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Studying Complementary and Alternative Therapies

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IN 1992, WITH AN INITIAL BUDGET OF \$2 MILLION, Congress created the Office of Alternative Medicine (OAM). Based on legislation sponsored by Iowa politicians Tom Harkin and Berkeley Bedell, OAM's mission was "to explore complementary and alternative healing practices in the context of rigorous science."¹ Senator Harkin reportedly believed that bee pollen had cured his hay fever, and Representative Bedell reportedly thought that cow colostrum had cured his Lyme disease.² They hoped that OAM would prove that alternative therapies like theirs should be brought into the mainstream. Harkin and Bedell's efforts reflected the popular culture; about 50% of US residents use some form of alternative medicine; 10% use it for their children.³

In 1999, OAM became the National Center for Complementary and Alternative Medicine (NCCAM), a center within the National Institutes of Health (NIH). Funding has steadily increased; by 2012, NCCAM's annual budget had reached \$130 million. Since their inception, OAM and NCCAM have spent \$1.6 billion.⁴ US taxpayers have a right to ask whether money appropriated for NCCAM—like money appropriated for all centers within NIH—has been well spent.

In support of NCCAM's mission, proponents argue that one century's folk medicine can be the next century's mainstream medicine. For example, Hippocrates used leaves from the willow plant to treat headaches and muscle pains. By the early 1800s, scientists had isolated the active ingredient: aspirin. In the 1600s, a Spanish physician found that bark from the cinchona tree treated malaria. Later, cinchona bark was found to contain quinine, an antimalarial drug. In the late 1700s, William Withering used foxglove to treat heart failure. Later, foxglove was found to contain digitalis, a drug that increases heart contractility. More recently, *Artemisia*, an herb used by Chinese healers for more than a thousand years, was found to contain artemisinin, another antimalarial drug. Indeed, most drugs on today's hospital formularies were originally derived from plants.

However, unlike studies of drugs derived from plants, many studies funded by NCCAM lack a sound biological

underpinning, which should be an important requirement for funding. For example, NCCAM officials have spent \$374 000 to find that inhaling lemon and lavender scents does not promote wound healing; \$750 000 to find that prayer does not cure AIDS or hasten recovery from breast-reconstruction surgery; \$390 000 to find that ancient Indian remedies do not control type 2 diabetes; \$700 000 to find that magnets do not treat arthritis, carpal tunnel syndrome, or migraine headaches; and \$406 000 to find that coffee enemas do not cure pancreatic cancer. Additionally, NCCAM has funded studies of acupuncture and therapeutic touch. Using rigorously controlled studies, none of these therapies have been shown to work better than placebo.⁴ Some complementary and alternative practitioners argue reasonably that although their therapies might not work better than placebos, placebos may still work for some conditions.

Although studies funded by NCCAM have failed to prove that complementary or alternative therapies are anything more than placebos, some proponents—pointing to studies of vaccine safety—argue that negative studies of biologically implausible hypotheses are worthwhile. For example, in 1998, Wakefield proposed that the combination measles-mumps-rubella (MMR) vaccine resulted in autism in some children. One year later, several parent advocacy groups became concerned that thimerosal—an ethylmercury-containing preservative in vaccines—also caused autism. Although neither of these claims made biological sense, media coverage in the United Kingdom caused thousands of parents to refuse to allow their children to receive the MMR vaccine; as a consequence, hundreds of children were hospitalized and several died from measles. The public health and academic communities responded by performing epidemiological studies, none of which were funded by the NCCAM, that showed MMR and thimerosal did not cause autism.⁵ These studies and their negative results were valuable; now clinicians had the data to calm parents' fears.

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Does the same value of rigorously conducted negative studies hold for studies of complementary and alternative therapies? Have negative studies changed behavior? The answer is probably best found in NCCAM-funded studies of dietary supplements and megavitamins. Several studies have shown that garlic does not lower low-density lipoprotein cholesterol, St John's wort does not treat depression, ginkgo does not improve memory, chondroitin sulfate and glucosamine do not treat arthritis, saw palmetto does not treat prostatic hypertrophy, milk thistle does not treat hepatitis, and echinacea and megavitamins do not treat colds.⁶ Moreover, some studies have found that megavitamins increase the risk of cancer and heart disease.⁷ Because the vitamin and supplement industry is not regulated by the US Food and Drug Administration (FDA), negative studies have not precipitated FDA warnings or FDA-mandated changes on labeling; as a consequence, few consumers are aware that many supplements have not delivered on their claims. In 2010, the vitamin and supplement industry grossed \$28 billion, up 4.4% from the year before.⁸ "The thing to do with [these studies] is just ride them out," said Joseph Fortunato, chief executive of GNC Corp. "We see no impact on our business."⁸

Although evaluating the research portfolio of any institute at the NIH is difficult, social and political pressures may influence area-of-interest funding, and decisions should be based on science. For complementary and alternative medicine, it seems that some people believe what they want to

believe, arguing that it does not matter what the data show; they know what works for them. Because negative studies do not appear to change behavior and because studies performed without a sound biological basis have little to no chance of success, it would make sense for NCCAM to either refrain from funding studies of therapies that border on mysticism such as distance healing, purgings, and prayer; redefine its mission to include a better understanding of the physiology of the placebo response; or shift its resources to other NIH institutes.

Conflict of Interest Disclosures: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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