

1 place is to have dialogue among interdisciplinary groups,
2 and beginning at very early levels so we don't become
3 arrested in our perspective. We always want to keep an
4 open mind.

5 In addition to teaching medical students, we
6 also have courses in biosociology, talking about the
7 various models for pre-medical students, which I would
8 encourage you to think about, this idea of inculturation,
9 particularly with research, occurs very early in the
10 training.

11 In terms of research design, I think we have to
12 be always very attuned to the fact that many of the
13 modalities that, I think, people often refer to as a CAM
14 are actually very specific. The field of chiropractic,
15 in my opinion, has many different fields within it.
16 There seems to be two dominant cultures, the
17 musculoskeletal, and then the group that I prefer to
18 relate to is just more holistic, and that is called the
19 subluxation-based approach. We need to understand this.
20 We can't view all those papers together.

21 I was glad to hear from my colleague, Dr.
22 Pizzorno, who I have never met, although it was very nice

1 to meet you, that his view of medicine at Bastyr is very
2 holistic. I think we should have naturopaths as triage
3 people at every medical school, largely because they are
4 dealing with the patient within the context of the
5 holistic discipline, not simply dealing with drugs and
6 medicines for treatment of disease.

7 I think we need to understand that we need
8 these broad measures of health. I am not going to hard-
9 sell this idea of health outcome measures using surveys,
10 but I think we need to understand that with multiple
11 outcome measures, including disease entities, including
12 various other social contextual assays, and particularly
13 the biopsychosocial measures of health, we can begin to
14 do multi-variate analysis, begin to subdivide the
15 variance, that is, the variability in the population
16 would be subdivided by specific outcome measures, using
17 multiple analysis.

18 There is probably no time, but I concluded, in
19 this model that we have done now, with a second page
20 where we talk about a model for health based on the
21 analysis of 3,000 people under care, in which we have
22 done path analysis, a very complicated statistical

1 analysis to look at the interaction between a specific
2 modality, in this case, network spinal analysis, which is
3 a modality within subluxation-based chiropractic, and how
4 that relates to the patient's perception of health.

5 Indeed, that model has been proven now, model-validated,
6 and it will be published very shortly.

7 Finally, I would just point out that, I think,
8 in terms of strategies for the Commission, I would
9 certainly recommend that we think about building
10 interdisciplinary teams, that these might be funded
11 through various interdisciplinary approaches and
12 interagency approaches, core center programs, where,
13 regionally, people can begin to develop cultures of
14 evidence about these modalities, and so forth.

15 Lastly, I think we are in the process of
16 building a certificate program for distance education, in
17 which we hope to train over the Internet, the Web,
18 various modalities here, and begin to talk about this at
19 interdisciplinary levels.

20 Lastly, I would just encourage you that, yes,
21 indeed, I believe that we need more funding for NCCAM,
22 largely because it is --

1 [Interruption.]

2 DR. GORDON: If a coincidence exists, that was
3 a coincidence.

4 DR. BLANKS: This is not the federal government
5 saying no.

6 [Laughter.]

7 DR. BLANKS: The bottom line is I believe we
8 need a national institute to respect this broad, holistic
9 view that NCCAM brings to the table, largely to increase
10 the dialogue, and largely to increase the lower levels of
11 the evidentiary base so we can bring these things and
12 percolate them to the top, allowing us, then, to respect
13 not only the holistic nature, but vitalistic nature of
14 these modalities.

15 DR. GORDON: Thank you very much.

16 Russell Phillips.

17 **Presenter: Russell Phillips, M.D.**

18 DR. PHILLIPS: First, thank you for the
19 opportunity to speak this morning to the Commission.

20 I serve as Director of the Harvard General
21 Medicine in Harvard Complementary and Alternative
22 Medicine Fellowship Program. I am a general internist,

1 teacher, and researcher. To date, most of my research is
2 focused on end-of-life care, but over the last few years,
3 it is increasingly focused on complementary and
4 alternative medicine.

5 I would like to respond directly to each of the
6 questions that were raised for our panel. First, what
7 training do conventional investigators need to conduct
8 CAM research?

9 Investigators need to be well-versed in
10 research methodology, usually requiring advanced training
11 at a master's or doctoral level. Investigators need an
12 understanding of CAM modalities they wish to study,
13 including the paradigms of health and healing held by CAM
14 practitioners, mechanisms of action where those are
15 understood, and knowledge of previous research on the CAM
16 modality of interest.

17 Investigators need mentoring, both by CAM
18 practitioners and experienced clinical investigators to
19 assist in developing research questions, methods,
20 analytic plans in preparation of reports for publication.
21 Ideally, investigators need direct experience in CAM
22 clinical work, or close collaboration with CAM

1 practitioners. Research training programs should provide
2 training and research skills, as well as clinical
3 complementary and alternative medicine opportunities.

4 At Harvard Medical School, we have a training
5 program for internal medicine physicians to develop
6 skills needed to perform CAM research. This program
7 provides master's level training and research methods,
8 introduction to CAM modalities and practitioners, and
9 mentoring, both by CAM practitioners and experience
10 clinical investigators.

11 I would like to describe our program briefly.
12 The Faculty Development and Fellowship Program in
13 Complementary and alternative Medicine accepts applicants
14 for a three-year fellowship program in both general
15 internal medicine and complementary and alternative
16 medicine.

17 The program offers each fellow an appointment
18 at Harvard Medical School hospitals. All fellows
19 participate in an intensive in clinical effectiveness at
20 the Harvard School of Public Health. Fellow qualifying
21 for acceptance at the Harvard School of Public Health
22 then pursue a rigorous curriculum that could lead to a

1 Master of Science or Master of Public Health degree.

2 The program also includes structured
3 experiences to improve teaching skills and supervised
4 clinical activities under the direction of experienced
5 faculty in both general medicine and complementary and
6 alternative medicine.

7 Each fellow is expected to design, conduct,
8 present, and publish one or more investigate projects.
9 This fellowship is funded by the NIH National Center for
10 Complementary and Alternative Medicine as a T-32 training
11 program, or institutional NRSA, as described earlier by
12 Dr. Pearson.

13 Our program begins each July 1st, with a seven-
14 week summer core curriculum taught by program faculty and
15 collaboration faculty at the Harvard School of Public
16 Health. This is what is known as a Clinical
17 Effectiveness Program. This curriculum includes required
18 courses in biostatistics, epidemiology, and elective
19 courses in health policy, health services research,
20 decision sciences, quality improvement, and public health
21 ethics.

22 The intensive summer experience includes about

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1 six hours per day of classroom time, and about four hours
2 per night of assignments, including required class
3 presentations and development of mini grant proposals.

4 After completion of the summer core curriculum,
5 fellows accepted in the Master's Program may then
6 continue to take advanced courses at the Harvard School
7 of Public Health, and upon earning 40 academic credits,
8 obtain a Master of Science or a Master of Public Health
9 degree.

10 Although the degree itself is optional, fellows
11 are strongly encouraged to take specific advanced course
12 work that will develop the investigative skills required
13 for the regional research projects.

14 Fellows also attend weekly seminars or research
15 conferences addressing research in progress and study
16 design. These sessions, which bring together fellows
17 located at various sites within the program, reinforce
18 skills learned in the classroom.

19 Monthly seminars in the Center for Alternative
20 Medicine Research and Education at Beth Israel Deaconess
21 Medical Center provide a forum to present and discuss
22 ongoing research, and a journal club provide

1 opportunities to review recently published research.

2 Beginning at the end of the summer core
3 curriculum of the first fellowship year, each fellow
4 provides care for patients. Fellows also work with
5 alternative providers, observing their practices. In
6 integrative practice site at Beth Israel Deaconess
7 Medical Center is under development and will likely serve
8 as a clinical site for our fellows in the future.

9 Each fellow participates in a series of
10 teaching how to teach seminars under the direction of
11 clinicians who are recognized as outstanding teachers.
12 In addition, each fellow has opportunities to serve as a
13 teacher of medical students and house staff in the
14 ambulatory practice of their sponsoring clinical site,
15 and also to teach undergraduate courses and continuing
16 medical education courses in alternative medicine at
17 Harvard Medical School.

18 Each fellow works in close collaboration with a
19 faculty mentor and initiates a research project during
20 the first year of the fellowship. The project may use
21 any or all of the methodologic disciplines that are
22 included in the academic curriculum and focus on

1 complementary and alternative medicine.

2 Projects may utilize a variety of methodologies
3 and topics that include clinical epidemiology, clinical
4 trials, decision analysis, patient outcomes, health
5 services research, health policy, et cetera. Fellows
6 present their plans in research in progress at seminars
7 within the program, and are encouraged and expected to
8 present their findings at regional and national meetings
9 of investigators, such as the upcoming International
10 Scientific Meeting on Complementary and Alternative
11 Medicine to be held later this week in San Francisco.

12 They will also be invited to present their work
13 at the Annual Continuing Medical Education courses
14 directed by the Center for Alternative Medicine Research
15 and Education at Beth Israel Deaconess Medical Center.

16 Faculty in the program are recognized leaders
17 in general internal medicine, and also include experience
18 CAM researchers and practitioners. I have listed a
19 number of those faculty in the materials that you have.
20 These include Joseph Audette [ph], who studies
21 acupuncture; Edward Chapman, homeopathy; and David
22 Eisenberg, who is interested generally in CAM research.

1 I direct the program, and Dr. Eisenberg,
2 Director of our Center for Alternative Medicine Research
3 and Education, serves as co-director. Our program is
4 particularly interested in applications from individuals
5 from underrepresented minority groups.

6 The reason I describe our program in such
7 detail, is I think it emphasizes the aspects of training
8 that I think should be incorporated into training for
9 clinical investigators in complementary and alternative
10 medicine.

11 The next question was, are there specific
12 issues involved in training conventional researchers to
13 study CAM questions?

14 Conventional researchers need to understand the
15 CAM practice being evaluated, and need to work
16 collaboratively with CAM practitioners who are expert in
17 the CAM modality being studied. Several research issues
18 are potentially problematic. These include consideration
19 of the placebo effect, difficulties in blinding both
20 patients and investigators, and difficulties
21 standardizing interventions.

22 I agree with the previous speaker, though, who

1 said that these are issues that we face in evaluating
2 conventional medicine as well, so are not necessarily new
3 or different.

4 The next question is, what training do CAM
5 professionals need to collect valid data, collaborate on
6 research projects, contribute as members of research
7 teams, and design and conduct high-quality research?

8 These research activities are obviously listed
9 in order of increasing complexity. For each of these
10 activities, the necessary training would be similar to
11 that required of other clinicians who participate in
12 research.

13 Commonly, clinicians are trained in relatively
14 short training sessions to collect and record data.
15 Member of our own research group did this successfully in
16 an NCCAM-funded study of patients seen by chiropractors,
17 acupuncturists, naturopaths, and massage therapists.
18 Training sessions should include the fundamentals of
19 research methods, how to collect and store scientific
20 data, and human subject protections that need to be in
21 place before research can be performed.

22 For CAM providers to collaborate and contribute

1 as members of a research team, they need increasing
2 research sophistication, which may vary depending on the
3 study under consideration. In order to design and
4 conduct high-quality research, CAM providers need the
5 same training we provide to our physician-researchers, as
6 I described earlier.

7 The next question is, how can CAM practitioners
8 become better educated in the critical evaluation of CAM
9 product claims and the results of CAM protocols in
10 clinical research?

11 Similar to the training physicians should
12 receive, CAM practitioners need training and skills
13 necessary to critically appraise a published study.
14 These skills include a basic understanding of research
15 design, and the limits of each approach, an understanding
16 of different measures of effect, of the meaning of p-
17 values, statistical significant, confidence intervals,
18 and potential sources of bias and confounding.

19 An excellent series of papers on critical
20 appraisal skills has been published in JAMA, which form
21 the basis, for many critical appraisal courses taught to
22 physicians, and could easily be adapted for CAM

1 practitioners. Ideally, these courses on critical
2 appraisal skills should be taught as part of the
3 undergraduate program or clinical training program for
4 CAM practitioners.

5 Given the limited regulation of CAM product
6 claims, it is especially important for CAM providers to
7 be able to assess the strength of evidence supporting
8 these claims.

9 The last question was, what policy
10 recommendations could I offer. First, I agree with the
11 speakers who recommended that there be increased funding
12 for CAM research and that this be made available for
13 training programs for both conventional investigators and
14 CAM investigators and practitioners.

15 We need increased funding for career
16 development awards to enable investigators focusing on
17 CAM to develop into independent investigators, and we
18 need increased funding for mid-career investigator awards
19 to provide support for the time required to mentor new
20 investigators. Thank you very much.

21 DR. GORDON: Thank you very much.

22 Richard Hammerschlag.

1 **Presenter: Richard Hammerschlag, Ph.D.**

2 DR. HAMMERSCHLAG: Good morning and thank you
3 for this opportunity to talk with you on issues related
4 to CAM research training.

5 I am fortunate to have had two careers in
6 research, one spanning 25 years at the biomedical lab
7 bench, and the other now reaching 10 years involved in
8 challenges of exploring acupuncture and CAM.

9 At present, I am the Research Director at the
10 Oregon College of Oriental Medicine. I am involved in
11 clinical research trials at the two NCCAM-funded centers
12 in Portland, and I serve as Co-President at the Society
13 for Acupuncture Research.

14 From my dual perspectives of biomedical and CAM
15 research, it is a pleasure to offer input for the
16 strategies you are developing to help sail the ship of
17 CAM on the seas of evidence-based medicine. I would like
18 to address three concerns.

19 First, the need for CAM research to more
20 clearly reflect CAM practice.

21 Second, the need for better training of both
22 CAM and conventional practitioners in the skills

1 necessary to evaluate the quality of CAM research
2 articles.

3 Third, the need to examine, systematically,
4 what CAM practice and research are revealing about how
5 the body works that biomedicine has not yet figured out.

6 First, I will address why I feel that much of
7 CAM research has been inadequate in its evaluation of CAM
8 practice. The need for CAM research is reflected in the
9 creation, first, of OAM, and its upgrade to NCCAM, has
10 been recognized because of the widespread public use of a
11 wide range of under-researched CAM therapies.

12 It follows that what needs to be evaluated in
13 clinical trials is how people are being treated. In
14 contrast, what too often appears in clinical trials is a
15 CAM therapy morphed into an allopathic-like treatment,
16 resulting in standardized protocols and variably
17 designed, non-validated placebo treatments. The
18 challenge for CAM research is to maintain rigorous
19 research standards, while having the protocols reflect
20 the real-world practice of the CAM therapies.

21 When a CAM practitioners reads a research
22 study, I often think, their response should not be, this

1 protocol is far too restrictive or simplified; I would
2 never treat a patient that way. Rather, their response
3 should be, well, I might not treat my patient in exactly
4 that way, but the protocol is reasonable, given the
5 presenting condition and diagnosis.

6 Well, my years in biomedical research have left
7 me with an appreciation of the need for controlled
8 trials. I believe, given the limited resources available
9 for funding CAM research, that undue emphasis is placed
10 on placebo-controlled trials.

11 What I see a greater need for are what
12 researchers call "trials of pragmatic efficacy," in which
13 two treatments are compared under conditions in which
14 they would applied in practice. To quote Kapchuk,
15 Edwards and Eisenberg, "A pragmatic perspective provides
16 less scientifically useful information, but potentially
17 provides more clinically relevant information."

18 As one example, a patient with tennis elbow,
19 and also the patient's practitioners, in this case, an
20 acupuncturist, are less interested in a clinical trial
21 that has demonstrated acupuncture to be more effective
22 acupuncture, than in an equally rigorous trial in which

1 acupuncture was found to be as effective as steroid
2 injection, and with fewer adverse effects.

3 So my recommendations here are, first, that
4 NCCAM be encouraged to call for research proposals that
5 clearly reflect real-world practice of CAM.

6 Second, that CAM research proposals submitted
7 to NCCAM and to the various NIH institutes, be required
8 to have had CAM practitioners involved in the research
9 design.

10 Third, that the CAM research design in such
11 proposals must be accompanied by a clear rationale, and
12 must have been approved by a consensus panel of
13 experienced CAM practitioners.

14 Fourth, that representatives from the NCCAM-
15 funded centers should meet periodically, not only to
16 present progress reports on their research, as they
17 currently do, but to exchange experiences of how best to
18 educated researchers in CAM practices, and how best to
19 introduce CAM practitioners to the research culture.

20 I will be briefer in presenting the second and
21 third of my three general concerns. My second concern
22 stems from teaching and lecturing about CAM research in

1 general, and acupuncture research in particular, to
2 students and practitioners of CAM, as well as
3 conventional medicine.

4 What I repeatedly encounter in this era of
5 evidence-based medicine is a serious need for training
6 and for continuing education in how to understand and
7 evaluate CAM clinical trials. Most practitioners, CAM
8 and conventional alike, are neither well trained in the
9 general principles of research design, nor appreciate the
10 difficulties inherent in applying conventional clinical
11 research methods to CAM research.

12 Yet, increasingly in their clinics, CAM and
13 conventional practitioners are facing, or at least should
14 be facing, the task of reading and evaluating CAM
15 research. Too often, there is more attention paid to
16 whether a trial's outcome is positive or negative, rather
17 than to whether the trial was designed well enough to
18 have provided an adequate test of the CAM therapy.

19 My recommendations here are, first, that
20 students at allopathic medical schools, as well as CAM
21 colleges must be taught how to understand and critique
22 CAM research trials. I echo Dr. Phillips here.

1 It is necessary, but not sufficient, to offer
2 survey courses of CAM practices, as an increasing number
3 of allopathic medical schools have been doing. There
4 must also be survey courses in CAM research.

5 Second, the CAM and conventional medical
6 practitioners should be encouraged, if not required, to
7 take continuing education seminars in how to understand
8 and critique CAM research trials.

9 My first two concerns focused on the question,
10 does CAM work. My final concern addresses the question,
11 how does CAM work. With all the current emphasis on
12 clinical trials, we are not paying enough attention to a
13 profoundly interesting parallel development of CAM
14 practice in research, that CAM is revealing ways in which
15 the body works that biomedicine has not yet figured out.

16 As we set off in these new directions, three
17 things need to be explored, the psychophysiological basis
18 of the placebo response, the physiology underlying Reiki,
19 qigong, therapeutic touch, and other CAM practices that
20 are defining the landscape and boundaries of energy
21 medicine, and third, the basis of healing practices,
22 including distant healing and intercessory prayer, that

1 unlike the phenomena underlying energy practices, appear
2 to be non-mediated, as well as non-local.

3 Notable for its virtual absence from the recent
4 NIH conference on the placebo was any studies on the
5 physiology of the placebo effects. While such effects
6 are certainly not solely within the province of CAM,
7 biomedicine appears little interested.

8 Yet, an understanding of the essential feature
9 of the placebo response, what I call the "transformation
10 of meaning into molecules," will surely provide us with
11 major insights into a range of mind-body CAM phenomena,
12 as well as improve the non-specific effects of healing.
13 As Harris Dienstrey [ph] elegantly understates, "The mind
14 as a source of medicine is waiting to be explored."

15 Second, while the term "energy medicine" is
16 often used today in an amorphous manner, research on
17 bioelectric magnetic fields produced by every organ and
18 tissue of the body, and detected at the palms of quigong
19 masters, is giving form and substance this term of
20 "energy medicine".

21 Even at the molecular, what I learned as a
22 graduate student in biochemistry is undergoing a sea

1 change, in which biochemistry is being considered,
2 largely, as a solid state phenomena.

3 Briefly, in this view, signaling occurring
4 within and between cells and tissues occurs alongside the
5 skeletal structures, along proteins that span the cell
6 membranes, and along the extracellular matrix. The fixed
7 ionic charges at the surface of these structures allow
8 electromagnetic signaling at orders of magnitude faster
9 than signals mediated by diffusible biochemicals.

10 Lastly, we must expand our understanding of the
11 human body by scientific study of healing phenomena that
12 do not appear explicable in terms of either molecular
13 medicine or energy medicine. The marked lessening of
14 symptoms in HIV-positive patients and the physiological
15 improvement of patients in coronary care units are recent
16 examples of elegantly designed, randomized, controlled
17 trials, assessing a therapeutic practice involving mental
18 intention by healers at sites remote from patients.

19 How is such healing received by patients, and
20 how does it alter physiology? Answers to such questions
21 are of profound importance for redefining our concepts of
22 self and for the reshaping of future health care.

1 Finally, my recommendations here are two: that
2 medical school survey courses of CAM and integrative
3 medicine should include research findings and emerging
4 concepts that challenge the prevailing views of
5 physiology and pathophysiology.

6 Second, that NCCAM, or perhaps even the
7 National Academy of Sciences, should be encouraged to
8 call for a conference that would propose evidence-based
9 models for expanding our present concepts of physiology,
10 and that would recommend an agenda for future research.
11 Thank you.

12 **Panel Discussion**

13 DR. GORDON: Thank you, and thank you for those
14 very thoughtful and stimulating suggestions. Thank you
15 all.

16 I have a general question that I would like to
17 ask Nancy Pearson and Neal West.

18 What has been the response to the training of
19 researcher's program, and what are the challenges or
20 obstacles, and where would you like to see things go with
21 the program?

22 DR. PEARSON: If you are talking about the

1 response from institutions who are applying, I think the
2 numbers are increasing, and we hope to increase the
3 number of training grants that we offer.

4 DR. GORDON: How many people have applied this
5 last year, or how many institutions?

6 DR. PEARSON: I don't have an exact number on
7 that. I could certainly get that information to you in a
8 written statement.

9 DR. GORDON: But it has been increasing each
10 year.

11 DR. PEARSON: It has been increasing each year,
12 yes. You can see that in the amount of funding that has
13 increased from 1.3 percent up to about 3.8 percent in
14 2000, and it continues to increase.

15 DR. GORDON: So the funding is not preset.

16 DR. PEARSON: No, not at this point.

17 DR. GORDON: Maybe you could explain to the
18 Commission a little bit about how that works.

19 DR. PEARSON: My understanding from our
20 director is that we will continue to increase up to a
21 certain level. If you look at all of NIH, the funding
22 for training NRSA and career development awards ranges

1 from about 2 percent up to 11 percent. So at this point,
2 since we are just starting out, we are closer to the
3 bottom end, but we are still increasing our funding, at
4 this point.

5 DR. GORDON: What do you see as the challenges
6 in getting more institutions and more individuals
7 interested in these particular grants?

8 DR. PEARSON: I think, just getting the word
9 out that we are interested. We are revising our website
10 right now to give a lot more information about this,
11 putting information about our presently funded centers
12 and institutional training grants on the website as
13 possible places where people can be trained. So any way
14 we can get out more information.

15 DR. GORDON: The other question related, is, I
16 noticed in the testimony you said some of the NCCAM
17 centers presently have research training, which implies
18 that some don't.

19 Does that mean that is not required for the
20 NCCAM centers?

21 DR. WEST: The first iteration of the NCCAM
22 center announcements did not require set-aside money for

1 training and career development, although we appreciated
2 that it would occur in the research, in the process of
3 doing research.

4 What we have done, as the center program has
5 been reannounced, is that we have not only included
6 training and career development as a specific item that
7 is adjudicated in peer review, we have suggested
8 guidelines for a set-aside of a portion of the total
9 award and requested that it be committed to training and
10 career development, and we, of course, track that in
11 several ways.

12 Following up on one of the things Nancy said
13 about our increased visibility in terms of the various
14 ways in which we can participate in training/career
15 development, one of the things that has occurred in the
16 last year is that every time the NIH, through the guide
17 process, has announced a new training and career
18 development initiative, and again, a lot of these are
19 done in a trans-NIH way, we have signed on.

20 Our name is on the top. It is very visible.
21 We have got a contact person, because there are a large
22 number of these. Our director has insisted that we sign

1 on the full range. A lot of NIH institutes and centers
2 tend to support only a narrow range of training and
3 career development grant mechanisms.

4 We are signing, given the diversity of our
5 community -- and you will note that in those
6 announcements, the CAM practitioner community is
7 specifically identified, by degree, as folks who are
8 invited to participate in that mechanism, rather than it
9 being understood in the other related language that often
10 occurs at the end of those announcements.

11 In addition, I have written as a separate pre-
12 doctoral fellowship announcement and Dr. Pearson has
13 recently published a post-doctoral fellowship
14 announcement, both specialized in complementary and
15 alternative medicine.

16 DR. GORDON: Thank you very much.

17 DR. HAMMERSCHLAG: Could I just add a quick
18 perspective? Christine Gertz from NCCAM recently told us
19 some very interesting statistics, that they have been
20 tracking how many proposals they have received from CAM
21 colleges, and the number is 26, if I am remembering
22 right. Only one CAM college, which is Bastyr, has ever

1 been funded, and they have submitted, maybe, 11 or 12 out
2 of those 26.

3 This speaks to a real need to improve the
4 research infrastructure and training at the CAM colleges
5 to get that perspective.

6 DR. GORDON: Hasn't there been a chiropractic
7 college?

8 DR. HAMMERSCHLAG: No. There is a chiropractic
9 center, which is a consortium, one of the currently
10 funded NCCAM sites.

11 DR. GORDON: I see. So your point is that --

12 DR. HAMMERSCHLAG: Talking about individual
13 grants, that this is what NCCAM has been tracking.

14 DR. GORDON: Do you have any more thoughts
15 about that?

16 DR. HAMMERSCHLAG: Yes, that there needs to be
17 -- I am most familiar with the acupuncture colleges, and
18 there are very few people like myself, with a research
19 background, in the acupuncture colleges. So their
20 ability to even develop the research infrastructure is
21 limited. They don't understand what is needed. A
22 training program that would be directed at the CAM

1 colleges would be extremely valuable.

2 DR. PHILLIPS: Could I just add one other
3 thing? As someone outside NCCAM, I should say that these
4 training grants are incredibly important to the
5 development of investigators who focus on CAM. The
6 general way our careers develop is that, generally, we
7 will spend a focused amount of time as a fellow to do
8 research, and then that allows us to create the track
9 record and focus that we can then use to apply for our
10 career development awards, which would be the K-08 or K-
11 23 award.

12 So the centerpiece really needs to be the
13 individual NRSA, or the institutional NRSA, which
14 provides a fellowship training, from which you can then
15 progress to a K award, which will allow you to develop
16 into the type of independent investigator that they can
17 successfully win R-01 grant support.

18 One other comment is that we are interviewing
19 now for our third group of applicants. We actually
20 applied for this award, the T-32 Training Grant, because
21 we had a large number of fellows coming to us, or
22 applicants coming to us, with specific interest in

1 complementary and alternative medicine.

2 Since we have started publicizing this program,
3 the numbers have grown fairly dramatically. The last
4 year, we had three or four applicants. This year, we are
5 about 15 or 16, which is almost as many as general
6 medicine applicants, as we get to our fellowship program
7 that has now been in existence for over 20 years.

8 DR. GORDON: Thank you very much. I have
9 Charlotte, Linnea, and Tieraona, and Effie, Wayne.

10 SISTER KERR: I am feeling just a little bit
11 sad this morning, and it is not because of your excellent
12 presentations or your dedication. I think I am speaking
13 to the whole morning when I speak, and predominantly as a
14 practitioner right now.

15 Yesterday, I spoke of a patient I saw recently,
16 and I want to say something about that. This person
17 presented with pain in the back of her leg, about a 33-
18 year old lady. In doing the history, many labels came up
19 from a biomedical model, for example, Reynaud's,
20 dysmenorrhea, allergic rhinitis, headache with her
21 period, brittle hair, some mild anxiety, not considered a
22 clinical problem, craving salt, she had lost her friends

1 because she couldn't run, and chronic constipation since
2 a little girl.

3 Now, it often might be possible that almost all
4 of those symptoms would go away, but her leg would still
5 hurt. This is not unusual, as we practice in traditional
6 acupuncture. What I want to say is, in traditional
7 acupuncture, and in other CAM therapies, we often -- I,
8 we -- want to study whole energetic systems. It is based
9 on an energetic physiology. We don't focus on one
10 symptom change as a desired outcome.

11 Now, these new understandings of new physiology
12 changes, in my opinion, future agenda methodologies, and
13 Richard, you spoke to this. I don't see this happening.
14 Now, you need to know I have been in this process for
15 several months, and so, this is not like just today I
16 thought of that.

17 I am listening to some of the most dedicated,
18 fine minds in this country, over many weeks. I had a
19 small part in planning the NIH Consensus Conference on
20 Acupuncture, and I understand the impact that had on this
21 country and the world. As an acupuncturist, I am
22 delighted that we know it helps dental pain and post-

1 operative nausea, but it was, in the South Carolina
2 language, podunk outcomes, as far as I am concerned, as
3 far as what is possible.

4 I am not discouraged because I don't see any of
5 this thinking, but I don't see enough investment in
6 acknowledging there is a new aspect of physiology. I
7 understand it is not in the West world's established view
8 of physiology yet, formally anyway, but I don't see the
9 desire. In these wonderful training programs, where is
10 it built in to do the epistemological reflection, the new
11 world view reflection?

12 So this is my general question to you, are we
13 moving there any faster? It gets a little bit back to
14 Ming's point this morning, that we can have an outcome
15 that something doesn't work, simply because we are not
16 studying the way we work. Thank you.

17 DR. BLANKS: Could I have the opportunity to
18 respond to that, please? I happen to agree with you 100
19 percent, and you might remember, I was trying to
20 paraphrase my comments, not so much evidence-based, but
21 more people-based, holistic-, vitalistic-based.

22 Indeed, I would hope that we are moving in that

1 direction so that we can begin to see, not only the
2 person as a total, but also how they related to their
3 social networks, how they relate to their environment and
4 their social structure.

5 I think there is a strong movement there. With
6 the incoming medical students, with my younger
7 colleagues, I see a very strong sense of, I am burned out
8 on the managed care system; I have to spend more time
9 worrying about the details of treating patients as
10 patients, and not just an endless list of symptoms.

11 I don't know that this being addressed well
12 enough at the NIH level, largely because it is
13 hypothesis-driven and it is very difficult to center a
14 hypothesis around quality of life as the single outcome
15 measure.

16 But we do see this. We see it, certainly, in
17 our cancer protocols. At our university, the physician
18 who is chair of the IRB will have \$50 million worth of
19 hypotheses or drug treatment protocols, and almost every
20 one of them now has a quality-of-life component. So that
21 part is beginning to drift in here.

22 I would applaud that perspective, and I am

1 going to hold my banner up and say, I am there but I am
2 also on the other side, too. I am hoping that we can go
3 in this direction very strongly.

4 DR. HAMMERSCHLAG: I will have a go at the
5 other part of your question about, there is a real need
6 to develop an energy physiology to start to become the
7 base for, and not just an energy physiology or a beyond-
8 energy physiology, but, how do we do this.

9 There are two general approaches to try to get
10 at some structure to this. Ann Harrington at the Placebo
11 Conference spoke elegantly about what she calls
12 "sightings". We don't know what the phenomena is, but
13 whatever it is, this and this and this phenomena, have to
14 be explained by it.

15 I will just give you one example. There was a
16 study in Japan where a new chemotherapy protocol was
17 being tested. Forty percent of the patients in the
18 placebo group experienced significant hair loss. This is
19 not just heart palpitations or slight dizziness, this is
20 a major biomedical symptom. What is going on here; we
21 don't have a clue about this.

22 Fabrizio Benedetti was the closest that

1 anybody talked about physiology of placebo at the Placebo
2 Conference, but he spoke eloquently. He drew on the
3 board a box. He said, I want you to know the placebo,
4 what we need to know is in that black box, and what I
5 found, the endorphins, those are outside of the box. We
6 need to know what the transduction, we call it in
7 biomedical terms, how does that meaning get transduced.

8 So sightings are one way. The other way that
9 Beverly Rubik goes about it, is she talks about an agenda
10 where she looks at parallels. She asks, what are the
11 parallels with biomedicine that we need to establish; are
12 there specific receptors for bioelectromagnetic fields;
13 what are the pathways in the body by which we can get
14 instant signaling between different parts of the body to
15 look at the parallels between existing physiology.

16 So those are two approaches that I can begin to
17 see, but there is enough out there to begin to bring the
18 mind-body people together with people. When we say
19 biomedicine isn't aware of this, it is not true. We have
20 been doing EEG and EKG and electroretinogram.

21 It is the same kind of bioelectromagnetic
22 fields that are produced at much lower levels by all the

1 tissues in the body, and this is surely our window into
2 the future way of diagnosis of subclinical imbalances
3 that need to be corrected before they become, in Western
4 science, symptoms.

5 SISTER KERR: I just want to say, as a policy
6 recommendation, we are going to say a lot about more
7 research. I would like to know some language so that we
8 can say, how can we be more specific, because we are
9 going to get the same biomedical research, I think.

10 DR. GORDON: Linnea.

11 MS. LARSON: Thank you all for your very wise
12 and useful observations. I could ask this question of
13 all of you, but I am going to limit it to Dr. West and
14 Dr. Pearson.

15 Of the fellowships that you have offered, how
16 many of your candidates come from the worlds of medical
17 anthropology, masters of divinity, law, social services,
18 family therapy, those areas that are considered quite
19 soft?

20 DR. WEST: I was Nancy Pearson before she
21 joined NCCAM. I was the fellowship coordinator for
22 NCCAM, even though she has as many years of experience

1 and fellowships. I was happy to be the program officer
2 during the time we did have applications, pre-doctoral
3 fellows, in areas such as you are describing, in studying
4 shamanics, for instance.

5 Two of our F-31 fellows, these are pre-doctoral
6 fellows who are actually doing research very similar to
7 what you are describing. One of the beauties of the pre-
8 doctoral fellowship program is to allow field studies
9 off-site for many months. Those individuals took
10 advantage of that. We have been very receptive to
11 medical anthropology as an area for support.

12 MS. LARSON: Medical anthropology, can you
13 expand that to include, let's say, M.D.V.s, law,
14 historians of science?

15 DR. WEST: Yes. Those are just areas that,
16 frankly, we haven't had applications in. One of the
17 points, and I tried to address it by describing, for
18 instance, our K awards in all the different categories,
19 is that, I am sure those of you who go to the NIH to
20 grants and contracts, you see that this is an incredible
21 variety and labyrinth of different grant mechanisms,
22 which tends to be way we are able to support people,

1 through peer review.

2 So we fall back on those mechanisms. There are
3 grant mechanisms that exist, including what we have and
4 some others that can accommodate almost any biomedical
5 approach need. Some of the ones you are describing, in
6 my mind, I immediately think of grant mechanism and
7 hypothetical applications, but those are not the kinds of
8 things that we have gotten in yet.

9 Again, one of the points I was trying to make
10 about our increased visibility and our signing on to
11 existing announcements and developing our own, is that,
12 when we do this, people appear. They don't just appear,
13 we work with them to put together applications.

14 Let me just say that training and career
15 development have very generous success rates across NIH.
16 Our director is very aware of this. NIH publishes
17 success rates, and the success rates, which are our
18 chances of getting money, are significantly higher in our
19 fellowships and in our career development awards compared
20 to research grants.

21 That is true across NIH, and it is certainly
22 true in our center. It really has to do with the

1 applicant community finding us and coming to us. We have
2 been going out. I went to the last two meetings of the
3 American Association in Naturopathic Physicians, and I
4 felt like the pied piper of Hammelin. People are very,
5 very interested. They come to us, and they start
6 thinking about it and talking about it.

7 Sure, there is a lag period. People need to
8 finish their chiropractic training, but the interest is
9 out there, and we are in a position to respond.

10 DR. PEARSON: If I could just make one
11 additional comment, which really reflects what Neal says.
12 We are really just gearing up, because we only started
13 funding in 1999.

14 I have just been with the organization for two
15 months, but during the time I have been there, I have
16 gotten many, many calls from people who do manage to find
17 us, either through our website or through other
18 publications. I have gotten calls from spiritualists,
19 people interested in hearing. I will admit I have not
20 gotten any calls from people who were in law, but that
21 could happen.

22 One of our roles is really trying to introduce

1 them to the NIH system, because it is very complicated
2 for people outside the system. So a big part of our job
3 is spending a lot of time on the phone, coaching people,
4 telling them how to apply for NIH grants. We do get
5 individuals from a wide variety of different disciplines
6 and professions calling us. I am sure that will expand
7 as we become better known.

8 DR. GORDON: Thank you.

9 Tieraona.

10 DR. LOW DOG: I am not quite sure how to ask
11 this and make it come out sounding the way I want it to
12 sound. I have heard we need to be studied in the way we
13 really work, or the way we really practice, that we need
14 to relate to the total person, that this whole,
15 vitalistic approach needs to be studied.

16 I guess I am sitting here as a somebody who
17 went to a medical school and a rural family practice
18 program where cross-cultural medicine was taught,
19 psychosocial impact on health, a month at the wellness
20 center for smoking cessation, exercise, weight
21 management, perspectives in medicine every two weeks for
22 ethics and social approaches to health, and I am curious,

1 because when you are studying antihypertensive, you are
2 not studying the way we practice, either.

3 You are not studying the way family doctors
4 practice in our office. You just don't come in, we take
5 blood pressure, and we give you a pill. I mean, I hope
6 not. That is not the way most of us practice. We know
7 who you are, and we know your issues, and we talk to you
8 about stress, and we talk to you about what is going on,
9 we talk to you about your diet and what you are doing,
10 and exercise. We do all of those things.

11 I am concerned, on some level, that in some way
12 we are saying that there is a different relationship that
13 occurs in complementary and alternative medicine between
14 the healer and the patient than what can occur, and
15 often, I do believe, does occur in many, many physicians'
16 offices, especially primary care and rural, where I have
17 seen just tremendous amounts of this, and that, if we are
18 going to do it for one, why wouldn't we do it for the
19 other; and why aren't you interested in studying rural
20 family practice docs in their real-life practice.

21 The reason, I understand, we don't do that, or,
22 my understanding is, because we want to remove the healer

1 from the equation so we actually know what is working.

2 And yet, all of us who are not researchers, who are just
3 doctors in the field, believe strongly in our
4 relationship with our patient.

5 There is a concern that I have, that somehow we
6 are separating these out as it is unique to a particular
7 modality, and that it is not actually across the board,
8 that most dedicated healers have this common belief and
9 experience.

10 Any comments?

11 DR. HAMMERSCHLAG: You are the White House
12 Commission on Complementary and Alternative Medicine, not
13 a general commission on health care practices, or health
14 care research. I do firmly believe that a large amount
15 of our research dollars should be studying health care as
16 it is practiced in the community.

17 I would offer you models of the National Health
18 Service in Britain. They are currently funding two very
19 large-scale trials of acupuncture compared to usual care.
20 In each arm, as the practitioner is free to treat as they
21 would treat in clinical practice.

22 The National Health Service is interested.

1 These were competitive grants that they put out. One of
2 them that got funded is in migraine, the other is low-
3 back pain. They are exciting not only for the scope of
4 what they are doing, but for the model within which they
5 are testing these studies. In this case, both
6 conventional and Chinese medicine practices are being
7 given full scope to treat, and they want to see how they
8 do.

9 In this model, of course, you can also test
10 relative cost effectiveness, relative onset, comparative
11 side effects, and how long each treatment effect lasts.
12 So that is a very powerful research approach for asking
13 very different kinds of questions than is, the treatment,
14 does it have efficacy, which strictly means, is it better
15 than placebo.

16 DR. PHILLIPS: I think your question emphasizes
17 the fact that there are parallels between studies that we
18 would do in conventional medicine and complementary and
19 alternative medicine. The issue are very similar. The
20 study that you talk about, potentially, is an important
21 one.

22 There is a large body of data that looks, for

1 instance, at whether subspecialists provide different
2 care than specialists. There are studies that look at
3 care provided by different types of practitioners, and
4 there are differences. There are studies that show that
5 female physicians do things differently than male
6 physicians, and excel in some areas more than male
7 physicians do.

8 I don't think we necessarily understand why all
9 those observations exist, but I think it is an important
10 area of study, both for conventional researchers studying
11 conventional medicine, like family practice or general
12 internal medicine, or for researchers who are interested
13 in looking at CAM practitioners.

14 DR. LOW DOG: Yes, but my feeling is that there
15 is some sort of common denominator, that there may be
16 common denominators that are unique to all of us that are
17 not CAM or conventional, and that if we are completely
18 looking at them separate and in isolation from one
19 another, we may miss what we have in common by simply
20 focusing on what we do different. That was my only
21 comment.

22 This is the White Commission on Complementary

1 and Alternative Medicine, but it doesn't exist in
2 isolation. It exists within the system that we are all
3 working within.

4 DR. GORDON: Effie.

5 DR. CHOW: Thank you all. I am not as sad as
6 Charlotte is. I am actually enlightened with some
7 comments here, relating to the human aspect and the
8 outside-of-the-square comments.

9 One of our concerns is that the multifaceted
10 approach with which CAM -- and as I said before, I don't
11 really like that term -- multifaceted approach to the
12 individual, worrying about it becoming reductionistic by
13 the process that we are putting it through, and the
14 discussion about research and how it is researched.

15 There are two questions here, or comments, and
16 I would like the comments from you folks. How do we keep
17 it multifaceted? Because acupuncture, using that as an
18 example, has been reduced to -- and maybe it will be
19 expanded later on -- to six usages. Whereas, it is a
20 system of practice in China, and it deals with the whole,
21 human health and ailings. So that has been reduced.

22 Also, the utilization of researchers. What are

1 the qualities of the researchers? Is it acupuncturists
2 and other practitioners that have had a 200-hour
3 training, and because of their qualifications in Western
4 medicine, that that qualifies them? Or, is it
5 acupuncturists who have had 2,000 hours of training or
6 more, and deal with the whole concept of the laws of the
7 five elements and the relationship of the human being to
8 nature, all the classical, theoretical concept with the
9 energetics concept? The results will be different
10 utilizing different types of practitioners.

11 That is a comment, but it is a real serious
12 consideration, and I would love some comments from you
13 folks. What are some of the qualifications, for example,
14 at Harvard, that you are utilizing for acupuncturists?
15 And comment on other practitioners, too, and for the
16 others, as well.

17 DR. PHILLIPS: I can't speak to the exact
18 credentials that are required. It varies, depending on
19 the different study, but I guess there are two principles
20 that a number of our studies follow. One is an
21 individual study trying define a scope of practice that
22 represents what practitioners would do in the community

1 for a specific problem.

2 So we are trying to avoid the problem of
3 providing such a narrow and prespecified intervention
4 that bears no relation to what a practitioner is really
5 doing, and we try to develop that scope of practice,
6 working with, in the case of acupuncture, groups of
7 acupuncturists who agree that certain treatments are
8 reasonable treatments for a specific condition.

9 We also, for all of our alternative
10 practitioners that we are involving in research studies,
11 have a lengthy credentialing process to ensure that all
12 the practitioners have had a certain level of training
13 and number of hours training and practicing. I don't
14 know, off hand, exactly what that requirement is.

15 DR. BLANKS: I would also like to address your
16 comments there. I, too, am very concerned about what are
17 holistic disciplines, complete health delivery systems.
18 Oriental medicine, I believe, is one, and I have some
19 familiarity there. Subluxation-based chiropractic, in
20 many respects, fits this entire health delivery system
21 concept; take care of the patient, and they will take
22 care of themselves. There is a vitalistic component

1 there, an innate intelligence, if you will, if take care
2 of that aspect.

3 I am concerned, and I tried to convey some
4 ideas about several different model approaches.
5 Hopefully, you don't settle on one, that you should
6 settle on several, which I believe would allow the
7 ability to deal with entire disciplines, not taking in
8 parts of those disciplines to treat specific symptoms.

9 To come back to the commonality here. If
10 indeed we are treating patients, patient health and their
11 wellness in the illness-wellness model, than we would
12 have done due diligence in terms of our health outcome
13 measures, our research documentation base, and so forth.

14 I will go back to her comment as well, and that
15 is, at our university, the only person allowed to deliver
16 acupuncture in a clinical setting is not a person trained
17 as a doctor of Oriental medicine, where they have --

18 DR. GORDON: Excuse me, I am going to
19 interrupt. We are already over time. If you could focus
20 on research training aspects in response to the question,
21 okay?

22 DR. BLANKS: Very quickly, then, I guess the

1 point is that we have done this reductionism so much now
2 that the only person who can deliver the acupuncture in
3 that setting, in primary health delivery, is the
4 physician. I think this is a problem that begins with
5 the training very early on, to realize that there is an
6 entire body of evidence that one has to learn in
7 delivering health in these other disciplines.

8 DR. HAMMERSCHLAG: Can I briefly just say one
9 thing? I want to point out what Alex White mentioned in
10 the early panel, that when the NCCAM centers are funded,
11 there is money for training CAM practitioners, but just
12 as it is with mainstream training grants, these are post-
13 doctoral awards.

14 The Kaiser Center realized that if they were
15 going to be post-doctoral, they could train chiropractors
16 and naturopaths, but they could not bring in
17 acupuncturists or massage therapists, so they called
18 NCCAM and got them to allow them to create half-time
19 fellowships that were open to any CAM practitioner who
20 had achieved the highest level of training in their
21 profession. So, another obvious mechanism for training.

22 DR. GORDON: That is very helpful.

1 Wayne, this is the last question, and then we
2 will take a break.

3 DR. JONAS: Dr. Blanks, outside of NIMH, which
4 I think has made an effort to begin to have a dialogue
5 about the synthesis of these different evidence
6 approaches that social science and the biomedical model
7 have taken, are there any things outside of the CAM world
8 and the conventional research that are beginning to
9 bridge these areas, that you know of?

10 DR. BLANKS: Actually, there are some other
11 disciplines. The National Eye Institute, for example,
12 has an approach that would be health outcomes-based,
13 broad health measures. It is something that I am seeing
14 drifting into the literature very quickly. There was a
15 recent RFA that would have addressed the specific issue,
16 and many of the others, I am not aware of.

17 DR. JONAS: I know, as more energy builds for
18 another methodology conference in this area, and I think
19 Dr. White is in the process of helping with others, this
20 might be a thing to consider, one of those aspects.

21 I wanted to ask Neal and Nancy -- first of all,
22 I wanted to congratulate you on the wide array of

1 participation in the training grants that you have
2 rapidly moved into in getting NCCAM involved. I think it
3 is heroic. Knowing the work that it takes to do that, it
4 is just an incredible feat.

5 I am wondering if one of the next steps is to
6 try to see if it can't be stimulated a little bit more
7 through an RFA process, specifically setting aside some
8 money targeting that. When that happens, as you know,
9 you get a lot of people that come out of the woodwork.
10 There are a lot of things, that even if they don't get
11 funded, begin to develop.

12 There has been one on curriculum development,
13 but it wasn't focused specifically on research training,
14 and I was wondering, is there any thought or discussion
15 of doing some specifically on research training to help
16 supplement this?

17 DR. PEARSON: I will just mention one thing.
18 There is an RFA out now on institutional training grants
19 for minority research, and that is getting some response.
20 To my knowledge, there is not a specific plan for another
21 one in the future, although Neal might want to talk about
22 curriculum.

1 DR. WEST: As you know, there is a curriculum
2 development announcement with set-aside money that is an
3 ongoing activity that provides CAM clinical trial
4 curriculum support. That is an ongoing announcement,
5 which has one more year left on it with set-aside money.

6 One thing I would like to address about our
7 training and career development, I know we have presented
8 you with a bit of what I call an alphanumeric soup of
9 different Ks and Fs and Ts, but there are really a couple
10 of threads, and one very specific thread, that runs
11 through all of our training and career development, and
12 that is that these all require an interdisciplinary,
13 integrated research training environment that includes
14 both CAM and conventional skills.

15 We really want to bring those skills together
16 into our training environment. Whether it is a K, a T,
17 an F, that is not important. We really have an
18 underlining belief that by bringing those folks together
19 in that training environment, that what has to develop
20 and has to be transmitted to the next generation of
21 researchers and practitioners is this mutual respect for
22 each other's healing approaches, and an appreciation that

1 there are overlapping paradigms in conventional and
2 complementary and alternative medicine.

3 DR. JONAS: I think that is fabulous, and I
4 think that it would be great if perhaps you could
5 stimulate. There is such a dearth of good, qualified
6 researchers in this area, as evidenced by difficulty in
7 sometimes getting good grant applications, that it really
8 needs an investment.

9 To do it right, of course, is complicated, and
10 you ideally need to partner with a number of the other
11 institutes. Anyway, that would be something I would
12 suggest to you.

13 DR. GORDON: Thank you. And thank you, Nancy
14 Pearson and Neal West for your, as Wayne said, heroic
15 work in moving the field ahead. I want to thank the
16 other three of you for the exemplary demonstration
17 efforts.

18 Also, Richard Hammerschlag, if you have that
19 curriculum for a course in CAM research, we would love to
20 see that. That would be very helpful to us in our
21 deliberations. So thank you very much.

22 We are going to take a 15-minute break, and let

1 me thank, in advance, the editors of the journals for
2 their patience as we have gone a little bit overtime. We
3 will back in 15 minutes.

4 [Recess.]

5 **Panel VII: Publication of Peer-Reviewed**

6 **CAM Research Results**

7 DR. GORDON: Good morning, all, and thank you
8 for being here with us. We would like to begin the panel
9 with Edward Campion, please.

10 **Presenter: Edward Campion, M.D.**

11 DR. CAMPION: Thank you, and thank you for the
12 invitation to appear before the Commission.

13 I am an internist trained in rheumatology and
14 geriatric medicine. I have appointments at Massachusetts
15 General Hospital and Harvard Medical School, and for 13
16 years, I have been a deputy editor at the New England
17 Journal of Medicine.

18 The first commitment of a medical scientific
19 journal is to publish research that is accurate and
20 relevant to the journals' readers. Hence, the journals
21 must assess both the evidence in a report and the process
22 by which it was obtained. Peer review is not infallible,

1 but it does improve the quality of scientific articles
2 and provides editors useful information as they make
3 decisions about manuscripts.

4 Some of the questions that editors at journals
5 ask are, how important is this research question; what
6 exactly is the question trying to be answered; how
7 rigorously was the work conducted; are the results
8 reproducible, generalizable; were the data analyzed in a
9 way that is valid, statistically; does the report
10 recognize other research that has been done on this
11 topic.

12 A fundamental obligation of every type of
13 medicine is to identify what treatments can help patients
14 and describe the basis of that information in a way that
15 is objective and useful. Researchers must identify
16 specific questions, and researchers must recognize that
17 their beliefs and prior impressions may turn out to be
18 mistaken. In any controversial area, it is useful to
19 gather basic descriptive information about what current
20 practices, beliefs, and economic consequences, actually
21 are.

22 Clinical studies must be conducted in ways that

1 minimize bias, including biases that may come from either
2 skeptics or enthusiasts, from investigators or patients.
3 Comparison with appropriate controls can increase
4 confidence and results, as will comparisons with other
5 treatments.

6 Research evaluations should try to identify
7 what degrees of change are clinically meaningful, and
8 recognize that small differences may not be of any real
9 benefit to patients. Particularly, in chronic
10 symptomatic conditions, the natural history may include
11 large variations, independent of any treatment. In all
12 clinical studies, more complete follow-up increases the
13 strength of the evidence.

14 We must also recognize that some very important
15 aspects of medical care are never captured very well by
16 any research. These include a patient's hopes and
17 expectations, and inner beliefs, the provider's attitude,
18 and manner toward the patient, the past histories of
19 both, and the personal relationship between them.

20 For policy recommendations, I will make three.
21 First, give priority to investigation of those few types
22 of unconventional treatment that can cause major harm,

1 especially unregulated use of drugs, herbal products, and
2 so-called dietary supplements. At our journal, I should
3 say we see little evidence of reports of rigorous
4 research of CAM. We have published some reports of
5 major, even life-threatening toxicities from substances
6 such as astrolochia, PC-Spez, and a dietary supplement,
7 ephedra.

8 I believe the FDA should have responsibility
9 for safety testing of herbal medicines and dietary
10 supplements.

11 The second recommendation. Encourage and
12 support objective research studies, but only for
13 modalities with evidence of genuine promise. Beware of a
14 research trap. Research dollars are precious. They
15 should not be wasted on trying to define 1,000 ill-
16 defined, unconventional practices, most of which are
17 harmless.

18 Finally, there should be more investigation of
19 the reasons why consumers seek out unconventional
20 therapies. One reasons may be dissatisfaction with our
21 nation's conventional health care delivery system. Thank
22 you

1 DR. GORDON: Thank you very much.

2 Jackie Wootton.

3 **Presenter: Jackie Wootton, M.Ed.**

4 MS. WOOTTON: Jackie Wootton, Executive Editor
5 of the Journal of Alternative and Complementary Medicine.
6 It is often known as the "Blue One".

7 I note that three of the Commissioners are on
8 our editorial board. One is a former member of our
9 editorial board. Two of the panelists today are on our
10 editorial board, and two of the panelists today are
11 authors in this latest issue of the journal.

12 We believe that the review process for the
13 Journal of Alternative and Complementary Medicine is
14 essentially the same as that for any major biomedical
15 research journal. I joined the journal in March 1996,
16 and I am responsible, with the editor-in-chief, Kim
17 Jobst, M.D., for running the peer-review process.

18 I was determined from the start to emulate the
19 high standards of expert and impartial review that are
20 accepted practice for all quality academic publications.
21 The journal was accepted for indexing by MEDLINE within
22 its first three years of publication, back-dated to the

1 start year, and has steadily gained a strong reputation
2 as a serious CAM research publication.

3 Ideally, the criteria for accepting articles is
4 that they are clear and coherent and scholarly, the
5 description of methods and materials is complete and
6 replicable, that studies are contextualized within the
7 appropriate existing bodies of knowledge, and that claims
8 and conclusions are supported by evidence.

9 When selecting reviewers, I take into
10 consideration the author's recommendations and requests
11 for excluding certain reviewers. We have a large
12 editorial board who review and are available for
13 consultation. I have also built up an extensive database
14 of expert specialist reviewers for the field.

15 Review is anonymous, but it is not double-
16 blinded. That is, the reviewers know who the authors
17 are, but the authors do not know the identity of the
18 reviewers. There are usually three reviewers, one with
19 the appropriate CAM knowledge and expertise, one
20 conventional biomedical researcher, and I am fortunate
21 that my office in Bethesda is right next door to the NIH,
22 so I have many friends and colleagues, and I can sort of

1 pop across and say, hey, I need a hepatologist or
2 whatever. This is a very, very important part of our
3 review process.

4 Then we also seek a methodologist or a
5 statistician, and I have to admit that that is actually
6 very difficult to sustain. I collate the reviews and
7 consult with my colleagues. The editor-in-chief, Kim
8 Jobst, ratifies the final decisions. We require
9 structured abstracts for the research papers, in
10 accordance with the Cochrane review process.

11 Like all the major journals, we receive
12 promotional articles sponsored by companies who need
13 third party literature. Like all the major journals, we
14 request a Declaration of Interest when the manufacturing
15 company is involved.

16 As for all the conventional medical journals,
17 occasional weak papers slip through. I am pleased to
18 hear that you said the same from the New England
19 Medicine. No peer-review process is infallible. As we
20 all know, publication is not the end of the scientific
21 process, fortunately.

22 The main reasons for rejection of papers is,

1 weak, unsubstantiated claims, strong unsubstantiated
2 claims, to use a variant of the quote, "Extraordinary
3 claims demand extraordinary evidence." Trivial,
4 overblown papers, promotional papers, and what I label
5 suspension of disbelief. These are papers where the
6 authors are so convinced by what they believe is true,
7 that they are incapable of objectivity.

8 These are problems facing all journal editors,
9 what I see as the unique challenges facing CAM journals,
10 and our journal specifically is, first of all, paucity of
11 material. I receive approximately 110 submissions of
12 research review papers in a year.

13 Secondly, many researchers have not been
14 exposed to stringent scientific standards. This point
15 keeps being made. There is a lack of experienced
16 researchers who have CAM experience and insights. For
17 the same reason, it is hard to find reviewers who
18 understand the code of expert and impartial review.
19 Another problem is the non-English speaking authors who
20 have difficulty expressing their ideas clearly.

21 From unique challenges come unique
22 opportunities. Dr. Jobst and I, and members of the

1 Board, spend a lot of time educating and encouraging
2 authors. Rather than reject out of hand, we help authors
3 to modify their claims. For example, we may require them
4 to add statements on the limitations of their experiment
5 or methodology, or to rework the paper.

6 An another instance, a poorly designed clinical
7 trial may have potentially interesting preliminary data
8 or insights that can be converted into a promising case
9 study or a short report. Unlike some of conventional
10 journals that might throw such papers out, we actually
11 try to seek out these little gems.

12 We tolerate successive stages of review and
13 revision. Most papers go through one major revision
14 stage, but some require several iterations, so that some
15 papers can take up to two years to get through the review
16 process. Our rejection rate is low, around 30 percent,
17 as a result, to a large extent, of our educative policy.
18 The attrition rate is high. Many authors don't return a
19 revised paper for reconsideration.

20 We are open to negative results. I think the
21 field actually needs some clear negatives, as well as
22 positives, to enhance credibility. However, authors do

1 not want to publish negative results. We do have safety
2 studies, and in this most recent issue of the journal, we
3 have a paper from two naturopathic doctors on the safety
4 of low-dose lariatridentarta [ph], a retrospective
5 clinical study.

6 Although the underlying principles of
7 publication are the same for CAM as for conventional
8 medical journals, as you say, the sea, the process does
9 have differences. CAM articles published by conventional
10 journals are predominantly based on the standard
11 pharmaceutical drug model of isolating and testing single
12 agents or interventions, typically using the randomized,
13 controlled trial.

14 At the Journal of Alternative and Complementary
15 Medicine, we encourage randomized, controlled trials, but
16 we encourage a broader perspective, too. Our feeling is
17 that new theories demand innovative methods, and,
18 provided researchers adhere to the basic scientific
19 principles of external and internal validity, they should
20 be free to innovate, develop new appropriate
21 methodologies and carefully crafted techniques.

22 Dr. Angell, in a previous session, made the

1 distinction between the scientific principles underlying
2 the methodology and scientific methodologies. I think
3 this is very important. We can say with confidence that
4 we understand the underlying principles, but I don't
5 think we can say that there aren't new methods out there
6 that we need to explore.

7 Unfortunately, the authors rarely do provide us
8 with these innovative methods, and this brings me to my
9 recommendations to the Commission. There is a need for
10 more academic departments and research positions, at
11 post-doctoral level, to attract the brightest and best
12 into the field.

13 There is also a need for more research money
14 for practitioner training schools, as they are the ones
15 with the knowledge and insights needed to develop
16 appropriate methodologies. There is a need to expand the
17 range of acceptable models of quality clinical research,
18 beyond the formulaic, large clinical trial protocols,
19 while retaining integrity and authority, and adhering to
20 those principles previously mentioned.

21 There is also a particular need for sponsorship
22 from independent funding sources that will encourage

1 innovative and imaginative but rigorous research.

2 I was speaking to a colleague a couple of days
3 ago. He is from Vienna. Just as an example of what I am
4 talking about, there are a lot of interesting groups in
5 Europe who are doing all sorts of experimental science
6 and trials of different methodologies. This one group
7 was testing out a diagnostic treatment device, rather
8 like a vega device for testing of allergies.

9 You plug this machine in, and you put in
10 various substances to which people might be allergic, and
11 then apply part of this diagnostic technique to the
12 patients. Then one of them said, hey, what happens if
13 you unplug it? So they unplugged it, and it still
14 worked. Then the next question, of course, was, well,
15 how far away does it have to be and still work, and they
16 found that it could be as far as five feet away and it
17 still worked.

18 Well, what I am saying here is, you do need
19 people to ask these simple but dramatic questions that
20 raise all sorts of other interesting issues.

21 DR. GORDON: Time is up.

22 MS. WOOTTON: Yes. I have left the statistics.

1 I don't know whether you want me to say those very, very
2 quickly.

3 When the journal changed from quarterly to bi-
4 monthly at the beginning of '99, more libraries
5 subscribed. Currently, 60 percent of our subscriptions
6 are medical or biomedical school libraries, and libraries
7 in research institutions. The other 40 percent of
8 individual subscribers are equally divided between
9 clinicians or practitioners, researchers, and others.
10 Thank you.

11 DR. GORDON: Thank you.

12 Phil Fontanarosa.

13 **Presenter: Phil B. Fontanarosa, M.D.**

14 DR. FONTANAROSA: Dr. Gordon, distinguished
15 members of the White House Commission, thank you very
16 much for the opportunity to participate in this meeting
17 and to provide information on the topic of publication of
18 complementary and alternative medicine, CAM, research
19 results and peer-reviewed medical journals.

20 My remarks are intended to address several of
21 the questions you provided by discussing, briefly, three
22 questions relevant to peer-reviewed general medical

1 journals, and from the perspective of my role as
2 executive deputy editor of JAMA.

3 First: Why should medical journals consider
4 publishing research on complementary and alternative
5 medicine?

6 Well, as you all well know, all too well, of
7 course, the use of complementary and alternative medicine
8 and visits to alternative medicine practitioners have
9 increased dramatically, along with marked increases in
10 expenditures for these therapies and increasingly
11 prevalent third party reimbursement for these therapies.

12 At academic medical centers, there has been
13 increased interest among medical students, residents, and
14 faculty members in gaining knowledge about alternative
15 therapies. Now, educational opportunities for CAM have
16 been added to the curriculum in many medical schools.

17 In addition, there have been significant
18 increases in federal funding for national academic
19 centers dedicated to CAM research, along with increased
20 funding from government and from industry to examine CAM
21 therapies.

22 Yet, despite the increasing interest in CAM,

1 high-quality scientific evidence that clearly establishes
2 the safety and efficacy, or a lack thereof, for many of
3 the widely used CAM interventions is lacking.

4 Consequently, physicians have traditionally viewed CAM in
5 general, and most practices contained therein, with
6 skepticism and a degree of mistrust, I would say.

7 Nonetheless, many patients use CAM therapies along with
8 their conventional medical therapies.

9 I believe that physicians should be the health
10 professionals who are aware of and responsible for
11 coordinating all medical care for their patients.

12 Accordingly, physicians require reliable information on
13 CAM to understand the complex interplay of CAM therapies
14 and conventional therapies to be prepared to serve as
15 resources for their patients, and to be comfortable
16 answering their patients' questions about CAM, and most
17 important, to provide evidence-based guidance and advice
18 about various CAM therapies.

19 Ideally, this information should be based on
20 critically evaluated methodologically rigorous and
21 scientifically valid articles published in reputable
22 journals, rather than on anecdotal reports, unfounded

1 opinion, or unproven theories regarding CAM therapies.

2 To be relevant to readers, medical journals
3 must respond to trends in medical science, react to
4 trends among the public regarding medical therapies, and
5 also must serve the needs of their readers. In a 1997
6 survey, physician readers of JAMA ranked alternative
7 medicine as the seventh most important topic of 70 topics
8 we presented them with for the journal to address. The
9 Editorial Board and editorial staff, after much debate
10 and deliberation, ranked alternative medicine in the top
11 three subjects to address for that year.

12 Thus, JAMA and the nine Archives journals
13 published by the AMA, The Archives of Internal Medicine,
14 Archives of Pediatrics and Adolescent Medicine, and so
15 on, planned and developed an initiative to objectively
16 assess various CAM therapies. We published coordinated
17 theme issues, largely devoted to CAM topics, November of
18 1998.

19 Through this initiative, we provided more than
20 80 articles on CAM topics to the peer-reviewed biomedical
21 literature. I was responsible for planning,
22 coordinating, and editing this issue of JAMA that we

1 published on complementary and alternative medicine, and
2 also helped to coordinate efforts with the Archives
3 journals.

4 The second issue: How do peer-reviewed journals
5 evaluate research on complementary and alternative
6 medicine?

7 I believe peer-reviewed journals should be
8 willing to consider papers on virtually any topic
9 relevant to the practice of medicine, medical research,
10 and relevant to their physician readers. Most research
11 papers on CAM should not be rejected out of hand, simply
12 based on the topic, but should receive an unbiased,
13 objective editorial evaluation based on assessment of the
14 following: the scientific importance of the study; the
15 methodologic rigor with which the research is conducted;
16 the novel contribution to the existing literature; and
17 the relevance of the study results for the journal's
18 readers.

19 Evaluation of the scientific qualities should
20 involve the same rigorous and critical appraisal used to
21 assess studies reporting research on conventional
22 therapies and the accepted framework of scientific

1 evidence should and must prevail.

2 Some key aspects in the evaluation of CAM
3 research studies include assessment of whether the paper
4 presents the following: and explicit, focused research
5 question; scientific or biologic plausibility; defined
6 target disease or condition; established and accepted
7 rigorous research methods, appropriate controls, for
8 example; measurable, objectively assessed endpoints, such
9 as by blinded assessment; meaningful patient-centered
10 outcomes; information on adverse effects and safety data;
11 and appropriate discussion of the clinical context,
12 public health importance, and study limitations.

13 The assessment of CAM research studies
14 frequently involves peer review. Peer review of these
15 studies involves selection of appropriate peer reviewers
16 who have expertise in the research methods and subject
17 matter of the study. The goal is to obtain an objective
18 and unbiased evaluation of the research.

19 Reviewers are identified and selected in
20 several ways, but most commonly from a large database of
21 reviewers we have at JAMA. This database includes self-
22 designated areas of expertise of the reviewers, along

1 with editors' ratings of the quality of the review. We
2 also frequently perform literature searches for
3 individuals who have expertise with the research topic
4 under evaluation.

5 These peer reviewers serve as important
6 consultants. They provide the editors with information
7 regarding the context and the contribution of the study,
8 in light of existing research, as well as a critical
9 appraisal of the research methods and statistical
10 analyses.

11 Peer reviewers also provide recommendations
12 about the suitability of the study for publication in the
13 journal, and constructive, objective suggestions to
14 improve the research report.

15 Comments of the peer reviewers are considered
16 very carefully in editorial decision-making about all
17 research papers, including CAM research. Physician
18 reviewers are now available for most topics evaluated in
19 CAM research.

20 In general, decisions to publish CAM studies in
21 a general medical journal, like JAMA, for instance,
22 involve assessment of the quality of the research, the

1 clinical applicability and importance of the research,
2 and the generalizability of the research findings.

3 An important consideration is the assessment of
4 the merits of the study compared with the information
5 provided in the many other papers submitted for
6 consideration for publication. As you might expect, in
7 large-circulation, general medical journals, competition
8 for space is extremely keen, particularly keen, with a
9 large number of submitted papers that span the entire
10 gamut of medical research, clinical care, and medical and
11 surgical specialties.

12 In 2000, the overall acceptance rate for all
13 manuscripts submitted to JAMA was about 10 percent, and
14 for unsolicited manuscripts, the acceptance rate was
15 about 8 percent. With this competition for space,
16 reports of large-scale, high-quality, multi-center,
17 randomized trials, our highest level of evidence, on
18 clinically important topics, are more likely to receive
19 priority for publication than are single-center studies
20 reporting intermediate or preliminary results about
21 specialized CAM therapies.

22 In fact, during the past year, of the several

1 studies that we published in JAMA on CAM therapies, most
2 have been randomized trials.

3 The third question I would like to address, the
4 final, is: What are some of the policy issues regarding
5 publication of CAM research in peer-reviewed journals?

6 In general, I would support Dr. Campion's
7 policy recommendations, and in addition, would offer
8 several others regarding publication of CAM research in
9 peer-reviewed journals.

10 Carefully conducted, high-quality, credible
11 research by established biomedical investigators is
12 necessary to evaluate the efficacy and safety of
13 complementary and alternative medicine therapies.
14 However, until convincing evidence is available that
15 demonstrates safety, efficacy, and effectiveness of these
16 interventions, the uncritical acceptance and widespread
17 application must stop.

18 With the recent increases in research funding,
19 the establishment of national centers for CAM research,
20 future publication of high-quality studies on CAM
21 therapies should help to establish the evidence base that
22 supports or refutes the safety and efficacy of these many

1 therapies.

2 Complementary and alternative medicine
3 therapies that are shown to cause, or that are
4 demonstrated to have no beneficial effect should be
5 abandoned. Decisions regarding the use of and
6 reimbursement for CAM therapies should be based on
7 published evidence and proper cost effectiveness
8 analyses, rather than tradition, anecdotal reports,
9 testimonials, consumer interest, market demand,
10 competition, or political pressures.

11 Answering fundamental questions about CAM
12 therapies requires critical and objective assessment,
13 using accepted standards for scientific investigation and
14 rigorous evaluation of scientific evidence. Peer-
15 reviewed medical journals provide one important mechanism
16 for such rigorous evaluation of CAM research, and for
17 providing physicians with reliable information about
18 these diverse and complex therapies.

19 Dr. Gordon, members of the Commission, thank
20 you very much for the opportunity to present these
21 perspectives on publication of CAM research in peer-
22 reviewed medical journals. I hope this information is

1 useful in your deliberations on complementary and
2 alternative medicine research policy. Thank you very
3 much.

4 DR. GORDON: Thank you very much.
5 David Riley.

6 **Presenter: David Riley, M.D.**

7 DR. RILEY: First, I would like to thank the
8 Commission, Dr. Gordon and the other members of the
9 Commission, for inviting me here.

10 My name is David Riley. I am a physician,
11 board-certified in internal medicine and the editor-in-
12 chief of the Journal Alternative Therapies in Health and
13 Medicine. We began publication in 1995, and were indexed
14 in 1996, and are in the National Library of Medicine.

15 We view ourselves as a forum for the
16 development of scientific information about the use of
17 alternative therapies and their role in preventing and
18 treating disease, healing illness, and promoting health.
19 We don't endorse any particular methodology, but we
20 promote the rigorous evaluation of all therapies.

21 We publish a variety of disciplined inquiry
22 methods, focusing on high-quality scientific research,

1 including randomized, controlled trials, outcome studies,
2 and case reports.

3 So you might ask the question, why do we need a
4 journal focusing on CAM, and also, is a journal focusing
5 on CAM able to be scientific. I think a recent letter to
6 "Science" illustrates many of these questions. It was
7 entitled, "Where Is The Next Einstein?"

8 It was submitted with a score of signatures
9 from respected academics, including Nobel laureate, Sir
10 Harry Kroto, who is a chemist in England at Sussex, and
11 Dudley Herschbach, a chemist at Harvard, stating that,
12 "All too often the academic research environment favors
13 objectives selected by consensus. Pioneers and consensus
14 can be very poor bedfellows. The vogue for expensive,
15 collaborative projects leave little space or money for
16 alternative thinkers. Thinkers whose research may appear
17 initially irrelevant, but who may come up with stunning
18 work."

19 I might also add that this letter was rejected
20 to the editors of "Science". We feel that our journal
21 tries to address this need, and provide a home for some
22 promising and innovative research.

1 Our journal is by paid subscription only, and
2 the readership consists, primarily, of conventionally
3 licensed health care providers, 60 percent physicians;
4 the balance made up of nurses, other licensed health care
5 providers, naturopaths. It is interesting that the
6 readership is primarily conventional physicians.

7 I have some statistics here that I want to go
8 over, briefly, and then I will talk a little bit about
9 the complexity of reviewing articles in a peer-reviewed
10 scientific journal devoted to CAM.

11 Eighty-seven percent of the original research
12 articles are rejected, 79 percent of brief reports are
13 rejected, 73 percent of hypothesis articles, which is a
14 new section, are rejected -- those statistics could
15 change -- and 64 percent of review articles are rejected.

16 We have taken an approach that we need a
17 variety of area in the journal to address different types
18 of research. So we have an Original Article section,
19 which is devoted, primarily, to randomized, controlled
20 trials, although I would say, frankly, that we generally
21 will not get large, randomized, multi-center trials
22 submitted to the journal. We have, on occasion, and we

1 have one in this issue. More commonly, we will get
2 smaller studies.

3 We also have brief reports. We also have
4 review articles, sometimes solicited. We also have some
5 other sections, too, that I think are critical. We have
6 case reports, which are beginning to lay the groundwork
7 for future research that might be done, and I think it is
8 important to have these areas there.

9 We also have introduced a new section that will
10 start in July on research letters, because, frankly, one
11 of our roles is to educate people who are doing research,
12 and to work with authors so that they can begin to learn
13 how to communicate, because if we are going to
14 communicate with the medical establishment, one of the
15 principles is that you have to communicate in their
16 language, and their language is primarily the peer-
17 reviewed biomedical publication.

18 So a medical journal that is going to focus on
19 complementary and alternative medicine, by definition, is
20 not designed just for the specialists in a given field.
21 They have their own forums for communication amongst
22 themselves. Our goal is to try to communicate the

1 results in complementary and alternative medicine with
2 the biomedical establishment.

3 I want to talk a little bit about the
4 difficulty of reviewing articles in complementary and
5 alternative medicine, because they can be considerable.
6 If you look at a conventional medical journal,
7 particularly a specialty journal, there may be a lot of
8 collegiality; everybody knows everybody. The research
9 areas are fairly well defined. The unknowns are known.
10 Frequently, the question becomes one of statistics and
11 methods.

12 Certainly, in our field, statistics and methods
13 are important. All articles that are submitted go
14 through a methodological review. One of our associate
15 editors is a methodologist, and we have several
16 statisticians and methodologists on our editorial board
17 that we turn to regularly, probably too regularly. That
18 is just the way it is.

19 We talked a lot about acupuncture research here
20 today. Let me take that as an example. If someone
21 submits an article on acupuncture, you need to know, is
22 the author coming from a five-elements school; do they do

1 traditional Chinese medicine; is this a medical
2 acupuncture community; are they doing Korean hand
3 acupuncture. You name it, there are a of different areas
4 that you need to know.

5 So not only do you need to find experts in
6 methodology in the given area, but you also have to find
7 an expert in that given therapy. So you have to pay
8 particular attention. We have run into issues where, all
9 of a sudden, we realized these two groups that are
10 actually subgroups of a therapy, may not agree with other
11 people about how these things are practiced.

12 So it can be quite challenging. Most articles
13 that come in, the original research articles, go through
14 at least revisions, which means there is a review at the
15 end of each revision, because they can be quite complex.
16 There may be as many as four or five, and I have had even
17 six reviewers on some articles. Consequently, one of the
18 problems with that is it can delay publication
19 significantly, because each review process, you kind of
20 start anew each time.

21 So publishing a biomedical journal that is
22 peer-reviewed and indexed, and focusing on complementary

1 medicine is quite challenging, but I also think it is
2 quite necessary, because we need to begin to lay the
3 groundwork for how to communicate with the biomedical
4 establishment. I also think we need to have a way to
5 begin to publish other kinds of studies.

6 The conventional medical establishment is much
7 more mature than the complementary and alternative
8 medicine community. The biomedical model is known. It
9 is taken for granted. It is taught in all medical
10 schools. In complementary and alternative medicine,
11 there are multiple models present.

12 Just as the randomized, controlled trial is the
13 current best tool we have for investigating a particular
14 type of decision, it is implemented against a background
15 of information, knowledge, and understanding that may not
16 be quite as widespread in complementary and alternative
17 medicine.

18 I would use the analogy, it is similar to
19 looking at a mural on a wall of building, if you would
20 imagine, with a telescope. You might get very finely
21 developed information about a very small part of that
22 mural, but you won't understand the mural.

1 Many of the randomized, controlled trials that
2 are being done, it is difficult to evaluate the results,
3 positive or negative, because you may not actually be
4 looking at an effective evaluation of that treatment.

5 And so, I think this is a really challenging
6 time and opportunity to begin to develop an evidence
7 profile for complementary and alternative medicine, and
8 to begin to stimulate the next generation of research.
9 Thank you.

10 DR. GORDON: Thank you, David.

11 Christine Laine.

12 **Presenter: Christine Laine, M.D.**

13 DR. LAINE: I am Christine Laine and I am the
14 Senior Deputy Editor of Annals of Internal Medicine. I
15 thank the Commission for the opportunity to present
16 Annals' perspective at this meeting.

17 A little bit of background about Annals.

18 Annals is a peer-reviewed biomedical journal that has
19 been published by the American College of Physicians
20 since 1927. Our circulation is over 100,000, making us
21 the third largest U.S. general medical journal, and the
22 largest medical subspecialty journal, since our focus is

1 on internal medicine.

2 Our readers are largely internists, but not
3 all. Some may practice integrative medicine or prescribe
4 CAM therapies themselves, but almost all of them who are
5 clinicians probably take care of patients who seek CAM
6 therapies as well as conventional medical therapies.

7 Our journal has a high impact factor. We
8 publish original research reviews, editorials,
9 perspectives, and guidelines. Aware of the prevalent and
10 increasing use of CAM by people who also seek care from
11 internists, Annals believes strongly that high-quality
12 research and discourse concerning the effectiveness and
13 the safety of commonly used CAM therapies is of great
14 relevance to our readership.

15 While the number of papers relating to CAM
16 submitted to Annals is increasing, the number remains
17 quite small. In preparation for this conference, I
18 looked over the information on submitted manuscripts from
19 January 1999 through April of 2001. Of the, roughly,
20 6,000 papers submitted to our journal for consideration
21 during that period, only 35 papers related to CAM
22 therapies.

1 Consequently, we have been developing a series
2 of papers on CAM in close collaboration with two guest
3 editors who are expert in the area. This series will
4 include somewhere between 15 and 20 papers, and will
5 include a combination of original health services
6 research, critical reviews of the literature, and
7 commentary on a variety of CAM-related issues.

8 The papers submitted for this series will be
9 subject to Annals usual review process. Unfortunately,
10 the series will not include original research on specific
11 CAM therapies. We do anticipate the publication of the
12 series will send out a signal that Annals is interested
13 in the topic and may stimulate investigators in the area
14 to send their original research reports to Annals.

15 When CAM papers are submitted to Annals, they
16 are subject to our usual rigorous review process.
17 Unfortunately, many of the papers concerning CAM have
18 important methodological weaknesses, which doesn't make
19 them all that different than many of the papers that
20 concern conventional therapies.

21 We try to get reviewers that have expertise in
22 alternative medicine, as well as reviewers that have

1 expertise in the particular clinical condition under
2 study. We have an electronic database of about 10,000
3 reviewers, but fewer than 100 of the people in that
4 database admit to having expertise in CAM. So it is a
5 challenge to get reviewers with this expertise.

6 Let me tell you a little bit about what
7 happened to the 35 papers on CAM submitted to Annals
8 between January '99 and April of 2001. Two were
9 ultimately published as full articles; one is the letter
10 to the editor; 31 were rejected; and one is in my
11 briefcase to be discussed at our Manuscript Conference
12 tomorrow.

13 This represents an 8 percent acceptance rate,
14 which is not all that different from Annals' general
15 acceptance rate, which hovers somewhere between 10 and 14
16 percent, depending on the year. The acceptance rate for
17 the papers that have been invited to the series is
18 somewhat higher. We have a special commitment to working
19 with authors through many more rounds of revisions of
20 those papers. Seventeen have been submitted; nine are
21 accepted; three have been reinvited after substantial
22 revision; three are currently under review; and two have

1 been rejected.

2 Over recent decades, journals, like the larger
3 medical community, have become increasingly aware of the
4 importance of evidence-based medicine, the growth of
5 large, clinical trials, advances in statistical and
6 analytic approaches, consensus guidelines such as the
7 consolidated standards of reporting trials, and consortia
8 such as the Cochrane Collaboration, are among the many
9 factors contributing to the greater general awareness of
10 the importance of methodological rigor in studies of
11 health care interventions.

12 In previous times, the medical community gave
13 more weight to anecdotal evidence from case reports, case
14 series, and uncontrolled trials. In current times, these
15 forms of investigation are considered hypothesis-
16 generating at best.

17 Unfortunately, much of the CAM-related
18 literature relies on methods that lack the rigor
19 conventional medical journals expect. This may be in
20 part, and as we have heard today, because CAM
21 practitioners generally do not have the training and
22 education in the experimental process that has become

1 part of the conventional medical education.

2 Many of the studies of CAM that authors submit
3 to our journal for consideration have important
4 weaknesses such being underpowered, uncontrolled,
5 conducted in non-representative populations, or having
6 inadequate adjustment for potential confounders.

7 The manuscript that is in my briefcase is one
8 of these. It is an RCT of a common CAM therapy for a
9 common medical condition. It is funded by the NIH, HRSA,
10 and industry. My prognosis is that it is unlikely to
11 make it into publication in Annals, despite having all
12 the trappings that elevate it. It has federal funding
13 and it is a randomized, controlled trial.

14 Part of the problems are that they used a
15 preparation that differs substantially from the ones that
16 are in common use in the community. They studied an
17 atypical study population that doesn't, probably,
18 represent the larger community that uses this therapy;
19 there is a lack of objective outcome measures; and they
20 have marginal statistical power.

21 Now, the study is reported as negative, but
22 when you look at it closely, it is not truly negative; it

1 is inconclusive. I think journals take the wrap for
2 being unwilling to publish negative trials. We have been
3 very aware at Annals, and have one of our statistical
4 editors who has a particular interest in proving that
5 there is no relationship between two things.

6 So we very carefully look at negative studies.
7 Most of them are inconclusive, not negative. Our feeling
8 is, to do a study that is unlikely to give you a
9 conclusive result is, at best, a waste of resources, and,
10 at worst, unethical.

11 Our suggestions are that we move beyond
12 anecdote and observation to higher levels of evidence;
13 that there is a particular focus on safety; another focus
14 on the interactions between CAM therapies and
15 conventional therapies; and that the CAM therapies be
16 subjected to study with the rigor that the public has
17 come to expect for conventional therapies, realizing that
18 innovative study design and methodologies may be
19 necessary, but that rigor can still exist. Thank you.

20 DR. GORDON: Thank you very much.

21 Arnold Relman.

22 **Presenter: Arnold Relman, M.D.**

1 DR. RELMAN: Dr. Gordon and members of the
2 Commission, I cannot speak for the current policies of
3 the New England Journal of Medicine because I retired
4 from the post of editor-in-chief nearly 10 years ago,
5 after serving in that capacity for 14 years.

6 However, I was familiar with NEJM's policies
7 under its next two editors until the present editor
8 assumed his post, a little less than a year ago. Given
9 those limitations, I can state confidently that from July
10 1977, when I first became editor, until July 2000, when
11 the current editor took over, the New England Journal
12 treated manuscripts dealing with CAM in exactly the same
13 manner it treated those concerned with more conventional
14 therapies, and that is the way it should be.

15 You have just heard Dr. Campion talk about the
16 philosophy of the current editorial leadership, and it
17 appears to be unchanged. You also heard a very forceful
18 and very articulate statements Drs. Fontanarosa and
19 Laine, speaking for JAMA and Annals, supporting that
20 idea.

21 Now, I emphasize this because one commonly
22 hears, particularly if you are an editor and you go

1 around to meetings and so on, you commonly hear the
2 complaint that your journal, the New England Journal, or
3 some other leading peer-reviewed journal, is biased
4 against manuscripts dealing with CAM.

5 Now, all rejected authors tend to have a
6 certain amount of paranoia about their manuscripts and
7 the reasons that they were rejected. That is part of
8 life. If you are an experienced editor, as I was for
9 decades, you expect this kind of paranoia and you know
10 how to deal with it, and that is by being absolutely sure
11 you and your staff apply the same standards to all would-
12 be authors and all submissions, including those from your
13 mother, your brother, or from eminent and powerful people
14 in your field who may affect your future in medicine.

15 If you don't do that, if you apply different
16 standards, you are in deep trouble. The first advice I
17 have always given to new, young editors who used to come
18 to me and ask me what philosophy do I want to impart to
19 them, is, one, always tell the truth because you can't
20 remember if you lie, and you will be caught sooner or
21 later. Always tell the truth, and always apply the same
22 standards for the same reason. You can't live with

1 yourself, and your journal can't survive without that.

2 So I want to lay to rest the idea that CAM
3 manuscripts, just because they are about alternative
4 medicine modalities, are treated somehow differently. As
5 far as I know, with the best peer-reviewed journals, and
6 you have heard a few representatives, they are treated
7 the same.

8 Now, I don't know how many CAM manuscripts we
9 at the New England Journal received during those 23 years
10 that I know something about. We kept no special file,
11 but there was certainly only a handful of such
12 submissions, and you hear now that there are still only a
13 small number. In any case, they were handled just like
14 all the other submissions and judged purely on their
15 scientific merits and their suitability for our kind of
16 journal and our readership.

17 Now, that means that, yes, each editor and each
18 editorial staff has to decide what its readership will be
19 interested in and what will be useful and will determine
20 the tone and the quality of that particular journal.

21 But given the mounting interest and the growing
22 discussions about its credibility, an editor would be

1 very ill advised to do anything but give CAM submissions
2 at least as much consideration as the others. I have to
3 tell you that, and I freely admitted my bias, I was
4 looking for good CAM manuscripts to publish. We got very
5 few, and very few of them met our publishing standards,
6 but I tried very hard to find the best that I could find.
7 The fact that the journal only published a few, primarily
8 reflects the paucity of really good submissions.

9 Now, I do not have any statistical data on the
10 relative success rates of CAM papers versus other papers,
11 but you heard some data from Annals. I just don't know
12 whether it is true of the New England Journal or not, but
13 certainly it was not any conscious editorial policy.

14 In any case, I think the issue is a fairly
15 straightforward one. I don't think you need to be a
16 rocket scientist to come to these conclusions. If CAM
17 research is to have any credibility, it will have to be
18 submitted to the same range of peer-reviewed journals as
19 the more conventional manuscripts dealing with similar
20 illnesses, and it will have to pass the same kind of peer
21 review. There cannot and there should not be two
22 standards of science. You have heard that before, nor

1 should there be two standards of peer review.

2 Unless CAM clinical investigators want to stay
3 outside the mainstream, they must play by the same
4 scientific rules of evidence and publish in the same
5 journals.

6 So my advice to you is the following:

7 (1) Emphasize to your constituents and your
8 stakeholders -- that seems to be a popular word. I don't
9 know what that means, but you know what it means -- your
10 stakeholders, emphasize to them that the time has passed
11 to make arguments based on unsubstantiated claims and
12 undocumented anecdotes; finished, enough of that, enough
13 of the books that claim miraculous cures with no
14 documentation, enough of all the statements in public
15 meetings about marvelous results from a particular case
16 without documentation.

17 I do not say that anecdotes are useless, and I
18 do not say that anecdotes are not used in ordinary,
19 conventional medical literature; they have been and they
20 should be, but the anecdotes must be documented. They
21 must be documented.

22 (2) Encourage the submission of CAM manuscripts

1 to the most rigorously peer-reviewed journals over a wide
2 spectrum, not just to CAM journals but to all journals.
3 Journals, after all, are not ultimate arbiters of
4 ultimate truth, neither the New England Journal, nor
5 JAMA, nor any other journal of which I am aware, was
6 given by God insight into what ultimate truth is and has
7 the power and has the credibility to say that what we
8 publish is, for sure, true, and what we reject is, for
9 sure, wrong. Not so.

10 Journals do the best they can, as Ed Campion
11 said, they do the best they can. They try to sift out
12 bad evidence from better evidence, and they try to
13 publish the best evidence on the most interesting and the
14 most relevant and important questions for their
15 readership. That opens the door for lots of journals,
16 but they have to be rigorous. They have to deal with
17 evidence, quantitative, where possible, objective
18 evidence and documented data.

19 Finally, my advice to you is to remember that
20 quality, not number of publications, is the important
21 thing. You don't understand the quality until you read
22 the whole paper, including the fine print, and the

1 methods, and the statistics, and the analysis, and the
2 discussion. You don't just read the summary, and you
3 don't read somebody else's opinion about what the journal
4 said.

5 There is no substitute for evidence, and there
6 is no substitute for saying, well, what, actually, did
7 they do; how did they do it; and, what their data are.
8 When you do that, you often come to different conclusions
9 than those that are generally bandied about.

10 For example, and I close with this, you heard
11 earlier this morning, that a meta-analysis of homeopathic
12 medicine -- published, I think it was in Lancet. I read
13 the paper, but I don't remember, was it Lancet, or maybe
14 BMJ -- a meta-analysis showed, beyond any doubt, that
15 homeopathy was effective.

16 Now, I can't quite remember what was in the
17 abstract, but I know very well what was in the paper, and
18 if you read that paper, it is very clear the data show,
19 and the authors of the paper recognize that the data
20 show, that the best studies, the most rigorous studies,
21 as judged by the analysts, were inconclusive, and the
22 ones that were statistically significant were, by and

1 large, much less rigorous. A slightly different
2 conclusion from what you heard a little while ago. Look
3 at the evidence, look at the data, and be guided by the
4 evidence. Thank you very much.

5 **Panel Discussion**

6 DR. GORDON: Thank you. Thank you, Dr. Relman.

7 Thank you all. It is a pleasure to see all of
8 you working so collaboratively with us in addressing
9 these questions. I feel there has been so much progress
10 made in terms of the dialogue with this field and the
11 major journals.

12 There was only one thing I was disturbed about,
13 Dr. Relman. Forty years ago, when I entered Harvard
14 Medical School, I could have sworn they told me God
15 dictated the contents of the New England Journal every
16 week.

17 [Laughter.]

18 DR. RELMAN: Well, you remember, Dr. Gordon,
19 and I was reminded of this just recently in a trip to
20 Jordan, that Moses was denied entrance to the Promised
21 Land, and the New England Journal has not yet gotten
22 there.

1 [Laughter.]

2 DR. GORDON: Thank you for that clarification.

3 I had one brief question. As I was listening
4 to a general consensus about the kinds of research that
5 might be published, it occurred to me that one of the
6 places where there might be more attention to CAM or
7 integrative approaches, particularly in the mainstream
8 journals, because I know it is there in the CAM or
9 integrative medicine journals, is in some of the columns
10 that are opinion columns, or the summaries of the
11 literature, or summaries of the clinical experience.

12 I wonder if you might respond to that, because
13 there has not been very much that I have read in the
14 mainstream journals.

15 DR. RELMAN: Is that addressed to me?

16 DR. GORDON: Well, you, Dr. Campion, Dr. Laine,
17 Dr. Fontanarosa.

18 DR. RELMAN: Well, most of the general medical
19 journals publish a variety of material. I think, as Dr.
20 Fontanarosa said, we publish not only original such
21 articles, but also reviews of the field, and commentary,
22 and editorial opinion, and so on. Yes, of course.

1 I remind you, The New England Journal published
2 the first study by David Eisenberg on the prevalence of
3 alternative medicine use, a very influential study. We
4 didn't consider it as an original research article in the
5 usual sense. I think it was a special article. That is
6 a category we have for thing that have documentation but
7 don't involve the classical kind of research.

8 DR. GORDON: No, I know that. I wasn't asking
9 in an accusatory way. I was wondering if that might not
10 be a way to open up publication to some of these other
11 issues and deal with them in a thoughtful, critical way.

12 Phil.

13 DR. FONTANAROSA: I would just like to comment
14 on two of the categories of articles you mentioned, one,
15 reviews, and one, commentaries or opinion pieces. We
16 require a very systematic approach for reviewing
17 articles, to look at the totality of the evidence.

18 For example, the executive summary of the NCP
19 Cholesterol Guidelines that are published in today's
20 issue of JAMA is the result of a summary and a review of
21 more than 800 references in a 200-page document vetted by
22 27 experts over about two years. I think if someone

1 looked at the evidence behind the CAM therapy with that
2 type of rigor, I think a journal would make a mistake not
3 to give it very serious consideration.

4 On the other extreme, our opinion pieces, or
5 commentaries, I gave you some data for our acceptance
6 rates overall for JAMA. I will tell you that the
7 acceptance rates for commentaries are even lower than
8 that.

9 We get a lot of papers that come in to
10 stimulate ideas or thought, or to provoke attention.
11 Many of those tend to be, quite frankly, not well
12 supported by references, but floating ideas, and we
13 really have to make a determination if we want to spend
14 space on those that would eliminate space from a research
15 paper.

16 So I would say that the two extremes are
17 rigorous totality of the evidence for reviews,
18 absolutely. Commentaries or opinion/thought pieces have
19 their place, but they tend to fair less well.

20 DR. CAMPION: I would just add that opinion
21 pieces are certainly an appropriate forum for discussion
22 of the issues.