The Politics of Alternative Medicine at the National Institutes of Health

By Eric W. Boyle

On February 26, 2009, Democratic Senator Thomas R. Harkin (Iowa) addressed the controversial 10-year history of the National Center for Complementary and Alternative Medicine (NCCAM) at a Senate meeting titled “Integrative Care: A Pathway to a Healthier Nation.” Harkin began by noting that as it had become fashionable recently to quote Abraham Lincoln, he would quote from Lincoln’s 1862 address to Congress—words that he argued should inspire health care reform legislation. One month before signing the Emancipation Proclamation, Lincoln wrote, “The dogmas of the quiet past are inadequate to the stormy present. The occasion is piled high with difficulty . . . As our case is new, so we must think anew, and act anew. We must disenthrall ourselves, and then we shall save our country.” \(^1\) After quoting Lincoln, Harkin continued: “Clearly, the time has come to ‘think anew’ and to ‘disenthrall ourselves’ from the dogmas and biases that have made our current health care system—which is based overwhelmingly on conventional medicine—so wasteful and dysfunctional.” \(^2\) He argued that it was time to end the discrimination against alternative health care practices; time for America’s health care system to emphasize coordination and continuity of care, patient-centeredness, and prevention. For Harkin, adopting an integrative approach meant taking advantage of the very best scientifically based medicines and therapies, whether conventional or alternative.

Yet, when turning his discussion to NCCAM’s past, Harkin expressed his disappointment with the work that the Center had conducted over the previous 10 years. He noted, “One of the purposes of this center was to investigate and validate alternative approaches. And quite frankly, I must say publicly that it has fallen short.” Harkin lamented that instead, “in this center and previously the office before it, most of its focus has been on disproving things rather than seeking out and approving.” \(^3\)

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\(^2\) Ibid.
\(^3\) Ibid.
Harkin’s words almost immediately became fodder for the critics of NCCAM in the blogosphere. One blogger explained:

Harkin is mad because the folks at NCCAM just don’t understand what being the beneficiary of an earmark is all about. If some helpful Democratic Senator from Iowa gets you and all your pals employed at a nice shiny center to study the impact of moonbeams and warm kum-bah-yahs on heart disease, then by God, you’d better find some beneficial effects on . . . heart disease, capiche? Because if you don’t validate your purpose—if you don’t show your loyalty to your patron by validating the money he brought home to you—why, you’re just throwing it all away.4

Meanwhile, at the Science-Based Medicine blog, David Gorski offered this take: “Tom Harkin does not want NCCAM to work by the scientific method. Not really. He has claimed that he does, but his statements above make it very clear that he only likes the scientific method when its results are what he wants them to be.”5

The comments of Harkin and his most vocal critics belie an important fact about the history of complementary and alternative medicine (CAM) at the National Institutes of Health (NIH): not only have the terms of the discussion about CAM shifted—from unconventional medical practices, to alternative medicine, to complementary and alternative medicine, and now integrative medicine—but the mandate from Congress has also shifted over time. The original mandate, outlined by Harkin, did call for the “validation” of the most promising unconventional medical treatments, but NCCAM’s revised mandate in 1998 included no such provision. NCCAM’s three-part mission, based on the revised mandate, represents a continuation of the original: 1) to explore complementary and alternative healing practices in the context of rigorous science; 2) to train complementary and alternative medicine researchers; and 3) to disseminate authoritative information to the public and professionals.6 This mission nevertheless obscures lessons learned from the history of CAM at the NIH, as well as important shifts in the terms of its mandate and associated efforts. Many of NCCAM’s harshest critics fail to acknowledge these changes and therefore remain rooted in the same kind of anachronistic perspectives that left Harkin open to criticism following the Senate meeting in 2009, as outlined above.

An Associated Press article from 2009 exemplifies the difficulty involved in meeting political demands for biomedical research. The article reported with some alarm that although $2.5 billion had been spent on CAM research at the NIH, no alternative cures had been found.7 According to the author, big government-funded studies had only shown that most CAM therapies worked no better than placebos. This evaluation grossly oversimplifies the research conducted at the NIH and epitomizes the political critique of NCCAM that has come from a number of circles throughout its history. A number of recent books, meanwhile, have offered similar critiques of

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7 Marilyn Marchione, “$2.5 billion spent, no alternative cures found: Big, government-funded studies show most work no better than placebos,” MSNBC (Sept. 11, 2009): http://www.msnbc.msn.com/id/31190909.
CAM, and its study at the NIH. Almost across the board, these critiques fail to address the mandate of NCCAM and the offices before it, along with the limitations associated with conducting research on controversial, under-researched topics within the confines of a federally funded scientific agency. While no miracle alternative cures have been found, NCCAM has nevertheless funded more than 2,500 research projects at scientific institutions across the United States and around the world, with many positive results.

The history of CAM at the NIH, and the terms used in ongoing debates, therefore offer insight into the historical and ongoing relationships between politics, science, and medicine. This paper argues that this history offers particularly important lessons about the complex relationship between political expectations and medical research realities. While government involvement created an unprecedented opportunity for the field of CAM, by mandating research that may have otherwise not been conducted, the political pressure to produce particular results also conflicted with the scientific mission of the NIH. Subsequent demands for accountability from Congress and other interest groups created particularly unique challenges for NIH leadership. Additionally, the nature of the government mandate made the NIH vulnerable to critics and skeptics who argued the research was politically motivated, and therefore unnecessary or flawed. Skeptics have seen NCCAM’s research investment as giving undue credibility to unfeasible CAM modalities and have called for less research funding. Meanwhile, advocates note that there have already been many positive study results with a wide range of therapies from acupuncture and dietary supplements to tai chi and yoga, and would like to see even more research dollars supporting various CAM approaches. Throughout its history, NCCAM has responded to political pressure on both sides by avowing its commitment to rigorous scientific investigation and championing its mandate. While fulfilling its commitment to conscientiously and diplomatically listening to conflicting beliefs and opinions on the direction, importance, and value of the work that NCCAM funds, the Center has maintained its position that science must remain neutral.

Origin Stories

Two very different origin stories have been told about the Office of Alternative Medicine (OAM), the forerunner of NCCAM, which Congress established in 1991 under the original name of the Office for the Study of Unconventional Medical Practices. Each origin story reflects political priorities and inherent biases. By one account, the OAM was not formed because of any medical or scientific need but because Senator Tom Harkin believed in implausible health claims as a result of his own experience with alternative medicine and the experiences of close friends. By another account, Senator Harkin pushed for the creation of the OAM to meet a medical and scientific need that no other organization adequately addressed—the question of whether alternative medicines were effective and safe. With this origin story, emphasis is placed on evidence for the broad interest in alternative medicine, as most

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clearly provided by the first national survey of alternative medicine use in the United States in 1993, which expressed surprise in reporting the “enormous presence” of healing alternatives in American society.\(^\text{11}\) The report found that a full one-third of American adults—some 63 million people—used at least one alternative therapy in 1990, the year before the OAM was created.\(^\text{12}\)

The true origin story for the OAM, of course, is much more complicated than either of these explanations. Harkin certainly acted as the key player behind the creation of the OAM, and may have made decisions based on questionable evidence when he used his position as Appropriations Committee chair to direct $2 million in NIH discretionary funds to start up the Office in 1992.\(^\text{13}\) Harkin subsequently reported that he had been urged to take this legislative step because of the widespread interest in alternative medicine among Americans, but two of his constituents were particularly influential, Berkeley Bedell and Frank Wiewel.\(^\text{14}\) Bedell, a longtime friend of Harkin and a former member of the House of Representatives, believed that alternative medicine had twice cured him of diseases after mainstream medicine had failed. He claimed colostrum, derived from cow’s milk, had cured his Lyme disease, and 714-X, derived from camphor, had prevented recurrence of prostate cancer after surgery.\(^\text{15}\) Wiewel had been a longtime supporter of the controversial alternative treatment for cancer known as immunomodulatory therapy. After the Food and Drug Administration barred the import of this mixture of blood sera, Wiewel started up an agency called People Against Cancer, a referral service for alternative cancer treatments that he ran out of his home in Otho, Iowa.\(^\text{16}\) Bedell and Wiewel subsequently also became members of the advisory panel for the OAM. Even if Harkin may have been most heavily influenced by the likes of Bedell and Wiewel, as his critics suggest, it is also nevertheless clear that he believed he was responding to an important public need, one reflected in the increased use of alternative medicines but also in the public demand for information regarding safety and effectiveness. Evidence for public interest in alternative medicine was, without question, widespread by the early 1990s.\(^\text{17}\)


\(^\text{12}\) Ibid., 250. Harvard Medical School researcher David Eisenberg and his associates also found that “the estimated number of visits made in 1990 to providers of unconventional therapy was greater than the number of total visits to primary care doctors nationwide, and the amount spent out of pocket on unconventional therapy was comparable to the amount spent out of pocket by Americans for all hospitalizations.”


\(^\text{14}\) In “The Development of the Office of Alternative Medicine,” Young suggests that Bedell and Wiewel were the only two constituents that pushed Harkin to establish the Office. Young also asserts that Harkin was “susceptible to an interest in alternative medicine” because he had lost two sisters to cancer (280).


The mandate establishing the Office for the Study of Unconventional Medical Practices (OSUMP) in 1992 was designed to meet the demand for authoritative information by opening up a new unit within the Office of the NIH Director, for the purpose of investigating, evaluating, and validating effective unconventional treatments.\textsuperscript{18}

The mandate also charged OSUMP with two additional tasks: 1) setting up a research training program to teach individuals to perform research on alternative medicine and to teach researchers about what key areas of inquiry merited priority status; and 2) establishing a public clearinghouse to facilitate exchange of information with the public. This would essentially put the authoritative NIH name on published information concerning many of the controversial and often under-researched areas in the field of alternative medicine.

Given the controversial and untested status of many different types of alternative medicine, the mandate to investigate and validate raised a number of concerns. In response to the creation of the Office, one Maryland constituent, worried about the potential for a laissez-faire attitude in the study and acceptance of alternative medical methods, fired off letters to consumer advocate Ralph Nader, Senator Harkin, and NIH Director Harold Varmus, with copies of all letters included for each recipient. In addition to recounting her disastrous personal experiences with two alternative health care providers that resulted in debilitating central nervous system damage, the letter writer warned that the public was being “taken for a ride by alternative medicine proponents,” while an “old boy network of Yale Medical School graduates” was poised to peddle their pet ideas to the new Office, in order to reap the benefits of research monies and legitimize their alternative approaches through NIH affiliation.\textsuperscript{19} The letters were passed on to new OAM Director Joseph Jacobs. He addressed the letter writer’s concern by insisting that the primary mission of the Office was to give fair evaluation of alternative medical practices by supporting research and clinical trials to investigate their effectiveness. “The position of the Office is as advocate for the fair evaluation of alternative medical treatments not as advocate for the alternative treatments themselves,” Jacobs insisted.\textsuperscript{20} Reiterating the apolitical stance of the Office and its commitment to objectivity, he ended his letter by reassuring, “We are as anxious as you are to obtain definitive results which will confirm or refute claims of efficacy and safety.”\textsuperscript{21}

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\caption{A CAM chart shows popular spending on self-care versus practitioners in 2007.}
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\textsuperscript{18} “OAM’s Legislative History,” Office of Alternative Medicine Series (OAMS), Office of NIH History Archives, National Institutes of Health, Box 4, Folder 7.
\textsuperscript{19} Letter from Sarah Marshall Tall to Harold Varmus, July 21, 1994; Tall to Ralph Nader, July 21, 1994; Tall to Tom Harkin, July 21, 1994; in file COMM-2-16, #135804, Official Files, Office of the Director, National Institutes of Health (ODNIH).
\textsuperscript{20} Letter from Joseph J. Jacobs to Sarah Marshall Tall, Sept. 16, 1994, in file COMM-2-16, #135804, ODNIH.
\textsuperscript{21} Ibid.
Early Political Debates at OSUMP and OAM

Carrying out this work proved to be quite challenging given the expectations implicit in the Office’s mandate. Initially, the Senate Appropriations Committee had declared in 1991 that it was not satisfied that the “conventional medical community as symbolized at the NIH” had “fully explored the potential that exists in unconventional medical practices.”22 In order to “more adequately explore these unconventional medical practices,” the Committee requested that the NIH establish an advisory panel to “to fully investigate and validate these practices . . . to screen and select the procedures for investigation and to recommend a research program to fully test the most promising unconventional medical practices.”23 With limited support from leaders at the NIH, and an initial annual budget of $2 million, the Office for the Study of Unconventional Medical Practices (OSUMP) became the first government-sponsored organization devoted to this type of study. Given the historical conflict between the forces of conventional biomedicine and the diverse ranks of unconventional medicine, the creation of the Office represented a major step toward realizing the “New Age of Alternative Medicine” that had been proclaimed on the cover of *Time* magazine that year.24

At the same time, the very name of the new office reflected the lingering stigma associated with what the media most commonly referred to as “alternative medicine.” Congress had mandated the study of “unconventional medical practices,” not “alternative medicine,” an act of differentiation based largely on a precedent-setting report by the Office of Technology Assessment (OTA), titled *Unconventional Cancer Treatments*, published in 1990. The OTA study had been initiated after it received letters signed by 42 individual members of Congress asking for an assessment of the controversial immunoaugmentative cancer therapy, also known as IAT. In 1986, an IAT clinic in the Bahamas had been closed following reports that AIDS and hepatitis viruses had been detected in the serum that Dr. Lawrence Burton had injected into patients.25

The OTA report began with the admission that an “objective, informed examination of unconventional treatments” was difficult, if not impossible.26 The introductory section, titled “The Terminology of Unconventional Cancer Treatments,” noted that “unconventional” was “just one of many terms, all imperfect descriptors, that were considered, for the purposes of this report, to refer to the wide variety of treatments that fall outside the bounds of mainstream medicine.”27 OTA authors made it clear they intended no implicit message in the use of the word “unconven-

23 Ibid.
25 Eliot Marshall, “OTA peers into cancer therapy fog,” *Science* 35 (Sept. 21, 1990): 67–68. Congressman Guy Molinari of New York, among whose constituents were a number of clinic patients, asked his House and Senate colleagues to cosign letters of request to the OTA concerning IAT. The U.S. House of Representatives Committee on Energy and Commerce (a committee with jurisdiction over a wide range of health issues) also then asked OTA to examine the subject of unconventional cancer treatments.
26 Office of Technology Assessment, *Unconventional Cancer Treatments. OTA-H-405* (Washington, DC: US Government Printing Office, 1990). According to the OTA Summary, which cited Michael Lerner, “The Role of Autonomous Cancer Self-Help Groups as a ‘Third-Force’ in the Development of New Perspectives on Health Promotion, Conventional Cancer Treatments and Complementary Systems of Cancer Therapy and Self-Care,” paper presented at the World Health Organization Conference on Health Promotion and Chronic Illness (Bad Honeff, Germany, June 1987) the acrimonious debate between unconventional and mainstream communities reached “well beyond scientific argument into social, legal, and consumer issues. Sides are closely drawn and the rhetoric is often bitter and confrontational. Little or no constructive dialog has yet taken place” (4). The “war over cancer therapies,” which had been widely publicized in the American media over the preceding decade, was also described as a highly polarized situation in which both sides had often described the opposition as a “malevolent monolith.”
tional,” rather they hoped that debate engendered by the report could center not on that word, but on the “issues themselves.” The issues included: the range of treatments offered, the people who offered them, the number and types of patients who used them, the costs, the reliability of information on the effectiveness and safety of unconventional treatments, and the different standards of evidence used by advocates and critics.

The language of the mandate to study unconventional medical practices at the NIH made no explicit reference to any of these issues raised by the OTA report, but it provided the basis for dialogue between the unconventional and mainstream medical communities. The 20 members of an Ad-Hoc Alternative Medicine Program Advisory Committee met in June 1992 to identify the central issues involved with evaluating unconventional medical practices.28 Committee members represented an eclectic mixture of policymakers, scientists, practitioners, and advocates, including university professors and MDs, popular promoters of alternative medicine, alternative medicine doctors and administrators, a former Congressman, and members of the Department of Health and Human Services Planning and Evaluation Department and the Food and Drug Administration. Such a motley group had likely never been assembled, especially for the purpose of evaluating unconventional medical practices (UMPs).

At initial meetings, and throughout the early history of the Office, stakeholders often used the terms “unconventional” and “alternative” interchangeably. In recounting some of the “tremendously rewarding breakthroughs once thought to be unconventional” over the course of his 36-year career in medicine, and identifying some promising recent developments, Associate Director for Science Policy and Legislation at the NIH, Jay Moskowitz, opened a September public forum convened in Chantilly, Virginia, by situating the task at hand within the broader mission of the NIH. Moskowitz conveyed a measured optimism about the “intriguing” and “promising” evidence that “modern day alternative or unconventional methodologies and practices could be employed in the treatment of disease and disability.” For Moskowitz, the primary problem with evaluating alternatives remained a lack of evidence.29

Nevertheless, over the course of the two-day meeting in Chantilly, committee members expressed the widely held view that the term “unconventional medical practices” itself should be abandoned. Despite the concern that the term “alternative medicine” was also inherently stigmatized, “unconventional medicine” was considered even worse, in the opinion of most. Ad-Hoc Committee member Frank Wiewel suggested that calling it the Office of Unconventional Medical Practices was like calling it the “Office of Weird Medicine.”30 Gar Hildenbrand, Executive Director of the Gerson Institute for alternative cancer treatments agreed with Wiewel—“that we shouldn’t call it the office of ’Un-’ anything”—adding that the OSUMP moniker sounded like something akin to “Monty Python’s Ministry of Funny Walks.”31

When the U.S. Government Printing Office published the results of the meeting in 1995, as the first comprehensive report on the status of alternative medicine in the United States, the optimistic title

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28 “Justification for Establishing the Alternative Medicine Program Advisory Committee,” Sept. 1992, OAMS, Box 18, Folder 1.
30 “National Institutes of Health Ad Hoc Advisory Panel on Unconventional Medical Practices Transcript,” June 17, 1992, OAMS, Box 7, Folder 2.
31 Ibid., 66.
of Alternative Medicine: Expanding Medical Horizons angered a number of alternative medicine skeptics. The publication itself, also known as the Chantilly Report, represented a significant landmark in the history of alternative medicine because it was the first time that the government paid for or published a report that took a sympathetic look at the subject. An article in U.S. News and World Report described the report as “an uncritical catalog of virtually every dubious and unproven treatment method of the past 100 years, from shark cartilage to treat arthritis and cancer to hypnosis as a way to increase breast size.” The report was also panned by some critics in the biomedical community as an extended advertisement for alternative therapies that were yet to be proven either safe or effective.

Following the publication of the Chantilly Report, Robert Schrieffer, the President of the American Physical Society, wrote to NIH Director Varmus to express dismay at what he referred to as a “most remarkable report” demonstrating “an appalling ignorance of basic physics.” He identified several pages from the report that offended “scientific sensibility.” In response, Varmus asserted that “the OAM and the National Institutes of Health as a whole are determined to ensure that scientific methods are rigorously applied to determinations regarding the effects of ‘alternative therapies’ in the improvement of the health of the American people.” Varmus reassured Schrieffer that the NIH welcomed “the assistance of all scientists and of the American Physical Society in defining the scientific approaches needed to study such therapies.”

Political Mandates and the Challenges of OAM Leadership

When the NIH appointed Dr. Joseph Jacobs as the first OAM director, many believed his unique background made him ideally suited for the job. Raised the son of a Mohawk mother and a part-Cherokee father, Jacobs felt he had been born into alternative medicine, having first learned about herbs and Native American healing ceremonies as a young boy. He attended college at Columbia University, then medical school at Yale, followed by further training at Dartmouth. After working as a pediatrician in the Indian Health Service, he returned to the University of Pennsylvania, where he earned an M.B.A. in health administration. He subsequently worked for the Public Health Service and then for the Aetna Life Insurance Company in Hartford as medical director of research and program development. A profile in People magazine suggested Jacobs

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53 Budiansky, “Cures or ‘quackery?’” 50.
54 Ibid.
57 Jacobs’s career was profiled in a number of media outlets. See, for example, Diana McLellan, “Medicine Man,” Washingtonian (May 1993): 46–47, 124–25. For an example of a radio interview, see John McLaughlin “One on One: Guest, Joseph Jacobs, Office of Alternative Medicine,” Reuters (Sept. 3, 1993), transcript available in OAMS, Box 7, Folder 1.
was the ideal “Medicine Man” for the job, while a New York Times interviewer reported he had “a way of disarming the surly and reassuring the dubious.” Jacobs was described as a “born diplomat and trooper” who remained patient even with the most querulous of callers, greeted hostility with calm and sanity, and never forgot that the best defense was a good punch line. Many who knew Jacobs and had seen him in action believed that if anybody could “balance the conflicting pressures of an entrenched and highly skeptical medical establishment on the one hand, and an alternative community sometimes prone to overexuberance and unfounded proclamations on the other,” it was Jacobs, a man whose unique background seemed custom-tailored for the position.

Jay Moskowitz, Associate Director for Science Policy and Legislation at the NIH, who hired Jacobs, understood that he brought a unique combination of experience in ethnomedicine and conventional medicine to the table. “I tried to stay away from individuals who were either totally conventional or totally alternative, and Joe seemed like one person who could bridge the gap.”

Yet, by March 1993, Jacobs, who was quick to address misconceptions and identify what he believed were unrealistic or overly ambitious goals, was already facing pressure to move the work of the Office more quickly. To make matters worse, his labors were being played out against a backdrop of upheaval at the NIH precipitated by the departure of Dr. Bernadine Healy as Director, and a Presidential directive that all federal agencies start slashing budgets and advisory committees, rather than beefing them up. Amidst pressure to decide on how to distribute the Office’s scarce funds, Jacobs was reportedly struggling to ensure that the OAM would not be pushed into any action without some rational basis for it. “I’m turned off by the idea of cures immediately,” he said. “When I hear that word, my defenses go up. Our challenge is to get people in the alternative medicine community away from the panacea notion and to be more realistic about what they’re trying to say.”

At the same time, Jacobs knew that it would not be easy to get advocates of alternative medicine into the sort of fighting trim required to generate solid data, so he expected to spend a great deal of time as a sort of bootcamp instructor, training unorthodox healers on the basics of medical research. For many of those who had been behind the movement to open the Office, including Wiewel, Bedell, and Harkin, this strategy seemed uninspired and overly cautious.

40 Ibid.
41 Ibid.
42 Ibid.
Jacobs and Harkin first tussled at a Senate subcommittee meeting on June 24, 1993, about eight months after he had been appointed as OAM’s first Director. Harkin began the meeting by restating the two main reasons for establishing the OAM, “first, to take a serious look into the potential of alternative medical practice; and second, to break down the bias in medical research against the review of worthy treatments not in the mainstream of conventional medicine.” On these fundamental purposes, Harkin and Jacobs were in agreement. When interviewed by Time in March 1993, Jacobs maintained that many alternative products and practices could be “just as good, cheaper and safer than many of the drugs and treatments we now use, but they’re still unproven.” At a minimum, Jacobs hoped the OAM would provide a service to consumers by scientifically evaluating relatively unexamined but nevertheless popular therapies. At best, he opined, “we may help promote a revolution in thinking among practitioners and researchers. It’s a bold new adventure, sort of like being on the Starship Enterprise. We’re going where no one has gone before.”

The testimony of former Congressman Berkley Bedell most clearly outlined the bureaucratic obstacles to studying alternative medicine. While openly admitting that his background did not qualify him as a scientific expert on health, Bedell asserted that this should be seen as a good thing. He started with no preconceived beliefs on health care that needed to be changed. As a member of the OAM’s ad hoc advisory committee, he was nevertheless knowledgeable about some of the problems it faced in “conducting the ‘investigations and validations’ called for” in its authorizing legislation. As a Washington Times article subsequently reported, Bedell complained that the advisory committee members “have been like pygmies trying to get an elephant to go where it should.” According to Bedell, this was at least partly because the OAM faced direct and indirect opposition from a number of powerful forces in this effort. The pharmaceutical industry and the American Medical Association, for example, had a “monopoly on the treatment of cancer and most degenerative diseases,” while the Food and Drug Administration held “unbelievable powers in regulating and controlling the health treatments of our country.” In summarizing the progress of the OAM in navigating these bureaucratic obstacles, Bedell concluded: “In my opinion, for this office to be successful in carrying out the investigations called for in this legislation, one of the requirements will be a director who is willing to stand up to these powerful forces. I am sorry to tell you that in my opinion, our current director has not yet shown that commitment. I hope this will change. I believe it must.” After answering a series of questions from Senator Harkin, a brief recess was taken.

Following the recess, Jacobs graciously thanked Harkin for the honor to appear before him and his committee as the director of what he considered “the historic Office for Alternative Medicine at the NIH.” Jacobs and his staff had faced the difficult task of responding to detractors and advocates of alternative medicine, each with their respective critiques. Navigating a difficult federal bureaucracy, meanwhile, had tested his personal and professional experiences. Developing a methodology for conducting clinical research on therapies that had never been studied pre-

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45 Ibid.
46 *Alternative Medicine*, 96.
49 Ibid., 112.
sented another series of challenges. “The task is difficult,” Jacobs concluded, “but it is made easier by keeping in mind that what we are doing is the right thing.”

Harkin took issue with what he perceived to be a lack of real progress toward meeting the Office’s mandate. Jacobs explained that because there was no handbook as to how you create an office of alternative medicine at the NIH, much of the early effort of the OAM had been focused on “overcoming misunderstandings about what alternative medicine was.” Nobody knew what the research and staffing needs would be, the methodological problems to be resolved, and the outlines of a clear program that needed to be established before work could begin.

The primary impasse between Jacobs and Harkins hinged on the question of what constituted the “investigation and validation” of alternative medicine, as laid out in the Office’s original mandate. Harkin used the example of his recent personal alternative medicine success story to illustrate this process. Having benefited from taking some 250 bee pollen capsules over six days, Harkin claimed to have been cured of his allergies two months before the June meeting. For Harkin, investigation and validation meant identifying promising therapies, like bee pollen, investigating them by setting up protocols with test groups, and then validating the effective product or procedure. “I want to get this cleared up in my head,” Harkin told Jacobs, “because maybe I am not right?”

Jacobs used the example of bee pollen to illustrate the challenges associated with meeting the mandate to “investigate and validate.” As outlined in his written statement, Jacobs explained the difficulties involved in setting up a protocol to study the effects of bee pollen, given the proponent’s claims that bee-pollen capsules could cure heart disease, reverse the aging process, prevent memory loss, improve one’s sex life, kill bacteria, promote weight loss, and cure allergies. Establishing a protocol required not only the cooperation of the bee-pollen proponent but also an independent researcher who could conduct the studies in a way that produced acceptable results for the rest of the medical community. Harkin eventually conceded that he understood these things did not happen overnight, but warned Jacobs that any footdragging, or any perceived failure to aggressively pursue the Office’s mandate, would not be tolerated.

Jacobs subsequently left the OAM in September 1994, after a tenure of less than two years. In departing, he complained of being pressured to fund pet interests of the “Harkinites,” to speed up studies, and bring dubious products swiftly to the marketplace. In one instance, Jacobs said a Harkin aide told him to issue a $200,000 grant to study bee pollen. The grant was never made, although the OAM did conduct a “field investigation” that yielded “nothing conclusive,” according to an NIH spokesman. Harkin maintained the OAM initiated its investigation “separate and apart from my endorsements.” In an interview after he resigned from the OAM, Jacobs also complained that Harkin had inappropriately held the entire OAM budget hostage until it was agreed to put three of

50 Ibid., 114.
51 Leslie Miller, “Alternatives Meet the Mainstream,” USA Today (July 22, 1993): 6D. Jay Moskowitz explained that few people at the NIH were familiar with the range of treatments considered “alternative” at the time the Office was created, so the office first had to seek experts from the alternative community. This would take time because mainstream medicine and alternative practitioners had “historically engaged in little or no constructive dialogue.”
52 Ibid.
53 Ibid., 140.
54 Budiansky, “Cures or ‘quackery’,” 49.
the Senator’s friends on the Office’s new advisory committee. As he departed to his former home, Jacobs quipped, “I prefer the ticks of Connecticut to the politics of Washington.”

In January 1995, four months after Jacobs resigned, NIH Director Harold Varmus announced the appointment of his successor, Dr. Wayne Jonas. Jonas’s background and experience likewise made him an ideal candidate. Jonas had begun experimenting with alternative remedies while still in medical school at Bowman Gray School of Medicine in Winston-Salem, NC. As he explained in an oral history interview with James Harvey Young, “I was looking for solutions to help patient problems that I didn’t have tools necessarily to help.” After developing an interest in homeopathy while working as an Army officer managing a general hospital in Dexheim, Germany, his special concern as Director of the Medical Research Fellowship Program at Walter Reed Army Institute of Research became research methodology as applied to both conventional and alternative medicine. Along the way, he received additional training in homeopathy, bioenergy therapy, diet and nutritional therapy, mind/body methods, and electro-acupuncture diagnostics. Jonas had also worked closely with the OAM as a consultant on research education and methods dating back to its first formal meeting. Later, he chaired a conference on research methodology in alternative medicine and contributed to that topic in the Chantilly Report.

Jonas moved quickly to reorganize the Office into six functional units in order to more effectively meet its three-pronged congressional mandate. The OAM staff doubled in size, and Congress continued expanding the Office’s budget to reach nearly $12 million for 1997. Dr. Ruth Kirschstein, Jonas’s NIH boss, asserted: “The OAM has a sense of activity and stability for the first time.” Meanwhile, on the political front, Senator Harkin’s legislative director, Peter Reinecke, assured the OAM that Harkin was interested in establishing a “good working relationship with Jonas and seeing that the office operate in a productive way.”

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55 Jack Raso, “The Three Faces of Medical Unreason,” *Nutrition Forum* (Sept./Oct. 1994): 43. In response to accusations that Harkin had stacked the advisory committee with his cronies in Budiansky, “Cures or ‘quackery’,” in *U.S. News & World Report*, Deputy Director Ruth Kirschstein explained in a memo that while the OAM received nominations for members from a wide variety of groups and persons, including Senator Harkin, nominees were chosen by the Office of the Secretary of the Department of Health and Human Services, which then issued invitations for membership. Kirschstein also noted: “It should be stated that, while there clearly has been considerable activity by proponents of alternative medicine, including Congress persons, it is the experience of the NIH staff that this is true in regard to activists in other fields, for example, AIDS, women’s health, and aging.” Ruth Kirschstein, “Note to the Secretary, Re: Background Information Related to Article in *U.S. News and World Report*, July 17, 1995,” Wayne Jonas Series (WJS), Box 26, Folder 17.


57 Wayne Jonas Interview by James Harvey Young, Oct. 8, 1996, Office of NIH History, National Institutes of Health.


59 Units included: the Public Affairs and Clearinghouse Section, the Database and Evaluation Section, the Research Development and Investigation Section, the Extramural Affairs Section, the Intramural Research Training Program, and the International and Professional Liaison Section.


61 “Note for the Record,” Sept. 8, 1995, WJS, Box 26, Folder 17.
have a good relationship with previous directors of the OAM but that from everything he has heard and read about Dr. Jonas he didn’t think this would present a problem in the future.” By February 1996, Jonas reported that the Office had already funded 42 exploratory grants, 10 clinical research centers around the country, and cooperative programs with 10 NIH institutes, centers, and divisions.62

Skeptics nevertheless panned Jonas, due primarily to his sympathetic stance on homeopathy, having co-authored two books on the subject, one targeting consumers and the other appealing to MDs to integrate homeopathic and conventional practice.63 An author in *Scientific American* considered it particularly inappropriate for Jonas to write one of those books in collaboration with a member of his advisory committee, while directing an office making scientific judgments about alternative approaches. Meanwhile, in a critical e-mail sent to the office of the NIH Director, one scientist argued that Jonas’s books on homeopathy demonstrated ignorance of basic quantum mechanics, molecular physics, and chaos theory (“terms that Jonas used with abandon”), as well as the very concept of the scientific method.64

Jonas also came under fire from NIH leadership when he identified purposes or goals for the OAM that either went far beyond the Office’s congressional mandate or did not clearly reflect the official position of the NIH. This was especially true with his critiques of the methodological limitations of investigating alternative medicine within the prevailing NIH research paradigm. An article on the challenges of researching alternative medicine in the journal *Nature Medicine* in 1997, for example, ultimately made its way up the chain of command until Director Harold Varmus got involved. In the article, Jonas argued that the OAM’s role was to “re-examine the goals of medicine and science in light of unorthodox systems and concepts” by pursuing “radical solutions” and no longer holding on with “blind faith to methodological and conceptual dogma within a narrow world view.”65 He was subsequently informed that his article had not been approved due to factual concerns, stating purposes and goals not reflective of the position of the NIH, the implication that the scientific method and current research paradigms at NIH were faulty and needed to be replaced, and the proposition that the freedom to ask new questions necessitated changing the paradigm.66 Unfortunately, Jonas was unable to withdraw the article before it went to press.

**OAM Under Fire**

At the same time that the heat was being turned up on Jonas, in July 1997 *Science* magazine reported that some big guns—including biologist Paul Berg of Stanford and physicist D.
Allan Bromley of Yale—were taking aim at the future of the Office of Alternative Medicine, a place the magazine referred to as the “home of far-out ideas on medical therapy” at the NIH.67 Amidst Senate hearings to discuss renewal of the OAM’s $12.5 million budget, a number of top scientists had sent letters to members of the appropriations committee, recommending that funding be cut or eliminated. Paul Berg, for example, called the OAM “an embarrassment to serious scientists,” adding that “quackery will always prey on the gullible and uninformed, but we certainly should not provide it cover from the NIH.” Maxine Singer, president of the Carnegie Institution in Washington, DC, wrote that the OAM’s work was “not usually congruent with” the rigorous standards of main-line research, and that funding should be cut or eliminated. Biologist Ursula Goodenough of Washington University in St. Louis also wrote: “Nothing coming from OAM indicates that it is conducting or planning any studies that would put any alternative treatments to [a] scientific test.” Former Presidential science adviser D. Allan Bromley, meanwhile, wrote that the OAM had given prestige to “highly dubious practices, some of which clearly violate basic laws of physics and more clearly resemble witchcraft than medicine.”68 He recommended terminating the Office.

Later that year, in October 1997, Republican and former heart surgeon Bill Frist, chair of the Labor and Human Resources subcommittee on Public Health and Safety, called a hearing to explore issues related to the OAM in the NIH reauthorization bill. Committee member Harkin was there to argue for his proposal to remove the OAM from the Office of the NIH Director and turn it into an independent center with the power to form its own peer-review panels and distribute grants. Two scientists testified in favor of Harkin’s proposal.69 Internist and assistant professor of medicine David Eisenberg of Harvard Medical School, a standing member of the OAM’s scientific advisory panel, noted that his latest studies showed an estimated 61 million Americans were using alternative therapies ranging from herbal treatments to hypnosis, spending as much as $14 billion a year.70 James Gordon, a professor of psychiatry and family medicine at Georgetown University School of Medicine, added that as many as 70 percent of cancer patients were reportedly seeking some form of alternative therapy. According to Harkin, those figures were reason enough to focus more research in an area “where the public has been voting with their pocketbooks all along.”71 Harkin’s proposal to elevate the OAM into an NIH Center ultimately fell short during the appropriations process, although the 60 percent increase in funding represented a victory of sorts for the Office and its supporters. The $8 million boost raised OAM’s budget to $20 million for 1998.

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68 Ibid.
70 Ibid. A third member of the panel, immunologist Robert Rich, dean of research at Baylor College of Medicine and representing the Association of American Medical Colleges, warned that creation of a separate center would double administrative costs and might actually hinder research by emphasizing the gap between so-called alternative and conventional therapies. “That dichotomy is wrong,” Rich said. “The dichotomy is between good science and bad science.” Robert Park of the American Physical Society, a longtime critic of OAM, agreed with the critique of Rich, and along with six other scientists, including Nobel laureates Berg and Jerome Friedman of MIT, had written a letter to Frist a week before the hearing expressing support for efforts to investigate alternative medicine “provided that the research is held to rigorous scientific standards, is suitably peer-reviewed, and is fairly administered.” But the letter added, “to elevate OAM to the status of a National Center without first examining its strengths and weaknesses would risk amplifying existing problems” (378).
From OAM to NCCAM

Despite facing the defeat of Harkin’s proposal, along with the departure of Director Wayne Jonas in 1998, the Office of Alternative Medicine was still upgraded to the National Center for Complementary and Alternative Medicine in 1999, expanding its budget from $20 million the previous year to $50 million, and granting the new NCCAM Director Stephen Straus unprecedented decision-making authority, especially concerning financial and administrative management and fiscal and review responsibility for grants and contracts. The authorizing language charged NCCAM to expand on the mandate handed down to the Office of Alternative Medicine in 1992, with a four-point emphasis on conducting and supporting basic and applied research, expanding research training, disseminating health information, and carrying out other programs with respect to identifying, investigating, and validating CAM treatment, diagnostic, and prevention modalities. 72

Dr. Straus, the first director of NCCAM, a highly respected NIH physician-researcher, seemed ideally suited for the task of exploring complementary and alternative medicine in the context of rigorous science. With 23 years of experience at the National Institute of Allergy and Infectious Diseases (NIAID), including 8 years as chief of the Laboratory of Clinical Investigation, Straus had investigated a range of diseases and established a track record that had earned him the respect of NIH institute directors. 73 Straus also quickly reassured critics and skeptics that he wanted to allay fears of NIH-sponsored quackery, writing in 2000 that he was not an advocate of alternative therapies, only an advocate of good science. 74 In taking the NCCAM job, Straus was nevertheless also cognizant of the fact that he was walking a tightrope—he understood that skeptical scientists and powerful supporters of alternative medicine would both be measuring his performance by their own criteria.

By 2001, just two years into his tenure, Straus was interviewed for another piece on the mainstreaming of alternative medicine in *The Lancet*, and there he reported that NCCAM had already quadrupled its staff, developed a strategic plan, added intramural and international research components, and started working with industry to develop product standards. Straus made it a fundamental goal to “transition the field from anecdotes to evidence” by emphasizing the importance of sponsoring large-scale clinical trials, while also concentrating effort on studying the neurological, chemical, and physiological bases for the underlying mechanisms of poorly understood CAM therapies.

Despite these changes, many of the same critiques faced by the fledgling Office of Alternative Medicine have remained among alternative medicine skeptics and medical quackery critics, throughout its history. Medical skeptics have questioned whether the goals established by NCCAM can even be met. They have argued that each new regime in the OAM and NCCAM has made the same promises, and each has said that the research that was done before was incomplete. But as new studies have come out in recent years, the authors of these studies have still frequently concluded that the evidence is too weak to draw definitive conclusions, or that flaws in the design of trials make the results inconclusive, therefore requiring more grants for more research. Additionally, critics argue that as consumers continue to seek out allegedly worthless and dangerous treatments, despite the fact that alternative practitioners have failed to produce definitive evidence that their therapies are safe and effective, alternative medicine advocates can claim that the government sees value in what they are doing.

Medical quackery critic Stephen Barrett of Quackwatch.com adds that “the overall message that the office or center has been sending since before it opened is that there’s really something here that the scientific community is overlooking, and if we study it, then we’re going to find out what it is.” According to Barrett and others, that message is nonsense. Even though some are willing to concede that NCCAM is now funding some “serious research,” the anti-quackery camp remains unconvinced that there is any justification for having a separate NIH center devoted to this work.

In fact, less than half of the money spent on CAM research at the NIH in recent years has been allocated to NCCAM. While Barrett and others might suggest that this is evidence that the study of CAM therapies should be conducted in other NIH institutes and centers where they have to compete among themselves for funding, it is important to remember that the funding of CAM research is only one of the important functions of NCCAM as an organization.

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75 Marilyn Larkin, “Alternative medicine centre aims for mainstream status,” *The Lancet* 358 (Aug. 18, 2001): 566. Intramural refers to research conducted by scientists at the NIH. Earlier research funded by OAM and NCCAM had been extramural, or conducted by researchers at other research institutions.

76 Ibid.


As the Winter 2009 issue of Medline Plus reported, newly appointed NCCAM Director Dr. Josephine Briggs intends to continue the Center’s commitment to investigating and evaluating alternative treatment modalities, supporting research training in the field of complementary and alternative medicine, and providing an information clearinghouse to exchange information with the public and medical professionals—the three responsibilities laid out in the original congressional mandate. 79 In marking its anniversary in 2009, NCCAM also distributed banners celebrating “10 Years of Rigorous Research.” In addition to 236 completed clinical trials and nearly 100 active trials on a wide range of therapies including dietary supplements like Echinacea, glucosamine, and ginkgo biloba, the effects of yoga, meditation, homeopathy, music therapy, osteopathic and chiropractic manipulation, Traditional Chinese medicine, and others, NCCAM has made a commitment to support research in the areas of international health, health care services, and the ethical and legal implications of complementary and alternative medicine. 80 As Director Briggs asserts, the results of the research in this area will be particularly important given that nearly 4 out of 10 American adults depend upon some form of CAM to treat various health conditions or maintain well being. 81

While we will have to wait to evaluate the effects of much of this work in the years to come, the short history of alternative medicine at the NIH indicates that its future success will require an effort to address its critics more directly while also carefully balancing its political mandate with budgetary and scientific realities. Thus far, NCCAM has effectively responded to political pressure by promising to develop reliable and useful evidence from research, while promoting the value of authoritative information on the benefits and risks of CAM. Additionally, Director Briggs has recently affirmed her “renewed appreciation for the value of listening to voices and perspectives” from staunch CAM advocates and skeptics alike. 82

On the occasion of NCCAM’s 10-year anniversary in February 2009, David Eisenberg suggested the future of the Center might very well depend on its ability to demonstrate the value of complementary and alternative medicine to a variety of its stakeholders: scientifically, by elucidating the underlying mechanisms for alternative therapies; clinically, with the potential benefits of integrative care for doctors and patients; economically, in the potential for reduced medical costs for consumers, corporations, and insurers; and socially, in the realm of health promotion and reduced disease burdens. 83 In crafting its third 5-year strategic plan, which is scheduled to be published early in 2011, NCCAM has sought input from all of these stakeholders and more. Throughout these discussions, NCCAM leadership has maintained a commitment to remain strictly objective by adopting the position that science must remain neutral. Whether NCCAM can effectively respond to a disparate group of stakeholders, while meeting its future mandate and effectively balancing political expectations and medical research realities, remains to be seen.