax: (803) 419-3338
E-mail: rick.gallion@bcbssc.com

Melinna Giannini
President and CEO
Alternative Link, Inc.
1065 South Main, Building C
Las Cruces, NM 88005
Telephone: (505) 527-0636
Fax: (505) 523-4152
E-mail: mg@alternativelink.com

Arthur Grollman, M.D.
Professor
Department of Pharmacological Sciences
State University of New York at Stony Brook
BHS T8, 160
Stony Brook, NY 11794-8651
Telephone: (631) 444-3080
Fax: (631) 444-7641
E-mail: apg@pharm.sunysb.edu

Richard Hammerschlag, Ph.D.
Research Director
Oregon College of Oriental Medicine
10525 S.E. Cherry Blossom Drive
Portland, OR 97216
Telephone: (503) 253-3443, ext. 156
Fax: (503) 253-2701
E-mail: rhammerschlag@ocom.edu

Daniel Hawkins, Jr., B.S.
Vice President
National Association of Community Health Centers, Inc.
Suite 122
1330 New Hampshire Avenue, N.W.
Washington, DC 20036
Telephone: (202) 296-0131
Fax: (202) 296-3526
E-mail: dhawkins@nachc.com

Max Heirich, Ph.D.
Professor and Research Scientist Emeritus
The University of Michigan
1111 East Catherine
Ann Arbor, MI 48109
Telephone: (734) 763-1187
Fax: (734) 763-0913
E-mail: mheirich@umich.edu

Jennifer Jacobs, M.D., M.P.H.
Clinical Assistant Professor
University of Washington
23200 Edmonds Way, Suite A
Edmonds, WA 98026
Telephone: (206) 542-5595
Fax: (425) 771-4789
E-mail: jjacobs@igc.org

Joy Johnson Wilson
National Conference of State Legislators

Douglas Kamerow, M.D., M.P.H.
Director, Center for Practice and Technology Assessment
Agency for Healthcare Policy and Research
6010 Executive Boulevard, Suite 300
Rockville, MD 20852
Telephone: (301) 594-4026
Fax: (301) 594-4027
E-mail: dkamerow@ahrg.gov

John T. Kelly, M.D.
Aetna/U.S. Healthcare

Kathleen King
Vice President
Washington Business Group on Health
50 F Street, N.W., Suite 600
Washington, DC 20010
Telephone: (202) 628-9320
Fax: (202) 628-9244
E-mail: king@wbgh.org

Alan Korn, M.D.
Blue Cross and Blue Shield Association

Christine Laine, M.D., M.P.H.
Senior Deputy Editor
Annals of Internal Medicine
190 North Independence Mall West
Philadelphia, PA 19106
Telephone: (215) 351-2527
Fax: (215) 351-2644
E-mail: claine@mail.acponline.org

Donald Lindberg, M.D.
Director
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
Telephone: (301) 496-6221
Fax: (301) 496-4450
E-mail: lindberg@nlm.nih.gov

William London, Ed.D., M.P.H.
President
The National Council Against Health Fraud, Inc.
P.O. Box 141
Fort Lee, NJ 07024
Telephone: (201) 723-2955
E-mail: ncahf@worldnet.att.net

Judith MacPherson
Benefits Manager
CACI International Inc.
1100 North Glebe Road
Arlington, VA 22201
Telephone: (703) 841-7836
Fax: (703) 528-8112
E-mail: jmacpherson@caci.com

Simeon Margolis, M.D., Ph.D.
Professor of Medicine and Biological Chemistry
Johns Hopkins School of Medicine
Room 336, 1830 Building
Johns Hopkins Hospital
Baltimore, MD 21287
Telephone: (410) 955-1777
Fax: (410) 955-8172
E-mail: smargoli@jhu.edu

Doriane Miller, M.D.
Program Vice President
The Robert Wood Johnson Foundation
Route 1 and College Road East
Princeton, NJ 08543-2316
Telephone: (609) 627-5772
Fax: (609) 514-5520
E-mail: dmiller@rwjf.org

Michael O'Grady
Project Hope, Center for Health Affairs

Nancy Pearson, Ph.D.
Program Officer
National Center for Complementary and Alternative Medicine
6707 Democracy Boulevard, Room 106
Bethesda, MD 20892
Telephone: (301) 594-0519
Fax: (301) 480-3621
E-mail: pearsonn@mail.nih.gov

Russell Phillips, M.D.
Director, Harvard Fellowship Program
Complementary and Alternative Medicine
Harvard Medical School
Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, MA 02215
Telephone: (617) 667-5384
Fax: (617) 667-2751
E-mail: rphillip@caregroup.harvard.edu

Bruce Rabin, M.D., Ph.D.
Professor of Pathology
University of Pittsburgh Medical Center
200 Lothrop Street
Pittsburgh, PA 15213-2582
Telephone: (412) 647-6150
Fax: (412) 647-7741
E-mail: bsr@pitt.edu

Arnold Relman, M.D.
Professor Emeritus of Medicine and of Social Medicine
Harvard Medical School
Channing Laboratory
181 Longwood Avenue, 5th Floor
Boston, MA 02115-5804
Telephone: (617) 525-2185
Fax: (617) 525-2186

David Riley, M.D.
Editor in Chief, Alternative Therapies in Health and Medicine
University of New Mexico Medical School
P.O. Box 4310
Santa Fe, NM 87502
Telephone: (505) 983-0546
Fax: (505) 983-4196
E-mail: dsriley@integrativemed.org

Tom Sawyer, Ph.D.
William M. Mercer, Incorporated
3131 East Camelback Road, Suite 300
Phoenix, AZ 85016
Telephone: (602) 522-6560
Fax: (602) 957-9573
E-mail: tom.sawyer@us.wmmercer.com

Wayne Sickels, M.T.S., M.Div.
Massage Therapist
Virginia State C.M.T.
489 A Carlisle Drive
Herndon, VA 20170
Telephone: (703) 481-6411
E-mail: tmasters@erols.com

Nathan Stinson, Jr., M.D., Ph.D., M.P.H.
Deputy Assistant Secretary for
Minority Health
Office of Minority Health
Office of Public Health and Science, DHHS
5515 Security Lane, Suite 1000
Rockville, MD 20852
Telephone: (301) 443-5084
Fax: (301) 594-0767
E-mail: nstinson@osophs.dhhs.gov

John Weeks
Principal
Integration Strategies for Natural
Health Care
3345 59th Avenue S.W.
Seattle, WA 98116
Telephone: (206) 933-7983
Fax: (206) 933-7984
E-mail: pihcp@aol.com

Neal West, Ph.D.
Program Officer
National Center for Complementary
and Alternative Medicine
6707 Democracy Boulevard, Room 106
Bethesda, MD 20892
Telephone: (301) 402-5867
Fax: (301) 480-3621
E-mail: westn@mail.nih.gov

B. Alex White, D.D.S., Dr.P.H.
Senior Investigator and Assistant
Program Director
Kaiser Permanente Center for Health
Research
3800 North Interstate Avenue
Portland, OR 97227-1110
Telephone: (503) 335-6765
Fax: (503) 335-6311
E-mail: alex.white@kpchr.org

John Whyte
Health Care Financing Administration

Jackie Wootton, M.Ed.
Executive Editor
Journal of Alternative and Complementary
Medicine
5411 West Cedar Lane, Suite 205-A
Bethesda, MD 20814
Telephone: (301) 581-0116
Fax: (301) 581-0119
E-mail: jcw@amfoundation.org

Candace Lee Campbell, B.A.
American Preventive Medical Association
Box 458
Great Falls, VA 22066

Diane Davis Cole, M.P.H.
University of Virginia Cancer Center
P. O. Box 800334
Charlottesville, VA 22908

Audrey Di Maria, M.A., ATR-BC
Secretary of Art Therapy Credential Board
4200 Cathedral Avenue, N.W., #901
Washington, DC 20016

Alan Dumoff
Private Practice

Richard Ira Goldberg, M.S.W.
Private Practice
4330 East West Highway, Suite 306
Bethesda, MD 20814

Katherine Jane Gorton, M.S.
American Dietetic Association
1120 Connecticut Avenue, N.W., #480
Washington, DC 20036

Nancy Kristine Haller, L.M.P., B.A.
Guild Certified Feldenkrais Practitioner
Feldenkrais Guild of North America
821 South 219th, #8
Des Moines, WA 98198

Christina Herlihy, Ph.D.
National Certification Commission on Acupuncture and Oriental Medicine
11 Canal Center Plaza, Suite 300
Alexandria, VA 22314

Su Liang Ku, A.P., Professor
Florida Institute of Traditional Chinese Medicine
5335 66th Street North
St. Petersburg, FL 33702

Alice McCormick, Dipl. Ac. & C.H.
National Certification Commission on Acupuncture and Oriental Medicine
11 Canal Center Plaza, Suite 300
Alexandria, VA 22314

Barbara E. Moquin, Ph.D.(cand), R.N., M.S.N., CS-P
National Naval Medical Center
8901 Wisconsin Avenue
Bethesda, MD 20878

Matt Ward Russell
National Integrative Medicine Council
5151 E. Broadway, Suite 1095
Tucson, AZ 85711

Carolyn Jones Sabatini, B.A., M.B.A.
Pharmavite Corporation
11904 Cherokee Lane
Leawood, KS 66209

James S. Sensenig, N.D.
American Association of Naturopathic Physicians
2558 Whitney Avenue
Hamden, CT 06518

Judy Simpson, MT-BC
American Music Therapy Association
8455 Colesville Road, Suite 1000
Silver Spring, MD 20910

Sharon Stevenson
National Center for Homeopathy

Christina Walker
The Shenk Human Energetic Institute