UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

VIETNAM VETERANS OF AMERICA, a Non-Profit Corporation; SWORDS TO PLOWSHARES: VETERANS RIGHTS ORGANIZATION, a California Non-Profit Corporation; BRUCE PRICE; FRANKLIN D. ROCHELLE; LARRY MEIROW; ERIC P. MUTH; DAVID C. DUFRANE; WRAY C. FORREST; TIM MICHAEL JOSEPHS; and WILLIAM BLAZINSKI, individually, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

CENTRAL INTELLIGENCE AGENCY; DAVID H. PETRAEUS, Director of the Central Intelligence Agency; UNITED STATES DEPARTMENT OF DEFENSE; LEON PANETTA, Secretary of Defense; UNITED STATES DEPARTMENT OF THE ARMY; JOHN MCHUGH, United States Secretary of the Army; UNITED STATES DEPARTMENT OF VETERANS AFFAIRS; and ERIC K. SHINSEKI, UNITED STATES SECRETARY OF VETERANS AFFAIRS

Defendants.

Case No. CV 09-0037-CW

EXPERT REPORT OF DANIEL E. FORD, M.D., M.P.H.

I. INTRODUCTION

A. Retention

1. I have been retained by Morrison & Foerster LLP on behalf its clients, plaintiffs in this matter, Vietnam Veterans of America, Swords to Plowshares: Veterans Rights Organization, Bruce Price, Franklin D. Rochelle, Larry Meirow, Eric P. Muth, David C. Dufrane, Wray C. Forrest, Tim Michael Josephs, and William Blazinski (collectively "Plaintiffs") to serve as a consultant and expert witness in the above captioned action.

2. I expect to testify at trial regarding the matters discussed in this expert report, and in any supplemental reports or declarations that I may prepare for this matter. I may also testify at trial regarding matters related to my opinions addressed by any expert or fact witness testifying on behalf of Plaintiffs or Defendants Central Intelligence Agency; David H. Petraeus, Director of the Central Intelligence Agency; United States Department of Defense; Leon Panetta, Secretary of Defense; United States Department of the Army; John McHugh, United States Secretary of the Army; United States Department of Veterans Affairs; and Eric K. Shinseki, United States Secretary of Veterans Affairs (collectively "Defendants"), including but not limited to any reports, testimony, exhibits, references, or demonstratives presented by Defendants.

3. I reserve the right to supplement or amend this report if additional facts and information that affect my opinions become available. It is my understanding that Plaintiffs have retained other experts and that Defendants may serve an expert report concerning one or more of the issues I address in this report. I reserve the right to testify concerning such other reports or testimony, and to respond to any such report from Defendants' expert(s) and to rebut at trial any opinions expressed in such a report. I also understand that depositions of additional fact witnesses may take place and that Defendants have just recently produced or will be producing additional documents that are still undergoing review. Furthermore, it is my understanding that Defendants have produced, and continue to produce, a substantial quantity of documents and other information in formats that are inaccessible or exceedingly difficult to access or evaluate properly, and that Plaintiffs' counsel is continuing to attempt to convert such information into a usable format. Should Plaintiffs' counsel's efforts be successful and information from these

sources become available to me I reserve the right to supplement this report to incorporate that information.

4. The headings in this report have been added to create sections for ease of organization. I do not intend these headings to be in any way restrictive of the information contained in the respective sections.

B. Compensation

5. I am being compensated for my work on this matter at my customary rate of $400 per hour, plus expenses. I am being compensated for travel time at a rate of $200 per hour up to a daily maximum of $1200. My compensation is not conditioned on the substance of my opinions, testimony at deposition or trial, or the outcome of this matter.

II. MY BACKGROUND AND QUALIFICATIONS

6. I am currently Vice Dean for Clinical Investigation at the Johns Hopkins University School of Medicine. In addition, I am the Director of the Institute for Clinical and Translational Research at Johns Hopkins. I am a Professor in the Department of Medicine at the Johns Hopkins University School of Medicine and hold joint appointments as a Professor in the Department of Psychiatry and Behavioral Sciences (Johns Hopkins University School of Medicine), Department of Epidemiology (Johns Hopkins University Bloomberg School of Public Health), and Department of Health Policy and Management (Johns Hopkins University Bloomberg School of Public Health). I am part of the active clinical staff at Johns Hopkins Hospital. My expertise encompasses clinical research, clinical study design, clinical medicine, psychiatry research, epidemiology, and public health.

7. I earned my Bachelor of Arts degree in 1978 from Cornell University. I completed medical school at the State University of New York at Buffalo, Buffalo, New York, obtaining my M.D. in 1982. My Master of Public Health degree (1986) is from the Johns Hopkins University Bloomberg School of Public Health. Following medical school, I trained as an Osler Medical Intern (1982-1983) and Osler Medical Resident (1983-1985) at Johns Hopkins Hospital. After completing my residency training, I pursued further training and work in an Epidemiology Training Fellowship in the U.S. Public Health Service from 1985 to 1988. During this time, I

was also a part-time Clinical Fellow in the Department of Medicine at Johns Hopkins Hospital (1985-1988) and a Medical Staff Fellow, Primary Care Section, Clinical Services Research Branch, Division of Biometry and Epidemiology, National Institute of Mental Health in Rockville, Maryland (1985-1988). I have held multiple academic positions at the Johns Hopkins University School of Medicine from 1988 to the present. I am board certified in internal medicine and practice under a medical license from the state of Maryland.

8. A major focus of my work has been to instruct clinicians and other investigators on how to perform clinical and epidemiological research and to promote the development of clinical research projects at The Johns Hopkins University. For example, I have been serving as the Principal Investigator of a $19 million "Institutional Clinical and Translational Science Award" from the National Institutes of Health (2007-2012). This grant supports clinical and translational research[1] throughout Johns Hopkins and includes support for the education and training of new translational investigators, facilities in which clinical research can take place, and infrastructure support for patient recruitment, bioinformatics, biostatistics and translational core centers. As part of my teaching responsibilities, I direct the Intensive Course in Clinical Research Methods at Johns Hopkins. I also lecture in courses at Johns Hopkins on epidemiology and outcomes assessment. I have served as a reviewer for numerous journals, including the *American Journal of Epidemiology*, the *Journal of the American Medical Association*, *Epidemiology*, and *Epidemiological Reviews*.

9. Psychiatry and psychology research has also been a major focus of my work. Although I am not a board-certified psychiatrist, I am an expert on the design and execution of psychiatry and psychology studies. I have served as Principal Investigator for many projects in psychiatry and psychology, including, for example: "Development of Internet Intervention for Depression" (National Institute of Mental Health, 2006-2008), "Evaluation of the Implementation Phase of the Depression in Primary Care Program" (Robert Wood Johnson Foundation, 2003-

[1] "Translational" research is research that helps to bring scientific discoveries into practical use in a clinical setting.

2005), and "Quality Improvement for Depression" (National Institute of Mental Health, 1998-2004). I am currently a Special Sections Editor for the journal, *General Hospital Psychiatry*, and I have served as a reviewer for the *American Journal of Geriatric Psychiatry*, *Journal of Clinical Psychiatry*, and *Archives of General Psychiatry*.

10. I have published more than 150 original research articles in peer-reviewed journals as well as 8 book chapters. I have been invited to present my research work at numerous professional meetings both in the United States and internationally. A current copy of my *curriculum vitae* is attached hereto as Exhibit 1, which includes a complete list of my publications to date.

11. I have not provided any expert testimony in either deposition or trial within the past four years. I have not prepared any expert reports for a litigation matter in the past four years.

III. BASIS AND SCOPE OF MY OPINIONS

12. I have been asked to review and assess various studies examining health outcomes in test subjects who participated in various U.S. military testing programs. Moreover, I have been asked to provide my opinion about the quality and methodology of these studies. I may testify about any or all of these topics.

13. In arriving at my opinions, expressed in detail in this report, I have relied on my personal and professional experience as well as various additional resources. I have relied upon the types of information and resources that are normally relied upon by experts in my field, such as articles in peer reviewed journals, treatises and similar scholarly works, and published reports regarding the testing programs at issue. Among the documents and studies that I have reviewed are several reports from the National Research Council ("NRC") that focus primarily on the testing programs conducted at Edgewood Arsenal.

14. I have also reviewed documents from various other sources which contain contemporaneous reports and accounts of actual tests. These documents were helpful to my understanding of the circumstances surrounding the experiments performed in the various testing programs and example test protocols used.

15. With respect to the doses and pathways of exposure, I have reviewed data drawn from several sources, including a database printout of Edgewood test subjects between 1955 and 1975, excerpted data from the Chem-Bio Database that was provided to me, and a book written by one of the principal researchers at Edgewood Arsenal, Dr. James Ketchum.

16. These are some of the primary references I have reviewed and relied upon in reaching my opinions; a complete list of documents I have consulted and considered is included as Exhibit 2 to this report. Throughout my report I have cited specific documents, and portions of those documents, to illustrate technical and historical points. These citations are only illustrative, not exhaustive, and I may rely on other specific portions of these documents, as well as any of the references listed in Exhibit 2 to support any of these points. Moreover, to the extent Defendants provide an expert report responding to any of the points addressed in this report, I reserve the right to consider, comment on, or rely on any documents referenced in any such report.

17. I reserve the right to provide further exhibits to be used as a summary of, or as support for, my opinions or testimony, including any testimony by experts or other witnesses at trial.

IV. COMMON METHODOLOGICAL PROBLEMS IN STUDIES RELIED UPON BY THE U.S. GOVERNMENT

18. It is my understanding that the U.S. Government is relying on certain studies to deny that long-term health effects have resulted from the participation by military test subjects in U.S. chemical and biological warfare programs. I have reviewed these key studies and have identified important study design flaws, methodological problems, and analytical issues that impact more than one of these studies. Since these problems and issues impact more than one study examined in this report, I present below a brief discussion as a way of introduction to these topics. These issues will be discussed in greater detail within the individual sections of this report.

A. Retrospective Study Design

19. Every study examining long-term health outcomes of veteran test subjects is essentially retrospective in design. This is because the original U.S. government chemical and

biological warfare testing programs were neither designed nor intended to follow the long-term health outcome of test subjects following exposure to chemical and biological weapons (see the discuss in section V.C. below.). Retrospective study designs have the potential to introduce a number of powerful systematic errors, or *biases*, that can reduce the ability of the study to detect clinically important health outcomes. These biases, discussed further below, include selection biases, recall biases, and retrospective biases.

B. Lack of Appropriate Control (Comparison) Groups—The Healthy Soldier and Healthy Test Subject Effect

20. As the discussion below will show, the original investigators conducting the chemical and biological warfare tests failed to include an appropriate control (or comparison) group within their testing program. Later investigators, such as scientific panels assembled by the National Research Council were therefore forced to come up with control groups of their own. This proved to be an extremely challenging task (see, e.g., the discussion in section V.C.4. below). The most obvious solution, making health comparisons between test subjects and the general U.S. population of males, was not a good option because of at least two powerful confounding factors. First, all of the test subjects were U.S. military personnel. Since entry into the U.S. military requires meeting certain physical and psychological health requirements, men in the military tend to be healthier than males in the general U.S. population. Since they are healthier earlier in life, military men also tend to be healthier later in life. This can make any adverse health reactions in military test subjects difficult to detect because their better overall health would tend to "mask" any such adverse health reactions when the comparison is made to the general U.S. population. This is called the "healthy soldier effect."

21. In addition, test subjects were screened for physical and mental health before they were allowed to participate in the chemical and biological warfare tests. The effect of this screening was to produce a military test subject population that was healthier overall compared to the general military population. Like the healthy soldier effect, this "healthy test subject effect" also tended to make it more difficult to detect any long-term adverse health outcomes when the comparisons were being made to the general U.S. population. Furthermore, the healthy test

subject effect also made it more difficult to detect any long-term adverse health outcomes when the comparisons were being made to the general U.S. military population.

C. Poor Documentation of Exposure

22. One of the most important pieces of information required when trying to determine whether an exposure to a test agent caused an adverse health outcome is documentation of the exposure itself. By "exposure" I mean: 1) what substance was administered; 2) how much of the substance was administered; 3) through what route (inhalation, skin application, etc.) was the substance administered; 4) how frequently was the substance administered; and 5) was the substance administered with any other substance in sequence or combination? These are key pieces of information regarding exposure. Unfortunately, the government did not always keep good records regarding exposure, and for some tests where protective equipment was being tested (e.g., mustard gas studies), it is very difficult, if not impossible, to know precisely how much of the test agent was administered to a particular subject. Without adequate exposure information, it is difficult to properly assess health outcomes.

D. Cross-Sectional Rather than Longitudinal Study Design

23. The best way to assess long-term health outcomes is to follow individuals over time. As the individuals go through life, an investigator could assess their health periodically and record the results. This type of study design is called a longitudinal study. In contrast, a cross-sectional study assesses health outcome at just one period in time. While a longitudinal study is analogous to a movie that continuously follows an individual or group, a cross-sectional study is like a single "snapshot" in time. Cross-sectional studies are often performed instead of longitudinal studies because they can be performed as part of a retrospective study (a longitudinal study requires preplanning—a "prospective" study design), generally require less time, labor, and money, and are generally simpler to execute. Unfortunately, cross-sectional studies are not nearly as good as longitudinal studies for detecting trends over time in health outcomes. While longitudinal studies are more likely to produce valid and reliable results, cross-section studies are often performed out of necessity and convenience.

E. Poor Documentation of Outcome

24. In order to compare health outcomes between two different groups, it is important to document outcomes accurately and thoroughly. Ideally, health outcomes would be evaluated repeatedly over time through direct interviews, physical examinations, and appropriate laboratory and/or diagnostic testing. Unfortunately, such investigations tend to be very expensive and labor intensive. As seen in the discussion below, the studies examining health outcomes in former test subjects generally used simpler, less costly methods, such as one-time surveys (see section V.C. below). Even if some studies employed physical examinations to assess health outcome, these were usually cross-sectional studies that looked at health at one point in time. Without good documentation of outcome, it is not possible to make meaningful comparisons between groups.

F. Confusing "No Difference" with Demonstration of Equivalence

25. One of the most statistically challenging tasks in clinical research is performing a study proving that two groups share an equivalent outcome. Such a study is often called an "equivalence study," and equivalence studies tend to be among the largest, most expensive, and best-designed studies in clinical medicine. The reason for this is that proving equivalence requires ruling out other factors that can result in an erroneous finding of equivalence—e.g., small sample size (lack of statistical power), poor documentation of exposure and outcome, the impact of important confounding factors (e.g., the healthy soldier effect and healthy test subject effect), and the lack of a proper comparison or control group. Finding equivalence is not the same thing as finding "no difference" between two groups. Finding equivalence requires an exceptionally well-designed, executed, and statistically powerful study. Finding "no difference" can be accomplished using a poorly designed and executed study. Indeed, a finding of "no difference" is often the ultimate result of poorly conceived studies. Unfortunately, even medical and scientific professionals confuse the difference between a finding of "equivalence" and a finding of "no difference." As the discussion below will show, there are plenty of poor quality studies finding "no difference" in the health outcomes between test subjects and a comparison group. However, in my opinion, no study that I have reviewed or discussed here in this report has ever truly demonstrated "equivalence" in health outcomes between test subjects and a comparison group.

V. METHODOLOGICAL PROBLEMS IN SPECIFIC INDIVIDUAL STUDIES

26. It is my understanding that the U.S. government has tested a very large number of chemical and biological agents as part of their weapons programs.[2] I have had the opportunity to review the major reports concerning the potential long-term health effects from exposure to these agents. One important observation is that these reports together examine a relatively small number of the agents tested by the U.S. government. For the vast majority of chemical and biological agents tested by the U.S. government, there does not appear to have been any effort to examine the long-term health effects resulting from exposure to those agents.

A. National Research Council, Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Volume I, Anticholinesterases and Anticholinergics

27. In response to a request from the Department of the Army, the Committee on Toxicology of the National Research Council evaluated the possibility of long-term or delayed adverse health effects of chemical agents tested on military volunteers during the 1960s and 1970s.[3] The NRC Volume 1 report examined the anticholinergic and anticholinesterase chemicals.[4] Because of important methodological deficiencies in the study, I do not believe that data presented in this study are sufficient to reach any firm conclusions regarding possible long-term health effects of exposure to anticholinesterase and anticholinergic agents. In addition, I believe methodological problems and the limited statistical power of the study design do not allow any firm conclusions to be reached regarding any potential impact of anticholinesterase and anticholinergic test exposure on mortality or morbidity rates.

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[2] Chemical Warfare Agent Experiments Among U.S. Service Members, Dept. of Veterans Affairs, Washington, D.C., updated 2006 at VET001_015677; VBA Outreach Efforts to Veterans Exposed to Chemical and Biological Substances, August 2008, at DVA003 010051-2.

[3] National Research Council, "Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Volume I, Anticholinesterases and Anticholinergics," National Academy Press, Washington, D.C. 1984 (hereinafter, "NRC Volume 1") at x.

[4] It is my understanding that a detailed description of these compounds will be presented in another expert report, and so I will not discuss the properties of these compounds in any great detail here. The panel discusses the properties of these compounds in some detail in Chapters 2 and 3 of NRC Volume 1.

28. The panel that authored the NRC Volume 1 report seemed to acknowledge the limitations of their study, concluding that they were "unable to rule out the possibility that some anti-ChE [anticholinesterase] agents produced long-term adverse health effects in some individuals."[5] Similarly, while the panel claimed—prematurely in my opinion—that "[n]o firm evidence has been seen that any of the anticholinergic test compounds surveyed produced long-range adverse human health effects in the doses used at Edgewood Arsenal," the panel also acknowledged that "[m]ore intensive study is required to confirm this conclusion."[6]

1. Problems in the Design and Execution of the Original Edgewood Testing Program[7]

29. The panel that conducted the NRC Volume 1 study was charged in part to determine whether "the data available are sufficient to estimate the likelihood that the test chemicals have long-term health effects or delayed sequelae."[8] It is my opinion that the data available were not sufficient to estimate the likelihood that the test chemicals have long-term health effects or delayed sequelae. A major reason for this is the poor design and execution of the original chemical warfare studies performed at Edgewood Arsenal. The quality of the data available to the NRC panel was seriously impaired by the relatively poor quality of data collected during the original chemical warfare studies. The original chemical warfare studies were not designed or intended to examine the long-term health effects of exposure to chemical warfare agents, but rather to assess the potential use and effects of these agents as military weapons. Therefore, insufficient data exists from these studies to assess long-term health effects from exposure to the test agents.

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[5] NRC Volume 1 at xi.

[6] *Id.*

[7] The NRC studies discussed in this report focus on testing conducted on service members at Edgewood Arsenal. I understand, however, that Defendants conducted testing at multiple other locations as well, including prior to the 1950s.

[8] NRC Volume 1 at x.

30. The original studies performed by the U.S. military had serious methodological problems that would be unacceptable in clinical research today.[9] Problematic aspects of the original testing program included, but were not limited to, potentially coercive test subject recruitment, failure to properly use placebos, exposure to dangerously high doses of test agents, poor quality and dose control of test agents, crude monitoring methods, and essentially non-existent long-term follow up of test subjects.[10]

31. *Problematic Test Subject Recruitment and Consent*. The NRC panel states that by 1954, "the Chemical Corps (formerly CWS) had established a framework within which to conduct human experimentation, but it lacked an adequate pool of volunteers."[11] Considering that the experimentation involved the use of test agents that could possibly be used for chemical warfare, the lack of volunteers should not have been surprising. Ultimately, military investigators settled on the "most practical source of volunteers," namely "enlisted men stationed at Army installations in the vicinity of Edgewood Arsenal."[12] Military investigators supposedly "emphasized that voluntary consent of each human subject was absolutely essential,"[13] but it is reasonable to believe that enlisted soldiers may have felt some coercive pressure to participate in these chemical warfare tests, even with the offering of certain "incentives" such as a small monetary allowance or a free weekend.[14] In addition, because the U.S. military lacked sufficient

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[9] t is also unclear whether substances were properly accounted for, as illustrated by the sudden appearance and disappearance of thirty to forty pounds of LSD from Dr. Ketchum's office with "no comment from anyone, no receipt form and no other paper work." (James S. Ketchum, *Chemical Warfare Secrets Almost Forgotten*, Chapter 19 (ChemBooks Inc. 2006) at 203; Ketchum Depo. Transcript July 14, 2010 at 187:1–188:24.)

[10] *See* NRC Volume 1 at 1-3.

[11] NRC Volume 1 at 1.

[12] *Id.*

[13] *Id.*

[14] NRC Volume 1 at 2.

knowledge about the chemical agents that they planned to test, it was not possible to obtain true informed consent where "subjects would be thoroughly informed of all procedures and of what might be expected as a result of each test."[15] Importantly, it is not possible that the military investigators knew enough about the chemical warfare agents to properly inform the test subjects about potential long-term health effects from exposure to such agents. As determined in U.S. Senate hearings that took place in 1975, "the consent information was inadequate by current standards."[16]

32. *Failure to Properly Use Placebos.* The original studies at Edgewood Arsenal appear to have been conducted at times in an *ad hoc* or haphazard manner, the sort of clinical study execution that would be unacceptable in modern clinical research. A good example of this is the failure of military investigators to properly use placebos in their studies. Placebo groups (where test subjects are given an inert or inactive substance that resembles the active test agent) can be very important in assessing the effects of test agents because they provide an appropriate comparison group. The original military investigators did not seem to adequately appreciate the importance of placebo groups. As described by the NRC panel, placebos "were used in some studies, but the cost with respect to subject confinement time, staff workload, and delay in achieving estimate of potency made this impractical except in special cases (e.g., evaluation of antagonists)."[17] Use of the word "impractical" here suggests that it was not practically possible to use placebos, which almost certainly was not the case. A better term would be "inconvenient," though inconvenience is not a legitimate reason for failing to use placebos. If an investigator is using high doses of a test agent then there may be less need for placebos. However if one has a reasonable concern for safety in human volunteers, investigators would start with small doses of the test agent where placebos would be necessary to detect true effects. The failure to properly use placebos made it much more difficult to assess the short-term and long-term health effects of

[15] NRC Volume 1 at 1.

[16] NRC Volume 1 at 2.

[17] NRC Volume 1 at 3.

exposure to test agents and is indicative of the poor planning, design, and execution of the original chemical warfare studies performed at Edgewood Arsenal.

33. *Exposure to Dangerously High Doses of Test Agents*. There are indications that some of the doses administered to test subjects at Edgewood Arsenal were high and unsafe. As the NRC panel noted, "Signs of drug effects at all but the lowest doses were significant,"[18] indicating that the doses administered were generally high enough to produce "significant" clinical symptoms and/or signs in the test subjects. The NRC panel also reports that an "incapacitating dose" for BZ, one of the anticholinergic test compounds, was determined by Edgewood Arsenal investigators to be approximately 5.5 µg/kg, and that administered doses sometimes exceeded 1.5 times this "incapacitating dose."[19] Any dose of a chemical agent that can be described as "incapacitating" must be very high, and to exceed that dose, even rarely, suggests that some test subjects were exposed to dangerous doses of agents like BZ. This is confirmed by the NRC panel's report that "one subject who had received BZ displayed hyperthermia, tachycardia, and spastic movements for a few hours, and required vigorous treatment."[20] Another subject who received BZ "developed signs of decerebrate rigidity with limb twitching" that was thought to represent "toxic encephalopathy" or "BZ delirium."[21] Furthermore, many test subjects received "multiple exposures" to test agents over a period of "days or weeks,"[22] increasing the likelihood that some, maybe many, test subjects received dangerous doses of test agents. For example, hyperthermia is now known to be a well-documented and potentially fatal adverse reaction to anticholinergic agents. All of this reinforces my opinion that the studies performed at Edgewood Arsenal were poorly planned, designed, and executed.

[18] *Id.*

[19] *Id.*

[20] NRC Volume 1 at 65.

[21] *Id.*

[22] NRC Volume 1 at 3.

34. *Poor Quality and Dose Control of Test Agents*. While we know from some of the severe acute reactions that some subjects received dangerous doses of the test agents, it is not possible to precisely quantify the doses they received. One reason for this is our uncertainty about the quality and purity of the test agents used. There is no indication that the original investigators had strict quality control protocols to ensure the purity of the test agents. Indeed, the NRC panel notes that subjects were given anticholinesterase agents of "unstated purity." This would not be surprising, since many of the test agents used—e.g., sarin and VX[23]—were never developed or intended to be marketed as commercially available pharmaceuticals. Precise control and documentation of exposure to test agents is an essential feature of a well-designed and executed clinical study. Poor quality and dose control of test agents make it even more difficult to properly determine the potential adverse effects of test agents, since many adverse effects are dose-dependent.

35. *Crude Monitoring Methods*. The original chemical warfare testing program was conducted many decades ago when only crude monitoring methods were available. For example, the original investigators used EEGs (electroencephalograms) as one of their monitoring tools for adverse reactions to test agents.[24] While EEGs continue to be used clinically today, they are relatively crude tools for monitoring adverse changes in brain function. Today, we have far more sensitive and powerful tools for assessing adverse effects on brain function (e.g., functional MRI brain scans). Modern advances are not limited to technologically advanced machines. Since the time of the original testing program, the field of neuropsychology has developed very sensitive clinical testing methods for detecting subtle cognitive impairments that may have been caused by exposure to toxic substances. Because these modern technologies and techniques were not available to the original Edgewood Arsenal investigators, only limited information from crude monitoring techniques was available to NRC panel reviewing the data. As an illustrative example, the NRC panel reported that one subject who had received the anticholinergic agent,

[23] NRC Volume 1 at 37, Table 3.

[24] E.g., NRC Volume 1 at 65.

BZ, had "developed signs of decerebrate rigidity with limb twitching,"[25] clinical signs that suggested possibly significant brain injury. As evidence that the subject suffered no long-term injuries, the NRC panel notes that an "EEG tracing 20 d after exposure was normal."[26] An EEG is hardly definitive evidence of normal brain functioning. It is certainly possible that a functional MRI study or neuropsychological testing could have detected subtle impairments in brain function and cognition that would have been easily missed on EEG. There are also more advanced techniques available today for monitoring other types of injuries as well. Since modern monitoring techniques were not available to the Edgewood Arsenal investigators, it is impossible to rule out the possibility that some test subjects experienced significant brain (or other) injuries that were not detectable by the monitoring techniques available when the original studies were performed.

36. *Lack of Long-Term Follow-up of Test Subjects*. Test subjects were recruited and "assigned for a 1- to 2- month period of temporary duty at Edgewood Arsenal."[27] There was no plan for systematic, long-term follow-up of these test subjects; the experiments were designed to assess the acute effects of these test agents as potential military weapons, not to evaluate the long-term health effects of acute exposure to these agents. As the NRC panel states in its discussion of the testing of anticholinesterase agents at Edgewood Arsenal, the case summaries made available to the panel were "brief and anecdotal" and with "the exception of one case, they deal only with the period immediately after the test dose."[28] The NRC panel concluded that the case summaries "do not provide hard data that would allow the panel to address, in a definitive manner, the question of whether or not there is a possibility of long-term or delayed effect."[29] The panel admitted that the "paucity of data in the medical records prevents further study in relation to the

[25] NRC Volume 1 at 65.

[26] *Id.*

[27] NRC Volume 1 at 2.

[28] NRC Volume 1 at 29.

[29] NRC Volume 1 at 30.

goal" of the panel's report, which was to investigate "the possibility of long-term or delayed effects."[30] I agree with these statements from the panel. The available follow-up data for the anticholinergic agents were similarly limited. For example, the NRC panel states that their "[u]nderstanding of the timecourse of effects [from BZ exposure] was confounded by erratic written documentation, which at best was rather sparse …."[31] In summary, the NRC panel's mission of definitively evaluating the long-term or delayed effects from exposure to anticholinesterase and anticholinergic agents was made extremely difficult, if not practically impossible, by the absence of any long-term follow-up data from the original experiments performed at Edgewood Arsenal.

2. Retrospective Design

37. Turning to the NRC panel's own investigation, the most fundamental weakness of the NRC Volume 1 study is its retrospective design. Unlike a pre-planned prospective study, a retrospective study is designed after most of the key data (e.g., information in medical records) have already been collected. As discussed above, the original studies at Edgewood Arsenal were not designed or intended to assess the long-term health effects of acute exposure to the various test agents used. Therefore, information on long-term health effects was not collected or analyzed by the original investigators at Edgewood Arsenal. The NRC panel had to look backwards at whatever information was available and their analysis was seriously limited by the quantity and quality of the available medical records. A retrospective study design makes the NRC Volume 1 study vulnerable to potential biases, including, but not limited to, selection biases, retrospective biases, and poorly documented exposures, which I discuss further below.

38. *Potential Selection or Sampling Bias—Anticholinesterase Study*. Retrospective studies are particularly vulnerable to selection or sampling bias, a type of error that can be introduced into a study by using a non-random method to select individuals or cases for inclusion in the retrospective analysis. The potential for sampling bias can be seen in the NRC Volume 1

[30] *Id.* (emphasis in original).

[31] NRC Volume 1 at 63.

study. The panel reported that 16 anticholinesterases were tested on 1,406 subjects.[32] For reasons that were not explained, the NRC panel reviewed information from only about 15% (219) of these cases.[33] While some of the cases were selected randomly based on the terminal digit of the case number (i.e., those case numbers ending in 3), others were selected non-randomly "on the basis of high dosage, repetitive exposure, or the presence of additional physiologic stress."[34] Presumably, the non-random selection criteria were chosen to select those cases where the test subjects received the highest exposure to test substances and, perhaps, exhibited the most adverse effects. However, it is also possible that those who received the highest doses were the test subjects initially deemed to be the most healthy and strong, and it may be possible that those test subjects who received repetitive exposures to test agents were also those who were most tolerant of their effects (e.g., one would not expect investigators, as a matter of good practice, to give multiple doses of a test agent if the test subject did not tolerate the first dose very well). In addition, the NRC panel also chose to include all 32 subjects tested with the V-series nerve agent, EA 3148, in their analysis, because EA 3148 was considered the most potent anticholinesterase agent.[35] While EA 3148 may have had the potential to produce the most severe adverse effects, it is also possible that individuals received EA 3148 because they were deemed the healthiest, strongest, or most tolerant test subjects. Because of the limited information available, we cannot know how the non-random selection criteria may have biased the NRC study's final results. In my opinion, there would have been less potential for selection or sampling bias if the NRC panel had selected cases using only random criteria or, even better, had reviewed and analyzed all 1,406 cases. Reviewing all of the cases would have been especially important for detecting rare or uncommon adverse effects.

[32] NRC Volume 1 at 29 and 37, Table 3.

[33] NRC Volume 1 at 29.

[34] *Id.*

[35] *Id.*

39. *Potential Selection or Sampling Bias—Anticholinergic Study*. Another example of potential sampling bias may be seen in the NRC panel's analysis of BZ cases. The NRC panel chose to review and analyze the medical records of only 36 of the at least 354 test subjects who were exposed to BZ.[36] There is no explanation regarding how these 36 cases were selected or why the NRC panel chose not to review all 354 cases. Certainly, any process that eliminates nearly 90% of all cases from the final analysis has the potential to introduce important selection or sampling biases that could impact the final results of the study. These concerns are magnified when the reported quality of the records was poor, as indicated by the NRC panel's description of "fragmentary data" and "erratic written documentation" of the time course of effects.[37]

40. *Potential Retrospective Bias*. When planning and executing a retrospective study, there is always the potential for retrospective bias, where the views, opinions, or biases of the investigators can impact the way information is collected and analyzed, thereby influencing the results of the study. As an example, the lead investigators of a retrospective clinical study may already have a pre-formed opinion on whether a new therapy works, and may—intentionally or not—design and execute the study in a way that favors a positive result for the new therapy. In reviewing the limited information available on the methodology of the NRC Volume 1 study, I cannot determine whether retrospective bias impacted the final results of the study. I can state only that retrospective studies are particularly vulnerable to this type of bias and that this fact should be kept in mind when reviewing and analyzing the results of any retrospective clinical study.

3. Problematic Use of General Population as Control Group—Healthy Soldier and Healthy Test Subject Effect

41. One of the key weaknesses of retrospective studies is that one cannot pre-plan data collection for an appropriate or suitable control group. Appropriate control groups are necessary to compare outcomes of interest with those of the test group. For example, in order to determine

[36] NRC Volume 1 at 63.

[37] *Id.*

whether exposure to anticholinesterase or anticholinergic agents has an effect on long-term mortality rates, the test group exposed to these agents must be compared to another group of non-exposed individuals who are similar with respect to key characteristics that may impact long-term health (e.g., gender, age at the time of testing, baseline health, smoking history). Ideally, the non-exposed control group would be drawn randomly from the same pool of individuals that provided the exposed test subjects. Unfortunately, the original investigators at Edgewood Arsenal abandoned the use of a placebo group, which could have served as an ideal control group, for questionable and inappropriate reasons—"cost with respect to subject confinement time, staff workload, and delay in achieving estimates of potency."[38] In essence, the original Edgewood Arsenal studies had no appropriate control group whatsoever, and the NRC panel was forced to come up with their own control group.

42. The NRC panel ultimately decided to compare mortality data for the test subjects exposed to anticholinesterase and anticholinergic agents to the mortality data for "the U.S. population."[39] It is not entirely clear whether the NRC panel is using both men and women from the U.S. population or just women, since the report describes the control group as "the U.S. population as a whole"[40] or simply "the U.S. population."[41] That particular detail is important, since women apparently were not among the test subjects at Edgewood Arsenal and their inclusion by the NRC panel in the control group would introduce a confounding factor that would make the final results of the study difficult to interpret. In addition, using mortality data from the general U.S. population would be highly problematic, since that would introduce two confounding factors, the "healthy soldier effect" and the "healthy test subject effect," that would tend to bias the study's results towards the null hypothesis—i.e., towards a finding of no

[38] NRC Volume 1 at 3.

[39] NRC Volume 1 at 30 and 68 .

[40] NRC Volume 1 at 30.

[41] NRC Volume 1 at 68.

difference in mortality rates between the test subjects and the control group. I discuss the healthy soldier effect and healthy test subject effect further below.

43. *Healthy Soldier Effect*. It has been well-established that there is a "healthy soldier effect" that may result in an underestimation of the adverse effects of an exposure in studies that use the general population as a comparison group.[42] Military personnel in the United States are required to undergo an initial physical screening in order to enter the armed services, and are required to maintain a certain level of physical fitness in order to remain in the military. In addition, military personnel are provided with health care services during their time in the military. All of this results in a military population that is overall healthier than the general U.S. population.[43] This "healthy soldier effect" is analogous to the "healthy worker effect" seen in civilian populations, where employed individuals are generally healthier than the population as a whole because a certain level of fitness and health is usually necessary to maintain employment.[44] Since all of the test subjects in NRC Volume 1 were active duty military personnel,[45] it is reasonable to expect that this healthy soldier effect would impact the results of the NRC Volume 1 study since these soldiers were being compared by the NRC panel to the general U.S. population. The expected impact of the healthy soldier effect would be to underestimate the adverse effects of exposure to anticholinesterase and anticholinergic agents, minimizing any differences seen in the long-term mortality rates between the exposed test subject population and the general U.S. population control group. This is a reasonable conclusion since there is evidence that the impact of the healthy soldier effect is apparent even after more than 30 years.[46] Indeed, the NRC panel essentially used the healthy soldier effect in explaining why standardized

[42] *See, e.g.,* M. Waller and A. McGuire, "Changes over time in the healthy soldier effect," *Population Health Metrics* 9:7 (2011), http://www.pophealthmetrics.com/content/9/1/7 (hereinafter, "Waller and McGuire").

[43] *See id.*

[44] *See id.*

[45] NRC Volume 1 at 2.

[46] Waller and McGuire at p. 1 of 9.

mortality rates for test subjects was actually less than the rates expected for the U.S. population as a whole.[47] As the NRC panel stated, this "presumably reflects the fact that those who enter the military service do not have chronic diseases."[48]

44. *Healthy Test Subject Effect*. The test subjects were not only healthier, on average, than the general U.S. population because they were soldiers (the healthy soldier effect), but were also healthier than the average soldier because test subjects underwent further screening before being selected for the experiments—what I would call the healthy test subject effect. As the NRC panel outlines,[49] recruiters for chemical warfare testing at Edgewood Arsenal would visit Army installations and give a presentation about the program to "a large number of enlisted men." Up to 20% of the audience would typically express interest in participating in the experiments. For some period of time at Edgewood, those soldiers who expressed interest were then "asked to complete a personal history, which included medical and psychologic items and the Minnesota Multiphasic Personality Inventory (MMPI)." It was "not unusual for 400-600 men to request assignment" to the testing program with "no more than 100" ultimately being selected. This highly selective process produced a group of test subjects who were "above average in physical and mental qualifications, with a mean IQ near 110, good behavior records, and 'normal' MMIPs [sic] …." The NRC panel recognized the existence of the healthy test subject effect in explaining why the standardized mortality rate for test subjects exposed to anticholinergic agents was significantly lower than that for the general U.S. population, stating that the result "probably represents a selection artifact, inasmuch as volunteers for these studies were especially screened for good health and thus would be expected to have lower than average mortality."[50]

45. The failure of the original Edgewood Arsenal investigators to use an appropriate control group forced the NRC panel to choose its own control group. However, by choosing the

[47] NRC Volume 1 at 30.

[48] *Id.*

[49] NRC Volume 1 at 2.

[50] NRC Volume 1 at 68.

general U.S. population as the control group for their study, the NRC panel introduced two powerful confounding factors—the healthy soldier effect and the healthy test subject effect. Both confounding factors biased the study's results towards the null hypothesis—i.e., towards a finding of no difference in mortality rates between the test subjects and the control group. The existence of both effects, essentially acknowledged by the NRC panel, made any comparisons to the general U.S. population very problematic and difficult to interpret. As a result, I do not believe it is possible to reach any definitive conclusions, based on the results presented in NRC Volume 1, about whether the chemicals tested are likely to produce long-term adverse health effects or delayed sequelae in the test subjects.

4. Evidence of Long-Term and Delayed Adverse Effects

46. The NRC panel discussed some "anecdotal" reports that clearly indicated that some of the test agents could produce long-term or delayed adverse effects. For example, two individuals who were accidentally exposed to the anticholinergic agent, EA 3167, displayed evidence of impaired cognitive function up to 12 months following the exposure.[51] The NRC panel also discussed the case of a test subject who "experienced long-lasting psychologic symptoms."[52] In addition, some test subjects were exposed to multiple doses of a test agent or multiple agents: an average of 3.1 tests each and some test subjects participating in 10 or more tests.[53] Multiple exposures to one or more test agents would presumably increase the risk of acute adverse effects and possibly long-term or delayed adverse sequelae. In summary, despite the limitations of the data available to the NRC panel, the panel still uncovered compelling evidence that some test subjects may have experienced long-term or delayed adverse effects from their exposure to test agents. Further evaluation of surviving test subjects may confirm this possibility.[54]

[51] NRC Volume 1 at 66.

[52] NRC Volume 1 at 30.

[53] NRC Volume 1 at 3 and 77.

[54] The most effective way to evaluate the test subjects for long-term adverse health effects would be a comprehensive medical follow-up program. In addition, it is important that each test

(Footnote continues on next page.)

5. Underpowered to Detect Small but Important Differences in Mortality Rates

47. It important to note that the NRC Volume 1 study had only enough statistical power to detect relatively large differences in mortality rates between the test subjects and the control group (the general U.S. population). Indeed, the NRC panel states that from "a statistical point of view, the experience being studied is incapable of demonstrating risks of dying increased less than three- or four-fold."[55] In other words, the NRC Volume 1 study was able to detect an increased risk of dying from exposure to test agents only if the risk was at least 300 to 400% greater for test subjects compared to the control group. I believe this is an accurate assessment of the statistical power of the NRC Volume 1 study. What this means is that smaller, but still very important increases in the risk of death—e.g., a 50%, 100%, or 200% increase in the risk of death—could not be detected by the NRC Volume 1 study and therefore cannot be ruled out.

6. Conclusions

48. The NRC panel stated two objectives for the NRC Volume 1 study: 1) to determine whether the data available are sufficient to estimate the likelihood that the test chemicals [i.e., anticholinesterases and anticholinergics] have long-term health effects or delayed sequelae; and 2) to determine whether the involved chemicals, as tested, are likely to produce long-term adverse health effects or delayed sequelae in the test subjects.[56] Since, for the reasons stated above, the original studies performed at Edgewood Arsenal have deficiencies in design and execution, in my opinion, data available from them alone are insufficient to conclude that the test chemicals have no long-term health effects or delayed sequelae. Similarly, because of the important limitations of the NRC panel's own study, it is not possible to determine through the

(Footnote continued from previous page.)

subject is informed about what substance or substances he was exposed to, the dose, route of administration, and any possible long-term adverse health effects from exposure to those substances or from participation in the testing program. Having such information is necessary so that the service member can obtain adequate ongoing health care and monitoring.

[55] NRC Volume 1 at 80.

[56] NRC Volume 1 at x.

NRC Volume 1 study whether the involved chemicals, as tested, are likely to produce long-term adverse health effects or delayed sequelae in test subjects.

B. National Research Council, Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Volume II, Cholinesterase Reactivators, Psychochemicals, and Irritants and Vesicants[57]

1. Cholinesterase Reactivators

49. The mortality data for this class of test agents was presented in NRC Volume 1 and shared the same methodology and methodological problems discussed above for NRC Volume 1.[58] Since the comparison group was the general U.S. population, and because the mortality data analysis was subject to biases from both the healthy soldier effect and healthy test subject effect, I do not believe any meaningful conclusions can be made from the study regarding increased mortality from exposure to cholinesterase reactivators.

a. Retrospective Design and Limitations of Available Data

50. The original U.S. government studies using cholinesterase reactivators did not plan for extended follow up of test subjects. Therefore, the quality of data available for assessing the long-term health of test subjects was practically non-existent. As the NRC panel conceded, "the lack of followup [sic] data on volunteers prevent certainty in predicting occurrence or absence of delayed effects."[59] The NRC panel also "found no data on the basis of which to determine or rule out carcinogenicity, mutagenicity, teratogenicity, or reproductive effects of the four oximes and therefore did not reach a conclusion in this area."[60]

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[57] National Research Council, "Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Volume 2, Cholinesterase Reactivators, Psychochemicals, and Irritants and Vesicants," National Academy Press, Washington, D.C. 1984 (hereinafter, "NRC Volume 2"). Among the general problems with this study is the possibility of a serious retrospective bias (i.e., a bias that tends to favor a particular result or outcome). It is my understanding that Dr. James S. Ketchum served as a technical consultant for the report. (NRC Volume 2 at Panel of Cholinesterase Reactivator Chemicals member list.) And I also understand that Dr. Ketchum played a major role in performing the tests at Edgewood Arsenal and that he has previously testified that he wrote much of the NRC Volume 2 report. (Ketchum Deposition Transcript 325:16 -327:5.)

[58] *See* NRC Volume 2 at 46.

[59] *Id.*

[60] *Id.*

51. The poor quality of data made available for review by the NRC panel is exemplified by the fact that "reports of physicians' examinations and physical findings were generally not included."[61] Because of this paucity of data, it would have been difficult to assess the *acute* effects of cholinesterase reactivators, much less the long-term effects of exposure to these agents.

b. Conclusions

52. I believe the paucity of good quality data available from the original experiments severely undercuts the conclusions of the NRC panel.

2. Psychochemicals

53. This retrospective NRC investigation looked primarily at phencyclidine (also, "SNA") and dibenzopyran.[62]

a. Problems with the Design and Execution of the Original Studies

54. This retrospective NRC investigation, like those described in NRC Volume 1, is limited by the quality of the original studies performed by the U.S. military. As noted by the NRC panel, no placebo control groups were used in the original studies, making the evaluation of the long-term health consequences of exposure to psychochemicals much more difficult.[63] I strongly disagree with the NRC panel's statement that placebo controls "were probably not appropriate, given the goals of the research."[64] Not only would it have been appropriate to use a placebo control group, but also necessary if one were interested in assessing the acute and long-term effects of the psychochemicals used.

55. One of the major problems with the original studies was the apparent "flexibility" in the protocols used.[65] Ideally, a study protocol is established before any research participants

[61] NRC Volume 2 at 31.

[62] NRC Volume 2 at 47.

[63] NRC Volume 2 at 52.

[64] *Id.*

[65] NRC Volume 2 at 51.

are actually enrolled, and the changes to the protocol are kept to a minimum. A rigid adherence to protocol helps prevent the introduction of biases and other errors into the experiment, which can skew or distort the results of the study. The NRC panel seems to recognize this problem and states, "A critical and skeptical reviewer, in retrospect, might say that there was too great emphasis on browsing and that the changes in protocol, with small groups tested under any single protocol, precluded definitive conclusions.[66]

56. The NRC panel acknowledged the poor design of the original study, noting that in the early 1960s, "optimal research strategy and design as we know them today, was truly in its infancy."[67] The fact remains, however, that the original studies had significant problems with design and execution—including the lack of a placebo group and a constantly changing study protocol.

b. Screening Process—Healthy Soldier and Healthy Test Subject Effect

57. The screening process of test subjects in the original experiments appears to have been especially rigorous, even compared to the other studies performed at Edgewood Arsenal.[68] The NRC panel acknowledges that this screening process used by the original investigators "likely introduced a 'healthy-test-subject-effect' into the [original] study."[69] This healthy test subject effect was likely exacerbated by the fact that the original control group for the exposed subjects were military personnel who had failed the screening tests for the study.[70] As the NRC panel states, since "the exposed subjects were healthier at the start than the nonexposed subjects, comparisons between these two groups may well yield results that understate the relative risk [of

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[66] *Id.*

[67] NRC Volume 2 at 52.

[68] NRC Volume 2 at 48.

[69] *Id.*

[70] *Id.*

the test agents] to the exposed subjects."[71] This problem arising from the healthy test subject effect only reinforces the need for a placebo group in such experiments.

58. The healthy test subject effect may have been particularly powerful in the psychochemical testing at Edgewood Arsenal because test subjects were divided into one of four categories.[72] Test subjects rated "A" were deemed suitable for any psychochemical testing, and were presumably the healthiest of all the test subjects.[73] Test subjects rated "B" were deemed suitable for only "low-dose" psychochemicals.[74] Those rated "C" were not deemed suitable for psychochemical testing, and a rating of "D" was deemed suitable for equipment testing only.[75] Such tiered classification of test subjects make any meaningful comparisons with the general military or civilian population difficult, if not impossible.

c. New Testing Methods Now Available to Detect Subtle Brain Injury

59. Exposure to psychochemical agents will not necessarily result in marked changes in mortality rates or obvious morbidities. Instead, many of the long-term adverse effects may involve subtle changes in cognition or brain function that may be missed by the evaluation tools (like EEG) used by the NRC panel. The NRC panel did not employ neuropsychological testing or newer monitoring techniques like functional MRI that could have identified subtle, but significant, changes in cognition and brain function.

d. Conclusions

60. Because of the absence of any suitable control group and design and execution problems with the original studies, I do not believe any definitive conclusions can be reached

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[71] *Id.*

[72] NRC Volume 2 at 50.

[73] *Id.*

[74] *Id.*

[75] *Id.*

regarding the acute and long-term health effects of psychochemicals based on this retrospective NRC panel report.

3. Irritants and Vesicants

a. Retrospective Record Review

61. The NCR panel's discussion of irritants and vesicants is less a clinical study and more a simple summary of findings from a review of the records of 147 human subjects who were exposed to mustard gas ("H")—most of them repeatedly—between 1955 and 1965.[76] There is no real quantitative analysis and only basic descriptive data are presented.

b. Lack of Follow-Up Data

62. There is no indication that the NRC panel attempted to perform any follow-up evaluations. The panel concludes that "[g]iven the absence of followup [sic] data, it is not possible to predict long-term health effects, except scarring from acute injuries."[77] I do not entirely agree with this statement. While it is true that we cannot fully determine long-term health effects without follow-up data, the severity of some of the reported acute injuries—e.g., at least two hospitalizations, one for five days[78]—allows us to confidently predict that at least some of the subjects experienced chronic sequelae following severe acute injuries from mustard gas exposure.

c. Original Testing Priority—Eliciting Acute Effects Over Safety

63. The mustard gas experiments at Edgewood Arsenal show that test subject safety was not a high priority for the original investigators. Indeed, the study was designed to repeatedly expose individuals to mustard gas until "dermal erythema indicated garment leakage." Other subjects were brought into direct contact with mustard gas through deliberate cutaneous exposures to "test the effectiveness of antidotes or treated cloths."[79] Most, if not all, of the

[76] NRC Volume 2 at 124-128.

[77] NRC Volume 2 at 127.

[78] *Id.*

[79] NRC Volume 2 at 124.

subjects underwent repeated exposures to mustard gas, up to 14 exposures in some cases.[80] Repeated exposures to a toxic substance will generally increase the risk of serious acute injuries, and possibly chronic or permanent injuries as well. The experiments were designed first and foremost to elicit the acute effects of mustard gas in human subjects, with safety a subordinated priority.

64. Some of the subjects' acute injuries were severe. As the NRC panel notes, blistering from mustard gas was seen in at least 11 men, with two of the men requiring hospitalization. A few of the skin injuries "might have been severe enough to cause permanent scarring."[81] These severe acute reactions to mustard gas exposure certainly increased the risk for long-term adverse health effects.

d. Unwarranted Assumptions of Safety

65. The NRC panel states that "[n]one of these subjects sustained ocular or respiratory tract injury," concluding that this "indicates that the ocular and respiratory systems were adequately protected during these tests."[82] I believe these assumptions of safety are unwarranted. Individuals developed erythema over a broad range of body parts, including the anterior trunk, genitalia, and groin.[83] And it may have been the case that injuries to the eyes and the lungs were more difficult to assess and detect than injuries to the surface of the skin.

66. The NRC panel properly notes that mustard gas "is not only a vesicant, but also a systemic poison."[84] The systemic effects of mustard gas have been demonstrated "in bone marrow, intestinal tract, and respiratory tract."[85] It is clear that the majority of test subjects

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[80] *Id.*

[81] NRC Volume 2 at 127.

[82] *Id.*

[83] NRC Volume 2 at 126.

[84] NRC Volume 2 at 127.

[85] *Id.*

experienced multiple episodes of dermal contact with mustard gas.[86] The skin is a major route of entry for chemical toxins, and it seems certain that many test subjects absorbed mustard gas systemically through the skin. This seems to be confirmed in the panel's discussion of one group of 11 subjects, with only 8 subjects having normal post-exposure blood counts and urinalyses.[87] Systemic injuries from a chemical toxin are often undetectable on a routine physical examination. It seems very likely that at least some of the subjects exposed to mustard gas at Edgewood Arsenal experienced systemic injuries from repeated dermal exposures to mustard gas.

e. Conclusions

67. The design of the mustard gas experiments at Edgewood Arsenal prioritized the elicitation of acute mustard gas effects, markedly increasing the risk for both acute and long-term adverse reactions.

68. It is very possible that some of the subjects exposed to mustard gas at Edgewood Arsenal experienced systemic injuries from repeated dermal exposures to mustard gas.

C. National Research Council, Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Volume III, Final Report, Current Health Status of Subjects

69. This investigation was a retrospective survey.

70. The NRC panel preparing this report[88] was charged with two tasks. The first task was to "prepare a final report for the series *Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents* on the basis of results of a questionnaire regarding current health status of test subjects.[89]

[86] NRC Volume 2 at 124-127.

[87] NRC Volume 2 at 124.

[88] National Research Council, "Possible Long-Term Health Effects of Short-Term Exposure to Chemical Agents, Volume III, Final Report, Current Health Status of Subjects" (hereinafter, "NRC Volume 3").

[89] NRC Volume 3 at Executive Summary.

71. The second task of the NRC panel was to "evaluate the implications of findings from the questionnaire for any of the conclusions reported in Volumes 1 and 2."[90]

1. Analytic Problems Related to Retrospective Survey Design

a. Limitations of the Original Edgewood Arsenal Studies

72. One problem with any retrospective investigation is that the analysis is limited by the data (or lack of data) collected by the original investigators. As the NRC panel states, the "main objective of [the Edgewood Arsenal] tests was to determine effects of various chemical agents on the ability of test subjects to function effectively in a military situation."[91] It was not the purpose of the Edgewood Arsenal tests to determine the long-term health effects from exposure to these chemical agents, and "[i]t was not anticipated [by Edgewood Arsenal investigators] that any late effects would occur."[92]

73. The NRC panel that prepared this report acknowledged that "the Edgewood tests were intended for short-term and not long-term study and were therefore deficient in adequate long-term controls."[93] I agree with this statement. In my opinion, the limitations of the original Edgewood Arsenal tests preclude any definitive statements regarding the long-term health of the human test subjects used in those programs.

b. Selection Biases

74. The NRC panel's investigation was also limited by problems in contacting the approximately 6,720 subjects who participated in the original Army tests.[94] These problems likely introduced substantial selection biases into the analysis, a common problem for studies that did not plan explicitly for followup. Among the 6,720 subjects, 325 were already known to be

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[90] *Id.*

[91] NRC Volume 3 at 3.

[92] *Id.*

[93] NRC Volume 3 at Executive Summary.

[94] NRC Volume 3 at 2.

dead.[95] It is possible that the deceased subjects experienced the most health problems following the Edgewood Arsenal tests, and their exclusion from the NRC panel's investigation probably resulted in an underestimate of long-term adverse health outcomes.

75. Among the approximately 6,395 test subjects presumed to be still living, another 1,399 subjects were lost from the analysis because the NRC panel could not obtain their current mailing addresses.[96] The NRC panel stated that it "is not known whether this could be a serious source of bias in the comparison of treatment groups,"[97] but I suspect that it was. This "lost" group comprised nearly 22% of the remaining test subjects, and it is possible that many could not be located because they were no longer living or were in poor health and no longer living independently in their own housing. The potential bias introduced by their exclusion from the analysis may have resulted in an underestimate of long-term adverse health outcomes.

76. The NRC panel also stated that the "911 men who received the questionnaire and failed to respond were considered to constitute another potential source of bias, inasmuch as their failure to respond could have resulted from an unhappy test experience."[98] It is possible that an "unhappy test experience" was the consequence of adverse reactions. If so, then at least some of these 911 men were probably at higher risk for developing long-term adverse health effects due to their participation in the tests at Edgewood Arsenal. If that is the case, then the NRC panel was correct to consider the loss of that group as a potential source of bias—a selection bias that may have resulted in an underestimate of long-term adverse health outcomes.

77. The NRC panel acknowledges the likelihood of selection bias, which they referred to as "Response Bias," because not all test subjects who were still assumed to be living had participated in the survey.[99] For reasons that they explain in their report, the NRC panel

[95] *Id.*

[96] *Id.*

[97] *Id.*

[98] *Id.*

[99] NRC Volume 3 at 15.

concludes that if a response bias exists, "it is in the direction of overestimation of current health problems of the living volunteers."[100] I disagree with this conclusion.

78. The NRC panel based their conclusion about the direction of selection bias on their reported finding that the men who responded to the survey were hospitalized at a greater rate than those who did not respond to the survey and those who could not be located.[101] In my opinion, the use of hospitalization rates—a necessity because of the paucity of other data available to the NRC panel—is a poor way to estimate the frequency of health problems among the different groups. There are multiple reasons, other than better health, that can explain the lower hospitalization rate among those who did not respond to the survey or could not be located. First, the NRC panel cannot even assume that all the non-located individuals are even alive. The NRC panel used burial allowance claims received by the Veterans Administration to determine who is alive or dead.[102] This is not a particularly good way to separate the dead from the living. The families of some deceased veterans may not have applied for a burial allowance (or even been aware of this benefit). As another example, a homeless veteran[103] dying anonymously on the streets of a major city is not likely to have a burial allowance claim filed on his behalf. So, some of the non-located test subjects were possibly already dead, but assumed alive by the NRC panel. Second, non-responding veterans and non-located veterans may not have been hospitalized because they lacked access to health care services. After all, individuals in the United States who have health insurance are more likely to utilize health care services than those who lack health care insurance. Yet, the NRC panel seems to assume—incorrectly, in my opinion—that the non-responding and non-located veterans had the same access to health care as the responding veterans.[104] If the lower hospitalization rate among non-responding and non-located veterans was

[100] NRC Volume 3 at 16.

[101] NRC Volume 3 at 15-16.

[102] NRC Volume 3 at 2.

[103] Homelessness can certainly explain why some veterans were not locatable.

[104] *See* NRC Volume 3 at 15-16.

indeed due, at least in part, to lack of access to health care, then the direction of selection bias could be assumed to go towards an underestimation of current health problems, since people without access to health care services tend to be less healthy overall compared to those who do have access. In my opinion, the NRC panel was wrong and the direction of the selection bias may very well be towards an underestimation of current health problems.

c. Recall Bias

79. This retrospective survey is also vulnerable to recall bias, where different veterans may remember their medical history differently based on other factors. For example, those veterans who had bad experiences during chemical testing may remember their subsequent medical history in a different way compared to those whose experiences during chemical testing was less negative. Recall biases are common for retrospective studies and make the interpretation of retrospective survey results more difficult to interpret and validate.

2. Underpowered Design Precludes Detection of Smaller Health Effects

80. Limitations in the original Edgewood Arsenal study protocols and problems with the NRC panel's own methods combined to make this study too underpowered to detect anything but very large differences in clinical outcome. Smaller, but clinically important, differences in outcome were likely to be missed entirely by the NRC panel's investigation. The NRC panel admits this in their report:

> The experimental methods and the available comparison groups were such that only large effects were likely to be uncovered. The large standard errors, the initial differences between the exposed and nonexposed groups, the possibility that more than one exposure might have led to the same adverse effect, and the self-reporting nature of the questionnaire study all would tend to obscure small differences.[105]

81. The NRC panel performed power calculations to help determine the probability that certain differences in outcome would be detected through the survey results.[106] The power

[105] NRC Volume 3 at Executive Summary.

[106] NRC Volume 3 at 5-6.

calculations are summarized in Tables 3 and 4.[107] These power calculations quantitatively confirm the NRC panel's qualitative assessment—i.e., that the statistical power of the survey study for detecting small (but potentially clinically important) differences in outcome is low. Unless an exposure caused a very large difference in clinical outcome, the difference in clinical outcome was likely to be missed by this underpowered survey.

3. Multiplicity of Chemical Exposures

82. The NRC panel preparing NRC Volume 3 recognized and acknowledged a major problem in the design and execution of the original chemical warfare testing program: the multiplicity of chemical exposures.[108] As the NRC panel explained, "For the sake of efficiency, many volunteers were used in two or more tests" involving exposure to multiple chemical agents.[109] Whatever efficiency may or may not have been gained, the decision to expose many subjects to multiple chemical warfare agents introduced potentially powerful confounding factors that make it very challenging to ascribe long-term health effects to a specific test agent. The NRC panel seemed to understand this, stating, "If a test substance produced detectable long-term adverse effects in a man who was also exposed to another substance, it could be difficult to ascribe the effect to the first substance alone, especially if many men were treated with both substances."[110]

83. In addition to the analytical challenges created by multiple exposures, it is also important to recognize that exposure to multiple chemical warfare agents could possibly increase the risk of long-term adverse health effects in an additive or synergistic manner. Therefore, while exposure to multiple chemical agents can increase a test subject's personal risk of developing long-term adverse health effects, the study design flaw introduced by the original investigators

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[107] NRC Volume 3 at 35-36, Tables 3 and 4.

[108] NRC Volume 3 at 3.

[109] *Id.*

[110] *Id.*

made it much more challenging for the NRC panel to ascribe the cause of such adverse health outcomes.

4. Control Group—Healthy Soldier and Healthy Test Subject Effect

84. The NRC panel recognized one of the main problems of the original chemical warfare testing programs: the failure to include an appropriate control group.[111] They also recognized the importance of the healthy soldier effect and the reasons why the U.S. general population was an inappropriate control group for statistical comparisons. As the NRC panel explained:

> Men who are selected to serve in the Army are, in general, in better physical and mental health than their peers. Because their later health would also be expected to be better than average, it is inappropriate to compare their health and life expectancies with those of the general U.S. male population.[112]

85. The NRC panel also recognized and acknowledged the problem of the healthy test subject effect, and explained why test subjects who did not receive any active test agent were an unsuitable control group for those subjects who were exposed to active chemical agents:

> The Volunteers received careful physical and mental screening examinations for contraindications to the planned tests. The health of a volunteer helped to determine the type of test in which he participated. The more healthy men were exposed to the active chemicals, and the less healthy were used as controls and in some cases tested equipment without being exposed to chemicals. Such selection bias means that the men not exposed to chemicals would be expected to have more illness; therefore, the likelihood of discovering effects in them (whether early or late) due to the treatments would be smaller.[113]

86. The NRC panel was essentially left with no adequate control group for their statistical analysis. The confounding biases introduced by the healthy soldier effect and healthy

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[111] *See id.*

[112] *Id.*

[113] *Id.* The "selection bias" is the healthy test subject effect. In my opinion, it is inappropriate to call the chemical warfare agents used, "treatments."

test subject effect decreased the likelihood that the NRC panel would be able to detect long-term adverse health outcome in the test subject population.

5. Limitations of Cross-Sectional Study Design

87. The NRC panel's survey is a cross-sectional investigation. In other words, the NRC panel is taking a "snapshot" in time of the health of test subjects through their use of a survey. Unlike longitudinal study designs where test subjects are followed over time, cross-sectional studies are not nearly as good in identifying health trends over time within the test subject population. The cross-sectional design of the NRC panel's survey made it less likely that the NRC panel would be able to identify long-term adverse health outcomes attributable to participation in chemical warfare testing programs.[114]

6. Conclusions

88. The NRC panel, recognizing the limitations of their retrospective survey, stated that they "believed that the study might detect major effects if they were present and that the limitations of the study could be appropriately described so its conclusions would not be overinterpreted."[115] In my opinion, any assertion that the NRC panel's findings represent a definitive or conclusive study of long-term adverse health outcomes in chemical and warfare test participants is an overinterpretation.

89. It is my opinion that the methodological problems in the original chemical warfare testing program and the weaknesses of the NRC panel's own survey investigation preclude any firm or definitive conclusions to be reached regarding the long-term health outcomes of test subjects.

D. Bullman and Kang, "A Fifty Year Mortality Follow-up Study of Veterans Exposed to Low Level Chemical Warfare Agent, Mustard Gas"

90. I have reviewed and analyzed a study published in 2000 by Tim Bullman and Han Kang of the Environmental Epidemiology Service, Department of Veterans Affairs, titled "A

[114] NRC Volume 3 at 2.

[115] NRC Volume 3 at Executive Summary.

Fifty Year Mortality Follow-up Study of Veterans Exposed to Low Level Chemical Warfare Agent, Mustard Gas."[116] The authors' stated purpose was to "determine if there is an increased risk of any cause specific mortality associated with low level mustard gas exposure among World War II Navy veterans." In their report, the authors found "no excess of any cause specific mortality risks associated with varying levels of mustard gas exposures among Navy veterans subject to the chamber tests."[117] As discussed below, I believe there are serious methodological problems that prevent any firm conclusions to be drawn from the data presented in their report.

1. Major Selection Bias in Excluding Important Veteran Populations from the Study

91. In discussing their methods, the authors note that mustard gas chamber tests were performed at several sites, including the Naval Research Laboratory ("NRL") in Washington, D.C., the Edgewood Arsenal in Maryland, and the Great Lakes Training Center in Illinois. Remarkably, Bullman and Kang simply note that since "NRL was the only site to maintain accurate records of veterans who participated in chamber tests, NRL test participants were selected as study subjects."[118] There is no explanation in the report discussing why the records of veterans from Edgewood Arsenal and the Great Lakes Training Center were not deemed "accurate," or whether the differences in record keeping also reflected differences in how the chamber tests were conducted at the various sites. The authors also fail to report how many veterans were excluded from the study because of the decision to include only NRL veterans. Just as importantly, there is no indication that the authors made any attempt to determine whether the Edgewood Arsenal and Great Lakes Training Center veterans differed in any important way—e.g., with respect to demographic characteristics, pre-existing conditions, or testing agent exposure—compared to the NRL veterans, meaning there is no way to fully determine the types

[116] T. Bullman and H. Kang, "A Fifty Year Mortality Follow-up Study of Veterans Exposed to Low Level Chemical Warfare Agent, Mustard Gas," *Annals of Epidemiology,* Vol. 10(5):333-338, 333 (2000) (hereinafter, "Bullman and Kang 2000").

[117] Bullman and Kang 2000 at 333.

[118] Bullman and Kang 2000 at 334.

of biases and confounding factors that may have been introduced into the study by excluding veterans from two of the three testing sites. The possible introduction of major selection biases raises serious questions about the validity of the study and the generalizability of any reported results to excluded veteran test subjects.

2. Misclassification Bias Due to Non-Existent Documentation of Actual Mustard Gas Exposure and the Use of Surrogate Exposure Markers

92. According to the authors, the World War II era testing programs evaluated the effectiveness of various protective clothing and equipment in preventing injury or incapacitation due to mustard gas exposure.[119] Because of the nature of the testing programs—evaluating protective clothing and equipment—as well as possible poor record keeping, it is virtually impossible to directly quantitate the physical exposure to mustard gas that veterans were subjected to during the government's testing programs. Bullman and Kang apparently recognized this and instead used two surrogate measures of mustard gas exposure: a calculated "CT score" and documented skin reactions to mustard gas. Exposure information is crucial for their analysis, but the authors fail to identify where they obtained the data for these surrogate measures of exposure and do not mention whether they performed any type of quality control assessment.[120] For the reasons that I discuss below, I believe the use of these questionable surrogate markers and the non-existent documentation of actual mustard gas exposure probably resulted in substantial misclassification bias that seriously undermines the results of the study.

a. Misclassification Bias Due to the Use of the "CT score" Surrogate Measure of Mustard Gas Exposure

93. One of the surrogate measures of mustard gas employed by the authors was a "CT score," defined as the concentration of mustard gas in the chamber air, usually in milligrams per liter, times length of exposure in minutes.[121] The problems with using this surrogate measure of

[119] Bullman and Kang 2000 at 333.

[120] *See* Bullman and Kang 2000 at 335 and Table 1.

[121] Bullman and Kang 2000 at 334.

exposure are obvious. Depending on the quality and effectiveness of the protective clothing and equipment being tested, the concentration of mustard gas in the chamber air may have little relation to the actual physical exposure of the test subject to the gas. For instance, a highly effective protective suit may have prevented any physical exposure of a test subject to mustard gas, even if testing was performed using a high concentration of mustard gas in the chamber air. Alternatively, even a very low concentration of mustard gas for a very short period of time could have resulted in a high physical exposure to mustard gas if the protective suit was defective or ineffective. As illustrated in these examples, the use of CT score as a surrogate measure of mustard gas exposure has the potential to either overestimate or underestimate the actual exposure of test subjects to mustard gas. In Bullman and Kang's study, this is a potentially important source of error, as the authors used CT score to classify test subject exposure to mustard gas as "high" or "low."[122] This type of bidirectional—sometimes called, non-differential—*misclassification bias* (error) has the very strong potential to drive the results of an analysis towards the null—i.e., towards a finding of no difference between exposure groups. The non-differential misclassification bias introduced by the authors' use of the CT score could very well explain, in part, their study's finding of no association between varying levels of mustard gas exposure and an increased risk of any cause specific mortality.

94. Another source of misclassification bias with the use of the CT score surrogate measure of mustard gas exposure is the authors' seemingly arbitrary designation of CT scores of 100-120 as "low" exposure and scores of 121-960 as "high" exposure. The decision to include CT scores of 120 in the "low" exposure group was especially crucial since more than half of all test subjects (51.7%) had a CT score of 120.[123] The authors provide no explanation of how they decided to use 120 as the cutoff for "low" exposure and there is no way to determine from their report how the results of the study may have been different if they had used a different cutoff number to differentiate between "low" and "high" exposures. This seemingly arbitrary method of

[122] *Id.*

[123] Bullman and Kang 2000 at 335, Table 1.

classifying test subjects into "low" and "high" exposure groups is another important reason to question the validity of the study's results.

3. Control Groups—Healthy Soldier and Healthy Test Subject Effects

95. The authors claim that the "use of veterans as a referent group for other veterans should minimize the effects of the so-called 'healthy soldier effect.'"[124] While this may or may not be true, the use of veterans stationed at the same location at the same time period would not reduce any effects from a healthy test subject effect. There is no reason to expect that non-exposed veterans based at the same location had the same general health risk profile as the veterans who served as test subjects. It is very likely that test subjects were screened in some way before being subjected to the mustard gas tests, likely resulting in a test subject population that was healthier and otherwise different from the general population of military personnel at the same location—i.e., a healthy test subject effect. With a better baseline health risk profile, one would have expected the test subject group to have had better long-term health outcomes had they not participated in the mustard gas experiments. We can infer that the test subject population was very different from the general veteran population because the study authors had to exclude 956 veterans from a "random" sample of 3619 sailors (more than 26%) stationed at the same location in order to obtain a control group that the authors perceived to be a match for the test subject population.[125] Also indicating a difference between the test subjects and the control group is a nearly three-year mean age difference between the groups,[126] suggesting that the test subjects were younger and perhaps healthier than the control group at the time of entry. The authors provide little information and virtually no statistical analyses comparing the demographic and other characteristics of the test subject population and the control group, making it impossible to fully assess whether the control population was an appropriate comparison group for the test subject population. The paucity of information regarding the characteristics of the two groups

[124] Bullman and Kang 2000 at 337.

[125] Bullman and Kang 2000 at 334.

[126] Bullman and Kang 2000 at 335.

also makes it impossible to know whether potential confounding factors (e.g., pre-existing medical conditions, smoking habits, etc.) were evenly distributed between the two groups. These problems lead me to question whether the control group used in this study was appropriate and raise important concerns about the validity of the reported results.

4. Underpowered to Detect Increases in Mortality Rate Under 100%

96. The authors assert that their study has "substantial statistical power," claiming "over 95% statistical power to detect a 2-fold or more increased risk of deaths due to respiratory cancers."[127] Even if the authors' claim is assumed to be true, this means the study was sufficiently powered to detect a 100% increased risk of death from respiratory cancers, a very large difference in mortality risk. Many investigators and most clinicians are likely to consider even a 25% or 50% increased risk of death to be very important, but this study was underpowered to detect such smaller, but important, differences in mortality rate. Furthermore, the authors make no assertion about the power of the study for detecting increased risk of death from other diseases, including skin cancers and chronic obstructive pulmonary disease. It is notable that the authors reported an approximately 50% increase in the risk of death from chronic obstructive pulmonary disease among test subjects with "high exposure" to mustard gas compared to all Navy veterans with no exposure.[128] While the reported relative risk values (1.44 and 1.57) were not deemed statistically significant,[129] the lack of statistical significance may reflect the underpowered design of the study. In summary, while this study may have been sufficiently powered to detect very large increases in risk of death, it was underpowered to detect smaller, but still very clinically important, increases in mortality risk from exposure to mustard gas.

[127] Bullman and Kang 2000 at 337.

[128] Bullman and Kang 2000 at 336, Table 3.

[129] *Id.*

5. Problematic Reliance on Death Certificates for Mortality Causation Data

97. The authors admit that "[r]eliance on death certificates for cause of death was a potential weakness" of their study.[130] As they acknowledge, the accuracy of death certificates "in recording cause-specific mortality, especially cancers, is somewhat variable."[131] There is no indication in the report that the authors attempted to independently verify the cause(s) of death for each deceased veteran. This is a weakness of the study, especially since the authors purport to compare cause-specific mortality rates between the test subjects and control group.[132] The authors attempt to downplay this flaw by stating, "Even if lung cancer is underreported [in death certificates], cancer rates would be equally underestimated for both exposed and unexposed veterans."[133] This reasoning is not reassuring, as underreporting in both groups would negatively impact the power of the study for detecting differences in cause-specific mortality rates by decreasing the overall number of reported cases in the test subject and control groups. In other words, the reliance on death certificates for determining cause-specific mortality may bias the study results towards the null hypothesis—i.e., towards a finding of no difference in relative mortality risk between the test subject and control groups for specific causes of death.

6. No Study of Morbidity

98. This study specifically examines only mortality rates, and does not investigate morbidity. Morbidity data are generally not available on death certificates, and at minimum, obtaining morbidity data would require a detailed review of each veteran's medical records. Therefore, the study cannot rule out long-term adverse health effects that may impact the risk of morbidity but may have a lesser, non-detectable impact on mortality rates.

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[130] Bullman and Kang 2000 at 337.

[131] Bullman and Kang 2000 at 337.

[132] Bullman and Kang 2000 at 336, Tables 2 and 3.

[133] Bullman and Kang 2000 at 337.

7. Conclusions

99. In my opinion, because of the methodological problems discussed above, no definitive conclusions about relative mortality risks following exposure to mustard gas can be drawn from the data presented by Bullman and Kang in this report.

E. The 1980 LSD Follow-Up Study Report

100. Between 1955 and 1967, the U.S. Army Chemical Corps and the U.S. Army Intelligence Corps conducted a series of experiments on human test subjects using lysergic acid diethylamide ("LSD").[134] Most of this testing was performed at Edgewood Arsenal, although other sites were used as well.[135]

101. After the studies had concluded in 1967, the U.S. Army was notified that one of the former LSD test subjects had developed temporal lobe epilepsy.[136] In addition, public and Congressional interest in the LSD testing program had grown because of the public disclosure of the suicide in 1953 of an Army mathematician shortly after being given LSD covertly by government experimenters.[137] The LSD Follow-Up Study was intended to evaluate former LSD test subjects for possible long-term adverse effects from their exposure to LSD and participation in the Army's testing program.[138] It is supposed to be the government's most complete follow-up study of former LSD test subjects.

1. Inability to Obtain a Matched Control Group—Healthy Soldier and Healthy Test Subject Effects

102. The authors of the LSD Follow-Up Study stated that a "major and eventually insuperable problem arose with regarding to the proposed study design; namely, it proved

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[134] U.S. Army Medical Department, "LSD Follow-Up Study Report," October 1980 (hereinafter, "LSD Follow-Up Study") at 1.

[135] LSD Follow-Up Study at 1-2.

[136] LSD Follow-Up Study at 2.

[137] *Id.*

[138] LSD Follow-Up Study at 2-3.

impossible to obtain matched controls for the LSD-exposed subjects."[139] Whether it was truly "impossible" to come up with a matched control group is debatable. It is at least clear that the investigators failed to produce an adequate control group for the study. Instead of using a matched control group for their study, the investigators compared the LSD test subject group with age-similar males in the general U.S. population.[140] Even the authors acknowledged that using the general U.S. population as a control group was a "much less satisfactory strategy."[141] I agree and believe the control group used in this study was inappropriate and inadequate for the reasons outlined below.

103. The major problem with using age-similar males in the general U.S. population as a control group is that the analysis will be biased towards the null hypothesis (i.e., a finding of no difference in health outcome) by two confounding factors: the healthy soldier effect and the healthy test subject effect (see my discussion above regarding these two effects). Since LSD test subjects had been U.S. military personnel, they were, as a group, more healthy on average than the general U.S. population—the healthy soldier effect. As discussed earlier in this report, this is because individuals must undergo physical and mental health evaluations before they are permitted to serve in the U.S. military. Since the LSD test subjects were, on average, healthier than the general U.S. population before they participated in the LSD experiments, any adverse effects would tend to be masked by a comparison between the two groups.

104. In addition, the "LSD subjects were not in any sense a random cross-section of the Army population."[142] For instance, the "average intelligence and level of education of the LSD-treated group … was considerably higher than that of the Army population in general."[143] Reportedly, many of the LSD test subjects were Army Chemical Corps or Intelligence Corps

[139] LSD Follow-Up Study at 4.

[140] LSD Follow-Up Study at Executive Summary.

[141] *Id.*

[142] LSD Follow-Up Study at 4.

[143] *Id.*

officers with advanced scientific degrees.[144] The likely effect of all this is that the LSD test subject group was, on average, healthier and probably more adaptable (because of their intelligence), than the general Army population—a healthy test subject effect. Since the LSD test subjects were likely, on average, to be healthier than the general Army population, this would again tend to bias the results of any comparisons with the U.S. general population towards the null hypothesis (i.e., a finding of no difference in health outcomes).

105. Since there was likely a very powerful healthy soldier effect and healthy test subject effect biasing the results of this study, I believe that any comparisons in the LSD Follow-Up Study between the LSD test subjects and the general U.S. population of age-similar males to be meaningless. Because the original LSD studies did not include an appropriate control group, and because the investigators failed to put together an appropriate matched control group, the LSD Follow-Up Study cannot be deemed to have any appropriate control group to which the LSD test subject group may be compared.

2. Biases Arising from Retrospective Design

106. It is important to remember that the original LSD studies performed by the U.S. Army at Edgewood Arsenal did not include any plan for long-term follow up of the test subjects. The LSD Follow-Up Study is a retrospective study and is therefore vulnerable to all the biases that can affect retrospective study designs.

a. Selection Biases

107. The investigators were only able to perform a follow-up examination or interview with a portion of the original LSD study participants.[145] Among 741 LSD test subject identified, only about 220 could be examined directly and another 100 questionnaires completed. Another 149 refused to participate and 193 others could not be located. Fifty-five LSD test subjects, for reasons that are not clearly explained, were followed separately because they were now U.S. Air

[144] LSD Follow-Up Study at 4-5.

[145] LSD Follow-Up Study at 11.

Force personnel.[146] There is no evaluation, qualitative or quantitative, presented in the report to determine whether any of these excluded groups differed in any significant way from the 320 LSD test subjects who were eventually evaluated. Therefore, it is very possible that significant biases were introduced into the study because of these exclusions.

108. Importantly, 24 of the 741 original LSD test subjects had already died and were not included in the final analysis.[147] This has the potential to introduce a major selection bias into the study since some of the deceased individuals may have been among those who had the most severe adverse reactions to LSD exposure.

b. Retrospective or Observer Bias

109. As the authors acknowledge, the LSD Follow-Up Study was designed and performed after the U.S. Army's LSD testing program had come under increased public scrutiny.[148] This raises the possibility that some type of observer bias may have been introduced into the study, since there may have been some pressure, whether intended or not, placed on the investigators to minimize any damage to the reputation of the U.S. Army, which had conducted the original LSD studies.

c. Limitations of Cross-Sectional Design

110. Since the original LSD testing program did not include any plans for long-term follow-up of the test subjects, it was not possible to follow the health of the test subjects in a longitudinal manner (i.e., over the course of time). Instead, partly because the LSD Follow-Up Study is a retrospective study, it has a cross-sectional design, meaning that the individuals assessed in the study are evaluated at just one "snapshot" in time. Since cross-sectional studies evaluate individuals at just one point in time, rather than follow the individuals over a number of years or decades, cross-sectional studies are not as good in identifying any trends (e.g., health

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[146] *Id.*

[147] *Id.*

[148] *See* LSD Follow-Up Study at 2.

trends) over time among the study population. This is a major limitation of the LSD Follow-Up Study.

3. Meaningful Data

111. Since the LSD Follow-Up study does not have an appropriate control group, the most meaningful data in the study is the survey of health problems reported by former LSD test subjects. While quantitative comparisons with the U.S. general population are not meaningful, it is still important that a substantial number of LSD test subjects report having adverse reactions—e.g., persistent flashbacks, depression, and personality changes—that are probably related to their exposure to LSD.[149] The investigators defined certain adverse reactions as a "probable LSD effect" if it was reported to have initially occurred within 2 years of LSD exposure and was an adverse reaction similar to known long-term effects of LSD or could conceivably have been caused by LSD even if not previously reported.[150] I think this definition of "probable" LSD effect may be too restrictive, since it is now known that certain long-term adverse reactions to LSD exposure (e.g., flashbacks) may initially occur more than two years following the last dose of LSD. The definition is also somewhat vague in defining adverse reactions that could conceivably have been caused by LSD. Even so, this survey of reported long-term adverse reactions is the most valuable data in the report and is clinically meaningful, despite the limitations of the LSD Follow-Up Study's design.

4. Conclusions

112. The lack of a proper control group and the retrospective design are major weaknesses of the LSD Follow-Up Study.

113. Nevertheless, the LSD Follow-Up Study provides meaningful data through its survey of reported long-term adverse reactions.

[149] LSD Follow-Up Study at 21-22.

[150] LSD Follow-Up Study at 21.

F. William Page Institute of Medicine Study

114. It is my understanding that this study[151] will be discussed in detail in another report. I give only some brief opinions here. I may testify more extensively and in greater detail regarding this study.

115. This study has a number of methodological problems which I will briefly outline here. First, it utilizes a cross-sectional design that provides only a "snapshot" in time of health outcome in the responding group.[152] A cross-sectional study is generally not as good as a longitudinal study for determining health trends over time.

116. In addition, the study appears to have an important selection bias, with the Nonrespondent group having important differences in key characteristics compared to the Respondent Group. For example, the Nonrespondent group had, on average, significantly less education beyond high school, a higher rate of hospital admissions between 1980 and 1985, worse overall health, higher levels of beer and whiskey consumption, and higher use of heroin.[153] All of that suggests that the Nonrespondent group was less healthy than the Respondent group, and that less healthy individuals were being systematically eliminated from the study. This can only make it less likely that the study can detect long-term adverse health outcomes in former test subjects.

117. The Page study used a survey method for gathering data[154], and therefore is subject to the confounding effects of recall bias (errors in the way subjects recall their own medical and personal history). This too makes the health outcome results of this study less trustworthy.

118. Also a source of selection bias is the decision to eliminate all known decedents from the analysis. Obviously, decedents cannot complete surveys, but there was no attempt to

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[151] W. Page, "Long-Term Health Effects of Exposure to Sarin and Other Anticholinesterase Chemical Warfare Agents," *Military Medicine* 168:239-245 (2003) (hereinafter, "Page").

[152] Page at 239-240.

[153] Page at 241, Table II, 242-43.

[154] Page at 239-240.

obtain detailed health histories of these dead former test subjects, who may have been among those with the most adverse health reactions to their participation in the military tests.

119. The study also lacks an optimal control group.

120. In my opinion, the methodological problems of this study preclude any definitive conclusions from being reached based on the study regarding the long-term health effects of exposure to sarin and other anticholinesterase chemical warfare agents.

VI. VETERANS OUTREACH LETTER, FACT SHEET, AND FREQUENTLY ASKED QUESTIONS

121. I have had the opportunity to review the Department of Veterans Affairs Chem-Bio Outreach Letter ("Outreach Letter"), which I understand is a generic form letter that was sent to some test subjects along with the Fact Sheet and Frequently Asked Questions sheet discussed below. The Chem-Bio Outreach Letter is not particularized to reflect the circumstances of any individual's exposures or those of any discrete group. It does not identify what substances a veteran receiving it was exposed to, and it does not disclose what sorts of long-term effects a veteran might suffer as a result of their exposure.

1. Fact Sheet from the Deployment Health Support Directorate

122. I have reviewed a document with the header, "Edgewood Arsenal Chemical Agent Exposure Studies: 1955-1975" ("Fact Sheet"). It is my understanding that the Fact Sheet was attached to the Department of Veterans Affairs' Outreach Letters sent to some of the veterans who served as test subjects.

123. I have a few observations concerning certain statements in the Fact Sheet. The Fact Sheet states that "The Institute of Medicine (IOM) published a three-volume study between 1982 and 1985 on the long-term health effects of exposure to the chemicals tested. The study did not detect any significant long-term health effects in Edgewood Arsenal volunteers." [citations omitted]. First, this statement mischaracterizes the conclusion of the study. Second, as discussed above, the design and quality of the study were inadequate to definitively determine whether there are any significant long-term health effects in Edgewood Arsenal volunteers. This statement in the Fact Sheet is therefore inaccurate because it fails to discuss the study's many methodological

limitations, including those acknowledged by the authors, and its generally indeterminate findings and conclusions.

124. The Fact Sheet also states that "The study investigators assured that the exposure levels administered would not result in serious or life-threatening side effects." There are numerous examples, however, of serious acute side effects from exposure to the chemical and biological agents used in these experiments. These serious side effects include, for example, the initiation of a life-threatening grand mal seizure in one case and hallucinogenic flashbacks in other cases. (See discussion above.)

2. "Frequently Asked Questions: Edgewood Arsenal Chemical Agent Exposure Studies: 1955-1975"

125. I reviewed a document with the header, "Frequently Asked Questions" ("FAQs"). It is my understanding that the FAQs were distributed with the Outreach Letters to some of the veteran test subjects. The FAQs state that "The Army obtained the voluntary consent of volunteers and provided them with study information." True "voluntary consent" comprises informed consent without coercion. It cannot be stated with certainty that coercion was not used to recruit military test subjects for the various chemical agent tests.

Respectfully submitted,

Dated: AUG 8, 2012

Daniel E. Ford, M.D., M.P.H.

Exhibit 1

Curriculum Vitae

Daniel E. Ford, M.D., M.P.H.

DEMOGRAPHIC INFORMATION

Current Appointments

2007- Director, Institute for Clinical and Translational Research
2005- Vice Dean for Clinical Investigation, Johns Hopkins University School of Medicine
2002- Professor, Johns Hopkins University School of Medicine, Department of Medicine, Division of General Internal Medicine, Welch Center for Prevention, Epidemiology and Clinical Research, Baltimore, Maryland
2002- Joint Appointment, Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine, Baltimore, Maryland
1988- Joint Appointment, Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland
1988- Joint Appointment, Department of Health Policy and Management, Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland
1988- Active Full-time Medical Staff, Johns Hopkins Hospital, Baltimore, Maryland

Education and Training

1978 (BA) Cornell University, Ithaca, New York
1982 (MD) State University of New York at Buffalo, Buffalo, New York
1986 (MPH) Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland
1980 Summer Geriatric Research Fellowship, State University of New York at Buffalo School of Medicine. Effect of nonsteroidal anti-inflammatory drugs on urinary prostaglandins and renal function in the elderly.
1982-83 Osler Medical Intern, Johns Hopkins Hospital, Baltimore, Maryland
1983-85 Osler Medical Resident, Johns Hopkins Hospital, Baltimore, Maryland
1985-88 Part-time Clinical Fellow, Department of Medicine, Division of Internal Medicine, Johns Hopkins Hospital, Baltimore, Maryland
1985-88 Epidemiology Training Fellowship, U.S. Public Health Service
1985-88 Medical Staff Fellow, Primary Care Section, Clinical Services Research Branch, Division of Biometry and Epidemiology, National Institute of Mental Health, Rockville, Maryland
1990-91 Faculty Development, Johns Hopkins Bayview Medical Center, Primary Care, Internal Medicine, "Curriculum Development for Primary Care Internal Medicine"
1991-92 Faculty Development, Johns Hopkins Bayview Medical Center, Primary Care, Medicine, “Clinician-Teacher in Primary Care Internal Medicine”

Professional Experience

1988-90	Instructor, Johns Hopkins University School of Medicine, Department of Medicine, Division of General Internal Medicine, Welch Center for Prevention, Epidemiology and Clinical Research, Baltimore, Maryland
1988-	Joint Appointment, Johns Hopkins University Bloomberg School of Public Health, Department of Epidemiology, Baltimore, Maryland
1988-	Joint Appointment, Johns Hopkins University Bloomberg School of Public Health, Department of Health Policy and Management, Baltimore, Maryland
1988-	Active Full-time Medical Staff Appointment, Johns Hopkins Hospital, Baltimore, Maryland
1990-95	Assistant Professor, Johns Hopkins University School of Medicine, Department of Medicine, Division of General Internal Medicine, Welch Center for Prevention, Epidemiology and Clinical Research, Baltimore, Maryland
1995-2002	Associate Professor, Johns Hopkins University School of Medicine, Department of Medicine, Division of General Internal Medicine, Welch Center for Prevention, Epidemiology and Clinical Research, Baltimore, Maryland
2002-	Professor, Johns Hopkins University School of Medicine, Department of Medicine, Division of General Internal Medicine, Welch Center for Prevention, Epidemiology and Clinical Research, Baltimore, Maryland
2003-	Joint Appointment, Johns Hopkins Department of Psychiatry

RESEARCH ACTIVITIES

Publications – Peer-Reviewed Articles

1. **Ford DE**: Principles of screening applied to psychiatric disorders. Gen Hosp Psychiatry 1988;10:177-188.
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147. Daumit, GL, Anthony, CB, **Ford, DE,** Fahey, M, Skinner, EA, Lehman, AF, Hwang, W, Steinwachs, DM. Pattern of mortality in a sample of Maryland residents with severe mental illness: Psychiatry Research 176 (2010); 242-245.
148. Blecker, S, Zhang, Y, **Ford, DE**, Guallar, E, dosReis, S, Steinwachs, DM, Dixon, LB, Daumit, GL, Quality of care for heart failure among disabled Medicaid recipients with and without severe mental illness: General Hospital Psychiatry, 2010 May-June:32(3): 255-261.
149. Goyal M., Haythornthwaite, J, Levine D, Becker D, Vaidya D, Hill-Briggs F, **Ford DE**, Intensive meditation for refractory pain and symptoms. J Altern Complement Med., 2010 Jun; 16(6): 627-31.
150. Houston TK, Sadasivam RS, **Ford DE**, Richman J, Ray MN, Allison JJ. The QUIT-PRIMO provider-patient Internet-delivered smoking cessation referral intervention: a cluster-randomized comparative effectiveness trial: study protocol. Implement Sci. 2010 Nov 17; 5:87.
151. Gross AL, Rebok GW, **Ford DE**, Chu AY, Gallo JJ, Liang KY, Meoni LA, Shihab HM, Wang NY, Klag MJ. Alcohol consumption and domain-specific cognitive function in older adults: longitudinal data from the Johns Hopkins Precursors Study. J Gerontol B Psychol Sci Soc Sci. 2011 Jan; 66(1): 39-47.

152. Khaykin E, Eaton WW, **Ford DE**, Anthony CB, Daumit GL. Health insurance coverage among persons with schizophrenia in the United States. Psychiatr Serv. 2010 Aug; 61(8):830-4.
153. Geller G, Boyce A, **Ford DE,** Sugarman J. Beyond "compliance"; the role of institutional culture in promoting research integrity. Acad Med. 2010 Aug; 85(8): 1296-302.
154. Khaykin E, **Ford DE**, Pronovost PJ, Dixon L, Daumit GL. National estimates of adverse events during nonpsychiatric hospitalizations for persons with schizophrenia. Gen Hosp Psychiatry. 2010 Jul-Aug; 32(4): 419-25.
155. Weston, CM, Bass EB, **Ford DE,** Segal JB. Faculty involvement in translational research and interdisciplinary collaboration at a US academic medical center. J Investig Med. 2010 Aug; 58(6): 770-6.
156. Selker HP, Strom BL, **Ford DE**, Meltzer DO, Pauker SG, Pincus HA, Rich EC, Tompkins C, Whitlock EP. White paper on CTSA consortium role in facilitating comparative effectiveness research: September 23, 2009 CTSA consortium strategic goal committee on comparative effectiveness research.Clin Transl Sci. 2010 Feb;3(1):29-37.
157. Cooper LA, **Ford DE**, Ghods BK, Roter DL, Primm AB, Larson SM, Gill JM, Noronha GJ, Shaya EK, Wang NY. A cluster randomized trial of standard quality improvement versus patient-centered interventions to enhance depression care for African Americans in the primary care setting: study protocol NCT00243425. Implement Sci. 2010 Feb 23; 5:18.
158. Houston TK, Cherrington A, Coley HL, Robinson KM, Trobaugh JA, Williams, JH, Foster PH, **Ford DE**, Gerber BS, Shewchuk RM, Allison JJ. The art and science of patient storytelling-harnessing narrative communication for behavioral interventions: the ACCE project. J Health Commun. 2011 May 2:1-12.

Publications – Non-Peer Reviewed Articles

1. Helzlsouer K, **Ford DE**, Berkowitz JE, Wilcox P. Prevention and Screening for Breast Cancer. Welch Center Prevention Report. Issue No. 1, May 1989.
2. **Ford DE**, Wilson M, Smith G. Prevention of Motor Vehicle Injuries. Welch Center Prevention Report. Issue No. 2, May 1990.
3. **Ford DE** and Levine DL. Smoking Cessation for the Practitioner. Forum Medicium, 1992.
4. **Ford DE** and Whelton PK. Trends in Cardiovascular Disease and Strategies for Prevention. Forum Medicium, 1992.
5. McCauley JE, **Ford DE**, Jones CA and Kern D. Psychiatric distress as a predictor of patients initiating a weight reduction program. The Bariatrician, Fall 1992.

Publications – Book Chapters

1. Hayward RSA, Steinberg EP, **Ford DE**, Roizen MF, Roach K. Guidelines for periodic preventive care. In: Eddy EM (ed.) Common Screening Tests. Philadelphia, PA: American College of Physicians, 1991.
2. Anthony JC, Romanoski AJ, Nestadt G, **Ford DE**, Kramer M. Psychiatric syndromes among persons in contact with general medical and psychiatric services in Eastern Baltimore. In: Cooper B, R Eastwood (eds.) Primary Health Care and Psychiatric Epidemiology. London. Rothledge. Pp 319-340, 1992.
3. **Ford DE**. Detection of psychiatric disorders by primary care physicians. In: Atkinson C, Miranda J, and Hohmann A (ed.) Mental Disorders in Primary Care. Jossey-Bass, Inc., 1994.
4. Klag MJ, **Ford DE**, Gottlieb S. Preventive Medicine. In: Stobo JD, Hellman DB, Ladenson PW, Petty BG, Traill TA (eds.) The Principles and Practice of Medicine. 23rd Edition. Norwalk CN, Appelton & Lange, Inc., 1997.
5. **Ford DE**, Cooper-Patrick L. Preventive Medicine. In: Stobo JD, Hellman DB, Ladenson PW, Petty BG, Traill TA (eds.) The Principles and Practice of Medicine. 24th Edition. Norwalk CN, Appelton & Lange, Inc., 1999.
6. **Ford DE**. Depression, Trauma and Cardiovascular Health. In: PP Schnurr and BL Green. Physical Health Consequences of Exposure to Extreme Stress. Washington D.C. American Psychological Association 2003
7. Nieto FJ, **Ford DE.** Report on Smoking and Cardiovascular Disease. Active Smoking and Health: A Report of the Surgeon General 2004

8. **Ford DE.** Depression, Mood Disorders, and Cognitive Impairment. In: Woolf SH, Jonas S, Kaplan-Liss E. Health Promotion and Disease Prevention in Clinical Practice. 2nd Edition. Lippincott Williams & Wilkins, 2008.

Publications – Miscellaneous

Letters to Editor: **Ford DE,** Sciamanna CN. Nutritional Counseling in Community Office Practices. Ach Intern Med 1997;157:361-362.

Editorial: **Ford DE.** Managing Patients with Depression: Is Primary Care Up to the Challenge. J Gen Intern Med 2000;15(5):344-345.

Book Review: **Ford DE.** Jenkins, Rachel and Ustun, T. Bedirham (Eds.) Preventing Mental Illness: Mental Health Promotion in Primary Care. New York: John Wiley & Sons, 1998. J Nerv Ment Dis 2000;188(5):315.

Beach MC, **Ford DE**. Compassion and integrity in medical education. Review of: Ward Ethics: Dilemmas for medical students and doctors in training. Yale Journal of Health Policy, Law and Ethics. 2001:2(1):211-217.

Editorship: **Ford DE.** Co-Editor with PK Whelton and Leon Gordis. Special Supplement of Journal of General Internal Medicine, September/October 1990. "Impact of the U.S. Preventive Services Task Force Report."
Associate Editor, Journal of General Internal Medicine 1999-2004

Inventions, Patents, Copyrights

None.

Extramural Sponsorship

Research Grant Participation – Current

Daniel E. Ford, Principal Investigator (25%) 09/30/07-09/29/12 5UL1RR025005-01A1 $19,008,590
National Institute of Health
Institutional Clinical and Translational Science Award
This CTSA grant will support clinical and translational research throughout Johns Hopkins. It includes support for education and training of new translational investigators, facilities in which clinical research can take place and infrastructure support of patient recruitment, bioinformatics, biostatistics and translational core centers.

Daniel E. Ford, Principal Investigator 07/01/94-06/30/11 T32 HP10025-15 $309,182
HRSA, Bureau of Health Professions
Institutional National Research Service Award-Primary Care Research
To identify general internists and support their development as creative and independent investigators in primary care research, determine the exact role for primary care in the health care delivery system and provide an opportunity for fellows to develop research skills in primary care.

University of Alabama Subcontract(Houston)04/01/2008-03-31/2013 $34,719
National Institute of Health
QUIT – PRIMO Web Delivered Clinical Microsystem Intervention for Tobacco Control

Research Grant Participation – Pending

Daniel e. Ford, Principal Investigator 07/01/10-06/30/15 R01 $448,166
National Institute of Mental Health
Health IT to Reduce Mental health Stigma in University Students
The objective of this study is to definitively test the efficacy of an innovative multi-level model of web-based continuous psycho-education (COPE) aimed to facilitate willingness to seek psychological help in university students.

Research Grant Participation – Previous

Daniel E. Ford, Co-Investigator 09/01/93-02/28/10 R01 AG01760 (Klag) $350,888
National Institute of Aging
Precursors of Premature Disease and Death
To continue the longitudinal description of the onset of disability and death in a standardized fashion in this cohort now approaching retirement, to identify those genetic, physiologic and health behavioral and death prior to the age of 65 years; to describe the role of a variety of midlife health behaviors in the prediction of premature aging, to develop a midlife psychological profile of factors, and to measure specific life events which may act as stressors

Daniel E. Ford, Co-Investigator (15%) 09/30/03-08/31/08 1 R01 AG01760 $1,820,808
National Institute on Aging. (Michael J. Klag, P.I.)
Precursors of Premature Disease and Death.
To identify factors associated with premature disease, disability and death in former Johns Hopkins medical students.

Daniel E. Ford, Co-Investigator (10%) 09/30/03-08/31/08 1 R01 HS13645 $2,132,297
AHRQ (Lisa A. Cooper, P.I.)
Patient-Centered Depression Care for African Americans
To improve primary care physician's knowledge and communication skills as they relate to African-American patients with depression so that these patients are more likely to receive high quality care for depression.

Daniel E. Ford, Principal Investigator (25%) 09/01/06-06/30/08 1 R34 MH073742 $334,000
National Institute of Mental Health
Development of Internet Intervention for Depression
The goal of this project is to develop and evaluate the benefits of an internet-based depression support group for patients presenting to primary care with depression.

Daniel E. Ford, Principal Investigator (5%) 07/01/03-06/30/08 2 T32 HP10025 $2,119,753
HRSA Institutional National Research Service Award.
To support and train six post-doctoral fellows annually in primary care research.

Daniel E. Ford, Co-Investigator (10%) 07/01/02-06/30/07 1 R01 MH47447 $3,723,120
National Institute of Mental Health (William W. Eaton, P.I.)
Evolution of Psychopathology in the Population.
To continue ten-year follow-up of the 1981-1982 Epidemiologic Catchment Area sample in East Baltimore; consequences of mental illness, such as mortality and cardiovascular disease.

Daniel E. Ford, Principal Investigator (25%) 02/01/03-01/31/05 045542 $458,602
Robert Wood Johnson Foundation Implementation
Evaluation of the Implementation Phase of the Depression in Primary Care Program.
To implement an evaluation process at designated clinical and HMO sites assessing current support of treatment for depression.

Daniel E. Ford, Co-Investigator (15%) 03/01/04-02/28/05 Subcontract $18,172
NIMH (Thomas G. McGuire, P.I. Harvard, Daniel Ford, P.I. JH) Subcontract
Economics of Racial/Ethnic Disparities in Mental Health

Daniel E. Ford, Principal Investigator (10%) 07/01/01-06/30/05 1-R01-CA-89011 $200,000
National Cancer Institute. Smoking Cessation Coach: An Internet Tailoring Program.
To explore potential methods of incorporating concepts of patient activation and social networking into an existing evidence-based primary care smoking cessation computer program; design and implement an Internet-based smoking cessation system and complete three pilot studies.

Daniel E. Ford, Subcontract P.I. (10%) 03/15/00-02/28/04 1-R01-MH57852

Daniel E. Ford, M.D., M.P.H.
National Institute of Mental Health. (Joseph Gallo, P.I.) Subcontract $94,648
The Spectrum of Depression Late Life: A Primary Study. Subcontract
To systematically describe and validate a depressive syndrome, apathetic depression, that does not meet standard criteria for major depression in older primary care patients; assess how physical illness, cognitive impairment, anxiety, and hopelessness among older primary care patients alters the course of.

Daniel E. Ford, Principal Investigator on Major Component Subcontract (17.5%) 10/01/01-09/30/04
CDC Funds (Association of Schools of Public Health Grant S1751-21/21)
(Louise-Anne McNutt, P.I. Univ Albany; Daniel Ford, P.I. JH) Subcontract $847,644
Evaluation of an Intimate Partner Violence Intervention Subcontract
To decrease intimate partner violence, and improve health outcomes by training physicians and entire health care team in OB and GIM clinics, screening protocols, patient education, tailored approaches based on severity of abuse; flexible treatment options and active follow-up

Daniel E. Ford, Principal Investigator (25%) 09/15/98-11/30/04 2 R01 MH54443 $959,012
National Institute of Mental Health. Quality Improvement for Depression.
Randomized clinical trial to determine if implementation of AHCPR Guidelines for Treatment of Depression in Primary Care changes medical practice and improves patient outcomes.

Daniel E. Ford, Co-Investigator (10%) 01/01/02-12/31/04 $249,995
Aetna/U.S. HealthCare (Lisa A. Cooper, P.I.)
Using Patient-Provider Communication Skills Training to Improve Depression Care for African Americans

Daniel E. Ford, Principal Investigator (25%) 03/01/02-12/31/03 040688 $149,921
Robert Wood Johnson Foundation Planning Phase
Evaluation Plan for the First Year of the Depression in Primary Care Program.
To understand health care organizations In terms of the current support of treatment for depression, their potential to achieve change, models and process for change.

Daniel E. Ford, Co-Investigator (10%) 10/01/01-09/30/03 1-R21-AA13251 $150,00
National Institute on Alcohol Abuse and Alcoholism (Rosa M. Crum, P.I.)
Sleep Disturbances and Risk for Alcohol Disorders

Daniel E. Ford, Co-Investigator (15%) 09/01/98-08/31/03 1 R01 AG01760 $1,199,683
National Institute on Aging. (Michael J. Klag, P.I.)
Precursors of Premature Disease and Death.

Daniel E. Ford, Principal Investigator (5%) 07/01/98-06/30/03 2 T32 PE10025 $1,382,755
HRSA Institutional National Research Service Award.
Daniel E. Ford, Co-Investigator (10%) 03/01/97-06/30/02 1 R01 MH47447 $1,296,038
National Institute of Mental Health (William W. Eaton, P.I.)
Evolution of Psychopathology in the Population.

Daniel E. Ford, Principal Investigator (15%) 11/01/98-06/30/02 $249,995
Aetna/U.S. Healthcare. Indicators of Quality of Care in Primary Care.

Daniel E. Ford, Principal Investigator (0%) 07/01/00-06/30/02 00-59301-A-HCD $67,844
John D. and Catherine MacArthur Foundation/RAND.
Improving the Quality of Depression Treatment for Disadvantaged Populations

Daniel E. Ford, Co-Investigator (0%) 09/01/00-05/01/02 00-577 $20,000
Bayer Institute for Health Care Communication. (Thomas Houston, P.I.)
Electronic Mail: The Potential Impact on Physician-Patient Communication.

Daniel E. Ford, Principal Investigator (15%) 09/01/96-08/31/00 406 $125,000
John D. and Catherine MacArthur Foundation. Quality Improvement in Depression.

Daniel E. Ford, Principal Investigator (25%) 04/01/94-03/31/00 1 R01 DA08199 $633,963
National Institute of Drug Abuse. Cancer Risk and Preventive Health for Marijuana Users.

Daniel E. Ford, Principal Investigator (20%) 09/30/94-08/31/98 1 U01 MH54443 $1,020.051
National Institute of Mental Health. Implementation of Depression Practice Guidelines.

Daniel E. Ford, Principal Investigator (0%) 07/01/94-06/30/98 1 T32 PE10025 $540,233
Health Resources and Services Administration. National Service Research Award. .

Daniel E. Ford, Principal Investigator (15%) 1995-1998 $175,874
Health Services Cost Review Commission of Maryland.
In-Patient Smoking Cessation Program.

Daniel E. Ford, Co-Investigator (15%) 09/01/93-08/31/98 1 R01AG01760 $1,343,999
National Institute on Aging. (Michael J. Klag, P.I.).
Precursors of Premature Disease and Death.

Daniel E. Ford, Co-Investigator (10%) 04/01/92-02/28/97 1 R01 MH47447 $3,117,003
National Institute of Mental Health (James C. Anthony and William W. Eaton, P.I.)
Evolution of Psychopathology in the Population.

Daniel E. Ford, Co-Principal Investigator 07/01/94-06/30/97 $71,438
Miles Institute for Health Care Communication. (Michael J. Klag, P.I.)

Daniel E. Ford, Co-Principal Investigator (10%) 10/01/93-09/30/96 H042SC $200,000
The Pew Memorial Trust. (Paul K. Whelton, P.I.) Health of the Public.

Daniel E. Ford, Principal Investigator (50%) 08/01/90-01/31/95 1 R29 MH46967 $298,726
National Institute of Mental Health.
Sleep and Mental Disorders in General Medical Settings.

Daniel E. Ford, Principal Investigator 07/01/91-06/30/92 $20,000
Johns Hopkins University Department of Medicine. Prevention Practice Project.

Daniel E. Ford, Co-Principal Investigator (25%) 10/01/87-09/20/92 T86-06020-003 $1,000,000
The Pew Memorial Trust. (Leon Gordis, P.I.) Health of the Public.

Daniel E. Ford, Co-Investigator (10%) 03/01/89-02/28/91 $358,291
Health Services Cost Review Commission of Maryland Illness Prevention Program. (Diane Becker, P.I.)
Family and Community Heart Disease Prevention Program.

EDUCATIONAL ACTIVITIES

Teaching Activities – Academic – Johns Hopkins University School of Medicine

1989-92	Medicine Clerkship (Year III) – Regular participant in computer-based learning segment
1989-	Medical School (Year IV) – Developed and Directs Senior Elective in Clinical Preventive Medicine
1990-98	Clinical Epidemiology Course (Year I) – Lab Instructor
1990-95	Introduction to Clinical Skills Course (Year II) – Assistant Director Organized Module on Sexual History and Male Rectal-Genital Examination
1992-96	Physician and Society Course – (Year I and Year II) Developed and Direct Unit on Physician-Patient Communication
1992-94	Member of Research Team Evaluating New Curriculum for the Johns Hopkins University School of Medicine
1996-2005	Introduction to Medicine, Clinical Skills Course (Year II)
1998-2002	Continuing Medical Education Course -- Clinical Preventive Medicine – Director
2003-2008	Basic Pharmacology Course MS II – Smoking Cessation – Lecturer
2008-	Intensive Course in Clinical Research Methods - Director

Teaching Activities -- Academic -- Johns Hopkins University Bloomberg School of Public Health

1988-2002 Course Director "Fundamentals of Clinical Preventive Medicine" - Johns Hopkins University School of Hygiene and Public Health
1989-2008 Course Director "Principles of Clinical Epidemiology" - Johns Hopkins University School of Hygiene and Public Health
1991- Lecturer in Epidemiology and Prevention of Cardiovascular Disease Course
1997- Lecturer in Outcomes Assessment Course

Teaching Activities -- Clinical -- Johns Hopkins University School of Medicine

1990-93 Lecturer and Preceptor at Blalock 2 Ambulatory Medicine, Internal Medicine Residents' Clinic

Mentoring -- Advisees Pre- and Post-Doctoral

1989 Stefano Marino PhD; Visiting Post-doctoral Fellow
Research: Use of general medical and specialty mental health services by individuals with incident psychiatric disorders
1991 Frederick Brancati, MD MHS; MHS candidate
Research: Weight reduction services in general medical settings
1991 Luis Camacho MD; PhD Candidate-Epidemiology
Research: Reliability and validity of quality of care measures
1991 Rosa Crum, MD MHS; MHS candidate, Department of Epidemiology
Research: Detection of alcohol abusers in general medical settings
1991 Edward Ellerbeck MD MPH; Fellow, Division of Internal Medicine
Research: Involving patients to improve preventive care
1991 Karen Johnson MD MPH; Preventive Medicine Residency
Research: Injury prevention counseling by primary care providers
1991 Ellen Strahlman MD MHS; MHS candidate; Fellow, Department of Ophthalmology Research: Vision screening
1991 Fang Wang MD; PhD Dissertation, Department of Epidemiology
Research: Vision screening in a primary care setting
1992 Robert Hayward MD MPH; Fellow, Division of Internal Medicine
Research: Implementation of prevention guidelines
1992 Joseph Gallo, MD MPH; Department of Mental Hygiene
Research: Use of general medical services by individuals with mental disorders
1992 Melinda Midzenski; MHS, Department of Epidemiology
Research: Perception of risk and cancer prevention activities of oncology center employees
1992 Aaron Tokayer, MD; MHS, Department of Epidemiology
Research: Decision analysis of work-up for occult blood in the stool
1993 Yuriko Egami, MD MHS; Postdoctoral fellow, Department of Epidemiology
Research: Psychiatric diagnosis in self-reported child abuse
1993 Lisa Cooper MD; MPH; Fellow, Division of Internal Medicine
Research: Management of depressed patients in general medical settings
1993 Alison Schecter, MD; Resident in Medicine
Research: Preferences for invasive cardiac care for CCU patients
1994 Patricia Chang; Medical student
Research: Risk factors for depression in physicians
1994 Louis Francescutti, MD PhD; Preventive Medicine Residency
Research: Preventive services in the emergency room setting
1994 Stephen D. Ryan, MD; MPH; Fellow, Division of Internal Medicine
Research: Implementation of clinical practice guidelines
1995 Fern Dickman, MPH
Research: Depression and ratings of functional status
1995 Christopher Sciamanna, MD, MPH; Fellow, Division of General Internal Medicine
Research: Smoking cessation counseling in primary care

1995 Robin Ann Yurk, MD MPH; Fellow, Division of General Internal Medicine
Research: Quality of primary care in Medicaid patients

1996 Michael Weiner, MD MPH; Fellow, Division of General Internal Medicine
Research: Health informatics in geriatric patients

1996 Jeanne McCauley, MD; Fellow, Division of General Internal Medicine
Research: Interventions for domestic violence in primary care

1997 Jean-Paul Cretien; Medical student
Research: Effect of recognition of depression in primary care patients on patient outcomes

1997 Thomas P. Erlinger, MD MPH; Fellow, Division of General Internal Medicine
Research: Inflammatory markers in depression

1997 Naresh Punjabi, MD PhD; Department of Epidemiology
Research: Screening for sleep apnea in general medical patients

1998 Katherine E. Lucas, MHS; Department of Epidemiology
Research: Impact of low blood pressure on fatigue

1998 Joyce Chih-I Cheh, BA; post-doctoral fellow, Department of Epidemiology
Research: Cholesterol level and incident cancer

1998 Christine M. Meyer, MHS; Department of Epidemiology
Research: Incident hypertension associated with depression and anxiety in the Baltimore ECA study: risk and validity

1998 Akira Kobayashi; D.Phil candidate, Health Policy and Management
Research: Factors that affect physicians self-esteem: a longitudinal study

1998 Gail L. Daumit, MD MHS; Fellow, Medicine
Research: Integration of psychiatric and medical care for seriously mentally ill patients

1998 Thomas K. Houston, MD MPH; Fellow, Medicine
Research: Internet and patient education

1998 Mary Catherine Beach, MD MPH; Fellow, Medicine
Research: Physician Self-Disclosure in Patient-Physician Communication.

1999 Dario Torre, MD MPH; Fellow, Medicine
Research: Physician Education via the Internet

1999 Jane Kozial-McClain, RN PhD; Post-doc, Nursing
Research: Reducing Interpersonal Violence in Emergency Room Patients

1999 Leigh Ebony Boulware, MD MPH; Fellow, General Internal Medicine
Research: Patient assessment of quality of hypertension care

1999 Jonathan Darer, MD MPH; Fellow, General Internal Medicine
Research: Quality improvement in managing chronic diseases

2000 Benjamin Van Voorhees, MD MPH; Fellow, Department of Medicine
Research: Managed Care and Quality of Mental Health Care

2000 Mahdavi Reddy Patt, MD MPH; Fellow, Division of General Internal Medicine
Research: Physician-Patient E-mail Communication

2000 Gabrielle Bruegelman, MHS; Doctoral candidate, Department of Epidemiology
Research: Functional Status in Sleep Disordered Breathing

2000 Celia Wills, PhD: Michigan State University, K08 Mentor
Research: Patient decision-making about antidepressant use

2001 Yngvild Olsen, MD: Fellow, Division of General Internal Medicine
Research: Patterns of Use of Oxycontin

2001 Leonardo Tamariz, MD: Fellow, Division of General Internal Medicine
Research: Marijuana Use and Inflammatory Markers

2002 Jose Arbalaez, MD PhD: Doctoral candidate, Department of Epidemiology
Research: Depression, Stroke and Inflammation

2003 Vijay Singh, MD: Fellow, Masters of Public Health Candidate, Health Policy and Management
Research: Reporting and Concepts of Domestic Violence by Male Primary Care Patients

2003 Joshua Fogel: Post-doc Fellow, Department of Mental Health
Research: Minor depression

2004 Constantinos Tsilidis: Doctoral student, Department of Epidemiology
Research: Depression and myocardial infarction

2004 Jochen Schmitt, MD: MPH student
Research: Assessing quality of life in psoriasis patients via the Internet

2004 Hillary Bogner, MD,MHS: Assistant Professor Family Medicine, University of Pennsylvania
Research: Depression in patients with cardiovascular disease

2007 Mollie Davis, MD, MPH: Postdoctoral Fellow, General Internal Medicine Fellow

Daniel E. Ford, M.D., M.P.H.
Research: Preventive Care in Childhood Cancer Survivors

2007 Monique Tello, MD MPH: Postdoctoral Fellow, General Internal Medicine
Research: Healthy Sexual Habits of Women

2007 Madhav Goyal, MD MPH: Postdoctoral Fellow, General Internal Medicine
Research: Vipasanna Meditation and Migraine Headaches

2008 Henry Michtalik, MD MPH: Postdoctoral Fellow, General Internal Medicine
Research: Delirium in Hospitalized Patient

Mentoring -- Thesis Committees

1995 Gregory Kirk (Role: Committee Member, Masters of Public Health, Epidemiology)
Hepatitis B and C as Risk Factor for Hepatocellular Carcinoma

1996 Yi-Hsin (Sidney) Chen (Role: Committee Member, Master of Public Health, Epidemiology)
Retinal Ischmia as Risk Factor for CVD

1996 Laurie Pratt (Role: Committee Member, Doctor of Philosophy, Epidemiology)
Depression as Risk Factor for Myocardial Infarction

1998 Andrea Kopstein, MPH (Role: Committee Member, Doctor of Philosophy, Epidemiology)
Motivational and Personality Factors Associated With Adolescent Alcohol, Tobacco and Marijuana Use

1998 Katherine E. Lucas (Role: Committee Member, Master of Health Sciences, Epidemiology)
The Association Between Low Systolic Blood Pressure and Fatigue

1999 Joyce Chen (Role: Committee Member: Masters of Health Science, Epidemiology)
Serum Cholesterol and Cancer Incidence in the Precursors Study Cohort

1999 Carolyn D.M. Furr-Holden (Role: Committee Member, Doctor of Philosophy, Epidemiology)
The Epidemiology of Drug Dependence: A U.S.-U.K. Cross National Study

1999 Akira Kobayashi (Role: Committee Chairman, Doctor of Philosophy, Health Policy and Management) Precursors of Self-Esteem and Distress among Middle-Aged Male Physicians: A Longitudinal Study

1999 Noah Lechzin (Role: Committee Member, Masters of Health Sciences, Epidemiology)
A Critical Review of Studies Characterizing Respiratory Muscle Involvement and Outcomes of Pulmonary Intervention in Patients with Amyotropic Lateral Sclerosis

1999 Sandra Hochman Lesikar (Role: Committee Member, Doctor of Philosophy, Mental Hygiene)
Health, Cognition, and Driving Behavior

2000 J. Gabrielle Breugelman, MS MPH (Role: Committee Member, Doctor of Public Health, Epidemiology) The Impact of Sleep Disordered Berating on Quality of Life in Patients and their Bedroom Partners

2000 Sonya Singh (Role: Committee Member, Masters of Health Science, Epidemiology)
Psychotropic Drug Use and the Risk of Fractures

2000 Gregory Stevens (Committee Member, Masters of Health Science, Health Policy & Management)
Family Racial and Insurance Disparities in Primary Care Quality for Children

2001 Marsha F. Rosenberg (Role: Committee Chairman, Doctor of Philosophy, Mental Hygiene)
Pharmacothanatology: An Epidemiological Investigation of Drug-Related Deaths

2001 Corey B. Smith (Role: Committee Member, Doctor of Philosophy, Mental Hygiene)
Religiosity and Psychosocial Correlates of Psychopathology in a Community Sample of Bereaved Persons

2002 Chiadikaobi Uchendu Onyike (Role: Committee Member, Masters of Health Science, Epidemiology) Is Obesity Associated with Major Depression? Results from the Third National Health and Nutrition Examination Survey (HANES III)

2002 Lillian Ingster (Role: Committee Member, Doctor of Philosophy, Health Policy and Management) Long Term Trends in Hospitalizations for Ambulatory Care Sensitive Conditions

2003 Jose J. Arbelaez (Role: Committee Chairman, Doctor of Philosophy, Epidemiology) Change in Depressive Symptoms and Risk of Stroke: Inflammatory Markers as Potential Mediators

2003 Darryl R. Brown (Role: Committee Chairman, Doctor of Philosophy, Health Policy and Management) The Influence of Patient Satisfaction on Outcomes in After-Hours, Telephone-Based Primary Care

2003 Vaishali Patel (Role: Committee Member, Doctor of Philosophy, Health Policy and Management) Case Study Approach to Understanding How Outcomes Management Systems are Used Within Child and Adolescent Mental Health Treatment Settings

2003 Efrat Shadmi (Role: Committee Member, Doctor of Philosophy, Health Policy and Management) Coordination of Primary-Specialty Care Interactions and its Impact on Referral Results

2004 Leigh Ann White (Role: Committee Chairman, Doctor of Philosophy, Health Policy and Management) Effects of Psychological Distress on Employment among Low-Income Women

2004 Erick Messias (Role: Committee Member, Doctoral, Department of Mental Hygiene) Treatment Needs and Services Utilization in Prevalent Mental Disorders

2004 Anne B. Woods (Role: Committee Member, Doctoral, Department of Nursing) Bio-Psycho-Immunologic Responses to Battering

2004 Ya-Pei Liu (Role: Committee Member, Doctoral) Predictors of Physical Decline and the Use of Compensatory Strategies in An Older Population

Mentoring -- Training Grant Participation

Daniel E. Ford, Core Faculty 07/01/00-06/30/04 T32MH20014 $1,087,568
National Institute of Mental Health. Interdisciplinary Research Training on Violence.
(Jacqueline Campbell, PI)

Daniel E. Ford, Core Faculty 06/01/00-05/31/05 HL07024 $2,421,444
National Heart, Lung and Blood Institute. Cardiovascular Epidemiology Institutional Training Program.
(Joseph Coresh, P.I.)

Editorial Activities

1999-2004 Associate Editor, Journal of General Internal Medicine
2005- General Hospital Psychiatry

Reviewer

American Journal of Epidemiology
American Journal of Geriatric Psychiatry
American Journal of Medicine
American Journal of Preventive Medicine
Annals of Internal Medicine
Archives of Family Practice
Archives of General Psychiatry
Epidemiology
General Hospital Psychiatry
Epidemiological Reviews
Journal of Clinical Psychiatry
Journal of Psychosomatic Medicine
Journal of the American College of Cardiology
Journal of the American Medical Association
Journal of General Internal Medicine
Hypertension
Medical Care
Medicine

CLINICAL ACTIVITIES

Certification

1982 Diplomate, American Board of Medical Examiners
1986 Diplomate, American Board of Internal Medicine
1986 State Medical License: Maryland

Service Responsibilities

Johns Hopkins Internal Medicine (Primary Care Physician, Hypertension), Attending Physician (10%)
University Health Service (Primary Care Physician), Director (10%) and Attending Physician (10%)

ORGANIZATIONAL ACTIVITIES

Organizational Activities -- Institutional Administrative Appointments

1993-2006 Director, University Health Service, Johns Hopkins University School of Medicine and School of Hygiene and Public Health

Organizational Activities -- Professional Society Memberships

1985- Society for General Internal Medicine
1985- American Public Health Association
1985- Johns Hopkins Medical and Surgical Association
1989- American College of Physicians/American Society of Internal Medicine
1995- Association for Health Services Research
2005- Clinical Research Forum
2008- Society for Clinical and Translational Science
2008- PRIM&R – Public Responsibility in Medicine & Research
2009- Association for Clinical Research Training
2009- Clinical Trials Transformation Initiative

Organizational Activities -- Conference Organizer

1999-2002 Clinical Preventive Medicine Course (2 days with CME credits)

Organizational Activities -- Advisory Committees

1992-93 Member, Abstract Selection Committee, Society for General Internal Medicine National Meeting
1998-99 Co-Chairman, Prevention Subcommittee on Abstract Selection, Society for General Internal Medicine National Committee
2002 NIMH Advisory Board to STAR*D Clinical Trial
2003 External Advisory Board, University of Pittsburgh Late Life Depression Center
2004 Advisory Board, University of Pennsylvania Advanced Center for Intervention Services Research
2009 External Advisory Board, Michigan Institute for Clinical and Health Research
2009 External Advisory Board – Cleveland CTSA
2009 CCTS External Advisory Board, University of Alabama
2011 CTSA External Advisory Board, University of Chicago

Organizational Activities -- National and State Committees

1992-99 Society of General Internal Medicine Representative to National Coordinating Committee on Clinical Preventive Services, Office Disease Prevention and Health Promotion, Assistant Secretary of Health and Human Services Office
1993-95 Maryland Cardiovascular Disease Prevention and Control Plan, Science Committee, State of Maryland, Department of Health and Mental Hygiene
1994- Foundation for Spirituality and Medicine, Board of Directors and Head of the Research Committee
1996-99 NIMH IRG Mental Health Services
1998-2004 Maryland State Advisory Council on High Blood Pressure and Related Cardiovascular Risk Factors, Office of the Governor, State of Maryland
1999-2002 NIMH IRG Interventions and Clinical Trials
2001 NIMH Committee to Develop Research Agenda for Mood Disorders
2002 Data and Safety Monitoring Board, PROSPECT study
2003 Chair, Data and Safety Monitoring Board, Treatment of Traumatic Grief
2004 Chair, Ad-Hoc Review Panel, NIMH
2007- Co-Chair, IT Roundtable, Clinical Research Forum
2008 Chair, Data and Safety Monitoring Board, TEAMcare Study (Wayne Katan, PI)
2008 Co-Director, CTSA Strategic Goal – Improving Clinical Research Management
2008- Faculty, Learning Sessions, National College Depression Partnership

Organizational Activities -- Johns Hopkins Committees

1988- Johns Hopkins University School of Hygiene and Public Health: Standing Committee on Residencies
1989- General Clinical Research Center, Outpatient Center Research Protocol Review Committee
1989- General Clinical Research Center Advisory Committee
1992-99 Internship Selection Committee, Johns Hopkins Department of Medicine
1993- Johns Hopkins University Student Health Steering Committee
1996-99, 03 Medical School Admissions Committee, Johns Hopkins University School of Medicine
1998 Liaison Committee on Medical Education, Johns Hopkins University School of Medicine
1998- President's Council on Urban Health, Johns Hopkins University
2004 - Chair, Student Assistance Program Advisory Committee
2004 - Search Committee, Director of Cancer Prevention and Control
2003- Committee on Faculty Development and Gender
2004 - Chair, Johns Hopkins Health Information Management Group
2006 - Chair, Task Force on Processing and Storage of Biospecimens
2007 - Dean's Representative to Oncology Center Director Search Committee
2009 Search Committee, Welch Center Director
2009 Search Committee, Faculty Position in Health Informatics

Organizational Activities -- Consultantships

1998-2003 Medical Advisory Board, Merck-Medco Pharmaceutical Benefit Management Company
2001- 02 Primary Care Depression and Anxiety Advisory Board, Pfizer, Inc.
2001-02 Johns Hopkins Health Care Consulting. Epidemiology of Anxiety and Depressive Disorders. Bristol Myers Squibb.
2002-04 Health Resources and Services Administration, Bureau of Primary Health Care, Health Disparities Collaborative, Changing Practice, Changing Lives. Institute for Healthcare Improvement
2002-03 CMS Depression Screening in Cardiac Rehabilitation Settings
2005- Medical Advisory Board – Medco-Accredo Company
2010 RAND Corporation Technical Advisory Group (TAG)

RECOGNITION

Recognition -- Awards

State University of New York at Buffalo
1981 Student Award in Obstetrics-Gynecology
1982 Alpha Omega Alpha Honor Medical Society
1982 David K. Miller Prize in Medicine
1998 David Levine General Internal Medicine Fellows Appreciation Award
2006 Delta Omega Delta Honor Public Health Society

Recognition -- Invited Reviews

1987 National Institute of Alcohol Abuse Contract, "Development of Comprehensive Medical School Curriculum on Alcohol and Substance Abuse"
1988 National Institute of Alcohol Abuse Contract, "Development of Primary Care Medical School Curriculum on Alcohol and Substance Abuse"
1992 AHCPR Small Grants Program
1993 National Institute of Mental Health Ad Hoc Reviewer
1996- Bayer Institute for Health Care Communication Research Grants Review Committee

Recognition - Invited Talks, Panels

1. Which Patients Discuss Mental Health Problems With Non-Psychiatrists. University of Pittsburgh School of Medicine, Department of Psychiatry, Pittsburgh, PA (1987)
2. Implementation of Prevention Guidelines in Practice. Johns Hopkins Department of Medicine Annual Conference, Baltimore, MD (1989)
3. Screening for Alcohol or Psychiatric Conditions. Johns Hopkins Conference: Implementation of U.S. Preventive Services Task Force Guidelines, Baltimore, MD (1989)

4. Treatment Adherence and Its Effects on Health Outcomes. Clinical Epidemiology Seminar. Wilmer Institute, Johns Hopkins Medical Institutions. Baltimore, MD (1990)
5. Prevention in the Office. Uniformed Health Services Medical School, General Internal Medicine Rounds, Bethesda, MD (1990)
6. Improving Prevention in the Office. Johns Hopkins Annual Obstetric-Gynecology Conference, Baltimore, MD (1991)
7. Assessment of Sleep Disturbances. Society of General Internal Medicine Annual Meeting Precourse, Seattle, WA (1991)
8. The Academic Medical Center Working with Communities. American Association of Medical Colleges Annual Meeting, Washington DC (1991)
9. Preventive Services and Physician Satisfaction. Johns Hopkins University Department of Medicine Research in Progress, Baltimore, MD (August 6, 1992)
10. Characteristics of Patients with Major Depression Who Received Care in General Medical and Specialty Mental Health Settings. Johns Hopkins University Department of Medicine Annual Retreat, Baltimore, MD (October 23-24, 1992)
11. Annual Health Exam. Johns Hopkins University School of Medicine, Grand Rounds, Baltimore, MD (November 14, 1992)
12. Models for Working with Communities. Prevention 92 Annual Meeting, Baltimore, MD (1992)
13. Assessment of Sleep Disturbances. American College of Physician National Conference, San Diego, CA (1992)
14. Collection of Prevention-Oriented Patient Data in Practice. Society of General Internal Medicine Annual Meeting, Washington, DC (1992)
15. Sleep Disturbances in General Medical Patients. Agency for Health Care Policy and Research. Third Primary Care Research Conference. Challenges in Practice-Based Research. U.S. Department of Health and Human Services, Bethesda, MD (January 10-12, 1993)
16. What factors influence job satisfaction among physicians? Health behaviors in physicians: less favorable in Blacks. American Medical Association, Physicians Health Foundation International Conference on Physician Health, Phoenix AZ (January 29-31, 1993)
17. Using Information Systems for Prevention Programs. Group Health Association of America, Prevention Programs: The Next Generation of Responsibilities and Initiatives in Managed Care, Colorado Springs CO (March 28-31, 1993)
18. Evaluation and Management of a Patient with a Sleep Disturbance. American College of Physicians, 74th Annual Session. Washington, DC (April 1, 1993)
19. What Prevention Topics Do Primary Care Patients Want to Talk About? Johns Hopkins University Department of Medicine Research in Progress, Baltimore, MD (August 5, 1993)
20. Chronic Diseases. American College of Preventive Medicine Review Course, Chicago, IL (August 29-31, 1993)
21. The Influence of Gender, Race and Education on Patient Preferences and Receipt of Invasive Cardiac Procedures Among Coronary Care Unit Patients. Johns Hopkins University Department of Medicine Annual Retreat, Baltimore, MD (October 22-23, 1993)
22. Screening for Colon Cancer. Johns Hopkins Medical Institutions. Topics in Ambulatory Medicine VI, Baltimore, MD (November 4, 1993)
23. How to Read and Write Clinical Literature. Risk of Cigarette Smoking and Smoking Cessation. Advance in Internal Medicine Evaluation and Prevention, Taiwan, R.O.C. (April 1994)
24. Expert testimony in the environmental on the epidemiologic risks for environmental tobacco smoke. Maryland Occupational Safety Health Hearing, Baltimore MD (May 1994)
25. Expert testimony on the epidemiologic risks for environmental tobacco smoke. Occupational Safety Health Administration, Washington DC (September 1994)
26. Practice Guidelines: The New Reality in Medicine. Maryland Association of Cardiovascular and Pulmonary Rehabilitation, Annapolis MD (November 4, 1994)
27. Can Outcomes Research Change the Way Doctors Practice? Johns Hopkins University School of Medicine, Baltimore, MD (November 10, 1994)
28. Diagnostic Tests. Critical Appraisal of Published Clinical Research, Baltimore, MD (March 1995)
29. Colon Cancer Screening. Johns Hopkins Medical Institutions, Grand Rounds, Baltimore, MD (April 29, 1995)
30. Putting Prevention into Practice. Harbor Hospital Medical Center, Grand Rounds, Baltimore, MD (June 23, 1995)
31. Controversies in the Treatment of Arterial Hypertension. Symposium on Cardiovascular Epidemiology and Treatment of Hypertension, Bucaramanga, Colombia (July 25-29, 1995)
32. Disease Prevention in the 1990's. American College of Physicians, Maryland Chapter,

Baltimore, MD (October 1995)

33. Primary Care: The ABC's of Screening for Malignancy. American Cancer Society. Eastern Shore Oncology Conference, Salisbury, MD (November 3, 1995)
34. U.S. Preventive Health Services Task Force: Recent Update. Johns Hopkins Medical Institutions, Topics in Ambulatory Medicine VII, Baltimore, MD (November 15-17, 1995)
35. Improving Outcomes Through Patient Participation. National Patient Empowerment Council. Washington, DC (December 8, 1995)
36. Prevention in Medical Practice. Baltimore City Medical Society, Baltimore, MD (April 11, 1996)
37. Health Communication in Managed Care Settings. American Academy of Physician and Patient Annual Meeting, (April 1996)
38. Update on the U.S. Preventive Services Task Force. Johns Hopkins University School of Medicine, Topics in Internal Medicine, Baltimore, MD (May 13-17, 1996)
39. Using Patient Outcomes to Improve the Quality of Health Care. National Institutes of Mental Health, Bethesda, MD (February 21, 1997)
40. Provider-Patient Communication, Patient Satisfaction and Health Outcomes: Are They Linked? Case Management Society of America, Boston, MA (May 31, 1997)
41. Religion and Medicine Course Survey. American Association of Medical Colleges, Washington, DC (November 4, 1997)
42. Depression and Cardiovascular Disease. Johns Hopkins Bayview Medical Center, Geriatric Grand Rounds, Baltimore, MD (January 13, 1998)
43. Recent Developments in Preventive Medicine. Harbor Hospital Medical Center, Baltimore, MD (January 30, 1998)
44. Primary Care: Potential for Preventing Comorbidity. National Institute of Mental Health Workshop: Research Issues in the Prevention of Comorbidity, Bethesda, MD (June 22-23, 1998)
45. The Treatment of Depression in Primary Care: What Have We Learned. Behavioral Pharmacology Research Unit at Bayview Medical Center, Baltimore MD. (February 10, 1999)
46. Depression and Cardiovascular Disease. Georgetown University School of Medicine. Department of Psychiatry Grand Rounds (March 25, 1999)
47. Treatment of Depression in Primary Care. Johns Hopkins Conjoint Clinic. (April 24, 1999)
48. What About Me and You? Patient and Physician Preferences in Ambulatory Care. Coen Lectureship, Baystate Medical Center, Springfield MA (May 19, 1999)
49. "Hot Topics" in Advanced Practice Nursing: Update on Hypertension. Institute for Johns Hopkins Nursing, Baltimore MD (September 16, 1999)
50. Update on Preventive Medicine. Grand Rounds at Harbor Hospital Center, Baltimore MD. (September 17, 1999)
51. Primary Care and Depression, Behavioral Pharmacology Research Unit at Bayview Medical Center, Baltimore MD (February 10, 2000)
52. Generalism in the New Millennium: Exploring Career Opportunities in Internal Medicine (Panel Discussion), Medical Student Workshop. Mid-Atlantic Regional Meeting of the Society of General Internal Medicine. Baltimore MD (March 10, 2000)
53. Depression in the Workplace. Aetna Academic Medicine and Managed Care, Washington DC (June 7-8, 2000)
54. Clinical Guidelines for Prevention in Primary Care. American Academy of Family Practice, Ocean City MD (June 9, 2000)
55. Challenges for the 21st Century: Mental Health Services Research. Depression in Primary Care: Diagnostic Instruments for Depression; Patient and Provider Factors Associated with Use of Sedative-Hypnotic Medications for Patients with Major Depression; Suicide, Depression and Panic Disorder in Primary Care (Paper Discussant); Washington DC (July 18-20, 2000)
56. Benzodiazepines and Treatment of Depression, University of Pennsylvania Geriatric Psychiatry Rounds, Philadelphia PA (January 17, 2001)
57. Depression and Coronary Artery Disease, Walter Reed Medical Center Medicine Grand Rounds (February 9, 2001)
58. Integrating Depression into Cardiovascular and Diabetes Disease Management, Institute for Health Care Improvement, Bureau of Primary Care, HRSA Conference, Dallas TX (April 21, 2001)
59. Improving Care for Depression through the Internet, National Institute of Mental Health, Grand Rounds, Bethesda, MD (May 18, 2001).
60. Marijuana Use Is Not Associated With Head, Neck, or Lung Cancer in Adults Younger Than 55 Years: Results of a Case Cohort Study, National Institute of Drug Abuse, Washington DC (August 13-14, 2001)

61. Surgeon General's Initiative "Bridging Mental Health and Primary Care: Crossing the Quality Chasm" Targeting Research, Practice and Financing Activities for Depression, Children and Adolescents and Serious Mental Illness. Discussion Group Participation. (August 21, 2001)
62. Clinical Practice Guidelines: Treating Tobacco Use and Dependence. Howard County General Hospital (CME Medical Staff Program) (December 5, 2001)
63. Depression as a Risk Factor for Cardiovascular Disease. Johns Hopkins Department of Medicine Grand Rounds, Baltimore MD. (March 22, 2002)
64. Smoking Cessation. Johns Hopkins Saturday Medicine, Baltimore MD. (March 23, 2002)
65. Depression and Risk for Cardiovascular Disease, Preventive Medicine Presentation, Welch Center Grand Rounds, Johns Hopkins Medical Institutions, Baltimore MD (March 27, 2002)
66. Evaluation Plan for Depression in Primary Care: Linking Clinical and System Strategies. Robert Wood Johnson Foundation Meeting, Pittsburgh PA (April 30 – May 2, 2002)
67. Antidepressant Selection Process: New Clinical Data Relevant to Medical Comorbidity. Mental Health in the Primary Care Setting: The Nurse Practitioner's Role in Diagnosing and Treating Mood and Anxiety Disorders. 17th Annual Conference Symposium. American Academy of Nurse Practitioners, Reno NV (June 19-23, 2002)
68. Epidemiology of Suicide in Physicians. Physician Suicide Workshop. American Foundation for Suicide Prevention, Philadelphia PA (October 5-7, 2002)
69. Depression and Risk for Cardiovascular Disease. NeuroScience, Inc., New York NY (December 13, 2002).
70. Depression and Cardiovascular Disease. Psychiatry Grand Rounds, Johns Hopkins University, Baltimore MD (December 23, 2002)
71. Integrating Behavioral Health and Medical Care. Improving Outcomes for Patients with Depression. Academy Health Meeting (June 26-27, 2003).
72. Depression and Risk for Cardiovascular Disease, Baltimore Medical Systems, Inc., Baltimore MD (July 31, 2003).
73. A Population-Based Approach to Treatment of Patients with Depression. Lecture to Pediatric Mental Health Trainees, Johns Hopkins, Baltimore MD (August 4, 2003).
74. Depression and Cardiovascular Disease, University of Pennsylvania, Department of Psychiatry, Philadelphia PA (September 22, 2003)
75. Modifiable Risk Factors: Marijuana and Head and Neck Cancers. Behavioral Science and Cancer: Relevance, Risk and Resilience. Howard University Cancer Center/Johns Hopkins Kimmel Cancer Center Partnership Symposium. Radisson Plaza, Baltimore, MD (November 19, 2003)
76. Depression and Coronary Artery Disease, University of Alabama Department of Medicine Grand Rounds (April, 2004) Birmingham, Alabama
77. Depression and Cardiovascular Disease: What is the link? Complementary and Alternative Medicine Rounds, Johns Hopkins Baltimore (Jan 4, 2005)
78. Depression and Coronary Artery Disease: What is the link? Department of Medicine Grand Rounds, MetroHealth Hospital, Cleveland (Jan 18, 2005)
79. Physician Health: What are the Risks? Department of Medicine Grand Rounds, St. Raphael's Hospital, New Haven, Connecticut (Feb 8, 2005)
80. Physician Health: What are the Risks? Department of Surgery Grand Rounds, St. Raphael's Hospital, New Haven, Connecticut (Feb 9, 2005)
81. Interrelationships between Depression, Schizophrenia and Cardiovascular Disease Department of Medicine Research Symposium Johns Hopkins, Baltimore MD (April 7, 2005)
82. Update on CTSA Activities: Workshop on Clinical Research Management, National Advisory Research Resource Council, Bethesda, MD (September 16, 2008)
83. Transforming Clinical and Translational Research at Johns Hopkins, International Symposium on Clinical Research and Translational Medicine, Fudan University, Shanghai, (September 24-29, 2008)
84. Community Engagement Green Group Regional Workshop, University of Pennsylvania (October 13, 2008)
85. National College Depression Partnership, Learning Sessions, Faculty Member (2008-)
86. Opportunities for IT in Clinical Research Support, American Medical Informatics Association Annual Symposium, Washington, DC (November 10, 2008)
87. Women in Clinical Trials, A Woman's Journey, Baltimore, MD (November 14, 2008)
88. Overview of Work Being Done in the Institute for Clinical and Translational Research, Blaustein Pain Grand Rounds, Baltimore, MD (December 2, 2008)
89. Resource Update – CTSA Implementation – Bayview Research Symposium, Baltimore, MD (December 23, 2008)

90. Keeping Pace with the Economic & Political Environment: A Challenge to Clinical Research, Clinical Research Forum, Washington, DC (January 13-14, 2009)
91. Interdisciplinary Research, Panel Discussion, Southern Nursing Research Society, Baltimore, MD (February 12, 2009)
92. Opportunities: The NIH CTSA at Johns Hopkins – a Role for HPM? Health Policy and Management Retreat, Bethesda, MD (February 20, 2009)
93. New Opportunities for Clinical Research in Difficult Times, Clinical Research Forum IT Roundtable, Washington, DC (April 15-17, 2009)
94. Next Steps – Plans for Larger Future Study, CTSA Clinical Research Management Workshop, Bethesda, MD (June 22-23, 2009)
95. Strengthening Partnerships Between HRA Member Organizations and Academic Health Centers, Health Research Alliance Members' Meeting, Chevy Chase, MD (September 23-24, 2009)
96. Clinical Research Challenges and Opportunities, National eHealth Collaborative. Arlington, VA, (October 21, 2009)
97. Closed-Door Roundtable on *Comparative Effectiveness Research and Health Care Innovations* sponsored by the National Institute for Health Care Reform, the Center for Studying Health System Change (HSC), AcademyHealth and the Association of American Medical Colleges (AAMC), Washington, DC (February 1, 2010).
98. Rand Corp. Technical Advisory Group Meeting, Developing an Evaluation Design for the Primary and Behavioral Health Care Integration Grant Program, Washington, DC, (February 24, 2010)
99. Regulatory Affairs Professionals Society (RAPS), 2010 Horizons Conference opening keynote speaker. Baltimore, Maryland (March 25, 2010).
100. The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Leadership Retreat. "Enterprise-wide IT solutions to support translational research". Baltimore, MD (May 24, 2010).
101. Henrietta Lacks Memorial Symposium, Baltimore, MD. (October 2, 2010).

Publications – Selected Abstracts

1. **Ford DE** and Anthony JC: Performance of the general health questionnaire among different health care utilizers. Clin Res 35:740A, 1987.
2. **Ford DE** and Kamerow DB: Sleep disturbances: Longitudinal course and relationship to psychiatric disorders. Clin Res 36:711A, 1988.
3. Liss A, **Ford DE**, Wilder LB, Sigmund WR and Becker DM. Drug treatment for hyperlipidemia: Knowledge among medical interns and residents in ambulatory practice settings. American Heart Association, November, 1990.
4. Johnson K, **Ford DE**, Smith G: Prevention of residential fire deaths in a general medicine clinic. Society of General Internal Medicine, Annual Meeting, May, 1990.
5. **Ford DE**, Klag MJ, Mead LA, Appel LJ, Levine DM. What factors influence job satisfaction among physicians? Society of General Internal Medicine, Annual Meeting, May, 1990.
6. **Ford DE**, Klag MJ, Whelton PK: Physician's knowledge of the CAGE and its relationship to medical practice. Society of General Internal Medicine, Annual Meeting, May, 1990.
7. Ellerbeck EF, **Ford DE**, Becker DM, Liss AS, Sigmund WR. Improving cholesterol management by residents in an ambulatory care clinic. Society of General Internal Medicine, Annual Meeting, May, 1991. Clin Res 39, 616A, 1991.
8. Hayward RSA, **Ford DE**, Steinberg EP and Roizen MF. Prevention practice information tools for the clinician. Canadian Organization for Advancement of Computers in Health, 1991.
9. **Ford DE**, McCauley JM, Jones CA. Factors associated with obese patients beginning a weight reduction program. Clin Res 29, 635A, 1991.
10. Brancati FL, **Ford DE**, Klag MF, Appel LJ, Whelton PK. Patient and physician factors related to intensity of weight reduction care in a university medical clinic. American Heart Association National Meeting, November, 1991.
11. Crum R and **Ford DE**. Factors related to recognition of alcohol abusers in a primary care clinic. Fifth Annual National Institute of Mental Health International Research Conference, Washington, DC, September, 1991.
12. Girman-Ratan AM, Wilcox PM, Helzlsouer KJ and **Ford DE**. Evaluation of a breast examination educational unit for medical residents. American Academy of Cancer Education, Baltimore, MD, June, 1991.
13. Hayward RSA, Smittner JP, Meyers P, **Ford DE**, Roizen M, Steinberg E. Computer versus Interview Administered Preventive Care Questionnaire: Does Survey Medium Affect Patient

Response Reliability? Society of General Internal Medicine, Annual Meeting, May, 1992. Clin Res 40(2):608A, 1992.

14. Hayward RSA, **Ford DE**, Summerell D, Roizen MF, Steinberg EP. Randomized clinical trial of a patient-administered computerized preventive care system to implement adult practice guidelines. Society of General Internal Medicine, Annual Meeting, May, 1992. Clin Res 40(2):608A, 1992.
15. Marino S, Gallo JJ, **Ford D**, Anthony JC. The pattern of health services use for individuals with incident mental disorder. 6th Annual NIMH International Research Conference on Primary Care Mental Health Research: Concepts, Methods, and Obstacles. October 18-20, 1992.
16. **Ford D**, McCauley J, Kern D. Functional status of primary care patients with sleep disturbances: agreement between patient and significant others. 6th Annual NIMH International Research Conference on Primary Care Mental Health Research: Concepts, Methods, and Obstacles. October 18-20, 1992.
17. Patrick LC, Crum R, **Ford D.** Characteristics of patients with major depression who received care in general medical and specialty mental health settings. 6th Annual NIMH International Research Conference on Primary Care Mental Health Research: Concepts, Methods, and Obstacles. October 18-20, 1992.
18. Crum RM, Patrick LC, **Ford D**. Depressive symptoms in general medical patients: prevalence and one year outcome in the Epidemiologic Catchment Area Study. 6th Annual NIMH International Research Conference on Primary Care Mental Health Research: Concepts, Methods, and Obstacles. October 18-20, 1992.
19. **Ford DE**, McCauley J, Kern D. Sleep disturbances in general medical patients. Agency for Health Care Policy and Research Third Primary Care Research Conference, Atlanta GA. January 10-12, 1993.
20. Klag MJ, Mead LA, Thomas John, Thomas Johniene, **Ford DE**, Levine DM, Visco R, Pearson TA. Health behaviors in physicians: less favorable in Blacks. International Conference on Physician Health, Scottsdale AZ. January 29-31, 1993.
21. **Ford DE**, Klag MJ, Mead LA, Appel LJ, Levine DM. What factors influence job satisfaction among physicians? International Conference on Physician Health, Scottsdale AZ. January 29-31, 1993.
22. **Ford DE**, Hayward RSA, Ellis P, Roizen M, Steinberg E. Which prevention topics do patients want to talk about? Society of General Internal Medicine, Washington DC. March 5, 1993.
23. Patrick LC and **Ford DE**. Identifying suicidal ideation in primary care patients. Society of General Internal Medicine, Washington DC. March 5, 1993.
24. Patrick LC, **Ford DE**, Klag MJ, Mead L, Levine DM. Exercise and Mental Well-Being in Physicians. 33rd Annual Conference on Cardiovascular Disease Epidemiology, Sante Fe NM. March 17, 1993.
25. Schecter AD, McKee G, Hoffeld D, Velez R, Myers M, Drayer T, Szych C, Chandra NG, Goldschmidt-Clermont PJ, **Ford DE**. Education level more than gender or race predicts patients' attitudes toward management in the coronary care unit. American College of Cardiology, 43rd Annual Scientific Session, March 16, 1994.
26. Chang PP, **Ford DE**, Mead LA, Graves PL, Klag MJ. Predictors in male medical students for subsequent psychiatric distress and clinical depression. 17th Annual Meeting, Society of General Internal Medicine, April 27-29, 1994, Washington DC. J Gen Intern Med 1999;9(suppl 2):26.
27. Chang PP, **Ford DE**, Mead LA, Klag MJ. Association of sleep patterns in young men with clinical depression and psychiatric distress: a prospective study. 17th Annual Meeting, Society of General Internal Medicine, April 27-29, 1994, Washington DC. J Gen Intern Med 1999;9(suppl 2):26.
28. Cooper-Patrick L, **Ford DE**, Mead LA, Klag MJ. Exercise and Psychological Distress: A Prospective Study. 17th Annual Meeting, Society of General Internal Medicine, April 27-29, 1994, Washington DC. J Gen Intern Med 1999;9(suppl 2):28.
29. **Ford DE**, McCauley J, Kern D. Association of Primary Care Patients and Physicians Ratings Concerning Whether a Mental Health Evaluation was Completed. 8th Annual NIMH International Research Conference on Mental Disorders in the General Health Care Sector, September 7-9, 1994, McLean VA.
30. Mead LA, Levine DM, **Ford DE**, Brancati FL, Coresh J, Klag MJ. Family history of myocardial infarction as an independent risk factor for coronary heart disease (CHD): results from the Precursor's Study. American Heart Association, 67th Scientific Session. November 14-17, 1994.
31. **Ford DE**, Mead LA, Chang PP, Levine DM, Klag MJ. Depression predicts cardiovascular disease in men: the Precursor's Study. American Heart Association, 67th Scientific session. November 14-17, 1994.
32. Chang PP, **Ford DE**, Mead LC, Levine DM, Klag MJ. Anger in young men and risk of cardiovascular disease: results from the Precursors Study. American Heart Association, 67th Scientific Session. November 14-17, 1994.

33. Schecter A, **Ford DE**, McKee G, Hoffeld D, Schulman S, Myers M, Chandra N, Goldschmidt-Clermont, P. The relationship of race, gender and education to CCU patient knowledge of modifiable cardiac risk factors: implications for patient education. American Heart Association, 67th Scientific Session. November 14-17, 1994.
34. **Ford DE**, Chang PP, Mead LA, Levine DM, Klag MJ. Serum cholesterol in young men and risk of subsequent depression. American Heart Association, 67th Scientific Session. November 14-17, 1994.
35. **Ford DE**, Mead LA, Wang N-Y, Chang PP, Cooper-Patrick L, Klag MJ. Anger in medical school predicts depression over 30 years of follow-up: the Precursors Study. 18th Annual Meeting, Society of General Internal Medicine, San Diego, May, 1995. J Gen Intern Med 1995;10(suppl 2):42.
36. Ryan S, Schecter A, Goldschmidt-Clermont P, Myers M, Hoffeld D, **Ford D**. Perceptions about health and preferences for invasive care and health locus of control in elderly cardiac care unit patients. 18th Annual Meeting, Society of General Internal Medicine, San Diego, May, 1995. J Gen Intern Med 1995;10(suppl 2):58.
37. Cooper-Patrick L, Crum RM, Pratt L, **Ford DE**. The Psychiatric and Socio-demographic Profile of Patients with Chronic Disease Who Do Not Receive Regular Medical Care. 18th Annual Meeting, Society of General Internal Medicine, San Diego, May, 1995. J Gen Intern Med 1995;10(suppl 2):64.
38. Dickman F, McCauley J, Kern D, **Ford DE**. Significant others rate primary care patients with psychiatric distress as having higher functional status than the patients themselves. National Institute of Mental Health Conference on Mental Health Services Research. Bethesda MD, September 11-12, 1995.
39. Klag MJ, Mead LA, Whelton PK, **Ford DE**. Prevalence of calcium channel blocker use among hypertensive physicians in the Precursors Study. American Heart Association. 36th Annual Conference on Cardiovascular Disease Epidemiology and Prevention. San Francisco, CA. March 13-16, 1996.
40. **Ford DE**, Butler J, Mead LA, Rardin K, Carroll JG, Klag MJ. Randomized trial of a physician-patient communication intervention in an HMO. 1996 Mid-Atlantic Regional Meeting, Society of General Internal Medicine, Baltimore, MD March 22, 1996
41. **Ford DE**, Mead LA, Butler J, Carroll JG, Klag MJ. Development of an instrument for patient rating of physicians' communication skills using factor analysis. 19th Annual Meeting, Society of General Internal Medicine, Washington DC, May 2-4, 1996. J Gen Intern Med 1996;11(suppl 1):133.
42. Cooper-Patrick L, Powe NR, Jenckes MW, Gonzales JJ, Levine DM, **Ford DE**. Using focus groups to identify patient attitudes and preferences regarding treatment of depression. 13th Annual Meeting of the Association for Health Services Research. Atlanta GA. June 9-11, 1996.
43. Cooper-Patrick L, Powe NR, Jenckes MW, Gonzales JJ, Levine DM, **Ford DE**. Ethnic and cultural experiences influencing patients' help-seeking and preferred treatment for depression. Picker-Commonwealth Meeting. Chicago IL. June 13-15, 1997.
44. Mueller BA, Mead LA, **Ford DE**, Brancati FL, Cooper-Patrick L, Klag MJ. Coffee drinking, cigarette smoking and risk of non-rheumatic atrial fibrillation in the Precursors Study. 4th International Conference on Preventive Cardiology. Montreal Canada. June 29-July 3, 1997.
45. Sciamanna CN, **Ford DE**, Stillman FA, Hoch JS. Validation of a simple method of measuring hospitalized smokers' motivation to quit. 21st Annual Meeting, Society of General Internal Medicine, Chicago IL. April 23-25, 1998. J Gen Intern Med 1998;13(suppl 1):107.
46. Sciamanna CN, Stillman FA, Hoch JS, **Ford DE**. Opportunities for improving inpatient smoking cessation program. 21st Annual Meeting, Society of General Internal Medicine, Chicago IL. April 23-25, 1998. J Gen Intern Med 1998;13(suppl 1):101.
47. Cooper-Patrick L, Gallo J, Gonzales JJ, Powe NR, Nelson C, **Ford DE**. African-American patients rate their physicians' decision-making styles as less participatory. 21st Annual Meeting, Society of General Internal Medicine, Chicago IL. April 23-25, 1998. J Gen Intern Med 1998;13(suppl 1):115.
48. Punjabi NM, O'Hearn DJ, Schwartz AR, Smith PL, Wise RA, **Ford DE**, Bandeen-Roche KL. Determinants of Multiple Sleep Latency Test (MSLT) in Patients with Obstructive Sleep Apnea (OSA). ALA/ATS International Conference, Chicago IL. April 24-29, 1998.
49. Punjabi NM, Bandeen-Roche KJ, O'Hearn DJ, Allen RP, Schwartz AR, Smith PL, Wise RA, **Ford DE**. Prediction of Obstructive Sleep Apnea (OSA) using Symptom Scores from the Hopkins Sleep Survey. ALA/ATS International Conference, Chicago IL. April 24-29, 1998.
50. Cooper-Patrick L, Brown C, Palenchar Dr, Gonzales JJ, **Ford DE**, Powe NR. Patients' Opinions Regarding the Importance of Various Aspects of Depression Treatment. 15th Annual Meeting, Association for Health Services Research. Washington, DC. June 21-23, 1998.

51. Cooper-Patrick L, Gonzales JJ, Gallo JJ, Rost KM, **Ford DE**. Patient preferences for treatment of depression. 12th International Conference on Mental Health Problems in the General Health Care Sector, Bethesda MD. July 13-14, 1998. The International Journal of Psychiatry in Medicine 1998;28(4):422-423.
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