Past NIH Staffer Clay: Who Is NCCAM Deputy Killen and Why Is He Demeaning Homeopathy in Newsweek?

Contributed by John Weeks
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Former NIH Staffer Beth Clay: Who Is NCCAM Deputy Killen and Why Is He Demeaning Homeopathy in Newsweek?

Summary: Shortly after former NIH staff member Beth Clay read the Integrator open letter regarding NCCAM leadership with no experience in complementary and integrative medicine, Clay was startled by a statement in a Newsweek article. NCCAM's acting deputy director Jack Killen, MD, described the science behind homeopathy in terms that Clay believes run "contrary to the actual evidence." Clay looked into Killen's background and found that his leadership of an AIDs research project in Africa was the subject of a very critical NIH report. NCCAM's acting #2 also had no background in complementary and integrative medicine. Clay's guest article, part investigative journalism, part commentary, raises additional questions about the fitness of NCCAM's staff to provide the optimal leadership for exploring the field. I sent the article to NCCAM for comment prior to publication; the NCCAM response is printed below Clay's article.

Send your comments to johnweeks@theintegratorblog.com

for inclusion in a future Your Comments Forum.

Advance Note

The material in this reader response article raises questions about an acting deputy director at NIH National Center for Complementary and Alternative Medicine. I publish this not to attack NCCAM. Rather, I do so because I believe that the fields of complementary, alternative and integrative medicine need experienced staff at NCCAM, especially at this moment as a new director, who herself has little experience in these fields, takes the helm.

My open letter to the incoming director of the NIH National Center for Complementary and Alternative Medicine (NCCAM) stimulated a quick response from Beth Clay, now nearly a month ago. Clay is a prior staff member for Wayne Jonas, MD. She served when Jonas was the director of NCCAM's predecessor entity, the NIH Office of Alternative Medicine. I met Clay in 1996 when I had the honor of being contracted by NIH and the then Agency for Health Care Policy and Research to write a white paper on coverage issues involved in CAM.

Clay's letter is a strong, referenced challenge to NCCAM's Deputy Director Jack Killen, MD. Before publishing this, I asked Clay to check her facts. I then sent Clay's letter, below, to NCCAM for any comments. The NCCAM are attached below. I then asked Clay for her response to the NCCAM letter. These, too, are attached below.

Clay has long been involved in CAM issues. Her government experience included a period with Jonas at the NIH and 5 years as the senior professional staff on the Congressional investigation of CAM with Dan Burton (R-IN), then chair of the House Oversight Committee who also co-chaired the Congressional "CAM Caucus" at that time. Clay is presently involved in two professional pursuits. She

provides technical expertise as "an integral health policy" and government relations consultant via her consulting firm, BC&A International.
She also works closely with long-time integrative medicine leader Len Wisneski, MD, as executive director of the newly formed Wisneski Institute. She can be reached at beth@bethclay.com.

Who Is NCCAM Deputy Jack Killen, MD

and Why Is He Demeaning Homeopathy in Newsweek?

- Beth Clay

"'There is, to my knowledge, no condition for which homeopathy has been proven to be an effective treatment.'

"This quote is not from someone from the ‘anti-CAM’ community, but is a quote in Newsweek magazine’s February 4, 2008, issue from none other than the Acting Deputy Director of the National Center for Complementary and Alternative Medicine (NCCAM) at the NIH. Dr. Jack Killen, goes on in the article to say that homeopathy 'goes beyond current understanding of chemistry and physics.'

"(Killen's) comment peaked my curiosity about Dr. Killen’s history."

- Beth Clay

"Of course, Killen’s statement
runs totally contrary to the actual evidence, as assembled and evaluated, for
instance, in an analysis published in the British Medical Journal. What is an acting deputy director of an agency, charged with developing
evidence on CAM, doing making a statement which so disregards the evidence?

"The
comment peaked my curiosity about Dr. Killen’s history. As it turns out, Dr. Killen is a long time
NIH staffer who came to NCCAM from the National Institute of Allergy and
Infectious Diseases (NIAID) after having served in numerous positions including
as the Deputy Director (1987 to 1993) and then Director of the Division of AIDS
Research (DAIDS) from 1994 to 2001. To connect the dots, Dr. Killen was
Director of DAIDS and thus responsible for the management of the Uganda HIV
study begun in 1997 known as the HIVNET012. An independent site visit of
the study conducted shortly after Dr. Killen's departure raised major concerns
about the project. It found an 'absence of investigator oversight,' and an 'absence of documented internal procedures.'
In a 2003 press release, the Medicines Control Council (MCC) of South Africa suspended
their approval of nevaprine as a single agent in reducing the risk of HIV
transmission from mother to child because the findings from the HIVNET012 study 'as a primary source of information for approval of this indication, no longer meets regulatory requirements.' The MCC included in this press statement
conclusions about the study provided to them by the NIH. 'Patients records could not support the
published results; there was problems with the manner in which the study was
conducted; records could not account for how the drug was stored handled and
distributed; records indicating which treatments were allocated to trial
participants were missing; the obtaining of voluntary informed consent for the
trial participants could not be confirmed in all cases.'

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- Clay

"Serious concerns were also made about the management of the study which would appear to be relevant to Dr. Killen given that the study was overseen by DAIDS while he was at the helm. The independent review concluded: 'Many adverse events and perhaps a significant number of serious adverse events, for both mother and infant, may not have been collected and reported in a timely manner to the FDA, under the IND.' Further: '… a remarkable lack of understanding of Good Clinical Practices, as applied to a Phase III, IND trial was apparent.'

"The whistle blower in this project was Dr. Jonathan Fishbein, a scientist brought into DAIDS to insure patient protection in clinical trials. He reported that the study was 'so poorly conducted that its data must be rendered invalid as a matter of law, policy, and human health.' Dr. Fishbein was initially fired for whistle blowing and eventually reinstated after a lengthy legal battle. (www.honestdoctor.org). While the controversy of Dr. Fishbein's firing was not on his watch, the serious concerns about the management of HIVNET012 which Dr. Fishbein and the independent auditors reported were.

"In an interesting coincidence – given Killen’s present position - one of the reports calling DAIDS 'a troubled organization' was from none other than Dr. Ruth Kirschstein, who until Dr. Brigg’s appointment was Acting Director of NCCAM. Kirschstein wrote the report from her prior position as Special Assistant to the NIH Director. Oddly, Kirschstein appointed Killen to be her deputy, with the wide ranging responsibilities which he holds today. Dr. Killen is Acting Deputy Director of NCCAM and Acting Director of the Extramural Research and Training Division of NCCAM. He is also the Director of the Office of International Health Research at NCCAM.

"What, then, is Dr. Killen doing with all of this power at NCCAM? He hasn’t a background in CAM and his track-record as an administrator especially as it relates to research in general and international research in particular is troublesome.

"Dr. Killen's quote about homeopathy raises serious concerns about the understanding of a very popular CAM therapy by senior NCCAM staff. It also raises questions about the management of the media message and the priority setting for research at NCCAM. In looking at how much emphasis has been placed by NCCAM on funding research to evaluate homeopathy, a quick CRISP database search finds

reference to only two researchers (Iris Bell and Wayne Jonas) who have been funded directly from NCCAM to conduct research on homeopathic remedies between 2000 and today.

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- Clay

"This
year, NCCAM’s total accrued budget will pass the billion dollar mark. The US taxpayer has provided these funds with the intention of having the safety and effectiveness of therapies such as homeopathy evaluated. Obviously, too little investment has been placed on this typically safe, inexpensive and globally popular therapy. I believe it is time for a review of NCCAM's utilization of that billion dollars to determine whether or not the Congressional intent (which reflects the will of the People) is being
met.

"From my
days at the NIH, when the Congress ordered the NIH to begin 'investigating and validating' complementary and alternative therapies, I have heard from literally thousands of individuals who were concerned that the bureaucracy of NIH would not be fair in their investigation of CAM. After NCCAM was

formed these people were very concerned when so many staff positions were filled with long-time NIH staff that had no background in CAM rather than the highly qualified individuals within the CAM community (some of whom were already with the agency). These concerns were compounded when Dr. (Stephen) Straus, the first NCCAM Director was quoted in the New York Times as having never used an alternative therapy and have resurfaced with the appointment of a second Director whose career has not been focused on CAM. There is a frustration among the community that a fair number of very qualified individuals who are experts in the conduct and management of research, the practices of whole systems and who understand the culture of CAM itself were ignored by the agency for the appointment of another insider or 'friend' of the NIH hierarchy.

"These concerns are compounded by what has happened to the National Advisory Council on Complementary and Alternative Medicine. Many within the community are increasingly concerned at the marginalization of non-MD CAM professionals and consumers. At present the advisory board is way out of compliance on both the Congressional instruction on membership as well as the long-time NIH practice of having 1/3 of the members to be 'public' i.e. non scientists from the patient community (at present there are no patient or public members).

"The community as a whole

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Dr. Killen's quote in Newsweek

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of NCCAM on homeopathy."

- Clay

"I attended the recent NCCAM advisory meeting in which Dr. Briggs was introduced. Dr. Briggs came across as a caring individual and announced there that she will spend her first six months as Director actively ‘listening.’ In this listening process, I hope that she will make herself available to listen to the broader community including the patient population. It is more important than ever for the

community - academic, practitioner, patient, and industry - to actively engage in a dialogue with Dr. Briggs about the current and future state of NCCAM and all government activities relevant to CAM.

"Meantime, the community as a whole deserves to know whether Dr. Killen's quote in Newsweek represents the official position of NCCAM on homeopathy. If not, then the community deserves an official statement rejecting Killen’s comments to be sent to Newsweek and issued to the press. I suggest there should be a public forum in the near future to develop a research agenda for homeopathy with adequate funds set aside in next year’s budget to see the agenda through.

Beth Clay

Beth Clay & Associates

Response from NCCAM

I sent Clay's letter, as printed above, to NCCAM for response.

"Dear Mr. Weeks,

"Thank you for inviting our comment.

"Regarding the material on HIVNET 012, the information you have is substantially incomplete. For example, considerable information is contained in an Institute of Medicine report which concluded the scientific findings were sound. (Please see here.) The document is available free online near the bottom of the page. The

Institute of

"The information [Clay

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- Alyssa Cotler,

NCCAM

Medicine "serves as adviser to the nation to improve health. Established under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public." We hope this is helpful in understanding the full context of this information.

"Dr. Killen’s statement regarding the current research available on homeopathy is consistent with the information that NCCAM has available to the public on [homeopathy on] our Web site.

"The new NCCAM director very much welcomes input from the public on future directions for NCCAM’s research on complementary and alternative medicine, and can be e-mailed to nccamdirector-r@mail.nih.gov."

"Thank you,"

Alyssa Cotler

Office of Communications and Public Liaison

National
Center for Complementary

and Alternative Medicine, NIH

http://nccam.nih.gov/

Beth Clay Responds

"I
appreciate Ms. Cotler's response and her praise of the Institute of
Medicine(IOM). However, she has changed the focus of the discussion
from a negative statement in the mainstream media by the Acting Deputy Director
of NCCAM and attempted to place the focus on the validity of
Nevaprine, (which I did not bring up).

"There is no disputing the
fact that the NIH admitted to the gross mismanagement of an international
clinical trial of women and children in Africa (note the quote from the MCC)
by DAIDs on Dr. Killen's watch. Dr. Killen has spent close
to 3 decades at NIH and now has significant responsibility at NCCAM, including
overseeing the international research portfolio and the extramural research
program, both of which involve the management of human trials. Are there
any human subject controversies on the horizon for NCCAM?

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- Beth Clay

"As to the IOM, this is not the forum for that discussion. As I was not discussing the effectiveness of nevaprine, the IOM review is irrelevant, however; I would point out that Kris Kolesnik of the National Whistleblower Center wrote to the IOM to complain about this particular review and noted, 'glaring irregularities' in the way the investigation was to be carried out; 'conflicts of interest among the appointed committee members' (at least five were recipients of NIH funding), a 'lack of objectivity, lack of expertise, and the insufficient scope of the investigation.' (For the commentary, click here.)

"Most disturbing in Ms. Cotler's response is an apparent endorsement of Dr. Killen's quote in Newsweek, which ought to give pause to every member of the CAM community, patient and professional. If after a decade and a billion dollars, the NCCAM has not yet invested adequate resources into researching homeopathy in any condition, then it is time to initiate a dialogue on where all the money is being going and whether it is the best use of taxpayer resources. I would suggest that a public discussion be a part of this planning process. At a time when total health spending in 2006 was projected to be $2.1 trillion and it is expected to reach $4.1 trillion by 2016, NCCAM has a public health responsibility to aggressively investigate the opportunity that homeopathy offers to the American public, to fund quality research in specific conditions on an escalated scale conducted by experts in homeopathy in order to provide the American public with solutions that are safe, affordable, and available."

Beth Clay

Comment: Clay raises many questions to anyone who believes that the complementary, alternative and integrative medicine fields deserve experienced, wizened leadership. Why did Killen end up at NCCAM? Was it for his international experience? But then why did former acting director Ruth Kirschstein, MD, whose own report to NIH raised serious questions about Killen's work, hire him? Why has he since been given a much more expansive portfolio - elevated to #2 at NCCAM? Where does he have the experience to support that role?

Clay's column, and the NIH response, don't answer these questions.
An examination of Killen's background shows that he was clearly done what some have declared exceptional work in his career. He has received multiple honors. Yet I can't escape a sense that in NIH's placement of Killen, NCCAM was used as either a dumping ground or a recovery room: Do well here and we'll take you back. The placement does not seem to be based on what is good for NCCAM, but what someone determined was good for Killen, or for another NIH agenda.

For me, as for Clay, the NCCAM response was also weak. While I am neither an authority on homeopathy, nor much of a user, I understand that the debate over the literature on homeopathy is just that: a debate. NCCAM's website reflects the tension; Killen's comments to Newsweek, as published, do not. I hoped that NCCAM's public relations would put some context around Killen's comment, perhaps share discomfort that the reporter had taken one comment out of a larger discussion in which the nuances of the debate, and on NCCAM's website, were noted. The NCCAM defense of Killen does not suggest openness to exploration of what those infinitesimal doses appear to have accomplished in the supportive literature.

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